



Ministero della Salute

The drugs tracking system in Italy

Brussels, 14th September

From a European directive to a national initiative...

The Italian project for the creation of a Central Data Base tracking all drugs for human use commercialized in Italy is consistent with the indications of the EU Parliament and Council Directive **2001/83/CE**. The last, in the introduction, point 35, says:



*“It is necessary to **exercise control over the entire chain of distribution of medicinal products**, from their manufacture or import into the Community through to supply to the public, so as to guarantee that such products are stored, transported and handled in suitable conditions. The requirements which must be adopted for this purpose will considerably **facilitate the withdrawal of defective products from the market** and **allow more effective efforts against counterfeit products**”.*



Law 39 1st March 2002 –
(art. 40)

Decree of the Ministry of
Health 15th July 2004

Through the issue of national laws, it was launched the project for the
“Monitoring of drugs packages within the distribution system”

Frauds countering, expenditure and consumption monitoring as the main objectives

The original objective...

Empowering the available measures for **countering the existing frauds safeguarding Public Health, included patient safety and the Treasury** through a system of drugs monitoring all along the distribution channel, by the tracking of sticky progressive identification codes ("*bollini*").

...was extended to a wider scope, leveraging the potential of the Central Data Base.

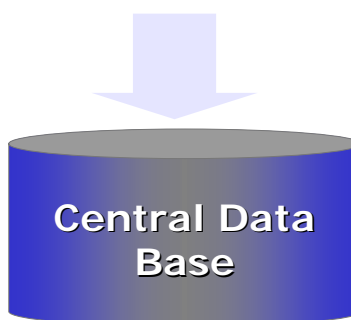
Objectives	The Central DB will provide..
Give the Regions a systematical support on the monitoring of drugs expenditure	... prompt information on expenditures for hospital and territorial consumption of drugs reimbursed by NHS
Monitor consumptions of drugs, both reimbursed by NHS and not	...prompt information on hospital and territorial consumption of drugs, both reimbursed by NHS and not
Promote appropriateness of prescriptions and drugs consumption	... direct link to patient and prescribing physician within the NHIS (National Health Information System) project
Ensure to all citizens prompt access to innovative drugs	... monitoring of drugs location over all the Italian territory

The creation of the Central DataBase

2001	Decree of the MH – 2 nd August
2002	Decree of the MH – 1 st February
2002	Law 39 – 1st March (art. 40)
2003	Law 14 – 3rd February
2004	Decree of the MH – 15 th July



Step 1:
"Bollino" ID system



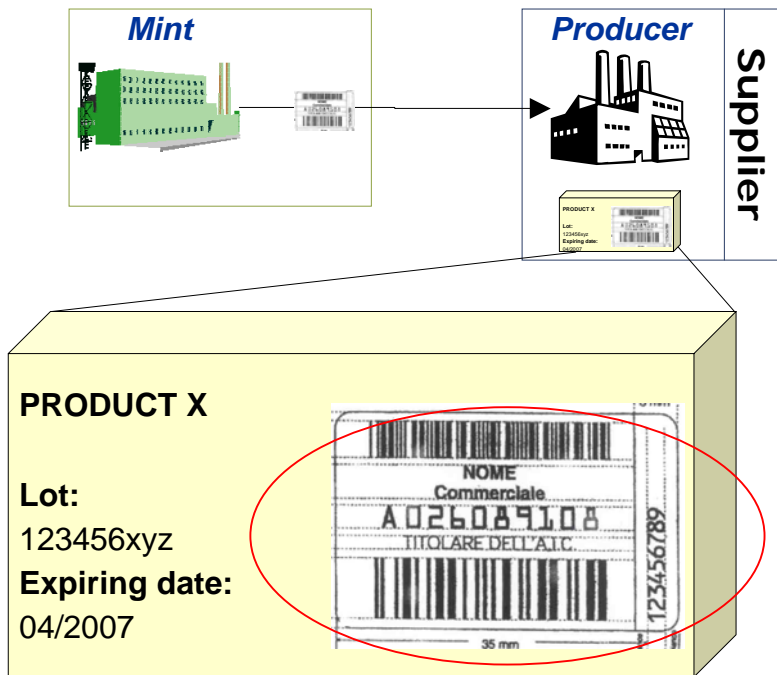
Step 2:
Central Data Base

The creation of the Central Data Base, core of the project, was realized implementing the following laws:

