The Global Language of Business

Maximiliano Derecho

National Administration of Drugs, Food and Medical Devices (ANMAT), Argentina

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Administración Nacional de Medicamentos, Alimentos y Tecnología Médica

Ministerio de Salud
Presidencia de la Nación

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REGULATION ON TRACEABILITY OF MEDICAL DEVICES IN ARGENTINA

Dr. Maximiliano Derecho

Legal Advisor – Direction of Health Products' Vigilance

A.N.M.A.T. - Argentina

mderecho@anmat.gov.ar

@mjderecho

Background

- **VERY COMPLEX MARKET**. Very different from Pharmaceutical products' market.
- "Medical device" term involves a wide range of quite dissimilar products (CT scanners, condoms, syringes, implants, etcetera)
- Plenty of models with varying size markets in each country (Argentina is not one of the biggest market in the global context)
- Distribution activities without health regulations in many parts of the world, and partly in Argentina. Argentina is a federal country comprised of 24 states. Not all the states regulate the distribution of medical devices.
- Constant innovation evolution. Exponential emergence of new products. Increasing international regulation.

VERY GOOD EXPERIENCE IN PHARMACEUTICAL TRACEABILITY

Why Traceability?

Medical devices' **TRACEABILITY** is an efficient **TOOL** to control products' transactions in **REAL TIME**, verify their origin, record the history of locations and movements along the **SUPPLY CHAIN**, in order to bring ***SAFETY to PATIENTS***

Benefits of MD-NTS

- To know where is, *AT ANY MOMENT*, each unit of medical devices involved.

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

- 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 implantation and patients' safety.

To allow agents to detect expired or recalled products before they reach the patient

- To reduce costs of Healthcare System, etcetera …

Traceability Project

RULES:

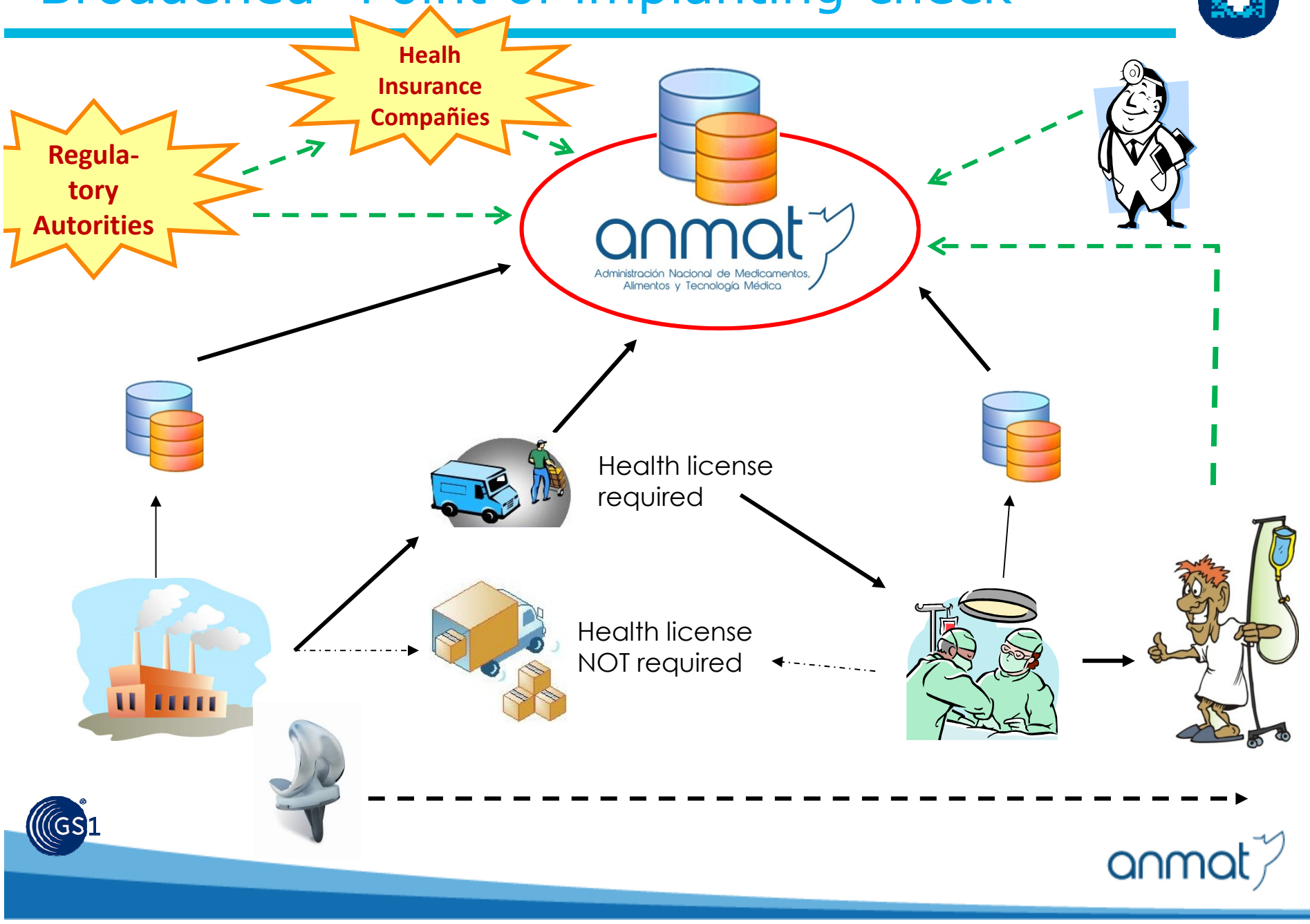
- ***RESOLUTION (MoH) 2175/2013***
- ***DISPOSITION (ANMAT) 2303/2014***



