



# ANMAT Traceability Project for Medical Devices

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# Agenda

- **Anmat Regulation Overview**
  - \*Reason, purpose, approach, proactive activities.
  - \* Technical guidance.
- **Application/ Implementation steps.**
- **Responsibilities & penalties**
- **UDI -differences with - Traceability project**
- **Challenges**

## The Traceability System provides a Unique Device Identification to enable tracking throughout distribution chain and implementation.

### Medical Device Traceability

- Law No. 2175/13

Establishes that physical or juridical persons involved in the chain of trade, distribution and supply or professional application of medical products registered before the Administración Nacional de Medicamentos, Alimentos y Tecnología Médica (ANMAT: National Administration of Drugs, Foods and Medical Technology) shall implement a traceability system to ensure product control and follow-up, from production or import through its application on users or patients.

- Provision No. 2303/2014

Establishes that the Medical Product Traceability System to be implemented by physical or juridical persons involved in the chain of distribution, supply and application of medical products registered before this National Administration comply with the terms stated in section 1° and following sections of Ministry of Health Law No. 2175/2013

# MEDICAL PRODUCT TRACEABILITY

## ANMAT : Reason and purpose?

- Product recall
- After-sales reports on adverse events and surveillance
- Follow-up, tracking and safety for supply chain and illegitimate product control (theft, counterfeiting, smuggling, etc.)
- Reducing medical errors
- Speeding up hospital information systems and claim data
- Enhancing ANMAT capability over data systems in search of relevant product information; enables evaluating comparative effectiveness of records.
- Planning for shortages and replacements.



# MEDICAL PRODUCT TRACEABILITY

## **ANMAT : Proactive approach toward illegal trade of medical products.**

Companies participating in the chain of trade, distribution and supply or professional application of medical products shall run a traceability system to allow for product control and follow-up from production or import all the way down to its application on users or patients.

The traceability system shall consist of the individual and unequivocal identification of each medical product unit put on the market, to allow follow-up of each unit throughout the distribution chain.

The information to be entered into the ANMAT central database for medical product traceability shall include identification data for the unit and distribution steps determined by the authority of application.

# MEDICAL PRODUCT TRACEABILITY

## **ANMAT : Technical Guidelines.**

Characteristics and modalities of the unequivocal code. GS1 Healthcare Reference Guide.

Gradual application timeline, based on degree of criticality and different medical product categories.

Define type of agents in the marketing chain.

Include lot number (if applicable) and serial number.

Establish additional requirements and even extend them to other agents in the chain, for accurate matching of units distributed with the respective documentation.



# Medical Product Traceability System Provision 2303/2014 / Application



Trazabilidad de  
**PRODUCTOS MÉDICOS**

Si ya es usuario:    
¿Aún no es usuario?  
  
Recuerde cumplimentar los pasos 01 y 02 antes de registrarse aquí.

-  Titular de Registro
-  Distribuidor
-  Médico
-  Establecimiento Asistencial
-  Persona



- a) defibrillators/cardioverters
- b) electric stimulators for cochlear hearing
- c) intraocular lenses
- d) cardiac pacemakers
- e) internal breast prostheses



- f) vascular coronary endoprosthesis (stent)
- g) hip prosthesis; and
- h) spine prostheses

**STEP 1**  
**FEBRUARY 2015**

**STEP 2**  
**AUGUST 2015**



# Implementation Steps:

- ✓ Acceptance of the identification system with FDA format (UDI)



(01)GTIN  
(17)Expiration date  
(21)Serial number  
(10)Lot (\*)

- ✓ Use of GLN code (GS1 Argentina)



- ✓ User register (ANMAT) & load products (GTINs and other information) in the Anmat system
- ✓ Upload manual information in the web page or interphase with SAP → Implementation

Report product logistics, linking the following distribution data to the unique code, in real time:

\*Code from consignee of shipment (GLN/CUFE). Should consignee not be identified in the System, identification shall be requested to the ANMAT before distribution, proving existence through supporting documents (tax and/or sanitary authorization).

\*Date.

\*Invoice and Delivery Note for distribution operation in question.

