



The drug tracking system in Italy

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Granada, 12th February 2008





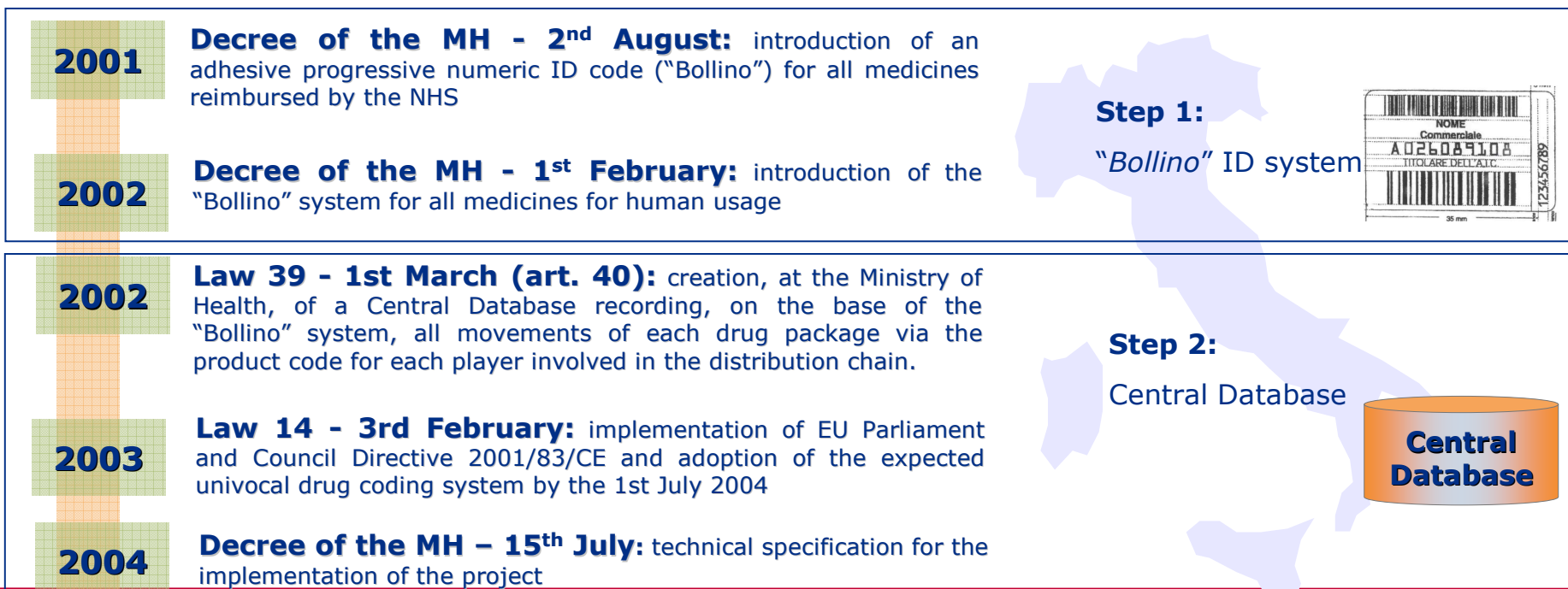
- **Normative context**
- **STEP 1 :The identification system of drugs wrappings**
- **STEP 2: the central database**
- **Project phase 1 - overview**
- **Other gathering information systems**
- **Project phase 2 - objectives**
- **Project phase 2 - approach**
- **Key Points**
- **Next steps**



From a European directive to a national initiative...

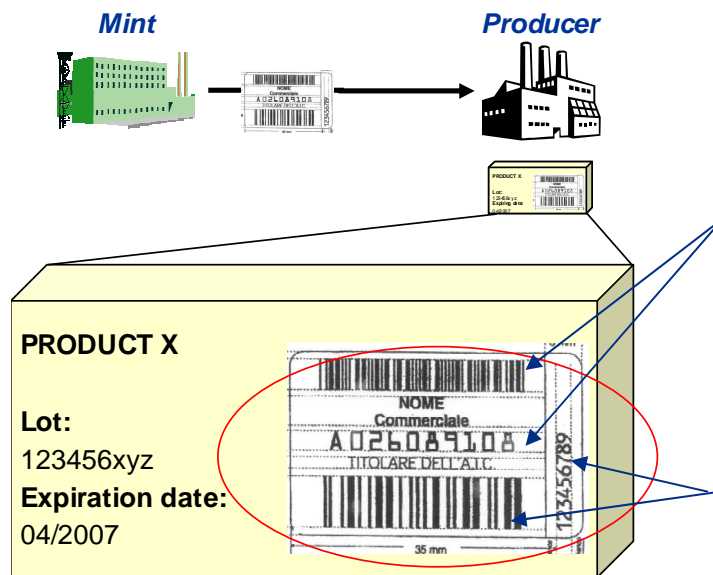
- The EU Parliament and Council Directive 2001/83/CE, article 35, declares:
- *"It is necessary to exercise control over the entire chain of distribution of medicinal products, The requirements which must be adopted for this purpose will considerably facilitate the withdrawal of defective products from the market and allow more effective efforts against counterfeit products".*