- Mix between "Full Track & Trace" & "Point of implanting check" System (***Broadened "Point of implanting check" System***).
- 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).
- Information Record: Each agent reached by the NTS must record "logistic movements" of medical devices and transmit that information to a Central Database managed by ANMAT.

(***2.231.467 transactions***)

Broadened "Point of implanting check"



Full Track & Trace System

Some of the EVENTS reported to the DATABASE:

MAH – PRODUCT STATE	Logistics movements	Other
• Quarantine • Export • Medical Sample • Stolen / lost • Retention counter sample	• Shipping to a next link • Reception from a previous link • Return / Recall • Implantation to patient	• Code damaged / destroyed • Destruction of the unit.

- Each agent is identified with a **GLN** and can only transmit events authorized by its license

- They must report the reception as well as the shipping of units and **logistic movements are validated** against previously reported movements. However, only reached agents are compelled to report.

- The system sends alerts when it detects a code duplication; an unconsolidated shipping; an expired or stolen product tried to be reported, etc.

Data carrier

• Media or device capable of storing a unique, unambiguos, code. **Any technology is allowed**. It is chosen by each company, but must be codified and stored in the container according to **GS1 standards**

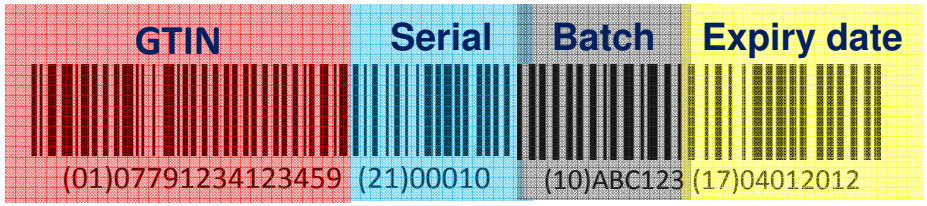
• It shall not be removed without leaving an obvious mark.

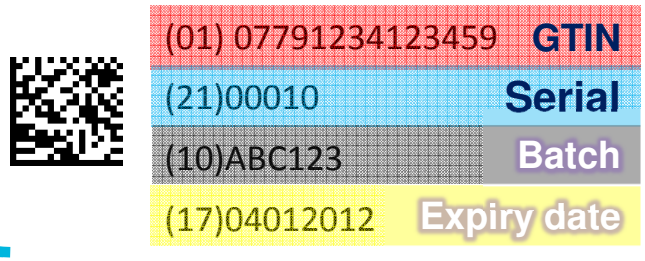
Product Identification

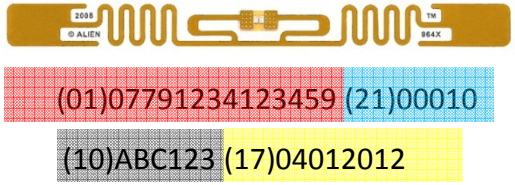
- Unambiguous code with a Harmonized language provided by ***GS1 standards***.
- Placed in the external packaging of each unit (printed or in a label).
- Composed by a **Global Trade Item Number (GTIN) + a Serial code + Batch + Expiry date.**
- The code must be codified in the "symbol" (BC, DM, RFID) and also in human readable language next to symbol.
-GTIN + Series is what identifies a specific unit (Same combination cannot be used with different batches)
- Additional data is allowed but not required

Packaging

Data carrier







Phased implementation

Products' Categories involved (art. 1, Disp. 2303/14)

