supplements evaluated; today, the monthly publication enables consultation almost in real time, both by citizens and industry operators.
In the same period of time, work continued on a European and national level for novel foods regulated by Regulation EC n. 258/97. The Ministry is involved in the procedures, which conclude with a European-level authorisation, evaluating the requests submitted by operators both on a national level and through a different Member State; these procedures take an average of four years, with some having taken far longer.
In 2013, the draft new European Regulation was presented, which the Ministry will be monitoring actively in 2014.
Finally, as part of the continuous training of its staff and regional staff in charge of official controls, the Ministry promoted three training courses on dietary supplements and novel foods.

Keywords Dietary supplements, foods with vitamin and mineral supplements, minerals, new foods, novel foods, plants, vitamins

7.11. Results of food controls

The Integrated National Plan (PNI) and related annual report are key elements of a circular process aimed at ensuring a gradual, constant optimisation of the official controls system.
The Report to the INP shows the main results of the work carried out in 2012 on food and animal feed (both in terms of safety and quality-related aspects), health and well-being of animals, health of plants, by-products, zoonosis in man and the environment.
Contributions were made by the various administrations involved in the Integrated National Plan of official controls. As part of the ordinary controls of food safety, in 2012, the local health trust (ASL – SIAN and Veterinary Services) verified 319,650 operating units (plants and equipment in premises, structures and means of transport, etc.), making for 21.5% of the total. Irregularities were found in 50,780 units (15.9%). The highest percentage of breach were seen in the catering sector (25.9%) and the category of manufacturers and packagers (21.3%).
As concerns analytical activities, the public laboratories of the official control analysed 124,648 samples, of which 1,746 were found to be non-regulatory, with a percentage of non-conformities totalling 1.4%. The highest number of violations related to microbiological contaminations and, to a lesser extent, chemical. The same trend is also seen in the notifications of the EU rapid alert system for food and feed (RASFF). Microbiological contaminants included a high number of notifications of *Salmonella* and *Listeria monocytogenes*, with an increased number of reports of *Escherichia coli* and *Norovirus*. The most frequently notified chemical contaminants were residual phytodrugs and mycotoxins, followed by heavy metals and the migration of materials and objects intended for contact with foods (MOCA).
Continuing on from previous years, with a total of 534 reports (17%), Italy is the top Member State in terms of the number of reports submitted to the European Commission, thereby showing the intense controls carried out on national territory.

Keywords Animal feed, foods, Integrated National Plan, official controls, Rapid Alert System for Food and Feed (RASFF)

7.12. Public veterinary health audit systems

In 2012 and 2013, the audits by the competent authorities for food and veterinary safety, in accordance with Art. 4.6 of Regulation (EC) n. 882/2004 recorded important progress made in the organisation of the official control, also thanks to the intense training delivered. However, a situation remains with extreme differences seen in performance and a non-homogeneous level of organisation of the official control, with critical issues emerging, above all in the definition of documented procedures, in the suitability of controls according to a risk-based approach, the verification of the effectiveness of official controls and the management of non-conformities.
On a regional level, some of the involute reorganisation processes of the structures in charge of managing the sector, dictated by needs to limit public spending and the presence of an undersized organisation that is

often inadequate in terms of professional qualification, have worsened the problems of management and organisation of the official control. On 07 February 2013, the State-Regions Conference approved Agreement n. 46/CSR: "Guidelines for the function and improvement of official controls on food safety and veterinary health", with the aim of improving and standardising the delivery of these activities throughout national territory. As part of the veterinary evaluation and the assessment of food safety performed by the LEA Committee, a verification is performed of the function and official control activities of the Autonomous Regions and Provinces, by means of a set of indicators. In 2013, the indicators used for the evaluation of the previous year recorded a percentage "compliance" of 67% of the Autonomous Regions/ Provinces. Over the years, the trend of the evaluations has shown considerable improvement, starting from 53% of Regions passing the evaluation in 2008, to 83% in 2011.

Keywords Audit, information flows, LEAperformance indicators, State-Regions Agreement n. 46/CSR of 7 February 2013

7.13 The use of veterinary medicinal products: system of controls and pharmacovigilance reports

Pharmacovigilance is the set of controls aimed at monitoring, evaluating and improving the safety and efficacy of the veterinary medicinal product available on the market; the Ministry of Health manage this together with the regional pharmacovigilance centres, through a National Pharmacovigilance System (SNF). Under the scope of these activities, for 2012-2013 a respective number of 238 and 301 reports were made to the SNF in Italy, of suspected adverse events. Sixty inspections were carried out at the facilities in charge of producing the veterinary medicinal products, nine at the offices of the holders of the MAs and, with the help of the NAS (the Health-related Division of the Italian *Carabinieri* military police force), 42 samples of veterinary medicinal products were taken to check quality. As from 2002, moreover, the Ministry of Health has adopted a quality management system in compliance with the requirements of international standard UNI EN ISO 9001, in order to ensure an improvement in provisions and services provided. As part of this system, in order to monitor the level of satisfaction and improve communication with users, namely pharmaceutical companies in the veterinary sector, the following tools have been prepared: annual satisfaction questionnaires, a complaint sheet that can be downloaded from the Ministry website and a dedicated e-mail address for all user communications relating to quality of services (qualitavet@sanita.it). Finally, in 2012-2013, two Infodays were organised; these are congresses aimed at allowing for a comparison of notes with the stakeholders of the sector on the main problems of veterinary medicinal products in order to encourage growth and dialogue between the Ministry, companies and category associations.

