

# 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.

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

### General Manager- Legal Advisor- Inspectors

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.

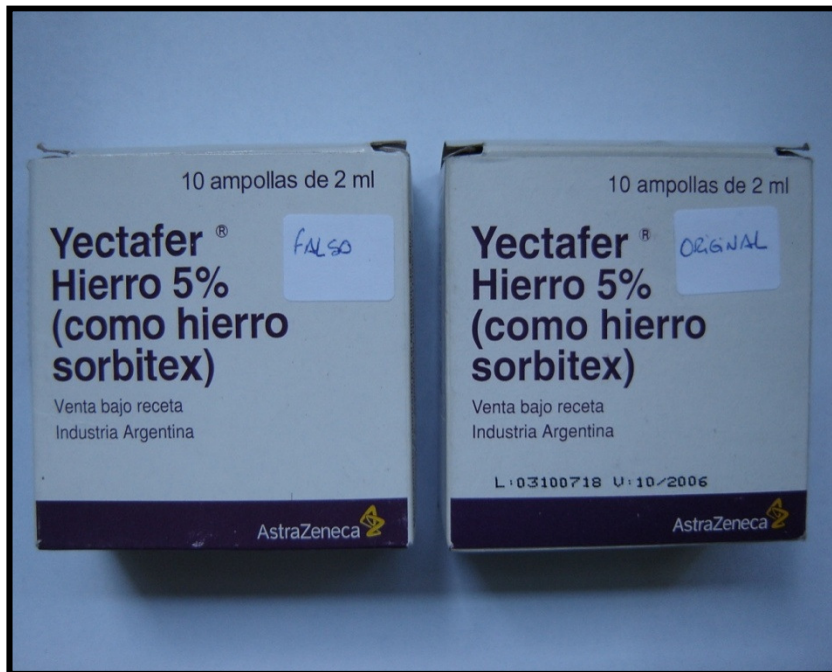
# PAST SITUATION





**DEC- 2004** – Death of a pregnant woman caused by the injection of Iron ( $\text{Fe}^{3+}$ ) 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

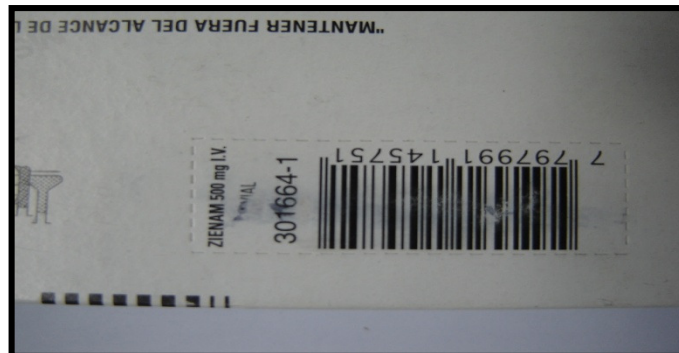
## 2005- GDP

- 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

### VERY SERIOUS

Are included all the events related to the commercialization of illegitimate medicines and commercialization outside the legal supply chain

### SERIOUS

Are included all the events that may directly affect the quality of products (cold chain – hygienic conditions – documentation – records)

### MODERATE

### MINOR

## PREVENTIVE MEASURES

### Preventive suspension

when serious or very serious deficiencies in GDP compliance are detected and can't be solved at the moment of the inspection.

