

# Pharmaceutical products traceability system pilot project in Brazil

## ABSTRACT

In order to break the vicious circle in the pharmaceutical market in which illegalities imply serious risks to public health, ETCO (Instituto Brasileiro de Ético Concorrencial, the Brazilian Institute of Ethical Competition) and the companies linked to the Pharmaceutical Chamber have entered in a partnership with the government. And, in a combined effort, we tested a simple and efficient mechanism, which can electronically track the course of any and every drug sold in Brazil. This article describes the new legislation establishing the obligation of such traceability system, and the lessons learned of the pilot organised by ETCO in collaboration with ANVISA (National Agency of Sanitary Surveillance).

## The pharmaceutical market in Brazil

A study of the pharmaceutical market in Brazil conducted in 2005 by the McKinsey consultancy office and the Pinheiro Neto law firm, by ETCO's request, showed that the high degree of the existing informality severely damages the industry and society as a whole.

The study conclusion was that informality must be fought with a set of specific actions, including the implementation of a traceability and authentication system, which aims at allowing a follow-up of each step of the pharmaceutical products, from the plant to the final consumer.

In accordance with information provided by IMS Health (December 2008), the Brazilian pharmaceutical market accounts for more than one billion units of Ethical products and 600 million OTC drugs. According to companies' estimates, 500 million drugs are directly sold to hospitals. The whole pharmaceutical chain comprises approximately 450 companies, over 2,000 wholesalers and a huge chain of 56,000 retail pharmacies and drugstores.

## Fighting counterfeiting in Brazil: legislative developments

The risks to the Public Health and the losses resulting from drugs manufactured in non-compliance with the norms and procedures adopted present incalculable dimensions. Brazilian authorities and companies have been long seeking for mechanisms to restrain illegality.



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In July 2nd, 1998, the National Congress qualified the counterfeiting of pharmaceutical products and raw materials as hideous crimes against public health, as defined in the Law no. 9,677/98. In this same year, the Secretary of Sanitary Surveillance of the Ministry of Health enacted the Administrative Rule no. 802/98, which instituted the Control and Inspection System for the whole chain of pharmaceutical products. The popular raspadinha (a scratch-off label with a reactive ink that helps in the verification of the authenticity of the drugs), the inviolability of the packages and the identification of the batch number in commercial transactions are some of the innovations established by that norm.

In 2002, the Administrative Act RDC no. 320 established that the wholesalers of pharmaceutical products should start to execute the commercial transactions and circulation operations with sale bills that presented, mandatorily, the product's batch number.

In spite of those measures, the level of informality in the Brazilian pharmaceutical industry is still alarming. Along the whole year of 2008, ANVISA seized approximately 45 tons of unregistered, smuggled and counterfeited products. According to ANVISA, in the first semester of 2009, 316 tons of fake medicines were seized. Another important issue is the cargoes thefts in the Brazilian cities and highways. In 2007, approximately 11,700 cargoes were stolen across the whole country, according to information provided by NTC & Logística (National Association of Cargo Transportation and Logistics). The estimated figure for 2008 is even higher: 12,400.

In March 4<sup>th</sup>, 2008, ANVISA published the Public Consultation no. 8. aiming at receiving reviews and suggestions associated to the minimum requirements for the definition of mechanisms to track the pharmaceutical products chain and to guarantee their authenticity. The purpose was to identify solutions that could allow the implementation of systems of drug tracking and authentication in the whole chain of pharmaceutical products.

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In January 14, 2009, the Law no. 11,903 was issued, which created the National System of Drug Control. The Bill was initially submitted by the Congresswoman Vanessa Grazziotin and carried out in the House of Representatives during two years.