- Decree of the MH – 2nd August 2001: Introduction of a **sticky progressive numeric ID code ("Bollino")** for all medicines reimbursed by the NHS
- Decree of the MH – 1st February 2002: Introduction of the **"Bollino" system for all medicines** for human usage
- Law n.39/2002 (art. 40) – Creation, at the Ministry of Health, of a **Central Data Base recording**, on the base of the "Bollino" system, **all movements of each drug package** via the product code **for each player involved in the distribution chain**.
- Law n.14/2003 – Implementation of EU Parliament and Council Directive 2001/83/CE and **adoption of the expected univocal drugs coding system by the 1st July 2004**.
- Decree of the MH – 15th July 2004: Technical specification for the implementation of the project

The coding and identification system

The Central Data Base stocks the input data on the base of a **univocal identification system** of both **drug packages** and **players** involved in the process.



Drugs Packages

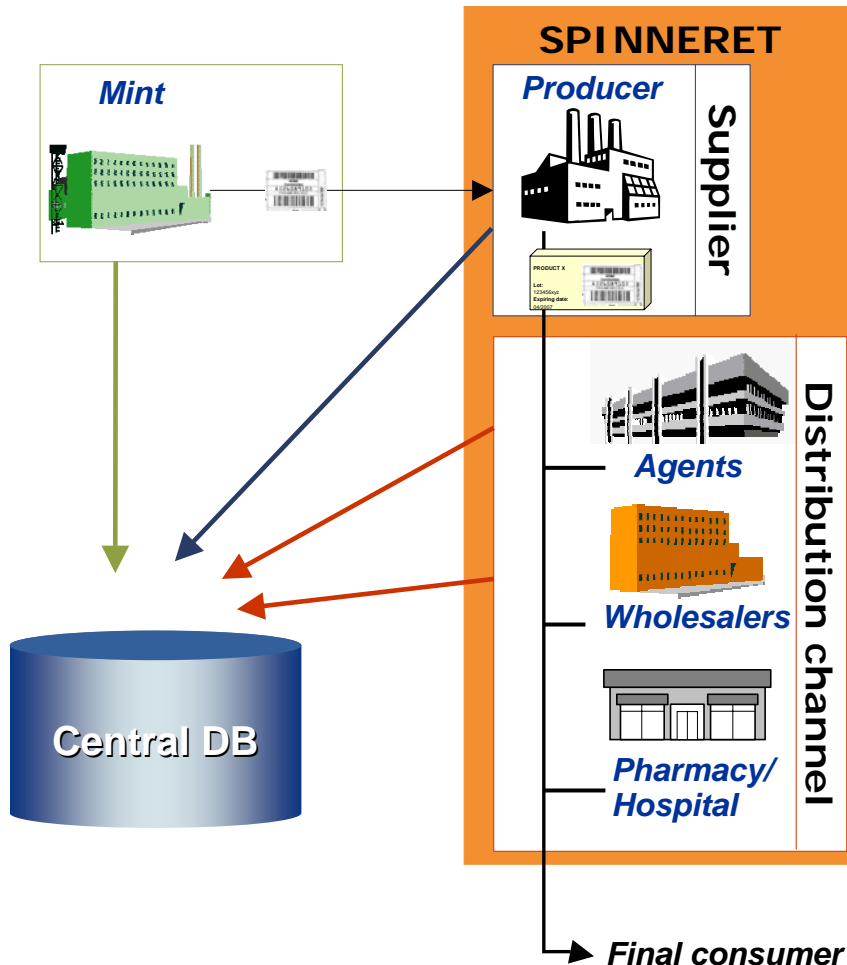
Each package has a "bollino" displaying:

- A.I.C. code** of the drug package that is the **authorization number issued by the Italian Medicines Agency (AIFA)** for commercialization
- Drugs **denomination**
- AIC owner** or **legal representative** of foreign owner
- Progressive identification code** of the single package

Involved players

Each logistic center is identified through a **ID code**, managed by a **central registry DB**.

