

than 280 hospitalisation structures throughout national territory.

The adhesion of all Autonomous Regions/Provinces, the involvement of the healthcare professionals and the commitment assured by citizens with the various representation and protection associations based in the territory, have enabled the finalisation and development of a model of cooperation between professionals and citizens for the evaluation and improvement of the quality of health services, according to the principles of the theory of empowerment.

Keywords Citizen empowerment, cooperation of operators and citizens, humanisation of hospitalisation structures, improvement in the quality of care, joint evaluation of quality

11. National “Communicating Health” communication plans and programmes

11.1. *Information campaigns for the promotion of healthy lifestyles*

Unhealthy lifestyles (alcohol abuse, smoking, incorrect nutrition and sedentary habits) are, directly or indirectly, the main causes of mortality and preventable morbidity. Communication to promote healthy lifestyles is, therefore, a priority and strategic objective. As part of this, the Directorate of communication and institutional relations, in the two years 2012-2013, concentrated its messages on the battle against sedentary lifestyles and the abuse of alcohol.

The campaign “Get moving!”, with the Department for Information and Publishing of the Presidency of the Council of Ministers, promoted daily physical activity among the general population. A testimonial was provided by the coach of the Italian national football team.

The press, internet and radio campaign, “Life is always one, even if you’ve had a drink” and the smartphone application “Pure adrenalin” made the young and very young aware about alcohol abuse. An intense information activity was carried out in schools with the scientific experts of the National Institute for Health. The 2012 and 2013 editions of Alcohol Prevention Day were financed.

11.2. *Campaigns against infections*

In line with the indications of the National AIDS Commission and consultation with the associations in the battle against AIDS, the Directorate General of communication and institutional relations carried out a communication campaign for the battle against AIDS entitled “United against AIDS is the way to win” in the two years 2012-2013.

The campaign sought to make the general population aware (as well as specific targets, such as immigrants) of the fact that AIDS still exists and that it is possible to prevent its spread by adopting suitable prevention measures (responsible behaviour and prophylactics). Television and radio spots, press announcements, viral activities on the web, in-depth discussions on line, leaflets and the toll-free number “AIDS and Sexually Transmitted Diseases”, under the auspices of the National Institute for Health, were the instruments and means used, with a remarkable financial investment by the Ministry. The campaign also saw the collaboration between the “L. Spallanzani” National Institute of Infectious Diseases of Rome, Bologna University and the most representative voluntary and patients associations in the Consultation. The assessment of the effectiveness of the campaign, assigned to Bologna University, showed the excellent success of the initiatives.

11.3. *The promotion of the health of women and children*

In the two years 2012-2013, the Health Ministry dedicated two special initiatives to the promotion of the health of women and children: the campaigns “You never forget mother’s milk” and “My health as a woman also depends on me”.

In order to make new mothers aware of the importance of mother’s milk as the best nutrition for newborns, the Directorate General of Communication and institutional relations - with the Directorate General of Food Safety - staged the 3rd and 4th editions of the campaign “You never forget mother’s milk”. A touring information exhibition was staged in the squares of Italian cities together with associations, institutions and local healthcare facilities.

In order to promote the value of “general health” among women, the Directorate General of communication and institutional relations, with the Department for Information and Publishing of the Presidency of the Council of Ministers, conducted the campaign “My health as a woman also depends on me”. This slogan underlined the importance of taking a more responsible attitude, on the part of women themselves, towards their own health, including by taking part in the free screening programme run by the NHS. Specific in-depth discussions (for example, on HPV, pregnancy, fertility etc.) were published on the internet portal of the Healthy Ministry www.salute.gov.it.

11.4. The Ministry of Health Portal

21 March 2013 marked the publication of the new Ministry of Health portal. On the one hand, the on-line communication of the Ministry ceases being self-referential and becomes focused on the citizen, transparency and the promotion of health, whilst on the other it is developed in such a way as to allow for the full appreciation of the work of the Ministry.

