Nuovo Sistema Informativo Sanitario

Ministero della Salute

The drugs tracking system in Italy

Roma, March 21st – 22nd 2006

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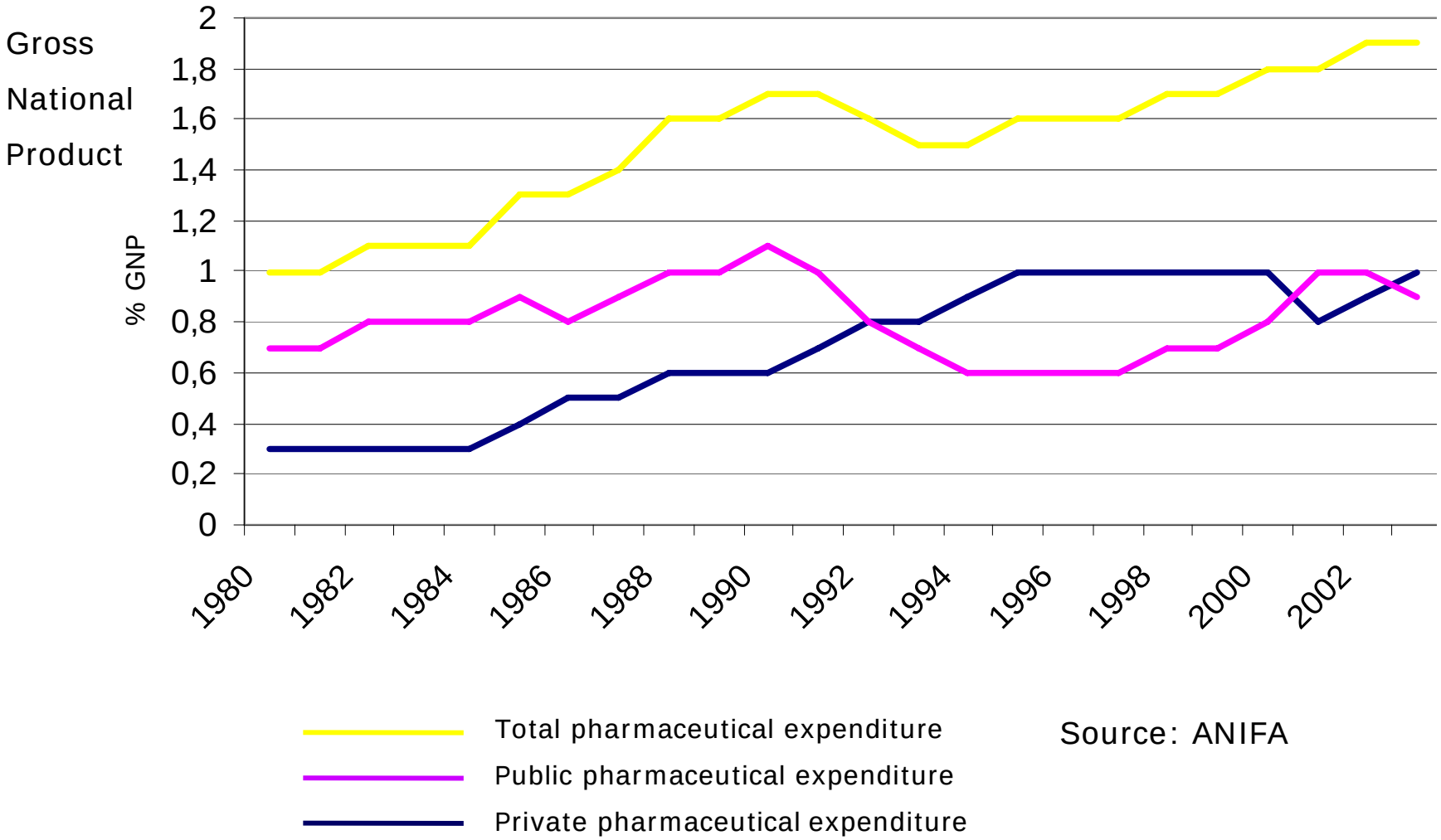
Ministry of Health

- ***The economic context***
- ***The normative context***
- ***The project objectives***
- ***The project working model***
- ***The project structure***
- ***State of the art***
- ***The integration with the NHIS***
- ***The activities toward the regimen***
- ***Data available and report***

Pubblic health expenditure



Source: ANIFA

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**, 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**".*

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

2001 **Decree of the MH - 2nd August:** introduction of a sticky progressive numeric ID code ("Bollino") for all medicines reimbursed by the NHS

2002 **Decree of the MH - 1st February:** introduction of the "Bollino" system for all medicines for human usage

2002 **Law 39 - 1st March (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.

