

# National and regional strategies against Fraudulent Medicines



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# MEASURES IMPLEMENTED BY ANMAT TO COUNTERACT FALSIFICATION OF MEDICINES

**1997 – CREATION OF NATIONAL PROGRAM FOR THE  
CONTROL OF DRUGS AND MEDICAL DEVICES MARKET**

**2005 - APPROVAL OF GDP  
2009 - STRENGTHEN GDP**

**2009 - CRIMINAL CODE REFORM**

**2011 - TRACEABILITY BY UNIT OF  
DRUGS**

# MARKET CONTROL PROGRAM

The **primary aim** of the Program is to counteract the distribution and supply of illegitimate drugs and medical devices in order to guarantee quality, effectiveness and safety of such products.-

Program **strategy** is based on a rigid control of the legal distribution channels.-

Working **methodology** is based on:

- ➔ Visual and organoleptic inspection of products
- ➔ Research of the documents that support the acquisition or holding of the products
- ➔ Products sampling along the national distribution chain

# ARGENTINE MODEL OF ACTION

## OPERATIONAL GROUP

Prosecutors  
Commission  
Res. 54/97 PGN



Market Control  
Program  
ANMAT



Argentine  
Federal Police  
(Special Division)



**ALWAYS FROM A HEALTH APPROACH !!!**

# CRIMINAL CODE OF ARGENTINA



**Art. 200:** Imprisonment from **three to ten years** and **fine from 10.000 to 200.000 pesos**, the one who

**a)** poison, adulterate or **falsify**,

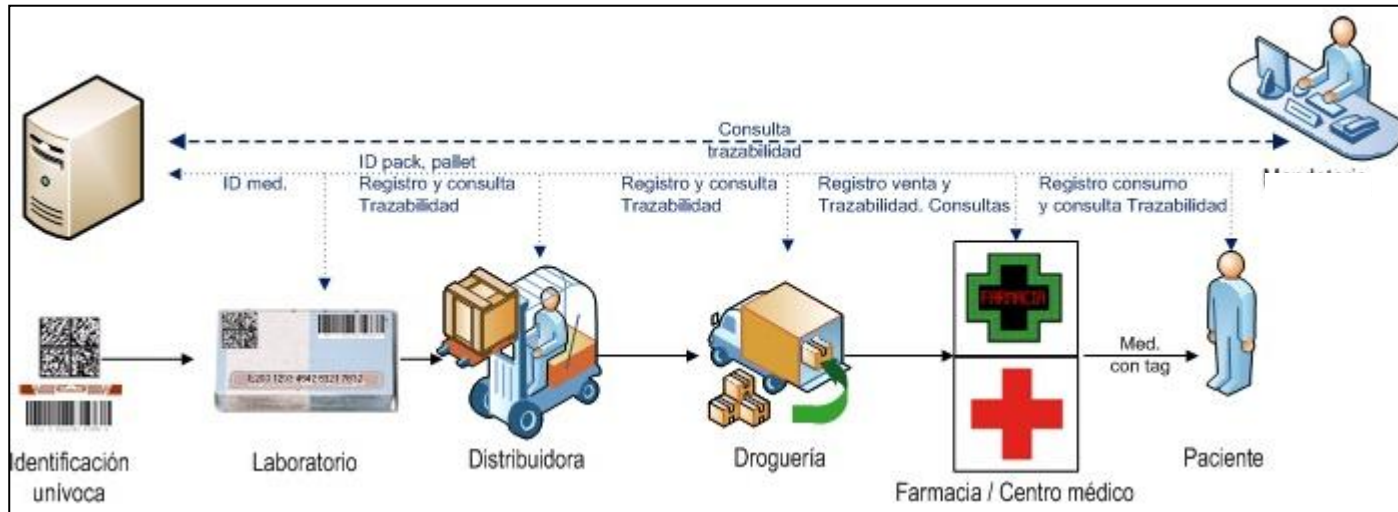
**b)** In a dangerous fashion for the health of others,

