Report on the Health Status of Country

2011
The Report on the Health Status of Country (Relazione sullo Stato Sanitario del Paese, RSSP) meets the requirement of producing a periodic report to Parliament, and consequently to citizens, on the state of health of the population and the implementation of health policies.

The RSSP was introduced by the law of December 23, 1978, no. 833 and was subsequently identified by the legislative decree (D.Lgs.) of December 30, 1992, no. 502 and successive amendments, as an instrument of evaluation for the process of implementation of the National Health Plan.

The 2006-2008 National Health Plan outlined the characteristics of the “Reporting System”, represented by the production of:

- a short-term Report produced annually and capable of satisfying the regulatory requirements, consisting of summary documents of a mainly political and institutional kind as well as documents with technical and economic analyses;
- a triennial Report, produced in tandem with the expiry date of the Health Plan and capable of highlighting the level of achievement of the Plan objectives, returning data, where possible, to the various Regions to try to build regional profiles for comparative purposes and to enable the emergence of typical group behaviours of Regions to be noted and used for future in-depth examination;
- documents on specific themes, in particular such as the Ministry of Health Journals, a publishing series of information and training intended to share the criteria of appropriateness of the Healthcare system in Italy.

The Report on the Health Status of Country 2011, by nature short-term, does not address the entire health system in its complex articulation of queries, stipulations and responses, but presents the main results achieved in 2011 in reference to the development priorities and system strategies shared between the State and the Regions.

The 2011 Report is divided into three sections which illustrate:

- the context relating to the state of health of the Country and the governance of the Healthcare system;
- interventions on the part of both central and regional levels, aimed at the implementation of the priorities for achievement of health goals;
- the quality of the system and the satisfaction of citizens, the human, financial and technological resources, as well as the monitoring, verification and appropriateness of the Essential Levels of Health Care.

The process of preparing the report is supported by an Editorial Board whose members are selected by the Minister of Health, with the task of direction and selection of themes, for which the individual Authors provide their own contribution. An Editorial Committee works in connection with the Editorial Board, whose coordination is entrusted to the Directorate General for Health Information and Statistical System.
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A year of coping with crisis

During 2012 the Italian health system has made a significant contribution to the policies adopted by the government aimed at leaving behind the financial and economic crisis that is traversing our country. It has done so in particularly difficult conditions, for several reasons. Firstly, the pressure on the endowment of financial resources to the National Health Service (Servizio sanitario nazionale, SSN) which has nevertheless conserved the primary responsibility of the health system in preventing and mitigating the effects of the crisis on the health of the population.

In addition, the interruption in funding for the 2011-2012 Fund for Non Self-Sufficiency – plans are currently underway to revive this funding – not only transferred the cost burden for those social services with a highly integrated element of health care to the health budget, but also created additional problems for the organisation and functioning of the territorial element of the SSN being rolled out in collaboration with the municipalities, and for which new requests for assistance made by the most vulnerable groups and created by the economic crisis cause a particular stress. Lastly, it should be remembered that data from the OECD demonstrate that public expenditure on health in Italy has increased at an annual rate of hardly 1.6% compared to the 4% observed overall in OECD countries.

Onto the immediate problems posed by the importance of the health component in overall fiscal policy have been grafted the needs of modernisation of the system, a need which the economic crisis has simply exacerbated and made more evident and more urgent. These necessities have been faced up to with an “extraordinary maintenance” through revising, reclassifying, and reorganising the system while guaranteeing unchanged levels of services to citizens. The change imprinted on health policy in accordance with the fundamental principles of the SSN aims to make the operation of the SSN more responsive to changes in society, to the new population structure and changes in epidemiology, while improving its sustainability in order to anticipate future problems of need and render it in greater accordance with the targets in public finance.

The two pillars on which to base this transformation are indicated by the decree law of July 6, 2012 no. 95, converted with amendments by the law of August 7, 2012 no. 135 (the so-called spending review), which establishes the revision of the hospital network on the basis of qualitative and quantitative standards, and by the decree law of September 13, 2012, converted by the law of November 8, 2012 no. 189 (urgent dispositions for promoting the development of the country through a higher level of health protection), which deals with the new configuration of general practice and primary care in the territory among other issues.

The new role for primary care and general practice

International tendencies suggest that primary care plays a central role in the proximity to citizens and their health needs, enabling an appropriate response to many clinical con-
ditions and avoiding the inappropriate use both of the accident and emergency service and hospital admission. The reform introduced by the decree law no. 158 establishes the strengthening and organisation of primary care into a network, and integration with the social care sector including home care and hospital services in both pre- and post-hospitalisation phases.

Innovative forms of organisation such as multi-disciplinary and multi-professional teams are also provided for general medicine and paediatricians of free choice, which will act in proactive and person-centred ways, ensuring access to services throughout the day and for each day of the week, thanks also to the unique role of general practice.

More qualified, safer and more integrated hospitals

Italian hospitals have a long historical and professional tradition and represent a heritage that should not be underappreciated. However they should be made more responsive to the challenges of modern medicine and more ready for the coming European challenge of health without borders, ensuring their compliance with specific accreditation requirements which guarantee an appropriate homogeneity between the Regions for standard of care. The regulation on hospital standards as provided for by the spending review and the State-Regions Understanding on the requirements for accreditation of health facilities is directed to these purposes. The goal is to achieve a more skilled offer of care that is differentiated by its intensity, organised internally according to innovative and flexible methods, more responsive to emergency and rehabilitation needs, integrated in a network of hospitals communicating with each other and with the territorial, home and residential care services. Services that ensure that the precise requirements for accreditation are more homogenous among the different Regions and which prepare for the European challenge of health without borders.

Innovation, research and continuing education

Health policy is one of the sectors with the highest rate of technological and organisational innovation, which involves both the practices and services provided (and their related production processes) as well as the administration and management of the production system.

In addition, the health sector mainly engages staff of professional qualification to a high level, the product of long processes of pre- and post-graduate training and an almost constant “learning on-the-job”.

A health care system that is unable to keep pace with innovation risks a loss of confidence and disaffection on the part both of those who work within it and those who are the recipients of its care, and is also under constant threat to its social sustainability, more important than just economic sustainability. For this reason, and even more so in a period of rapid renewal, research in all its forms (basic, clinical and organisational) cannot be viewed as other than an essential activity to be practised in every SSN facility by a staff which is constantly trained and re-trained by theoretical, distance and on-the-job training programmes.

Government efforts have paid special attention to both of these activities, developing the national programme of continuous education in medical sciences and preparing the call for health research finalised by art. 12-bis of legislative decree no. 502/1992.

The quality aspects of both the training outcome and the provider entity were deemed as priorities for the national system of continuous training, and also the tangible effective-
ness of training in practical and professional skills measured in outcomes. Six primary themes were outlined and defined from these priorities in the 2012 tender for continuing education, which pay particular attention to the most innovative techniques such as distance learning and on-the-job training.

The call for targeted research committed over Euro 136 million, half of which went to clinical care projects and half to translational research. The eight recommended thematic areas (metabolic disorders and cardiovascular disease, neurological diseases, oncology, infections and immunity, new biotechnology, food safety and animal welfare, disease of environmental origin, safety at the workplace and occupational diseases) include within them basic and translational research as well as clinical and evaluative research, so as to ensure the full integration of the various fact-finding activities taking place within the health sector. A special attention is given to projects created “on the network” between different institutions, to those presented by young researchers, and to collaborations with Italian researchers who are based abroad, as well as projects co-financed with the industrial sector. The continuing education and targeted research programmes are intended to achieve a close integration and a robust synergy with the new organisational structure of primary and hospital care currently being defined. The new system of hospital care which follows the hierarchical network Hub & Spoke model, and already tested in some Regions, identifies specific referral hospitals by their main care functions and which represent the complex end-point of each specific subsystem. The referral hospitals [which include but are not limited to the Scientific Institutes for Research, Hospitalisation and Health Care (Istituti di Ricovero e Cura a Carattere Scientifico, IRCCSs) and university-hospitals] will be chosen based on the entirety of both their technological equipment and the professional expertise of their operators. Their selection will make use of minimum (or optimum) thresholds of activity volumes as defined by the National Agency for Regional Health Services (Agenzia Nazionale per i Servizi Sanitari Regionali, AgeNaS) and their results will be evaluated according to the standards defined by the national programme for evaluation of outcomes. Due to their particular level of qualification, these hospitals are therefore the ideal place to direct patients with more complex problems in order to achieve both organisational appropriateness and operational efficiency as well as ensuring the highest levels of favourable final results. However, they must also contemporaneously symbolise the ideal point of permeation for research and training programmes and of delivery of organisational solutions to be shared across all points of the care network. The now extensive network of IRCCSs can take the primary responsibility for this assignment in order to fully carry out their research function within the context of SSN institutions.

Health as well as healthcare

Many diseases are caused by environmental, social and economic factors which require the adoption of cross-sectoral policies in the areas of work, the environment, and the school. The awareness of the importance of the social and environmental determinants of health has increased, often inextricably intertwined with those of an individual and behavioural characteristic.

We are strengthening our partnerships with other economic and social sectors and we must continue further on this road to reduce the risks associated with improper eating habits, a sedentary lifestyle, pathological gambling, and environmental pollution. Some of these risk factors were the object of particular attention in the decree law no. 158. The monitoring of sites of national interest, including that of Taranto, and the commitment to combat pollution from asbestos and other substances will continue with more resources.
We would like to devote a special attention to support initiatives aimed at combating inequalities by promoting information and intervention programmes with the Regions, and for which the apportioning of resources for 2012 already contains a significant outline.

**Universalism, transparency and trust**

The National Health Service is the “shared home” for all citizens and persons throughout the country. This principle of universality of the right of access to SSN practices and services cannot be divorced from the principle of transparency in the evaluation of its results, the identification of its most talented management, nor from the principle of law in the scrupulous conduct of its administrative procedures. Everyone should be aware of how they are accountable for the results achieved, for the appropriate and efficient use of entrusted resources, and for the autonomy and neutrality with which decisions are made.

The crisis is not only economic and structural: it is also a crisis of trust and of representation that requires an extraordinary response and a credible individual and collective commitment on the part of everyone, together with that high sense of responsibility and thoroughness which must characterise the owner of a public good that is so precious.

*The Minister for Health*

*Prof. Renato Balduzzi*
A veritable nautical chart, sailing directions for navigation in the complex and delicate terrain of Italian medicine and health in the unfurling of its many sectoral, institutional and territorial expressions. This publication under the coordination of Prof. Giovanni Simonetti responds fully to the increasingly perceived need for a proper communication with Parliament and therefore with all citizens of the country of a comprehensive overview of the state of progress and the implementation of health policy.

Prof. Simonetti is President of the First Section of the National Health Council, an academic of high scientific calibre, an investigator of great worth, an expert and organiser with an in-depth knowledge of medical and healthcare facilities.

The Editorial Board is composed of the most qualified management from the Ministry of Health, who have worked closely with the heads of institutions bearing an implicit and acknowledged national and international prestige: the National Health Council, the National Institute for Health, the Italian Medicines Agency, the National Agency for Regional Health Services.

Consequently the work of different authors in the preparation of this volume is a guarantee of quality, appropriateness and scrupulousness: talents, these, which consent an extensive and comprehensive information on the entire subject matter in question.

While the National Health Plan 2006-2008 outlined the characteristics of the reporting system, the current factual survey aims to present the main results achieved in 2011, outlining lines of priority and system strategies. Full-fledged directors which are shared between the State and the Regions.

From a careful reading of the Chapters and paragraphs of this text, which trace the patterns of the many-constellated universe which is that of medicine, health and health care, one clear and certain fact emerges: the will of the Government and this Ministry to maintain and safeguard the public National Health Service.

The right to health – as recently written in an editorial by the eminent jurist Vladimir Zagrebelsky – is the only right that the Constitution, our civil Bible, qualifies as fundamental. We wish to defend it without a diminution of the quality of care.

Our National Health Service, even taking account of its negative as well as positive aspects, is a great social achievement. We may recall that in the United States – the leading world economic and democratic power – 21 million people are without health care, despite the efforts of President Obama.

Certainly adjustments impossible to postpone have been made to achieve savings by means of necessary and burdensome requirements, essential in a time of depression and severe economic and financial crisis not only in Italy, but in all economically advanced countries.

These measures were aimed at ensuring a greater robustness of the system, and were included in the “Pact for Health”, striving to eliminate vast areas of inefficiency and pockets of illegality in our healthcare system.

A review of the hospital network has been arranged for, bringing order to the profile of departments, while health services in the territory finally have started to be realised.
Minimum levels of performance, thresholds both for risk and for the relationship between facilities and user catchment areas have been defined. Positive actions in favour of medical specialist training and of international cooperation may also be highlighted, especially that with Mediterranean Countries, in this age of ever-growing interdependence.

It is possible, in our view, to assure substantial savings through certain approaches: eHealth meaning electronic Health; the appropriateness, efficiency and effectiveness of services; counter-measures to tackle defensive medicine and waiting lists; primary and secondary prevention; sole purchasing centres; and public-private subsidiarity.

This complex of measures, even though at the initial point, is part of a wider circle of overlapping relationships: health, the food chain, veterinary health, the ecosystem. It is the beginning of a journey which is unlikely to be interrupted, its route having already been traced out.

A broad ambit of health and social policies that is fully consistent with the recent counsel from the President of the Republic Giorgio Napolitano encouraging the preservation of social cohesion and the maintenance of a favourable level of care through innovative ideas and scientific research.

In complete synchronisation with these directions, the appropriate Chapter highlights that defining and boosting competitiveness in health research is a necessary tool for optimising not only economic investment, but investment too for cultural and social growth.

In particular, health and biomedical research is of fundamental importance to the scientific and technological progress of the Country, not only for its direct impact on people’s health, but also for the development of the pharmaceutical industry and biomedical research. A line of verse re-echoes: ‘it would be enough for me to be the father of a good idea’.

Therefore this work confirms itself as a reliable point of reference and orientation for all Italian citizens and for those who work in Healthcare, and who want to place their work in a context of interpretation of national policies for the protection and promotion of Health.

Prof. Adelfio Elio Cardinale
Under-secretary of State for Health
Context analysis
1.1. Epidemiological framework

**Planning framework.** Diseases of the circulatory system and cancers are the two most frequent causes of death, and have been for some years now. Diseases of the circulatory system represent one of the most important public health problems in almost all high-income countries, including Italy: in fact, these diseases are among the leading causes of morbidity, disability and mortality and their impact causes high levels of human, social and economic damage.

It is therefore necessary to reduce the impact of cancer, cardiovascular diseases, diabetes and chronic lung diseases on the population, developing and strengthening policies and programmes that take into account the various “determinants of health” through the implementation of appropriate “intersectoral” policies at national, regional and local levels. The focus must be on prevention, reducing the risk factors at the individual level and acting in an interdisciplinary and integrated manner to remove the causes that prevent citizens from making healthy lifestyle choices.

There are many factors that are known to increase the risk of developing disease, some of which are modifiable, and on which prevention can function, while others are non-modifiable. The modifiable risk factors are hypertension, dyslipidaemia, diabetes, cigarette smoking, overweight/obesity, physical inactivity and alcohol abuse. Advanced age, male gender and familiarity are, however, non-modifiable risk factors. These factors interact in a causal or part-causal manner; the control of body weight, for example, through proper diet and physical activity, in addition to being crucial for the reduction of cardiovascular risk, is pivotal in the primary prevention of diabetes.

A transversal and “intersectoral” approach to risk factors allows, therefore, for interventions that modify unhealthy behaviours, which act on the individual’s personal lifestyle, and which also create conditions conducive to the changing of individual behaviour and to maintaining these changes over time.

There is scientific evidence that primary and secondary prevention of cardiovascular disease and diabetes is not only possible but also sustainable from the economic and organisational point of view. Simple but effective interventions such as quitting smoking, increasing physical activity, improving diet and reducing intake of alcohol, allow not only a reduction in premature deaths from cardiovascular diseases, but also of the morbidity that these diseases bring with them. It is necessary, however, that the counter-measures to these risk factors are adopted in a coordinated and integrated manner, in order to allow a systemic response to the problem of health. Italy has therefore adopted a national strategy of “Gaining Health: making healthy choices easy”, promoted by the Ministry of Health and based on the principle of “Health in all policies”, with the aim of disseminating and facilitating the adoption of behaviours that positively affect the health of the population. For many years, Italy has been committed to the prevention and treatment of nicotine addiction, a complex task that requires much commitment and the development of policies and inter-
ventions in other than strictly medical areas. Controlling of addiction to nicotine is one of the areas of focus of the “Gaining Health” programme.

**State of implementation in regional contexts.** The Regions are the institutions best able to implement intersectoral policies of health promotion, both because of their role and their “nearness” to citizens. The sharing of the priority objectives of public health with the Regions has led to the initiation and development of actions and interventions for prevention of the main chronic non-communicable diseases at local level. These interventions are characterised by a transversal approach and by the development of agreements and collaborations between the different Institutions and representatives of civil society, as also outlined in the “Gaining Health” programme. The National Centre for Disease Prevention and Control (CCM), by involving several Regions in the testing of intervention models and Regional Prevention Plans, are gradually making the involvement of large numbers of people possible. This is done through information and communication initiatives, as well as by changing local environmental contexts, making them more conducive to healthy choices, according to a mode of working that increasingly aims at a responsible and conscious participation of local communities in order to improve the health and welfare of all citizens.

**Description of the data** National Institute for Statistics (Istat) data show that in 2009 the number of deaths occurring in Italy amounted to 588,438; in detail, 286,619 males (48.7%) and 301,819 females (51.3%). Analysis of deaths by cause confirms that diseases of the circulatory system were the primary cause with 224,830 in that category (38.2%), followed by cancers with 174,678 deaths (29.7%). For females, cardiovascular diseases were the primary cause of death with 127,060 deaths (42.1%), while cancers represent the second most-frequent cause with 76,112 deaths (25.2%). For males, the primary cause of death was however cancer with 98,566 deaths (34.4%), closely followed by diseases of the cardiovascular system with 97,770 deaths (34.1%). Diseases of the respiratory system were the third cause of death in Italy, responsible for 39,949 deaths (6.8%), of which 22,329 male and 17,620 female.

The Istat data for 2011 show that the prevalence of diabetes mellitus in Italy has been increasing steadily over the last decade. In fact, 4.9% of the overall population is diabetic (5.0% of the female population, 4.7% of the male population), almost 3 million persons. The prevalence of diabetes increases with age with 19.8% of persons aged 75 years or over having the disease. In the 35-64 age group the prevalence is greater among males, while for the over-65 group the prevalence is greater among females. With regard to geographical distribution, prevalence is highest in the South and Islands, with a value of 6.0%, followed by Central Italy with 5.1%, and 4.0% in the North.

Data from the Progress made by Health Authorities for Health in Italy (**Progressi delle Aziende Sanitarie per la Salute in Italia**, PASSI) system in 2010 show that 32% of adults are overweight, while 11% are obese; since 2007, moreover, a tendency towards an increase in the number of those who take no exercise may be observed.

With regard to tobacco smoking, it is estimated that between 70,000 and 83,000 deaths are caused by smoking each year, with over 25% of these deaths occurring between 35 and 65 years of age. According to the Istat numbers, of 52 million inhabitants over the age of 14 years there are about 11.6 million smokers (22.3%), of which 7.1 million are men (28.4%) and 4.5 million women (16.6%).

With regard to alcohol consumption, according to the specific risk indicator adopted by the National Institute for Health (**Istituto superiore di sanità**, ISS)-National Alcool Observatory, which acknowledges the national guidelines for healthy eating proposed by the National Institute for Research in Food and Nutrition (**Istituto Nazionale di Ricerca per gli Alimenti e la Nutrizione**, INRAN) and take into account the recommendations of the World Health Organiza-
general overview of the state of health in Italy

in 2010 the prevalence of alcohol consumers at risk in the population aged over 11 years was equal to 25.4% among males and 7.3% among females, a total of over 8,600,000 individuals who ignore the public health guidelines for the consumption of alcohol. There remain strong gender differences in all age groups, except in the below legal-age group (11-15 years), in which there are no statistically significant differences between males and females and where the prevalence of female at-risk drinkers is very high; higher than the national average.

Presentation and critical evaluation of data. In our country, changes in lifestyle and increasing life expectancy are, in large part, responsible for the increase in the prevalence of chronic non-communicable diseases, particularly type 2 diabetes. The most significant increase, with a prevalence of 14%, was recorded among the elderly (age > 65 years), who currently account for two-thirds of the Italian diabetic population. Moreover, the prevalence of smokers is still high, and also of concern is the change in patterns of alcohol intake, especially among younger people.

Despite their frequency, these diseases are largely preventable through the adoption of healthy lifestyles, but in order to discourage unhealthy behaviours, it is also essential to tackle the environmental, social, economic and cultural factors that give rise to them. In the absence of initiatives aimed at prevention, as well of those for the optimisation of care for people already suffering from chronic diseases, available human and economic resources may soon no longer be sufficient to ensure adequate care.

Through the PASSI monitoring system, social inequalities in relation to lifestyles, to the presence of chronic diseases and to risk factors have also been documented. In particular, smoking, physical inactivity, obesity, diabetes and respiratory diseases are more common in people with lower levels of education and with greater economic difficulties. Reducing inequalities, caused in particular by the different social and economic conditions in which certain strata of the population live, is an imperative that cannot be postponed if the promotion and protection of health of the entire population can continue to be pursued.

Essential bibliography

Ministero della salute. Appropriatazza clinica, strutturale, tecnologica e operativa per la prevenzione, diagnosi e terapia dell’obesità e del diabete mellito. Quaderni del Ministero della salute, n. 10, luglio-agosto 2011

1.2. Environment

1.2.1. Environmental pollution and health

Planning framework. The study of mortality in populations living near contaminated sites is a priority in the examination of the effects of environmental pollution on health. In this context, part of SENTIERI Project (National Epidemiologic Study of Territories and Sites Exposed to Risk from Pollution, Studio Epidemiologico Nazionale dei Ter-
Context analysis

ritori e degli Insediamenti Esposti a Rischio da Inquinamento), funded by the Ministry of Health as part of research completed in 2006, was coordinated by the ISS and concluded in 2011.

SENTIERI Project analysed mortality of populations residing near areas where large industrial centres are located – either active or abandoned – or areas where industrial and/or dangerous waste disposal occurs. These areas present a picture of environmental contamination and possible health risk that has resulted in their inclusion in the “Sites of National Interest for environmental remediation” (SNI) programme.

The study took into account 44 of the 57 SNI sites included in the 2010 “National Programme of Remediation”, and which coincide with the major national industrial clusters; a collection of data specifications has been carried out for each of them, followed by a synthesis of these data.

Most of the data collected comes from reclamation projects intended for the different sites, and show that private industrial areas were the primary subject of data specification and risk assessment, namely those areas considered as causing different types of pollution (defined as environmental exposures in the SENTIERI project). The public areas of the city and/or public parks and agricultural areas included within the SNI have been defined with a lower level of specification.

The SNI sites studied include one or more communities. Mortality occurring from 63 single causes or groups of causes was studied for each site in the period 1995-2002, using the following indicators: crude rates, standardised rates, standardised mortality ratio (SMR), and SMR adjusted for an index of socio-economic deprivation prepared ad hoc. Regional populations were used as the reference for the indirect standardisation. The SMR estimate had a corresponding confidence interval of 90% (90% CI).

The deprivation index was calculated based on census variables using the following indicators: education, unemployment, home ownership and population density. The indicators of mortality were calculated. The results of the analysis of mortality in the 44 SNI sites individually and as a whole were published in 2011.

In SENTIERI project, the environmental exposures taken from the decree of delimitation of the SNIs were classified into: chemical plant, petrochemical plant and/or refinery, steel plant, power station, mine and/or quarry, port area, asbestos or other mineral fibres, waste dump, and incinerator. A characteristic feature of SENTIERI project was the a priori assessment of epidemiological evidence of the causal association between environmental exposures and the causes of death analysed; this evidence was classified as Sufficient, Limited or Inadequate. Procedures and results of the evaluation are detailed in a 2010 supplement of Epidemiology & Prevention.

Status of implementation in regional contexts. SENTIERI project covered the whole country; observed mortality in each SNI was compared with that expected based on the data for the Region in which the SNI is located.

Description of the data. Table 1.1 shows the observed and expected mortality rates, by gender, in all SNIs, for environmental exposures present in the SNIs. For each type of exposure, data were provided on causes of death for which the evidence of a causal association was assessed a priori as Sufficient or Limited.

Presentation and critical evaluation of data. In all SNIs (data not shown in Table 1.1), the mortality for causes of death with Sufficient or Limited a priori evidence and where the environmental exposures were present, exceeded the expected, with an SMR of 115.8 for men (90% CI 114.4-117.2; 2,439 excess deaths) and 114.4 for women (90% CI 112.4-116.5; 1,069 excess deaths). Even in the analysis of all causes of death (data not shown in Table 1.1), i.e., not restricted to the causes of death with a priori Sufficient or Limited evidence, this excess of mortality is observed: total deaths, for men and women, is 403,692, 9,969 more...
# General overview of the state of health in Italy

Table 1.1. Excess or defect of death by type of environmental exposure: cause of death with evidence evaluated as Sufficient or Limited. Period 1995-2002, adjusted for age and socio-economic deprivation

<table>
<thead>
<tr>
<th>Asbestos/other mineral fibres</th>
<th>Cause</th>
<th>Men</th>
<th>Women</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Observed</td>
<td>Expected</td>
<td>SMR</td>
<td>Obs-exp</td>
</tr>
<tr>
<td>Cancer of trachea, broncus and lung</td>
<td>4,935</td>
<td>4,612</td>
<td>107.0</td>
<td>323</td>
</tr>
<tr>
<td>Cancer of the pleura</td>
<td>440</td>
<td>164</td>
<td>268.6</td>
<td>276</td>
</tr>
<tr>
<td>Cancer of the ovary</td>
<td>471</td>
<td>465</td>
<td>101.2</td>
<td>6</td>
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</table>

<table>
<thead>
<tr>
<th>Petrochemical and refineries</th>
<th>Cause</th>
<th>Men</th>
<th>Women</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Observed</td>
<td>Expected</td>
<td>SMR</td>
<td>Obs-exp</td>
</tr>
<tr>
<td>Diseases of the respiratory system</td>
<td>4,884</td>
<td>4,875</td>
<td>100.2</td>
<td>9</td>
</tr>
<tr>
<td>Acute respiratory diseases</td>
<td>1,213</td>
<td>1,125</td>
<td>107.8</td>
<td>88</td>
</tr>
<tr>
<td>Asthma</td>
<td>97</td>
<td>134</td>
<td>72.5</td>
<td>–37</td>
</tr>
<tr>
<td>Cancer of trachea, broncus and lung</td>
<td>6,674</td>
<td>6,139</td>
<td>108.7</td>
<td>535</td>
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</table>

<table>
<thead>
<tr>
<th>Steel plants</th>
<th>Cause</th>
<th>Men</th>
<th>Women</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Observed</td>
<td>Expected</td>
<td>SMR</td>
<td>Obs-exp</td>
</tr>
<tr>
<td>Diseases of the respiratory system</td>
<td>3,083</td>
<td>2,828</td>
<td>109.0</td>
<td>255</td>
</tr>
<tr>
<td>Chronic pulmonary diseases</td>
<td>1,616</td>
<td>1,499</td>
<td>107.8</td>
<td>117</td>
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<tr>
<td>Acute respiratory diseases</td>
<td>783</td>
<td>714</td>
<td>109.7</td>
<td>69</td>
</tr>
<tr>
<td>Asthma</td>
<td>49</td>
<td>68</td>
<td>72.4</td>
<td>–19</td>
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</table>

<table>
<thead>
<tr>
<th>Landfills</th>
<th>Cause</th>
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<th>Women</th>
<th>Total</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>Observed</td>
<td>Expected</td>
<td>SMR</td>
<td>Obs-exp</td>
</tr>
<tr>
<td>Congenital malformations</td>
<td>490</td>
<td>502</td>
<td>97.5</td>
<td>–12</td>
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</table>
### Table 1.1. (Continue)

#### Incinerators

<table>
<thead>
<tr>
<th>Cause</th>
<th>Men</th>
<th>Women</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Observed</td>
<td>Expected</td>
<td>SMR</td>
</tr>
<tr>
<td>Cancer of the stomach</td>
<td>172</td>
<td>167</td>
<td>103.0</td>
</tr>
<tr>
<td>Primary cancer of the liver and intrahepatic bile ducts</td>
<td>137</td>
<td>60</td>
<td>230.0</td>
</tr>
<tr>
<td>Cancer of trachea, broncus and lung</td>
<td>617</td>
<td>475</td>
<td>130.0</td>
</tr>
<tr>
<td>Malignant cancers of connective and other soft tissues</td>
<td>4</td>
<td>7</td>
<td>58.8</td>
</tr>
<tr>
<td>Malignant cancers of lympho-ematopoietic tissue</td>
<td>153</td>
<td>122</td>
<td>125.5</td>
</tr>
<tr>
<td>Non-Hodgkin lymphomas</td>
<td>57</td>
<td>46</td>
<td>124.2</td>
</tr>
</tbody>
</table>

#### Harbour areas

<table>
<thead>
<tr>
<th>Cause</th>
<th>Men</th>
<th>Women</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Observed</td>
<td>Expected</td>
<td>SMR</td>
</tr>
<tr>
<td>Diseases of the respiratory system</td>
<td>5,050</td>
<td>4,966</td>
<td>101.7</td>
</tr>
<tr>
<td>Asthma</td>
<td>89</td>
<td>123</td>
<td>72.3</td>
</tr>
<tr>
<td>Cancer of the pleura</td>
<td>514</td>
<td>291</td>
<td>176.4</td>
</tr>
</tbody>
</table>

#### Chemical plants

<table>
<thead>
<tr>
<th>Cause</th>
<th>Men</th>
<th>Women</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Observed</td>
<td>Expected</td>
<td>SMR</td>
</tr>
<tr>
<td>Diseases of the respiratory system</td>
<td>8,338</td>
<td>8,005</td>
<td>104.2</td>
</tr>
<tr>
<td>Asthma</td>
<td>194</td>
<td>219</td>
<td>88.7</td>
</tr>
<tr>
<td>Colorectal cancer</td>
<td>3,520</td>
<td>3,493</td>
<td>100.8</td>
</tr>
<tr>
<td>Cancer of the stomach</td>
<td>2,404</td>
<td>2,443</td>
<td>98.4</td>
</tr>
</tbody>
</table>
than expected (SMR 102.5, 90% CI 102.3-102.8), with an average of 1,200 cases per year. Almost all of the excess deaths were observed in the Centre-South SNI sites. The distribution of causes of death shows that the increase in mortality in relation to that expected among residents of the 44 SNI sites is not uniform for the different causes: cancer mortality causes 30% of all deaths, but 43.2% of excess deaths (4,309 deaths from cancer from 9,969 deaths). In contrast, the percentage of excess deaths for non-cancer causes was 19%, lower than 42% of total deaths.

The results indicate, consistently with previous studies, that the state of health of the population that lives near an SNI, insofar as measured by the analysis of mortality, is less favourable than that of the regional reference population. Despite some limitations of the data and methodologies, the analysis restricted to causes identified in SENTIERI project as more plausible, namely, those with a priori Sufficient or Limited evidence, provides a further indication of the need to promote and implement the effective remediation of SNIs and, in any case, to minimise the sources of contamination, or, in the case of industrial sites in operation, to significantly reduce industrial emissions, in order to limit as much as possible the effects on health of exposure to environmental pollutants.

Essential bibliography


1.2.2. Indoor air

**Planning framework.** The prevention and control of indoor pollutants present themselves as priority objectives of the European Union (EU) Environment and Health Action Plan 2004-2012, which strongly supports the importance of protecting children’s health from the threats present in living environments.

These objectives are also among the priorities of the Parma Declaration, signed by the Ministers of Health and Environment of the 53 countries in the WHO European Region at the Fifth Pan-European Conference on Environment and Health on the theme “Protecting the health of children in a changing environment” (Parma 2010).

In line with EU and WHO guidelines, the National Health Plan 2006-2008 set out large-scale objectives on environment and health issues and among health priorities includes the goal of ensuring that all children may live and study in healthy and safe environments. Similarly, the new National Prevention Plan 2010-2012, launched by the State-Regions Agreement of April 29, 2010, includes as one of its central planks (on the basis of which the Regions prepare their prevention plans for their area) strategies aimed at improving hygiene requirements of indoor air quality (IAQ) in schools and other environments frequented by children. In implementing the above guidelines, the State-Regions Agreement of November 18, 2010, entitled “Guidelines for prevention of risk factors for indoor allergies and asthma in schools”, outlines a programme of integrated actions for implementation in schools, to limit the contact of students with the indoor risk factors implicated in the induction and aggravation of respiratory diseases, asthma and allergies. The programme indicates a series of multi-disciplinary and intersector actions to be followed that relate to the fields of health and environment prevention, communication, education, and research.

**State of implementation.** The Ministry of Health, in order to develop a comprehensive approach to monitoring, diagnosis, prevention and control of chronic respiratory diseases, in 2009 joined the international GARD (Global Alliance Against Chronic Respiratory Disease), a voluntary alliance promoted by WHO, which includes organisations, institutions and agencies working for the common goal of improving global respiratory health. The working group “GARD-1 for indoor prevention in schools” was established as part of the Italian GARD initiative, with the specific task of facilitating the implementation of the Guidelines for the prevention of indoor risks for respiratory diseases, asthma and allergies in schools. The working group concluded in November 2011 a context analysis of the situation of indoor pollution in Italian schools and consequent effects on the health of students. The group’s next goal is to develop the Guidelines for the improvement of the IAQ in schools; for this purpose synergies and links with other working groups operating within the context of European and national research projects on indoor pollution in schools were set up, listed below.

- The three-year project (2009-2012) entitled “Exposure to indoor pollutants: Guidelines for the assessment of risk factors in school environments and definition of measures to protect the respiratory health of schoolchildren and adolescents”, approved and funded by the Ministry of Health under the expertise of the National Centre for Disease Prevention and Control (Centro nazionale per la prevenzione e il controllo delle malattie, CCM). The study’s primary objective is to implement the guidelines on the control of risks of exposure to a poor IAQ for respiratory diseases and allergies in primary and secondary schools of the first grade.

  - The European SINPHONIE project (Schools Indoor Pollution and Health: Observatory Network in Europe), of 2 years duration, approved and financed by the European Commission through the DG SANCO (Directorate-General for Health and Consumer Affairs, Luxemburg), which is part of the EU Environment and Health
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Action Plan 2004-2012. The project, which will finish at the end of 2012, includes 24 European countries. Three Italian Regions are participating: Lombardy, Tuscany and Sicily. The study’s primary objectives are:
- critical review of the most important effects of exposure to pollution in the school environment;
- assessment of air quality in classes in the selected schools and of effects on health of pupils.

The RESPIRA project (Indoor and outdoor Air quality and Respiratory Health in Malta and Sicily): a two-year project developed under the Italy-Malta Cross-Border Cooperation Programme [Operational Programme (PO) 2007-2013], which will end in spring 2013. It involves 1,200 children from the Province of Caltanissetta (Sicily) and 600 Maltese children. In the study health data will be compared with environmental data, internally from both schools as well as homes, with particular attention to chemical pollutants (gaseous and PM$_{2.5}$) and biological (bacterial endotoxins and allergens). A sample of parents will be assessed to better understand the family component of allergic respiratory disorders.

Finally, the GARD-1 group also collaborated with the National indoor study group established by the ISS, for the definition of Guidelines on the main indoor pollutants and standards for monitoring and assessment of indoor exposures.

Description of the data. As part of its mandate, the GARD-1 group conducted a survey on the state of building and environmental hygiene in schools and educational facilities in Italy and collected the available scientific evidence on the effects of indoor air pollution on the health of students. The survey showed that in school buildings, several critical structural and environmental-hygiene situations are present, resulting both from regulatory gaps and deficiencies in management; the Italian school building stock has a percentage of schools which are still too old, 17% of them built before 1945 and 59% built before 1975; energy efficiency in the education building stock is in a critical state, because much of it was built in the thirty years between 1950-1980, in the absence of specific regulations on energy saving in buildings. In the light of all this, some European and Italian studies have shown that poor air quality in classrooms and non-optimal microclimatic conditions may adversely affect the health and performance of students (Table 1.2).

Presentation and critical evaluation of data. Epidemiological studies conducted to date in Italy, in addition to providing general guidance on how to tackle the IAQ problem in schools, are also a source of new methods of multidisciplinary working, based on collaboration of various institutions and bodies and on the skills and experience of technicians, researchers, teachers and students. Therefore, these experiences should be reproduced and distributed throughout the territory to ensure dissemination of greater knowledge about the phenomenon of indoor pollution, its health consequences and the real possibilities of prevention. In parallel, other important steps to protect the health of all those who attend school for study or work are: strengthening and updating regulatory tools (e.g., application of the ban on smoking in schools and a review of current construction legislation for the rehabilitation of existing school buildings and the design/construction of new buildings); and definition of guidelines to improve indoor air quality and promoting healthy behaviour and lifestyles via the educational institution.

Essential bibliography

Accordo, ai sensi dell’art. 9 del D.Lgs. 27 agosto 1997, n. 281, tra Governo, Regioni, Province Autonome di Trento e Bolzano, Province, Comuni e Comunità montane concernente “Linee di indirizzo per la prevenzione nelle scuole dei fattori di rischio indoor per allergie e asma”. Repertorio atti n. 124/CU, 18 novembre 2010. GU del 13 gennaio 2011, SG n. 9


Ministero dell’istruzione e della ricerca, Dipartimento
Table 1.2. Studies on evidence of associations between quality of indoor air in school environments and respiratory/allergy symptomatology in children

<table>
<thead>
<tr>
<th>Study</th>
<th>Country, No. subjects, Age</th>
<th>Type of exposure</th>
<th>Outcomes</th>
<th>Odds ratio</th>
<th>Association*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Taskinen et al., 1999</td>
<td>Finland No. 622 7-13 years</td>
<td>Mould/moisture (yes vs no)</td>
<td>Urgent visits</td>
<td>2.0</td>
<td>2.1</td>
</tr>
<tr>
<td>Smedje et al., 2001</td>
<td>Sweden No. 1,347 7-13 years</td>
<td>Cat allergens Dust Airborne particles</td>
<td>Asthma Asthma Domestic animal allergies</td>
<td>1.4 per 10 ng 1.4 per 50 mg 1.8 per 10 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Fraga et al., 2008</td>
<td>Portugal No. 1,607 14 years</td>
<td>CO₂ (x 100 ppm)</td>
<td>Nighttime cough Exercise-induced bronchoconstriction</td>
<td>Per CO₂ &gt; 2,100 ppm: 1.40 1.86</td>
<td></td>
</tr>
<tr>
<td>Simoni et al., 2010</td>
<td>Studio HESE** No. 654 10 years</td>
<td>CO₂ (x 100 ppm)</td>
<td>Dry nighttime cough Recent rhinitis</td>
<td>1.06 1.06</td>
<td></td>
</tr>
<tr>
<td>Kim et al., 2007</td>
<td>Sweden No. 1,014 Primary School</td>
<td>Temperature Relative humidity CO₂ No. of air changes/hour Total MVOCs Mould Formaldehyde</td>
<td>Wheezing Asthma diagnoses Daytime respiratory difficulty Nighttime respiratory difficulty</td>
<td>The highest concentrations of MVOC with nighttime respiratory difficulty (p &lt; 0.01), asthma diagnoses (p &lt; 0.05)</td>
<td></td>
</tr>
<tr>
<td>Simoni et al., 2011</td>
<td>Italy, Norway, Sweden, Denmark, France No. 654 10 years</td>
<td>Mould &gt; 300 cfu/m³</td>
<td>Dry nighttime cough Rhinitis Persistent cough</td>
<td>3.10 2.86 3.79</td>
<td></td>
</tr>
</tbody>
</table>

* OR, odds ratio (relation between exposures to a risk factor and the evolution of a pathology with respect to non exposures which nevertheless have developed that pathology. If the value of the OR is > 1, the risk factor is or may be associated with the appearance of the illness.

** Italy, Sweden, Denmark, Norway, France.

Wargocki P, Wyon DP. The effects of moderately raised classroom temperatures and classroom ventilation rate on the performance of schoolwork by children. HVAC & R Research 2007; 13: 193-220

1.3. Lifestyles

1.3.1. Diet and exercise

Planning framework. Overweight and obesity represent a major challenge for public health; in particular, the epidemic that is emerging in children is worrying. WHO projections show that, for 2015, overweight adults will number around 2.3 billion and those obese more than 700 million. In parallel, the prevalence of diabetes will increase to 6.3% in 2025, involving 333 million people around the world. This situation is particularly worrying because of the high associated morbidity, particularly of the cardiovascular type, in addition to type 2 diabetes, usually preceded by the various components of
the metabolic syndrome (hypertension and atherogenic dyslipidaemia), with progressive atherosclerosis and increased risk of cardio- and cerebro-vascular events.

A healthy diet combined with an active lifestyle is a valid instrument for the prevention, management and treatment of many diseases. The promotion of physical activity and proper nutrition is therefore a topic of primary interest for public health and which has such positive effects on the health of the population that it deserves to occupy a central place in strategic health planning. Policies and actions that promote physical activity, as well as representing an investment for the prevention of chronic diseases and the improvement of health, also have positive effects on society and the economy. Physical inactivity, in fact, also has an economic impact, on both the direct and indirect costs of health care and the impact on productivity and the years of healthy life.

Integrated strategies are needed to promote healthy and active lifestyles that should include not only healthcare environments, but also educational, urban planning, transport and agricultural policies. The intersectoral approach allows unhealthy behaviours to be changed, recommends behavioural (acting on individual lifestyles) and social interventions (creating environmental conditions favourable for changing individual behaviours and maintaining them over time), as indicated by the programme “Gaining Health: making healthy choices easier”, approved by prime ministerial decree (DPCM) on May 4, 2007. The strategy proposed by the National Prevention Plan 2010-2012, furthermore, is not limited to the promotion of actions in specific health areas, but also acts in other areas, especially those (environmental, social and economic) with greater influence on individual behaviour, living environments and work.

**State of implementation in the regional contexts.** A healthy diet and an active lifestyle are important tools for the prevention, management and treatment of many diseases and, therefore, are cornerstones of the Regional Prevention Plans for 2010-2012, as well as being the subject of specific projects in the territory providing training for operators as well as information and communications.

All the Regions, within the Universal Prevention macro-area of the National Prevention Plan, have developed general intervention guidelines for the prevention and monitoring of habits, behaviours, unhealthy lifestyles and related diseases, with particular reference to issues of unhealthy diet and inactivity, which are being realised according to the methodological approach proposed by the “Gaining Health” programme.

The project “Good nutrition practices - promoting fresh fruit and vegetables”, better known as “Let’s go...with fruit”, saw the involvement of the Tuscany, Campania, Marche, Apulia, and Sicily Regions, with the scientific support of the Centre for Research and Health promotion of the University of Siena (CREPS). The project aimed to increase consumption of fruit and vegetables in primary as well as first- and second-grade secondary schools and in workplaces, through the implementation of training programmes aimed at children, teachers and workers with the use of training courses and specific educational materials, as well as the preparation of information and awareness campaigns. Health authority workers were also involved.

Twenty classes were included in each Region, between intervention and control, at every scholastic level and school year, where a pre/post questionnaire on knowledge, attitudes and behaviours was distributed. Data analysis showed a statistically significant improvement on the three aspects investigated, in particular in the increase in consumption of fruits and vegetables. Hence, the availability of fruit in primary schools and the automatic distribution of fruit and vegetables in secondary schools when accompanied by training have proven to be valuable tools to increase their consumption.

**Description of the data.** Data from the 2010 PASSI report, a system of continuous monitoring of the adult Italian population on the major behavioural risk factors, show that one third of the population between
18 and 69 years is completely sedentary, i.e. they do not perform any type of physical activity, either at work or during leisure time. Physical inactivity is more common in the South of the country, in those between 50-69 years old, in women, in people with lower education levels and in those who report many economic difficulties. A positive signal, probably due to awareness activities promoted at various levels, is the reduction in the percentage of people with sedentary lifestyles who perceive their level of physical activity as sufficient (from 25.7% in 2007 to 20.1% in 2010).

The 2010 PASSI data also show that 32% of adults are overweight, while 11% are obese: overall, then, more than 4 adults in 10 (42%) are overweight. Excess weight increases significantly with age and is more common in men, in people with lower levels of education and in those with greater economic problems, with statistically significant differences among Regions: the Autonomous Province of Trent is the Region with the lowest percentage of people who are overweight/obese (29%), while Apulia is the Region with the highest (49%).

In total, 97% of respondents reported eating fruit and vegetables at least once a day. Among these, 39% reported eating 3-4 servings. Only 10%, however, has adhered fully to the recommendations, reporting consumption of at least 5 daily servings of fruits and vegetables (five-a-day). Women most frequently consume 5 servings a day, followed by older people (50-69 years) and those with a high level of education. The lowest value (6%) is recorded in the Calabria local health authority (Azienda sanitaria locale, ASL), the highest in Liguria (20%).

Presentation and critical evaluation of data. The current epidemiological situation, characterised by the prevalence of chronic-degenerative diseases and the role played in their determinism by several factors including those of behaviour or lifestyle, requires that interest be focussed on health promotion for the period before a disease establishes itself, in order also to reduce inequalities in health and health and social costs. The need to monitor closely the nutritional situation and living habits of the general population and in particular those of children is strongly motivated by the direct implications for health. The development of national and territorial monitoring systems is, therefore, a principle underlying Italian strategies of prevention and health promotion (the Government Programme “Gaining Health” and the National Prevention Plan). As part of the intersectoral “Gaining Health” programme, these monitoring systems promote collaboration among the network of operators involved, allowing testing and developing of methods of communication addressed to multiple stakeholders and facilitating the integration between the different professionals and services.

Continuous monitoring of the phenomenon is necessary to allow the construction of temporal trends and evaluation of health outcomes, but also to plan public health interventions that may be decisive for various age groups and, at the same time, provide the elements necessary for an evaluation in terms of effectiveness, cost, accessibility and health inequalities.

It is essential to discourage unhealthy behaviours, following the principles of “Gaining Health”, and to tackle the environmental, social and individual determinants of physical inactivity and unhealthy eating, to implement sustainable actions through a collaboration between multiple sectors at national, regional and local levels and to strengthen the active role of advocacy by health professionals, in order to ensure that economic, agricultural, commercial and educational policies are designed to promote and facilitate the adoption of healthy choices by citizens.

Essential bibliography
Ministero della salute. Appropriatezza clinica, strutturale, tecnologica e operativa per la prevenzione, diagnosi e terapia dell’obesità e del diabete mellito. Quaderni del Ministero della salute, n. 10, luglio-agosto 2011
Ministero della salute. Relazione sullo Stato Sanitario del Paese 2009-2010
1.3.2. Smoking, alcohol, drug and psychotropic agents

Planning framework. Cigarette smoking, alcohol abuse and drug use are some of the major behavioural factors of risk for mortality in our country. Smoking prevention requires cooperation and coordination among many different individuals and Institutions/Administrations, according to the intersectoral and transversal approach to risk factors proposed by the National “Gaining Health: making healthy choices easier” programme. The Italian strategy for the fight against smoking is based on protecting the health of non-smokers, the reduction of the numbers of new smokers, and support for quitting by current smokers. Next to primary prevention and cure of smoking and related illnesses, it is necessary to develop and support legislation on smoke-free environments, adopt measures governing the labelling and advertising of products, define fiscal policies and prices, take part in international initiatives for tobacco control by implementing in particular the measures recommended by the WHO Framework Convention for Tobacco Control of 2003, as well as actively participate in the process of drafting legislation and other activities promoted by the EU.

Regarding alcohol, the current prevention policies of the Ministry of Health are included in the National Prevention Plan 2010-2012, which includes, as a priority, the reduction in the different categories of at-risk consumers of alcohol, such as those who drink between meals, consumers of daily amounts that are not compatible with good health, “binge drinkers”, consumers who drive in a state of mental and physical impairment due to alcohol, and consumers in the workplace.

The use/abuse of drugs and associated lifestyles also represent a public health problem, both for the direct effects on the consumers, and for the general population not directly exposed to them. The National Anti-Drug Action Plan 2010-2013, approved by the President of the Council of Ministers in 2010, aims to strengthen prevention interventions based on their efficiency, and aimed both at the general population and, especially, at those with vulnerable and at-risk behaviour among the young population. The Plan emphasises the need to implement the offer of “testing” for the main drug-related infectious diseases in the Services that treat those with addictions, to ensure actions of prevention of related diseases, encouraging collaboration and coordination between socio-health services in relation to situations of psychiatric co-morbidity, infectious diseases, etc., with particular regard to detained persons.

State of implementation in regional contexts. The role of the Regions, as institutions close to citizens and responsibility-holders for the organisation of health care, is crucial for the development and dissemination of activities and interventions promoting healthy lifestyles and prevention of risk behaviours. The CCM of the Ministry of Health promotes the realisation of numerous projects, largely entrusted to coordination by the Regions and the ISS, in support of prevention and health promotion. From 2004 to 2011, for example, seventeen CCM anti-smoking projects were started, which facilitated among other things the inclusion of anti-smoking in the institutional actions of all Regions. In addition, at the local level, models of intervention for prevention of smoking among young people have been tried as well as the strengthening of the network of socio-health workers, the development of community and workplace programmes, as well as training activities and brief motivational interviews for health workers and those in other sectors (pharmacists, teachers, sports workers etc.). Based on the results and the indications of these CCM projects, sixteen regional authorities have included anti-smoking projects in their territorial plans as part of a specific course of action for the promotion of healthy lifestyles of the National Prevention Plan 2010-2012 (40 projects out of a total of 153 in total on this theme) [Table 1.3].

The Regions also, as is clear from the monitoring reports prepared for the purpos-
es of the Report to Parliament under the 125/2001 law, are continuing their efforts to combat alcohol-related problems and have focussed in particular on the planning of activities for treatment and prevention, increasingly adopting a model of intersector and interdisciplinary approach.

The country has 525 active public services for persons with drug addictions that ensure the management of individuals with problems of addiction to legal and illegal substances. Following the January 21, 1999 Agreement, these services have been included in the remit of Departments of Addiction, established by different Regions. In order to make policies to combat drug addiction more effective, further consultation and coordination of objectives is required between the central, regional and local institutions who are involved, in order also to address emerging issues such as compulsive gambling.

**Description of the data.** The prevalence of at-risk consumers of alcohol in the population aged over 11 years is equal to 25.4% among males and 7.3% among females according to the indicator of risk used by the ISS, for more than 8.6 million individuals. Among young people of 11-25 years, 20.1% of males and 10.1% of females, and among people older than 65 years, 44.3% of males and 11.4% of females, present as being at-risk. There remain strong gender differences in all age groups, except the under legal age group (11-15 years), where there are no statistically significant differences between males and females. Consumption and consumption patterns in the different Regions and Autonomous Provinces remain high (Table 1.4), most of the at-risk consumption values above the national average are found in North-eastern and North-western Italy, while the lower values are concentrated in central and southern Italy, as well as the islands. In particular, the national maximum values for consumption between meals, binge drinking and overall at-risk consumption are found in the male population of Northeastern Italy.

With regard to substance abuse, in 2010 the activities of 486 public services for addiction treatment were surveyed, from a total of 525 active in total (92.6%). 177,227 patients with substance abuse problems were cared for.

The substance of abuse for which the request for treatment is the most widespread is heroin (70.1% of patients), followed by cocaine (15.2%) and cannabinoids (9.2%). 8.7% of all patients cared for by public Services were treated at rehabilitation centres (a decreasing trend compared to previous years); 62.9% of public service patients were treated with integrated pharmacological programmes.

Regarding the issue of youth smoking, the “Global Youth Tobacco Survey”, sponsored by the CCM, which in the school year 2009-2010 involved 1,800 boys of 13, 14 and 15 years, showed that 46% of respondents had smoked at least once in their lifetime and 92% of these said that retailers had never refused to sell them cigarettes, despite the fact that current legislation prohibited sales.

<table>
<thead>
<tr>
<th>Region</th>
<th>Projects</th>
</tr>
</thead>
<tbody>
<tr>
<td>Piedmont</td>
<td>5</td>
</tr>
<tr>
<td>Aosta Valley</td>
<td>NA</td>
</tr>
<tr>
<td>Lombardy</td>
<td>3</td>
</tr>
<tr>
<td>Aut. Prov. of Bolzano</td>
<td>NA</td>
</tr>
<tr>
<td>Aut. Prov. of Trent</td>
<td>1</td>
</tr>
<tr>
<td>Veneto</td>
<td>4</td>
</tr>
<tr>
<td>Friuli Venezia Giulia</td>
<td>2</td>
</tr>
<tr>
<td>Liguria</td>
<td>1</td>
</tr>
<tr>
<td>Emilia Romagna</td>
<td>1</td>
</tr>
<tr>
<td>Tuscany</td>
<td>3</td>
</tr>
<tr>
<td>Umbria</td>
<td>2</td>
</tr>
<tr>
<td>Marche</td>
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</tr>
<tr>
<td>Lazio</td>
<td>2</td>
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<tr>
<td>Abruzzo</td>
<td>1</td>
</tr>
<tr>
<td>Molise</td>
<td>0</td>
</tr>
<tr>
<td>Campania</td>
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</tr>
<tr>
<td>Apulia</td>
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<td>Basilicata</td>
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<td>Calabria</td>
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<tr>
<td>Sicily</td>
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<tr>
<td>Sardinia</td>
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</tr>
<tr>
<td>Total</td>
<td>40</td>
</tr>
</tbody>
</table>

*NA, not available.*
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to persons under 16 years. As shown by the “Health Behaviour in School-aged Children” (HBSC) survey conducted in 2010 of approximately 77,000 children between the ages of 11 and 15 years, 1% of males and 0.2% of females of 11 years, 4.14% of males and 3.68% of females of 13 years and, above all, 19.08% of males and 19.42% of females of 15 years smoke at least once a week.

**Presentation and critical evaluation of data.** It is necessary to consolidate the achievements made and to set new goals, because each progress made in the prevention of at-risk behaviour has a tremendous result in terms of health and quality of life of all citizens, as well as in terms of reduced health and social costs for the related diseases.

An emerging problem, for example, is the

### Tabella 1.4. Type of consumer (%) classified by territory, Region and gender (Year 2010)

<table>
<thead>
<tr>
<th>Territory</th>
<th>All alcoholic drinks</th>
<th>Between meals</th>
<th>Binge drinking</th>
<th>At risk (ISS criterion)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>M</td>
<td>F</td>
<td>M</td>
<td>F</td>
</tr>
<tr>
<td>Italy North-western</td>
<td>80.6</td>
<td>57.8</td>
<td>41.0</td>
<td>18.5</td>
</tr>
<tr>
<td>Piedmont</td>
<td>80.9♦</td>
<td>57.4</td>
<td>39.0</td>
<td>17.7▲</td>
</tr>
<tr>
<td>Aosta Valley</td>
<td>80.8▼</td>
<td>63.6</td>
<td>51.2</td>
<td>25.4▲</td>
</tr>
<tr>
<td>Lombardy</td>
<td>80.6</td>
<td>58.4</td>
<td>42.0</td>
<td>19.4</td>
</tr>
<tr>
<td>Liguria</td>
<td>79.7</td>
<td>55.7</td>
<td>39.2</td>
<td>14.6</td>
</tr>
<tr>
<td>Italy North-eastern</td>
<td>78.6</td>
<td>58.5</td>
<td>45.2</td>
<td>19.4</td>
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<tr>
<td>Aut. Prov. of Bolzano</td>
<td>80.5</td>
<td>66.0</td>
<td>57.8</td>
<td>34.3</td>
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<tr>
<td>Aut. Prov. of Trent</td>
<td>78.5</td>
<td>54.1</td>
<td>56.1</td>
<td>21.7</td>
</tr>
<tr>
<td>Veneto</td>
<td>78.9▼</td>
<td>59.4▼</td>
<td>48.6</td>
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<tr>
<td>Friuli Venezia Giuli</td>
<td>80.1</td>
<td>59.5</td>
<td>55.8</td>
<td>24.5</td>
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<tr>
<td>Emilia Romagna</td>
<td>77.8▼</td>
<td>57.0▼</td>
<td>35.8</td>
<td>14.3</td>
</tr>
<tr>
<td>Italy central</td>
<td>79.4</td>
<td>54.9</td>
<td>33.3</td>
<td>13.5</td>
</tr>
<tr>
<td>Tuscany</td>
<td>80.8</td>
<td>58.1▼</td>
<td>32.4</td>
<td>13.8</td>
</tr>
<tr>
<td>Umbria</td>
<td>78.2</td>
<td>52.7▼</td>
<td>33.5</td>
<td>11.6</td>
</tr>
<tr>
<td>Marche</td>
<td>78.7▼</td>
<td>51.8▼</td>
<td>31.9</td>
<td>11.6</td>
</tr>
<tr>
<td>Lazio</td>
<td>78.9</td>
<td>54.0</td>
<td>34.3</td>
<td>14.2▼</td>
</tr>
<tr>
<td>Abruzzo</td>
<td>83.5</td>
<td>50.5</td>
<td>41.4</td>
<td>11.1</td>
</tr>
<tr>
<td>Molise</td>
<td>83.8</td>
<td>45.7</td>
<td>45.6</td>
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</tr>
<tr>
<td>Italy south</td>
<td>78.1</td>
<td>46.5</td>
<td>29.1</td>
<td>8.0</td>
</tr>
<tr>
<td>Campania</td>
<td>74.7</td>
<td>43.0▼</td>
<td>23.1</td>
<td>6.4</td>
</tr>
<tr>
<td>Apulia</td>
<td>80.1</td>
<td>49.2</td>
<td>29.0</td>
<td>8.6</td>
</tr>
<tr>
<td>Basilicata</td>
<td>79.3</td>
<td>45.5</td>
<td>35.5</td>
<td>8.4</td>
</tr>
<tr>
<td>Calabria</td>
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<td>48.9</td>
<td>33.5</td>
<td>8.7</td>
</tr>
<tr>
<td>Italy islands</td>
<td>75.7</td>
<td>45.5</td>
<td>32.6</td>
<td>9.5</td>
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<tr>
<td>Sicily</td>
<td>74.2</td>
<td>45.2</td>
<td>27.2</td>
<td>8.2</td>
</tr>
<tr>
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<td>80.0</td>
<td>46.4</td>
<td>48.5</td>
<td>13.7</td>
</tr>
<tr>
<td>Italy</td>
<td>78.9▼</td>
<td>53.4▼</td>
<td>18.5</td>
<td>14.2▼</td>
</tr>
</tbody>
</table>

▲ Statistically significant increase between 2009 and 2010 (* increase between 2008 and 2010).

Source: Processing by National Alcohol Observatory CNESPS and WHO CC Research on Alcohol on Istat data – Multi-scope Inquiry on families 2010.
need to take care of persons who are compulsive gamblers. From the 2012 Report to Parliament on Addiction it is estimated that people who have a gambling problem number about 700,000, and of these, about 300,000 at a pathological level. From 2011 data limited to those Regions/Autonomous Provinces which transmitted them, 4,687 subjects were noted as being treated for pathological gambling, 82% of which were male. It is therefore necessary to define how to manage and assist these patients, providing them with pathways of care and rehabilitation based on scientific evidence. To improve the planning of effective interventions the National Information System on Dependencies (Sistema Informativo Nazionale, SIND) on patients receiving treatment should be operating and included in the New Health Information System (Nuovo Sistema Informativo Sanitario, NSIS), in collaboration with the Regions and with the coordination of the Department for Anti-Drug Policies of the President of the Council of Ministers.

The data of the Independent Administration of State Monopolies (Amministrazione Autonoma dei Monopoli di Stato, AAMS) show that in 2010 cigarette sales decreased by 2.4% compared to 2009 (about 1 packet less a month purchased by each smoker). A further significant increase (+32.7%) of the sales of shredded tobacco (for “do it yourself” cigarettes) should be noted, however. This type of tobacco currently accounts for 3.2% of the market, but costs less than cigarettes, and is therefore particularly “attractive” to young consumers. It is necessary, therefore, to facilitate the activation of preventive interventions against smoking, characterized by participation and coordination between educators and community health workers, with the aim of reaching an ever-increasing number of young smokers, of building a smoke-free society, and also of involving young people who are already smokers, with particular emphasis on girls, through cross-sectional interventions on smoking, physical activity and proper nutrition. These interventions must be implemented not only in schools but also in formal and informal places where young people gather.

The risks arising from new manners of drinking that have spread in our country in recent years endanger, in addition to the health of the individual drinker, community safety, especially when the consumption of alcohol occurs in particular contexts and situations such as driving, performance of work activity or the pursuit of extreme fun; in any case, even traditional consumption levels are unsafe if unaccompanied by necessary and strict moderation. The situation requires complex and well developed preventive interventions, especially considering that exposure to risk is seen in very diverse subjects; among them, in particular, about 1,300,000 young people between 11 and 25 years of age with an at-risk consumption of alcohol between meals or by binge drinking, more than 3 million seniors who do not adhere to the Mediterranean model of moderation and approximately 390,000 minors under the legal age who are not totally abstinent from alcohol consumption. Women’s consumption of alcohol, while being far less common than men’s, has seen an alarming increase in between meals consumption and binge drinking in the last decade, especially among younger women.

In conclusion, the variety of risk situations for smoking, alcohol and drugs observed in the individual Regions requires a great responsibility to be accepted on the part of the latter, both now and in the future, to enable development of more appropriate interventions for the range of problems detected.

Essential bibliography

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Presidenza del Consiglio dei Ministri – Dipartimento per le Politiche Antidroga – Relazione al Parlamento 2011
Presidenza del Consiglio dei Ministri – Dipartimento per le Politiche Antidroga – Relazione al Parlamento sulle tossicodipendenze 2012
1.4. Social determinants

In 2009 the European Commission, through the communication “Solidarity in health: Reducing health inequalities in the EU”, declared that it was as if, both in European policies and in regional and local authority planning as well as between the main social players, there was still insufficient awareness of health inequalities and their consequences on the wellbeing of populations. The communication, received and implemented by the European Parliament in 2011, with a resolution of the same name, reminded all EU Member States of the need to confront these challenges: improving the capabilities of monitoring of inequalities; giving priority to studies evaluating the impact of policies on health and health inequalities and basing interventions to tackle inequalities on evidence of efficacy, stimulating efforts to coordinate policies in this regard; enhancing the incentives and assistance that European-wide policies can ensure. In particular, starting from the assumption that an equitable distribution of health in the population is the basis for comprehensive economic and social development, the Commission proposed to focus on: 1) the need for better measurement of health inequalities as a key step to better address actions to reduce them; 2) the involvement and commitment of civil society; and 3) particular attention to be devoted to vulnerable groups and weaker sections of the population.

Over the following twelve months, other European institutions adopted the conclusions of the Communication making recommendations for priorities and for directions. The European Commission also funded a Joint Action through the Community action in the field of health 2011-2013, called Equity Action, in support of the engagement of Member States in actions to implement the recommendations of the Commission, including exercises of equity audit of specific policies at regional, national and European level, attracting the attention of stakeholders to these issues, promoting research on knowledge gaps and finally, developing tools and technical knowledge to better understand the mechanisms that generate inequality and the impact of health and non-health policies on these mechanisms.

A first Italian response to the Communication was made through the political initiative of the Conference of Regions and Autonomous Provinces; in April 2011, its Health Commission in fact established and entrusted to the Piedmont Region the setting up of a technical interregional working group, to which was assigned the task of giving continuity to the European recommendations. The group, called Equity in Health and Healthcare (Equità in Salute e Sanità, ESS) and which currently consists of representatives of 10 Regions, aims to develop: 1) a report on the state of inequalities in Italy including the epidemiological profile of health inequalities, assessment of the knowledge on the expected effectiveness of actions and an estimate of the potential reduction (targets and monitoring indicators) of health inequalities achievable by such actions; and 2) a report on priority recommendations oriented towards equity in health and reduction of health inequalities both in the main health planning acts (such as prevention plans or the Pact for Health) and in some areas of planning policy outside the health sector (such as the use of structural funds), for submission to the relevant institutions.

Italy is also involved (through the National Agency for Regional Health Services, and the Veneto and Piedmont Regions) in the European Equity Action initiative sponsored by the European Commission, with a contribution towards the definition and sharing of methods and tools for assessment of the impact of political choices on health inequalities, towards the building of a network of Regions with which to identify examples of regional policies that may be subject to a practical exercise of impact assessment and towards the involvement of decision makers and players in health and other policies in responsibilities for tackling health inequalities.

On the technical-scientific level, the Italian network of experts funded in 2010-2011 by
the National Institute for Health, Migration and Poverty (Istituto Nazionale per la promozione della salute delle popolazioni Migranti e il contrasto delle malattie della Povertà, INMP), through the “Constructing the ability to manage health inequalities in Italy project”, surveyed and shared the main experiences of research and interventions already conducted in Italy on monitoring and tackling in non-health policies and those of health prevention and of health care. This project demonstrated the technical expertise of several academic institutions and of the SSN in measuring the extent of inequality and identifying useful actions, especially in prevention and health care, albeit in an un-systematic manner. Regarding policies outside those of the health sector, these skills are less consolidated, since the development of the strategies of Gaining Health and of Health in All Policies and the intersectoral collaborations implied are still in their infancy. The skills surveyed in the INMP project will be mobilised to meet the inquiry needs of the ESS group, developing a real agenda for an Italian capacity building useful in the development of actions to reduce health inequalities, including, for example: the adaptation of health and statistics information systems to enable a systematic equity audit and evaluation of impact of the social determinants on health; the development of forecasting tools that allow the identification of risk factors and/or health promoters with the greatest impact on inequalities, in order to identify priorities and targets; the documenting of effectiveness of interventions used to reduce health inequalities in different policy areas; the realisation of ex ante evaluations of the impact of new policies to be undertaken on health inequalities (e.g. the response to the financial crisis); training of health professionals in the SSN for the support of these objectives; and the indication of priorities in research objectives. The CCM introduced health inequalities as one of the priorities in the 2012 programme, showing a first sign of sensitivity of the planning acts to the recommendations of the European Commission.

**Essential bibliography**


Governance of the health system: the central level and actions of connection with the Regions and entities of local government

The evolution of the National Health Service (Servizio sanitario nazionale, SSN) takes account of different demands arising on the one hand from the international and European context, with a consequent commitment to follow up those goals shared with other countries within the context of international organisations and, within the meaning of Community law, harmonising legislation relating to health care decisions in the European Union (EU) and, on the other, nationally, by the gradual devolution of powers in health matters up to the Constitutional Reform of 2001, with the new division of powers between the State and the Regions. From the Tallinn Charter, signed in 2008, derive the efforts of Member-States of the European Region of the World Health Organization (WHO) to improve the health of their populations through strengthening health systems, promoting transparency and accountability by investments in health services and in the various sectors that influence the state of health, while acknowledging the available evidence on the relationship between socio-economic development and health. It was also agreed in that forum to include the need to make health systems more responsive to citizens’ expectations, educating them on the their rights and responsibilities in health, involving all stakeholders in the development of health systems, promoting a holistic approach to health problems and an integrated management of diseases, including the theme of health in all policies and the monitoring of performance of the health service.

The Constitution has entrusted to the State the definition of the essential levels of health services in order to assure all citizens have the right to health and, according to the principle of subsidiarity, to the Regions the responsibility for their full implementation, within the planned budget constraints. Government and Regions co-operate on the identification of systems of guarantee for the protection of health, while respecting universalism, equity of access and other basic principles of the SSN.

As regards art. 119 of the Constitution, during 2011, legislative decrees were perfected and issued on health issues under the law of May 5, 2009, no. 42 “Government Delegation on fiscal federalism, in implementation of art. 119 of the Constitution”:

- D.Lgs. no. 68, May 6, 2011 “Provisions on autonomy of income of the Regions and of the Provinces by ordinary statute, as well as the determination of costs and standard requirements in the health sector”;
- D.Lgs. no. 118, June 23, 2011 “Provisions on harmonisation of accounting systems and financial statements of the Regions, local entities and their agencies, under articles 1 and 2 of the law of May 5, 2009, no. 42”;
- D.Lgs. no. 149, September 6, 2011 “Reward and sanction mechanisms related to Regions, Provinces and municipalities, under articles 2, 17 and 26 of the law of May 5, 2009, no. 42”.

Fiscal federalism, which strengthens powers and responsibilities of the Regions, allows the adoption of measures to improve quality and equity of the system to be combined with effective interventions to rationalise spending.

The framework that emerged, led to the development of a model of “multi-level governance” based on the new distribution of powers, where alongside the State as the guarantor of constitutional rights, the Community, Regional and Local levels contribute
to decision making, according to the respective areas of competence.
In this context, conventions and institutional arrangements have assumed great importance in the relationship with Regions and local Entities through the years, in which are recognized the diversity of the roles for the State, the Regions and local Entities, but also the equal importance in pursuing the common good. It is worth remembering that over the course of 2011 at sittings of the Conference for relations between State, Regions and Autonomous Provinces of Trent and Bolzano 17 Agreements and 27 Institutional Understandings on the most relevant health issues were signed. To be noted in particular are the understandings and agreements concerning:
- technical guidance document on reducing the disease burden of cancer – years 2011-2013;
- electronic health records – national guidelines;
- guidance plan for rehabilitation;
- criteria for the reorganisation of the network of systems of laboratory diagnostics;
- National Plan for the Elimination of Measles and congenital Rubella syndrome (Piano Nazionale per l’Eliminazione del Morbillo e della Rosolia congenita, PNEMoRc) 2010-2015;
- document for the evaluation of regional prevention plans 2010-2012;
- guidelines for accreditation of umbilical cord blood banks;
- annual programme for national self-sufficiency in blood and blood products for the year 2011;
- changes and updates to the national classification system of medical devices (Classificazione Nazionale dei Dispositivi medici, CND);
- document relative to the national transplant network;
- Project for the transplantation of solid organs in HIV+ patients,
as well as the agreements and understandings of distribution by the Regions of SSN funding and of limited resources in accordance with specific regulations. Eleven opinions were also expressed, in accordance with governing regulations, on various schemes of ministerial decree, such as the decree on “Good practice in clinical trials of veterinary medicines in animals” and on the recognition of the status of research hospital for some structures.
Regulations were also approved for the operation of important technical meetings of monitoring and verification such as the technical committee for the verification of compliance, the standing committee for the verification of the delivery of Essential Levels of Health Care (Livelli essenziali di assistenza, LEA), and the joint technical monitoring facility. At sittings of the Unified Conference, which includes the State and the Regions, Provinces, Municipalities, Communities and Mountain Entities, 8 agreements and understandings were signed and an opinion expressed on the legislative decree plan concerning re-organisation of institutions supervised by the Ministry of Health.
The main health-care acts focussed on:
- guidelines for assistance to persons in a Vegetative State and those in a State of Minimal conscience;
- overall management of people with neuromuscular diseases or similar diseases in terms of assistance;
- an understanding on the National Health Plan for the period 2011-2013;
- additions to the guidance priorities for interventions in Judicial Psychiatric Hospitals (Ospedali Psichiatrici Giudiziari, OPGs) and in nursing and custody homes (Case di Cura e Custodia, CCCs) in Annex C of the DPCM April 1, 2008.
The awareness that the maintenance of a good state of health for the community and for the citizen is also a function of many determinants external to the medical world with the consequent need to engage in intersectoral interventions and policies, has resulted in the need for different levels of government to bring forward the exchange between a multiplicity of players (environment, industry, schools, as well as media and social groups) – who often bring conflicting policies and interventions with them – to achieve the objectives of health, the proper allocation and proper use of resources for the government of the system, overcoming...
the traditional vertical hierarchical model. National planning is hence increasingly taking on a role of stewardship, meaning by that term, not yet accurately translated into Italian, a new model of governance, promoted in Tallinn by WHO and adopted by other European countries, in which meetings and inter-institutional collaborations are privileged, and eventually include the interest-holders, for the development of shared goals and strategies, with levels of responsibility consistent with decision-making powers, promoting autonomy, and respecting the principle of subsidiarity. The authority that derives from a rigid hierarchical approach at the various levels of the system is replaced by an authoritative that comes from an organic and structured knowledge of data and of the information needed to define the policies and tools and conditions for their practical implementation, and their evaluation for the detection of possible improvements. The various levels of government, becoming nodes in a network in a polycentric system in both the vertical and horizontal senses, also take actions of stewardship in relation to the other subjects involved. The identification of the different players with the agreed objectives leads to a greater responsibility on themselves to improve the effectiveness and efficiency of the system. Constant and timely monitoring, implemented at national level through the use also of the New healthcare information system, of processes, of achievement of objectives and of trends in economic performance, allows the feedback required for the development and implementation of necessary corrective actions so as to ensure effective delivery of the LEA in line with the observance of the constitutional right to health and economic objectives established. The surveys carried out, while taking into account the socio-economic and demographic differences of the populations residing in each Region, highlight inconsistencies and disparity in supply and demand, due to the different stages of development of different regional systems, and of the consequent abilities to transform need into health demand and to provide responses that are appropriate, qualitatively valid and homogeneous. The differences that occur in regional costs for individual levels of care show deficiencies in the provision of certain types of assistance that will demand concrete actions to promote and ensure the equity of the system and the actual delivery of the LEA, by overcoming the structural and qualitative gap in health services in the various regional and local contexts, a priority objective in national health planning. Similarly, in the early part of the new decade (year 2000 onwards), the differences encountered at the regional level and in particular the emergence and persistence of large deficits in some Regions (three of them responsible for 50% of the deficit) led to the need to define a complex path of recovery for those same Regions. This began with the enactment of law 311/2004, which is characterised by a strong central governance and, while respecting institutional responsibilities, sees the State committed to perform, among other things, the role of “accompaniment”, and Regional Authorities being asked to prepare a plan of reorganisation, requalification and strengthening of the Regional Health Service: “Realignment Plan for the health deficit” (law 311/2004). This Plan is part of an Agreement that the Region stipulates with central government, and which defines goals, interventions, and expected results. The structural deficit, with respect to usual financing and own revenues which oblige the signing of the Agreement and the planning of the relevant Realignment Plan, was re-defined by the Finance Act 2010 (191/2009) as 5%. The results achieved to date in the Regions for the Realignment Plan show a lessening of the deficit, which in some is substantial, such as Sicily and Abruzzo. In those in which the deficit was more conspicuous, such as Lazio and Campania, a decrease of the same has been recorded even if the outcome is still linked to the adoption of important structural changes in the Regional Health System. The total deficit in 2011 amounted to Euro 1.779 billion, which appears to be the best operating result in recent years, achieved thanks to the joint efforts of the central and regional Governments.
In the last decade, beginning with the constitutional Act of October 18, 2001, no. 3, Reform of Title V of the Constitution, health has been the main area for the progressive strengthening of regional autonomy and of evolution in the federal sense. The determination of Essential Levels of Health Care (Livelli essenziali di assistenza, LEA) and the monitoring of their delivery was assumed at the highest level of the State legal system as an instrument of equity in health care.

The processes of reform of the National Health Service (Servizio sanitario nazionale, SSN) have generated profound changes in patterns of regulation at the community level. After the first drastic reduction in the number of local health authorities or ASLs (65%) following the implementation of the legislative decree (D.Lgs.) 502/1992, the decrease observed nationally in subsequent years is not homogeneous across all Regions (Table 3.1); the interregional variability in values for the ASL catchment area averages increases sig-

### Table 3.1. The change in the process of authority creation. Number of Local Health Authorities and Districts activated (Years 1992-2011)

<table>
<thead>
<tr>
<th>Region</th>
<th>Local health units (USL)</th>
<th>Local health authorities (ASL)</th>
<th>Districts activated</th>
</tr>
</thead>
<tbody>
<tr>
<td>Piedmont</td>
<td>63</td>
<td>22</td>
<td>22</td>
</tr>
<tr>
<td>Aosta Valley</td>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Lombardy</td>
<td>84</td>
<td>44</td>
<td>14</td>
</tr>
<tr>
<td>Aut. Prov. of Bolzano</td>
<td>4</td>
<td>4</td>
<td>4</td>
</tr>
<tr>
<td>Aut. Prov. of Trent</td>
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<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Veneto</td>
<td>36</td>
<td>22</td>
<td>21</td>
</tr>
<tr>
<td>Friuli Venezia Giulia</td>
<td>12</td>
<td>6</td>
<td>6</td>
</tr>
<tr>
<td>Liguria</td>
<td>20</td>
<td>5</td>
<td>5</td>
</tr>
<tr>
<td>Emilia Romagna</td>
<td>41</td>
<td>13</td>
<td>13</td>
</tr>
<tr>
<td>Tuscany</td>
<td>40</td>
<td>12</td>
<td>12</td>
</tr>
<tr>
<td>Umbria</td>
<td>12</td>
<td>5</td>
<td>4</td>
</tr>
<tr>
<td>Marche</td>
<td>24</td>
<td>13</td>
<td>13</td>
</tr>
<tr>
<td>Lazio</td>
<td>51</td>
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<td>12</td>
</tr>
<tr>
<td>Abruzzo</td>
<td>15</td>
<td>6</td>
<td>6</td>
</tr>
<tr>
<td>Molise</td>
<td>7</td>
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<td>4</td>
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<td>Campania</td>
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<td>13</td>
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<td>Apulia</td>
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<td>Basilicata</td>
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<tr>
<td>Calabria</td>
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<td>11</td>
</tr>
<tr>
<td>Sicily</td>
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<td>9</td>
</tr>
<tr>
<td>Sardinia</td>
<td>22</td>
<td>8</td>
<td>8</td>
</tr>
<tr>
<td><strong>Italy</strong></td>
<td><strong>659</strong></td>
<td><strong>228</strong></td>
<td><strong>196</strong></td>
</tr>
</tbody>
</table>

Source: Ministry of Health. Management and economic activities of local health authorities (ASL).
significantly after 2001 and this increase can be interpreted as a result of the application of regional autonomy (Figure 3.1).

In 2011, the tendency towards creation of health authorities at the provincial level was confirmed (145 in all), while the model of the authority at regional level is found in areas of smaller size (Aosta Valley, Autonomous Provinces of Bolzano and Trent, Molise). The exception is the Marche Region, which in 2003 introduced a Regional Health Authority (Azienda sanitaria unica regionale, ASUR) in a territory of about 1,500,000 inhabitants, but the trend toward the provincial health Authorities seems to be confirmed also in this case, considering that the Region has through the Regional law no. 17 of 2011 arranged for the extension of the ASUR to five broad territorial areas of substantially provincial dimensions, with ample economic and managerial autonomy, with competence for the delivery of the LEA and with “Directors of broad territorial areas” designated by the Regional Council. Local health authorities at the sub-provincial level remain both in metropolitan areas and in the Veneto, Umbria and Friuli Venezia Giulia Regions. The composition of broad territorial areas at the inter-institutional level is anticipated in different Regions, whose functions are mainly of centralisation and rationalisation of purchases of goods and services, but sometimes sufficiently open to include socio-health areas (Table 3.2). The number of Hospital Authorities (Aziende ospedaliere, AOs) is slightly decreasing by virtue of unifications made by some Regions, especially those engaged in the Realignment Plan, with important differences in the number and size of the AOs between Regions. Lombardy is the only region that has carried out the unbundling of all hospital centres from the local health authorities (Aziende sanitarie locali, ASLs), which latch on to the 29 established AOs.

At the same time the process of transformation of the public Research Hospitals (Istituti di Ricovero e Cura a CarattereScientifico, IRCCSs) into Foundations is continuing, particularly evident in some Regions such as Lombardy.

Regarding territorial organisation, the number of Districts decreased from 998 in 1998 to 742 in 2005, and was down to 701 by 2011; the territorial structures are ample and slightly increasing in number over time (Figure 3.2). Contrary to what was observed for the ASLs, the interregional variability of average population by District was declining after 2001 and remained more or less stable thereafter. In 2011, 70% of the Regions and

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**Figure 3.1.** Average catchment area usage per ASL (1992-2011).