Data transmission of all drugs movement to a Central Data Base



- Each player involved is considered as a warehouse with in (loading) and out (unloading) movements, each linked to a “reason for movement”.
- **The sender** has to transmit to the system the **out movements** and the related addressees.
- **The addressee**, before using the received material, has to **check the delivery** connecting to the Central Data Base, in order to obtain the information related to the incoming drugs.
- **The addressee** has to communicate any **anomaly and eventually the exit of the drugs** form the distribution channel (loss, thefts, disposal).
- **All movements have to be transmitted “almost” online.**

A step by step approach

The first hypothesis of solution took into consideration:

- the participation of **all the players** involved in the system
- the tracking of **in and out** movements

In order to guarantee the **organizational and technical sustainability** of the initiative and to **reduce the risks related to the complexity** of the solution, it has been decided, together with the players involved, to:

- structure the project in **progressive phases** of implementation
- set up a **technical working team**, including all relevant stakeholders, to manage the project toward the regimen

Technical working team:

Ministry of Health
Italian Medicines Agency - AIFA
Istituto Superiore di Sanità
Regions
Pharmaceutical Companies
Drugs wholesalers
Pharmacies
Hospital Pharmacies
Discharge operators



Technical working team

The phases structure

The **progressive approach** based on phases, each characterized by a gradual implementation, was designed to ensure:

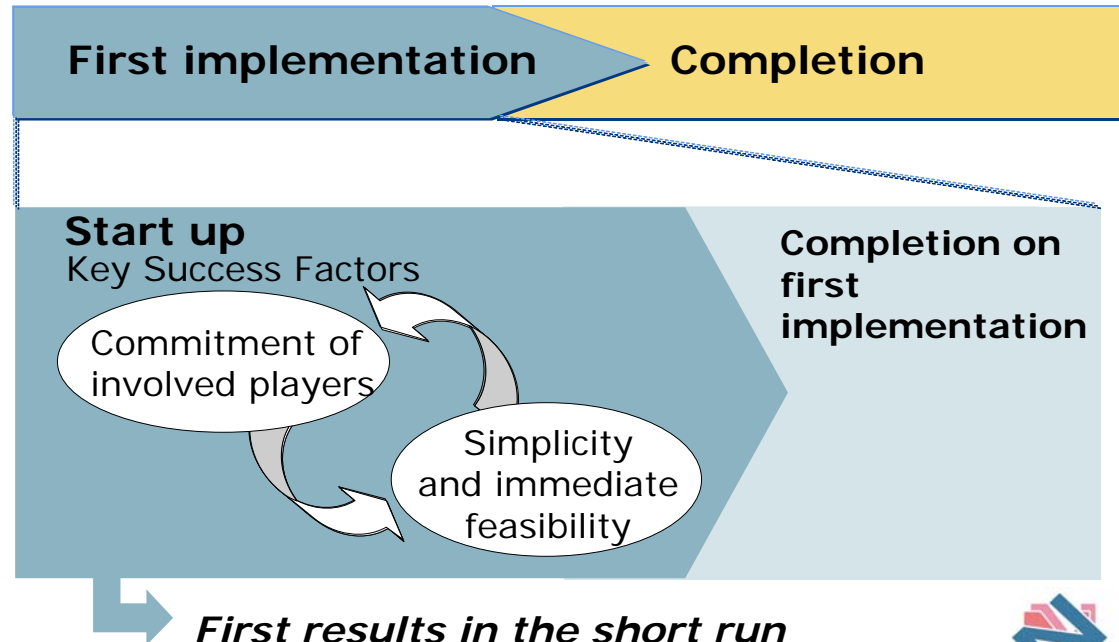
- The fulfillment of first results in the short run;
- A mitigation of the system impact on the players involved.