**c)** Potable waters or food or medicinal substances, intended for public usage or for consume of a group of people.



# NATIONAL TRACEABILITY SYSTEM

- Unambiguous products identification using a variety of hardware.
- Harmonized language: GS1 Standards.
- **PHASED IMPLEMENTATION** (Step by step plan)
- Information Record: Each agent involved in the supply chain must record “logistic movements” of drugs and transmit that information, on a **real-time** basis, to a Database managed by ANMAT (over **53.000.000 events**)





# DASHBOARDS

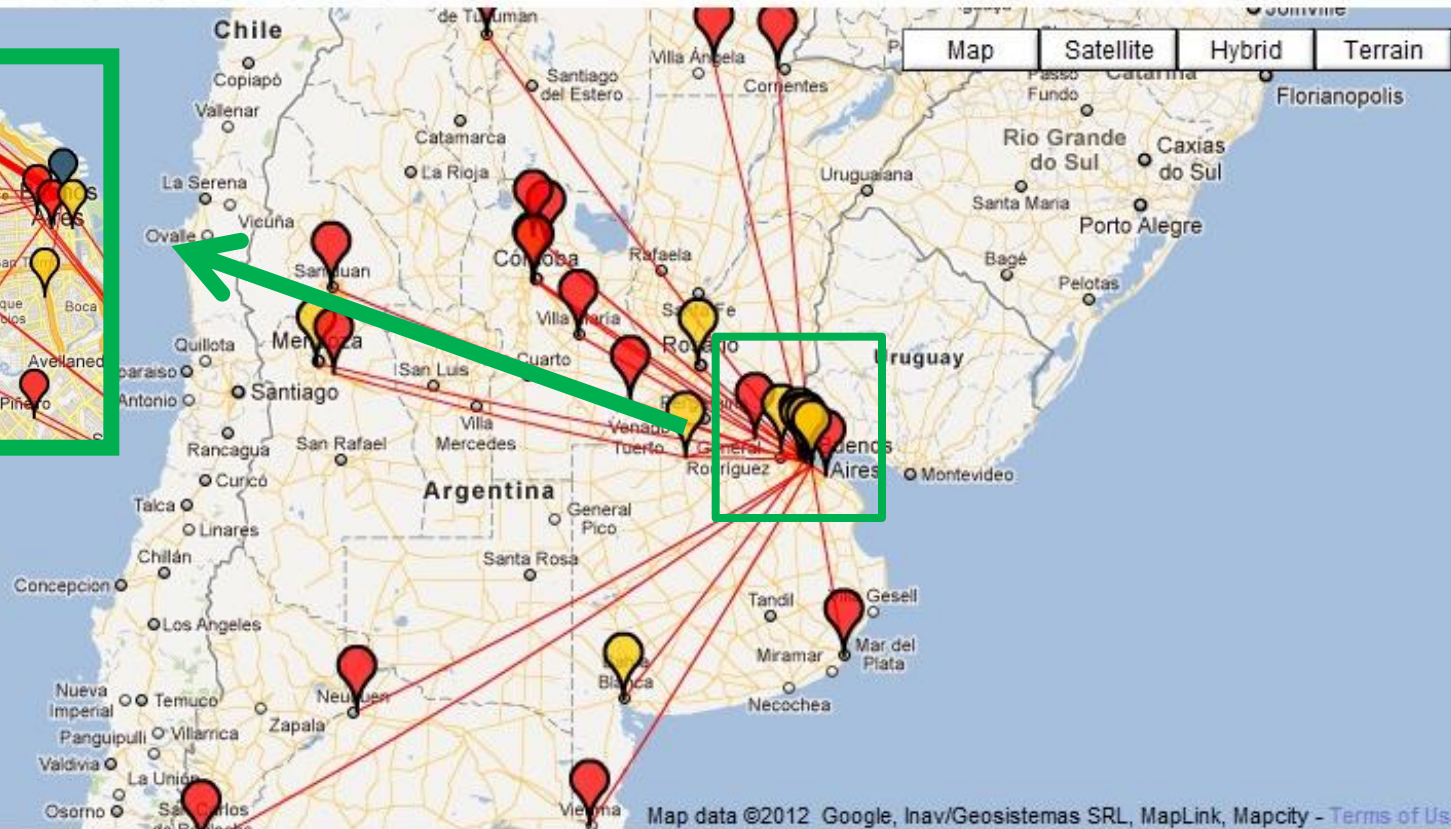
laboratories Argentina S.A