2003 **Law 14 - 3rd February:** implementation of EU Parliament and Council Directive 2001/83/CE and adoption of the expected univocal drugs coding system by the 1st July 2004

2004 **Decree of the MH – 15th July:** technical specification for the implementation of the project

Step 1:

"*Bollino*" ID system

Step 2:

Central Data Base

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Frauds countering, expenditure and consumption monitoring as the main objectives

From the original objective…

To empower the available measures for **countering the existing frauds safeguarding Public Health and the Treasury**

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

The project serves **multiple aims** and **gains full support** by the involved players providing each with information and services customized to meet their needs.

From ex post controls…

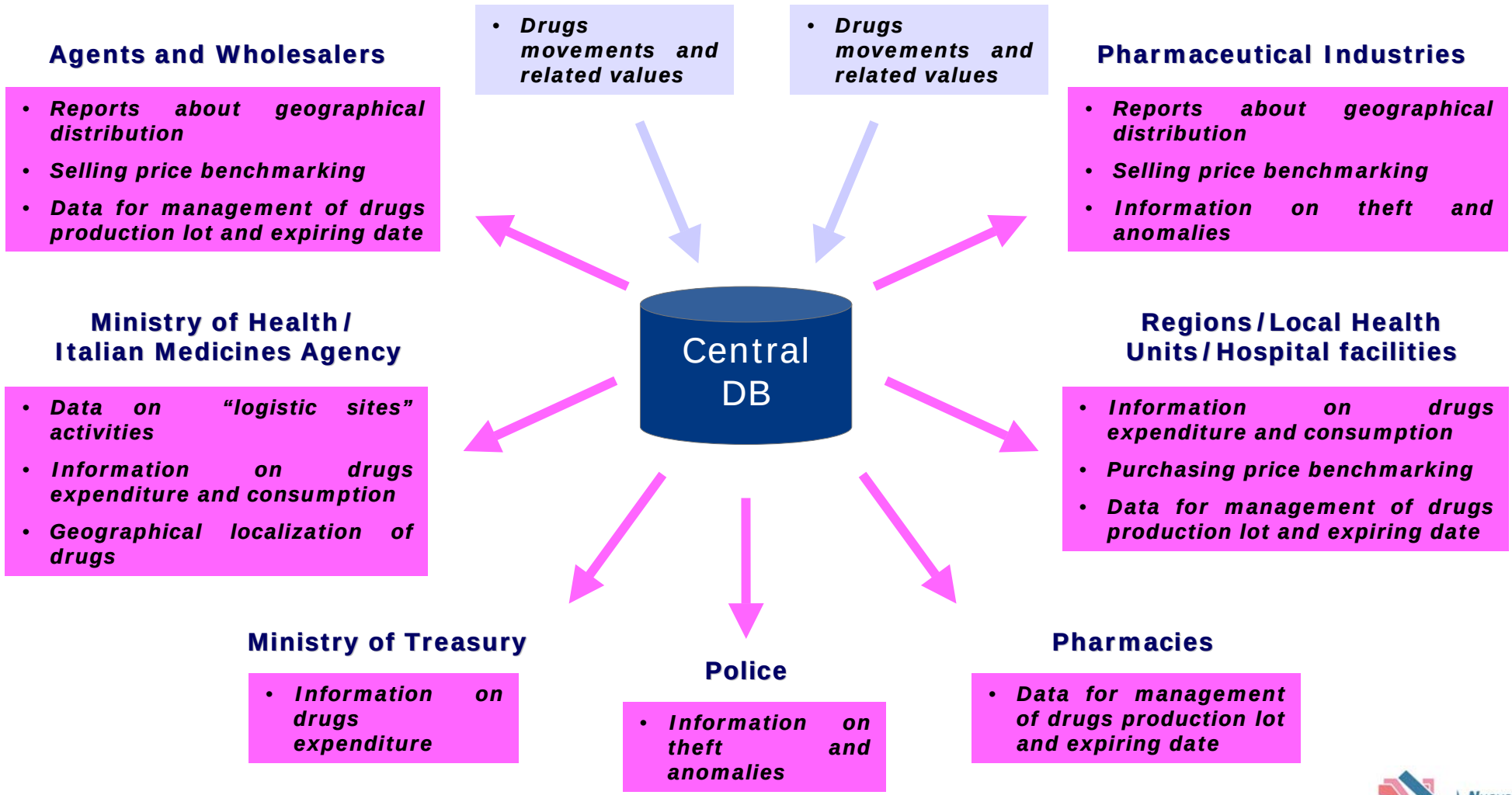
- **Control over drugs expenditure**
- **Control over consumptions of drugs, both reimbursed by NHS and not**
- **Control over distribution chain**

…to provisional actions

- **Promote appropriateness of prescriptions and drugs consumption**
- **Ensure to all citizens prompt access to innovative drugs**
- **Promote quality and effectiveness of care services**
- **Ensure the respect of normative limitation on public health expenditure**