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Source: Ministry of Health. Management and economic activities of the ASLs.
<table>
<thead>
<tr>
<th>Region</th>
<th>Broad Territorial Areas (AV) and Territorial Catchment Areas (BT)</th>
<th>Functions and denominations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Piedmont</td>
<td>5 AVs, anticipated by the LR18/2007 (art. 23); DGR 9-9007/2008 (in phase of reorganisation in 6 super-zonal Federations)</td>
<td>Function of coordination of super-zones and functional integration of services; administrative, logistical, technical-economic services and of support</td>
</tr>
<tr>
<td></td>
<td></td>
<td>1. Turin Area – Local health authorities</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2. Turin Area – Hospitals</td>
</tr>
<tr>
<td></td>
<td></td>
<td>3. Novara Area</td>
</tr>
<tr>
<td></td>
<td></td>
<td>4. Cuneo Area</td>
</tr>
<tr>
<td></td>
<td></td>
<td>5. Alessandria Area</td>
</tr>
<tr>
<td>Veneto</td>
<td>5 AVs, anticipated by the DGR 3456/2004; DGR 2846/2006</td>
<td>Inter-authority planning and technical-logistical functions</td>
</tr>
<tr>
<td></td>
<td></td>
<td>1. AV Vicenza, ULSS n. 6 leader</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2. AV Treviso and Belluno, ULSS no. 9 leader</td>
</tr>
<tr>
<td></td>
<td></td>
<td>3. AV Venice and Rovigo, ULSS no. 12 leader</td>
</tr>
<tr>
<td></td>
<td></td>
<td>4. AV Padua, ULSS no. 16 leader</td>
</tr>
<tr>
<td></td>
<td></td>
<td>5. AV Verona, ULSS no. 20 leader</td>
</tr>
<tr>
<td>Friuli Venezia Giulia</td>
<td>3 AVs, anticipated by the PSSR 2006-2008 (DGR 2843/2006); PSSR 2010-2012 (DGR 465/2010)</td>
<td>Organisation of health activity, instrument of government of the public and private offer and planning (through the broad territorial areas agreement); limited intervention areas and especially for specific projects: waiting times, rehabilitation plan</td>
</tr>
<tr>
<td></td>
<td></td>
<td>1. AV Trieste-Gorizia (TS-GO) - Giuliano Isontina</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2. AV Udine (UD) - Udinese</td>
</tr>
<tr>
<td></td>
<td></td>
<td>3. AV Pordenone (PN) - Pordenonese</td>
</tr>
<tr>
<td>Liguria</td>
<td>3 Optimum Territorial Areas, anticipated by the LR 41/2006 (art.7); PSSR 2009-2011 (DCR 22/2009)</td>
<td>Unique functions of inter-authority planning in an integrated network of: assistance and care; unified management of technical-economic activity; technological updates</td>
</tr>
<tr>
<td></td>
<td></td>
<td>1. Levante Area</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2. Metropolitan Area</td>
</tr>
<tr>
<td></td>
<td></td>
<td>3. Ponente Area</td>
</tr>
<tr>
<td>Emilia Romagna</td>
<td>3 AVs, anticipated by the PSR 1999-2001 and PSSR 2008-2010</td>
<td>“Supra-authority planning, production of intermediate services, purchases (administrative, logistical services, intermediate health production). Administrative and technical support to health function”</td>
</tr>
<tr>
<td></td>
<td></td>
<td>1. AV Emilia Nord (AVEN), includes the Piacenza, Parma, Reggio Emilia, Modena ASs</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2. AV Emilia Centrale (AVEC), includes the Bologna, Imola and Ferrara ASs</td>
</tr>
<tr>
<td></td>
<td></td>
<td>3. AV Romagna (AVR), includes the Rimini, Ravenna, Forli and Cesena ASs</td>
</tr>
<tr>
<td>Tuscany</td>
<td>3 AVs, each one with a Hospital Authority of reference, for health and public health planning, with arrangements and agreements with local institutions</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>1. Central Tuscany, includes the ASLs of Florence, Empoli, Prato, Pistoia and the Careggi and Meyer AOUs</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2. North-west Tuscany, includes the ASLs of Massa and Carrara, Lucca, Versilia, Pisa, Livorno and the Pisa AOU</td>
</tr>
<tr>
<td></td>
<td></td>
<td>3. South-east Tuscany, includes the ASLs of Arezzo, Siena, Grosseto and the Siena AOU</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Three bodies for technical-administrative AV - ESTAV services (bodies with a public juridical character and management autonomy)</td>
</tr>
<tr>
<td>Marche</td>
<td>5 AVs, anticipated by the DGR 115/2009; LR17/2011 (AV such as Organisational ASUR structures)</td>
<td>The DGR 115 of 2009 selected 4 AVs at the provincial level (except Fermo); with logistical-administrative and planning importance. The LR 17 of 2011 transformed them into “broad territorial areas”, such as articulated by the Regional Health Authority (ASUR). The AVs have ample management, economical-financial and administrative autonomy, for the purchase of goods and services and property autonomy. The director of the AV is nominated by the Regional government in a similar way to that of the Director-general of the Local health authorities</td>
</tr>
<tr>
<td></td>
<td></td>
<td>1. AV no.1: Pesaro - Urbino - Fano</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2. AV no.2: Senigallia - Jesi - Fabriano - Ancona</td>
</tr>
<tr>
<td></td>
<td></td>
<td>3. AV no.3: Civitanova Marche - Macerata - Camerino</td>
</tr>
<tr>
<td></td>
<td></td>
<td>4. AV no.4: Fermo</td>
</tr>
<tr>
<td></td>
<td></td>
<td>5. AV no.5: San Benedetto del Tronto - Ascoli Piceno</td>
</tr>
<tr>
<td>Sicily</td>
<td>2 BTs, anticipated by the LR 5/2009 (art.5)</td>
<td>The “Western Sicily” and the “Eastern Sicily” catchment areas have been set up; two Committees for these areas coordinated by the Regional Health Assessor or deputy, and composed of the AS provincial Director-general of hospitals and universities. The first task of the BTs is to participate in a regional project for centralisation of purchases</td>
</tr>
</tbody>
</table>

Source: AgeNaS – National Agency for Regional Health Services.
Regional health structures

Autonomous Provinces (15 out of 21) exceed the legislative regulation of a minimum population of reference by District of 60,000 inhabitants (art. 3-quater of legislative decree no. 229/1999), with large differences, both with respect to organisational choices (some Regions show 100,000 inhabitants as an average reference level of Districts), and to different geographical areas, particularly mountainous and disadvantaged areas.

The national survey on the implementation of Districts in Italy, carried out in 2010 by the National Agency for Regional Health Services (Agenzia Nazionale per i Servizi Sanitari Regionali, AgeNaS) in collaboration with the Regions, showed that the District is viewed by the Regions as the base that coordinates socio-health pathways, and ensures the integration of services and professionals. At the same time, some elements of differentiation can be noted: depending on whether the emphasis is placed more on the role of care/client (where how services are organized derives from a needs analysis) or on the role of production of services and provision of benefits, or otherwise production outside of the District and the ASL (through the involvement of public and private health providers and an integrated management with local entities); depending on the role assigned to general practitioners (medici di medicina generale, MMGs), which may be internal to the local health unit and the District, or external; and depending on the modality selected to ensure socio-health integration.

The implementation of legislative requirements has produced very different effects in each local Region, with differences in both the institutional model as well as in the outcomes in terms of health and control of expenditure. A methodologically rigorous and thorough analysis of the situation described will provide the elements necessary to support the choice of systems of governance and different models of financing and organization.

Essential bibliography

4.1. The general context: challenges and opportunities

Like all healthcare systems of the member states of the World Health Organization (WHO)-Europe, the National Health Service (Servizio sanitario nazionale, SSN) too is called to address major health challenges in a context of gradual demographic and epidemiological change, of increasingly large socio-economic disparities, and of technological developments that, in turn, raise the expectations of citizens; all this in a historical moment characterised by an economic crisis that severely limits the resources available.

Moving in such a dynamic context, one that is also fraught with difficulties, requires the need to address the challenges by seizing any opportunity that the international scene may nevertheless yet provide. The best strategy is undoubtedly the activation of partnerships and alliances that operate in multidimensional areas. The European Union (EU) has reaffirmed in the programme “Europe 2020”, in the parts that relate to the health sector, the need to strengthen in a single policy framework cooperation at EU level in areas where Member States cannot act alone (so-called “lighthouse” initiatives such as major health threats, the impact of international or cross-border issues such as pandemics and bioterrorism, issues related to the free movement of goods, services and people), to ensure a greater understanding of good health and to focus more on health in the totality of policies of the Governments of the EU Member States. It is now understood how health actions undertaken at Community level generate added value to the measures taken by individual countries, especially in the field of prevention. In this context, work on food safety and nutrition, on safety of medicines, actions to combat smoking, regulations on blood, cells, tissues and organs, on transplants, campaigns on water and air quality are all included. The fundamental concept of “health in all policies” has thus been strengthened.

In dealing with WHO, Italy also shares the view that better health contributes to overall social welfare, through the favourable impact on economic development, competitiveness and productivity. Investing in health is therefore investing in human development, in social and economic welfare. National health systems take on a significance that goes beyond merely – though important – health care, including the promotion of health as psycho-physical well being, disease prevention, as well as all efforts to influence other sectors who would wish to include health in their policies (labour, economy, environment, transport, industry, etc.). The fact that the SSN is decentralised should ensure that the system will grow as a whole through improved responsiveness and an ever wider allocation of responsibility to local administrators which respects the necessary adjustments to EU standards, and leads to the acquisition of that added value that only a proper health management can offer to the development of a country. The role of the Regions, increasingly sensitive to wider health strategies – European and international – may be decisive for the achievement of health goals through proper management of their specific socio-economic determinants.
As will be seen in the following paragraphs, Italy intends to use its public health system as a real resource for contributing to the economic and social development of its territory, willing to be a partner with anyone who pursues and shares the same goals of a welfare which should be aspired to and which is continuous and sustainable. The initiatives described below, although mostly supranational, all aim to increase the health status of our country, bringing to the SSN and its users that contribution of knowledge and impulse of development that can only come by sharing experiences and by the continuous and constructive dialogue with the realities that surround us.

4.2. WHO – Most relevant global initiatives

With regard to the most relevant global initiatives and activities of the WHO and the United Nations and in which the Ministry of health has actively participated, the following may be noted.

Executive Council WHO (January 2011). The Council debate was strongly influenced by the serious budget deficit of WHO, against the background of the global financial crisis. The proposed budget for the period 2012-2013 has been conditioned by the objective difficulties of the Member States of the Organization, who are not willing to accept an increase in their required contributions. Therefore, faced with a concomitant decrease in voluntary contributions (which represent almost 80% of the total budget of the Organization), WHO has initiated a reform process aimed at containing costs and optimising working methods. WHO is also favouring an approach of consolidation instead of expansion of its activities, aiming at strengthening its most exclusive competences (health security; defining regulations, standards and guidelines for health policies, analysis and strengthening of health systems, data collection and epidemiological surveys, and promotion of dialogue among all stakeholders of global public health).

The Executive Board has examined and discussed several topics of great importance and relevance to public health internationally, from the millennium Development Goals (with increasing risk of failing to reach them on time) to the prevention and control of chronic non-communicable diseases, from unresolved challenges, such as malaria, HIV/AIDS, leprosy, neglected tropical diseases, to issues relating to children (nutrition and accidents). All threads have a common denominator: the need to strengthen health systems.

World Health Assembly (May 2011). The 64th World Health Assembly was characterised by three key issues: the process of the reform of WHO, budget approval for the period 2012-2013 and the final approval of the Report of the Review Committee of the International Health Regulations.

On the basis of the considerations of the executive Council outlined above, the Assembly approved a “zero growth” budget with respect to the previous two years. This involved a careful review of expenditure and Organization programmes in order to cope with a concomitant decrease in voluntary contributions.

The Assembly also approved the Report of the Review Committee of the International Health Regulations, which focussed primarily on pandemic influenza crisis management. The Report confirmed the absence of malpractice by WHO in its dealings with the pharmaceutical industry. The International Health Regulations confirmed itself as a fundamental tool of the international community with regards to “global health security”. Several topics of great importance and relevance to international public health, already discussed at the last Executive Council and described in the preceding paragraph, were reviewed and considered. As already noted, all discussions had as their common denomi-
nator the need to strengthen national health systems. In this respect, the Assembly approved four Resolutions concerning the role and the strengthening of health systems.

**European Regional Committee (September 2011).** The WHO European Regional Committee, which met in Baku (Azerbaijan) on September 12-15, 2011, saw the launch of the report of the activities of WHO/Europe in the previous two years, characterised by particular reference to situations of crisis and emergency health which seriously affected the populations of the Region. In this regard, the report highlighted a critical situation in the Mediterranean area due to migration from North African countries, highlighting the initiative of the Italian Ministry of Health, originating from the meeting held in Rome in April 2011 and ending with the signing of a three-year collaboration project between WHO/Europe and the Ministry of Health on aspects of public health and migration.

Remaining on the theme of emergencies, the report cited the excellent work done by WHO and its Member States in implementing the International Health Regulations, through continuous monitoring of events that can potentially become major international public health emergencies.

The following key items that characterized the main activities of the European Office of WHO were underlined.

- the epidemic of poliomyelitis in Tajikistan, which affected three other countries (Kazakhstan, the Russian Federation and Turkmenistan), causing paralysis in 475 persons and 30 deaths;
- the alarming situation relative to the diffusion of multidrug- and extensively drug-resistant tuberculosis (M/XDR-TB), for which Dr. Jakab started an ad hoc project at the Copenhagen Office;
- the increase in cases of HIV/AIDS in Eastern Europe and Asia-Central countries;
- the worrying spread of antibiotic resistance, the theme chosen this year for World Health Day;
- the progress made towards the elimination of malaria from the European Region. In 2010, only 176 cases of malaria acquired locally were recorded, in 5 countries (Azerbaijan, Kyrgyzstan, Tajikistan, Turkey and Uzbekistan);
- chronic non-communicable diseases (“silent killers”, as they have come to be known), an argument whose scope and relevance are proven by the special event dedicated to it by the UN General Assembly (New York, September 19-20, 2011). A worldwide phenomenon that must be addressed comprehensively and with maximum intensity of effort, both in its scope, and the fact that many of these diseases (not just the main ones – cardiovascular diseases, cancer, diabetes and chronic respiratory diseases – but those less widely spread) are preventable. Of fundamental importance is the intersectoral approach, according to the consolidated “Health in All Policies Approach” strategy;
- in terms of lifestyles, good progress has been made in the field of anti-smoking, although much remains to be done. The fight against alcohol abuse remains a priority for the European Region, and that is why the Regional Committee in Baku included this issue in a specific European Action Plan;
- the fifth Ministerial Conference on Environment and Health, held in Parma in March 2010, gave new impetus to the programmes and activities of the European Region, thanks to the adoption of the Declaration of Parma. The closure of the WHO office in Rome did not have an adverse impact on ongoing and future programmes, thanks to the commitment of the German Government to incorporate it within the Bonn Office responsibilities.

Among the most important topics dealt with by the Regional Committee in 2011 were:

- the European Action Plan for the reduction of alcohol abuse – 2012-2020;
- the European Action Plan on antibiotic resistance;
- drug-resistant tuberculosis in the WHO European Region;

Within the United Nations, 2011 was characterised by a series of global events of great interest and a strong impact in international public health. The Global Ministerial Conference on lifestyle and chronic non-communicable diseases, held in Moscow on 28 and 29 April 2011, permitted the revision of the main initiatives for health promotion and prevention and for control of chronic diseases in the countries of the WHO European Region, emphasising the importance of an intersectoral approach, as outlined in “Health in All Policies”.

The High Level Meeting of the United Nations on chronic non-communicable diseases, which took place in New York on 19 and 20 September 2011, and the Global Conference on social determinants of health, held in Rio de Janeiro on October 19-21, 2011, stressed the global reach of the problem of non-communicable diseases and of the social determinants of health and made a high priority of these issues.

4.3. Council of Europe activity and the effects on national health policy

The Institutions of the European Community dealt with a wide range of health issues in 2011 that had a significant impact on the state legal system. Throughout the year, important meetings of the Councils of the EU were held, in the course of which fundamental regulatory disciplines were developed and/or adopted, some of which are binding or others simply for guidance.

The Ministry of Health participated at the Informal Council of the EU (April 4-5, 2011 – Gödöllő, Hungary). Fundamental health issues were brought to notice on which a basic prior consent was expressed, and which marked the period of the Hungarian presidency of the EU. In detail, the issues discussed focused on issues of perspective, ranging from investment in health systems of the future to the health professions in Europe and the launch of the next Programme of Community action in public health.

Secondly, the board meeting of the EU Ministers of Health was held on June 6, 2011, in Luxembourg.

The Council meeting was marked by a formal discussion and adoption of fundamental acts of “soft law” (Conclusions of the Council), through which the European Community promotes detailed responsible and sustainable regulatory activity in member countries in areas such as prevention of depression and suicide, innovation in medical devices, the spread of vaccination programmes for children and the launching of prospective targets for a modern European health. In reference to the issues addressed in that forum, the Ministry of Health shared and supported the spirit, purposes and objectives of the previously mentioned legislative texts, and also called for a change of perspective as regards future health, promoting more effective management solutions and innovation in research and development.

In the second half of the year, the European Ministers of Health met again, having a broad informal and formal discussion resulting in guidelines and regulatory acts of decisive impact in the legal systems of EU member states. First of all an initial informal meeting was held under the auspices of the Polish Presidency of the EU (July 5-6, 2011, Sopot) during which health issues were addressed including childhood communication disorders, transplantation of human organs, the emergence of the phenomenon of “designer drugs” in the actuality of European youth, the analysis of health inequalities between EU States and the prospects for development of e-health in state health systems.

The next meeting (Formal Meeting in Brussels, December 2, 2011) saw the material-
isolation of certain strategies developed in the informal Council meeting in Sopot; the meeting adopted a set of “soft law” (Conclusions of the Council) regulations ruling on the combating of chronic respiratory diseases of childhood, on the treatment of communication disorders of children and the rebalancing of the existing gaps in health within the EU. This concluded the debate launched at the beginning of the Polish Presidency of the EU and EU Member States were encouraged to take timely measures to implement the strategies and direction provided for by the EU Council.

On these occasions, the Ministry of Health shared and supported the aims of the individual pieces of legislation approved, promoting useful thrust in the field of health inequalities based both on the development of new orientations and on the identification of a consistent sequence of systematic measures to be implemented at European level. Also at this meeting, the Council of European Ministers of Health continued the institutional discussion on other key EU legal texts, including the proposed EU Regulation on information for the public on prescription medicines, on pharmacovigilance and on the proposal for Regulations on food for infants and children and on foods intended for special purposes.

Alongside this activity, Italy participated in an effective manner in a series of project initiatives in close collaboration with the European Commission and several EU member states, all focused on health and mental well-being; cited in this regard is the initiation of a “Joint Action” on dementia, included in the Second Programme of community action on health (2008-2013); the implementation of the “European Pact on mental health and well-being”, taken into account in a Communication of the European Commission in June 2011; and, lastly, the launch of a “Joint Action” on mental health, promoted in September 2011. All the above activities will continue during 2012 and to these will be added other regulatory proposals of a relevant health impact that govern specific areas, such as:

- proposal for the revision of the Directive 2001/37/CE (June 5, 2001) on tobacco products, aiming to standardise profiles of better protection for vulnerable social groups and young people;
- proposal for the revision of the EU regulatory framework concerning medical devices, currently established in three sectoral Directives (relating to medical devices, active implantable devices and in vitro diagnostic devices), in view of the adoption of a regulation to include the first two categories of medical devices;
- proposal for the adoption of an EU regulation on the activation of a specific Programme of action on health for development covering the period 2014-2020 (November 9, 2011);
- proposal for the adoption of an EU regulation for dealing with health threats;
- proposal for the adoption of instruments of soft law (Conclusions of the Council) on promoting healthy lifestyles and combating chronic diseases.

During 2011, implementation of the Programme of community action on consumer policy (2007-2013) continued. The programme aims to complement, support and pursue the policies of Member States and to contribute to the protection of the health, safety economic and legal interests of consumers and the promotion of their right to information, education and organisation of the protection of their interests.

### 4.4. Bi-lateral agreements on health collaboration

Also in 2011, bilateral relations continued with the intention of creating a network of institutional relationships and scientific-technical partnerships between the central health Authorities, the Regions and scientific Institutes and hospitals in their respective
countries, to be used in multilateral projects and programmes. The activities of bilateral health collaboration can be grouped into four main areas:

- signing of new agreements and action plans;
- implementation of existing agreements, through the accomplishment of workshops, training courses, study visits, exchange seminars, etc.;
- bilateral meetings between Ministers of Health;
- receipt of official delegations.

Moreover, a role in promoting and coordinating the dissemination of information and direct or mediated participation will be carried out through SSN bodies and scientific and hospital Institutes, through twinning projects and EU-funded partnerships (ENI; IPA; TAIEX) and, where possible, multilateral projects of cooperation on a regional basis, such as the EUROsociAL II programme for the development of social cohesion in Latin American countries.

Regarding the first point, during 2011 two new Memoranda were signed:

- the Memorandum of Understanding with Serbia between the respective Ministers of Health;
- the Memorandum of Understanding between the National Institute of Health (Istituto superiore di sanità, ISS) and the Albanian Minister of Health.

In order to implement current arrangements and to strengthen the initiatives of scientific and technical partnership, several Action Plans and technical protocols were signed, such as the 2011-2014 Action Plan with China, the 2011-2014 Action Plan with Jordan, some technical protocols of cooperation between specialised Agencies (haematology, cancer) with Azerbaijan, and three cooperation protocols with the Ministry of Health of Malta (2 on organ transplants and 1 on medicines).

With regard to the second activity, in addition to meetings of the Boards of monitoring and coordination provided for by the Memorandum, several activities of exchange and staff training were carried out. In particular:

- the period of on-the-job training for two Armenian doctors at the Unit of Plastic and Reconstructive Surgery at the San Camillo Forlanini hospital;
- the Italian-Moldovan training course in Rome on health financing and auditing, which was attended by five senior directors of the Moldovan Ministry of Health;
- the technical mission to Belgrade to assist the Serb authorities with the selection of a cyclotron for the production of radio-pharmaceuticals;
- the Italy-Serb workshop on intensive care and ECMO experience, organised by the Italian Ministry of Health in collaboration with the University of Belgrade;
- the Italy-Mexican training course in the City of Mexico on health technologies;
- the participation in November 2011, at the invitation of the Uzbekistan Authorities, in a high-level international conference on maternal and child health and the achievement of the Millennium Development Goals (MDG).

The work of revival of relations with the new Libyan authorities is also emphasised, initiated by the agreements reached during the visit of President Monti to Tripoli, to ensure the support of the Italian Government for the care of Libyan citizens wounded by bombs during the recent war events.

With regard to the third activity, several visits were organised at the political level designed to raise awareness of our health system and our best excellence, in an international exchange that favours the overall growth of the system.

The activities of bilateral cooperation also related to the receipt of various delegations of foreign countries for bilateral technical meetings. Among these can be noted:

- a government delegation of four countries of Central Asia on “One Health” and the multidisciplinary and integrated approach to health (veterinary and human health);
- a delegation of directors of the Offices for food control and quarantine of several Chinese provinces, on food safety;
- a Chinese delegation from the province of Tibet on emergency services and primary care;
■ a Korean delegation on the system of financing of the SSN;
■ a delegation of Japanese functionaries from the health insurance industry, as part of a study tour and cultural exchange with various Italian institutions;
■ a delegation from Kazakhstan composed of senior representatives of the Ministry of Health, the Ministry of Economy and specialised centres of “Public-private partnership”;
■ a delegation from the Ministry of Labour of Turkey on legislation and occupational medicine.

Finally, with regard to the EU-funded twinning projects, the award of a project with Turkey for laboratory checks on immunobiological products and the launch of multilateral EUROsociAL II project, coordinated by Spain, for the development of social cohesion in Latin American countries should be noted.

4.5. Euro-Mediterranean partnership projects

The Euro-Mediterranean partnership projects supported by the Ministry of Health, though occurring in specific and therefore limited sectors, allowed an extensive comparison between the countries involved and helped cohesion among the representatives of various countries, even in a particularly delicate moment in history spanned by both internal and transversal tensions. In particular, the comparison between different national health systems has allowed areas of excellence as well as areas of greatest weakness to be identified, present on both sides, giving them an important opportunity for mutual growth. With regard to the Euro-Mediterranean partnership projects promoted and financially supported by the Ministry of Health, in 2011 two directions of activity have developed:
■ the development, consolidation and strengthening of the six projects underway, signed in 2010 (Table 4.1);
■ the signing of five cooperation agreements at the end of 2011 and at the start-up phase (Table 4.2).

<table>
<thead>
<tr>
<th>Project</th>
<th>Beneficiary</th>
<th>Countries involved (non-EU)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Paediatric cardiac surgery/vascular surgery</td>
<td>University of Milan Bicocca</td>
<td>Egypt, Kosovo, Morocco, Syria, Tunisia</td>
</tr>
<tr>
<td>Cancer Registries Network</td>
<td>AIRTUM – Italian Association of Cancer Registries</td>
<td>Algeria, Egypt, Israel, Lebanon, Morocco, Palestinian Territories, Syria, Tunisia, Turkey</td>
</tr>
<tr>
<td>Cancer Screening &amp; Early Diagnosis Programme</td>
<td>ASL TO1 and CPO (Centre for Oncological Prevention) Piedmont</td>
<td>Albania, Algeria, Egypt, Israel, Kosovo, Morocco, Tunisia</td>
</tr>
<tr>
<td>MediCel (Food induced diseases – Coeliac disease)</td>
<td>University of Naples – ELFID (European Laboratory for Food Induced Diseases)</td>
<td>Albania, Algeria, Bosnia-Herzegovina, Croatia, Egypt, Israel, Lebanon, Morocco, Palestinian Territories, Syria, Tunisia, Turkey</td>
</tr>
<tr>
<td>MTN (Mediterranean Transplant Network)</td>
<td>National Institute for Health (ISS) – CNT</td>
<td>Algeria, Egypt, Israel, Lebanon, Morocco, Palestinian Territories, Tunisia, Turkey</td>
</tr>
<tr>
<td>Episouth Plus</td>
<td>National Institute for Health (ISS) – CNESPS</td>
<td>Albania, Bosnia-Herzegovina, Egypt, Former Yugoslav Republic of Macedonia, Jordan, Israel, Kosovo, Lebanon, Morocco, Montenegro, Palestinian Territories, Serbia, Syria, Turkey</td>
</tr>
</tbody>
</table>
The National Health Service and EU and non-EU policies with regard to health

4.6. Internationalising the SSN: the International Building Brick Project as a model of growth for the system

With the CIPE Resolution of December 18, 2008, on the proposal of the Minister of Health, the award of Euro 8,000,000 for the implementation of a programme of actions and interventions aimed at skill enhancement and organisational structure of the Regions and Autonomous Provinces in the field of international collaborations was established, particularly with regard to the process of European integration and planning in the field of public health and research. The project, called International Building Brick, is under the functional coordination of the Ministry, the Veneto Region (leader) and the Tuscany Region. The programme was formally launched in November 2010, with a national launch-event, while from the operational point of view the appointment of the General Coordination Group (GCG) was essential, through the ministerial decree (DM) of December 21, 2010. The GCG was entrusted with the duties of general supervision in that it was a body representing the three coordinating entities, as well as those of approval of scheduling and assessment of appropriateness (with respect to both content and affordability) of the sub-projects/procedures that make up the programme. The year 2011 represented a turning point for the project, in that the involvement of all the Italian Regions that have brought and will bring shared useful contributions to the process of internationalisation of the SSN, was fully realised. Through regional contacts nominated by the regional health Assessors, a series of joint activities allowed for the receipt of information on the work by local levels (“ascending process”) useful to the interlocutions and/or consultations launched by the European Commission and international Institutions (coordination of inputs, working groups etc.) and for the transfer of information at the local levels (information days, workshops, training seminars etc.) useful for the empowerment of local players in the fields of health and research (“descending process”).

By way of example with regard to local levels, many Regions started working committees with the health and hospital authorities of their territories, in order to establish synergies which, through a widespread and transversal process of concrete awareness of their respective roles, may contribute to enabling the regional health systems to exhibit competitiveness at a European level. For the implementation of the Plan approved on December 22, 2010, the creation of a series of initiatives aimed at information provision and micro-training of groups was pro-

<table>
<thead>
<tr>
<th>Project</th>
<th>Beneficiary</th>
</tr>
</thead>
<tbody>
<tr>
<td>Registry of myocardial infarction population</td>
<td>National Institute for Health (ISS)</td>
</tr>
<tr>
<td>Epidemiological surveillance for the control of neo-plastic diseases in Mediterranean countries: from cancer registration to statistical models</td>
<td>National Institute for Health (ISS)</td>
</tr>
<tr>
<td>Mediterranean International Network for increasing organ donations</td>
<td>National Institute for Health – CNT</td>
</tr>
<tr>
<td>MEDICEL – The Mediterranean network for coeliac disease</td>
<td>University Federico II, Naples – ELFID</td>
</tr>
<tr>
<td>Screening and early diagnosis of tumours in the Mediterranean zone</td>
<td>S. Giovanni Battista University Hospital Turin</td>
</tr>
</tbody>
</table>

Table 4.2. Agreements concluded in 2011
ceed with during 2011, as proposed by individual Regions and with the unanimous approval of the initiatives on a case-by-case basis by the GCG.

In the same year, specific incentive mechanisms (funding dedicated to the Regions) were activated, to increase the skills and qualification-based competitiveness of the Regions in the European and international arena.

The Regions, in cooperation with the Ministry, were thus able to programme training and information activities at the local levels directly, and to plan actions for the acceptance of EU funds in the areas of health, research and international cooperation in health.

The International Building Brick Project, whose official closing is set for December 31, 2013, implementing activities already planned and maintaining future planning actions, continues its work to support the international growth of the SSN in all its many ramifications.

Essential bibliography


4.7. International activity in the context of veterinary and food safety issues

The international activity of the Ministry as part of food and veterinary safety extends mainly along two axes:

- co-operation with international Organisations of reference (the World Organization for Animal Health - OIE - FAO and WHO) and the Authorities of third countries with the aim of protecting consumer health and the animal population;
- negotiation with the Authorities of the countries involved with Italian food of the health guarantees necessary to facilitate the distribution of our best food products in international markets.

Initiatives taken at international level by our Minister are particularly relevant for the protection of consumer health and the safety of Italian livestock.

Among the international veterinary events of greater prominence in 2011 is the successful eradication of rinderpest. This is the second disease for which it has been possible to declare the worldwide eradication, after human smallpox. Rinderpest, a devastating, highly contagious and often fatal disease, has been a real curse for farmers over the centuries, often contributing to famines, which, in turn, have fuelled unrest and wars.

Our country has played a leading role in efforts to eradicate the disease; this role has been recognised by the international community and made manifest with the unveiling of a commemorative work in stone by the Maestro Alessandro Romano at the headquarters of the Ministry of Health in via Ribotta in Rome. The unveiling ceremony, which took place in the presence of more than 150 ambassadors and representatives of foreign countries, was attended by the Minister of Health, the Director-General of the FAO, the Director-General of the OIE and the Deputy Mayor of Rome.

Among the international events of a more regional character, i.e. relative to Europe and/or the Mediterranean, mention should be made of two that were organised by our Ministry, both of which had important significance for the protection of consumer health and the health of the animal population: the workshop of the countries of the European Region of the OIE and the meeting of the Permanent Joint Committee (Comitato Permanente Congiunto, CPC) of REMESA (Réseau Méditerranéen de Santé Animale).

The focal points workshop for food safety in the European Region countries of the OIE, held in Brescia from 8 to 10 November, saw the participation of 46 countries, and
the presentation of reports and relations of a high technical level that can significantly contribute to the fight against zoonoses, in particular echinococcosis, trichinellosis and salmonellosis.

On the October 20-21 in Rome, the 4th CPC of REMESA took place under joint Italy-Tunisian presidency. The participation of the CVO (Chief Veterinary Officers) from the majority of the 10 member countries (the 5 Maghreb countries – Morocco, Algeria, Tunisia, Libya and Mauritania – plus Egypt and the 4 Southern European countries– Italy, France, Spain and Portugal), as well as representatives of the international organizations involved (FAO, OIE, EU, African Maghreb Union), made it possible to define the main actions to be undertaken in 2012 to eradicate or control the major diseases in the area (especially foot and mouth disease, Blue tongue, West Nile disease, Rift valley fever, rabies and peste des petits ruminants).

The Ministry also has a major role in promoting the export of animals and animal products, including in particular meat products (e.g., Parma and San Daniele ham, salamis, bresaola, etc.) and dairy products (e.g., parmesan, mozzarella, pecorino cheeses etc.), and also animal feed, animal genetics, egg products, etc.

In order to export the goods indicated above, Italian producers have to provide adequate guarantees hygiene and health to the authorities of the importing countries. In this sense, the role of the Ministry is relevant, in that at the request either of the associations involved or of the Association of Italian Industries – the Italian Food Industry Federation and via our Embassies, the Ministry negotiates specific technical agreements and/or health certificates with the authorities of the countries concerned. The year 2011 was, from this point of view, a particularly busy year, with the signing of a technical Understanding, the establishment of 44 new health certificates and the modification/updating of 36 existing health certificates. The development of new health certificates and the inclusion of new countries for export of our products (including Chile, Colombia, Indonesia, Macedonia) have reputedly contributed to the optimum success in exporting the products of Italian delicatessen, which in 2011 achieved an increased by 11%.
Implementation of lines of priority in order to meet health objectives
1.1. Implementation of the “Gaining Health” planning document

Planning framework. More than a quarter of a century ago, the Ottawa Conference on the Promotion of Health requested the “Building of a public health policy” and to “create supportive environments” for health. It is now widely recognised that health is crucial for the overall development of society, including the economy. While the effects on health derive from interrelated causes, skills in the health sector to improve health and prevent disease are increasingly limited. Strategies are therefore necessary that involve other sectors, according to the principles of “Health in all policies”, which outline the need for new alliances to promote human development, sustainability and equity, and to improve health. This requires a new approach in policy and in governance where there is shared leadership across all sectors and levels of government, to address risk factors through the commitment and active participation of non-health sectors, such as planning, agriculture, industry, trade, economy and education. It requires also the intervention of the private sector and that of civil society. This is particularly necessary when referring to the emergency comprising chronic non-communicable diseases, which share some risk factors (smoking, alcohol abuse, unhealthy eating, overweight and/or obesity, sedentary lifestyle) related, in large part, to unhealthy individual behaviours that are changeable, but which are conditioned by the economic, social and environmental context in which people live and work.

To combat the major risk factors for chronic disease and ensure the sustainability of our health care system, Italy approved the “Gaining Health: making healthy choices easier” programme in 2007, a global strategy that follows the guidelines of the World Health Organization (WHO) and European Union (EU) who urge in various documents that policy-makers follow an intersectoral approach for the implementation of interventions to change unhealthy behaviours. “Gaining Health” promotes health as a public good, through the integration of actions that are the responsibility of the community and those that are the responsibility of individuals; it is characterised by the transversal approach to risk factors and the definition of coordinated intersectoral strategies, acting on environmental factors and on socioeconomic determinants that influence the onset of chronic diseases, according to the principles of “Health in all policies”.

State of implementation in regional contexts. The active participation of the Regions is an essential element for the implementation of intersectoral policies for health promotion. The Regions are, in fact, owners of institutional competence in the field of health promotion. They accept their role by actively contributing to the determination of strategic directions by developing the National Prevention Plan (Piano Nazionale della Prevenzione, PNP) within their Regional Prevention Plans (Piano Regionale della Prevenzione, PRP) and participating in the
Implementation of lines of priority in order to meet health objectives

National Platform as institutions responsible for planning of health promotion activities of the National Health Service (Servizio sanitario nazionale, SSN). In the regional context, they focus on inter-institutional agreements or those with group associations on a national scale, increasing the efficiency of the transversal strategies and building networks, alliances and involvements to induce stable and clear modifications of the living environment. The construction of a regional “Gaining Health” organisation, activated in different Regions, has allowed the testing in local communities of preventive interventions, based on the strategy of the national programme and characterised by a transversal approach to the various risk factors and by the leadership of the health authorities. These interventions, implemented mainly through projects sponsored by the National Centre for Disease Prevention and Control (Centro per la Prevenzione e il controllo delle malattie, CCM), have favoured the consolidation and dissemination of experiences of excellence of territorial integration in other contexts, capable of inducing stable and clear modifications in the living environment of citizens and thus competing to “facilitate healthy choices”.

The interoperability between “School” and “Health” has been established even at the regional level, through formal agreements between the health sector and the Regional Schools Offices, which is helping to develop a shared planning in some key areas (diet and physical activity, smoking and addiction, oral hygiene), with the aim of avoiding “one-off” interventions, developing long-term programmes instead.

As part of the macro-area of Universal Prevention, the new PNP 2010-2012, provides for the consolidation of partnerships and alliances with schools, the implementation of programmes aimed at increasing consumption of fruits and vegetables in the general population, the promotion of breastfeeding, improvement and control of the nutritional quality of school and business canteen menus, and the development of interventions for the promotion, facilitation and prescription of mobility through intersectoral and multidisciplinary interventions. All the Regions have developed projects for the prevention of unhealthy behaviours and lifestyles and diseases linked to them in their Regional Plans, 153 projects in total, involving the intersectoral and transversal approaches proposed by the “Gaining Health” programme.

Description of the data. The improvement of living conditions for all levels of society has not led to a reduction of health inequalities. The PASSI vigilance system (Progress made by Health Authorities for Health in Italy, Progressi delle Aziende Sanitarie per la Salute in Italia) has documented the dimension in relation to lifestyle, presence of chronic diseases and risk factors. Smoking habits, physical inactivity and obesity are more common in people with low education and those who report having financial difficulties. The prevalence of chronic respiratory diseases and diabetes is higher in people with low educational qualifications and among those who report having financial difficulties. Among the few exceptions, the at-risk level of consumption of alcohol, is more frequent among women with more education.

Presentation and critical evaluation of data. “Closing the gap” is, at the global level, a new challenge for public health systems to reduce inequalities caused in particular by the so-called “social determinants”. The national “Gaining Health” programme has identified the cross-sector approach of “Health in all policies” as the framework within which to act to promote health, aiming to prevent chronic diseases already in early childhood, while aiming at the same time to support fairness.

To share specific health goals, therefore, the “National Platform on Diet, physical activity and smoking” was established at the Ministry of Health. The platform comprised representatives from relevant central government Institutions, from the Regions and Autonomous Provinces of Trent and Bolzano, from the National Association of Italian Municipalities (Associazione Nazionale Comuni Italiani, ANCI), from general prac-
tioners, paediatricians and pharmacists, as well as from trade associations of the food distribution chain and the most representative consumer associations and national trade unions, who signed memoranda of understanding with the Ministry of Health. The Memoranda of Understanding are, in fact, among the main tools for the development of intersectoral strategies. They represent the acts of institutional ownership of the goals of the Programme, between the Ministry of Health and the central State Institutions who are national policy makers both in terms of proposed legislation and in terms of administrative management. Through the Memoranda of Understanding, the realities of the world of manufacturing and civil society can collaborate with the Institutions by taking on voluntary commitments and by coordinating their activities in areas difficult to influence by political and administrative tools.

Further work is required with a view to strengthening the multi-stakeholder approach, in which the health sector must continue to play an important role of advocacy in order to promote integrated policies and to make it understood that all policies (education, agricultural, social, environmental, economic, commercial) have effects on health. The Regions, in particular, should further develop the opportunity of a local action made to “facilitate healthy choices”, as institutions “close” to the citizens who build innovative and stable relationships with the local community.

Essential bibliography

- Libro Bianco: Una strategia europea sugli aspetti sanitari connessi all’alimentazione al sovrappeso e all’obesità. UE 2007
- Regione Europea OMS. European Charter on counteracting obesity. Istanbul 2006

1.2. Implementation of the National Prevention Plan


The first is related to the strategic decision to invest in prevention to achieve greater health outcomes.

The second is connected to the choice of adopting a jointly-held line of governance, which led the Ministry to make the best use of the potentialities of coordination of the CCM, the Regions to profitably engage in planning a series of common operational guidelines and the health agencies, in a cascading manner, to use an additional tool to help reduce the real burden of disease and disability. The third reason relates to the decision to subordinate planning to the knowledge and information available.

The PNP 2010-2012 (State-Regions Agreement of April 29, 2010), picking up the baton from the previous, re-interprets it and extends the mandate, pivoting on two key principles:

- selection of interventions based on evidence of their effectiveness, which expresses the need for prevention activities not only systematically based on evidence of effectiveness (evidence-based practice, EBP), but also able to generate “knowledge” through the implementation and deployment of registries, monitoring systems and information systems as well as the strengthening of data use at all stages.
of an intervention (design, planning, implementation, monitoring and evaluation) and social reporting;

- selection of fields of intervention on the basis of a scale of priorities, promoting the centrality of the person or a cultural view in which the focus of action is no longer the self-referentiality of services, but the citizen (healthy or ill) with their expectations and needs, and where support for “feeling good” requires both targeted and horizontal interventions from a point of view that provides continuity and direction.

The structure of the PNP is essentially devoted to five thematic areas: epidemiological surveillance, transversal in every respect, and the 4 macro-areas of intervention (predictive medicine, universal prevention, prevention in the population at risk, prevention of complications and the recurrence of disease). For each of the macro-areas one or more lines of general intervention are defined (altogether 22) and, for each of the lines, the overall objective of health is identified, and any sub-objectives. Roles of healthcare institutions are defined for the achievement of each objective and are specified thus: lines of support (central Actions) by the Ministry, and regional lines of intervention (assigned to regional planning through the PRP).

On this newly synthesised framework, the Regions have been asked to formally adopt their specific PRP, identifying (based on the needs analysis of its territory) precise and measurable objectives, intervention targets and useful indicators for monitoring the degree of approach to the desired results. The Ministry was given the task of “accompanying” the regional pathway by means of the expression of a set of functions all related and attributable to the governance model known as stewardship, promoted by WHO and whose expression in “sub-functions” was taken as a strategic outline and methodological basis for the definition of the Central Actions to support the PNP [ministerial decree (DM) November 10, 2010] and of a subset of them [Priority Central Actions (Azioni Centrali Prioritarie, ACPs), adopted by DM August 4, 2011]. These functions merit priority attention because they are relevant to issues of critical importance for the implementation of the PRPs.

Moreover, with the State-Regions Agreement of February 10, 2011, for the first time in the history of healthcare in our country, a “Document for the evaluation of PRPs from 2010 to 2012” was approved. The document, an assessment tool for planning acts, extends to some of the most significant areas of prevention and expresses the object, criteria, roles, responsibilities, procedures, timing and rules of the evaluation process and, therefore, materially inserts, as part of the objectives of the PNP, also the measuring of its performance, albeit in a “rudimentary” way.

Finally, the Ministry and the Regions expressed the need to explore and build alliances and partnerships with various stakeholders to support the implementation of the objectives of the PNP. This need has resulted:

- in the launch of the national Project “Support of the PNP and of training for managers and operators involved in PRP 2010-2012 projects”, assigned, through bilateral agreement, by the Ministry-CCM to the National Centre for Epidemiology, Surveillance and Health Promotion (Centro Nazionale di Epidemiologia, Sorveglianza e Promozione della Salute, CNESPS) of the National Institute of Health (Istituto superiore di sanità, ISS), at the request of the interregional Coordination of prevention and then merged in the ACP 2.2 “Provisions of support to the Regions”. The general objective of the project is the realisation of a real process of accompaniment for all phases of the PNP, through the development and sharing of different pathways and tools (training of central and regional staff, creating a Community of practical, scientific and methodological support in planning, monitoring, and evaluation);

- in the role entrusted under the ACP 3.1 (“Definition of alliances with stakeholders”) and by the specific instrument of the Charter of reports to scientific Enterprises, from whom the Ministry intended to collect a contribution (formalised through a project currently underway) respecting the
need for “multidimensional” analysis of the PRPs to seek elements of reasoned knowledge that can help to better understand how prevention is evolving in Italy and, if necessary, to re-orient future planning. All the Regions and Autonomous Provinces (with the exception of Aosta Valley and Bolzano) adopted their PRP by Regional resolution and submitted them to the Ministry, for a total of over 700 projects/programmes. All the PRPs were certified in 2010, i.e., they had a successful outcome to the “ex ante” evaluation, the measurement of quality of planning inherent with respect to the “framework” methodologies and shared criteria. Evaluation is currently underway of progress in the implementation of the PRPs against targeted objectives, with the certification for the year 2011 as the goal.

As expected, given the vastness of the argument and the need to give continuity to the previous PNPs as well as the importance of the matter for the future of our health care system, the macro-area of most frequent “visits” (more than 60% of programmes/projects) was that of universal prevention and, within this, the line of intervention that took reference from the “Gaining Health” programme (with as many as 153 projects). Much attention was also paid to the development of interventions in the area of prevention in populations at risk, which includes within it population-based screening programs for the main oncological diseases. The macro-areas 1 and 4, “newer” to the PNP, have nevertheless seen all the Regions involved put in place interventions dedicated to them.

**Essential bibliography**


### 1.3. Implementation of the National Plan for Alcohol and Health

**Planning framework.** The National Plan for Alcohol and Health (Piano Nazionale Alcool e Salute, PNAS), approved by the State-Regions Conference in its session of March 29, 2007, is a planning document with directions agreed between the Ministry and the Regions, in accordance with the provisions of law 125/2001. It has the goal of promoting the implementation of a set of strategies and actions aimed at strengthening prevention of and combating alcohol-related damage in regional territories. The PNAS plan incorporates the objectives proposed in important international documents such as the European Action Plan for Alcohol by the WHO, the EU Council Recommendation on alcohol consumption in children and adolescents and the EU Council Conclusions on a Community strategy for the reduction of alcohol-related damages.

In particular, the PNAS plan aims to promote prevention actions in regional territories in eight key areas identified as priorities: information-education, driving, work, treatment of abuse and of alcohol-dependency, responsibility in the alcohol production and distribution sectors, monitoring of alcohol-related damage and policies of prevention, social capacity to cope with alcohol-related risk, the potential of voluntary organisations and of self-help.

A specific inter-institutional collaboration between the Ministry of Health and the Regions was planned for its implementation and for this purpose, a specific technical group was formed with the participation of the ISS.
The PNAS plan was of a three-year duration (January 1, 2007-December 31, 2009), but its implementation was subsequently placed among the objectives of the PNP 2010-2012; the strategic lines of the PNAS plan are therefore still a valid point of reference for the actions of prevention and contrast at national and regional levels.

**State of implementation in regional contexts.** During the first year of operation, the combined Regions-Ministry group for the implementation of the PNAS plan addressed as a priority task, the strategic area of “Monitoring of alcohol-related damage and related policies of prevention” and prepared a consensus document of a technical-scientific nature that outlines a National Monitoring Plan for Alcohol and Health (*Piano Nazionale di Monitoraggio Alcool e Salute*, PNMAS). The document defines the goals, objectives, actions, indicators and organisational aspects for a national monitoring of alcohol-related matters.

The PNAS was also implemented through the realisation of projects in the Regions or at central level.

The two-year “Agorà” project, coordinated by the Friuli Venezia Giulia Region, strengthened the coordination actions of the Regions in terms of alcohol and health, promoting and activating interventions in regional areas and monitoring their correct implementation. In particular, the project allowed the creation of a database of reference of the regional administrations and local services in charge of alcohol-related issues, starting a communications network for a more widespread dissemination of information on prevention activities carried out.

The two-year project “Centralised collection and analysis of information and data flows for monitoring the impact of the use and abuse of alcohol on health in Italy, in support of the implementation activities of the National Plan on Alcohol and Health”, carried out by the ISS CNESPS, allowed the preparation of two successive Reports, referring respectively to the years 2007 and 2008, in which the latest data, with regional detail, on the impact of the use and abuse of alcohol made available by the most qualified national- and international-level sources of information and monitoring, were collected and processed. In particular, data on consumption and consumption patterns, on alcohol-related mortality and morbidity, and on the activities of self-help associations were processed and analysed by comparison with other European countries.

The two-year project “Monitoring the impact of alcohol on health in Italy in support of the implementation activities of the National Plan on Alcohol and Health”, also supervised by the ISS, is a continuation of the previous project and provided updated data on the most important indicators of risk and alcohol-related problems published in two reports that refer to the years 2009 and 2010. The work of publication and dissemination of this data has made it possible for national and regional administrations to acquire tools of knowledge so that they can promote, at their respective levels of competence, appropriate programmes and actions, adapting their interventions to evolving problems.

The “Reinforcement of the monitoring of alcohologic data and of activities of information and prevention in the Regional Authorities as per law 125/2001” project, which ended recently and was coordinated by the Friuli Venezia Giulia Region, promoted actions aimed at disseminating best practices in relation to issues deemed most urgent in specific territories in the Regions in a coordinated manner and in line with PNAS strategies. Local and regional projects were carried out in many areas of intervention, on prevention activities in schools (Molise, Liguria, Marche, Autonomous Province of Trent, Basilicata, Sardinia), implementation of a regional alcohologic medical record (Umbria), prevention in the night entertainment and leisure areas (Tuscany, Calabria, Piedmont, Sicily), prevention in the elderly population (Apulia, Lazio), the responsible sale of alcohol (Emilia Romagna), the rehabilitation of alcoholics (Veneto), prevention in the Emergency Services (Autonomous Province of Bolzano), the problems of alcohol and driving (Lombardy, Abruzzo), the problems of alcohol and work (Campania),
and the spread of the culture of healthy lifestyles (Abruzzo, Aosta Valley).

Of particular strategic importance was the two-year project “Training on early identification and brief intervention for the prevention of problems and alcohol-related harm in the context of workplaces and in basic health care”, coordinated by the Tuscany Region, which resulted in the development, in the 14 participating Regions, of educational activities for the acquisition of methods of early identification and brief intervention for at-risk drinkers in the contexts of basic care and work. These methodologies were validated and standardised in projects initiated and funded by WHO and the European Commission and were previously introduced and tested in the Italian context by the ISS. Many operators of varied qualifications were trained, such as doctors and staff from the Departments of Prevention and Addiction, occupational health physicians, doctors and other health professionals and professionals from the world of work who were identified by partners of the Regions and Autonomous Provinces. The methodologies adopted, based on the training of trainers, will facilitate the autonomous creation of other similar regional or local courses. The concluding conference of the project, held in Florence in September 2011, presented the main results and material produced.

**Essential bibliography**


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### 1.4. Oncological prevention

#### 1.4.1. Universal prevention (primary)

The objective of reducing the incidence of tumours involves the implementation of universal or primary prevention interventions that are effective against determinants that may be characteristic of the population and/or its subgroups and/or individuals. Since the determinants of incidence at the population level and of individual susceptibility are interrelated, interventions against these must be spread over several levels and coordinated efficiently. The health objectives which are considered at the actual state of knowledge, supported by evidence of efficacy and/or on which internationally policies have been agreed to which Italy has adhered, are:

- combat smoking;
- promote healthy nutrition and physical activity;
- combat alcohol consumption;
- combat infectious oncogenic agents;
- combat exposure to oncogenes in living and working environments;
- promote technological development.

The following are instrumental in achieving these targets and functional for the interventions to be implemented: intersectoral policies, the creation of partnerships, coordination and synergy of even basic research (such as increasing knowledge of determinants).

**Planning actions.** The main actions to be implemented to achieve the health goals are summarised as:

- “actions by central systems”: concerned primarily with objectives whose achievement is related to the responsibilities of national government, but also, in their own area, of the regional government with assumption of responsibility too on the part of the main social players (industry associations, trade unions, etc.); 
- “actions by the health system”: relate to
the objectives and actions implemented under the responsibility of the health system in its national, regional and local dimensions and, therefore, for both the structural and delivery aspects.

1.4.2. Secondary prevention (screening)

The goals of secondary prevention of cancers (screening) for purposes of reducing cause-specific mortality (sometimes also the incidence) can be achieved through public health interventions in the population or by an initiative of professionals specialised in the sector. Public health interventions in the population are through “organised screening programs”. These interventions have been included since 2001 in the Essential Levels of Health Care (Livelli essenziali di assistenza, LEA) with regard to breast, cervical and colorectal cancers.

State of progress of regional screening programmes. The progress of the screening programmes is routinely published in the “Report of the National Screening Observatory” (Osservatorio Nazionale Screening, ONS) and highlights both the extent (adjusted) and the percentage of take-up of screening invitations, sub-divided by macro-area; an analysis of the PASSI data allows for an estimation of access to spontaneous individual prevention (Table 1.1).

The activity data show that full compliance with this particular LEA has not yet been achieved as well as the persistence of a marked North-South divide, even if decreasing. Also evident is the intense involvement of the healthcare system produced by this individual access to preventive actions (in parallel with organised screening programmes), at least for breast and cervical-uterine cancers.

Table 1.1. Extent of invitations and percentage of adhesion to screening programmes

<table>
<thead>
<tr>
<th>Cancer Type</th>
<th>Organised screening*</th>
<th>Individual prevention**</th>
</tr>
</thead>
<tbody>
<tr>
<td>Breast cancer (age 50-69 years)</td>
<td>Invitation Regions</td>
<td>Participant Regions</td>
</tr>
<tr>
<td>North</td>
<td>92.2</td>
<td>68.3</td>
</tr>
<tr>
<td>Centre</td>
<td>82.1</td>
<td>57.0</td>
</tr>
<tr>
<td>South</td>
<td>45.4</td>
<td>40.2</td>
</tr>
<tr>
<td>Italy</td>
<td>73.9</td>
<td>59.4</td>
</tr>
<tr>
<td>Cancer of the colon/rectum (age 50-69 years)</td>
<td>Invitation Regions</td>
<td>Participant Regions</td>
</tr>
<tr>
<td>North</td>
<td>81</td>
<td>50.2</td>
</tr>
<tr>
<td>Centre</td>
<td>56.4</td>
<td>42.2</td>
</tr>
<tr>
<td>South</td>
<td>17.2</td>
<td>22.2</td>
</tr>
<tr>
<td>Italy</td>
<td>56.4</td>
<td>45.5</td>
</tr>
<tr>
<td>Cervical cancer (age 25-64 years)</td>
<td>Invitation Regions</td>
<td>Participant Regions</td>
</tr>
<tr>
<td>North</td>
<td>69.5%</td>
<td>49.9%</td>
</tr>
<tr>
<td>Centre</td>
<td>83.1%</td>
<td>38.6%</td>
</tr>
<tr>
<td>South</td>
<td>54.7%</td>
<td>28.3%</td>
</tr>
<tr>
<td>Italy</td>
<td>67.1%</td>
<td>41.0%</td>
</tr>
</tbody>
</table>

** Source: PASSI (Progress made by Health Authorities for Health in Italy) – Year 2011.
Objectives of screening programmes. The primary objective is the extension of the screening program for tumours of the breast, colon-rectum and cervix throughout the national territory, according to the Recommendations of the Council of Europe. This objective, intrinsic to meeting the LEA, requires a modulation for the underperforming Regions. The modulation reflects the need to achieve new PNP objectives more efficiently and is exactly attributable to that anticipated in the guarantee mechanism of the LEA, where the new monitoring system provides summary measures of achievement of the objective (first-level indicators) and threshold levels capable of modulation by each Region in order to foster a virtuous process of adaptation. Consistent with that objective is the planning of interventions of re-engineering of individual preventions because, as the scientific evidence available shows, these can be inappropriate and of minor practical efficiency. These interventions become substantially mandatory for the economic sustainability of programmes of intervention and implementation of the screening programs. Therefore, both the PNP and the technical guideline Document for reducing the burden of cancer disease (Years 2011-2013) pose among their objectives these innovative developments for which there is sufficient evidence of effectiveness (or efficiency gain equal to effectiveness) as:
- programmes of systematic management of high risk (family-based) for cancers of the breast and colon-rectum;
- technological upgrading (digital mammography and any additional technical components) for mammography screening;
- support the extension of the age-range for mammography screening;
- technological upgrading (use of HPV-DNA test) for screening of the cervix.

Identify a “disease management” in early detection of prostate cancer. The spread of PSA may be considered in the broader perspective of secondary prevention of cancer. Because the literature-based evidence does not agree that an “active” screening programme is effective or free from the problems of over-treatment, the need to govern a behaviour widespread among professionals and the public is outlined.

Prevention and “public health genomics” (or “population health genomics”). The central priority Actions of the PNP (DM August 4, 2011), and the technical guidance Document for reducing the disease burden of cancer, in relation to the large growth of genetic knowledge in basic research and the application to individuals, identify the need to govern the development of this research and the need for the evaluation of its applicability in the health system, in particular in the area of prevention. They also identify the need to build a network to promote the goals of genomics at the population level (public health genomics, PHGen); for this purpose the preparation of a “Protocol of usage for public health genomics” has been started.

1.4.3. Tertiary prevention

In addition what has been stated above on primary and secondary prevention, another way to prevent deaths from cancer is, obviously, to treat tumours that recur (tertiary prevention) adequately. Functional for this purpose are: the general progress of medical science and, in particular, the improvement of diagnostic technologies (especially imaging), of surgery, of chemotherapy and radiotherapy. The phenomenon of the differential between the incidence (usually increasing) and mortality (generally decreasing) found for several cancers in recent years is largely due to this performance. However, people who survive cancer are an important population group with special characteristics and who need customised risk-assessment and measures to improve the quality of life. The initiatives of partnership with the patient Associations contribute to this objective.

Essential bibliography

Council of The European Union. Council Conclusions on reducing the burden of cancer 2876
1.5. Health interventions and safety in the workplace

Planning framework and state of implementation. In reference to the policy framework designed by the “Pact for Health and Safety in workplaces” and by the PNP 2010-2012, the balance that can be drawn for the year 2011 appears broadly positive with respect to the activities developed at the central and territorial levels for prevention in workplaces, for combating accidents at work and for occupational diseases. Regional Coordination Committees have been constituted in all Regions. These are real nerve centres, which together with the established Committee for the guidance and evaluation of active policies and for the national coordination of supervisory activities in the field of health and safety at work, complete the inter-institutional control room. They are responsible in particular for the definition of the common lines of intervention in national policies on health and safety at work, identification of priority areas, of planning and coordinated implementation of prevention measures to be implemented in a uniform and homogeneous manner throughout the country.

The results achieved in 2010 by the Regions for prevention at the workplace were: fully meeting the coverage of limits set by the LEAs, the implementation and post-implementation of uniform training initiatives to ensure consistency of interventions of prevention and surveillance at the national level, in support of the National Agriculture Plan and the National Building Plan [approved by the Committee pursuant to art. 5 of legislative decree (D.Lgs.) 81/2008] and the development of surveillance systems, based on investigations conducted by ASL operators, of fatal accidents and occupational diseases and of workers previously exposed to carcinogens.

Description of the data – accident trends. Preliminary INAIL estimates of the trend of accidents for the year 2011 came to 726,000 injuries, on the basis of complaints acquired from the INAIL administrative archives on February 28, 2012. This was a decrease of 6% compared to 775,659 accidents reported in 2010 and confirms a further accentuation of the negative trend of a decreasing number of accidents including fatal cases, which show an overall reduction of deaths at work of −4.4% over the year.

The consolidated data related to the period 2001-2010 show that the rate of decline in accidents at work reached 28.4%, despite positive employment figures of +5.9%.

Presentation and critical evaluation of data. The reduction in the number of accidents at work in 2011 affected all sectors of production. The greatest fall occurred in the industry sector – a drop of −9.9% of accidents reported over the previous year – followed by agriculture, in which the drop reached −6.3%, while in the services sector the smallest reduction was recorded with a decrease of only −4.2%, but it should be taken into account that in this last sector, contrary to other sectors of production, there was, in contrast, an increase in the number of employees, which reached +1% of the number of workers employed annually in the sector.

The analysis of the territorial distribution of the frequency of accidents at work reported in 2011 shows a general decline, which in Northern and Central Italy reached −6% compared to the previous year, while in the South the decline was greater, reaching a contraction of −8.1% in the number of incidents reported in the same year.

The assessment of the distribution of accidents at work that occurred in the year by
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gender shows that while the difference in the drop in accidents was modest, the decrease in men was −6.8%, while for women, the decrease was −5.5%. The difference is more marked between the two sexes for fatal cases for that occurred during the year; in fact, the overall decline of −4.4% in the number of workplace fatalities for the year 2011, which resulted in the lowering of the annual incidence from 2.9 to 2.5 deaths per 100,000 workers, was positively influenced mainly by the decline in male deaths, which for that year showed a reduction of about −6.1%.


**Planning framework.** Measles is a highly contagious disease that continues to be a significant cause of mortality, both in industrialised countries and in the countries in the developing world. Rubella in children is generally an exanthematous disease of modest import, whose relevance in public health is related to the teratogenic potential of infection contracted during pregnancy, which can cause miscarriage, stillbirth or birth of a baby with congenital rubella syndrome (*sin-
drome della rosolia congenita*, SRC). Since the time that both infections have been technically eliminated, WHO developed a strategic plan in 2001 with the goal of reducing measles mortality worldwide, and achieved significant progress towards elimination. In particular for the WHO European Region the interruption of indigenous transmission was expected by 2007 and the certification of elimination in 2010.

In Italy, the elimination plan was initiated in 2003, with the enactment of the National Plan for the Elimination of Measles and Congenital Rubella (*Piano Nazionale per l’Eliminazione del Morbillo e della Rosolia congenita*, PNEMoRc) 2003-2007, and set out as the Agreement of November 13, 2003 in the State-Regions Conference. This plan was prepared in view of the need to estab-

lish national implementation guidelines that would allow the avoidance of new outbreaks of measles, after the extended outbreak that had affected the south of the country between 2002 and 2003, with its epicentre in the Campania Region, and which caused according to estimates more than 40,000 cases of measles, hundreds of hospitalisations, dozens of complicated cases (pneumonia and encephalopathy) and eight deaths.

In Italy, in the period 2003-2010 significant efforts were made to improve vaccination coverage for the first dose of trivalent vaccine against measles, mumps and rubella (*morbillo, parotite e rosolia*, MPR) within 2 years of age (from 79.8% in 2002 to 90.6% in 2010). Efforts also included the establishment of a system of special surveillance for measles, the start of mandatory reporting for rubella and congenital rubella in pregnancy, and the introduction of the second dose of the MPR vaccine. However, as in the rest of Europe, in Italy the goals of elimination have not yet been achieved and, because of the persistent presence of extensive groups of unvaccinat-

ed persons, resulting in the accumulation of individuals susceptible to infection among young adults, many outbreaks have continued to occur, with some complicated cases. Therefore, in September 2010 the WHO Re-

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Decreto del Presidente del Consiglio dei Ministri 17 dicembre 2007. Esecuzione dell’accordo del 1° agosto 2007, recante “Patto per la tutela e la prevenzione nei luoghi di lavoro”


Relazione della Conferenza delle Regioni e delle Province Autonome su “Attività delle Regioni per la prevenzione nei luoghi di lavoro e per il contrasto agli infortuni sul lavoro e alle malattie professionali” Anno 2010
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Regional Committee for Europe, considering that the targets for the elimination of these diseases in the European Region could not be reached for 2010, moved the target date to 2015. In order to implement the appropriate corrective action, Italy too drew up a new elimination plan and, on March 23, 2011 in the State-Regions Conference, a new understanding on a “National Plan for the Elimination of measles and congenital rubella 2010-2015” was sanctioned. The plan re-affirmed the general objectives to be achieved by 2015 and described the specific goals and actions to be implemented to achieve them. 

State of implementation in regional contexts. During 2011, 14 out of 21 Regions acknowledged with formal acts (Resolutions, Circulars or Regional Notes) the Agreement of 23 March 2011 or its objectives. Three of these Regions included the objectives of vaccination coverage anticipated by the PNEMoRc in the objectives assigned to the General Managers of the health services, for the purposes of valuation of activities for 2011. Four Regions announced that the acknowledgement is in progress and will be finalised during 2012. Seven Regions held refresher courses or conferences on the new plan and 2 prepared information materials on measles and rubella and modes of prevention for their populations. Furthermore, as part of the regional planning provided for by the PNP 2010-2012, 18 out of 21 Regions presented specific projects or projects related to the PNEMoRc objectives. Regarding the vaccination coverage for the MPR vaccine, of the 10 Regions that have sent data for 2011 at the time of preparation of this report 7 have a coverage of between 90% and 95%, 2 between 90% and 85% and one less than 85%. Finally, it should be noted that in 2011 5,024 cases of measles were reported, 1 case of congenital rubella and no cases of rubella in pregnancy. At the time of writing, however, the data relating to rubella in the general population are not available. 

Presentation and critical evaluation of the data. The adoption of the Agreement by a regional act has a value that should not be underestimated, especially in a time of economic crisis such as the one that the country is experiencing. This action, in fact, formally undertakes policy-makers to make the necessary resources available to implement the plan at regional and local level, including through a more rational use of resources already allocated to health and in particular to prevention. It is therefore desirable that all the Regions formally acknowledge the Agreement, both because the goals of elimination of measles, rubella and congenital rubella are a priority for public health (whose cogency is emphasised by the fact that actions were rescheduled and the date for achieving them postponed, which involved the setting up of a new plan) and also because these goals can be achieved by the country only through joint efforts and consistency across all the Regions. In light of these considerations, it will be necessary to focus more intensely on the training of health professionals and the initiatives of communication and awareness for the general population. The data on the incidence of measles, sent monthly to the European Centre for Disease Prevention and Control (ECDC) in Stockholm, which support WHO and member countries on the pathway of elimination of the disease, reveal that the disease is still present in endemic form in Italy and that further efforts are needed to bring and then maintain vaccination coverage values above 95%. Finally, a special surveillance of postnatal rubella must be started as soon as possible, in order to monitor in an effective and timely manner the incidence of the disease and the circulation of the virus, obtaining information for the planning and implementation of prevention programmes and for assessing progress towards the elimination of the disease at the same time. 

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## 1.7. Prevention of HIV infections

**Planning framework.** The law 135/1990 defined the interventions of health planning so as to ensure the best care for patients with HIV and AIDS infections. In the context of prevention it is therefore necessary to continue to promote early detection, to guarantee access to testing and early therapeutic treatment, and to strengthen information campaigns and education on the prevention of HIV/AIDS infection.

Italy was one of the first countries to respond positively to the EU requests for policies for the early diagnosis of HIV, drawing up a “Consensus document on access policies and procedures of implementation for the HIV test” which was approved at the State-Regions Conference of July 27, 2011. It was clearly essential to establish a connection at the national level with what had been developed on a regional basis, planning a Technical Conference of Consensus to improve the HIV testing for provision, the occasion of an update of the cited document, supported both by the National Commission for the fight against AIDS and by the Advisory committee.

In detention centres, the prevalence of infectious diseases, including HIV infection, is higher than in the general population due to the large concentration of high risk groups. The DPCM guidelines of April 1, 2008, for the passage of medical duties from the Prison Authority to the SSN, include a specific reference to the prevention of infectious diseases. The results of surveys conducted in Italian detention centres and those in other industrialised countries show that adoption of risk behaviours during the period of detention is not uncommon, and transmission of infections such as HIV is possible. In addition, a series of pilot studies were conducted at the ISS National AIDS Centre (Centro Nazionale AIDS, CNAIDS) in collaboration with the Ministry of Health, the Ministry of Justice, the National Advisory committee for the fight against AIDS, and territorially competent health facilities in some of the Italian Regions. The pilot studies were aimed at defining monitoring parameters such as: access to prevention programmes, accurate information about HIV, and testing; condom-use rate; the percentage of recent infections among new diagnoses of HIV infection and study of circulating HIV. Last but not least, in order to provide assistance to HIV-positive inmates comparable to that guaranteed to those outside the centres, the document “Prison assistance for persons with HIV+ disease” was prepared, which was presented in the State-Regions Conference and discussed at the Permanent consultation Committee on prison Health.

The National AIDS Commission (Commissione Nazionale AIDS, CNA) and the National Transplant Centre (Centro Nazionale Trapianti, CNT) approved the Document “Project for the Transplantation of solid organs in HIV+ patients”. The project, started in 2002, finally concluded the pilot phase in 2009, and took on the character of a procedure of care, the coordination of which was entrusted to the CNT. Updated national protocols have therefore been drafted. Organ transplantation in patients with HIV infection presents a complexity that makes it essential to ensure maximum safety for both patients and for healthcare professionals, as well as the maintenance of a close collaboration between the Transplant Centre and external facilities that follow the patient in

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Risoluzione EUR/RC60/R12. Renewed commitment to elimination of measles and rubella and prevention of congenital rubella syndrome by 2015 and Sustained support for polio-free status in the WHO European Region. 16 settembre 2010


Planning framework. The law 135/1990 defined the interventions of health planning so as to ensure the best care for patients with HIV and AIDS infections. In the context of prevention it is therefore necessary to continue to promote early detection, to guarantee access to testing and early therapeutic treatment, and to strengthen information campaigns and education on the prevention of HIV/AIDS infection. Italy was one of the first countries to respond positively to the EU requests for policies for the early diagnosis of HIV, drawing up a “Consensus document on access policies and procedures of implementation for the HIV test” which was approved at the State-Regions Conference of July 27, 2011. It was clearly essential to establish a connection at the national level with what had been developed on a regional basis, planning a Technical Conference of Consensus to improve the HIV testing for provision, the occasion of an update of the cited document, supported both by the National Commission for the fight against AIDS and by the Advisory committee.

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The “Italian Guidelines on the use of antiretroviral drugs and on the diagnostic and clinical management of persons infected with HIV-1 (LG-HIV)” were drafted in July 2010 and updated in October 2011. The guidelines were presented at the State-Regions Conference, and an ad hoc technical Committee with the Regions was established.

State of implementation in regional contexts. As part of the 2010-2012 PNP, it was demonstrated that about 75% of the Regions provided for specific interventions in their PRP in the field of HIV and AIDS, with particular reference to systems of surveillance and prevention, peer education, the promotion of responsible sexuality, risk behaviour, vulnerable populations (immigrants and teenagers) and, more generally, the reduction of sexually transmitted infections.

1.8. Prevention and control of tuberculosis

Planning framework. The epidemiological situation to date regarding tuberculosis in Italy has been characterised by a low incidence of the disease in the general population. In the last 10 years in fact, the trend has been substantially stable, with an incidence of approx. 7 cases per 100,000 inhabitants. In 2010 (the most recent year for which definitive data are available) the incidence was at 7.78 cases per 100,000 inhabitants. Significant differences are found between the North and South of the country, with a greater incidence of the disease in the Central-North Regions, probably due to the presence in them of metropolitan areas with more than 500,000 inhabitants. Incidence of the disease ranges from approx. 12 cases per 100,000 inhabitants in Emilia Romagna and Lombardy to approx. 2.5 cases per 100,000 in Abruzzo and Molise.

Both the prevention and control of this disease represent an important and recurrent problem for both national and global public health even today.

Tuberculosis (TBC) is a notifiable disease as indicated in the DM of 15 December 1990, with an ad hoc board of supervision, updated in 1999.

In 1998 Guidelines for TBC control were issued, to promote the standardisation of anti-tubercular treatment and follow-up of patients treated, the prevention and control of TBC in high-risk patients especially including those in contact with affected cases, and the improvement of access to services. In 2006, WHO launched the “Global plan to stop TB 2006-2015” to supply countries with directions to programme long-term interventions aimed at achieving the elimination of TB by 2050. In 2007 the document “End Tuberculosis in Italy” identified ten priority targets to achieve a reduction of TBC in Italy and the priority actions for this purpose, proposing also the harmonisation of interventions at the regional level. Based on the changing epidemiological conditions of this disease, 2 documents updating the above Guidelines were published in 2010: “Managing of contacts and of tuberculosis in the care context” and “Effective policies to combat tuberculosis in the immigrant population”.

Finally, on August 23, 2011 the Ministry of Health reiterated the importance of implementing effective monitoring systems to detect and quickly notify suspected cases of TBC with an appropriate Circular, a crucial activity for the programmes of control of the disease, as well as the importance of surveillance programs and training for health professionals.

State of implementation in regional contexts. In May 2011, the Inter-Regional Coordination of prevention discussed and approved the document “National Programme for control of tuberculosis. Health goals, standards and indicators 2011-2013”, currently in the final stages of approval by the
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State-Regions Conference, which represents the natural continuation of the project that created the document in 2007. This document has among its objectives the improvement of the TBC surveillance system, the translation at the regional level of the 2010 Guidelines into Technical and Operational Guidelines on activities of TBC control, and the activation of an “extraordinary” programme of health education and training of operators at different levels. Moreover, some Regions – Piemonte, Lombardia, Veneto, Umbria, Marche, Molise and Calabria – presented specific projects dedicated to TBC in the context of the PRP for the period 2010-2012.

Presentation and critical evaluation of the data. Overall, 65% of the Regions/Autonomous Provinces provided for activities for the prevention and control of TBC in 2011 (updating of Regional guidelines, programmes of prevention of TBC in prisons, improving information flows by aligning the content to the system of international indicators, etc.). Only 37% of the Regions organised training courses to raise awareness of the disease among health care workers and that may present an obstacle to overcoming the current situation of delay in diagnoses. On a yearly basis, the ECDC/OMS requests data relative to TBC for the preceding year, by June 15 of the current year for publication in the “Global TB Control Report” and by September 30 of the current year for publication in “European Tuberculosis Control”. The purpose is to provide a comprehensive assessment of the epidemiology of TBC and the progress made in controlling the disease globally, regionally and nationally. A complete collection and validation of national data using the current systems of information flow requires lengthy periods of time; definitive and complete data regarding the notification of instances of TBC for the year 2011 have been sent in by 80% of the Regions and Autonomous Provinces.

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Decreto Ministeriale del 15 dicembre 1990
Linee guida per il controllo della malattia tubercolare, su proposta del Ministro della sanità, ai sensi dell’art. 115, comma 1, lettera b), del D.Lgs. 31 marzo 1998, n. 112
Ministero della salute. Aggiornamento delle raccomandazioni per le attività di controllo della tubercolosi “Gestione dei contatti e della tubercolosi in ambito assistenziale”. 2010
Ministero della salute. Aggiornamento delle raccomandazioni per le attività di controllo della tubercolosi “Politiche efficaci a contrastare la tubercolosi nella popolazione immigrata”. 2010
Ministero della salute. Circolare del 23 agosto 2011 “Misure di prevenzione e controllo della tubercolosi”
The Global Plan to Stop TB 2006-2015 (OMS 2006)

1.9. Syndromic surveillance in migrant populations

Planning framework. From 2011, the political instability in many countries of North Africa has resulted in a reduction of border controls; for Italy, this has generated an exceptional wave of immigration. Although migrants arrived in good health, it was appropriate to monitor the occurrence of potential outbreaks of disease at the reception centres. Immigrants were received in 20 Regions/Autonomous Provinces and, when housed at immigration centres, had access to clinics managed independently by the organisations which managed the centres themselves. The territorial dispersion of their reception and the large number of players involved made it essential to ensure a single, regular flow of information between the host structures and the SSN. The Ministry of Health and the ISS CNESPS in collaboration with the Regions established an ad hoc syndromic surveillance system with the aim of early detection of possible emergencies of public health.

State of implementation in regional contexts. Each immigration reception centre reports new cases of 13 syndromes under sur-
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Surveillance. Individuals presenting each day are stratified by age group. The data collection forms, sent by the centres or the ASL/Regions, are analysed at the ISS CNESPS. Statistically significant deviations of incidence are identified by the trend of expected incidence for each syndrome (rolling average of incidence observed in the previous 7 days) and by statistical thresholds set based on incidence observed using the Poisson distribution. The aggregate data, summarised in a national epidemiological bulletin, is sent to all facilities involved in the supervision, and is regularly published online at the Epicentro website (www.epicentro.iss.it).

**Description of the data.** From 11 April to 31 December 2011, 121 centres in 13 Regions sent reports. The average population under surveillance every day was 5,000 people. Overall, 76.1% of the population was made up of teenagers and adults between 15 and 44 years; 4,174 cases of syndromes under surveillance were reported at the beginning of the surveillance. The syndromes most reported were “respiratory infection with fever” (63.7%) and “gastroenteritis without blood in the stool” (26.3%). After the first month of consolidation of the surveillance data, the incidence was stably maintained at very low levels. There were nine statistical alarms, all closed spontaneously within 72 hours. The investigations undertaken by the centres involved, in collaboration with the CNESPS, showed no evidence of ongoing epidemics. Therefore no health emergencies occurred during the surveillance period (**Table 1.2**).

**Presentation and critical evaluation of the data.** Syndromic surveillance has provided timely epidemiological data from a particularly vulnerable population managed in a territorially and institutionally complex manner, which has allowed health care providers to promptly identify possible health emergencies and disprove anecdotal alarms spread by the media.

All of these efforts happened very quickly, without the use of automation for data collection. Consequently, the daily commitment to the operation of the system was manifest at both local and central level. There has been a consequent impact on the acceptability of the system at the regional level: the regional adhesion to syndromic surveillance had monthly fluctuations between 19% and 48%, although overall 13 of the 20 Regions involved in the admission plan sent reports (with the exception of Abruzzo, involved in post-earthquake reconstruction).

As part of a surveillance system designed for and limited to response to a humanitarian emergency, that level was considered acceptable. However, the system is not sustainable and its current limitations, particularly the lack of representativeness, are unacceptable in the long term.

**Essential bibliography**


Riccardo F, Napoli C, Bella A, et al. Syndromic surve-
1.10. Monitoring of arboviral diseases

**Planning framework.** Ever since these diseases have made their appearance in the European landscape, most European states have been committed to the implementation of epidemiological surveillance of human cases of these illnesses, activating specific monitoring systems, implementing laboratory diagnosis, training healthcare personnel to recognise these diseases in differential diagnoses, and providing informational events for the general population. The ECDC has published scientific and technical documents, after consultation with experts, for the evaluation of the risk from arboviral diseases in Europe. Italy is also actively involved at the national and regional level in the fight against these diseases, essential as it is to continue surveillance to monitor the progress of the phenomenon, to implement vector control and to have early recognition of indigenous cases or clusters so as to implement all appropriate control measures in the affected area. In 2011, the Circular of June 15, 2011 “Surveillance of human cases of vector-borne diseases with particular reference to Chikungunya, Dengue and West Nile Disease – 2011” was issued, which provided information on the modes of surveillance for human cases of these diseases.

**State of implementation in regional contexts.** During 2011, in accordance with the issue of the Circular of June 15, 2011 “Surveillance of human cases of vector-borne diseases with particular reference to Chikungunya, Dengue and West Nile Disease – 2011”, the following activities were performed by the Regions: issue of planning/regulatory documents, training for health personnel, implementation of the epidemiological surveillance and laboratory network for vector-borne disease with activation of regional reference laboratories, implementation of the notification of human cases via the Web, and the integration of monitoring plans in human and veterinary fields. Given the importance of these diseases in the public health context, many Regions have included surveillance of vector-borne diseases in their PRP, as a line of planning. In 2010, these regional projects were positively assessed by the Directorate-General of Prevention; the regional reports on process indicators for the year 2011 are underway.

**Description of the data.** In 2011, two cases of Chikungunya fever and 45 cases of Dengue fever have been reported, according to the case definition of the June 15, 2011 Circular. Regarding West Nile Disease, in 2011, 14 confirmed cases have been reported of neuroinvasive illness from the West Nile virus (WNV), of which were 8 in the Veneto, with 1 death (1 in Venice, 6 in Treviso, 1 in Belluno), 4 cases in Sardinia, with 3 deaths (3 in Oristano and 1 in Olbia) and 2 cases in Friuli Venezia Giulia (Udine). 2011 witnessed the widening of the viral circulation, with cases of a neuroinvasive form in humans in two Regions: Friuli Venezia Giulia and Sardinia. Furthermore, for the first time in Italy, the viral circulation of lineage 2 of the West Nile virus has been shown, isolated in Hungary and Greece. This virus was isolated from a patient with a febrile illness in the Marche, and then in a patient with neuroinvasive illness in Sardinia. Moreover, the entomological surveillance data for the *Culex pipiens* mosquitoes in the Veneto have demonstrated the isolation of sequences of lineage 2 strains of WNV in these insects, confirming the circulation of the virus in the North-East of the country.
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1.11. Nutrition

In recent decades, the Italian way of life has changed, and this has led to rapid modifications that take us further and further away from healthier lifestyles. The “new” habits are accompanying us to a nutritional transition no longer in line with our culture. To this must be added a growing prevalence of inactive persons. The most obvious result of the change in lifestyle is the spread in the population of obesity, metabolic disorders and chronic or degenerative diseases that are becoming more widespread, with estimated spending on socio-health care steadily increasing. Prevention is the most effective way to maintain good health and avoid the development of those chronic diseases (cardiovascular, respiratory, cancer and diabetes) that are responsible, according to the latest WHO data, for the majority of deaths and suffering as well as health care costs in the world. These diseases have risk factors in common related to individual behaviour, such as smoking, alcohol abuse, unhealthy eating, being overweight and/or obesity, physical inactivity, even if these in turn are conditioned by the economic, social and environmental context in which people live and work.

