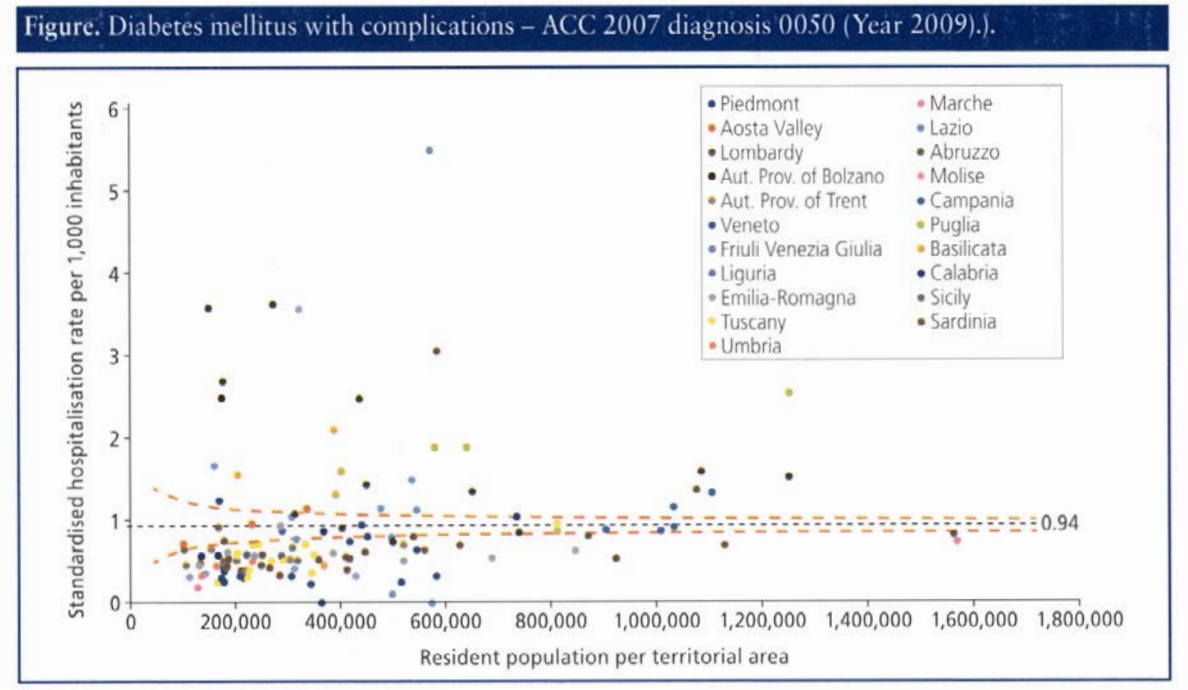

7.8. Appropriateness and guidelines in oncological diseases

Defining criteria of appropriateness in oncology and hemaeto-oncology and providing common guidelines on such criteria lie at the core of achieving consistent healthcare across Italy.

As a result, this approach will lead to better standards of care and better and more rational use of the resources available, as well as comprehensively lower healthcare expenses for superficial diagnostic and therapeutic services. A balance must be struck between innovation and results within a scientifically-validated context whereby it is possible to offer new technologies only to those who can truly benefit from them.

To achieve regular and coherent standards of care it is necessary to define criteria of appropriateness for diagnosis, staging, therapeutic strategy, the approach according to stage and follow-up procedure so that a global view of patient management by each pathology can be obtained and all citizens can receive the "best" care given their clinical situation and not "all" in an acritical manner.

To reach this goal, we must search for a multidisciplinary approach that involves all the professional figures, i.e. general practitioners, specialists in radiology/nuclear clinicians, pathologists, surgeons, medical oncologists, radiotherapists and pain and palliative therapists, in diagnostic and therapeutic decisions.

By identifying criteria of appropriateness we should also be able to narrow, and possibly close, the gap among the various Regions of Italy and among the various areas within the Regions themselves.

This process should be in accord with the National Oncological Plan that includes "full management" of oncology patients by the National Health System and the ever increasing "shift" of patient care from the hospital to the outpatient surgery and to home care.

Criteria of appropriateness must be established for all oncological and hemaeto-oncological diseases. The Ministry of Health Document no. 3 "Diagnostic and therapeutic appropriateness in oncology" serves as a model for developing subsequent flowcharts through the cooperation of "scientifically-recognised" experts in the various pathologies and through a truly multidisciplinary approach.

The objective should be to "build" diagnostic-therapeutic guidelines for the vari-

ous entities that, on the one side, take into account the resources available and, on the other side, "obligate" doctors to follow them in terms of the indication and timing of diagnostic, stadiation and therapeutic procedures.
Obviously, doctors must be free to decide autonomously, and their decisions might not comply with the flow-chart or diagnostic-therapeutic guidelines. In this case, the reasons underpinning the doctor's decision must be clearly illustrated.
Pathology networks play a key role in this process and have already been implemented in various regions throughout Italy. Their advantages are clear not only in terms of providing consistent care and reducing wastefulness, but also in terms of creating Centres of Excellence or Comprehensive Cancer Centres able to care for patients with specific pathologies, for example, rare tumours, or with specific clinical conditions, such as patients with multimorbidity.