The development of the portal followed a project phase in 2012, according to the “Guidelines for on-line communication on the protection and promotion of health” developed by the Ministry together with the “*La Sapienza*” University of Rome in 2011. In 2013, in order to encourage the process of change in the portal, a Publishing Committee was established. This involved representatives of all Directorate Generals of the Ministry of Health, the NAS and the National Transplants Centre.

At the same time, the collaboration was launched between the Ministry, ISS, Ifo and other structures of excellence of the NHS, in order to give a boost to the production of new contents dedicated to citizens, including an essential medical dictionary, interactive pages and applications for mobile telephones on smoke, vaccinations and skin tumour prevention.

The Ministry web portal and the related themed government websites recorded 6,301,895 one-time visitors in 2013, 8,470,445 user sessions and a total of 26,364,054 pages viewed.

Keywords Application, citizen, communication, internet, promotion of health, transparency

11.5. Integrated information campaigns [AgeNaS, AIFA, ISS (CNT), INMP]

During the two years 2012-2013, the Ministry has developed information and communication campaigns together with AgeNaS, AIFA, INMP and ISS.

The range of subject matters goes from palliative treatment and pain therapies to emergency-urgent services, flu, antibiotics, health integration of foreigners, the risks of smoking and organ donations.

As concerns pain, the campaign run with AgeNaS has seen the censure and publication on the ministerial portal of all operating care structures in Italy, together with the activation of a telephone and information channel with citizens for six months, involving thousands of users. Alongside this, publications were also organised and a TV advertisement, run free of charge on Rai networks throughout 2013. Again with AgeNaS, information was given on the correct use of emergency-urgent services. The campaigns with AIFA aimed to increase awareness on vaccinations, as a tool by which to prevent flu and eliminate inappropriate, excessive use of antibiotics.

With the Institute for migrants and poverty, 12 prisons selected throughout Italy were involved and more than 1,500 people (prisoners, police force members and healthcare staff), to promote the interaction of foreign citizens through health.

Finally, together with the ISS, the Ministry ran a communication campaign on the risks of smoking targeting children and adolescents, focusing prevention on the very young. In terms of organ transplants, an area that for years has involved the National Transplant Centre, an annual campaign was instead promoted on the culture of donation, in collaboration with transplant patient associations: the aims are to inform and promote a “call to action” that drives the population to declare their wish to donate.

11.6. Communicating suitability: The Health Books

In 2012 and 2013, the ministerial publication Books of the Ministry of Health, intended to

standardise and establish suitability criteria over time in our health system, and managed by the Directorate General of Communication and Institutional Relations, published six monographs.

The publication is produced both as a hard copy and on the website www.quadernidellasalute.it and can also be accessed via applications. In 2012, issues 13, 14 and 15, respectively “Criteria of structural, technological and clinical suitability in the prevention, diagnosis and treatment of andrological pathologies” (February 2012), “Criteria of structural, technological and clinical suitability in the prevention, diagnosis and treatment of cerebrovascular pathologies” (April 2012) and “State of the art and prospects on the fight against asbestos-related pathologies” (June 2012) were produced and distributed, the latter dealing with the very delicate matter of asbestos – a constant challenge for public health.

In 2013, issue 16 (January 2013) “Promotion and protection of health in the child and adolescent: criteria of clinical, technological and structural suitability”, issue 17/22 (July 2013) on “Clinical, structural and operative suitability in the prevention, diagnosis and treatment of eating disorders” and issue 23 (October 2013) regarding “Criteria for the clinical, technological and structural suitability in assisting the complex patient”, were produced and distributed.

The publication was first started in 2010. In the last few years, monographs have been published devoted to the following different pathologies: cardiovascular system, strokes and stroke units, oncology, osteoporosis, health user satisfaction, elderly assistance, community dentists, rehabilitation, digestive diseases, obesity and diabetes mellitus, ophthalmology and interventional radiology.

11.7. The impact of the communication campaigns

Following the issue of the General Directive for administration and management for 2013, the Ministry set itself the aim of trying out a new method of communication for the administration, aimed at listening to the citizen's needs, as well as encouraging the proactive use of information. In this context,

the evaluation of the campaign results has become more important.