Prevention of chronic diseases is however possible through policies and interventions of proven efficacy with respect to risk factors, which modify individual behaviours harmful to health.

Health promotion must involve the whole population, beginning with the family, so that from childhood healthy lifestyles are adopted that promote wellness.

Prevention can improve the quality of life, reduce costs and increase the participation and productivity of the labour market in Italy.

With regard to obesity, the most alarming data are certainly those that affect infants and children.

An updated profile of overweight/obesity among Italian children has been achieved thanks to the project “OKkio alla Salute” 2010, which the Ministry/CCM entrusted to the ISS CNESPS. The data collected showed a very high prevalence of overweight and obesity: at the national level: 11.1% are obese and 22.9% are overweight, i.e., more than 1 in 3 children are heavier than they should be for their age. Significant differences by Region were also shown: from 49% of children being overweight/obese in Calabria to 15% in Bolzano.

The survey also found that 22% of children play sport for no more than 1 hour per week, 1 in 4 either do not exercise or perform it at an insufficient level, while half of children spending (1 out of 2) more than 2 hours a day watching television.

Action is therefore needed to correct imbalances affecting both life-expectancy and quality of life.
Nutrition education is an important preventive factor of obesity, with particular reference to children, and is a key element of the “Gaining health” programme of our Ministry in line with the guidelines of international and EU institutions in relation to chronic non-communicable diseases in the European WHO Action Plan 2007-2012.

Among the strategies to be adopted, particular attention should be given to schools, particularly with regard to catering. In this regard, the Ministry of Health prepared the National Guidelines for school catering approved at the State-Regions Conference and published in GU on June 11, 2010. These guidelines develop from the need to facilitate the adoption of healthy eating habits for health promotion and prevention of chronic degenerative diseases from childhood. The document, prepared by a technical Committee specially set up by the Directorate-General of Food Safety and Nutrition, is a point of reference and consistency for the Regions, and is aimed at all those involved in school catering. It focuses on some substantive aspects, in order to provide nationwide direction to improve the quality of catering, and that of nutrition in particular. It also provides elements for planning and managing the catering service, for defining the terms of reference and ensuring a proper meal for the needs for different age groups, educating the child to acquire healthy eating habits.

Taking into account the ability of communication media to create certain stereotypes and images of the body and the role of mass media to inform, educate and persuade the benefits of a healthy and balanced diet, a cooperation with the media sector is required to encourage and promote physical activity. Similarly, it is appropriate to encourage industry to employ special care in food advertising specifically aimed at children, limiting the advertising of foods of poor nutritional value that have children as a specific target. It was their importance within the community and the consequent ethical and social responsibilities of companies that work with consumers, that were the main motivations for the setting up of a technical Committee at the Ministry of Health, which produced the document “Rules for Commercial Communication on food and drinks, to protect children and their proper nutrition”, which aimed to explain best practices and transmit externally the system of values and ways of being and acting employed by the more receptive companies.

Despite the efforts made by the industry in recent years to improve foods for children and adolescents from the nutritional point of view, the drafting of this document is highly strategic, insomuch as we should arrive at shared and appropriate modes of advertising necessary to provide correct information. Closely linked to the code, as part of the strategies suggested by the EU, the policy document “Shared objectives for improving the quality and nutritional information on the label of food products for the paediatric population” was produced in order to optimise the state of nutrition of the infant population, and to fight the rise of the condition of overweight and obesity and more generally of chronic degenerative diseases.

**Essential bibliography**

ISTISAN. OKkio alla Salute. Rapporto 2010
WHO European action plan for food and nutrition policy 2007-2012

1.12. Special diets

With regard to special diets, the Ministry of Health conducts direct verification and control. In fact, the marketing of certain foods for particular nutritional uses, such as products for athletes, those for special medical purposes, those gluten-free (ex Directive 2009/39 and Regulation CE 41/2009), of formulas used for the feeding of infants...
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under 6 months of age (ex DM 82/2009 in transposition of Directive 2006/141/CE) is subject to a notification procedure, which consists of the transmission to the Ministry of a model of the product label contextual to its being placed on the market. This procedure allows the ensuring of compliance with the specific regulations for the above product areas, with particular reference to the adequacy of the constituents, their contributions and properties claimed on the label.

In 2011, approximately 1,351 new notifications were received and 289 instances of review.

Furthermore, the three sections of the National Register of products for particular nutritional uses supplied by the SSN according to the DM of June 8, 2001, are published and updated every 3 months on the website. The Ministry has provided for the enactment of the DM of May 19, 2011, no. 84, which contains the rules on penalties for infringements of DM 82/2009 transposing Directive 2006/141/CE on infant formulas and follow-on formulas.

In 2011, the Ministry, as central competent authority, received a visit from the Food and Veterinary Office (FVO) division of the DG-SANCO, in order to verify the status of implementation of the actions taken as a result of the sector audit conducted by the Commission in Italy in 2009 to assess the appropriateness of official controls on food for infants. Within the context of the training of staff responsible for official controls, conferences on matters related to food for young children were organised during 2011.

The office of the Ministry is actively monitoring regulatory developments at EU level in defining the new EU regulation on food intended for infants and foods for special medical purposes.

With a view to simplification and to ensure consistent and timely information to the public, the area dedicated to these products on the website is continually updated.

As part of the activities related to the Digital Administration Code (Codice dell’Amministrazione Digitale, CAD) the services project was completed, which includes all the procedures for the notification of products, as well as all the forms for submitting requests to the Ministry. In particular, 13 procedure reports were drafted with 44 specific modules.

1.13. Promoting healthcare among migrant populations and combating poverty-related diseases

From the analysis of the Istat data carried out by Caritas and Migrantes Foundation it emerges that, at January 1, 2011, there were 4,570,317 foreign nationals resident in Italy, an increase of 330,000 with respect to 2010. In a total population of 60,626,442 persons, foreign nationals comprise 7.5%. More than half of the entire foreign presence is represented by Romanian (21.2%), Albanian (10.6%), Moroccan (9.9%), Chinese (4.6%) and Ukrainian (4.4%) national groups. Regarding the new arrivals during the course of 2010, more than 50% of these persons came from the following six countries: Romania (24.1%), Ukraine (7.9%), Moldova (7.6%), People’s Republic of China (6.4%), Morocco (6.2%) and Albania (4.8%). These data confirm the quantitative significance of the communities of historic immigration in our country (Albania and Morocco), which are flanked by the communities emerging after the regularisation measures of 2002 (Ukraine and Moldova) and those currently growing, especially from Asia and Africa.

The nationalities that experienced the greatest percentage increase between 2009 and 2010, in order, are Pakistani (+16.7%), Indian (+14.3%), Peruvian (+12.4%), Chinese (+11.5%), Bangladeshi (+11.5%), Senegalese (+11.5%), and Nigerian (+10.1%).
The socio-demographic characteristics of the population of foreign nationals resident in Italy show a slight female predominance between the sexes (51.8%), although there are substantial differences with regard to individual nationalities. Indeed, there is a clear predominance of women in the citizens of Ukraine (79.8%), Poland (71.2%), Moldova (68.8%), Peru (61.8%), Ecuador (61.8%) and the Philippines (58.7%), while the native peoples of Senegal (75.6%), Egypt, Algeria and Tunisia show a clear male domination. The imbalance in favour of males was also recorded among citizens of Asian countries such as Pakistan, Bangladesh, India, Sri Lanka, and of African countries such as Nigeria and Ghana.

The average age of the foreign population resident in Italy at the end of 2010 amounted to 31.1 years, younger than the Italian one, which was 43 years. This data is weighted by the incidence of children between the ages of 0-17 years among foreign couples, with 993,238 individuals, i.e., 21.7% of all the resident foreign population. As regards the percentage of foreign national women giving birth in Italy, the average number of children for them is 2.13 compared to 1.41 for Italian women.

The eighth CeDAP Report on births in Italy, published in June 2011 and analysing data collected from the information gathered on the delivery assistance certificates from 549 maternity locations, reveals that in 2009 18% of births were to mothers of foreign nationality (16.9% in 2008). This phenomenon was more widespread in the Centre-North, where more than 20% of births taking place were to non-Italian mothers; in particular, in Emilia Romagna almost 28% of births reported were to foreign national mothers. The major geographical areas of origin were those of Africa (27.8%) and the EU (24.7%). The mothers of Asian and South American origin comprised, respectively, 18.2% and 8.8% of the non-Italian total. Caesarean delivery was more common in women with Italian citizenship than in foreign national women; caesarean section was used in 28.6% of births to foreign national mothers, while the figure for the share of Italian mothers was 40.1%.

The average age of the mother was 32.5 years for the Italian woman, but dropped to 29.1 years for female foreign nationals. The median values were however 32.2 years for the Italian woman and 28.3 years for the female foreign nationals. In almost all Regions, the average age for Italian women for having the first child was over 31 years, with substantial changes between the Regions of the North and the South. Women of foreign nationality give birth to their first child on average at 27.5 years.

Of the women with Italian citizenship who gave birth in 2009, 45% had a medium to high education, 33.7% medium-low and 21.3% a bachelor’s degree. Among foreign nationals, medium-low schooling prevailed (52%). The professional status of foreign nationals who gave birth in 2009 was housewife in 55.7%, compared with 65.8% of Italian women on the other hand with an occupational position.

With regard to the population of minors, second-generation migrant children in the country numbered 650,802, accounting for 65.5% of the total of foreign national minors resident in Italy. Considering country of origin, children aged between 0 and 14 originated mainly from Morocco (19.2%), Albania (16.1%) and the People’s Republic of China (8.3%). In the 15-17-year age group, minors were largely Peruvian, Ecuadorian, Moldovan, or Filipino.

The health of migrant persons on arrival. The year 2011 was characterised by the occurrence of a prolonged phase of emergency related to the arrival of migrants that affected in particular the island of Lampedusa. Between January and September 2011, coinciding with the political and social upheavals that occurred in Egypt and the Maghreb countries, there were 440 landings on the island, of 50,522 migrants (Table 1.3). Based on the data available on the clinical-symptomatic conditions encountered on immigrant arrival and observed during clinical-diagnostic triage at the quayside, two different groups of migrants can be distinguished:

- a first group consisting largely of Tuni-
sian migrants, mostly male, aged between 15 and 36 years, who presented with systemic pathologies and non-serious organ pathologies (general malaise, asthenia, cephalalgia, nasopharyngitis, epigastric pain) and which rarely led to emergency interventions;

■ a second group with a prevalence of sub-Saharan migrants (Ivory Coast, Ghana, Nigeria, Mali, Burkina Faso, etc.), including men, women, accompanied and non-accompanied minors, aged between 5 and 35 years. These persons had much more serious pathologies, because, after having been moved in many directions within Africa, they then ended up in Libya from where, after a further long and gruelling sea voyage, they eventually landed on the island of Lampedusa.

Table 1.3. Number of migrants arrivals by month in Lampedusa (Year 2011)

<table>
<thead>
<tr>
<th>Month</th>
<th>Disembarkations (n)</th>
<th>Immigrants (n)</th>
</tr>
</thead>
<tbody>
<tr>
<td>January</td>
<td>9</td>
<td>156</td>
</tr>
<tr>
<td>February</td>
<td>32</td>
<td>5,232</td>
</tr>
<tr>
<td>March</td>
<td>197</td>
<td>15,278</td>
</tr>
<tr>
<td>April</td>
<td>54</td>
<td>7,306</td>
</tr>
<tr>
<td>May</td>
<td>41</td>
<td>8,617</td>
</tr>
<tr>
<td>June</td>
<td>24</td>
<td>4,392</td>
</tr>
<tr>
<td>July</td>
<td>17</td>
<td>2,229</td>
</tr>
<tr>
<td>August</td>
<td>48</td>
<td>5,902</td>
</tr>
<tr>
<td>September</td>
<td>18</td>
<td>1,410</td>
</tr>
<tr>
<td>Total</td>
<td>440</td>
<td>50,522</td>
</tr>
</tbody>
</table>

With regard to the clinical-symptomatic conditions of women belonging to the second group of migrants, cervico-vaginal inflammation was frequently observed, as a result of poor hygienic conditions in the days before boarding and during the sea voyage. In reference to the activities of triage of migrant adult males carried out on the quayside, the medical teams were able to detect pathologies such as: moderately severe and severe hypothermia, moderately severe and severe dehydration with its cardiovascular sequelae (major and minor arrhythmias such as extrasystoles and atrial fibrillation). These pathologies resolved promptly after appropriate medical treatment and hydration with pre-warmed intravenous fluids. With regard to organ pathologies, those encountered most often were in the respiratory system (pharyngitis, tonsillitis, laryngitis, bronchitis, pneumonia) and in the urinary apparatus (anuria, dysuria, haematuria, urinary retention with presence of distended bladder, cystitis, urethritis).

Most commonly found gastrointestinal pathologies were: nausea, vomiting, heartburn, epigastric pain, diarrhoea and abdominal colic. Deserving of special mention is the ingestion of seawater by migrants, after days of travel without drinking water. This caused complications due to alterations in the electrolytes and blood volume. Drinking seawater also caused irritation of the brain due to dehydration, with clinical manifestations ranging from visual hallucinations to psychomotor agitation, and coma.

As regards skin pathologies, in addition to dermatitis, burns and hyperaemic skin, a type of dermatitis was found to be due to contact of the skin with a mixture of seawater and petrol. In contact with the skin, petrol causes burns and maceration of large areas of skin, usually affecting the buttocks and the lumbosacral region. Injuries were serious but resolved quickly when treated with advanced medications, with full recovery within 15 days.

Osteoarticular pathologies occurred with bone pain from forced posture and functional limitations leading to antalgic limp, diffuse polyarthralgia, bruises and broken bones on arrival.

Regarding pathologies of the male genitalia, due to infections caused by lack of sanitation and of water supply, the most prominent were balanoposthitis, orchitis and scrotal fistulas. Pathologies of the eye that were observed included conjunctival hyperaemia, conjunctivitis and corneal leucomas.

Pathologies of the heart and circulatory apparatus observed included: bradycardia, tachycardia, extrasystoles, atrial fibrillation,
hypotension, hypertension and peripheral oedema from cardiac decompensation. Patients needing emergency/urgent care [184 (3.6‰ of the total)] were transferred through the SUES 118 service to specific Sicilian hospitals where they were hospitalised according to their clinical needs. Of these patients 88 were women, 62 of whom were pregnant; 1 seropositive; 11 abortions; 1 ectopic pregnancy; 5 pelvic pain; 1 bartholinitis; 4 acute appendicitis; 1 pulmonary TB; 1 visceral leishmaniasis; 1 haemorrhagic-mucoid enteritis. The 96 male patients presented with the following clinical profiles: 10 cases of TB; 2 pneumonia; 3 gastroenteritis; 1 endocarditis; 1 meningitis; 2 acute myocardial infarction; 2 scabies; 4 acute appendicitis; 23 acts of self-harm; 2 acute urinary retention; 5 acute abdomen; 1 cerebral ictus; 1 heroin withdrawal syndrome; 3 traumatic brain injuries with fracture of the skull; 11 limb fractures; 5 epileptic seizure; 5 severe abdominal/pelvic pain; 2 bacterial bronchial pneumonia; 1 herpes virus infection with skin and mucous membrane involvement; 1 bacterial pneumonia; 7 severe dehydration; and 4 skin ulcers.

Overall, the available data indicate that the clinical profiles presented on arrival were related to the sea crossing (23%), reproduction (1%), infectious pathologies (1%) and other pathologies (1%). In the remaining 74%, no clinical problem was encountered. These data allow us to confirm the occurrence of a “healthy migrant effect”, which, over time, has characterised migration inflows to our country: the observation of good migrant health at the time of their arrival has highlighted the selection processes operating at the origin of migration. Thus, it has been found that the people who arrive are in a better state of health than their countrymen.

The health of foreign nationals present on Italian territory. The information on the health status and access to health services of legally resident and undocumented foreign nationals in our Country, is still rather fragmented and lacking in detail at the local level. It would therefore be desirable to provide a standard template for the collection of clinical as well as social data, in order to monitor the health of migrants adequately. Some of the most important data on the state of health of migrant populations in the urban context were collected in the city of Rome by the National Institute for Health, Migration and Poverty (INMP). They relate to 46,010 people who visited the INMP outpatient department of Rome in December 2011, of which 36,654 were foreign nationals. Of the latter, 63.1% had irregular status. In terms of age groups, the most represented was the 18-34 range, the second 35-54, and then the group of less than 17 years, followed by those in the 55-64 range and, lastly those over 65 years old.

The migrants who came to the facility were mainly from Europe and Africa. In detail, by adding those from the EU to those of other European countries, European migrants represent the vast majority, with 13,971 admissions, followed by migrants from Africa, with 9,956 admissions, and then Asia, with 5,527 admissions. It can be noted, finally, that a limited but significant number of people did not declare their origin.

With regard to the health of the foreign nationals visited, diagnoses observed in the period of observation are shown in Figure 1.1 in descending order. It shows how most of the diagnoses fall within the class ICD9-CM V01-V82. This class includes visits and specialist services, including blood chemistry analysis. Next, in descending order, were diseases of the digestive system, including those of the teeth and the oral cavity, followed by diseases of the skin and subcutaneous tissue, and (almost equal) infectious and parasitic diseases, followed by symptoms, signs and ill-defined conditions and then diseases of the genitourinary apparatus. In seventh place were the diseases of the nervous system and sense organs, in eighth were musculoskeletal and connective tissue system diseases, and lastly, diseases of the respiratory system, the circulatory system, the endocrine glands, nutrition, metabolism, and immune disorders.

It should be noted that the picture emerging from the description of the diagnoses may not reflect the real epidemiological state of the foreign national population in the urban
Implementation of lines of priority in order to meet health objectives

context of reference. It must be taken into account that the types of services offered by the INMP outpatient department, on the one hand, favour some medical disciplines over others (as is the case with dermatology and gastroenterology) and on the other, defer some secondary diagnostic confirmations to other public hospitals in the city.

At the same time, the experience gained over the years shows that, in general, the health status of foreign nationals living in semi-urbanised and metropolitan contexts worsens with the passage of time: the foreign national who accesses to the INMP outpatient department in Rome usually presents in a worse state of health than his newly arrived fellow-citizens. This is due on the one hand to the difficult access to health services and, secondly, to the absence of certain prerequisites for health. The poor quality of some of these prerequisites, such as housing and food, as well as a lack of or difficult access to health services, leads to a worsening in the health status of the individual migrant. Difficult access, also intended as a problem of finding appropriate answers to the real needs expressed, results in exclusion from social opportunities, eroding over time the individual’s initial health status.

Essential bibliography

INMP. Salute e Migrazione. Strumenti e risorse nella società multiculturale. 2011

1.14. Communications activities on the use of medicines

In 2011 the Italian Medicines Agency (Agenzia Italiana del Farmaco, AIFA) implemented several institutional communication activities.

AIFA, in cooperation with the ISS, run an awareness campaign sponsored by the Ministry of Health, on the proper use of antibiotics: “Antibiotics, defend your defense. Use them with caution”. The campaign was fully integrated, using various communica-

| A | Supplementary classification of factors which affect the state of health |
| B | Diseases of digestive apparatus |
| C | Diseases of the skin and subcutaneous tissue |
| D | Infective and parasitic diseases |
| E | Ill-defined symptoms, signs and morbid conditions |
| F | Diseases of the genitourinary apparatus |
| G | Diseases of the nervous system and of the sense organs |
| H | Diseases of the musculoskeletal and connective tissue system |
| I | Diseases of the respiratory system |
| L | Diseases of the circulatory system |
| M | Diseases of the endocrine glands, nutrition, and metabolism; immune disorders |
tion tools such as commercials on publicly broadcast networks and billboards. The Campaign is part of a communication strategy dating back to 2008 that includes guidelines set by international public health institutions such as the WHO and the ECDC, whose goal is to raise awareness in the general population about the importance of a proper and responsible use of antibiotics as a fundamental mean to fight the threat of antibiotic resistance. Addressing this issue is of utmost importance for public health protection, because it could expose the population to the risk of not having any possibility of curing infections in the near future.

In 2011 communication and independent information dissemination activities were undertaken, including participation in international regulatory events, in order to raise awareness among citizens and professionals of all the actions carried out by the Agency in the field of health protection. Specifically, the Agency participated in The Organization for Professionals in Regulatory Affairs’ (TOPRA) Annual Symposium and, for the third consecutive time, in the 47th Annual Conference held by the Drug Information Association (DIA) in Chicago (USA).

For what regards web-based communication in 2011, many sections of the Agency’s website were enhanced, providing new services and features. Access data for 2011 show that AIFA was increasingly recognized by stakeholders as an authoritative source of timely and transparent information for the public. It should also be noted that the comparison of time-series data showed that AIFA’s web portal registered a substantial increase in the number of visits, especially those by “unique visitors”. Also, the visibility of “Health Professional”, “Company” and “Citizen” channels experienced a significant growth, a success largely due to the vast array of services made available by the Agency.

Lastly, in 2011 AIFA edited and published books in the subject of drug counterfeiting, in order to provide an insight into the different aspects of the phenomenon with the aim of spreading trustworthy information on a topic often subject to misinterpretations.
The legislative decree (D.Lgs.) 153/2009, adopted pursuant to law 69/2009, and subsequent decrees of the Ministry of Health December 16, 2010, assigned new functions to pharmacies operating within the ambit of the National Health Service (Servizio sanitario nazionale, SSN), outlining for them an important role in care in their area, their focus helping overall accessibility to possible health reference points and the process of customisation of care.

Pharmacies can, in particular, within the limits and procedures laid down by regulations:

- participate in the service of integrated home care and support at the request of the general practitioner (medici di medicina generale, MMGs) or paediatricians of the patient’s choice (pediatri di libera scelta, PLSs) through the dispensing and delivery of medicines and medical devices to the home, the preparation and dispensing to the home of blends for artificial nutrition and pain medication, dispensing of medicines of direct distribution, the making available of socio-health workers, nurses and physiotherapists for the performance of specific professional practices in the home;
- co-operate with initiatives aimed at ensuring the proper use of prescribed medications and monitoring thereof, in order to promote the adherence of those who are ill to medical therapies, including also through participation in specific pharmacovigilance programmes;
- provide first-level services for the implementation of health education programmes and campaigns for the prevention of major diseases which have a strong social impact;
- provide second-level services aimed at individual persons being assisted in line with the guidelines and diagnostic/therapeutic pathways provided for specific diseases, on the order of the MMGs or PLSs, with the assistance of nursing staff, providing also for the inclusion of pharmacies as places equipped with semi-automatic defibrillators;
- perform, on a doctor’s request, first-level analytical procedures which are of the self-care type;
- enable persons being assisted to book specialist outpatient care and provide for the payment of their share of the costs, and collect reports relating to services of specialist care.

The legislation assigns the task of regulating the conduct of activities to the Regions through issuing guidelines and measures that also establish the quality requirements. The forms of assistance described above have the essential characteristic of responding in particular to the needs of weaker sections of the population who are not self-sufficient, and who require careful monitoring of chronic conditions, or are in need of specific continuous supplies which have been designed to avoid the worsening of a state of health already partly compromised.

The aid that the nurse may provide for the execution of diagnostic tests in a protected environment such as the pharmacy, for example for glycaemia, can only be a positive impetus for decreasing any errors in the execution and reading of the test by the very elderly or frail. In addition, the nurse can reinforce the empowerment of the patient on these occasions for the proper application and interpretation of the test at home. Similarly, it may be said that the activity of physiotherapy deliverable at the pharmacy or at home is addressed mainly to patients.
belonging to vulnerable social groups with chronic diseases, the elderly, or the disabled who are stabilised residents at their homes, for whom the need is to prevent possible deteriorations through appropriate interventions. Their condition of fragility, in fact, is such that on the one hand it is in itself a cause of possible complications and, on the other that these same possible complications could generate additional disease states with the need for interventions of greater care intensity and of uncertain result.

The most innovative aspect of the reform legislation is to have promoted through the involvement of pharmacies the overall increase in accessibility of health services currently provided by the SSN, of which people in situations of fragility will particularly benefit.

In order to ensure the quality of the services provided by the “new” pharmacy, a Workgroup has been established at the Ministry of Health which will produce a Manual containing guidelines for the safety of care for the citizen within the context of a multi-disciplinary and multi-professional approach.

**Essential bibliography**

**Decreto Ministro della salute 16 dicembre 2010.**
Disciplina dei limiti e delle condizioni delle prestazioni analitiche di prima istanza, rientranti nell’ambito dell’autocontrollo ai sensi dell’art. 1, comma 2, lettera e) e per le indicazioni tecniche relative ai dispositivi strumentali ai sensi dell’art. 1, comma 2, lettera d) del D.Lgs. n. 153 del 2009

**Decreto Ministro della salute 16 dicembre 2010.**
Erogazione da parte delle farmacie di specifiche prestazioni professionali

**D.Lgs. 3 ottobre 2009, n. 153.** Individuazione di nuovi servizi erogati dalle farmacie nell’ambito del Servizio sanitario nazionale, nonché disposizioni in materia di indennità di residenza per i titolari di farmacie rurali, a norma dell’art. 11 della legge 18 giugno 2009, n. 69

**Legge 18 giugno 2009, n. 69.** Disposizioni per lo sviluppo economico, la semplificazione, la competitività nonché in materia di processo civile

**Ministero della salute.** Criteri di appropriatezza clinica, tecnologica e strutturale nell’assistenza all’anziano. Quaderni del Ministero della salute, n. 6, novembre-dicembre 2010

**Ministero della salute.** La centralità della Persona in riabilitazione: nuovi modelli organizzativi e gestionali. Quaderni del Ministero della salute, n. 8, marzo-aprile 2011

**Piano Nazionale di Prevenzione 2010-2012**
3. Primary healthcare

National Planning in this last decade has been directed to provide answers within demographic, epidemiological and organizational contexts in which some special factors such as the progressive aging of the population, the increasing relevance of chronic diseases, dependent persons and disability, the increase in the immigrant population, as well as the new socio-economic conditions, have increasingly distinguished themselves. This has oriented health policy towards the reorganisation of territorial care through the development of organisational models based on professional integration and participation of patients and families. This has seen a changing role for hospitals, now increasingly specialised and technologically equipped for the treatment of acute illnesses and strengthening of the primary care system – the interface between the population and the National Health Service (Servizio sanitario nazionale, SSN).

The need to refocus the health care system from hospital to the community is a priority in order to adequately respond to new health needs related mainly to epidemiological changes due to increased quality of life and increased rate of chronic disease, frailty and loss of autonomy, especially in older age groups. This also requires a systemic response in which community health services are reorganised to shift attention from the disease to the person with their overall health needs. This shift recognises that “only a person-focused model can bring a real improvement in the quality of chronic disease care in disadvantaged persons”.

To this end, the national planning indications [National Health Plan (Piano Sanitario Nazionale, PSN) 2006-2008 and proposed PSN 2011-2013] give special attention to the reorganisation of primary care as a strategy that, through the integration of professionals working in the territory, allows for the improvement of socio-health care and of the network of long-term care while ensuring the sustainability of the system. This also makes it possible to pursue both prevention (reduction of disease incidence) as well as chronic disease management (reduction of complications and of disease progression to disability).

In this sense the planning indications note the importance of continuous improvement in the quality of care, through the direct involvement and accountability of all players in the system in the implementation of care pathways with a more pronounced orientation towards the so-called “initiative medicine” for the active promotion of health.

In this context, the Regions operate complex levers of governance, by redefining the organisational structure of Districts, providing for an ample territorial dimension [with an average catchment of more than 60,000 inhabitants provided for by art. 3-quater of legislative decree (D.Lgs.) 502/1992 and subsequent amendments], although with notable differences in the local area. The redefined dimension will be better suited to the definition of a network of socio-health services with management of a range of territory socio-health pathways highly integrated within the social context. It should be noted that almost all the Regions anticipate that the District territorial areas will coincide, in part or
in total, with the social areas, identified by the national law (art. 8 of law 328/2000) and will facilitate the integrated health and social welfare planning of territorial services, particularly for people with chronic diseases and for dependent persons.

With respect to district functions, a greater orientation towards the District taking the role of facilitator of the integration processes and of protection of public health may be highlighted. In simplified form, it is intended to strengthen the role of the client (particular responses to particular needs), while the role of production will sometimes be attributed to other individuals of the same health agency (such as the Departments of primary care). In other models, the production is entrusted to a plurality of external public or accredited private subjects.

With respect to management and operation, the Regions are moving towards the identification of:

- forms of organisation of general medicine, provided for by the National Collective Agreements of General Medicine (ACN July 29, 2009 and ACN July 8, 2010), such as the Functional Territorial Groupings that achieve some fundamental conditions for the professional integration of activities of individual general practitioner (medico di medicina generale, MMG) and the Complex Primary Care Units (Unità Complesse delle Cure Primarie, UCCPs), which realise the continuity of care 24 hours and 7 days a week through the involvement of various professionals;

- processes of integration both at the level of coordination (diagnostic and therapeutic pathways, integration between hospital and territory, socio-medical integration) and at the computer/informational level (ACN July 29, 2009 e ACN July 8, 2010).

The institutions demonstrated their commitment to promote the implementation of primary health care through the identification of funds dedicated to the presentation of specific regional projects in implementation of the planning guidelines of the PSN. For the year 2011, in particular, it was confirmed that the bond of 25% of the total resources, amounting to approx. Euro 360 million, would be allocated to projects which meet and/or enhance the development of specific methods for improving the organizational network of territorial care with the State-Regions Agreement of April 20, 2011. With the successive Agreement of July 27, 2011 guidelines were identified on “continuity of care in an integrated system: organizational models for 118 and Continual Assistance” for the integration of the preceding.

State of implementation in regional contexts. Under the impetus of the national planning legislation, regional actions have been geared towards the upgrading of the system of primary care through the adoption of organisational models able to provide care answers integrated with the hospital system and emergency-urgency care system in order to “broaden the horizon of health care”, in compliance with the relevant contexts.

Among the main models used by the Regions are the House of Health and the Territorial Units for Primary Care (Unità Territoriali di Assistenza Primaria, UTAPs). The first model to be set up in the Tuscany Region was designed as a multipurpose facility capable of delivering an overall socio-health service in the same physical space, thereby enabling the unity and integration of essential levels of performance through the spatial proximity of services and operators. The second (UTAP), a territorial structure with high multidisciplinary and inter-profession integration, has been present for some time and in respectable numbers especially in the Veneto Region. The Nuclei of Primary Care (Nuclei di Cure Primarie, NCPs), base organisational models of primary care operating in geographical areas with homogeneous geomorphological characteristics, are represented mainly in Emilia Romagna.

Less represented however is the Community Hospital (Ospedale di Comunità, OC) that, understood as a district health facility able to treat a portion of the population that in the past depended on the traditional hospital stay in a residential and semi-residential manner, has been adopted mainly in the Veneto, Abruzzo and Liguria Regions.

A widespread diffusion of 24-Hour Models
Implementation of lines of priority in order to meet health objectives is occurring in almost all Regions, because considered as a useful means for an immediate boost to the reorganisation of medicine of the territory, especially in those local contexts where there was an improper use of the structures of emergency. Also varieties of territorial aggregation of functions of general practice such as the UCCP, designed to ensure both continuity of care and the enhancing of sharing of pathways between operators as well as between them and the users (initiative medicine), have been widespread, especially in the Centre-North Regions. In that macro-area resources have also been dedicated to the implementation of supply models of primary care such as the “Chronic Care Model”. Ample space has been given too to models that ensure the continuity of 24-hour care even for infants (Calabria Region).

Presentation and evaluation of the data. Although data on the state of implementation of the organisational models identified by individual Regions are still incomplete, in 2011 about 39 projects have been carried out in accordance with guidelines agreed with the State-Regions Agreement of April 20, 2011 and July 27, 2011 in the field of primary care, with a total investment of about Euro 346 million. In particular, an analysis of planning acts sent by individual Regions show the following as either activated and/or being implemented:

- 20 Houses of Health divided between Tuscany (16), Molise (1), Marche (1), Umbria (2);
- 220 NCPs, of which 215 realised in Emilia Romagna;
- 45 UTAPs of which 35 in the Veneto Region.

As part of the redevelopment and improvement of the regional and territorial service and hospital network, which the Regions subject to the Realignment Plans are engaged in, some organisational models aimed at reshaping the care on offer by small hospitals were also identified. These include the Centres for Primary Care (Centri di Assistenza Primaria, CAPs) in the Calabria Region, Territorial Centres for Assistance (Presidi Territoriali di Assistenza, PTAs) in Abruzzo and Sicily, as well as the District Clinical-care Centres (Centri Clinico-Assistenziali Distrettuali, CeCADs) in the Lazio Region.

In 2011 moreover, different Regions started or continued implementation of innovative models for proactive management of the major chronic diseases in the territory [e.g. diabetes, heart failure, chronic obstructive pulmonary disease (COPD), etc.] involving both the district with different primary care professionals and area hospitals and specialist centres, each with different roles and modes of intervention. These models present as reference elements, which enable healthcare organisations to diversify the implementation modalities of Diagnostic-Therapeutic Care Pathways (Percorsi diagnostico-terapeutici assistenziali, PDTAs).

In 2011, an initial legislative proposal to re-organise primary care was made, modifying art. 8, comma 1, of the D.Lgs. 502/1992, part of a working Committee between the Ministry of Health and the Regions, which involved the main related trade union organisations. In discussion were some of the fundamental aspects that aim to provide citizens with improved access and continuity of care throughout the day (24-hour assistance) without and integration of different professionals, the management of patients in a comprehensive manner and procedures for participation in clinical governance with the valuation too of assets and health outcomes. With respect to territorial services, there is a great diversity in the Regions, both with regard to residential and semi-residential structures, and to Integrated Home Care (Assistenza domiciliare integrata, ADI). The work carried out within the “Building Bricks of the SSN” programme and the Essential Levels of Health Care (Livelli essenziali di assistenza, LEA) Commission documents in 2006 and 2007 on the characterisation of residential and home performance led to the start of the national information flows in the years 2010-2011, approved with separate ministerial decrees of December 17, 2008.
This allows a better understanding of the level of realisation of home and residential care LEA and, above all, ensures a process of progressive articulation and structuring to respond adequately to the increasing complexity of health needs, not only in managing chronic diseases, but also for complex disabilities and cancer and terminal cases.

**Regulatory references.**
- **Accordo Collettivo Nazionale per la Medicina Generale 29 luglio 2009** [Collective National Agreement for General Medicine July 29, 2009]: this provides for a doctor, in order to carry out duties and functions, to carry out activity as an integral part of a functional territorial aggregation of MMGs (art. 26 bis) and operate within a specific UCCP, when activated (art. 26 ter), which may include collaboration with other health and social operators.
- **Accordo Collettivo Nazionale per la Medicina Generale 8 luglio 2010** [Collective National Agreement for General Medicine July 8, 2010]: provides guidance for the consolidation of organisational structures imposed by the previous Agreement with the definition of “unique referents” appointed to carry out the task of connecting with the Health Authority within the UCCP, as well as representing the same UCCP. Also provides for the assumption of the obligation to transmit and make available the “patient summary” data through the computer network set up by the Region by the doctor – a tool for synthetic summary information of the health profile of each person assisted.
- **Accordo Stato-Regioni del 26 febbraio 2009** [State-Regions Agreement February 26, 2009]: provides for the objectives of priority and of national importance in the year 2008 pertaining to the primary care line.
- **Accordo Stato-Regioni 25 marzo 2009** [State-Regions Agreement March 25, 2009]: provides for the objectives of priority and of national importance in the year 2009 relating to the project line “Primary Care – assistance 24 hours a day, reduction of improper access to the Accident & Emergency and improvement of the service network.”

**Essential bibliography**

### 3.2. Continuity of care

The social, economic and cultural changes of the past thirty years involve the need for health policy interventions that require the territory to be characterised as an active subject capable of intercepting healthcare needs and bearing the health, socio-medical and welfare requirements of citizens in a coordinated, single and continuous manner.

**Continuity of assistance.** One of the main objectives of the SSN is to ensure continuity of care between the diverse intra- and extra-hospital professionals (e.g. through teamwork, elaboration and implementation of shared diagnostic-therapeutic pathways, etc.) and between the different levels of care, especially in the relationship between hospital and territory, and of therapeutic treatment when necessary. The model of care focussed on continuity of care requires the design of specific routes and of a constant management by a team characterised by social and health skills over time, as well as monitoring of assessment and appropriateness by appropriate instruments in the stages of transition between the various care settings.

Patients most in need of continuity of care are:
- post-acute care patients discharged from hospital who run high levels of risk of being re-hospitalised when not adequately assisted. They require clinical and nursing skills in a dedicated facility or at home in the charge of a case manager;
chronically ill patients, established in the territory, with high needs of assistance and at risk of inappropriate admission when not adequately assisted. Their course of treatment requires a strong integration between multidisciplinary care teams (doctor, nurse and social worker), with place of care either the patient’s home or a protected structure;

chronically ill patients in good health overall whose objective is monitoring of their health status, who live at home and who have the characteristics necessary to be trained to self-cure and self-empowerment.

Networks of assistance. Continuity of care, understood as the succession without interruption of pathways, services and care processes of the preventive, curative and rehabilitative types, becomes feasible through the implementation of the care network, with definition of nodes and of functional interrelations. It is a complex system of integration/continuity that must be characterised by flexibility allowed by the mix of heterogeneous services in relation to the level of integration between health and social components of the professions involved, for ease of access, for the appropriateness of services provided and for the satisfaction of the patients. To this end, the establishment of centre-of-gravity territorial care networks assumes a strategic role in which the District takes on the coordination and promotion of the integration of all health and social care activities. The District is also responsible for the research, promotion and implementation of the appropriate synergies between all systems of territorial supply and provides a focal point for local entities in line with institutional policies.

Integrated hospital-territory networks of assistance. Regarding integrated care, the need becomes more and more urgent to make choices for the reorganisation of the health services so that the centre-of-gravity moves from the hospital to the territory. A health planning aware of this requirement has long been committed to the continued development and integration of primary care. It is about giving a greater impetus through all the means available to a reorganisation of territorial medicine that certainly comes through greater involvement of MMGs. To this end, one of the initiatives of health planning has been the proposed Guidelines for experimental projects related to “Organisational arrangements to ensure 24-hour health care: reduction of improper access in emergency facilities and improvement of the territorial service network”. That is, in order also to respond to the phenomenon observed in recent years, throughout the national territory, of the constant and progressive increase of access visits to the facilities of Accident & Emergency and of Emergancy Admissions Departments (Dipartimenti emergenza e accettazione, DEAs) for diseases of medium-low clinical criticality that can often find a proper and better response in the primary care system. This phenomenon, which was also observed for the services that the citizen accesses by telephone (118 number), leads to situations of discomfort both for operators and for the persons in conditions of real emergency. A national campaign was launched to support the correct information on service use. This saw collaboration between the Ministry of Health and the National Agency for Regional Health Services (Agenzia Nazionale per i Servizi Sanitari Regionali, AgeNaS), with the aim of promoting the culture of emergency-urgency at national level in order to raise awareness and inform the public on the proper use of the services for emergency-urgency situations, and illustrate the characteristics and conditions of access. National planning also deemed it necessary to provide useful information in this regard through the State-Regions Agreement of April 20, 2011, which confirmed that the project line “24-hour assistance: reduction of improper access to the PS and improvement of the service network”, provided for in the Agreements relating to the PSN objectives – lines of Primary Care – for the year 2009 and 2010 and the successive integrated Agreement of July 27, 2011. This agreement provided for the establishment by the Regions of projects designed to create and/or enhance the development of organisational arrangements that allow the integration
of Emergency-Urgent Services (118) and of Continual Assistance (CA – former Emergency Medical Service), in order to overcome the fragmentation of assistance and ensure appropriate responses to the needs of the citizen from the initial telephone access, to 24-hour, 7 day-a-week health services. In 2011, the Regions and Autonomous Provinces were committed to the planning and implementation of the rationalisation of the emergency-urgency network by integrating it with that of care in the territory. This was in accordance with instructions received and awareness that improper use of the emergency facilities decreases the more the citizen feels the presence of a network of primary care that anticipates/intercepts their health needs. This rationalisation manifested itself both through the strengthening of the system of primary care and through the identification of organisational models aimed at improving the quality of care in the Accident & Emergency. These models included clinics for the management of codes of emergency of lesser severity (white and green), the outpatient district Centres, managed by Continual Assistance doctors, and the Centres of Early Intervention (Presidi di Primo Intervento, PPIs) to be implemented in disadvantaged geographical areas to ensure a first response to an emergency-urgency and situations of less severity. In addition to these models, anticipated by the Agreements of 2009, 2010 and 2011 and set up in most of the Regions, others are included which were anticipated under the Agreement of July 27, 2011. Models included integration through the identification of areas devoted to Continual Assistance (Continuità Assistenziale, CA) within the provincial 118 telephone exchanges, providing for the establishment of a dedicated CA area within the 118 telephone exchanges with functional integration with the Operation Centre (Centrale Operativa, CO) 118 exchange, where there are existing CA counselling centres of autonomous coordination, particularly in some metropolitan areas with autonomous CA counselling centres, which have an obvious workload and are located in different sites away from the 118 telephone exchanges.

Finally, it appears that a number of Regions have directed efforts towards the implementation of IT systems that allow for the connection and exchange of information between the various players involved in 24-hour activity (Piedmont, Lombardy, Liguria, Abruzzo, Emilia Romagna, Lazio and Campania).

**Presentation and evaluation of the data.** Although data on the status of implementation of organisational models identified by individual Regions are still partial, in 2011, the Regions that set up projects in accordance with guidelines in the agreement of July 27, 2011 on the organisational arrangements which enable the integration of Emergency-Urgent Services (118) and CA were seven in total: Lazio, Calabria, Emilia Romagna, Piedmont, Basilicata, Campania and Sicily. This is about half the total number of Regions that set up primary care projects. The expenditure committed to the realisation of these models is included in that of overall primary care, which for 2011 was around Euro 346 million.

In order to verify the impact of regional projects on the reorganisation of territorial health care in implementing 2009 objectives, the Ministry, in collaboration with AgeNaS, initiated monitoring of projects submitted by the Regions that adhered to the primary care objective, “24-hour Assistance - Reduction of improper access to the PS and improvement in the care network”. The monitoring aims to:

- share with Regions a methodology for analysing and monitoring the progress of projects and of good practices;
- ensure a systematic comparison between experts and regional stakeholders and to identify proposals to guide further planning choices;
- enable an assessment of the results in terms of process of care, 24-hour assistance, and reduction of improper access to emergency services.

The final results of the monitoring will be available from December 2012.

**Regulatory references.**

year relating to the project line “Primary Care – 24-hour assistance reduction of improper access to Accident & Emergency and improvement in the care network”.

- Schema Piano Sanitario Nazionale 2011-2013 [Outline National Health Plan 2011-2013]: poses as one of the main objectives of the SSN, the guarantee of continuity of care both between different intra-and extra-hospital professionals, so that the fragmentation created by the development of ultra-specialist skills integrates itself into a unified framework (teamwork, preparation and implementation of diagnostic therapeutic shared pathways etc.), and between the different levels of assistance – particularly in the delicate boundary between hospital and territory.

- Accordo Nazionale per la Medicina Generale 8 luglio 2010 [National Agreement for General Medicine July 8, 2010]: provides guidance for the process of consolidation of the organisational structures established under the previous Agreement through the definition of “one-stop persons of reference” deputised to perform the task of connection with the Health Authority as part of the UCCP as well as to represent the same UCCP. It also provides for the assuming among the doctor’s obligations of the duty to transmit and make available, via the computer network set up by the Region, the “patient summary” data, synthetic summary information of the health profile of each person being managed.

- Accordo Collettivo Nazionale 2009 [Collective National Agreement 2009]

- Accordo Stato-Regioni 27 luglio 2011 [State-Regions Agreement July 27, 2011]: provides guidance for the preparation of projects by the Regions aimed at achieving and/or enhancing the development of organizational arrangements that allow the integration of the Emergency-Urgency Services (118) and of CA (former Emergency Medical Service) also in order to overcome the fragmentation of assistance and ensure adequate responses to the needs of the citizen from the beginning onwards of telephone access to 24 hour/7 days a week health services.

### 3.3. Assistance for dependent persons

**Policy framework.** The “Road Map for European Ageing Research” (www.futurage.group.shef.ac.uk) presented at the European Parliament identifies among the priorities for the future of the elderly: to live longer, but in health; maintain and enhance mental capabilities; ensure the quality and sustainability of the social protection system; promote the welfare of senior citizens at home and in community settings; overcome inequalities in aging.

It is now a common belief that to improve the effectiveness and quality of care, it is necessary to move towards systems that provide for the organisation of multidisciplinary and multi-professional teams organised around the patient care pathway and centred on the principles of a comprehensive and integrated care, and which emphasize in particular the monitoring of processes and results of activities centred on transparency and accountability.

The organisational process of taking into care elderly persons with complex health and social needs should be developed in four strategic steps to get the best response in terms of health for the person concerned: access to the system, the multidimensional assessment of care needs and the provision of an Individual Care Plan, the care coordination and, finally, monitoring.

National health planning has already incorporated these guidelines for some time in order to improve the quality of service provided and to prevent or delay disability and support choice to ensure, as far as possible, that the dependent person remains in their own life ambient.
These indications, however, were not accompanied by adequate financial support and have not yet received a strong commitment by the players involved, especially at the local level; the findings to date are fragmented and inconsistent, not only throughout the country but also within the Regions that had begun the process of reorganisation of services for dependent persons some time ago. Progress is being achieved in reaching, by 2013, the figure of 3.5% (Code S.06) of elderly treated in ADI compared to the total elderly population (65 years and over) provided for by the National Strategic Framework 2007-2013 among the “Service Objectives” for the Southern Regions.

The Regions recognise the inevitability of having both a planning function and a monitoring function that checks results in terms of production of health, but information systems for quality evaluation of home care and residential output are still poorly consolidated and databases not fully systemised in the territory.

On this issue, AgeNaS carried out a research project in the period 2010-2011 on “Evaluation of the effectiveness and fairness of territorial organizational models for access and management of people with complex health and social needs”, in which three Italian Regions participated (Lombardy, Veneto, Tuscany) as well as other Operational Units such as the Institute of Hygiene of the Università Cattolica del Sacro Cuore, the ARS Tuscany, and the Department of Physical Education and Health at the University of Cassino. The overall objective was to define and test a system of indicators to monitor the organisational process of management of persons with complex health and social needs aged 65 years or over, both in terms of response to their needs and in terms of appropriateness, through the integrated use of information flow related to the New Health Information System (Nuovo Sistema Informativo Sanitario, NSIS), from those more traditional and consolidated [Hospital Discharge Form (Scheda di dimissione ospedaliera, SDO), Accident & Emergency] to those more recently activated, in particular, the flow relating to home care (SIAD) and that of residential and semi-residential care (FAR).

Research has shown that the system of management of a person is fragmented and generally characterised by considerable variability among the geographical areas analysed, reflecting organisational peculiarities typical of the contexts examined. What emerged was a difficulty in accessing local health services, with late responses to individual health needs and problems in the organisational coordination of the process. The Aggregate Bed Day Rate has been calculated for the same age and gender; this is an indicator which allows a measurement to be taken of the frequency and duration of the necessity for hospitalisation in the course of a year while in either home- or residence-based care. Results show that 35.5% of persons in home-based care in the Lombardy area of the study, 25% in the Tuscany area and 50% in the Veneto area were admitted to hospital during the study period. The Aggregate Bed Day Rate for these persons was 13.5 days per person per year in the Lombardy area of the study; 3.8 days per person per year in the Tuscany area of the study; and 7.5 days per person per year in the Veneto area of the study. Both the percentage of persons admitted to hospital and the Aggregate Bed Day Rate were less when looking at persons in either part- or fully residence-based care.

With regard to the time elapsed between hospital discharge and delivery of the service, persons in home-based care in Tuscany passed 13.4 days, those in Lombardy 8 days, and 6.6 days for those in Veneto. Persons in residence-based care in Lombardy passed 5.1 days, 2.8 days in Tuscany and 3 days in Veneto.

Lastly, figures regarding inappropriate usage of A&E/Emergency services by elderly persons in home-based care show that on a yearly average, the elderly make 0.7 visits to these Emergency services with a white/green triage colour code in Tuscany and Lombardy, while the figure is 0.3 in Veneto (see the 10th Supplement for No. 30/2012 of the Monitor Journal entitled “Understand in order to decide. The management of non-self-sufficient elderly persons”; available on the AgeNaS website http://www.agenas.it).
Within the broad category of care for dependent persons, special attention must be given to the initiatives taken in 2011 by the Ministry and the Regions for persons in a Vegetative State (Stato Vegetativo, SV) or in a State of Minimal Consciousness (Stato di Minima Coscienza, SMC), mostly due to more severe brain injuries of varying natures, and for people with severe neuromuscular degenerative diseases such as amyotrophic lateral sclerosis (sclerosi laterale amiotrofica, SLA).

With regard to persons in an SV or SMC state, an analysis of Ministry of Health data deriving from SDO for the period 2007-2010 for patients discharged with the code 780.03 (“Persistent Vegetative State” - ICD-9-CM) shows that during that 3-year period 5,608 patients were discharged in the whole country (also including those with repeat hospital admissions); 1,397 (34.8%) of whom had a normal discharge from hospital to home. The Integrated Domestic Care programme was initiated for only 1.4% of these persons. This may be due to the particular nature of the care requirements for persons in an SV or SMC state, characterised as they are by a high level of complexity and by varying degrees of intensity of the support required based on the level of progress of the condition, the occurrence of complications and the family and socio-environmental conditions.

For this reason, in the context of the lines of national planning were defined in the Agreement set out at the Joint Conference on May 5, 2011 (GU no. 126 of June 1, 2011) in the document “Guidelines for assistance to persons in the Vegetative State and Minimally Conscious State”. This agreement provided guidance to the Regions on promoting the use of specific care pathways, providing appropriate arrangements for information and communication with families and support for family members, in particular the caregiver.

Among the initiatives undertaken in the year 2011 in relation to vegetative states were the results of a national research project on “Functioning and Disability in Vegetative States and in the State of Minimal Consciousness”, funded by the Ministry of Health through the CCM, coordinated by the IRCSS Foundation Carlo Besta Neurological Institute of Milan. The observational multicentre study involved 78 Italian centres and 39 family associations and federations with the aim of creating a network between different Italian realities caring for patients with disorders of consciousness, in order to evaluate the operation and disability of persons diagnosed with SV and SMC from a bio-psychosocial perspective. The research was targeted at patients, family members and professionals in the sector. An analysis of the numerous study data has shown, relative to the mode of territorial care, that a significant majority of patients (64.1%) usually live at home, a third in residential structures and only a small fraction (2%) in hospital or other facility. In particular, it was observed that almost one quarter of patients living at home have no home care service (especially in the South).

In relation to persons affected by SLA, the literature indicates a prevalence of 6-8 cases per 100,000 of population, based on which the number of affected subjects in Italy may be estimated at between 3,600 and 4,800; the estimate is confirmed by the figures reported by some patient Associations and also by reportings sent to the ISS (National Institute for Health) Rare Disease Registry, which doesn’t usually cover the entire population of patients: there were 3,292 reported in 2011.

The involvement of the institutions with this category of illness (as well as with every person affected by serious and progressive neuromuscular diseases) was also manifested in a series of initiatives; among these, the Agreement between the Government and the Regions on “Overall management of persons with neuromuscular disease or similar diseases from the point of view of assistance” has been authorised, which states the need to promote the use of care pathways characterised by different complexities and intensity in relation to the type of pathology, its stage of evolution and the family and socio-environmental context, and commits the SSN to ensure continuity of care, the integration of measures for the same patient and the
coordination between persons, structures and services, following the networking and overall management mode, knowing that the centrality and unity of the individual represent the fundamental elements for the organisation of care intervention. In the Agreement, lastly, the necessity of taking care of the patient by the district team, the multidimensional assessment and the establishment of an Individualised Care Plan (Piano Assistenziale Individualizzato, PAI) that outlines the interventions to be performed and the welfare goals is emphasised.

The Agreement reiterates and summarises the outcome document of the national Council for neurological diseases of neuromuscular involvement, which was attended by representatives of institutions, of patient Associations, specialists and health policy experts in the period 2009-2010, with the aim of providing useful information to promote the quality of care for severe and progressive neuromuscular diseases.

As regards, the strengthening of social assistance in favour of people with SLA – the responsibility of local authorities – the D.Lgs. 225/2010, converted in law 10/2011, provides for the allocation of funding of up to Euro 100 million to be used for research and home care for persons suffering from SLA, from the ‘5 per thousand’ resources 2011. This funding, which goes to the National Fund for the dependent persons, is divided between the Regions by the Ministry of Labour and Social Policy and assigned based on specific projects that may be monitored during their implementation.

In order to support the Regions in the development of local services and to ensure greater uniformity in organisational models for care-taking and the management of care processes (with the Agreement of April 20, 2011 between the Government, the Regions and Autonomous Provinces of Trent and Bolzano on the guidelines for the use of resources earmarked for the achievement of objectives of national importance and priority for the year 2011), directions were provided to the Regions for the presentation of projects relating to interventions for dependent persons. For this, Euro 240 million was allocated of which Euro 20 million was allocated to the project “Support for patients with degenerative and disabling neurological diseases” and Euro 20 million allocated to the project “Assistance for patients affected by dementia”.

**State of implementation in regional contexts.** About Regional PSN Projects financed in 2011, for the implementation of national guidelines, there were 62 Regional projects in total prepared in the year 2011 that identified strategies for the management of non-self-sufficient persons based on “overall care” that allowed a reducing of the burden of care-giving by the families, of hospital admissions and of health and social spending through the integration of health and social services, allowing also an improvement in the quality of life of dependent persons and their families. To this end, the Regions favoured the strengthening of Single Access Points (Punti Unici di Accesso, PUAs) in their planning, which allow the coordination and integration of health and social skills, the promotion of a multi-professional approach to the patient through the preparation of the PAI and the increase of the ADI with particular attention to the elderly population.

The interest of the Regions with respect to that issue was also manifested by the identification of interventions for patients with dementia, such as the creation of specific evaluation and management services [Alzheimer Evaluation Unit (Unità di Valutazione Alzheimer, UVA)] and specialised treatment services (day Centres for Alzheimer’s disease and dementia, Functional Alzheimer Nuclei). Finally, as part of planning for the ADI, some Regions introduced “relief” initiatives, aiming to support families with the provision of night shelters, weekend packages and relief admissions to hospital. Many Regions have also considered the significant presence of organised voluntary associations and families in the approach to care for dependent persons, appropriately training them so they can become part of the care network.

With regard to interventions to assist people
Implementation of lines of priority in order to meet health objectives

in SV and SMC, the general trend in which regional planning is directed concerns the rationalisation of its diagnostic and therapeutic approach, through the definition and adoption of shared and scientifically validated pathways of care for patients in SV and SMC, capable of ensuring the requirements of continuity, coordination, consistency and sharing of the processes of care, both in the Special Units of Permanent Reception (Speciali Unità di Accoglienza Permanente, SUAPs), and in home care.

In particular, most of the Regions prepared specific projects aimed at creating and/or extending care pathways for patients in SV and SMC, for a total spending commitment of Euro 32 million. The Region which committed most resources in percentage terms (10%) in 2011 was Basilicata, followed by the Molise and Piedmont Regions, who committed circa 7%.

Some regional areas intended to organise the care network, defining the phases of access, of transfer and discharge for the pathways, up to reintegration in the home; in others the care pathway for persons in SV and SMC was added to the network of care for patients with severe brain injury (GCA).

Lastly, only a few projects provided for the SUAP and home care for patients with conditions of SV and SMC in the chronic phase.

Essential bibliography

Accordi tra il Governo, le Regioni e le Province Autonome del 25 marzo 2009 e dell’8 luglio 2010 che individuano tra le linee progettuali per l’utilizzo da parte delle Regioni e delle Province Autonome delle risorse vincolate, ai sensi dell’art. 1 cc. 34 e 34 bis della legge 23 dicembre 1996, n. 662, per la realizzazione degli obiettivi di carattere prioritario e di rilievo nazionale rispettivamente per gli anni 2009 e 2010

Accordo della Conferenza Unificata tra lo Stato, le Regioni, le Province Autonome di Trento e di Bolzano e gli Enti Locali sul documento “Linee di indirizzo per l’assistenza alle persone in Stato Vegetativo e Stato di Minima Coscienza” del 5 maggio 2011. GU n. 126 dell’1 giugno 2011

Accordo sancito dalla Conferenza Stato-Regioni il 25 maggio 2011 sulla “Presa in carico globale delle persone con malattie neuromuscolari o malattie analoghe dal punto di vista assistenziale”

Accordo tra il Governo, le Regioni e le Province Autonome di Trento e Bolzano del 20 aprile 2011 sulla proposta del Ministero della salute di Linee guida per l’utilizzo da parte delle Regioni e Province Autonome delle risorse vincolate, ai sensi dell’art. 1, commi 34 e 34bis, della legge 23 dicembre 1996, n. 662, per la realizzazione degli obiettivi di carattere prioritario e di rilievo nazionale per l’anno 2011 (rep. Atti n. 83/CSR del 20 aprile 2011)

Libro Bianco sugli Stati Vegetativi e di Minima Coscienza, presentato alla stampa il 7 giugno 2010, elaborato dal “Seminario permanente di confronto sugli Stati Vegetativi e di Minima Coscienza” istituito dal Ministero del lavoro, della salute e delle politiche sociali nel maggio 2008


Risultati del Progetto Nazionale CCM “Funzionamento e disabilità negli Stati Vegetativi e negli Stati di Minima Coscienza” (Executive Summary - febbraio 2012)
4.1. Reorganisation of hospital networks

During the last few years, the hospital network has been undergoing profound reorganisation, oriented towards clinical and organisational appropriateness, the recovery of management efficiency, a multidisciplinary approach, horizontal integration between Operational Units and vertical integration within the specialty networks, to assist continuity of care between hospital and community and the guarantee of safety of care.

The Pact for Health 2010-2012 set the standard for allocation of hospital beds equal to 4 per 1,000 inhabitants, including 0.7 beds for rehabilitation and long-term care, with the commitment by the Regions and Autonomous Provinces to adopt measures to reduce the standard of accredited hospital beds which are actually paid for by the National Health Service (Servizio sanitario nazionale, SSN). The aim was to promote the transition from hospitalisation to day care and from day care to outpatient care and to support home and residential care. Regions subject to Realignment Plans were to provide for this requirement by December 31, 2010 and the other Regions by June 30, 2011.

Therefore, at national level in 2011, compared with data from the Report on the Health Status of the Country 2009-2010, there was a decrease in the allocation of beds, from 211,936 units (3.5 beds per 1,000 residents) to 202,736 (3.3 beds per 1,000 residents), while for post-acute care beds there was a slight increase (37,252 beds in 2011 compared to 37,153 in 2009). The national average indicator of non-acute beds, amounting to 0.6 per 1,000 residents, was unchanged (Tables 4.1 and 4.2).

The reduction in numbers of acute care beds has been widespread and particularly pronounced in Regions subject to the Realignment Plan – those who in 2009 had a high allocation of beds for acute care compared to the expected standard and who therefore contributed to nearly 80% of the total national reduction recorded in 2011.

The adjustment to the standard of bed provision established by the Pact on Health is taking place with different trends between the different Regions, due to various factors including the different timescales established in the 2010-2012 Pact on Health.

The SSN used 1,121 health institutions for inpatient care in 2011, including 596 public and equivalent structures corresponding to 53% of the total and 525 accredited private nursing homes representing 47% of the total of institutions used.

The public and equivalent structures went from 638 (2009) to 596 (2011) as a result of mergers, conversions or closures.

The remodelling of the offer was primarily focussed on hospitals with facilities of up to 120 beds (−31 institutions in 2011 with respect to 2009, with a percentage reduction of 15% circa).

The number of medium-sized hospitals (between 121 and 400 beds) reduced by 5% circa (−12 institutions in 2011 with respect to 2009).

The reduction in the number of hospitals with facilities of up to 400 beds was mainly in the Regions subject to the Realignment Plan, which make up 53% of the overall reduction, but significant structural reorganisations also emerged in other Regions, such as in Marche.
Implementation of lines of priority in order to meet health objectives

At the national level the average of facilities available in each institution increased, which in 2011 was equal to 324 beds (in 2009 equal to 315) [Table 4.3]. The accredited nursing homes that provide hospital care decreased by 10 units, from 535 in 2009 to 525 in 2011 (a decrease of just under 2%).

An analysis of hospital beds by hospital speciality shows a marked variability in regional allocations. This may suggest that in the presence of needs that are based on specialities related to each other, regional planning chooses to assign beds based on factors that affect different realities with a different measure, such as:

- “historical” characteristics of the supply network;
- interregional mobility;
- age distribution of the population;
- clinical decisions;
- presence of universities;
- development of the territorial network.

In addition, the following may be noted:

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<td>12,854</td>
<td>4,816</td>
<td>17,670</td>
<td>444</td>
<td>1,259</td>
<td>1,703</td>
</tr>
<tr>
<td>Apulia</td>
<td>11,340</td>
<td>1,815</td>
<td>13,155</td>
<td>1,029</td>
<td>716</td>
<td>1,745</td>
</tr>
<tr>
<td>Basilicata</td>
<td>1,745</td>
<td>56</td>
<td>1,801</td>
<td>266</td>
<td>104</td>
<td>370</td>
</tr>
<tr>
<td>Calabria</td>
<td>5,023</td>
<td>1,572</td>
<td>6,595</td>
<td>171</td>
<td>770</td>
<td>941</td>
</tr>
<tr>
<td>Sicily</td>
<td>11,850</td>
<td>3,610</td>
<td>15,460</td>
<td>852</td>
<td>821</td>
<td>1,673</td>
</tr>
<tr>
<td>Sardinia</td>
<td>5,210</td>
<td>1,065</td>
<td>6,275</td>
<td>96</td>
<td>270</td>
<td>366</td>
</tr>
<tr>
<td><strong>Italy</strong></td>
<td><strong>173,795</strong></td>
<td><strong>28,941</strong></td>
<td><strong>202,736</strong></td>
<td><strong>19,377</strong></td>
<td><strong>17,875</strong></td>
<td><strong>37,252</strong></td>
</tr>
</tbody>
</table>


classification of some specialities is not always consistent from Region to Region, for example in hospital facilities organized by areas of intensive care;
assignment of responsibility for territorial residential activities (e.g., hospices, psychiatry services) to the hospital network;
It seems appropriate, therefore, to investigate the causes that lie behind the most significant interregional differences.
The reduction in number of hospital beds available for acute patients has led to a reduction in the rate of hospitalisation also, with reference to normal inpatient admissions who have been discharged from public and private accredited facilities.
The comparison of standardised hospitalisation rates by age and sex for 2009 and 2011 show an overall reduction in hospitalisation, which at the national level shifts from 120 to 108 discharges per 1,000 inhabitants. At regional level, even more pronounced decreases in hospitalisation are found in some Regions, such as Calabria, Friuli Venezia Giulia.

### Table 4.2. Available beds in hospital wards at beginning of year – Public or equivalent recovery facilities and accredited private nursing homes – Distribution by acute/non-acute patients – Indicators for 1,000 inhabitants (Year 2011, provisional data)

| Region               | Acute beds | | | | | | Non-acute beds | | | |
|----------------------|------------|---|---|---|---|---|---|---|---|---|---|
|                      | Public     | Accredited | Total | Public | Accredited | Total | Public | Accredited | Total | Public | Accredited | Total |
| Piedmont             | 2.9        | 0.3         | 3.2   | 0.5     | 0.5         | 1.0   |       |       |       |       |       |       |
| Aosta Valley         | 3.5        | 0.0         | 3.5   | 0.1     | 0.6         | 0.7   |       |       |       |       |       |       |
| Lombardy             | 2.9        | 0.5         | 3.4   | 0.5     | 0.4         | 0.9   |       |       |       |       |       |       |
| Aut. Prov. of Bolzano| 3.4        | 0.1         | 3.5   | 0.2     | 0.4         | 0.6   |       |       |       |       |       |       |
| Aut. Prov. of Trent  | 3.1        | 0.2         | 3.3   | 0.4     | 0.8         | 1.2   |       |       |       |       |       |       |
| Veneto               | 3.2        | 0.2         | 3.3   | 0.5     | 0.1         | 0.6   |       |       |       |       |       |       |
| Friuli Venezia Giulia| 3.6        | 0.4         | 4.0   | 0.3     | 0.1         | 0.3   |       |       |       |       |       |       |
| Liguria              | 3.7        | 0.0         | 3.7   | 0.4     | 0.1         | 0.5   |       |       |       |       |       |       |
| Emilia Romagna       | 3.1        | 0.6         | 3.8   | 0.5     | 0.4         | 0.9   |       |       |       |       |       |       |
| Tuscany              | 3.0        | 0.4         | 3.4   | 0.1     | 0.2         | 0.3   |       |       |       |       |       |       |
| Umbria               | 2.9        | 0.3         | 3.1   | 0.3     | 0.0         | 0.4   |       |       |       |       |       |       |
| Marche               | 3.2        | 0.3         | 3.5   | 0.3     | 0.3         | 0.5   |       |       |       |       |       |       |
| Lazio                | 2.9        | 0.4         | 3.4   | 0.3     | 0.6         | 0.9   |       |       |       |       |       |       |
| Abruzzo              | 2.8        | 0.4         | 3.3   | 0.2     | 0.3         | 0.6   |       |       |       |       |       |       |
| Molise               | 3.4        | 0.3         | 3.8   | 0.7     | 0.3         | 0.9   |       |       |       |       |       |       |
| Campania             | 2.2        | 0.8         | 3.0   | 0.1     | 0.2         | 0.3   |       |       |       |       |       |       |
| Apulia               | 2.8        | 0.4         | 3.2   | 0.3     | 0.2         | 0.4   |       |       |       |       |       |       |
| Basilicata           | 3.0        | 0.1         | 3.1   | 0.5     | 0.2         | 0.6   |       |       |       |       |       |       |
| Calabria             | 2.5        | 0.8         | 3.3   | 0.1     | 0.4         | 0.5   |       |       |       |       |       |       |
| Sicily               | 2.3        | 0.7         | 3.0   | 0.2     | 0.2         | 0.3   |       |       |       |       |       |       |
| Sardinia             | 3.1        | 0.6         | 3.7   | 0.1     | 0.2         | 0.2   |       |       |       |       |       |       |
| **Italy**            | **2.9**    | **0.5**     | **3.3** | **0.3** | **0.3**     | **0.6** |       |       |       |       |       |       |

Implementation of lines of priority in order to meet health objectives

Giulia, Apulia and Campania. In particular, the lowest hospitalisation rate in 2011 occurred in Friuli Venezia Giulia (74 per 1,000) followed by Veneto and Calabria, with values lower than 100 (respectively 92 and 94 per 1,000) [Figure 4.1].

Indicators such as raw average length of stay are proposed here in order to assess organisational efficiency, as well as average hospital stay standardised for case-mix to overcome the confusing effect of the varying complexity of case histories. The average preoperative hospital stay is also shown. All the proposed indicators are related to acute hospitalisation in normal care. The average hospital stay shows a slight increase but does not change significantly from 2009 to 2011. The average preoperative hospital stay varies from a minimum of 1.32 days for the Marche Region to 2.43 of Lazio Region (Table 4.4).

The following indicators jointly assess the complexity and efficiency of the services provided in acute inpatients under normal care: the Case-Mix Index (Indice di Case-Mix, ICM), which expresses the degree of complexity of the case history treated compared to a standard reference case history (the complexity of the case history is assessed based on the weight given to each diagnosis-related group, or DRG) and the Comparative Performance Index (Indice Comparati-

### Table 4.3. Regional distribution of public or equivalent recovery facilities and available beds by type and average size of the facility (Year 2011, provisional data)

<table>
<thead>
<tr>
<th>Region</th>
<th>Number of public institutions by type of bed available</th>
<th>Total of public institutions</th>
<th>Average size (beds available)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>≤ 120</td>
<td>121-400</td>
<td>&gt; 400</td>
</tr>
<tr>
<td>Piedmont</td>
<td>7</td>
<td>15</td>
<td>17</td>
</tr>
<tr>
<td>Aosta Valley</td>
<td>7</td>
<td>20</td>
<td>34</td>
</tr>
<tr>
<td>Lombardy</td>
<td>3</td>
<td>3</td>
<td>1</td>
</tr>
<tr>
<td>Aut. Prov. of Bolzano</td>
<td>3</td>
<td>3</td>
<td>2</td>
</tr>
<tr>
<td>Aut. Prov. of Trent</td>
<td>7</td>
<td>12</td>
<td>19</td>
</tr>
<tr>
<td>Veneto</td>
<td>4</td>
<td>9</td>
<td>3</td>
</tr>
<tr>
<td>Friuli Venezia Giulia</td>
<td>2</td>
<td>1</td>
<td>9</td>
</tr>
<tr>
<td>Liguria</td>
<td>2</td>
<td>10</td>
<td>15</td>
</tr>
<tr>
<td>Emilia Romagna</td>
<td>14</td>
<td>16</td>
<td>11</td>
</tr>
<tr>
<td>Tuscany</td>
<td>2</td>
<td>7</td>
<td>2</td>
</tr>
<tr>
<td>Umbria</td>
<td>2</td>
<td>11</td>
<td>3</td>
</tr>
<tr>
<td>Marche</td>
<td>25</td>
<td>34</td>
<td>11</td>
</tr>
<tr>
<td>Lazio</td>
<td>6</td>
<td>9</td>
<td>3</td>
</tr>
<tr>
<td>Abruzzo</td>
<td>4</td>
<td>1</td>
<td>5</td>
</tr>
<tr>
<td>Molise</td>
<td>16</td>
<td>23</td>
<td>10</td>
</tr>
<tr>
<td>Campania</td>
<td>2</td>
<td>27</td>
<td>8</td>
</tr>
<tr>
<td>Apulia</td>
<td>3</td>
<td>5</td>
<td>1</td>
</tr>
<tr>
<td>Basilicata</td>
<td>22</td>
<td>8</td>
<td>4</td>
</tr>
<tr>
<td>Calabria</td>
<td>39</td>
<td>19</td>
<td>8</td>
</tr>
<tr>
<td>Sicily</td>
<td>15</td>
<td>12</td>
<td>4</td>
</tr>
<tr>
<td>Sardinia</td>
<td>181</td>
<td>248</td>
<td>167</td>
</tr>
</tbody>
</table>

Note: All types of beds were considered (day hospital, day surgery, normal inpatient and paying normal inpatient), shown in the HSP.12 register, for hospital wards active at the beginning of the year.
Figure 4.1. Standardised rate of hospitalisation (acute admissions under normal care) – Standardisation by age and sex, with reference to the resident population at the 2001 Census.

<table>
<thead>
<tr>
<th>Region</th>
<th>Average stay (days)</th>
<th>Average stay standardised by case-mix (days)</th>
<th>Average pre-operative stay (days)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Piedmont</td>
<td>7.09</td>
<td>6.97</td>
<td>7.16</td>
</tr>
<tr>
<td>Aosta Valley</td>
<td>8.23</td>
<td>8.35</td>
<td>7.73</td>
</tr>
<tr>
<td>Lombardy</td>
<td>6.63</td>
<td>6.84</td>
<td>6.93</td>
</tr>
<tr>
<td>Aut. Prov. of Bolzano</td>
<td>6.84</td>
<td>6.79</td>
<td>6.96</td>
</tr>
<tr>
<td>Aut. Prov. of Trent</td>
<td>7.95</td>
<td>7.67</td>
<td>7.63</td>
</tr>
<tr>
<td>Veneto</td>
<td>8.07</td>
<td>8.21</td>
<td>7.66</td>
</tr>
<tr>
<td>Friuli Venezia Giulia</td>
<td>7.47</td>
<td>7.48</td>
<td>7.21</td>
</tr>
<tr>
<td>Liguria</td>
<td>8.05</td>
<td>8.16</td>
<td>7.15</td>
</tr>
<tr>
<td>Emilia Romagna</td>
<td>6.38</td>
<td>6.35</td>
<td>6.25</td>
</tr>
<tr>
<td>Tuscany</td>
<td>6.66</td>
<td>6.48</td>
<td>6.26</td>
</tr>
<tr>
<td>Umbria</td>
<td>6.03</td>
<td>6.01</td>
<td>6.19</td>
</tr>
<tr>
<td>Marche</td>
<td>6.89</td>
<td>7.01</td>
<td>6.82</td>
</tr>
<tr>
<td>Lazio</td>
<td>7.00</td>
<td>7.13</td>
<td>7.15</td>
</tr>
<tr>
<td>Abruzzo</td>
<td>6.75</td>
<td>7.10</td>
<td>6.82</td>
</tr>
<tr>
<td>Molise</td>
<td>6.89</td>
<td>6.97</td>
<td>7.15</td>
</tr>
<tr>
<td>Campania</td>
<td>5.49</td>
<td>5.90</td>
<td>6.22</td>
</tr>
<tr>
<td>Apulia</td>
<td>6.29</td>
<td>6.32</td>
<td>6.65</td>
</tr>
<tr>
<td>Basilicata</td>
<td>6.92</td>
<td>6.85</td>
<td>6.76</td>
</tr>
<tr>
<td>Calabria</td>
<td>6.67</td>
<td>6.64</td>
<td>6.99</td>
</tr>
<tr>
<td>Sicily</td>
<td>6.19</td>
<td>6.57</td>
<td>6.34</td>
</tr>
<tr>
<td>Sardinia</td>
<td>6.94</td>
<td>6.83</td>
<td>7.25</td>
</tr>
<tr>
<td><strong>Italy</strong></td>
<td><strong>6.69</strong></td>
<td><strong>6.81</strong></td>
<td><strong>6.69</strong></td>
</tr>
</tbody>
</table>
Implementation of lines of priority in order to meet health objectives

Figure 4.2. Index of Case-Mixes (ICM) and Comparative Performance Index (ICP) [acute admissions under normal care – Year 2011].

vo di Performance, ICP), which expresses the degree of efficiency in comparison with a reference standard. The combined reading of the two indicators in a graphical representation divided into quadrants (Figure 4.2) provides an immediate and brief overview of the degree of complexity of case history and efficiency detected for each Region. In particular the graphic identifies four areas with different combinations of complexity and efficiency: the right lower quadrant (ICM > 1, ICP < 1) is characterised by high complexity with hospitalisation lower than the reference standard; the right upper quadrant (ICM > 1, ICP > 1) is also characterised by a complexity and hospitalisation higher than the standard of reference, while the upper (ICM < 1, ICP > 1) by a hospitalisation higher than the standard which is not justified by the degree of complexity of the case history being treated.

Essential bibliography
Ministero della salute. Annuario statistico del Servizio sanitario nazionale
Ministero della salute. Rapporto annuale sull’attività di ricovero ospedaliero

4.2. Emergency/urgency network

Planning framework. The emergency medical system has assumed a key role in the SSN in recent years and has reached an organisational and operational maturity that, in meeting the needs of the population, ensures not only timely and professional assistance
intervention in the territory, but also targeted access to the hospital network thereby securing and guaranteeing the continuity of aid.

The system has grown at a national level, although unevenly, and has become the link between citizens, local services and the hospital network, thus responding to the health policy targets which provide that an increasingly specialist hospital network should correspond to a strengthening of activities in the territory.

At present, 20 years after the beginning of the system, the consolidated experience and the available data, in the light too of technological advances and changes in the population’s needs, allow it to be affirmed that updating of legislation can no longer be postponed.

National planning, awaiting a more complex activity of revision of the Guidelines on emergency/urgency care, primarily focussed on some critical issues, such as: early defibrillation activity in the territory (a provision for this was included in the Decree of 18 March 2011), Short Intensive Observation (Osservazione Breve Intensiva, OBI), monitoring of data from the new information flow (EMUR) and from the Regions subject to the Realignment Plan relative to some specific aspect.

Once the above initiatives have been launched, focus will need to be directed to the completion of the network of acute pathologies which have highly complex care patterns and which are time-dependent, such as acute coronary syndrome, stroke and trauma. The levels of structures will be defined according the Hub & Spoke model, in harmony with the network of Emergency Admission Departments (Dipartimenti emergenza e accettazione, DEAs), using the most advanced technology of image and data transmission.

**State of implementation in the regional contexts.**

- The decree of March 18, 2011, in relation to the management of cardiac arrest in extra-hospital environments in order to allocate resources amounting to Euro 8 million over the 3-year period provided directions to the Regions for the implementation of regional programmes aimed at the distribution and use of semi-automated external defibrillators (defibrillatori semiautomatici esterni, DAEs). It also indicated criteria for the identification of places, events, facilities and means of transport where the availability of semi-automated external defibrillators needs to be ensured, as well as the arrangements for the training of assigned operators.

- During 2011, a survey on OBIs was initiated at the national level, preparatory to the development of specific guidelines for them, aimed at demonstrating the OBI model as an instrument of control the appropriateness of admissions.

- Considering that the emergency-urgency system is one of the most critical areas of the SSN, it is not surprising that most of the Regions subject to Realignment Plans have provided, and in many cases already begun, actions to improve their performance in this area. It should be noted, in fact, that all nine Regions are implementing what has been planned for the reorganisation of the emergency-urgency systems.

- Based on the Ministry of Health decree of December 17, 2008, which established the information system for the monitoring of the emergency-urgency services being provided (EMUR System), the first data received from the Regions have been processed. It should be noted that from January 1, 2012, the provision of data to the New Health Information System (Nuovo Sistema Informativo Sanitario, NSIS) is included among the obligations that Regions must meet in order to have access to additional financing from the State, in the terms of the Understanding sanctioned by the State-Regions Conference of March 23, 2005.

**Presentation and evaluation of the data.**

- DAE Data: in implementation of this decree, all Regions sent data on the regional-only programmes, revealing that more than half of them, such as the Aosta Valley, Liguria, Emilia Romagna, Veneto, Marche, Molise and Lazio, were regulat-
Implementation of lines of priority in order to meet health objectives

...ing these activities with appropriate provisions, particularly for training activities, and therefore the programme had been prepared in line with what had already been started. In many Regions, in addition, DP projects had been launched, as in Liguria, Lombardy, Emilia Romagna, Basilicata and Sicily, where as well as a large number of DAEs located in various group and association facilities (other than those supplied to ambulances) numerous PAD (Public Access Defibrillation) projects are also present.

In respect of purchase of equipment, it is to be noted that almost all the Regions anticipated the number of DAEs to be acquired, except for the Regions of Friuli Venezia Giulia, Apulia and Sardinia. The number of DAEs to be acquired varies from 4 anticipated in Aosta Valley to 400 in Campania, for an expected total of ≈ 2,650 defibrillators. The regional-only programmes were approved by the LEA Committee and the resources provided by the DM for the first year of operations (Euro 4,000,000) were paid at the end of 2011.

**OBI Data:** From the survey conducted in 2011 on the state of regional provisions for the establishment of the OBIs, an overall picture was reported making clear that all the Regions/Autonomous Provinces expressed the need to equip Accident & Emergency Units with OBI areas, although the degree of activation was rather uneven (Figure 4.3).