7.9. Appropriateness and guidelines in cardiovascular diseases

Appropriateness of care to cardiovascular patients has been the subject of specific analysis by a scientific work group established at the Ministry of Health. The final document has provided the elements needed to define appropriate standards for the functional structure and organisation of care provided to cardiovascular patients, indicating the necessary procedures and indicators for accreditation. The key model is the integrated network of services and user identification to be created by achieving maximum operational and functional cooperation among all structures interested in the diagnosis, therapy and prevention of cardiovascular diseases so that patients may have an overall assessment of the disease and so that a diagnostic and therapeutic approach that is not confined within strict disciplines can be identified. One such model is the Hub & Spoke model based on a series of key elements, such as geographical reach, level of care of the structures, development of care protocols.
The goal of the programming is to integrate the various phases for promoting cardiovascular health within departmental organisations, providing citizens with points of access to adequate systems and assuring the efficacy and comprehensiveness of the care pathways and the continuum of care. The programming defines the functions, professional skills required, pathways for acute patients, the operational and instrumental standards and the organisation of the various functional components that make up the integrated network of services for the care of cardiovascular patients. This integrated network comprises the acute cardiopathic patient network, the cardiology emergency network, which also identifies pathways for acute patients, the network for chronic cardiopathic patients with integration between hospital and community, the post-acute rehabilitation network, the secondary long-term prevention network and the paediatric cardiology network.
In terms of cardiovascular surgery, the objective and responsibility of this branch of medicine is to manage cardiopathic patients requiring surgical treatment in both acute and chronic phases and to develop diagnostic and treatment pathways for these patients together with Cardiology. Within this context, the Centres for Cardiovascular Surgery play a specific role in terms of both the emergency cardiology network and the chronic cardiopathic network. For cardiovascular surgery, the Centre identifies the pathologies for which hospital stays are appropriate, the procedural requirements, volumes of activity, estimates of demand and organisation and optimisation of supply.
The Centre also establishes the criteria of appropriateness of Cardio-TC and Cardio-RM, as well as the features of the vascular surgery and interventional radiology structures and the care pathways and structural requirements for cerebrovascular patients.

7.10. Assessing and monitoring the quality of care and performance of health systems

The quality of the healthcare system stems from a multi-dimensional approach aimed at constantly improving six areas: accessi-

bility, efficacy, effectiveness, fairness, safety, acceptability/patient-focus.

By assessing performance, quality can be monitored and/or assessed in terms of reached target goals.

At national level, the monitoring system of Essential Levels of Care (LEA) stands as an important and fundamental structured system of multi-dimensional assessment and as a benchmark for developing instruments and methodologies aimed at making the assessment of the centralised guarantee and protection system more efficacious.

Also at national level, the structured systems for assessing performance already implemented on national data are:

- Performance assessment of Regional Health Services;
- National Outcome Programme.

The "National Outcome Programme (PNE-2) – Assessment of the outcomes of tumour care and chronic pathologies in primary care" represents the development of a pathway launched with the project Mattone no. 8 – Misura dell'Outcome aimed at comparatively and systematically measuring the outcomes of health interventions at provider (production) level and at population (customer) level. The recommendations and results emerged from the "Progetto Mattoni del SSN - Misura dell'Outcome" led to the development of:

- in 2008, the PROGRESSI (PROGRamma ESiti) programme, which intended to further develop the methodology for the production of outcome estimates at national level and the instruments necessary for outcome assessment;
- in 2009, the "Performance evaluation: evaluation programme on the decisions and activities of healthcare facilities - PNE1" programme financed with funds from the Committee for Medical Collaboration (CCM).

On a mandate from the Ministry of Health and the regional governments, Italy's National Agency for Regional Health Services (AgeNaS) is responsible for developing a system to monitor health service quality. Based on literature analysis and international and national experiences, a macro-model founded on four axes of protection and guarantee of the National Health Service was shared:

- health (health protection and level of care guarantee) ⇒ efficacy;
- resources (good use of economic-financial resources guarantee) ⇒ efficiency;
- rights (customer satisfaction and citizen participation guarantee) ⇒ empowerment;
- values (fighting inequality in healthcare) ⇒ fairness.

On the basis of these axes, a total of 237 indicators were chosen to be submitted to scientific companies and professional associations for sharing. Furthermore, citizens' associations will be directly involved in the indicators concerning the empowerment criterion. All indicators, analysis methods and data dictionary models will be submitted to the regional authorities for approval before being published on the Ministry of Health and AgeNaS websites.

The following evaluation systems are currently adopted at regional level:

- multidimensional evaluation structured systems;
- mixed systems supporting one or more levels of care or of specific dimensions of care quality;
- systems directly linked to Realignment Plans.

In the Regions subject to Realignment Plans, indicators linked to rehabilitation operations and Essential Levels of Care (LEA) requirements are the main point of reference of every evaluation procedure.

As far as involving stakeholders in the evaluation, the Regions appear to clearly favour directive levels and professional networks, while cross-sectional sectors and citizens are only marginally involved.

The variety of performance evaluation systems currently available at regional level in Italy is an important resource of the healthcare system that, despite the rapid evolution and precarious stability of certain solutions, makes it possible to seize the best opportunities fairly and transparently only through further coordinated action. The "stewardship" function promoted by the

WHO is a specific responsibility of the Italian national health service through which to guarantee transparency and accountability at all levels by strengthening monitoring activities, publishing outcomes and divulging best practices at national level.

7.11. Customer satisfaction with the National Health Service

There is a strong link between service quality and user satisfaction. In terms of healthcare, customer satisfaction should be one of the main signs that objectives have been achieved.

The investigation conducted by the Ministry of Health through the Centre for Social Investment Studies (Censis) and presented in 2010 on the expectations, opinions and evaluations of Italians with respect to healthcare provided new data on perceived quality and the level of satisfaction of citizens. An analysis of the data clearly reveals three levels of satisfaction. The majority of Italians feel that they have a very positive relationship with the national health service with regard to first access services (primary care general practitioners and paediatricians, local pharmacies). Critical areas concern hospitalisation, in particular concerning the disadvantage of southern Regions in terms of numbers of hospitals and emergency rooms and central regions as far as waiting time for hospital and emergency services. Decidedly more critical were the evaluations regarding the new local services, and, specifically, the areas of social-health integration and chronic illness care.

While on average 3 out of 4 Italians believe that cases of malpractice are rare, it should be noted that the percentage falls to 58.3% in southern Italy and the Islands and is around 90% in the North.

The feedback obtained from citizens who have been hospitalised in the last year shows that the vast majority of patients are essentially satisfied with the quality of care received.

