[Frontpage, title]

A joint effort against falsified medicines

DMVO
Dansk
Medicin
Verifikation
Organisation

A joint European system for protection of medicinal product packs' authenticity.

In order to protect patients against falsified medicines all prescription medicines shall have special safety features on the package from February 9, 2019. This is a result of an amendment of an EU directive (201/83/EU) and a new regulation (EU/2016/161) that demands that all prescription medicinal products in the future must be packed in sealed packages with a pack specific barcode, a 2D data matrix barcode. Initially, the requirement applies to all prescription medicines and some non-prescription medicines.

The new safety system requires implementation of a special pan European verification system. It appears from the EU rules that the marketing authorisation holders (manufacturers of original and generic products and parallel importers) shall finance the implementation and running of the verification system.

In February 2015, in order to carry out this task the relevant European trade associations and stakeholders established a non-profit organisation - the European Medicines Verification Organisation (EMVO). EMVO shall administer, run and manage the verification system on the European level. In Denmark, we have established a corresponding national data storage system that the Danish Medicines Verification Organisation (DMVO) is responsible for as regards administration and running in accordance with the EU directive's requirements.

As manufacturer, you shall upload your data to the European database. Information is transferred via the central database to the national databases. Before the prescription medicines are dispensed to the citizens at the pharmacy or hospital a safety check is carried out – a so-called verification of the product in the European database via the national database. The structure of the new model is described in the following pages.

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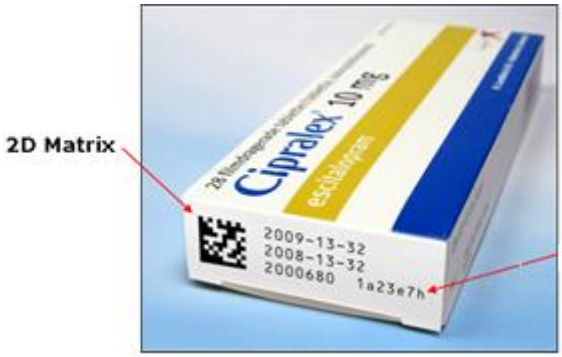
Improved patient safety

The purpose of the new verification system is to improve the patient safety by individual control of authenticity of all medicine packs. In practice, the model means that the EAN barcode shall be replaced by a 2D matrix code that, among other things, contains identification code, batch number, expiry date and a random serial number - printed with small characters on the package.

2D Barcode Data Matrix with 200 characters



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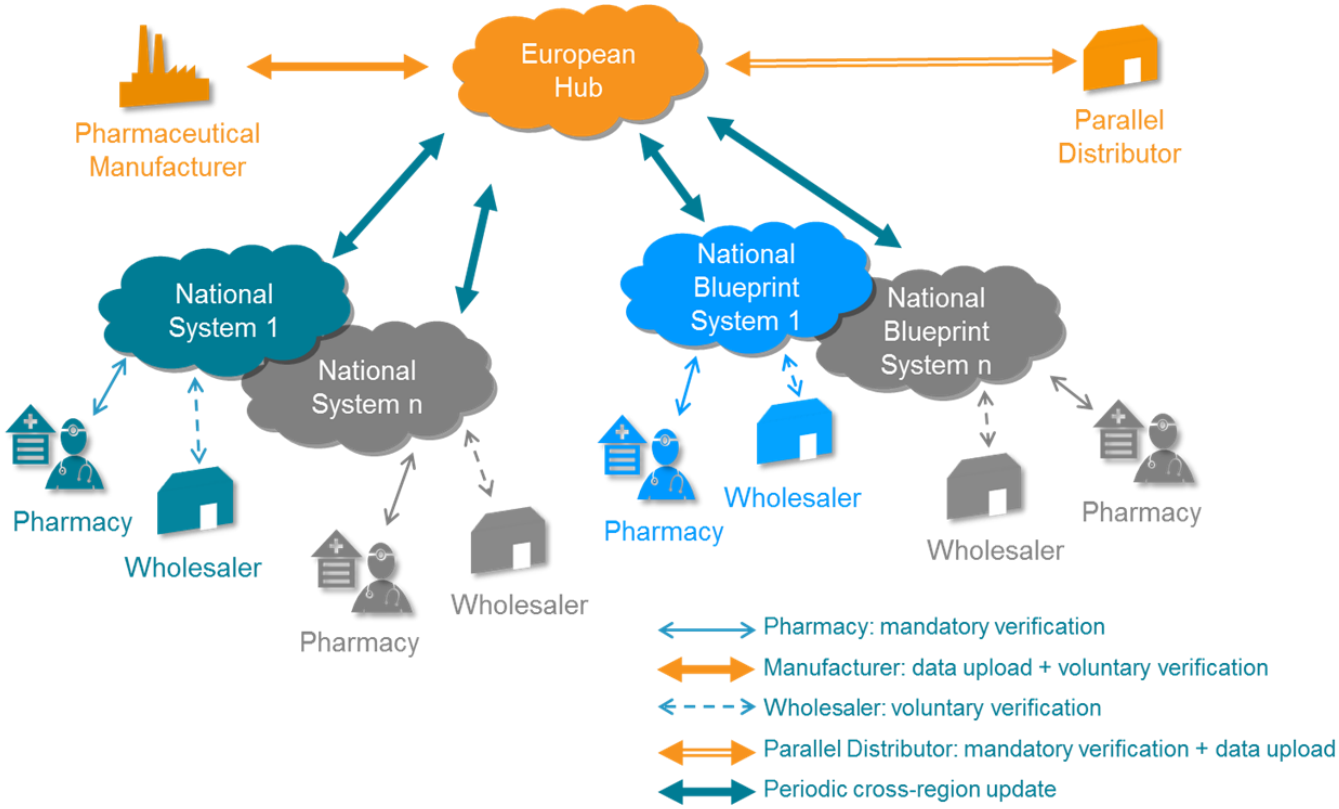
Concept for database model