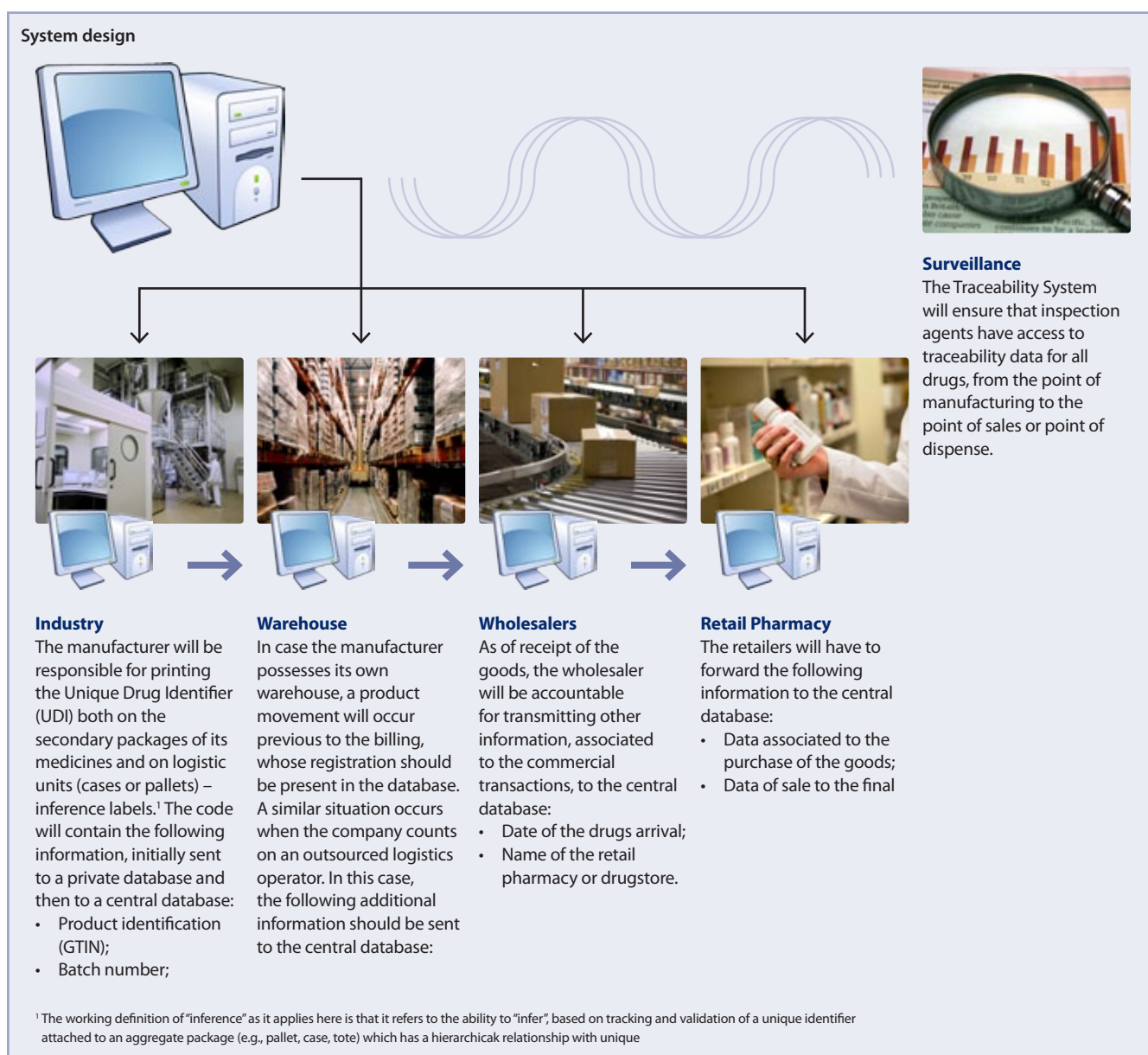
The Law establishes the tracking of all kinds of drugs existing in the country, from their manufacture to their sale to the final consumer. The control will be performed by means of technologies for electronic capture, storage and transmission of data. Each product will have to display an exclusive identification code.

