

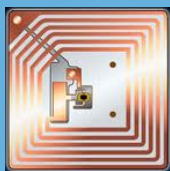


# EVOLUTION OF TRACEABILITY IN ARGENTINA

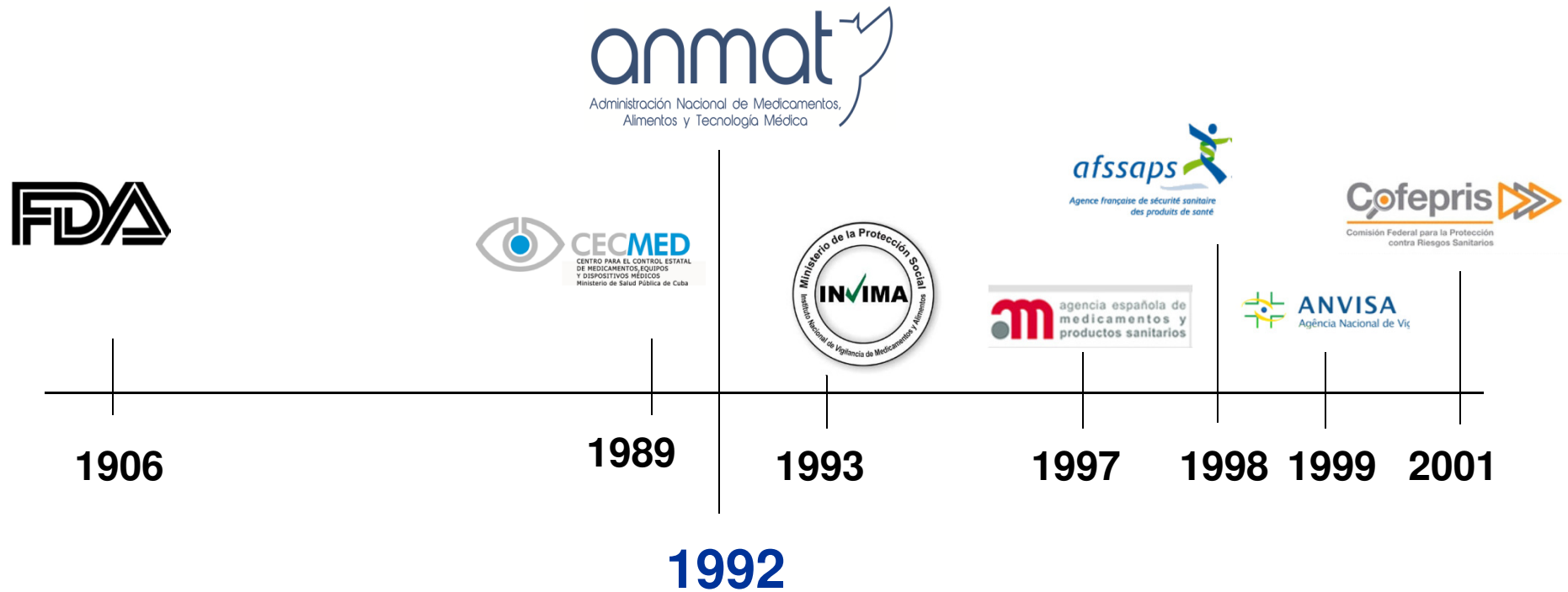


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## Creation of ANMAT – International context



