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.

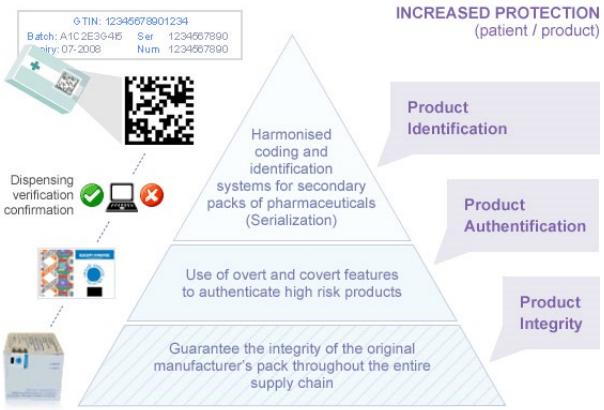
All these reasons are linked to **patient safety** and the need to control the distribution system in order to avoid false medicines. For more information on this topic, see the Fighting Falsified Medical Products factsheet in our Documents Center.

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).



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.

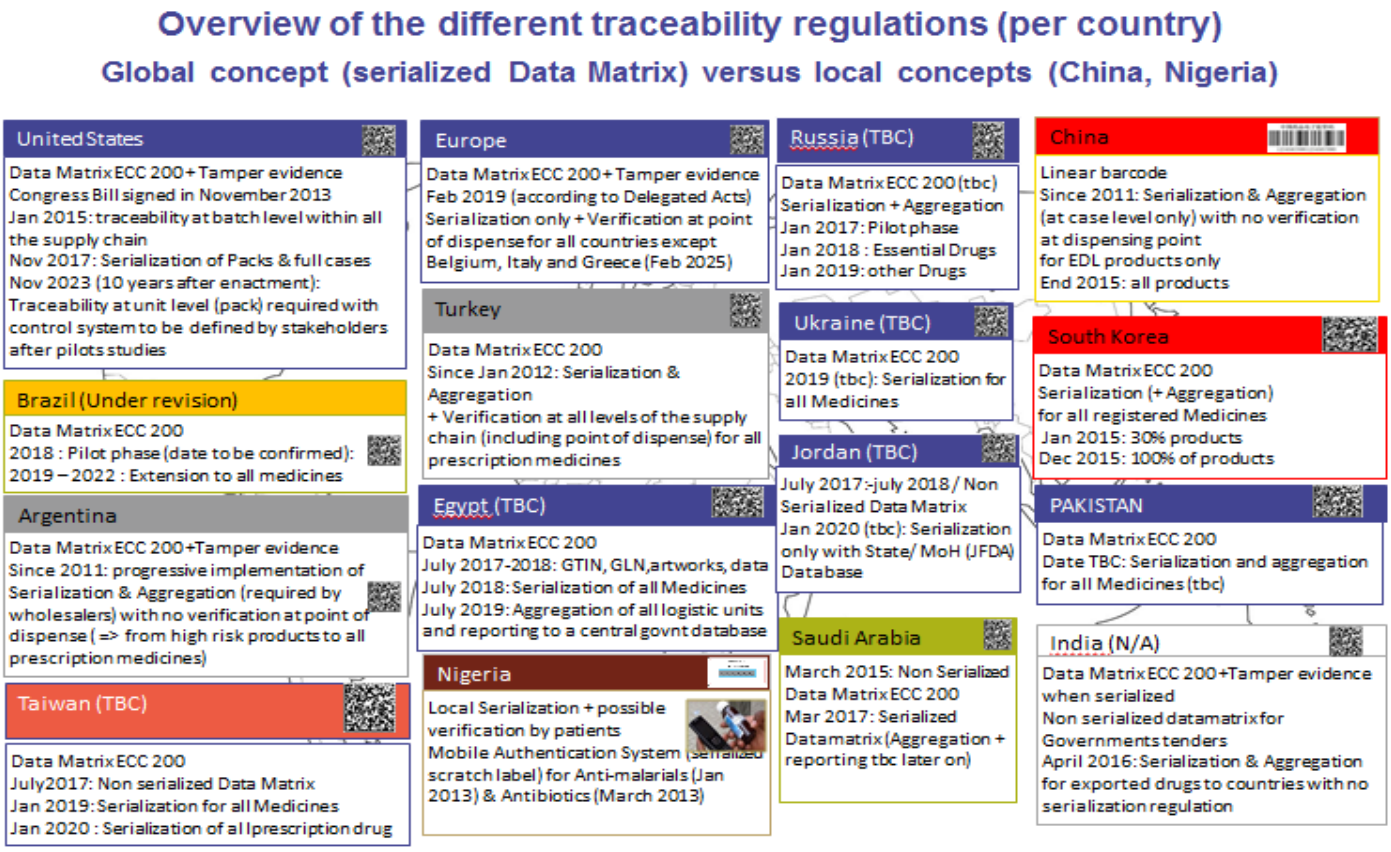
The program includes support functions and appointed resources in divisions/sites where implementation will be carried out. Regular meetings with divisions' coordinators allow to implement the program from a regulatory and a technical point of view.

