Serialization

Medicine Identification, Authentication & Traceability

GRI Standards:

103: Management Approach

417: Marketing and Labeling

EXECUTIVE SUMMARY

Protecting patients against falsified products and fighting reimbursement fraud requires controlling the entire supply chain of medicines to pharmacies and hospitals where they will be prescribed and distributed to patients. Sanofi has decided to take a voluntary position by implementing proof of inviolability for all products included in its serialization program. The organization of this program is part of the Industrial Affairs Department and is fully in line with Sanofi's anti-counterfeiting strategy.

TABLE OF CONTENTS

1. Background and protection methods

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 falsified drugs;
- avoiding social security fraud (reimbursement fraud); and
- 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, see our Document Center: the Fight Against Falsified Medicine and Illicit Trafficking Factsheet.

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

1.1. LEVEL 1: PROTECTING INTEGRITY AND INVIOLABILITY OF THE PACKAGING

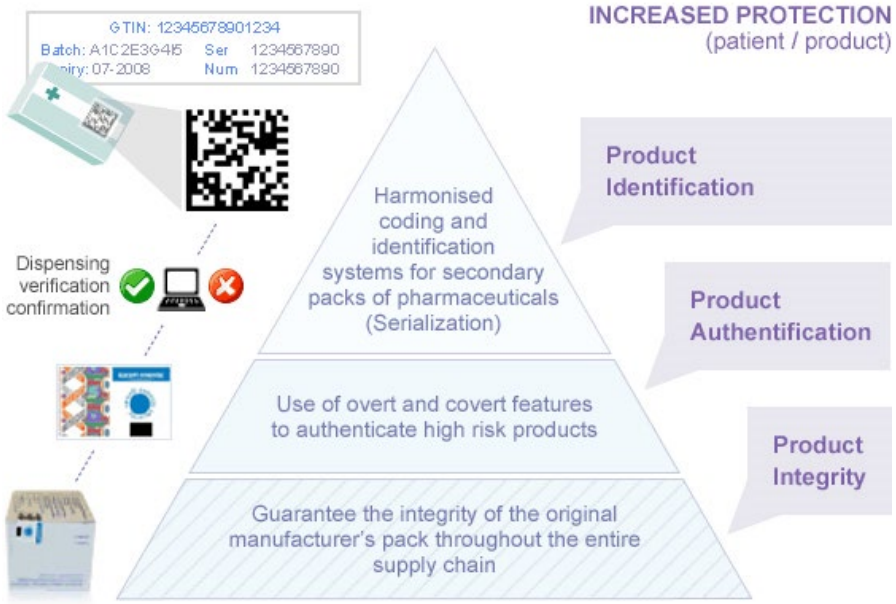
Tamper-evident packaging is dedicated to reducing the risk of violating the integrity of the original manufacturer's packaging. Sanofi decided to take a voluntary position, implementing tamper-evidence for all products included in the scope of its serialization program. While in some countries, such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

1.2. 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). It is implemented on all Sanofi new products and on some products chosen based on their risk of being counterfeited.

1.3. 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.

2. 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.

3. Regulation

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.

In countries such as Turkey, Argentina, China, Russia, US and South Korea, the aggregation is also required, allowing to verify the full supply chain activities (see 4.1).

In past years, traceability legislation across the world has progressed; below is an overview of the different traceability regulations (subject to changes, not to be used as reference):

- Argentina: progressive serialization and aggregation of Medicines - started in 2011;
- Turkey: serialization and aggregation with verification in the supply chain - 2012;
- South Korea: serialization and aggregation - 2015;
- China: serialization and aggregation - 2015;
- US: serialization and aggregation by manufacturers - Nov 2018:
    - Nov 2019: verification by wholesalers of saleable returns, and
    - Nov 2023: aggregation data management to be defined,
- India: serialization and aggregation for exported products (except EU and RU) - 2018;
- Europe: serialization with check at dispensing point - Feb 2019;
- Gulf countries: serialization - 2019:
    - Barhain: aggregation for May 2022.
- Egypt: serialization and aggregation progressively implemented - starting 2019;
- Russia: serialization and aggregation - July 2020;
- Saudi Arabia: serialization and aggregation - August 2020;
- Indonesia: progressive serialization and aggregation planned 2021 – 2025; and
- Brazil: serialization and aggregation - 2023.