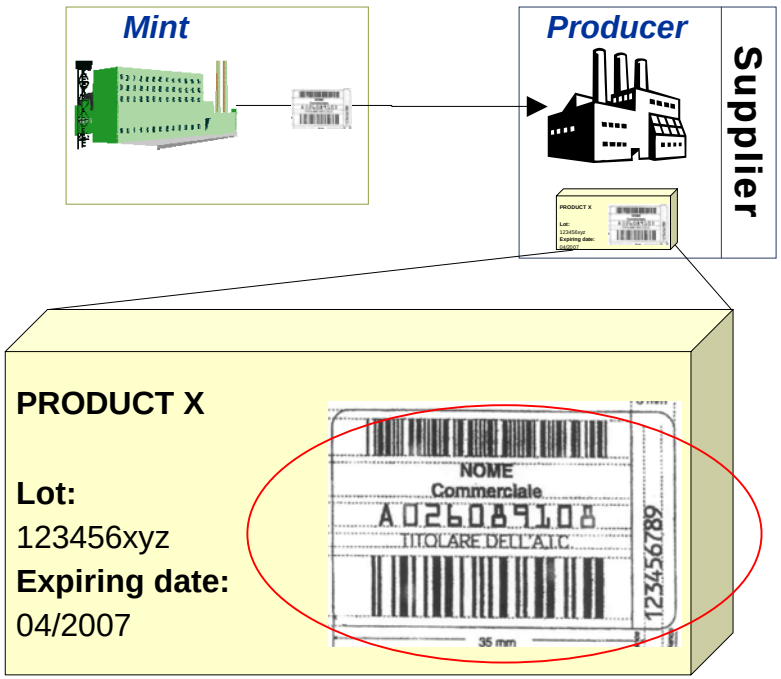
Central database, shared knowledge

The Central Data Base provide significant data for all the players involved in the tracking system.



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) **A.I.C. code** of the drug package that is the **authorization number issued by the Italian Medicines Agency (AIFA)** for commercialization

b) Drugs **denomination**

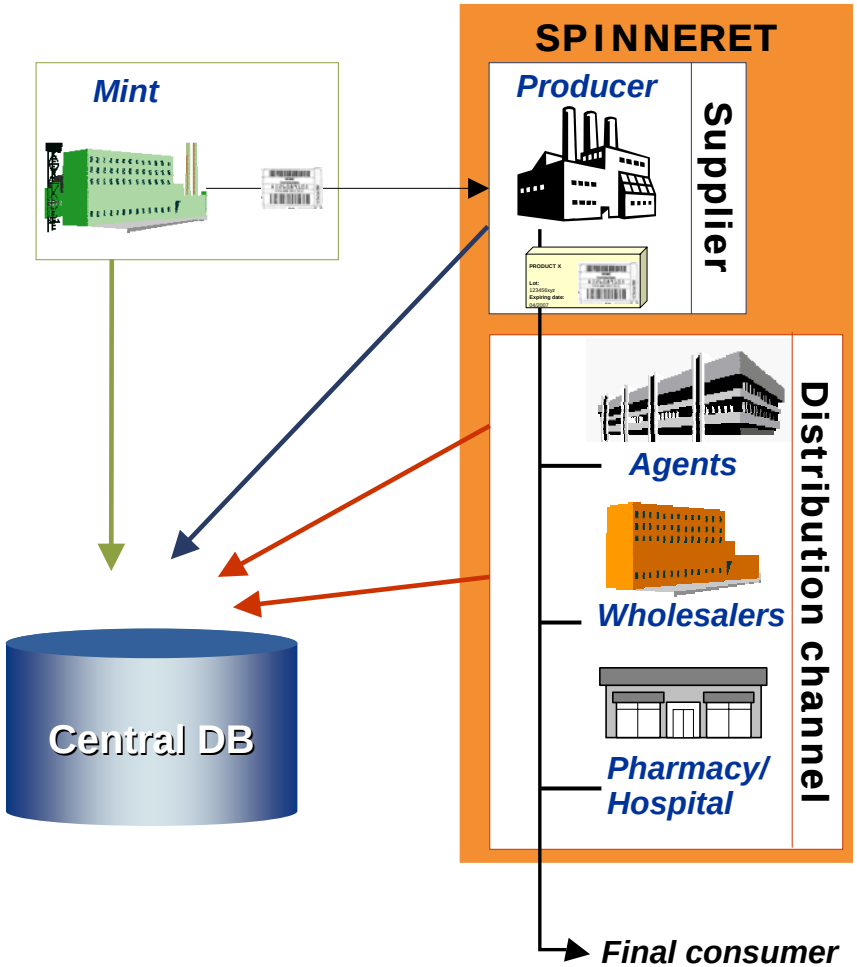
c) **AIC owner** or **legal representative** of foreign owner

d) **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 within 24 hours**.
- All movement are authenticated wirh digital signature of player's representative

