SUPPLY CHAIN CONTROL IN ARGENTINA AS STRATEGY TO ASSURE LEGITIMACY, QUALITY, EFFICACY AND SAFETY OF MEDICINES

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REVIEW MEASURES IMPLEMENTED BY ANMAT TO COUNTERACT FALSIFICATION OF MEDICINES

1997- NATIONAL PROGRAM OF MARKET CONTROL

2005- GDP
2009- STRENGTHEN GDP

2011- TRACEABILITY BY UNIT OF DRUGS
1997 – Patients denounced lack of effectiveness and adverse effects of drugs for the treatment of Parkinson (L-dopa/c-dopa), and of other drugs such as Carbamazepine.

RESULT: FALSIFIED

Measure implemented by ANMAT

NATIONAL PROGRAM FOR THE SEARCH OF ILLEGITIMATE DRUGS (MARKET PROGRAM)

The primary aim of the Program is to counteract the distribution and supply of illegitimate pharmaceutical products in order to guarantee quality, effectiveness and safety of such products.
The inspection methodology to detect illegitimate products is based on:

- **Visual Inspection** of pharmaceutical products (supply chain).
- **Research of the documents** that support the acquisition and/or holding of the products.
- **Drug Sampling** along the national distribution chain.
PAST SITUATION
DEC- 2004 – Death of a pregnant woman caused by the injection of Iron (Fe3+) used for anemia treatment.

RESULT: FALSIFIED
NATIONAL PROGRAM FOR THE SEARCH OF ILLEGITIMATE DRUGS (MARKET PROGRAM)

GENERAL MANAGER

LEGAL ADVISOR

PRODUCT COORDINATOR

SUPPLY CHAIN COORDINATOR

INSPECTORS
PHARMACIST – BIOCHEMISTS
Measures implemented by ANMAT

- Adoption of the **GDP Guidelines (MERCOSUR RES)** addressed to wholesalers

- Implementation of **regular inspections** to verify the GDP compliance

- Requirement of **batch number recorded** in all the commercial documentation among wholesalers
2008 – Many cases of original packaging with adulterated substance (refilled) were found.

RESULT: FALSIFIED– ADULTERATED
Measure implemented by ANMAT

2009- STRENGTHEN GDP

-New regulation – all the wholesalers must **renew** their license and comply with GDP (The new licenses are **renewable** every two years).

-New regulation - **Deficiencies classification** based on a risk analysis and associated to specific preventive measures.

-Start to work on a **traceability system**
## DEFICIENCIES CLASSIFICATION

<table>
<thead>
<tr>
<th>Classification</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>VERY SERIOUS</td>
<td>Are included all the events related to the commercialization of illegitimate medicines and commercialization outside the legal supply chain</td>
</tr>
<tr>
<td>SERIOUS</td>
<td>Are included all the events that may directly affect the quality of products (cold chain – hygienic conditions – documentation – records)</td>
</tr>
<tr>
<td>MODERATE</td>
<td></td>
</tr>
<tr>
<td>MINOR</td>
<td></td>
</tr>
</tbody>
</table>

## PREVENTIVE MEASURES

<table>
<thead>
<tr>
<th>Preventive Measures</th>
</tr>
</thead>
<tbody>
<tr>
<td>Preventive suspension</td>
</tr>
<tr>
<td>when serious or very serious deficiencies in GDP compliance are detected and can’t be solved at the moment of the inspection.</td>
</tr>
<tr>
<td>Inhibition of products</td>
</tr>
</tbody>
</table>

## CORRECTIVE MEASURES

<table>
<thead>
<tr>
<th>Corrective Measures</th>
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</thead>
<tbody>
<tr>
<td>Immediate measures</td>
</tr>
<tr>
<td>Mediate measures</td>
</tr>
<tr>
<td>Programmed measures</td>
</tr>
</tbody>
</table>
• It’s a TRACK AND TRACE SYSTEM that allows to establish and record the way followed by a particular drug from its manufacture to its final destination.
2011 – TRACEABILITY BY UNIT OF DRUGS

IMPLEMENTATION: step by step plan

DEPENDING ON PRODUCTS — Nowadays involves 329 APIs
88 1° Step (500 EM) + 226 2° Step (2300 EM) + 11 3° Step

DEPENDING ON AGENTS — Nowadays all the agents
- Consists of using a **UNIQUE AND UNAMBIGUOUS CODE** placed (printed or glued) on the packaging of each retail unit of the pharmaceutical products, which is transmitted to a centralized Database managed by ANMAT.

- Each agent involved in the supply chain must record **“logistic movements”** of drugs and transmits that information, on a **real-time** basis, to the Database.

- The code has associated information.
The associated information is loaded by each agent, but is not in the data carrier.

ASSOCIATED INFORMATION
- Batch number
- Expiry date
- Consignee code (GLN/CUFE)
- Consignee address
- Date of delivery
- Invoice (and other commercial documents) number
Some of the EVENTS TRANSMITTED into a DATABASE

- Each agent can only transmit event authorized by their license

- The system sends alerts when it detects a code duplication; an unconsolidated shipping; if an agent reports the reception of a series not sent to him by a previous holder, etc.
2011 – TRACEABILITY BY UNIT OF DRUGS

- Each agent is identified with a Global Location Number (GLN) or CUFE
- Each agent must inform upon reception as well as upon shipping
- Each logistic movement is validated to previous movements reported to a Central database
- The information is kept in ANMAT Central Database, where we can check it
2011 – TRACEABILITY BY UNIT OF DRUGS

HOW TO IDENTIFY THE PRODUCT?