While, overall, patients have a positive opinion of their own hospitalisation experiences, a small number reported problems relating to malfunctioning and poorly managed hospital services. For example, the process for planning a hospital stay is often still ambiguous. Patients expressed further dissatisfaction with care received on a day-to-day basis during their hospital stays, with 8.0% (14.5% in the South) reporting that for reasons unclear to them they went at least a day without being seen by a doctor or receiving medical treatment, while 11.5% (18.1% in the South and Islands) report that they received different information from different doctors.

Yet the most problematic issues emerge primarily from an analysis of patients' opinions on the procedures for scheduling appointments and waiting lists. Indeed,:

- as widely reported across various macroareas, a minor percentage of users (higher in the South and Islands) scheduled their hospital stays through regional (31.0%) or hospital (21.3%) Consolidated Booking Centres (CUP), while most preferred to liaise directly with the hospital (47.7% of Italians surveyed, 59.2% in the South);
- of the users that scheduled through regional Consolidated Booking Centres, 57.5% reported long lines before being able to speak with an operator, whereas among those who liaised directly with the hospital chosen for their diagnostic exam, 48.7% (55.4% in the South and Islands) reported waiting over 20 minutes at the desk;
- 36.4% feel that they had to wait too long on the waiting list and 17.5% believe that if there had not been a waiting list or if the wait had been shorter, their pathway of care would have been better and that the waiting list adversely affected their access to care.

In relation to the system of outpatient diagnostic services, 70.6% of the users surveyed feel that the issue of waiting lists is the one most in need of improvement, whereas 27.2% indicates investments in newer and more efficient machines, 25.5% cites the organization of appointments and 25.9% the organization of the booking system, and a mere 6.7% indicates personnel availability and training.

On the whole, Italians are satisfied with the services provided by the national health system. Their trust appears to stem from the universal and free nature of the system. This is likely the reason why in the most widespread and accessible areas of healthcare, such as general medicine and local pharmacy services, the percentage of trust is so high. At the same time, Italians feel that the lack of accessibility due to waiting lists and the availability of services is the most critical area.

For a quality evaluation and satisfaction system to become a real tool for continuously improving service quality, the opinion of citizens must become an integral part of a constant and systematic monitoring system that helps create indicators and establish methods that make it possible to intercept signs of mismanagement and identify margins of improvement.

8. Healthcare online

The issue of healthcare online – or electronic healthcare – has been the subject of numerous initiatives at the European, national, regional and local level for the dissemination of *eHealth* as a standard tool available to operators, patients and citizens to improve the quality of care and the productivity of the healthcare sector, with a positive impact also in terms of sustainability of health systems as a whole.

In Italy, the initiatives in progress are in line with the EU's strategic approach and fall within the strategic framework defined by the New Health Information System, the Electronic Health Plan, and the Health Card system.

The online healthcare of the future cannot be designed without taking into account the ongoing evolution of the national strategic framework of reference: the New Health Information System (NSIS).

The need for local information systems made available through the development of electronic healthcare and able to generate and provide, within the NSIS, quick and reliable quality data is now more stringent than ever, considering the institutional tasks of the Ministry of Health, as set forth (among others) by Law no. 172 of November 13, 2009 on the "Establishment of the Ministry of Health and increase in the total number of Under Secretaries of State", aimed at monitoring the quality of regional healthcare activities as compared to the essential levels of the services delivered. Additionally, this need is also confirmed by the Legislative Decree concerning "Provisions for the internal revenue independence of ordinary statute Regions and of Provinces, and for the determination of standard costs and requirements in the health sector", currently under definition, which in Article 22, paragraph 2, provides that "for the determination of the Regions' standard costs and requirements, reference shall be made to the information stored in the NSIS".

Within the context of the situation existing in the different Regions in terms of maturity of the regional information systems, differences in the methods of use of technological innovation depending on the specific organizational models implemented in the Regional Health Systems, as well as the different investment capabilities of the Regions, all current and future projects should have as common denominators, on the one hand, the dematerialization of health records, and on the other the harmonization of online healthcare solutions. For this purpose, it is also essential to facilitate the sharing of initiatives undertaken throughout the national territory and the adoption of best practices.

As regards the dematerialization of health records, the Ministry of Health is conducting a series of activities and has drafted a document containing "Guidelines for the dematerialization of clinical records in imaging diagnostics". This document has been prepared by a work group composed of experts from the Ministry and other central government agencies, as well as representatives of health associations and scientific societies. Its purpose is to provide the General Managers, Healthcare Managers, Information System Managers, and managers of Imaging Diagnostics, Radiology and Nuclear Medicine Departments

and Operating Units the guidelines required to handle text and image clinical documentation obtained directly in digital format, in compliance with current regulations, and to prescribe practical and feasibility directions for the complete digitization of diagnostic reports and images. A formal opinion on the document has been received from DigitPA (formerly CNIPA) and from the Personal Data Protection Authority. The document is currently being shared with the Regions, and will be the subject of an understanding within the "Conferenza Stato-Regioni" (State-Regions Permanent Conference). The Ministry is also planning the preparation of additional Guidelines in support of clinical and healthcare records, including the results of laboratory tests.

As far as the harmonization of online healthcare solutions is concerned, the Ministry of Health has identified a series of priority intervention areas to promote, in line with the national strategic framework, the implementation of local information systems designed to provide practical support to patient care as well as to the governance of the National Health Service (SSN); these include the Consolidated Booking Centres (CUP), the Electronic Health Record (FSE), telemedicine, and web transmission of prescriptions and medical certificates.

As regards the regional CUP systems, the Ministry of Health in consultation with the Regions has set up national guidelines intended to harmonize CUP systems through the definition of consistent minimum requirements of such systems at the national level. The guidelines focus primarily on organizational-managerial and informational-semantic aspects, as well as on functional aspects, as prerequisites for an effective use of the new technologies. The inclusion within the guidelines concerning the CUP systems of community pharmacies as a potential channel for citizens to access booking services was later confirmed by Legislative Decree no. 153 dated 3 October 2009, which outlines a new model of pharmacy: the "full-services pharmacy". According to this model, the pharmacy is a healthcare centre where citizens can find a range of high social-value services in addition to medicinal products.