Keywords Infoday, National Pharmacovigilance System, pharmacovigilance, Quality management system, Regional pharmacovigilance centres

7.14. Veterinary pharmacosurveillance and antibiotic resistance

The rational use of veterinary medicinal products guarantees the protection of public health, ensuring, amongst other aspects, a correct use of antibiotics. The improper use of veterinary medicinal products, and in particular of antibiotics in productive livestock, entails considerable risks to public health, due to the presence of pharmacological residues in animal-origin food and the spread of resistant micro organisms. Moreover, it also diffuses and develops a resistance to antibiotics in both animals and men, limiting their efficacy. In this regard, the ASL monitor farms and operators involved in the distribution and use of veterinary medicinal products, according to the minimum frequencies established, controlling the use of antibiotics. This system has been implemented with the establishment of the national pharmacosurveillance

unit. The national reference centre (CNR) for antibiotic-resistance is also active at the Experimental Zooprophylactic Institute of Lazio and Tuscany. In order to guarantee a responsible use of drugs in zootechnical productions and pets, the Ministry of Health has taken numerous initiatives, including special warnings on information sheets, the dissemination of brochures and the creation of web pages, the manual entitled "Biosafety and the correct, rational use of antibiotics in zootechny", Guidelines for the preparation, organisation and management of controls on the distribution and use of veterinary medicinal products", collaboration with associations of producers for the preparation of voluntary plans to reduce the use of antibiotics in zootechnical productions, the publication of antibiotic sales data in the veterinary sector and the development of a veterinary medicinal products traceability system. The action taken resulted in the recording of a 14% reduction in sales of medicinal products containing antibiotics in 2010-2011.

Keywords National pharmacosurveillance unit, National reference centre for antibiotic resistance

8. Health research in Italy

8.1. Health and biomedical research

Health research is fundamental in order to guarantee that healthcare keeps pace with scientific and technological progress and must be considered a valid investment.
Indeed, it is this that has determined the transformation of certain mortal diseases into curable diseases with a reduction in the suffering of people, but also in the costs to the SSN system. The Health Ministry, in line with this, finances translational research, that is, research that begins in the laboratory but which as a matter of course reaches the patient. This is research on behalf of people, not research for a general increase in knowledge and, therefore, it is aimed at meeting the health needs of the citizen (from health care to health).
The instrument of this policy is the Health Research Programme (HRP) (under article 12 bis, paragraph 3, Legislative Decree n. 229/1999) that defines, on a three-year basis, the research strategies and the corresponding allocation of resources, ensuring indispensable synergies between public and private research, as well as between national, European and extra-European research.
The health research programme is broken down into current research and research aimed and directed at identifying the priority objectives for the improvement of the health of the population, to encourage experimentation of the methods of operation, management and organisation of the health services and clinical practices, to improve integration of multiple professions, health care continuity and communication with citizens, as laid down by the provisions of articles 12 and 12 bis of the Legislative Decree 502/1992.
The Ministry's initiatives have, for some years, been directed at transparency in the allocation of financing through the use of objective criteria, made public and accessible to all those concerned. Only in this way is it possible to increase the efficiency, effectiveness and financial soundness of the SSN, while not losing sight of its humanization, since health is the primary asset of the individual citizen.

8.2. Research relating to HIV/AIDS and associated tumours

The National AIDS Research Programme, coordinated by the Directorate General of Research of the Ministry of Health, is organised into 4 macro areas: epidemiology; aetiology, pathogenesis and vaccine development; clinics and therapy; opportunistic infections.
The CNAIDS has launched a programme for the development of a vaccine against HIV/AIDS as a special project financed by the Ministry of Health for Italy and the Ministry of Foreign Affairs for South Africa. On the basis of the excellent safety and immunogenic results achieved with the Tat vaccine in phase I clinical trials, the phase II multicentre clinical trial (ISS T-002) has been carried out in Italy and a similar study launched in South Africa (ISS T-003), financed by the Ministry of Foreign Affairs in collaboration with the

Government of South Africa. In three Italian clinical sites, phase I trialling has begun of the preventive vaccine, based on the regulatory protein Tat and the structural protein Env, deletion of Region V2 (ISS P-002). In relation to infection from HIV/AIDS and associated tumours, CNAIDS has conducted preclinical and clinical trials on HIV protease inhibitors (HIV-PI). Preclinical and clinical trials aimed at evaluating the anti-tumour action of HIV-PI on the onset, progression and recurrence of CIN are at an advanced stage. The ISS, Drug Department, coordinates: the Network of Excellence on clinical research into HIV/AIDS in Europe (NEAT) for the conducting of clinical research and the dissemination of excellence through training programmes; the EARNEST study of the European programme EDCTP, with the aim of evaluating various different strategies for a second line of therapy in patients with HIV infection in countries with limited resources; the operational research project (CASA) with the goal of improving treatment for people with HIV infection and the main associated pathologies in Ethiopia; and the Italian participation in the ESTHER programme aimed at reducing the prevalence of HIV infected population and slowing disease progression. The Drug Department also runs the project for the "Prevention of maternal-foetal transmission of HIV infection" for the evaluation of the safety and efficacy of the new preventive strategy for the transmission from mother to child of HIV in countries with limited resources and the SMAC (Safe Milk for African Children) STUDY in collaboration with the DREAM programme of the Community of Sant'Egidio, in order to evaluate the safety and efficacy of an antiretroviral therapy administered to women during pregnancy and breast-feeding to prevent the mother-child transmission of HIV.

Keywords AIDS, anti-tumoral effects, antiretroviral therapy, HIV, HIV protease inhibitors, pharmacoresistance, pregnancy, Tat, vaccine

8.3. Veterinary health research

The Department of Public Veterinary Health, Food Safety and Collegial Bodies for the Protection of Health coordinates research in the ten Experimental Zooprophylactic Institutes, in order to obtain a standardisation of strategy and avoid a duplication of projects in the various themed areas: in thus doing, the aim is to develop the different research lines prepared on the basis of the needs of the NHS and thereby obtain operative instruments with which to face up to both routine analytical activities and any health emergency states. Special attention is paid to the dissemination of the results of this research carried out through all scientific communication channels. In 2013, three new national reference centres have been established.