The simplicity and prompt implementation of the first phase favors:

- a sharing process with the involved players
- to define the best solution at regimen

Simplifications introduced

- Reduction of number of players involved;
- Tracking of out movement;
- The out movement could be grouped by AIC code
- All movements have to be transmitted within 24 hours

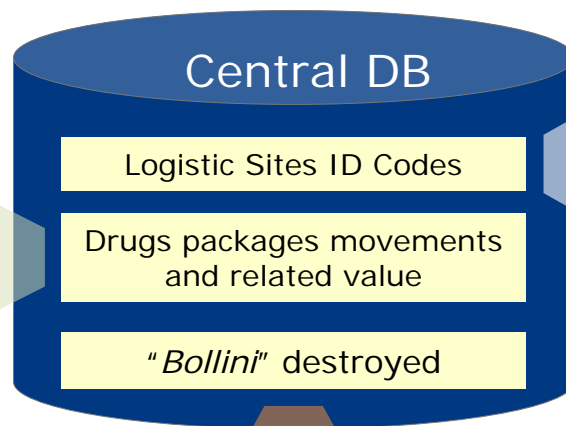


The Data Base information content

The information gathered and managed by the central Data Base are the following:

Drugs movements and related values

- Sender
- Addressee
- Reason for movement
- AIC codes for drugs moved
- Drugs production lot
- Drug expiring date
- Quantity
- Transfer documents (waybill)
- Date and time of issue of waybill
- Buyer
- Invoice owner
- Supply value*



Logistic Sites ID Codes

- Company Name
- Address
- City
- Province
- ZIP cod
- Type of license

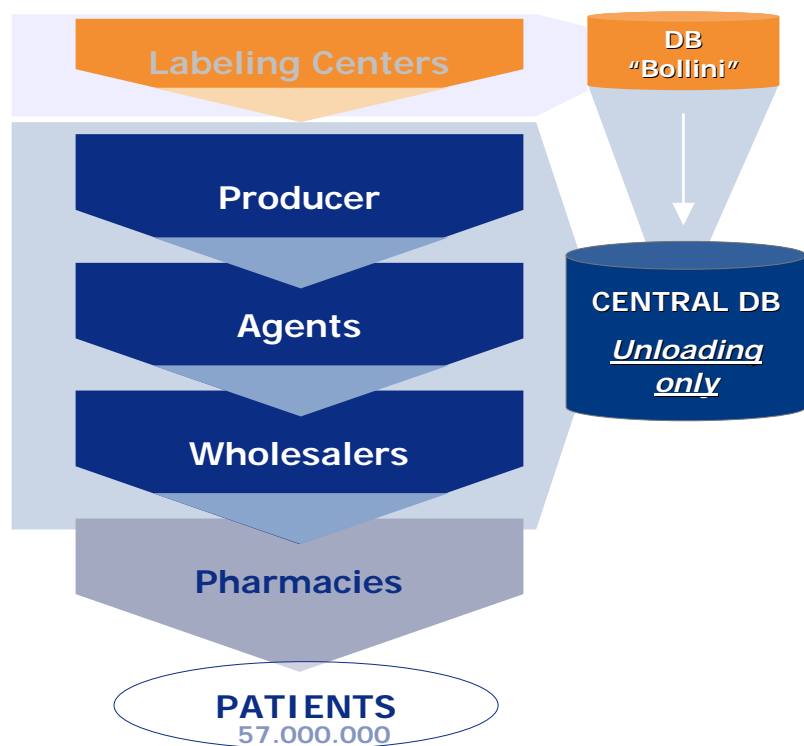
"Bollini" destroyed in the production process

- Sender (logistic site destruction occurs)
- Date of destruction
- AIC code
- "Bollino" production lot
- Drugs' production lot
- Number of "bollini" (also for quantity=0)

* Exclusively for supplies to NHS facilities

First steps in the creation of the Data Base

Phase 1



Starting from **June 2005** we had:

- Transmission of **out movements** (number of drugs packages aggregated by AIC) within 24 hours from expedition, included number of "Bollini" destroyed, related to the period starting **from the 1st of June**
- Transmission of data related to the **supply of *Bollini*** by the IPZS (the national mint).
- Transmission of the **value of all drugs supplied to hospitals and facilities of the NHS**, aggregated by AIC and number of units.