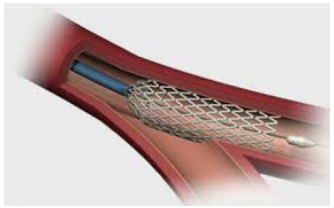
A) Implantable cardiac defibrillators / cardioverter
B) Implantable Electrical stimulators for hearing in the cochlea (cochlear implants)
C) Intraocular lenses (IOL's)
D) Implantable cardiac pacemakers
E) Internal breast prosthesis

6 Months (Since 19/Feb/15)

F) Coronary stents
G) Hip prosthesis
H) Spine prosthesis

12 months (Since 19/Aug/15)

High cost / Variable volumes for each category

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Physicians' role

✓ They can Confirm / Alert the implantation of MD
✓ They can Confirm / Alert the delivery of a MD from an importer, manufacturer or distributor to them.

✓ Surgeons should record Medical device GTIN + serial implanted in the patient's medical history and give the medical device packaging with traceability data carrier to the patient.

Physicians are registered into the Database by entering their professional license number, which is verified by ANMAT, and they are indentified in the System by their Single Tax Identification Number (CUIT)

Trazabilidad de
PRODUCTOS MÉDICOS

SYSTEM DASHBOARDS:
Traceability history of a unit

Promus Element Plus (08714729795964) - 0100011741 (BOSTON SCIENTIFIC ARGENTINA SA)

Traza de Productos por Serie

Evento	Fecha Origen	Origen	Fecha Destino	Destino	
Distribucion a eslabón posterior	17-nov-2015	BOSTON SCIENTIFIC ARGENTINA SA	18-nov-2015	MED BAY S.A.	
Distribucion a eslabón posterior	20-nov-2015	MED BAY S.A.	20-nov-2015	FV ENDOVASCULAR SRL	
Distribucion a eslabón posterior	15-dic-2015	FV ENDOVASCULAR SRL	16-dic-2015	CENTRO CESI S.A.	

Estadísticas de Traza

Cantidad de Operaciones	3
Distancia de Traza (Km)	26
Tiempo de Traza (Días)	29

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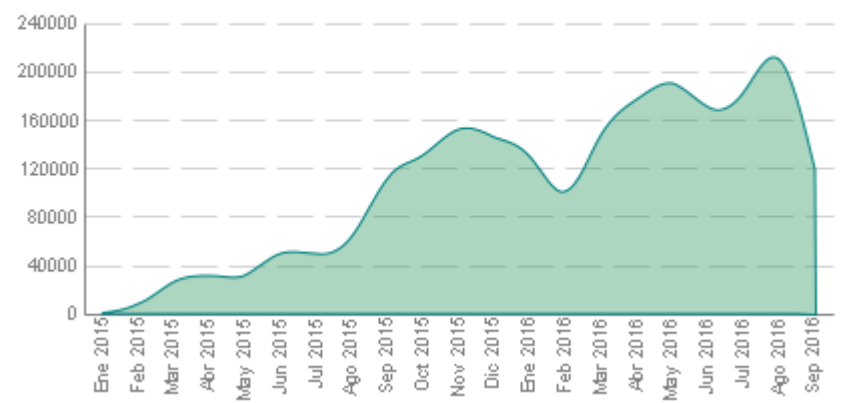
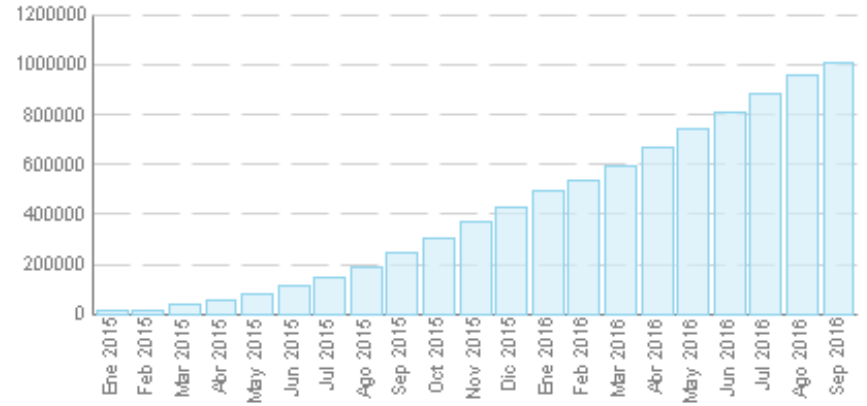
Some up-to-date figures