Through some normative interventions, the "Monitoring of drug packages within the distribution system" has been introduced in Italy





In Italy is commonly used the AIC code for identification of drugs: AIC code is the number of the authorization for the commerce (9 digits) of a drug package.

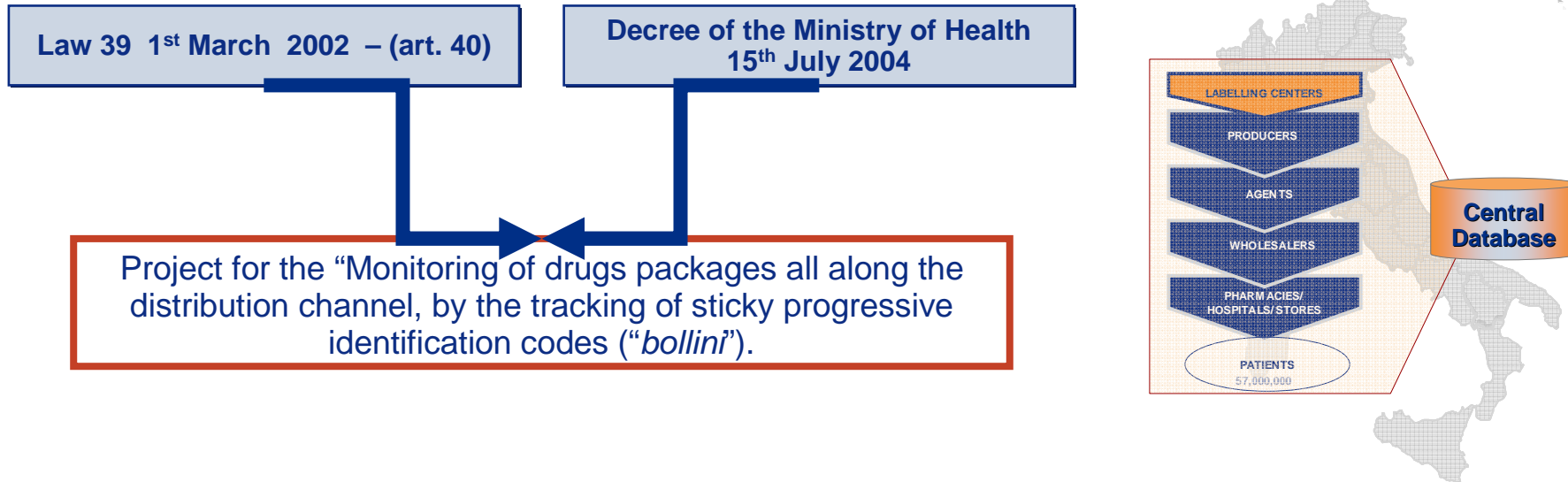


Today each package has an **adhesive label** (*bollino*) displaying:

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

The AIC code and the serial number are in clear text and in bar code on the label

A national institute (IPZS – Mint Institute) produces adhesive labels with serial number to apply on the drugs in commerce in Italy.

