



The Global Language of Business

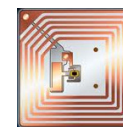
# Maximiliano Derecho

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

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 **GS1 Healthcare Conference – 25/10/2016**

# EVOLUTION OF DRUGS TRACEABILITY IN ARGENTINA



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# BEFORE Traceability



**2007-2011**

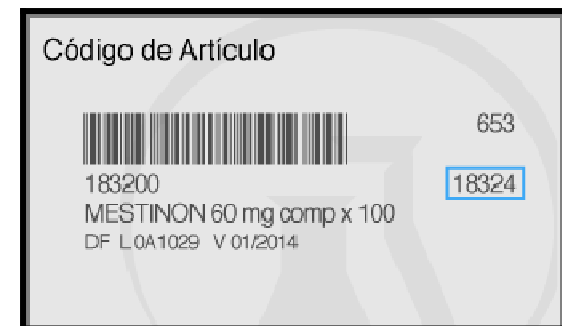
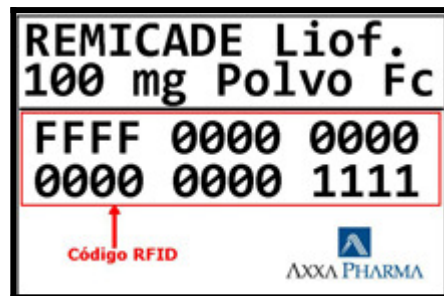
Many cases of original packaging with adulterated substance (refilled) were found.



# BEFORE Traceability



- Private initiatives
- Good experiences
- Information in labels *NOT* harmonized