As concerns European research, it is important to consider the new context in which the EU public veterinary health researchers are working, a virtual network place and coordination activities. The objective we set ourselves, as Ministry of Health and Department of Public Veterinary Health, in line with the EU Strategy for 2020, is to once again guide national research, science and innovation policies according to the challenges faced by our society, like climate change, the efficient use of resources and energy, health and demographic change. The Department represents the Ministry in three European coordinated research actions, ERA-Net, an experience that began with EMIDA, a specific ERA-Net on infectious diseases. Following this experience, the Commission financed a second coordination action, ANIHWA, in animal welfare and health, which was launched on 1 January 2012. Under the scope of these ERA-Nets, the Department has been able to take part in the Europe-wide coordination of three transnational research tenders. The Ministry of Health is also participating in the first coordination action financed by the EU on a global level, GLOBAL-Net in animal health (STARIDAZ "Global Strategic Alliances for the Coordination of Research on the Major Infectious Diseases of Animals and Zoonoses", February 2011 - March 2015).

8.4. Pharmaceutical health research

Clinical pharmaceutical research has been remodulated by Law n. 189/2012 and Min-

isterial Decree of 8 February 2013 on the reorganisation of Ethics Committees. The concept of the centralised competent authority with AIFA has been introduced; the number of Ethics committees operating at the health structures has been reduced. Documents will only be managed telematically and this will enable us to achieve maximum system operative efficiency.

In a parallel fashion, the European Commission is about to dismiss the new European Parliament and Council Regulation on the clinical trial of medicinal products for human use, which will abrogate Directive 2001/20/EC, which is still in force. This new rule, in addition to speeding up the technical time necessary for the activation of a new clinical trial, also involves major interaction of all competent authorities involved in the process and Ethics Committees. Everything will be focused on a "Single Portal" to be managed by the EMA in view of its previous experience with the European Clinical Trials Database (EudraCT).

Quality of the system, resources, information tools, monitoring of LEA, communication

1. Safety of care

1.1. Prevention of hospital infections

Although infections correlated to healthcare (ICH) have been known for more than a century, the political, economic and health and social services changes require appropriate prevention interventions for the new context. Since 2000, the Council of the European Union has recommended that Member States implement a national strategy for the prevention and control of infections associated with healthcare, along with strategies targeted at the prudent use of antimicrobial agents, creating or reinforcing surveillance systems and providing training for specialist healthcare personnel in the control of infections. At the national level, with an initial *ad hoc* project (Project INF-OSS, 2006-2008), protocols have been defined for the surveillance of surgical site infections (SSI) and intensive care infections, the feasibility has been assessed of a national surveillance system of SSIs, a national inquiry has been conducted on the status of control programmes and a document of recommendation on standard healthcare practices has been drawn up. The results of a prevalence study conducted in 29 countries, published by the ECDC in 2013, show that the most frequent infections in our country are respiratory, urinary and cutaneous in nature. Although significant advances have been made in the construction of surveillance systems of the ICHs at the national level and in the dissemination of safe practices, it is evidently necessary to better coordinate the activities in this regard, especially to ensure respect through the country for common, agreed standards.

Keywords Healthcare, ICH, infections

1.2. Surveillance of the antibiotic resistance phenomenon

Antibiotics are precious medicines that have contributed to combatting aetiological bacterial infectious diseases and enabled the development of modern medicine. At the European level, since 1998, recommendations have been put forward, including the reinforcement of the European surveillance networks of resistance to antibiotics and the creation of campaigns for the prudent use of antibiotics, and the European Commission has issued guideline documents in this regard. Italy has set up a national surveillance network of AMR, the data from which augments the European database (EARS-Net) each year and, starting from 2010, a dramatic increase has been observed in the resistance to carbapenems for *Klebsiella pneumoniae*. The phenomenon of AMR is more widespread in central and southern Italy, where a greater consumption of antibiotics has been observed compared to northern Italy.

The Health Ministry has promoted various initiatives of communication and information, aimed both at the general population and healthcare personnel, but it is necessary to continue the commitment to promote greater awareness of a more appropriate use of antibiotics.

Keywords AMR, antibiotics, antibiotic resistance

1.3. Sentinel events

In the healthcare sector, as with other complex systems, adverse incidents and events can occur which, with adequate and appropriate actions to prevent and remove the causal factors, can be controlled. From this perspective, the surveillance of the sentinel events (adverse events of particular gravity that cause death or serious harm to the patient) constitutes an important public health action and an indispensable instrument for the prevention of these eventualities and for the promotion of the safety of treatments. For this reason, the Health Ministry, among the numerous activities aimed at the quality of healthcare services, has begun the monitoring and analysis of

the sentinel events, with the aim of collecting data concerning their occurrence and to find out the causal factors in order to provide the Regions and healthcare agencies with a single method of surveillance and management on national territory to guarantee of the essential levels of healthcare (ELH). Starting in 2005, the monitoring of sentinel events was launched with an initial experimental phase, brought into full operation with the decree of 11 December 2009, published in the Official Gazette of 12 January 2010, by which , within the scope of the New Healthcare Information System, the Information System for the Monitoring of Healthcare Errors (SIMES) was set up, under the supervision of the National Monitoring Centre for the Monitoring of Sentinel Events (OsMES) at the General Directorate of Healthcare Planning and, starting from 2010, the monitoring of sentinel events is one of the assessment criteria for the monitoring of the effective distribution of the essential levels of healthcare (ELH). On the outcome of the monitoring activity, a report will periodically be drawn up; currently, the 5th Report has been produced giving the results of 6 years of operation (September 2005-December 2012), which reveals 1,918 notifications, of which 24.6% were correlated to falls by patients with 40% of the events reported occurring in hospital wards. Among the factors contributing to the occurrence of the events, the "lack, inadequacy or failure to observe the guidelines, recommendations, healthcare protocols and procedures" were especially indicated.