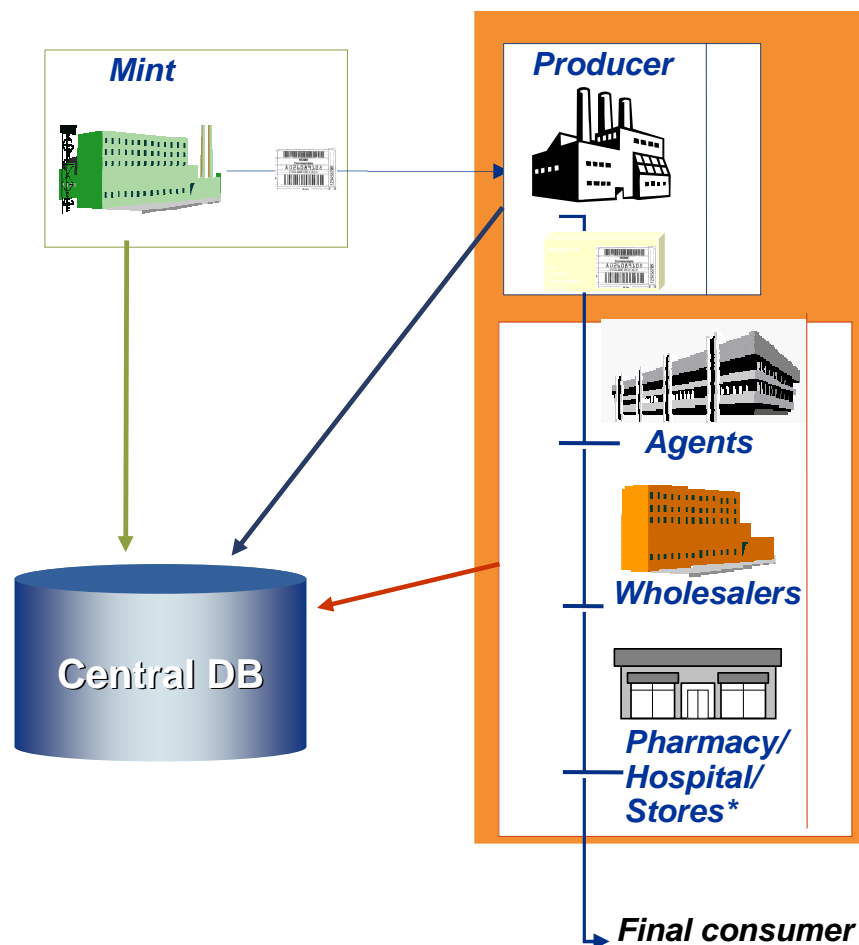


The article 40 of the law 39, foresees the creation of a central database: all the movements of drugs (with serial number) on the Italian territory, from the production to the distribution in the hospitals or in the pharmacies, must reach the central database. Every actor of the supply channel must record and send to the central database, the id code + serial numbers of the drugs that he send to the downstream partner, and the actor that receives drugs must records the serial numbers of the drugs received.

The Decree (July 2004) defines the technical rules for the feed of the Central DB.



Data transmission of all drugs movement to a Central Database



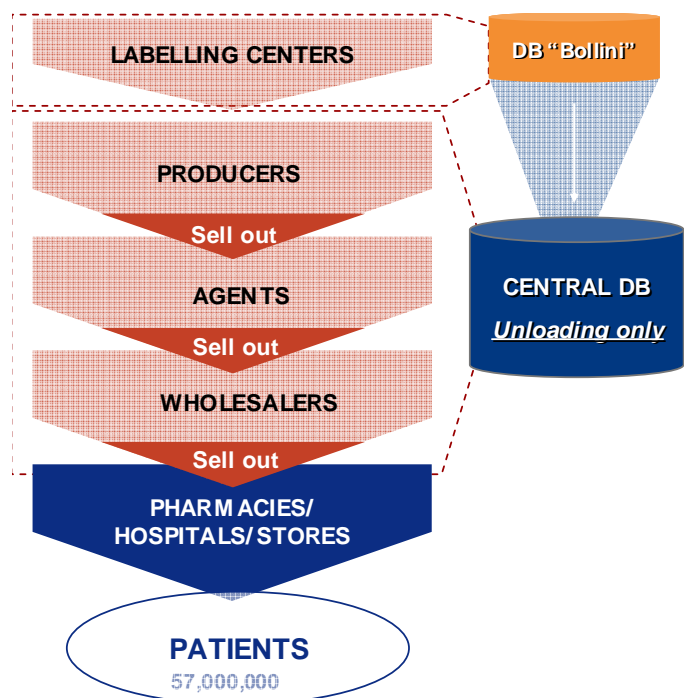
- Each player involved is considered as a warehouse with inward (loading) and outward (unloading) movements, each linked to a "reason for movement".
- **The sender** has to transmit the **outward movements** and the related addressees to the system
- **The addressee**, before using the received products, has to **check the delivery** connecting to the Central Database, 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** from the distribution channel (loss, theft, disposal, export).
- **All movements have to be transmitted within 24 hours with digital signature.**

* Licensed to sell drugs available without prescription and Over The Counter since 4 July 2006 (decree 223/2006)



To obtain some first results in the short time and to mitigate the system impact on the involved players, was adopted a progressive approach based on phases.

Phase 1 ▶ Started on June 2005



Information gathered:

- outbound movements (number of drugs packages per AIC) within 24 hours from expedition, included number of "Bollini" destroyed, without serial number;
- data related to the supply of *Bollini* by the IPZS (the national mint);
- value of all drugs supplied to facilities of the NHS.