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).



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.

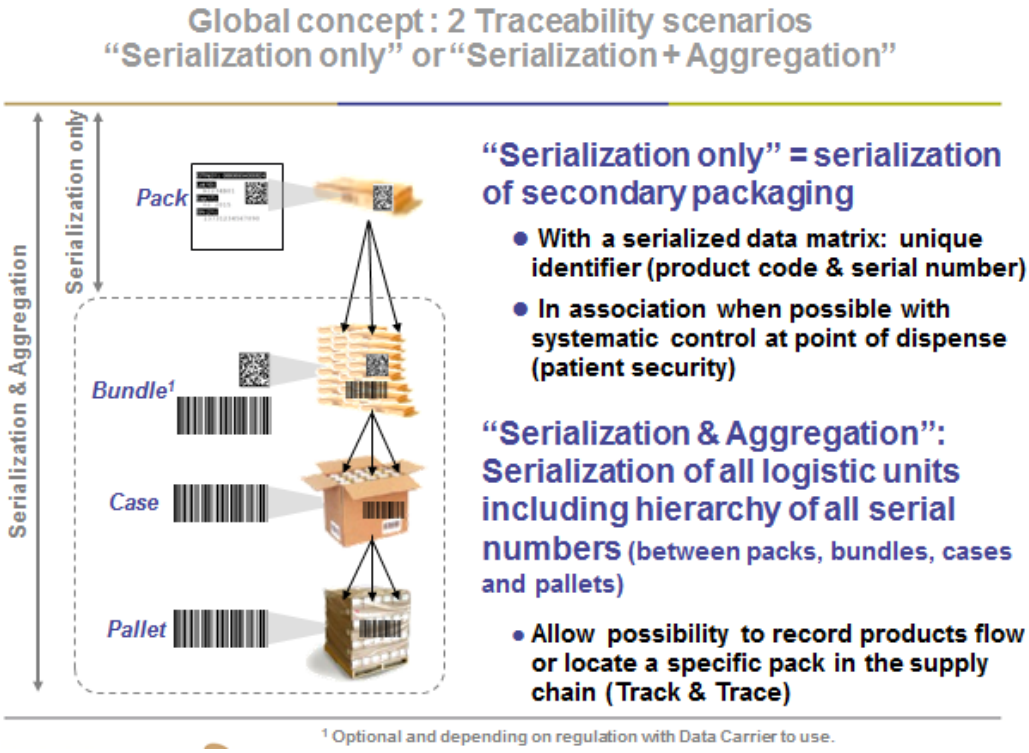
The implementation of the serialization operation on packaging lines follows regulatory timelines. More than 320 lines had been equipped at the end of 2018, which represents 70% of our impacted equipment worldwide. This covers all our businesses: Pharma, Genzyme and Sanofi Pasteur (vaccines).

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.

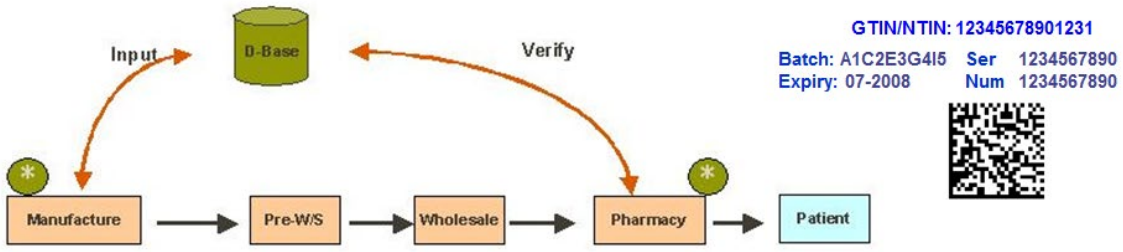
Countries such as Turkey, Argentina, China and South Korea have already implemented serialization and the aggregation allowing to verify the full supply chain activities.

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.