The European Medicines Verification System (EMVS) celebrates its first anniversary!

The EMVS: A crucial system upholding patient safety – one year on

The European Medicines Verification Organisation (EMVO), would like to celebrate a significant milestone on World Anti-Counterfeiting Day; the EMVS's first birthday! The EMVS (launched just over a year ago), is a system enabling end-to-end verification of prescription medicines, designed to uphold patient safety by preventing falsified medicines from entering the legal supply chain.

#patientsafety #fakemeds

The EMVS was put in place—under the mandate of the Falsified Medicines Directive (Directive 2011/62/EU) and the associated Delegated Regulation (EU/2016/161)—to be a secure, interoperable, and cost-effective system across Europe. This is in collaboration with stakeholders[1] spanning the pharmaceutical sector, with the EMVS affecting the lives of millions across the European continent.

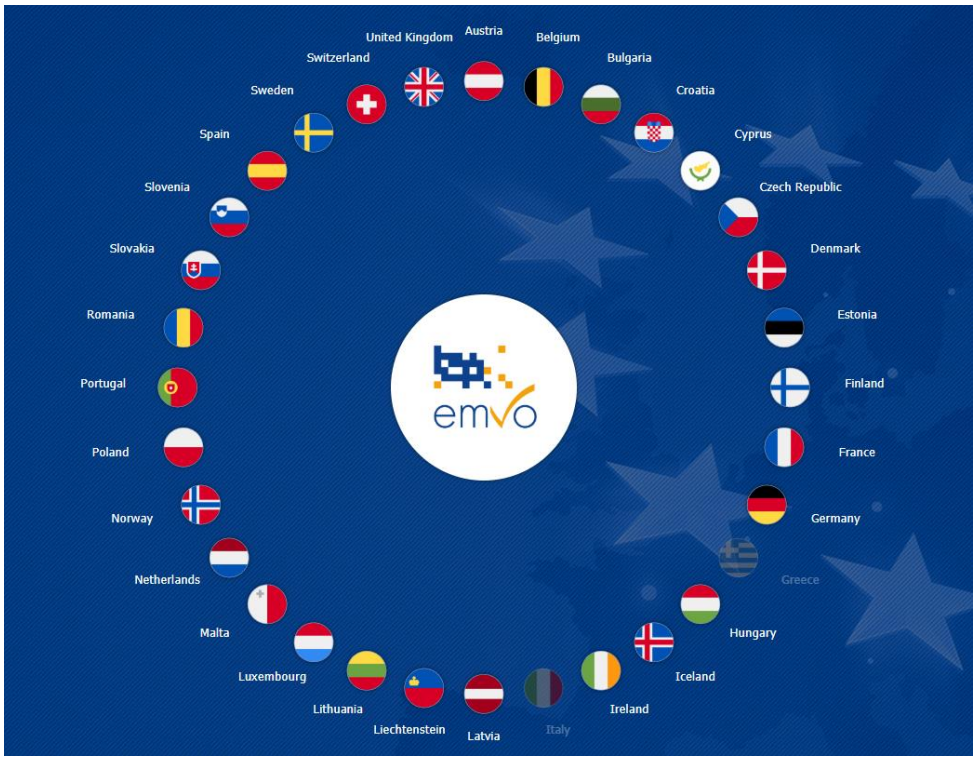
One year on, the EMVS stands as a vanguard against illegal medicines infiltrating the pharmaceutical supply network and is at the forefront of patients' wellbeing—especially important during these unprecedented times.

How does the EMVS work?

Pharmaceutical companies that would like to distribute medicines within the EEA must become contractual On-Boarding Partners (OBPs) with EMVO. This is performed via the EU Hub: a centralised database and router that stores key information about the manufacturers (or parallel distributors) and their products.

The OBP connects and uploads data to the EU Hub on behalf of the European Marketing Authorisation Holder(s) (MAHs); affiliated companies to the OBP holding the licenses to market and distribute medicines in the EU and European Economic Area. The OBP uploads Product Master and Batch Data—including a Unique Identifier (UI) code, expiry date, batch, and serial numbers for every product—into the EU Hub. These UIs are distributed to national systems across 30 countries within Europe.

National Medicines Verification Organisations (NMVOs) manage these national systems that use this information to ensure that products can be verified by end-users (pharmacies, hospitals, or wholesales).



NMVOs receiving the information from the EU Hub[2]

When an end-user (for example, a pharmacy) scans the Data Matrix code on the pack, they can identify if it's authentic by checking the UI code on the pack against the one stored in their national system's repository:

1. The system will notify the end-user whether the pack is authorised to be decommissioned and dispensed to the patient.
2. Every individual pack for sale has an anti-tampering device on the outer box to prevent misuse.

