

1.6. *Safety of products available for free sale*

The safety of products available for free sale is guaranteed, from a regulatory standpoint, by Directive 2001/95/EC, assimilated in Italy by Legislative Decree 172/2004 and subsequently incorporated into Legislative Decree 206/2005, also known as the “Consumption Code”, which harmonises and reorganises the regulations concerning purchase and consumption processes, to guarantee a high level of consumer and user protection. This regulation established an EU system for the rapid exchange of information (RAPEX) between Member States and the European Commission, aimed at avoiding consumers being supplied with products that constitute a serious risk to their health and safety, by facilitating the monitoring of efficacy and market surveillance activities and other control activities in the Member States and to provide consumers with adequate information, by means of a detailed description of these products on a freely accessible website.

The vigilance work that started in 2007 has undergone significant increases in recent years, as indicated by the number of research orders sent to the *Carabinieri*’s NAS Division and the increase in the number of reports submitted to the European Commission.

Following European reports (top-down system), concerning the risk in question (chemical and microbiological risk) in Italy for 2009 the NAS Division was issued 175 different research orders, whereas research in 2010 concerned 309 different articles.

To test these articles, the National Institute for Health (ISS) performed 108 analyses in 2009 and 109 in 2010, in addition to the further 153 analyses performed to identify dimethyl fumarate (DMF), a biocide not authorised in Europe.

As regards the bottom-up system (from peripheral reports to the article’s evaluation and market withdrawal), in 2009 Italy filed 33 reports, of which 28 were submitted by the Ministry of Health. In 2010, this figure rose to 87, of which some 86 were generated by the Ministry of Health.

Another important issue that came to light in 2009 and 2010 concerns the need to perform microbiological checks on soap bubbles imported from China. In July 2009, in a sample of 242 boxes of children’s soap bubbles, the ISS detected a number of colonies similar to those present in very to moderately contaminated water (exceeding 10^4 CFU/ml). The prevalent species was found to be *Pasteurella multocida*, a microorganism that causes zoonosis and is present amongst livestock and wild animals. The Italian Ministry of Health was the first authority to report this issue to the other EU countries and imposed stringent controls on the sale of these toys.

In 2010, in an effort to step up its monitoring on the possible use of toxic substances in clothing, the Ministry of Health signed a partnership agreement with Piedmont Regional Authority for the performance of a “Cognitive investigation on the presence of hazardous substances in textile, leather and footwear products”, making it possible, through the cooperation of the Associazione Tessile e Salute [Textiles & Health Association] to perform the necessary chemical analyses on textile materials reported using the RAPEX system or believed to be harmful to health.

1.7. *Reduction of risk factors*

According to the most recent data published by the WHO, cardiovascular and respiratory diseases, cancer and diabetes are responsible for the majority of deaths, suffering and expenditure on health worldwide. These are chronic diseases that share a number of risk factors (smoking, alcohol abuse and incorrect diet, overweightness and/or obesity and sedentary lifestyle), which are linked, to a great degree to modifiable unwholesome individual behaviours that are affected by the economic, social and environmental contexts in which a person lives and works.

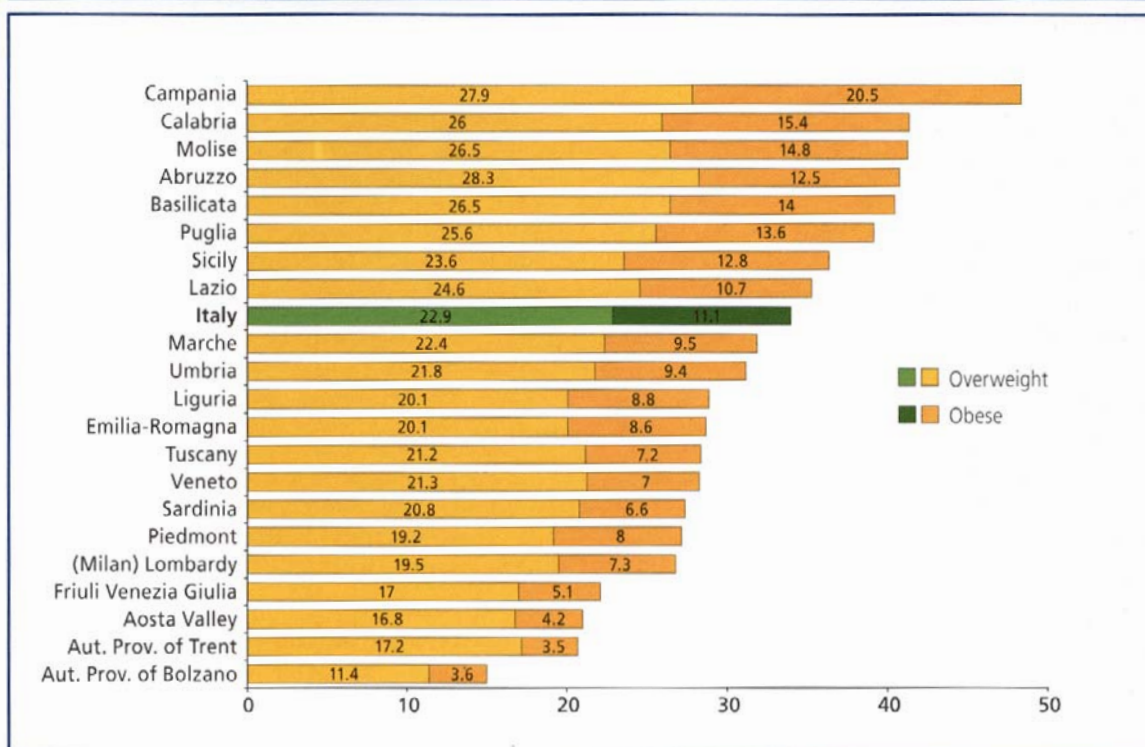
The percentage of the population that is overweight or obese increases with age: from 19% amongst youngsters aged 18-24 years to over 60% amongst 55 to 74 year-olds, before dropping slightly amongst the