## Mission

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

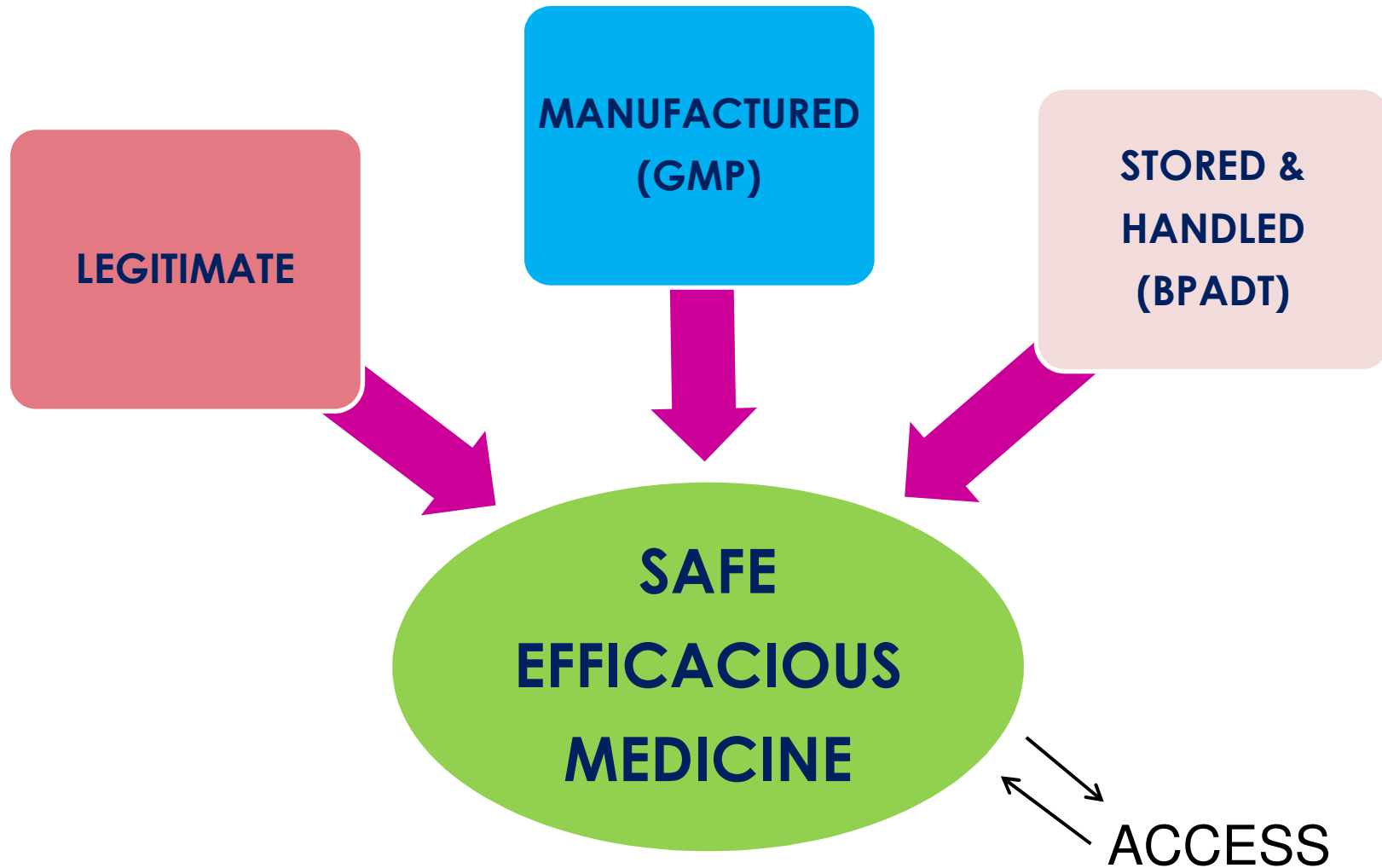
## Vision

- 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

## HEALTH AUTHORITY ROLE



# Traceability Project

Creation of  
**anmat**  
Administración Nacional de Medicamentos,  
Alimentos y Tecnología Médica