Thus an operative model has been created, which enables the Administration to evaluate the efficacy of the initiatives and verify the approval obtained from the population. The model, finalised with the Department of Social and Economic Sciences of the “*La Sapienza*” University of Rome, has envisaged the creation of an Observatory on Health, which will take the form of a permanent structure managing communication flows and analysing the needs expressed by the population in terms of health.

In this regard, for 2013, the Observatory has already used investigations carried out by the Ministry in the past. The information collected has been computerised and a first analysis prepared of the results, both in terms of contents and the social-demographic characteristics of those answering.

More specifically, as concerns the initiatives relating to the campaign for the protection of fertility “Fertility is a common asset” and the promotional tour for breast-feeding “A mother's milk is never forgotten”, the opinions collected on a significant sample of the female population (1,516 women) have been very positive: approval of 97.5% has been recorded for the campaign on breast-feeding and 80% for that on fertility.

12. The contribution made by Consiglio superiore di sanità

12.1. The context and the activity of the Higher Health Council

In the two years 2012-2013, the Higher Health Council (HHC), a technical consultative body of the Ministry of Health, gave its views, as laid down by its institutional mandate, on a wide range of matters and on sectors concerning the health of the country, in line with its own dual role as a consultative and propositional body.

The array of subjects dealt with included the prophylaxis of infectious diseases, especially concerning tubercular diseases and, in the veterinary field, paratuberculosis in cattle, hygiene-health prevention and protection, such as the problems connected with the use

of electronic cigarettes, mobile phones and three-dimensional glasses, foodstuffs, including the safeguarding of the protection of the health of consumers of raw milk and cream, drinking water and mineral water.

On veterinary matters, the Higher Health Council approved the “Guidelines concerning the minimum health prerequisites for the use of stem cells in veterinary medicine” bearing the general conditions and procedures for operators engaged in the harvesting, manipulation, preservation and clinical use of autologous stem cells in veterinary medicine.

For the purpose of ensuring safe and appropriate use of medical devices and, therefore, to enable the competent Directorate General to take appropriate initiatives of particular relevance, including in response to the interest invoked in public opinion by these subjects, opinions were expressed by the Council on matters of breast implants and metal-on-metal hip implants. Similarly, for the purpose of ensuring the safe use of medicines, the Higher Health Council was called to express an opinion on the contents of the document entitled “Position paper – Management of the notifications of donors with Creutzfeldt-Jakob’s disease (post donation information)”. Furthermore, opinions were expressed by the Council on medical technologies with diagnostic features, such as group B 3 Tesla magnetic resonance equipment, and therapeutic features, such as hadron therapy equipment, for example.

Of particular relevance was the opinion with which the Higher Health Council approved the national guidelines for the implementation of telemedicine services and for the identification of the key elements required for the coherent planning and use of these systems within the NHS and the wider European context.

As part of its propositional role, the Higher Health Council tackled issues of importance from the socio-healthcare perspective, drawing up documents that were the subject of the following specific “Reports of the Health Ministry” published on the institutional website: “Promotion and protection of the health of children and young people: criteria of clinical, technological and structural appropriateness”, “Clinical, technological, structural and

operational appropriateness in the prevention, diagnosis and treatment of eating disorders”, “Criteria of clinical, technological and structural appropriateness in the treatment of complex chronic patients”, “State of the art and future prospects on matters of combatting asbestos-related diseases”.

In a context such as the current one, characterised, on one hand, by the growing provision of instruments and interventions to protect health and, on the other, by the availability of increasingly meagre resources compared to the perceived and/or stated needs, the Higher Health Council - by virtue of respect for the central role of the individual in the choice of preventive and therapeutic interventions, the autonomy of judgement and scientific rigour that distinguishes its actions - has constituted an irreplaceable point of reference for the exercise of the missions entrusted to the Health Ministry.