1.4. Recommendations

The need to provide practices and recommendations for safety that are acknowledged as effective is one of the pillars of the strategies for the management of clinical risk and the safety of patients. Therefore, within the scope of the interventions for the management of clinical risk and patient safety, the Health Ministry has provided a programme for the drawing up and dissemination of safety recommendations with the aim of providing effective instructions to contain the risks and reduce the probability of adverse events occurring. Within the scope of the programme, 16 recommendations were set forth concerning the main sentinel events envisaged in the monitoring protocol that constitute an instrument for improving the response capacity of healthcare facilities, encouraging the change of the system from the perspective of safety and promoting the assumption of responsibility by the operators.

One of the most significant, and at the same time, critical factors is the implementation of these practices and recommendations and the monitoring of the results achieved, as well as the assessment of factors of resistance or obstacles to their implementation. The commitment of the Ministry is therefore not only to update the recommendations and publish them again with respect to emerging issues, but also to carry out prompt verification of their correct interpretation at the local level. Therefore, starting in 2011, these documents have been subject to verification of their implementation at the regional level and therefore placed within the verifications of ELH (Essential Levels of Healthcare). A rising trend has been seen in the results, but the established objective of the complete implementation of the recommendations throughout national territory has not yet been reached.

In 2012, the Recommendation for the prevention of errors in treatment with antineoplastic medicines was drawn up, disseminated and subject to monitoring within the scope of the ELH (Essential Levels of Healthcare), arising from the recognition that errors correlated to chemotherapy are frequent, requiring suitable strategies in order to ensure appropriate therapeutic treatment that meets the safety requirements.

1.5. Safety in the operating theatre

Surgery is one of the strategic areas of the SSN, both due to the high volume and extreme complexity of the services. Data from the HDS (hospital discharge sheets) show there were more than 4 million discharges following surgical intervention in 2012, that is, 43.51% of the total acute services.

In all healthcare systems, surgery is the focus of particular attention and the application of appropriate procedures and instruments is directed towards this to ensure high quality

and safety levels. The international literature shows the effectiveness and sustainability of instruments such as the operating theatre checklist, demonstrating that its correct, systematic use is applicable in various contexts and is associated with a reduction in the mortality rate and post-operative complications. In addition to this primary goal, there are studies that demonstrate its usefulness in avoiding additional and unnecessary charges that impact on the system.

The Health Ministry, as part of the activities for patient safety, has launched a specific programme directed at safety in surgery, in adherence to the instructions of the OMS, identifying, among the basic elements, the use of the checklist.

The programme includes the drawing up and dissemination of recommendations, as well as an analysis of the financial component of sentinel events in the field of surgery, estimating, through methods developed at the international level, the costs linked to the extension of hospital stays in relation to the use of the checklist.

In addition, the application of the operating theatre checklist is verified through the ELH (Essential Levels of Healthcare) monitoring, from which it emerges that all the Regions have provided instructions for the adoption of a surgery checklist and that it is now in use in more than half the operational surgical units. These data show that, notwithstanding the evidence, adherence is not total and underlines the importance of continuous monitoring to assess the level of use and the factors obstructing this.

Finally, the application of the surgery checklist is the subject of an extended study of a sample of European healthcare facilities, provided as part of the activities of the European Union (EU) on patient safety (*Joint action–PASQ*) in which our country is also participating.

1.6. Quality and safety in the donation and transplant of organs, tissues and cells

The European Directive setting out guidelines for quality, safety and traceability (starting from Directive 2004/23/EC of 31 March 2004 and subsequent technical implementing Directives 2006/17/EC and 2006/86/EC and Directive 2010/53/EU) constitute an essential basis for the sharing of rules to improve quality and safety in the tissue, cell and organ transplant sector. The definition of common standards enables, including with formal agreements between States, the collaboration and operative interchange, as vehicles for the dissemination of good clinical practice and cooperation with countries whose health systems are less developed, also in line with the "Plan of action for the donation and transplant of organs – 2009/2015", with which, in 2008, the Commission indicated the strengthening of cooperation between Member States as being one of its objectives. In 2013, the contents of the decree incorporating Directive 2010/53/EU were defined, in accordance with Art. 1, paragraph 340 of Italian Law n. 228 of 24 December 2012 whereby the Commission Directive 2012/25/EU of 9 October 2012 is incorporated on the information procedures for the exchange between Member States of human organs for transplant and adapted to comply with the new provisions of the Transplant Information System pursuant to art. 7 of Italian Law n. 91 of 1 April 1999.

Patient safety, a national and European health policy priority, is particularly important in donations and transplants due to the complexity and ethical implications distinguishing these highly-specialised activities.

The national transplant network has resulted in national and international initiatives aimed at ensuring safe transplant of organs, tissues and cells through specific projects aimed at improving quality and safety in the donation-transplant process and the system for reporting events and severe adverse reactions.

1.7. The LASA drugs

In 2008, the General Directorate of Healthcare Planning of the Health Ministry launched the project "LASA Medicines and Patient Safety", the aim of which is the prevention of errors in treatment with the so-called Look-Alike/Sound-Alike (LASA) medicines, the term used to indicated medicines that appear interchangeable due to their graphical and/or phonetic similarities. The Health Ministry has made available a specific section on

its website and an email address dedicate to receiving all the information with regard to the use of LASAs. The notifications received have enabled a list of medicines to be drawn up, updated annually, based on agreed criteria, including the frequency of notifications and the exchange of equivalent, oncological medicines. The Health Ministry, in consideration of the importance of the problem to patient safety, has drawn up Recommendation n. 12 "Prevention of errors in treatment with Look-Alike/Sound-Alike medicines", directed at all professionals who work in healthcare agencies, community pharmacies, general medicine studies and family paediatrics, as well as the pharmaceutical companies. Within the scope of the monitoring programme of the implementation of the recommendations, the Ministry and AgeNaS have arranged the monitoring of the Ministerial Recommendation in order to assess the degree of its implementation by health facilities, detecting any problems and identifying the consequent actions. This verification activity has revealed difficulties in the application of the recommendation, especially at the territorial level. As a consequence, in order to support pharmacists, doctors and nurses involved in various ways in the management of pharmacological treatments in the territory, appropriate guidelines have been drawn up, also in the light of the new services distributed by community pharmacies. This project has brought a positive response and the commitment of pharmaceutical companies to tackle the confusing elements by adopting colour codes and specific measures that, however, still require delicate and agreed actions of uniformity and systematic discussion between Institutions and companies to resolve the problem.

