

# SERIALIZATION: MEDICINE IDENTIFICATION, AUTHENTICATION & TRACEABILITY

## GRI Standards:

103 : Management Approach

417 : Marketing and Labeling

## I. BACKGROUND

In many countries, such as Belgium, Greece and Italy, drug identification at unit of sale (i.e., serialization) uses linear barcodes printed either by the government (Italy) or by the manufacturer (Greece, Belgium). However, no traceability information is included in the code. Historically, the code was made to prevent reimbursement fraud.



**Bollino (Italy)**  
Already in place

In recent years, a need for additional measures to protect medicines has occurred for three major reasons:

- fighting counterfeit drugs;
- avoiding social security fraud (reimbursement fraud);
- ensuring traceability of the product quality.

All these reasons are linked to **patient safety** and the need to control the distribution system in order to avoid false medicines. For more information on this topic, see the Fighting Falsified Medical Products factsheet in our [Documents Center](#).

Several methods ensure the quality of medicines with a layered (three-level) approach to protect the packaging:

### Level 1: protecting integrity and inviolability of the packaging

Tamper-evident packaging is dedicated to reduce the risk of violating the integrity of the original manufacturer's packaging. Sanofi decided to take a voluntary position, implementing tamper-evidence for all products included in the scope of its serialization program. While in some countries, such as the United States, this goes beyond strict regulatory requirements, it represents for Sanofi an additional means of ensuring patient safety.

### Level 2: authenticating the product

Authentication of the product uses a specific label known as the Sanofi Security Label (SASL). It contains the means for visible verification (by distributors and patients) as well as invisible verifications (known only by Sanofi).

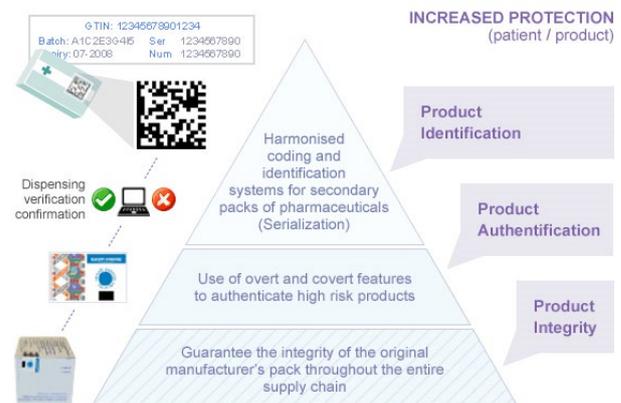
### Level 3: identifying each box with a data matrix code

A code printed on the secondary packaging contains unique identification information (product code and serial number) in addition to traceability data (batch number and expiration date).

- Product code
- Batch number
- Expiry date



Unique Identifier = Product code  
+ Serial Number



However, these initiatives were conducted at the country level and sometimes on a voluntary basis. As a result, a real need for harmonization emerged.

## II. GOVERNANCE

The Serialization Program Organization is part of Industrial Affairs and is fully connected with the Sanofi anti-counterfeiting strategy.

The program includes support functions and appointed resources in divisions/sites where implementation will be carried out. Regular meetings with divisions' coordinators allow to implement the program from a regulatory and a technical point of view.

## III. REGULATION

A new piece of legislation was issued in 2011. The EU Directive 2011/62/EU created a harmonized codification and verification system for medicines, based on the use of data matrix technology, mass serialization and systematic controls when dispensation by pharmacies and hospitals.

Only level 1 and 3 (tamper evidence and serialization) are required by the European Directive governing falsified medicines.

Since then, traceability legislation across the world has progressed; the following table gives a picture of the legislations (subject to changes, not to be used as reference).

