

Nacional Traceability and Authentication Project in Brazil

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The pharmaceutical market in Brazil:

- 1 billion units of prescription medicines
- 500 millions units of OTC
- 400 millions units to Hospitals

- 450 industries
- 4.500 packing lines
- 350 wholesalers and warehouses
- 56.200 pharmacies

- 5.600 cities
- 8.514.215 km²
- 185 million people



Founded in 2003, the Brazilian Institute of Ethical Competition - ETCO is a nonprofit organization that brings together non-governmental business entities with the objective of promoting ethical principles of business competition and stimulate action to prevent tax evasion, informality, products counterfeiting and smuggling.

Our activities beyond specific sectors and companies to cover the whole economy, in the fight for improvements in the business environment.

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

- To identify the factors that encourage unfair competition practices, such as: high tax burden, high level of bureaucracy, slowness in Court Procedures, poor enforcement and others.
- To inform and to create awareness about ethical behavior benefits among public and specific audiences, and about the economic and social damages caused by unfair competition.

→ To mobilize and to support the public authorities and private entities to achieve institutional improvements and legislative changes that encourage fair competition.

→ To propose new legal and technological instruments to prevent conduct deviation and to punish transgressions.

✓ **Tracing and Authentication System
for Medicines**

→ Fuel Distribution

- Sindicom

→ Breweries

- Ambev
- Femsa

→ Tobacco

- Souza Cruz (BAT)
- Philip Morris

→ Beverage

- Ambev
- Coca-Cola
- Pepsi

→ Technology

- Microsoft

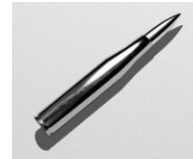
→ Pharmaceutical Companies

- Aché
 - Cristália
 - Eurofarma
 - Mantecorp
 - Interfarma →
- | | |
|-----------------|---------------------|
| Abbott | Merck Sharp & Dohme |
| Actelion | Novartis |
| Astrazeneca | Novo Nordisk |
| Bayer Schering | Nycomed |
| Biogen | Organon |
| Boehringer | Pfizer |
| Daiichi Sankyo | Roche |
| Farmalab Chiesi | Sanofi-Aventis |
| Galderma | Schering Plough |
| Genzyme | Servier |
| Glaxosmithkline | Shire |
| Janssen-Cilag | Stiefel |
| Lilly | Wyeth |
| Lundbeck | Zambon |
| Merck Serono | |

- 33 companies with US\$ 8.6 bi Sales, which means around 60% of total brazilian pharmaceutical market (IMS December 2008)

The high degree of informality brings relevant damage to the sector development and for society as a whole:

- Population's exposure of the to health risks;
- Inappropriate use: non-prescribed medicine, dangerous drugs interaction and/or wrong regimen;
- Reduction of access to medicines due to higher prices charged by illegally switched similar in relation to the generic;
- Tax distortion and restrictions to the Governmental investment;
- Unfair competition to formal companies and restrictions to sector's development.