Medicamento: KALETRA:05013158775831:120

Cantidad de Cajas en Lote

## Referencias

-  = LABORATORIO
-  = DISTRIBUIDORA
-  = OPERADOR LOGÍSTICO
-  = DROGUERÍA
-  = FARMACIA
-  = ESTABLECIMIENTO ASISTENCIAL
-  = LABORATORIO DE MEZCLA INTRAVENOSA



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# PAST situation:





# PROCEEDINGS AT ILLEGAL LABS



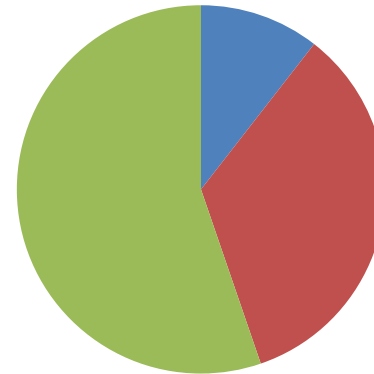
# CURRENT situation:



# RESULTS IN FIGURES

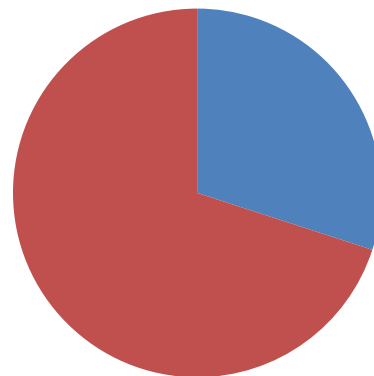
YEAR	REPORTS
1997-2003	253
2004	51
2005	45
2006	20
2007	19
2008	48
2009	25
2010	12
2011	38
2012	20
<b>TOTAL</b>	<b>531</b>