### Overview of the different traceability regulations (per country) Global concept (serialized Data Matrix) versus local concepts (China, Nigeria)

<b>United States</b> Data Matrix ECC 200+Tamper evidence Congress Bill signed in November 2013 Jan 2015: traceability at batch level within all the supply chain Nov 2017: Serialization of Packs & full cases Nov 2023 (10 years after enactment): Traceability at unit level (pack) required with control system to be defined by stakeholders after pilots studies	<b>Europe</b> Data Matrix ECC 200+Tamper evidence Feb 2019 (according to Delegated Acts) Serialization only + Verification at point of dispense for all countries except Belgium, Italy and Greece (Feb 2025)	<b>Russia (TBC)</b> Data Matrix ECC 200 (tbc) Serialization + Aggregation Jan 2017: Pilot phase Jan 2018: Essential Drugs Jan 2019: other Drugs	<b>China</b> Linear barcode Since 2011: Serialization & Aggregation (at case level only) with no verification at dispensing point for EDL products only End 2015: all products
<b>Brazil (Under revision)</b> Data Matrix ECC 200 2018: Pilot phase (date to be confirmed): 2019 – 2022: Extension to all medicines	<b>Turkey</b> Data Matrix ECC 200 Since Jan 2012: Serialization & Aggregation + Verification at all levels of the supply chain (including point of dispense) for all prescription medicines	<b>Ukraine (TBC)</b> Data Matrix ECC 200 2019 (tbc): Serialization for all Medicines	<b>South Korea</b> Data Matrix ECC 200 Serialization (+ Aggregation) for all registered Medicines Jan 2015: 30% products Dec 2015: 100% of products
<b>Argentina</b> Data Matrix ECC 200+Tamper evidence Since 2011: progressive implementation of Serialization & Aggregation (required by wholesalers) with no verification at point of dispense (=> from high risk products to all prescription medicines)	<b>Egypt (TBC)</b> Data Matrix ECC 200 July 2017-2018: GTIN, GLN, artworks, data July 2018: Serialization of all Medicines July 2019: Aggregation of all logistic units and reporting to a central govnt database	<b>Jordan (TBC)</b> July 2017-:july 2018/ Non Serialized Data Matrix Jan 2020 (tbc): Serialization only with State/ MoH (JFDA) Database	<b>PAKISTAN</b> Data Matrix ECC 200 Date TBC: Serialization and aggregation for all Medicines (tbc)
<b>Taiwan (TBC)</b> Data Matrix ECC 200 July 2017: Non serialized Data Matrix Jan 2019: Serialization for all Medicines Jan 2020: Serialization of all prescription drug	<b>Nigeria</b> Local Serialization + possible verification by patients Mobile Authentication System (Serialized scratch label) for Anti-malarials (Jan 2013) & Antibiotics (March 2013)	<b>Saudi Arabia</b> March 2015: Non Serialized Data Matrix ECC 200 Mar 2017: Serialized Datamatrix (Aggregation + reporting tbc later on)	<b>India (N/A)</b> Data Matrix ECC 200+Tamper evidence when serialized Non serialized datamatrix for Governments tenders April 2016: Serialization & Aggregation for exported drugs to countries with no serialization regulation

Sanofi has supported the EFPIA (European Federation of Pharmaceutical Industries and Associations) serialization project to identify each box of high-risk medicines (mainly prescription drugs).

## IV. IMPLEMENTATION OF DATA MATRIX TECHNOLOGY FOR INCREASED TRACEABILITY

Since January 1, 2011, in compliance with the French legislation, all products marketed by Sanofi in France have been equipped with a data matrix identification system, a two-dimensional barcode printed on each box that contains traceability information:

- product code (CIP code);
- batch number;
- expiration date.

Data matrix codes are read when drugs are dispensed, improving traceability and enabling the automatic detection of falsified or expired products. They also facilitate batch recalls.

Serialization is adding a new data in this datamatrix: a Serial number, which builds a unique identifier in combination with the Product code.

