THE ANVISA EFFORT ON COMBATING COUNTERFEIT MEDICINES IN BRAZIL

National Plan on Combating Counterfeit
COUNTERFEIT MEDICINES IN BRASIL

The Philippines Code (Brazil Colony)

“... If someone counterfeit any goods, like wax for example, or anything else, and if it cost a silver mark, die for that. And if it costs less than that, the person has to be banished forever to Brazil.” (book V, Kingdom ordinances – The Philippines Code).

COUNTERFEIT MEDICINES IN BRASIL

First cases

• English water (Água Inglesa): was the very first case of counterfeit medicine that was known in Brazil, in the year of 1877;

• In 1991, it was detected that out of eleven marks of Tetracycline nine were fake;

• From 1997 to 1998 the counterfeit practice aggravated, and the denunciations on fake medicines had increased.
COUNTERFEIT MEDICINES IN BRASIL

DECRETO 2848, DE 07.12.1940
(Brazilian Criminal Code)

- Originally its version did not make any mention to the counterfeiting crime;
- It was last modified by the Law no. 9.677/98 that added, among others, the articles 273 to 277;
- Article 273: “To Fake, to Corrupt, to adulterate or to alter a product that is destined to a therapeutical or medicinal purpose.
COUNTERFEIT MEDICINES IN BRASIL

Crime Legislation

• Lei nº 9.677/98 – Art. 273 – Counterfeit crime:
  - Penalty: 1 to 3 years - 10 to 15 years + multa;
  - Without parole or amnesty;
  - Its is applied equally to whom import, sell, expose, keep under guard, or distribute.
• Law 9695/98 – has classified the penalty as a hideous crime.

COUNTERFEIT MEDICINES IN BRASIL

Advances – Specific legislations

Portaria 802/98
- Security seals (hot melt and other)
- Reactive ink, that when its scratched reacts chemically with the air and then is shown the word: qualidade with the logotype of the company
- Distributors registry

Portaria 2.814/98 - GM
- Requirements for the medicines acquisition to the public sector;
COUNTERFEIT MEDICINES IN BRASIL

ANVISA CREATION

Federal Law nº. 9782/1999

- It defines The National System of Health Surveillance;
- Reorganization of the acts and health regulations;
- Administrative independency, directors stability and monetary autonomy;
- Coordination of the National System of Health Surveillance.

QUALITY AND POST COMMERCE MONITORING

PROGRAM OF MEDICINE QUALITY VERIFICATION - PROVEME

SENTINELS HOSPITALS NETWORK – a hospitals network that are prepared to notify adverse events and technical complaints of: medicines, health products, basic components, sanitizing products and laboratory kits.
Currently there are more than 160 sentinel hospitals

NATIONAL PLAN ON PREVENTING AND COMBATING FRAUD AND COUNTERFEIT MEDICINES

Antecedents

1997 - I Pan-American Conference of Harmonization and Pharmaceutical Regulation

1999 - II Pan-American Conference of Harmonization and Pharmaceutical Regulation

• It was created the Technical Group “Counterfeit Medicines” of which Brazil was the Coordinator
After the III Conferencia de Armonización Farmacéutica, with the approval of the Plan of Americas, the health surveillance authorities of different countries had assumed the commitment to start the implantation of their National Plan on Preventing And Combating Fraudulent And Counterfeit Medicines.

Counterfeit medicine definition

IV Conference Proposal:

“Falsified medicine is a manufactured product improperly, in a deliberate and fraudulent way in what tells respect to its identity or its origin. They can include products with the correct ingredients or with incorrect ingredients, without active ingredients, with insufficient active ingredient or with falsified packing”.
ANVISA’s proposals:

Today Brazil still doesn’t have an harmonized concept. ANVISA is discussing the concepts:

Falsification of medicines: illicit reproduction of registered medicine, made by third, with the fraudulent intention of giving a legitimate appearance of what is not legitimate;

Adulteration:

Intervention of third, with the purpose of altering legitimate medicine in way to commit therapeutic effectiveness and/or to turn it noxious to the health; or

Intervention that modifies the specifications of the registration fraudulently, changing it registered formulation;

Alteration:

Modification for addition or subtraction of components of the medicine and/or of the pharmaceutical formula, without previous and expressed approval of the National Agency of Health Surveillance.
It was build in 2001 a National committee to subsidize the structure of the Brazilian National Plan:

- ANVISA
- VISAs of the States
- Pan American Health Organization / World Health Organization

The National Committee has defined 5 items as priority to work with:

- Action/inspection Strategies;
- To enable Human Resources;
- To revise and to fortify the Legislation;
- To create and to implement a trustworthy and solid Data Base;
- To fortify the education spreading to the society.
NATIONAL PLAN ON PREVENTING AND COMBATING FRAUD AND COUNTERFEIT MEDICINES

Current situation

1. Human resources

130 qualified inspectors
(federal, state and municipal)

Focal points
Harmonized Investigation procedures

2. Strategies of Action/Inspection

Combined action of the state VISAs with the General offices of Finance in the distributors, to verify the execution of the Good Practices of Distribution of Medicines, with views to strength preventive actions.

The works are in implanted in the states of RS, PR, RJ, GO, MS, BA, CE, PE, RN e PB.
3. Legislation

- **RDC 320/02** determines the inclusion of the batch number in the distributors’ invoices;
- **Portaria 364/03**, institutes GT for the regulation of mechanisms to assure the tracking of the medicines;
- **RDC 55/05** regulates the withdrawal of medicines of the market;

4 – Information System

**SINAVISA** - System of Information of Health Surveillance:
- to integrate the three administration levels
- give tools for taken decisions

**NOTIVISA** (Module):
- receive denunciations and aid in the investigations
5 - Divulgation

Acting points that have been reinforced by ANVISA and the states.

26 States + Federal District

25 States + PD

5560 Cities
SECURITY PROJECT AND MEDICINES TRACEABILITY

Technical Cooperation Agreement between ANVISA and Casa da Moeda do Brasil to propose ways to guarantee the authenticity, packing inviolability and the traceability of the medicines that are sold in Brazil.

Last Results

It has been a significant reduction of the medicines fraud and counterfeiting cases between the years of 1997 and 2005.
Critical Points

Occurred an increase of medicine load robbery notifications

Challenges

1. Articulation of the organisms and institutions;
2. Clear identifications mechanisms of the authentic product by the consumer;
3. To improve the access to medicines for the population.
4. To work in the systematic of the Net;
5. To publish for the society;
6. To structure the VISAS of the states and Municipals, for the combat of Falsification;

7. Use of appropriate technology for the improvement of the tracking of the medicines;

8. To monitor the activities of the risk establishments;

9. Application of the penalties that are in the legislation
The Vaxigrip Case
The Counterfeit Nandrolone Case

The Fluarix Case
The Fluarix Case

FALSIFICADO

The Cialis Case
The Cialis Case

Original

Fake product

The Viagra Case
The Viagra Case

Thank you!

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