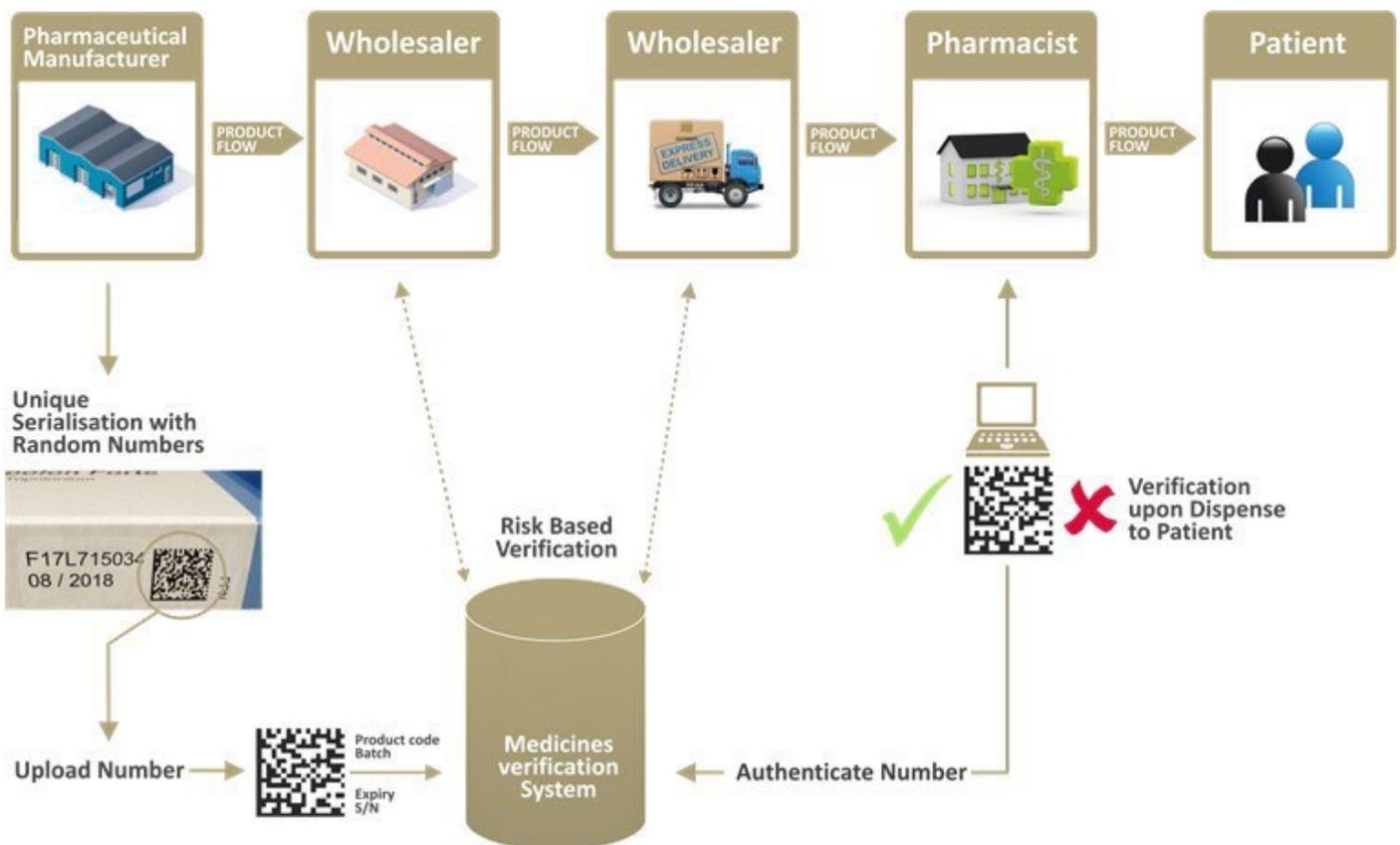


Medicines Verification System

In order to counter the threat of falsified medicines entering the legal supply chain, the European Parliament and Council have released a Directive on Falsified Medicines (2011/62/EU) (amending Directive 2001/83/EC). It aims at improving patient safety by mandating the Marketing Authorisation Holders and manufacturers to put a system in place that is preventing falsified medicines from entering the legal supply chain. This system, the European Medicines Verification System (EMVS), should guarantee Medicines authenticity by an end-to-end verification.

The manufacturers are required to apply two safety measures on the outer packaging: an anti-tampering device and a Data matrix code which incorporates a unique identifier (UI) for each sale package.

At the point of dispense the medicine will be scanned, checked and verified for authenticity against a national (or supranational) repository. If the UI on the pack matches the information in the repository, the pack is decommissioned and supplied to the patient. Otherwise, if there is a warning related to this pack, then the system will highlight this as an exceptional event and the package will not be supplied to the patient. An investigation needs to determine whether the pack has been falsified or not.



The European Medicines Verification System (EMVS) is composed of a central HUB and the different National Verification Systems (NMVS).

Typically, the Market Authorisation Holders and the Parallel Distributors are connected to the Hub for uploading the product information and the Unique Identifiers. These stakeholders are also responsible for adapting their production line to the new requirements and finance the set up and management of the EMVS, i.e. the Hub and the National systems.

The end-users, such as the wholesalers for risk-based verification, and the pharmacies, in retail and hospital, for patient delivery verification are connected to the NMVS. These stakeholders are responsible for adapting their system and finance the required connection.