- ✓ Distributor Follow-Up: *(sold only to distributos registered in Anmat Database)*

(\*) Notes:

*if products have a Serial Number, lot will not be necessary (orally accepted by Anmat)*

*Expiration date DD/MM/YY : conflicts with globally harmonized standard (orally accepted by Anmat)*





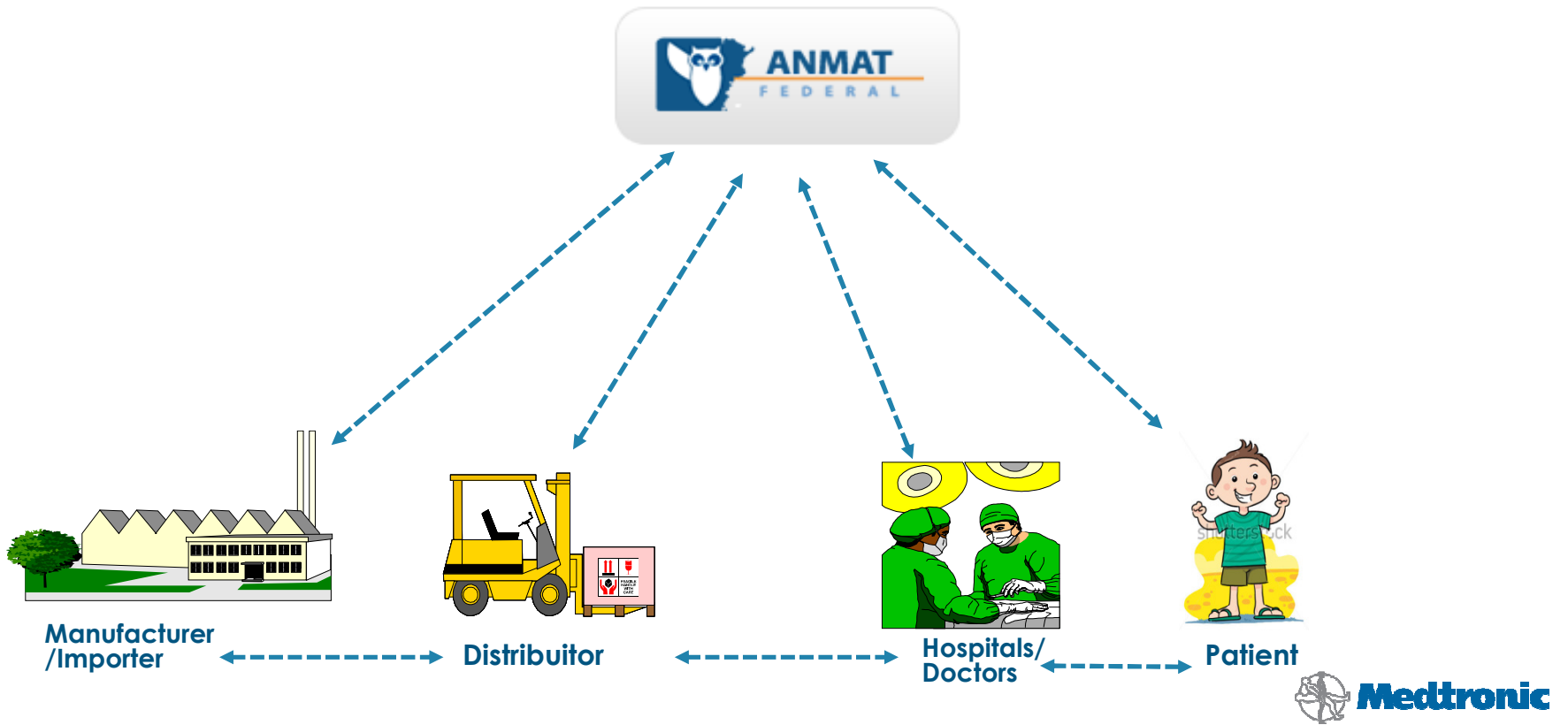
## Responsibility

Holders of medical product registries under the Traceability System and their technical directors shall be responsible for proper use of unique codes and related information incorporated to the Database, as well as for the performance of physical and/or software support providers, in case of purchases from third parties.

