



Pharmaceutical Products Track and Trace Pilot Project

GS1 Global Healthcare Conference
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INSTITUTO BRASILEIRO DE
ETCO
ÉTICA COMERCIAL



About us

With the intention to promote a healthier business environment, a group of Brazilian executives founded in 2003, the Brazilian Institute for Ethics in Competition – ETCO. ETCO is a nonprofit organization with the mission to improve the business environment and to propose and endorse initiatives aiming at avoiding disequilibrium in competition caused by tax evasion, informality, piracy and other transgressions.

Our mission

"Promoting the ethical competition, to improve the business environment."

Our Affiliates

→ Fuel Distribution

- Sindicom
(National Union of the Oil
Distributing Companies)

→ Breweries

- Ambev (AB Inbev)

→ Tobacco

- Souza Cruz (BAT)
- Philip Morris

→ Beverage

- Ambev
- Coca-Cola
- Pepsi

→ Technology

- Microsoft

→ Pharmaceuticals

- Aché (Local Company)
- Cristália (LC)
- Eurofarma (LC)
- Mantecorp (LC)
- Interfarma (Research based companies)

Diagnosis of Informality in Pharmaceutical Industry

- According to a research conducted by McKinsey Corporation, 25% of the pharmaceutical market is informal or illegal.
- These illegalities comprises non-authorized, falsified, fake, smuggled or stolen products and tax evasion.
- These misbehaviors generate unfair competition for legal companies who put up with the law.

**Several actions should be taken.
The main one was:**

Track and Trace System

Enabling pharma traceability in Brazil: the pilot project

- With the purpose of collaborating with ANVISA in the implementation of a Track and Trace system, the ETCO's Pharmaceutical Chamber has offered to the regulatory agency the development of a pilot project.

Technical Cooperation Protocol



Signature of the Technical Cooperation Protocol between ETCO and ANVISA.
December 18th, 2009

... This system is an important tool to prevent counterfeiting, cargoes deviations and other illegal procedures in the pharmaceutical sector in Brazil that mean population exposure to health risks.

This agreement is a significant step against the market unfair competition ...