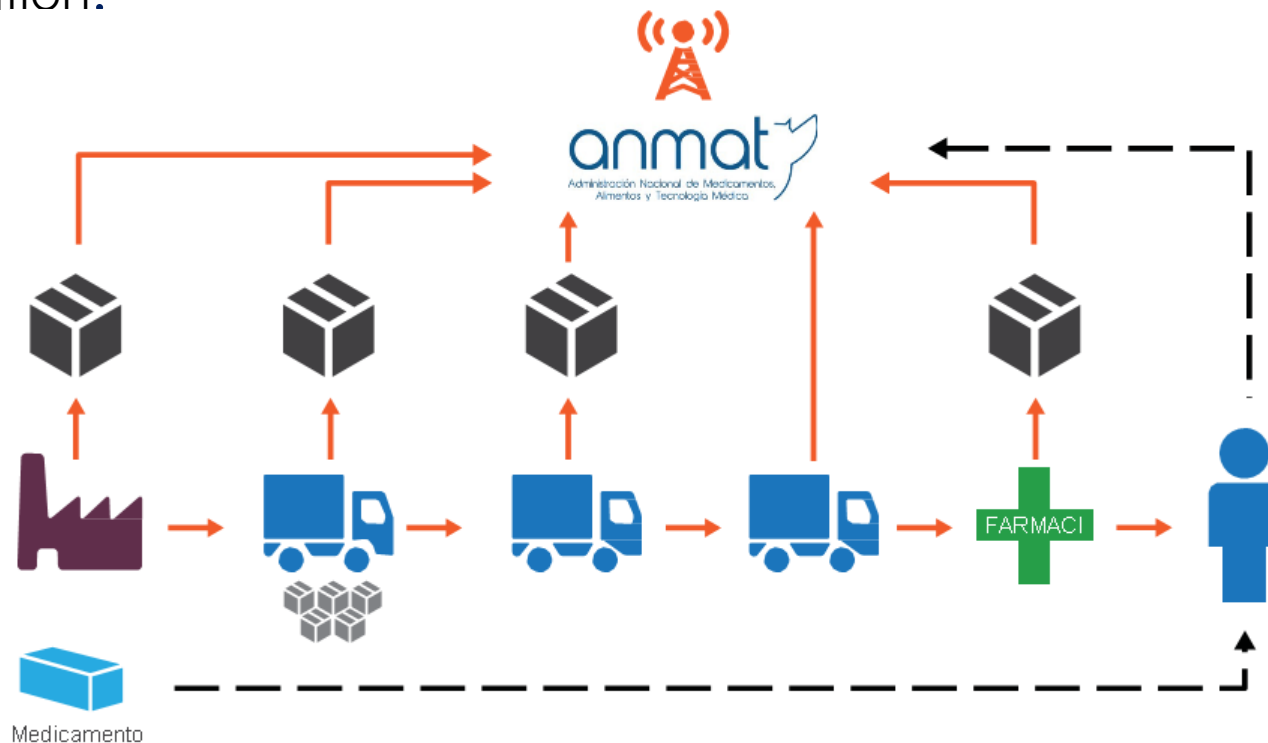
### Inhibition of products

## CORRECTIVE MEASURES

Immediate measures  
Mediate measures  
Programmed measures

## 2011 – TRACEABILITY BY UNIT OF DRUGS

- 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**

## 2011 – TRACEABILITY BY UNIT OF DRUGS

- 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.



## 2011 – TRACEABILITY BY UNIT OF DRUGS

- 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

Lab – PRODUCT STATE	Logistics movements	Other
<ul style="list-style-type: none"><li>• Quarantine</li><li>• Export</li><li>• Clinical Trial</li><li>• Medical Sample</li><li>• Stolen / lost</li><li>• Retention counter sample</li></ul>	<ul style="list-style-type: none"><li>• Shipping to a next link</li><li>• Reception from a previous link</li><li>• Return / Recall</li><li>• Dispensation to the patient</li></ul>	<ul style="list-style-type: none"><li>• Code damaged / destroyed</li><li>• Destruction of medicine</li></ul>

- 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

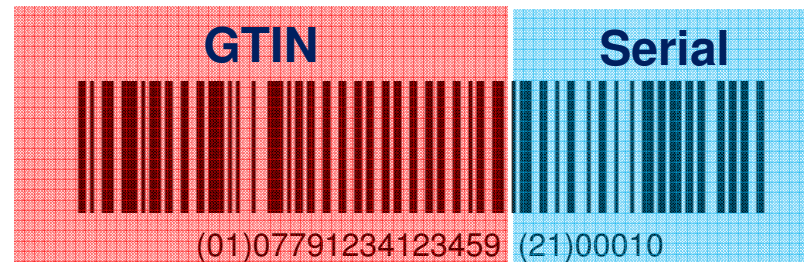
## HOW TO IDENTIFY THE PRODUCT?

- 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

### Packaging



### Data container/Carrier



Source: GS1 Argentina. © 2011, GS1.

# 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.



# 2011 – TRACEABILITY BY UNIT OF DRUGS

## 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





## 2011 – TRACEABILITY BY UNIT OF DRUGS

### 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](http://www.anmat.gov.ar/trazabilidad/principal.asp)



The screenshot displays the main interface of the ANMAT drug traceability system. On the left, a vertical navigation menu lists seven roles: LABORATORIO, DISTRIBUIDOR, OPERADOR LOGÍSTICO, DROGUERÍA, FARMACIA, ESTABLECIMIENTO ASISTENCIAL, and PERSONA. The main area features the system's logo and title, 'Trazabilidad de Medicamentos SISTEMA NACIONAL DE TRAZABILIDAD'. To the right, there are login and registration options: 'Ingresar al Sistema' and 'Regístrese', with a note to complete steps 01 and 02 before registration. A background image shows a person in a white lab coat working at a desk with a computer keyboard, a tablet, and various medical supplies like pills and a syringe.

**Trazabilidad de Medicamentos**  
SISTEMA NACIONAL DE TRAZABILIDAD

Si ya es usuario: [Ingresar al Sistema](#)

¿Aún no es usuario? [Regístrese](#)

! Recuerde cumplimentar los pasos 01 y 02 antes de registrarse aquí.