With reference to FSE systems, in order to support the implementation of a single regulatory framework required to define a national reference model and at the same time to leverage the results achieved at all levels of the SSN, the Ministry of Health established in 2008 an inter-institutional panel whose members, in addition to internal and external Ministry experts, also include representatives of the Ministry for Public Administration and innovation, Region representatives, and a representative of the Personal Data Protection Authority in the capacity of observer. Consistently with its mandate and in line with the need repeatedly expressed by the Personal Data Protection Authority, the Panel has formulated a proposal to regulate the FSE at the national level. This proposal has been included in the government's bill proposed by the Minister of Health concerning "Clinical trials and other healthcare provisions", approved by the Council of Ministers on 10 March 2011.

The Panel has also defined national Guidelines for the implementation of an FSE system, identifying the characteristics of the FSE and of the patient summary (a summary of the patient's medical history), the infrastructural aspects, technological standards, and levels of security and data protection, in accordance with applicable privacy regulations. This document was the object of an Understanding by the State-Regions Permanent Conference on 10 February 2011 and was published in the Official Journal no. 50 of 2 March 2011. The Panel is currently working on the preparation of an implementation directive which, once the proposed regulation to be included in the aforesaid Bill is effective, will regulate the different aspects concerning the establishment and use of the FSE, including its contents, the guarantees and protection measures to be adopted in processing personal data to ensure respect of the patient's rights, the methods and different levels of access to the FSE.

As to telemedicine, it is believed to be one of the main areas of application of online healthcare, as it promotes social and health integration by promoting innovative forms of home care. For this reason, a technical Panel on telemedicine has been formed at the Superior Health Council with the objective to put in place specific national guidelines aimed at supporting the systematic use of telemedicine within the SSN. The purpose of the Panel is to outline a strategic framework that will encompass the primary areas of application of telemedicine and will provide a basis to analyze models, processes and methods for the integration of telemedicine services into clinical practice, define common taxonomies and classifications, as well as aspects concerning the regulatory profiles and financial sustainability of telemedicine services. The Panel is composed of members of proven scientific excellence and strong professional competence. The guidelines aim to identify the fundamental requirements for the development of telemedicine in our Country.

In regard to the *ePrescription* (digitization and electronic transmission of prescriptions), the Ministry of Health considers its development essential, particularly in view of the resulting positive impacts in terms of clinical and care processes, including easier access to treatments, more accurate monitoring and supervision of same, better prevention of clinical errors, lower social costs. At this regard, Law Decree no. 78 of 31 May 2010, containing urgent measures for financial stabilization and economic competitiveness (converted, as amended, into Law no. 122 of 30 July 2010), sets out the equivalence to all legal effects between a paper prescription and a medical prescription transmitted via the web, creating a regulatory basis for the concrete implementation of the *ePrescription* to the national level. The above-mentioned decree also provides that the same platform available for the electronic transmission of medical certificates should also be used for sending prescriptions.

With reference to medical certificates online, a decree issued on 26 February 2010 by the Minister of Health in consultation with the Minister of Labour and Social Policies and with the Minister of Economy and Finance, having obtained the opinion of INPS, regulates the methods for the electronic transmission of medical certificates from SSN physicians to INPS and from the latter to private and public sector employers.

In order to orient its initiatives and actions also in line with the priorities set at EU level, in 2010 the Ministry of Health participated, together with a large group of Member States, Entities and Associations of the healthcare as well as the electronic communications industry, in the development of a project proposal, submitted to the Executive Agency for Health and Consumers (EAHC) and to the Directorate General of the Information Society and Media (DG INFSO), as part of the Second Community Action Programme in the field of health. The project proposal has been evaluated positively and will be co-financed through two EU financial instruments: joint action and thematic network. The purpose of the project, named "*eHealth Governance Initiative*", is to create a governance mechanism through which to coordinate eHealth activities at EU level.

The project is in the process of being formalized and will have a duration of 36 months starting in 2011.

The Ministry of Health intends to continue with the process it has undertaken, strengthening its role as promoter and implementer of initiatives for the development of online healthcare, both at Community and at the national level, through coordination activities aimed at orienting, and therefore optimizing, the efforts and resources made available by all the stakeholders.

9. Investments in technology and in healthcare building projects

The policies for the planning of public investments dedicated to the structural and technological assets of the National Healthcare Service have followed closely the course of the general policies for the im-

provement of healthcare services. The objectives initially identified by legislators, in Article 20 of Law no. 67/1988, such as the building renovation and technological upgrading of public healthcare facilities and the construction of care homes for elderly and non self-sufficient patients, have been expanded with specific provisions for actions to achieve compliance with building and system safety regulations, re-establish the balance between the hospital and the community, and create spaces for the conduct of independent professional activities within public hospitals.

Law no. 67/1988 authorized a multi-year investment programme amounting to Lit. 30,000 billion, equal to 15.494 billion euro, organized in different phases. The resources initially allocated were subsequently increased to a total of 24 billion euro for the multi-year programme of healthcare projects.

In order to overcome the issues that arose during the first phase of implementation of the extraordinary investment programme, issues caused by the pulverization of the funds and the lack of an organic project, the Regions and the central Government exercised their political determination requesting in the second phase of the programme a stronger planning capability in concentrating the fundings on a limited number of strategic and consistent projects within a network logic that requires large reference hospital facilities functionally connected with the district facilities.

For the implementation of the second phase, the Planning Agreement (Accordo di programma) was selected as negotiated planning tool. An essential element of the Planning Agreement is the Planning Document, which illustrates the planning of the parties involved and defines the strategies and the general and specific objectives of the investments envisaged in the Agreement.

At 30 September 2011, 58 Planning Agreements and Supplementary Agreements had been signed by the Ministry and the Regions and Autonomous Provinces, 7 of which are Master Planning Agreements within the framework of institutional planning Understandings pursuant to Article 2, paragraph 203, of Law no. 662/1996, and 51 are Planning Agreements in accordance with Article 5-II of Legislative Decree no. 502/1992. In particular, 11 Planning Agreements were signed in the 2009-2010 period.