12.2. Considerations

In 2012-2013, the *Consiglio superiore di sanità*, the technical advisory body of the Ministry of Health, expressed an opinion, as indeed is its institutional duty, on a wide range of matters and sectors relating to the country’s health, constantly assuring its two cornerstones, namely providing advice and making recommendations.

The list of matters discussed include the prophylaxis of infectious diseases, with specific regards to tuberculosis and in the veterinary sector to paratuberculosis in bovine farms, the prevention and health-hygiene protection like problems relating to the use of electronic cigarettes, mobile telephones and three-dimensions glasses, foods, including the safeguarding of the protection of the health of consumers of raw milk and cream, drinking and mineral water.

As concerns veterinary matters, the *Consiglio superiore di sanità* has approved the document entitled “Guidelines on the minimum health requirements for the use of stem cells in veterinary medicine”, which sets out the conditions and general procedures for operators dealing with the collection, handling, storage and clinical use of autologous stem cells in veterinary medicine.

In order to ensure the safe, appropriate use of medical devices and, therefore, to enable the competent Directorate General to take all appropriate initiatives, of particular importance, also due to the interest seen in public opinion on the matters, the Council has given opinions on breast prostheses and metal-on-metal hip prostheses. In a similar fashion, in order to guarantee a safe use of medicinal products, the *Consiglio superiore di sanità* has been called to express an opinion on the contents of the document referred to as “Position paper – Management of reports made by donors with Creutzfeldt-Jakob disease (post-donation information).

Moreover, the Council has also given opinion on medical technologies with diagnostic characteristics, like group B 2 tesla magnetic resonance equipment, and therapeutic technology, such as adrotherapy equipment.

The opinion whereby the *Consiglio superiore di sanità* approved the national guidelines for the implementation of remote medicine services and the identification of the reference elements necessary for a coherent design and use of these systems under the scope of the NHS and the broader European context, is particularly important.

As part of its guidance function, the *Consiglio superiore di sanità* has covered important social-health matters preparing documents concerned by specific “Ministry of Health Books” published on the institutional website: “Promotion and protection of health in the child and adolescent: criteria of clinical, technological and structural suitability”, “Clinical, structural and operative suitability in the prevention, diagnosis and treatment of eating disorders”, “Criteria for the clinical, technological and structural suitability in assisting the complex patient” and “State of the art and prospects on the fight against asbestos-related pathologies”.

In a context like that seen today, characterised on the one hand by an increasing range of tools and interventions designed to protect health, and on the other by an increasingly limited availability of resources with respect to the needs perceived and/or expressed, by virtue of the central role played by the person in choosing preventive and therapeutic interventions, independence of judgement and scientific rigour of its action, the *Consiglio superiore di sanità* has formed an irreplaceable point of reference for the fulfilment of the duties assigned to the Ministry of Health.

Emerging challenges and outlooks

1. The Health Pact

In the session of the State-Regions Conference of 10 July, the Understanding on the New Health Pact 2014-2016 was signed. In a renewed political-institutional context, looking towards Europe, the new Health Pact is the instrument agreed between the Government, the Regions and the Autonomous Provinces of Trento and Bolzano for the creation of a new system of healthcare governance.

The main features of the Pact, from the perspective of the structural efficiency of the system, are made up of:

- three-year planning of the standard costs and regional needs that will enable the launch and implementation of innovative policies in the National Health Service (NHS) on the territory;
- the definition of the standards regarding hospital care, which, together with cross-border healthcare, the updating of the Essential Levels of Healthcare (ELH) and the actual promotion of territorial healthcare, are the pillars of support for all the initiatives necessary to ensure the uniform protection of health for all citizens on national territory.

The issue of investments in healthcare is also central to ensure conditions of competitiveness, quality and safety of the healthcare facilities.

The issue of digital healthcare, with the expectations of the Pact for digital health, is also an instrument of rationalisation and efficiency of the system.

The Pact will be governed by a political Steering Committee which will ensure its constant monitoring and will verify the implementation of all the provisions, making use of an appropriate Technical Board, set up at the AgeNaS, which must also monitor the application of the measures in the healthcare field arising from the review of expenditure, following the instructions of the Extraordinary Commissioner for the review of expenditure contained in the government's programme.