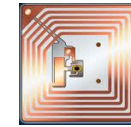


# Traceability Project

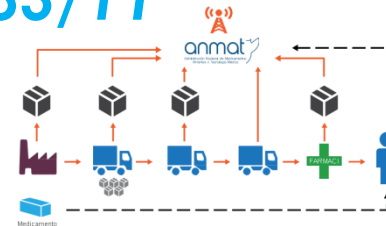


## INITIAL RULES:

- **RESOLUTION (MoH) 435/11**
- **DISPOSITION (ANMAT) 3683/11**



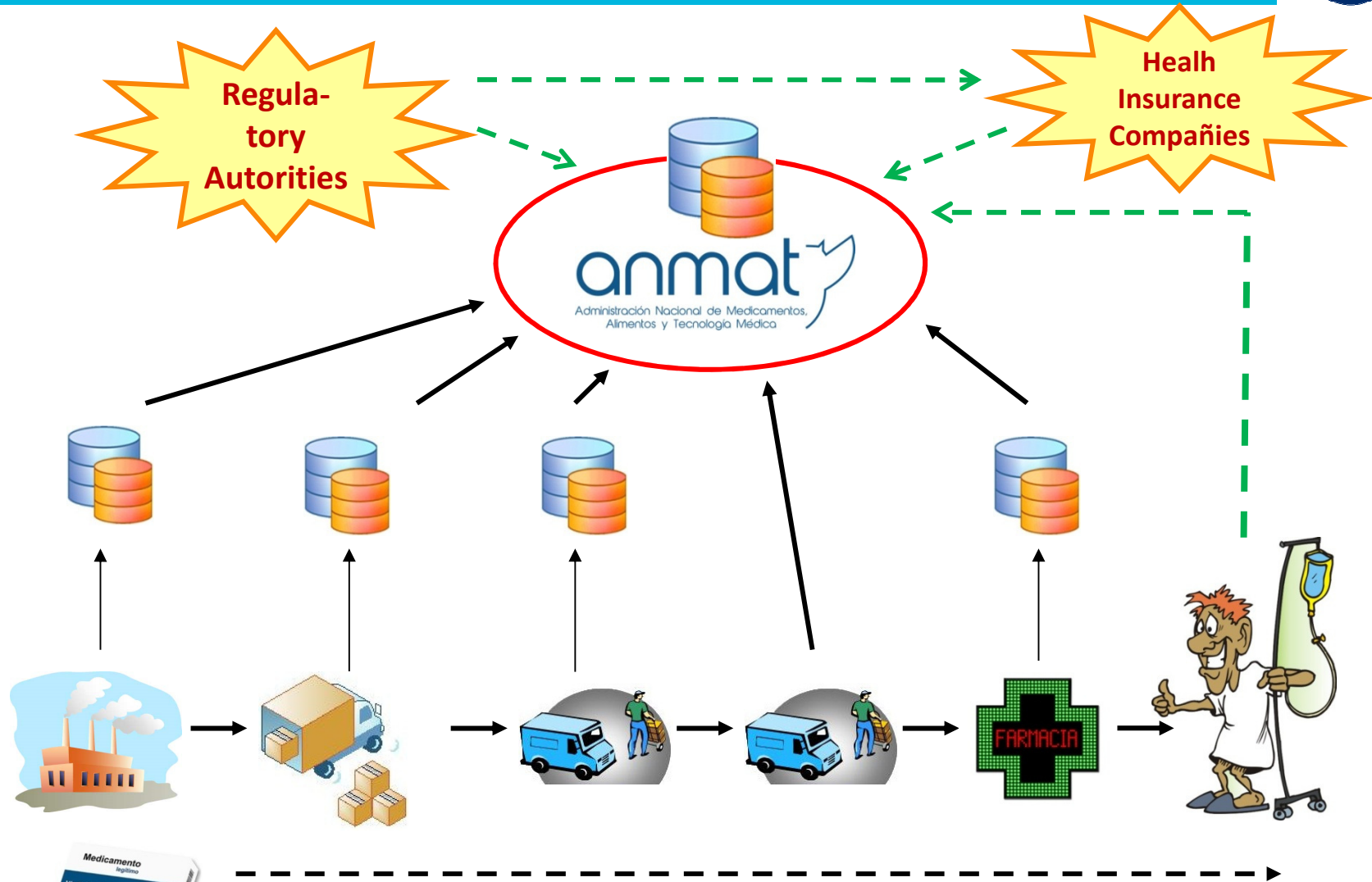
- Full Track & Trace System
- Unambiguous products identification using a variety of data carriers.
- Harmonized language: GS1 Standards (**GTIN** & **GLN**).
- **PHASED IMPLEMENTATION** (Step by step plan, in relation to products and agents). **NEW PRODUCTS INVOLVED IN 2012, 2013, 2015 & 2016**
- Information 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 Central Database managed by ANMAT



**(1.167.111.822 transactions)**



# Full Track&Trace System



# Full Track & Trace System



Some of the  
EVENTS  
reported to  
the  
DATABASE:

Lab – PRODUCT STATE	Logistics movements	Other
<ul style="list-style-type: none"><li>• Quarantine</li><li>• Export</li><li>• Clinical Trial</li><li>• Medical Sample</li><li>• Stolen / lost</li><li>• Retention counter sample</li></ul>	<ul style="list-style-type: none"><li>• Shipping to a next link</li><li>• Reception from a previous link</li><li>• Return / Recall</li><li>• Dispensation to patient</li></ul>	<ul style="list-style-type: none"><li>• Code damaged / destroyed</li><li>• Destruction of medicine</li></ul>

- 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 **every logistic movement is validated** against previously reported movements.
- The system sends alerts when it detects a code duplication; an unconsolidated shipping; if an agent reports the reception of a series not sent to him by a previous holder, etc.





# Data carrier



- Media or device capable of storing a unique, unambiguous, 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.





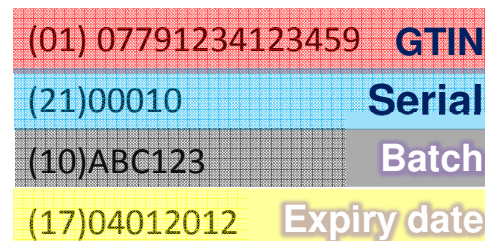
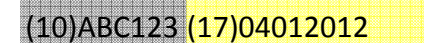
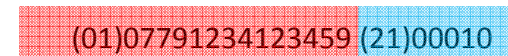
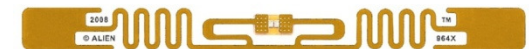
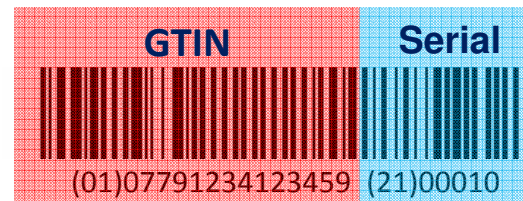
# Product Identification