elderly (55.9% amongst the over-75s). Overweightness is more common amongst males (45.2% versus 27.75% of women). For obesity, the differences are smaller (11.3% in men and 9.3% in women). The PASSI programme conducted in 2009 confirms that excess body weight is associated in a statistically significant way to age, sex, level of schooling and perceived economic situation. In order to fight overweightness and obesity it is essential to back actions aimed at favouring wholesome behaviour from birth, through the promotion of breastfeeding, correct information on nutrition in childhood, the promotion of the Mediterranean diet, nutritional education as a permanent course for school-age children and the qualification of collective meal services. The new National Prevention Plan 2010-2012, in continuity with its predecessor, indicates various lines of action to be implemented on a regional level, as part of an integrated approach to reducing the risk factors related to chronic diseases, including the prevention of obesity. According to the

intersectorial approach advocated by the “*Guadagnare Salute*” [Gaining Health] Programme, a number of structured activities have been implemented, with a view to promoting wholesome behaviour in partnership also with schools, which, together with the family, are the place in which each individual is aided and guided in his/her development and growth as a person and as a citizen. A range of activities have been shared and developed with schools, from operator awareness, using the “Research – Action” method through the “*Scuola e Salute*” [School and Health] Project to the trial of educational initiatives on certain key topics (diet and exercise, smoking and addiction, oral hygiene). A partnership with the Department of Youth Policy has made it possible to perform actions for the prevention of eating disorders and to promote exercise in all ages of life.

As far as alcohol consumption is concerned, the most recent data concerning our country confirms the transformation that has taken place in Italy over the past

Figure. Overweightness and obesity by Region, children aged 8-9 years in 3rd year of primary school.



Source: ISS: Report “OKkio alla SALUTE “2010” – 2010.

decade, which has seen a gradual shift by the population, and especially youngsters and young adults, away from the traditional Mediterranean patterns of consumption, based on a moderate, daily consumption of alcohol, above all wine. Drinking patterns imported from the north of Europe, such as binge drinking, in which a high number of units of alcohol (5-6 or more) are consumed over a short period of time, are now commonplace in Italy and in 2009 were practiced by 12.4% of men and 3.1% of women. Following the approval of Law 125 of 30 March 2001 - "Framework law on alcohol and alcohol-related issues" Regional and Autonomous Provincial Authorities have dedicated ever-greater attention to alcohol as a risk factor for health and safety. All Regional Authorities now consider the prevention of alcohol-related damage to be one of their priority areas of action as regards programming and a dedicated inter-regional technical subgroup on alcohol-related issues has been established. To favour the implementation of the National Alcohol and Health Plan adopted in 2007, a number of strategic national projects to support and guide regional alcohol policy have been promoted and implemented. Of particular importance in this area is the diffusion of methods for the early identification of abuse and rapid intervention on a primary care level and in the workplace.

To reduce the prevalence of young smokers, the Ministry of Health/CCM has promoted a number of projects, identified as "good practices" that develop the prevention of smoking from infant school through to secondary school.

The nationwide "*Mamme libere dal fumo*" [A non-smoking mum] programme aimed at helping female smokers, and particularly pregnant and nursing mothers to give up smoking, has involved the training of selected, professional midwives on how to provide non-smoking counselling and advice.

As regards the reduction of road accidents, the most significant areas of action involved the new road safety laws that intro-

duced a number of bans and obligations concerning alcohol levels and the growing commitment of the Regional Authorities in the prevention area is tangible particularly as regards driving and recreational activities amongst young people, with an increasingly close involvement of the school world in initiatives addressing students, teachers and parents alike.

1.8. The prevention of infectious diseases

Infectious diseases still represent a public health priority, on account of the ease with which they can be contracted and spread.

In Italy, infectious disease surveillance is based on the Mandatory Reporting System that, pursuant to Ministerial Decree of 15 December 1990 - "Infectious and Transmissible Diseases Information System", involves the mandatory reporting by doctors of cases of the diseases listed in the same decree. Recently-introduced European regulations establish a new definition of cases for the purposes reporting of transmissible disease to the EU surveillance network and the obligation to collect, analyse, validate and submit data, on a European and international level, concerning the infectious diseases arising in the individual countries. In Italy, the new definition of "case" must be assimilated as soon as possible and the new infectious diseases reporting system must be made systematically accessible in all Regions of the country. The Ministry has organised a project, currently in its pilot phase, involving the creation of a web-based platform to support, in a single solution, the routine reporting system, special surveillance systems and the zoonosis surveillance system, to assimilate European directives on the construction of an EU surveillance network aimed at the epidemiological control of transmissible diseases and for the establishment of a rapid alarm system, by means of which information concerning events requiring urgent action can be exchanged in order to protect public health.

It would also be appropriate to place new emphasis on the surveillance concerning the incidence of acute flaccid paralysis and

polio virus infections. Although Italy, like the rest of the WHO's European Region, was declared polio-free in 2002, the risk of re-introduction is nevertheless still present. The objectives concerning nationwide elimination of measles and a reduction and maintenance of the incidence of congenital rubella syndrome to values of less than 1 case per 100,000 live births by 2007, indicated in the National Plan for the Elimination of Measles and Congenital Rubella Syndrome (PNEMoRc), have yet to be achieved and outbreaks of measles and congenital rubella syndrome continue to occur. A strong, joint commitment is required to reach an Intent on the new National Vaccination Plan, making it possible to overcome the differences in the supply of vaccination across the country and to fully implement the new PNEMoRc, which requires approval through issuance of a State – Regional Authority Intent.

Lastly, in the light of the recent requests received from the EU, zoonosis surveillance and control activities must be implemented and extended to include diseases that are transmitted through foods.

1.9. Cancer prevention

Cigarette smoking is the main risk factor for cancer in humans. In Italy it is estimated that cigarette smoke is responsible for between 70,000 and 83,000 deaths a year. Tobacco is known or thought to cause at least 25 different illnesses, not all of them cancers. Smoking in males is responsible for 91% of all lung cancer deaths and 55% of cases for women, amounting to a total of approximately 30,000 deaths a year. Anti-smoking initiatives are aimed at preventing smoking or delaying the age at which people start smoking, helping individuals give up smoking and eliminating or reducing exposure to passive smoking.

It has been estimated that approximately 30% of all forms of cancer in industrialised countries can be attributed to dietary factors, putting the diet at second place behind smoking amongst the causes of avoidable cancer. The consumption of alcohol, particularly when combined with tobacco smok-

ing, is an important risk factor for the onset of upper airway, intestinal, liver and breast cancer. According to ISTAT data for 2009, the individuals exposed to a consistent risk of alcohol-related diseases represented 25% of the male population and 7.3% of the female population over the age of 11.