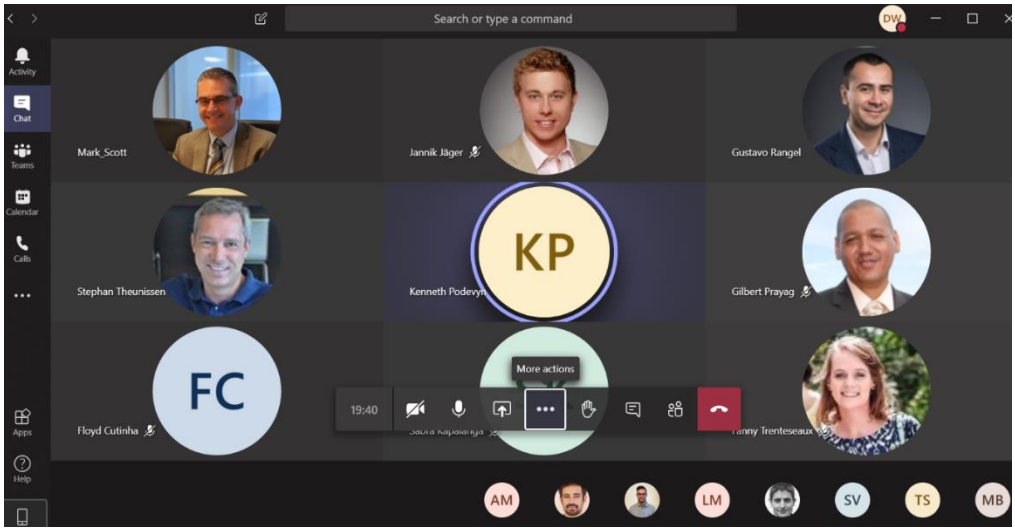
A pack containing a UI with a product code, serial number, batch and expiry date

The EMVO Team: Meeting the challenges of COVID-19 while working from home (WFH)

The novel coronavirus (COVID-19) is providing challenges that EMVO is facing, head-on. The EMVO Team has also been affected by COVID-19, working from home and reorganising the office to adhere to the social distancing guidelines. While working remotely, the team is using WFH tools to make sure that the operation runs smoothly.

The team is also in high spirits, scheduling daily conference calls to stay in touch and providing changes to the EMVS/EU Hub to stakeholders via the website, online meetings and scheduled reports.

The team is even growing to meet the demands of the pandemic and future projects in the pipeline.



The EMVO team during the Daily Stand-up meeting

Andreas Walter, General Manager, is aware of the challenges, but is confident that EMVO has the capabilities and infrastructure to meet these demands during this uncertain climate:

"In this challenging period, EMVO continues to work tirelessly to fulfil the mission entrusted to us by the regulatory authorities and our various stakeholders—to protect patients against falsified medicines. At the heart of this mission is the EMVS.

Andreas Walter, General Manager

"As the focal point, the EMVS is crucial, unifying EMVO's stakeholders with NMVOs, manufacturers, pharmacies, hospitals, and wholesales. And, although it has only been a year, the importance of the EMVS is clear.

"Without the EMVS, the EEA is more vulnerable to counterfeit medicines entering the legal supply chain, jeopardising patient safety. Protecting the health and wellbeing of patients will always take precedence, especially in this uncertain time."

EMVS key facts

Here are some facts about the EMVS in relation to our affected supply chain partners:

1) The EMVS was launched on 9th February 2019.
2) 30 European countries are participating in the EMVS. These 30 countries are all in the European Economic Area (EEA). Italy and Greece will make use of a longer implementation period.
3) 2,000+ pharmaceutical companies are currently connected.
4) 6,000+ wholesale distribution authorisation holders are currently connected.
5) 140,000+ pharmacies are currently connected to the EMVS.
6) 5,000+ hospital pharmacies.

For more information on the EMVS and EMVO's ongoing mission, please visit our website.

An initiative to protect the European pharmaceutical supply chain from the entry of falsified medicines.

Notes:

[1] EMVO's founding stakeholders are EFPIA (The European Federation of Pharmaceutical Industries and Associations), Medicines for Europe (The European Generic and Biosimilar Medicines Association), PGEU (The Pharmaceutical Group of the European Union), GIRP (The European Healthcare Distribution Association) and Affordable Medicines Europe (Former EAEPC). EMVO's affiliate stakeholders are EAHP (European Association of Hospital Pharmacists) and HOPE (European Hospital and Healthcare Federation).

[2] Member States of the European Union (EU), European Economic Area (EEA) and Switzerland. Italy and Greece will make use of a longer implementation period.