1.8. Training on clinical governance and patient safety

The quality and safety of clinical practice and healthcare processes are based on the competence of the individual operator and the clinical teams, therefore basic training and continuous training are an effective and essential lever for improving the quality and safety of the healthcare system.

The Health Ministry, from the perspective of increasing the expertise of the operators in terms of the quality and safety of the treatments, in accordance with the principles of Clinical Governance, has for some time placed training at the centre of its initiatives as a strategic factor in attaining the objectives set by national planning, implementing a training programme for clinical governance, extended to all healthcare professionals and created in collaboration with the doctors association, *Federazione Nazionale degli Ordini dei Medici Chirurghi e degli Odontoiatri* (FNOMCeO) and the nurses', healthcare assistants and childminders' association, *Federazione Nazionale Collegi Infermieri professionali, Assistenti sanitari, Vigilatrici d'infanzia* (IPASVI).

The programme envisages the drawing up of technical documents and the provision of ECM accredited training courses, distributed through the FAD and residential methods. The issues identified for the purposes of the extensive training of all healthcare operators are the clinical audit, patient and operator safety and appropriateness, with the aim of:

promoting the systematic, continuous use of the clinical audit, acknowledged as an integral part of the professional activity and an instrument aimed at improving quality;

reinforcing awareness of certain issues concerning patient and operator safety, such as legal aspects and the handling of disputes, the risk of infection and the prevention of infections related to treatment, the prevention of adverse advents in pharmacological therapy, the putting together and management of working groups, organisational wellbeing and violence against operators:

broadening awareness on the issue of appropriateness, as regards the conceptual framework and the operational definitions and interventions.

1.9. Safety of drugs, pharmacovigilance and health protection

2012 was a very important year for European pharmacovigilance. In actual fact, new provisions of law governing medicinal safety came into force, with further amendments approved in 2013, which basically modi-

fied the whole pharmacovigilance system. These changes aim to strengthen the capacity to identify alarm signals. One high-impact change on pharmacovigilance activities is clearly that of defining ADRs (Adverse Drug Reactions), which has resulted in an overall increase in the number of reports of suspected ADRs for drugs and vaccines.
In 2013, the National Pharmacovigilance Network recorded 40,957 reports of suspected ADRs, equivalent to a report rate of 690 cases per million inhabitants – a higher result than that of other European countries with a strong tradition of pharmacovigilance and than the value defined by the WHO as the gold standard for an efficient pharmacovigilance system able to promptly identify any alarm signals (300 reports per million inhabitants).
Approximately one third (31%) of the reports were defined as serious, to a large extent because they resulted in a hospital stay or prolonged hospitalisation. Hospital doctors were the main source of reports (52%), followed by pharmacists (16%), specialists (9%) and GPs (7%).
Most pharmacovigilance reports concerns antimicrobial drugs (24%), anti-neoplastic drugs (18%), central nervous system drugs (14%), blood (12%) and cardiovascular system (9%).
The most frequently reported problems were skin-related (19%) followed by issues relating to general condition (14%), gastrointestinal issues (14%) and problems with the nervous system (10%). The other organisations and systems were involved with a percentage of less than 10%.

Keywords Adverse drug reaction (ADR), adverse reactions, National Pharmacovigilance Network, pharmacovigilance, reports

1.10. The quality of pharmaceutical products and management of deficiencies

AIFA carries out its post-marketing supervision of the quality of medicinal products in two ways: following the reporting of potential defects and with an annual control programme.
Each time defects are found in the quality of medicinal products marketed, national and/or international precautionary measures are taken. These defects may emerge due to spontaneous reporting or following scheduled controls on medicinal products present in the distribution channel.
In all cases where the defect in quality found may entail a serious risk to health, including with regards to medicinal products marketed abroad, the AIFA activates an International Alert on the information exchange network in the production and quality sector (the "Rapid Alert System" or RAS).
The medicinal product Annual Control Programme is an essential tool by which to guarantee that the drugs marketed comply exactly with the quality specifications of the authorisation procedures and is carried out by means of sampling and the analysis of medicinal products in the distribution channel with the collaboration of the NAS and ISS.
To monitor the safety of vaccines and blood-derivatives, the AIFA ensures the technical/administrative management of the State Control Certificates, including those issued by other European Community Member States, in accordance with European guidelines.
The AIFA may order the revocation of the MA for official reasons and to protect public health, if the conditions are met pursuant to art. 141 of Italian Legislative Decree n. 219/2006. Revocation may also be granted upon renunciation by the owner of the MA, having verified that this does not result in a market deficiency.
The monitoring and management of drug deficiencies comes as part of the activities of the AIFA, which activates a series of initiatives in order to ensure a ready substitute availability of the medicinal product lacking.
Said activities are described and reported.

1.11. The counterfeiting of medical devices and other products with an impact on health

In 2012-2013, Italy reinforced its action against pharmaceutical crime and extended its commitment to include new types of crimes.
Sectors of activities:

- legal-legislative scope: support with the process of adjustment to the provisions of

Directive 2011/62/EU and national legislation;

- networking: extension of collaborations in the university sector, through the stipulation of memorandums with Rome "La Sapienza" University and Trento University, together with the reinforcing of the cooperation with other regulatory agencies, which resulted in the development of two projects financed by the EU Commission, named FAKECARE and FAKESHARE;
- controls: structuring and intensification of the monitoring work, as shown by the adhesion to the international operation PANGEA and the organisation of two operations on national territory for the control of products in the non-pharmaceutical sale channels; in turn, these have resulted in the identification of false supplements, in actual fact containing pharmacologically active ingredients and at times prohibited substances;
- e-pharmacies: established of the Service Conference to investigate and assess reports on e-pharmacies, involving, in addition to AIFA, the Ministry of Health, the Ministry of Economic Development, the NAS, the Antitrust Authority and the IT Register (CNR). The joint activity of the various different Italian administrations has resulted in the blocking of numerous illegal websites;
- drug thefts: development of a pilot project together with the NAS, Farmindustria and ASSO-RAM, with the support of the Ministry of Health, aiming to collect and structure data on the phenomenon, through a web platform managed by AIFA.