Epidemiological and biological studies have definitively confirmed that infectious agents represent some of the most important and specific aetiopathogenetic factors for malignant tumours, causing 15-20% of these conditions (26% in developing countries; 8% in industrialised countries). The public health initiatives undertaken to prevent the onset of infection-induced tumours include a vaccination campaign for human papilloma virus (HPV), which causes cervical cancer, amongst twelve year-old girls.

Environmental factors to be considered include air, soil and food chain pollution, electromagnetic and radiofrequency fields, asbestos, indoor pollution, exposure to chemical substances, UV radiation and occupational exposure to carcinogens.

The main initiatives undertaken to prevent and reduce cancer were assimilated, during 2010, into the National Prevention Plan 2010-2012 and in the document entitled "Guidance for the reduction of the cancer load" (known as the National Oncology Plan).

Secondary cancer prevention (screening) aimed at reducing cause-specific mortality has been included in the essential levels of care since 2001, for breast, cervical and colorectal cancer. In 2008, the "First Report on the implementation of the Council Recommendation on cancer screening" highlighted a positive general increase in these activities in Italy and stressed the importance of their continued implementation. Programming in Italy concerned two levels: the inclusion of screening programmes in the National Prevention Plan 2005-2007 and support provided to regional facilities through the funding envisaged by Law 138/2004 and Law 286/2006. This dual level of planning was once again adopted in the new NPP for 2010-2012.

The data concerning these activities shows that our country is currently significantly extending its screening programmes with (in 2009): for breast cancer: 2,464,701 individuals invited and 1,370,272 screened; for cervical cancer: 3,547,457 invited and 1,393,243 screened and, for colorectal cancer: 2,975,278 invited and 1,423,063 screened.

However, the targets have not yet been met completely.

The experience of screening programmes and the indications of European and Italian screening (NPP 2010-2012) indicate the importance of undertaking, for secondary cancer prevention, a unitary and united approach inspired by evidence-based medicine and appropriateness and to conceive secondary prevention initiatives as “pathways” (care profiles) provided to citizens within the various organisational facilities in the community, aimed at efficacious practices, by assuring technological innovation and guaranteeing research activity and development promoted on a central level (through the CCM, the cancer network, network of scientific institutions for research, hospitalisation and healthcare (IRCCS), Universities, etc.) to provide evidence on the efficacy of new technologies. The breast cancer data available in literature has proven the efficacy (a reduction in mortality of up to 30%) of secondary prevention by mammogram (every 12-18 months) even in women aged 40-49 years.

1.10. Cardiovascular prevention

Epidemiological studies have provided plentiful evidence that cardiovascular risk is reversible and that a reduction in the levels of risk factors leads to a reduction in the number and severity of events. Infarction and stroke share risk factors that can be modified through actions that promote correct lifestyles and, when this is not adequate, through appropriate pharmacological therapy.

In Italy, the mortality rates for coronary heart disease have followed a downward trend since the 1970s, maintaining levels far lower than those observed in Northern

Europe and the United States. Since 1980, the age-adjusted coronary death rates have dropped from 267.1 to 141.3 per 100,000 in men and from 161.3 to 78.8 in women aged 25-84 years, producing 42,930 fewer coronary deaths in 2000 (24,955 in men, 17,975 in women). Approximately 40% of this drop was due to specific treatments, particularly for decompensated heart failure (14%) and secondary prevention treatment following myocardial infarction or a revascularisation procedure (6%). On the other hand, about 55% is due to changes in the main cardiovascular risk factors in the Italian population, primarily the drop in arterial pressure (25%) and in total cholesterolaemia (23%).

In order to prevent and reduce cardiovascular disease in the population, it is essential to promote correct lifestyles from an early age (e.g. school prevention schemes; programmes for the prevention of smoking in pregnant women and the involvement of the food industry, etc.) in order to maintain a favourable risk profile throughout life. To do so, Italy has implemented a “*Guadagnare salute: rendere facili le scelte salutari*” [Gaining Health: how to make healthy choices easy] programme to promote health as a common good, whose broad spectrum of initiatives involves Ministries, scientific and research institutes and Regional, Provincial and Municipal Authorities.

The health objectives according to the current state of knowledge, supported by evidence on efficacy are, in particular, fighting smoking and promoting a healthy diet and exercise.

For over a decade, the identification of individuals at increased cardiovascular risk has involved the concept of absolute overall cardiovascular risk (OCR), which suggests the doctor needs to investigate the probable multifactorial aetiology of cardiovascular disease, thereby also facilitating treatment choices, with multiple therapy alternatives to meet patient preferences, considering that most risk conditions have no clinical presentations, thus making it possible to evaluate the cost-benefit profile of the various potential treatment alternatives.

Once the high-risk subject has been identified, he/she is introduced into a cardiovascular prevention programme.

Another way of preventing cardiovascular deaths is, of course, to provide adequate treatment for relapsing conditions. In this sense, it is essential to design and implement programmes that guarantee the continuity of patient management, by improving the integration within the health services and between them and social services. Ultimately, all patients with cardiovascular diseases must be guaranteed the chance to use the best diagnostic and therapeutic practices through both the organisation of healthcare in the patient's local area and an active involvement that guarantees equity. The health objective is to restrict complications amongst those who have suffered an event, slow down the process by which the condition becomes chronic and favour the recovery of subjects with heart disease and infarction and stroke patients.

1.11. Prevention in dentistry

In recent years, the Ministry of Health has undertaken a series of initiatives aimed at producing and disseminating guidelines for the various professionals involved in the prevention and care of the oral conditions most commonly encountered in the adult age (tooth decay, gum disease, tooth loss and cancer of the mouth) and the clinical management of the side effects of cancer treatments that may occur in the mouth, during the treatment of solid and blood cancers in patients in the developmental age.

This commitment led to the drafting and publication of "National guidelines for the promotion of oral health and prevention of oral disease in the adult age" and "National guidelines for the promotion of oral health and the prevention of oral disease in individuals in the developmental age undergoing chemo- and/or radiotherapy", given that the oral cavity is often affected by the side effects of chemo- and radiotherapy on the head and neck area and conditioning protocols for bone marrow transplantation that can delay recovery from the

primary condition and cause a worsening in the quality of life. These conditions are caused by the direct action of antitlastic agents on the rapid turnover cells of the oral mucosae and saliva glands, the myelotoxic action that, due to the systemic immune depression it causes, is responsible for the development of secondary infections and, last but not least, the alterations to dental and skeletal development generated by the effects of therapy on growing structures.