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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

Simplifications introduced

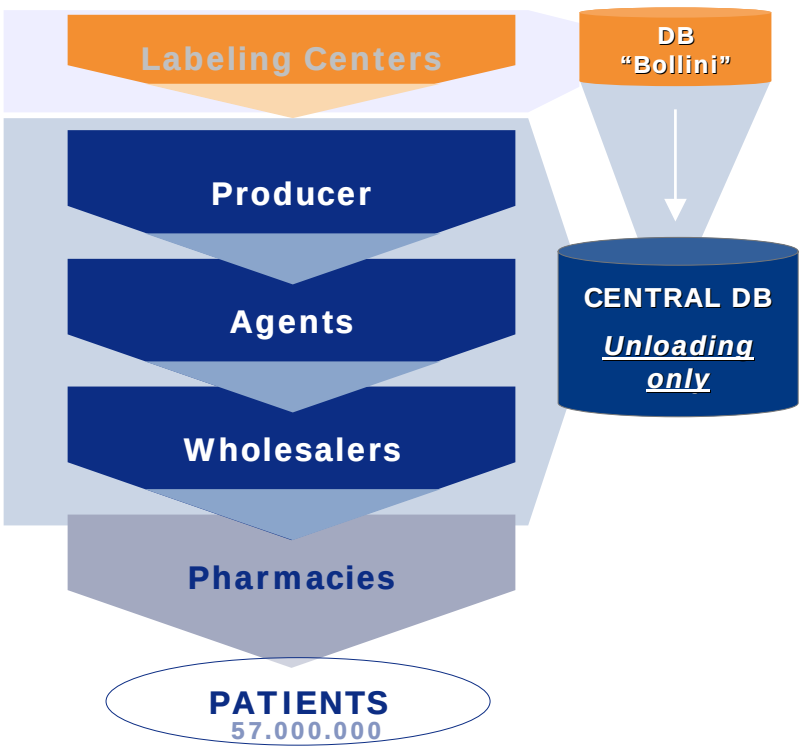
Reduction of number of players involved;

Tracking of out movement;

Progressive alignment to the informative contents set by law n.39/2002.

First steps in the creation of the Data Base

Phase 1



Starting **from June 2005** we had:

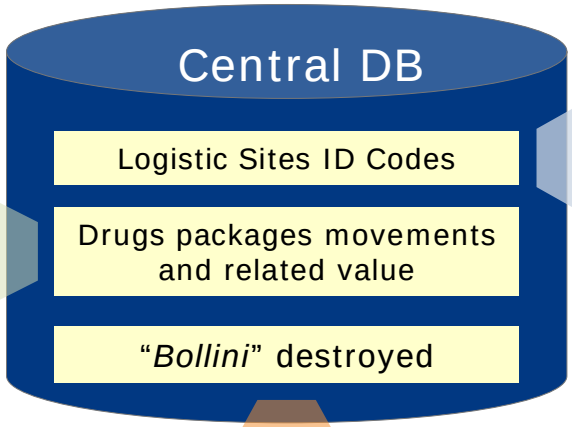
- Transmission of **out movements** (number of drugs packages aggregated by AIC) within 24 hours from expedition, included number of "Bollini" destroyed, related to the period starting **from the 1st of June**
- Transmission of data related to the **supply of *Bollini*** by the IPZS (the national mint).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

