same consolidated data for the year 2009 was 110.219 billion euro showing a 0.9% annual increase, below the increase recorded in 2009 (2.9%), but above the GDP annual increase (2.2%). The 7.10% GDP portion absorbed by SSN in 2010 was slightly lower than the 7.20% in 2009.
A similar dynamic is observed as regards the SSN funding which in 2010 represented 7.0% of the GDP, the same as reported in 2009, although with a greater reduction in the trend: +1.8% in 2010 compared with +3.2% in 2009.
In 2010, the SSN shows again a deficit of 2.3 billion euro with a continuation of the reabsorption trend begun in previous years (3.2 billion euro in 2009), with an even more drastic reduction (–6.3% in 2009 compared with –28.5% in 2008): the differentiated penalty system for the Regions that have not subscribed to the Realignment Plan and those that have subscribed/applied it in order to ensure the actual coverage of the deficit not covered within the healthcare sector, together with the increase in the funding of the SSN in the last few years, has achieved the expected result of a gradual freezing of health expenditure and reduction of the healthcare deficit. Also in relative terms, the deficit shows in 2010 a small reduction, from 0.21% to 0.15% of the GDP.
At a regional level, it must be noted that, both in 2010 and in 2009, the healthcare deficits continued to represent a mainly localized issue in the central and southern regions of the country and in particular in a group of 4 regions (Lazio, Campania, Puglia and Sardinia) which reported over 90% of the overall net deficit of SSN in 2010. The highest per-capita deficit is attributed to Lazio, followed by Molise, Campania, Sardinia, Valle d'Aosta and Calabria.

4.2. Human resources and continuing education in medicine

In 2009, 812,263 personnel units were reported as operating daily in different hospitals and public and territorial facilities in Italy as well as in SSN accredited regional private healthcare facilities.
Of these, 575,999 units operate in the healthcare segment, 150,636 units operate in the technical segment, 94,481 operate in the administrative segment and 2,574 units in the professional segment. Within the healthcare segment, medical personnel account for 144,068 units and the nursing sector accounts for 311,188 units.
The ratio between nurses and doctors, at a national level, stands at 2.2 nurses per doctor.
The National Committee for Continuing Education has defined continuing education among the most relevant objectives for the SSN and for the regional healthcare services and as a tool for the guidance and update of healthcare professionals in order to help them achieve the priorities benefiting the SSN.
The new continuing education system was launched in its first phase as a single type of training. By the year 2010, the new objectives were set out with the accreditation of organisations providing remote training.
The benchmark for the accreditation of continuing education in medicine training consists of:

- Humanisation of the treatments: treatment of acute and chronic pain, and palliation;
- Quality of the clinical-healthcare systems and processes: application, in daily practice, of the principles and procedures of Evidence Based Practice (EBM, EBN, EBP); appropriateness of the health services based on LEAs; systems for the assessment, review and improvement of efficiency and efficacy; relational aspects (internal communication, external with the patient) and treatment humanisation;
- Knowledge in terms of specialist skills: technical-professional content (knowledge and skills) specific to each profession, specialisation and ultra-specialist activity.

As regards the above-mentioned areas, the training activities associated with the priorities of SSN and provided remotely, have reported a significant increase in 2011: from 119 requests for accreditation in 2010 (about 180,000 expected participants) to about 450 requests for accreditation which have

been submitted in 2011 (about 880,000 expected participants).
In the last few years, particular attention was paid to the issue of over 180,000 healthcare operators through the establishment of a specific technical panel with representatives from the Ministry of Health, Regions, Unions, Ipasvi and Mipeg, in order to assess, after 10 years from the creation of this professional profile, its role, functions and training.
As regards the availability of medical personnel for the SSN in the coming years, some considerations must be taken into account. If one considers the current breakdown by age of the doctors employed by the SSN, a high concentration of medical personnel is in the 50-55 and 55-60 age groups which represent two thirds of the total SSN medical directors.
Similar figures apply to general medicine physicians: only 5,800 of the 45,000 doctors enrolled in the ENPAM pension fund for general medicine physicians have an age below 50 years and therefore the majority of general medicine physicians (above 87%) will reach retirement age in the next 15 years.
However it must be noted that the above described issue does not concern exclusively the public sector and the standard agreement healthcare, but it will involve all the medical profession as a whole.
In order to correct this situation, the Ministry of Health has requested the broadening of medical education, i.e. the number of enrolments in the schools of Medicine and Surgery, starting from the academic year 2008-2009. Consequently, from the academic year 2007/2008 to the academic year 2010/2011, the openings in medical schools increased by 29%. However, since a medical specialisation is required for joining the SSN and is determinant for practising the profession and since it is estimated that the academic path for physicians is 11 years long, it will not be before 2020 that a higher number of graduate students with a specialisation is available to the market.
At any rate, one should not yet talk about a "physician emergency" in the short term since in the last few years the financial limitations and the hiring freeze have created a large number of never-employed from which the SSN can draw to ensure an adequate turnover of human resources.
On the other hand, it is necessary that a generational replacement occurs in the near future, also to guarantee the adequate and essential development of skills and knowledge that only clinical experience can provide.