The aim of overcoming oral problems in paediatric cancer patients and guaranteeing an acceptable quality of life calls for clinical protocols based above all on a close, concrete cooperation between the various professional figures: paediatric dentist, paediatrician, haematology/oncology specialist, radiotherapist, infectious diseases expert, professional nurse and dental hygienist.

1.12. The prevention of fragility fractures

As reiterated by the WHO on several occasions, fragility fractures are one of the biggest challenges facing the Health Services of Western countries, due to their increasing frequency related to their ageing populations. In women over 45, osteoporosis-induced fractures lead to more days in hospital than many other important conditions, such as myocardial infarction, diabetes and breast cancer. In order to reduce the medical and social impact of skeletal fragility there is an increasing call for prevention initiatives and actions aimed at improving the recording and processing of epidemiological data. The increase in osteoporosis is known as a "silent epidemic", not merely because the disease does not give any signs before the fracture, but also because even after the fracture, it often goes unnoticed, unreported and untreated: statistical estimates suggest that there is a gross underestimation of vertebral fractures and fractures of the proximal humerus and distal radius and that although ICD9 includes the classification of "pathological fracture" for fractures occurring in the absence of trauma or presence of minor trauma, frequent-

ly it is only fractures caused by primary or metastatic tumours that are classified using this code.

In addition to bone mineral density measurements forming the basis of the diagnosis of osteoporosis, a number of other parameters also provide information on fracture risk: age, treatment with glucocorticoids, personal history of fragility fractures, family history of fragility fractures, smoking, low body weight and excess alcohol consumption. The evaluation of fracture risk must therefore be performed separately from the diagnosis of osteoporosis.

The need for a clinical approach to patients with or suspected of suffering from osteoporosis has been stressed in a number of studies according to which up to approximately 30% of women with involutional osteoporosis also suffer from another, unsuspected condition that is responsible for the disease, as there are a great many conditions that cause the onset of osteoporosis. The identification of other causes responsible for a reduction in bone mass is even more essential in the male population where, depending on the various caseloads examined, the prevalence of secondary osteoporosis could be as high as 60% of cases.

The instrumental approach includes diagnostic biochemical and instrumental procedures and semi-quantitative visual techniques. The diagnostic tools suited to the diagnostic pathway include methods for the measurement of bone mass, which constitutes a fundamental reference point in the diagnosis of osteoporosis and the estimated individual risk of fracture, as well as the follow-up of patients on pharmacological therapy.

Research activities are aimed above all at developing new diagnostic applications for studying the geometric and microstructural parameters of bone tissue able to grasp relevant characteristics of bone “quality” that go unnoticed using the current purely quantitative methods.

In order to prevent the disease, it is essential to develop primary prevention programmes that promote the establishment from the developmental age of more whole-

some lifestyles, such as a balanced diet, regular exercise and abstinence from drinking and smoking. It has been estimated that a 5% increase in peak bone mass at the end of skeletal development – which can be achieved by optimising teenagers’ diet and exercise habits – would lead to an approximately 30% reduction in fracture events in the elderly age.

Secondary prevention focuses on early diagnosis of the disease and estimates of the risk of a fracture, and tertiary prevention is provided for those patients who have already suffered a fracture and includes a full programme for the prevention of further fractures, taking into account, in elderly patients, the typical complexity connected with comorbidities and multiple pharmacological treatments.

The medicinal products that inhibit skeletal reabsorption include bisphosphonates, which are considered the therapy of election, and raloxifene, which belongs to the selective oestrogen-receptor modulator (SORM) class. In the more severe cases of osteoporosis, the use of purely anabolic medications such as parathyroid hormone (PTH 1-84) and teriparatide (PTH 1-34) are indicated. In Italy, the prescription of these medicinal products by the NHS is governed by AIFA circular no. 79 and restricted to categories of patients at particularly high risk of fracture.

Lastly, it must not be underestimated that, with an increase in age, the intrinsic fragility of bone tissue can be associated with other factors, such as falls, for the prevention of which an assessment of the risks in the home should be performed. This calls for an integrated approach including a number of different professional figures with specific knowledge of the various aspects to be dealt with, as part of an efficient patient management programme with the introduction, on an organisational level, of integrated management models involving the various specialists.

In the management of patients at risk of fragility fractures, musculoskeletal rehabilitation should be used as a prelude to or in combination with pharmacological treat-

ment, in order to improve musculoskeletal health and the quality of life and to reduce the risk of fracture and repeat fracture. Fracture, particularly of the limbs, in elderly people is connected with poor bone quality associated with a higher risk of falls, which are frequent events in the population over-65.

Specialist prescription of exercises that improve balance, muscle strength and gait, associated with adequate regular exercise, should be part of a multidisciplinary programme aimed at preventing falls and fractures in the elderly. An efficacious organisational model envisages, amongst other things, the need to:

- improve the levels of health in the elderly population and at the same time in the efficacy and efficiency of the medical services already available;
- prevent the risk of refracture and reduce the risk of falls, by promoting lifestyle changes and increasing the degree of self-sufficiency following a fracture event;
- apply an approach centred on scientific evidence and international best practices;
- stimulate interaction between orthopaedic surgeons and other specialists;
- promote the role of non-orthopaedic specialists in the management of patients with fragility fractures, in order to achieve an aetiological (and therapeutic) framework including the causes that led to the fracture event;
- prevent or restrict disability through the definition of an integrated rehabilitation programme (both inside the hospital and out), with the direct involvement of physical medicine experts (formulation of a treatment plan to be gradually re-assessed and altered);
- favour dialogue between the specialists managing the patient in hospital and the community services belonging to the various social and healthcare districts;
- build partnerships between hospital specialists and general practitioners who deal with the patients on a daily basis and can more easily monitor course, compliance

with therapy and any improvement/worsening.

The Fracture Unit models tested in other parts of Europe and elsewhere have shown a positive measurable effect in terms of a reduction in post-fracture complications, mortality, duration of holiday stays and the need for re-admissions.