INAME – National  
Price to Quality



2009

1992

1997

2003

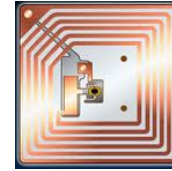
2008

2011

Creation of Monitoring  
Program on  
Illegitimate Drugs



Sistema Nacional de  
**TRAZABILIDAD**

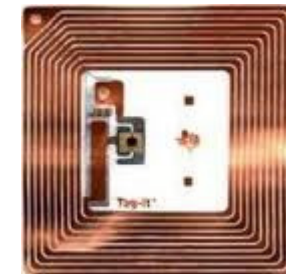


### RULES:

- **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

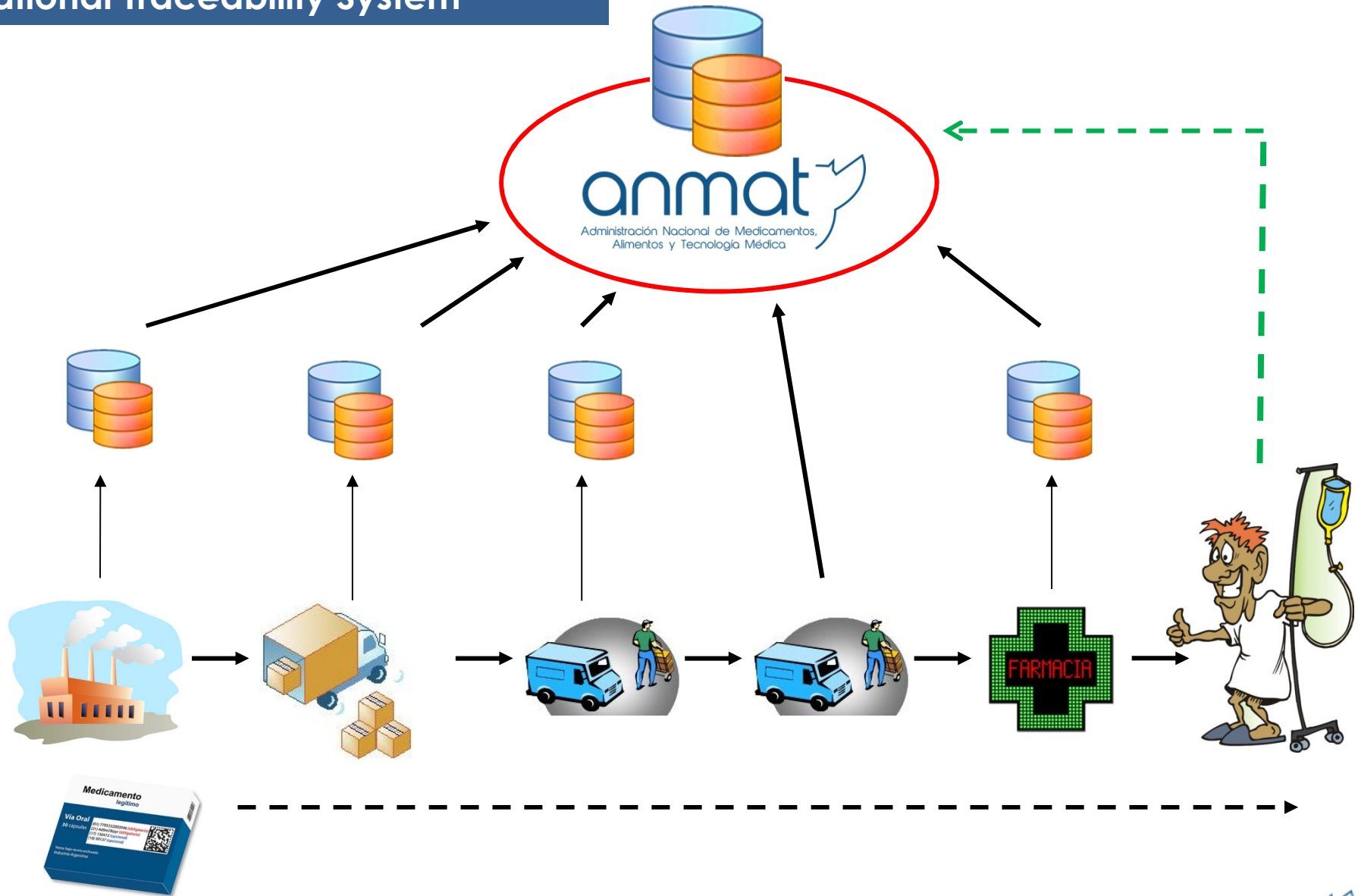
- Media or device capable of storing a unique, unambiguous, code, according to GS1 standards.



- It shall not be removed without leaving an obvious mark.



