EVOLUTION OF TRACEABILITY IN ARGENTINA

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Creation of ANMAT – International context

Mission

• Perform actions leading to registration, control, monitoring and vigilance of the quality, efficacy and safety of health products.

Vision

• To be a reference authority that, through the correct application of the rules as well as monitoring compliance, ensure all products subject to sanitary surveillance proven effectiveness, safety and quality.

Values

• Transparency, Credibility, Predictability and Efficiency
SAFE
EFFICACIOUS
MEDICINE

HEALTH AUTHORITY ROLE

LEGITIMATE

MANUFACTURED
(GMP)

STORED &
HANDLED
(BP ADT)

ACCESS
Creation of INAME – National Price to Quality

1992

1997

Creation of Monitoring Program on Illegitimate Drugs

2003

2009

2008

2011

Traceability Project

anmat

Administración Nacional de Medicamentos, Alimentos y Tecnología Médica

Organización Panamericana de la Salud

ANMAT

Autoridad Reguladora de Referencia Regional para Medicamentos

PIC/S

Sistema Nacional de Trazabilidad
Traceability Project

**RULES:**

- **RESOLUTION (M.H.) 435/11**
- **DISPOSITIONS (ANMAT) 3683/11, 1831/12 & 247/13**

- Unambiguous products identification using a variety of data carriers.

- Harmonized language: GS1 Standards (GTIN & GLN).

- **PHASED IMPLEMENTATION** (Step by step plan, in relation to products and agents). *NEW PRODUCTS INVOLVED IN 2012 & 2013*

  - 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 *(73.000.000 events)*
Data container

- Media or device capable of storing a unique, unambiguous, code, according to GS1 standards.

- It shall not be removed without leaving an obvious mark.
National Traceability System
Dash boards
Benefits of N.T.S.

- To know where is, AT ANY MOMENT, each unit of pharmaceutical products.
- To prevent risks caused by illegitimate products, detecting duplication and diversion of the authorized supply chain.
- To discourage falsifying / forgery, theft and smuggling.
- To ensure proper dispensation.
- To assure patients’ safety.
- To reduce costs of Healthcare System, etc. …
Benefits of NTS

Results

- Lots of agents incorporated into the NTS and interacting with it (over *10,000 agents* nationwide).
- Regulated sector engagement in compliance with the Health Authority regulations.
- Provincial Health Authorities adhered to the NTS and committed to its implementation.
- Continuous improvement of all aspects of the NTS.
- Constant accompaniment of pharmacist, industry, distributors and Healthcare Institutions Associations.
- Follow-up inspections in agents’ premises.
Next activities & challenges

• Training and ongoing support in the Provinces (Public and Private Sector)

• Targeted inspections in agents’ premises aimed to solve difficulties.

• Discussion meetings with ALL actors involved, listening to proposals that help to improve NTS implementation.

• Evaluation of technological advances and their potential.

• Improvement of NTS implementation at Healthcare Institutions.

• Regulation of hospital presentations’ traceability and level below the each supply (unit dose tracing)

• Traceability of implantable medical devices.

• Traceability of Active Pharmaceutical Ingredients.
Thank you!
¡Gracias!