4.3. Technological resources

The Health Information System assesses the availability of technical-biomedical equipment for diagnosis and treatment in hospitals and in public and private territorial health facilities. Since 2007, some new types of equipment that have acquired special significance in the last decade, such as PET and CT/PET integrated system, Gamma Camera/CT integrated, Digital Angiography system and mammographers, have been included in the availability assessments. Within the above-mentioned period of time, the availability of equipment has increased especially as regards CT and MRI. In fact the number of available CT machines has increased from 29.4 units per 1 million inhabitants to 30.4 units, whereas MRI machines have increased from 18.1 units for 1 million inhabitants to 20.7. As regards equipment assessed beginning in 2007, there is a total of 118 PET and CT/PET integrated systems with an availability of 2 machines per 1 million inhabitants; the availability of mammographers is 189.2 units per 1 million women between the ages of 45 and 69. The number of technical-biomedical machines is increasing especially in the public sector showing very different numbers of available machines at the regional level.
A new central database of all medical machines, installed in 2007 for the purpose of creating a Registry of all medical equipment and monitoring the equipment entering the Italian market, was gradually introduced in order to facilitate the technical and organisational update of the subjects involved and ensure an alignment to the

national requirements of applicable laws implementing EU rules. The years 2009 and 2010 registered an increasing and ongoing implementation of data carried out by the subjects involved (manufacturers, agents and designated subjects) who have contributed to the setting up of an important registry with a uniquely complete collection of information.
The heterogeneous sector of medical devices and their strategic role have increasingly drawn the attention of the Healthcare System that requires initiatives seeking to acquire a more complete and updated knowledge of their use, promote scientific research, monitor accidents or malfunctions and give, in general, more attention to the quality of the marketed products.
Tools that would respond to these needs, in terms of safety and adequate use of medical devices, were identified in the set up of a method for a national codification and classification (CND) system – to be used by all subjects operating in the sector –, in the development of a national database (Registry) of all medical devices and their main characteristics, in the assessment of the cost/benefit ratio of each of them and finally in the implementation of a monitoring system applied specifically to the expenditure for medical devices.
The Regions, because of the planning, regulatory and control functions assigned to them within the healthcare area, need also more updated and precise information regarding biomedical technologies, in particular the level of use of these technologies, the status of the regional technology resources and the comparison between the acquisition prices of these technologies by their own facilities and those of other Regions.
The setting up of the new database of medical devices, containing also the Registry of the devices sold to the SSN, represents the response to a vital requirement for the achievement of the above described cognitive objectives.
The sustainability of the Healthcare System depends also, to a large extent, on the capacity of regulating the adoption of innovative technologies in clinical practice, both in the pharmacology and medical devices sectors. The criteria applied must ensure positive results in terms of health and possibility of treatment, based on the appropriateness, financial sustainability, equality and integration of the interventions. Therefore, it is necessary that the purchasing processes adopted by the Healthcare Facilities are carefully assessed by the healthcare system; in fact, the financial factor is relevant for the buyer, who is responsible to ensure the best use of public funds, and for the seller who aims at the best corporate results deriving from its stable presence in a secure market.
The need to improve the governance of healthcare expenditure, including the expenditure related to medical devices, has been often evoked and strongly pursued by many parties. As regards the expenditure related to medical devices, it was deemed necessary to promote strategies for the management of resources, the efficacy of services and the transparency of the activities, through the set up of a database that would monitor the expenditure related to the medical devices that the SSN healthcare facilities purchase directly.

5. New Healthcare Information System

5.1. Information System and integration of healthcare information

The strategic objectives of the New Healthcare Information System (NSIS) are mostly seeking to monitor the harmonisation of costs and quality of the healthcare services and are based on two fundamental principles: on the one hand, the availability of an integrated system of Healthcare Information aiming at collecting, on an individual basis, information on the healthcare services provided to the population, and on the other hand, the availability of a Healthcare Network Monitoring System aiming at acquiring a in-depth and timely knowledge of the services offered by healthcare facilities at a national level.
The intersection of these two principles entails the availability of a system that is extremely rich in information, an essential re-

quirement for the analysis and understanding of healthcare practices and issues.
The data collected through the Integrated System of Healthcare Information, in compliance with privacy laws and regulations applied to the processing of confidential data, may be used in improving healthcare quality as well as in the governance functions of SSN.
As regards the Healthcare Network Monitoring System, the Ministry of Health has defined, in partnership with the Regions, a new methodology for the assessment of the entire healthcare network. The system that implements this new assessment model, called Healthcare Network Monitoring System (MRA System), aims at capturing comprehensive information on the facilities that are part of the regional healthcare network of services. The MRA System will enable the depiction, through appropriate geo-referencing tools, of the distribution of facilities and production factors active in the territory and will enable, consequently, to effectively support both the definition of health policies and healthcare planning, as well as the planning of infrastructure investments at a local and regional level. The MRA System has been subject to an experimental phase in which eight Regions have participated and that ended in 2010. Subsequently, a transitional phase has started, with the gradual adoption of the MRA Model by the Regions, through their subscription to a Memorandum of Understanding. This transitional phase is expected to end in 2012 with the issuing of a Ministerial Decree that will formally activate the MRA System.
Other specific initiatives, aiming at monitoring healthcare equipment, an essential production element for the provision of LEAs, were launched. In order to expand the amount of monitored data, in the first six months of 2010, a Workgroup was setup with the participation of Regions and Provinces, the Ministry of Health, the Ministry of Economics and Finance, AgeNaS and AIFA. Following the conclusion of activities performed by the Workgroup, a Ministerial Decree will be issued for the purpose of regulating the monitoring of medical devices beginning in 2012.
The data collected by the NSIS will represent a database of reference that will meet the monitoring and control requirements of the SSN with appropriate levels of accuracy, reliability and timeliness, in particular in the following areas:

- Out-patient specialists and pharmaceutical treatments: this information will be collected through the Health Insurance Card System pursuant to article 50, Law 326/2003 and systematically sent to the NSIS, pursuant to paragraph 10 of the same article 50;
- Direct and indirect distribution of medications and medicinal products;
- Home care;
- Rest and care homes for the elderly;
- Emergency care;
- Hospital pharmaceutical care;
- Drug addiction care;
- Psychiatric care to adults patients;
- Healthcare provided at Hospice facilities.