**There is no
"silver bullet"**

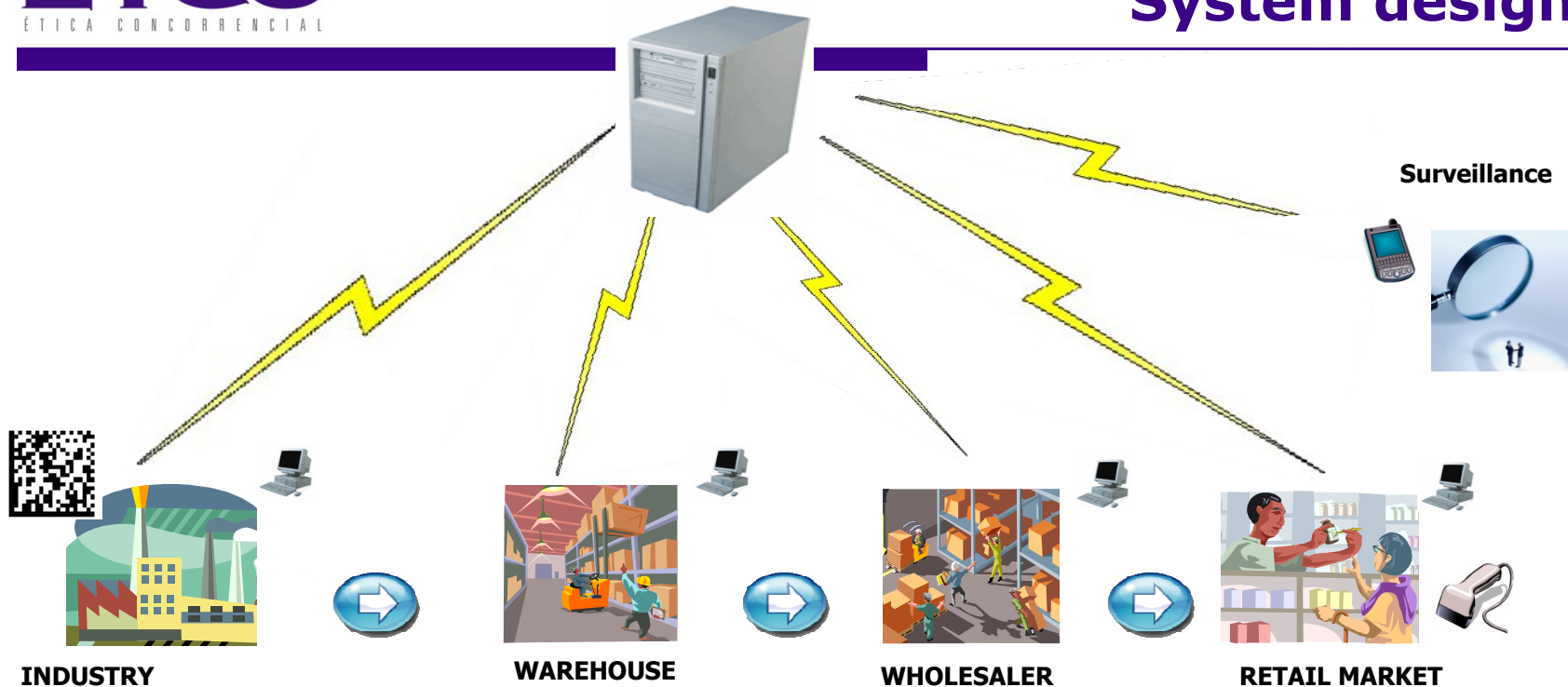


**Success will be achieved
through several
simultaneous actions.
The main one is:**

Tracing System

- Low deployment, operation and maintenance costs
- Ability to supply a national and international solution – adoption of an open standard
- Mechanism of single reading, with authenticity confirmation in real time and able to identify possible technologies adopted in other countries
- Technology that guarantees information security and confidentiality in the database
- IUM (Unique code identification) - serialized identification in the secondary package
- Capacity of checking of the information hosted in the database

- ➔ **Technological solutions, with print of two-dimensional code in secondary package, which enable tracing and authenticity and meet the minimum requirements:**
 - ➔ Possibility of aggregation of information on all the links in the chain;
 - ➔ Possibility of segregation of access to information (public sector, companies and users);
 - ➔ Industrially proven, possible, measurable, robust and efficient, ensuring good manufacturing practice.



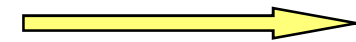
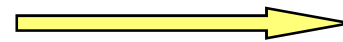
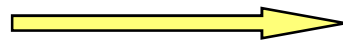
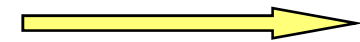
INDUSTRY

- Product Identification
- Code print and storage in the database

WAREHOUSE

WHOLESALER

RETAIL MARKET



- Product Identification (IUM)
- Production date
- Print date
- Product characteristics:
 - Name / Packing
 - Registration number
 - Batch number
 - Expiry date
 - Name / Producer code
- Code activation (production site, machinery, etc.)

- Product identification
- +
- Ordering data (date, source, destination)
- Receiving data (date, source, etc.)
- Additional data

- Product identification
- +
- Ordering data (date, source, destination)
- Additional data

- Product identification
- +
- Ordering data (date, source, destination)
- Surveillance data
- Additional data

- ➔ **Public Consultation N. 8 of March 4th, 2008.
(Minimun Requirements)**
 - **Low total implementation cost.**
 - **Capacity of immediate equipment reposition or correction.**
 - **Capacity of providing national and international solution.**
 - **Capacity of immediate identification of the product authenticity.**
 - **Availability and access to information to trace a product.**
 - **Presence of Unified Medication Identifier (UMI) in the package.**

- **ETCO presents Pilot Project proposal to ANVISA and a Technical Agreement is signed**
- **ETCO started the pilot project with:**
 - **Pfizer**
 - **Bayer Schering**
 - **Sanofi Aventis**
 - **Nycomed**
 - **Eurofarma**
 - **Ache**
 - **Mantecorp**
- **January/2009: Act 11.903 issued creating the official national tracking system**

Establishing traceability of production and consumption of medicine through the means of technology using electronic capturing, storing and transmission of data.

Article 1: It is created the Brazilian System of Medicine Control, which includes the production, marketing, dispensing and medical, dental and veterinarian prescription, as well as any other types of movements forecasted in sanitary controls.

Article 2: All medicine manufactured, dispensed or sold within the Brazilian territory shall be controlled by means of the Brazilian System of Medicine Control.

Sole Paragraph: The control equally applies to medical, dental and veterinarian prescriptions.

Article 3: Control will be performed by means of an exclusive identification system which will identify product, suppliers and users by employing technology to electronically capture, store and transmit data.

Paragraph 1: Products and their distributors will receive specific identification based on data capturing system via electronic for the components of the Brazilian System of Medicine Control.

Paragraph 2: Besides those items listed in sections of paragraph 1 of this article, Brazilian Health Authorities may yet include other components connected to production, distribution, importing, exporting, trading, medicine prescription and use.

Article 4: Competent Brazilian Health Authorities will implement and coordinate the Brazilian System of Medicine Control.

Article 5: Competent Brazilian Health Authority will implement the system **within a gradual schedule of 3 (three) years**, as the inclusion of the components (...) will be performed in the following manner:

I – in the first year:

- a. Manufacturer (operation permit, state license, and local manufacturer sanitary permit);**
- b. Supplier (wholesalers, retailers, medicine exporters and importers);**

II – in the second year: Buyers, Products, transportation / logistic units

III – in the third year: consumer/patient; prescription; doctors, dentists and veterinarians

Article 7: **This act is considered effective on the date of its publication.**

Brasília, on the 14 of January of 2009.

LUIZ INÁCIO LULA DA SILVA

→ **ANVISA is still working in some important definitions such as:**

- **Code definition (ANVISA has already expressed interest in adopting the GS1 Datamatrix, but specifications are still pending)**
- **Databases Management**
- **Code printed directly or on a special label**

- ➔ **Considering the risks and losses that counterfeit medicines and products not manufactured within the rules, the implementation of a tracing and authentication system is a powerful tool to correct these deviations.**

- ➔ **Considering the actions that are being conducted over the world, it is essential to be in line with international initiatives – GS1 Global Standards.**

Thank you for your attention.

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