The possibility of actually achieving the objectives set out in the new Health Pact is

ensured not only by the savings arising out of the measures therein envisaged, which will remain available to the Regions solely for healthcare purposes, but also of those achieved by the expenditure review, which will be used to improve the levels of quality of the entire healthcare system.

Among the innovations contained in the Pact, there is the provision to activate a system of monitoring, analysis and control of the progress of the individual regional healthcare systems, which enables the detection in advance, through an appropriate alert system, of any significant shifts in the performance of the health agencies and the regional healthcare systems, in terms of quality, safety, effectiveness, efficiency, appropriateness and fairness of the services delivered. It is envisaged that this task will be assigned to AgeNaS as the operational instrument of the Health Ministry, similar to what happens in other countries of the European Union.

The issue of the review of the ticket system and exemptions is dealt with in the Pact in the light of reform, in order to avoid the ticket system becoming a barrier to access to healthcare services and the main cause of citizens' curtailing treatments.

There is also a definite commitment in the Pact on the issue of managing the human resources, as well as a concrete instrument to proceed to a reform of the current system through specific provisions that will be drawn up by the Government, together with the Regions.

The new Health Pact 2014-2016 aims at a general increase in the efficiency of our national health service from the perspective of appropriateness. All the provisions contained within it were inspired by the health needs of the citizens and, currently, it constitutes the only instrument for the construction of health provision that is more centred on the individual, the means of achieving a more effective and efficient health provision that is safe, high quality and on a par with the rest of Europe.

2. Appropriateness and hospital planning

The appropriateness of the healthcare interventions, in all the various clinical and organisational manifestations, constitutes a vital technical instrument to accompany the phases of development of interventions in healthcare planning. Various factors can contribute to increasing the risk of inappropriateness, leading to the inconsistent use of resources, especially the tendency of operators and users in ensuring and demanding an ever-wider range of services in step with the rapid dissemination of scientific information, the development of the doctor-patient relationship and the phenomenon known as “defensive medicine”. In a systematic vision, each service directed at an individual patient leads to a subtraction of resources, potentially required by others. In the light of this awareness and as a result of the limits on the expansion of resources earmarked for health, the assessments of appropriateness must be constantly married to the principle of the safety of the treatments and with the ethical tension that characterises every phase of the planning process, from the identification of the objectives to the division of the resources. Aware that an adequate action of control must be a necessary element for the promotion of appropriateness, activities connecting to the functions of monitoring and verification have initially been conducted. In this way, through the SiVeAS systems, actions of verification have been carried out of the corporate activities and, for the Regions concerned, the monitoring of plans to curtail deficits, and further actions of monitoring the regional planning have been conducted within the scope of the ELH Committee through the analysis of specific sets of qualitative and quantitative indicators. As part of the activities of organisational review for the increase in the degree of appropriateness of the services, specific projects have been launched concerning the activities of breast units, recourse to innovations with particular regard to robotic surgery and integrated pathways for the management of chronic diseases. Furthermore, patient guides have been drawn up and disseminated for the appropriate and safe use of healthcare services and manuals

for the training of operators on the subject of appropriateness and clinical governance.

Healthcare planning activities to boost the degree of appropriateness of healthcare services should not contemplate the mere introduction of expenditure ceilings, but the optimum use of resources must be guaranteed at the level of efficiency and allocation of resources, with respect for the principle of equity.

3. Assessment of the standard costs of the Essential Levels of Healthcare

Legislative Decree 68/2011 laid down, starting from the year 2013, the introduction of standard costs in healthcare, to be implemented through the use of a set of indicators that will enable the assessment of the levels of efficiency and appropriateness for each Region, with reference to a group of services rendered within each of three macro-levels of healthcare.

During the 2013 allocations, therefore, the cost levels found in the three Regions of reference were applied to all Regions. Best practices were identified in the various regional organisations through a set of indicators defined by the resolution of the Council of Ministers of 11 November 2012.