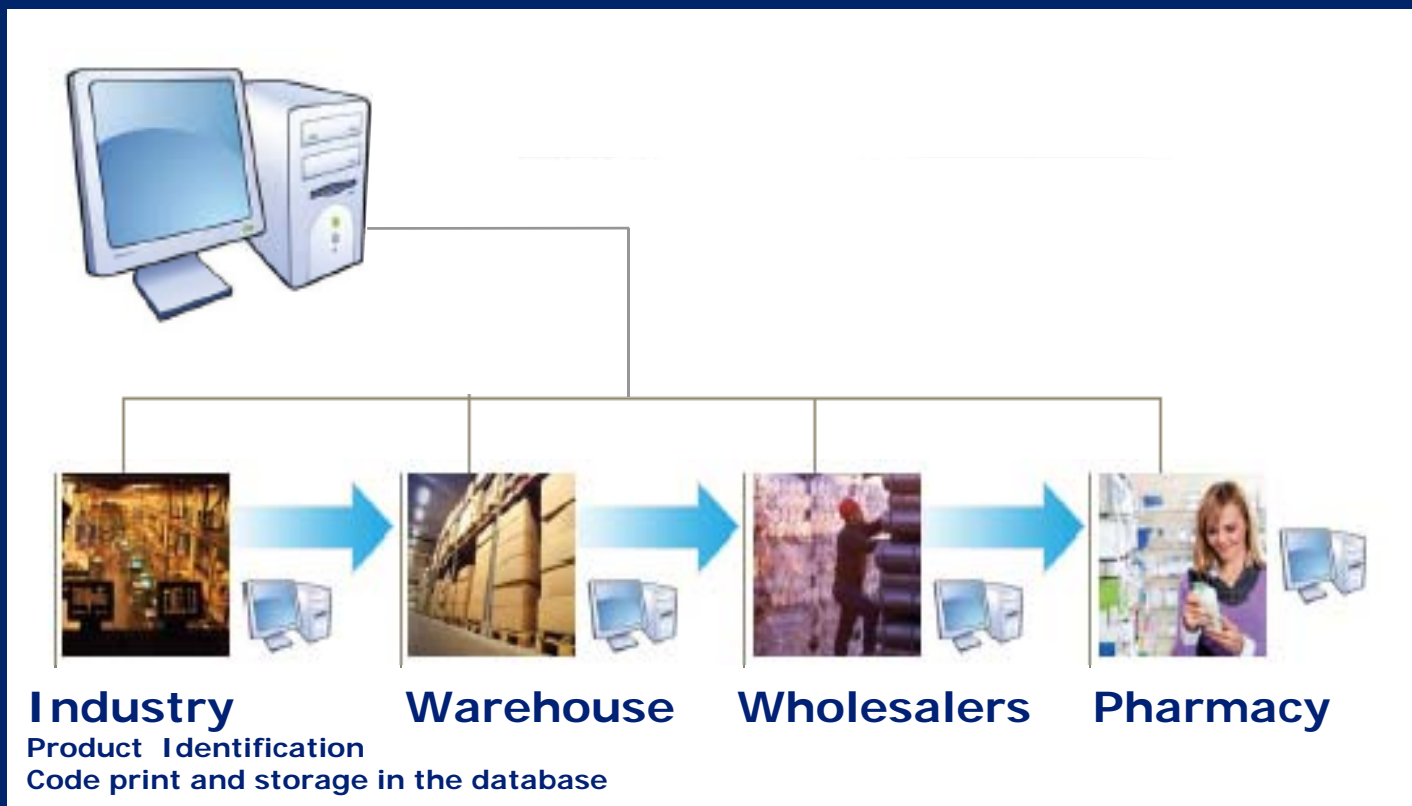
Law no.11,903

- In January 14, 2009, the Law no. 11,903 was issued, which created the National System of Drug Control.
- The Law establishes the tracking of all kinds of drugs existing in the country, from their manufacture to their sale to the final consumer. The control will be performed by means of technologies for electronic capture, storage and transmission of data.
- The law establishes that the system will have to be totally implemented within a period of three years.