All these different activities pursued have strengthened and extended the strategies to fight pharmaceutical crime.

1.12. Medicinal products: controlling production, protecting health

The institutional duties of AIFA include the authorisation and quality control of the production of drugs produced and marketed in Italy. This activity is regulated by Italian Legislative Decree n. 219/2006. More specifically, the Agency is responsible for authorising and monitoring the production of medicinal products and pharmacologically-active raw materials produced in Italy.

Compliance with production quality criteria is assured through inspections carried out once every two or three years.

Controls are carried out on all types of medicinal products: large and small volume sterile liquids, solids and semi-solids, pressurised preparations, capsules, tablets, homoeopathic medicines, biological medicinal products, medicines for cell therapy, immunological products, blood derivatives, vaccines, radio drugs, etc. The production is also controlled of all types of raw materials: antibiotics, hormones, animal tissue extracts, plant extracts, synthesis products and biotech production.

There were 85 inspections for API (active pharmaceutical ingredient) in 2012 and 63 in 2013, whilst inspections for medicinal products numbered 179 in 2012 and 165 in 2013. There were also 24 foreign inspections (medicinal products and APIs).

In Italy, 270 facilities operate producing medicinal products, 197 facilities produce medicinal gases and 141 facilities produce active pharmaceutical ingredients (APIs).

Through its control of pharmaceutical productions carried out by the Inspections and Certifications Area (inspection audits, evaluation of corrective action taken by the companies, evaluation of documents on changes of facilities, etc.), AIFA guarantees one of the key aspects of public health protection.

1.13. Inspections

In the healthcare sector, adverse events can occur which, with adequate and appropriate actions to prevent and remove the causal factors, can be controlled. The attainment of these objective covers many aspects and, to these, the State, Regions and Autonomous Provinces, as well as all healthcare operators, must contribute. The audits and inspections of SSN facilities carried out by the Health Ministry in the case of adverse events of particular severity must be seen in this light, with the aim of acknowledging the system's vulnerabilities, the factors that underlie the events and the respective improvement measures.

The analysis of the causes/factors correlated to the occurrence of adverse events and the development of effective solution for safety are laid down by the recommendation on safety of treatments issued by the Council of the European Union in June 2009. In Italy, the State-Regions Understanding of March 2008 defined priority actions for safety and, among these, were the monitoring and analysis of the sentinel events. The Ministry also has the role of guarantor of the effective distribution of the Essential Levels of Healthcare (ELH) and those of supervisory oversight that it may carry out through its offices and/or the NAS, also required to respond to the dynamics of European integration.

The assessment of any deficiencies in the quality and safety of treatments is carried out in accordance with the methods indicated in the literature and by experienced, competent personnel and in compliance with the prerequisites laid down by the Directive of the Civil Service Department of July 2002 for the inspections.

The purpose of the inspections is to define actions and support for the facilities subject to the verification in support of the policies of improvement.

Since the assessment activities conducted with the appropriate instruments and methodologies are an opportunity to introduces changes for the safety, appropriateness and quality of treatment, the Ministry and Regions, in planning for safety, must provide structured investigations and inspection activities through appropriately established centres that are multidisciplinary and possess specific expertise on the methodologies and instruments for the management of clinical risk.

1.14. Scientific advice

Regulatory scientific advice is now consolidated and results are clearly evident. In recent years, HTA Agencies have also begun providing scientific advice (also referred to as "early dialogue"), with a view to clarifying the requirements needed to obtain a correct HTA evaluation.

AIFA has been involved in multi-dimensional and multinational scientific advice initiatives since its very beginning. At the same time, in 2011 it began formalising its own national advice activities, also in respect of HTA aspects.

National scientific advice comes under the third party services offered by the Agency as part of its appointment. The scientific advice provided by AIFA can cover various different aspects relating to the development of a medicinal product, with specific reference to the parts of a file relating to quality, non-clinical aspects, clinical and technological aspects for all medicinal products for human use. The scientific advice procedure may be requested to support the interpretation and application of legislation and/or specific guidelines, including aspects connected with the production and development of Good Manufacturing Practices (GMPs). This type of scientific advice regards both finished medicinal products and pharmaceutical substances in general and provides strategic support to the sector in the development of new plants or production lines. In 2012, ten scientific advice procedures were completed, of which one relating to GMP aspects. In 2013, twenty-four scientific advice procedures were completed, of which three relating to GMP aspects and four to HTA.

Keywords Early dialogue, Health Technology Assessment (HTA), scientific advice

1.15. The counterfeiting of medical devices and other products with an impact on health

All counterfeit or illegal goods are a potential hazard to the health of society since they are not subject to any controls, but when the counterfeiting concerns medical devices, *in vitro* medical-diagnostic devices, biocides, medical-surgical aids and other products with direct and indirect impact on health, the problem becomes even more serious and demands particular attention by the legislature. Perfecting a strategy to combat counterfeiting is particular urgent in the cases of medical devices and *in vitro* medical-diagnostic devices, given the trend is on the rise.

As with medicines, it is particularly critical to objectively assess whether a device suspected of being counterfeit is in reality a device that does not comply with the prerequisites laid

down by the respective directives. The diversity of medical devices and the lack of an authorisation process make the monitoring of the flow of such devices, in terms of counterfeiting and illegality, critical. A specific, targeted strategy is therefore necessary. Currently, in the absence of a codified procedure within a regulatory framework, reports of counterfeiting are received thanks to collaboration between Member States. The defence strategy currently proposed at the European and international levels is an integrated strategy that provides a system of tracking the transactions.