A review and reclassification of the criteria under article 27 of Legislative Decree 68/2011 has already begun in order to identify the regions of reference in years to come on the basis of the level of the quality of the services delivered, appropriateness and efficiency.

Keywords Best practices, standard costs, indicators, Regions of reference

4. From Continued Care Service to 24/7 Care

One of the main issue under evaluation by national programming in the last few years regarded aspects related to Continued Care Service.

To this end, the Regions have been invited to try out new organisational models aimed at merging different healthcare expertise and territorial services.

Currently, the implementation of these models finds a favourable scenario since the Re-

gions, especially those participating in the Repayment Plan, are still working on the reorganisation of healthcare networks with the objective of providing the most effective responses to the new healthcare needs of the population.

The integration of Continued Care Services with emergency territorial 118 services is one of the most useful organisational models since it allows the timely identification of less severe conditions (the so-called white and green codes) and the routing of the patient to a more appropriate and prompt care.

Starting from an analysis of the characteristics of the territory and the pre-existing organisational structures, the Regions have provided for the testing of organisational models aimed at ensuring healthcare 24/7 through the integration of Operating Stations 118 and Continued Care Services.

Most of the projects proposed by the Regions would involve the functional integration of the two services through telephone connections and technological support in order to ensure the management of citizens by routing them, if necessary, to the most appropriate territorial service.

The evaluation of the extendibility of such models to other situations is still a problem since the majority of the projects, although at an advanced stage of testing, are still in their initial implementation phase.

Keywords 24/7 care, continuity of care, healthcare networks, Operating Stations 118

5. Active ageing

The significant increase in life expectancy recorded in the last ten years is not matched by a parallel increase in the length of life in good health. This difference between life expectancy and life in good health is linked to the burden of disease, especially the non-communicable chronic diseases which occur in this and in earlier age groups and that may ultimately result in disabilities. Many of these diseases are directly associated with lifestyle and therefore are quite preventable or deferable by adopting measures of proven effectiveness.

Based on a European indicator that was de-

veloped during the Active Ageing Year (2012), Italy ranks 15th (out of 27) in the general index, but 22nd for employment, 2nd in participation in society, 19th for self-sufficiency and independent life and 15th in the environmental capacity to promote active ageing.

Within the European context, noteworthy are two important initiatives for the development of strategies and policies in support of active ageing without disabilities: the “European Plan for active and healthy ageing in the years from 2012 to 2020”, sponsored by the European Division of WHO, and the “European Innovation Partnership on Active and Healthy Ageing” sponsored by the EU. Both documents indicate priorities and objectives, together with the tools to use for their achievement, for the ultimate purpose of fighting fragility and functional decline in the elderly.

To this end, it is necessary to adopt a life-course approach, acting early and over the course of one's life so as to minimise individual risk factors (smoking, alcohol abuse, sedentary lifestyle and inadequate diet) and remove the causes that prevent the choice of a healthy life.

Through the programme “*Guadagnare Salute*” and the NCDC projects, several initiatives were promoted for the support of active and healthy ageing, the prevention of fragility in the elderly including the risk of a progressive loss of autonomy, and the preservation, for as long as possible, of a good quality of life. In conclusion, it can be stated that active and healthy ageing is a priority objective of all Governments in order to ensure at all ages a high level of quality of life and at the same time ensure the sustainability of social and healthcare services that will enable the achievement of the European objective, for 2020, of an additional 2 years of good health for European citizens.

Keywords Active ageing year, European Plan for active and healthy ageing, life time approach, sustainability of healthcare systems

6. Nanomaterials

Among the new technologies that have emerged in the last few years, of a particular importance are the nanotechnologies, i.e.

technologies with components in nanometric dimensions called nanomaterials (NM). OECD has estimated that in 2015 the global market of nanotechnologies will reach about 1 trillion US dollars and will create about two million new jobs. Therefore, nanomaterials have clear commercial and practical prospects for use in different industrial (medicine, medical devices, cosmetics, etc.), agriculture and environmental (green economy, food, biocides, etc) sectors but their use has already been questioned since 2004 regarding the potential effects on health and the environment. The Ministry of Health, in particular the Directorate General of medical devices, of the pharmaceutical service and safety of treatments, in line with the existing laws and within the time frames planned by the European Commission, is meeting the challenge by focusing, on the one hand, its commitment on a shared and not taken for granted technical-scientific definition of nanomaterials and, on the other, by promoting national scientific cooperation for the study and the research of nanoforms and their safety.