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

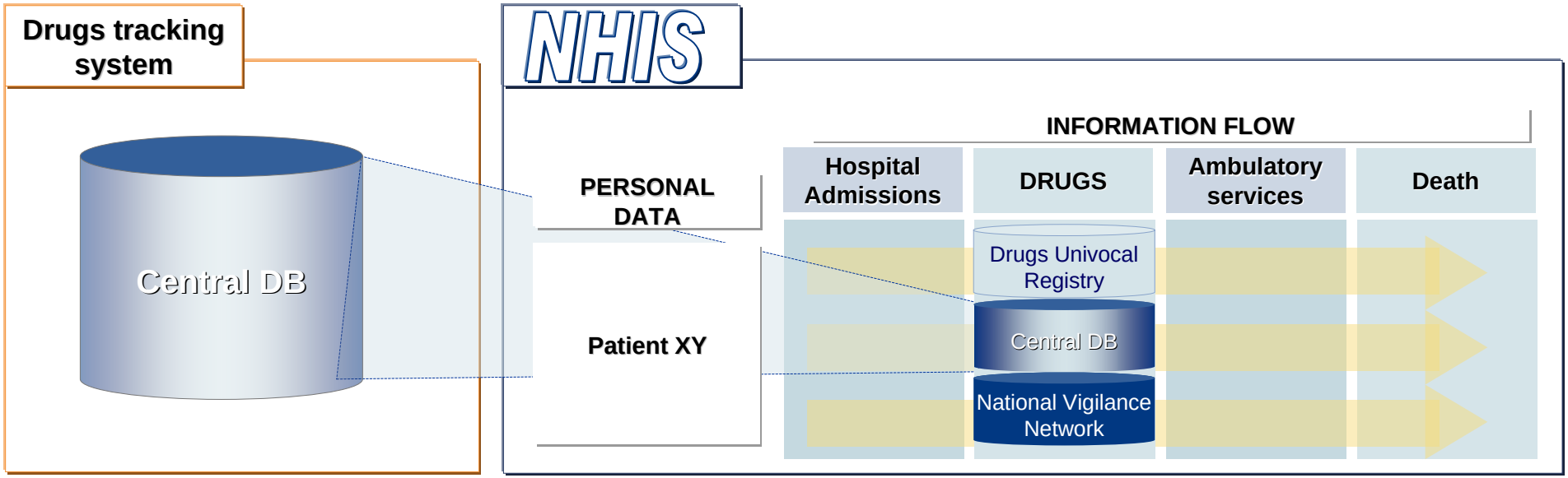
The figures of the project up to now

- Number of logistic sites mapped:
  - Producers: **233**
  - Agents: **264**
  - Wholesalers: **392**
  - Pharmacies: **16.910**
  - Hospital facilities
    - ✓Pubblic: **1.417**
    - ✓Private: **1.344**

- Number of movements tracked (June – dicember 2005): **350 milion**
  - Average per day: **1,7 milion**

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.

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

Another relevant step is the **Evaluation of technical solutions** to favor the tracking of the drugs (i.e. RFID).

The participation of **international groups** is important to ensure the application of international standard and safeguard enterprise investments.

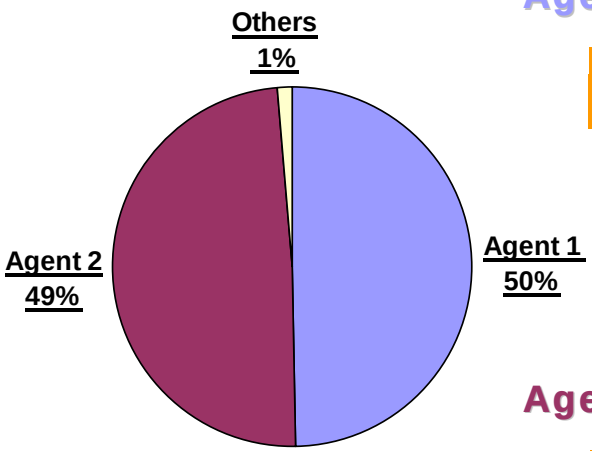
Example of report

Report A1: The distribution path of a medicinal product

AIC: *XXX*

AIC Class: C

Period: June – November 2005



Agent 1

Agent 1 addressees	Quantity	%
Wholesalers	308.303	93,38%
Hospitals	10.611	3,21%
pharmacies	5.946	1,80%
Others*	5.307	1,61%
Total	**330.167**	**100%**

Agent 2

Agent 2 addressees	Quantity	%
Wholesalers	291.820	89,62%
Hospitals	25.400	7,80%
pharmacies	3.700	1,14%
Others*	4.687	1,44%
Total	**325.607**	**100%**

*The entry in the distribution channel is manly assured by **2 agents***

Both agents delivery manly to wholesalers.

(*) Includes: foreign countries, patients, representatives for pharmaceutical firm, etc.

Example of report

Report A2: The distribution path of a medicinal product

AIC: *XXX*

AIC Class: C

Period: June – November 2005

Distribution channel \ Final destinations	Hospitals	%	pharmacies	%	Others*	%	Total distribution channel	%
Direct	35.340	98%	9.646	3,31%	5.894	58,98%	**50.880**	**15,07%**
Wholesalers	671	2%	282.036	96,69%	4.100	41,02%	**286.807**	**84,93%**
Total	**36.011**	100%	**291.682**	100%	**9.994**	100%	**337.687**	100%

(*) Includes: foreign countries, patients, rappresentatives for pharmaceutical firm, etc.

The distribution to hospitals is assured directly by agents (98%), while the distribution to pharmacies is assured by wholesalers (97%).