At 30 September 2011, approximately 97.2% of the resources allocated in the signed Agreements were contractable, and an expenditure of approximately 8.986 billion euro was authorized.

However, strong differences persist in the times of signing and implementation of the Agreements due to the different regional complexities. The different evolution in the use of the resources is the result of the experience gained by the different Regions, as well as of the planning solidity ensured by the presence of a regional plan for the reorganization and improvement of the hospital network, and/or of the local health services system in general, conditions which have allowed a rapid and effective implementation.

The selection of the actions to which the investment programme's resources should be allocated reflects the growing adoption by the Regions and the Ministry of a shared "planning culture", in the widest sense of the term, i.e. not only the setting up of a methodological planning process, but also an approach that extends across the other development and sector policies with respect to particularly significant healthcare requirements.

10. 2000-2006 European Structural Funds and 2007-2013 National Strategic Framework

A National Strategic Framework (QSN) has been developed on the basis of the contribution provided by the different central Administrations and by the Regions, and on the basis of a very intense partnering process between the Administrations and the economic and social parties. The QSN, established under Article 27 of EC Regulation 1083/2006, is the planning document with which Italy pursues the objectives set by the EU cohesion policy 2007-2013. In

particular, the Italian government has identified 4 objectives and 10 specific priorities for its 2007-2013 planning.
The overall strategy relies on resources made available both by EU and national resources.
While not specifically included in the QSN, the theme of health is a key intervention area both in the domain of service objectives and in that of regional operating programmes, which show a special attention to projects related to the development of eHealth, the strengthening of infrastructure and public social and health services, and the promotion of urban and rural improvement projects.
Within the QSN, the Ministry of Health owns to two projects:

- system and technical support actions for service objectives – ADI project;
- technical support operating project (POAT Salute).

The general objective of the ADI Project is to support the Southern Regions in the planning and implementation of the planned home care services in a manner that is integrated within the communities (involving all the social, health and care services) and monitored according to consistent criteria.
The project has been funded with FAS resources for 1 million euro, and the first phase, financed with a first installment of 500,000 euro, has been completed. For the next two years, as soon as the funds of the second installment (500,000 euro) are available, further technical support activities will be carried out in collaboration with the Ministry of Labour and Social Policies and the Department of Family Policies of the Presidency of the Council of Ministers.
The POAT is part of the National Governance and Technical Support Operational Programme (PON GAT) European Regional Development Fund 2007-2013 and with reference to Objective II.4 "Strengthening of the operating structures and responsibilities of the Public Administration".
The project, which will have a duration of three years and an expected cost of 11,000,000 euro, relates to the "Capabilities Reorganization and Strengthening Plan" organized into two mutually functional parts:

- the Technical Support Operating Project focusing on the individual policies and aimed at meeting the needs for support and institutional cooperation expressed by the Regional Administrations of the Convergence Objective;
- the Internal Reorganization Plan (PRI), promoted exclusively through internal resources of the Administration, the purpose of which is to improve the management and implementation of the POAT through the appropriate Operating Unit with direction and coordination responsibilities.

Through the delivery of technical support services to the Regions of the Convergence Objective (Campania, Puglia, Calabria and Sicily) the project aims to meet the regional requirements, identified mainly on the basis of the 2007-2013 regional planning documents and of the results emerging from the numerous meetings and exchanges with the individual regional administrations. These requirements essentially concern four macro-areas:

- planning and direction tools for the implementation of the interventions,
- monitoring and assessment methodologies and techniques;
- information on the contents and actions relating to the management of sector interventions;
- knowledge of the tools to establish cooperation networks and to come in contact with significant experiences at the national and EU level.

11. Healthcare research: Reality and perspectives

Healthcare in line with scientific and technological progress must use the instrument of research and perceive it as a true investment. Indeed, there can be no good healthcare without good research.
As a strategic health policy instrument, the research funded by the Ministry of Health presents a number of particular aspects. It is broken down into current research and

targeted research. The former (current research) applies to Scientific Institutes of Research, Hospitalisation and Healthcare, whereas the latter (targeted research) is open to all NHS researchers. Both constitute priority objectives for the improvement of the population's health, in order to favour the experimentation of ways to operate, manage and organise health services and clinical practices, to improve multiprofessional integration, continuity of care and communication with citizens.

Targeted research addresses institutional subjects: Regional Authorities, ISS, ISPESL, AgeNaS, public and private scientific institutes of research, hospitalisation and healthcare and IZS, centred on the preparation of objective projects and, since the 2009 call for projects, it is open to all NHS researchers. To realise their projects, the institutional recipients can use partnerships with other public and private research organisations, Universities and even public and private enterprises, on the basis of agreements and contracts for the performance, in the multicentre research field, of specific project parts.

Biomedical research and technological innovation are characterising and profoundly transforming care processes and health services. Within this innovation context, the way to be followed is that of a new treaty in which the State, Regional Authorities, Universities and businesses work together for a R&D promotion and support strategy whose application represents a qualifying and essential point for the whole national system.

With these premises, the Ministry of Health's consequent strategy is to favour the aggregation of the Institutes belonging to its institutional network, Regional Authorities, IRCCS, ISS, IZS, ISPESL, with universities and other public and private research centres.

The objective from a research point of view is to promote the knowledge that research is aimed at improving the services offered to citizens, that can occur both in the form of a new, more efficacious medicinal product and a new organisational model that reduces waiting times.

This setup is further evident in the funding set aside in recent years, where the strategy has been to increase the critical mass of research to face issues with a high social impact such as cancer, without neglecting clinical governance innovation and the optimisation of the organisational dimension of health services.

Therefore in recent years, due to this particular commitment, translational research has occupied a prominent position, creating synergies between basic and clinical research, with the ultimate aim of transferring as rapidly as possible the most advanced innovations and knowledge to the NHS and, therefore, to the citizen.