Keywords Nanodevices, nanoforms, nanomaterials, nanomedicine, nanoparticles, nanotechnologies, nanotoxicology, safety, security

7. Technological development

Medicine has been subject in the past few years to a very rapid transformation with the marketing of innovative technologies which, although allowing for an evolution toward diagnostic and therapeutic procedures that are increasingly more accurate, may involve, if not used correctly, a global increase in the costs for healthcare systems and risks for the patient. The products from these technologies are in part, but not always, subject to certification.

This section discusses, through a description and critical evaluation of the collected data, the challenges emerging from technological developments in the healthcare area, which are closely connected and range from ICT (Information and Communications Technology) in the healthcare sector, to technological innovations in neuroscience, diagnostic imaging, in-

novative treatment technologies based on the use of radiations such as HIFU (High-Intensity Focused Ultrasound) as well as to the new treatments with X-rays and adrones. Among these technologies, HIFU is particularly promising in the treatment of prostate cancer which is currently treated through prostatectomy (removal of the prostate). As for the territorial services, ICT represents the driving force in new developments but it also generates concerns regarding the integration of the currently available services and the new risks related to a connection with the biomedical technologies subject to new regulations.

Applications for the remote monitoring of vital parameters are now available through low cost wireless technologies.

As for the technological innovations in neuroscience, artificial devices directly associated with the nervous system are now being rapidly developed and range from prosthetic replacement to direct stimulation of the nervous system for the control of neurological disease symptoms.

8. Innovative therapies and hospital pharmaceuticals

The Italian SSN, within the G10 countries, is the only solidarity and universal system left. AIFA has improved its performance by ensuring that every citizen has available the most innovative, safe and effective medications that the pharmaceutical research has been able to develop. The introduction of the new biotechnology medications will contribute to an important turning-point in the decision-making processes of clinical practice while providing the citizen with a guaranteed customised treatment, a trend that is likely to continue into the future. Within this context, the biosimilar medicinal products represent a real opportunity to improve access to care and the sustainability of the system. For this reason, AIFA has launched in the course of 2013, important initiatives directed at informing and raising the awareness of the healthcare operators and citizens also through the publication of a specific Position Paper. The long term strategies must be aligned with the introduction of new regulations aiming at governing and standardising

the access time to medications. In order to meet this need, several legislative provisions have been issued. Legislative decree 158/2012 has established the automatic marketing of medicinal products already authorised in Europe and classified in segment C; the second, the so-called "Decreto Fare" (Legislative Decree 69/2013) provides for a preferential path for orphan medicinal products and medicinal products of exceptional therapeutic relevance and gives AIFA a maximum of 100 days for completing the procedures for their inclusion in the NHS pharmaceutical handbook. The emerging issues that AIFA will have to address, within the particularly complex economic context of Italy, is the guaranteed access to treatment for the patients who must be placed at the centre of the system.

Keywords Biosimilar medicinal products, biotechnology medicinal products, innovative medicinal products, Legislative Decree 158/2012, Legislative Decree 69/2013, Position Paper

9. Creation of clinical risk units

The establishment of a corporate department permanently dedicated to clinical risk management was formalised under the State-Regions Agreement of 20 March 2008 on the safety of treatments. In defining the framework of reference for the governance of clinical risk, the Understanding identified the strategic structure of the clinical risk management unit to which to assign the role of implementing corporate policies on the issue of safety through the indication of objectives, methods and instruments in the context of the specific corporate reality and in harmony with the regional and national indications.