**Realignment Plans:** the interventions implemented in some Regions (Piedmont, Liguria, Lazio) have a progressive nature, in others (Abruzzo, Campania, Calabria) the Hub & Spoke model is being introduced. In the review, some Regions took steps to eliminate centres that no longer met the DEA level I requirements from the emergency network, de-classifying them to Accident & Emergency-only structures. Considerable attention was given by all Regions to the activation and/or strengthening of Early Intervention Points (Punti

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**Figure 4.3. State of progress in the activation of the OBIs (Short Intensive Observations).**

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</tr>
</tbody>
</table>

* Source: Desk analysis of information in the public domain, both from official sources (regional/provincial regulations, circulars, acts of incorporation, service dispositions, websites of the entities themselves) and from third-party sources (specialised and general press). The analysis is therefore representative in that it has not involved the Regions/Autonomous Provinces.

^ Source: Regional/provincial regulations.
Hospital networks

**Facility data.** With regards to emergency services and facilities, the available SIS data for the year 2010 showed 550 Accident & Emergency services present in the national territory, including 513 in public recovery facilities and 37 in accredited private clinics; 100 paediatric Accident & Emergency services, of which 98 in public recovery facilities and 2 at accredited private clinics; the total number of DEA activated was 350, of which 330 was in public recovery facilities and 20 in accredited private clinics. There were, in addition, 380 resuscitation centres in public facilities and 50 in accredited private clinics.

**Activity data.** An information system called EMUR was established by decree of the Minister of Health of December 17, 2008 for the detection and monitoring of services provided in the emergency-urgency context on the part of both the 118 System and hospitals with regard to Accident & Emergency activities (A&E). Detection through the EMUR System, as provided for in the decree, was launched experimentally in 2009. The provision of data to the NSIS (New Health Information System) as of January 1, 2012 is included among the obligations to which Regions are subject in order to access additional financing from the State, in the terms of the Understanding sanctioned by the State-Regions Conference March 23, 2005. According to the figures for the month of March 2012, a total of 15 out of 21 of the Regions/Autonomous Provinces sent A&E/Emergency data for the year 2011; of these, 13 Regions submitted complete data for public care and treatment facilities equipped with PS/DEA, while two Regions sent partial data. At the national level, the structures that sent data to the EMUR System accounted for approximately 61% of facilities equipped with PS/DEA. Analysis of EMUR System data shows that the triage entry procedure was used in 97% of the accesses; in detail, white codes represent approximately 14.7% of cases, green codes 65.6%, yellow codes 15.7% and red codes 1.2%. Approximately 66% of the incoming yellow codes were confirmed as such, while about 33% were nominated by the doctor as a green code instead.

**Essential bibliography**


4.3. Oncology hospital network

**Planning framework.** On the 10 February 2011 an agreement was enshrined between the Government, the Regions and the Autonomous Provinces of Trent and Bolzano on the “Technical Guidance Document for the reduction of the disease burden of cancer - Years 2011-2013”.

In order to allow the Regions and Autonomous Provinces – as part of their autonomous planning activity – to best use the planning indications of the “Technical Guidance Document for the reduction of the disease burden of cancer” for the years 2011-2013, the Ministry, the Regions and Autonomous Provinces committed to provide, through their representatives, joint working groups in order to define:

- a guideline document for the implemen-
tation of Oncology networks (with both scientific-technical and organisational content based on analysis of evidence and good practice);

- a document addressing the use of system resources by identifying areas of “recovery” through the re-engineering of “obsolete” or inefficient practices and of less efficient organisational models;

- a Health Technology Assessment (HTA) document, based on synthesis of the available evidence on cost-effectiveness of the main technologies.

In the context of cancer patient care, not only the clinical and psychological aspects of the disease must be considered, but also there is a need for a substantial expansion of oncology rehabilitation and management of the care pathway, at the different stages of disease development – specifically during the acute and immediate post-acute phase, assistance with making it chronic, outcomes of the disease, supervised healing and the terminal phase. In this way, a better quality of life at all stages of treatment and care can be ensured for the sick person and their family, enhancing home and territorial interventions, on a par with those of the hospital. The maintenance of the best possible quality of life is in fact both a medical and social priority. The management of the care pathway also denotes the importance of networking together the various schemes of assistance, to promote the integration and coordination of resources as well as clinical and experimental research, which is an essential component of innovation and of the quality of the therapeutic moment. In other words, it means achieving synergy between the components involved in the management of care processes, complicated both because of the nature of the problems treated and for their intensity and duration. Networking realises a system by which the cancer patient can receive the most appropriate care organized on the multidisciplinary level, whatever their entry point to the socio-care health sphere. The recognition of disparities in the supply of cancer care in different Regions of the country should also be reported, and the problem of economic sustainability associated with the increased incidence of cancer, with lower mortality and the consequent increase in prevalence, which is estimated to be at about 2 million in 2010. The increased costs caused by management of “cancer survivors” are further increased by the introduction of personalised care and the necessary preparatory molecular diagnosis of the cancers to be treated.

State of implementation in regional contexts. The coordination of all actions that concern cancer patient care inside and outside the hospital is an essential if high quality standards of cancer care are to be achieved and is a key requirement to allow equal access to health care throughout the national territory. The technical guideline Document for reducing the burden of cancer disease (Years 2011-2013) anticipates the activation of Regional Oncology Networks (Reti Oncologiche Regionali, RORs) of which some working examples are already activated in Piedmont [Piedmont and Aosta Valley Oncology Networks (Rete Oncologica Piemonte e Valle d’Aosta, ROPVA)], in Lombardy [Lombardy Oncology Network (Rete Oncologica Lombarda, ROL)] and in Tuscany (Istituto Tumori Toscana, ITT), with others due to be activated in other Regions. The concept of a regional network will be revised from a demographic/epidemiological viewpoint, not just geographical. Furthermore, it is expected that each Network can refer to a Scientific Institute for Research, Hospitalisation and Health Care (Istituto di Ricovero e Cura a Carattere Scientifico, IRCCS) which deals exclusively with cancer, or a care facility of excellence. In the case of specific requirements, to be identified at a later stage, the network itself may obtain IRCCS recognition or that of a facility of excellence. The scenario set up by the State-Regions Agreement of February 23, 2011 is based on regional autonomy and the coordinating role of the Ministry of Health, according to a governance model defined as a Network of networks, which ensures the dissemination of good practice, the interfacing of the various solutions that regional networks will implement for the computerisation of medical records and the creation of biobanks.
The establishment of biobanks and their organisation in the network are part of those projects financed by the Ministry of Health-CCM, whose coordination is entrusted to the National Institute of Health (ISS) which also has the task of connecting the national initiatives with similar European initiatives (a European network of networks).

The coordination of care activities must be ensured at the regional level and organised in networks through the definition of “service profiles”. The regional network has the following objectives:

- coordinate the professionals and institutions involved in oncology prevention, diagnosis, therapy and rehabilitation;
- assure the management of the client throughout the entire care pathway;
- activate and share all essential tools with the professionals involved in cancer care: information systems, computerised folders, guidelines, records of pathology, etc.;
- facilitate the exchange of information between all parties concerned with oncological pathology to provide greater assurance to the cancer patient of receiving appropriate treatment;
- enhance the resources made available by volunteers who operate in the territory.

The task of the regional network is to define the planned care pathways for major diseases and clinical situations, encouraging the inclusion of patients in clinical research programmes. All those involved in cancer care will have to work within multidisciplinary and multi-professional teams. It is desirable that the regional coordination of the oncology network is formalised and has functions of technical-scientific direction, of clinical governance and of the monitoring of health service activities. In addition, regional coordination should complement the existing facility and performance indicators through the elaboration of a shared oncology plan and the development of outcome indicators. The development of regional cancer networks is a prerequisite for an improvement in the diagnostic-therapeutic pathways (Table 4.5).

**Essential bibliography**

Ministero della salute. Documento Tecnico di Indirizzo per ridurre il carico di Malattia del Cancro – Anni 2011-2013

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**Table 4.5. Innovation in oncology – The Oncology Network**

<table>
<thead>
<tr>
<th>Planned Actions for the 3-year Period 2011-2013</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Define planned care pathways for the principal pathologies and clinical situations</td>
</tr>
<tr>
<td>2. Assure management of the person being assisted for the entire care pathway</td>
</tr>
<tr>
<td>3. Assure the multidisciplined approach to care by the setting up of specific groups for each pathology</td>
</tr>
<tr>
<td>4. Enable the inclusion of patients in programmes of clinical research</td>
</tr>
<tr>
<td>5. Promote the creation of infrastructures aimed at clinical research (e.g. bio banks)</td>
</tr>
<tr>
<td>6. Guarantee equity in access to oncological treatments to all citizens</td>
</tr>
<tr>
<td>7. Define shared clinical pathways for specific oncological pathologies (clinical pathways or PDTA)</td>
</tr>
<tr>
<td>8. Develop organisational models designed to optimise the coordination and integration of care pathways for cancer, rehabilitative and palliative care, based on the needs expressed by patients</td>
</tr>
<tr>
<td>9. Experiment with innovative management systems with reward based on care pathways, rather than on individual performance</td>
</tr>
<tr>
<td>10. Define a common platform of patient information available to the institutions/professionals involved in care : information systems, computerised patient folders, guidelines, disease registers, etc.</td>
</tr>
<tr>
<td>11. Emphasize the resources of voluntary help operating in the hospital and the territory</td>
</tr>
<tr>
<td>12. Create a system of regional cancer Networks, a network of networks, whose governance is delegated to the Ministry of Health</td>
</tr>
</tbody>
</table>

4.4. Catering as a means of preventing malnutrition in hospitals

Nutritional status contributes to the quality of life of every individual and diet is an important risk factor for numerous diseases. Hospital catering is an integral part of clinical therapy and the use of food becomes the first and most economical instrument for the treatment of malnutrition, since malnutrition is an often-overlooked problem that is manifested during hospitalisation, particularly in the elderly and those in long-term care. Malnutrition increases the vulnerability of and complications for the patient; it also adversely affects therapeutic procedures, prolonging the time of hospitalisation and resulting in an increase in annual hospital costs that has been quantified in different countries. An incorrect management of the patient from the nutritional point of view can cause complications and, therefore, become a “disease within the disease”. The nutritional aspect becomes part then of a broader vision of the health care pathway included within care activity and clinical quality.

The problems related to catering in hospitals have been confronted by a technical Committee at the Ministry of Health that prepared the “National guidelines for hospital and care catering”. They represent a unique model that aims to standardise the activities connected with hospital catering, improving the relationship of hospitalised patients with food and including nutrition within pathways of diagnosis and treatment. The current Italian situation, in fact, sees a particularly marked heterogeneity between the Regions, but also within the same Region, between the different facilities. This heterogeneity is manifested not only in terms of nutritional quality, but also in catering management issues (Figure 4.4).

The lines of guidance recognise the centrality of the hospitalised patient and respect for their specific nutritional needs. The topics addressed are both timely and of strategic importance, since they suggest methods of organisation and management, as well as clinical-nutritional directions to be taken for the prevention and treatment of malnutrition.

Figure 4.4. Distribution of hospital meals by Region/Autonomous Province (Year 2010).

NR, not received.
The Ministry of Health has started a programme of monitoring in order to improve the quality of service, using a specific questionnaire intended to evaluate the acknowledgement and efficiency of the guidelines. The data refer to slightly more than 10% of the total of hospital and/or in-care meals.

**Nutritional intervention.** The patient’s nutritional risk assessment is carried out at admission and subsequent monitoring can counteract the establishment of states of malnutrition in the hospital, and/or correct situations of earlier malnutrition. Nutritional intervention aims to maintain and promote health in the healthy subject, while it has specific therapeutic purposes and/or those of prevention of complications in the patient affected by disease. To this end, it is essential that the hospital provides for the adoption of a dietetic formulary that includes a common diet, a set of menus accessible for all situations, with variety for at least 15 days and which allows for seasonal variation with an emphasis on local produce, and standard diets (e.g., low-calorie, high-calorie, gluten-free, low protein, a low intake of fibre and lactose, for dysphagia, for re-feeding, etc.), or dietary-therapeutic plans suitable for specific pathologies. These diets must be classified based on nutritional characteristics and not those of the disease. Finally, personalised diets are required to provide individual dietary-therapeutic plans for subjects with complex nutritional problems.

The nutritional needs of people in hospital who are fed normally (i.e., not with special diet) are comparable to those of the general population of similar age, sex and body weight, with specific adaptations to be made in the presence of protein-energy malnutrition and/or associated diseases as described in reference books devoted to such conditions. The vitamin and mineral needs to be provided are those recommended by the daily intake Levels of Nutrients Recommended for the Italian population (Livelli di Assunzione giornalieri Raccomandati di Nutrienti, LARN) and should be increased if there are hyper-catabolic conditions present or on the basis of available biochemical evidence.

**Hospital and extra-hospital catering.** Different modes of preparation and distribution of meals are chosen based on the characteristics of the facility, each of which requires specific procedures in order to obtain an optimal catering. In relation to the resources available and/or to be used the facility chooses an internal, external or mixed management. Regardless of the type of management chosen, each activity carried out is provided for in the contract for catering services. The preparation of meals may be based on a traditional or hot-cold or conventional system, a frozen or cook and freeze system, chilled or cook and chill, a mixed system. The contract is an integral element of catering and is the only instrument capable of preventing discretionary elements and episodes of disputes with contractors occurring. An integral part of the contract is the hospital Diet, needed for planning and optimising the nutritional intervention in hospitals. It should include common dietary guidelines for food in the common diet and diets developed considering the different nutritional needs of residents.

**Quality.** In the new health culture, the involvement of patients in care processes assumes considerable importance. Patient satisfaction is an argument of primary focus, and is central to the issue of quality. The active role of patients favours, in fact, a greater focus on risk prevention and strengthens the relationship of trust between the citizen and the health system. The patient must be informed of all matters concerning meals, from their composition to the system of reservation and distribution. The guidelines highlight the fact that meal-time should be as near as possible to that of the patient’s daily routine, and consider that as one aspect of dietetic-nutritional quality. Improving the quality of catering requires an extensive training programme for all staff, taking into account the lines of guidance that promote the increase in hygiene-sanitation awareness, and of legislative, dietary and nutritional awareness among the staff.
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of the suppliers, those engaged in the preparation of meals, of hospital treasury staff and inpatient departments, and of dietetic and clinical services personnel, in order to eventually put into practice their knowledge of issues related to catering.

Essential bibliography

The adoption of the new model of the highly technological acute care hospital for the treatment of complex acute diseases with confinement in hospital increasingly limited purely to the acute phase of the disease or that of post-surgery, even for complex or fragile patients, entails the need to ensure the activation of an integrated service network capable of delivering flexible care in the management of post-acute care patients, also in consideration of the fact that patients are reaching the post-acute care stage more and more quickly and with ever more complex and unstable clinical problems.

It is also possible and necessary to work towards a reduction in hospital stay for both the long-term and rehabilitative type, even in post-acute care wards, given the improved surgical techniques and devices, advances in pharmacology, the use of ICT (Information and Communication Technology), but in particular by creating a network system that correlates the clinical activities of the two phases in a truly synergistic process. This “virtuous” pathway has been favourably proposed for the area of rehabilitation through the related National Policy Plan 2011 being implemented in many Regions, and which must be completed with a parallel analysis of the skills to be allocated to the so-called long-term care facilities. This will allow, in addition, a systematic overview that also includes the area of intermediate care activities, which in turn can play a very important role in this perspective of the overall appropriateness of the offer in meeting the real and diverse needs of the population. Many chronic patients, especially older people with multiple disabling diseases, can hardly be called stable in an absolute sense and some types of residential structures, or nuclei within them, are able to deal with and overcome episodes of relative instability that may be presented by patients. The dividing line for the appropriateness of admission to hospital is then represented by a state of clinical instability requiring a 24-hour medical presence or highly complex diagnostic needs deliverable only in that care setting.

On the other hand, the need to allocate hospital beds to patients requiring intensive medical care sometimes leads the hospital to send frail patients to the post-acute area while their condition is worsening, and who instead would be more appropriately treated in acute care facilities.

These considerations have led to a re-evaluation within the Pact for Health 2010-2012 of the national standard for provision of beds and to set it at 4 beds per 1,000 inhabitants, of which 3.3 for acute care and 0.7 for post-acute care.

The analysis of regional data on the supply of post-acute care with respect to this standard shows a very uneven situation with a shortage in some areas and oversupply in others, as if to prove a difficulty in some realities in taking effective planning directions. Besides this, the problem in identifying precise parameters of appropriateness makes improper use of available hospital beds a real possibility, also due to an absence of intermediate care facilities. Finally, in not all of the realities can patients be referred promptly for a multidimensional assessment with definition of shared care pathways between the hospital and territory. At other times, post-acute care facilities perform a vicarious function by comparison with the appropriate territorial structures for the patient [Residential Care Homes (Residenze Sanitarie Assistenziali, RSAs), different care efforts] because of
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the lack of the latter. Furthermore, the presence in some Regions of structures dedicated to intensive rehabilitation in the territory (and the lack in others) necessarily implies the need to define standard hospital rehabilitation to take account of the presence in the regional territory of facilities where interventions of intensive rehabilitation can be provided, and which should be used when it is no longer appropriate for the patient to be admitted to hospital. The precise definition of care pathways is, therefore, made difficult by the large regional variability in the supply network relative to the disciplines found in the rehabilitation hospital, to long-term post-acute care and to the territorial medical facilities (or those with a strong medical component) both in terms of hospital beds and the ability to offer assistance (a function also of variations at the regional organisational requirement level) and, finally, by the fragmentation or absence of a functional link between the structures themselves. One of the primary tasks is, therefore, to ensure a consistent level in all Regions, in particular, residential and home care.

All of this raises the need for reflection and rationalisation of the entire network of post-acute care and territorial structures, so as to ensure a response to health needs and flexible care for the patient, respecting appropriateness, quality and proper use of resources, and ensuring an early multidimensional assessment of needs and definition of the care plan, with homogeneous tools shared between hospital and territory, in conjunction with the district. The various types of network segments must be clearly defined with respect to the clinical-care objectives and with consistent requirements of appropriateness, particularly for facilities dedicated to intermediate care, and specific clinical, relief, rehabilitation and socio-environmental criteria.

As with other health interventions appropriateness of care is also here a function not only of the disease, but also the individual needs of rehabilitation with respect to the patient’s clinical condition, disclosing according to them the applicability or otherwise of the interventions of intensive rehabilitation.

With regard to the appropriateness of the use of beds in hospital rehabilitation facilities, either public and private accredited, the work of the National Agency for Regional Health Services (Agenzia Nazionale per i Servizi Sanitari Regionali, AgeNaS) published in edition no. 27 of Monitor on the re-organisation of hospital networks in the Regions subject to the Plan of Realignment has, among other things, proposed:

- adaptation of a 95% utilisation rate of beds;
- adaptation of the relationship between ordinary hospital admission (ricovero ordinario, RO) and day-hospital beds (DH);
- the reformulation of the threshold values for periods in hospital, taking into account what has already been defined by some Regions, for units of recovery and functional rehabilitation (code 56), while the values for units of neuro-rehabilitation and spinal units (codes 75 and 28) will be defined after the putting in place of beds for continuous outpatient care;
- the strengthening of home interventions, in the phase of broad rehabilitation, within a rehabilitation plan that identifies specific phases and objectives that are alternative to hospital stay, while managing and controlling disability/chronic illness, in order to identify possible phases of progression of the debilitating state.

The notable regional difference in the offer of care that occurs in the provision of beds for neuro-rehabilitation (code 75) and spinal units (code 28) requires an evaluation of the opportunity to identify a common standard for these disciplines and to have unique access criteria providing for them a distribution by catchment areas that permits the conclusion of agreements between neighbouring Regions. After the acute phase, long-term hospital care answers the needs for care and treatment of highly complex patients – care that can only be provided in a hospital – with the goal of achieving clinical improvement and stabilisation. The ideal location for it, then, is close to the acute area, so that a multidisciplinary team is available if necessary, and, if this cannot be guaranteed, to ensure a close functional connection with acute care.
The standard offer as proposed by AgeNaS is 0.2 per 1,000 inhabitants. For this form of assistance also shared criteria of appropriateness should be identified for patients, the threshold of hospital stay reduced (AgeNaS proposes 30 days) and an appropriate level of utilisation. These preliminary findings should be included in an overall reorganisation as mentioned of tasks and of the structure of long-term care facilities in hospitals, as well as analysing the relationships to be developed with rehabilitation facilities in order to offer appropriate interventions to these long-stay patients in order to prevent and minimize risks of disability linked to pathological conditions or to a prolonged stay in hospital. The reorganisation of the network of post-acute care must be distributed homogeneously in the territory, both for type of offer and for complexity of the facility, in order to rationalise the patients’ clinical care paths. In addition to hospital beds for post-acute care, the establishment of intermediate care functions for patients for whom hospital admission or discharge home is not appropriate needs to be provided for. The peculiarity of this function requires careful consideration of the requirements and the clinical appropriateness, in order to avoid double functions sometimes present in residential care, or the entrustment of hospital functions to the territory. Furthermore, with respect to the commitment to welfare of different types of facilities, it is noted that the same is not always higher in recovery facilities, because some chronic conditions that require life support, such as ventilation or parenteral nutrition, may require a comprehensive level of care greater than the benefits of hospitalisation in acute care conditions. Finally, some considerations should be made on the description and remuneration of the rehabilitation survey. The system currently in use is the classification system based on the DRG Grouper software with reference to Major Diagnostic Categories (MDC), which constitute the intermediate level of aggregation of cases. Even the materials produced by the “Building Bricks” project (Building Brick 3 - Evolution of the National DRG system) show that the system has a number of limitations, designed as it is primarily for the description and remuneration of acute care activity. The MDCs comprise very large groups containing synthetic descriptions of morbidity profiles, which as dissimilar in particular in the needs for rehabilitation, in their complexity and in use of resources. Therefore, MDCs fail to provide a reliable description of rehabilitative activities or identify iso-resource interventions; indeed, each MDC contains a very wide spectrum of clinical conditions, treatments and production costs. This state of inadequacy of the MDCs in the representation and description of the needs of patients and of treatments provided has over the years also resulted in the absolute inadequacy of the criteria for accreditation of rehabilitation facilities (hospital and non-hospital, intensive and extensive) with regard to the framework codes 56 (Recovery and functional rehabilitation), 75 (Neurorehabilitation) and 28 (Spinal Units), producing a profound lack of correlation between skills, structural and operational equipment, activities performed by the different organisations for the care needs of patients in admission and for financial development. As stated in the National Policy Plan for Rehabilitation, and in synergy with this revision of the refund system, it is appropriate to revise the methods and content for the accreditation of facilities dedicated to rehabilitation, in order to create a clear relationship between the quality and mission of the structure with the assigned tasks and activities actually carried out for the benefit of patients. Following the considerations given so far it seems necessary to develop with the Regions a thorough analysis and related technical documents on the following points:

- Definition of national standards for the spinal unit (code 28) and neuro-rehabilitation (code 75) disciplines with explanation of the functions and clinical and organisational appropriateness criteria for the admission of patients;
- Definition of a comprehensive national standard for the various types of intensive hospital and territorial rehabilitation in
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different delivery models (hospitalisation, day hospital, residential scheme, semi-residential scheme);
■ adoption of an information card targeted for rehabilitation admissions (SDO-r), in order to make possible a more adequate assessment of the quality, efficiency and appropriateness of hospital rehabilitation admissions. The introduction of this card is preparatory for the study of the definition of a new method of payment for inpatient rehabilitation services;
■ definition of clinical and organisational criteria of appropriateness for admission and stay in the hospital long-stay wards;
■ definition of a national standard for hospital long-term care;
■ re-defining of the threshold values for post-acute hospitals;
■ definition of a set of indicators to assess, among other things, timeliness, appropriateness of admissions, the effectiveness of territory-hospital management, and outcomes of interventions.
6.1. The registration process for a generic medicinal product

The current norm of reference for the registration of a medicinal product is the Directive 2001/83/CE and subsequent amendments, enacted by legislative decree (D.Lgs.) no. 219/2006 and subsequent amendments. This norm represents the community Code on medicinal products for human use; it describes in detail the features and contents of a dossier for the authorisation of a drug, prepared in five standard forms, including any scientific information which demonstrates the suitability of the product, in any production phase, compared to the requirements of the current norms. These norms are flanked by numerous reference guidelines of a regulatory and scientific type prepared by the European Medicines Agency (EMA) or other competent European institutions. The whole cycle of the medicine, from the manufacturing process of the active substance to the production of the finished product, and to clinical trials carried out to demonstrate its effectiveness, is fully described. EU rules provide for different authorisation procedures depending on the market where the product will be marketed. It may be purely national with mutual recognition, decentralised (i.e. addressed to several European countries) or centralised [for innovative therapeutic medicines or for specific types of medicines, approval occurs at the central level by the EMA, which coordinates the evaluation phase through the activities of the Committee for Medicinal Products for Human Use (CHMP)]. For some categories of medicines, the legislation provides that the dossiers are adapted to the specific characteristics of the same, so that the documentation to be submitted to support the application for the Marketing Authorisations (Autorizzazione all’Immissione in Commercio, AIC) contains more information and studies related to the nature of the medicine. The normative reference for the registration of a generic medicine is art. 10 of D.Lgs. 219/2006, paragraph 5, letter b) of which defines it as a medicinal product which has compared to the reference product the same qualitative and quantitative composition in active substances, the same pharmaceutical form and a bioequivalence demonstrated by appropriate bioavailability studies. The reference medicinal product is that authorised with that given active substance based on a full dossier of preclinical (safety) and clinical (efficacy) studies, in accordance with art. 8 of D.Lgs. 219/2006 and subsequent amendments. That said, under the same qualitative and quantitative composition of active substance between the two medicines, the law provides that, subject to the rules governing the protection of industrial and commercial property, it is not necessary to submit full data on safety and efficacy for the issue of the marketing authorisation of a generic medicinal product (already defined for that active substance in the dossier of the reference medical product). In this case, proof of the equivalence between the two therapeutic products is sufficient. In other words, an in vivo bioequivalence study must be supplied that compares the pharmacokinetic parameters between the generic medicinal product and the reference product. The confidence interval of the relationship between these parameters must be within an acceptable range, usually defined as 80-125%, set by European guidelines on
the basis of intra-individual variability of the pharmacokinetics response of the medicine. If the results confirm what was anticipated in the standard, the performance of the two products can be considered comparable in terms of safety and efficacy in the general population and therefore the authorised generic is equivalent to the reference. In 2011 there appears to have been about 800 generics authorised with national, mutual recognition and decentralised procedures. Tables 6.1 and 6.2 and Figures 6.1, 6.2 and 6.3 show the data relative to refunded expenditure and the trend of consumption (DDD) in 2011 and provides a comparative analysis from 2005 to 2011, intended to allow for an enhanced interpretation of these figures. Lastly the regional costs and consumption are shown, as well as the trends for pure generic drugs in the principal European markets.

**Table 6.1. Italy – Trend of refunded costs in 2011 in proportion to patent protection**

<table>
<thead>
<tr>
<th>Market</th>
<th>2011</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total refunded [1+2]</td>
<td>€10,102,931,903</td>
</tr>
<tr>
<td>Δ vs previous year</td>
<td>–7.0%</td>
</tr>
<tr>
<td>Δ vs previous year</td>
<td>–9.8%</td>
</tr>
<tr>
<td>Incidence of equivalents with respect to total refunds</td>
<td>67.6%</td>
</tr>
<tr>
<td>Equivalent (lapsed patent) [2]</td>
<td>€3,277,274,722</td>
</tr>
<tr>
<td>Δ vs previous year</td>
<td>–0.7%</td>
</tr>
<tr>
<td>Incidence of equivalents with respect to total refunds</td>
<td>32.4%</td>
</tr>
<tr>
<td>Lapsed pure generic</td>
<td>€968,419,637</td>
</tr>
<tr>
<td>Δ vs previous year</td>
<td>5.9%</td>
</tr>
<tr>
<td>Incidence of equivalents with respect to total refunds</td>
<td>9.6%</td>
</tr>
</tbody>
</table>

Source: Processing by the Centro Studi AIFA on database sfera.

**Table 6.2. Italy – Trend of consumption (DDD) in 2011 in proportion to patent protection**

<table>
<thead>
<tr>
<th>Market</th>
<th>2011</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total refunded [1+2]</td>
<td>21,054,029,949</td>
</tr>
<tr>
<td>Δ vs previous year</td>
<td>1.2%</td>
</tr>
<tr>
<td>Δ vs previous year</td>
<td>–7.8%</td>
</tr>
<tr>
<td>Incidence of equivalents with respect to total refunds</td>
<td>44.1%</td>
</tr>
<tr>
<td>Equivalent (lapsed patent) [2]</td>
<td>11,766,168,132</td>
</tr>
<tr>
<td>Δ vs previous year</td>
<td>9.7%</td>
</tr>
<tr>
<td>Incidence of equivalents with respect to total refunds</td>
<td>55.9%</td>
</tr>
<tr>
<td>Lapsed pure generic</td>
<td>3,424,999,034</td>
</tr>
<tr>
<td>Δ vs previous year</td>
<td>19.5%</td>
</tr>
<tr>
<td>Incidence of equivalents with respect to total refunds</td>
<td>16.3%</td>
</tr>
</tbody>
</table>

Source: Processing by the Centro Studi AIFA on database sfera.

**Figure 6.1. Italy – Trend of SSN costs (A) and consumption (B) with reference to total market refunds and pure generic drugs in the period 2005-2011.**

A

Source: Processing by the Centro Studi AIFA on database sfera.
6.2. Innovative medicines

From the second half of the last century to the present, biomedical sciences and technological applications have had an impressive development, contributing to the extension of life expectancy and improving its quality in the population.

The development of innovative medicines has meant that the pharmaceutical sector earned a leading position both in the field of industrial production, and on that of societal benefits. With particular reference to recent years, Italy is meeting some strong challenges, among which:

- maintaining current levels of assurance in health care compared with a projected growth of the elderly population among the highest in Europe;
- making more efficient use of health care resources in the context of a federal organisation of the State;
introducing regulatory mechanisms on spending so as to free up resources for the financing of innovative medicines. The development of innovative therapies requires the identification of a suitable equivalent economic value and identification of the most appropriate means of financing. This is even truer in the Italian context, where there are specific constraints on regional pharmaceutical expenditure. The Italian Medicines Agency (Agenzia Italiana del Farmaco, AIFA) launched a complex process of reviewing the ways of enhancing innovation in 2011. The innovative value of a new drug, in fact, is not only linked to the intrinsic property of the active substance with which it is composed, but depends on the specific context in which it is introduced and the availability of alternative treatment options. Until now, most innovation has been evaluated primarily in terms of quality of care, and often the cost to achieve innovation has been ignored, thus diminishing the real value of it. The new strategies of drug development require a process of harmonisation with areas of common and shared regulation even with those who must then define the parameters of reimbursement and the price of the medicines. In this sense, the AIFA launched a joint scientific advice activity between the regulatory sector and the sector defining reimbursement and pricing, developing to the fullest its constituent potential. This same strategy was also promoted at the European level, in order to create a framework of common rules between those involved in the

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Figure 6.3. Importance of pure generic drugs with respect to the total territorial market* in the principal European countries. A) Revenues. B) Consumption.

* Does not include data for direct distribution.
Source: Processing done by the Centro Studi AIFA on an international Midas database.
registration phase of a new drug and those who then must define the value of it. The most important issue is represented by the measurability of innovation – closely linked to the quality of clinical trials, the robustness of the endpoints, the choice of comparator treatments and the assessment of the scope of therapeutic effect. It is precisely these elements of uncertainty that lead many countries today to be incapable of ensuring repayment for those drugs commonly regarded as innovative. The choice of pharmaceutical policy adopted so far has been to guarantee access to all new drugs. The use by AIFA of the Health Technology Assessment (HTA) is an indispensable tool to ensure a robust methodological approach to the assessment phase. The HTA is used both in the pre-marketing and at the of re-evaluation stage of the place in therapy of every product. In particular, AIFA has chosen to promote the use of “contingent repayment tools”, also called Managed Entry Agreements, together with the implementation of specific Monitoring Registries, designed to identify in a unique way the population most likely to benefit from a particular treatment. This is an alternative approach to the definition of a threshold, which implies the exclusion of a therapy from the possibility of use, even if only for a limited sub-population of patients. Pharmacoeconomic cost-effectiveness evaluation tools are essential to ensure future access to innovative medicines in a fair and efficient manner. Analyses of quality of life produced by care and of socio-economic factors, such as the reduction of the total costs of medicalisation/hospitalisation or general reduction in social costs, will affect the mode of introduction of the medicine itself, transforming it from “accounting” mode, where dynamics of use are analysed in the short-term, to a medium-long term “economic” mode, which is able to connect medicine use to the temporal evolution of the diseases that it is intended to cure.

6.3. Medicine traceability

**Territorial Pharmaceutical expenditure – direct and ‘on behalf of’ distribution.** Approved pharmaceutical expenditure, i.e. the expenditure incurred by the National Health Service (Servizio sanitario nazionale, SSN) for the delivery of medicines to citizens on prescription through pharmacies open to the public, excluding direct and ‘on behalf of’ delivery, has shown a constant trend of increase over the years. This is ever-increasing consumption of resources is determined by several factors, such as increase in life expectancy, inappropriate use of medicines in some therapeutic areas, and increase in the price of new marketed drugs. However, manoeuvres taken to contain SSN pharmaceutical expenditure implemented during the last few years have allowed, a substantial stability in the most recent period. Among the various interventions that have influenced pharmaceutical spending, particular attention should be paid to the phenomenon of direct distribution. The law 405/2001 introduced new ways of distribution of medicines, alternative to that provided in the conventional channel through pharmacies open to the public. This is done with the purchase of medicines of high consumption by public structures through tender procedures that help ensure a purchase price lower than the reimbursement mechanisms provide for in the distribution channel which is in convention. Direct distribution can occur in two distinct ways:

- **medicine delivery by the Public Health Facilities to patients for the first cycle of therapy, after discharge from hospital or subsequent to specialist outpatient visits or to patients requiring periodic checks.** This mode of dispensation takes on significance not only for expenditure reduction but, above all, for the clinical care of the patient and the guarantee of continuity of care between hospital and territory,
as well as the appropriateness of the use of medicines;
- medicine delivery, on behalf of the Local Health Authorities, by pharmacies open to the public on the basis of specific agreements between the Regions and Autonomous Provinces with the Association of Affiliated Pharmacies, to allow those with chronic disease, and who therefore require continuous pharmaceutical assistance, to get supplies from pharmacies in the same way as distribution performed directly by the SSN facilities (the so-called ‘on behalf of’ distribution).

The supply of medicines by direct distribution has allowed spending on the purchase of medicines to be rationalised, allowing the economic balance to be substantially maintained while increasing the doses distributed. The displacement of spending to direct distribution was then observed through analysis of the data collected from the information flow on direct distribution, established by the decree of the Minister of Health of July 31, 2007 under the New Health Information System (Nuovo Sistema Informativo Sanitario, NSIS).

Table 6.3, with reference to the period 2008-2011, shows the annual growth of pharmaceutical expenditure incurred in direct distribution: this increase, partly due to the improvement in the coverage of data transmission, is determined by both the introduction on the market of new innovative medicines and by the movement of certain categories of medicines from the channel of approved pharmaceutical distribution to that of direct distribution. In particular, focusing on medicines of group A included in the PHT (Formulary of hospital-territory continuity of care) – the set of medicines that can be dispensed either through pharmacies open to the public or by means of the public health facilities, and which are, therefore, the medicines predominantly in direct distribution – there was a significant increase in expenditure compared with the overall total registered (Table 6.4).

**Hospital pharmaceutical expenditure.** Hospital pharmaceutical expenditure is an important item in total pharmaceutical costs. The flow of data pertaining to medicines used in public health facilities is a more recent creation within the NSIS (decree of the Ministry of Health February 4, 2009). Data on consumption of medicines in direct distribution and on medicines used in the facilities themselves for inpatients and outpatients are transmitted by the Regions and Autonomous Provinces of Trent and Bolzano and then allow the for quantitative representation of how medicinal products directly purchased from the SSN are used.

**Medicine traceability.** To effect analyses of the historical trend of expenditure in the last

<table>
<thead>
<tr>
<th>Anno</th>
<th>Cost of purchase</th>
<th>Δ annual absolute</th>
<th>Δ annual %</th>
</tr>
</thead>
<tbody>
<tr>
<td>2008</td>
<td>1,165,194,370</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2009</td>
<td>1,322,437,664</td>
<td>157,243,294</td>
<td>13.50%</td>
</tr>
<tr>
<td>2010</td>
<td>1,732,966,208</td>
<td>410,528,544</td>
<td>31.00%</td>
</tr>
<tr>
<td>2011</td>
<td>2,187,366,700</td>
<td>454,400,492</td>
<td>26.20%</td>
</tr>
</tbody>
</table>

five years and in particular the changes in the costs of purchase of medicinal products in the last year, reference is made to the database of medicine traceability (decree of the Ministry of Health July 15, 2004) with information supplied by medicine production and distribution companies, and within the NSIS remit. This database allows data to be collected on the movements of packs of medicines in the country and abroad, as well as for economic costs of supply for medicines purchased by public health facilities.

The trend analysis of expenditure and consumption over the past four years (Table 6.5) shows how, in the face of increased consumption, the average price for the acquisition of medicines by public health facilities has declined over the years, particularly in 2011 compared to 2010.

The main value of the database of medicine traceability is found, however, in the monitoring of packs of medicines along the distribution channel, which allows the effect produced by legislative initiatives to be analysed. In the case, for example, of the D.Lgs. July 4, 2006 no. 223, converted with amendments by law August 4, 2006 no. 248, which introduced, among others:

- the opportunity for businesses to engage in public sale of over-the-counter medicines or those of self-medication,
- the repeal of paragraph 2 of art. 100 of the D.Lgs. April 24, 2006 no. 216 prohibiting pharmacies to make wholesale distribution of medicines,

it is possible to measure the effects produced by these provisions.

At the end of 2011, there were 3,900 commercial enterprises, the so-called para-pharmacies, carrying out the sale of medicinal products distributed between:

- neighbourhood businesses (with a sales area not exceeding 150 m$^2$ in towns with a population of less than 10,000 inhabitants and 250 m$^2$ in towns with a population of more than 10,000 inhabitants), 86% of the total;
- medium-size sales facilities (with an area exceeding the limits referred to above and up to 1,500 m$^2$ in towns with population of less than 10,000 inhabitants and 2,500 m$^2$ in towns with population of more than 10,000 inhabitants), 7% of the total;
- large retail outlets (with a surface area exceeding the limits referred to in the preceding paragraph) equal to 8% of the total.

In only 4% of cases (147) were the owners of a para-pharmacy also the owners of a pharmacy.

Legal entities which are pharmacy owners and who also carry out wholesale distribution of medicinal products total 140, i.e., about 1% of the total number of pharmacies open to the public, but represent 17% of the total of authorised logistic sites for the wholesale distribution of medicinal products.

### Table 6.5. Pharmaceutical expenditure of public health structures (Year 2008-2011)

<table>
<thead>
<tr>
<th>Year</th>
<th>Expenditure (€)</th>
<th>Consumption (DDD)</th>
<th>Average price (DDD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2008</td>
<td>5,612,166,986</td>
<td>2,275,061,878</td>
<td>2.47</td>
</tr>
<tr>
<td>2009</td>
<td>6,010,482,169</td>
<td>2,264,396,289</td>
<td>2.65</td>
</tr>
<tr>
<td>2010</td>
<td>6,736,811,893</td>
<td>2,540,901,255</td>
<td>2.65</td>
</tr>
<tr>
<td>2011</td>
<td>7,014,413,472</td>
<td>3,586,247,295</td>
<td>1.96</td>
</tr>
</tbody>
</table>

7.1. Organ transplants

**Planning framework.** Organ transplants are a safe and well-established therapy for the treatment of serious organ failure. With the law of April 1, 1999, no. 91 (“Provisions for removal and transplantation of organs and tissues”) the development of the transplant network became an objective of the National Health Service (Servizio sanitario nazionale, SSN). From the enactment of the law, the Italian Transplant Network was consolidated with the National Transplant Centre and divided into four national, interregional, regional and hospital/authority levels, as redefined by the State-Regions Agreement of October 13, 2011. The reorganisation clarified some technical and organisational profiles and expanded the culture of donation in our Country, so as to place the National Transplant System among the first in the European rankings for quality, safety and efficacy. The National Transplant Network is a valid model for planning and management of a clinical-care system in balanced co-participation between Government and the Regions.

The pilot project “The organ donation as part of identity” began in 2011, a CCM project of the Region of Umbria involving the Ministry of Health, the National Transplant Centre and the Federsanità-ANCI group. The project, also promoted implementation of art. 3, paragraph 8-bis of the legislative decree (D.Lgs.) December 30, 2009, no. 194, converted into law February 26, 2010, no. 25 (the so-called decree of a “thousand extensions”), under which the citizen’s identity card may contain the consent or objection to the donation of organs and tissues. In Perugia and Terni, citizens of age may indicate to the city registry office, on the occasion of the issuance or renewal of their identity cards, their wishes regarding the donation of organs and tissues. This declaration will be recorded directly in the Transplant Information System of the Ministry of Health, allowing the Regional Centres of Transplantation to consult it at any time. To promote this project, the communication initiative “A choice at City Hall. A choice for the community” was also designed, the aim of which was to increase the public awareness of sharing a gesture of solidarity, such as organ donation, and involving the Municipalities, the sites of the institutions closest to citizens. The project results will provide guidance for the implementation of the regulation in all municipalities.

Throughout 2011, Italian transplantation continued to play a leading role in international cooperation activities between Italy, European countries and those bordering the Mediterranean. In particular, an agreement was signed with Egypt which stipulates that Italian experts assist Egyptian physicians in the programme of organ donation from the deceased, and assist transplantation operators in the implementation of organisation of the transplantation network, in the creation of a quality system that provides for the accreditation and verification of standards for activities of the structures and in the training of professionals involved in the donation and transplantation procedures.

At the international level, our country, through the National Transplant Centre and in collaboration with the World Health Or-
ganization (WHO), participated as a major player in the launch of the NOTIFY project, a global initiative to create a database to collect information on adverse organ events, tissues, cells and reproductive cells and the management of the same in order to facilitate comparison between experts. Presentation and critical evaluation of the data. In 2011, the total number of donors was 1,319 as against 1,301 in the previous year, with total growth of 1.4% (Table 7.1). The growth trend stabilised in the second half of the year. A comparison of the figures for 2010 and those of 2011 show a widespread in-

<table>
<thead>
<tr>
<th>Region</th>
<th>Brain death</th>
<th>Non-consents (no.)</th>
<th>Non-consents (%)</th>
<th>Donors</th>
<th>Donors used</th>
<th>Certified standard neurological deaths</th>
<th>Donors</th>
<th>Donors used</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abruzzo</td>
<td>35</td>
<td>14</td>
<td>40.0%</td>
<td>17</td>
<td>12</td>
<td>26.1</td>
<td>12.7</td>
<td>9.0</td>
</tr>
<tr>
<td>Basilicata</td>
<td>14</td>
<td>9</td>
<td>64.3%</td>
<td>4</td>
<td>4</td>
<td>23.8</td>
<td>6.8</td>
<td>6.8</td>
</tr>
<tr>
<td>Calabria</td>
<td>47</td>
<td>12</td>
<td>25.5%</td>
<td>29</td>
<td>21</td>
<td>23.4</td>
<td>14.4</td>
<td>10.5</td>
</tr>
<tr>
<td>Campania</td>
<td>135</td>
<td>56</td>
<td>41.5%</td>
<td>67</td>
<td>57</td>
<td>23.2</td>
<td>11.5</td>
<td>9.8</td>
</tr>
<tr>
<td>Emilia Romagna</td>
<td>208</td>
<td>59</td>
<td>28.4%</td>
<td>113</td>
<td>96</td>
<td>47.3</td>
<td>25.7</td>
<td>21.8</td>
</tr>
<tr>
<td>Friuli Venezia Giulia</td>
<td>56</td>
<td>11</td>
<td>19.6%</td>
<td>45</td>
<td>44</td>
<td>45.4</td>
<td>36.5</td>
<td>35.7</td>
</tr>
<tr>
<td>Lazio</td>
<td>249</td>
<td>73</td>
<td>29.3%</td>
<td>105</td>
<td>72</td>
<td>43.8</td>
<td>18.5</td>
<td>12.7</td>
</tr>
<tr>
<td>Liguria</td>
<td>57</td>
<td>11</td>
<td>19.3%</td>
<td>42</td>
<td>39</td>
<td>35.3</td>
<td>26.0</td>
<td>24.1</td>
</tr>
<tr>
<td>Lombardy</td>
<td>348</td>
<td>83</td>
<td>23.9%</td>
<td>238</td>
<td>214</td>
<td>35.4</td>
<td>24.2</td>
<td>21.8</td>
</tr>
<tr>
<td>Marche</td>
<td>72</td>
<td>16</td>
<td>22.2%</td>
<td>50</td>
<td>44</td>
<td>46.2</td>
<td>32.1</td>
<td>28.2</td>
</tr>
<tr>
<td>Molise</td>
<td>5</td>
<td>1</td>
<td>20.0%</td>
<td>3</td>
<td>2</td>
<td>15.6</td>
<td>9.4</td>
<td>6.2</td>
</tr>
<tr>
<td>Piedmont</td>
<td>222</td>
<td>71</td>
<td>32.0%</td>
<td>121</td>
<td>116</td>
<td>49.9</td>
<td>27.2</td>
<td>26.1</td>
</tr>
<tr>
<td>Aut. Prov. of Bolzano</td>
<td>9</td>
<td>4</td>
<td>44.4%</td>
<td>4</td>
<td>4</td>
<td>17.9</td>
<td>7.9</td>
<td>7.9</td>
</tr>
<tr>
<td>Aut. Prov. of Trent</td>
<td>15</td>
<td>3</td>
<td>20.0%</td>
<td>12</td>
<td>11</td>
<td>28.6</td>
<td>22.9</td>
<td>21.0</td>
</tr>
<tr>
<td>Apulia</td>
<td>114</td>
<td>36</td>
<td>31.6%</td>
<td>53</td>
<td>46</td>
<td>27.9</td>
<td>13.0</td>
<td>11.3</td>
</tr>
<tr>
<td>Sardinia</td>
<td>62</td>
<td>12</td>
<td>19.4%</td>
<td>42</td>
<td>34</td>
<td>37.1</td>
<td>25.1</td>
<td>20.3</td>
</tr>
<tr>
<td>Sicily</td>
<td>154</td>
<td>81</td>
<td>52.6%</td>
<td>62</td>
<td>52</td>
<td>30.5</td>
<td>12.3</td>
<td>10.3</td>
</tr>
<tr>
<td>Tuscany</td>
<td>280</td>
<td>67</td>
<td>23.9%</td>
<td>175</td>
<td>125</td>
<td>75.1</td>
<td>46.9</td>
<td>33.5</td>
</tr>
<tr>
<td>Umbria</td>
<td>15</td>
<td>5</td>
<td>33.3%</td>
<td>9</td>
<td>9</td>
<td>16.7</td>
<td>10.0</td>
<td>10.0</td>
</tr>
<tr>
<td>Aosta Valley</td>
<td>1</td>
<td>0</td>
<td>0.0%</td>
<td>1</td>
<td>1</td>
<td>7.8</td>
<td>7.8</td>
<td>7.8</td>
</tr>
<tr>
<td>Veneto</td>
<td>173</td>
<td>27</td>
<td>15.6%</td>
<td>127</td>
<td>110</td>
<td>35.2</td>
<td>25.9</td>
<td>22.4</td>
</tr>
</tbody>
</table>

**Table 7.1. Number and rate (per 1,000,000 inhabitants) of donors, by type and Region, by interregional Centre and by geographic area (Year 2011)**

PMP, per million of population.
crease in the rate of donation, especially in the Centre-South Regions. In 2011, the registered number of the findings of standard neurologic death compared with the opposition on the part of family members was 28.7%, down sharply compared to 2010 (–2.8%). In the second half of 2011, the percentage of opposition dropped further to 25.8%. The total of patients on a waiting list in 2011 was 8,783, a significant reduction (–7.44%). A very important fact recorded in 2011 was the increase of 13% in kidney transplants from living donors. From February 1, 2011, the national “hyper-immune” programme is also active in Italy. The programme is designed for those patients who are antibody reactive against more than 80% of the representative selection of the donor population, a condition that reduces the possibility of finding a compatible donor. A year after the protocol was begun, transplants were carried out in 18 patients who were on the waiting list for over 10 years.

Ragulatory references.

- Legge 1 aprile 1999 [law April 1, 1999], no. 91 “Provisions relating to the removal and transplantation of organs and tissues” (GU/Official Gazette General Series no. 87 of April 15, 1999).

7.2. Cells and tissue: traceability, safety and quality

Planning framework and state of implementation. The 91/1999 law had already provided rules for the discipline of tissues as well as of organs. The D.Lgs 191 November 6, 2007, transposing the European Directive 2004/23/CE, laid down standards of quality and safety for human tissues and cells intended for human applications in order to ensure a high level of protection of human health. The successive D.Lgs of January 25, 2010, no. 16, which implements the Directives 2006/17/CE and 2006/86/CE, and 2004/23/CE, further integrated decree no. 191 defining technical requirements for the donation, procurement and testing of human tissues and cells, as well as requirements in terms of traceability, notification of serious adverse reactions and events. In this context, the National Transplant Centre plays an active role as a technical reference body for supervision and surveillance.

As part of the national network of cord blood Banks [Italian Cord Blood Network (ITCBN), instituted with DM November 18, 2009], the regulatory framework was completed first with the definition of the minimum organisational, structural and technological requirements (State-Regions Agreement of October 29, 2009) and then with the State-Regions Agreement of April 20, 2011, where the Guidelines on the accreditation of blood Banks were defined, pursuant to D.Lgs. 191/2007, on the basis of international and national standards. As part of the verification programme for requirements of Banks of tissues to date 112 inspections have been conducted in 32 Banks since the start in 2004. Inspections have so far shown a consolidation of the structure and activities of the Banks, a reduction in “non-compliance” related to donor selection and operation of instruments and equipment and to labelling and distribution of tissues. Every year there is a plan for meetings and refresher courses and training for inspectors, to ensure the continuous training of the team.
Presentation and critical evaluation of the data. The operation of the network of Banks in terms of traceability, safety and quality is proven also by the results obtained in terms of tissue donation. Italy was the leading European country for cornea donation in 2011: 7,388 donors, compared to 6,772 in 2010, representing an increase of 9%. Even donations of musculoskeletal tissue showed a significant increase (10.5%), from 3,046 in 2010 to 3,364 in 2011.

In terms of the donation of hematopoietic stem cells (HSC), in 2011 the number of donors registered with the Italian Register of Bone Marrow Donors (IBMDR) sited at the Ospedale Galliera in Genoa, was more than 400,000, or about 3% more than in 2010, while the number of new registrations increased by 15% over the previous year (11,582 to 10,038). These data confirm the trend of growth over the last three years. It should be noted that in 2011 3,588 searches for donors were carried out at the IBMDR, of which 2,025 for foreign patients and 1,563 for Italian patients.

In our country, the total number of HSC donors in 2011 amounted to 186; donations in favour of Italian patients were 127, while 59 donations were for international patients. The total number of patients transplanted with HSC from an unrelated donor in 2011 was 757 versus 741 in 2010 (an increase of 2%); the transplants were performed in 11% of cases with HSC from umbilical cord blood, in 56% with HSC from peripheral blood and in 33% with HSC from medullary blood. In total, 927 transplants of HSC donated by family members were also carried out and 2,925 with HSC taken from the patients themselves. In line with the implementation of HSC transplant activity, there was also an increase in the exporting and importing of units of HSC (DM September 7, 2000); in particular, in 2011, 678 units of HSC were imported for Italian transplant centres and 126 units exported at the request of foreign centres.

Since the beginning of inspection activities, which began in 2007 in collaboration with the National Blood Centre (Centro Nazionale Sangue, CNS) and Jacie (Joint Accreditation Committee of International Society for Cellular Therapy and European Group for Blood and Marrow Transplantation), 17 audits of compliance with the requirements of the regulations were conducted at facilities where programmes of HSC transplant are active. At the same time, in collaboration with the CNS, investigations of compliance were carried out in 10 cord blood Banks related to the national Network of cord blood Banks and documentary audits were conducted on 20 functional nodes of the IBMDR network in collaboration with the IBMDR (Regional Registers, Donor Centres and Recruiting centres – State-Regions Agreement April 29, 2010).

Regulatory references.

- Accordo [Agreement], in the meaning of art. 6.1 of the D.Lgs. November 6, 2007, no. 191, between the Government, the Regions and the Autonomous Provinces of Trent and Bolzano containing the “Organizational, structural and technological requirements for the healthcare activities of banks of umbilical cord blood” (GU/Official Gazette General Series no. 288 of December 11, 2009).

Transfusion services

8.1. Transfusion activity

Planning framework. The national blood system, as designed by law No. 219 of October 21, 2005, is a system whose operation is entrusted to the synergy between various actors: National Institutions, Regions, Associations and Federations of voluntary blood donors, scientific associations. Thanks to the implementation of recent measures, the strong points for an effective governance of the national blood system were defined and established. These consisted of planning, monitoring, coordination and scientific-technical control of the system with the aim of ensuring the achievement of the goal to harmonise quality, safety and appropriateness levels, thus uniformly ensuring the Essential Levels of Health Care (Livelli essenziali di assistenza, LEA).

In this sense, the features and functions of the Regional Blood Coordinating Centres (Strutture regionali di coordinamento, SRCs) have been defined by the State-Regions Agreement of October 13, 2011 in order to ensure the provision of uniform LEA in transfusion medicine.

To achieve these goals – as required by the law – the SISTRA [National Blood Information System, which is part of the New Health Information System (Nuovo Sistema Informativo Sanitario, NSIS)] has been made a complete data access available in terms of blood issues.

Data is collected and validated by the SRCs, and subsequently transmitted to the Italian National Blood Centre (Centro Nazionale Sangue, CNS) for analysis, processing and reporting.

Description of the data. From the data and essential information concerning blood donors, donations, blood products and components transfused and patients undergoing transfusion therapy in the years 2009 and 2010, it results that in 2010, 1,722,503 donors gave blood showing an increase of 1.9% over the previous year, therefore confirming the growth trend observed in the last five years. An increase of 4.9% in new donors has been recorded, representing a relevant data for the purposes of maintaining the turn-over of the overall donor population. There has been a 3% increase in aphaeresis donors who also donate whole blood and a 7.9% increase in donors who donate only through aphaeretic procedures (Table 8.1). These increases are of considerable importance in terms of flexibility and diversity in the donation of blood and blood components, as well as a positive response to the objectives of production of plasma to be delivered for pharmaceutical processing.

The regional distribution of total donors showed an important variability among Regions with a maximum of 44.3‰ donors in Friuli Venezia Giulia and a minimum of 20.9‰ in Calabria.

In 2010, 3,199,787 donations were made, recording an increase of 3.8% compared to 2009. Donations of whole blood represent 84.3% of the total, while aphaeresis donations amount to 15.7%. The overall index of donations at the national level is 53‰ of the total, while aphaeresis donations amount to 15.7%. The overall index of donations at the national level is 53‰ in 2010, significantly higher than the average of the Member States of the Council of Europe, which is approximately 43%. In Italy, however, there is a wide variation among re-
Implementation of lines of priority in order to meet health objectives

Table 8.1. Transfusion activity: Indicators relative to the period 2009-2010

<table>
<thead>
<tr>
<th>Transfusion activity</th>
<th>2009</th>
<th>2010</th>
<th>Difference</th>
</tr>
</thead>
<tbody>
<tr>
<td>No. of responding transfusion structures</td>
<td>296</td>
<td>293</td>
<td>−1.01%</td>
</tr>
<tr>
<td>Resident population</td>
<td>60,340,328</td>
<td>60,626,442</td>
<td>0.47%</td>
</tr>
<tr>
<td>Total donors</td>
<td>1,690,426</td>
<td>1,722,503</td>
<td>1.90%</td>
</tr>
<tr>
<td>Total donors /1.000 inhabitants</td>
<td>28.01</td>
<td>28.41</td>
<td>0.00%</td>
</tr>
<tr>
<td>Total periodic donors</td>
<td>1,329,591</td>
<td>1,344,113</td>
<td>1.09%</td>
</tr>
<tr>
<td>New donors (including those who haven’t donated for more than 24 months)</td>
<td>360,835</td>
<td>378,390</td>
<td>4.87%</td>
</tr>
<tr>
<td>Apheresis donors</td>
<td>228,544</td>
<td>243,149</td>
<td>6.39%</td>
</tr>
<tr>
<td>Apheresis-only donors</td>
<td>103,199</td>
<td>111,383</td>
<td>7.93%</td>
</tr>
<tr>
<td>Whole blood donations</td>
<td>2,598,305</td>
<td>2,697,270</td>
<td>3.81%</td>
</tr>
<tr>
<td>Apheresis donations</td>
<td>485,001</td>
<td>502,517</td>
<td>3.61%</td>
</tr>
<tr>
<td>Total donations</td>
<td>3,083,306</td>
<td>3,199,787</td>
<td>3.78%</td>
</tr>
<tr>
<td>Whole blood donations /1.000 inhabitants</td>
<td>43.06</td>
<td>44.49</td>
<td>3.22%</td>
</tr>
<tr>
<td>Apheresis donations /1.000 inhabitants</td>
<td>8.04</td>
<td>8.29</td>
<td>3.12%</td>
</tr>
<tr>
<td>Total donations /1.000 inhabitants</td>
<td>51.1</td>
<td>52.8</td>
<td>3.29%</td>
</tr>
<tr>
<td>Blood component products</td>
<td>7,489,857</td>
<td>7,706,129</td>
<td>2.89%</td>
</tr>
<tr>
<td>Blood component transfusions</td>
<td>3,372,999</td>
<td>3,383,241</td>
<td>0.30%</td>
</tr>
<tr>
<td>Transfusion patients</td>
<td>555,204</td>
<td>623,119</td>
<td>12.23%</td>
</tr>
<tr>
<td>Blood component transfusions/transfusion patients</td>
<td>NA</td>
<td>5.43</td>
<td>NA</td>
</tr>
<tr>
<td>Red cells produced (unit)</td>
<td>2,547,377</td>
<td>2,612,894</td>
<td>2.57%</td>
</tr>
<tr>
<td>Red cells transfused (unit)</td>
<td>2,436,428</td>
<td>2,471,516</td>
<td>1.44%</td>
</tr>
<tr>
<td>Red cells unused (unit)</td>
<td>106,484</td>
<td>108,368</td>
<td>1.77%</td>
</tr>
<tr>
<td>Red cells unused/produced</td>
<td>4.18%</td>
<td>4.15%</td>
<td>−0.78%</td>
</tr>
<tr>
<td>Platelets produced adult therapeutic dose</td>
<td>287,584</td>
<td>283,581</td>
<td>−1.39%</td>
</tr>
<tr>
<td>Platelets produced adult therapeutic dose /1.000 pop</td>
<td>4.77</td>
<td>4.68</td>
<td>−1.86%</td>
</tr>
<tr>
<td>Platelets transfused adult therapeutic dose</td>
<td>205,215</td>
<td>205,791</td>
<td>0.28%</td>
</tr>
<tr>
<td>Platelets unused adult therapeutic dose</td>
<td>58,096</td>
<td>66,304</td>
<td>14.13%</td>
</tr>
<tr>
<td>Plasma produced unit</td>
<td>2,974,804</td>
<td>3,061,029</td>
<td>2.90%</td>
</tr>
<tr>
<td>Plasma transfused unit</td>
<td>513,540</td>
<td>480,394</td>
<td>−6.45%</td>
</tr>
<tr>
<td>Plasma unused unit</td>
<td>117,695</td>
<td>123,736</td>
<td>5.13%</td>
</tr>
<tr>
<td>Plasma unused unit/plasma produced unit</td>
<td>3.96%</td>
<td>4.04%</td>
<td>2.17%</td>
</tr>
</tbody>
</table>

NA, not available.
Source: SISTRA – National Blood Centre data.

Regions, ranging from more than 70‰ in Friuli Venezia Giulia, Veneto and Emilia Romagna to 36‰ and 26‰ in Lazio and Campania, respectively (Figure 8.1). The national average index of donation per donor was 1.9 on an annual basis, with significant variability among Regions.

In 2010, 3,383,241 blood components were transfused, amounting to 9,269 units per day. The number of patients who underwent transfusion was 623,119 that, compared to 2009, records an increase of 12%, partially due to the improvement in terms of information quality provided by the SRCs. Each patient transfused received, on average, 5.43 units of blood components. The detail of the production and transfusion data related to the use of the three main components of blood transfusion (red cells, platelets and plasma) is substantially in line with the av...
transfusion services

Figure 8.1. Donations in total (whole blood and apheresis) by 1,000 inhabitants (Years 2009-2010).

Source: SISTRA – National Blood Centre data.

Average of similar data in European Countries comparable to Italy at a socio-economic level. The preliminary analysis of the data on blood services, mostly those related to annual planning for self-sufficiency, indicate that the national blood system in 2011, as in 2008-2010, has fully complied with the quantitative provisions and achieved most of the performance targets set out in the annual programme for self-sufficiency in blood and blood products.

Notwithstanding that the qualification pathway and audit processes envisaged by the State-Regions Agreement of December 16, 2010 involve a series of actions and interventions that represent fundamental elements of supervision and continuous improvement of the quality and safety of products, the overall performance of the blood system, as well as the new National Haemovigilance System plays a pivotal role in terms of monitoring blood safety. The System was implemented in 2009 in accordance with the relevant European standards. This system, operating through the Web-based SISTRA platform (Sistema Informativo dei Servizi Trasfusionali), is designed to record adverse events associated to transfusion and donation, as well as information related to the surveillance of transfusion transmissible infections (malattie infettive trasmissibili con la trasfusione, MITs) in blood donors.
Since 2009, the coverage of MIT surveillance has reached 100%, allowing a comprehensive portrait of relevant epidemiological value, which is also a mandatory requirement as for European Law in order to achieve full plasma for industrial use quality. In the same year the detection of information on adverse events associated with transfusion and donation was started (Figure 8.2); up to 2011, coverage was not yet complete, showing a reasonable level of underreporting in terms of adverse events associated to transfusion in several Regions. Nevertheless, there is already a significant amount of validated information available that can be analysed and evaluated in order to design and implement actions to improve the quality. Furthermore, that information can be used as evidence for the revision of standards for clinical use of blood components and for the definition of technical guidelines in order to raise the level of safety of transfusion therapy.

**Essential bibliography**


**Figure 8.2. Adverse events due to blood component transfusion (Year 2010).**

- **Allergic reactions**
- **Non-haemolytic febrile reaction**
- **Other**
- **Dyspnea associated with transfusion**
- **Hypotension**
- **Hypertension**
- **Circulatory overload (TACO)**
- **Alloimmunization**
- **Anaphylaxis**
- **Noncardiogenic pulmonary oedema (TRALI)**
- **Other bacterial infections**
- **Hypothermia**
- **Post transfusion purpura**
- **Acute haemolytic reaction ABO**
- **Delayed haemolytic reaction**
- **Delayed haemolytic reaction by other systems of haemolytic groups**
- **Non-immune haemolysis**
- **Physical cause**
- **Non-immune haemolysis Mechanical cause**
- **Anaphylactic shock**
- **Autoimmune haemolytic anemia**
- **Non-immune haemolysis Chemical cause**
- **Hypocalcemia**
- **Acute haemolytic reaction from other blood group systems**
- **Immediate haemolytic reaction**

Source: SISTRA – National Blood Centre data.
8.2. Planning for the transfusion system

**Planning framework.** The blood system is delegated to the provision of products and services being strategically important to the support of many healthcare pathways in the areas of medicine, surgery, emergency-urgency and other specialties. The production activities of the system, in addition to the transfusion use of blood components, also include the collection of plasma to be used in industrial processing for the production of plasma-derived medicines. The blood system is also extensively involved in the collection, processing and storage of hematopoietic stem cells (HSC) and the development of cell therapies.

Blood services, like few other areas in healthcare, are regulated by a complex provisions “corpus”, both National and European. Law No. 219 of October 21, 2005 profoundly reshaped the national blood network defining its basic principles and strategic objectives and also introducing, in conformity with regional autonomy, a number of innovative features such as the establishment of both national and regional bodies (the National Blood Council and the CNS and SRC), the definition of LEA in terms of blood services, as well as recommendations regarding the reassessment requirements as regards authorization and accreditation. Moreover the same law sets the strategic goals of the system, such as blood and blood product regional and national self-sufficiency, high levels of quality and safety of products and services provided by the blood system and, last but not least, the appropriateness of management and clinical use of the blood resources.

As far as blood services are concerned, national legislation was accompanied by important and challenging European provisions essentially aimed at establishing common European quality and safety standards of products, as well as blood services. From this perspective, considering the significant inhomogeneity among Regions, with the adoption of the State-Regions Agreement of December 16, 2010, (on the minimum organizational, structural and technological requirements for blood services and blood collection units, as well as a blood inspection system), the need to homogeneously conform blood services to the national laws transposing European Directives on blood, blood components and blood medical products was shared. This provided a pathway (deadline December 31, 2014 fixed by Decree No. 225 of December 29, 2010, converted, with amendments, into law No. 10 of February 26, 2011, article 2, paragraph 1-sexies) on the completion of the activities related to a further qualification of all blood services, blood collection units and blood components, as well as the biannual verification activities on-site of all blood structures operating nationwide.

In 2011 the implementation of the State-Regions Agreement of December 16, 2010, began by the establishment of a national blood system auditors List (Decree of the Minister of Health of May 26, 2011) after the organization of five editions of official training courses for regional auditors aimed at their qualification and subsequent inclusion in the List. The first national blood system auditors List has been made available by CNS to the Regions and Autonomous Provinces since December 1, 2011.

Thanks to the regulatory action of the aforementioned law No. 10 of February 26, 2011, actions for an effective implementation of article 15 and 16 of law No. 219 of October 21, 2005, have been contextually and simultaneously identified (this implementation process had suffered an operational stand-by due to several previous legislative changes), with the aim of definitively regulating the very sensitive area of the production of medicinal products derived from plasma collected in the country and the import and export of blood and blood products.

To the Italian blood system, the achievement of the described goals represents a very demanding challenge that cannot be either renounced or postponed, considering also the need to comply with the European obligations related to plasma as a raw material.
for the production of medicinal products. Therefore, for the years 2011-2014, the prior strategic goal of the Italian blood system is to even out the system itself to the level of the most developed Countries of the European Union, in order to sustainably and effectively ensure a constant and ready availability of blood products and services, which are strongly necessary for the provision of LEA. This shall be accomplished meeting both national and European quality and safety standards, as well as regulatory and service requirements, at the same time guaranteeing the alignment of blood products and services to the most updated scientific and technical advances in transfusion medicine.

**Description of the data.** In accordance with Law No. 219 of October 21, 2005, blood and blood products self-sufficiency is an indivisible and supra-regional interest that the Regions and the national Health Authorities shall cooperatively pursue. Furthermore, it aims at quantitatively and qualitatively ensuring to all citizens constant and prompt availability of blood products and services, based on the ethical principle of voluntary, regular, responsible and non-remunerated donation.

National self-sufficiency is guaranteed thanks to the irreplaceable contribution of blood donor Associations and Federation, as well as the regional system networking and blood component exchanges. Furthermore, a crucial contribution is provided by the more recent blood and blood product self-sufficiency annual planning whose implementation dates back to 2008, the first year in which the provisions of article 14 of Law No. 219, 2005, were actually applied. Since then a Programme for blood and blood product self-sufficiency is annually issued by a Decree of the Minister of Health according to the indications provided by the CNS, the Regional blood coordinating centres and the associations and federations of blood donors. The sixth Programme is forthcoming. Besides providing for their internal blood needs, some Regions (especially Piedmont, Veneto, Lombardy, Friuli Venezia Giulia and Emilia Romagna) annually plan – in cooperation with the CNS – an additional production of blood components for those Regions, mainly represented by Lazio and Sardinia, that are not self-sufficient. In 2010, such regional exchanges were regulated at the administrative level through their inclusion into the interregional healthcare service compensation scheme, thus establishing a high degree of equality and transparency. In 2010, homologous and autologous blood components (87,746 units) were exchanged for an overall budget of € 14,138,422.

Importantly, being the commercialization of blood components prohibited by law, these financial flows pertained only to expense refund.

As far as national plasma-derived blood product self-sufficiency is concerned, the situation is different. In 2011, the Italian Regions and Autonomous Provinces have reached an annual level of plasma for fractionation of approximately 750,000 kg, recording the third highest level in Europe, after Germany and France. This allows a partial, national self-sufficiency for plasma-derived medicinal products, ranging 55-70%, depending on the product concerned, with a high extent of self-sufficiency in the Centre-Northern Regions and much lower average levels in the Centre-South.

The planning methodologies adopted to define the annual programmes for national blood and blood product self-sufficiency can both accurately estimate the fundamental information and forecast on regional and national production and consumption planning in order to meet appropriate needs nationwide, including measures to cope with unpredictable shortages, like those occurred in occasion of the Chikungunya and West Nile virus epidemics.

For this purpose, the so-called *driver* blood components of annual planning (red blood cells and plasma for fractionation are quarterly (red blood cells) and monthly (plasma) monitored through a dedicated section of SISTRA. Action compliance with the annual programme is verified at least twice a year by representatives of all the system’s stakeholders in plenary sessions.

In order to cope with unplanned shortages,
since June 2011 the CNS has implemented a 24 hour national electronic bulletin in SISTRA, which allows managing occasional unpredictable shortages in real time.

As mentioned above, since December 16, 2010, the Italian blood system is called to face the challenge of upgrading its quality levels making them fully complying with the relevant European provisions, by December 31, 2014. Self-sufficiency, defined as the ability to ensure a constant and prompt availability of blood products and services all over the country, both qualitatively and quantitatively, is definitely a part of said challenge, in terms of sustainability, efficiency, effectiveness and appropriateness.

Essential bibliography

Accordo, ai sensi dell’art. 4 del D.Lgs. 28 agosto 1997, n. 281, tra il Governo, le Regioni e le Province Autonome di Trento e Bolzano sui requisiti minimi organizzativi, strutturali e tecnologici delle attività sanitarie dei servizi trasfusionali e delle unità di raccolta e sul modello per le visite di verifica, sancito il 16 dicembre 2010 (Rep. Atti n. 242/CSR)

Decreto 26 maggio 2011 “Istituzione di un elenco nazionale di valutatori per il sistema trasfusionale per lo svolgimento di visite di verifica presso i servizi trasfusionali e le unità di raccolta del sangue e degli emocomponenti (11A09651)”. GU n. 162 del 14 luglio 2011


Rare diseases

Planning framework. Rare diseases are the subject of particular attention by the Ministry of Health and the entire National Health Service (Servizio sanitario nazionale, SSN), since 1998, the year of approval of the National Health Plan (Piano Sanitario Nazionale, PSN) 1998-2000. Since then, the network of clinics competent in rare diseases, established by ministerial decree (DM) no. 279, May 18, 2001, has developed in all Italian Regions with the identification, at present, of 215 structures to which affected patients can present for diagnosis and the preparation of a therapeutic Plan (the figure does not include the clinics of the Piedmont Region).

The high number of structures distributed in the country is due to the heterogeneity of choices made by the Regions, each of which, based on the organisation of its Regional Health Service (Servizio sanitario regionale, SSR), proceeded using different criteria, sometimes for a single disease, sometimes for groups of diseases, some choosing to concentrate all powers in a single centre, others distributing them among all the other structures in the territory. In general, the structures included in the national network are of different types and legal nature (hospitals, university polyclinics, ASL clinics, IRCCS, individual operational units or ASL territorial services).

Although the national network has now reached a good level of territorial coverage, linking between the clinics, essential to optimise the path for diagnosis and treatment of people suffering from rare diseases and to improve the management of the disease, is still not fully achieved, nor is there yet satisfactory circulation of information on rare diseases, especially among health professionals involved in the early stages of the diagnostic effort.

To facilitate the implementation of the network and strengthen coordination and cooperation between the Regions in the field of rare diseases, since 2008 the Ministry of Health has given specific funding for this sector, both through the regulation of special funds intended for achieving goals of priority and of national importance and through the co-financing of specific regional projects implemented under the PSN.

The procedures for the definition and the allocation of those funds continued in 2011. In particular, with the DM of October 7, 2011, the Ministry of Health allocated Euro 4,984,727 to the Regions for co-financing of 2009 projects; in addition, the Agreement ratified by the State-Regions Conference at its meeting on April 20, 2011 (Rep. Acts 84/CSR) identified project targets for the achievement of objectives of priority and of national importance for rare diseases and confirmed that Euro 20 million would be distributed among the Regions for the year 2012. The projects presented by the Regions are mainly focussed on the enlargement of the clinical-care activity shared over the network and the development of pathways for specific diseases, with special attention to those most critical for the cases detected in the territory.

In 2011, work began on the drafting of a national Plan for rare diseases that Italy intends to adopt by 2013, in line with the recommendations of the European Commission (Recommendation 2009/C 151/02).

This Plan in line with the strategies of planning and preparation already in place in our country will have the characteristics of a framing document that will give unity to all
the actions taken and will be shared with the subjects who will make use of it at different levels. The additional function is to contribute to the better definition of priorities, so that the different institutions involved may, each at their own level, give a boost to the entire system.

The plan will cover aspects of care [the Essential Levels of Health Care (Livelli essenziali di assistenza, LEA), prevention, care pathway, medicines], organisation (the national network, inter-regional coordination), the basic tools of management of the system (the national registry, regional and inter-regional registries, the disease registries and bio banks, nomenclature and coding), training activities, information and research, and the role of associations for those who are ill.

State of implementation and description of the data. For a good governance system, it is essential that rare diseases are included in the current health care data stream, including the Hospital Discharge Form (Scheda di dimissione ospedaliera, SDO), but even now, only a part of them can be traced by a specific code in the international system of classification and coding of diseases (International Classification of Diseases, ICD) and, therefore, the source of information for these diseases is still lacking. Specific activities for the codification of rare diseases are still ongoing in the international arena, in particular by the European Committee of Experts on Rare Diseases, a working group in the process for review of classification systems carried out by the World Health Organization (WHO) and of which Italy is a part. The National Register of Rare Diseases (Registro Nazionale Malattie Rare, RNMR), established at the National Institute for Health (Istituto superiore di sanità, ISS) by the DM 279/2001 (art. 3), is the scientific instrument for the national surveillance of diseases at the central level, receiving epidemiological data from regional and inter-regional registers. RNMR operators carry out quality checks and perform analysis on the data collected.

Currently, surveillance through RNMR only affects rare conditions indicated in the DM 279/2001, which includes 284 diseases and 47 groups. The introduction of new disease entities and the complicated taxonomy of rare diseases, subject to continuous revisions resulting from research results especially in the field of genetics, are the cause of the limitations of the current list. The updating of the list and the review of the coding are necessary, therefore, not only for the definition and the adaptation of the LEA, but also for effective monitoring. The RNMR is also affected by delays in diagnosis and the consequent late reporting of cases, leading to inaccurate estimates of incidence and prevalence.

The Report on the activities of the National Register and the Regional Registries for the year 2011 was presented on February 22, 2012.

At June 31, 2011, the RNMR contained 114,936 cases of rare disease. The category of rare diseases most widely reported was that of congenital malformations with a percentage of 15.4%. Diseases of the nervous system followed (7.5%), diseases of the endocrine glands, of nutrition, metabolism and immune defects (5.8%) and diseases of the blood and blood-forming organs (1.2%). Among the groups of disease, as defined by the DM 279/2001, the most frequently reported are hereditary coagulation defects (9,721 cases), undifferentiated connective tissue (6,846 cases), and hereditary anaemia (5,793 cases).

The activities of the RNMR included initiatives to strengthen the territorial registries of rare diseases in 2011; activities are ongoing for the development of a consensus report with all Regions to increase the quality of the data and their coverage in the territory. In this way, the RNMR will not only make an estimate of the epidemiological indicators, but also monitor the welfare activities of the national network by providing support to policy-making and national planning.

The database of the Orphanet portal for rare diseases and orphan drugs, founded and managed by the French Institut National de la santé et de la recherche médicale (INSERM), receives data from collaborating institutes in individual countries. In Italy,
the database is managed by the paediatric Ospedale Bambin Gesù and has reviewed, up to December 2011, 1,802 professionals dedicated to rare diseases, 262 diagnostic laboratories that perform 3,522 types of test, 83 patient registers, and 44 networks of rare diseases.

The research is active, with 764 dedicated projects: 44% of which are basic genetic studies, 24% clinical studies, 7.5% pre-clinical gene or cell therapy studies, 6% studies dedicated to the development of diagnostic protocols, 2% studies dedicated to identification of biomarkers and 2.5% epidemiological studies. The remaining 14% are clinical trials of new drugs of interest for rare diseases.

**Essential bibliography**


The Lancet Neurology. Rare neurological diseases: a united approach is needed. Lancet Neurol 2011; 10: 109
10.1. Palliative care

The law of March 15, 2010 “Measures to ensure access to palliative care and pain therapy” was approved by Parliament on March 15, 2010. Two years after the day when the law registered the unanimous consent of the House, the review of progress of the implementation path is substantially positive. The commitment of the Ministry of Health, as enshrined in art. 1 of law 38/2010, to ensure access to palliative care and pain therapy was timely and consistent during 2011 addressing the critical issues still unresolved and proposing specific solutions. The opportunities for discussion, at the international level, have confirmed how the legislation on palliative care and pain management is comprehensive and innovative and represents an excellence in the European scene. The actions taken during this year in both areas have as main purpose the building of a support network that can offer consistent performance in the national territory, in order to allow citizens to find an adequate response to their needs. To render operational the principles of the law, two technical documents that mark a decisive step towards the development of an efficient network of care were prepared in 2011. Art. 5, comma 2, required, the identification of professionals working within the two service networks, through an agreement at the Permanent Conference for relations between the State, the Regions and the Autonomous Provinces of Trent and Bolzano. Pursuant to art. 8, with specific decrees and produced jointly by the Ministry of Health and the Ministry of Scientific Research and the University, five master training programmes were approved aimed at palliative care doctors, physicians of pain management, physicians of palliative care and pain treatment for the paediatric patient, and psychologists and nursing figures. Art. 5, paragraph 3 also required the preparation of an agreement at the Conference of the State and the Regions, in which the minimum requirements and the organisational arrangements necessary for the accreditation of structures of care for the terminally ill and units of palliative care and pain therapy directed at the adult and paediatric patient are defined. To this end, a technical document was developed, which aims to eliminate any ambiguity regarding the essential elements that must exist in residential care and home care. Equity of access (quality and appropriateness of care in a uniform way throughout the country) appears ensured by the identification of quantitative and qualitative elements that must be present in the three networks of assistance, while not interfering with the right of every patient to a customised treatment programme that meets the main needs of the patient and his family. In addition, in an area so varied with respect to the supply of services, it is important to emphasize the shared work done by the Ministry of Health, in collaboration with the “National Commission in implementation of the dictates of the law no. 38 of March 15, 2010”, and the Regions, who must then establish a system of services and facilities in line with the guidelines of the document, while respecting regional autonomy. The understanding was endorsed on the July 25, 2012 at the permanent Conference for relationships be-
tween the State, Regions and the Autonomous Provinces of Trent and Bolzano.

The development of palliative care has received a new impulse in recent years, in particular after the enactment of law 38. The subsequent preparation of technical documents, with reference in particular to the Guidelines approved in State-Regions Conference December 16, 2010 setting out the need for the presence of a regional coordination dedicated to palliative care and pain therapy, requested pathways of implementation from the Regions. However, the situation, as evidenced by Table 10.1 is still not homogeneous throughout the country, and the presence of a regional coordination within the health department is also not yet in evidence throughout the national territory.

The Regions that have a structure of regional coordination for palliative care, activated by a deliberated act, are Piedmont, Sicily, Liguria, Veneto and Lazio.

With this necessary premise, it is important to emphasise, however, the presence of commissions, committees and working groups, who are active in different tasks and operational in supporting the development of palliative care in almost all Italian Regions.