2. Healthcare services

2.1. Primary care and continuity of care

Over the past decade, the re-engineering of primary care that Italy is currently undergoing, although it is not yet complete in all areas of the country, has seen the switch from provision of fragmented services to the creation of programmes involving a number of medical professionals as well as the users themselves, thereby transforming the paradigm of “waiting medicine” into “initiative medicine”, centred on the “active promotion” of health and the responsabilisation of the citizen as regards his/her own wellness. In this context, general practitioners and primary care paediatricians have a more important role to play in the creation of aggregate forms of primary care and integration with other professionals in the community. In line with this, the National Collective Labour Contract for General Practitioners (ACN) of 29 July 2009 considers that the doctor goes about his/her practice as a key part of a local, functional system of general medicine and works inside a Complex Primary Care Unit.

Therefore, in the current context, the general practitioner and other NHS facilities work together to provide a network-type response to citizens’ needs, thereby promoting empowerment, making the person and his/her family members responsible for pursuing the highest possible level of wellness, using computerised technological media to contact other professionals, thereby allowing the sharing of data and knowledge. The Contract of 8 July 2010, expects the GP to include in his/her tasks using the intranet provided by the Regional Authority to send and make available the data

contained in patient summaries, which summaries the medical profile of each individual and can be used, without violating privacy obligations, by the whole health-care system, thus favouring the interaction between the various professional figures, particularly when we consider 24/7 health-care and patient safety a strategic objective of healthcare governance.

In Italy, continuity of care is one of the NHS' main objectives and it is intended both as continuity between the various professional actors working as part of the same framework (team work, devising and implementation of joint diagnostic-therapeutic pathways, etc.) and as the continuity between the different levels of care on the delicate boundary between the hospital and the community. GPs are the cornerstone in the integrated management of chronic situations and they are jointly-responsible for choosing the most appropriate management and diagnostic and therapeutic programme for their patient, also considering local organisation, which contemplates vacancies in community and/or residential services, inside dedicated intermediate care facilities, as well as integrated home support services.

In 2009, primary care was guaranteed, nationwide, by 46,051 GPs, of whom 30,139, or 65.5%, were part of associated practices, representing an increase of 7.1% compared to 2007. In 2009, the mean number of patients for each GP was 1,133.

35,917 GPs, 78% of the total, use computers in their work. In 2009, there were 7,683 primary care paediatricians practising in Italy, with a mean number of 857 patients each. 59% of primary care paediatricians worked in associated practices, which was 11.4% higher than the previous value and 68.5% use computers in their work. In 2009, the Continued Care Service involved 12,359 doctors, with an average of 21 doctors per 100,000 inhabitants, who provided a total of 17,229 contacts per 100,000 inhabitants. Healthcare services were provided for a total of 19,680,879 hours. Lastly, integrated the Home Support Service was provided to 526,568 people, with a na-

tional mean of 877 per 100,000 inhabitants. 84% of these are elderly people and 9.4% are terminally ill patients. When comparing this data with that for 2007, we observe an approximately 10% increase in the number of patients managed.

The aims to be pursued in the years to come are:

- to promote wellness and deal with the main healthcare problems in the community, by helping people to obtain better control over their health and to improve it;
- to favour complete, holistic patient management, by developing a type of care based on a multidisciplinary approach that promotes the integration of social, medical, care and rehabilitation services;
- to favour continuity in care, through the implementation of the primary care service network, by defining hubs and the functional interactions in a management and relational network between professional practitioners, characterised by clarity of responsibility and procedures for the definition and implementation of a care programme and the switch, where necessary, between different facilities and care settings;
- to contribute to demand governance processes in which the GP performs gate-keeping actions by analysing needs, including those that are not expressed, in his/her choice of clinical and therapeutic response and efficacious and appropriate care pathway;
- to evaluate the health outcomes generated in the individual and in the community;
- to favour patient empowerment in the care process;
- to favour specific training in general medicine, which must be considered an essential part of learning, even at university level;
- to improve hospital-community integration through a correct management of the discharge process and evaluation of the clinical, social and care conditions of the patient as an inpatient;
- to promote the establishment of single

Table. Integrated Home Care Services (Year 2009)

Region	Cases treated	Cases per 100,000 inhabitants	Of which elderly %	Of which terminal patients %
Piedmont	30,096	679	77.2	17.8
Aosta Valley	166	131	60.8	34.3
Lombardy	93,766	962	85.2	7.4
Aut. Prov. of Bolzano	650	130	55.4	38.0
Aut. Prov. of Trent	1,915	368	57.4	42.2
Veneto	56,829	1,163	82.0	10.2
Friuli Venezia Giulia	25,069	2,037	88.1	2.3
Liguria	16,273	1,008	91.7	5.2
Emilia-Romagna	89,933	2,073	90.6	1.2
Tuscany	24,505	661	78.3	17.0
Umbria	18,074	2,021	87.0	9.1
Marche	15,043	958	85.0	13.8
Lazio	51,324	912	86.2	7.9
Abruzzo	16,892	1,266	80.2	12.2
Molise	2,108	657	81.3	16.2
Campania	22,434	386	76.7	12.7
Puglia	17,991	441	83.7	13.7
Basilicata	7,382	1,250	81.5	16.2
Calabria	11,708	583	81.4	12.3
Sicily	14,697	292	67.9	25.5
Sardinia	9,713	581	76.2	14.8
Italy	526,568	877	84.0	9.4

Source: Ministry of Health – General Information System Directorate – Statistics Bureau.

access centres in the community for the management of fragile individuals, as part of a vision of continuity in care.

2.2. The emergency medicine and ambulance system

Twenty years after the establishment of the emergency and ambulance system, in addition to the good results achieved, we can also identify critical elements that call for a reflection on and a review/updating of the service in order to make it more efficient and homogenous. In recent years, a great deal has been done to favour integration between the services, in order to guarantee continuity in care along the patient's entire pathway and there is still a great deal to be done in the hospital-community integration phase. Indeed, in recent years, throughout Italy, there has been a constant and progressive increase in A&E and Emergen-

cy Department admissions that has led to an overcrowding of the intra-hospital emergency area creating inconvenience and inefficiency also to those patients who require, within short timeframes, multi-specialist services that are typical of hospital care. The significant flow of usership mainly involves diseases characterised by medium-low clinical criticality that can often find an adequate and even better response in clinical and care terms in the network of primary care services, when properly structured. This phenomenon, which also occurs for those services that citizens can access by telephone (the 118 ambulance call-out service), causes improper use of facilities and services that should be reserved for true emergency situations or conditions. Inappropriate use of A&E services occurs for various reasons, the most important being the citizen's perception of an immediate

need in relation to procedures that cannot be deferred but that are not urgent. This perception will be greatly reduced if the citizen feels managed within a primary care network able to anticipate/intercept his/her need, considered as being undeferrable. It is therefore necessary to develop new integrated organisational pathways with the aim of reducing improper admissions, rationalising the resources present in the community and providing a more efficacious answer to the population's health needs. With this in mind, one of the initiatives launched to favour a harmonious development of all community and hospital health services, such as to guarantee a complete and efficient response to the citizen for a holistic management of the person requiring healthcare, a mixed Ministry-Regional Authority-AgeNaS working group has been set up with the aim of reorganising the system, by separating inside A&E Depts. the clinical and care pathways of patients classified with Red and Amber codes from those with Green and White codes, associated with different medical teams.

