SERIALIZATION:
MEDICINE IDENTIFICATION, AUTHENTICATION & TRACEABILITY

G4 indicators: G4-DMA, G4-PR3

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 come about 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 controlling the distribution system in order to avoid false medicines. For more information on this topic, see the Fighting Counterfeit Medicines factsheet in our Download Center.

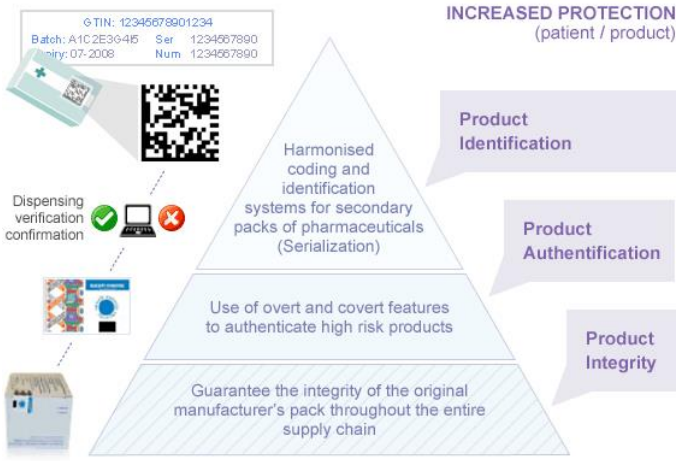
Several methods ensure the quality of medicines by taking a layered (three-level) approach to pack protection.

Level 1: Protecting integrity and inviolability of pack
Tamper-evident packaging to reduce the risk of violating the integrity of the original manufacturer's packaging is in place on many products (secondary packaging boxes, bottles or syringes).

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, for Sanofi it represents 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 (which are 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

GTIN/NTIN: (01) 07046261398572
Batch: (10) TEST5632
Expiry: (17) 221018
S/N: (21) 12345678901234567890

Unique Identifier = Product code + Serial Number

These initiatives were, however, conducted at the country level and sometimes on a voluntary basis by companies. 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 anticounterfeiting strategy.

The program is organized with a support function team and appointed resources in divisions/sites where implementation will be carried out. Regular meetings with division coordinators make it possible to implement the program from both a regulatory and a technical point of view.

III. REGULATION

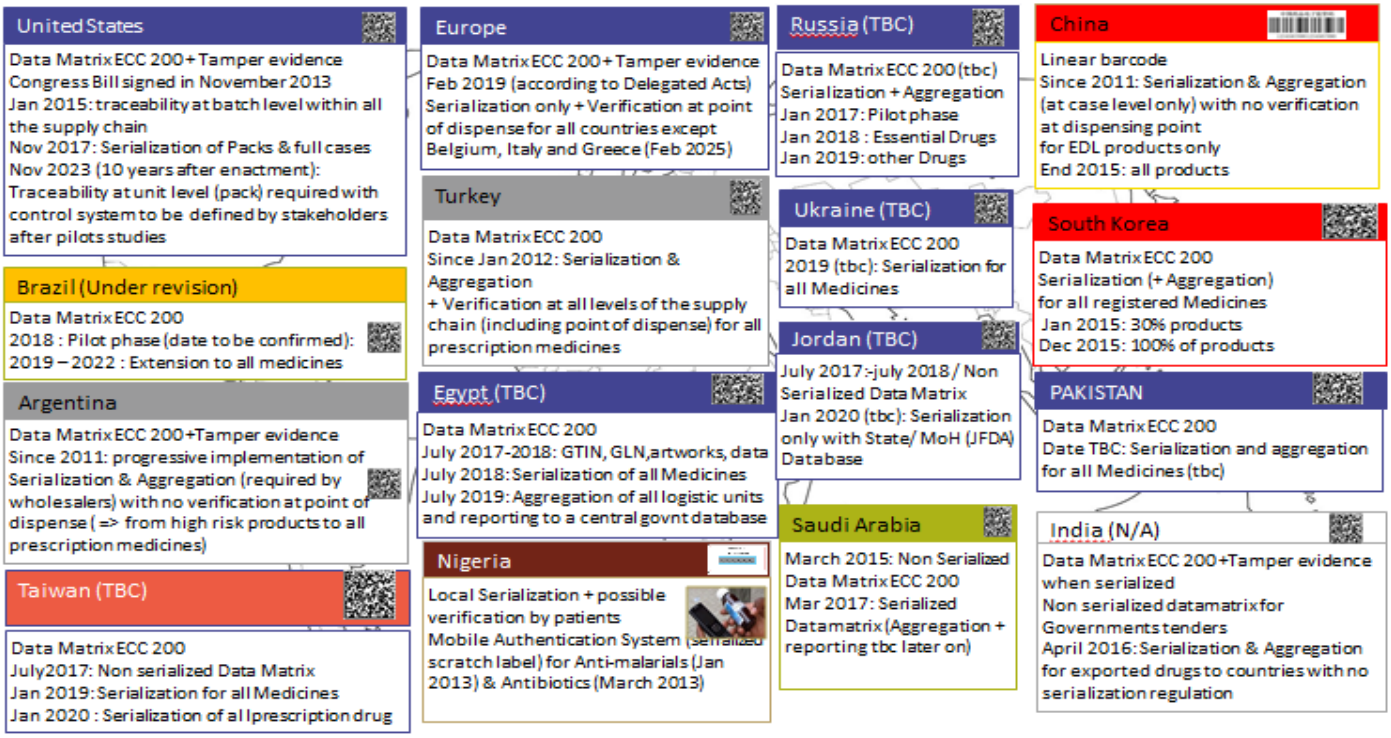
A new piece of legislation was issued in 2011. The EU Directive 2011/62/EU creates a harmonized codification and verification system for medicines based on the use of data matrix technology, mass serialization and systematic controls at the time of dispensation by pharmacies and hospitals.