The Ministry manages information that represents a very important source of data at a national level and that, in the last few years, has been subject to extensive enhancements and optimization. The availability of more extensive information has made it possible to define and to adopt increasingly advanced indicators and analysis instruments in order to obtain useful guidelines during planning and control phases, in addition to providing a fundamental support for the understanding of the current main healthcare issues and of the decision-making process in terms of healthcare policies, planning of interventions, prioritization of actions and monitoring of the related effects benefiting all levels of SSN.

5.2. Veterinary and food safety information system

Among the information systems related to animal health, in addition to some systems dedicated to specific illnesses (vesicular disease in swine, blue tongue, salmonella, etc), noteworthy are four specific transversal systems:

- The National Animal Disease Information System (SIMAN) reports on the onset of infectious diseases in animals;
- The Reporting Information System (SIR) provides data on co-financed EU plans;
- The Zoonoses Information System provides data to EFSA on zoonoses control;
- The SANAN Information System for data management of activities related to specific control plans.

Starting in 2002, the Ministry, in partnership with the Regions and ASL, has strongly urged and supported the setup and implementation of the National Database for farming and for bovine cattle and buffalo and later for sheep, swine and goats. Lately it has been implementing a registry of companies that practice aquafarming and beekeeping.

As for bovine cattle and buffalo, detailed information has been collected on individual animals including the registration of ID, date of birth, animal mother's ID, breed, sex, with the possibility of obtaining information on the movements of the animals, their lactation, slaughter or death.

The information system of the animal registry represents, in Italy, one of the first examples of the successful implementation of an integrated coordination among different information systems at various levels of Public Administration.

The national information system, SINTESI-Scambi, has been in operation since 2001 and regards the organisation of controls on all incoming shipments from other EU countries, pursuant to Legislative Decree 28/1993 as amended.

The National Information System, SINTESI-Importazioni, has been in operation since the year 2000 and has enabled the collection of information related to the import of those types of products (e.g. vegetable-based feed) currently not falling within the scope of the EU Information System TRACES.

The EU Information System TRACES, active since 2004 in all member states, is mostly involved in the collection, transfer and management of data related to the following two sectors:

- Import of live animals and animal-based products from other countries to the territories of the EU;
- Trade of live animals and genetics products among member states.

Pursuant to Directive 96/23/EC, each member state must implement a monitoring system for the identification of residues in animal-based products.

The National Plan of Residue Control, as part of the New Information Food System, enables the Ministry to collect and process data and information coming from the national territory and subsequently to transfer them to the European Commission.

Legislative Decree 282 of 18 June 1986, amended by Law 462 of 7 August 1986, providing for urgent measures in the areas of the prevention and suppression of food frauds, has required the establishment, within the Healthcare Information System (SIS) of the Ministry, of a Centre for the collection of the results of laboratory analyses in order to provide the Ministry with tools aimed at ensuring safety in food products and to provide the regions with updated information to support activities of prevention and suppression of food frauds.

The Plant Synthesis System was created in 2000 in order to feed and manage the database of the Italian plants that produce animal-based food products, pursuant to national and EU laws. The users of this system are the Ministry of Health, the Regions and Provinces Health Councillor's Offices.

6. Monitoring of clinical trials and use of medicinal products

AIFA is the organisation in charge of monitoring all clinical trials conducted in Italy through a dedicated resource, the National Clinical Trial Database (OsSC), which also allows for information sharing among patients and healthcare operators. Furthermore, in order to guarantee the best quality levels in terms of prescription and use of medicinal products and to ensure the sustainability of healthcare systems, AIFA monitors the consumption of medicinal products and the pharmaceutical expenditure (public

and private) through the National observatory on the Use of Medicines (OsMed).
Italy participates, in various ways, in all clinical trial phases. The number of Phase I and II studies conducted in Italy is increasing in respect to the total research studies conducted in Italy, standing, last year, at 43.5% (versus 42.0% in 2008). Similarly, Phase III studies confirm the trend started in 2005, i.e. remaining below 50% of the sample: in 2009 they declined, for the first time, below 40% of the total. The most researched therapeutic area is oncology (about one third of all clinical trials), followed by cardiology/vascular diseases, neurology and immunology/infectious diseases, each of them representing 9% of the total.
Clinical research activity is reviewed by the Ethics Committees that operate at the local level.
In Italy, in the year 2009, 1.8 billion of drug packages were dispensed within the territory (an average of 30 packages per inhabitant) with a 16.5% increase compared with the year 2000. Most of the medicinal products are reimbursed by SSN (about 70% of the expenditure).
Within the general population, a 76% prevalence of use is observed, with a difference between men and women, i.e. 71% men and 81% women. The population above 65 years of age consumes annually about 60% of all medicinal products and accounts for about 60% of the total expenditure. The population up to 14 years of age consumes less than 3% of the total despite a high exposure level especially to antibiotics.
Italy is one of the European countries with the highest insurance coverage of pharmaceutical care. SSN provides for the free dispensing of all the most important drugs for relevant, acute and chronic diseases.
Anti-neoplastic and cardiovascular medicinal products are those with the highest degree of public coverage (93-94%). Of the 5 billion euro spent in the year 2009 for cardiovascular medicinal products, more than 4.7 billion euro was disbursed by SSN. The therapeutic category with the highest consumption rate is represented by cardiovascular medicinal products (439 DDD (Average Number of Treatment Days)/1,000 inhabitants per day) which represents almost 50% of the medicinal products consumed within the territory. Medicinal products for the digestive system and metabolism (including anti-diabetic products) [125 DDD/1,000 inhabitants per day] represent 14% of total consumption. The other categories of the most used medicinal products are represented by haematology drugs (9%), nervous system drugs (6%), respiratory system drugs (6%) and musculoskeletal system drugs (5%).
All together these six categories of medicinal products account for almost 90% of the total medicinal products used in Italy.
Noteworthy is the consumption of antibiotics since Italy is one of the countries with the highest consumption thereof and, contrary to some other European countries, shows a growth trend (from 24.0 to 24.4 DDD/1000 inhabitants per day; +6% in the five year period, from 2005 and 2009).
An excessive use of antibiotics, besides increasing the risk of adverse reactions, is one of the main causes for the occurrence of bacterial resistance and for this reason, many European countries monitor very closely the use of this type of medicinal product as well as the trend of bacterial resistance. The European Antimicrobial Resistance Surveillance System (EARSS) places Italy among the countries with the highest level of antibiotic resistance, with a great disparity between North and South.
The OsMed 2009 Report has studied the appropriateness of the use of medicinal products in hypertension treatment. It was reported that only 57% of the patients respond to the treatment with a wide range of regional variation. The response seems to be tied to the gender (higher in men) and to the age (higher in the age group from 66 to 75 years).
In the same Report, the prevalence of use of hypolipemiant medicinal products has been studied within the general population and in subjects with specific indications for the treatment. The response to the treatment with hypolipemiant varies according to the clinical characteristics of the treated