The tasks and objectives of these organisations vary, in some cases with a consolidated organisation and defined work objectives, as in the case of the Regions of Lombardy, Emilia Romagna and Umbria, in other cases, they are newly established, in a phase of some uncertainty.

Although unresolved problematical areas still appear alongside examples of good practice, overall, the network of palliative care is fairly structured and present throughout the country.

Table 10.1. Number of hospice structures and number of beds (December 2011)

<table>
<thead>
<tr>
<th>Region</th>
<th>Population (Istat 2006)</th>
<th>Total structures</th>
<th>Total beds</th>
<th>Beds per 10,000 inhabitants</th>
<th>Structures activated</th>
</tr>
</thead>
<tbody>
<tr>
<td>Piedmont</td>
<td>4,341,733</td>
<td>18</td>
<td>191</td>
<td>0.44</td>
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<td>Aosta Valley</td>
<td>123,978</td>
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<td>7</td>
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<td>Lombardy</td>
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<td>332</td>
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<td>Aut. Prov. of Bolzano</td>
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<td>10</td>
<td>0.21</td>
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<td>Aut. Prov. of Trent</td>
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<td>Friuli Venezia Giulia</td>
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<td>Emilia Romagna</td>
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<td>220</td>
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<td>Tuscany</td>
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<tr>
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<td><strong>188</strong></td>
<td><strong>2,069</strong></td>
<td><strong>0.35</strong></td>
<td><strong>120</strong></td>
</tr>
</tbody>
</table>
The North-West area of Italy (Aosta Valley, Piedmont, Liguria, Lombardy) has had important developments in residential hospice activities as well as in home-based activities, albeit unevenly, and presents a structuring adapted to the needs of patients, particularly in the Lombardy Region. Although also united in a geographical area, the significant territorial differences between the different Regions must be remembered, some large and with a large population and others with specific population density and presence of small communities located in areas not easily accessible making more difficult an organized network of home care. The lowest common denominator of an area so identified is the presence of trained professionals dedicated to palliative care, especially in Lombardy and Piedmont, motivated also by a strong tradition of many non-profit organisations that support the development of the care network.

In the North-East area (Veneto, Friuli Venezia Giulia, Trentino Alto Adige, Emilia Romagna) the offer of hospice residence has developed in a positive way in recent years. In particular should be noted the presence of a paediatric hospice in the Veneto Region, and specific regulations on the theme of palliative care following the enactment of the law 38/2010 in the Regions of Friuli Venezia Giulia and Emilia Romagna. More varied is the situation of palliative home care, as in the rest of the country, with a tendency in this area not to provide dedicated staff for this type of activity; though positive experiences of integration between professionals in the network and experimental training projects directed to this topic are developing. In the Central area (Tuscany, Umbria, Marche, Abruzzo, Molise, Lazio) there is an increase in supply of residential hospice structures, not always related to palliative home care. The models of palliative care, in particular for home assistance, are very varied, with good coverage in Tuscany, Lazio and Umbria, and other areas that have a lower level of response. Even in this case, the historical and well-established presence of non-profit organisations that support these three Regions and who have provided the care network for years, is to be emphasized. Conversely, Abruzzo and Molise Regions still need to develop a network of palliative care efficient for both residential and for home care.

Finally, in the South and Islands areas (Campania, Apulia, Calabria, Basilicata, Sicily, Sardinia), the supply of residential hospice structures has grown in recent years, except in Campania and Calabria, where the presence of structures is very poor. In these Regions, problems of coordination within the network between palliative care and home care continue to exist, as well as a lack of homogeneity in the offer also caused by the presence of budget deficits, which have serious repercussions on Regional Health Systems (Sistema sanitario regionale, SSR). However, there is a renewed interest in developing the subject of palliative care, with training programmes for professionals and campaigns to raise awareness among citizens. In addition, a regional co-ordination on the theme of palliative care should be noted, as in Sicily.

### 10.2. Pain therapy

The law no. 38 of March 15, 2010 provides the possibility of further development of the care network for pain relief, in different areas. The passing of the “Hospital without pain” project, which was approved in the State-Regions Conference in 2001 in favour of a medical offer to patients suffering from chronic pain, and renamed, as indicated in art. 6, “Hospital-Territory without pain”, anticipated the passage of assistance from a hospital-centric vision to one which provides for a greater care presence in the territory. One of the most significant differences in relation to the project in 2001 is the precise and unambiguous definition of the structure that will manage the patient, included in the
Implementation of lines of priority in order to meet health objectives

memorandum of understanding pursuant to art. 5, paragraph 3 of law 38/2010 concerning the minimum organizational and structural requirements for the definition of the network of pain therapy, with an organisation currently pending approval. The new model organised at three levels – hospitals (Hub), territorial structures (Spoke) and networks of general practitioners (medici di medicina generale, MMGs) – has been implemented in a non-organic fashion throughout the country, by different Regions. In some cases creating, as specifically approved in the Regions of Piedmont, Lombardy, Liguria, Emilia Romagna, Lazio, Basilicata, Calabria and Sicily, the coordination structures of the network of pain therapy, as indicated by the agreement of the State-Regions Conference of December 16, 2010, in other cases by regional decree, identifying the specialist facilities and hospital outpatient facilities. The “Hospital-Territory without pain” project is expected to have a total funding of Euro 2,450,000 to be distributed among the Italian Regions in the years 2010-2011. The resources available are intended to finance pilot projects in the area of the fight against pain; in particular, the lines of development that the legislature has seen fit for direction concern organisational, training and communication aspects. Given this availability of funds, it should be noted that in 2011 only six Italian Regions submitted their projects to the Ministry of Health (Emilia Romagna, Lombardy, Tuscany, Marche and Calabria). An important role is reserved for the MMG who has been delegated the function of referring the patient to the appropriate structure; it therefore appears necessary to undertake a specific training programme that will make them the reference on issues affecting painful conditions in their territory of relevance. For these reasons, all the projects submitted by the Regions mentioned have as their common denominator an important space dedicated to training on the subject of pain, aimed at both MMGs and paediatricians (pediatri di libera scelta, PLSs) of the patient’s choice, involving all those healthcare professionals who are in daily contact with the patient.

Another element that has been given special attention in 2011 is the theme of communication, with the aim to propose a cultural change in the manner of dealing with the theme of pain. A multimedia information campaign was set up, in collaboration with the National Agency for Regional Health Services (Agenzia per i Servizi Sanitari Nazionali, AgeNaS), for the creation of a poster, a logo, a slogan and a TV spot that could convey a positive message regarding the fight against pain.

The path towards the realisation of an efficient network in pain therapy still reveals some critical points. Law no. 38 provides criteria of simplification in art. 10 in the procedures for access to medicines used in the treatment of pain, with particular reference to the prescription of opioids, but this possibility has not yet reached the expected results. The comparison with other European countries, where there is a per capita Italian consumption of Euro 1.17 for strong opioids compared to the European average of 4.47 euro, shows that cultural prejudices are still complex to overcome, even if when considering the increase in the period 2010-2011 the difference starts to record significant progress. The Italian figure, moreover, describes a country split in two, both for the consumption for strong (Figure 10.1) and weak opioids (Figure 10.2), where the North recorded consumption consistent with the national average and the South a consumption below the Italian average.

10.3. Paediatric network

The creation of a network of care dedicated to the paediatric patient has been expressly provided for by law no. 38. The need for pathways independent of those of the adult patient and of needs and specific needs not assimilated into the other two care networks
Palliative care and pain therapy

has resulted in the autonomy of a dedicated model for paediatric patients. The remarkable diversity of the problems and the great variety and fragmentation of the diseases in question, often rare and requiring highly specialized interventions, should not be an obstacle to the development of a homogeneous support network based in the community. In order to optimise the structural resources and professional care of the paediatric patient, and unlike those models outlined for the adult patient, the networks of palliative care and of pain management converge into a single network, with the ref-

Figure 10.1. Pro-capita consumption of strong opioids in Euro (Year 2010).


Figure 10.2. Pro-capita consumption in Euro of weak opioids (Year 2010).

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erence centre coinciding with the Hub, with
decisive contributions from both aspects of
daediatrics, hospital and patient-selected.
The Regions may, within this conceptual
framework, provide assistance, in relation
to the characteristics of the different systems
that they operate, and in which the network
is going to develop, with the aim of improv-
ing patient management and care. To do this,
the aim is to drastically reduce the long stays
in hospital wards, focusing on the home as a
place of care or on residential facilities dedi-
cated exclusively to paediatric patients.
In order to verify the implementation of re-
gional networks of palliative care and pain
management, a specific questionnaire struc-
tured in 17 questions was sent to all the
Italian Regions during 2011, the prepara-
tion and administration of which was car-
ried out by the Ministry of Health in col-
laboration with the Conference of Regions.
The aforementioned questionnaire ensures
the commitment, on the part of all the Ital-
ian Regions, to build support in the field of
palliative care and pain therapy to paediat-
ic patients and their families.
In the Piedmont, Aosta Valley, Lombardy,
Autonomous Province of Trent, Veneto, Friu-
li Venezia Giulia, Emilia Romagna, Marche,
Lazio, Campania, Apulia and Basilicata Re-
gions the paediatric network was formally
established with a specific regional act; in
other Regions there are working groups and
technical meetings aimed at discussion and
debate on this issue. Among the Regions that
have set up the network Piedmont, Lomb-
dardy, the Autonomous Province of Trent,
Veneto and Apulia have determined by de-
cree one or more regional centres of refer-
ence for palliative care and pain therapy.
Moreover three Regions (Piedmont, Veneto
and Tuscany) have set up a residential facil-
ity (paediatric hospice) in which dedicated
health personnel operate.
The activated regional networks thereby en-
sure 100% of assistance provided to the pae-
diatric population in Piedmont and the Au-
tonomous Province of Trent (where there is a
space dedicated to paediatric patients within
three hospices for adult patients), Veneto,
Emilia Romagna and Tuscany, 75% cover-
age in Lombardy, and 50% in Basilicata.
In all Regions, a particular attention to the
issue of information and training was de-
tected. In the first case by campaigns to raise
awareness among citizens and in the second
case with training projects dedicated to the
management and care of young patients.
Thus is confirmed a general will to develop
an efficient care network, with manner and
timing of activation different between Re-
gions, but all aimed at ensuring an adequate
response to the complex needs of paediatric
patients and their families.
Maternity care and appropriateness of the birth path

11.1. Implementation of the 2010 Agreement for the birth pathway

The “Guidelines for the promotion and improvement of quality, safety and appropriateness of care interventions in the birth path” approved by Agreement at the Joint Conference of December 16, 2010 represent the means of ensuring appropriate care to women throughout the birth path, from the pre-conception to the postnatal period. In order to ensure a birth path that meets the appropriate requirements of care and safety, management and continuity of care are essential which can only be addressed through the networking of services and their institutional, management and training integration for the achievement of health objectives. The National Birth Path Committee (Comitato Percorso Nascita nazionale, CPNn), anticipated in the Agreement, is providing support to the Regions in implementing the Agreement and monitoring the actions entered into over time.

The actions required by the 10 points of the Agreement at central and regional certain actions already completed or close to being so are:

- definition of organizational, structural and technological standards for birth points (midwifery and neonatal care/TIN) that the Regions should refer to in the reorganisation of their care network;
- identification, for the first time, of the minimum standard for personnel in family planning clinics, while for the other standards, reference was made to the law 34/1996 and Project Objective Mother and Child;
- development of guidelines on physiological pregnancy and caesarean section [official presentation at the National Institute for Health (Istituto superiore di sanità, ISS) January 31, 2012];
- recommendation for the prevention of maternal mortality (already processed);
- establishment of a monitoring system of sentinel events/adverse events/near misses and related audits (now fully operational since 4 years);
- recommendation for the prevention of neonatal mortality (underway);
- implementation of FAD (Formazione a Distanza) training on clinical auditing (already underway from September 2011 and with more than 20,000 operators who have completed the FAD course);
- establishment of relationships with the MIUR for the verification and adjustment of the theoretical-practical training levels of schools specialising in gynaecology, obstetrics and paediatrics/neonatology, and of the degree course in obstetrics, to ensure that it is consistent with the standards of welfare. The review at Community level of the Directive 36/2005, with the National Federation of the College of Midwives, is being closely followed;
- creation of a Handbook: at the same time as the inauguration of the CPNn a working group was activated formed by
the major scientific societies of reference (SIMM, SIGO, SIN, SIP, SIMP) together with IPASVI, FNCO and major Associations of the sector (Active Citizenship, WAVE, the Living non-profit organisation), for the creation of a “Handbook for the quality certification of birth points”, the latter activity financed by AgeNaS, which has already prepared a first draft of the manual;
- development of a Service Charter for the birth path (underway);
- development of guidelines for hospital-territorial integration. In this regard, the organisational response of the Regions should be through the coordination of the Committee, while safeguarding their organizational models, respecting and ensuring a “lowest common denominator” in all Regions;
- implementation of a project for the Minor Islands: this has been prepared, as regional reorganisation of health services cannot take into account the peculiarities and specificity of an island territory, which for geographical features, often for weather conditions, renders complex transfers to medical facilities located outside the island, especially in emergency-urgency cases.

Much attention will be placed on the activities that the Regions put in place in respect of the implementation of the guidelines, which are undoubtedly, the most sensitive aspect in terms of change in the sense of appropriateness. The Regions are responsible for identifying problems and finding solutions to them, comparing existing practices in their own context with the standards specified, in order to identify the gap which exists through analysis of the care context at regional and local levels, and to adopt those recommendations that can/must be implemented to remove obstacles to change (or at least mitigate their effects) and identify guidelines useful for clinical care pathways that promote continuity of care and hospital-territorial integration, enhancing the role of the various professionals involved.

Point 10 of the Agreement provides for the establishment, by the Regions, of a permanent coordination function for birth paths even at the regional level [Regional Birth Path Committee, (Comitato Percorso Nascita regionale, CPNr)].

To date, almost all the Regions have formally acknowledged the Agreement (not as yet the Aosta Valley and the Autonomous Provinces), and only 7 of the 21 Regions (Abruzzo, Calabria, Emilia Romagna, Molise, Apulia, Sicily and Umbria) have formed a CPNr, while 2 Regions (Friuli Venezia Giulia and Veneto), despite not having set up a CPNr, have appointed a coordinator.

The low participation of some Regions in the initiatives activated to date should be noted, as well as the total silence from Campania, Lazio and Sardinia, regardless of various reminders.

Among the requirements and evaluation criteria for the review of the Essential Levels of Health Care (Livelli essenziali di assistenza, LEA) the following will be considered as key points:
- the implementation of the State-Regions Agreement of December 16, 2010 and the establishment of CPNr;
- the reorganisation of regional Birth Points based on the lines of guidance of the December 16, 2010 Agreement, subject to any justified exceptions with respect to the principle of a value of more than 500 births/year per structure.

The Regions were provided with the forms prepared by the CPNn regarding the conduct in each Region of an accurate perinatal audit in the birth points (obstetric and neonatology units) and a check of the standards set forth in the Agreement. The Regions have been asked to submit a report on the implementation of individual actions provided for in the Agreement to the CPNn as from June 2012, and then every six months.

**Essential bibliography**

Accordo ai sensi dell’art. 9 del D.Lgs. 28 agosto 1997, n. 281, tra il Governo, le Regioni e le Province Autonome di Trento e Bolzano, le Province, i Comuni e le Comunità montane sul documento recante “Linee di indirizzo per la promozione e il miglioramento della qualità, della sicurezza e dell’appropriazione degli interventi assistenziali nel percorso nascita e per la riduzione del taglio cesareo”. Rep. Atti n. 137/cu del 16 dicembre 2010
11.2. Birth by Caesarean section: analysis of regional variability

The objective of the Agreement as set out in the Joint Conference of December 16, 2010 was to improve the appropriateness of assistance offered to pregnant women during the entire birth path, implement the hospital-territorial integration and ensure organisational, structural and technological standards in birth points and in territorial services (particularly family planning clinics) and to achieve a reduction in the excessive recourse to Caesarean section.

The available evidence, with regard to Caesarean section and, in general, care during pregnancy and childbirth, confirms the increase in Italy’s use of a set of procedures whose value is not based on scientific evidence and is not supported by a real increase in risk conditions. Their use is often completely independent of socio-demographic characteristics of women and their clinical condition and is instead primarily associated with the availability in the structures involved and their organisation.

In Italy in 2008 about 220,000 Caesarean section operations were performed, with a significant human and economic cost: the risk of maternal death is in fact 3-5 times higher than that of birth by vaginal delivery, and puerperal morbidity is 10-15 times higher. In 2010, the number of births by Caesarean section reduced to little more than 211,000. There remains a very high variability of recourse to Caesarean section in the territory: in general, the Regions in the South have a rate of Caesarean delivery greater than 40% and also present a considerable variability within the Region, thus characterised by the presence of structures with exceptionally high Caesarean delivery rates.

The percentage of Caesarean sections was analysed according to Robson’s Ten Group Classification System and the amplitude of the birth point (Figure 11.1). The classification has among its objectives that of dividing births into a limited number of reproducible classes that are homogenous when considered according to the category of pregnancy, obstetric case history and type of labour and delivery, comparable between different geographical areas and different birth points. The analysis was performed using data from the survey of delivery assistance Certificates (CeDAP) in 2009; the CeDAP certificate provides all the necessary variables for the Robson classification.

The association between the size of the birth point in terms of the number of births annually and the incidence of Caesarean sections, is negative and seems more pronounced in the 2, 4 and 9 Robson categories of birth in which expert obstetric care, medical and technology care is required to guarantee adequate levels of safety both during labour and delivery. It is of interest also to note how in class 2 (nulliparous women, single foetus, cephalic presentation, at term-induced labour or elective Caesarean) and class 4 (multiparous women, single foetus, cephalic presentation, at term-induced labour or elective Caesarean section and without previous Caesarean section) the two components (Caesarean section after failed induction and elective Caesarean) exhibit very different rates.

While there are no huge variations between Caesarean sections subsequent to induction of labour between the birth points with ≥ 2,500 births and those with < 500 births (differences of 24.5% to 31.2% for class 2 and 6% to 8.5% for class 4, for ≥ 2,500 and < 500 births, respectively), considerable differences exist with regard to elective Caesareans. Indeed, these represent the type of Caesarean that contributes most to the value of these classes (differences of 28.4% to 69.3% for class 2 and 27.7% to 50.6% for class 4, for ≥ 2,500 and < 500 births, re-
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11.3. Promotion, safeguarding and support of breast-feeding

The National Multi-sectoral Committee for Breastfeeding has been set up at the Ministry of Health in line with the “National guidelines for the protection, promotion and support of breastfeeding” (State-Regions Agreement December 2007) without additional costs for public finance. The Committee consists of representatives of various departments (Ministry of Education, University and Research, the Ministry of La-


d respectively). Very important differences are also present in geographical Regions with higher values in the Southern Regions and the Islands compared with others.

Essential bibliography


Figure 11.1. Percentage of Caesarean sections according to the Robson classification and the size of the birth point (Year 2009).
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bour and Social Policy, Department of Family Policies), UNICEF, the World Health Organization Collaborating Centre for Maternal and Child Health (WHO), the ISS, as well as representatives of the scientific Enterprises involved in paediatrics, neonatology and gynaecology, and health profession associations. The activities of the Committee are intended to facilitate the effective operation of a national network of protection, promotion and support of breastfeeding. The objectives as set out in the aforementioned guidelines will be achieved in this way.

Among the proposals advanced is the changing of the CeDAP model (Delivery Assistance Certificate) required to collect standardised information across the national territory in relation to the type of breastfeeding and hospital practices on child nutrition in the first 72 hours after birth. A system of indicators was established, using UNICEF-WHO guidance, to create a data collection system as homogeneous as possible throughout the country (birth – 3 months – 6 months).

Furthermore, given that the issue of monitoring of rates of exclusivity and duration of breastfeeding after discharge from the hospital has a particular importance, a document aimed at defining guidelines of national importance was submitted to the Conference of Regions (Interregional Coordination for Food Safety). It is proposed to monitor the rates of breastfeeding with data collected during the sessions of vaccination, i.e. at about 3, 5 and 11 months of age according to the current vaccination schedules. This proposal has the advantage of bringing monitoring and resulting data near to the end user: health care operator, paediatrician, district manager, staff of the departments of prevention (including SIAN), responsible for planning and evaluation at institutional and regional level. Among the Committee’s work, the request to the Regional and Autonomous Provinces Health Departments of a report on the programmes, projects and/or studies in the territory, either completed or under construction, on matters pertaining to the protection, promotion and support of breastfeeding, should be mentioned.

Some plans were subject to evaluation by the Ministry of Health within the National Prevention Plan (Piano Nazionale di Prevenzione, PNP) 2010-2012, signed with the Agreement of April 29, 2010 at the State-Regions Conference. For 2011 and 2012, the progress in the implementation of the interventions planned by the Regions will be assessed and the results obtained compared with the stated goals.

Based on the experience gained so far in the analysis of the issue, and the fact that the national guidelines provide for collaboration between the Ministry of Health and the Ministry of Education, University and Research, the Committee proposed the establishment of two inter-ministerial working groups:

- the first, in collaboration with the Directorate-General of Human Resources and health Professionalism of this office, which will review the curriculum for all health professions relevant to the identification of criteria for the selection of curriculum vitae;
- the second will be for the educational pathways for breastfeeding within schools of all grades and levels to raise awareness of the subject among school administrators and teachers, in accordance with institutional autonomy.

The need to disclose the contents and promote respect for the “International Code of Marketing of Breast-milk Substitutes” has led the Committee to take action on the marketing of infant formulas. This action is required to demonstrate that, while appreciating that when mothers do not breastfeed or only do so partially there is a legitimate market for infant formulas and for suitable ingredients in their preparation, these formulas should not be marketed or distributed in ways that would interfere with the protection and promotion of breastfeeding. To this end, the document “Commitment to self-regulation by scientific Enterprises, professional bodies and associations which are members of the multi-sector Committee for breastfeeding in dealing with industries that make products covered by the International Code” prepared and signed by the Scientific Enterprises and professional groups and associations represented on the Committee,
should lead, progressively, to a decrease in violations of the International Code for better protection of breastfeeding.

Among the communication actions taken by the Committee special attention goes to the Campaign “Mothers and breastfeeding festival”, which was held in 2010 in Campania (Naples, Caserta) and Sicily (Messina and Palermo), and in 2011 in Apulia (Foggia and Bari) and Calabria (Cosenza and Reggio Calabria).

The communication campaign, which originated from the desire to raise public awareness about the value of breastfeeding, is an important action that involves the Ministry of Health and the regional and local realities in order to maintain high attention and sensitivity on the problems of the same, involving progressively the whole country and especially those Regions where breastfeeding rates are less than satisfactory.

In agreement with that indicated in the guidelines (“maternal milk, whether from the breast or from a milk bank of breast-milk provided by the mother or another donor, is also, where not otherwise indicated, the food most suited to the nutritional requirements of prematurely-born infants in hospital care”), a small technical group was formed as part of the Committee’s area of expertise, comprising some members of the Committee itself as well as national experts in the sector, who began the work intended to produce a document relative to the organisation and management of banks of donated human milk, as part of the protection, promotion and support of breastfeeding.

**Essential bibliography**

Ministero della salute. “Linee di indirizzo nazionali sulla protezione, promozione e sostegno dell’allattamento al seno” approvate in Conferenza permanente per i rapporti tra lo Stato, le Regioni e le Province Autonome di Trento e Bolzano – 20 dicembre 2007

### 11.4. Activity arising from the obligations of DM 82/2009 on infant formulas and follow-on formulas

In 2009, the ministerial decree (DM) no. 82 “Regulation on the implementation of Directive 2006/141/CE for the part relating to infant formulas and follow-on formulas intended for the European Community and for export to third countries” entered into force which implements the Directive 2006/141/CE and which disciplines infant formulas and follow-on formulas.

This measure made the notification prior to marketing of infant formulas compulsory; in detail, 53 products were examined in 2011. The same regulation stipulates that the Ministry assesses conferences that deal with nutrition for infants, in terms of validity of the content and method of dissemination of correct information in that area.

For this purpose, a working group within the Ministry was established with the responsibility for assessing that the scientific congresses and events that have as their subject the nutrition of early childhood, are oriented to the dissemination of adequate and correct knowledge in the food of pregnant women, of infants and young children and related diseases, and possess the technical and scientific objectives for an effective professional development. If necessary, the group estimates whether, for these types of meetings, the conditions exist to apply the exception to the ban on sponsorship by companies involved in the food for infants sector. In 2011, 150 meetings were evaluated, of which five had an unfavourable outcome.
In 2011, the Ministry of Health took on the task of collaboration with the Regions in the field of mental health, focussing efforts on two specific areas of strategic intervention:
■ the joint drafting of the “Plan of Action for Mental Health” (Piano di Azioni per la Salute Mentale, PANSM) was completed which is now being forwarded to the Joint Conference for the conclusion of the Understanding. The objective of the Plan is to ensure effective and verifiable results through the definition of the objectives of health for the population, the declination of the priority actions, and the definition of criteria and the indicators to be used in the evaluation;
■ a specific document of guidelines for action in the field of autism was drawn up, which will soon be discussed in the technical meeting of the Joint Conference. The aim of the document is to review the priorities in the area, discuss the offer of services in order to improve the appropriateness and quality of interventions based on scientific evidence and evidence.
Another priority line of action has been that of prison Health and the process of phasing out of the Judicial Psychiatric Hospitals (Ospedali Psichiatrici Giudiziari, OPGs).
The DPCM of April 1, 2008 (and in particular with Appendices A and C) governed the procedures and criteria for transfer of medical duties, labour relations, financial resources, equipment and capital goods in the field of prison health to the National Health Service (Servizio sanitario nazionale, SSN).
Following the transfer, the Regions and health authorities assumed the responsibility for health care in prisons, in OPGs and in the institutions and services of juvenile Justice, with the exception of Sicily, which to date has not yet completed the transposition. Monitoring of the implementation of the DPCM was carried out by the “Inter-Institutional Committee for prison health” through a series of hearings of the Regions carried out to detect problems and suggest appropriate health responses.
The completion of the entire pathway was in turn supported by the stipulation of applicable Agreements.
For example, in the context of mental health care in the penitentiary environment, the agreement on the “Guidelines for the reduction of self-injurious and suicidal risk” in the prison population may be cited, which arose from the need to respond to the increase in the number of suicides in Italian prisons in terms of prevention.
With regard to the complex issue of the closure of the OPGs, it is recalled that six are still active in Italy:
■ Castiglione delle Stiviere (MN);
■ Reggio Emilia;
■ Montelupo Fiorentino (FI);
■ Napoli;
■ Aversa (CE);
■ Barcellona Pozzo di Gotto (ME).
During the year, a series of documents were drawing up that contributed to the drafting of art. 3-ter, subsections 2 and 3, of legislative decree December 22, 2011, no. 211,
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with which the closure of existing structures is formalised.
Without prejudice to the continuation of direct management by the Departments of Mental Health (Dipartimenti di Salute Mentale, DSMs) of subjects suitable for release, already included in the prime ministerial decree (DPCM) of 2008, a parallel activation of small regional structures was established, designed to accommodate the persons currently in OPG who not meet the criteria of suitability for release.

Currently, the Ministry of Health, the Ministry of Justice and the Regions are working to define what is necessary for the application of the provisions of the law, including the criteria for the accreditation of the quoted structures.

Essential bibliography
Decreto del Presidente del Consiglio dei Ministri 1 aprile 2008, GU Serie generale n. 126 del 30 maggio 2008
Decreto legge 22 dicembre 2011, n. 211, GU Serie generale n. 297 del 23 dicembre 2011

12.2. The protection of mental health in a pharmacological context

The protection of mental health of the population is one of the primary objectives of a country and contributes to the determination of its degree of civilisation. The term “mental health” as defined by the World Health Organization (WHO), refers to a state of emotional, psychological and social wellness in which the individual is able to exploit his cognitive or emotional abilities, carry out his role in society, establish satisfactory relations with others and adapt to external conditions and internal conflicts. Mental health, perhaps even more than in other therapeutic areas, cannot refer solely to the absence of disease.

WHO data show that brain disorders account for 35% of all diseases in Europe, that every 40 seconds, someone commits suicide, and that 50 million people worldwide are suffering from epilepsy. In 2020, depression will be the second leading cause of death and disability after cardiovascular diseases. The Italian analyses of pharmaceutical consumption also show a movement in this direction. According to the OsMed report that collects data on the National pharmaceutical expenditure and consumption from January to September 2011, in fact, medicines for the treatment of diseases of the central nervous system (CNS) are in fourth place by amounts prescribed, with 58.2 daily doses consumed per 1,000 inhabitants. Within the group of medicines for the CNS, the most prescribed by territorial area are antidepressants, in particular active ingredients such as paroxetine, escitalopram, sertraline, citalopram and venlafaxine. As for public consumption, the first place including haloperidol among typical antipsychotics and olanzapine, quetiapine, risperidone and aripiprazole among atypical antipsychotics.

The data indicate the need to formulate more effective intervention strategies to promote and ensure better protection of mental health. Mental disorders are one of the major sources of suffering for patients and their families as well as a heavy burden for the NHS and for the country (in lack of productive capacity or days of absence from work). For this reason it’s necessary to set out surveillance tools and appropriate monitoring systems.

It is also essential, in order to make available innovative drug treatments that are still required for many brain disorders, to promote research and development through a greater number of dedicated experiments. Since the process of development of new drugs for the treatment of mental disorders requires long lead times and large investments, pharmaceutical companies apparently seem less interested in this field. Consequently, the therapeutic
categories of medicines that operate in the CNS field still have a low level of innovation. Within this framework the intervention of the institutions is strategic, at all levels, and for this reason the Italian Medicines Agency (Agenzia Italiana del Farmaco, AIFA), considers innovation in the field of neurological and mental disorders as an economic and cultural challenge to be dealt with and therefore intends to further enhance:

- the activity of scientific-technical consultation both nationally and internationally;
- the cooperation between regulatory agencies and all organizations which increasingly employ Health Technology Assessment strategies in order to identify a sustainable approach for the development of new drugs in this area.
Planning framework. Healthcare-associated infections (HCAI) have been a major issue for many years in public health in terms of the quality of care, cost of hospitalisation and the damage that these infections can lead to in terms of increased patient morbidity and mortality.

Since 2006, the Ministry of Health along with the National Centre for Disease Prevention and Control (Centro nazionale per la prevenzione e il controllo delle malattie, CCM) has activated a number of projects and conventions on this issue, including: “National Project for Safe Care” with the title of “Prevention and Control of healthcare-associated infections”, which, under the leadership of Emilia Romagna, has involved all the Italian Regions; two conventions on “Patient Safety and Infectious Risk” and the convention “Support of integration of the surveillance systems of infections associated with the care and surveillance of tuberculosis”.

These projects produced some scientific and technical documents, including the “Compendium of the main measures for the prevention and control of healthcare-associated infections” and a paper on the surveillance of sentinel organisms.

Given the public health importance of this issue, many Regions have included the supervision and control of HCAIs in their Regional Prevention Plan, as regional prevention projects.

All projects received a favourable opinion from the competent Office of the Ministry of Health for the year 2010; reporting on process indicators for the year 2011 is awaited.

In September 2011, a questionnaire was received from the European Centre for Disease Prevention and Control (ECDC) on measures of implementation of the Recommendation of the European Council of June 9, 2009 on patient safety and the prevention and control of HCAIs. The questionnaire included a part of national competence and a part of regional competence. Therefore, the questionnaire was sent through the Interregional Coordination of Prevention to regional contacts.

Description of the data. 8 Regions responded to the questionnaire: Piedmont, Liguria, Autonomous Province of Trent, Aosta Valley, Lombardy, Friuli Venezia Giulia, Emilia Romagna and Apulia.

The results of the questionnaire show that 7 out of 8 Regions have a strategy for the prevention and control of HCAIs, in accordance with the guidelines in force at national level; 7 Regions have in place action plans that include the publication of Guidelines for HCAIs, implementation of the standard sanitation measures for HCAI prevention and adoption of preventive measures, risk-based in all health facilities, and monitoring and reporting programmes on the measures of prevention and control for health personnel who assist certain types of patients; 3 Regions are considering in their action plans, the promotion of adherence to the measures of prevention and control of HCAIs so as to obtain public accreditation of the structure by the Region; 1 Region is carrying out the surveillance of the HCAI with prevalence studies; 1 Region is doing ongoing surveillance of the HCAI, with assessment of the
impact of certain types of HCAI, in order to provide useful data to national and regional level, and monitoring of infections by sentinel pathogens; 1 Region is carrying out the surveillance of alert organisms. All other regions use prevalence studies, the surveillance of the incidence of more frequent HCAI, the monitoring of infections by sentinel pathogens and analysis of indicators of structure and process to evaluate the strategy for the prevention and control of HCAIs. All the Regions who responded to the questionnaire have in place the following programmes and plans of action at the level of care facilities: programmes for measures of control and prevention of HCAIs, which involve organisational and structural aspects of the facilities of assistance, diagnostic and therapeutic aspects relative to HCAIs; workgroups of health care workers assigned to the control of HCAI, monitoring of the surveillance of the most representative HCAIs at national/international levels and monitoring of sentinel pathogens events; personnel assigned to the training of health workers on HCAI hygiene practices and control measures, and updating procedures in laboratory methods documents; and information for patients on the prevention of HCAI and evaluation of the implementation of HCAI control measures by indicators of process and structure.

Presentation and critical evaluation of the data. In light of the above, it appears that national and regional prevention of HCAIs has become a major concern of public health. However, further efforts must be made to implement the surveillance, prevention and control measures of HCAIs in all Regions and implement actions of “stewardship”, through the preparation of guidance documents and through the establishment of surveillance systems on a national basis for data collection, which can be shared with Europe, in order to assess more effectively the impact of these diseases.

Essential bibliography


13.2. Monitoring of the phenomenon of antibiotic resistance

Planning framework. The emergence of bacterial strains resistant to antibiotics is a well-known phenomenon among clinicians and microbiologists that first made an appearance after the placing on the market of the first antibiotics in the 1940s.

The documents published by the World Health Organization (WHO) in 1998, and the “The Microbial Threat” conference held the same year in Copenhagen, confirmed that the Member States of the European Community had to stiffen or reinforce sur-
Implementation of lines of priority in order to meet health objectives

surveillance networks for AMR (antimicrobial resistance) and to promote training and information campaigns for the prudent use of antibiotics. From the regulatory point of view, the European Community with the “Recommendations of the European Council on the prudent use of antibiotics in human medicine” of November 15, 2001, and in subsequent papers published in 2008, reaffirmed the importance of the existence of co-ordination structures at the national level and the strengthening of epidemiological surveillance and laboratory networks for the monitoring and control of AMR.

Since the 1990s, the European Community has supported the European System of Surveillance of antibiotic resistance programme (Early Antimicrobial Resistance Surveillance System, EARSS), supported by the Directorate-General for Health and Consumer Protection (DG-SANCO) of the European Commission; since 2010, under the name EARSS-net, this programme is co-ordinated by the ECDC in Stockholm.

The figures supplied by the National Institute for Health (Istituto superiore di sanità, ISS) to EARSS-net denote that Italy is one of the European countries most affected by the phenomenon of AMR. The results reported in 2010 show that 37% of Staphylococcus aureus strains are methicillin-resistant (MRSA), a stable trend in recent years. In addition, there was an increase in the percentage of strains of Escherichia coli resistant to fluoroquinolones to approximately 39%, and an increase of around 15% in the frequency of infection of Klebsiella pneumonia strains resistant to carbapenem, compared with 2009.

**State of implementation in regional contexts.** Since 2008, the ECDC has campaigned for the prudent use of antibiotics, targeted, respectively, at the public, general practitioners (medici di medicina generale, MMGs) and hospital doctors.

Some Regions have promoted training events throughout the area and in Local Health Authorities to coincide with the events promoted by Europe.

In November 2011 the Ministry of Health launched the “IV European Day on prudent use of antibiotics”, in conjunction with the European initiative, for the celebration of which were involved experts in the field from central institutions, hospital physicians, pharmacists and regional representatives, in order to discuss the activities put in place to deal with the phenomenon of AMR.

**Description of the data.** The following initiatives were noted among the Regions that participated in the event:

- the Piedmont Region, in the context of programmes of surveillance, prevention and control set up by the regional Circular “Guidelines for the implementation of programmes of surveillance and control of HCAIs in the Piedmont Region” in November 1997, annually values the process indicators on surveillance of healthcare-associated infections and prepares a report on the frequency of isolation of antibiotic-resistant strains, including MRSA strains; in addition, hygienic control measures have been arranged, including the precautions for contact with and isolation of patients infected by AMR bacteria, and training activities for health personnel were conducted;

- the Lombardy Region, in the context of an organisational model provided for by the regional decree 7846 of July 2009, enhanced epidemiological AMR surveillance at the regional level as part of the surveillance of hospital-based infections (INFOSP), and established technical study groups from 2007 onwards, including the monitoring of Staphylococcus aureus bacteremia (BASALOMB) and monitoring of antimicrobial resistance (RESILOMB). Such monitoring provides a stream of Web-based data, through which information on the laboratory carrying out the diagnosis, type of hospital ward and the type of bacteria isolated is collected;

- Emilia Romagna established a regional programme of AMR surveillance that provides for surveillance of antibiotic-resistant bacterial infections, reported by hospital laboratories (76-100% of public laboratories), for monitoring of infections by sentinel microorganisms, for monitoring of in-
fections related to assistance (surgical site infections, pneumonia caused by ventilator, infections in intensive care, etc.). These activities are accompanied by the publication of updated guidelines on AMR, from monitoring of antibiotic use, to training events for health staff on AMR. Monitoring is based on the transmission of AMR data via the web from laboratories of public hospitals, collected every six months; these data are integrated with those from hospital discharge records, from hospices, and the pharmaceutical distribution network, both for the assessment of the risk of contraction for some infections and for carrying out ad hoc studies. From the organisational point of view, this model involves meetings at the institutional and regional levels to compare experiences, problems and possible solutions;

- the Tuscany region conducts projects of AMR surveillance, coordinated by university Hospitals. These projects involve the application of AMR monitoring and control measures, applied to the institutional environment, with regular checks of the effectiveness and adherence to action plans and the evaluation of the feasibility of care pathways in the event of epidemic outbreaks of bacteria resistant to antibiotics.

**Presentation and critical evaluation of the data.** From the above, it is clear that, despite some regional experiences denoting the activation of ad hoc organisational models, it is necessary to have guidelines at national level in order to better coordinate the activities of prevention and control of AMR. The activation of a network of national AMR surveillance is expected in the new model for the web-based transmission of infectious disease data under construction at the Directorate-General of Information Systems (with technical-information contribution of the Directorate-General of Prevention). This national AMR surveillance network is the necessary basis to provide data that can be used to assess the impact of this problem in public health.

**Essential bibliography**


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### 13.3. Sentinel events

The State-Regions Understanding of March 20, 2008 provided for the establishment of the National Observatory for the Monitoring of Sentinel Events (Osservatorio Nazionale di Monitoraggio degli Eventi Sentinella, OsMES) at the Ministry of Health, to which such events are reported through the Information System for the Monitoring of Adverse Events (Sistema Informativo per il Monitoraggio degli Eventi Avversi, SIMES), established by the decree of December 11, 2009. A report was produced on the activity of the Observatory and published on the Ministry website, with the data reported for the first 5 years of operation (September 2005/December 2010).

In the indicated period, 1,047 reports of sentinel events were received and 873 of these were validated as at December 31, 2010 (Table 3.1).

Suicide is the event most commonly reported (19%) and the mortality rate is 45.36%. Regarding the places where suicide occurred, 37.5% occurred in hospital patient
rooms, while 22.1% occurred in the operating room. The specialities most affected by events were obstetrics and gynaecology, general medicine, general surgery and orthopaedics and trauma. The most common contributing factors were health technologies, drugs, guidelines and barriers to adequate care (355).

After 5 years of operation, it can be said that:
- in all the Regions and Autonomous Provinces there is a SIMES contact person;
- in 19 Regions and Autonomous Provinces data entry is done with the web-based application (SIMES), in 1 Region data flows are sent through the Management of Reception of Data Flows, in 1 Region notifications are still done on paper.

Based on information derived from the monitoring of sentinel events, the Ministry identified a number of critical issues and, to make the system more efficient, provided for some changes to be made to the SIMES application. In particular, the system can separately manage the annulment of the A and B notifying forms and provide for a more accurate monitoring of the proposed action plans and associated indicators. These changes will make the best use of the instrument and facilitate monitoring activities at both central and local level.

**Essential bibliography**


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**Table 13.1. Distribution of sentinel events**

<table>
<thead>
<tr>
<th>Type of event</th>
<th>N.</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Suicide or attempted suicide of a hospitalised patient</td>
<td>166</td>
<td>19.0%</td>
</tr>
<tr>
<td>Death or serious harm due to patient fall</td>
<td>147</td>
<td>16.8%</td>
</tr>
<tr>
<td>Any other adverse event that causes death or serious harm to a patient</td>
<td>134</td>
<td>15.4%</td>
</tr>
<tr>
<td>Instrument or other material left inside the surgical site requiring further surgery or other procedures</td>
<td>76</td>
<td>8.7%</td>
</tr>
<tr>
<td>Unexpected death or serious injury following a surgical procedure</td>
<td>76</td>
<td>8.7%</td>
</tr>
<tr>
<td>Death or permanent disability in healthy newborn weighing &gt; 2,500 grams not related to congenital illness</td>
<td>52</td>
<td>6.0%</td>
</tr>
<tr>
<td>Acts of violence against health workers</td>
<td>48</td>
<td>5.5%</td>
</tr>
<tr>
<td>Transfusion reaction resulting from ABO incompatibility</td>
<td>44</td>
<td>5.0%</td>
</tr>
<tr>
<td>Death, coma or severe functional impairment resulting from errors in medication</td>
<td>35</td>
<td>4.0%</td>
</tr>
<tr>
<td>Maternal death or serious illness related to labour and/or delivery</td>
<td>31</td>
<td>3.6%</td>
</tr>
<tr>
<td>Wrong procedure performed on correct patient</td>
<td>17</td>
<td>2.0%</td>
</tr>
<tr>
<td>Death or serious injury resulting from incorrect attribution of triage code in the 118 operations centre and/or in the emergency facility</td>
<td>16</td>
<td>1.8%</td>
</tr>
<tr>
<td>Procedure in the wrong patient</td>
<td>11</td>
<td>1.3%</td>
</tr>
<tr>
<td>Death or serious injury resulting from a malfunction in the transport system (intra-hospital, extra-hospital)</td>
<td>9</td>
<td>1.0%</td>
</tr>
<tr>
<td>Surgical procedure on the wrong body part (side, organ or site)</td>
<td>8</td>
<td>0.9%</td>
</tr>
<tr>
<td>Violence towards hospitalised patient</td>
<td>3</td>
<td>0.3%</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>873</td>
<td>100%</td>
</tr>
</tbody>
</table>
13.4. Recommendations

In the context of interventions for clinical risk management and patient safety, the Ministry of Health and the Directorate-General of Health Planning, on the basis of information provided by the monitoring of sentinel events, have taken steps to develop and disseminate currently thirteen specific documents, or Recommendations, available on the website of this Department. These are designed to provide effective tools to reduce risks and promote accountability on the part of the operators, but, above all, encourage institution-wide responses in order to facilitate change of the system.

The Authority managements must constantly monitor the adoption and results following the implementation of the recommendations. The Recommendations were developed following a participative process, which anticipates sharing between the Regions and Autonomous Provinces, national experts, scientific companies and representatives of professionals and citizens associations, in the spirit of co-operation with the Technical Committee of the Regions and Autonomous Provinces for the Safety of the patient, and are documents “open” to update and suggestions from outside through the possibility of feedback from the health professionals who are the recipients of the text.

In view of the number of cases and the severity of the effects, especially in elderly patients, in a range of care facilities, Recommendation no. 13 was published in November 2011, dealing with the prevention and management of a patient fall within the health care facilities, to prevent the occurrence of the sentinel event “Death or serious harm due to patient fall”. The purpose is to lessen the risk of falling and, in the case of the event occurring, to minimise the consequences through early and appropriate intervention.

The proposed actions involve the overall structure, with responsibilities at both management and operational level, to identify the individual patient risk profile in relation to personal and environmental factors, to define preventive measures, taking into consideration the factors of protection and precaution, to activate an urgent action procedure in the case of a fall, and a system for reporting events and missed events that would allow the adoption of the most appropriate corrective measures and the provision of information to health operators. Lastly, the strategic role of training for all staff in relation to awareness of risk factors and prevention strategies is emphasised, as well the maintenance of vital functions in the event of trauma, and limitation of restraint. The document highlights the need to provide operational tools to provide an adequate continuity of care in order to protect the health care procedure in the specific context.

Essential bibliography


13.5. Safety in the operating theatre

Surgery, due to the high complexity that distinguishes it, is one of the environmental contexts in which it is necessary to ensure high levels of security, as adverse events in this area represent a substantial proportion of the total, both globally and in our country. The surgical safety checklist for the operating room, the use of which has been introduced in the health systems of many countries, is a valuable tool to promote adequate
levels of quality and safety. In Italy, activities were promoted to encourage widespread use of the operating room checklist and in 2010 the Ministry produced a Manual with the 16 Recommendations, accompanied by a surgical safety checklist which was developed from the WHO checklist and adapted to the Italian context.

Over the past twenty years, the implementation of so-called robotic surgery or “tele-surgery” has had a remarkable development, that which sees the use of a robotic device called a surgical robot in operating theatres; for that reason, a survey was done on the prevalence of these instruments with the aim of improving the efficiency and effectiveness in their use to improve quality and safety of care, as has been done for other technologies. The use of a surgical robot has the advantage of increasing the dexterity of the operator and facilitating a more ergonomic position at the console by the surgeon, as well as minimising the risks of contagion.

With regard to the surgical safety checklist, a national survey was conducted in 2011 in the context of actions by the observatory for the monitoring of safety in the operating room at the Ministry of Health and the Department of Planning and Organisation of the SSN - Directorate-General of Health Planning, for the purpose of verifying the state of implementation of the checklist. The survey involved accredited public and private surgical providers for inpatients. Compliance with the survey was optimal, all the Regions and Autonomous Provinces completed the questionnaire prepared by the Ministry. Twelve Regions and Autonomous Provinces carried out verification and monitoring of implementation for the surgical safety checklist, while 5 showed these activities were “in progress for the year 2011”; 7 of the Regions and Autonomous Provinces formally adopted the Manual for Safety in the Operating Theatre and the surgical checklist. Descending from the regional to the authority level, 263 structures including ASL, AO, AOU, university polyclinics, IRCCS and classified hospitals responded to this survey. Of the 263 responding structures, 83.4% (219) of them have implemented use of the manual for safety in the operating room, 91.6% (241) adopted the safety checklist in the operating room and 81.6% (215) identify a responsible authority person or a coordination group for the checklist. Of the 3,914 Operating Units that provide inpatient surgical services, it appears that 2,898 (74%) of them are using the checklist.

In order to assess the level of dissemination of robotic systems, a survey was conducted through a questionnaire on behalf of the National Institute for Health, which showed that the disciplines in which a surgical robot is used are urology, general surgery, gynaecology, heart surgery and otolaryngology. The investigation revealed a wide variability in the data relating to the number of interventions carried out with a surgical robot, both as an annual figure and in relation to the total of surgical procedures carried out since the introduction of the equipment, which does not allow for evaluation of whether there has been appropriate usage or under-usage of the equipment. Further study therefore seems necessary in the light of medical governance, to allow appropriateness, efficacy, quality and safety of care to be combined with a rational management of financial resources.

**Essential bibliography**


Merry AF. Role of anesthesiologists in WHO safe surgery programs. Int Anesthesiol Clin 2010; 48: 137-50


13.6. The risk of infection in relation to donation and transplant procedures

The “National Report on Procedures for Donation and Transplantation with reference to safety and quality”, prepared in 2007 in conjunction with the National Transplant Centre, allowed the excellence of the transplant system in our country to be demonstrated. At the same time, it revealed the need to examine the areas of technology, organisation and management of laboratory activities related to the procedure of organ donation/transplantation and the degree of sharing and integration between regional transplant centres and laboratories more closely, for the purposes of security against infectious diseases. Laboratory activities are involved in a decisive way in defining the levels of risk for the use of organs and tissues. Their support in screening potential donors for infectious diseases is substantial, both in relation to common infections such as HIV, HCV and HBV, and infectious diseases hitherto little-known or widespread such as A/H1N1 influenza or the febrile Chikungunya disease and West Nile virus, which can likewise affect or preclude organ donation.

**Actions taken.** A Commission set up by the Ministry of Health and the National Transplant Centre, performed an audit at the 19 Regional Transplant Centres and two laboratories in all the Regions and Autonomous Provinces involved in transplantation, selected based on predetermined criteria and shared with the regional Departments. This activity resulted in a document that, through the analysis of data collected during the Site visits, identifies five guidelines to ensure and improve the quality and safety of the activities of the laboratories involved in the process of organ donation and transplantation: 1) commitment of Regional Coordination; 2) operator training; 3) organisation, formal recognition and quality management; 4) computerisation and data traceability; 5) technologies and volumes of activity.

The rationale of these guidelines is to stimulate transplant donation activity to conform to a national networked system; one that has as its strong points the promotion and dissemination of the culture of safety, extended to all levels of the transplant network, in line with the principles of clinical governance, according to the guidelines of the National Health Service (*Servizio sanitario nazionale*, SSN).

**Essential bibliography**


13.7. LASA medicines

Preventing errors in the course of medicinal therapy (errors in therapy) is also considered a priority of health care in our country. In view of this, the Third Office of the Directorate-General of Health Planning of the Ministry of Health has been carrying out a specific project since 2008 – “LASA medicines and Patient Safety” – on safety related to the use of so-called “Look-Alike/Sound-Alike” or “LASA” medicines, an Anglo-Saxon acronym used to refer to medicines that can be mistaken for others due to the graphic and/or phonetic name similarity between them.

**Actions taken and future planning.** The methodology used involved the activation on the Ministry website, as of November
Implementation of lines of priority in order to meet health objectives

2008, of a special section dedicated to the project with an email address (terapiaesicurezzapazienti@sanita.it) intended to receive all information about the safe use of LASA medicines. The survey, conducted in the early months of 2009, and its report, allowed the development and dissemination in 2010 of a specific Recommendation for the prevention of errors in therapy with LASA medicines and a first list of LASA medicines. The Recommendation was addressed to all health professionals involved in various capacities in the process of medicine management in hospitals, in territorial ASL services, in community Pharmacies, in MMGs and family paediatrician clinics and also to the management of the Health and pharmaceutical Authorities. The implementation of the document was monitored by the Ministry and by AgeNaS, in order to assess hospitals’ efforts and to detect problems that could require the development of further guide-

lines to be designed with the Italian Medicines Agency (Agenzia Italiana del Farmaco, AIFA), Regions and Autonomous Provinces. The Recommendation is also of strategic importance for the implementation of medicine policies in the territorial area and the verification of the first list of LASA medicines, updated to December 2011. This list of medicines has been the basis for development of studies and the drawing up of operational guidelines for community pharmacies in order to support all the healthcare professionals who are involved in various capacities in the medicine sector whether in the hospital or in the territory.

Essential bibliography

13.8. Training in terms of clinical governance and patient safety

The Ministry of Health, in line with international guidelines on improving the quality of services provided, and in accordance with the principles of Clinical Governance, has developed the Manual of clinical audit. The aim of the Manual is to promote in all areas of the SSN the systematic and continuous usage of clinical audit as a tool for evaluating and improving the quality of services and treatments. In fact, the audit should be an integral part of health activities conducted at different organisational and clinical care levels, and the results must be included in the improvement plans of the authority. Clinical audit is a tool long since recognised as an integral part of health care professional activity and is one of the main tools of support for the discussion and evaluation of the activities and services provided. It can be defined as a “structured and systematic analysis methodology to improve the quality of health services applied by professionals through the systematic comparison of care with explicit criteria to identify deviations from known standards or best practices, to implement the identified opportunities for change, and the monitoring of the impact of the corrective measures introduced” (Ministry of Health, 2006). It is thus configured as an objective tool to be used by professionals who are able to analyse the treatment and care provided, to understand the problems and deviations from best practices, and consider the context and identify the most appropriate corrective actions, favouring a positive and proactive attitude.

Therefore, as part of a training programme on issues of clinical governance, the Ministry of Health, in collaboration with professional orders and guilds, has promoted a clinical audit training course that aims to facilitate the dissemination of this instrument.
among professionals engaged in health care and to promote its effective use to enhance the role and responsibility of all professionals working in health.

This course, credited with 12 credits by the CME Commission (Continuous Education in Medical Sciences), is delivered in a FAD manner (Distance Learning) and is available and usable on the FNOMCeO and IPASVI portals.

**Results.** Since its publication online on September 9, 2011, more than 99,000 health care workers have enrolled in the course, and 42,064 – of which 9,965 doctors, 804 dentists, 30,780 nurses, 263 health assistants, and 252 paediatric nurses – have passed.

The Customer satisfaction analysis shows a significant acceptance by operators that in 98% of cases judge as relevant the subject and the quality of training and sees the knowledge acquired as especially useful and applicable in practice.

**Essential bibliography**

ANAES. Evaluation des pratiques professionnelles dans les établissements de santé. Reussir un audit Clinique et son plan d’amélioration. ANAES Service évaluation des pratiques; 2003


Wienand U. Audit clinico: che cosa è e che cosa non è, l’uso inappropriato del termine depaupera il metodo. QA 2009; 19: 82-90

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**13.9. Legal and management aspects of mediation**

In order to meet the need to take specific actions to enable the court settlement of disputes which derive from damage resulting from services provided by operators of the SSN, one that has been felt for a long time, the legislature responded with the legislative decree (D.Lgs.) no. 28 of March 4, 2010, “Implementation of art. 60 of law June 18, 2009, no. 69, in the area of mediation aimed at settling civil and commercial disputes”, designed to lessen the load on the Italian justice system with respect to arrears and the risk of accumulating new delays. This legal Act defines the institution of civil and commercial mediation and extends it to the health sector, even though mediation in health care is marked by several specific features compared to mediation systems by tradition applicable to other types of conflicts, such as the difficulty in defining the cause-effect relationship, the qualification and quantification of the damage, the heterogeneity of subjects and the exact identification of all players involved in the event, the high specificity of the cases, the complexity of health systems and the sensitive nature of the underlying asset, namely health, guaranteed by the Constitution as an inviolable right.

The purpose of the agreement between the parties, when the dispute has been generated by a health event, must pursue an objective that is adjunct to the formal Agreement between them, which is the protection and recovery of the fiduciary relationship towards the SSN.

In light of this, the decree presents certain profiles that may be problematical for its application in health care, which has reduced its usefulness. The problems found will require the addressing of the following issues:

- definition of the territorial jurisdiction of the bodies of an breadth that health Authorities may be called upon to bring mediation efforts in other Regions also, with an increase in operating costs;
- development of a glossary of shared terms that exposes interpretative conflicts;
- definition of the role of Insurance companies in a mediation process that hampers their presence in such proceedings with
13.10. Pharmacovigilance and protection of health: identification and minimisation of risks

AIFA, as part of its intensive post-marketing surveillance of all medicines in the national territory, collects and evaluates information with particular regard to adverse reactions and inappropriate use. It promotes regional projects of active Pharmacovigilance, with specific funding to the Regions, and ensures evaluation of renewals of Marketing Authorisations (Autorizzazioni alle Immisioni in Commercio, AICs) and of Periodic Safety Update Report (PSUR). In addition, AIFA processes Assessment Reports in support of the activities of the Offices of the same Agency, the Committee for Medicinal Products for Human Use (CHMP) and of the Pharmacovigilance Working Party (PhVWP) of the European Medicines Agency (EMA). The data on the safety of medicines are derived from different sources: spontaneous reports of suspected adverse reactions, observational studies, clinical trials, scientific literature, and reports submitted by the pharmaceutical industry. In particular, spontaneous reports of adverse reactions (ADR) are collected by the National Pharmacovigilance Network (Rete Nazionale di Farmacovigilanza, RNF), a network extended throughout the national territory which connects more than 1,290 users in real time and is, in turn, connected to the European Eudra-vigilance network, which collects European Union (EU) and non-EU data related to authorised medicinal products or in clinical trials within the EU. During 2011, the RNF recorded 23,742 reports of suspected adverse medicine reactions, with an 8% increase compared to 2010. In 2011, through funds allocated by the State to the Regions, 146 regional and multi-regional projects were assessed and approved, evaluated by AIFA and deemed capable of increasing knowledge of specific categories of medicinal products and their safety profile. All newly marketed medicines are subjected to intensive monitoring for at least two years after their placing on the market. The same monitoring is also guaranteed for medicinal products for which there are special issues of pharmacovigilance or for which a substantial change in the conditions of use has been approved. In 2011, medicines included in the list of intensive monitoring totalled 192 (of which 41 were newly inserted). PSURs are an integral part of the monitoring of medicine safety. For the period 2010-2011, around 2,300 Periodic Safety Reports were estimated. Conspicuous also in the years 2010-2011 were the activities of preparation of Assessment Reports (AR) by the Italian members of the CHMP and the PhVWP and the other regu-
The AIFA promptly carries out investigations of the defect whenever quality defects of medicinal products in use are experienced. In all cases in which the quality defect can lead to serious health risks AIFA is responsible for the activation of an International Alert on the network for exchange of information in the field of production and quality (Rapid Alert System, RAS) and the recalling or seizure of the batches to protect public health.

In 2011, 573 reports of quality defects were received (60 more than in 2010). In total, 38 samples were prepared and three rapid alerts issued. There were seventy-three recalls of batches, 23 seizures and 5 bans on selling. The Agency is also responsible for managing the Annual Programme of Control of Medicinal Products (PCA), based on art. 53, paragraph 15 of the Community Code for medicinal products, and which is defined each year by AIFA, following consultation with the Technical and Scientific Advisory Committee. This programme consists of an annual plan of laboratory analysis, to be carried out on samples of drugs chosen according to critical criteria defined and agreed by AIFA with the ISS. The PCA is an essential tool to ensure that marketed medicines match exactly the quality specifications outlined in the authorisation procedure. Of 141 samples prepared in 2011, with delivery requested by October 26, 2011, 60 were generic medicines, 48 biological medicinal products, 10 blood-derived products and 23 sterile medicinal products.

To monitor the safety of vaccines and blood derivatives, AIFA manages the technical/administrative aspect of the State Certificates of Control. The pharmaceutical company wishing to put batches of vaccines or blood-derived medicinal products on the Italian market forwards the documentation to AIFA to obtain approval for release of the batch (Batch Release) for marketing, which includes a form bearing a series of information (Marketing Information Form, MIF) and the certificate of inspection issued by an OMCL (Official Medicines Control Laboratories). In 2011, 1,808 procedures for issuing batches were completed, of which 402 were treated by emergency procedure.

AIFA may withdraw AIC authorisation for official reasons or by waiver on the part of the AIC holder. Official revocation is a measure taken after formal objection by “notice of revocation”, in the case of the occurrence of any of the conditions referred to in art. 141 of D.Lgs. no. 219/2006, that is, when in the opinion of the AIFA: a) the medicinal product is harmful under normal conditions of use; b) the medicinal product does not allow for the therapeutic effect or the effect for which it has been authorised; c) the risk/benefit balance is not positive under the normal conditions of use; or d) its qualitative and quantitative composition is not as declared.
In 2011, four Official withdrawals were performed. In the case of revocation by waiver on the part of the company AIC holder, AIFA performs preliminary investigations into whether the withdrawal could lead to market shortages, if there were no other medicines containing the same active ingredient available, and on the possible consequential damages in terms of public health. In 2011, 111 determinations of revocation by waiver were issued.

The shortage of a medicinal product, which is the temporary unavailability of the medicine in the market throughout the country, can be caused by problems with production or distribution.

AIFA has set up a system of monitoring and management of such deficiencies, to ensure patients a continuity of treatment. In particular, it checks the availability of medicines similar to those lacking, issues an import authorisation to healthcare facilities or the AIC holder who request it and, in special cases, adopt specific determinations. In 2011, the AIFA issued 3,362 permits of importation for medicinal products similar to those authorised in Italy and temporarily in short supply, of which 3,135 requested by health facilities, 120 from companies who were marketing authorisation (AIC) holders, 90 were for blood-derived medicinal products and 17 were issued in the form of determinations. A “List of drugs currently unavailable” is always visible on the institutional website for public consultation with directions to address the shortage.

13.12. Combating pharmaceutical counterfeiting and distribution of illegal products

Italy is considered one of the reference countries in the fight against pharmaceutical counterfeiting, thanks to the various initiatives taken to combat a phenomenon whose incidence in recent years has grown exponentially worldwide.

In the light of the hearings conducted by the XII Senate Commission for Hygiene and Health with the support of AIFA, the conclusions of which identified some possible areas of improvement in interventions, the Agency, in cooperation with the administrations involved in the national IMPACT Italy task-force, developed a series of activities (Table 13.2), which allowed the achievement of objectives in 2011 in line with the wishes of the cited survey:

- development of an appropriate regulatory framework consistent with the current scenario;
- strengthening of intersectoral partnerships already in place;
- extension of controls to types of “borderline” products such as food supplements;
- intensification of training activities for professionals in the sector and of those of information directed to the public.

The conclusion of the negotiation of two important international instruments of regulation, the EU Directive 2011/62 and the “Medi-Crime” Convention of the Council of Europe,

| Table 13.2. In 2010-2011 no cases of pharmaceutical counterfeiting were encountered in the legal distribution networks; AIFA and IMPACT Italy increased their activities of support in the combat of illegal distribution chains |
|-----------------|--------|--------|
| **Training: operators involved in training on counterfeiting** | 100    | 500    |
| **Training and information: books published at international level** | 2      | 5      |
| **Support of customs activities: units seized in Operation PANGEA** | 10,000 | 50,000 |
| **Support for police activities: illegal Internet pharmacies subject to blocking** | /      | 50     |
will amend the existing legislative framework, with results visible already in 2013. The implementation of the new EU Directive 2011/62 amending the European pharmaceutical code to take account of the fight against counterfeiting, will further strengthen the controls on the pharmaceutical supply chain; each member state should also regulate the sale of medicines over the Internet, ensuring the safety of medicines purchased over the network from legally authorised pharmacies. The implementation of the Council of Europe MediCrime Convention will allow the rules of criminal law that cover not only medicines but also other types of health products to apply to cases of forgery. AIFA, which actively participated in the definition and the creation of both texts in the relevant international forums, is currently in the process of transposition of them into national law. In addition to these legal-regulatory activities, a series of initiatives of different types took place in 2011:

- development of IT Intelligence projects designed to ensure the monitoring of the Internet and identification of illegal online pharmacies;
- development of publications and educational events (web based and classroom teaching), for operators responsible for carrying out USMAF (Ministry of Health), Customs, NAS (police) and other administrations controls;
- participation and support for control operations in the territory such as “PANGEA IV”, carried out in collaboration with the police, customs and other administrations of IMPACT Italy. The solidity of the Italian legal distribution chain, to this day never affected by cases of counterfeiting, has allowed a focus on “hidden” markets. From this point of view, the increase of customs seizures (obtained thanks to the collaboration between AIFA, the Ministry of Health and customs operators) and the launch of an operational phase to contrast illegal e-commerce, which, thanks to an AIFA-LegitScript agreement, has already led to the blocking of numerous illegal sites operating in our market, testify to the effectiveness of the approach chosen for the purpose of protection of Italian patients.

**Essential bibliography**


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**13.13. Medicines: control production, protect health**

Among AIFA’s institutional tasks are those to authorise and control the quality of medicines manufactured and marketed in Italy. This activity is regulated by D.Lgs. no. 219/2006, which is the implementation of a series of European Directives relating to the production and marketing of medicinal products intended for human consumption. In particular, the Inspections and Certifications Area of AIFA authorises and keeps under control the production of medicines and raw pharmacologically active materials produced in Italy. The fulfilment of production quality criteria is monitored through inspections carried out in the frequency range of between 2 and 3 years. The inspections are carried out by specially trained and qualified inspec-
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As part of the institutional arrangements, inspections are performed by specialised personnel belonging to the ISS, the Military Chemical-Pharmaceutical Works and to the Carabinieri Command for the Protection of Health (NAS). The production licenses and GMP certificates for pharmaceutical plants are included in the community database (EudraGMP), managed by the EMA, in order to share the results of inspections. The number of permits issued for the years 2008-2011 is shown in Figure 13.1.

As of the date of publication of the determination of July 26, 2011 - GURI No. 194 of August 22, 2011, in Italy 270 manufacturing plants were active in the production of medicinal products, 196 plants in the production of medicinal gases and 150 plants in the production of active pharmaceutical ingredients (API).

AIFA, as part of its mission, also carries out international inspections of companies in countries located outside of the EU and with which an agreement of Mutual Recognition is in force. These inspections may also be carried out within the framework of cooperation agreements with EMA, OMS, EDQM and PIC/S.

In 2011, AIFA carried out 175 inspections on medicines, 58 API inspections and 14 inspections in non-EU countries. The number of inspections carried out in the years 2008-2011 is shown in Figure 13.2.

From the above and from data in graphs in Figures 13.1 and 13.2, it can be concluded that AIFA, through effective and documented control activities on pharmaceutical production activities carried out by Area inspection and Certification (audits, evaluation of corrective actions implemented by companies and document assessment on the changes made in plants), operates in a relevant and proactive way in order to ensure greater protection of public health.

Figure 13.1. Authorisations issued subdivided by type of production (Years 2008-2011).

AIFA submits the entire life cycle of a medicine, from clinical trials to imports of raw materials, from production to marketing, to a thorough system of controls to protect the quality, safety and efficacy of the medicinal product. The Agency monitors the manufacturing plants of medicinal products and pharmacologically active raw materials, ensuring regulatory compliance with Good Manufacturing Practice (GMP), controlling the application of the rules of Good Clinical Practice (GCP) in the conduct of clinical trials and evaluating the compliance of pharmaceutical companies with Italian and Community legislation on safety monitoring of medicines administered to patients, through inspections of company pharmacovigilance systems (Good Pharmacovigilance Practice, GPvP).

Without the prior written consent of AIFA, no company can produce medicines in Italy, even for export. The pharmaceutical manufacturing plants producing medicines, medicinal gasses and pharmacologically-active raw materials (APIs) are therefore subject to AIFA inspections of activation, periodic monitoring and review of the authorisation in order to ensure respect for and compliance with the standards of Good Manufacturing. Specifically, AIFA in 2011 ordered 520 inspections of production authorisations for medicinal products, 604 inspections of authorisation for the production of APIs and 59 authorisations for the production of medicinal gasses.

Also in 2011, the Agency carried out 10 international inspections of manufacturing plants of medicines and active pharmaceutical ingredients.

The safety and ethics of the pharmaceutical market are guaranteed by AIFA through relevant activities carried out in order to veri-
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Strive for compliance with the standards of Good Clinical Practice, with regard to drug trials involving human subjects.

In the 2010-2011 period, the inspectorial activities performed were 51 and involved experiments in a number of areas of greatest risk to human health (cancer, AIDS, cardiology); a significant proportion of the inspections was directed to pharmacokinetic laboratories performing bioequivalence studies for some generic drugs. Finally, five inspections were performed in collaboration with the Food and Drug Administration (FDA), one on behalf of WHO and three on request of the EMA.

The safety of medicines on the market is also guaranteed through activities verifying compliance by the pharmaceutical companies with the legislative provisions and guidelines on Pharmacovigilance activities. The main function of the GPvP Inspectorate is therefore to evaluate the conformity of the pharmaceutical companies with the Italian and Community legislation on monitoring the safety of medicines through the application of inspections of the companies’ pharmacovigilance systems.

In 2010-2011, 16 inspections were conducted, including 14 national and two requested by the EMA. The 16 inspections involved 25 marketing authorisation (AIC) holders. Another task of the GPvP Inspectorate is to conduct inspections of clinical trials with issues related to pharmacovigilance.
14.1. Italian food safety authorities

The food crises affecting European countries at the beginning of the century as a result of emergencies in food safety led the European Union (EU) to a profound reconsideration of food safety policy. This critical reflection led European institutions to radically change both the organisation of the Commission, with the conferral of powers that had previously been divided among various Directorates to a single Directorate (DG SANCO – Directorate-General for Health and Consumers), and the normative regulation, through the establishment of a clear distinction between the functions of management and of evaluation of food risks, anticipated by the introduction of new legislation on food safety – the so-called “hygiene package” – of which EC Regulation no. 178/2002 is the key pillar for ensuring a high level of protection of human health.

Another fundamental innovation has been the involvement, through consultation, of consumers. The EC Regulation no. 178/2002 set up the European Food Safety Authority (EFSA) and established the basic principles for the subject, oriented to the involvement of all stakeholders from producers to consumers, allowing them to have full confidence in decision-making based on scientific evidence and assessed by both European and national independent Institutions. With these objectives, the EFSA, European Institutions and Member States committed themselves to the adoption of appropriate and effective measures over the years – based on analyses of risk (for each component: assessment, management and communication) – that aims at the protection of public health through an independent, objective, and transparent risk assessment based on available scientific information and data.

The EFSA provides the necessary scientific and technical support to the European Institutions responsible for risk management in the food chain and is the scientific point of reference whose independence in the assessment, information and communication of risk helps to achieve consumer confidence. In addition, the European Food Safety Authority is expressly called upon to act in close cooperation with national bodies whose functions are similar to those of the EFSA. In Italy, the implementation of the planned collaboration with the EFSA was achieved with the establishment in 2006 of the National Secretariat for risk assessment in the food chain as part of the Department of Veterinary Public Health, Nutrition and Food Safety within whose remit the functions of assessment, management and communication of risk were organised.

Furthermore, in order to adhere to European guidelines for the creation of a national reference institution that interfaces with the EFSA, the insertion of the National Food Safety Agency (Comitato Nazionale per la Sicurezza Alimentare, CNSA) within the Department of Veterinary Public Health, Nutrition and Food Safety was previewed, with the task of providing technical-scientific advice to all administrations dealing with risk management for food. The allocation of these powers to the aforementioned Department as well as national
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Implementation of lines of priority in order to meet health objectives was confirmed by the presidential decree (DPR) no. 108 of March 11, 2011, which provided for the new organisational layout for the Ministry of Health. Other national bodies concerned with the management of health protection include the Directorates-General for Animal Health and Veterinary Medicines and the Directorate-General for Hygiene, Food Safety and Nutrition, the newly-established Directorate-General of National Boards for Health Protection, under which the CNSA and the Board of Health operate with the specific role of risk assessment in the food chain.

The CNSA acts in collaboration with the EFSA according to art. 22, paragraph 7 of EC Regulation no. 178/2002, actively participating with a representative on the Consultative Forum of the EFSA itself (art. 27 of the same Regulation), and providing scientific opinions at the request of Italian central administrations and those of the Regions and Autonomous Provinces of Trent and Bolzano.

The CNSA committee is appointed by the Minister of Health, in consultation with the Minister of Agriculture, Food and Forestry, and is composed of experts with proven scientific expertise and high professionalism in matters pertaining to risk assessment in the food chain and particularly in the following areas:

- food additives, flavourings, technology aids and materials in contact with food;
- additives and products or substances used in animal feed;
- plant health, plant protection products and their residues;
- genetically modified organisms;
- diet, nutrition and allergies;
- biohazards;
- contaminants in the food chain;
- animal health and welfare.

The CNSA may also collaborate with independent scientific experts who are competent in matters related to the particular argument to be dealt with.

For matters which require an expert opinion, the President – who is elected by the CNSA members themselves – appoints a supervisor and may set up workgroups while nominating their coordinators. Opinions can take the form of resolution, recommendation or investigation, the latter in order to obtain further information and data which can provide guidance based on quantitative analysis. The CNSA which had been reconstituted following the ministerial decree (DM) of March 18, 2011 took office on September 15, 2011, and met on a monthly basis, overseeing the investigation of requests for opinions on the following topics:

- informational documents concerning “Energy drinks and alcoholic drinks” and “Food allergies and safety of consumers”, prepared by the Directorate-General for Hygiene, Food Safety and Nutrition;
- detection of thorium residues in foods of animal origin (honey and milk-based products);
- an EFSA proposal for modernising and simplifying the inspection of pork meats;
- human consumption of sheep and goat meat originating from where outbreaks of transmissible spongiform encephalopathies (encefalopatie spongiformi trasmissibili, ESTs) had occurred.

Finally, the process for the establishment of an Advisory Council of consumer and producer Associations involved in food safety was begun in 2011, as provided for by art. 8, paragraph 4 of the DPR no. 108, March 11, 2011, completing the set of functions in the field of risk assessment in the food chain. This Advisory Council has been given the task of facilitating the exchange of information between consumer and producer associations in order to enhance the citizen’s ability to choose by promoting an awareness of consumption and of proper diet, and to contribute to the communication initiatives of the competent bodies.

The Council – chaired by the Head of the Department of Veterinary Public Health, Food Safety and National Boards for Health Protection – is composed of representatives of the Departments of Health, of Economic Development, of Agriculture, Food and Forestry and of Environment, Land and Sea as well as the Regions and Autonomous Provinces, with one representative from each of...
14.2. Experimental Institutes for animal disease control and prevention (IZSs)

The Experimental Institutes for animal disease control and prevention (*Istituti Zooprofilattici Sperimentali, IZSs*) have a precise institutional position with the law no. 503 of June 23, 1970, which defined them as “Health Bodies with legal personality under public law”. Subsequently, the regulation was updated with the law no. 745 of December 23, 1975, with the transfer to the Regions of administrative functions previously assigned to the State.

In 1993, the enactment of legislative decree (D.Lgs.) no. 270 of June 30 helped to strengthen and confirm the nature and functions of IZSs, better identifying areas of their intervention such as that of veterinary pharmacovigilance, of epidemiological surveillance through veterinary epidemiological centres, the upgrading and training of veterinarians and other operators, the study of alternative models to the use of animals in animal experimentation and current and proposed scientific research funded by the National Health Fund.

In addition, the IZSs along with other organisations provide their own services and technical and scientific collaboration to the Ministry of Health for guidance and coordination activities which are within their competence and necessary to ensure the uniform implementation of EU and international legislation, as established by the D.Lgs. no. 502 of December 30, 1992, “Reorganisation of health-related disciplines”.

The IZSs represent an indispensable operational tool for the guarantee of technical-scientific services necessary to ensure a proper balance between the needs of development of the system of food production and the protection of consumers of animal products both for Italy and, in the present context, for EU Member States and third-party countries who import Italian products.

In order to fulfil their statutory mandate, apart from their “mission”, of services for livestock breeding and food safety assurance, the IZSs are evenly distributed throughout the country with 10 main offices (*Figure 14.1*) and 85 Provincial Diagnostic Sections with jurisdiction over the territory of one or more Regions. This widespread distribution comprises a set of public laboratories in the service of the State and the Regions which ensures the protection of public health through the control of food of animal origin, the hygiene and health status of livestock and the welfare of animals, in conjunction with other National Health Service (*Servizio sanitario nazionale, SSN*) facilities.

There are 41 active IZS National Reference Centres that are defined as “Operational instruments of high competence located at an IZS that perform specialised activities in the fields of food safety, animal health and animal hygiene”. Moreover, given the experience and scientific value accrued over the years by the IZSs, international organisations such as the World Organisation for Animal Health (OIE/Office Internationale des Epizooties), the World Health Organization (WHO) and the Food and Agriculture Organization (FAO), have recognised some of the IZSs as Collaboration Centres and Reference Laboratories of these international organisations. Another fundamental aspect of IZS activity is that related to research directly connected to the functions that the IZSs have within the SSN such as that of facilities providing technologically-advanced services.

Experimentation and research are institu-
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14.3. Plant protection products and food safety

Plant protection products, also called pesticides or anti-parasitic products, are designed to protect crops before and after harvesting from diseases and parasites which are responsible for seriously reducing the yield of agricultural and fruit and vegetable crops. In this sense, an adequate level of funding is highly important for productive activities and consumer protection, in order to certify the quality of health and hygiene of food and fully perform actions of prevention.
tion 1107/2009 of the European Parliament and Council of October 21, 2009 concerning the placing of plant protection products on the market and subsequent related regulations, with effect from June 14, 2011. New harmonised procedures were signed for the release and the mutual recognition of authorisations for plant protection products. In 2011, the Ministry of Health’s Directorate General for Food Hygiene, Food Safety and Nutrition planned and implemented several initiatives to define a new organisational and procedural framework to adapt the services provided by the Directorate-General to the new Community provisions relating to authorisation processes that will no longer have a national profile only, but a Community one also; other stakeholders in the sector were also involved. The presidential decree (DPR) no. 55 of February 28, 2012, “Regulation amending presidential decree April 23, 2001, no. 290, for the simplification of authorisation procedures for the production, marketing and sale of plant protection products and related adjuvants”, prepared in 2011, was published in the Official Gazette on May 11, 2012. In addition, the inclusion of an article by proxy in the 2011 Community law plans for the issuance of one or more of legislative decrees in order to coordinate the regulations in force for the production and marketing of plant protection products was proposed and approved.

A review of the rates covering the costs of services rendered was also begun.

In this sector, official control of pesticide residues in food is one of the health priorities in food safety and is aimed at verifying the compliance of foodstuffs with the laws designed to prevent risks to public health, to protect the interests of consumers and to ensure honesty in commercial trade. The above control activity is regulated by Regulation 396/2005 and subsequent related Regulations, by EC Regulation 882/2004 and by the DM of December 23, 1992 and subsequent amendments. The EC Regulation 396/2005 harmonises at Community level the maximum levels of residue permitted, while EC Regulation 882/2004 lays down general rules for the performance of official controls. The DM of December 23, 1992 defines the annual testing plans for residues of plant protection products, providing a detailed programme of controls for the Regions and Autonomous Provinces of Trent and Bolzano with an indication of the minimum number and type of samples to be analysed, based on production and consumption.

National results for 2010 and comparison with the EU. 2010 marks the eighteenth year of implementation of the annual programme of official controls on pesticide residues in food. The national report, prepared at the central level, contains results of the analysis of pesticide residues carried out in 2010. These analytical results were provided by the official regional/provincial control laboratories through the “New foods – pesticides system” channel on the Ministry of Health’s New Health Information System (Nuovo Sistema Informativo Sanitario, NSIS) website. Overall, 8,449 samples of fruit, vegetables, cereals, oil, wine, baby food and other products were analysed. Regular samples were 99.6% of the total, while only 32 samples were found to be irregular, with an extremely low percentage equal to 0.4%. The number of regular samples was 5,376. The number of these samples in regulation were 5,355 (99.6%), while the number of irregular totalled 21 (8 fruit and 13 vegetable) equal to 0.4%. With regard to cereals, oils and wine, of 1,313 samples analysed only two samples were irregular, equal to 0.2%. 106 samples of baby food were also analysed, all of which were regular. In total, 1,654 samples of other products were also analysed of which 9, or 0.5%, were found to be irregular (Table 14.1). The EFSA report on the monitoring of pesticide residues of vegetable origin shows that approximately 67,000 samples were analysed in total, 97.4% of which were regular, while only 2.6% were irregular. From a comparison of the percentage of irregularities found in fruits, vegetables and cereals throughout Italy compared to those in Europe for the years 1996-2009, percentages of irregular samples resulting from the European monitoring programme ranged from 3.0% in 1996 to 2.6% in 2009, show-
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Table 14.1. Summary statement of results of official controls of residues of plant protection products in foods of plant origin by type of analyzed product – Year 2010

<table>
<thead>
<tr>
<th>Food products</th>
<th>Total samples</th>
<th>Regular samples</th>
<th>Samples with residues exceeding permitted maximum level (LMR)</th>
<th>Samples with residues within permitted maximum level (%)</th>
<th>Samples without traceable residues</th>
<th>Samples without traceable residues (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fruit</td>
<td>2,775</td>
<td>1,390</td>
<td>8</td>
<td>0.3</td>
<td>1,377</td>
<td>49.6</td>
</tr>
<tr>
<td>Vegetables</td>
<td>2,601</td>
<td>516</td>
<td>13</td>
<td>0.5</td>
<td>2,072</td>
<td>79.7</td>
</tr>
<tr>
<td>Cereals</td>
<td>583</td>
<td>276</td>
<td>2</td>
<td>0.3</td>
<td>420</td>
<td>72.1</td>
</tr>
<tr>
<td>Oil</td>
<td>232</td>
<td>83</td>
<td>0</td>
<td>0.0</td>
<td>149</td>
<td>64.2</td>
</tr>
<tr>
<td>Wine</td>
<td>498</td>
<td>241</td>
<td>0</td>
<td>0.0</td>
<td>257</td>
<td>51.6</td>
</tr>
<tr>
<td>Baby food</td>
<td>106</td>
<td>1</td>
<td>0</td>
<td>0.0</td>
<td>105</td>
<td>99.1</td>
</tr>
<tr>
<td>Other products*</td>
<td>1,654</td>
<td>345</td>
<td>9</td>
<td>0.5</td>
<td>1,300</td>
<td>78.6</td>
</tr>
<tr>
<td>Total</td>
<td>8,449</td>
<td>2,737</td>
<td>32.4</td>
<td>32</td>
<td>5,680</td>
<td>67.2</td>
</tr>
</tbody>
</table>

* Fruit juices - flour-canned fruit - canned vegetables - bread - pasta - biscuits - spices - tea - herbal infusions - grain legumes and others.