The presence of an operational unit/department for managing the clinical risk in the SSN structures has witnessed a gradual increase, as shown by surveys carried out over the years (in 2003, it was 17%, in 2005 it was 28%, in 2009, 97%). The national survey on the state of the art on the issue of patient safety, conducted in 2012 in collaboration with the Regions and Autonomous Provinces, enabled the organisation of the corporate department for the clinical risk to be analysed in more

detail and to reveal a slight variation between the SSN units with respect to the organisational solutions adopted. The national survey was also directed at revealing the presence of a unit/centre/facility for the coordination for the clinical risk activities at the regional level that produced a result of more than 84% of the Regions and Autonomous Provinces and the activities promoted, from which initiatives of training/information of professionals (89%), the drawing up, promotion and application of instruments and procedures of regional values for safety (79%), and the application of practices for safety (95%), emerged as priorities.

The strategies and actions in favour of informing and involving patients in the programmes/activities for safety and the definition of standards and indicators in order to activate an effective system of assessment require further development, however; it is the objective of the Ministry and the Regions to share guidelines aimed at strengthening the capacity for clinical risk management by giving impetus to the assessment of the programmes and actions undertaken on the basis of specific indicators.

10. Outlook of cross-border healthcare

Directive 2011/24/EU, concerning the rights of patients to cross-border healthcare, was implemented by Legislative Decree n. 38 of 4 March 2014, effective on 5 April 2014.

These regulations on cross-border healthcare give a new impulse to international healthcare mobility from which new opportunities may arise for EU patients.

The opening of a free market in healthcare services creates an inevitable competition among the different national systems while representing, at the same time, a development opportunity and a challenge for the NHS given the probable increase in the flow of patients who go abroad to receive treatment and the corresponding economic impact that this phenomenon can have on the internal resources allocated to it.

Among the primary objectives of the regulations in question, there is the development of an effective cooperation system among different healthcare systems as well as the

harmonisation, where possible, of the regulations themselves.

Fostering cooperation among member states has the purpose of achieving a greater efficiency and transparency of healthcare services while strengthening scientific and technological developments.

These objectives will be achieved through the creation, on a voluntary basis, of the European Reference Networks (ERN) among healthcare service providers and centres of excellence. Thanks to these networks, it will be possible (i) to optimise the costs and the use of human resources, thus avoiding the risk of research duplication and making the best use of expertise, results achieved and good practices in use in the other member states; (ii) to train on an on-going basis the healthcare professionals and help the countries that do not have proper equipment, to provide highly specialised and high quality service. A fundamental tool for the creation of this information healthcare network among member states is the use of an integrated system so that, thanks to the informed consent of the patient, the clinical records of the patient, as well as all details on the provided services including invoices, can be accessed on-line from a database shared by all EU countries. This would allow for saving time and money in the procedures of indirect refunds (submission of invoices issued abroad by the patient to the member state of affiliation) and would give the possibility of adequate on-going treatment in the member state of affiliation. Finally, the use of the HTA

(Health Technology Assessment) assessment system by ERN (European Reference Network) would involve a targeted technological development based on the type of structure, the type of medical treatment and the available financial resources.

Cooperation and continuous exchange of information at the European level, made possible by ERN, will improve the process of diagnosis and treatment of rare diseases, thus ensuring that the healthcare professionals, the patients and the entities responsible for the funding are informed about the possibility, granted by the regulations in effect, of the transfer of patients with rare diseases to other states, if the member state of affiliation cannot provide the necessary care.

Consequently, high specialisation and excellence is where a real opportunity for investment lies, as per the Directive 2011/24/EU, and it is on this high specialisation that the strategy of Italy needs to focus in order to promote excellence and attract citizens from other member states of the EU to our healthcare facilities. Therefore it is through the development of a system for the monitoring of one's own performance, sustained by valid and strict indicators of best practices, that it will be possible to reach the best quality in healthcare which then translates into greater well-being for the patients. In this way it will be possible to incentivise the individual structures to achieve excellence and more in general to improve the quality of the entire healthcare system of the country, making it more competitive with other European countries.

PAGINA BIANCA