- With an unambiguous code and a Harmonized language provided by GS1 standard, a Global trade item N° (GTIN) identifies the product and packaging, and a SERIAL N° identifies the specific unit.
- The code must be placed on the packaging in a data carrier with a visible code
2011 – TRACEABILITY BY UNIT OF DRUGS

DATA CONTAINER/CARRIER
• Any technology is allowed

The data carrier to be used is chosen by each company, but must be codified and stored in the container according to GS1 standards.
DATA CONTAINER/CARRIER

- It shall not be removed without leaving an obvious mark.
- If we find traces of a traceability label, it is considered an adulterated product.
RESULTS

Logistic movements
128,619,176

Univocally serialized drugs
28,376,308

Drugs dispensed to patient
6,624,955
BENEFITS OF N.T.S.

• Locate, AT ANY MOMENT, each unit of pharmaceutical products.

• To assure that all the transactions are executed within the legal supply chain

• To prevent risks caused by illegitimate products, detect duplication and diversion of the authorized supply chain.

• To discourage falsifying / forgery, theft and smuggling.

• To assure proper dispensation and patients safety

• It allows agents to detect expired or recalled products before they reach the patient

• To reduce costs of Healthcare System, etc. …
www.anmat.gov.ar/trazabilidad/principal.asp
REPORTS OF N.T.S.
Stock de Medicamentos por Lote

Laboratorio: Bioprofarma S.A.  Medicamento: INF 5:07798021442772  Lote: TODO

Ver reporte detallado del lote seleccionado

Medicamentos en Stock

Map Satellite Hybrid Terrain

STOCK *1 of 1*

Agente: San Martin de Pores SRL
Medicamentos en Stock: 30
CUIT: 30694541581
Direccion: MALABIA 487
# Vencimiento de Medicamentos

## Medicamentos que vencen dentro de los próximos 30 días

<table>
<thead>
<tr>
<th>Lote</th>
<th>Medicamento</th>
<th>Fecha Vencimiento</th>
</tr>
</thead>
<tbody>
<tr>
<td>100</td>
<td>MESINIB</td>
<td>30/03/2012</td>
</tr>
<tr>
<td>25250</td>
<td>BIOFERON</td>
<td>30/03/2012</td>
</tr>
<tr>
<td>3132</td>
<td>ADVATE</td>
<td>31/03/2012</td>
</tr>
<tr>
<td>A736414H</td>
<td>FORTEO 250 MQML</td>
<td>31/03/2012</td>
</tr>
<tr>
<td>C9058</td>
<td>TAXOCRIS</td>
<td>31/03/2012</td>
</tr>
<tr>
<td>CLA006</td>
<td>CLITAXEL</td>
<td>31/03/2012</td>
</tr>
<tr>
<td>CLA006</td>
<td>CLITAXEL 30 MG</td>
<td>31/03/2012</td>
</tr>
<tr>
<td>R4722568</td>
<td>TYKEBI 250 MG</td>
<td>31/03/2012</td>
</tr>
<tr>
<td>075388d</td>
<td>KALETRA</td>
<td>01/04/2012</td>
</tr>
<tr>
<td>0DE015A2</td>
<td>BARACLIDE</td>
<td>01/04/2012</td>
</tr>
<tr>
<td></td>
<td>MIRCERA</td>
<td>01/04/2012</td>
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</tbody>
</table>

## Medicamentos vencidos

<table>
<thead>
<tr>
<th>Lote</th>
<th>Medicamento</th>
<th>Fecha Vencimiento</th>
</tr>
</thead>
<tbody>
<tr>
<td>101017</td>
<td>TEMOLA 20</td>
<td>10/01/2012</td>
</tr>
<tr>
<td>101018</td>
<td>TEMOLA 20</td>
<td>10/01/2012</td>
</tr>
<tr>
<td>101110</td>
<td>TEMOLA 250</td>
<td>11/01/2012</td>
</tr>
<tr>
<td>110506</td>
<td>DALTYS 100</td>
<td>11/01/2012</td>
</tr>
<tr>
<td>110506</td>
<td>DALTYS 100</td>
<td>11/01/2012</td>
</tr>
<tr>
<td>110507</td>
<td>DALTYS 150</td>
<td>11/01/2012</td>
</tr>
<tr>
<td>110508</td>
<td>PLUSTAXANO ANIHDO</td>
<td>11/01/2012</td>
</tr>
<tr>
<td>AFA11T</td>
<td>TORisel</td>
<td>30/01/2012</td>
</tr>
<tr>
<td>012932E</td>
<td>RIFINAVIR ABBOTT</td>
<td>31/01/2012</td>
</tr>
</tbody>
</table>
TRACEABILITY OF UNIT BY BATCH
TRACEABILITY BY UNIT OF DRUGS

<table>
<thead>
<tr>
<th>Num. Série</th>
<th>Medicamento</th>
<th>Fecha Evento General</th>
<th>Evento Origen</th>
<th>Fecha Origen</th>
<th>Agente Origen</th>
<th>Fecha Destino</th>
<th>Agente Destino</th>
</tr>
</thead>
<tbody>
<tr>
<td>0207778007</td>
<td>ORENCIA</td>
<td>03/08/2011</td>
<td>R DE CIARENTE</td>
<td>14/12/2011</td>
<td>Global Farm S.A.</td>
<td>13/02/2012</td>
<td>DROGUERI A REDFARM S.A.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>13/02/2012</td>
<td>DISTRIBUCION DEL PRODUCTO A UN EJABON POSTERIOR</td>
<td>13/02/2012</td>
<td>Global Farm S.A.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Singularesidades**
- En tránsito
- Consistente
- No vencido

**Estadísticas de Línea**
- Cantidad de Operaciones: 6
- Distancia de Traza (Km): 774
- Tiempo de Traza (Sis): 165
Thanks!

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