...ing an average level of irregularity significantly higher than the average recorded in Italy (Figure 14.2). As in previous years, the results of official Italian controls continue to be fully in line with those found in other European countries. Overall, the balance of results and data from the 2010 annual national report as well as the participation of Laboratories and territorial SSN Facilities continue to be satisfactory and provide a broad and comprehensive framework able to meet the targeted health objectives in relation to official control of foodstuffs both in Italy and in the European Community. The results also confirm a high level both of food safety and consumer protection.

Figure 14.2. Comparison of percentage of irregularities with European Union (Years 1993-2011).

14.4. Environmental contaminants and food safety

National monitoring plan for environmental contaminants in food of animal origin produced in Sites of National Interest (SIN Site Plan). In view of the strong influence that the environment of the places of food production has on the quality and the safety of the food itself, the Ministry issued the “National monitoring plan for environmental contaminants in food of animal origin produced in Sites of National Interest” (hereafter SIN Site Plan) in 2011. This plan aims to create a monitoring activity on a national scale for food of animal origin produced in areas with high environmental impact, in those areas in fact already identified as SIN sites. With the results obtained, it is possible to make a correct definition of levels of risk for the main contaminants in food of animal origin, thus strengthening measures to protect consumers. Such a study is also a valuable support for decision-making by the competent environmental authorities relating to the sites to be reclaimed and can prevent the adoption of measures not dictated by a real public health risk, such as the disqualification of agricultural areas, but that will result in an economic loss on agricultural food production. The plan has a total duration of three years, with annual re-planning of activities based on results obtained. In the first year of operation, 19 of the 57 SIN sites surveyed and demarcated with specific decrees by the Ministry for the Environment, Land and Sea were assessed. The Aosta Valley Region and the Autonomous Province of Bolzano were exempted from the assessment due to the lack of a SIN site of relevance for food safety. Each SIN site identified by the Region or Autonomous Province underwent an extensive evaluation in conjunction with the Technical Coordination Group (Gruppo Tecnico di Coordinamento, GTC), set up within the Site Plan, in order to prepare an operational plan with details of sampling and analytical research to be performed in the context of each site. A proper evaluation was possible thanks to the sharing of the results of previous health and environmental monitoring activities carried out in these sites among all those involved. In addition, a Geographic Information System (Sistema Informatico Geografico, GIS) was developed in support of the monitoring plan able to represent the territories falling within each of the SIN sites adequately and to relate them to all the environment and health variables useful for a correct characterisation of the risk. The monitoring involves the use of bio-indicators for the evaluation of environmental contamination, such as sheep and goat milk (in the case of a SIN site containing land areas) and clams from natural banks (in the case of a SIN site having marine, lagoon or lake areas). In the absence of these species, it is possible to sample shell eggs from hens raised on land and outdoors, or Mytilus galloprovincialis species mussels. In order to estimate with a precision of about 1/3 of the standard deviation the concentration of the substances to be traced in relation to the different environments sampled, the number of samples of a research type for each environment is equal to 30. If the actual number of livestock within the perimeter of the SIN site does not allow this sample size to be reached, then the monitoring is extended to surrounding areas, with a buffer of 10 km. The samples taken by the local
Implementation of lines of priority in order to meet health objectives

Competent Authorities are transferred to the laboratories in the national IZS network and to the National Institute for Health (Istituto superiore di sanità, ISS) for the carrying out of the analysis for the detection of the main contaminants such as: dioxins (PCDD-PCDF), dioxin-like polychlorinated biphenyls (DL-PCB) and non-dioxin-like polychlorinated biphenyls (NDL-PCB); nonylphenol; pentachlorophenol; polycyclic aromatic hydrocarbons (IPA) and heavy metals (As, Be, Cd, Cr, Hg, Ni, Pb, Tl). All information relating to both the sample and the results of the analyses is included in an information system provided by the Ministry of Health.

Dioxin-like polychlorinated biphenyls (DL-PCB) contamination in fish products of Lake Garda. As a result of a monitoring activity on some of the fish species being fished in Lake Garda conducted by the Inter-university Consortium “Chemistry for the Environment” and the no. 22 Local Health Authority (Azienda sanitaria locale, ASL) of Valeggio sul Mincio in November 2010, it was found that 3 of the 4 samples of eels taken were contaminated with PCB-DL at levels above the limit laid down in the EC Regulation 1881/2006, which sets maximum levels for certain contaminants in foodstuffs. These results, although to be considered preliminary due to the reduced sample size and the consequent limited representation of the actual situation of the lake, led to the implementation of a monitoring plan, coordinated by the Ministry, to assess the level of contamination of eels and other fish so as to provide scientific information on which to base any action related to the basin of the lake. The monitoring plan concerned not only eels, of interest for their high fat content (compounds with strong lipophilic properties), but also other species of commercial interest such as shad and whitefish (representing 90% of the lake fish catch), pike and perch (of interest for their predator characteristics) and tench as a sedentary species. One hundred and twelve samples were collected from 10 sampling stations distributed in different areas of the lake to verify the distribution of the contamination (Table 14.2).

The analyses carried out revealed widespread contamination of eels for dioxin-like polychlorinated biphenyls (DL-PCB). In this species, in fact, a significant percentage (38.5%) of the examined samples exceeded the upper limit established by Community legislation. The geographical distribution of the contamination extended to the entire basin of Lake Garda, with samples above the limit on both sides of the lake (western and eastern) and non-compliant samples even in the far north of the lake, suggesting a variety of sources of contamination most likely attributable to specific technical mixtures of PCBs, once used as dielectric fluids, lubricants and in many other industrial applications. The situation was however favourable for other species of greatest commercial interest for Lake Garda, including the shad and whitefish. The levels found in these species, in fact, were all below the threshold limit for entry as human food consumption laid down by the Community. Given that the similar levels of PCB dioxin contamination found in eels and the high proportion of contaminated eels did not guarantee a safe consumption of this fish species, the Ministry issued an Ordinance on May 17 last prohibiting the trading and marketing of Lake Garda eels intended for human consumption while at the same time tasking the Regions involved and the Autonomous Province of Trento with ensuring proper information for both operators and consumers regarding the health risks associated with the consumption of eels caught in Lake Garda. The local competent Authorities also took steps to establish a fishing ban on eels from Lake Garda for reasons of health and public health.

<table>
<thead>
<tr>
<th>Collected species</th>
<th>Number of samples</th>
</tr>
</thead>
<tbody>
<tr>
<td>Eel</td>
<td>39</td>
</tr>
<tr>
<td>Shad</td>
<td>38</td>
</tr>
<tr>
<td>Whitefish</td>
<td>11</td>
</tr>
<tr>
<td>Pike</td>
<td>10</td>
</tr>
<tr>
<td>Perch</td>
<td>9</td>
</tr>
<tr>
<td>Tench</td>
<td>5</td>
</tr>
</tbody>
</table>

Table 14.2. Distribution of samples by species
14.5. Food production technologies and biotechnologies

*Production technologies.* Food production technologies that were created to obtain various food products from the raw materials of agricultural plant and animal production have been refined and developed to this day with the aim of improving food quality, shelf life, taste and also appearance using the latest scientific innovations in addition to traditional knowledge. In this context, the Ministry of Health is responsible for regulating the chemical safety aspects for additives, flavourings, enzymes and materials and articles intended to come into contact with food.

*Additives, flavourings and enzymes.* The framework regulation on food additives – EU Regulation 1333/2008 – requires that their use is safe, technologically justified and does not mislead consumers. Three regulations were published in 2011 that complete the regulation of the industry, making clearer the rules for consumers, food business operators and control authorities. The EU Regulation 234/2011 sets out the requirements for the authorisation for use of a new additive (toxicological data and other information). The EU Regulation 1129/2011 concerns additives in food and will be in force as of June 2013 (the transition period is necessary to allow the food industry to adapt to the new rules), while the EU Regulation 1130/2011 concerns additives in food ingredients, such as other additives, enzymes, flavourings and nutrients and will ensure that the exposure of the consumer to these ingredients remains limited.

A complete review of all authorised additives is also in progress at the EFSA, according to priorities such as time elapsed since the last evaluation, new scientific information available, frequency of use and human exposure. Aspartame sweetener and food colourings will be the first to be taken into account.

With a view to simplification and usability, the DM no. 158 was published on August 4, 2011, transposing the Directive 2010/59/EU and repealing previous national decrees, defining in the Annex a single list of extraction solvents which may be used in foodstuffs.

The activities of health checks on food, throughout the supply chain, include checks on the purity of food additives and flavourings used, the compliance of the indications for use, the production and verification of ingredients and the labelling of food products for sale.

*Materials intended to come into contact with food.* Food contact materials are regulated by both national and Community measures in order to ensure food safety.

The EU Regulation 10/2011 redesigned the specific rules for plastic materials. Plastic was the first area of revision for Community legislation that had been in force since the 1980s, because it is by far the most widely used product in the market. In this context, the use of bisphenol A in infant feeding bottles was limited through the adoption of the decree of February 16, 2011 transposing the Commission Directive 2011/8/EU.

Regulation of the steel products sector however is not as yet harmonised at Community level, so an intervention at national level took place with the decree no. 258 of December 21, 2010, in force since 2011, which combines the numerous updates that have occurred since 1973 into one measure. The decree lays down requirements for the composition of stainless steel products and specific content limits for certain chemical elements of public health interest, such as nickel, chromium and manganese. The activities of official control provide for a verification of compliance of materials from production to importation, the use and the control of objects and packaging placing on the market.

*Biotechnologies.* The issue of biotechnologies and the use of genetically modified organisms (GMOs) has always been of great interest to both industry and consumers, resulting also in questions and concerns. For the Ministry of Health a deepening and
strengthening of the risk assessment of these products is a fundamental in order to satisfy the needs of public opinion and in particular of Italian consumers, concerned as they are about the impact on health and environment and the loss of national agricultural heritage. A GMO and its derived products can be placed on the European market only after it has been authorised on the basis of a complex process that includes an EFSA’s risk assessment regarding human and animal health and the environment. The Ministry carries out activities of guidance and coordination for the official controls planned by the Regions and Autonomous Provinces and performed by local health services that arrange specific control plans.

National official plan of control for the presence of genetically modified organisms in food: two-year results 2010-2011. Implementation was given to the National control Plan in all Regions and Autonomous Provinces through the performance of official testing by the health Authorities involved, each for their respective competences (Figure 14.3). At the import Port, Airport and Border Health Offices (USMAFs) performed both documentary and identity checks on all consignments of imported foods of non-animal origin and analytical checks with sampling. The control activities carried out by these Offices during the two-year period 2010 -2011 is reported in Figure 14.4.

The official control laboratories who car-

![Figure 14.3. Control activities by the Regions and Autonomous Provinces.](image-url)
ried out detection tests of GMOs in food are listed in Figure 14.5. Most laboratories participated in training activities and were involved in national and international ring tests concurring in different degrees to the total number of analysed samples. During the territorial control activities processed products and raw materials of corn, soybean

**Figure 14.4.** Samples taken at imports.

![Sample data graph showing the number of samples taken at imports.](image)

**Figure 14.5.** Official Control Laboratories testing.

![Laboratory data graph showing the number of samples tested.](image)
Implementation of lines of priority in order to meet health objectives

and rice were sampled. As regards to the analysed products a comparison between the 2 years is shown in Figure 14.6. In two years there were no non-compliant results from any sample taken in the national territory. Figure 14.7 shows the results of USMAFs sampling. The checks included 54 samples in 2010 and 41 samples in 2011, all belonging to the conventional products. In Tables 14.3 and 14.4 the data for rice for 2010 and 2011 are shown and compared. In 2010, the detection of three non-compliance regarding unauthorised GM Bt63 rice is highlighted, for which the Community RASFF (Rapid Alert System for Food and Feed) alert system was activated.

Conclusions. The 2-year period 2010-2011 confirms that official testing activities for presence of OGMs in food involved all the Regions and Autonomous Provinces in a complete and homogeneous manner. The extremely low number of non-conformities found in the two years highlights the growing awareness of food business operators who pay special attention to this issue.
Food safety and veterinary health

throughout the supply chain: from raw material procurement to marketing of the finished product.

With regard to imports, this is a key point in the chain of official controls. Although Italy does not grow OGMs, some third-level countries who are exporters of vegetable products do so. The testing activities performed by public laboratories were particularly intense given the complexity of the analytical control although there remains the need to extend accredited analytical activity to a greater number of elements for screening and to OGM events.

It can be concluded that during the 2010-2011 period in the Italian market the presence of authorised and non-authorised OGMs in food was substantially very limited and at trace levels, and that food products comply with the labelling required by law, thereby ensuring that information is provided to the consumer.

| Table 14.3. Official testing for rice samples in Italy |
| --- | --- | --- |
| Region | Total samples 2010 | Total samples 2011 |
| Abruzzo | 3 | 2 |
| Calabria | 0 | 2 |
| Campania | 4 | 5 |
| Emilia Romagna | 8 | 11 |
| Friuli Venezia Giulia | 4 | 3 |
| Lazio | 0 | 11 |
| Liguria | 2 | 4 |
| Lombardy | 25 | 25 |
| Marche | 1 | 0 |
| Molise | 5 | 5 |
| Aut. Prov. of Bolzano | 0 | 1 |
| Piedmont | 12 | 5 |
| Apulia | 1 | 6 |
| Sardinia | 3 | 7 |
| Sicily | 0 | 0 |
| Tuscany | 0 | 4 |
| Umbria | 0 | 1 |
| Veneto | 16 | 19 |
| **Total** | **84** | **111** |

| Table 14.4. Official testing for rice – for imports |
| --- | --- | --- |
| Collection entity | Total samples 2010 | Total samples 2011 |
| USMAF Civitavecchia | 2 | 0 |
| USMAF Genoa | 9 | 6 |
| USMAF Livorno | 2 | 0 |
| USMAF Naples | 2 | 5 |
| USMAF Palermo | 1 | 0 |
| **Total** | **16** | **11** |
14.6. Health status of livestock

Monitoring and eradication programmes of certain animal diseases which as well as having an impact on commercial and livestock pose a risk to human health are carried out in Italy, co-financed by the EU. The plans adopted here have been very successful, especially in some areas, which over the years have reached a free status. In other areas, however, there are still difficulties in the application of national standards, with particular reference to health management of breeding locations, which affects not only local health status but also causes negative effects in a commercial environment. The epidemics in Europe in the last decade led to considerable economic and social costs related to the implementation of a sole policy of eradication based on the cull and destruction of infected animals or those suspected of being infected. The Italian public veterinary system has shown itself to be sound and adequate based on an effective risk analysis, balancing of costs and responsibilities, compatibility with EU requirements and the flexible application of the norms.

**Bluetongue.** With regard to the epidemiological situation in relation to bluetongue virus serotypes circulating in Italy since 2001 (serotypes 1, 2, 4, 8, 9, 16), in the last two years there has been a limited number of cases (seroconversions) in sentinel animals. Constant monitoring of circulation of the virus is implemented through a surveillance system, which provides for the periodic inspection of sentinel farms and traps for insect vectors in order to verify the presence of different serotypes and the introduction of new serotypes in the territory. Since 2011, vaccination against the disease is on voluntary basis in Italy, done at the request of farmers, either for the movement of susceptible animals or for areas “at risk” from outbreaks in neighbouring countries (e.g. France). During 2011 21,944 cattle and 21,545 sheep and goats were vaccinated against the serotypes BTV1 and BTV8; 18,093 cattle and 32,075 sheep and goats were vaccinated against the serotypes BTV2 and BTV4. The limited number of vaccinations is most likely due to the lack of availability of necessary vaccination centres within the national territory and to the ability to move non-vaccinated animals of susceptible species within the framework of specific inter-regional agreements, taking into account the favourable trend of the national epidemiological situation.

**African swine fever.** The epidemiological situation of African swine fever in Sardinia during the second half of 2011 is changed in contrast to the positive trend of the previous two years, with the notification of 35 outbreaks that affected the entire regional territory, except for the province of Carbonia-Iglesias. One of the main critical factors responsible for the persistence of the disease in the territory has been identified in the usage of large municipal uncultivated areas for agricultural and livestock-related activities for which the management is not known, particularly with respect to the regulation for the granting of such land for such usage. The failure of the struggle against African swine fever should not be ascribed to the lack of national regulatory measures, but to their uneven and imprecise application in the territory, thereby contributing to the negation of the effectiveness of strategies to combat the disease. Actions of control by local authorities are expected to be strengthened in 2012, involving all the organisations that can contribute to the common goal of eradication.

**Swine vesicular disease.** Under the plans approved and co-financed by the European Commission, only two Regions (Campania and Calabria) have not yet been accredited as free of the disease. The effectiveness of the measures taken from 2008 with the Ordinance of April 12, 2008 and subsequent national plans has been demonstrated by the sharp decrease in the prevalence of infection and the number of outbreaks reported in Italy in 2009-2010. In 2011, there were five primary outbreaks of disease in pig farms,
four in the Campania Region and one in the Molise Region. In 2011, the Ministry, in cooperation with the National Reference Centre for vesicular Diseases, launched a special plan of action and technical assistance to support regional and local veterinary services through a dedicated task force in order to gain the accreditation status of disease-free in the Regions of Campania and Calabria.

**Avian influenza.** In 2011, the national programme funded annually by the European Commission helped to carry out the surveillance activities to detect the presence of the influenza virus in both domestic and wild birds. 8,751 industrial and rural farms were sampled, while the monitoring of wild birds collected 1,805 samples. These activities allowed the identification of 23 outbreaks of low pathogenic avian influenza (LPAI), 13 of which were from H7 subtype and 10 from subtype H5, and which were mostly found of the rural or hobby-ornamental farms (over 70%) compared to those of the industrial type. The latter type of farming is the biggest risk for any viral spread, given the particular characteristics of the Italian territory and considering the high density of industrial farming particularly in Northern Italy. As a consequence of the confirmed outbreaks in 2011, listed above, the total number of animals slaughtered and destroyed amounted to 30,697. Expenses related to the culling and destruction of animals affected by the outbreaks are partially reimbursed in accordance with EC Regulation no. 349/2005 which lays down rules on the Community financing of emergency measures and of the campaign to combat certain animal diseases, whose Monitoring plans, approved by the European Commission, are subject to co-financing.

**Scrapie.** Scrapie is a neuro-degenerative disease caused by agents defined as “prions” that affects sheep and goat species. The national plan for the control of transmissible spongiform encephalopathies in sheep and goats for 2011 provides for an active surveillance of slaughtered animals and animals belonging to categories at risk, and a passive surveillance of animals of clinical suspicion and eradication where there are outbreaks. 36,173 tests were carried out in 2011, about 13,534 of which were on regularly-slaughtered sheep, about 10,174 on dead sheep, 7,747 on regularly-slaughtered goats and 4,718 on dead goats. 87 scrapie outbreaks were recorded in a total sheep and goat population of 8,557,076 (estimated on a statistical basis) and in compliance with the Regulation CE no. 999/2001, genotyping tests were carried out on 1% of the animals present in outbreaks for a total of 32,950 tests. The regional data taken from the reporting system on animals slaughtered in 2011 indicated 12,462. It remains essential to target, and therefore invest in, plans of genetic selection as the only means to eradicate the disease and have a stable and “resistant” sheep and goat population.

**Equine infectious anaemia.** With regard to equine infectious anaemia, there is a national surveillance programme which has resulted in a progressive reduction in the number of outbreaks since 2007 (outbreaks went from 356 in 2007 to 132 in 2010) and a consecutive dilution in the number of tests in 2011-2012 for the Regions of low risk (one control with a two-year validity). Testing activity was unchanged in Central Italy (with a control valid for one year in Abruzzo, Lazio, Umbria, and Molise), where the increased spread of the disease was observed due to the presence of particular types of rural or work farms, with a total of 76 outbreaks in Italy for 2011 (Table 14.5).

**Other issues in the animal health sector.** In May 2011, 20 years after the last recorded case in Italy, clinical outbreaks of dourine (a parasitic disease that affects only equines and is transmitted through sexual intercourse) were reported in the Sicily and Campania Regions. This resurgence has led to an increase in activities of serological surveillance first throughout the country and then from January 2012 only in the Centre-South Regions with particular reference to horses for sale of a reproductive age and to animals showing symptoms of the disease.
Last but not least, is the emergency virus Schmallenberg. In the second half of 2011, a new virus named the “Schmallenberg virus” – after the German town in which it was reported for the first time – was found in some EU Member States. The virus appears to be transmitted by insect vectors and susceptible species are ruminants (cattle, sheep and goats). This new emergency led to the issuing of a circular calling on veterinary Services to implement a passive surveillance. This activity led to the identification of our country’s first confirmed case, in a goat. Efforts of control and monitoring as recommended by the European Commission and the OIE are ongoing, while the EFSA is carrying out an analysis of the epidemiological data provided by Member States for a risk assessment of the possible spread of the infection taking into account the resumption of vectoral activity in the summer season.

**Essential bibliography**

Gibbs PEJ, Anderson TC. “One World – One Health” and the global challenge of epidemic diseases of viral aetiology. Veterinaria Italiana 2009; 45: 35-44

Risoluzione del Parlamento Europeo del 22 maggio 2008 su una nuova strategia per la salute degli animali nell’Unione Europea (2007-2013)

### 14.7. Zoonoses

Zoonoses are an important group of diseases that have the characteristic of being transmissible from animals to humans and vice versa. For some of them (brucellosis in cattle, sheep and goats, tuberculosis, salmonellosis, trichinosis) national, long-term plans for eradication in susceptible species are in place. For other zoonoses, such as rabies, where the risk to human health is particularly high, specific plans aimed at rapid eradication of the disease are in place. For the so-called “emerging zoonotic diseases”, such as West Nile Disease or aetiology of prion diseases (transmissible encephalopathies) monitoring, surveillance and eradication plans approved and co-financed by the European Commission have been adopted and implemented.

**Bovine, sheep and goat brucellosis.** In Italy, as in other EU countries, long-term plans are in place for the eradication of the disease and related activities are being carried out in cattle, buffalo, sheep and goat breeding centres with the aim of achieving and maintaining the status of sites officially free of brucellosis. At present the Regions recognised as officially free from bovine brucellosis within the meaning of Community law (Directive 64/432/CEE and subsequent amendments) are shown in Table 14.6. The details of the inspections conducted in 2011

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**Table 14.5. Outbreaks of infectious anaemia confirmed by CRAIE [Centre of National Reference for Infective Anaemia in Equines] in Italy in the period January 1, 2011 to December 31, 2011 (OM August 6, 2010 published in the GU no. 219 September 18, 2010)**

<table>
<thead>
<tr>
<th>Region</th>
<th>Outbreaks notified in 2011</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abruzzo</td>
<td>22</td>
</tr>
<tr>
<td>Basilicata</td>
<td>2</td>
</tr>
<tr>
<td>Calabria</td>
<td>2</td>
</tr>
<tr>
<td>Campania</td>
<td>8</td>
</tr>
<tr>
<td>Emilia Romagna</td>
<td>1</td>
</tr>
<tr>
<td>Lazio</td>
<td>11</td>
</tr>
<tr>
<td>Lombardy</td>
<td>2</td>
</tr>
<tr>
<td>Molise</td>
<td>5</td>
</tr>
<tr>
<td>Piedmont</td>
<td>1</td>
</tr>
<tr>
<td>Apulia</td>
<td>4</td>
</tr>
<tr>
<td>Tuscany</td>
<td>6</td>
</tr>
<tr>
<td>Umbria</td>
<td>9</td>
</tr>
<tr>
<td>Veneto</td>
<td>3</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>76</strong></td>
</tr>
</tbody>
</table>

show that in the Provinces not yet officially brucellosis-free 98.93% of the bovine livestock farms and 91.36% of the sheep and goat farms were tested. 2.39% of the bovine livestock farms and 2.47% of the sheep and goat farms were positive for brucellosis. The prevalence in farm enterprises is slightly diminished compared to previous years, with regard to sheep, goat and bovine brucellosis. The Region with the highest prevalence in 2011 was Sicily, with 4.79% of farm enterprises positive for bovine brucellosis and 7.44% of them positive for sheep and goat brucellosis. The figures for 2011 continue to demonstrate the satisfactory running of the eradication programme in Northern and Central Italy compared to previous years and a slow improvement in disease prevalence in the Regions of Southern Italy. Human cases of brucellosis, notified to the National notification System for infectious and spreading diseases according to the ministerial decree of December 15, 1990, are in total 167, sub-

**Table 14.6. Bovine brucellosis – Provinces officially free 2011 (as at April 2012)**

<table>
<thead>
<tr>
<th>Region</th>
<th>Province</th>
</tr>
</thead>
<tbody>
<tr>
<td>Emilia Romagna</td>
<td>Entire Region</td>
</tr>
<tr>
<td>Lombardy</td>
<td>Entire Region</td>
</tr>
<tr>
<td>Marche</td>
<td>Entire Region</td>
</tr>
<tr>
<td>Sardinia</td>
<td>Entire Region</td>
</tr>
<tr>
<td>Tuscany</td>
<td>Entire Region</td>
</tr>
<tr>
<td>Bolzano</td>
<td>Entire Province</td>
</tr>
<tr>
<td>Trent</td>
<td>Entire Province</td>
</tr>
<tr>
<td>Aosta Valley</td>
<td>Entire Region</td>
</tr>
<tr>
<td>Umbria</td>
<td>Entire Region</td>
</tr>
<tr>
<td>Piedmont</td>
<td>Entire Region</td>
</tr>
<tr>
<td>Friuli Venezia Giulia</td>
<td>Entire Region</td>
</tr>
<tr>
<td>Liguria</td>
<td>Imperia, Savona</td>
</tr>
<tr>
<td>Veneto</td>
<td>Entire Region</td>
</tr>
<tr>
<td>Lazio</td>
<td>Frosinone, Latina, Rieti e Viterbo</td>
</tr>
<tr>
<td>Abruzzo</td>
<td>Pescara</td>
</tr>
<tr>
<td>Molise</td>
<td>Campobasso</td>
</tr>
<tr>
<td>Apulia</td>
<td>Brindisi</td>
</tr>
</tbody>
</table>

*Source: European Commission Decision 2010/391/EU.*

**Table 14.7. Bovine tuberculosis – Provinces officially free 2011 (as at April 2012)**

<table>
<thead>
<tr>
<th>Region</th>
<th>Province</th>
</tr>
</thead>
<tbody>
<tr>
<td>Emilia Romagna</td>
<td>Entire Region</td>
</tr>
<tr>
<td>Lombardy</td>
<td>Entire Region</td>
</tr>
<tr>
<td>Marche</td>
<td>Ascoli Piceno and Fermo</td>
</tr>
<tr>
<td>Tuscany</td>
<td>Entire Region</td>
</tr>
<tr>
<td>Piedmont</td>
<td>Asti, Biella, Novara, Verbana, Vercelli</td>
</tr>
<tr>
<td>Friuli Venezia Giulia</td>
<td>Entire Region</td>
</tr>
<tr>
<td>Veneto</td>
<td>Entire Region</td>
</tr>
<tr>
<td>Sardinia</td>
<td>Cagliari, Medio-Campidano, Ogliastra, Olbia-Tempio, Oristano</td>
</tr>
<tr>
<td>Bolzano</td>
<td>Entire Province</td>
</tr>
<tr>
<td>Trent</td>
<td>Entire Province</td>
</tr>
<tr>
<td>Lazio</td>
<td>Rieti and Viterbo</td>
</tr>
<tr>
<td>Abruzzo</td>
<td>Pescara</td>
</tr>
</tbody>
</table>

*Source: European Commission Decision 2010/391/EU.*
ed in 2010. The figures for 2011 continue to demonstrate the satisfactory running of the eradication programme in the Regions of Northern and Central Italy compared to previous years. In some Southern Regions, and particularly in Sicily, the prevalence of the disease continues to be high. Human cases of *Mycobacterium bovis* infection, notified to the National notification System for infectious and spreading diseases according to the ministerial decree of December 15, 1990, are in total 15, subdivided by Region as follows: Emilia Romagna (1), Lombardy (3), Marche (1), Piedmont (4), Apulia (2), Sardinia (1), Aosta Valley (1) and Veneto (2).

**Salmonelloses.** Italy is carrying out a Community plan for monitoring and control of salmonelloses in poultry species along with other EU Member States. The plan includes a series of health measures for groups of animals that were found positive for salmonellas of relevance to public health through investigations carried out either by self-checking or because of official testing. The figures for 2011 show the following percentages of positives for the most important serotypes in the groups of animals checked:

- breeding (*Gallus gallus*): 1.08% for *Salmonella typhimurium* (including the monophasic variant) and *Salmonella enteritidis*, 0.36% for *Salmonella hadar*, *Salmonella virchow* and *Salmonella infantis* (in 1,088 groups controlled);
- hens (*Gallus gallus*): 3.34% for *Salmonella typhimurium* (including the monophasic variant) and *Salmonella enteritidis* (in 1,287 groups controlled);
- broiler chickens: 0.31% for *Salmonella typhimurium* (including the monophasic variant) and *Salmonella enteritidis* (in 953 groups controlled);
- breeding turkeys: no positive findings (in 40 groups controlled);
- turkeys for fattening: 0.27% *Salmonella typhimurium* and *Salmonella enteritidis* (in 367 groups controlled).

**Rabies.** There is currently an active control plan of sylvatic rabies in some areas of North-East Italy (Friuli Venezia Giulia, Autonomous Provinces of Trent and Bolzano and Veneto) after the detection of some cases of rabies in foxes in Italian territory along the Italian-Slovenian border. This plan, which began in December 2009 and will end in early 2013, is based mainly on vaccination of foxes through baits containing vaccine that are deployed with aircraft in the territories at risk. In 2011, more than 1 million such baits were distributed in these territories. The vaccination campaign conducted in 2010-2011 resulted in a significant reduction of cases of the disease in wildlife (mainly foxes): from 209 confirmed cases in 2010, to only one confirmed case in 2011.

**Trichinellosis.** Trichinellosis is a serious zoonosis, kept going by a group of nematodes with cosmopolitan distribution; infection occurs by ingestion of swine or equine meat/sausages, either raw or undercooked. In 2011, both *Trichinella pseudospiralis* (in one bred boar) and *Trichinella britovi* were detected in native animals; the latter was isolated in both pigs and in foxes. The presence of *Trichinella britovi* in foxes makes it difficult to implement a plan that will lead to the complete eradication of the disease in the country. With Regulation 2005/75/CE, the possibility was introduced, however, for individual pig farms to receive the status of “holding officially free of Trichinella”, based on specific criteria. Since 2008, there has been a significant increase in holdings accredited as disease-free in the National Data Bank, while in 2011 holdings with this status amounted to 1,048. In 2011, 6 cases of human infection with *Trichinella britovi* were reported in Italy and 10 pigs and 8 foxes identified as a result of subsequent epidemiological investigation, resulted positive for the same parasite in the same control area.

**West Nile Disease.** In 2011, there were also reports of human illness from the neuro-invasive West Nile Disease, for which for more details see the section “Monitoring of arboviral diseases”. Based on the problems that emerged in the course of plans implemented during the 2009-2010 period (an incomplete
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equine Registry and poor implementation of the poultry Registry by the sentinel poultry farms) objectives of a plan aimed at early detection of viral circulation were identified. From the second week of September 2011 numerous outbreaks of disease were confirmed in equine species in Sardinia: mainly outbreaks with clinical symptoms (nervous symptomatology), while the serological tests showed an infection of recent origin. The 2012 criteria are slightly different and aimed primarily at strengthening the surveillance of wild migratory synanthropous birds and an entomological surveillance able to detect the presence of the virus in insects. Within the context of the strengthening of epidemiological surveillance, a monitoring plan for West Nile Disease in urban areas was held in 2011 to complement the activities under the national plan. This monitoring Plan focussed on specific geographical areas of Italy (Rome, Turin, Naples, Italy, Cagliari, Palermo). Highlights were both an outcome of positivity, probably of indigenous origin, in urban areas never before affected by the disease, and the detection of positive serology in two of the 430 dogs examined in the urban area of Cagliari. The results of monitoring in dogs have confirmed the usefulness of the serological monitoring of these animals in areas where there are insufficient numbers of equine animals.

BSE. In the ten years that passed between 2001, the year of initiation of the programme of surveillance and eradication, and 2011, there were in total 145 cases of BSE 140 of which related to indigenous livestock and 4 to livestock of foreign origin. Of the 145 cases, five were atypical cases (L-type), the occurrence of which is not attributable to the use of meat meal. The favourable epidemiological trend of the disease made it possible to review the risk analysis and gradually raise the age of cattle to be sampled that had been set at 72 months for slaughtered animals and 48 months for those at risk with the adoption of the EU Decision 2011/358/CE. The sampling of all dead animals over the age of 48 months, however, is not uniform throughout the country, and in fact some Regions do not even reach 75%.

Essential bibliography

14.8. Animal welfare

Safeguarding farm animal welfare. The protection of livestock during rearing, during transport and at slaughter, with its potential impact on the protection of public health, is one of the priorities for the European Community, which, since 1974, has issued legislative provisions on the subject; also following the increased sensitivity of citizens and consumers on animal welfare issues especially in relation to breeding techniques and modes of transport. In 2011, the realisation of the 2010 National Animal Welfare Plan was confirmed, which outlines the minimum percentage of checks to be made on farms, during transport and at slaughter at the slaughterhouse. Concerning animal welfare on the farm, the D.Lgs. nos. 122 and 126 of July 7, 2011 transposed, respectively, the European Commission Directive 2008/120/CE laying down minimum standards for the protection of pigs, and the CE Directive 2008/119 laying down minimum standards for the protection of calves. Since January 1, 2012, on which a number of important provisions on the structural characteristics of holding cages, laid down in the CE Directive 1999/74/CE concerning the welfare of laying hens will become law, the Ministry of Health was active throughout 2011, carrying out two national surveys on the state of the structural adjustments to be made for breeding centres and raising aware-
ness among the relevant associations and the official veterinary services, in readiness for the approaching date on which the new EC legislation will come into force. In the Italian community law of 2011, pending approval, an amendment was inserted that gives the Government a mandate to revise the rules on penalties relating to the protection of laying hens, and which will permit the amendment to art. 7 of D.Lgs. no. 267/2003 so that the penalty system is reinforced to make it more effective, proportionate and dissuasive and whose modification procedure has already been shared with the Regions. Particular attention has been paid by the legislator to the protection of animals during transport, because very often livestock are transported on long journeys that represent a source of possible stress and suffering, as well as a potential risk for the spreading of infectious diseases. In order to implement the provisions of Regulation no. 1/2005 for the protection of animals during transport and related operations, which became applicable on January 5, 2007, a Memorandum of Understanding between the Ministry of Health and Ministry of the Interior was signed on October 3, 2011 to unify and strengthen roadside checks on the international transport of live animals in the national territory. The 2010 edition was prepared of the annual report that the Ministry of Health sends to the European Commission on inspections carried out in the previous year by the Local Health Authorities (ASLs), by the Veterinary Offices for Compliance with EU Obligations (Uffici Veterinari per gli Adempiimenti degli Obblighi Comunitari, UVACs) and by the police on transport of live animals under EC Regulation n. 1/2005. The report found that there were 241 total offences detected, 88 of which related to vehicles carrying cattle, 62 to those carrying pigs, 31 to those carrying sheep and goats, 46 to those carrying horses, 4 to those transporting dogs and cats and 10 to those carrying birds. Considerable importance is attributed in the current legislation to the training of both operators (farmers, transporters, slaughterers) and veterinary staff performing official tests. In compliance with current legislation, the Ministry of Health in collaboration with the IZSs of Lombardy and Emilia Romagna and with relevant associations, put in place training and information events regarding animal welfare on the farm and during slaughter for both veterinarians and operators in the sector during 2011. The territorially competent Veterinary Services who carry out checks on the implementation of legislation on animal welfare report annually to the Regions and Autonomous Provinces on the results of this activity, and who in turn transmit the aggregated data to the Ministry. Monitoring data must be submitted by February 28 of the year following the reference year, and Tables 14.8 and 14.9 report the data for 2011.

Safeguarding companion animal welfare. In 2011, the Operating Unit (OU), following telephone and email reports received from citizens and animal protection societies, carried out monitoring and inspection activities throughout the nation with the purpose of verifying the correct application of national legislation regarding the protection of companion animals or household pets, stray dog control and the prevention of animal cruelty. In order to have a real picture of the situation in the country and to plan the verification activities, updates were requested from the Regions and Autonomous Provinces on the number of facilities authorised to house stray animals; the census showed that there are 181 health shelters temporary accommodation and 1,033 definitive housing, for a total of 1,214 facilities (2011 data). The data provided also indicates that these structures house approximately 142,689 dogs (2011 data). In particular, inspections were carried out at kennels, catteries, unlicensed animal shelters and zoos, as well as checks regarding on the welfare of horses, in order to check the correct application of the Ministerial Ordinance of July 21, 2009 and subsequent modifications. The inspections revealed both structural and management shortcomings and conditions of maintenance of the animals that equated to ill-treatment, for which it was decided to send the report to the Public Prosecutor’s Office. The data for activities per-
formed during 2011 are synthesised in Table 14.10. During the year, several coordination meetings were also held with the authorities of territorial competence (Veterinary Services and Municipalities) in order to support them in the management of the various issues raised. Alongside the most virtuous Regions, which are successfully dealing with the issue of stray dogs and have a supervision of compliance with the regulations, are found the most problematic Regions (Molise, Calabria, and Campania, as well as Sicily and Lazio), for whom the issue of stray dogs was included in Health Realignment Plans and therefore supported by the OU in the effort of gradual remediation of this area. In order to provide clarification on how to perform checks in accordance with law 201/2010 “Ratification and implementation of the European Convention for the Protection of Pet Animals, made at Strasbourg on November 13, 1987, as well as provisions for adjustment of internal laws”, the Ministry of Health in collaboration with the National Federation of Italian Orders of Veterinarians and the Anti-vivisection League developed a manual entitled “Procedures for the implementation of controls in the Community handling of dogs and cats”. Guidelines have been developed for the application of the Ministerial Ordinance (Ordinanza Ministeriale, OM) of December 18, 2008 and subsequent amendments and additions, on “Guidelines on the prohibition of the use and possession of bait or poisoned bait” and for Assisted Interventions with Animals (Interventi Assistiti con gli Animali, IAA). Finally, technical support was provided to the Ministry of Infrastruc-


<table>
<thead>
<tr>
<th>Requirement</th>
<th>Number of total irregularities</th>
<th>Number of measures adopted accordingly (by category of non-compliance)</th>
<th>2011</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Personnel</td>
<td>50</td>
<td>Request to remedy the non-compliance within a period of less than 3 months – no penalty</td>
<td>26</td>
</tr>
<tr>
<td>2. Inspection (control of animals)</td>
<td>35</td>
<td>Request to remedy the non-compliance within a period of more than 3 months – no penalty</td>
<td>23</td>
</tr>
<tr>
<td>3. Record keeping (registration of the data)</td>
<td>112</td>
<td>Immediate administrative or legal sanction</td>
<td>1</td>
</tr>
<tr>
<td>4. Freedom of movement</td>
<td>13</td>
<td></td>
<td>1</td>
</tr>
<tr>
<td>5. Available space</td>
<td>44</td>
<td></td>
<td>1</td>
</tr>
<tr>
<td>6. Livestock buildings</td>
<td>183</td>
<td></td>
<td>1</td>
</tr>
<tr>
<td>7. Minimum illumination</td>
<td>41</td>
<td></td>
<td>1</td>
</tr>
<tr>
<td>8. Flooring</td>
<td>56</td>
<td></td>
<td>1</td>
</tr>
<tr>
<td>9. Manipulable material</td>
<td>85</td>
<td></td>
<td>1</td>
</tr>
<tr>
<td>10. Food, water supply and other substances</td>
<td>84</td>
<td></td>
<td>1</td>
</tr>
<tr>
<td>11. Animal feeds containing fibre</td>
<td>14</td>
<td></td>
<td>1</td>
</tr>
<tr>
<td>12. Mutilations</td>
<td>14</td>
<td></td>
<td>1</td>
</tr>
<tr>
<td>13. Breeding procedures</td>
<td>146</td>
<td></td>
<td>1</td>
</tr>
<tr>
<td>14. Automatic and mechanical equipment</td>
<td>45</td>
<td></td>
<td>1</td>
</tr>
<tr>
<td>Total</td>
<td>908</td>
<td></td>
<td>30</td>
</tr>
</tbody>
</table>

Implementation of lines of priority in order to meet health objectives

Protection of animals used for experimental purposes. In 2011, 19 inspections were carried out (of which 10% were not announced beforehand) in facilities using animals, to verify both the issuance of required approvals and to verify the continued meeting of the requirements by the structures already authorised, as well as the correct application of legislation on animal experimentation. Ten permits for new enclosures were issued while at the same time there was an equal number of revocations or waiver of such authorisations, thereby leaving unchanged the total number of establishments in use and confirming the trend of recent years. As part of the update of the legislation, the inclusion of the European Parliament Directive 2010/63/EU on the protection of animals used for scientific or experimental purposes in the bill “Community Law 2011 - Provisions for fulfilment of obligations deriving from Italy’s membership of the European Community” may be highlighted. On the adoption of the Directive 2010/63/EU various initiatives were undertaken aimed at the closure of kennels present in the country breeding dogs to be used in the experiments, an activity which met with the approval of the public and had a


<table>
<thead>
<tr>
<th>Requirement</th>
<th>Number of total irregularities</th>
<th>Number of measures adopted accordingly (by category of non-compliance)</th>
<th>2011</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Personnel</td>
<td>42</td>
<td>Request to remedy the non-compliance within a period of less than 3 months – no penalty</td>
<td>166</td>
</tr>
<tr>
<td>2. Inspection (control of animals)</td>
<td>4</td>
<td>Request to remedy the non-compliance within a period of more than 3 months – no penalty</td>
<td>176</td>
</tr>
<tr>
<td>3. Record keeping (registration of the data)</td>
<td>42</td>
<td>Immediate administrative or legal sanction</td>
<td>100</td>
</tr>
<tr>
<td>4. Available space</td>
<td>29</td>
<td></td>
<td>10</td>
</tr>
<tr>
<td>5. Livestock buildings</td>
<td>76</td>
<td></td>
<td>10</td>
</tr>
<tr>
<td>6. Minimum illumination</td>
<td>5</td>
<td></td>
<td>10</td>
</tr>
<tr>
<td>7. Automatic and mechanical equipment</td>
<td>51</td>
<td></td>
<td>10</td>
</tr>
<tr>
<td>8. Food, water supply and other substances</td>
<td>8</td>
<td></td>
<td>10</td>
</tr>
<tr>
<td>9. Mutations</td>
<td>1</td>
<td></td>
<td>10</td>
</tr>
<tr>
<td>10. Breeding procedures</td>
<td>18</td>
<td></td>
<td>10</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>275</strong></td>
<td></td>
<td><strong>10</strong></td>
</tr>
</tbody>
</table>


Table 14.10. Checks carried out in kennels and shelters with relative results – Year 2011

<table>
<thead>
<tr>
<th>Activities</th>
<th>No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total of Inspections in kennels/shelters</td>
<td>34</td>
</tr>
<tr>
<td>Seizures</td>
<td>2</td>
</tr>
<tr>
<td>Compliance orders and reports to the Public Prosecutor’s Office</td>
<td>5</td>
</tr>
<tr>
<td>Disclosure to the Legal Authorities</td>
<td>1</td>
</tr>
<tr>
<td>Compliance orders</td>
<td>26</td>
</tr>
</tbody>
</table>

Source: Ministry of Health, Operating unit for the care of companion animals and the fight against strays – Year 2011.
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strong presence in the mass media. The Directive 2010/63/EU should be transposed by the Member States through their own legislation by November 2012 and these provisions will then enter into force as of January 1, 2013. Paragraphs 2 and 5 of the cited Directive provide for the appointment by the Member States of a national laboratory for development of alternative research methods and to act as a national contact point. To this end, Italy has identified the “National Reference Centre for alternative methods, well-being and care of laboratory animals”, established by the DM of April 20, 2011, and based in Brescia at the site of the Lombardy-Emilia Romagna IZSs. The Reference Centre will be a point of union between the different national working groups and the European Centre for the Validation of Alternative Methods (ECVAM), in order to develop contacts between the parties and improve the validation time of alternative methods to animal testing.

Essential bibliography


14.9. Animal feed

Quality and safety of animal feed are fundamental prerequisites for animal health and welfare and for the production of healthy and safe foods of animal origin in order to protect public health. To this end, the Ministry of Health has established since 2000 a system of official control on animal feed through the “National Health Monitoring and Surveillance Plan for Animal Feed (Piano Nazionale di Sorveglianza e di Vigilanza Sanitaria sull’Alimentazione degli Animali, PNAA)”.

Inspection and sampling activity. The inspection activities at the FBO’s establishments saw the veterinary services engaged in a massive control activity aimed at ensuring the protection of animal and human health, as well as that of the environment. This activity is performed in accordance with minimum frequencies indicated by the PNAA and modulated according to the risk categorisation of establishments that is carried out locally. During 2011, 29,150 inspections were made for the entire production chain, from primary production to feeding of the animals, with 1,395 findings of structural and management non-compliance, which led to the order of 64 administrative penalties and 2 complaints to the Judicial Authority. In 2011, 12,467 official samples of animal feed were collected throughout the country, compared with the planned 12,362. Figure 14.8 shows schematically the planning of samples for 2011 and subsequent activity, illustrated by comparing the number of samples that should have been taken (expected) – divided into the various control programs under the Plan – with the number of samples actually taken. Examination of Figure 14.8 shows that in 2011 a full sampling implementation (108%) was achieved with an overtaking of the number of expected samples for the second consecutive year. This figure shows the good level of efficiency achieved by the system of official controls, thanks also to a good coordination with all the authorities involved. In 2011, 82 feed samples were non compliant with legislation disposition following analysis carried out by the laboratories of the IZS:

- 31 for the presence of active ingredients and additives which were either prohibited or in a concentration not permitted;
- 3 which were in the monitoring programme for banned active ingredients and additives;
- 19 for Salmonella spp. contamination;
- 1 for presence of dioxins;
- 4 for presence of micotoxins;
- 2 for presence of other contaminants substances;
- 22 for presence of GMOs.
These non-compliances are often linked to problems of carry-over during production, to inadequate storage conditions on the farm or to environmental contamination, while for the non-compliances due to GMOs it is necessary to emphasise that these were due to incorrect labelling.

Analysing the data, it should be noted that the percentage of non-compliance increased slightly by 0.17 percentage points from 0.48% in 2010 to 0.65% in 2011, and in absolute terms the number of non-compliances increased significantly, passing from 65 of 2010 to 82 in 2011. This finding may be an expression of a further refinement of the risk assessment underlying surveillance planning activities; the most significant samples have in any case been adequately identified. The data express a general compliance of animal feed with the legislation all the same, with 99.35% of feed results in compliance based on laboratory analyses (Figure 14.9).

**Import controls.** Based on the data received, it should be noted that in 2011 overall 3,429 consignments of animal feed were presented for import. All consignments were subjected to documentary and identity control, while...
physical check, with sampling for analysis, was performed in 249 consignments, corresponding to a sampling rate of 7.26% (298 samples). The division of sampling was as follows:

- 129 samples (43.28% of the total) for the detection of prohibited constituents of animal origin (BSE prevention);
- 71 samples (23.82% of the total) for the detection of Salmonella spp.;
- 52 samples (17.44% of the total) for the detection of contaminants (arsenic, cadmium, melamine, mercury, nitrates, chlorinated pesticides, lead and radionuclides).

It is useful to note that of 4 consignments from Japan 3 were sampled for the detection of radionuclides as a result of the nuclear accidents which occurred at the nuclear power plant in Fukushima, with favourable results;

- 21 samples (7.04% of the total) for the detection of mycotoxins; 12 samples were collected for the detection of dioxins and PCBs (4.02%);
- 7 samples (2.34%) for the detection of active ingredients and additives;
- 6 samples (2.01%) for the detection of GMOs.

These samples showed 6 non-compliant consignments of animal feed, and appropriate enforcement actions were taken.

**Evaluation of the data.** Confirming the positive trend, in 2011 there were no non-compliances for the presence of prohibited constituents of animal origin, confirming the safety of the national animal feed concerning the transmission of BSE. Only the presence of positive samples for Salmonella spp. is still a risk element for the protection of animal and human health, though less than in the past. It is underlined that the 22 non-compliances (2.7% of the total) for the presence of GMOs, an increase compared to 2010, are due to labelling non-compliance (non-declaration of the presence of GM material). Furthermore, in this context “accidental contamination” plays an important role, responsibility for which is and will remain that of the operator. The finding of 34 non-compliant samples (0.9% in 2011 compared to 0.53% in 2010) is often an expression of poor or lack of knowledge of the rules, or ineffective activities of self-monitoring at the animal feed production plants (e.g. ineffective cleaning activities, inadequate training for staff on good practice in hygiene and manufacturing). The non-compliances due to the presence of contaminants were 4 for mycotoxins (0.2% of total) and 2 for other contaminants (0.19% of total); in this case, being of very low percentages and less with respect to the 2010 total, indicating a substantial compliance with the regulations in force. With regard to the detection of dioxins and PCBs, a non-compliance equal to 0.2% of the samples is reported.

**Essential bibliography**

Ministero della salute. Relazione Piano Nazionale Integrato – Anno 2011

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**14.10. Import of animals and animal products**

**Activities of Border Inspection Posts (BIPs).** The Italian Border Inspection Posts carry out controls on consignments of animals, products of animal origin and feed imported from Third Countries and destined for the entire EU, together with BIPs located in other EU countries. In 2011, 58,753 consignments of animals, products of animal origin and animal feed from more than 100 Third Countries were presented at Italian BIPs, a decrease of 5.1% over the previous year (Figure 14.10). To these consignments must be added 11,566 goods imported into Italy through other EU BIPs, for a total amount of 70,319 consignments. The control of these goods has been systematic for each consignment, in order to
Implementation of lines of priority in order to meet health objectives

Figure 14.10. Imports: distribution of testing (Year 2011).

<table>
<thead>
<tr>
<th>Consignments presented for import</th>
<th>4,200</th>
<th>5,372</th>
<th>545</th>
<th>39,586</th>
</tr>
</thead>
<tbody>
<tr>
<td>Documental and identity Control</td>
<td>4,200</td>
<td>5,372</td>
<td>545</td>
<td>39,586</td>
</tr>
<tr>
<td>Physical/Material Control</td>
<td>4,051</td>
<td>2,100</td>
<td>276</td>
<td>17,487</td>
</tr>
<tr>
<td>Laboratory control</td>
<td>28</td>
<td>293</td>
<td>39</td>
<td>1,453</td>
</tr>
<tr>
<td>Non-compliant consignments</td>
<td>16</td>
<td>21</td>
<td>7</td>
<td>174</td>
</tr>
</tbody>
</table>

Source: Traces system – DGSAFV Uff. VIII.

Verify the correctness of the documentation and the identity of the products. Veterinary inspection on products of animal origin was conducted with a differing control frequency however, depending on the type of product and the country of origin, as provided for by Community legislation. When deemed appropriate by veterinary inspectors or in compliance with specific ministerial or community dispositions (European Council Regulation no. 136/2004 and the BIPs Monitoring Plan), the physical/material control has been supplemented by appropriate laboratory tests. The framework of import controls is completed by the activity of support to Customs for inspections of products of animal origin introduced by travellers from Third Countries.

Checks on intra-EU trade on live animals and food of animal origin – UVACs activities. The UVACs are peripheral offices of the Ministry of Health and are responsible for checks on arriving goods at destination of Community origin only. In 2011 1,309,071 consignments of animals, of food of animal origin and other products of animal origin not intended for human consumption were pre-notified to the UVACs (+4.1% compared to 2010) representing a volume nearly 19 times higher than that of the consignments imported from Third Countries (Figure 14.11). Veterinary control of live animals and food of animal origin highlighted 136 cases of non-compliance in 2011. A significant proportion of these cases were explained by the presence of mercury (25), of *Listeria monocytogenes* (27) and anisakis (13) in prepared fish and salmonella (4) in meat. In addition to the above testing arranged by the UVACs and performed by the Local
Health Authorities (ASLs), some UVAC offices operate either directly or in collaboration with the Police, the NAS health division of the Carabinieri or the Forest Service for the performance of checks on the welfare of animals during road transportation (EC Regulation no. 1/2005).

**Essential bibliography**


### 14.11. Import of products of non-animal origin

**Planning framework – USMAFs.** USMAFs are divided into 12 Offices at a non-general executive level and 37 Territorial Units, evenly distributed throughout the country in major ports and airports. As for the official control of foodstuffs of non-animal origin and materials in contact with them, the USMAFs operate in compliance with national regulations.
Implementation of lines of priority in order to meet health objectives and EU legislation, according to the POS 11 (Unified Standard Operating Procedure “NOS/DCE Release on the import of food of non-animal origin”) and to Central or Local Operating Instructions. The EC Regulation 669/2009 introduced important changes for increased controls such as the use of the Common Entry Document (the document that must be completed by the animal feed and food sector operator or his representative, as well as by the competent authority who confirms the completion of official controls) and the definition of a Designated Point of Entry (PED) for imports into EU territory. A special Central Operating Instruction (IOC 1002) indicates the “Conditions for recognition as Designated Points of Entry (PEDs) and Designated Points for Import (PDIs)”.

**Description of the data – Control activities in 2011.** On average each year, more than 120,000 official controls are performed on food of non-animal origin and materials and articles which come into contact with food, of which 100% are documental, about 9-10% inspective and 5-6% with sampling of the goods. The rejections on average amount to less than 1%. In 2011, official checks concerned 125,159 consignments of food or materials in contact with food, as shown in Table 14.11.

The USMAF data on testing of imports of food of non-animal origin are shown in Table 14.12, sub-divided by the individual Territorial Units. Presentation and critical evaluation of the data. The number of official controls carried out on foods of non-animal origin in 2011 is in line with that in 2010 (84,810 consignments compared with 85,971, a percentage change of –1.35%), while for materials in contact with food (40,349 consignments) a significant increase was reported compared to 2010 (37,612 items), with a percentage change equal to +7.3%.

With regard to sampling rates, these are in total conformity with the provisions of the national legislation and POS 11, as rates should arrive at 5.65% of consignments presented for import for food of non-animal origin. Of the 180 consignments of foods rejected, 20 were on the basis of documents, 34 on an inspection basis and 126 after sampling with laboratory analysis. About a third of rejections were caused by the discovery of aflatoxins.

**Training activities.** In the course of 2011, using a reallocation of funds resulting from the application of D.Lgs. no. 194 of November 19, 2008 “Regulation on refinancing of official health checks in implementation of the European Parliament Regulation no. 882/2004”, the Office II of the Directorate-General for Hygiene, Food Safety and Nutrition organised a “Food safety course for USMAF doctors and technicians”. The course took place from May to October 2011: it was divided into eight editions of two days each, and involved over 10 teachers (selected from among experts of the Ministry of Health, the ISS and IZSs and 132 participants, including doctors and technicians of prevention (49 doctors and 83 technicians), with the purpose of updating the knowledge for effective control of food of non-animal origin.

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**Table 14.11. Overall data on testing of imported food of non-animal origin and food contact materials – USMAF activities 2011**

<table>
<thead>
<tr>
<th>Territorial unit</th>
<th>Consignments</th>
<th>Controls of inspection</th>
<th>Controls with sample</th>
<th>Refusals</th>
<th>% samples</th>
<th>% refusals</th>
</tr>
</thead>
<tbody>
<tr>
<td>Italy</td>
<td>125,159</td>
<td>9,758</td>
<td>5,815</td>
<td>304</td>
<td>4.65%</td>
<td>0.24%</td>
</tr>
</tbody>
</table>

*Consignments: number of consignments arriving in each Territorial Unit, each of which has been issued a Health Authorisation (100% of documental checks); Controls of inspection: physical checks of the goods and conditions of carriage; Controls with sample: controls provide for the taking of a sample for analytical purposes; Refusals: cases where the goods have been rejected at the end of the checks.*
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non-animal origin, of materials coming into contact with food, supplements and novel food presented for import. The course was CME-accredited and was held at the Ministry of Health.

Activities for the One-Stop Customs service. On January 29, 2011, the decree of the President of the Council of Ministers (DPCM) no. 242 of November 4, 2010, (GU no. 10 of January 14, 2011) came into force concerning “Definition of the terms of conclusion of the administrative procedures which contribute to the fulfilment of customs import and export operations” for the establishment of the one-stop Customs service.

Table 14.12. Inspections by USMAF on imports of food of non-animal origin

<table>
<thead>
<tr>
<th>Territorial Unit</th>
<th>Consignments</th>
<th>Inspections</th>
<th>Samples</th>
<th>Refusals</th>
<th>%Cmp</th>
<th>%referrals</th>
</tr>
</thead>
<tbody>
<tr>
<td>Genoa</td>
<td>19,326</td>
<td>1,362</td>
<td>951</td>
<td>47</td>
<td>4.92%</td>
<td>0.24%</td>
</tr>
<tr>
<td>Trieste</td>
<td>14,878</td>
<td>1,734</td>
<td>1,408</td>
<td>9</td>
<td>9.46%</td>
<td>0.06%</td>
</tr>
<tr>
<td>Milan-Malpensa</td>
<td>11,947</td>
<td>196</td>
<td>126</td>
<td>8</td>
<td>1.05%</td>
<td>0.07%</td>
</tr>
<tr>
<td>Livorno</td>
<td>6,314</td>
<td>1,156</td>
<td>254</td>
<td>1</td>
<td>4.02%</td>
<td>0.02%</td>
</tr>
<tr>
<td>Naples</td>
<td>5,966</td>
<td>658</td>
<td>601</td>
<td>33</td>
<td>10.07%</td>
<td>0.55%</td>
</tr>
<tr>
<td>Savona</td>
<td>5,198</td>
<td>64</td>
<td>59</td>
<td>3</td>
<td>1.14%</td>
<td>0.06%</td>
</tr>
<tr>
<td>Salerno</td>
<td>3,599</td>
<td>501</td>
<td>373</td>
<td>17</td>
<td>10.36%</td>
<td>0.47%</td>
</tr>
<tr>
<td>La Spezia</td>
<td>3,140</td>
<td>113</td>
<td>93</td>
<td>1</td>
<td>2.96%</td>
<td>0.03%</td>
</tr>
<tr>
<td>Ravena</td>
<td>2,504</td>
<td>221</td>
<td>208</td>
<td>16</td>
<td>8.31%</td>
<td>0.64%</td>
</tr>
<tr>
<td>Reggio Calabria</td>
<td>2,364</td>
<td>98</td>
<td>86</td>
<td>4</td>
<td>3.64%</td>
<td>0.17%</td>
</tr>
<tr>
<td>Turin Caselle</td>
<td>2,168</td>
<td>36</td>
<td>36</td>
<td>1</td>
<td>1.66%</td>
<td>0.05%</td>
</tr>
<tr>
<td>Venice</td>
<td>2,131</td>
<td>397</td>
<td>220</td>
<td>11</td>
<td>10.32%</td>
<td>0.52%</td>
</tr>
<tr>
<td>Fiumicino</td>
<td>1,685</td>
<td>259</td>
<td>31</td>
<td>11</td>
<td>1.84%</td>
<td>0.65%</td>
</tr>
<tr>
<td>Civitavecchia</td>
<td>909</td>
<td>19</td>
<td>14</td>
<td>0</td>
<td>1.54%</td>
<td>0.00%</td>
</tr>
<tr>
<td>Palermo</td>
<td>813</td>
<td>156</td>
<td>81</td>
<td>3</td>
<td>9.96%</td>
<td>0.37%</td>
</tr>
<tr>
<td>Bari</td>
<td>429</td>
<td>154</td>
<td>84</td>
<td>4</td>
<td>19.58%</td>
<td>0.93%</td>
</tr>
<tr>
<td>Ancona</td>
<td>263</td>
<td>188</td>
<td>30</td>
<td>4</td>
<td>11.41%</td>
<td>1.52%</td>
</tr>
<tr>
<td>Imperia</td>
<td>223</td>
<td>20</td>
<td>15</td>
<td>2</td>
<td>6.73%</td>
<td>0.90%</td>
</tr>
<tr>
<td>Siracusa</td>
<td>192</td>
<td>86</td>
<td>40</td>
<td>0</td>
<td>20.83%</td>
<td>0.00%</td>
</tr>
<tr>
<td>Bergamo-Orio al Serio</td>
<td>181</td>
<td>2</td>
<td>1</td>
<td>1</td>
<td>0.55%</td>
<td>0.55%</td>
</tr>
<tr>
<td>Trapani</td>
<td>113</td>
<td>86</td>
<td>28</td>
<td>0</td>
<td>24.78%</td>
<td>0.00%</td>
</tr>
<tr>
<td>Ciampino</td>
<td>90</td>
<td>34</td>
<td>0</td>
<td>3</td>
<td>0.00%</td>
<td>3.33%</td>
</tr>
<tr>
<td>Pescara</td>
<td>77</td>
<td>71</td>
<td>7</td>
<td>0</td>
<td>9.09%</td>
<td>0.00%</td>
</tr>
<tr>
<td>Bologna</td>
<td>75</td>
<td>13</td>
<td>9</td>
<td>0</td>
<td>12.00%</td>
<td>0.00%</td>
</tr>
<tr>
<td>Cagliari</td>
<td>66</td>
<td>51</td>
<td>11</td>
<td>0</td>
<td>16.67%</td>
<td>0.00%</td>
</tr>
<tr>
<td>Catania</td>
<td>61</td>
<td>23</td>
<td>5</td>
<td>0</td>
<td>8.20%</td>
<td>0.00%</td>
</tr>
<tr>
<td>Rome</td>
<td>27</td>
<td>27</td>
<td>3</td>
<td>0</td>
<td>11.11%</td>
<td>0.00%</td>
</tr>
<tr>
<td>Taranto</td>
<td>23</td>
<td>11</td>
<td>5</td>
<td>1</td>
<td>21.74%</td>
<td>4.35%</td>
</tr>
<tr>
<td>Brindisi</td>
<td>21</td>
<td>20</td>
<td>5</td>
<td>0</td>
<td>23.81%</td>
<td>0.00%</td>
</tr>
<tr>
<td>Pisa</td>
<td>17</td>
<td>6</td>
<td>3</td>
<td>0</td>
<td>17.65%</td>
<td>0.00%</td>
</tr>
<tr>
<td>Manfredonia</td>
<td>8</td>
<td>8</td>
<td>8</td>
<td>0</td>
<td>100.00%</td>
<td>0.00%</td>
</tr>
<tr>
<td>Naples-Capodichino</td>
<td>2</td>
<td>1</td>
<td>1</td>
<td>0</td>
<td>50.00%</td>
<td>0.00%</td>
</tr>
<tr>
<td><strong>Italy</strong></td>
<td><strong>84,810</strong></td>
<td><strong>7,771</strong></td>
<td><strong>4,796</strong></td>
<td><strong>180</strong></td>
<td><strong>5.65%</strong></td>
<td><strong>0.21%</strong></td>
</tr>
</tbody>
</table>

%Cmp: samples for analysis as percentage of total consignments inspected; %referrals: percentage of rejections in the total of consignments inspected.
service. The one-stop Customs service will give the opportunity to operators to present all requests that relate to the obtaining of the necessary documentation to carry out operations of importation through mainly computerised data transmission and a single documental transmission. Once transmitted to a single point of entry (interface), these requests are then sent to the various authorities concerned, who then process their response and return it via the interface.

As of February 15, 2011, numerous meetings were held with the Customs Agency, which involved a Coordinating Committee (composed of the Director-General) and a Working group called the “Functional-Procedure Customs-Health Council”, made up of technical staff from the Office II of the Directorate-General for Hygiene, Food Safety and Nutrition (DGISAN), from the Directorate-General for Prevention and the Directorate-General for Health Information and Statistical System, with the aim to develop operational procedures for the exchange of data between the competent institutions. The Working group is currently finalising the draft document “Model of interoperability for the Customs Agency - Ministry of Health”, which involves mostly computer experts of the two Institutions.

14.12. Hygiene and safety of food of animal origin

Planning framework and state of implementation. In 2011, the tracing of zoonotic agents in foods of animal origin saw the sampling of elements of meat, fish, milk, eggs and their derivatives in the various facilities involved in the production, processing, storage or distribution of food: from slaughterhouses to canteens, catering, restaurants, processing laboratories and retail points of sale. 46,830 samples for the detection of salmonella were carried out and, in relation to individual sectors of production, the meat sector is the one in which traces were more frequently isolated, albeit low in absolute terms (1.4%). Tracing of the Listeria pathogen (43,120 tests) has confirmed its ubiquity.

Tests for the presence of Trichinella larvae saw 11,262,592 tests being done for pork meat, all negative, as well as 73,251 tests in wild boar meat that found 2 carcasses infected. In addition, following human cases of trichinosis in Sardinia, tests showed 10 positive samples in pig meat from illegal slaughter. Checks in the shellfish sector have evidenced the presence of Escherichia coli in samples collected during breeding as the main cause of non-compliance, indicating faecal contamination and the presence of algal bio-toxins. Checks carried out during breeding helped avoid the marketing of non-conforming products.

In the milk sector, 8,935 samples were made of raw milk sold either by a company or provided through vending machines, compared to 2,302 registered facilities. The presence of thermo-tolerant Campylobacter was registered at 2%, while non-conformities to the presence of coagulase-positive staphylococci and Listeria were lower at 1%.

In total, 228,622 visits by the competent services of the ASLs regarding their activities, inspections, audits, sampling etc. were registered at factories for production of food of animal origin, related to official controls. Non-conformities encountered most often were, in order, in conditions of the facilities and the equipment, the management of prerequisites (pest control, staff training, potable water used, etc.) and the preparation of the plan of factory self-checking.

Results of the National Plan for Residues. The Ministry audit of the official testing in the “Hygiene of food of animal origin” sector affected nine Regions and Autonomous Provinces: Campania, Veneto, Tuscany, Sardinia, Molise, Marche, Friuli Venezia Giulia, Trent and Bolzano.
The detection of residues of chemical substances during the process of breeding of productive animals and during the initial processing of animal products (National Plan for Residues) saw 38,882 analyses performed, 17,651 of which for category A substances (unauthorised substances with anabolic effect) and 21,131 for those of category B (pharmacologically-active substances and environmental contaminants). The minimum number of samples required by Community rules (142.7%), and the planned number of samples by the Ministry (111.3%) were both exceeded. In addition to this activity, a further 2,419 tests were carried out on samples taken in cases of suspicion and 7,771 analyses based on particular regional and/or local issues. Samples that gave irregular results were 75 in implementation of the Plan (0.19% of total analyses carried out), including 35 for the presence of residues of category A (46.7%) and for the detection of residues in category B (53.3%); in the latter case, the main molecules highlighted belonged to antibacterial agents (34%), while the area most affected by the non-compliance was the cattle sector (63%), probably as a result of the large number of tests intended for it, 17,543 analyses comprising 45.1% of the total.

14.13. Food safety of dietary supplements and foods with added vitamins and minerals

In the case of food supplements and foods containing added ingredients, the Ministry of Health carries out direct verification and control.

In fact, the marketing of:
- foods with added vitamins, minerals and certain other substances (ex Regulation CE 1925/2006),

is subject to a notification procedure, which consists in the transmission to the Ministry of a model of the product label upon its placing on the market. This procedure allows compliance with the specific sector norms for the above products to be ensured, with particular reference to the adequacy of the constituents, their contributions and the properties claimed on the label. In 2011, approximately 8,528 new notifications were received with 2,182 instances of review.

In addition, the registry with a list of dietary supplements that have concluded the notification procedure has been published on the website, with quarterly updates. Establishments located throughout the country are subject to ministerial authorisation for the production and packaging of the products mentioned above; the list of the specific types of products is available on the Ministry website. In 2011, 45 acts authorising production and packaging were issued. The Ministry is also the competent authority in the field of novel food, i.e., those products that do not have a history of significant consumption as food in the EU before May 15, 1997. Novel foods are governed by Regulation 258/97 of the European Parliament and of the Council of January 27, 1997 concerning novel foods and novel food ingredients, which defines two authorisation procedures. The procedures (one complete and one called “substantial equivalence”) directly involve the Ministry, which initially evaluates the presented scientific dossiers. In this respect it should be noted that in 2011, which is the year to which this Report on the Health Status of the Country refers, the Ministry evaluated:
- 3 instances of substantial equivalence addressed to Italy;
- 47 instances in total of both substantial and complete equivalence submitted through other EU Member States.
In the sector of food supplements, the Ministry prepared a DM on the use of plants and derivatives in the supplement industry, notified to the European Commission, and set up a Working Group on the use of plants and derivatives in the supplement industry with representatives of the relevant Authorities of France and Belgium; a document on the use of probiotics in food and supplements has also been produced published on the website. The relevant office of the Ministry actively monitors regulatory developments in the areas to which the products mentioned belong at EU level, supporting the positions and the criteria defined at national level. In this context, EU working groups defining the maximum levels of vitamins and minerals present in food, as well as on novel food, have been pursued. The Ministry promoted 15 training courses in the sector of food supplements and novel food at headquarters and in the regional offices which requested them for the continuous training of its staff and of regional staff deputised to perform official testing.

With a view to simplification and ensuring consistent and timely information to the public, the area dedicated on the website to the products in question is continually updated. The services project, which includes all the procedures for the notification of products, as well as all the forms for submitting requests to the Ministry, was completed as part of the activities related to the CAD (digital administration code). Specifically, 17 procedures forms have been drafted with 44 specific modules.

14.14. Results of checks on foodstuffs

**Planning framework and state of implementation in regional contexts.** 2011 represents a turning point for the sharing of system strategies aimed at protecting the health of citizens through food safety. It was actually the first year of implementation of the National Integrated Plan (Piano Nazionale Integrato, PNI) 2011-2014, approved by the State-Regions Understanding of December 16, 2010 on a proposal submitted by the Ministry of Health. The 2011-2014 PNI, structured in accordance with the dictates of the European Parliament Regulation 882/2004 and Commission Decision 2007/363/CE, combines in a single framework the description of all the components of official controls guaranteeing the safety, quality and authenticity of food production and agro-livestock. To achieve this goal, the Ministries of Health, of Agriculture, Food and Forestry and of the Environment, Land and Sea, the ISS, the Customs Agency, the Regions and Autonomous Provinces, the Police Force and bodies of the Judicial Police, as well as public laboratories and other departments involved in the conduct of controls participate in their various competences. The official control of food and beverages is carried out at all stages of the supply chain: production, processing, storage, transport, trade and administration, with inspections, sampling, laboratory analysis, with Hazard Analysis And Critical Control Points (HACCP) and of the hygiene of responsible personnel. The Ministry carries out mostly functions of guidance and coordination. This coordination is then delegated to the regional level, to the regional health Departments, while the functions of control of production, trade and provision of food and beverages are the municipalities’ responsibility, exercising them through the ASLs Departments of Prevention. In the case of a non-compliance of a health variety found in a food, animal feed or materials coming into contact with food, the Food and Nutrition Hygiene Services (Servizi di Igiene degli Alimenti e Nutrizione, SIAN) and the Veterinary Services activate the warning system, as provided for by the applicable regulations: the European Parliament Regulation 178/2002 and the European Commission Regulation 16/2011. In fact, if a serious risk to the consumer is found,
immediate action is required by the competent Authorities in the territory to ensure the protection of public health. The immediate adoption by the food sector operators (operatori del settore alimentare, OSAs) of measures of withdrawal and/or recall from the market for non-compliant food products, together with verification of their effectiveness by the competent authority, ensures a high level of protection of human health. As required by the European Parliament Regulation 882/2004, the 2011 version of the annual report for the National Integrated Plan (PNI) was sent to the European Commission and published on the portal. Furthermore, the report of the Surveillance and testing Plan for food and beverages will be written, the preliminary data from which are reported here next; this report will be forwarded to Parliament.

Presentation and critical evaluation of the data. Inspections conducted by the ASLs Food and Nutrition Hygiene Services and Veterinary Services units totalled 358,196 on operational units (plant and equipment of the premises, facilities and means of transport, etc.), 53,180 (14.8%) of which showed infringements. The highest percentages of irregularities were found in the restaurant sector (26.2%) and in the category of producers and packagers (19.5%). Units controlled amounted to 24.7% compared to the number of facilities reported overall in the country.

In particular, the operational units (OUs) controlled by the Food and Nutrition Hygiene Services amounted to 155,654, 35,262 of which with offences, a percentage of 22.7%. The major irregularities concern the food service industry (26.9%) and producers and packagers who mainly sell retail (26%). Units controlled amounted to 18.3% compared to the number of facilities reported overall in the country. The ASL Veterinary Services, however, checked 202,542 OUs, 17,918 (8.8%) of which showed infringements. The highest percentages of irregularities were found in the category of producers and packagers (20.8%). Units controlled amounted to 33.9% compared to the number of facilities reported overall in the country. Relative to the analytical activity performed by the IZSs, food samples analysed totalled 95,941, 1,148 of which were non-compliant, a percentage of 1.2%. The largest number of offenses covered microbiological contamination, in order Listeria monocytogenes and Salmonella, and to a lesser extent, chemicals, heavy metals, histamine and residues of veterinary medicines. The Regional Agencies for Environmental Protection (Agenzie Regionali per la Protezione ambientale, ARPA) and the Public Health Laboratories set up in different Regions analysed 21,244 samples. In total, 381 samples were not in regulation, equal to 1.8%. The largest number of offenses covered microbiological contamination, especially moulds and yeasts, Escherichia coli, and to a lesser extent, chemicals, primarily mycotoxins and heavy metals. This trend is also reflected through notifications by the Community alert system. Among microbiological contaminants, there were a large number of alerts for Salmonella (396 alerts), an increase in the number of alerts for Listeria and for the detection of Anisakis larvae. Chemical contaminants most frequently reported are mycotoxins, followed by pesticide residues and those of migration of materials being exposed to food. Italy is once again the first among Member-State countries for the number of notifications sent to the European Commission, as has been the case in previous years, showing an intense activity of control over the national territory with 553 notifications (14.8%). With regard to product origin, there were 105 domestic products with irregular results, making Italy the fourth EU country for number of notifications received after Germany, Spain and France. Considering also third-party countries, however, Italy is in seventh place.

Essential bibliography
Main audit findings. Among the mechanisms in place to ensure the effectiveness and relevance of official controls, art. 4 section 6 of the European Parliament Regulation 882/2004 provides that the competent authorities carry out audits on official control systems. The national audit system consists of a cascade audit system on the Competent Authorities (Ministry of Health, the Regions and ASLs) designated by the D.Lgs. no. 193/2007. The Department of Veterinary Public Health, Food Safety and National Boards for Health Protection (DSVETOC) of the Ministry of Health carries out audits on regional systems of prevention in food safety and veterinary public health. Regions in turn carry out audits on the ASLs. In 2011 the Ministry of Health carried out 30 audits (3 system and 27 sector), for a total of 18 Regions and Autonomous Provinces concerned with 3 cycles of audits concluded, an increase of 36% compared with 2010 audit activities.

The ministry audit activities showed:

- a strengthening of the interaction and cooperation between the Regional Competent Authorities (Autorità Competenti Regionali, ACRs) and the local entities involved in various ways in food safety;
- progress by the ACRs in systems of planning of official controls, although some critical areas remain either due to the lack of planning tools, or the application of control policy based on risk, regardless of respect for the minimum levels of controls established by certain norms, with the consequent risk of modulating the level of performance solely on the basis of human and financial resources available;
- interventions of organisational and structural reorganisation of some regional health directorates and ASL units due to budgetary needs that, if not properly done, could weaken the operational capabilities of such structures;
- a lack of permanent regional staff for the task due to the recruitment freeze, which is overcome by a type of flexible and discontinuous collaboration, able to cope with temporary and immediate operational needs but unable to ensure either stability or a continuity of improvement to the system.

Based on the information received from the Regions and Autonomous Provinces via the information flow on audit activities carried out by them, 58 system audits and 133 sector audits of Local Competent Authorities (Autorità Competenti Locali, ACLs) were performed in 2011, a significant increase of 82% compared to 2010 audit activities. In particular, it was highlighted that 18 Regions and Autonomous Provinces (Campania, Emilia Romagna, Lazio, Lombardy, Autonomous Province of Bolzano, Tuscany, Aosta Valley, Friuli Venezia Giulia, Abruzzo, Sicily, Autonomous Province of Trent, Umbria, Veneto, Sardinia, Calabria, Liguria, Apulia and Marche) are putting in place an audit system on ACLs, while two Regions (Molise and Basilicata) are still in various stages of implementation of an audit system.

It should also be noted that the Piedmont Region carried out audits on hospital catering, and on FBOs, using personnel from ASLs outside of where the facility is located, allowing the evaluation, albeit partial and indirect, of the organisation, the operation and the compliance to operate in accordance with EC Regulation no. 882/2004 and with respect for regional planning of official controls in the different ASLs. Although the audit activity carried out by the Regions has shown some improvement in the usage of “planning and control” instruments (despite the persistence of some aspects of heterogeneity between Regions and even within the same Region) ensuring a greater appropriateness of official control and increased use of it tools for the collection, processing and reporting of activity data, some operational criteria still need further strengthening, in particular with regard to the preparation of reports on the official controls carried out, the management of non-compliance and verification of their resolution, the adoption and updating of documented
Food safety and veterinary health

procedures and the verification of the effectiveness of official controls. Of note, with regard to human resources involved in official controls in veterinary public health and food safety in 2011, was the reduction of 9% in ASL veterinary staff compared to 2006 (year of first analysis), with the sharpest decline in veterinary services in animal health (−14%); the analysis shows, moreover, an increase of 25% of graduates in temporary employment compared to 2006. An analysis of the state of regional veterinary and food systems shows that the responsibilities of food safety are normally located within the Regional Health Departments, except for the Autonomous Province of Bolzano where the veterinary service is part of the regional agriculture Department. In general, it was found that the management of food safety and veterinary public health is assigned to a single organisational structure in 13 Regional Departments of Health, while for the remaining 8 the two areas are separated. In this case, the unification of the offices occurred in the Regions of Abruzzo, Tuscany and Liguria in 2010 and Piedmont in 2012.

Evaluation systems in veterinary health and food safety through indicators. A verification of the official control activities carried out in 17 Regions and their ASLs is also performed using a pool of indicators, as part of the evaluation system adopted by the Essential Levels of Health Care (Livelli essenziali di assistenza, LEA) Committee. The elements assessed are the information flows that the Regions must guarantee for the Ministry of Health and the five performances are evaluated within the context of the “LEA Grid”. In 2011, 18 information flows were evaluated through 36 indicators; 14 Regions (82%) achieved a rating of adequacy, while the other three (18%) did not meet the criteria. In this regard, it is worth pointing out that the elements evaluated can be regarded as a signal of situations that then need to be investigated in-depth based on a wider set of elements. The indicators chosen, in fact, do not cover the entire spectrum of lines of activity under official control, but offer guidance on the level of efficiency and effectiveness achieved by each regional health system. Regarding the results of the evaluation of the compulsory information flows in food safety and veterinary health, for the 17 Regions evaluated in four years a general trend towards improvement has remained (especially for satisfying the quality criterion): from 53% of Regions assessed as sufficient in 2008 to 83% in 2011. Two Regions have had a constant evaluation of failure for the years 2007-2010. For both of them, targeted initiatives are underway: a two-year plan of commitments was agreed for one (2012 will be the second year of operation) focused on the creation of an internal structure in the Region specifically dedicated to the management of information flows, which allowed the Region to be much closer to an assessment of sufficiency in 2011; for the other a specific structure of the Commissioner type was set up with the task to organise, plan and monitor the entire management of regional veterinary health.