Keywords Counterfeiting, medical devices, *in vitro* medical-diagnostic devices

2. Governance and development of human resources

2.1. The National Health Service staff

The term "staff of the NHS" is used in its strictest sense to refer to employees of the ASL (local structures and hospitals), of hospitals, university hospitals, public IRCCSs (Scientific Institutes for Research, Hospitalisation and Healthcare) and staff employed with ESTAV Tuscany, ISPO, ARES Lazio and ARES Lombardy. The information in relation to this staff can be obtained from the annual accounts, the census run by the IGOP – State General Accountancy and the relevant flows can be accessed using the NSIS information system.

As concerns 2011, the amount of staff employed on permanent contracts with the above structures totalled 665,031, of whom more than 70% are healthcare staff (managers and sector). Again for these entities, 34,125 staff are hired on "flexible" employment contracts, which include fixed-term, work-training contracts, socially-useful works (SUW), temporary work and remote work. Finally, the total number of staff working for the NHS must also include the 16,836 members of university staff who, despite not being employed by the NHS do serve and provide service and assistance at NHS structures. In short, the NHS entities have a total of 715,992 members of staff.

Thanks to the availability and complementary nature of the information obtained from the different official data sources, a complete overview can be traced of the professional figures operating in Italy, namely professionals operating on the whole of the Italian health system and not only the (public) NHS. It can therefore be declared that, as concerns 2011, the following work in the Italian health system:

- 243,855 doctors, of whom 51% operating on the NHS, 33% NHS "authorised" doctors and 16% working in the public structures and private care homes (authorised and otherwise);
- 332,857 nursing staff, of whom approximately 86% on the NHS;
- 49,555 rehabilitation staff, of whom 43% working at the NHS structures, approximately 41% with rehabilitation centres or institutes (pursuant to Art. 26 of Italian Law n. 833/197) and 16% in the public structures and private care homes;
- 45,285 members of technical-health staff, of whom 83% operate at NHS structures;
- 10,894 members of staff assigned to monitoring and inspection duties, operating almost exclusively (96%) in the NHS entities.

Only as concerns NHS employed staff, the information given in the annual accounts allow further, interesting data to be gleaned.

The average age of NHS staff is 47.3 years old.

There are 109,170 doctors operating in the NHS structures, equating to 1.84 doctors per 1,000 inhabitants and nursing staff (nurses, paediatric nurses and obstetricians) number 276,862, making for 4.46 nurses per 1,000 inhabitants: the ensuing ratio is 2.43 nurses per doctor.

Keywords fixed-term, flexible work, medical directors, members of staff, National Health Service (NHS), nurses, obstetricians, paediatric nurses, permanent contract

2.2. Health staff programming: the European joint action

To stimulate growth and employment, Europe has identified seven priority initiatives, under the scope of which the European and

national administrations are called to coordinate efforts, in order that they should be as effective as possible.
The "New skills and jobs" agenda is one of these and, with it, the European Commission seeks to help the EU achieve, by the end of 2020, the goal established for employment, in terms of improving the quality and conditions of work, creating new jobs and developing skills.
It is under this scope that the Action Plan for the EU Health Workforce falls, whereby the European Commission has proposed a set of joint actions aimed at supporting Member States in facing up to these challenges.
The first of the actions included in the Action plan, is the "EU Joint action on health workforce planning and forecasting", the aim of which is to create a collaboration platform between European States, which will enable a better management of the lack of healthcare professionals in Europe forecast for the coming years (approximately one million healthcare professionals in 2020).
The Joint Action that proposes exchanging the good practices for the development of methods for forecasting needs for healthcare staff and improving the quality and dissemination of data on the workforce in the health sector, was launched in April 2013 and is scheduled to run for three years.
The project is organised into seven work packages, each guided by a team leader and consisting of institutions from the various countries and stakeholders, who are partners to the actual work package.
Work package 5 (WP5), the "Exchange of good practices in planning and forecasting methodologies" has Italy as its team leader and it is the Directorate General of healthcare professions and human resources in the NHS of this Ministry that guides the working party, in a partnership with AgeNaS. The aim of WP5 is to develop a platform aimed at assuring the sharing and exchange, between Member States, of good practices and forecasting methods, in order to promptly define the need for healthcare staff.
The working party guided by Italy consists of 32 institutional subjects, including Ministries, Associations and Federations of professionals, International organisations (OECD and WHO) and universities from 18 different European countries.
The first few months saw a great many national and international workshops and the presentation of the "minimum planning data requirement", the first "product" of the WP5, containing the definition of the set of indicators for the construction of a healthcare staff forecasting model.
The Joint Action also brings great added value within Italy to the planning and defining of needs, as the group also includes the Italian Regions (currently seven), which are called to jointly reflect "in a Community scenario" on the methods used by the various countries to forecast staff, exploiting the information exchange platform on the best practices currently used.
The final product of the WP5 should be the experimenting of a planning model, to be carried out, not only in a partner country (candidate country: Portugal), but also in the Autonomous Regions/Provinces of Italy declaring willing to conduct the trial.

Keywords Demand for healthcare staff, forecasting, good practices, health workforce, Joint Action, New skills and jobs, planning, work package 5 (WP5)

2.3. Professional operation and training of healthcare professions

After a lengthy comparison of notes, that began in 2012, by the professional and trade union representatives concerned, procedures were launched for the approval of the draft State-Regions Agreement on the "Redefinition, implementation and investigation of skills and responsibilities of nurses and paediatric nurses".
The initial doubts expressed by the doctor trade unions were overcome with the current proposal on which all trade unions agreed that "nurses and other healthcare professions, under the scope of the responsibilities already outlined by the specific professional profiles of reference, are guaranteed assistance and this is why the professional evolution towards advanced and specialised skills is now necessary and can no longer be deferred."