- LABORATORIO
- DISTRIBUIDOR
- OPERADOR LOGÍSTICO
- DROGUERÍA
- FARMACIA
- ESTABLECIMIENTO ASISTENCIAL
- PERSONA

# REPORTS OF N.T.S.

# STOCK

The screenshot shows a web application interface for tracking drug stock by lot. At the top, there is a toolbar with navigation icons and a zoom level of 100%. Below this is a header section titled "Stock de Medicamentos por Lote".

The main interface includes three dropdown menus for filtering data: "Laboratorio: Bioprofarma S.A.", "Medicamento: INF 5:07798021442772", and "Lote: TODOS". Below these are several icons for map interaction and a link to "Ver reporte detallado del lote seleccionado".

The central part of the interface is a map of Buenos Aires, Argentina, with several location pins. A pop-up window titled "STOCK \*1 of 1\*" is displayed over one of the pins, providing the following information:

- Agente: San Martin de Porres SRL
- Medicamentos en Stock: 30
- CUIT: 30694541581
- Direccion: MALABIA 487

The map includes a legend at the bottom right with options for "Map", "Satellite", "Hybrid", and "Terrain".



# EXPIRED

Vencimiento de Medicamentos

Medicamentos que vencen dentro de los próximos 30 días [Exportar a PDF](#)

Lote	Medicamento	Fecha Vencimiento
100	MESINIB	30/03/2012
25258	BIOFERON	30/03/2012
3132	ADVATE	31/03/2012
A736414H	FORTEO 250 MCG/ML	31/03/2012
C905B	TAXOCRIS	31/03/2012
CLA006	CLIFAXEL	31/03/2012
CLA006	CLIFAXEL 30 MG	31/03/2012
R472268	TYKERB 250 MG	31/03/2012
075388d	KALETRA	01/04/2012
0D6015A2	BARACLUDE	01/04/2012
..	MIRCERA	..

Medicamentos vencidos [Exportar a PDF](#)

Lote	Medicamento	Fecha Vencimiento
101017	TEMOLA 20	10/01/2012
101018	TEMOLA 20	10/01/2012
101110	TEMOLA 250	11/01/2012
110506	DALYS 100	11/01/2012
110506	DALYS 100	11/01/2012
110507	DALYS 150	11/01/2012
110508	PLUSTAXANO ANHIDRO	11/01/2012
AFIA/1T	TORISEL	30/01/2012
012932E	RITONAVIR ABBOTT	31/01/2012

**Mapa de Stock**

Map data ©2012 Google, Inav/Geosistemas SRL, MapLink - Terms of Use

Detalle de los agentes con unidades correspondientes al lote seleccionado



# TRACEABILITY OF UNIT BY BATCH

Laboratorio:  Medicamento:  [Ver Leyenda](#)

Lote:

- .1124154-2
- .1124227-1
- 1024153-6
- 1124154
- 1124154-2
- 1124154-5
- 11241542**

Cantidad de Cajas en Lote  [Map](#) [Satellite](#) [Hybrid](#) [Terrain](#) [Exportar Detalle de Traza a PDF](#)

The map displays a red trace path connecting three locations in Buenos Aires: Florida Oeste (top), Villa Gral. Paz (middle), and Constitución (bottom). The path is highlighted in red and includes a yellow pin at each location. The map shows various streets and landmarks, including the airport and several reserves. The interface includes a search bar, a list of lots, and map controls.

Map data ©2012 Google, Inav/Geosistemas SRL - Terms of Use

# TRACEABILITY BY UNIT OF DRUGS

**Medicamento**

Laboratorio: BRISTOL MYERS SQUIBB A

Medicamento: ORENCIA

Lote: 1369470

**Singularidades**

En tránsito     Consistente     No vencido

**Estadísticas de Línea**

Cantidad de Operaciones	6
Distancia de Traza (Km)	774
Tiempo de Traza (Días)	103

Num. Serie	Medicamento	Fecha Evento General	Evento Origen	Fecha Origen	Agente Origen	Fecha Destino	Agente Destino
029777899 7	ORENCIA	030000321 87127	R DE CUARENTENA		SOCIEDAD DE RESPONSABILIDAD LIMITADA		S.A.
			LEVANTAMIENTO DE CUARENTENA	14/12/2011	Global Farm S.A.		Global Farm S.A.
			DISTRIBUCION DEL PRODUCTO A UN ESLABON POSTERIOR	13/02/2012	Global Farm S.A.		DROGUERIA REDFARM S.A.

Mapa interactivo con herramientas de navegación (Uno, zoom, etc.) y un botón para "Exportar detalle de traza a PDF".



Thanks!

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