Essential bibliography


Intesa della Conferenza Stato-Regioni. Rep 2271/CSR del 23 marzo 2005


15 Healthcare research in Italy

15.1. Healthcare and biomedical research

Planning framework. Qualifying and boosting competitiveness in health research is a necessary tool to optimise not only economic investment, but also for cultural and social growth: innovation and support for the individual researcher who proposes quality ideas are instruments which improve the National Health Service (Servizio sanitario nazionale, SSN). In particular, healthcare and biomedical research is of fundamental importance to the scientific and technological progress of the country, for the direct impact on people’s health but also for the development of the pharmaceutical and biomedical industries. Health and the technologies and services connected with it are one of the priorities of investment to overcome the crisis and promote economic recovery. In Europe, Japan and the United States research in the biomedical area produces scientific results of high impact and visibility, with immediate impact on treatment and care, promoting the transition to an evolved model of welfare. They also have a high value in terms of intellectual property and industrial exploitation. Research has therefore three objectives: to improve the care and health of citizens, introducing advanced protocols and up-to-date methods of treatment; the reorganisation of services and benefits for the purpose of cost containment; and the possible industrial fallout in terms of progress for the pharmaceutical industry and national biomedical technologies.

In 2011, in line with what has been started in the last three years, efforts were encouraged to ensure the transparency and quality of health research funded by the Ministry of Health, in the belief that good care is accompanied by good research. Applied research extended to hospitals is also an essential element for the qualitative growth of the SSN, as well as functional for expenditure restraint, whilst ensuring the improvement and efficiency of services and care. Therefore, the development of initiatives and expertise in the territory and in the SSN network in 2011 also led to the provision of substantial financial resources to support research projects, through the concessions of 295 projects which were the winners of the “Call for targeted research” and the “Young Researchers 2009” funding projects (funding about Euro 100 million) [Figure 15.1] and the launch of the new “Call for targeted research” and “Young Researchers 2010” (about Euro 84 million), which saw a massive turnout this year with presentations of as much as 2,826 research projects for evaluation by operators throughout the SSN, as well as an increase in training, support and comparison that involved all the players of the system whether as institutional recipients or as individual researchers.

To achieve the objective of rewarding excellence in Italy, the selection of the best projects is ensured through peer review with procedures that ensure transparency, impartiality and effectiveness of the evaluation system confirmed in 2011 by the Ministry of Health. This procedure of review requires that projects submitted by researchers through the Institutional Recipients recognised by law [Regions, Scientific Institutes for Research, Hospitalisation and Health Care (Istituti di Ricovero e Cura a Carattere Scientifico, I.R.C.C.S.)] must be evaluated by independent experts who are not affiliated with the institutions that submitted the projects. The evaluation process is based on a blinded peer review, where experts are asked to evaluate the scientific merit of the projects without knowledge of the names of the applicants. This ensures a fair and unbiased assessment of the research proposals. The experts submit their evaluations to a centralised evaluation body, which then ranks the projects and makes recommendations to the Ministry of Health for funding decisions. The evaluation process is designed to ensure that the best projects are selected based solely on the scientific merit of the research proposals, rather than any other factors such as the reputation or influence of the institutions or researchers involved. The Ministry of Health then makes the final decisions on which projects to fund based on the recommendations of the evaluation body and the overall priorities of the government at the time.
IRCCSs), Experimental Institutes for animal disease control and prevention (Istituti Zootrofili Sperimentali, IZSs), National Institute for Health (Istituto superiore di sanità, ISS), the Italian Workers’ Compensation Authority (INAIL) and the National Agency for Regional Health Services (Agenzia Nazionale per i Servizi Sanitari Regionali, AgeNaS) are subject to assessment by international referees with automatic assignation to assessors who are accredited on the system according to an area of expertise identified at international level. The refereeing system provides that at the time the application is made, the coordinator researcher (principal investigator) classifies their own project using a classification of the area of expertise derived from that provided by the American NIH-CSR (National Institutes of Health – Center for Scientific Review). The information system that manages automatically the allocation of projects to be assessed to auditors assigns them to auditors who are ranked in the same area of expertise as the project. The system of evaluation for the studies provides that the referees attribute for each of the four evaluation criteria (scientific quality, innovation and transferability, facilities and equipment available for research and researcher profile) a score from 1 (best grading) to 9 (worst grading), as well as a motivation to justify the allocated score. Using this system of evaluation, the area that received the best performance among all the projects presented was that of musculoskeletal disorders and dermatology (Musculoskeletal, Oral and Skin Sciences) followed by vascular and haematological diseases and immunology. Among the winning projects, the

![Figure 15.1. Call for projects 2009: distribution of winning projects by area of expertise.](image)
best was that in the area of the molecular and cellular aspects of neuroscience (Molecular, Cellular, and Developmental Neuroscience) followed by translational oncology (Oncology Basic Translational) and then by immunology (Figure 15.2). The quality of the system is ensured by the selection of the assessors involved. To this end, international collaborations have been initiated with the NIH-CSR, which in the first instance has made available a database of about 3,000 assessors, and collaboration started in 2011 with ISSNAF (Italian Scientists and Scholars of North America Foundation), that involved a large number of evaluators resident in North America in the system.

The research aim is coordinated by those who the law defines as the institutional recipients. For the implementation of projects these bodies may also collaborate with other public and private research institutions, universities and even public or private companies, on the basis of agreements, conventions or contracts. In 2011, allocation of resources anticipated under the Call for Projects in 2009 saw the financing of 295 projects, distributed as shown in Figure 15.3 by the institutional recipients and the two macro-areas of clinical care and biomedicine.

Also the 2009 Call for submissions funded Italian participation in 2 European projects: ERA-Net-Rare Diseases [initiative launched by the European Union (EU) since 2007 to promote cross-national research on rare diseases] and EMIDA ERA-Net (Emerging and Major Infectious Diseases of Livestock European Research Area Network), a European research network on key and emerging infectious diseases of livestock. In addition, the Ministry of Health participates as a coordinator in the “Transcan” project (ERA-Net for translational cancer research) and “NEURON” (project for research in neuroscience).
The 2010 Call for Targeted Research was launched in 2011 (with funding of about Euro 84 million), introducing two new types of project on an experimental basis:

- **project abroad (Euro 10 million):** projects submitted by researchers belonging to the SSN, with researchers of Italian nationality living and working abroad, in order to promote the knowledge network;
- **co-funded project (Euro 5 million):** project applications by researchers belonging to the SSN, with a private co-financing at least equal to that of the Ministry, guaranteed by companies with operations in Italy in order to ensure development of ideas or products and encourage a greater relationship between the public world and the private sector with the pooling of ideas on economy.

On the recommendation of the National Commission for Health Research, in order to have all the information needed to plan an increasingly consistent and focussed programme of health research to support and/or complement research areas more directed to the needs of public health in the country, a recognition of excellence in health research was initiated in 2011, conducted in the years 2008-2010 in the context of each Region, defining the specific areas and the characteristics of its projects, as well as access to finance (whether ministerial, regional, European or private), and this in order to prepare the first National Plan for Health Research. In addition an acceleration was made of the process of monitoring of the projects funded in previous years and still underway in 2011, starting a new policy of attention and of respect for the execution time of the research. Finally, the network of excellence already present in the country was integrated with the recognition of three new Institutes (Figure 15.4):

- **San Martino University Hospital - IST - National Institute for Cancer Research,** in the “Oncology” discipline, in Genoa;
- **Arcispedale Santa Maria Nuova Hospital,** for the Institute for advanced technologies and models of care in oncology, in Reggio Emilia;
- **Bologna Local Health Authority (Azienda sanitaria locale, ASL),** for the Institute of

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**Figure 15.3. Call for projects 2009: distribution of type of winning projects by institution and by macro-area (biomedicine/clinical care).**
Neurological Sciences, in the Neurological Sciences discipline. The network of IRCCSs currently comprises more than 8,500 researchers who have produced over 9,000 scientific publications for qualified national and international journals (Table 15.1). This work is assessed on the basis of the Impact Factor (IF) of the journal, normalised (distribution of a journal on a specific theme based on IF values in quartiles) in order to allow a comparison between themes that are different from each other. These values, in addition to the other objective parameters related to clinical care, are the basis of the system of calculation that attributes funds for current research to each Institute in the year following journal publication. The percentage distribution of the scientific production of the IRCCSs among the Institutes by Normalised IF is shown in Figure 15.5.

In 2011, the second edition of the National Conference on Health Research took place, under the scientific direction of the Ministry of Health, which promoted the study and
Figure 15.5 Normalised IF for IRCCS institutes in 2011.
Implementation of lines of priority in order to meet health objectives

the comparison among all stakeholders on the current status and on the likely development of health research in Italy, facilitating the creation of partnerships and collaborations between the participants themselves. The Conference was aimed at all players in the Research System (Ministry of Health, Regions, Researchers, IRCCS, ISS, Research Institutes and Entities, IZSs, CNR, MIUR, Universities, Networks and technology parks, Pharmaceutical companies, Medical Device enterprises, institutional Investors) and represented a moment of analysis and training, a privileged place of encounter with an “it can be done” approach, presenting and sharing projects, ideas and results. In addition to expressing excellence in research, the projects represented the result of a new selection model based on the peer-review system of foreign experts, able to ensure transparency and quality in the process. The National Conference on Health Research involves all players in Research in making a contribution in terms of ideas, knowledge and experience for the common objective of the growth of Italian research.

15.2. Research related to HIV/AIDS and associated cancers

The National Research Programme on AIDS (Ministry of Health). The National Research Programme on AIDS has allowed Italy to acquire a leading role in the international scientific community. The programme, coordinated by the Directorate-General for Health Research of the Ministry of Health is organized into four main areas: epidemiology; aetiology, pathogenesis and vaccine development; clinical and therapy aspects; and opportunistic infections. The specific objectives were the study of time to progression and survival in HIV-positive persons, the determinants of clinical progression, the effect of new antiretroviral therapies in the HIV-1 infected population and the percentage of patients on therapy. Studies also continued the analysis of changes in viral tropism, the pathogenetic role of mutations/deletions in regulatory or structural genes, the interaction between structural and regulatory proteins of HIV and immune responses to viral antigens in the context of surveys aimed to understanding the pathogenesis of HIV infection. Such studies are essential for developing preventive and therapeutic vaccine approaches and identifying new strategies for the use of antiretroviral drugs and new treatment protocols. Clinical trials on the packaging and testing of both preventive and therapeutic vaccines are simultaneously advanced.

Development of a preventive and therapeutic vaccine for HIV/AIDS (Ministry of Health/ISS). The ISS National AIDS Centre (CNAIDS) conducts translational research in the fight against HIV/AIDS and associated cancers with the development of vaccines and innovative therapies based on the pathogenetic mechanisms of infection. On the basis of safety, immunogenicity and efficacy results obtained in preclinical studies in monkeys, CNAIDS has initiated a programme to develop a vaccine against HIV/AIDS as a special project funded by the Ministry of Health. Based on the very good results of safety and immunogenicity data obtained with the Tat vaccine in phase I clinical trials, conducted in both healthy and HIV-positive subjects, the multi-centre phase II clinical trial (ISS T-002) in 168 HIV-positive subjects on highly active anti-retroviral therapy (HAART) was launched in Italy. The results obtained confirm that the therapeutic immunisation with Tat is safe and immunogenic and show that, in synergy with the HAART, the Tat vaccine promotes the reconstitution of the immune system to levels never observed previously with therapy alone and/or other vaccines. A similar study has recently been initiated in South Africa (ISS T-003) in 200 HIV-positive patients on HAART, with funding from the Ministry of Foreign Affairs. In the area of development
of new vaccine strategies the Phase I trial of a preventive vaccine based on the regulatory protein Tat and the structural protein Env deleted of the V2 region (ISS P-002) started in 3 Italian clinical centres.

HIV/AIDS infections and associated cancers (Ministry of Health/ISS). Preclinical and clinical studies conducted by the CNAIDS have shown that inhibitors of HIV protease (HIV-PI) exert anti-angiogenic and anti-tumour actions through blocking of the cellular invasion and the activity of extracellular matrix metalloproteases, contributing to the reduced incidence and regression of AIDS-associated cancers such as Kaposi’s sarcoma (KS) and cervical intraepithelial neoplasia (CIN) observed in HAART. The results of a phase II clinical study conducted to evaluate the activity of the HIV-PI indinavir (IDV) in HIV-negative patients with classic KS (CKS) indicate that treatment with IDV is well tolerated and active, particularly in patients with initial tumour. A phase II study designed to evaluate the treatment of advanced CKS with IDV in combination with chemotherapy was therefore initiated. Preclinical and clinical studies aimed at evaluating the anti-tumour activity of HIV-PI on the emergence, progression and recurrence of CIN are also at an advanced stage. In particular, studies conducted in CIN models in vitro and in animal, preliminary to studies in humans, have demonstrated preclinical efficacy. In parallel, epidemiological studies to determine the incidence, the risk of progression and the regression of CIN have started, and are still ongoing, in areas where a clinical study in HIV-negative women affected by CIN1 is planned to assess the effects of HPV-PI on disease progression.

Essential bibliography


15.3. Healthcare research in the veterinary sector

The Ministry of Health promotes, finances and coordinates a health research of high quality [as clearly defined in art. 12-bis of legislative decree (D.Lgs.) no. 502, December 30, 1992], with a view to planning interventions aimed at improving the state of health of both the human and animal population, in a phrase “One health”.

The Office II of the Department of Veterinary Public Health, Food Safety and National Boards for the Health Protection, acting within its jurisdiction and on the basis of the needs of the country as well as those of the Directorates-General of the Ministry, provided the guidelines for the three broad areas of veterinary research: animal health, welfare and food safety. In this way the research strategies of its scientific bodies – the IZSs and National Reference Centres – are prepared.

These research bodies, uniformly distributed throughout the country with 10 main sites and about 90 diagnostic territorial branches, form a system of control and prevention with both analytical and research activities that is not found in other countries,
Implementation of lines of priority in order to meet health objectives

and which contributes to the preservation of public health and the maintenance and continuous improvement of standards of safety and production in the agro-food sector. The technical work of the Office II of the Department is performed in this context; the Office has implemented a documental procedure in order to standardise relations with the IZSs and for the management of the process of research since almost a decade. An important part of this management is to determine the funding for the activities of Current Research for each Institute. This determination is done on the basis of the measurement of parameters which are agreed by the parties and officially approved by the National Commission for Healthcare Research (Commissione Nazionale per la Ricerca Sanitaria, CNRS) every three years. The parameters in the last two three-year periods were increasingly focussed on the development of research, rising from 53% to 70% for specific indicators in scientific activities conducted in the period 2009-2011; in the present period 2012-2014 the figure reaches 85%, progressively reducing the value assigned to activities that the Institute performs for institutional obligation. And in this context, an important part of the activities is devoted to the communication of the results obtained through this research, which in 2012 will be demonstrated in the organisation of a conference in Rome at the headquarters of the Ministry of Health with the participation of all IZSs.

With regard to European research, an important result can be achieved in preventing the spread of infectious diseases only through the implementation of research in the field of animal health. In this regard, it may be noted that these areas of applied research for production activities have been addressed in the last three years with the participation both of institutions who perform research in the veterinary field and of the Office II of the Department in research projects of the EU’s Seventh Framework Programme. The close relationship between public health, economics and animal health is a concept now well-received in Europe. In this regard, the European Community has focused the strategy of Animal Health 2006-2013 on preventive measures to be taken to reduce the incidence of animal diseases, with the aim of minimising their impact on farming, public health, and on trade between EU Member States and therefore the economy in general. To achieve effective results in the short and medium term, a division of funds among research bodies in relation to their strengths is needed. In order to coordinate funds available for research into the improvement of the health of the livestock sector at European level and thus encourage the development of a long-term partnership between the European funding bodies in order to share information, coordinate activities and build a common research agenda, the EMIDA (Emerging and Major Infectious Diseases of Livestock) project was launched in 2007. The project was funded by the seventh EU Framework Programme as part of the European Research Area Network (ERA-Net) and was attended by twenty-seven partner organisations and four associates from nineteen different countries who manage a total research budget of about Euro 270 million. The Ministry of Health participated in this ERA-Net and adopted its same objectives: to identify the distribution of research programmes carried out by each country participating in the ERA-Net (22 countries) on the themes of veterinary health; identify the management tools and funding of research in animal health, and assess their effectiveness. In addition, again as part of the EMIDA project, the Ministry of Health invested Euro 2 million (RF 2008 and RF 2009 Funds) in animal health through participation in two transnational calls involving 19 and 22 countries respectively, promoting the aggregation of best European research centres in issues considered strategic at Community level, with excellent results by the Italian partners who participated in the call. The provision of a successor for ERA-Net EMIDA was achieved (in the field of animal health and welfare) on a proposal from the Directorate-General for Health Research, with funding by the EU Commission for the establishment of a second coordinating body, the Animal Health and Welfare ERA-Net
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consortium (ANIHWA) launched on the January 1, 2012, in which the Department continues to represent the Ministry of Health in the governing board (Leader of Work Package 2). At the moment, transnational calls for research proposals are planned with coordination by ANIHWA. The Ministry of Health, through the Department of Veterinary Public Health, also participates in the first coordination action funded by the EU at the global level, the Global Network for Animal Disease Research (STAR-IDAZ). The Department participates in the activities of the “Working Group on Animal Health and Animal Welfare” (Collaborative Working Group, CWG), established in late 2005, and the new strategic Fisheries and Aquaculture Group (April 2012), under the remit of the EU Standing Committee on Agricultural Research (SCAR), with the aim of providing a place for debate to improve collaborations in research, creating the dynamics needed both by political leadership and the European livestock industry. Such participation ensures, moreover, the sustainability of the various ERA-Net outcomes, such as for example databases developed by EMIDA. Within the CWG, the Department of Veterinary Public Health, for Nutrition and Food Safety and the IZSs use their own resources to interact and share information on current and planned research activities.
Quality of the system, resources and monitoring of the LEA
1.1. Indicators of hospital appropriateness

Since the reform of Title V of the Constitution of 2001, which introduced federalism to the organisation and management of the Health Services, the Ministry of Health has assumed a major function of guidance, monitoring and control in order to guarantee the health of all citizens. The Offices of the Directorate-General for Health Planning that were put in charge and enhanced over time, allowed and still allow the development of methodologies to identify any problems in the health system and promote appropriate and effective corrective directions through the construction of appropriate indicators, based on the wealth of information available [the New Health Information System (Nuovo Sistema Informativo Sanitario, NSIS)].

In the 2010-2012 Pact for Health, the aspect of appropriateness plays a major role in hospital care, as mentioned several times in different articles. Annex 3 of the Pact defines the set of indicators to be used to monitor the achievement of an appropriate service delivery and performance in health matters. The indicator system affords the Regions the opportunity to do their own analysis and define standards of organisational appropriateness for the purpose of self-assessment in order to optimise the delivery of care. Defined standards will be the goal to attain for regional health planning purposes and which calibrate regional strategies such as, determining the threshold values within which to permit inpatient admissions, providing the rates to charge for services and defining measures to be taken for services that are out of the ordinary.

For example, rationalisation of the hospital network is achieved by increasing appropriateness of admissions through selecting the correct patient treatment – ordinary or day hospital admission – through the correct use of hospital care as opposed to care as an outpatient, or in residential or home care basis. One of the indicators used is the percentage of hospitalisations with surgical Diagnostic-Related Group (DRG) in ordinary care regime in total inpatient admissions (Figure 1.1), which measures the ability to respond correctly to the mission of hospital acute care. The higher the value of the indicator, the greater the appropriateness of the response to the demand for health in terms of hospital care; in fact, most of the demand for non-surgical hospitalisation may find more appropriate and effective response in a non-hospital setting, with the exception of a small residual portion consisting of patients who are “critical” because of age and the presence of several diseases. In approximately 50% of the Regions, an increase can be observed over time in the values that indicate the commitment of the Regions to improve the quality of care.

A comparison of the values of indicators between the different Regions makes it possible to identify critical areas within them that are a priority for interventions of guidance and help from the central level. The percentage of patients (aged > 65 years) with a principal diagnosis of hip fracture operated on within 2 days in ordinary care regime measures both the ability to manage at the hospital level and the response time to the need for aid of patients with hip fracture (Figure 1.2).
High indicator values denote contexts in which the efficiency of the organisation of the hospital is reflected in an increased clinical effectiveness of aid provided; in fact, the scientific literature clearly shows that waiting times for surgical intervention over those limits result in an increase in the risk of death and disability, especially in the elderly. Analysis of the temporal trend of the indicator shows a high regional variability,
Monitoring, verification and appropriateness of the Essential Levels of Health Care

in which only 10 Regions showed an increase which for some of them only occurs in recent years. All this suggests the need for action to help the Regions to reallocate resources in order to reorganise the network of aid to overcome the difficulties.

Essential bibliography
Intesa Stato-Regioni 3 dicembre 2009

1.2. Variability of organisational appropriateness in hospitalisation facilities

The increasing attention paid in recent years to the concept of “Appropriateness”, aimed at improving the quality of health services provided and the proper use of resources, is widely attested by the numerous legislative measures taken thus far. By monitoring the Essential Levels of Healthcare (Livelli essenziali di assistenza, LEA) both the organisational appropriateness in the choice of suitable care settings for the provision of services and the clinical appropriateness through the verification of the effectiveness of these is evaluated.

The analysis of the variability in hospitalisation rates in different Local Health Authorities (Aziende sanitarie locali, ASLs) allows the identification of reasons for discharge which, being characterised by a high variability in the territory, and not explainable in epidemiological terms, could be an indication of potential inappropriateness of the hospital care provided.

The “Box-Plot” graph is used to represent the variability in hospitalisation rates (age-standardised on the Italian population in 2001) for different ASLs within the same Region and between different Regions. Fifty percent of ASL hospitalisation rates are contained in the rectangle (box); the vertical axis values of the bases of the rectangle correspond to the values of the rates on which 25% of the ASLs with the lowest hospitalisation (first quartile) and 25% of ASL with the highest rates (third quartile) are placed. The horizontal line inside the rectangle (regional median rate) is the rate value that divides the vertical distribution of the ASL rates into two equal parts, while the diamond represents the regional average rate. Within the rectangle, the non-central location of the median indicates an asymmetric distribution of the values of the rates compared to the average and median values, due to the presence of situations that are very different from each other within the same Region. The top and bottom “whiskers” of the rectangle represent the minimum and maximum value of the observed rates, within a defined range that contains all the observations; with the exception of the ASLs with values considered “abnormal” because they differ in a clear manner from the rest of the distribution and are represented by dots placed above or below the “whiskers” in an order corresponding to the rate of hospitalisation registered. The graphs are capable of identifying care realities for which it is appropriate to conduct a more thorough examination and possibly make a suitable corrective action.

Figure 1.3 shows the graph for the Aggregate of Clinical Codes (Aggregato Clinico di Codici, ACC) for diagnoses of “0205 – Spondylosis” for the years 2006 and 2010. There has been a decrease in the rate of national hospitalisations (from 1.13 to 0.66 per 1,000 inhabitants) and a significant reduction in variability, both within Regions and between different Regions.
Figure 1.4 shows the rates observed for the ACC procedure “0014 – Interventions for Glaucoma”. The national rate passes from 0.18 in 2006 to 0.15 per 1,000 inhabitants in 2010. The reduction of variability is most evident in the individual Regions, especial-
Monitoring, verification and appropriateness of the Essential Levels of Health Care

In general, the reduction of the observed variability can be read as an indicator of an improvement in appropriateness, in terms of a tendency towards homogeneity of performance in delivery of hospital care that is desirable in similar epidemiological conditions. The two ACCs considered represent an ex-

Figure 1.4. ACC procedure 014 – Interventions for glaucoma. A) Year 2006. B) Year 2010.
The lack of homogeneity in the demand and supply of health services in different Italian Regions is reflected in the work of the Standing Committee on the audit of provision of Essential Levels of Health Care (LEA Committee), established at the Directorate-General for Health Planning at the Ministry of Health with the ministerial decree (DM) of November 21, 2005.

Based on the State-Regions Understanding of March 23, 2005 and applicable regulations, the LEA Committee identifies and certifies the compliance with regional obligations, among which are the adjustment of the number of available hospital beds to the standard required by law, the strengthening of the policy of de-hospitalisation and of care in the community, the control of pharmaceutical expenditure, the containment of waiting lists, the verification of accreditation procedures, the implementation of national plans of active prevention and training of health personnel.

The main tool for monitoring and verification of effective delivery of performance in the national territory (cf. paragraph 2 of art. 10 of the State-Regions Understanding of December 3, 2009) is the “LEA Grid” that helps to better understand and grasp overall the diversity and uneven level of provision of levels of healthcare, through the use of a defined set of indicators divided between the provision of care in the contexts of life and work, territorial care and hospital care. The methodology for overall evaluation provides for the giving of a reference weight to each indicator and calculating a score based on the level reached by the Region in relation to national standards. The total score allows an evaluation of the Region as either “accomplished”, “accomplished with commitment” or “critical” with regard to maintenance of LEA (Figure 1.5).

In the measuring of accomplishment for the LEA in 2010, the central and northern Regions (with the exception of Liguria, Abruzzo and Lazio), together with Basilicata, reached the “accomplished” level, while Liguria and Abruzzo were classified as “accomplished with commitment”, and so will have to demonstrate in a successive verification (2011) that they have fulfilled commit-
ments to resolving problems found in certain areas of health care.

The situation of the southern Regions and Lazio is “critical” and therefore the way for them to achieve a more positive outcome is closely related to overcoming the problems identified through the Plan of Realignment. In addition to assessing overall accomplishment, the LEA Grid allows the individual Region to identify those critical areas where an adequate provision of the essential levels of assistance is considered impaired and enables areas of accomplishment to be highlighted.

Figure 1.6 presents the situation of each Region in 2010 for each of the selected indicators, identified by the circular sector; the position and colour of the label allow easy identification of the strengths (green) and increasing levels of criticality (from yellow
Figure 1.6. (Continue)

Labelling of the indicators, as classified in the LEA Grid, trackable in the regional rosettes:

1.1 Vaccination coverage in children of 24 months per cycle (3 doses)
1.2 Recommended vaccinations (MPR)
1.3 Recommended vaccinations (influenza in elderly)
2 Percentage of people who took a first level screening test in an organised programme by: cervical, breast and colorectal cancer
3 Cost per capita of collective care in living and working environments
4 Percentage of units controlled in total units to be controlled
5.1 Percentage of breeding centres checked for bovine TB
5.2 Percentage of breeding centres checked for sheep, goat, bovine and buffalo brucellosis
5.3 Sheep and goat farm enterprises controlled as percentage of sheep and goat registry total
6.1 Percentage of analysed samples in total samples planned by the National Residues Plan (search for medicines and contaminants in food of animal origin) – D.Lgs. 158/2006
6.2 Percentage of samples performed in total number of samplings scheduled in marketing and catering enterprises – arts. 5 and 6 of DPR July 14, 1995
7 Weighted sum of normalised specific rates for certain avoidable conditions/diseases in ordinary hospitalisation: paediatric asthma, diabetes complications, heart failure, urinary tract infections, bacterial pneumonia in the elderly, COPD
8 Percentage of elderly ≥ 65 years treated in ADI
9 Number of equivalent beds for elderly care in nursing homes per 1,000 elderly residents
10 Number of equivalent residential and semi-residential beds in care facilities for disabled for every 1,000 inhabitants
11 Available hospice beds in total deaths from cancer (per 100)
12 Percentage cost of pharmaceutical territorial care (including direct and ‘on behalf of’ distribution)
13 Number of specialised outpatient MRI operations per 100 inhabitants
14 Users managed by community mental health centres per 100,000 inhabitants
15.1 Standardised hospitalisation rate (ordinary and day) by age per 1,000 inhabitants
15.2 Rate of day hospitalisation of diagnostic type
16 Percentage of hospitalisations with surgical DRG under ordinary care in total of inpatient admissions
17 Standardised hospitalisation rate of inpatient admissions (of 2 or more days) attributed a high risk of inappropriateness by DRG from the Pact for Health 2010-2012
18 Percentage of caesarean births
19 Percentage of patients (age 65+) with a principal diagnosis of hip fracture operated on within 3 days under regime of ordinary care
20 Average quarterly length of stay standardised by case-mix
21 Interval of Target-Alarm of emergency vehicles

to purple, to red) with respect to their relevance (amplitude of the circular sector) in the group of monitored aspects within the Region.

The high variability in the maintenance of delivery of the LEA either within the same Region or between different Regions, including those that reached a level of accomplishment, indicates the need for targeted interventions differentiated at both local and national level.

Essential bibliography

1.4. Monitoring of clinical trials

The Italian Medicines Agency (Agenzia Italiana del Farmaco, AIFA) monitors all clinical trials conducted in Italy through a dedicated body, the National Monitoring Centre for Clinical Trials (Osservatorio nazionale sulla Sperimentazione Clinica, OsSC), which also allows the sharing of information for the benefit of patients and operators in the sector. The AIFA OsSC collects data from all clinical research conducted at national level. Clinical trials in this large archive are 7,441 (Tables 1.1 and 1.2).

Italy participates in all stages of experimentation, albeit in different ways. The percentage of phase I and II studies is increasing in respect of the total clinical research in Italy, amounting last year to 45.4% (from 43.2% in 2009). In parallel, phase III studies confirm the trend that began in 2005 and remain below 50% of the sample: in 2010, they comprised 42.1% of the total.

The percentage of multi-centre trials has remained stable at around 80% of the total in the entire reference period, while the percentage of international studies is decreases.

### Table 1.1. Clinical trials with positive single opinion by year (clinical trials total: 7,441)

<table>
<thead>
<tr>
<th>Year</th>
<th>Clinical trials</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>2000</td>
<td>557</td>
<td>7.5</td>
</tr>
<tr>
<td>2001</td>
<td>605</td>
<td>8.1</td>
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<tr>
<td>2002</td>
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<td>2003</td>
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</tr>
<tr>
<td>2006</td>
<td>778</td>
<td>10.5</td>
</tr>
<tr>
<td>2007</td>
<td>795</td>
<td>10.7</td>
</tr>
<tr>
<td>2008</td>
<td>878</td>
<td>11.8</td>
</tr>
<tr>
<td>2009</td>
<td>752</td>
<td>10.1</td>
</tr>
<tr>
<td>2010</td>
<td>660</td>
<td>8.9</td>
</tr>
<tr>
<td>Total</td>
<td>7,441</td>
<td>100</td>
</tr>
</tbody>
</table>

### Table 1.2. Clinical trials by year and phase (total clinical trials: 7,441)

<table>
<thead>
<tr>
<th>Year</th>
<th>Phase I</th>
<th>Phase II</th>
<th>Phase III</th>
<th>Phase IV</th>
<th>Bioeq/Bioav</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>CT %</td>
<td>CT %</td>
<td>CT %</td>
<td>CT %</td>
<td>CT %</td>
<td>CT %</td>
</tr>
<tr>
<td>2000</td>
<td>0 0</td>
<td>156 28</td>
<td>346 62.1</td>
<td>43 7.7</td>
<td>12 2.2</td>
<td>557 100</td>
</tr>
<tr>
<td>2001</td>
<td>0 0</td>
<td>203 33.6</td>
<td>328 54.2</td>
<td>55 9.1</td>
<td>19 3.1</td>
<td>605 100</td>
</tr>
<tr>
<td>2002</td>
<td>0 0</td>
<td>214 38.2</td>
<td>293 52.3</td>
<td>40 7.1</td>
<td>13 2.3</td>
<td>560 100</td>
</tr>
<tr>
<td>2003</td>
<td>0 0</td>
<td>202 35.6</td>
<td>312 54.9</td>
<td>47 8.3</td>
<td>7 1.2</td>
<td>568 100</td>
</tr>
<tr>
<td>2004</td>
<td>6 1</td>
<td>223 35.7</td>
<td>326 52.2</td>
<td>57 9.1</td>
<td>12 1.9</td>
<td>624 100</td>
</tr>
<tr>
<td>2005</td>
<td>24 3.6</td>
<td>230 34.6</td>
<td>325 48.9</td>
<td>78 11.7</td>
<td>7 1.1</td>
<td>664 100</td>
</tr>
<tr>
<td>2006</td>
<td>19 2.4</td>
<td>305 39.2</td>
<td>355 45.6</td>
<td>81 10.4</td>
<td>18 2.3</td>
<td>778 100</td>
</tr>
<tr>
<td>2007</td>
<td>22 2.8</td>
<td>307 38.6</td>
<td>355 44.7</td>
<td>103 13</td>
<td>8 1</td>
<td>795 100</td>
</tr>
<tr>
<td>2008</td>
<td>46 5.2</td>
<td>326 37.1</td>
<td>395 45</td>
<td>104 11.8</td>
<td>7 0.8</td>
<td>878 100</td>
</tr>
<tr>
<td>2009</td>
<td>43 5.7</td>
<td>282 37.5</td>
<td>296 39.4</td>
<td>124 16.5</td>
<td>7 0.9</td>
<td>752 100</td>
</tr>
<tr>
<td>2010</td>
<td>53 8</td>
<td>247 37.4</td>
<td>278 42.1</td>
<td>77 11.7</td>
<td>5 0.8</td>
<td>660 100</td>
</tr>
<tr>
<td>Total</td>
<td>213 2.9</td>
<td>2,695 36.2</td>
<td>3,609 48.5</td>
<td>809 10.9</td>
<td>115 1.5</td>
<td>7,441 100</td>
</tr>
</tbody>
</table>
Quality of the system, resources and monitoring of the LEA

ing amounting in 2010 to 72.4% of the total of multi-centre trials in Italy (compared to 74.3% in 2009).

The most-studied therapeutic area as a whole is oncology (about one-third of clinical trials), followed by cardiology/vascular diseases, neurology and immunology/infectious diseases, each reaching about 9% of total.

For the rest of the therapeutic areas, there is a wide spread of interests: research in anesthesiology is almost exclusively supported by no profit sponsors, while pharmaceutical companies are more oriented towards rheumatology, respiratory diseases and endocrinology.

With regard to the type of facilities involved in clinical trials, the university hospitals, the university polyclinics and universities participate in 75% of the studies, hospitals in 60.2%, and the Scientific Institutes for Research, Hospitalisation and Health Care (Istituti di Ricovero e Cura a Carattere Scientifico, IRCCSs) 56.5%.

Emilia Romagna and Liguria record the highest average number of trials by facility, respectively 69 and 64, despite Lombardy continuing to be more involved in clinical trials (45.7%), followed by Lazio (41.6%), Piedmont (21.6%) and Liguria (20.8%). The facilities most involved in clinical trials are the IRCCS Fondazione Centro S. Raffaele del Monte Tabor, Milan (14.6%), the University Hospital Policlinico S. Orsola Malpighi in Bologna (14.4%) and the University Hospital Policlinico Gemelli in Rome (11.5%).

All clinical research is evaluated by ethics Committees, which operate at local level. In 2009, the total number of ethics Committees, although still significant, was down to 254 (269 in 2008). In 2010, the phenomenon of aggregation of ethics Committees continued with a corresponding decrease in the total number, which dropped to 245. Lombardy is the Region with the highest number of ethics Committees, followed by Lazio, Sicily and Campania.

It is interesting to note that activity is registered for only 66.1% of these Committees. In fact, of 254 ethics Committees present in Italy, 162 of them have released at least one single opinion as coordinators in the period 2007-2010. Among these, 19 issued on average at least one opinion per month (48 in four years). With regard to the acceptance/refusal of the single opinion, in the same period 241 satellite ethics Committees expressed a view, 116 of which issued on average at least one opinion per month.

1.5. Pharmaceutical care in Italy

The year 2011 was characterised by a continuous decrease in national spending. The confirmation of a well-established trend has been further reinforced by the making generic of important molecules and the effects of regulations introduced in 2010, in particular the provisions of law 122 of July 30, 2010, art. 11, paragraphs 7a, 7b, 9, 10.

In detail, with regard to paragraph 9 the AIFA implemented the provisions of the legislation with the Determination of April 8, 2011, reducing the price of reference for expired medicine patents through a complex and detailed work of comparison of the Italian situation with the European one. There has been a gradual reduction in the price of medicines included in lists of transparency following the entry into force of the measure, with an alignment to the new refund price, primarily by companies that marketed generic equivalent medicines.

As an element of information for the public, since July 2011 AIFA publishes on its website the lists of transparency which list all the medicines whose patents have expired together with details of any price difference compared to the reference price.

The need to take measures in order to have a reduction in the price of medicines whose patents have expired confirms, once again,
that the market for such medicines in Italy has a difficulty in asserting itself, in contrast to other European countries where such products represent a substantial share of the total market. This is certainly due to the fact that people do not know enough about them and that doctors themselves often find it difficult to prescribe generic medicines. However, the general guarantee arising from established therapies and the opportunity to rationalise spending on pharmaceuticals that the appropriate use of generic medicines provides must form the basis for overcoming the mistrust of health professionals and patients. In each pharmaceutical system, the equivalent generic medicine is, in fact, an instrument of strategic and crucial importance and the sustainability of pharmaceutical expenditure is strongly related to such availability. The expiry of the rights of patent protection by law automatically produces reductions in costs, with an average cost reduction close to 50% compared to the prices of originator medicines of reference in 2011, realising significant savings, which are then used to finance more innovative therapies; all within a policy context of accountability of the citizen, regarding individual contribution to a more efficient use of resources. Wider dissemination of information on the importance of the reimbursement system and the price differential of branded medicine compared to the generic-equivalent is essential so as to correctly understand the value of the latter, removing the equation “lower cost, lower quality” permanently from the discussion. In hospital medicine, the use of bio-similar medicinal products has begun to play an important role. These are similar but not identical to reference medicines, constituting therefore a therapeutic alternative with potentially different pharmacokinetic and pharmacodynamic properties but a definite advantage in economic terms. The important aspect that should not be overlooked, in fact, is that in obtaining at a lower cost, the bio-similar medicine can ensure better access to treatment for all patients. Today, the distribution of these medicines is still very limited, but the AIFA in collaboration with the Regions is committed to ensuring that they can fully become one of the treatment options in use. Also regarding pharmaceutical policy, many efforts have been made in promoting prescriptive appropriateness, a key element in ensuring both patient’s health and control of pharmaceutical expenditure. For this reason, the AIFA has undertaken a review both of the main Notes of prescriptive appropriateness (such as Note 13) and a more general review of the National Pharmaceutical Formulary in 2011.

1.6. Monitoring of the use of medicines and pharmaceutical expenditure

In the first nine months of 2011, the gross national expenditure on medicine in the National Health Service (Servizio sanitario nazionale, SSN) decreased by 3.7%. For medicines distributed at the local level, in fact, Euro 9,370 million was spent compared with 9,726 million in the first 9 months of 2010. However, consumption has gone up, albeit modestly (+1.2%); prescribed doses were in fact 965.4 per 1,000 inhabitants compared to 954.2 in the previous year; this is in line with demographic factors such as aging of the population and the making chronic of some diseases. In the presence of a slight increase in consumption and a constant mix effect, the reduction in prices (–5.2%) was the main cause of the decline in spending. Private spending, totalling Euro 4,840 million, increased by 5.3% compared to the first nine months of 2010, primarily due to increased spending on private class A (+14.3%), followed by an increase in expenditure on medicines for self-medication (+3.9%) and expenditure for class C with prescription (+3.5%).
The sharing of costs by the citizen, which includes the cost placed by the Regions for the ticket for prescription and the price differential that the citizen pays when choosing an originator medicine instead of the generic equivalent for which they would not pay anything, amounted to Euro 974 million in the first 9 months of 2011, a significant increase of 36.5% over the same period last year. This expenditure now accounts for 10% of gross expenditure on pharmaceuticals, which in 2006 equalled 3%.

Wide variation between Regions both in consumption and in territorial spending was observed in the first nine months of 2011. In parallel with a national average value of 965.4 for Defined Daily Doses (DDD)/1,000 inhabitants/day, consumption oscillates from a maximum value of 1,090.8 DDD/1,000 inhabitants/day for Sicily to a minimum value of 725.6 DDD/1,000 inhabitants/day in the Autonomous Province of Bolzano. Consumption is increasing in all Regions, with the exception of Campania (–5.9%) and Apulia (–2.2%). The highest increases registered compared to 2010 were in the Autonomous Province of Bolzano (+3.6%), in the Umbria Region (+3.3%) and Lombardy (+3.3%). Regional spending, compared to a national average of Euro 153.10 per capita, ranged from a maximum of Euro 193.20 per capita in the Region of Sicily to a minimum of Euro 111.60 per capita in the Autonomous Province of Bolzano.

Direct and ‘on behalf of’ distribution today represents an item of expenditure that is on the increase, and which reached Euro 2 billion in the first 9 months of 2011. The therapeutic category with the highest impact of expenditure and consumption is represented by medicines for the cardiovascular system (Euro 55.1 per capita and 455.4 DDD/1,000 inhabitants/day), which alone accounts for 36% of expenditure and 47% of prescriptions of medicines reimbursed at the national level. Although compared to the same period of 2010 the consumption in this class is in slight increase (+1.1%), spending declined by 4.7%, consistent with the sharp drop in prices (–6.9%); most of the medicines included in this category, in fact, lost patent protection. Within this class, statins are the subgroup both of greatest expense (Euro 12.3 per capita) and number of doses (55.2 DDD/1,000 inhabitants/day) followed for expenditure by sartans either alone or in association (Euro 16.9 per capita) and, for prescriptions by ACE-inhibitors alone or in combination (116.5 DDD/1,000 inhabitants/day). A significant increase in spending (+37.8%) and consumption (+30.5%) for new medicines for the treatment of angina is observed compared to 2010, particularly for ivabradine and ranolazine.

The alimentary tract and metabolism are the second therapeutic category for impact of spending (Euro 23.7 per capita) and consumption (141.7 DDD/1,000 inhabitants/day).

As for the cardiovascular system, this class shows a decrease in expenditure (–4.7%) and prices (–6.7%) over the previous year, compared with an increase of prescriptions (+3.2%). Pump inhibitors are the medicines with the highest value of expenditure (Euro 11.2 per capita) and consumption (62.4 DDD/1,000 inhabitants/day) in this category. Compared to 2010, these medicines have shown a sharp increase in consumption (+9.5%) compared to a decrease in expenditure (–6.9%), mainly due to the continuous decline in prices (–12.9%). Within the same category, incretin-mimetics medicines alone or in combination recorded the largest increase in the values of expenditure and consumption compared to the previous year, respectively, 78.2% and 94.6%, compared to a price reduction of 14%.
Communications and citizens’ satisfaction levels

2.1. Communication appropriateness: the Ministry of Health Journal

The Ministry of Health Journal continued for the second year with publications aimed at standardising and establishing the criteria for appropriateness of health care in our country in order to promote common standards of work. The monographs, from the Directorate-General for Communication and Institutional Relations, are an integral part of the Report on the Health Status of the country, which represent a constant updating and deepening of the central themes of care. Numbers 7-12 in the bi-monthly series were published in 2011.

- **Community Dentistry: criteria for clinical, technological and structural appropriateness.** Real community dentistry finds its maximum expression in primary prevention, especially in young people, without neglecting aspects of tertiary prevention that contribute to improving the state of health of the whole population.

- **The centrality of the individual in rehabilitation: new organisational and management models.** Rehabilitative medicine has acquired over time hermeneutic evidence and a specific epistemology, outlining a peculiar model of intervention very different to that of medicine and organ surgery. Given the complexity of rehabilitation care pathways and their necessary and coherent articulation in the ambit of types of hospital setting, extra-hospital setting, territorial, health and social settings, the volume highlights the indispensability of having a departmental-type organisation of rehabilitation activities set up in all Regions.

- **State-of-the-art and planning of the care of digestive diseases.** The detail on the epidemiological situation and care of digestive diseases in Italy: the need for more effective organisation and modulation between territorial and hospital activities, making it possible to optimise the use of resources guaranteeing proper care activities.

- **Clinical, structural, technological and operational appropriateness for the prevention, diagnosis and treatment of obesity and diabetes mellitus.** The monograph outlines the relationship between primary care and territorial specialist centres and hospitals, as well as organisational models for the integrated management of follow-up care (chronic care model) and the criteria of appropriateness for the multidisciplinary team and the care setting. A significant space is dedicated to glycaemia self-monitoring in the home, to treatment with continuous subcutaneous insulin pump therapy, to telemedicine, pancreas transplants and, not least, to therapeutic education.

- **Appropriateness in the prevention, diagnosis and therapy in ophthalmology.** Ophthalmology also needs more development and implementation of care networks for managing patients, with a proper level of functional harmonisation in the different territorial facilities, hospitals of first and second level and Centres of excellence, identified on the basis of size and type of technological equipment, on professional skills, on the volume of activity and geographic location. The monograph
illustrates too new imaging techniques for the study of the retina and the optic nerve and their appropriateness of use to aid in the selection of instrumentation to be used in various pathologies. A significant part of the Journal is dedicated to the needs and realities of the visually impaired or blind.

Criteria of clinical, structural and technological appropriateness for Interventional Radiology. The last 2011 edition of the Ministry of Health Journal looked in an organic way at the use of innovative diagnostic and therapeutic techniques made possible with Interventional Radiology, defining the criteria of organisational, functional and technological appropriateness as a model and standard for the existing Centres and those under construction.

All monographs are published on the ministerial portal, accompanied by presentation videos of the authors, on the dedicated themed site (www.quadernidellasalute.it) and through the “Health kiosk” mobile App.

2.2. Measuring the impact of communication campaigns: the case of proper nutrition for children

The communication campaigns developed over the years by the Ministry of Health have helped to promote and develop processes of empowerment and responsibility-taking of citizens aimed at changing health aspects of lifestyles that promote psychophysical well-being.

To measure the impact of a campaign specific aspects are measured and analysed, such as the level of penetration, acceptance, understanding, recognition of the source and recollection of the message at a later date. It is also important to evaluate the effects during the campaign, so as to correct and calibrate the messages being transmitted in the best way.

Among the initiatives carried out in the course of 2011 for the promotion of healthy lifestyles by the Directorate-General for Communication and Institutional Relations of the Ministry, worthy of mention are the stop smoking campaign and the launch of the “Captain Kuk” project to promote the consumption of fruit and vegetables by children. The assessment of the effects of the “I will never smoke” campaign against smoking, which was scheduled on television, in the press and on circuits of street billboards in 2010-2011, was conducted by a specialised research institute through a two-stage investigation, before and after exposure to the message by the sample. The research provided a very positive outcome from the public for both the appreciation and the appraisal of the endorsement, and an effectiveness that rewarded an integrated media planning.

In fact, radio and television programming reached particularly high percentages of penetration of the target population (81.4%) compared to the average value of reference (63%). Particularly relevant were the data relating to the raising of awareness in children, which was the main campaign goal. After the campaign, in fact, the percentage of smokers who were asked to quit by their children increased significantly (+21.4%). In general, the percentage of non-smokers who asked smokers present in the household to quit increased from 39.9% to 74.3%. In the family, especially in homes of smokers with children, the interest and frequency of discussion about smoking and the damage it causes grew. In some cases, the subject had been dealt with for the first time in the family. Finally, over 60% of smokers who saw the advertisement said it encouraged them to change their habits: more than 64% thought about quitting, almost 20% decided not to smoke in the presence of children, and 14% tried to stop smoking.

As for the promotion of healthy nutrition at an experimental level, the impact of the
Communications and citizens’ satisfaction levels

Launch of the “Captain Kuk” campaign was measured, the first cartoon produced by the Ministry of Health in collaboration with RAI (the Italian national television broadcaster) and aimed at promoting the consumption of fruit and vegetables among children. At the launch of the project a questionnaire on satisfaction was given to the more than 200 children present at the screening of the first episodes of the cartoon, and nearly all expressed great appreciation and demonstrated full understanding of the topics covered. Most of the children went on to say that they had felt involved and been made aware by the cartoon and wanted to try to change their eating habits involving their parents and introducing greater consumption of fruit and vegetables in the daily diet. With regard to the share registered by the cartoon, the data provided by RAI, relative to the transmission time, show a high degree of acceptance since the airing of the first episodes – on the children’s Rai Yo-Yo channel – and higher viewer numbers than those of other Rai thematic channels, with an average share of 1.82 compared to the usual channel figure of 1.41. The airing of “Captain Kuk” will continue in 2012 and the initiative will also cover the production of information material for schools with the collaboration of the Ministry of Education and local Authorities.

2.3. The online survey of user satisfaction with the National Health Service (SSN)

Guidelines for Public Administration websites (2011) require government departments to adopt evaluation systems centred on users of the services and which are able to record the perceived quality and the level of satisfaction continuously. Among the models of reference is “Let’s face it”, an initiative of the Department of Public Administration aiming to gauge customer satisfaction with the quality of public services provided at the counter or through other channels (telephone and web) in a systematic way through the use of icons signifying emotion (so-called emoticons). The initiative, launched on a trial basis throughout the country in March 2009, is consistent with the strategy outlined in the 2012 e-government Plan and is in line with the legislative decree (D.Lgs.) no. 150/2009. Almost 1,000 Administrations have joined the initiative. In the field of health services, 9 health facilities implemented the survey in 2011, based on data provided to the Department by the Ministry of Public Administration of the Presidency of the Council of Ministers.

The service delivery channel that was mainly reviewed by users was the counter (almost 78%); 22% of the evaluations covered services provided on-line. More than 20,000 citizens expressed their own assessment on the service they received from the health facility used in 2011; 77.6% of them were satisfied (green smiling face emoticon) and 10.2% declared the service adequate (yellow face emoticon), while negative judgments (red face emoticon) were given by 12.2% of users.

In particular, with reference to the counter services in the facilities (e.g. clinics, single booking centre, office of public relations), 73.2% were satisfied and 12.1% gave an opinion of adequate, while 14.7% were dissatisfied. The reasons for dissatisfaction were: waiting time (47%), lack of professionalism (18%) and the need to return (11%). For services provided on-line (e.g. the withdrawal of lab reports, the single booking centre, choice and change of doctor), 91.4% of users were satisfied, 4.2% indicated sufficiency and 4.4% dissatisfied. The reasons for dissatisfaction were: difficulty of access (48%), lack of clarity of instructions (43%) and failure to update information (9%).
With regard to the content of the online pages, in February 2011 the Ministry of Health adopted a detection system for user satisfaction (with a scale from one to five stars) with the information available in the ministerial portal www.salute.gov.it in a web 2.0 format suggested by the Guidelines. In 2011, the votes cast were about 3,600. 36.5% of the voted pages scored an average of five stars, 18.2% received four stars, 22.1% three stars, 7.9% two stars and 15.3% one star. The pages that received the most votes were those containing information on health care abroad, exemptions from the ticket, lifestyles, communication campaigns, health professions, women’s health, anti-doping, pharmacies, narcotic drugs and psychotropic substances. The pages that received five stars dealt with exemptions from the ticket, the campaign on donation of organs, tissues and cells, influenza, health food and physical exercise, the campaign against AIDS, heat waves and infectious diseases. The Ministry YouTube channel had over 65,000 views in 2011, while the pages that received the most “I Like it” votes were those relating to videos on the life of nurses, the fight against the mistreatment of animals and the anti-smoking campaign.

**Essential bibliography**


Presidenza del Consiglio dei Ministri, DIGIT PA, Dipartimento per la digitalizzazione della pubblica amministrazione e l’innovazione tecnologica, Dipartimento della Funzione Pubblica, Formez PA - Linee guida per i siti web della PA 2011

3.1. Professional practice and training for health professions

Institution of a Master’s degree in palliative care and pain management and the joint working Group on professional profiles of the health professions. In the context of the provisions concerning the training of health professions, the law 38 of March 15, 2010 on “Measures to ensure access to palliative care and pain therapy” planned for the protection of the right of every citizen to access to palliative care and treatment of pain. The norm states that with the Agreement between the State, the Regions and Autonomous Provinces, on the proposal of this Ministry, professionals with specific expertise and experience in the field of palliative care and pain therapy would be identified, including that for paediatric age, with particular reference to general practitioners (medici di medicina generale, MMGs) and medical specialists in anaesthesia and intensive care, geriatrics, neurology, oncology, radiotherapy, paediatrics, physicians with three years’ experience in the field of palliative care and pain management, to nurses, psychologists, social workers and to other professional figures deemed essential.

To enable these professionals to work in the system that makes up the network of palliative care and pain management with the appropriate knowledge and skills, a specific section of the Act provides for the establishment of a Master’s degree in palliative care and pain therapy by the Ministry of Education, University and Research in consultation with this Department.

The efforts of the two Ministries and that anticipated by the norm are both reflected in the preparation of five provisions which concern the setting up of Master degree programmes for specific professional figures and which were issued by the two ministers on April 4, 2012 and published in the Official Gazette of April 16, 2012 after a scrutiny by the National University Council and the Board of Health.

In detail:

- a Master’s degree in “Palliative care and pain management”. Reserved for the health professions of nurse, paediatric nurse, physiotherapist, and rehabilitation therapist. The programme has a duration of one year and provides for the acquisition of 60 training credits, 40 of which relate to theoretical training and 20 to practical training. The provision indicates the learning profiles and the basic educational objectives, as well as characterising specific educational objectives for nurses and paediatric nurses and for physiotherapists and occupational therapists, the mandatory apprentice activities which contribute to the acquisition of professional skills, and standards and requirements of the training network;

- a Master’s degree in advanced training and qualification in “Pain therapy”. Reserved for doctors holding one of the specialisations listed in art. 5, paragraph 2 of law 38/2010, including those which may subsequently be identified by State-Regions agreement, with documented training in pain therapy. It is expected that
the course in question will have a duration of 12 months, with the acquisition of 60 training credits, 30 of which devoted to theoretical training and 30 devoted to practical training. In this case too, the provision indicates in detail the learning profiles, the educational objectives, mandatory practical activities and standards and requirements of the training network;

- a Master’s degree in advanced training and qualification in “Palliative Care”, reserved for doctors holding one of the specialisations listed in art. 5, paragraph 2 of law 38/2010, including those which may subsequently be identified by State-Regions agreement. It is expected that the course will have a duration of 24 months with the acquisition of 120 training credits, 60 of which devoted to theoretical training and 60 devoted to practical training. As with the other decrees, the provision in question identifies the learning profiles, educational objectives, mandatory practical activities and the standards and requirements of the training network;

- a Master’s degree in advanced training and qualification in “Pain therapy and paediatric palliative care” reserved for doctors holding a specialisation in paediatrics and those with specialisation in anaesthesia, resuscitation and intensive care who have specific training and experience in paediatrics. It is expected that the course will have a duration of 24 months with the acquisition of 120 training credits, 60 of which devoted to theoretical training and 60 to practical activities. In this case also, the provision identifies the profiles of learning, educational objectives, mandatory practical activities and standards and requirements of the training network;

- a Master’s degree in “Palliative care and pain therapy”, reserved for first-level/second-level graduates specialised in psychology. It is expected that the course will have a duration of one year with the acquisition of 60 training credits, 40 of which devoted to the theoretical part and 20 to practical activities. As with the previous, in this case the decree defines the profiles of learning, the educational objectives, mandatory practical activities and standards and requirements of the training network.

In relation to professional practice and training of health care professionals, the joint Council for professional profiles took office for the first time on December 15, 2011 on a proposal of the Regional Health Coordination Commission, with the task of developing suggestions for the implementation of areas of expertise for health professionals and of introducing the specialisations provided for by art. 6 of law 43/2006 for those professionals. The joint Council is made up of representatives appointed by the Regions and Autonomous Provinces and from the Ministry. The nursing, vocational, rehabilitative, prevention health professions, as well as midwifery, have been the subject and object of a profound change in structure and training under the laws and regulations in the sector in the last twenty years.

This innovation has meant that most personnel in the health sector are graduates and specialised graduates trained in the same university faculty, that of medicine and surgery, all professionals with their own specific independent sphere of action, subject from time to time to both scientific and technological evolution as well as that of the organisational models of their own work in the National Health Service (Servizio sanitario nazionale, SSN).

It follows that in order to ensure an organisational homogeneity within the SSN, a process of adaptation of the organisation of work to the reality of work legislation through a progressive overhaul of the whole system of the health professions needs to be started, re-evaluating the relationship between the different health and socio-health care professions, and the organisation of productive processes in a logic of integration, collaboration and cooperation between the various professionals, with consequent benefits for the same professional activity and for the citizen.

The redefinition of the health professions is one of the most topical issues, in line with the innovations that radically change the organisation of care provided by the SSN. Areas
such as emergency-urgency care, de-hospitalisation and chronic illness require a revision of the entire health care system to ensure health care in the territory that is qualified. This choice is reinforced by positive experiments already in place which are to the proven satisfaction of operators, administrators and especially of citizens, such as:

- the See and treat model adopted by the Region of Tuscany, on the suggestion of the local Emergency Medicine Enterprise, which allows properly-trained nurses to manage white and green codes in Emergency Acceptance Departments (Dipartimenti Emergenza Accettazione, DEAs);
- INDIA ambulances, in which nurses prepared for the task manage life-saving operations immediately before hospital admission; this model is being extended to various Regions;
- perioperative treatment carried out by nurses, made in Emilia Romagna;
- the spread in many Centre-North Regions of a hospital model for intensive treatment which by entrusting the management of the hospital bed to nursing staff thereby enhances the functions of the medical profession by freeing it from inapt duties.

The review of the health professions has as its fundamental objective the guarantee of the quality of the benefits to the citizen for the purpose of better realisation of the right to health from a technical and professional point of view, in the light of the development of the functions and the role of the professions of nursing, midwifery, technical, rehabilitation, and prevention and in accordance with their respective competences so as to avoid an overlapping and, at the same time, a duplication of functions.

In order to put this review process into effect, a constructive dialogue with the Ministry of Education, University and Research becomes important in order to work together to promote the broadest form of professional development to support those mechanisms of professional development which are capable of recognising the value and contribution of these professionals in the care and organisation process, given that the best usage is an important strategic choice for both the State and the Regions and also therefore for the same SSN.

Remaining within the sphere of the health professions, a Technical Council was established to study issues relating to the training and the role of the socio-medical operator at the Ministry of Health in 2010. This Council continued its work in 2011 with the involvement of trade unions and, in particular, has set itself the aim of solving the problems of non-uniformity of training across the country, the absence of additional training in some Regions, as well as the issues arising from the terms of the professional relations existing between socio-health operators and nursing and midwife personnel.

In this perspective a proposal has been prepared for a final document containing an analysis of the phenomenon and with subsequent proposals for reorganisation of the relevant professional profiles.

Also at the Ministry of Health in 2011 a meeting table was set up for physiotherapy graduates and graduates in physical education to outline the areas of professional competence for the two disciplines, with participation of the Regions and professional associations in the sector as well as the Ministry of Education, University and Research.

### 3.2. Continuous education in medical sciences

The national Commission for continuing education in 2011 maintained its contribution to the achievement of the “strategic objectives” outlined by the Ministry of Health through the provision of training characterised by “learning outcomes” present in the State-Regions Agreement of 2009. The Commission thereby identified training...
activities that correspond to the priorities of interest of the SSN.
In 2011 there was a significant increase in the training on offer using distance learning (Formazione a Distanza, FAD): from 119 applications for accreditation in 2010 (approximately 180,000 expected participants) to more than 450 proposed applications for accreditation in 2011 (approximately 880,000 expected participants).
Compassionate care, quality of clinical care systems and processes, and knowledge in the field of specialised expertise were of particular interest to providers who planned training activities for the year 2011.
Regarding other types of training, residential activities proposed for 2011 have been quantified to date at around 6,000 events.
Requests made with the experimental accreditation system for events still in progress must also be added to the total, with an estimated participation in them of around 480,000 healthcare professionals.
Events that use on-the-job training in areas of reference for accreditation of CME (Continuous Education in Medical Sciences) training may be noted; with more than 100 projects present in the provider training plans for 2011 to date, and an expected participation of more than 3,000 health professionals.
The training programmes sponsored by the Department of Veterinary Public Health, Food Safety and National Boards for Health Protection together with other public bodies such as the Regions, Local Health Authorities (Aziende sanitarie locali, ASLs) and Experimental Institutes for animal disease control and prevention (Istituti Zootrofiliattivi Sperimentali, IZSs) contributed to the training of personnel involved in all levels in the controls for animal health and food safety. In that sense, the above mentioned Department involved Ministry of Health professionals in two training events that provided very specific qualifications to those involved, and whose subjects were: “Veterinary training, Better Training for Safer Food (BTSF) course, quality schemes (organic farming/geographical indications)” and “Veterinary training - Course on veterinary checks at border inspection posts (Posti di Controllo Frontaliero, PIFs)”.
Each year the Department identifies the subjects for many training courses with help from the Directorates-General, and which will be delivered in collaboration with the IZSs and/or National Institute for Health (Istituto superiore di sanità, ISS) on the basis of specific skills.
The Department provided the following accredited training events for CME in 2011 for the personnel at the Ministry of Health, the SSN and the IZSs: “Safety of by-products of animal origin: scenarios and new perspectives”, “Controls for food for early childhood”, “Controls for novel foods”, “Paratuberculosis and Crohn’s disease”, “Training course on aquaculture and fish pathology regulations”, “Developments in the animal feeds sector: the applicable norms”, “A managerial approach to Veterinary Public Health”, “Systems of management for quality in laboratory testing according to the UNI CEI EN 17025:2005 regulation”, “The evaluation of microbiological criteria and control of salmonella in foods of animal origin”; and “Methods of analysis for clinical risk management”.
The National Commission for continuing education also initiated and established a collaboration with the Directorate-General of Food safety on the basis of legislation which prohibits accreditation of training events that have advertising of infant formulas. Events that deal with matters pertaining to the supply of foods for early childhood were evaluated, which, after preliminary evaluation by the aforementioned Directorate, were either granted CME accreditation or rejected in the case of negative opinion. In this area for 2011, the Commission through the CME Secretary accredited 91 events, requested the abstracts of the reports for 31 events regarding children’s food, asked for clarification on the sponsors for 14 events, and did not allow 2 events.
In the context of the National Centre for Disease Prevention and Control (CCM) training plan for the Ministry of Health, four training courses were organised in collaboration with the ISS, which involved respec-
Management and development of human resources

The data extracted from the reports on the training courses listed above reported appreciation on the part of participants of the relevance of the subject to their normal activity, while negative trends were observed in the perception of quality and effectiveness of the event with respect to the trainees. Furthermore, in line with international guidance on improvement of the quality of services provided and in accordance with the principles of Clinical Governance, the Ministry of Health called for the Regions and Autonomous Provinces to include the systematic and continuous use of clinical auditing as part of the targets to be provided to both the Directorates-General of health care facilities and the institutional representatives of the health professions.

To support this line of direction, the Ministry prepared a document in which the method of how to spread the use of “clinical auditing” among health care workers is presented, described in didactic form although substantive in content. It is opportune that the application of this method be encouraged at local, regional and national levels in the manner deemed most appropriate, such as in the field, in accredited CME training and inclusion in the budget targets. The purpose of the Ministry’s document is to provide a guide for the development of the different phases of a clinical audit and its indispensable complement, the improvement plan.

Clinical auditing offers the novice an excellent opportunity to engage with professionals in a method for improving quality, and which in fact is a first-line method of evaluation as well as a progressive and rigorous approach which implies efficiency both in its execution and in the implementation of the action plan.

In the short run, this strategy provides better visibility and improved quality of care while in the medium to long term it accelerates the acquisition of knowledge and skills and promotes the development of quality. For the foregoing reasons, the national Commission has accredited the course in distance learning, at the initiative of the Directorate-General for Health Planning in collaboration with the National Federation of the Orders of Physicians, Surgeons and Dentists (FNOMCeO) and the IPASVI nursing federation.

The data received following the delivery of the course of distance-learning type – though partial data – show extremely positive evidence for passing the test of learning by the health professionals involved, which bodes well for its continuation in 2012. The professions involved are surgeons, dentists, nurses, health visitors, and paediatric nurses.

3.3. Training programmes sponsored by the Department of Veterinary Public Health, Food Safety and National Boards for Health Protection

Under the National and Community laws (law 532/1996; ministerial decree (DM) of December 14, 2006; European Council Regulation 882/2004/CE) the Ministry of Health and, in particular, the Department of Veterinary Public Health, Food Safety and National Boards for Health Protection, is in charge of coordinating and planning training programmes in the fields of core competence of the Department. Each year
the Office II of the Department identifies a training plan with the help of the Directorates-General and in accordance with specific priorities. This way, together with the other Competent Authorities throughout the country, it contributes to ensuring a continuous and independent training of personnel involved in official controls on food safety, animal health and animal welfare at all levels, working at the Ministry of Health, the NHS (National Health Service) and IZSs. Every year, in collaboration with the Directorates-General, the Department identifies the topics of any training courses which will be delivered in collaboration with the IZSs and/or the NHS, on the basis of specific skills.

In 2011, the Department was able to provide 8 accredited CME (Lifelong learning) courses directed to personnel of the Ministry of Health, the NHS and the IZSs. Since 2010 Office II of the Department has initiated an evaluation of the courses offered, through questionnaires. A First evaluation takes place at the end of the courses, as foreseen by the CME. In addition, the office II sends a further questionnaire by e-mail, 3-4 months after the course, as it has been shown that more objective evaluations are obtained after this period, especially on the actual effectiveness and applicability of concepts learned. The questionnaire consists of little more than 10 questions, with several blank spaces dedicated to comments. Questions are grouped into 5 areas:

- overall assessment of the course;
- teaching;
- teaching methodology and classroom atmosphere;
- organisation;
- services.

The choice of rating scale is for most part numerical, identifying 1 as a minimum and 5 as a maximum value. Questions are also about the way of dissemination of the topics learned and judgments on their applicability to daily activity, in order to evaluate how the course can impact on employment activity. Generally assessments have been positive. The comments show a request to devote more time to exercises and discussions and to try to set up courses which include practical aspects, especially on some issues where current legislation, especially Community, allows for different interpretations and therefore needs more clarification.

The Department is also the National Contact Point for the training project “Better Training for Safer Food” of the European Commission Directorate-General for Health and Consumer Protection - DGSANCO. This programme provides an additional source of training for the staff involved in activities related to official controls at various levels. The purpose of these courses is to try to standardise controls as much as possible across Europe, providing a single interpretation of the legislation. Participation in these courses is fully resourced by the European Commission that, since 2006, has been able to implement the programme enriching it year by year, with an increasing number of issues and therefore of trained personnel. However, considering the budget limit, one of the objectives of the Commission is also to train the trainers, so the invited participants are required to share as much as possible what they have learned.

For these courses too, the Department carried out an ex post evaluation, using a questionnaire similar to the above, with an additional section dedicated to the National Contact Point activity. The results were more than satisfactory, confirming the high quality of this programme (Figures 3.1 and 3.2). With regard to the sharing of information learned, important for both the national and European training activities it emerged that most of the personnel arranged short presentations in their offices. A very small percentage of them published articles and about 10% organised training events locally.

For more information on all training activities managed by Office II please consult the relevant topic page within the Ministry of Health web site.

**Essential bibliography**

Management and development of human resources

Figure 3.1. Evaluation of DSVETOC courses 2011.

Source: Ministry of Health. Department of Veterinary Public Health, Food Safety and National Boards for Health Protection – Office II.

Figure 3.2. General evaluation of BTSF courses 2011.

Source: Ministry of Health. Department of Veterinary Public Health, Food Safety and National Boards for Health Protection – Office II.
4.1. New Health Information System (NSIS)

The New Health Information System (Nuovo Sistema Informativo Sanitario, NSIS) constitutes the essential instrument for the government of health at national, regional and local levels, helpful in evaluating the qualitative and quantitative standards of the Essential Levels of Health Care (Livelli Essenziali di Assistenza, LEA).

The growing need for information to allow a real understanding and distinguishing of facilities on different levels of supply has made possible the development of the system of Monitoring of the Care network as a result of the work done by the writing Directorate in collaboration with the Regions. The complete activation of this system is scheduled for January 1, 2014, after a period of adjustment by the Regions and Autonomous Provinces to allow for the sending on time of information provided for by the system by a special Decree currently being defined. The knowledge of those who provide the services within the National Health Service (Servizio sanitario nazionale, SSN), of the elements that characterise the activity and factors of production, understood to be resources enabling the provision of the service, is a key aspect of the development of the NSIS.

In 2011, with particular reference to information systems established by decrees of the Minister of Health on December 17, 2008 [Information System for Monitoring of the Services provided in Emergency-Urgency health care (Emergenza-Urgenza, EMUR), Information System for Monitoring of Home Care (Sistema Informativo per l’Assistenza Domiciliare, SIAD) and a database aimed at the detection of performance for residential and semi-residential structures (FAR)], whose launch is anticipated from January 1, 2012, a significant improvement of the information transmitted to the NSIS in terms of completeness and quality was found. The information that pertains to these systems allows new and additional data relating to the most strategic welfare area of the SSN to be acquired on a forward-looking basis: towards the territory. In particular, the EMUR Information System collects information relating to health care services provided in emergency-urgency care on the part of both the 118 system and the accident and emergency services. The SIAD detects information about the integrated set of interventions, procedures and activities and health and social care provided to those assisted at home. Finally, the FAR Information System detects information on residential and semi-residential services provided in respect of elderly and dependent persons in critical conditions and/or the relative stabilisation of the clinical condition.

2011 saw the start of transmission of information to the systems established by decree of the Minister of Health on June 11, 2010 and October 15, 2010 [respectively, National Information System for Dependencies (Sistema Informativo Nazionale per le Dipendenze, SIND) and the Information System for Mental Health (Sistema Informativo Nazionale per la Salute Mentale, SISM)] and, consequently, to activities of analysis aimed at verifying, in terms of completeness and quality, the information communicated to the NSIS. The SIND information system, which at present focuses on drug addiction, allows the integration of the wealth of information within the NSIS with services carried out for health care given to drug addicts, with the charac-
4.2. Health on the Internet

In 2011, the Ministry of Health continued its efforts to support the development and dissemination of health on the Internet, at both Community and national level.

As regards the EU level, the Ministry of Health provided its contribution in different institutional forums, including the Ministerial eHealth Conference 2011 held in Buda-

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Essential bibliography

Accordo quadro tra il Ministro della sanità, le Regioni e le Province Autonome di Trento e di Bolzano per lo sviluppo del nuovo Sistema Informativo Sanitario Nazionale sancito dalla Conferenza permanente per i rapporti tra lo Stato, le Regioni e le Province Autonome di Trento e di Bolzano nella seduta del 22 febbraio 2001 (Rep. Atti n. 1158).

GU n. 90 del 18 aprile 2001
DM 17 dicembre 2008 “Istituzione del sistema informativo per il monitoraggio delle prestazioni erogate nell’ambito dell’assistenza sanitaria in emergenza-urgenza”. GU n. 9 del 13 gennaio 2009
DM 17 dicembre 2008 “Istituzione del sistema informativo per il monitoraggio dell’assistenza domiciliare”. GU n. 6 del 9 gennaio 2009
DM 17 dicembre 2008 “Istituzione della banca dati finalizzata alla rilevazione delle prestazioni residenziali e semiresidenziali”. GU n. 6 del 9 gennaio 2009
DM 11 giugno 2010 “Istituzione del sistema informativo nazionale per le dipendenze”. GU n. 160 del 12 luglio 2010
DM 15 ottobre 2010 “Istituzione del sistema informativo salute mentale”. GU n. 254 del 29 ottobre 2010
pest (Hungary) in May 2011, and the Informal Meeting of Ministers of Health held in Sopot (Poland) in July 2011, with the aim of representing, on the one hand, the strengths of our country in the field of eHealth and, secondly, of the legislative, organizational and financial constraints imposed by national realities, in order to steer the requirements of Community status in the direction of a concrete workability. The European Council Directive 2011/24/EU of March 9, 2011 on the application of patients’ rights in cross-border healthcare provided for the establishment of a voluntary network called eHealth Network in art. 14. The eHealth Network aims to create the conditions to enhance continuity of care and to ensure an access to care at Community level that is safe and of high quality, and provide guidance and support Member States in developing common measures for facilitate transferability of data in cross-border healthcare. With the European Commission Decision 2011/890/EU of December 22, 2011, the rules instituting eHealth Network were laid down. The Ministry of Health participates in the eHealth Network on behalf of our country.

In 2011, the Ministry of Health also actively participated in two major project initiatives within the EU. The first, called eHGI (eHealth Governance Initiative), is aimed at the goal of creating a governance mechanism through which to coordinate activities in the field of eHealth at EU level. This project, which officially started on February 1, 2011, will last for a period of 36 months. As regards the second project initiative, called PARENT (Cross-Border Patient Registries Initiative), the Ministry of Health, together with other Member States, was directly involved in the preparation of its project proposal. The project has the aim of supporting the development of disease registries that are comparable and consistent between the different Member States in relevant areas such as chronic diseases and rare diseases. The project is currently being finalised and will run for 30 months from 2012.

Initiatives in the field of eHealth implemented by the Ministry of Health are consistent with the development guidelines defined in the national eHealth Information Strategy. The following is a brief update regarding the status of implementation of these initiatives.

**Single Booking Centre Systems (Centro Unico di Prenotazione, CUP).** 2011 was the first year of assessment by the Standing Committee for verification of the LEA, according to art. 9 of the State-Regions Agreement of March 23, 2005 for the transposition by the Regions of national Guidelines aimed at harmonisation of CUP systems, prepared by the Ministry of Health and which were enshrined in the State-Regions Conference Understanding on April 29, 2010.

**Electronic Health Record Systems (Fascicolo Sanitario Elettronico, FSE).** The Ministry of Health prepared a document containing national Guidelines for the creation of a system of FSE, which was published in the Official Gazette no. 50 of March 2, 2011 after the Understanding sanctioned by the State-Regions Conference of February 10, 2011. The implementation of the Guidelines by the Regions will be assessed by the Standing Committee for verification of the LEA, pursuant to art. 9 of the State-Regions Agreement of March 23, 2005, during the annual verification of regional compliance. Moreover, the proposed legislation developed by the Inter-institutional council specially set up by the Ministry of Health, which will regulate the FSE not only in terms of the aims of treatment but also for the aims of study and research, planning, management, monitoring and evaluation of health care, has been included in the draft law of the Ministry of Health pro-tempore on “Delegation to the Government for the reorganisation of the legislation on clinical trials and for the reform of the orders of the health professions, as well as provisions on health”, approved by the Chamber of Deputies at first reading on the September 28, 2011.

**Electronic transmission of medical certificates.** In 2011 the activities were concluded of three working groups set up by the Min-
The Ministry of Health with the aim of regulating the technical procedures for the preparation and electronic transmission of certificates of illness in the case of access to accident and emergency services and hospital admission, as well as that of monitoring the electronic transmission of medical certificates of illness by SSN doctors to the Italian Social Security (INPS) institute, and by the latter to both private and public sector employers. Preparation began of the decree amending the ministerial decree (DM) of February 26, 2010, entitled “Definition of the technical procedures for the preparation and electronic transmission of certifications of illness to the central sickness certificate collection system (SAC)”.

**ePrescription.** Pursuant to art. 11, paragraph 16, of the decree law 78/2010, converted, with amendments, by law no. 122 of July 30, 2010, the Ministry of Health and the Ministry of Economy and Finance adopted the decree of November 2, 2011, and relevant technical specifications, published in the Official Gazette no. 264 of November 12, 2011, with which the technical procedures for the use of an electronic system for paper-based doctor’s prescriptions within the SSN and the Healthcare Services for Sea-faring and Flight Personnel (Servizi Assistenza Sanitaria Naviganti, SASN) were defined. The implementation of the provisions of the aforementioned DM is left to the distribution plans to be signed with individual Regions by September 2012.

**Use of an electronic system for clinical-health documentation.** The Ministry completed the document entitled “Guidelines for the use of an electronic system for clinical documentation in medical imaging” in 2011, as a result of agreement with the Regions with technical Coordination by the Health Commission, and which will be the subject of an Understanding at the State-Regions Conference. In 2011, the Ministry of Health also initiated the preparation of a further document of Guidelines focused on the use of an electronic system for medical laboratory records.

**Telemedicine.** The Directorate-General for Health Information and Statistical System provided a contribution in 2011 to the preparation of the National Guidelines for Telemedicine, being developed as part of the tasks of the technical Council that was set up by the Board of Health on February 24, 2011. In the same period, further impetus was given to the census of Telemedicine projects in place at national level within the National Observatory for the assessment and monitoring of eCare applications. The Ministry of Health considers it essential to continue along the path so far undertaken, aimed at creating a level playing field to create innovative ways of organisation and delivery of health services, ensuring the maximum synergy and cooperation among all stakeholders, within a single strategic and institutional nature framework for eHealth, in order to ensure harmonisation and consistency of the solutions identified.

**Essential bibliography**

Decreto 26 febbraio 2010 del Ministro della salute, di concerto con il Ministro del lavoro e delle politiche sociali e il Ministro dell’economia e delle finanze recante “Definizione delle modalità tecniche per la predisposizione e l’invio telematico dei dati delle certificazioni di malattia al SAC”. GU n. 65 del 19 marzo 2010

Decreto 2 novembre 2011 del Ministero dell’economia e delle finanze, di concerto con il Ministero della salute, recante “Dematerializzazione della ricetta medica cartacea, di cui all’art. 11, comma 16, del decreto legge n. 78 del 2010 (Progetto Tessera Sanitaria)” GU n. 264 del 12 novembre 2011

Direttiva 2011/24/UE del Parlamento Europeo e del Consiglio del 9 marzo 2011 concernente l’applicazione dei diritti dei pazienti relativi all’assistenza sanitaria transfrontaliera. GU n. 88 del 4 aprile 2011

Disegno di legge del Ministro della salute pro-tempore recante “Delega al Governo per il riassettamento della normativa in materia di sperimentazione clinica e per la riforma degli ordini delle professioni sanitarie, nonché disposizioni in materia sanitaria”, approvato dalla Camera dei Deputati, in prima lettura, il 28 settembre 2011


Intesa tra il Governo, le Regioni e le Province Auto-
4.3. Veterinary and food safety information systems

The National Veterinary Information System for Food Safety (SINVSA). The “Steering Committee” in charge of the implementation of an integrated system of information flows relating to animal health and food safety which combines the advantages of harmonisation and effectiveness with those derived from the more general process of simplification and computerisation of the relationship between Public Administrations and citizen users has recently presented the National Veterinary Information System for Food Safety (Sistema Informativo Nazionale Veterinario per la Sicurezza Alimentare, SINVSA) to the Regions, which represents the evolution and organisation of all the applications made available online by the Ministry of Health and is currently able to collect and make available information relating to the animal registry, to control activities and the results of tests carried out. This system also includes a section devoted to the management of the checks carried out in implementation of the National Plan for the monitoring of environmental contaminants in food of animal origin produced in the Sites of National Interest [SIN (Siti di interesse nazionale) Site Plan]. In addition, it has been enhanced through the use of portions of funds from the National Integrated Plan, with a geographic information system (sistema informativo geografico, GIS) which can adequately represent the territories within the SIN sites and place them in relation to all the environment and health variables useful to a correct characterisation of risk. The Steering Committee’s Animal Registries Working Groups have defined the minimum amounts of information necessary for the implementation of a national registry of countrywide facilities and enterprises active in the field of animal health and food safety. They also outlined the constituent elements of the registry of transporters of live animals under Regulation 1/2005 whose registration in SINVSA starts in 2012, and shared a summary of the results of the checks on animal welfare in breeding centres that will be recorded in the information system. The trace identifier to be used for enterprises/establishments/activities taken from the registry of food production plants registered under the Regulation 852/2004 has been agreed and the level of aggregation useful to the classification of production activities for the purposes of business registration and planning/reporting of controls and risk categorisation is in the process of definition. To respond to the common need to collect and present the entire body of medical and other data to all players in the supply chain, useful for government of the national animal health and food safety system, the experimentation of a link between the regional information platform PISA and the central system of information flow relating to Co-funded Plans has also been undertaken, with a cooperation between applications, and the results of which are currently being evaluated. In the light of information sharing which is the most effective approach in modern veterinary medicine, the start of the computerisation of the National Plan for Animal Feed also took place, to collect and make available data and information relating to the biographical data of Companies in the feed sector through the SINVSA information system, as well as monitoring and surveillance activities and their outcomes. Finally, the activities of implementation and monitoring of the National Animal Disease
Information System (Sistema Informativo Malattie Animali Nazionale, SIMAN), of Reporting Information System (Sistema Informativo Rendicontazioni, SIR), and the ZOONOSES and SANAN (Information System for animal health) systems continued in 2011.