Table. Consumption (DDD/1,000 inhabitants/day) of NHS class A medicines by ATC code (Years 2005-2009)

ATC code	2005	2006	2007	2008	2009	Change % 2009-2005
C - Cardiovascular system	388.3	417.8	431.6	454.3	439.1	13.1
A - Alimentary tract and metabolism	91.8	101.4	105.8	115.8	124.9	36.0
B - Blood and blood-forming organs	71.7	80.1	81.2	84.7	87.5	22.1
N - Nervous system	45.9	49.5	50.8	53.2	55.4	20.8
R - Respiratory system	47.6	48.8	49.2	49.2	50.5	6.1
M - Musculoskeletal system	37.5	39.9	41.2	43.6	44.0	17.3
G - Genitourinary system ahd sex hormones	39.8	40.3	40.1	40.3	40.3	1.2
H - Systemic hormonal preparations excluding sex hormones and insulins	27.4	29.6	30,6	31.5	32.3	17.6
J - Antiinfectives for systemic use	24.0	24.0	24.5	25.1	25.4	5.9
S - Sensory organs	15.5	16.7	16.7	17.0	17.7	13.8
L - Antineoplastic and immunomodulating agents	5.7	5.4	4.6	4.5	4.4	-23.0
D - Dermatologicals	3.0	3.1	3.2	3.7	4.0	33.9
P - Antiparassitic products, insecticides and repellents	0.5	0.6	0.6	0.6	0.7	33.4
V - Various	0.1	0.1	0.1	0.1	0.1	-25.1
Total	**798.9**	**857.2**	**880.3**	**923.7**	**926.2**	**15.9**

The DDD values of some molecules changed in 2009.
Source: Datawarehouse AIFA.

patients, but remains inadequate also in subjects with a greater cardiovascular risk. Overall, the analysis data, in terms of appropriateness, shows that there is definitely room for improvement in all the Regions with related positive effects on public health (number of preventable events) and on healthcare expenditure.

The project "Traceability of the medicinal product" has enabled the carrying out, in the first five years of its implementation, of the effective monitoring of the distribution industry as regards the medicinal products authorized to be marketed in Italy. In fact, the database that was developed collects all data related to the medicinal products' outward movements from each distribution site, with the indication of the receiving party and of any identified issues, as well as the elimination of some medicinal products from the distribution channel (products that are stolen, disposed of and/or lost), in addition to the economic value of the medicinal products supplied to the SSN public facilities. In addition, data is collected regarding the pharmaceutical labels (to be placed on the box of medicinal products), provided to the pharmaceutical companies by the Italian Poligraphic Institute and State Coinage Office, and the labels that are destroyed during production.

Therefore, the Ministry of Health owns a significant amount of information which enables the monitoring of the pharmaceutical market with a remarkable level of detail, unique worldwide, that is useful and shared at a central level among different areas of responsibility (Italian Drug Administration, Ministry of the Economy and Finance, Police force) and at a local level (Regions, SSN facilities). Furthermore, the database represents an effective vehicle for combating counterfeiting and the illegal entry of medicinal products into the market, for the protection of the population and of a legitimate distribution. As regards the medicinal products purchased by SSN, two new monitoring systems were added to the medicinal product traceability project:

- Information flow for the distribution of medicinal products performed directly by hospital pharmacies or by means of independent pharmacies;
- Information flow for the consumption of medicinal products at in-patient and outpatient facilities.

7. System for evaluating the health services provided by the Italian National Healthcare System

7.1. National System for the monitoring and control of public healthcare (SiVeAS)

The objective of the National System for the monitoring and control of public healthcare (SiVeAS), established pursuant to Law 266/2005, is to ensure that, in providing health services, the appropriateness and quality criteria, as well as the efficiency in the use of production factors, are satisfied in respect to the allocated funding. Other objectives were entrusted to SiVeAS by the 2007 Financial Law in terms of Realignment Plans.

- The Ministry of Health, through the SiVeAS activity performs two fundamental tasks:Provides its support for the development of tools for the evaluation and implementation of good practices in terms of efficiency, efficacy and quality of the healthcare services provided;
- Guarantees the performance of all necessary actions for the support and control of the Regions committed to Realignment Plans.

SiVeAS avails itself of, and coordinates, the cooperation of external bodies (with which the Ministry enters into Agreements or Partnership Agreements), of qualified experts and internal personnel, for the implementation of a program that can be broken down into 10 lines of activity.