# National Traceability System





# Dash boards

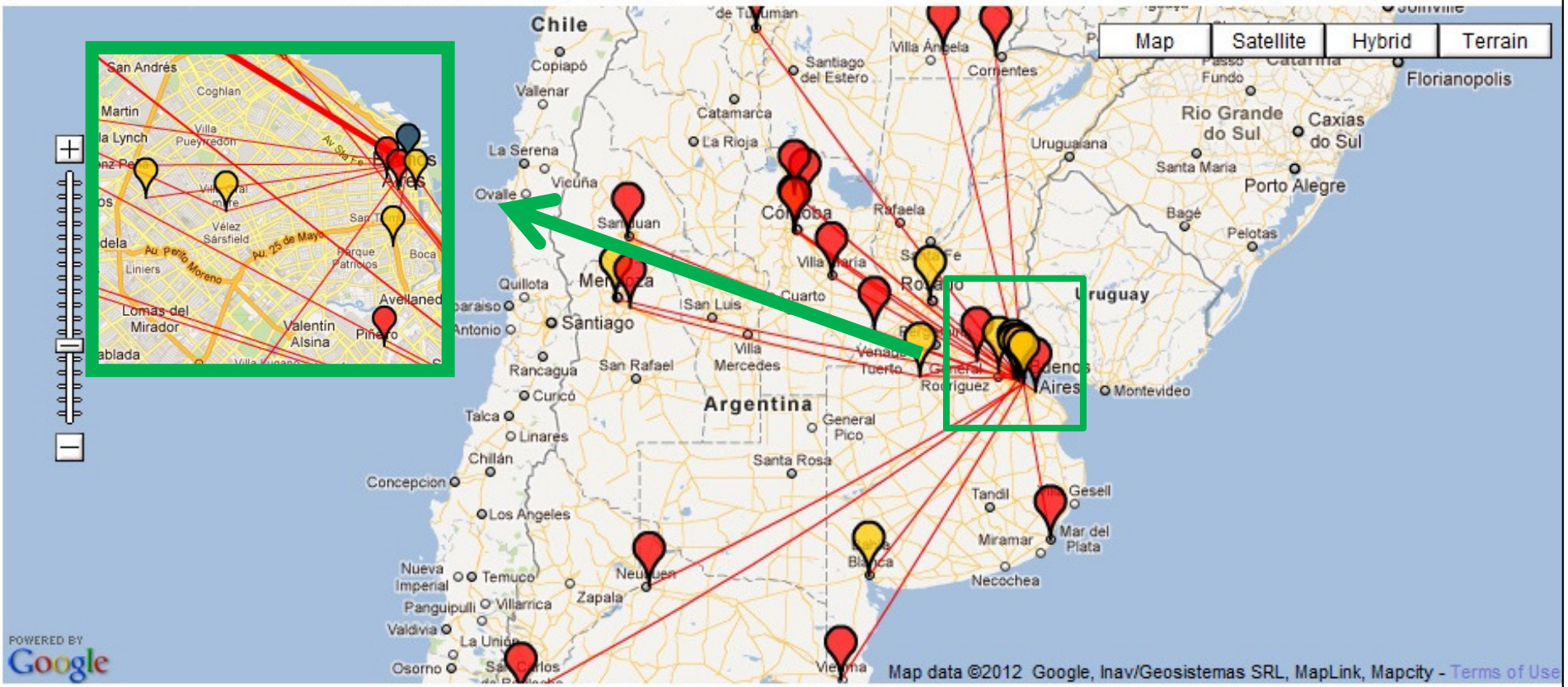
ratories Argentina S.A

Medicamento: KALETRA:05013158775831:120

**Referencias**

 = LABORATORIO	 = FARMACIA
 = DISTRIBUIDORA	 = ESTABLECIMIENTO ASISTENCIAL
 = OPERADOR LOGÍSTICO	 = LABORATORIO DE MEZCLA INTRAVENOSA
 = DROGUERIA	

Cantidad de Cajas en Lote



## 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. ...

## 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)**
- **Trageted 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.**



Ministerio de  
**Salud**  
Presidencia de la Nación

# Thank you!

# ¡Gracias!

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