**Animal registers.** The information system for animal registers is the central and irreplaceable point of reference for all information systems that in some way have to do with farms or farming enterprises, herds of animals and the animals themselves. Imagining any system of epidemiological surveillance or traceability of food of animal origin, without reference to an animal registration system would not be possible. Together with the implementation of bovine and buffalo registers, sheep and goats, and swine and poultry registers, registries of companies engaged in aquaculture and apiculture are currently under active development. *Table 4.1* shows the number and distribution of livestock farms in Italy updated to May 1, 2012.

**SINTESI food establishments information system.** The Integrated System for Trade and Imports (Sistema INTEgrato per gli Scambi e le Importazioni, SINTESI) allows the management of a database of the Italian food establishments producing food of animal origin approved under art. 4 of EC Regulation 853/2004 and food establishments for the processing and handling of animal by-products approved under EC Regulation 1069/2009. The system performs a daily up-

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**Table 4.1.** Enterprises registered in National Databases of animal registry data divided by Region and by type of animal bred (data updated to May 1, 2012)

<table>
<thead>
<tr>
<th>Region</th>
<th>Cattle and buffalo</th>
<th>Sheep and goats</th>
<th>Pigs</th>
<th>Poultry</th>
<th>Equines</th>
<th>Other species</th>
</tr>
</thead>
<tbody>
<tr>
<td>Piedmont</td>
<td>16,511</td>
<td>10,486</td>
<td>2,818</td>
<td>1,098</td>
<td>11,952</td>
<td>2,083</td>
</tr>
<tr>
<td>Aosta Valley</td>
<td>2,653</td>
<td>1,200</td>
<td>127</td>
<td>31</td>
<td>2</td>
<td>0</td>
</tr>
<tr>
<td>Lombardy</td>
<td>21,058</td>
<td>13,703</td>
<td>8,621</td>
<td>2,639</td>
<td>14,780</td>
<td>5,277</td>
</tr>
<tr>
<td>Aut. Prov. of Bolzano</td>
<td>8,812</td>
<td>5,520</td>
<td>4,569</td>
<td>112</td>
<td>168</td>
<td>33</td>
</tr>
<tr>
<td>Aut. Prov. of Trent</td>
<td>1,689</td>
<td>1,580</td>
<td>640</td>
<td>31</td>
<td>1,386</td>
<td>115</td>
</tr>
<tr>
<td>Veneto</td>
<td>22,394</td>
<td>4,381</td>
<td>8,334</td>
<td>2,256</td>
<td>9,452</td>
<td>1</td>
</tr>
<tr>
<td>Friuli Venezia Giulia</td>
<td>3,370</td>
<td>1,024</td>
<td>1,933</td>
<td>289</td>
<td>1,267</td>
<td>140</td>
</tr>
<tr>
<td>Liguria</td>
<td>1,620</td>
<td>3,005</td>
<td>594</td>
<td>60</td>
<td>3,972</td>
<td>685</td>
</tr>
<tr>
<td>Emilia Romagna</td>
<td>9,058</td>
<td>4,024</td>
<td>4,911</td>
<td>850</td>
<td>8,897</td>
<td>1,023</td>
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<tr>
<td>Tuscany</td>
<td>6,207</td>
<td>7,369</td>
<td>7,378</td>
<td>164</td>
<td>7,893</td>
<td>898</td>
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<td>Umbria</td>
<td>4,502</td>
<td>3,395</td>
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<td>230</td>
<td>4,358</td>
<td>310</td>
</tr>
<tr>
<td>Marche</td>
<td>6,745</td>
<td>5,109</td>
<td>14,420</td>
<td>1,541</td>
<td>3,846</td>
<td>415</td>
</tr>
<tr>
<td>Lazio</td>
<td>17,243</td>
<td>10,689</td>
<td>4,513</td>
<td>3,244</td>
<td>13,924</td>
<td>2,521</td>
</tr>
<tr>
<td>Abruzzo</td>
<td>7,156</td>
<td>7,469</td>
<td>13,325</td>
<td>613</td>
<td>4,721</td>
<td>1,407</td>
</tr>
<tr>
<td>Molise</td>
<td>3,790</td>
<td>3,789</td>
<td>4,821</td>
<td>303</td>
<td>1,679</td>
<td>124</td>
</tr>
<tr>
<td>Campania</td>
<td>16,438</td>
<td>10,025</td>
<td>20,898</td>
<td>202</td>
<td>6,262</td>
<td>525</td>
</tr>
<tr>
<td>Apulia</td>
<td>5,667</td>
<td>5,711</td>
<td>962</td>
<td>283</td>
<td>5,823</td>
<td>272</td>
</tr>
<tr>
<td>Basilicata</td>
<td>3,412</td>
<td>7,657</td>
<td>6,548</td>
<td>38</td>
<td>3,003</td>
<td>342</td>
</tr>
<tr>
<td>Calabria</td>
<td>10,200</td>
<td>12,422</td>
<td>9,117</td>
<td>133</td>
<td>1,965</td>
<td>374</td>
</tr>
<tr>
<td>Sicily</td>
<td>11,744</td>
<td>11,507</td>
<td>1,586</td>
<td>334</td>
<td>12,919</td>
<td>488</td>
</tr>
<tr>
<td>Sardinia</td>
<td>10,357</td>
<td>20,405</td>
<td>15,918</td>
<td>777</td>
<td>6,470</td>
<td>1,175</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>190,626</strong></td>
<td><strong>150,470</strong></td>
<td><strong>134,975</strong></td>
<td><strong>15,228</strong></td>
<td><strong>124,739</strong></td>
<td><strong>18,208</strong></td>
</tr>
</tbody>
</table>

*Source: Ministry of Health – BDN Animal registries.*
Quality of the system, resources and monitoring of the LEA

date of the official lists (published on the Ministry of Health website) every time new operations of insertion, updating, or withdrawal are made either by Regions for food establishments producing food of animal origin or by the Ministry of Health for cold storage vessels and factory ships. In 2011, the system for food establishments approved or registered in accordance with EC Regulation 1069/2009 was adjusted to the new specifications required by the EU Directorate-General for Health and Consumer Protection (DGSANCO) for publication of food establishments in the official Community lists.

Essential bibliography


4.4. New SINTESI System: update and integration with the New Health Information System (NSIS) platform

Italy is a country heavily dependent on other EU countries as regards the flow of live animals and products of animal origin and has therefore historically had the need to have tools of knowledge for information regarding this flow, in respect of rules of free intra-Community trade. The creation of the national information system SINTESI in 1998 was born from this need.

The use of SINTESI-Scambi (Integrated System for Trade and Imports) as well as being fundamental from the management point of view, is also provided for by the D.Lgs. no. 28/1993 which, together with the D.Lgs. no. 27/1993 – which established the Veterinary Office for Compliance with European Union Obligations (Uffici Veterinari per gli Adempimenti Comunitari, UVAC) – created the legal basis that allows Italy to have, unlike in other member countries, an original and effective monitoring system for goods coming from abroad, in compliance with the rules of free movement within the EU. The national system currently supports the Community information system TRACES (Trade Control and Export System), that records only data on live animals and certain types of products (7% of the total), leaving unmonitored, then, about 93% of all goods subject to veterinary supervision originating from other member States.

Given the demonstrated effectiveness of the SINTESI system in particular for the management of traceability of goods during public health emergencies that have affected the European Union in recent years (BSE, foot and mouth disease, avian influenza, dioxin, etc.), in 2011, an important task of re-engineering was made, inserting SINTESI within the technological platform of the NSIS. The main benefits of this re-engineering are represented by the use of shared architectural components that minimise the activities and costs of maintenance, safety standards, high performance and modern technology in order to:

- simplify the administrative burdens for businesses for UVAC offices, as well as to the Local Health Authorities (Aziende sanitarie locali, ASLs), respecting the principles adopted by the Digital Administration Code (D.Lgs. 82/2005 and subsequent amendments);
- ensure application interoperability and cooperation with other national and Community systems (e.g., TRACES, customs systems, database of food establishments approved in accordance with Regulation 853/2004 and Regulation 1069/2009, the national database of the bovine registry).

During 2012, further changes will be made that take into account all of the updates
and innovations, suggested also by the direct users of the SINTESI system, and in particular:

- modes of access to the system, which must be adapted in terms of facilities and computer services targeted to users as specified in the D.Lgs. 82/2005 “Code for Digital Administration”, making use, where possible, of external demographic databases of reference (e.g., Chamber of Commerce databases) and tools such as the National Services Card (Carta Nazionale dei Servizi, CNS);
- interoperability with other national and Community systems [TRACES, BDN (the Italian National Database of Animal Registries), etc.] in order to enhance and develop the potential of each of them; and
- improving the quality of data on the biographical information of facilities (registered operators and reference facilities) and their geo-location.
5.1. Major equipment

Medical equipment is a key element for the provision of the Essential Levels of Health Care (Livelli Essenziali di Assistenza, LEA), in particular for those types characterised by a large number of performances, and huge investments by the National Health Service (Servizio sanitario nazionale, SSN). Currently there is no organic inventory of the equipment available throughout the country, but different systems of data collection related in any case to certain types of equipment: the more consolidated and organic refers to the data on Models HSP14 and STS14 provided for by the ministerial decree of December 5, 2006 that collects information annually on technical and biomedical equipment, by type, present in individual care and non-hospital facilities. In addition, the Database/Directory system of Medical Devices that, using the CND classification (National Classification of Medical Devices), gathers key information pertaining to devices marketed in Italy, including equipment.

Using the HSP14 and STS14 templates of data collection, availability of certain classes of equipment in public and private accredited facilities can be monitored and, since 2007, the availability of equipment particularly important for diagnostics and therapies, such as PET, the integrated CT/PET system, the integrated CT/gamma camera system, the system for digital angiography and the mammography unit.

The analysis of the data recorded for some major equipment (supplied in absolute value and indicator per 1,000,000 inhabitants), in the period 2008-2010 shows an increase in national average availability, in particular as regards Computerized Axial Tomography – passing from a value of 29.8 to a value of 30.9 for devices per 1,000,000 inhabitants – and magnetic resonance tomography – that passes from 19.4 to 22 devices per 1,000,000 inhabitants. As regards other equipment, in 2010 there were 131 PET and CT/PET integrated systems with an availability of 2.2 devices per 1,000,000 inhabitants; the availability of mammography units is equal to 189.2 per 1,000,000 women aged between 45 and 69 years (Table 5.1).

The wealth of information available does not allow for a detailed picture of equipment and its utilisation rate, so that specific projects have been initiated at regional and national level for these aspects. To provide a sense of homogeneity and of a systemic approach to data detection thereby ensuring greater detail than that already available, the Ministry of Health in collaboration with the Regions and Autonomous Provinces launched a Working Group for the “Feasibility Study for the collection of information relating to medical equipment” in 2010; the working group then carried out a “Survey of state of the art”, in order to find out what data are held at regional or local level on medical equipment. Sixteen out of 21 Regions took part in the survey, which showed that in 11 of them systems to collect data relating to medical equipment are active, although with very different characteristics between them; activation in the remaining 5 is expected shortly, however. In terms of recorded information, the recording of details for the facility and Operational Unit location, type,
date of acquisition, the purchase price, operating costs and total number of services provided during the period under observation are the principal ones made for each device (Figure 5.1).

Taking into account the systems already available at the regional level, albeit with different levels of detail in the data collection, in order to converge towards a homogeneous view of information for the proper monitoring of equipment at national level, the Working Group has decided to observe the following details for analysis: Location, Features (with particular reference to config-

![Table 5.1. Major equipment present in public and private accredited hospitals and territorial facilities (Years 2008-2010)](image)

<table>
<thead>
<tr>
<th>Equipment</th>
<th>2008 Absolute value</th>
<th>2008 Per 1,000,000 inhabitants</th>
<th>2009 Absolute value</th>
<th>2009 Per 1,000,000 inhabitants</th>
<th>2010 Absolute value</th>
<th>2010 Per 1,000,000 inhabitants</th>
</tr>
</thead>
<tbody>
<tr>
<td>Linear accelerator</td>
<td>343</td>
<td>5.8</td>
<td>380</td>
<td>6.3</td>
<td>394</td>
<td>6.5</td>
</tr>
<tr>
<td>Computerised gamma camera</td>
<td>681</td>
<td>11.4</td>
<td>711</td>
<td>11.8</td>
<td>680</td>
<td>11.3</td>
</tr>
<tr>
<td>MRI scanner</td>
<td>1,155</td>
<td>19.4</td>
<td>1,245</td>
<td>20.7</td>
<td>1,328</td>
<td>22.0</td>
</tr>
<tr>
<td>Computerised axial tomography unit</td>
<td>1,776</td>
<td>29.8</td>
<td>1,826</td>
<td>30.4</td>
<td>1,866</td>
<td>30.9</td>
</tr>
<tr>
<td>System for digital angiography</td>
<td>630</td>
<td>10.6</td>
<td>677</td>
<td>11.3</td>
<td>707</td>
<td>11.7</td>
</tr>
<tr>
<td>Positron emission tomography</td>
<td>42</td>
<td>0.7</td>
<td>36</td>
<td>0.6</td>
<td>30</td>
<td>0.5</td>
</tr>
<tr>
<td>Integrated CT/PET system</td>
<td>76</td>
<td>1.3</td>
<td>82</td>
<td>1.4</td>
<td>101</td>
<td>1.7</td>
</tr>
<tr>
<td>Mammography unit*</td>
<td>1,761</td>
<td>183.3</td>
<td>1,842</td>
<td>189.2</td>
<td>1,869</td>
<td>189.2</td>
</tr>
</tbody>
</table>

*The indicator is calculated per 1,000,000 women aged between 45 and 69 years.

Figure 5.1. Type of information received from the Regions for devices.
5.2. Governance of the medical device sector

In recent years the medical device industry in Italy has become a subject of great interest on the part of public institutions, and in particular the Ministry of Health, with the primary objective to deepen the understanding of data and other information on supply and demand of these technologies in our country. While, in fact, spending on medical devices in Italy is becoming increasingly important on the one hand, on the other the introduction of technological innovation in health care is likely to increase, as well as making a structural change in some diagnostic and therapeutic patient pathways of care and clinical management of diseases with a consequent profound impact on the organisational structure of hospitals. Consider, for example, the increasing introduction of new surgical techniques to replace traditional surgical procedures and the impact that this phenomenon has and will have even more on the organisational structure of the hospital, on strategies for planning of hospital services at the regional level and the quality and efficiency of health services provided. It is therefore of great importance to understand not only the size of the medical device market in terms of volume and expenditure, but also to understand what are the processes and strategies of purchase such as the level of coordination within enterprises and between Regions of these strategies and how hospitals manage the flow of acquisition-use-control information of the performance.

In this respect, 2011 has highlighted the great interest in expenditure by the SSN in the medical device sector. In particular, much attention has been paid to the activities carried out in the national territory for a systematic and homogeneous monitoring of consumption and related expenditure. The awareness, in fact, to have available the information needed for a specific knowledge of the sector, as well as for other areas related to expenditure for the purchase of goods and services, is now very much present in the regulatory approach to rationalise spending (cf. art. 17 of decree law 98/2011 converted with amendments by law 111/2011).

The path followed to implement systematic and homogeneous monitoring in spending on medical devices has been developed, substantially and where possible in an overlapping manner, fully in line with what has already been implemented for the pharmaceutical sector and that is to allow an integrated approach at all levels of the government of health spending of these different areas of consumption and expenditure. The start of data collection established by the decree of the Minister of Health of June 11, 2010 – “Establishment of the flow of information to monitor the use of medical devices purchased directly by the SSN” – has allowed the move in 2011 from the design to the operational phase of monitoring. The work carried out jointly by the Regions and Autonomous Provinces and the Ministry of Health has made it possible to begin a process of making the sector transparent that probably has no precedent in our country. Critical to achieving this goal was the important work of semantic sharing of information and data and, in particular, of the registry of reference consisting of the Database and Directory of medical devices: the use of the registration number of the management systems of healthcare authorities was the first major change to be managed, given the large number of products concerned, with repercussions also throughout.
the medical devices supply sector by public health facilities. In this regard, the quality of the demographic information contained in the medical devices Database, necessary to the supply for the flow of expenditure monitoring, as well as the acquisition and proper use of medical devices, is of fundamental importance and depends in particular on continuous updating of data for each medical device. It is therefore necessary to combine the needs of companies in the legal and commercial area with the purely regulatory aspects of medical devices in order to allow the data in the system to be constantly and regularly updated. The change management of the data already in the system represents a very complex task and very particular to the area.

The variety and number of census information within the database is shown in Figure 5.2, that presents the distribution of medical devices according to the National Classification of medical devices (CND) registered in the BD/RDM system.

![Figure 5.2. Distribution of medical devices according to the National Classification of Medical Devices (CND) registered in the BD/RDM system.](image)

Quality of the system, resources and monitoring of the LEA

tion of Medical Devices (Classificazione Nazionale dei Dispositivi medici, CND), and Figure 5.3, which shows the percentage distribution of medical devices for class of risk.

Certainly the publication on the website of the Ministry of Health of the demographic information of the devices found in the database and repertoire in December 2011 al-

Figure 5.3 Distribution in percentages of medical devices by class of risk in the BD/RDM system.

![Percentage Distribution of Medical Devices](image)


Table 5.2. Monitoring of use of medical devices – Quarterly expenditure by Region (Year 2011)

<table>
<thead>
<tr>
<th>Region</th>
<th>Quarter I</th>
<th>Quarter II</th>
<th>Quarter III</th>
<th>Quarter IV</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>010 - Piedmont</td>
<td>31,153,400.42</td>
<td>28,229,369.77</td>
<td>26,489,997.27</td>
<td>33,458,468.28</td>
<td>119,331,235.74</td>
</tr>
<tr>
<td>020 - Aosta Valley</td>
<td>2,243,763.09</td>
<td>2,142,652.21</td>
<td>2,392,633.32</td>
<td>2,638,225.43</td>
<td>9,417,274.05</td>
</tr>
<tr>
<td>030 - Lombardy</td>
<td>97,674,734.16</td>
<td>103,200,483.25</td>
<td>91,176,338.28</td>
<td>93,163,858.52</td>
<td>385,215,414.21</td>
</tr>
<tr>
<td>041 - Aut. Prov. of Bolzano</td>
<td>10,142,555.36</td>
<td>11,452,979.72</td>
<td>10,040,837.30</td>
<td>11,910,797.26</td>
<td>43,547,169.64</td>
</tr>
<tr>
<td>042 - Prov. of Trent</td>
<td>1,935,713.29</td>
<td>365,557.15</td>
<td>1,013,247.43</td>
<td>702,686.28</td>
<td>4,017,204.15</td>
</tr>
<tr>
<td>050 - Veneto</td>
<td>50,043,352.34</td>
<td>61,269,965.89</td>
<td>48,006,463.01</td>
<td>71,915,176.42</td>
<td>231,234,957.67</td>
</tr>
<tr>
<td>060 - Friuli Venezia Giulia</td>
<td>3,786,886.18</td>
<td>5,031,513.72</td>
<td>4,477,483.60</td>
<td>5,709,219.40</td>
<td>19,005,102.90</td>
</tr>
<tr>
<td>070 - Liguria</td>
<td>21,030,217.35</td>
<td>23,088,034.59</td>
<td>20,725,719.73</td>
<td>22,002,907.01</td>
<td>86,846,878.68</td>
</tr>
<tr>
<td>080 - Emilia Romagna</td>
<td>78,531,988.17</td>
<td>82,809,023.29</td>
<td>76,043,409.04</td>
<td>91,879,101.61</td>
<td>329,263,522.10</td>
</tr>
<tr>
<td>090 - Tuscany</td>
<td>44,446,359.83</td>
<td>50,308,423.75</td>
<td>41,187,235.64</td>
<td>46,242,902.89</td>
<td>182,184,922.11</td>
</tr>
<tr>
<td>100 - Umbria</td>
<td>7,574,422.76</td>
<td>8,600,220.42</td>
<td>7,197,343.67</td>
<td>7,473,308.94</td>
<td>30,845,295.79</td>
</tr>
<tr>
<td>110 - Marche</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>120 - Lazio</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>130 - Abruzzo</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>140 - Molise</td>
<td>3,411,366.23</td>
<td>3,718,636.46</td>
<td>2,622,185.47</td>
<td>2,864,064.49</td>
<td>12,616,252.65</td>
</tr>
<tr>
<td>150 - Campania</td>
<td>4,182,931.85</td>
<td>6,012,358.69</td>
<td>6,873,023.55</td>
<td>123,078,740.00</td>
<td>140,147,054.10</td>
</tr>
<tr>
<td>160 - Apulia</td>
<td>9,543,480.63</td>
<td>14,686,797.67</td>
<td>13,240,268.00</td>
<td>18,159,903.42</td>
<td>55,630,449.72</td>
</tr>
<tr>
<td>170 - Basilicata</td>
<td>7,087,360.15</td>
<td>8,444,751.55</td>
<td>7,927,501.90</td>
<td>12,161,617.63</td>
<td>35,621,231.23</td>
</tr>
<tr>
<td>180 - Calabria</td>
<td>709,163.66</td>
<td>5,190,519.60</td>
<td>3,177,011.48</td>
<td>3,382,273.39</td>
<td>12,458,968.13</td>
</tr>
<tr>
<td>190 - Sicily</td>
<td>2,251,318.95</td>
<td>3,328,725.24</td>
<td>4,566,926.84</td>
<td>5,164,086.11</td>
<td>15,311,057.14</td>
</tr>
<tr>
<td>200 - Sardinia</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>Total</td>
<td>375,749,014.41</td>
<td>417,880,122.99</td>
<td>367,157,625.53</td>
<td>551,907,337.07</td>
<td>1,712,693,990.00</td>
</tr>
</tbody>
</table>

NA, not available.

allowed a more easy diffusion of these data, even if the size and structure of the sector allows for an understanding of the complexity of the start-up of monitoring activity for consumption and expenditure and the efforts made and expense borne by the Regions and Autonomous Provinces.

The first results are very encouraging, however: in 2011, the year of initiation of the flow of information, 17 Regions and Autonomous Provinces have actually started the collection and transmission of consumption data at the central level reaching, in many cases, the involvement of 100% of health authorities in their territory, while one Region (Lazio) has started the phase of transmission of test data, and collection and transmission of data on contracts was initiated by 16 Regions and Autonomous Provinces.

Table 5.2 shows the summary of expenditure data for total consumption recorded for the year 2011: it is of course still incomplete data, but the large number of medical devices detected (over 55,200) and the overall figures of expenditure are indicative of the actual accumulation of information. Table 5.3 shows the summary of the data relating to contracts for the purchase of medical devices for 2011: also, in this case, the data are partial, where the large number of contracts and medical devices detected is indicative of the actual accumulation of information.

### 5.3. Monitoring and surveillance of the medical devices market

The Ministry of Health, as the Competent Authority for medical devices, monitors the implementation of the national legislation [legislative decree (D.Lgs.) no. 46/1997 and D.Lgs. no. 507/1992] through a constant control programme in the different components of the marketing chain of medical devices (manufacturers, distributors and users). This activity, described in all forums and Community documents as “market surveillance”, is a central pillar of the system of CE marking of medical devices in the absence of a system of prior authorisation by the public Administration. In the same Community context, however, ‘surveillance’ means activities related to the management of information concerning the alteration of devices and accidents, i.e. adverse events related to the characteristics or performance of medical devices.

The surveillance takes the form of various modes of control designed to check the

### Table 5.3. Purchase contracts for medical devices relative to 2011

<table>
<thead>
<tr>
<th>Region</th>
<th>No. contracts transmitted</th>
</tr>
</thead>
<tbody>
<tr>
<td>010 - Piedmont</td>
<td>1,008</td>
</tr>
<tr>
<td>020 - Aosta Valley</td>
<td>440</td>
</tr>
<tr>
<td>030 - Lombardy</td>
<td>51,647</td>
</tr>
<tr>
<td>041 - Aut. Prov. of Bolzano</td>
<td>338</td>
</tr>
<tr>
<td>042 - Aut. Prov. of Trent</td>
<td>NA</td>
</tr>
<tr>
<td>050 - Veneto</td>
<td>28,523</td>
</tr>
<tr>
<td>060 - Friuli Venezia Giulia</td>
<td>NA</td>
</tr>
<tr>
<td>070 - Liguria</td>
<td>6,604</td>
</tr>
<tr>
<td>080 - Emilia Romagna</td>
<td>30,053</td>
</tr>
<tr>
<td>090 - Tuscany</td>
<td>107</td>
</tr>
<tr>
<td>100 - Umbria</td>
<td>NA</td>
</tr>
<tr>
<td>110 - Marche</td>
<td>NA</td>
</tr>
<tr>
<td>120 - Lazio</td>
<td>NA</td>
</tr>
<tr>
<td>130 - Abruzzo</td>
<td>79</td>
</tr>
<tr>
<td>140 - Molise</td>
<td>NA</td>
</tr>
<tr>
<td>150 - Campania</td>
<td>514</td>
</tr>
<tr>
<td>160 - Apulia</td>
<td>218</td>
</tr>
<tr>
<td>170 - Basilicata</td>
<td>41</td>
</tr>
<tr>
<td>180 - Calabria</td>
<td>2,166</td>
</tr>
<tr>
<td>190 - Sicily</td>
<td>159</td>
</tr>
<tr>
<td>200 - Sardinia</td>
<td>NA</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>121,897</strong></td>
</tr>
</tbody>
</table>

work of manufacturers, distributors, retailers, and importers, ensuring public and end-user health. In order to carry out checks on medical devices, the Ministry of Health may order tests directly at the points of production and/or storage of the products, or by acquiring all the information necessary for an test in progress, or by resorting, if deemed useful and appropriate in the specific case, to the temporary possession of a model of the device that is object of control for the execution of examinations and tests.

The surveillance actions are initiated following reports or inspections carried out in the course of routine inspections (inspections, database of medical devices, the issue of so-called certificates of free sale, management of withdrawn or suspended CE certificates, etc.). Of fundamental importance are the reports from the territory (health facilities, Ministry maritime, air and border health offices, Carabinieri NAS, etc.). Finally, a constant and timely communication with other competent European authorities and participation in the activities coordinated by the European Commission are another source of information to be managed for the purposes of market surveillance.

*Figure 5.4* shows the distribution of the main surveillance activities carried out in 2011 in relation to the reasons that generated them. In the last few months of 2011, thanks also to the impact of the media, important questions on the safety of medical devices have emerged, such as to trigger broad and deep reflections on the approach and on the forms of the EU and national regulatory framework. The events relating to certain types of breast implants and hip replacements have brought to the fore the need to know quickly of episodes that are or may be the source of serious damage to health along with other aspects of the life cycle of medical devices, and the need to make widely known measures to deal with the consequences of accidents and to prevent their recurrence.

The need to govern actions to protect the health beyond the practices of the manufacturers under their own responsibility also took particular significance.

In order to obtain scientific evaluations and clinical indications necessary to ensure the best protection of public health, the Ministry of Health took charge of a meeting with scientific and technical bodies, requesting the Board of Health to express themselves on the issues and participating in the activities of a similar Community body, the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR).

In Italy, health care workers are obliged to report incidents, which is not the case in many other European countries. In this way, the Ministry of Health, even where the man-

*Figure 5.4. Principal actions of market surveillance (Year 2011).*

![Figure 5.4: Principal actions of market surveillance (Year 2011).](source: Ministry of Health.)
manufacturer does not fulfil his obligations, as happened in the case of PIP implants, still manages to have news of accidents, to quantify them and estimate their relevance. Despite the lack of reliable data on the total number of devices in use, a lack that becomes even more sensitive when the wait for establishment of registers for implantable devices is considered, the presence of a computer system that collects data from accident reports allows an evaluation of the cases of accidents for those devices which require further insights into their safety, based on the reports of other European competent Authorities or particularly serious episodes. In 2011, 1,276 mishaps were recorded, a number substantially equal to that of the previous year. There was also a significant increase in reports other than accident reports and calls (see under “Other” in the histogram for the data on accidents), increases to a large extent explained by the abolition, through D.Lgs. 37/2010, of the case of non-accident (which in some cases have been wrongly declared by the operators) and the concomitant increase in reports related to devices, which have presented alterations in their characteristics or performance without causing accidents (Figure 5.5).

Moreover, at the end of 2011, the first phase of implementation of a new computer system that enhances the ability to collect and analyse surveillance data was concluded, accessible via the web for health professionals and equipped with the best features for statistical elaboration.

In addition, the Ministry of Health contributes, through publication on its website, to the dissemination of warnings that manufacturers produce to make known their corrective actions. In 2011, 411 Safety Alerts were published on the website of the Ministry. Where publication of the notices on the website of the manufacturer appears to be insufficient to meet the needs of dissemination, as happened in the case of breast implants and that of hip replacements, the Ministry also provides for the issuance of circulars that can reach those concerned more directly and promptly.

Figure 5.5. Data from medical devices surveillance years 2007-2011.

* “Other” includes National Competent Authority Reports, security alerts, complaints and other communications.

6.1. European Structural Funds in regional planning

As part of European Structural Funds, the National Strategic Framework (Quadro Strategico Nazionale, QSN) for additional policy 2007-2013, anticipated by art. 27 of EC Regulation 1083/2006, is the planning document with which Italy pursues the objectives of the policy of Community cohesion.

In order to achieve the priorities set out in the QSN reference framework Italy has developed the National Governance and Technical Assistance Operational Project (PON GAT) whose operational objective II.4 provides for the “Strengthening of structures and competences in Public Administration”.

In this context, the Ministry of Health has developed the Health POAT (Technical Assistance Operational Project for Health), a three-year project and with an expected cost of Euro 11 million, aimed at the implementation of the “Plan of Reorganisation and Capacity Building” in two parts, each functional:

- the Technical Assistance Operational Project for specific policies, aimed at meeting the needs of institutional support and cooperation requested by the Regional Administrations for Convergence Objective;
- the Internal Reorganization Plan (Piano di Riorganizzazione Interna, PRI), sponsored entirely by the internal Administration, instrumental for better management and implementation of the POAT itself through an Operating Unit with responsibility for policy and coordination (Figure 6.1).

Technical Assistance Operational Project – Health POAT. The Health POAT (Progetto Operativo di Assistenza Tecnica) has as its main objective the satisfaction of regional needs, identified and defined both through regional planning documents and through specific meetings on convergence with individual regional administrations (Campania, Calabria, Apulia and Sicily).

In particular, the Ministry aims to achieve the following specific objectives, defined following the analysis of particular regional needs:

- support the strategic and operational definition for planning of regional interventions;

Figure 6.1. Financial resources assigned to POAT Health as part of PON GAT.
Ordinary and extraordinary financial resources

- support the process of implementation and realisation of regional interventions;
- increase the capacity for use of techniques and methodologies for monitoring and evaluation by administrators and operators in the field.

The Health POAT was operationally launched with the award of contracts to two in house organisations – Formez PA (an international research and training Center to the modernization of the Public Administration) and the National Agency for Regional Health Services (Agenzia Nazionale per i Servizi Sanitari Regionali, AgeNaS) – through two specific Conventions, concluded respectively on April 20, 2011 and May 11, 2011. With a third party implementing body – RTI ATESI – a specific Contract was entered into on December 28, 2011, following the completion of an open tender.

The Ministry of Health intends to offer its support to the Regions interested by the project through transversal and specific regional lines of action.

The transversal lines of action respond to the needs and requirements common to the four Regions and are linked to the following four area of intervention:

- support for the development of the various stages that accompany the planning cycle;
- support for the definition and use of projects and tools to integrate the “health impact assessment” (valutazione d’impatto sulla salute, VIS) in planning;
- support the activation of cooperation networks and exchange of best practices in health;
- actions of assistance, information and awareness-raising for the benefit of the regional governments, local entities and sector operators.

The regional intervention actions meet specific territorial needs and thus provide numerous and articulate technical assistance activities related to the following macro-areas:

- identification of innovative organisational and management models for enhancing health care and social services;
- operational support to the dissemination of planning skills, adherence to research projects and to international, community, national and regional cooperation;
- support for the development of telemedicine services;
- support for the development of innovation and computerisation of health care;
- support for the identification of models and planning tools and epidemiological support;
- support for the testing of operating modes, borrowed from other contexts, for accessibility to health services;
- support for the improvement of institutional communication in health care;
- support for the analysis of the most common methods of Health Technology Assessment.

In 2011, the meetings attended by all the Regions concerned for the definition of their respective needs necessarily contextualized and updated ended and the project was initiated.

Internal reorganisation plan. The management of activities related to POAT is entrusted to Office VII – responsible for Structural Funds – of the Directorate-General for Health Planning, assisted by a technical structure – the Operating Unit for the management of projects for Technical Assistance – provided for by the National Strategic Framework (NSF) and established by directorial decree of April 6, 2009 and consisting of 15 internal Ministry resources. The presence of the Operating Unit represents an important tool for the Administration, which may be used not only in dealing with the Intermediate Body and the National Managing Authority, but especially in relations with the Regions receiving technical assistance. It is believed that, in this way, the Administration’s own professionals can enhance their skills through on-the-job training alongside technical assistance activities delivered by the implementing bodies.

Essential bibliography

6.2. Levels of funding of the SSN and rationalisation measures for health expenditure

Public health expenditure incurred in 2011 amounted to Euro 112.889 billion, corresponding to an average *per capita* amount of Euro 1,862 with significant regional differences. The percentage increase in spending last year was equal to 1.4%, an increase compared to 2010. This increase includes the effect due to the recognition in 2011 of the costs related to the amortisation of investments, which were not included in the spending level of previous years. Net of this cost component, the variation is 0.1%.

The deficit in 2011 amounted to Euro 1.779 billion and is the best performance of the operating results in recent years due to the effect of the regulatory framework put in place by the legislature and regional implementation of Plans of Realignment. In particular, the Regions that have signed a Plan of Realignment are: Abruzzo, Calabria, Campania, Lazio, Molise, Piedmont, Apulia and Sicily. Also significant is the reduction in Regions that recorded significant deficits such as Lazio and Campania, although the process still requires significant and structural actions. Furthermore, as a system of ordinary funding (capital) for the renewal and maintenance in efficiency of fleets of vehicles or for maintaining the productive capacity of health authorities no longer exists, the performance achieved so far in terms of limiting current health expenditure is even more worthy of appreciation. In fact, some authorities have used some of their current financing for investment, while maintaining the financial equilibrium required for the guarantee of Essential Levels of Health Care (*Livelli essenziali di assistenza*, LEA) performance, while others have renewed investment, worsening the debts to suppliers. The results of an economic-financial nature are the result of a gradual upgrading of health care that has seen significant reduction (11%) in hospitalisation rates, from 197 per 1,000 inhabitants in 2007 to 176 per 1,000 population in 2010, with particular emphasis in Regions that showed excessive use of hospital facilities. With reform of the National Health Service (*Servizio sanitario nazionale*, SSN) in 1992 a high level of responsibility has been attributed to individual Regional governments as regards to continuing economic and financial equilibrium and delivery of levels of healthcare; since 2001, with the reform of Title V of the Constitution, which introduced federalism the role of the state has been revised, through the Ministry of Health, giving it a strong function of monitoring, control and guidance for the purpose of ensuring the health of all citizens. The Standing Committee on the audit of LEA provision contributes to these functions.

The resources allocated to the SSN in 2011, not considering the revenues from extraordinary management and those for intramural costs for private specialists in public institutes, which were considered as a balance in the level of expenditure, amounted to Euro 111.110 billion, of which Euro 110.469 billion refer to Regions and Autonomous Provinces and Euro 0.641 billion for other SSN bodies funded directly by the State. These values discount own revenues actually collected by the SSN bodies, transfers from the Regions, the wider public sector and from private citizens. The percentage increase of the total funding of the SSN in 2011 compared to 2010 is 1.8%, while in the previous year was 2.2%, while the national average funding per capita is Euro 1,833, with a broad differentiation at regional level.
6.3. Public investment in health

Planning framework. Art. 20 of the law of March 11, 1988, no. 67 authorises a multiannual programme of investment in construction and health technologies. The general objectives of the programme as set by the legislature are aimed at the rehabilitation of the public building stock and technology and the construction of nursing homes. The multiannual program authorises an investment of Euro 24 billion.

State of implementation. The first phase of the programme ended in 1996, with the authorisation to spend the sum of Euro 4,854,694,851.44 of which Euro 216,240,503.65 was reserved for institutions: Scientific Institutes for Research, Hospitalisation and Health Care (Istituti di Ricovero e Cura a Carattere Scientifico, IRCCSs), University Polyclinics under direct management, classified hospitals, Experimental Institutes for animal disease control and prevention (Istituti Zooprofilattici Sperimentali, IZSs), and National Institute for Health (Istituto superiore di sanità, ISS) pursuant to art. 4, paragraph 15 of law December 30, 1991, no. 412 and subsequent amendments.

The second phase, which started in 1998, initially allocated Euro 1,291,142,247.72 to a specific programme for the completion of construction of facilities that had started and interventions aimed at safety measures, in the Regions and Autonomous Provinces and organisations. The resources were all used. Other resources provided by the programme were intended for Agreements and specific lines of action as shown below.

- Programme agreements: the resources allocated for programme agreements amounted to Euro 15,285,958,367.91; 58 programme agreements were signed on December 31, 2011 for an amount of Euro 9,193,515,969.86. The resources remaining to be used for the subscription to programme agreements amounted to Euro 6,092,442,398.03. Table 6.1 shows in detail for each Region the resources allocated for the subscription to programme agreements, the resources involved in signed programme agreements, the resources requested and approved for financing with the corresponding number of actions funded and the remaining funds for the subscription to programme agreements.

- Radiotherapy Programme: in relation to the resources allocated for the strengthening of radiotherapy facilities by law December 23, 1999, no. 488, art. 28, paragraph 12, amounting to Euro 15,493,706.97, divided among the Regions and Autonomous Provinces and organisations with the decree of the Minister of Health of December 28, 2001, 28 operations were eligible for funding for an amount of Euro 13,672,487.09 paid by the State, or 88.2% of the allocated resources.

- Public liberal professions programme: in relation to the resources allocated to the programme for public liberal professions by law of December 23, 2000, n. 88, art. 83, paragraph 3, amounting to Euro 826,143,140.92 and re-distributed with the decree of the Minister of Health of June 8, 2001, 426 interventions were eligible for funding assistance for an amount of Euro 755,865,927.07 paid by the State, equal to 91.5% of the allocated resources.

- Institutions (IRCCSs, University Polyclinics, IZSs, classified hospitals, ISS): the resources reserved for institutions amounted to Euro 856,392,845.27 and were divided and assigned to the IRCCSs, IZSs, University Polyclinics under direct management, classified hospitals and the ISS, with CIPE (Inter-ministerial Committee for Economic Planning) resolutions and decrees of the Minister of Health. Of the Euro 831,392,778.70 in allocated and assigned resources, Euro 640,647,382.72 have been approved for financing. Euro 25,000,000.00 remain to be divided and allocated, such as residual resources deriving from the reserve set aside by the CIPE 97/2008.
Quality of the system, resources and monitoring of the LEA

As at December 31, 2011 98.3% of resources committed to Agreements signed was open to tender and spending about Euro 9.041 billion was authorised.

Strong differences in the times of subscription and implementation of the Agreements persist, however, due to the different regional complexities; the total figure has to be divided into regional and annual components, as shown in Table 6.1. The same shows that 16 Regions have requested funding of 100% of the resources subscribed and 3 Regions over 80%. The two remaining Regions have requested funding of more than 50%

It should be noted, moreover, how the Autonomous Province of Bolzano has signed 100% of the resources allocated, while the remaining 7 Regions have passed the level of 70%.

The different trend in the use of resources depends not only on the experience gained in different regional contexts, but also the solidity of planning, guaranteed by the presence of a regional plan of reorganisation and upgrading of the hospital network and/or more generally the system of health services for the provision of services in the area, conditions which allowed a rapid and effective implementation of the investment programme.

### Essential bibliography

### Table 6.1. Pluriannual Programme of investments in health art. 20 law 67/1988 – Monitoring of programme acceptance – Situation at December 31, 2011

<table>
<thead>
<tr>
<th>Region</th>
<th>Resources allocated to Programme Agreements</th>
<th>Value of Programme Agreements subscribed as of 31 December 2011</th>
<th>% Resources allocated</th>
<th>Resources permitted for financing as a value of Agreements subscribed</th>
<th>% Resources permitted for financing as a value of Agreements subscribed</th>
<th>Number of interventions financed</th>
<th>Number of interventions to be financed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Piedmont</td>
<td>1,049,050,970.75</td>
<td>671,405,557.03</td>
<td>64.0%</td>
<td>669,887,453.81</td>
<td>99.8%</td>
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<td>377,645,413.72</td>
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<td>Aosta Valley</td>
<td>43,750,726.69</td>
<td>31,460,246.57</td>
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<td>12,290,480.12</td>
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<td>1,579,773,354.89</td>
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<td>1,579,772,305.58</td>
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<td>492,877,538.64</td>
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<td>Aut. Prov. of Bolzano</td>
<td>115,118,394.47</td>
<td>115,118,394.47</td>
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<td>67,688,907.21</td>
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<td>Aut. Prov. of Trent</td>
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<td>Liguria</td>
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<td>304,558,235.51</td>
<td>61.7%</td>
<td>304,558,245.49</td>
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<td>189,017,553.22</td>
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<td>Emilia Romagna</td>
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<td>739,896,214.16</td>
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<td>207,233,252.61</td>
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<td>Tuscany</td>
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<td>673,954,156.90</td>
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<td>Umbria</td>
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<td>256,567,207.21</td>
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<td>Lazio</td>
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<td>596,783,717.43</td>
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<td>100.0%</td>
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<td>105,956,719.16</td>
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<td>499,866,999.87</td>
<td>100.0%</td>
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<td>Apulia</td>
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<td>640,229,424.91</td>
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<td>339,592,975.80</td>
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<td>100.0%</td>
<td>199</td>
<td>243,879,245.02</td>
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<td><strong>Total</strong></td>
<td><strong>15,285,958,367.91</strong></td>
<td><strong>9,193,515,969.86</strong></td>
<td><strong>60.1%</strong></td>
<td><strong>9,041,338,143.63</strong></td>
<td><strong>98.3%</strong></td>
<td><strong>2,115</strong></td>
<td><strong>6,092,442,398.03</strong></td>
</tr>
</tbody>
</table>
7.1. Implementation of administrative-accounting procedures

The diversity of accounting systems in use to date [economic-patrimonial for National Health Service (Servizio sanitario nazionale, SSN) institutions and financial for Regional institutions], and the different accounting principles adopted by the Regions for the recognition of positive and negative income components have contributed to budget results that are not completely homogeneous and comparable, generating over the years many difficulties in reading the accounting data. In today’s national regulatory panorama, accounting data reliability and comparability of public health budgets are reflected on two fundamental pillars such as the harmonisation of accounting and the goal of being certifiable. The argument concerning the harmonisation of accounting finds its legal basis in the law 42/2009 on fiscal federalism, as amended by law 196/2009 for the reform of the public accounting system. Even the legislature has intervened in the matter, during the implementation of fiscal federalism, where the Title II of legislative decree (D.Lgs.) no. 118/2011 adopted specific rules of coordination of public finance aimed at ensuring, among other things:

- the implementation of economic-patrimonial accounts for the so-called centralised regional health management (Gestione Sanitaria Accentrata, GSA);
- the overcoming of the differences in the various corporate accounting practices of individual Regions;
- and their regulations concerning public accounting; greater transparency of financial flows related to the management of health through the establishment of special separate treasury accounts.

As regards the implementation of fiscal federalism, with art. 11 of the 2010-2012 Pact for Health, with which the Agreement of December 3, 2009 has been enshrined, the State, Regions and Autonomous Provinces have supported the need to initiate a process for the certification of financial statements of Healthcare Authorities and of consolidated regional statements. In particular, the possibility to make an extra evaluation of the state of administrative and accounting procedures is anticipated for the Regions, leading to certification of the quality of the financial data of the consolidated regional and local Health Authorities, working at the same time to initiate the procedures for pursuing the certification of budgets. Following the development of this preparatory activity concerning the extra evaluation, divided into four distinct phases, each Region will proceed with the preparation of plans for realisation for the certification of their budgets (PAC). These preparation plans are aimed at achieving the organisational standards and accounting procedures necessary to ensure the certification of the data and the budgets of SSN institutes, as well as the consolidated regional health budgets. Finally, in light of the specific characteristics of the health sector, formal procedures for the adoption of the first documents regarding accounting principles have been initiated, the so-called applied case-study, on the set of examples on treatment and assess-
ment of specific budget items that due to the peculiarities of the area of application were not of immediate deduction from accounting principles. Other documents relating to the applied case-study for proper valuation and accounting of all assets and liabilities in the balance sheet are currently being prepared, as well as certain income statement items specific to the health sector, not reimbursable by prevailing accounting standards, including, for example, the principles of consolidation of financial statements and the drafting of consolidated financial statements, the method of connection between the financial bookkeeping of the regional budgets and the general bookkeeping of the regional bodies and the Guidelines for the preparation of the initial balance sheet.

7.2. Standard costs of the LEA

The determination of costs and standard requirements, which must ensure a final reference to the criteria for allocation of resources for health hitherto adopted by 2013 as required by D.Lgs. no. 68/2011, will be through the use of a set of indicators to assess the levels of efficiency and appropriateness achieved in each Region, with reference to an aggregate of services provided within each of the three macro levels of health care. The values recorded in the three reference Regions (selected from among the five listed by the Ministry of Health who have distinguished themselves for quality, appropriateness and efficiency of the services provided, and on the basis of operating results recorded) will then be applied to each Region, weighted by the population age. It is necessary, however, that each Region and Health authority implements systems of management control and analytical accounting to avoid any lack of data on flows of production and management systems. It is also necessary to introduce in each Region structural manoeuvres aimed at recovering efficiency, especially where there are substantial deficits and where the process of reorganisation of the regional health services has not completed, so that there are no disadvantaged areas: the less performing Regions in the delivery of Essential Levels of Health Care (Livelli essenziali di assistenza, LEA) are the same that have accumulated health budget deficits and show more waste of resources planned ex ante than to financing of the LEA and expenses recorded in the final balance. The new methodology for the allocation of public funding for health care should be able to overcome the differences that still markedly characterise the regional health services, promoting the adoption of organisational models designed for efficiency and quality of care.

Already since last year, the Ministry has implemented a project aimed at supporting the process of establishing criteria for quality, appropriateness and efficiency through specific indicators, such as to enable the determination of the regional benchmarks on standard costs.

The project involved a thorough recognition of the national and international literature available on the subject, which led to the identification of more than 500 indicators. After overlaps were eliminated, a careful analysis of the specificity and/or significance led to the identification of about 100 indicators. A card containing source, formula, note for developing and threshold reference has been prepared for each indicator. The provisions of art. 27, paragraph 3, letter a) of D.Lgs. no. 68/2011 were taken into account for the criterion of weighting of the indicators. The project, implemented on an experimental basis, has highlighted a number of shortcomings related to:

- indicators reported in the Pact for Health 2010-2012 that are in some cases outdated and not overly specific;
- lack of valid indicators of quality and safety of care, mainly due to a lack of established and routine information;
partial and difficult ability to identify suitable thresholds of acceptability for each indicator, dictated by the specificity of objectives and not affected by the current distributions of the values of the indicators in the Italian Regions;

last but not least, difficulty to determine whether and how the economic and financial resources, directly integrated by the Regions to achieve financial balance (e.g. Emilia Romagna), have had an effect on the achievement of performance.
8 Regulation of the public/private relationship

8.1. Remuneration for services and expenditure ceilings

The relationship between public and private sectors according to legislative decree (D.Lgs.) no. 502/1992, as amended by D.Lgs. no. 299/1999, is basically regulated by accreditation of facilities and private practitioners who, once accredited, are entitled to provide performance on behalf of the National Health Service (Servizio sanitario nazionale, SSN) with fees fixed by the Regions within the maximum amounts established at national level. The number of accredited bodies is not unlimited, but linked to the performance requirements that every Region self-determines in its own territory, which also includes what is offered by public facilities. With annual contracts signed by the providers, the volume of activity and expenditure ceilings within which structures must maintain activities are then fixed, on pain of regression tariff mechanisms, which attempt to maintain the same planned total expenditure. In fact, the serious risk of collapse of the entire SSN necessarily requires that regional planning takes strict account of budgetary constraints; however, the allocation of a budget to health facilities is also a measure that gives certainty to enterprises to obtain the remuneration of performance within the available resources. That is because while the public facilities are bound to provide health services considered as necessary within the limits of their structural and organisational performance, private hospitals do not have such an unconditional obligation and so can then deny the service requested by the citizen, or supply it at a cost borne by the latter. The remuneration of private accredited facilities is made by payment of a tariff amount for each service provided; the exception to this scheme is the remuneration of care functions (e.g., emergency services) which cannot be accounted for on the basis of individual services rendered. The remuneration for productive inputs (personnel, goods and services, depreciation of structures etc.) remains the exception. The activities related to the determination of tariffs involve the State (the Ministry of Health in collaboration with the Ministry of Economy and Finance) as regards the fixing of feasible maximum rates in the national context and regional authorities as regards setting of regional tariffs (within the maximum national amounts). As part of this activity counter-arguments are always present such as associations of private producers claiming an automatic adjustment of rates based on the rate of inflation; on the other hand, it should be noted how the technologies and organisational models that underlie the delivery of services are also subject to changes that do not necessarily produce an increase in costs, but, in many cases, a decrease of the same. Within the framework of relations with the private sector, problems related to narrow financial margins available have recently been presented which make the contents of contracts more stringent and increase competition between private enterprises, encouraged by the lack of transparency and by excessive subjectivity of the selection procedures. A serious problem also emerged in relation to accredited private providers equated to public in accordance with previously set rules (e.g., law 833/1978) or subsequent D.Lgs. no. 502/1992. These are religious hospi-
Regulation of the public/private relationship

tals, classified hospitals, private Scientific Institutes for Research, Hospitalisation and Health Care (Istituti di Ricovero e Cura a Carattere Scientifico, IRCCSs) and private Polyclinics that, acting as de facto public facilities have been increasing litigation arising from a lack of regulatory coordination between the recalled D.Lgs. and the specific establishing legislation. Finally, the experience of recent years has highlighted the need to introduce an amendment to legislation that allows pathways to specific accreditation for centres of excellence with respect to facilities that provide care activities of an ordinary character, with allocation of dedicated budgets.

8.2. Accreditation

The last major action of the national legislature to govern the complex subject of accreditation is the law of December 27, 2006, no. 296, as amended, which set certain terms to overcome both for transient and provisional accreditation and to achieve final institutional accreditation of private facilities, ensuring quality services for citizens.

This process is currently being finalised. The original deadline of January 1, 2010 set by that law for the termination of provisional accreditation of private facilities was delayed in the first instance, to January 1, 2011, by the law of December 23, 2009, no. 191 and following, but only to health care facilities other than hospitals and outpatient structures and private socio-health facilities, the latter being deferred to January 1, 2013. The need to provide for a longer time period for the socio-health sector has been determined among other things by the greater differentiation of them not only with respect to the types of structures, but also in reference to the framework set for them within the health or social welfare sector.

The provisions of the legislation have certainly helped to give a strong boost to the verification processes of the quality of private facilities and pathways of final institutional accreditation, as it became clear both from the surveys conducted by the National Agency for Regional Health Services (Agenzia Nazionale per i Servizi Sanitari Regionali, AgeNaS) in 2009 and 2010, and the assessments of the Standing Committee to verify the delivery of the Essential Levels of Health Care (Livelli essenziali di assistenza, LEA).

It can therefore be noted that in 2011 all the Regions and Autonomous Provinces, with the exception of some involved in realignment plans following a health deficit, have completed the institutional accreditation of private and outpatient hospital facilities. There is no doubt also that the lack of definition of common elements of guarantee for the citizen that respect the principles of fairness in the provision of care at the national level has led to an uneven development of regional programmes and the adoption of different methods of implementation.

In this context, the need was felt, both at national and regional level, for a sharing of meaningful elements of the system, in view also of the recent European guidelines (notably the Directive 2011/24/EU of the European Parliament and of the Council of March 9, 2011 on the application of patients’ rights in cross-border healthcare) designed to promote cooperation mechanisms between Member States to ensure access to safe and quality health care in the European Union (EU) within a common and strategic policy framework.

To respond to the expressed needs and to implement the provisions of art. 7 of the Pact for Health 2010-2012, notably including a revision of the legislation on accreditation and remuneration of health services, the Ministry of Health has set up a special working Council made up of representatives of the Ministry, AgeNaS, and the Regions and Autonomous Provinces.

The working Council on the revision of the legislation on accreditation (TRAC) has de-
developed a first document (Technical Regulations), in which were identified common requirements for the accreditation of institutions that essentially take the contents of two documents prepared by an ad hoc working group, coordinated by AgeNaS and composed of representatives of the Ministry of Health and the Regions and Autonomous Provinces, during the first half of 2011:
- “Factors/criteria of quality of health care organisations to share in authorisation/accreditation systems of the Regions, as elements of guarantee of the system of care”,
- “Guidelines for the adoption of the factors/criteria of quality of health care organisations within the systems of authorisation/accreditation of the Regions and Autonomous Provinces”.

The choice was to select criteria/requirements already in the manuals of authorisation/accreditation, in applicable regional regulations already drawn up in many of the Regions/Autonomous Provinces.

The technical Body emanating from the Work Council has identified eight criteria for the Authorisation/Accreditation of public and private accredited facilities, and the arrangements for their monitoring and checking at the national level.

**Essential bibliography**

AgeNaS. Indagine sullo stato di implementazione del percorso di accreditamento delle strutture sanitarie private (ai sensi dell’art. 1, comma 796, Legge n. 296/2006), luglio 2009

AgeNaS. Indagine sullo stato di implementazione del percorso di accreditamento delle strutture sanitarie private (ai sensi dell’art. 1, comma 796, legge n. 296/2006), luglio 2010

Direttiva 2011/24/UE del Parlamento Europeo e del Consiglio del 9 marzo 2011 concernente l’applicazione dei diritti dei pazienti relativi all’assistenza sanitaria transfrontaliera. Pubblicata nella GU dell’Unione Europea 4 aprile 2011


The Realignment Plans for healthcare deficits were born with the financial law for 2005 (law December 30, 2004, n. 311, art. 1, paragraph 180) as conventions that commit the Regions to take steps to rebalance the delivery profile of the Essential Levels of Health Care (Livelli essenziali di assistenza, LEA) and, above all, measures for clearing of the deficit by 2010, in accordance with the provisions of the State-Regions Understanding of March 23, 2005. The Plans, adopted with the signing of an agreement between the Minister of Economy and Finance, the Minister of Health and the President of the Region concerned, confer on the Region the competence and the responsibility for institutional rebalancing measures and on the Ministries duties of coaching and monitoring the achievement of the objectives. The Regions that signed the Agreement in the years 2007-2008 were Abruzzo, Campania, Liguria, Lazio, Molise, Sardinia and Sicily; among them, Liguria and Sardinia have completed the Plan of Realignment: one (Liguria) in December 2010, winning a share prize in 2008 and resources from the transitional Fund of accompaniment in 2009; the other (Sardinia) in 2011, the conditions for the loss of the possibility of access to remaining resources having been verified. Subscriptions to the Agreement by the Regions of Calabria, Apulia and Piedmont followed in the years 2009-2010. The Pact for Health 2010-2012 (art. 13) and the Finance Act 2010 (art. 2 paragraphs 76-91) have brought innovation to the pre-existing regulatory framework for the “Plans of Realignment”. In particular, a “new level” of the standard size of the structural health deficit (from 7% in the previous legislation to 5%) has been defined, for which the Region with the deficit is required to submit a Plan of Realignment indicating a reaching or exceeding of this target. A “new procedure” for approval and evaluation of the “new Plans of Realignment” has also been introduced (proposed by the Regions) in which the plans will be preventively subjected to test by the State-Regions Conference technical monitoring Structure (a support organisation of the State-Regions Conference) and then approved by the Council of Ministers, becoming immediately effective and enforceable for the Region. In the reference year (2011), no “new Plans of Realignment” have been approved. The financial law for the year 2010 (and subsequent modifications) made new laws that may also apply to the “old Plans of Realignment” (those started in the years 2007, 2009 and 2010), regarding among other aspects: ■ automatic blocking of turnover of staff of the Regional Health Service; ■ the prohibition of non-compulsory expenditure; ■ the nullity of acts and contracts made in violation of the block on turn-over and the ban on non-compulsory expenditure; ■ the recognition of regional legislative measures of “obstacle” to completion of the implementation of Plans of Realignment in order to promote the removal and/or modification of these laws in conflict by the Regional Council or the Council of Ministers; ■ the increase in regional rates on productive activities (to the extent of 0.15%) and of additional income tax (IRPEF) to the extent of 0.30%, in addition to the applicable rates, in the event of failure to achieve the objectives of the Plans of Realignment;
in the event of receivership in the implementation of the Plan of Realignment, the suspension of non-obligatory revenue transfers.

The Regions involved in the “old Plans of Realignment” stand out among those who continued the original Plan of Realignment, signed in 2007 and completed in 2009, choosing to complete their implementation through an Operational Programme (Programma Operativo, PO) [Lazio, Sicily, Abruzzo, Molise and Campania], and those that are still implementing the Plan of Realignment signed in 2009 (Calabria) and 2010 (Piedmont and Apulia).

Among the Regions that presented the PO differences in the interpretation and use of instruments referred to in the financial law of 2010 (art. 2, paragraph 88 of law 191/2009) are noticed.

Some Regions in fact, such as Sicily, have taken the opportunity to complete the work that had been partially implemented while the Plan was pending. Others however, such as Lazio and Molise, presented work on all the areas previously covered by the Plan of Realignment through their PO (and not implemented).

Of 8 Regions with Plans of Realignment, five (Lazio, Calabria, Abruzzo, Molise and Campania) were “put into administration” as institutional bodies have not reached their goals, on time and in the quantity planned. The instrument of “putting the regional bodies into administration”, as set by current legislation, has not been shown, however (including in particular the Molise), as effective in many cases to overcome the problems encountered during implementation of programmes.

In Table 9.1 some of the information mentioned in general is shown in synthesis.

In 2011, the National Agency for Regional Health Services (Agenzia Nazionale per i Servizi Sanitari Regionali, AgeNaS) called to assist in some Regions with their Plan of Realignment, in collaboration with the activities carried out by the Ministry of Health with the National System for the Monitoring and Control of Public Healthcare (Sistema Nazionale di Verifica e Controllo sull’Assistenza Sanitaria, SIVEAS), prepared a technical paper with a proposal of reorganisation of the hospital network (including a proposal for a redefinition of the complex structures at authority level), of the network of emergency-urgency care and the territorial network, as a contribution to the technical and operational restructuring of health services, to be redefined on the basis of different regional contexts and needs.

Among the macro-areas of intervention provided for in the plans, those on which the Regions were found to be mostly concentrated in were the care networks, management of personnel, institutional accreditation, relations with private providers, and pharmaceutical care.

With regard to hospital networks, the interventions were targeted primarily at closure or conversion of hospital clinics of an inadequate size to ensure the safety parameters prescribed for patients (in terms of clinical risk), to effectiveness, efficiency, as well as

<table>
<thead>
<tr>
<th>Region</th>
<th>Plan of Realignment (PDR)</th>
<th>Into administration</th>
<th>Operational Programme 2011-2012</th>
<th>Deficit 2010</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abruzzo</td>
<td>From March 6, 2007</td>
<td>From September 11, 2008</td>
<td>From July 6, 2011</td>
<td>Euro 51.6 million</td>
</tr>
<tr>
<td>Calabria</td>
<td>From December 17, 2009</td>
<td>From July 30, 2010</td>
<td></td>
<td>Euro –13.7 million</td>
</tr>
<tr>
<td>Campania</td>
<td>From July 13, 2007</td>
<td>From July 28, 2009</td>
<td>From June 20, 2011</td>
<td>Euro –72.2 million</td>
</tr>
<tr>
<td>Lazio</td>
<td>From February 28, 2007</td>
<td>From July 11, 2008</td>
<td>From December 31, 2010</td>
<td>Euro 159.3 million</td>
</tr>
<tr>
<td>Molise</td>
<td>From March 27, 2007</td>
<td>From July 28, 2009</td>
<td>From November 23, 2010</td>
<td>Euro –27.1 million</td>
</tr>
<tr>
<td>Piedmont</td>
<td>From November 29, 2010</td>
<td></td>
<td>Euro 0.6 million</td>
<td></td>
</tr>
<tr>
<td>Apulia</td>
<td>From November 29, 2010</td>
<td></td>
<td>Euro 2.7 million</td>
<td></td>
</tr>
<tr>
<td>Sicily</td>
<td>From July 31, 2007</td>
<td>From December 30, 2010</td>
<td>Euro 282.4 million</td>
<td></td>
</tr>
</tbody>
</table>
Realignment Plans and monitoring of their progress

correspondence with the actual needs of the regional population. These interventions, in some cases affected by decisions of the administrative courts that determined the maintenance of certain small structures (e.g. in Abruzzo, Molise and Lazio), translated into a differentiated implementation in the various Regions. In some, such as Puglia, the administration took steps to convert the majority of clinics indicated by the Plan, while in other cases (Piedmont, Molise), there have been various re-planning interventions that have not yet led to a redefinition of the network. In the network of emergency-urgence care delays have occurred in most Regions (Abruzzo, Sicily, Piedmont), in some of which are underway efforts to adapt the network of birth centres to the levels provided for by national guidelines. Further actions have affected the simple Accident and Emergency points and areas of deprivation, the Points of first response and the reorganisation of the service for continuity of care, including through integration with other local services. This action represents a focal point for both the rationalisation of the service and the creation of an interface between the network of territorial emergency care and the network of primary care.

The implementation of a regional network, which for the most part should be the result of interventions of conversion of hospital facilities at this stage, has seen a delay in realisation in most of the Regions monitored. As positive experiences, for example, the realisation of Single Access Points (Punti Unici di Accesso, PUAs) in the Lazio Region or local structures such as the PTA (Territorial Care Clinics) in Abruzzo, Molise and Sicily can be reported. Problems remain, however, in residential and home care for the elderly and disabled which characterises some Regions, such as Sicily and Molise. In the field of palliative care, there has been a difficulty in building an integrated organisational hospital-territory model, in which the treatment of pain is guaranteed at the different organisational levels.

In all the Regions, in varying degrees, either a total (in accordance with art. 2, paragraph 76 of law 191/2009) or partial (as a target of containment of personnel costs, provided for in the respective Plans of Realignment and POs) block has been applied on staff turnover of the Regional Health service. In many cases, however, the Regions have shown deficiencies in the governance of this sector, resulting in non-compliance also with related economic objectives.

In the area of “relations with accredited private providers as well as related institutional accreditation procedures”, the capacity of government demonstrated by the monitored Regions was very poor. The procedures for institutional accreditation in virtually all Regions in a Plan of Realignment have not been completed within the terms and according to the indications required by national legislation. The management of relationships with private providers (which in some regional contexts, such as Lazio, Molise and Campania and Sicily, provide a significant portion of the offer) affects the ability of the Administration to identify and respond to regional needs, for the correct distribution of resources, as well as the early definition of the contractual agreements provided for by legislative decree (D.Lgs.) no. 502/1992. In this context, an ample litigation also occurs, sponsored by private providers, which makes management of the sector even more complex and burdensome.

All the Regions have adopted initiatives to reduce costs of pharmaceutical spending, with very different results. Among the main changes witnessed have been the adoption of new therapeutic formularies, the centralisation of purchasing, distribution “in the name and on behalf of”, as well as the regulation of medicine administration in the territorial facilities. With regard to the safety of food, attention has been focused on the preparation of the Regional Integrated Plan of Controls on food safety. In this context, there has been a positive trend towards the full implementation of the regulations of the so-called hygiene package in the Regions of Campania, Calabria and Molise (EC Regulations No. 178/2002, 852/2004, 853/2004, 854/2004, 882/2004 and 183/2005 and Directive 2004/41/EC), the package which redesigned the system of Community legislation on food

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safety introducing an integrated approach with the allocation of responsibility to all players in the food chain from primary agricultural production to final delivery to the consumer. Regarding the implementation of D.Lgs. no. 194/2008, there was, however, an increase in the difficulty of the Regions in the enforcement of charges for official controls in relation to regulatory interventions which occurred (art. 48, paragraph 5 of law 96/2010), intended to exempt agricultural entrepreneurs from the payment of appointed fees for all the activities referred to in art. 2135 of the Civil Code and which are also not included in primary production.

The planning of controls for food safety still seems weak in the additives sector, that of materials in contact with food, as well as for genetically modified organisms (organismi modificati geneticamente, OGMs) and there were difficulties in the control of residues of plant protection products, residues of medicines and of contaminants in foodstuffs.

The regional documentation highlights, again, problems related to testing laboratories and sampling plans on foods of plant origin as well as for the control of the sale of foodstuffs in markets and public areas. It is also clear that there are major problems with respect to the control of water for human consumption.

Moreover, even in the application of EC Regulation 852/2004 there are still issues related to the registration of food businesses. From the financial point of view, in the face of initial resistance in reducing debt, which led to subsequent amendments to the legislation, there was a positive result in a slowdown of rising costs and a reduction in deficits. To testify to this are the data reported by the Court of Auditors’ Report on the financial management of the Regions for the years 2009-2010, released in August 2011. The Court has pointed out that the programmes of structural reorganisation have shown, on the whole, a positive trend compared to the impact on the efficiency and quality of the system.

**Essential bibliography**

- AgeNaS. Documento di proposta di riorganizzazione della rete. Monitor, n. 27/2011
The National Health Council is a technical advisory body of the Minister of Health and performs the following functions:

- examines facts about public health, at the request of the Minister of Health;
- proposes the study of problems related to hygiene and health;
- proposes scientific investigations and surveys on events of major interest in the field of health and hygiene;
- proposes the formulation of health policies and schemes of measures for the protection of public health to the health administration; and
- proposes the formulation of construction and organisational standards and requirements for the construction of hospitals, nursing homes and other sanitary works by public administrations.

The National Health Council expresses binding opinions on:

- the regulations prepared by any central administration which affect public health;
- the international conventions relating to the above matter;
- the lists of unhealthy works and harmful dyes;
- the measures of coordination and instructions required for the protection of public health to be adopted by the Ministry of Health, pursuant to paragraphs 2 and 3 of art. 1 of law March 13, 1958, n. 296;
- the determination of hazardous, arduous or unhealthy work involving women and children and the hygiene of work;
- applications for certificates of industrial inventions and discoveries concerning edible varieties of any kind;
- changes to be introduced in the list of drugs;
- the refusal and revocation of registration of medicinal products;
- direct services to prevent and eliminate the damage caused by radioactive emanations and atmospheric contaminations in general, which are not the responsibility of the Local Health Units.

The Council is composed of fifty members who are experts in various fields of medicine and surgery and public health, appointed by the Minister of Health, and twenty-five members of the law profession.

The Council has an Executive Committee, a General Assembly and five Sections dealing with various issues of a health and social nature, in particular: health planning, health professions and training of health personnel, blood and blood products, organ transplants, health and hygiene protection of elements of pollution, prevention of infectious and contagious diseases, preventive nutrition, food safety, animal health and welfare, veterinary prophylaxis and infectious and contagious diseases, animal medicines and feed, medicines for human use, and medical devices.

During 2011, the Health Council has expressed itself, as required by its institutional function, on a wide range of subjects and areas related to the health of the country constantly keeping the two sets of activities that are its own, namely that of an advisory nature and that of a proactive character. This Chapter presents the main topics covered during the year.

Infectious diseases. With regard to the case of tuberculosis infection at the Policlinico Gemelli hospital in Rome, the Lazio Regional Administrative Court (TAR) ruled that all children born in the maternity ward of the hospital during the presence of the source of contagion in the same department should be tested for the finding of tuberculo-
sis, working backward towards the absence of findings of positivity for the same test. The National Health Council, called upon to comment on the most appropriate test to use for the above-mentioned retrospective study, defined the screening criteria indicating the tests and operating methods to be used.

As in previous years, the Council was asked to consider the Circular containing recommendations for the prevention of influenza and the active offer by the National Health Service (Servizio sanitario nazionale, SSN) of influenza vaccination for people at higher risk of complications following influenza infection either because of their age or because of the presence of co-morbidities, as well as for prevention by vaccine for people of all ages employed in public services of primary public interest. The Council, in line with the World Health Organization (WHO), considers as the primary goal of vaccination the prevention of serious and complicated influenza and reducing premature mortality in groups at increased risk of severe disease, in view of the fact that a vaccination strategy based on these assumptions has a favourable cost-benefit and cost-effectiveness ratio.

Health and hygiene activities of prevention and protection. Following the classification by the International Agency for Research on Cancer (IARC) of radiofrequency electromagnetic fields as “possibly carcinogenic to humans”, the National Health Council expressed itself on the desirability of any initiatives resulting from this action. Noting that at the moment no causal relationship between exposure to radiofrequencies and cancer has been shown, and that scientific knowledge does not allow, however, for the complete ruling out of the existence of such a causal relationship in relation to heavy use of a mobile phone, the Council has decided:

- to promote research into the possible health effects resulting from exposure to radiofrequency electromagnetic fields associated with mobile phone use in children and adolescents;
- to produce studies that go beyond the methodological problems associated with the assessment of exposure to radiofrequency electromagnetic fields, with particular reference to the correct assessment of previous use of the mobile phone.

Pending the availability of this information from the scientific community, the Council suggested the launch of an information campaign that:

- outlines the state of the art on the basis of available scientific information;
- promotes the adoption of simple individual behaviours, such as the use of “hands-free” systems for mobile phones (headsets and hands-free systems), making only necessary calls, the use of text messages, as it can help to limit exposure to the radiofrequency electromagnetic fields emitted from mobile phones;
- states that the possible adoption of such measures is of an entirely prudent character, because, given the uncertainty about the possible effects of exposure to radiofrequencies emitted by mobile phones there remains a doubt about the health benefits resulting from the reduction in the use the phone itself;
- emphasises, however, the opportunity for children to be educated and sensitised to a not indiscriminate use of the phone and which should not be proposed to them as a common object, but limited instead to situations of need.

In addition to considerations on the potential health effects of radiofrequencies, it was also decided to point out that the suggestion of WHO to avoid the use of mobile phones while driving vehicles has a clear preventive meaning in terms of public health benefits. The decrease in attention caused by the use of the mobile phone, in fact, increases the risk of motor vehicle accidents significantly, even where “hands-free” devices are in use. With regard to the assessment of the requirements for the issuance/renewal of a driving
licence, the Council evaluated the procedures practiced directly by single doctors to discriminate between subjects with normal vision and those with reduced vision, worthy of an in-depth evaluation by a specialist. This because to the large number of annual renewals and releases of driving licenses – roughly estimated at about 5 million people subject to a doctor visit – which makes it difficult in practice to perform specialist eye care investigations in a timely fashion, without considering the futility of further additional costs in terms of money and time for specialised in-depth investigations for persons not affected by significant visual defects.

The Council expressed a view also on possible measures of prevention and control useful to protect from exposure to noise sources exceeding threshold limits provided by law, an area that is often ignored and disregarded. In view of the intensification in the last years of attendance at nightclubs and discotheques, it was decided to avail of the opportunity to identify appropriate measures to prevent damage to health of an auditory and non-auditory type, deriving from exposure to sources of loud noise by users and workers in the sector, recommending information campaigns on both the damage and the risks resulting from prolonged exposure to noise. Finally, the Council expressed a view on the appropriateness of measures to protect the health of consumers of electronic cigarettes with nicotine and especially of children. The Council recommended the adoption of measures similar to those for the control of cigarette smoke, which include a ban on sales to minors under 16 years of age, taking into account that at present are lacking: knowledge relative to most of the electronic systems concerned about the health effects of organic compounds and products used in them for creating vapours; studies demonstrating the actual and safety efficacy of these devices in promoting smoking cessation; evidence that excludes the occurrence of possible effects because of their use which on the one hand induce the maintenance of nicotine dependence and on the other promote the initiation and transition to cigarette smoking; a specific regulation.

Foodstuffs. The work of the National Health Council has been intense in relation to drinking water and the recognition of mineral and thermal waters. The annual verification of the maintenance of the chemical-physical and microbiological characteristics of all mineral waters recognised in Italy was carried out. The adoption of indications proposed by the Council by a large number of laboratories as to the manner of reporting has made it easier in 2011 to read and examine the data contributing significantly to a speeding-up in overall verification times compared to previous years.

Requests for waivers of certain parameters for water from geographically limited areas intended for drinking have also been examined. In particular, the Council, in the light of the scientific literature and the results of the experimental study conducted by the National Institute for Health (Istituto superiore di sanità, ISS), amended the parameter value of vanadium in water intended for human consumption in line with the latest evidence. The Council has operated under the principle of precaution with regard to materials in contact with foodstuffs that can introduce elements that can alter the organoleptic characteristics and may cause potential health hazards.

Appropriateness of care: proposals of reorganisation.

- “Criteria for structural, technological and clinical appropriateness in prevention, diagnosis and treatment of andrological diseases”. As part of its proposals, the Council considered it necessary to investigate the issue of the organisation of the functional services of andrology, the branch of medicine with a cross-specialist field of activity which is important in all stages of life and is focused on diagnosis and treatment of diseases and malformations of the male reproductive organs that may affect physical development, sexual activity and fertility. The document “Criteria for structural, technological and clinical appropriateness in the prevention, diagnosis and treatment of andrological diseases” was approved, whose objectives are:
- to provide operators and decision-makers with up-to-date knowledge on the main andrological diseases and disorders of sexuality, outlining specific criteria for clinical, structural, technological and operational appropriateness for the prevention, diagnosis and treatment in this area;
- to provide the necessary elements for the definition of appropriate standards for the functional organisation of the services and facilities dedicated to andrology;
- to define the theoretical basis and the most suitable channels, so that high quality standards are guaranteed in this area confirming the importance of the territory as a place of needs analysis and of integration of the various levels of care;
- to investigate major issues of relevance for clinical andrology with a method based on epidemiological evidence and attentive to the prevention and detection of risk factors, proceed in a targeted manner to the diagnoses and cure of various diseases of the male reproductive system;
- to give instructions for the definition of clinical-diagnostic-therapeutic pathways of diseases such as male infertility, hypogonadism, testicular cancer, rare genetic disorders, sexual problems;
- to provide elements which allow for the establishing of uniform criteria for defining operating models, based on scientific evidence, describing the common requirements of the process.

**“Criteria for structural, technological and clinical appropriateness of the Centres of Interventional Radiology”**. Another issue dealt with in the proposals was the organisation of the functional services of Interventional Radiology. The document “Criteria for clinical, structural and technological appropriateness for Centres of Interventional Radiology” was approved, whose objectives are:

- to provide the necessary elements for the definition of appropriate standards for the functional organisation of the services and facilities dedicated to Interventional Radiology (minimum standards for clinical spaces, time spent on clinical functions, the need for equipment, technical support services and programmes for continuous quality improvement);
- to define the theoretical basis and the most suitable channels so that Interventional Radiology ensures high quality standards;
- to provide useful elements for the definition of a model aimed at standardising the operating modes on the basis of scientific evidence at the national level, describing the common requirements of the process;
- to indicate possible solutions for improvement of the organisational forms already existing.

The documents were the subject of specific issues of the “the Ministry of Health Journal”, which represent an important project – a consistent objective of a bi-monthly publication covering the institutional guidelines on the most important issues in health care. They assume an important role of guidance for planning of care in the various sectors covered. The full electronic version of the Journal can be found on the websites http://www.salute.gov.it/ and www.quadernidellasalute.it/ and is available free of charge through applications for mobile devices.

**Proposals in the pipeline.** In 2011, the discussion began of two topics of major significance in terms of social and health care. The first concerns the “Criteria for clinical, technological and structural appropriateness in the care of the complex chronic patient”. The non-communicable chronic diseases (NCD in the WHO definition), recently defined as “long-term disease entities of generally slow progression”, are recognized as the principal public health problem partly due to the prolongation of life and their impact on the sustainability of health systems management. International bodies have clearly identified a more deep-rooted understanding of the complexity level of the specific characteristic of the individual patient as a top priority for the prevention and control of NCDs. The Council, considering as essential that our country defines an ad-
made by the Council led to the conclusion that, to date, CCSVI may not be recognised as a nosological entity and that its epidemiological link with multiple sclerosis has not been shown. Therefore, the intervention of vascular correction cannot be indicated in patients suffering from this disease, and a clear-cut clinical indication is required for the provision of measures to diagnose, monitor and correct abnormalities of the venous vascular apparatus due to pathological conditions that can certainly be linked to these abnormalities. The Council considered it necessary that any corrective procedures for venous disease in patients with multiple sclerosis are carried out exclusively in the context of randomised controlled clinical trials and approved by ethics Committees. The Council also considered appropriate – making a pronouncement valid for any new therapy that is being proposed without yet having put in place randomised controlled clinical trials approved by ethics Committees – that every purely speculative and economic intention must be countered and that everything possible should be done to protect patients from easy enthusiasms, from economic speculations and risks associated with the treatment itself, remembering that biomedical research and clinical practice should be guided by the binding principle of inviolability of the psycho-physical integrity of the person.

**Safety and appropriate use of technology and substances with health impact.** In this regard, opinions have been expressed by the National Health Council on medical technologies with diagnostic features, such as Group B Magnetic Resonance equipment at 3 Tesla, and treatment features, such as equipment for hadron therapy. Hadron therapy involves the use of subatomic particles (mostly protons and ions) in the treatment of neoplastic diseases and exploitation of the special physical and radiobiological properties of the same. The rationale for the use of hadron resides mainly in the particular spatial selectivity of deposition of the dose,
which allows a highly conformal radiotherapy to be obtained with relatively simple methods and with a full dose to healthy tissue significantly lower than that delivered even with the most advanced techniques in conventional radiotherapy.

The Council considered that the treatment for “compassionate use” with protons can be authorised for the same conditions (cordomi and chondrosarcomas of the skull base, cordomi and chondrosarcomas of the spine, intracranial meningiomas), for which the treatment has been shown, from the scientific viewpoint, to be more advantageous than other conventional radiotherapy.

Of particular importance, also for the interest aroused in the public by the subject, was the opinion of the Council on the reclassification of anorectic substances (Amfepramone-diethylpropion, Phendimetrazine, Phentermine and Manzidolo) in Table I of narcotic and psychotropic substances by decree of the President of the Republic on October 9, 1990, n. 309, entitled: “Consolidated law on the regulation of narcotic drugs and psychotropic substances, prevention, treatment and rehabilitation of states of drug dependency”, thus excluding the possibility of use of the above substances in medicinal products or magistral preparations. The Council also considered various requests for inclusion of a number of psychoactive substances with pharmacological action directly on the central nervous system in the above table, contained in products marketed through the Internet, as scents for rooms, bath salts, fertilisers for bonsai.

Conclusions. In a context such as the present, characterised on the one hand by an increasing offer of tools and actions to protect health and on the other by the increasingly scarce availability of resources compared to the perceived and/or expressed needs, the National Health Council – by virtue of compliance with the central role of the person in the choice of both preventive and therapeutic interventions, of autonomy of judgment and the scientific rigour that characterises its actions – has been an irreplaceable point of reference for the performance of the missions entrusted to the Ministry of Health.