1. LEAs Monitoring: activities have focused on the development of quantitative measurements of the healthcare services provided, in terms of their quality, appropriateness and costs, through a set of suitable resources and methodologies. The future objective is to strengthen the assessment of the integration among the different levels of healthcare, as well as the assessments of quality, appropriateness and accessibility of services.
2. Promotion and assessment of management efficiency: as regards the management of personnel in the Regional Healthcare Service (SSR), an indicator-based system was developed and implemented at facility and regional levels, aiming at identifying and understanding any difference in the average remuneration to different operators; as regards the management of purchasing of goods and services, an assessment was carried out on the different organizational and institutional solutions adopted by the Regions toward a centralized management of the purchasing processes, in order to determine the efficacy of these centralized solutions in terms of actual improvement of the procurement process.
3. Promotion and assessment of efficacy and quality: activities have focused on the assessment of the results of treatments and on the perceived quality. The initiatives were launched aiming at identifying the critical areas that would require improvements as regards the monitoring the trend in the quality of treatments over time, the assessment of the efficacy of implementing new technologies, and the definition of cognitive instruments that would facilitate a systematic and standardised monitoring of the quality as perceived by users and operators.
4. Appropriateness promotion and assessment: in terms of organizational appropriateness, activities have focused on the formulation of a methodology for an integrated and effective reading of assessment indicators at the corporate level, through the application of clinical governance fundamentals, as well as on the conduct of a national survey regarding the departmentalization process underway. As for the clinical appropriateness, activities were carried out in support of the promotion, organization and assessment of healthcare continuity, as well as of the monitoring of healthcare paths, implementation and presentation of audio-visual media on the application of a checklist for safety in the operating room, development and/or update of guidelines on tonsillectomy, perioperative antibiotic pro-

phylaxis in adult patients, flu syndrome, diagnostic imaging and pre-operatory testing.

5. Accreditation and organization of the services offered: activities have focused mainly on the Regions under Realignment Plans, seeking to redefine the criteria and the methods applied to the reorganisation of the network in order to ensure greater efficiency and responsiveness to public needs. Still in this area, oncology paths within the SSR were studied through specific analyses of the network services offered.
6. Accessibilities: activities have focused on monitoring the organizational models adopted by *intra moenia* private practices at the regional and corporate level, on monitoring the implementation of participation in costs of the services, and on the analysis of the impact of social and territorial inequalities on general health and access to healthcare services.
7. Health and social care: the Regions under a Realignment Plan were given specific support through a technical-professional assistance in the development of local initiatives, and through the monitoring of initiatives geared to fulfil the commitments under the Realignment Plans.
8. International comparisons and database integration: activities have focused on the development of methodology and operative models applied to a comparison between our healthcare system and foreign healthcare systems in order to overcome self-referentiality in the assessment of the levels of fulfilment of the needs for protection of public health, as guarantee by our national system.
9. Support of the Regions under a Realignment Plan implemented through the following macroactitivies:
   - Centralised support: includes the prior approval, in partnership with the Ministry of Economy and Finance, of the provisions related to the implementation of the Realignment Plans as well as a periodic assessment of the achievement of interim objectives, as set forth in the Realignment Plan;
   - Monitoring of the impact of the Realignment Plans: activities have focused on assessing, also through indicators, the effects generated by the changes implemented, in particular, in the areas related to the management of personnel, centralisation of purchasing activities, decisions on the setup of hospital networks;
   - Support at a regional level: it offers technical support to the Regions as regards areas of particular interest.
10. Transfer of the developed models: it was initiated in 2010 and is dedicated to the transfer of models developed and tested to other lines of activities.

7.2. Realignment Plan

The Regions that defaulted, according to the Assessment Panel, in reference to a series of organisational and management fulfilments including costs reduction, and to the obligation to guarantee the economic-financial balance of the healthcare system, are signing an agreement with the Government aimed at setting up a Realignment Plan of the deficit resulting from healthcare expenditure. The Regions that have entered into this agreement, in the years 2007-2008, were: Abruzzo, Campania, Liguria, Lazio, Molise, Sardinia and Sicily. They were followed, in 2009-2010, by Calabria, Piedmont and Puglia.

The reasons for the default and consequent critical areas in the Regions that have signed the Realignment Plan, appeared to be mostly homogenous: failure to reorganize the hospital services and failure to comply with the standards for the availability of acute and post-acute beds; complete lack of territorial facilities, both as district facilities/services and as rest and care homes for the elderly; delay in signing national collective bargaining and in signing contracts with the accredited private parties as well as failure to regulate the relationship with the latter; lack of controls over pharmaceutical expenditure; delays in

corporate organisation and in the information flows necessary for monitoring expenditure, services and supply network.
The Plans are configured as an industrial restructuring program which, through an overall reorganisation of the SSR, and by attacking the structural causes for the deficit, is capable of impacting expenditure and thus re-establishing an economic-financial balance in the sector, in compliance with the LEAs and with a new attention given to the appropriateness and quality of the services rendered. The relationship with the Government is based on cooperation and support recognizing the full institutional competence and responsibility of the Regions.
The implementation of the Realignment Plans has shown, at its launch, more difficulties than expected. In the first few years, all efforts were focused on reducing the debt through the containment of expenditure, activities toward correcting waste, ineffective management models and inappropriateness, without an adequate intervention on the structural causes of the deficit. The result has been modest in terms of deficit reduction.
This explains the subsequent Government interventions which have led to the management by a commissioner, in the Lazio, Abruzzo, Campania, Molise, Calabria regions, with the purpose of overcoming political and bureaucratic resistance, and of re-launching the programs.
With "Patto per la Salute" (Public Health Contract), drawn up by "Intesa Stato-Regioni" (Government-Regions Agreement) dated 3 December 2009, and with the Financial Law n. 191 of 2009, the Regions were given the opportunity to formulate operational programs for the continuation of the Realignment Plans for the year 2010 and subsequently 2011-2012. The Regions that have submitted this Operational Program are: Abruzzo, Campania, Lazio, Molise, Sicily.
More urgent interventions, also structural, are currently taking place thanks to a process that has led to the strengthening of the regional structure as regards its planning, managing and control competence and capacities, as well as to the adoption of more advanced models following measurements against other Regions. New healthcare plans, hospital plans, development of centralised regional purchasing offices, new organisational models for territorial emergencies, further development of information systems, development of services quality and appropriateness controls, have been recently approved.
The Technical Support Panel, in operation from 2007 until 15 March 2011, has held 143 meetings aiming at assessing the implementation of the Realignment Plans by the involved Regions.
SiVeAS has carried out three types of monitoring activities:

- formal monitoring of the adoption of the measures provided for in the Realignment Plan;
- system monitoring: development of models, based on information sources, for the assessment of the impact of activities carried out at the regional level, in particular as regards hospital care, personnel dedicated to outside-hospital care and emergency care;
- implementation monitoring: the following areas were subject to study and intervention: reorganization of the diagnostic laboratory; implementation of the Single Points of Access and adoption of the multi-dimensional evaluation cards.

7.3. Monitoring of the Essential Levels of Healthcare (LEAs)

The monitoring of LEAs, in order to assess the achievement of the objectives of public health protection pursued by the Healthcare System of the individual Regions, is carried out through the "Guaranteed System" (Ministerial Decree of 12 December 2001) and the "Implementation Assessment" under the responsibility of the permanent Committee for LEAs assessment.
The Ministerial Decree of 12 December 2001, under review and update, contains a multi-stage indicators system (input, output, process and, if possible, outcome) which enables the monitoring of the provi-

sion of LEAs to Italian citizens, within the different regional contexts.
Since 2001, the results of the monitoring are published in a national annual report, freely accessible, available on the Ministry site.
The other assessment tool, as set forth in the Government-Regions Agreement of 23 March 2005, is represented by the "Implementation Assessment" under the responsibility of the LEA Committee, which within the area of "services provided in compliance with LEA" performs a concise assessment of the actual compliance with LEAs within the entire territory. To this purpose, a set of indicators was defined (LEA grid) for the different sectors of healthcare which is annually subject to review by experts in the field. The choice of indicators reflects, on the one hand, the breakdown of SSN resources at the various levels of healthcare and, on the other hand, the main political-programmatic indications. In the preliminary phase, the overall assessment model provides for a weighting system and the assignment of a score based on the level achieved by the Region when measured against national standards. During the implementation assessment process of 2009, the Centre-northern Regions, except for Lazio, were found compliant with LEAs. The area "implementation with commitment" comprises those Regions (Basilicata, Sardinia and Puglia) which, although reaching an intermediate score, must demonstrate in the next assessment year to have fulfilled the obligations associated with the identified critical areas. The situation of the Southern Regions and of Lazio remains problematic as they have defaulted. For these Regions, overcoming the default situation is strictly tied to the development of the Realignment Plan, in particular as regards the most critical areas that were identified.

7.4. Government National Plan for the Waiting Times

The issue of waiting lists represents one of the most critical aspects of all universal healthcare systems operating at a high level. Our country considers the reduction of the waiting times as a high priority on the basis of clinical and organisational appropriateness and clinical governance; this entails a close cooperation between the Government and the Regions and the sharing of interventions based on criteria of accessibility to the services and timeliness of payment for the services provided, in compliance with the requirement of defining priority classes and the full implementation of the network booking system (CUP).
Among the various issues to be considered in terms of waiting lists management, the implementation of a transparent and updated communication of data concerning times and waiting lists is very important. The web sites made available by almost all the healthcare facilities represent an effective and easily assessable source of information and communication.
In November 2010, the Ministry of Health has carried out the fourth survey on the use of the internet as an effective vehicle for the communication of data on times and waiting lists through the web sites of Regions, Provinces, ASLs, Hospitals, IRCCS and Policlinici. This survey, which followed three other surveys carried out in October 2005, December 2007 and November 2009, found that 44% of the surveyed Web sites have increased the communication of data on waiting times and waiting lists by 21%, 22% and 10% compared with the surveys conducted in 2005, 2007 and 2009 respectively.

- Through the Government-Regions Agreement of 28 October 2010, the National Management Plan of Waiting Lists (PNGLA) for the three year period between 2010 and 2012 has been approved; the regions reaffirm their commitment to guarantee an appropriate access by the citizens to healthcare services in compliance with rigorous criteria of appropriateness, respect for priority classes and transparency of the system at all levels. The New National Plan, by systematizing the available information flows, is implementing several activities, some of them already developed in the last two

years, and in particular:updating the list of diagnostic, therapeutic and rehabilitation services for out-patient specialist healthcare and in-patient healthcare for which the maximum waiting times must be set out by the individual Regions within their own Plan; identifying cardio-vascular and oncology as priority areas for the development of diagnostic-therapeutic paths (PDT) that guarantee that diagnosis and treatments are provided in a timely manner;

- identifying, as a guarantee of transparency and accessibility to data on waiting list and waiting times, the necessity to systematically monitor such data availability on the web sites of Regions and Provinces as well as of public and private accredited health facilities;
- promoting the models for the use of *intra moenia* private practices within the management of waiting lists, and computer features for booking the services provided by private practices;
- identifying assessment tools applicable to the monitoring of waiting times:
  - *ex ante* monitoring of the waiting times for critical, booked out-patient services, carried out through an information flow, within the NSIS system, based on a six months assessment within an index period of time set forth at the national level
  - *ex post* monitoring of the waiting times for services provided, carried out through an information flow of ex article 50 of Law 326/2003;
  - monitoring of hospitalization waiting times carried out through the SDO information flow;
  - monitoring of the waiting times for the services provided by *intra moenia* private practices, carried out through the related information flow.