Some figures up to now*:

- **Number of movements tracked:**
1.629.275.561
- **Logistic sites mapped:**
 - Producers: 593
 - Agents: 633
 - Wholesalers: 1.000
 - Pharmacies: 19.674
 - Stores: 2.263
 - Discharge operator: 372

* Since 1 January 2006



Italy presents several active information systems gathering pharmaceutical data:

Tracking system for NHS prescriptions

Transmission of data related to the NHS pharmaceutical prescriptions provided to consumers by pharmacies.

The system is based on the linkage between the prescription code, the patient identification number (fiscal code) and the A.I.C code with its bar code.

Prescription



A.I.C
code



Fiscal code

The tracking system for NHS has been working for about 20 years with recent changes



Phase 2

To accomplish a complete tracking, as declared by Decree July 2004, through gathering information not included in phase 1:

- *Serial number of drug packages, involved in all movements;*
- *Inward movements;*
- *Data about lot and expiration date*
- *Tracking movements on final distribution and on exit from distribution channel*
- *Harmonization with other information flow*



Technical working team

Set up of a **Technical Working Team** including all relevant stakeholders (*producers, agents and wholesalers, Regional Authorities, Pharmacies Hospital Pharmacies and discharge operators*) to manage the project towards the implementation of the regimen. TWT started on March 2007.



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 analyze the system based on the following **working hypotheses**:

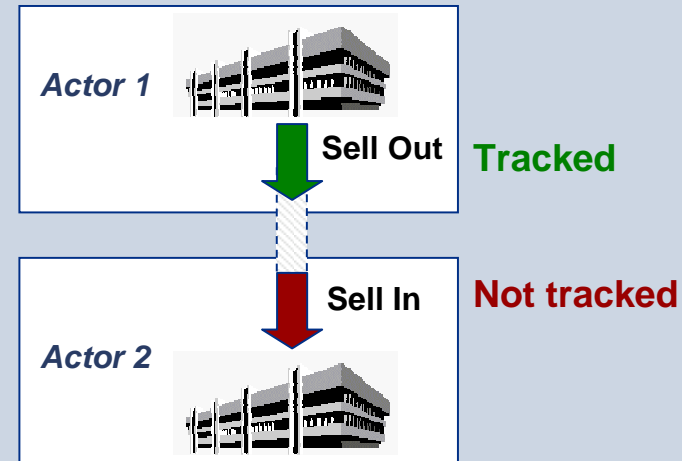
Use Datamatrix as vector

- Align tracking Italian system with main international developments
- Allow to store more information, as settled from Decree 15th July 2004, on the vector than the present solution (barcode code-32/ITF)



Tracking of outward movement only

- Guarantee more sustainability of the identified solution compared to complete tracking of inward – outward movements





Analyses of players about this two points lead to the following evidences:

Datamatrix

- Production and distribution processes need modifications in order to manage and read serial number
- Optical devices - at the moment used for reading bar code - need adjustment; in particular it is necessary the reengineering of automatic picking devices, used by wholesalers, to include camera on the expulsion systems

Tracking outward movements

- Possibility to send data in asynchronous mode (within 24/H instead of real time)
- Based on trust information by sender

The working team is putting particularly attention about technical solutions that are able to guarantee tracking of drugs:

Product ID code

Linking to RX prescription process

Secondary pack ID code



Discussion about product codes has two alternative solutions:

USE OF AIC

- Product Identification code issued by the Italian Drug Agency (AIFA) for commercialization

EVIDENCES

- AIC managed by a National agency
- National operability and standards
- Static approach towards possible changes (i.e. AIC stays the same notwithstanding secondary changes to either drug package or the instruction leaflet)

USE OF GTIN

- Company identification code issued by GS1
- product identification code issued by drug manufacturers
- GTIN transmitted to AIFA for linkage with AIC code

EVIDENCES

- International standard and use
- Need link with AIC
- Link table (GTIN vs AIC) must be communicated to players by central agency
- Dynamic approach towards possibility of managing multiple product ID codes for each AIC (i.e. GTIN allows to identify specific factories, changes in package configuration, etc.)



FACTS

- Packages inserted in a cartons have to be managed in combined mode in order to allow tracking without unpacking. The informations are: product code, serial number, lot and expired date

Two alternative models proposed

1st Model

- Use the secondary pack Identification code
- Detailed packages information via electronic flow

EVIDENCES

- Electronic flow management
- Secondary pack identification code

2nd Model

- Serial Numbers of all drugs packages encoded on the secondary pack by an appropriate vector (Datamatrix / RFID)

EVIDENCES

- Datamatrix:
 - difficulties in multiple data representation
 - need to define a standard to represent all information on Secondary packs
- RFID: ?



In the next months, the working group will clarify the previous open issues and will work towards a final solution addressed to all the actors involved.



Thank you for the attention

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