4. 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; and
- expiration date.

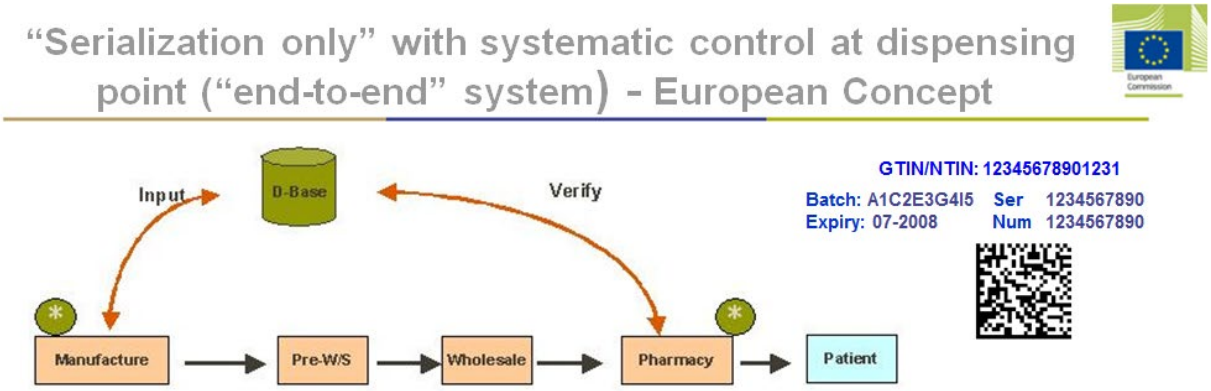
Data matrix codes are read when drugs are dispensed, improving traceability and enabling the automatic detection of falsified or expired products. They also facilitate batch recalls.

Serialization is adding a new data in this data matrix: a Serial number, which builds for each sales unit a unique identifier in combination with the Product code.

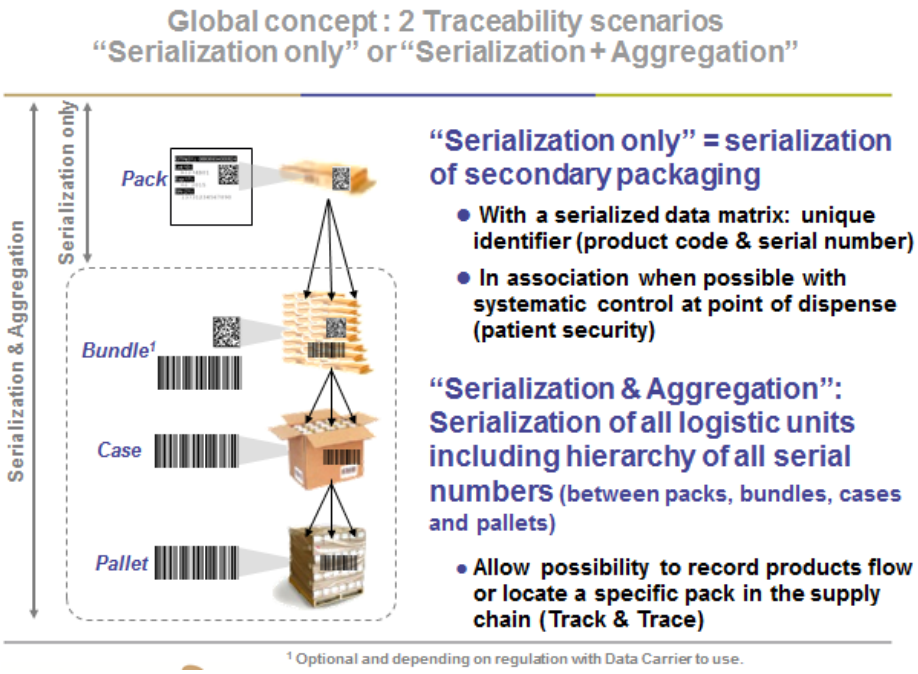
The implementation of the serialization operation on packaging lines follows regulatory timelines. More than 320 lines had been equipped at the end of 2019, which represents 70% of our impacted equipment worldwide. This covers all our businesses: Pharmaceuticals (CHC, General Medicines, Specialty Care) and Vaccines.

4.1 Serialization versus serialization and aggregation

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.



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



In this case, 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 must 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.