The indisputably positive elements are: the complete activation throughout the country of the 103 Ambulance Callout Centres envisaged in the individual regional programmes; the common knowledge of the single telephone number "118"; the presence of 343 active Emergency Admissions Departments and 550 A&E services.

As far as the large-scale emergencies or emergency situations involving multiple facilities are concerned, experience has shown that a joint commitment between Regional Authorities, central State Administrations (Ministries and Civil Protection Corps), national governmental and non-governmental organisations is required.

Given the Emergency Medicine and Ambulance System's position as one of the most critical areas of the NHS, it comes as no surprise that all the Regional Authorities subject to Realignment Plans have prepared, and in many cases already implemented, actions aimed at improving the services provided in this area as regards

both the quality and rapidity and cost-effectiveness. Certain measures derive from and are closely connected to hospital network reorganisation schemes and in other cases, these contingency measures are part of specific, planned initiatives for the reorganisation of the Emergency and Ambulance Network, aimed at solving the critical aspects identified, in order to complete actions already partly performed and/or to increase the system's levels of efficiency and efficacy.

The EMUR information system has been introduced for the identification and monitoring of the services provided in the emergency sector and, as of 2012, it will provide information useful for programming purposes. So far 12 Regions have already submitted their ambulance callout data for 2010 and 15 Regions have submitted their data flows for A&E admissions.

The SIS data for 2009 reveals the presence in Italy of 550 A&E services, of which 512 in public hospital facilities and 38 in accredited private facilities.

There were a total of 343 active Emergency Admissions Departments, of which 325 in public hospitals and 18 in accredited private facilities. It also indicated the presence of 376 intensive care centres in public facilities and 60 in private ones. Of the 96 paediatric A&E departments in Italy, just 2 are located in accredited private facilities (Lombardy). Lazio and Tuscany are the Regions with the highest number of paediatric ambulances (8 and 6, respectively), whereas Lombardy has the greatest number of ambulances dedicated to the transportation of newborns. Activity-related data shows that in 2009 there were 378 admissions to A&E per 100,000 inhabitants, of which 15.5% required hospitalisation. Compared to 2007, there was an increase in the number of admissions (from 364 to 378), but a reduction in hospitalisations, which dropped from 17.3% to 15.5%.

As far as paediatric activities in 2009 are concerned, there were 144 admissions per 100,000 inhabitants (0-18 years), of which 9.2% required hospitalisation.

The number of bases and helicopters used

is 44, as it was in 2005. There are, however 10 more helipads, making a total of 30 and with a nationwide need of at least twice as many (60-70). Generally speaking, the number of helicopters is sufficient, however distribution is not homogeneous: some Regions, such as Sardinia, lack this service altogether, whereas others, such as Sicily, have a high number of helicopters.

The emergency network plays a key role in guaranteeing the safety of the entire population; however it also affects the efficiency of the whole healthcare system. We must promote greater appropriateness of this network by introducing corrective rationalisation elements, such as, for instance:

- identifying organisational models that favour the integration between hospital and territorial services in a network approach;
- promoting cooperation with the District for an integrated management of the less severe cases;
- governing the contribution of voluntary work;
- favouring relations with the institutions involved in emergency management, in view also of the imminent introduction of the single European number 112;
- to guarantee fair, homogeneous services, even in the most disadvantaged areas;
- to create or implement regional or local early defibrillation projects across the country;
- to promote staff training on dealing with heart attacks in hospitals and the institution of hospital and regional Registers.
- to promote the dissemination of the hospital triage method, taking into account the special needs of paediatric settings;
- to set up alternative pathways to A&E, with the establishment of GP-run clinics to provide a 24/7 service for non-emergency healthcare needs;
- to set up Intensive Short-stay Observation units.

Lastly, another fundamental element for guaranteeing the continuity of emergency care is the creation or completion of networks for acute, complex patients for acute coronary syndrome, stroke, trauma and

paediatric, gynaecological and obstetric emergencies.

2.3. *Hospital care*

With the State-Regional Authority Intent of 3 December 2009, the Regional Authorities undertook to adopt measures aimed at reducing the number of hospital beds, in line with the new standard of 4 beds per 1,000 inhabitants, including 0.7 beds for rehabilitation and post-acute long-stay patients, which could be increased by 5% depending on the weight of the population of over-75 year olds, and at the same time to reduce hospital services at high risk of clinical and organisational inappropriateness for ordinary and day hospital patients. The Intent document refers to a subsequent agreement, yet to be signed, for the definition of an additional number of beds to be dedicated exclusively or primarily to patients from other regions. The reorganisation of the hospital network will lead to the completion, for those services that can be provided in more appropriate settings, of the current process aimed at dehospitalisation, by promoting a model of a hospital rooted to the community, functionally connected to the care networks present, also through the adoption of procedures and protocols that are certified and shared with community facilities, equipped with modern technology and connected via a network to the other hospital facilities of varying complexity identified by regional programming according to specific vocation, the type of cases treated, the growing presence of sophisticated technologies, through to the centres of excellence and the Technological Complexes. Care, provided in observance of care quality and safety standards, for processes characterised by a highly interdisciplinary, polyspecialist and integrated approach, can be gauged to meet the intensity of care required by each patient, facilitated also by structural choices, flexible flows and pathways, giving precedence, where appropriate, to alternative options to ordinary hospitalisation, in order to obtain better patient satisfaction.