- 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) that identifies the product and presentation + a Serial code that identifies that specific unit.
- The code must be codified in the “symbol” (BC, DM, RFID) and also in human readable language next to symbol.
- Batch identification and Expiry date mandatorily required when using DM symbols and RFID tags.

## Data carrier

### Packaging



# Phased implementation



**Disp. 3683/11**  
**May - 2011**

- **88 API's**
- ~600 registered presentations (GTIN)
- High cost, low incidence meds. Oncology drugs, antiretrovirals, haemofilia & special pathologies treatments.

**Disp. 1831/12**  
**Mar - 2012**

- **219 API's**
- ~3200 registered presentations (GTIN)
- Low and middle cost antiretrovirals and oncology drugs, antibiotics, antidepressants, Parkinson's treatments, etc.

**Disp. 247/13**  
**Jan - 2013**

- **11 API's**
- ~600 registered presentations (GTIN)
- Psychotropics and narcotic substances.

**Disp. 963/15**  
**Jan -2015**

- **70 API's**
- ~255 registered presentations (GTIN)
- High cost meds, products subject to intensive pharmacovigilance, meds offered in Internet, another psychotropics, etc

**Art. 12°**  
**Disp.**  
**1831/12**

*"Any new medicinal product to be registered in the future and not having a similar product in Argentina, regardless of its Active Pharmaceutical Ingredient (API), shall comply with the requirements provided for in this regulation"*



# Phased implementation



## LAST RULE:

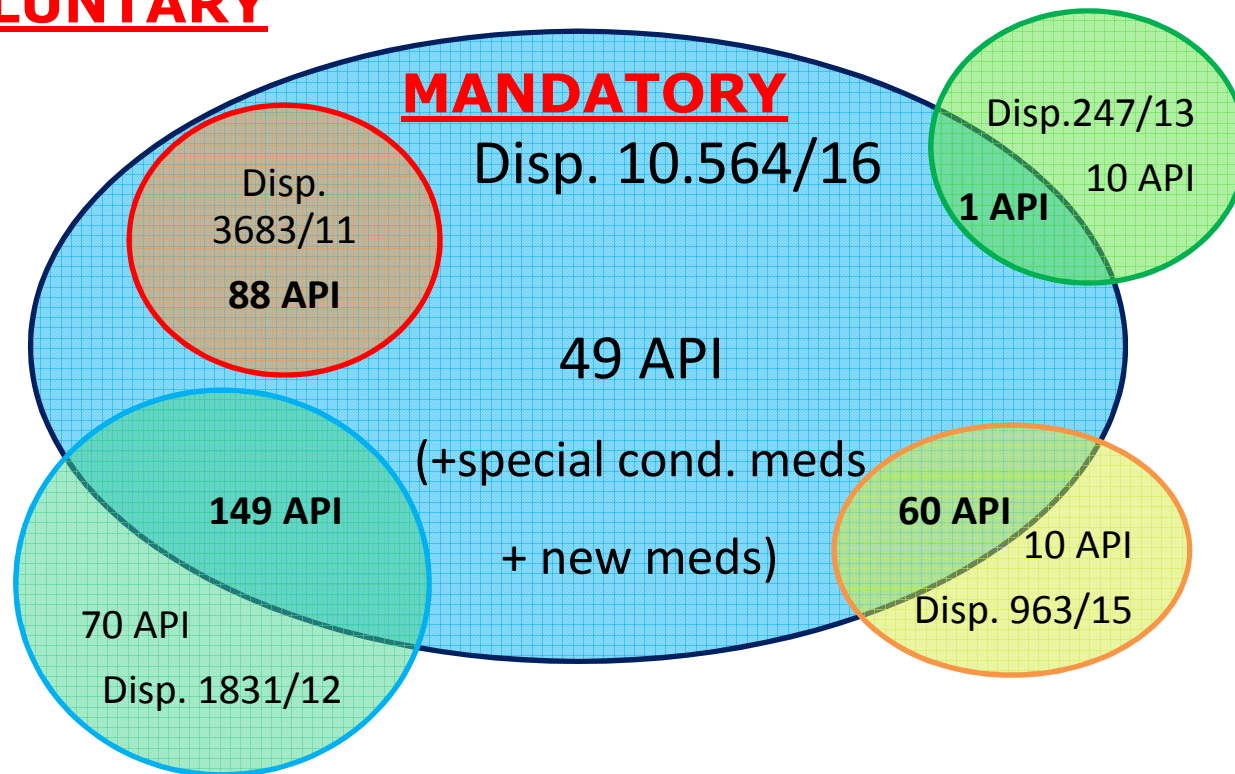
- **DISPOSITION (ANMAT) 10.564/2016** (23/09/2016)