The New National Plan PNGLS requires the Regions to monitor the PDTs in the cardiovascular and oncology areas, in terms of compliance with the maximum waiting times set forth for the formulation of a clinical diagnosis and for the start of the treatment that is most appropriate for that kind of condition, in order to ensure that the patients have completed the PDT within an acceptable time; the maximum waiting times for each PDT, for clinical conditions under monitoring, must not exceed 30 days for the diagnostic phases and 30 days for the start of the treatment from the diagnosis time, for at least 90% of the patients.

7.5. Waiting times in cardiovascular diseases

The issue of waiting times referring to vascular diseases, their reduction as well as the reduction of migrations of patients across Regions, has been studied by a Commission appointed by the Ministry.

The requests for diagnostic exams and treatments do not have the same priority: the services must be provided according to clinical priority criteria, to the severity of the condition, whether suspected or confirmed, in order to protect the health of the patient. The Regions must identify the paths that enable the identification of cases with priority access to specialist services. These priority determinations are tied to the severity of the medical condition assessed by the physician, according to the organizational models defined at the Hospital Trust level, and based on criteria agreed upon by General Medicine Physicians and Specialist Physicians.

In the case of cardiovascular diseases, when a suspected medical condition is identified, the appropriate path for a quicker execution, proportionate to the health risk to which the patient is exposed, must be adopted. The most appropriate path must be agreed upon between the General Medicine Physician and the Specialist Physician and must be initiated by the General Medicine Physician. The subsequent priority path is decided by the Specialist Physician based on clinical criteria.

The priorities are divided into the four following levels, A B C D:

- A: Emergency service for which the alternative is the Emergency Room, or within 72 hours due to a possible serious clinical progression of the medical condition.

- B: Service that, if promptly provided, i.e. within a few days, will determine the short term prognosis of the patient, or may impact significantly pain, dysfunction or disability. To be provided within 10 days.
- C: Service that, if promptly provided, does not determine the short term prognosis but that it is required based on pain, dysfunction or disability. To be provided within 30 days.
- D: Service that can be planned within a longer period of time since it would not impact prognosis, pain, dysfunction or disability.

The waiting lists must be divided between those requiring diagnostic procedures and those requiring treatment, which entail different parameters and health care issues.
Screening and check-up procedures do not fall into the priority category and must not be included in the general waiting lists, but they must follow specific paths set out by the facility that has performed the treatment or has formulated the first diagnosis according to the Guideline for that particular specialty.

7.6. Waiting times in oncology diseases

It is necessary that the diagnostic exams (diagnostic imaging, endoscopy, clinical pathology) and the treatments for patients with confirmed or highly suspected diagnosis of an oncology disease, have priority over other diseases. Except for cases of emergency within the oncology area, both of a surgical and medical nature, the conditions that would require absolute priority are divided into 4 different groups of patients:

- Urgent diagnostic priorities (within 3 days):
  - patients with an oncology disease in rapid/symptomatic progression,
  - serious complications related to the treatments provided;
- Diagnostic priority for an adequate therapeutic program (within 10 days):
  - patients with a confirmed or suspected diagnosis of cancer or cancer relapse,
  - patients at an initial stage or with a relapse of a neoplastic disease,
  - re-assessment under way or at the end of a cancer treatment;
- Follow-up of patients already treated for neoplastic disease (within the limits defined by the guidelines);
- Organised or opportunistic screening (within the limits defined by the guidelines).

The conditions of groups A and B are to be treated as priorities. The conditions of groups C and D are not to be treated as priorities: for indication and times, please refer to the national and international guidelines. Services requested for patients who do not have specific symptoms are not to be prioritized.
As regards the waiting lists for screening exams, they should be separate from those of other categories and, if possible, these exams should be performed in facilities specifically dedicated and certified for these types of services.
The patients who are candidates for priority paths (Group A and B) can be identified by adopting methods that enable an immediate recognition. As a cyto-hystological diagnosis is fundamental for an adequate stage determination and treatment plan, the timeframe for these exams must be extremely short (7 days maximum).
As for the waiting lists for treatment, the issue regarding their time reduction is more complex and not-easily solvable in the short term without an overall, drastic reorganisation of the entire healthcare systems. Implications and control methods are very complex and different between surgery, chemotherapy and radiotherapy.
Even in the case of surgery and chemotherapy, there are different types of patients for whom different priorities must be applied in relation to the clinical condition and the progression/aggressiveness of the disease. These timeframes should be observed:

- urgent priority treatment (within 3 days):
  - patients with an aggressive/rapidly growing cancer;
  - patients with a highly symptomatic condition;
  - treatment complications;
- standard priority treatment (within 15 days):

- patients diagnosed with a neoplastic/relapsed condition and who require a specific treatment. This group includes most clinical conditions occurring in solid tumours and a significant part of oncohaematology conditions. These are diseases that, especially in the operable stage, benefit from very prompt treatment;

■ Low priority treatment (within 30 days):
- patients with slow-growing cancer for whom a delay in starting the treatment would not affect the prognosis;

■ Palliative therapy approach (within 60 days):
- asymptomatic patients who are candidates for palliative therapies and for whom a quick start of the treatment is not necessary.

Groups A and B require priority of treatment. For these two groups a delay above 3 to 15 days respectively, before starting the optimal treatment, from the day of the diagnosis/stage determination, is not acceptable.

Groups C and D do not represent a priority even though an acceptable timeframe for starting treatment is expected.