The wholesalers channel represents 85% of the total distribution

Example of report

Report B1: Regional hospital facilities sell in - quantity

AIC: *XXX*

AIC Class: C

Period: June – November 2005

Regions	Regional quantity	% (Regional quantity)	Quantity per 1000 inhabitant* (Q/I)
Lombardia	7.051	19,58%	0,77
Veneto	6.121	17,00%	1,35
Emilia Romagna	3.620	10,05%	0,90
Toscana	2.843	7,89%	0,80
Puglia	2.507	6,96%	0,61
Piemonte	2.503	6,95%	5,20
Lazio	1.867	5,18%	0,35
Marche	1.672	4,64%	1,14
Campania	1.334	3,70%	0,23
Sicilia	1.250	3,47%	0,25
Liguria	1.165	3,24%	0,72
PA di Bolzano	920	2,55%	0,21
Abruzzo	839	2,33%	0,65
PA di Trento	747	2,07%	1,62
Friuli Venezia Giulia	481	1,34%	0,40
Sardegna	421	1,17%	0,26
Calabria	374	1,04%	0,18
Basilicata	159	0,44%	0,26
Molise	127	0,35%	0,39
Umbria	10	0,03%	0,01
Total	**36.011**	**100%**	**0,62**

(*) Year 2004

The report displays the AIC XXX distribution to Italian hospital per regions

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Example of report

Report B2: Regional NHS facilities sell in - price

AIC: *XXX*
AIC Class: C
Period: June – November 2005

Regions	average price	Δ Price
MOLISE	19	28%
CALABRIA	19	23%
LAZIO	18	21%
BASILICATA	18	20%
CAMPANIA	18	17%
UMBRIA	17	14%
PUGLIA	17	10%
SICILIA	16	8%
MARCHE	16	3%
FRIULI V. G.	15	1%
ITALIA	**15**	**0%**
VENETO	15	-1%
LIGURIA	14	-6%
PIEMONTE	14	-7%
SARDEGNA	14	-8%
ABRUZZO	14	-8%
LOMBARDIA	13	-13%
BOLZANO	13	-14%
TRENTO	13	-14%
EMILIA R.	13	-17%
TOSCANA	12	-23%

The report displays the NHS facilities sell in regional average price.

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Example of report

Report B3: Regional pharmacies sell in - quantity

AIC: *XXX*
AIC Class: C
Period: June – November 2005

Regions	Regional quantity	% (Regional quantity)	Quantity per 1000 inhabitant* (Q/I)
Lombardia	51.207	17,56%	5,61
Veneto	32.915	11,28%	7,25
Lazio	28.216	9,67%	5,32
Campania	25.843	8,86%	4,47
Puglia	23.286	7,98%	5,70
Sicilia	20.271	6,95%	3,99
Toscana	18.888	6,48%	5,32
Emilia Romagna	15.175	5,20%	3,79
Piemonte	14.747	5,06%	3,44
Friuli Venezia Giulia	9.770	3,35%	8,22
Liguria	9.717	3,33%	5,99
Abruzzo	8.213	2,82%	6,41
Umbria	7.555	2,59%	8,99
Marche	6.629	2,27%	4,51
Calabria	6.613	2,27%	3,24
PA di Trento	3.598	1,23%	7,47
PAdi Bolzano	3.051	1,05%	6,61
Sardegna	2.350	0,81%	1,43
Molise	1.819	0,62%	5,56
Basilicata	1.426	0,49%	2,36
Valle d'Aosta	393	0,13%	3,26
Total	**291.682**	**100%**	**5,04**

(*) Year 2004

The report displays the AIC XXX distribution to Italian pharmacies per regions

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Example of report

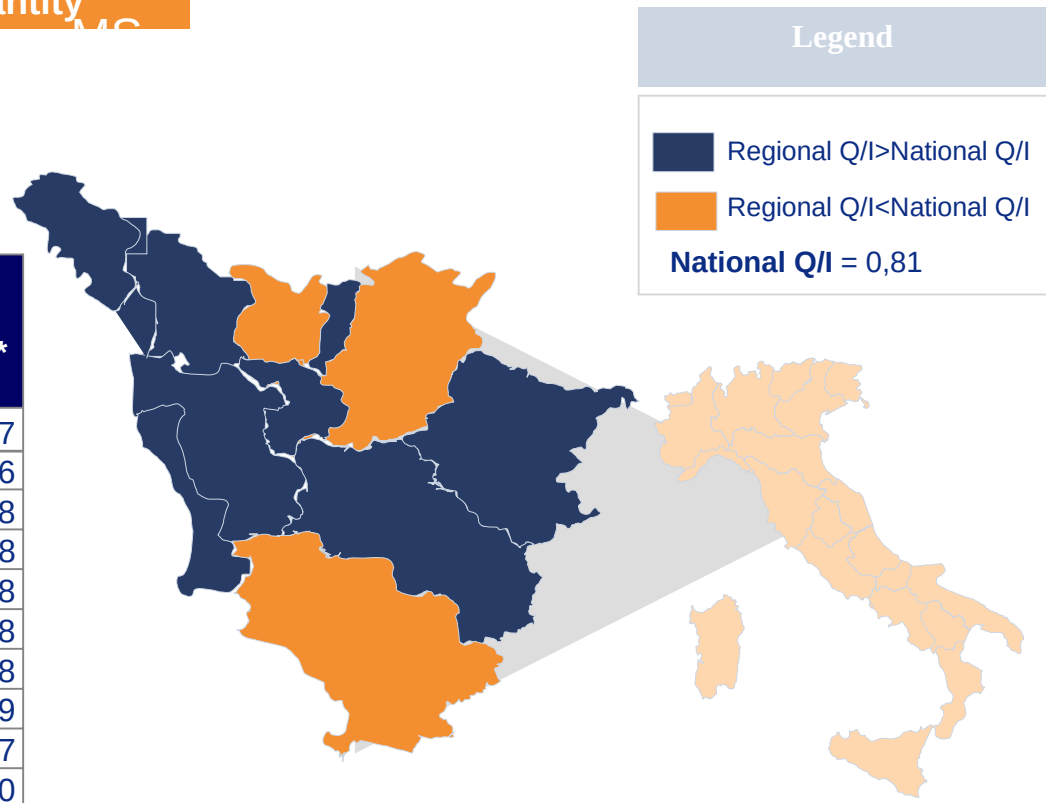
Report C1: Toscana hospital facilities sell in - quantity