### VOLUNTARY

### MANDATORY

**TOTAL:**

- 347 API traced
- +15.000 GTIN involved.



# Phased implementation

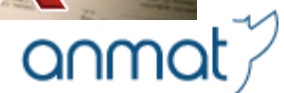


## TRACEABILITY AS A TOOL FOR HEALTH INSURANCE REIMBURSEMENT:



- **DISPOSITION (ANMAT) 6301/2015** (06/08/2015)

- The die ("troquel", a square and punched portion of the product cardboard packaging) was traditionally used as a mean of proving the dispensation of the product to patient.
- The new rule (entry into force in 13-02-2016) provides that meds reached by [Disposition ANMAT N° 3683/11](#) shall be released to the market **without die identification**.
- In its place, access to NTS is now used as an available tool for health insurance companies and organizations (and their regulatory authority) to verify safe dispensation of meds to their covered patients.





## SYSTEM DASHBOARDS: Traceability history of a unit

ACTEMRA 400 MG / 20ML (07792371933881) - 26490214

Traza de Medicamentos por Serie

Fecha	Evento Origen	Fecha Origen	Agente Origen	Fecha Destino	Agente Destino	Estado de Tramo
21/06/2016	Distribucion del producto a un eslabon posterior	21/06/2016	PRODUCTOS ROCHE S A QUIMICA E INDUSTRIAL	23/06/2016	ROFINA S A I C F	●
03/08/2016	Distribucion del producto a un eslabon posterior	03/08/2016	ROFINA S A I C F	03/08/2016	DROGUERIA META S A	●
31/08/2016	Distribucion del producto a un eslabon posterior	31/08/2016	DROGUERIA META S A	31/08/2016	CISALE ESPERANZA	●
03/09/2016	Dispensacion del producto al paciente	03/09/2016	CISALE ESPERANZA		Paciente	●