The figures of the project up to now:

- Number of files transmitted: **27.000**
- Number of movements tracked: **86 million**
- Drugs supplies to NHS tracked:
 - Value: **€ 1.543 million**
 - Number of packages: **94 million**
- Number of logistic sites mapped:
 - Producers: **218**
 - Agents: **215**
 - Wholesalers: **347**

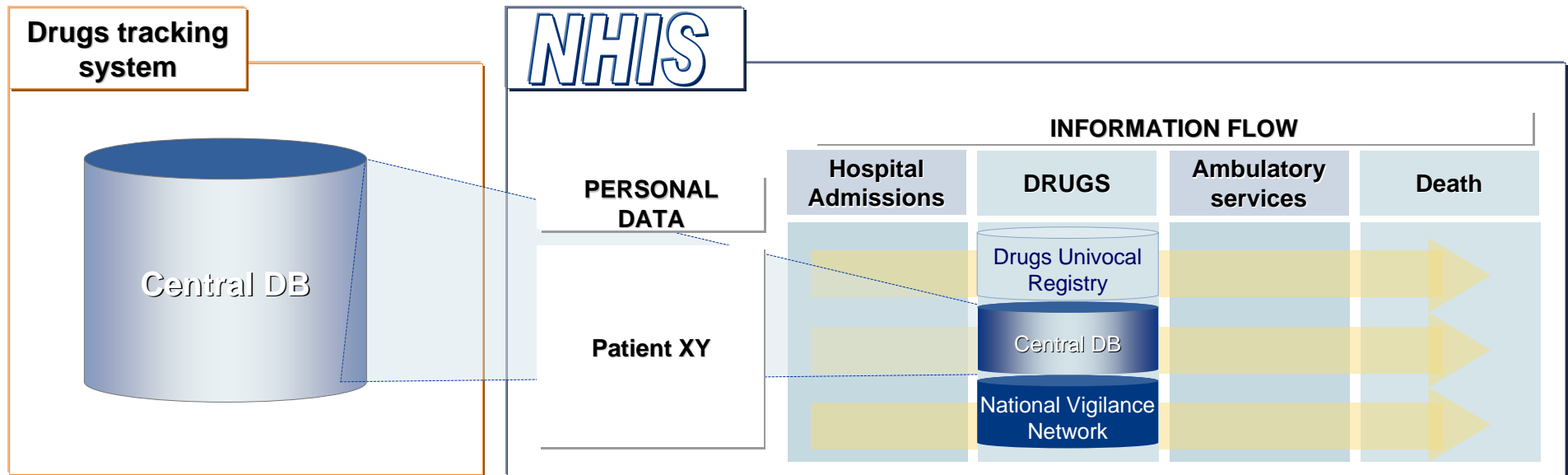
Next steps

To complete the first phase of implementation, in order to start the regimen phase, the **next activities** to start are:

- **Involvement of pharmacies**, relevant player to start the reading of “bollino”
- **Integration** between data of the Central Data Base and information regarding **patients and prescribing physicians**
- Evaluation of solution to **standardize drugs code** within the distribution channel
- Evaluation of **technical solutions** to favour the tracking of the drugs (i.e. RFID)

The Central Data Base as part of a comprehensive initiative

The Central Data Base is an essential of within the **new NHIS (National Health Information System)**.



The NHIS' aim is the implementation of a **System of Individual Health Records** designed to:

- serve the NHS governance needs allowing for a full **monitoring of the assistance network**;
- to support, at an advanced stage, the provision of proper diagnostic services and treatments by **connecting each "event" of provision of care to the citizen it was provided to** and assuring the availability of all information relevant to the definition of the clinical path.