AIC: *XXX*

AIC Class: C

Period: June – November 2005

Local Health Units (LHU)	LHU quantity	% (LHU quantity)	Quantity per 1000 inhabitant* (Q/I)
LHU PISA	620	21,81%	1,97
LHU LIVORNO	591	20,79%	1,76
LHU LUCCA	378	13,30%	1,78
LHU SIENA	325	11,43%	1,28
LHU AREZZO	320	11,26%	0,98
LHU VERSILIA	256	9,00%	1,58
LHU MASSA CARRARA	253	8,90%	1,28
LHU FIRENZE	70	2,46%	0,09
LHU PISTOIA	20	0,70%	0,07
LHU GROSSETO	10	0,35%	0,00
Total	**2.843**	**100%**	



The report displays the AIC XXX distribution to Hospital facilities of Toscana region

(*) Year 2003

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Example of report

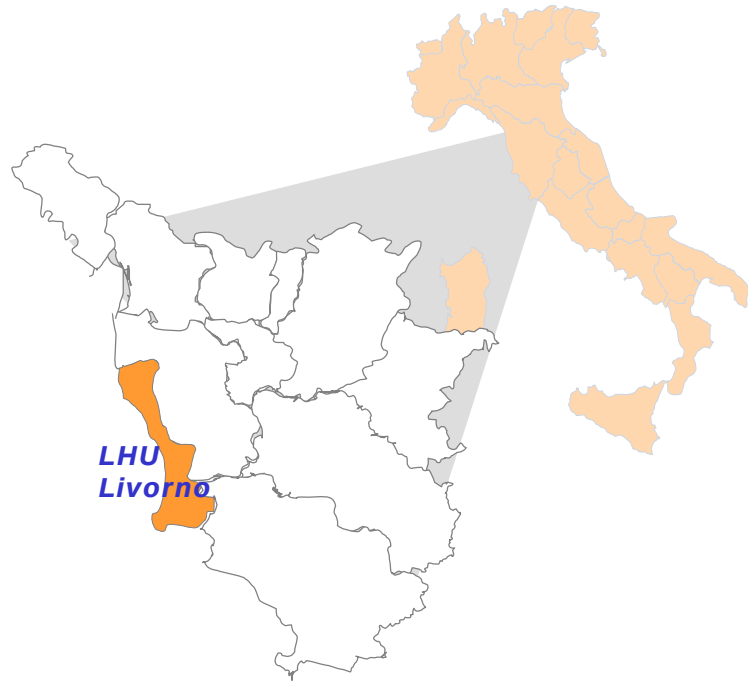
Report D2: LHU Livorno hospital facilities sell in - quantity

AIC: *XXX*

AIC Class: C

Period: June – November 2005

Hospital facilities LHU Livorno	Quantity	%
OSPEDALE CECINA	21	3,55%
OSPEDALE LIVORNO	400	67,68%
OSPEDALE PIOMBINO	150	25,38%
OSPEDALE DI PORTOFERRAIO	20	3,38%
Total	**591**	**100%**



The report displays the AIC XXX distribution to each hospital facility located in the LHU Livorno

Example of report

Report D2: Ospedale Livorno

Focus: Ospedale Livorno – LHU Livorno, Toscana
Period: June – November 2005

The report displays top ten AIC and DRG related to Ospedale Livorno.