As for radiotherapy, the following parameters are to be applied:

■ Treatments to be started within 15 days:
- presence of clinical conditions suggesting that a possible delay may potentially jeopardize the probabilities to obtain the expected therapeutic outcome,
- treatments aiming at relieving symptoms;

■ Treatments to be started within 30 days:
- elective treatments with curative objectives;

■ Treatments to be started beyond 30 days:
- planned adjuvant treatments, integrated in sequential therapeutic strategies

Appropriateness of the treatments

■ *Diagnostics*. The diagnostic appropriateness for oncological pathologies is determined by the primary care physician (General Medicine Physician, Specialist Physician) and confirmed by the imaging diagnostic physician (radiologist, nuclear medicine physician) and/or by specialists in endoscopy; the assumption of responsibilities is therefore shared (control mechanism); in particular the appropriateness of choices and/or of the sequence of priority investigations must comply with the consolidated guidelines ("Imaging diagnostic. National guidelines of reference" issued by SIRM, AIMN, AINR, ASSR); as provided for by current laws, these choices are the responsibility of the prescribing physician, but also of the imaging diagnostic physician who may change the type of investigation. This way the characteristics of appropriateness for access by the individual patients as well as the correct diagnostic procedure are identified.

■ *Surgical treatments* Given the possibility that patients, whose characteristics may exclude them from surgery, may be considered for this treatment, highly prevalent is the application of national and international guidelines on the appropriateness of surgical interventions in oncology and rules for professional correctness, on scientific updates and constant review of the parameters to be used for determining the appropriateness of surgery. The determination of the appropriateness of the indications may be guaranteed by the sharing of decisions by multi-disciplinary teams which periodically meet in order to discuss the individual clinical cases and their treatment within standard or investigational protocols. Also possible would be the institution of surveillance bodies composed of an adequate number of professionals within the surgical and oncology areas, external to the Institution, who should also have the task of drafting periodic reports on the activities carried out in each hospital. The experiences of other countries are definitely positive as regards the results obtained through this type of audit system. Specific recommendations, communicated also to citizens and patients, must be made regarding the minimum requirements in terms of experience and volume of surgeries performed

by the individual surgical team in previous years, for each type of pathology, within the oncology area. These recommendations may represent determinant factors in terms of accreditation and certification obtained by the facility for the performance of the surgery and therefore for the treatment of the individual cancer pathologies (facilities of excellence).*Radiotherapy*. The category to which the patients belongs (based on the type and stage of the disease, condition of the patients, etc) in compliance with the priority parameters of the "programmatic lists" is determined by the primary care physician (General Medicine Physician, Specialist) and confirmed by the physician specialized in radiology: the responsibility is therefore shared (control mechanism). In particular, the appropriateness of the decision must be compliant with the consolidated guidelines (NCI, AIRO, AIOM, etc.). As set forth in the applicable laws, these decisions are the responsibility of the prescribing physician but also of the specialist physician (radiologist) who may change the type of treatment. Any change in the type of radiotherapy carried out, must be explained by the radiotherapist.

- *Medical treatments*. Also in this case, the requests for medical treatment, based on the above listed priorities, must be confirmed by the oncologist; therefore the responsibility is shared. The confirmation of the appropriateness of services and prescriptions, based on the guidelines formulated by the appropriate scientific organisations (AIOM, ESMO, ASCO), is advisable.

From a general point of view, in terms of controls and confirmation of the appropriateness, the following initiatives should possibly be carried out:

- Having a clear understanding of the waiting lists and of their evolution over time, at the level of the individual hospital and Region;
- In the case of non-appropriateness determined by the control committees, established for control purposes, punitive mechanisms must be taken into consideration;
- The setting up of a regional oncology network for clinical-healthcare services must be supported, under the coordination of the oncology facilities of excellence, with an identification of all Oncology Departments, also inter-facility, operating in the territory. This network, besides supporting healthcare services at a higher level, must guarantee the reduction of waiting times and costs, as described above, thanks to a better appropriateness of prescribed treatments, always agreed upon by multi-disciplinary teams.

7.7. Appropriateness of services

In the last few years, there has been a growing attention and sensitivity demonstrated by the facilities toward the importance of determining the appropriateness of the services provided, paid by SSN, and in particular of the indicators measuring some aspects of the quality of the services and use of healthcare resources, in order to promote the improvement of the quality of services and healthcare provided.

Within the scope of the SiVeAS Project, several analyses models have been developed for this purpose, among which are the "Assessment of the performance of regional healthcare services" developed by the Management and Healthcare Laboratory of Scuola Superiore S. Anna di Pisa and the "Analysis of the variations in hospitalisation". The first provides for a set of 34 indicators applicable to pharmaceutical, hospital, district and collective/prevention care, regarding specifically the measurement of appropriateness, in clinical and organizational terms, as well as in terms of the efficiency of healthcare services. The indicators are then illustrated in a graph for an immediate understanding of the complex situation of the Region in question. The second one, by analysing the variations in hospitalisation rates in the various territorial aggregations, enables the identification of the services that, being characterised by a high variability within

the territory, not explainable in epidemiological terms, may be an indication of a potential non-appropriateness.

The Healthcare Agreement 2010-2012 introduces a wide range of indicators, among which are some specifically directed to the monitoring of organisational appropriateness, further updating the list of DRGs at high risk of appropriateness, if provided within ordinary hospitalisation.

On this subject, the Ministry has recently published the indicators of organisational appropriateness, under attachment 3 of the Healthcare Agreement, and the "Appropriateness Operational Programme", an in-depth study and experimental application of indicators in order to determine the level of appropriateness of hospitalisations due to the lack of other forms of care, according to data from the information flow of the Hospital Discharge Records (SDO).

All the indicators have been calculated in reference to the hospitalisations occurring in the period of time between 2001 and 2009, in order to allow for a more accurate interpretation of the results and a more correct reading of the "appropriateness" concept. This data is available on the portal of the Ministry of Health in the section dedicated to hospitalisations.

Within this area, the Ministry plays a significant role as a guarantor of the transparency of SSN by promoting the cooperation between Government and Regions toward a constant improvement of the flows of information from the New Health Information System and of their use for the purpose of analysis, monitoring and control of the care provided, and support of health planning activities.

Figure. Target chart.