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

Since that time, traceability legislation across the world has progressed; the following table gives the state of the art.

Overview of the different traceability regulations (per country)

Global concept (serialized Data Matrix) versus local concepts (China, Nigeria)



Sanofi has supported the serialization project put forward by the EFPIA 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 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

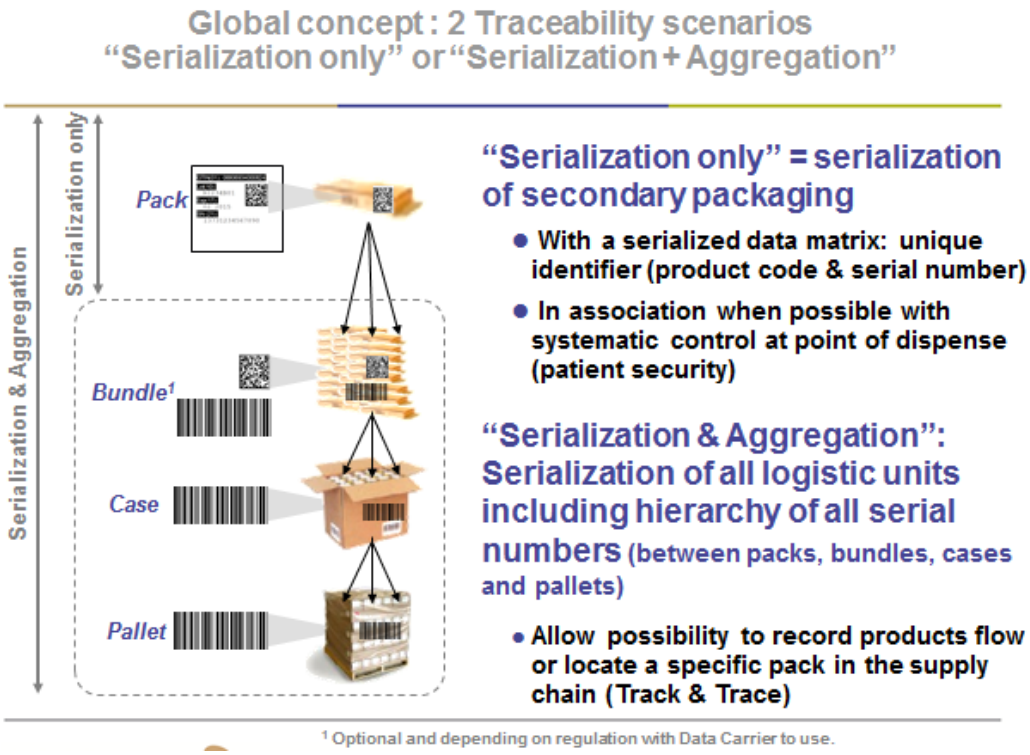
Data matrix codes are read when drugs are dispensed, improving traceability and enabling the automatic detection of falsified or expired products. They also facilitate batch recalls.

The implementation of the serialization operation on packaging lines follows regulatory timelines. More than 130 lines had been equipped at the end of 2016, which represent 33% of our impacted equipment worldwide. This covers all our businesses: pharma products but also Genzyme and Sanofi Pasteur (vaccines).

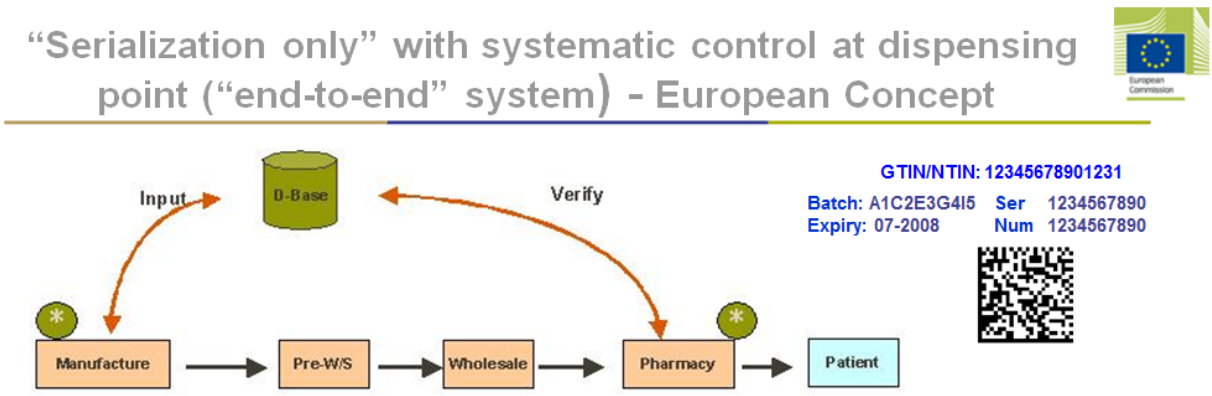
In accordance with national regulations, Sanofi is implementing a medicines serialization program. A serialized data matrix identification system is printed on each pack of prescription drugs sold in Turkey, Argentina, China and South Korea. India, Saudi Arabia, Russia, Brazil, the U.S. and Europe are the priorities for the next three years.

Countries such as Turkey, Argentina, China and South Korea have already implemented **serialization** and the aggregation making it possible 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 for data verification.



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.