Two Italian Health Authority Databanks in the field of Medical Devices

The “Data Bank and Repertory of medical devices” and the “Data Bank for monitoring consumptions of medical devices directly acquired by Italian NHS” represent two key tools for collection and management of relevant information related to medical devices and for safety, affordability and quality promotion in their use.

The Data Bank and Repertory of medical devices

The “Data Bank and Repertory of medical devices”, created in the 2007, is a broad reach tool; it concerns in depth aspect referred to surveillance and vigilance on medical devices. In particular, the database collects information related to medical devices marketed in Italy, the Repertory includes, instead, all information related to medical device, market in Italy, whose manufacturers have declared the willingness to provide them to Italian NHS facilities. The “Data Bank and Repertory of medical devices” includes the following information:

- Manufacturer’s Data (Denomination, Tax identification number, VAT Number, Legal office, Other operating location, etc.)
- Medical device’s data (Medical device type, National Classification of Medical Devices code, Complete GMDN repertoire, etc.)
- Medical device’s documentation (Label, Instruction for use, Technical dossier, Scientific bibliography)
- CE Certification data (issued/extended/protracted/suspended/revoked)

Once a medical device has been notified in the “Data Bank and Repertory of medical devices”, an identification number is associated to medical device; this number, which represents an useful reference for products’ identification and for the consultation of related information by Regions and NHS Facilities, allows medical device identification, univocally, also in the “Vigilance” monitoring system and, above all, in the “Data Bank for monitoring consumptions of medical devices directly acquired by Italian NHS”.

Medical devices recorded in the Data Bank are classified according to National Classification of medical devices (in brief “CND”), that represents an original classification system adopted in Italy in order to allow, when possible, comparisons among different medical devices.

At present, about 290,000 medical devices are recorded in the “Data Bank and Repertory of medical devices” distributed in the different risk classes, as showed in the following graph.

Distribution of medical Devices by risk classification

- Class I: 110,200, 42.6%
- Class IIa: 77,000, 27.3%
- Class IIb: 49,700, 18.6%
- Class III: 4,070, 1.4%
- Active implantable devices

The “Data Bank and Repertory of medical devices” allows the creation of an unambiguous and certain referential register that is essential for the following strategic goals achievement:

- Managing in a safe and controlled manner medical devices’ acquisition in the Italian NHS;
- Promoting centralized purchasing procedures, savings and more transparency in the purchasing procedures;
- Improving safety for patient and induct vigilance activities on medical devices;
- Correlating, where possible, healthcare procedures with medical devices involved.

The “Data Bank and Repertory of medical devices” makes it possible to:

- Carrying out quantitative and qualitative analyses related to medical devices marketed in Italy;
- Monitoring supply of medical devices from the first introduction to the exit from the market, giving responsibility to manufacturers (and their agents) with regard to affordability and integrity of information;
- Offering to Regions and to Italian NHS facilities specific services of consultation.

The Data Bank is directly held by Manufacturers (or their Agents/other delegated persons); they are allowed to modify registered information autonomously: the systems guarantee indeed registration of all changes. Manufacturers (or their Agents/other delegated persons) are also responsible for recorded data and for their maintenance and, in order to ensure data authenticity, all registration are properly subscribed with electronic signature.

Users of “Data Bank and Repertory of medical devices” are briefly indicated below:

- Manufacturer (or his Agent/other delegated persons): he is responsible for data entry in the “Data Bank and Repertory of medical devices” through a procedure of notification that is carried out only electronically and that ends with validation of recorded data through electronic/p Dimitria signature.
- Ministry of Health - General Directorate for Pharmaceuticals and Medical Devices (DGDFM - MoH): it carries out monitoring of data recorded in the “Data Bank and Repertory of medical devices” and controls data quality.
- Regions and Italian NHS facilities: they could be allowed, on the basis of proper criteria, to consult information related to recorded medical devices. At the present Ministry of Health makes available to Regional users a xml file, updated weekly, that can be consulted and downloaded from the “Data Bank and Repertory of medical devices”. From this point of view “Data Bank and Repertory of medical devices” represents the most relevant source of information necessary to properly purchase and use medical devices, and Regions/NHS facilities’ users are its principal beneficiaries.

The Data Bank for monitoring consumptions of medical devices directly acquired by Italian NHS

The institution of “Data Bank and Repertory of medical devices”, promoting creation and sharing of a “common language” (identification number of medical devices) capable to guarantee unambiguous interpretation of health phenomenon linked to medical devices, signed a fundamental step for the “Data Bank for monitoring consumptions of medical devices directly acquired by Italian NHS” creation. This databank, regulated by the Decree of Ministry of Health of 11th June 2010, satisfies Regions’ need of quantity, in their territory, consumptions and expenditure for medical devices that health facilities, directly managed by Italian NHS, purchase and make available from the 1st October 2010.

Health facilities involved are the following:

- Hospitals (Local Healthcare Units’ facilities, Hospital Farms, National Institute for Scientific Research -IRCCS - University Hospital Farms)
- Laboratories, ambulatories and other territorial facilities
- Rehabilitation centres
- Penitentaries

This informative flow follows, as showed in the picture below, monitoring of contracts and consumptions of medical devices through NHS public facilities.

Informatio flow foresees acquisition of relevant information related to medical devices used in the Italian NHS facilities, and in particular following data:

- Year
- Month
- Facility
- Hospital ward
- Identification n. in the “Data Bank and Repertory of medical devices”
- Distributed quantity
- Price

In addition, the Ministry of Health’s Decree (11th June 2010) foresees pilot transmission of some data related to purchase contracts, and in particular:

- Contract identification number
- Date of contract stipulation
- Contract’s duration
- Type of contract
- Identification n. in the “Data Bank and Repertory of medical devices”
- Awarded quantity
- Unitary price awarded

Data transmission is carried out by users, properly allowed in each Region, only electronically through the upload a XML file.

Each Region can consult other regions’ data: in this way it is possible to make comparisons between two or more Regions and to carry out benchmarking:

- Local Healthcare Unit level
- at Healthcare Facility level
- at Hospital ward level

Feed of “Data Bank for monitoring consumptions of medical devices directly acquired by Italian NHS” will be carry out gradually in three years:

- 2011 - Transmission of essential data related to contract stipulated from 2010.10.61
- 2012 - Transmission of data related to medical devices consigned in each Local Healthcare Unit.
- 2012 - Transmission of data related to medical devices consigned at healthcare facility/hospital ward level