**2011**



- Illegal production of Drugs.
- Internet Sales
- Other causes

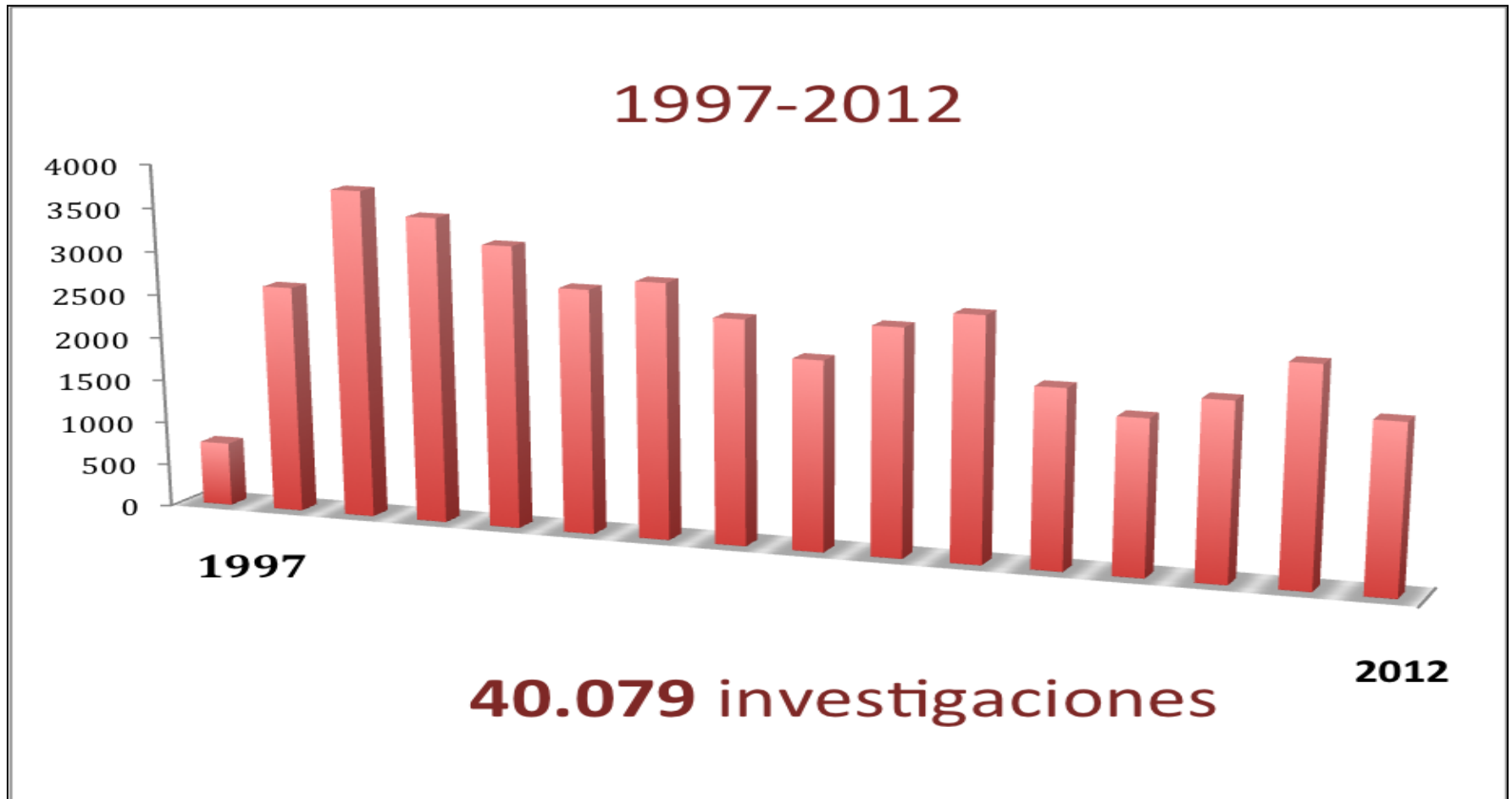
**2012**



- Illegal production of Drugs.
- Internet Sales

# RESULTS IN FIGURES

## INSPECTIONS





# RESULTS IN FIGURES

Year	Suggested prohibitions
2012	37
<b>TOTAL 1997 - 2012</b>	<b>260</b>

Year	Legal Proceedings	Underground labs dismantled
1997	7	1
1998	62	5
1999	43	7
2000	33	1
2001	43	4
2002	64	4
2003	63	3
2004	58	4
2005	66	5
2006	110	6
2007	12	0
2008	68	0
2009	123	0
2010	40	2
2011	39	0
2012	22	0
<b>TOTAL</b>	<b>853</b>	<b>42</b>



# REGIONAL STRATEGIES: PAHO

## *MOST IMPORTANT FACTS*



- **Active participation in Working Group to Combat Falsified Medicines.**
- **Document “Executory Unit”:** Reference model based on Argentine experience.
- **Workshops for Prevention and Combat of Falsified Medicines conducted by Argentina y Brazil with the support of PAHO (Panama 2008, Bolivia 2009, English Caribbean 2009, Costa Rica 2011).**
- **Document “Single point of contact Network” (Brasilia 2011).**
- **Document “Guidelines to be consider by Health Authorities in case of suspicion of falsified medicine” (Brasilia 2011)**



# UNASUR AND WHO



- Active participation in Group of Universal Access to Medicines of UNASUR.
- Uniform position of States with common interests.
- Block position before the World Health Organization in meetings of the WG on SSFFC Medical Products: proposal to create an Intergovernmental Group to work on the issue.
- Res. WHA N° 65.19 (May 2012): Creation of a Member State Mechanism on SSFFC, for international collaboration among MS, from a public health perspective, excluding trade and intellectual property considerations.
- November 2012: First meeting of MSM.

# ¡Thank you very much!

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