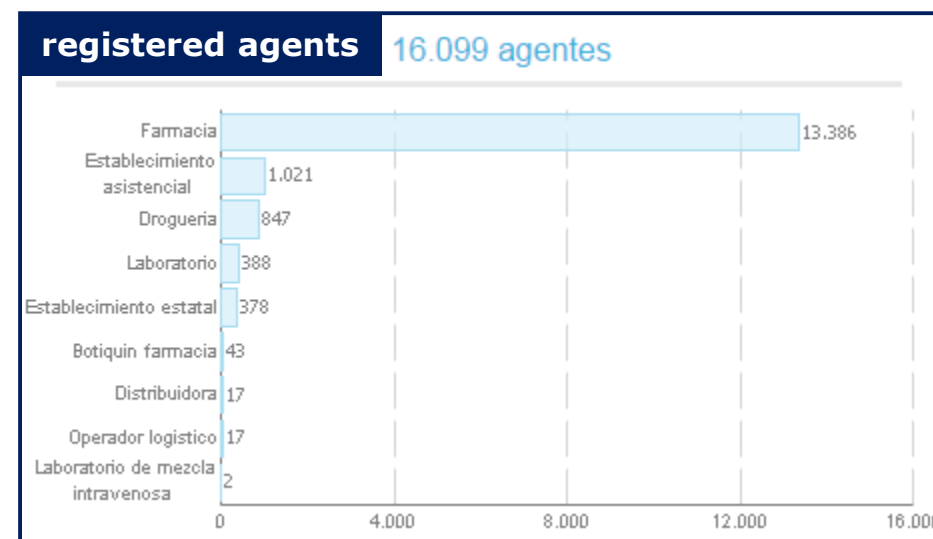
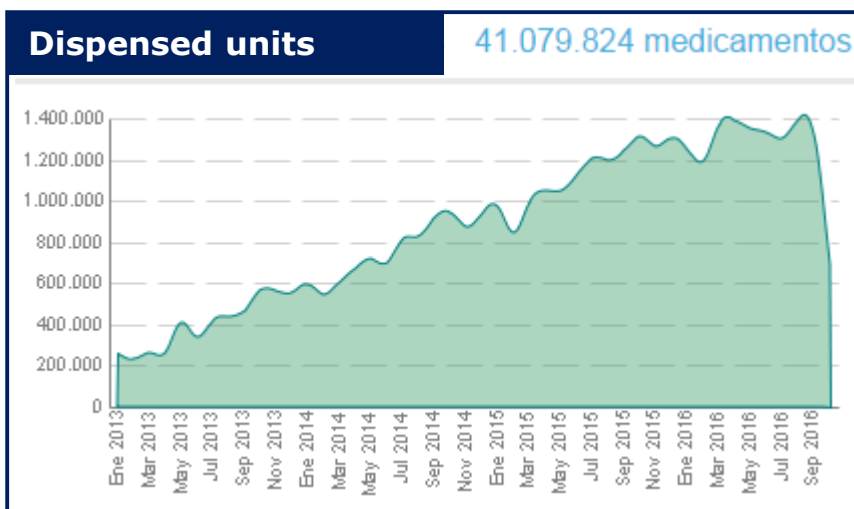
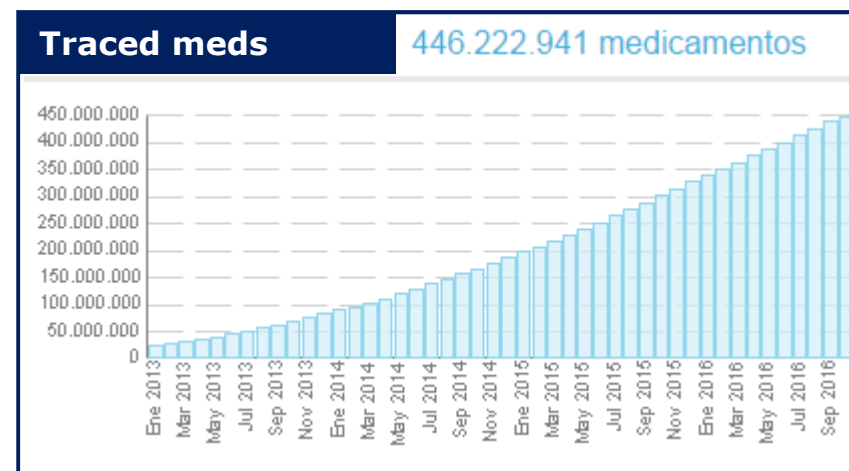
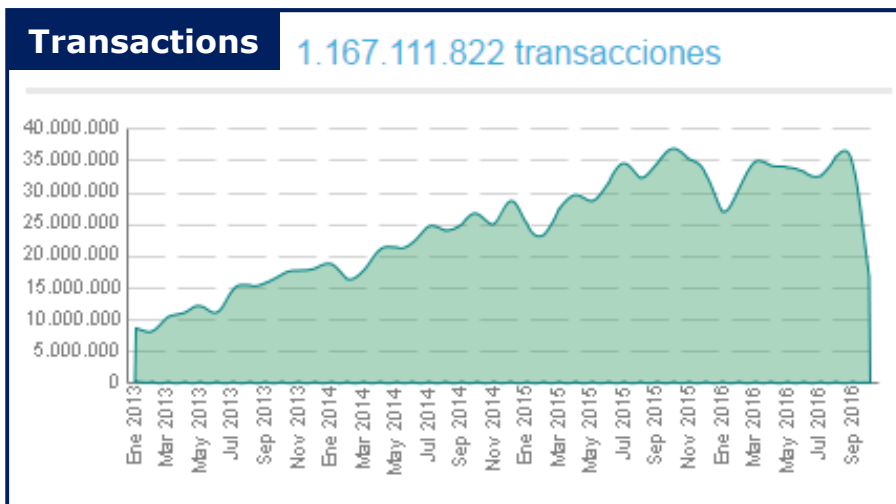
### Mapa de Trazabilidad

