ANMAT marking the way

A new contribution to the security of drugs in Argentina

anmat
Administración Nacional de Medicamentos, Alimentos y Tecnología Médica

www.anmat.gov.ar

The National Traceability System

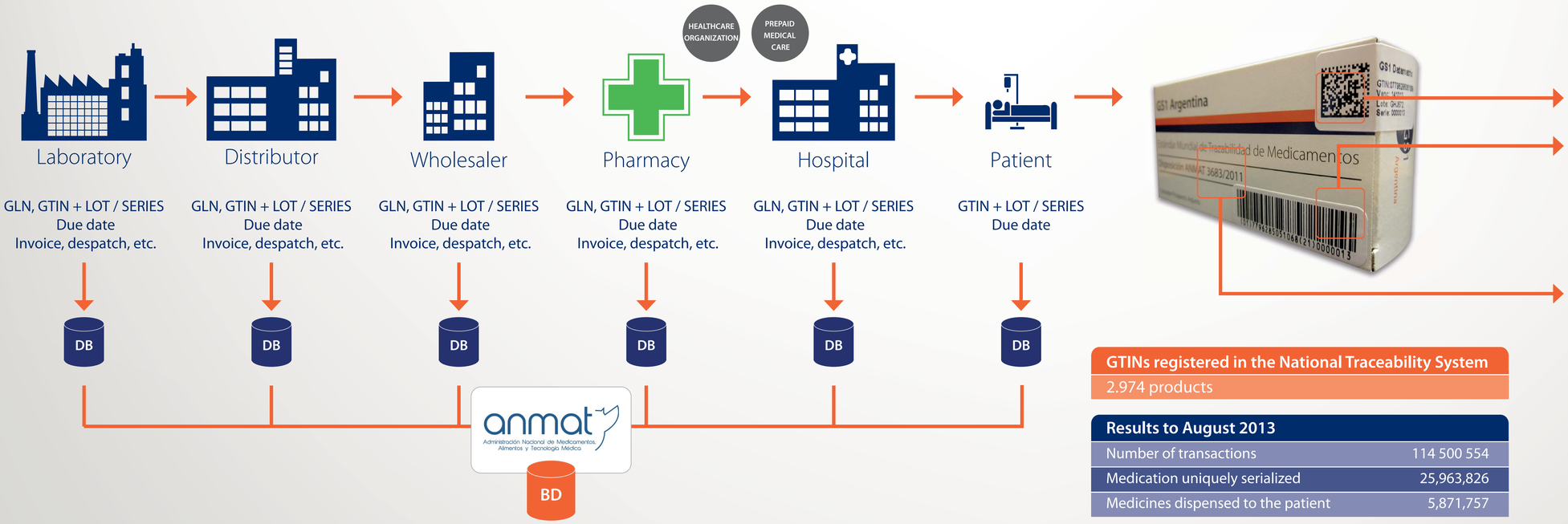
The system requires the individual and unambiguous identification of each pharmaceutical product to allow its traceability all along the distribution chain (pharmaceutical companies, logistic operators, drug wholesalers, pharmacies, healthcare institutions and patients). At each step of the process, the product data is confirmed in real-time through a central database managed by ANMAT. As each container has an inviolable and incorruptible code, the security and authenticity of the drug is therefore ensured and guarantees that the product has never abandoned the legal trail of production and distribution.

In order to allow a scaled implementation scheme, the system takes into account the different categories of drug products and the means and technological systems available, whilst reducing any obstacles that the patient may face. Today the National Traceability System has already been applied to a wide list of costly critical drugs used to treat conditions such as cancer, AIDS, haemophilia, rheumatoid arthritis and cystic fibrosis. It has also been applied to drugs treating illnesses such as asthma, acromegaly, wet macular degeneration and anaemia associated to the chronic renal disease. In addition, it is applied to various sedative drugs, antihypertensive and cough medicines, and analgesics for central action, psychoactive drugs and other substances which can cause addiction. The scheme will then be extended to all new drugs registered and launched in the market. It is worth mentioning that it applies both to local-produced and imported products.