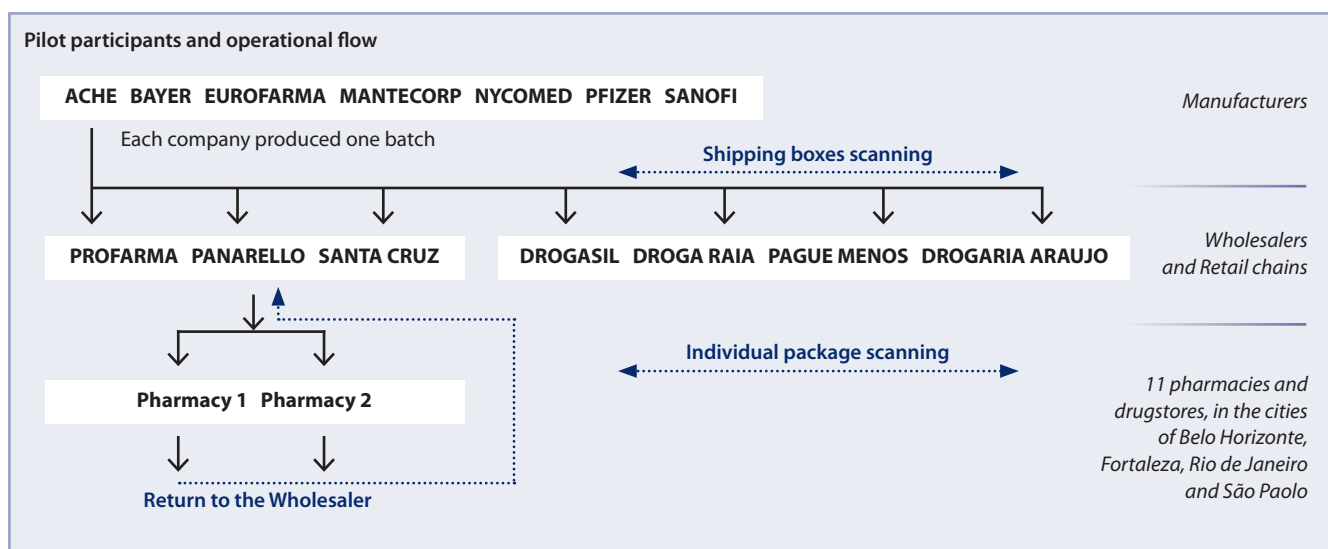
The law establishes that the system will have to be totally implemented within a period of three years. At the end of this period, the drug control in Brazil should reach levels of excellence, ensuring, in addition to the traceability, an effective monitoring about the drugs' use and prescription.

## Enabling pharma traceability in Brazil: the pilot project

With the purpose of collaborating with ANVISA in the implementation of a tracking and authentication system, the ETCO's Pharmaceutical Chamber has submitted to the regulatory agency the proposition of developing a pilot project. The consolidation of efforts was discussed and the final agreement was signed in December 18, 2008.

From January to July 2009, ETCO conducted the pilot test of the Traceability System Pilot Project, supported by technicians from ANVISA. According to the Technical Cooperation Protocol, the Institute's work aimed at helping the regulating agency to define the best technological solution to effectively fight informality in the pharmaceutical industry.





## Pilot planning

The pilot test was established in different stages, in order to evaluate a significant representation of the industry's reality. In the first stage of the project ETCO's group detected and mapped needs and expectations of its partners: companies, wholesalers and retailers. In the second stage, the practical section of the pilot test, which was put into operation in June 2nd, 2009, was executed. In the course of approximately 40 days, the processes of printing and scanning the identification codes on the secondary packages were assessed, and the collection and transmission of all information generated by the companies participating in the initiative was equally evaluated.

## Pilot participants and operational flow

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.

| COMPANY             | PRODUCT                             | AMOUNT |
|---------------------|-------------------------------------|--------|
| Aché (Biosintética) | BROMOPRIDE 1 mg/ml bottle w/ 120 ml | 3,333  |
| Bayer               | ADALAT RETARD 10 mg w/ 30 tablets   | 29,800 |
| Eurofarma           | ASTRO 500 mg display w/ 60 tablets  | 1,650  |
| Mantecorp           | CELESTAMINE syrup 120 ml            | 9,600  |
| Nycomed             | RIOPAN suspension 240 ml            | 14,350 |
| Pfizer              | PONSTAN 500 mg w/ 24 tablets        | 14,000 |
| Sanofi-Aventis      | DORFLEX box w/ 30 tablets           | 3,000  |
|                     | TOTAL                               | 75,733 |

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.