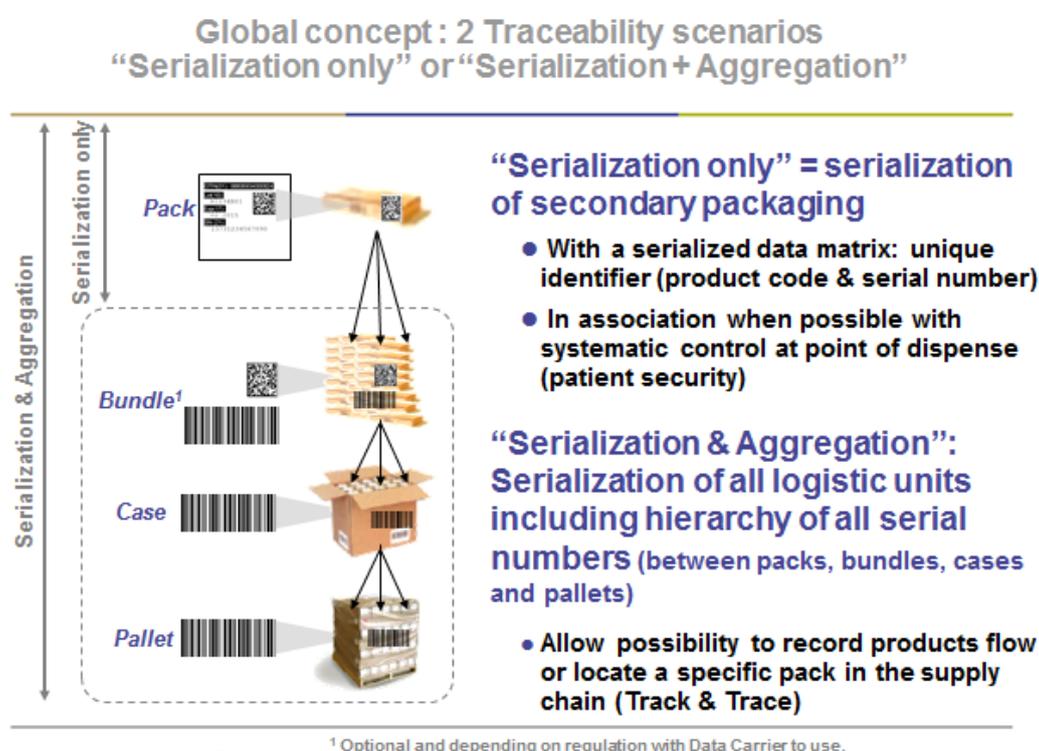
The implementation of the serialization operation on packaging lines follows regulatory timelines. More than 320 lines had been equipped at the end of 2018, which represents 70% of our impacted equipment worldwide. This covers all our businesses: Pharma, Genzyme and Sanofi Pasteur (vaccines).

In accordance with national regulations, Sanofi is implementing a medicines serialization program. A serialized data matrix identification system is printed on each pack of prescription drugs sold in Turkey, Argentina, China, South Korea, Saudi Arabia, US and Europe.

Russia and Brazil are the priorities for the next three years.

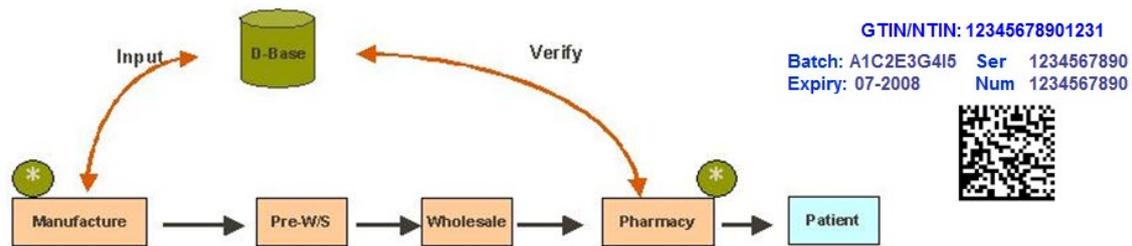
Countries such as Turkey, Argentina, China and South Korea have already implemented serialization and the aggregation allowing to verify the full supply chain activities.

In these cases, not only the individual box is concerned, but also the bundle, the case and the pallet itself (see next figure).



In the “**serialization only**” scenario, systematic verification of serialized data matrix (ECC200) at the point of dispensation will be effective to protect patients from counterfeit products and will help fight reimbursement fraud (by detecting duplicate serial numbers). This is the simplest, least costly and most efficient option for pharma companies to implement. Pharmacies/hospitals must invest in equipment in order to read data matrix codes and verify data.

## “Serialization only” with systematic control at dispensing point (“end-to-end” system) - European Concept



In the case of “**serialization and aggregation**”, checking all logistic units with systematic controls is possible at different levels of the supply chain.

This is highly complex and costly to put in place. It has to be checked by wholesalers in case of pallet opening. For patient safety, the added value is limited, but this approach provides full product visibility across the supply chain. It is already in place for all products in Turkey and China.