The draft Agreement currently being sent to the State-Regions Conference is based on the following grounds.
In the last twenty years, the healthcare professions of nurses, technicians, rehabilitation, prevention and obstetrics, by virtue of the sector legislation, have undergone a major evolution in terms of their order and training; this innovation has meant that the majority of the staff in the health segment now consists of university graduates and specialised graduates trained in the same university faculty of medicine and surgery.
The consolidation of this phenomenon and the provision for a physiological downsizing of the active presence of doctors in the NHS, which is still high as compared with the average of EU States, has entailed the need to revise the skills of these health professions.
The Ministry of Health has therefore established a technical round table with the regional councillors for health, in order to verify the current skills of the health professionals, in view of the university training development and the positive experiences already in place in some Regions, the consolidated European and non-European experience and the positive approval of operators, doctors and nurses, administrators and, above all, citizens.
The proposal prepared, which had involved vast consultation with professional and trade union representatives of all healthcare professions, including the medical profession, reviews the ratio of medical profession and nursing profession.

Keywords Healthcare professions, nurses' responsibilities and skills

2.4. Continuous training in medicine

Within the varied scenario covering the continuous training of healthcare staff, literature highlights the validity of interactive teaching approaches, providing for maximum involvement and acceptance of responsibility by participants. Already from 1987, the ISS has upheld this perspective, adopting an active training method referred to as "Problem Based Learning" (PBL). In 2004, the ISS also launched e-learning experimental events, inspired by the principles of PBL, using open source web platforms to develop different levels of interaction with participants. Remote training courses with high levels of participant interaction and/or with assistants/experts, enable PBL to be reproduced faithfully, facilitating the networking of practices and knowledge between the various professional figures and, therefore, ensuring greater training effectiveness.

Keywords Andragogic methods, continuous training, interactive teaching, PBL, public health, remote training

2.5. The new directive on the recognition of professional qualifications

Directive 2005/36/EC on the recognition of professional qualifications already regulated the circulation of workers and the use of professionals from all Member States, but the European Parliament, with its Directive 2013/55/EU has intervened further to simplify certain aspects of the previous Directive; Member States have until 18 January 2016 to ensure compliance.
The tendency is to consolidate a system of mutual recognition between States of the professional qualifications, to ensure clarification and standardisation of the study path required to achieve such, to strengthen thè domestic market and promote the free circulation of professionals; the European professional card is also introduced, excluding legal professions which are instead regulated by Directives 77/249/EEC and 98/5/EC.
To ensure the correct, quick issue of the card, the IMI (International Market Information) should be used. This multilingual information tool guarantees rapid cooperation between Member States and was created in connection with the obligations deriving from Directive 2005/36/EC in relation to the recognition of professional qualifications, before being extended under Directive 2006/123/EC.
The many focus points of Directive 2013/55/EU include the encouraging of mobility of specialising doctors, with aspects dedicated to the nursing and obstetrics professions. It highlights the fact that the European Qualification Frameworks (EQFs) also include specialisations that for now to do not benefit

from automatic recognition and trusts that a high level of protection of public health and patient safety is always ensured.
The minimum training requirements of the sector professions (doctor, nurse, dentist, veterinary surgeon, obstetrician and pharmacist) have also been revised in terms of knowledge and ability and ECTS (European Credit Transfer and Accumulation System) credits have also been considered, along with hours of study; for example, the minimum training for a doctor has gone from 6 to 5 years, equal to at least 5,500 hours, which can also be spent on ECTS credits; the "European Qualification Framework" then enables the automatic recognition of professions included in that document, which the European Commission will be preparing with the Member States.
The specific alert mechanism for healthcare professions, the transformation of the current national contact points in citizen treatment centres with possibility of physical access and the notification procedure by each Member State of the issue of qualifications for automatic recognition through the IMI system, should all be stressed.

Keywords Directive 2013/55/EU, International Market Information (IMI), professional training, recognition of professional qualifications

2.6. Training routes of Veterinary Public Health and Food Safety

Given the great sensitivity and attention paid by the media and public opinion to matters of Food Safety and Veterinary Public Health, great responsibility therefore ensues for staff involved in assuring that the entire production chain, from the primary sector (farming, cultivation, etc.) to the product presented on our tables, is healthy and safe.
Considering the continuous changes in food habits or the repercussions that climate change or the disappearance, in many senses, of geographic limits and the improvement of trade relations may have on the dissemination of diseases or potentially unhealthy, unsafe foods, the strategic importance of continuous training appears very clear indeed.
The Ministry of Health has been identified as amongst those responsible for the training of staff involved in Animal Health and Food Safety controls. As the Central Competent Authority, the Ministry acts on two levels: national and European.
On a national level, the Ministry of Health develops its own Training Plan, created on the basis of specific needs detected from specific controls organised by the Ministry on the territory, or by the European Commission with regards to the Ministry and, consequently, on the system of controls throughout national territory. The annual training plan that ensues targets staff of the Regions, the NHS and the Ministry itself; its main aim is to ensure suitable, standardised controls throughout national territory. This is why particular attention is paid to ensuring that courses are practical and applicable, seeking to adapt the best teaching techniques to suit an audience of professional adults.
Alongside, and complementary to the national training, we have the teaching project of the European Commission – DG SANCO, referred to as "Better Training for Safer Food" and aimed at staff involved in the official controls in Food Safety and Veterinary Public Health in Member States. The Ministry of Health has been identified as the National Contact Point, i.e. between the European Commission, the national Competent Authorities and the organisers of courses.
One of the aspects most pointed out by participants is the cultural exchange that takes place between those from different countries of the EU and some third party countries. This comparison of ideas is, in fact, always seen by those concerned as a great opportunity for professional enrichment.
Thanks to the application of evaluation methods and direct confrontation with all parties involved in the process, it would appear clear that the training activities of the Ministry of Health, in terms of Food Safety and Animal Welfare, is, over the years, striving to come into line as far as possible with national and international needs, with a view to acquiring and supplying the territory with a broad overview of the system of controls aimed at guaranteeing Public Health and coming with-