## Penalties

Holders of medical product registries under this Provision and the following steps of distribution and implementation chains, as well as those who do not implement the traceability system under this regulation, shall not be able to continue with the production and/or import, distribution and implantation to patients once deadlines have expired.

# Traceability Process



# UDI ≠ TRACEABILITY

## UNIQUE DEVICE IDENTIFICATION (UDI)

•This regulation pertains to medical devices approved for sale in the United States.

•**The UDI System is Comprised of 3 Main Elements:**

**UDI assignment by labeler** (manufacturer), by FDA-Accredited Issuing Agency;

**UDI on packaged device label and/or the device itself** (stated in plain text, automatic identification and data capture technology (AIDC);

**FDA Global UDI Database**, containing Device Identifier and device information for each UDI.  
FDA database not used for tracking and traceability.

## TRACEABILITY IS A COMPREHENSIVE PROCESS FOR IMPLEMENTATION IN ARGENTINA

The traceability system consists in the individual and unique identification of each medical product unit (through GTIN, serial number and expiration date) released to the market, allowing for tracking of each unit through distribution chain in logistics.

# CHALLENGES

*Not all products have a Serial Number and if they do, in most cases they do not have a Batch Number, depending on device type .*

*Production identification is a manufacturing process – how the devices are identified in the manufacturing process. The manufacturing process differs by volume, cost, and risk category of the device. Decisions to serialize or batch control are manufacturing decisions.*

*Most medical device manufacturers do not currently have IT systems and processes in place to handle serialized transaction-based reporting for **all** products. High volume, low cost, lower risk class products would be unaffordable to serialize. Going from a batch manufacturing process to a serialized process involves several millions of dollars for additional space, manufacturing line clearance. Single-piece part would slow down manufacturing flow , documentation in DHR, quality system upgrades, validations, qualifications.*

*Anmat Purposes : Do it locally!*



## CHALLENGES (cont)

Working with companies which provide :

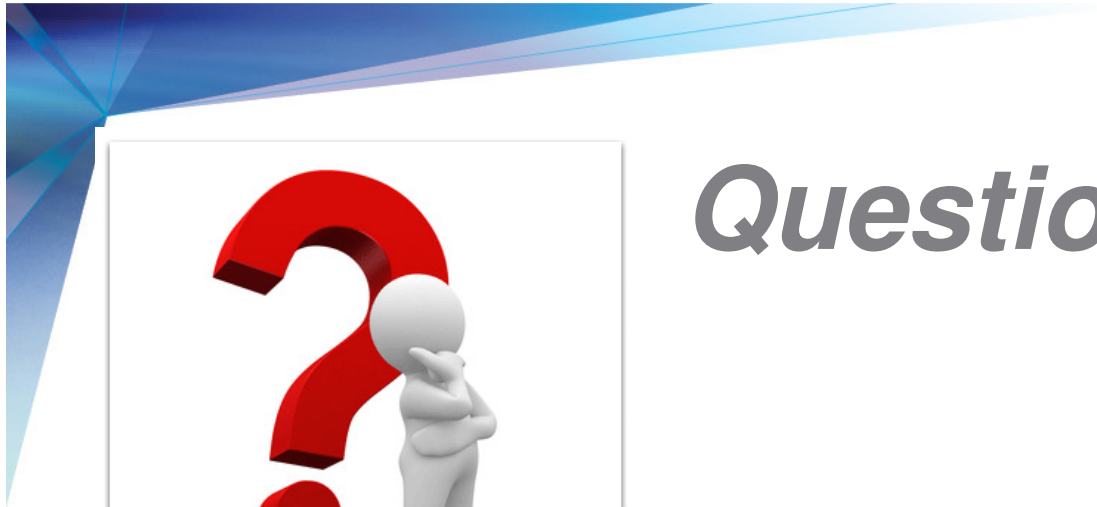
•Solutions in Serialization and aggregation process:

- a. Create numeric and alphanumeric serial number
- b. Create sequential or random serial numbers
- c. Custom: Import external serial numbers



•Labels: label requesting, production line printing (both linear barcode and datamatrix) and logging destruction.

•Medication/medical products: releasing each product with a unique code, grouping codes by packs, grouping pack codes by pallets, logging quarantine and unit destruction.



***Questions?***

***Thanks for your attention***

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