The European Medicines Verification Organisation (EMVO) has established a central EU database (EU hub) where the manufacturer shall upload all packages with serial numbers. Information from the central database (the hub) is transferred to the national databases (in Denmark administered by DMVO).

Further information is available on EMVO's homepage: www.emvo-medicines.eu.

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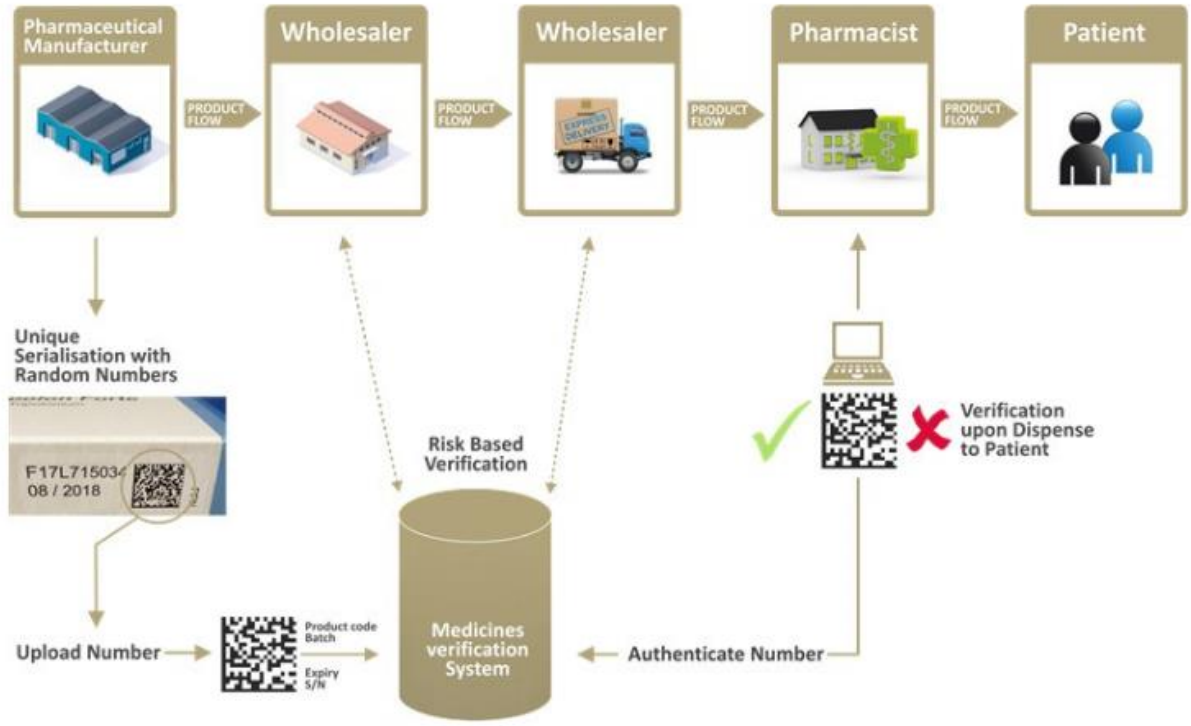
Concept for “point of dispense” verification of packages’ authenticity



The manufacturer shall provide each package with a package specific barcode. The content of the codes shall be forwarded to the European database (hub). The product is verified before it is released via the national data storage system. The pharmacy verifies each package prior to dispensing to the patient by scanning the barcode and comparing information with the information in the database.

More about the Danish Medicines Verification Organisation (DMVO)

DMVO is established as a private limited company (Ltd.) in November 2016 with Lif, The Danish Generic and Biosimilars Medicines Industry Association (IGL) and the Associations of Parallel importers and Pharmaceuticals, as owners of capital. Furthermore, a Board has been set up which besides the above-mentioned owners of capital is composed of the other stakeholders in the area represented by the Association of Danish Pharmacies, Megros and Amgros.

The day-to day management is handled by the secretariat whose purpose is, among other things, to run the verification project, take care of involvement of authorities and stakeholders and offer operational support to pharmacists and wholesalers regarding establishment of connection to the national data storage system. Further information about DMVO is available on www.dmvo.dk.

Manufacturers' and parallel importers' application to DMVO

The new verification system requires a future collaboration between the manufacturers / parallel importers and DMVO. Manufacturers / parallel importers can apply easily and quickly to DMVO below.

Use the QR code to forward contact information and DMVO will contact you directly.

Thank you for your application.

DMVO Ltd. – Lersø Parkallé 101 – 2100 Copenhagen Ø – www.dmvo.dk – info@dmvo.dk

DMVO Dansk Medicin Verifikation Organisation