Top ten AIC acquired			
AIC cod	**AIC Description**	**ATC code**	**ATC Description**
26405340	AGRIPPAL	J07BB02	Vaccine - Influenza, antigene purificato
26458012	TARGOSID200	J01XA02	Antibacteria - Teicoplanina
26966046	CLEXAN	B01AB05	Antitrombotici - Enoxaparina sodica
32391029	TAXOTERE	L01CD02	Antineoplastici - Docetaxel
34092015	COMBIVIR	J05AF30	Antiviral - Associazioni
34411025	ELOXATIN	L01XA03	Antineoplastici - Oxaliplatino
34430456	NEORECORMON	B03XA01	Antianemic - Eritropoietina
34528012	REMICADE	L04AA12	Immune depression - Infliximab
34949014	HERCEPTIN	L01XC03	Antineoplastic - Trastuzumab
36584011	ERBITUX	L01XC06	Antineoplastic - Cetuximab

Top ten DRG	
DRG code	**DRG description**
410	Chemotherapy w/o Acute Leukemia As Secondary Diagnosis
012	Degenerative Nervous System Disorders
373	Vaginal Delivery w/o Complicating Diagnoses
127	Heart Failure & Shock
381	Abortion w D&C, Aspiration Curettage or Hysterotomy
162	Inguinal & Femoral Hernia Procedures Age >17 w/o CC
132	Atherosclerosis w CC
088	Chronic Obstructive Pulmonary Disease
316	Renal Failure
209	Major Joint & Limb Reattachment Procedures of Lower Extremity

Example of report

Report D3: LHU Firenze pharmacies sell in - quantity

AIC: *XXX*

AIC Class: C

Period: June – November 2005

Top ten pharmacies - LHU Livorno	Quantity	%	% COM
FARMACIA COMUNALE	104	5,90%	5,90%
FARMACIA BERTELLI	78	4,43%	10,33%
FARMACIA JOLE PILETTI BIAGI DI EREDI BIAGI	75	4,26%	14,59%
FARMACIA TAGLIERANI DI SVEVA FRANCESCONI & C. SNC	74	4,20%	18,79%
FARMACIA TAGLIERANI	73	4,14%	22,93%
FARMACIA CAPPAGLI AUGUSTO	66	3,75%	26,67%
FARMACIA TRONCI ENRICO	58	3,29%	29,97%
FARMACIA COMUNALE	43	2,44%	32,41%
FARMACIA ELIOPOLI ANNA	42	2,38%	34,79%
FARMACIA CENTRALE SNC DEL DOTT. VINCHESI MASSIMO & C.	41	2,33%	37,12%
Total top ten	**654**	**37,12%**	**37,12%**
Total LHU Livorno	**1.762**	**100%**	**100%**

The report displays the AIC XXX distribution to top ten pharmacies located in the LHU Livorno

Conclusions

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

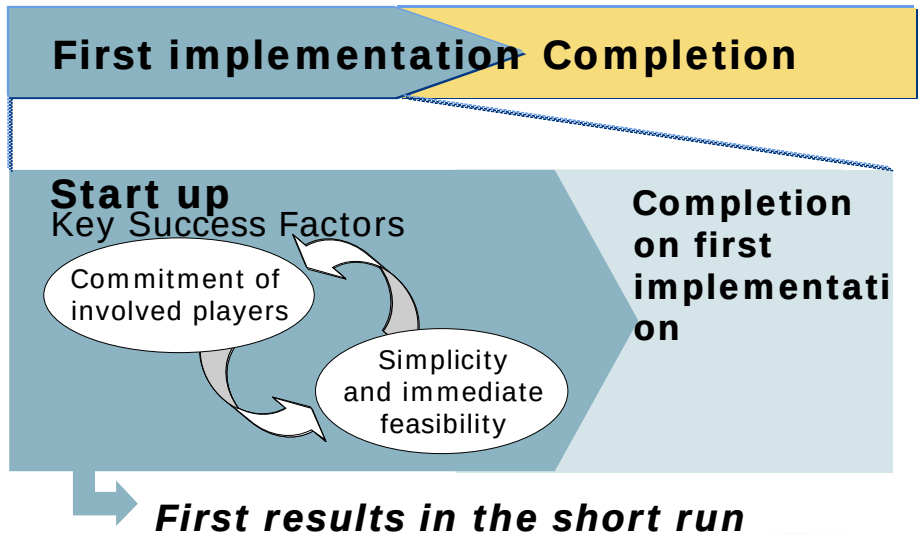
- To implement a unique, central database shared with all the player, with 'almost' real-time data about drug products location, consumption and expenditure for public health structures
- The fulfillment of first results in the short run;
- A mitigation of the system impact on the players involved.

The simplicity and prompt implementation of the first phase favors:

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

A necessary condition to start the completion phase is to find an agreed solution to standardize univocal ID system and to propose technical solutions for traceability

GS1 contribution is welcome!



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