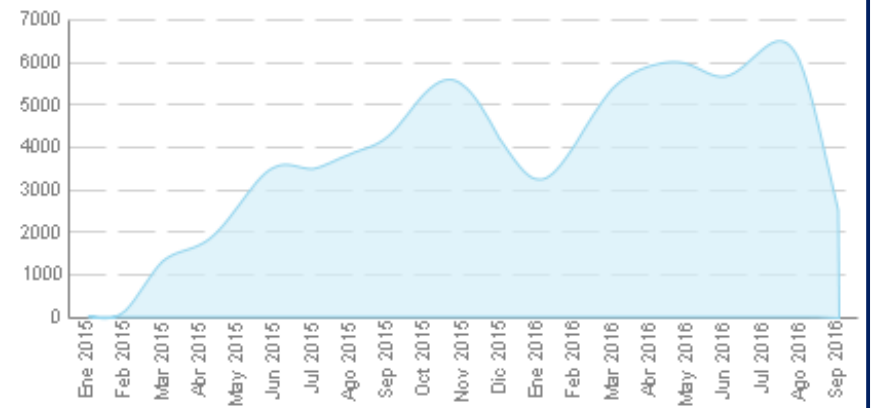
Transactions 2.231.467 transacciones



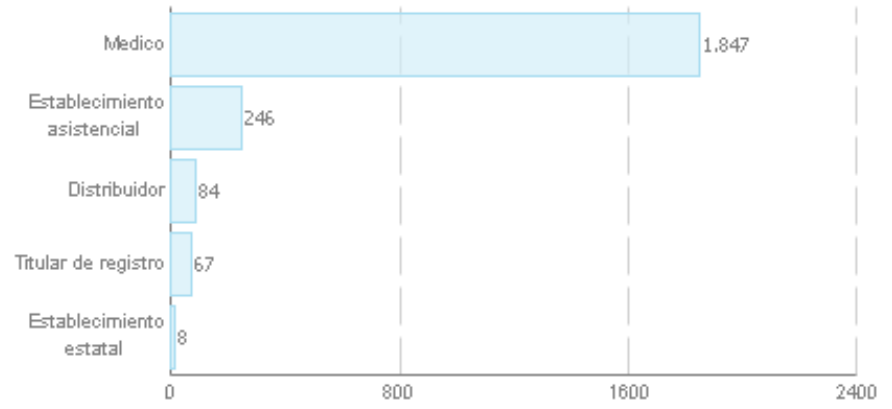
Traced products 1.012.047 unidades



Implanted units 80.510 unidades



Registered agents 2.252 agentes



Results

- Lots of agents incorporated into the MD-NTS and interacting with it (over *400 reporting agents* nationwide).
- Manufacturers/Importers engagement in compliance with Health Authority regulations.
- Some Provincial Health Authorities adhered to the MD-NTS and committed to its implementation, while others are working in the regulation of MD distribution.
- Continuous follow-up of all aspects of the MD-NTS in order to identify aspects for improvement.
- Constant accompaniment industry Chambers & Associations.
- Follow-up inspections in agents' premises.

At a global level

World Health Organization

http://apps.who.int/gb/ssffc/pdf_files/MSM4/A_MSM4_10-en.pdf

http://apps.who.int/gb/ssffc/pdf_files/MSM4/A_MSM4_10-ch.pdf

FOURTH MEETING OF THE MEMBER STATE MECHANISM ON SUBSTANDARD/SPURIOUS/FALSELY-LABELLED FALSIFIED/COUNTERFEIT MEDICAL PRODUCTS

A/MSM/4/10
15 December 2015

EXISTING TECHNOLOGIES AND "TRACK AND TRACE" MODELS IN USE AND TO BE DEVELOPED BY MEMBER STATES

Draft document submitted by Argentina

会员国目前使用的和准备开发的技术以及"跟踪和追溯"模式

阿根廷提交的文件草案

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On going activities & remaining challenges

- **Constant 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 MD-NTS implementation.**
- **Improvement of Distribution regulation and adherence by Federal States.**
- **Improvement of NTS implementation at Healthcare Institutions.**
- **Requirement by Health Insurance companies & organizations as a tool to assure supply chain integrity and avoid fraud.**
- **Improvement of patients and physicians' involvement.**
- **Incorporation of new products in accordance with the results obtained.**

MOVING FORWARD TO A FULL TRACK&TRACE SYSTEM…

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Thank you!
¡Gracias!
謝謝

Maximiliano Derecho

Lawyer specialized in Health Law and Sanitary Legislation

Legal Advisor - Direction of Health Products' Vigilance - ANMAT

Argentina

mderecho@anmat.gov.ar

@mjderecho

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