Funds for current research have an annual duration and are directed at making sure that the Institutions involved can, in the context of their own recognition, carry out their institutional research activities, within the lines of research approved. They are distributed by measuring scientific and care performance.

As far as targeted research is concerned, with its Targeted Research Call for Projects 2009, the Ministry gave all NHS researchers the chance to present research projects whose evaluation, through the peer review system, is assigned to reviewers who preassess the projects, who work abroad and are indicated by the prestigious NIH-CSR (a US governmental body dedicated to selecting and funding biomedical research projects). The final judgement lies with the Assessment Committee whose members are 2/3 foreign experts.

Again for the Targeted Research call for projects 2010, which is currently ongoing and to which the State has granted € 82,127,000, the same spirit has been maintained and it is open to research project proposals, most of which translational, in all areas of biomedical research. Furthermore, to strengthen the capacity of the national research system, through the transfer of experience accrued abroad, a 10 million Euro fund has been set up for "foreign research projects" performed in partnerships between researchers operating in the institutions of the Institutional Recipients

and Italian researchers who have lived abroad for at least three years. The reason behind this choice was to avoid losing the level of experience and know-how that Italians have carried and continue to carry around the world and to therefore allow a strengthening in contacts and partnerships to allow Italian researchers living abroad not to feel abandoned by Italy and, on the other hand, to strengthen the national research system thanks to the huge contribution that these researchers can make to Italy in terms of both quality and work methodology. Five million more have been set aside for "*co-funded research projects*" in which industry in the Italian biomedical sector undertakes to co-fund the winning projects with additional resources, at least equal to the Ministerial funds. This will make it possible to increase the financial backing made available to health research and will help to create that partnership between the world of research and the private sector in the citizen's interest.

The Ministry of Health is involved in multiple European projects in support of research. In particular, it is involved in a series of ERANET projects where the participant States share their resources for joint research programmes by financing, each for the part under its responsibility, national institutions that operate jointly within an international context. In this domain, in addition to the ERANET TRANSCAN project relating to the development of oncological translational research projects, the Ministry participates directly in the ERANET NEURON project for neurological research, as well as in the ERANET PROCHILD paediatric project, in the ERANET rare diseases project and the ERANET Emida animal health project. It is also committed to supporting EU projects on the development of the European Strategy Forum on Research Infrastructures (ESFRI) in the health research sector.

Research in the veterinary sector

In the last decade, the Italian health research in the field of veterinary medicine has reached a high level of quality and concreteness, and this is the result of the teamwork conducted between the Ministry of Health, whose responsible Department coordinates, promotes and finances research studies, the IZSs and the National Reference Centres (CRN), which together with the ISS carry out strategic research activities from an institutional point of view, studying and developing new diagnostic strategies, perfecting and implementing those that are already established, standardizing and validating operating protocols both in the field of food safety and of animal health and well-being, meeting the demand for high quality services, and ensuring consistent levels of intervention throughout the national territory. Their action, carried out at grass-roots level thanks to local diagnostic units, allowed our Country to grow both from the health point of view, particularly in the area of food safety, and from the business point of view, with significant results in the exports of food of animal origin.

As regards European research, the organizations that conduct research in the veterinary sector participate in the research projects of the 7th European Union Framework Programme. Additionally, through the implementation of a transnational notice that involved 19 Countries, 1 million euro was invested by the Ministry of Health (RF 2009 Funds) in animal health, promoting the consolidation of the best European research centres to focus on themes considered strategic at EU level, with excellent results of the Italian partners who participated in the competition. Lastly, it should be emphasized that public veterinary health, in light of the new emergencies that constantly need to be addressed – from market globalization to climate change – is inextricably linked to human health according to the internationally recognized principle of "one health".

12. The international arena

12.1. How EU policies on the mobility of European and non European citizens reflect on the National Health Service

Looking at the territory of the European continent in the 2009-2010 period, incom-

ing and outgoing health mobility flows have impacted the healthcare state of the Country in organizational and economic terms. In 2009 the refunds paid for health services provided to Italian citizens amounted to 129,960,161.35 euro, while 61,000,805.02 euro was the amount received for health services provided by Italy to patients from other UE Countries; in 2010, payments amounted to 163,787,194.21 euro, while receipts amounted to 86,907,818.57 euro. These data refer for the most part to previous years, and are not yet stable because of the delay in mutually notifying and subsequently checking the amounts payable.

From a regulatory perspective, the period under examination saw a significant effort to implement the new health mobility regulations (EC Regulation 883/2004 and EC Regulation 987/2009).

In the 2009-2010 period, the healthcare provided to the beneficiaries of the social security agreements with non EU countries (Argentina, Australia, Bosnia-Herzegovina, Brazil, Croatia, Macedonia, Principality of Monaco, San Marino, Serbia, Tunisia), while minor in volumes because of lower mobility levels and of the more limited scope of the healthcare services, generated 7,703 receivable invoices for an amount of 22,251,133.17 euro, and 14,921 payable invoices for an amount of 5,633,684.21 euro.

12.2. Communication and information initiatives to facilitate immigrants' access to health services

As part of the actions to facilitate access to healthcare services by the immigrant population, a project named "Integration process at the time of requesting the stay permit and the summons to report to the Single Desk (Sportello Unico)" has been launched with the presence of specialized operators in charge of supporting Single Desk operators in handling health issues and of distributing the booklet "Informa Salute", written in different languages to inform immigrants on their right to receive the services and on the availability of the services within the foreigner's province of residence.

The 12-month project was started in July 2010 and involved 14 Local Healthcare Companies (ASL) nationwide and 5 Single Desks for immigration.

12.3. Development lines of EU policies in the public health sector and Italian participation in Community research programmes

The Ministry is strongly committed in terms of resources to participating in EU institutional activities in the public health sector. Within the "Public Health" work group, it cooperates in the preparation of regulatory dossiers under the responsibility of EU institutions, and promotes the implementation (after their transposition, if required) of said regulations. The Ministry also follows the activities of a large number of EU Commission and Council committees and work groups.