One important instrument that provides

Table. Regional break-down of public and equivalent institutes for hospitalisation classified according to the number of beds and mean structure size (2009: provisional data)

Region	Number of public institutes according to number of beds			Total public institutions	Mean Size (beds)
	≤ 120	121-400	> 400		
Piedmont	6	17	15	38	390
Aosta Valley			1	1	455
Lombardy	6	22	33	61	561
Aut. Prov. of Bolzano	3	3	1	7	269
Aut. Prov. of Trent	4	3	2	9	224
Veneto	7	12	19	38	484
Friuli Venezia Giulia	4	9	3	16	290
Liguria	3		9	12	564
Emilia-Romagna	3	9	15	27	598
Tuscany	16	12	14	42	301
Umbria	2	7	2	11	267
Marche	20	12	1	33	166
Lazio	31	31	13	75	256
Abruzzo	7	10	4	21	213
Molise	1	6		7	225
Campania	18	27	10	55	261
Puglia	4	26	8	38	353
Basilicata	4	4	1	9	225
Calabria	25	9	3	37	145
Sicily	32	29	8	69	216
Sardinia	16	12	4	32	172
Italy	212	260	166	638	315

Note: The data considers all bed types (day hospital, day surgery, inpatients and private inpatients) recorded using the HSP.12 form for hospital wards that were operative at the start of the year. For two facilities in the Friuli-Venezia-Giulia Region no data was submitted for 2009; the most recent data submitted was used for these facilities.

Source: Ministry of Health – Directorate General for the IT System – Statistics Office.

information on hospital activities is the information flow of hospital discharge record data that includes clinical information on inpatients, as well as data for the assessment and programming of the activities performed in hospitals.

Guidelines for discharge record coding were recently updated taking into account regional experiences and in some cases suggestions made by medical and scientific companies and from national and international literature sources.

Ministerial Decree 135 of 8 July 2010 identifies further information in addition to that already envisaged by Ministerial Decree 380/2000 concerning the regulation of information flows on hospital discharges, to be integrated into the national discharge

record system and progressively reduces the interval for the transmission of data from the competent Regional Authority to the Ministry, taking it to a monthly frequency for hospital activities for 2011, in order to respond with greater rapidity to the knowledge of hospitalisation phenomena across the country. The new information required also facilitates the analysis of health phenomena related to social and economic status and epidemiological studies on accidents and incidents.

In 2009, the rate of hospitalisation in ordinary wards for acute inpatients was 120 discharges per 1,000 residents, with significant regional differences. The total number of hospital beds for acute inpatients in public and equivalent structures and in ac-

credited private facilities was approximately 212,000 units, and in rehabilitation and long-stay wards, it was just over 37,000 units. This number of hospital beds, considering the resident population, corresponds to 3.5 and 0.6 beds per 1,000 inhabitants, respectively.

In providing hospital care, the Italian NHS uses 1,173 treatment facilities, of which 638 are public or equivalent, accounting for 54% and 535 are accredited private clinics, representing 46% of all institutes. Nationwide approximately 41% of public and equivalent hospitals are medium-sized, in terms of the number of beds for ordinary day hospital- and inpatients. More than 33% has fewer than 120 beds and most of these facilities are located in central and southern regions of Italy. The remaining centres in the central and northern parts of the country are primarily medium-sized. Overall, on a national level, the mean number of beds for 2009 was 315 beds per centre. There is a concentration of facilities with more than 400 beds in Piedmont, Lombardy, Veneto, Liguria, Emilia-Romagna and Tuscany.

2.4. Rehabilitation

The purpose of a rehabilitation programme is to “gain health” as part of a vision in which the person with a disability and/or impairment is no longer considered a “patient”, but rather a “person with rights” (Conference in Madrid in 2002, European Year of People with Disabilities). The aim is to manage “the person” in order to allow him/her to achieve, in a vision of true empowerment, the best possible functional and participation conditions, in relation to his/her own will and the context. The “integrated care pathway” is the term used to indicate the set of medical and non-medical components of the rehabilitation programme. In this setting, the Individual Rehabilitation Project is the specific, synthetic and organic tool used to implement the programme.

At the current state, the rehabilitation treatments provided are those envisaged in the applicable Prime Minister’s Cabinet Decree

defining the essential levels of care. There is great unbalance in the workloads and distribution of the services amongst the various Regions and, whereas in some cases, these services are based primarily on inpatient facilities, in others they are provided primarily on an outpatient basis.

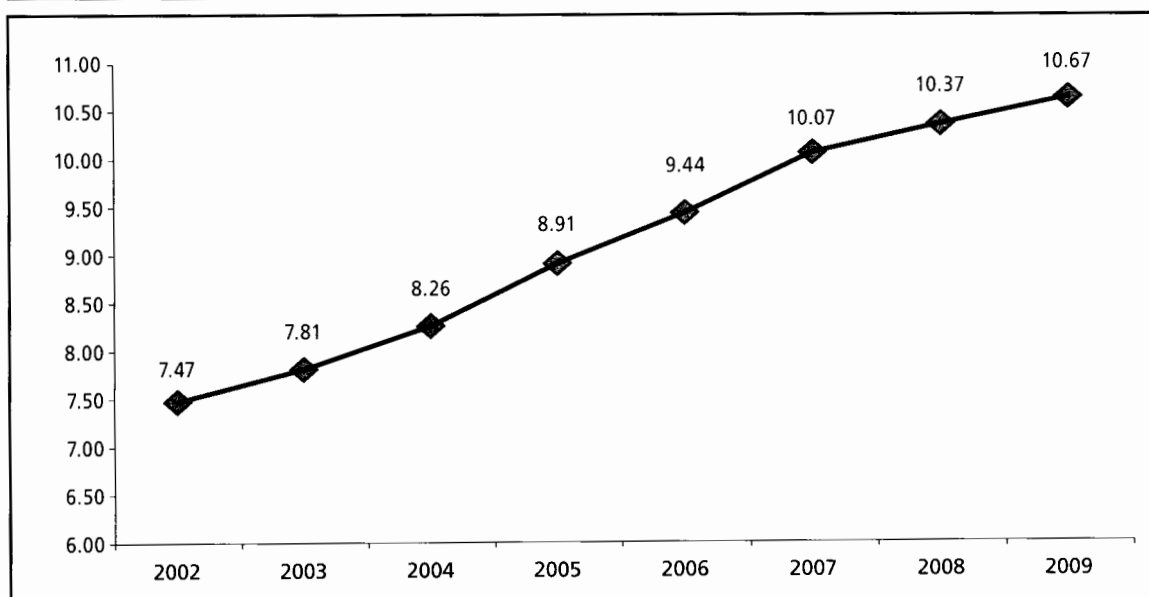
All the Regions dealt with the intensive phase for ordinary inpatients with the activation of dedicated public hospital, equivalent hospital and extra-hospital facilities – albeit with difference in proportions from one Region to another, whereas in the extensive phase, rehabilitation initiatives often overlap with maintenance services and are sometimes confused with social inclusion programmes.