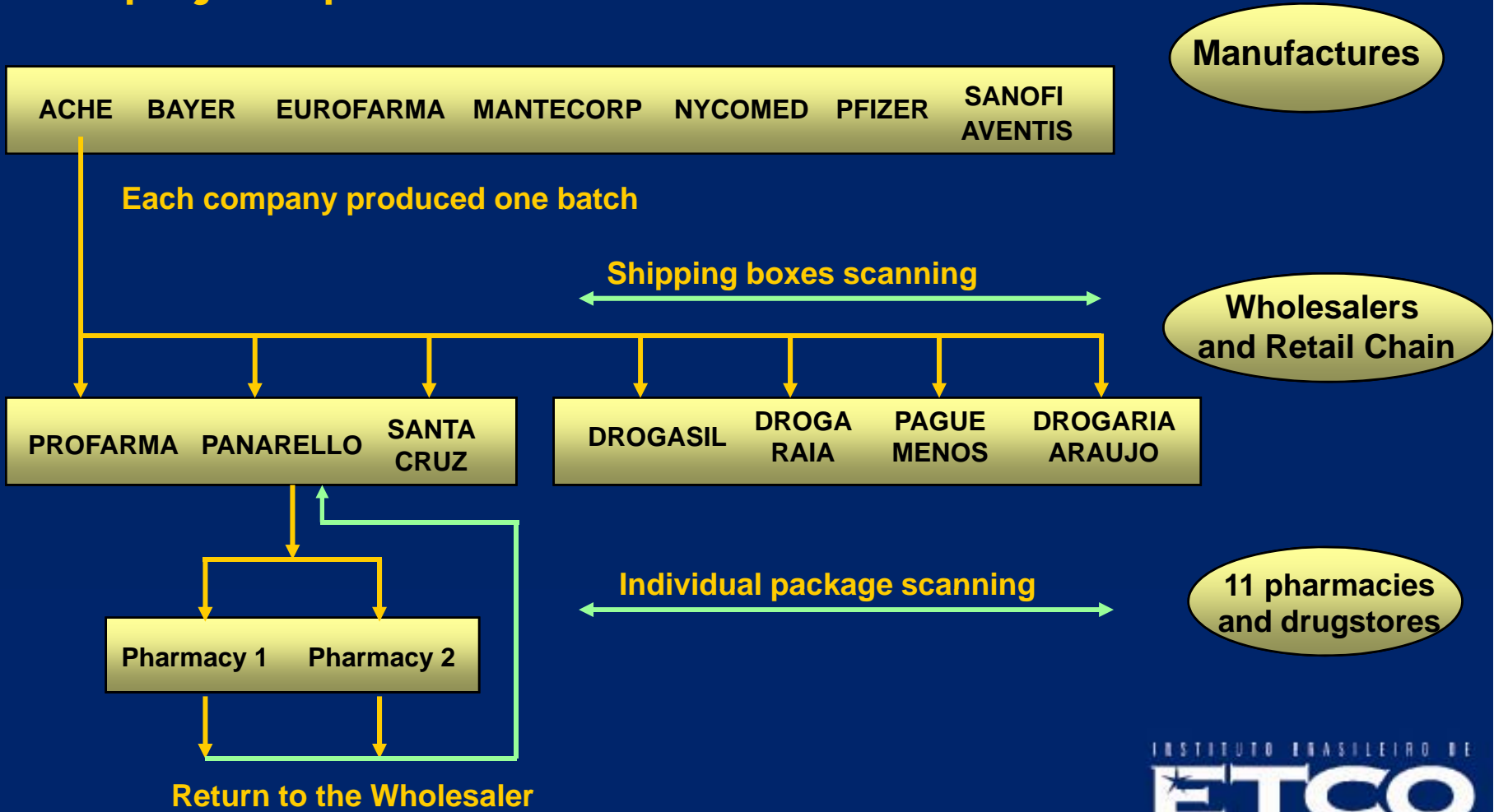
Enabling pharma traceability in Brazil: the pilot project

- From January to July 2009, ETCO conducted the pilot test of the Track and Trace Pilot Project. According to the Technical Cooperation Protocol, the Institute's work aimed at helping the regulatory agency to define the best technological solution to effectively fight informality in the pharmaceutical industry.

System Design



Pilot project operational flow



General information / Procedures

- For the test an adequate volume of drugs was adopted (approximately 75 thousand) in order to support improvements and changes of route in the processes.
- Open technological solutions of public domain were adopted to allow the required technical flexibility to meet the specificities of each company's processes.
- GS1 Brazil was responsible for the definition of international standards of coding, the entity acted as a certifier of the quality of the codes printed on the packages.
 - The two-dimensional barcode, internationally accepted - GS1 DataMatrix (ECC 200), was adopted and printed on the secondary packages. The barcode included the following information about the product: GTIN, batch number, expiry date, and serial number.
 - Usage of GS1-128 bar code with SSCC key on the logistic unit (case) to ensure the link with the content (secondary packs).

General information / Procedures

- Adoption of several technologies for item marking (continuous ink-jet, laser and thermal ink-jet printers) in different equipments with low, medium and high speed and complexity.
- The pharmaceutical sector could select the equipment for the electronic capture of data (DataMatrix scanners) that was more compatible with their industrial and commercial processes.
- The data obtained during the test in every change of establishment, from the manufacture to the point of purchase, were stored in a central database, allocated in a data center.

Test conclusion

The purpose of ETCO's Pharmaceutical Chamber was to test a traceability system as close as possible to the reality of the pharmaceutical chain and to demonstrate its feasibility.

- The pilot project totally fulfilled its purpose of providing guidelines to all agents in the pharmaceutical chain for the implementation of the National System of Drug Control.
- The system can be implemented with the adoption of open technological solutions, of public domain, with characteristics and flexibility to be used by the companies regardless of their size.
- The pilot test showed the advantages of the direct printing model with open technologies.
- The major paradigm change for the pharmaceutical industry is the introduction of the "unitary codification", which is crucial for the achievement of the required tracking level for compliance with the Law.