In particular, Italy participated in the preliminary meetings for the drafting of the "Services Directive" and the so-called "Pharmaceutical package". The package includes the "Pharmacovigilance Directive", already approved, the "counterfeit drugs Directive" and the "patient information Directive", the evaluation of which is currently suspended.

The importance of these activities is also demonstrated by the top political bodies' participation in a series of meetings and ministerial conferences at EU level, including:

- EU - "*Innovation and solidarity on Pharmaceuticals*" ministerial conference on the access to innovative drugs;
- EU – Council of the Ministers of Health (EPSCO);
- EU – Informal Council of the Ministers of Health (EPSCO) on a six-monthly basis.

In addition to the activities conducted at the EU institutions, the Ministry is also active at Council of Europe level, where Italian experts take part in work groups in charge of drafting recommendations that are then adopted by the Ministries of Health during Council meetings.

Another important form of cooperation is participation in the works of the OECD and in the "Second Community Action

Programme in the field of health", where 5 projects in the "Promoting Health" area were approved in 2010, and in a "Joint Action" in the "Improving citizens' health security" area.

12.4. Results of commitments undertaken at non-European levels to improve citizens' health through the strengthening of healthcare systems (implementation of the Tallinn Charter – WHO European Region – Bilateral relationships – Euromed Projects)

The commitments undertaken in Tallinn include the Euro-Mediterranean partnership with the EUROMED-Health projects, and the bilateral health agreements as an expression of this strong implementation commitment.

Within the Union for the Mediterranean, Italy has promoted several important initiatives for the strengthening of the health systems and medical care offering in that area. Italy has undertaken to launch concrete multi-lateral health projects with all the countries of the Southern coast of the Mediterranean and of the Near East, with the involvement of European countries like France, Spain, and more recently Malta.

The Ministry of Health sought to raise awareness within the new Organization so that the subject of Health should be an integral part and should be considered a priority in the EuroMed-UfM programme.

Six EuroMed-UfM projects are currently in progress:

- EpiSouth;
- EuroMed Cancer Registries Network;
- Cancer Screening and Early Diagnosis Programme;
- MediCel: Food-induced Diseases;
- Cardiovascular Diseases – Congenital Heart Diseases;
- Mediterranean Transplant Network.

During the 2009-2010 period, panels were formed for the coordination between all the EuroMed countries of the management and monitoring of the individual projects.

The success of the promoted activities is demonstrated by the Ministry of Health's decision, in late 2010, to re-finance the projects for a further twelve months.

Promotion of technical-scientific partnerships, exchange of information on the organization of the respective National Health Services, personnel training activities, possibility of sending patients to Italy for targeted treatment cycles, are just a few examples of how the bilateral Memorandums of Understanding, through which these partnerships are established and started, can be applied for cooperation in the field of Health and Medical Sciences.

The existence of different memorandums of Understanding, already effective for several years with the Countries of the Southern coast of the Mediterranean and of the Near East, such as Tunisia, Algeria, Libya, Egypt, Israel, Jordan, as well as Gulf countries like Saudi Arabia or European countries like Malta, has helped to create a series of institutional relationships between the central health Authorities, the Regions and the scientific and hospital institutes, which – besides promoting multi-lateral projects and contacts, as in the Union for the Mediterranean – represent an important binding element to improve the relations and the social and structural conditions of many countries, and therefore supports business and commercial partnerships as well as scientific and cultural cooperation partnerships.

Another area of great and renewed interest is Latin America, which through recently signed agreements with Mexico, Brazil, Venezuela, and existing agreements with Argentina, allows our country to come in contact with health systems that are physically distant but close and similar in language and traditions. In this same area, bilateral relationships may be very useful in large-scale multi-lateral projects, like EUROsociAL II, financed by the European Union to improve the social cohesion of those populations through projects aimed at forms of cooperation and exchange of good practices, not only in the areas of education and health, but also in other fields like social protection and labour policies, safety and justice, promotion of the rule of law and struggle against corruption.

The bilateral agreements also concern Balkan countries like Albania, with which Ita-

ly has entertained privileged relations for may years; Serbia and Montenegro, for which the negotiations are about to be completed; the three countries of the Caucasian area, Azerbaijan, Armenia and Georgia, which allow our country to come in contact with different realities and to provide a significant contribution in the establishment and exchange of good practices.

13. The ethics of treatment: the contribution of the Superior Health Council

In the 2009-2010 period the Superior Health Council (CSS), the Minister's technical-scientific consulting body, constantly maintained the two activity approaches that are typical of this agency, i.e. the consulting approach and the proposing approach. The breadth and complexity of the subjects was impressive: the CSS expressed its opinion, as required by its institutional function, on a wide range of matters and sectors relating to the country's health. The subjects it dealt with, in over 900 "opinions", included the prophylaxis of infectious diseases, and in particular of the AH1N1 epidemics; the new National Vaccination Plan; the prevention and hygienic protection of the environment (as with the issues related to the Mortuary Regulations); the use of glasses for stereoscopic vision; the hygiene and safety of food products, including the sale and consumption of raw milk; potable and mineral waters; treatment safety and correct information to patients, in particular for proposed endovascular treatment for multiple sclerosis and for kidney transplants from "Good Samaritan donors". The CSS also gave its opinion on healthcare planning, care of the elderly, palliative treatments, and pain therapy. As regards the safety and appropriateness of the use of technologies and substances that impact health, the CSS expressed opinions on the use of medical technologies with diagnostic characteristics, like "Cone beam" volumetric CT scan equipment, or therapeutic characteristics, like adrotherapy equipment, as well as of non-medical technologies like the different types of body scanners.

Particularly significant, also because of the interest it stirred in the public, was the CSS's opinion on the inclusion of new substances, like JWH-018 and JWH-073 and mephedrone in the lists of narcotic and psychotropic substances.

This brief summary of the activities carried out by the CSS shows how this body, because of its scientific accuracy, respect for the person and independent judgment, continues to represent an important point of reference even in the current growing availability of tools and actions for the protection of health, which at times give rise to ethical and legal concerns in the face of an evolving society that increasingly attributes to the individual a central role in choosing the course to take for the prevention and treatment of diseases and a limited availability of resources.