Open technological solutions of public domain were adopted to allow the required technical flexibility to meet the specificities of each company's processes.

- Adoption of several technologies for item marking: continuous ink-jet, laser and thermal ink-jet printers.
- Availability and flexibility so that the pharmaceutical chain's agents could select the equipment for the electronic capture of data (DataMatrix scanners) that was more compatible with their industrial and commercial processes.
- Equipment with low, medium and high speed and complexity, usually utilised by the whole pharmaceutical chain, was tested.
- Adaptation of the information technology systems of the pharmaceutical chain companies, so that the whole tracking process was put into operation in a validated form.

Adoption of an identification system, so that all essential information required for the tracking can be captured from each medicine package.

- 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).

The data obtained during the test, from the manufacture to the point of purchase, were stored in a central database, allocated in a data center, in order to reflect what should occur in the real model. Every change of establishment was informed to the system in all of the tested stages: reception, incorporation to the inventory and sorting for the dispatch. The UDI lifecycle begins with the generation of a serial number and its storage in a database.

## Lessons learned

- During the tests, no insoluble technical difficulty was detected in the implementation of the unitary coding technology in the manufacturers' packing lines.
- The choice of the adequate technology was based on the type of the manufactured products, the boxes' layout, the packing lines' speed, and the packing process, among other aspects.
- The available packing materials were used and some parameters of printing quality of the DataMatrix codes did not integrally comply with the GS1's recommendations. The tests showed, however, that occasional problems in the processes of code application and scanning are solvable.
- Regarding to the required equipment and software solutions, there are several companies in the market that can provide technologies complying with the specific demands of each link of the pharmaceutical chain.
- Investments on equipment, training courses and infrastructure should also be taken into consideration. Every professional directly involved in the production, storage and dispatching process should be trained in the traceability concept. They should understand that each box will be dealt with as a single package by the whole pharmaceutical chain.
- Important aspects were identified, which should be taken into consideration by the agents of the pharmaceutical chain and the regulatory authorities in order to ensure a greater efficiency in the implementation of the system.
- The mobilisation and gathering of forces of all of the key stakeholders, besides the support and availability for discussion from the federal government, are crucial for the definition of the best possible system, to be executed within the period established by law.
- The DataMatrix printing process was also tested in a logistics operator, where ink-jet printers and scanners were installed in a conveyor belt, out of the packing line, in which over 10 thousand boxes were printed and scanned. The test evidenced that, in a controlled environment, it is possible to obtain a printing level in the same standard found in the manufacturers' packing lines, taking into consideration the "Good Manufacturing Practices".

## 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 is the introduction of the "unitary codification", which is crucial for the achievement of the required tracking level for compliance with the Law.

## About ETCO

Created in 2003 as a public interest entity of the civil society, ETCO's basic mission is to foster an ethics-based competition, fighting the competition unbalances generated by counterfeiting, tax evasion, smuggling and other business conduct deviations. Such practices result in illicit advantages for the transgressors, harming the companies that comply with the laws. Thus, the ethical companies find themselves discouraged to invest, to innovate and to grow, opening more room for illegalities.

## ABOUT THE AUTHORS

**André Franco Montoro Filho** is Chairman of the Brazilian Institute of Ethical Competition – ETCO, a non-profit organisation that congregates non-government and entrepreneurial that aims to establish ethical parameters for competition. Mr. Montoro is Ph.D. in Economics from Yale University (USA), is full professor of the Economics and Administration College of the University of São Paulo (Brazil). He was Secretary of Economy and Planning of the State of São Paulo and President of the Brazilian Economic and Social Development Bank (BNDES) from 1985 to 1988.

**Patrícia Blanco** was Executive Director of ETCO – Brazilian Institute of Ethical Competition. Patricia was responsible for the management of the ETCO's project pilot of the pharmaceutical products traceability system.

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