**Estadísticas de Trazabilidad**

Cant. Operaciones	4
Dist. de Trazabilidad (Km)	23,2
Tiempo de Trazabilidad (Días)	74,0

Legend: Laboratorio (blue triangle), Farmacia (red cross), Droguería (orange pharmacy icon), Op. Logístico (green truck), Distribuidora (green cart), Est. Asistencial (red pharmacy icon).

# Some up-to-date figures





# 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-en.pdf)

[http://apps.who.int/gb/ssffc/pdf\\_files/MSM4/A\\_MSM4\\_10-ch.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

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**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**





# At a global level



## 6. Challenges to take into account

60. Regardless of previous impact assessment that may be made, operational problems are likely to occur during system implementation, which NRRA should be prepared to face and solve.

61. The inclusion of a large number of products may result in the need for companies to add traceability data carriers in an automated manner. To this end, certainly, companies will have to add new technologies, change production lines and validate them. Even though desirable, this may cause delays in improving production lines, slowdowns in production processes, and the need for adopting corrective measures to remedy inconveniences and maintain plant productivity.

62. On the other hand, the application of the data carrier will require product packaging with contrasted colours which enable code reading and sufficient space available to include data carriers without affecting the mandatory text required by regulations. Thus, companies may need to redesign product packaging.

63. Consideration should be given to the integrity and security of the data carrier and ensure that the appropriate materials are used so that the data carrier cannot be tampered with or altered throughout the whole chain. For instance, fast dry ink should be used, and the varnish usually used on cardboard should not be applied to the code printing area.

64. Additionally, account should be taken of the fact that as the volume of serialized products increases, receipt and dispatch time delays may occur at wholesaler distributors.

65. Access to safe, quality, efficacious and affordable medical products needs to be taken into account when developing and implementing the appropriate track and trace system.



# At a global level



## VI. LESSONS LEARNT

69. The implementation of a traceability system based on unit of sale (secondary/outer packaging) is an objective to be attained and entails an enormous effort for stakeholders and NRRA as new technologies are to be adopted which enable substantial enhancement in patients' access to safe and efficacious products. The primary objective of stakeholders should be health-based and be to protect patients. This will enable understanding of the problem and the need for implementation regardless of economic implications.

70. The inclusion of numerous stakeholders from different geographies and with technological interaction, presents challenges that need to be addressed by inclusive policies that bring NRRA closer to stakeholders, allow them to learn from each other and to change roles in order to obtain maximum benefits through constant feedback.

71. Reasonable timeframes are to be considered when working, taking into account the globalization of the pharmaceutical industry, and without forgetting that each Member State has its own specific circumstances and needs, when the moment comes to define a traceability system of their own.

**- Experience of Argentine companies in Drugs Traceability allowed a National Manufacturer to export meds to China complying Chinese FDA Traceability requirements.**



# On going activities & remaining challenges

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- **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 NTS implementation.**
- **Evaluation of technological advances and their potential.**
- **Improvement of NTS implementation at Healthcare Institutions.**
- **New and agile solutions for high volumes of units. Implementation of grouping tags for logistic units involving many serialized units of meds (up to 3 aggregation levels, possibly using Serial Shipping Container Code, SSCC)**





Ministerio de  
Salud  
Presidencia de la Nación



Thank you!  
¡Gracias!  
謝謝



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