14. Institutional health communication

Institutional health communication plays a strategic role in the relationship between the SSN and the citizens, and the Internet has strengthened this role during the last decade. The central objective of communication is citizens' empowerment. Empowered citizens are individuals who understand and choose, who build their own lifestyle, who make decisions about their wellbeing and are able to interact responsibly with the SSN. The Regions' planning, as shown in many of the recent Regional Health Plans (PSRs) in line with the National Health Plan (PSN), is based on the awareness of the strategic role of communication.

Internet is becoming the main source of information on health and medical care in Italy as well. To handle this change and make sure it is favorable to patients and the SSN, the Ministry has set up the "Guidelines for online communication on health protection and promotion". The guidelines contain recommendations on websites' minimum contents, usability, editing criteria, interactivity, web 2.0, a sheet for the self-assessment of the quality of SSN websites, and a customer satisfaction questionnaire (www.salute.gov.it), and also present the

results of studies and preliminary investigations.

As part of the Guidelines, an analysis was conducted on the quality of the information provided in ASL websites. Synthetic indicators subdivided by geographic areas have been developed. Key results are listed below:

- protection mechanisms (availability in the site of sector regulations, information on the services charter, code of conduct of public employees, and explicit statement on personal data processing): the national average value is 7.3; the ASLs of Northern Italy were rated higher (8.4);
- access rights (availability in the home page of links to the Urp and newsletter, availability of forums, chat rooms, mailboxes, weblogs, Pec); the ASLs of Northern (5.5) and Central Italy (5.2) were rated higher than the national average (5.2);
- forms an booking systems (possibility of downloading forms or completing them directly online from the ASL website, or of booking and paying health services): the average rating of the ASL of Northern Italy was 4.3, higher than the national average of 3.6

Another survey concerned the presence of the theme of health promotion in the Regions' websites. For 18 of the 21 Regions examined, the home page contains links to awareness campaigns or to dedicated website areas. In most cases the campaigns are sponsored by the Region (in 18 cases), or in cooperation with the Ministry.

The conduct of communication campaigns was one of the most effective tools for the pursuit of the health objectives set out in the National Health Plan. The promotion of healthy lifestyles, the prevention of infectious diseases, health education and the protection of mother and child health, social and healthcare solidarity, animal protection and well-being were some of the main themes on which the Communication and Institutional Relations Directorate focused during the reference period. A summary of the most significant large-impact initiatives carried out in the last two years is provided below.

In the 2009-2010 period, the Ministry focuses in particular on the fight against smoking. The 2009 campaign was aimed especially at habitual smokers, inviting them to stop smoking to protect both their own health and the health of those who suffer second-hand smoke, especially children. The 2010 campaign was aimed at youngsters, with the goal to prevent their initiation to smoking by encouraging an attitude of strong refusal since their early school years. The 2009 campaign, "Smoke Kills – Protect Yourself" won the first prize in the Public Communication category of the 2009 edition of the "Aretè" national competition.

In line with the PSN communication objectives and with the indications contained in Law no. 125/2001 "Framework law on alcohol and alcohol-related problems", a campaign was launched against alcohol abuse by teenagers, particularly with the aim to reduce the number of road accidents. "Ragazzi vediamoci chiaro" (Guys, let's see clearly) was the slogan in 2009.

The information campaign on the influenza epidemics was conducted in the 2009-2010 period in line with the WHO's indications.

The campaign on the seasonal influenza carried out by the Ministry in autumn was directed in particular at the population categories at risk of being infected.

For the 2009-2010 period, the Ministry chose the goal of fighting the growing neglect of the problem of AIDS, and in particular of encouraging people to take the HIV test. The message "Don't lower your guard. Take the test ... AIDS. Its strength ends where your begins!" was broadcast on television and on the radio through the leading TV and radio channels and was also published in the main newspapers and periodicals.

For the protection of women's health, in this two-year period the Ministry addressed the problem of endometriosis.

The campaign, titled "Things I don't know about myself" aimed at providing information and raising awareness among female teenagers on the symptoms of this disease, to encourage them to seek medical help, to increase the number of early diagnoses,

and most importantly to prevent related infertility.

In 2009, in collaboration with the ISS, the Ministry conducted a campaign on the causes of possible disorders of the reproductive system and on the importance of prevention. Radio and TV spots were produced and broadcast to convey the campaign's basic message: "Fertility is a common good. Take care of it".

In 2009 and 2010, on the subject of the donation and transplant of organs, tissues and cells, the Ministry promoted nationwide educational and awareness raising initiatives together with the National Transplant Centre and sector Associations.

A 2009 campaign aimed to raise awareness in the population on the abandonment of dogs, along the lines of the 2008 campaign by photographer Oliviero Toscani.

With the launch in 2010 of the new paper and online periodical "Ministry of Health Notebooks" the Ministry resumed its high scientific level publishing activities. The purpose of these publications was to promote a culture of appropriateness in clinical and diagnostic procedures, firstly among SSN operators. The subjects discussed with a monographic approach issue after issue address the key areas of expertise where common standards need to be defined. Six issues were published at two months intervals in 2010:

- Clinical, technological and structural appropriateness criteria in the treatment of disorders of the cardiovascular system;
- Organization of stroke care: the Stroke Units;
- Diagnostic-therapeutic appropriateness in oncology;
- Diagnostic and therapeutic appropriateness in the prevention of osteoporosis-related fragility fractures;
- The Italians' satisfaction with the health system;
- Clinical, technological and structural appropriateness criteria in the care of the elderly.

AIFA directed its communication activities to the dissemination of correct and independent information on the safe and responsible use of medicinal products; in particular, in the years 2009 and 2010 it conducted campaigns on the responsible use of antibiotics: "Antibiotics? Use them with caution" (2009) and "Antibiotics: Protect your protection. Use them with caution" (2010).