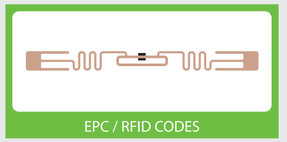
The National Traceability System imposes that all drugs be serialised through the application of an unambiguous code, according to the recommendations of the GS1 Standards. Each drug should contain the Commercial Product Code, the Global Trade Item Number (GTIN) and a unique Serial Number placed on the secondary packaging. This information can be integrated into any type of data carrier, provided that it complies with the standards mentioned above, allowing each owner to choose the most appropriate data carrier for their products (whether it is a linear bar code, GS1 DataMatrix, EPC/RFID tag or any other). Notwithstanding the data carrier of choice, the information must always be placed in human readable format so the patient may read it.

Argentina does not impose the data carrier and the choice is left to the manufacturer. Nevertheless, the rule highlights that: "The data carrier cannot be removed without leaving an evident mark on the packaging. A drug that shows signs of label tampering or that cannot be read by an electronic reader shall be considered adulterated..."

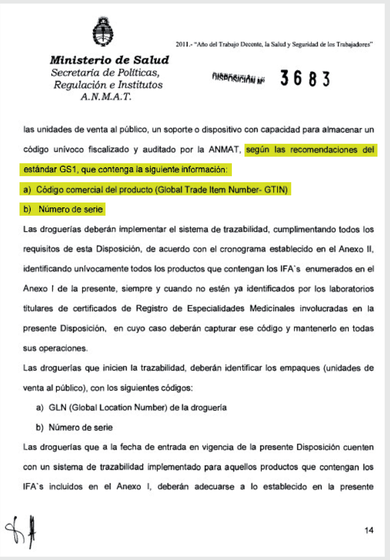
National Drug Traceability System



Identification options



Regulation 3683/2011



Ministerio de Salud
Secretaría de Políticas, Regulación e Institutos
A.N.M.A.T.

2011 - "Año del Trabajo Decente, la Salud y Seguridad de los Trabajadores"

DISPOSICIÓN Nº 3683

las unidades de venta al público, un soporte o dispositivo con capacidad para almacenar un código unívoco fiscalizado y auditado por la ANMAT, según las recomendaciones del estándar GS1, que contenga la siguiente información:

a) Código comercial del producto (Global Trade Item Number- GTIN)

b) Número de serie

Las droguerías deberán implementar el sistema de trazabilidad, cumplimentando todos los requisitos de esta Disposición, de acuerdo con el cronograma establecido en el Anexo II, identificando unívocamente todos los productos que contengan los IFA´s enumerados en el Anexo I de la presente, siempre y cuando no estén ya identificados por los laboratorios titulares de certificados de Registro de Especialidades Medicinales involucradas en la presente Disposición, en cuyo caso deberán capturar ese código y mantenerlo en todas sus operaciones.

Las droguerías que inicien la trazabilidad, deberán identificar los empaques (unidades de venta al público), con los siguientes códigos:

a) GLN (Global Location Number) de la droguería

b) Número de serie

Las droguerías que a la fecha de entrada en vigencia de la presente Disposición cuenten con un sistema de trazabilidad implementado para aquellos productos que contengan los IFA´s incluidos en el Anexo I, deberán adecuarse a lo establecido en la presente

14

Objectives of the system

With the implementation of the National Traceability System, the following objectives should be achieved:

- Regularise the distribution of drugs at a federal level
- Prevent the diversion of products and the distribution of falsified drugs
- Detect product code duplication
- Improve efficiency and reduce the costs of the healthcare systems
- Provide patients with quality, security and efficacy of the drugs they consume
- Minimise wrong supply of products
- Discourage theft and adulteration of products
- Facilitate effective product recalls from the market
- Evaluate in real time the consumption of each type of drug
- Encourage the rational use of drugs

GTINs registered in the National Traceability System

2.974 products

Results to August 2013	
Number of transactions	114 500 554
Medication uniquely serialized	25,963,826
Medicines dispensed to the patient	5,871,757

Agents in the System	
Laboratories	221
Distributors	11
Logistic Operators	10
Wholesalers	577
Pharmacies	8,685
Healthcare Institutions	405
Public Establishments	172
Lab. of Intravenous Mixtures	1
TOTAL	**10,082**