Hospital activities in the Functional Recovery and Rehabilitation, Neurorehabilitation and Spine Unit areas are almost always provided on an ordinary inpatient basis. Just under 9% of beds are dedicated to day-hospital services. The availability of hospital beds in relation to the resident population has increased both in absolute terms (4% points in 7 years) and in relation to total hospital services, to reach a percentage of 10.65% of the total number of beds in 2009, with national mean of 0.4%, again with significant differences between the various Regions. Similar differences can be observed for the hospitalisation rate and the number of beds “pursuant to article 26”, thus producing a condition of substantial deformity in the overall operating approach.

The most frequent causes of hospitalisation are for musculoskeletal and connective tissue, nervous and cardiovascular diseases.

The priority areas for improvements are

- holistic management of the person;
- intervention timeframes that are acceptable in relation to the patient’s type of need, biological phases of recovery and social and environmental requirements;
- a coherent succession and integration of the various services and setting types according to clinical, family and environmental conditions;
- the preparation and implementation of an Individual Rehabilitation Project;

Figure. Percentage of hospital beds dedicated to rehabilitation out of the total number of beds.

Source: Ministry of Health – Healthcare Information System.

- the provision of services of recognised validity and with causal rather than symptomatic purposes;
- the active, well-informed participation of the patient and his/her family in the treatment programme;
- patient coaching for correct self-management of their conditions, thereby promoting coping mechanisms;
- the creation of an independent, unbiased and objective system for the assessment of the efficacy and efficiency of the management of each patient.

2.5. Pharmaceutical care

Medicinal products are constantly-evolving instruments that respond to patients' increasing demands for health and the needs of health services to provide efficacious and safe responses for the treatment of disease. We are currently experiencing the development of approaches destined for specific patient targets (gender medicine) and fragile populations (paediatric and the elderly), the study of areas that were neglected in the past, such as, for example, those connected to the treatment of rare diseases or unmet medical needs that are now finding an efficacious response.

The demand for healthcare in relation to

the age of the patients would appear a determining factor in the increase in consumption and costs of therapy, alongside the increase in the demand for health and demand for access to innovative and costly therapies by citizens. We now have treatment options that act on new pharmacological targets that are increasing specific and selective, such as molecular targeted drugs, advanced (cell and gene) therapies and the first pharmacogenetic and pharmacogenomic applications.

Since 2009, the Italian Medicines Agency has adopted important measures for the governance of expenditure and regulation of the pharmaceutical sector and has undertaken initiatives to guide the use of medicinal products, aimed at greater prescriptive appropriateness, that have made it possible to keep pharmaceutical spending in the various areas under control with the use of equivalent generic products, which has grown since 2001 from a value of less than 1% to a current value of about 8% for NHS prescriptions and the sustainability of pharmaceutical expenditure is closely connected with this possibility. The expiry of patent rights automatically and by law generates reductions in costs that between 2009 and 2010 involved peak reduction of

over 60% compared to the prices of the original proprietary medicines, thus generating important savings destined for the financial coverage of more innovative therapies. GP involvement has been identified as an essential element for the clarification and dissemination of the meaning of equivalent medicinal product as a high quality, safe and efficacious medicinal product, thereby doing away, once and for all, of the belief that “lower cost = lower quality”.

The action promoted by the government with the 2010 budget law also favoured a closer interaction between the Ministries involved, Regional Authorities and AIFA, in order, once again, to promote the dissemination of best practices. Specifically, for equivalent generic medicinal products, for certain specific therapeutic categories representing the main items of local expenditure on pharmaceutical products, such as proton pump inhibitors, statins, serotonin selective inhibitors, sartans, and antibiotics, inter-regional comparison tables have been drawn up using the data provided by the Health Card system.

Although extra-hospital pharmaceutical expenditure remains within the values envisaged by the National Health Fund, thus registering a decrease of over 2 percentage points in 2010 compared to 2009, concerns persist regarding pharmaceutical spending in hospitals. Indeed, although the growth rate dropped from 10.53% in 2009 to 6.5% in 2010, the reference value established by Law 222/2007, equal to 2.4% of the National Health Fund, it was systematically exceeded by all Italian Regions.

The new biotechnological medications and targeted therapy, which are proving particularly efficacious above all in treating cancer, as well as future gene and cell therapies, in other words all the most innovative pharmacological solutions for the treatment of the most important diseases, must necessarily be managed inside hospitals only.

For these products, in recent years, AIFA has stringently applied conditional refunding mechanisms, such as registers, cost sharing, risk sharing and payment by results, aimed at combining expenditure monitoring

and control instruments with other mechanisms that analyse the dynamics of use, in order to verify their effective efficacy.

During 2009, the causes of deviations of use of these instruments in the various Regions were analysed and investigated, following reports from citizens on the difficulties experienced in accessing innovative treatments.

In connection with this, in 2010 an important State-Regional Authority Agreement was stipulated concerning the direct assimilation by Regional Hospital Formularies of medicinal products judged to be innovative by AIFA, an important and fundamental step towards guaranteeing uniformity and rapidity in access to medicinal products throughout the country.

Indeed this State-Regional Authority Agreement envisaged that all those medicinal products considered innovative by AIFA shall be immediately made available in all Regions, before and regardless for their inclusion in regional formularies.

As far as the criterion with which AIFA defines innovativity is concerned, this will be decided by the Agency's Technical & Scientific Commission, which evaluates the severity of the condition treated, the existence or absence of alternative treatments and the expected results of the new therapy.

The Agreement reiterates the need to avoid incorrect medicinal product access in Italy at all costs, highlighting AIFA's role as the Agency that represents all the various components and is able to make operative all the decisions undertaken for the country as a whole.

Italy has confirmed its status as one of the countries where, faced with a pro capita pharmaceutical expenditure that is lower than in other European countries, the availability and above all the quality of the medicinal products are, quite obviously, superior.

2.6. *Transplants*

On a European level, Italy has achieved positive results both in terms of donations and transplants and in terms of the quality of its facilities and organisation of its net-