European Medicines Verification System (EMVS)

Frequently Asked Questions (FAQ)

Basics

What is the EMVS?

The European Medicines Verification System (EMVS) is a new system which allows for the end-to-end pharmaceutical product verification designed to ensure that patient safety is protected. The EMVS introduces new safety features to prevent falsified medicines from entering the legal supply chain: a Unique Identifier (UI), which is encoded in a 2D data matrix barcode holding information related to the uniqueness of the pack, and an anti-tampering device, such as a seal.

The EMVS is a data repository system comprised of a European Hub and national data repositories in each country.

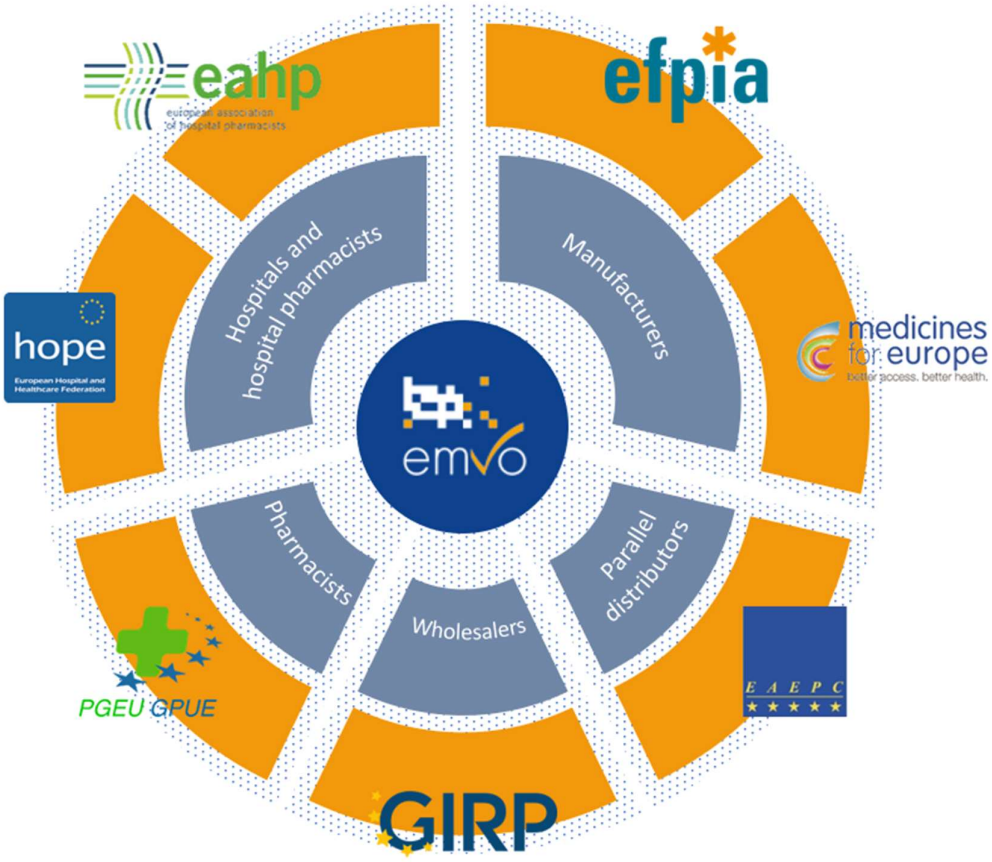
Why was the EMVS set up?

The EMVS was foreseen in the Falsified Medicines Directive (Directive 2011/62/EU) (FMD) and the associated Delegated Regulation (EU/2016/161). The Regulation provides for prescription medicines intended for human use to include the new safety features introduced by the EMVS in the EU. In the initial Operational Phase, Italy and Greece have a longer transition period.

Who is involved in the EMVS?

The European Medicines Verification Organisation (EMVO) is the organisation responsible for setting up and running the European Hub. EMVO is a multi-stakeholder undertaking, devised, funded and run by the stakeholders of the pharmaceutical sector. It brings together manufacturers, parallel distributors, wholesalers, pharmacists and hospitals associations.

- European Federation of Pharmaceutical Industries and Associations (EFPIA)
- Medicines for Europe
- European Association of Euro-Pharmaceutical Companies (EAEPC)
- European Healthcare Distribution Association (GIRP)
- Pharmaceutical Group of the European Union (PGEU)
- European Association of Hospital Pharmacists (EAHP)
- European Hospital and Healthcare Federation (HOPE)



When will the EMVS go live and how will it be rolled out?

The EMVS will enter its operational phase on 9th February 2019 after several years of thorough preparations.

It should be noted that this will not result in a complete change overnight. During the operational phase, prescription medicines that were placed on the market before 9th February will not be required to include the FMD safety features. These medicines packages are still safe and have been produced

under a regulatory framework that already prioritises the safety of patients. These medicines packages will no longer be produced from 9th February and will, over time, permanently wash out of the supply chain.

All medicines newly released for sale on the market after 9th February will have to comply with the FMD requirement (i.e. have the safety features affixed to their packs).

How does the EMVS work?

Pharmaceutical manufacturers will now serialise their packaging with a Unique Identifier (carried by a a two-dimension barcode), as well as seal the packaging with an anti-tampering device. The Unique Identifiers are then uploaded by the manufacturer in the EMVS via the European Hub.

Using specifically designed software, wholesalers and other stakeholders in the supply chain will scan the two-dimension barcode on the packaging to verify the authenticity of the UI. They will do so via their respective country's national system, known as a National Medicines Verification System (NMVS). The EMVS is fully interoperable, which means that national systems can 'talk' to each other, for example, in the case of Inter-Market Transactions.

Finally, when a pharmaceutical product reaches a pharmacy, the pharmacist will now scan the data matrix before dispensing it to a patient. This provides a final safety measure to ensure the end-to-end verification of the pharmaceutical product's authenticity.

Who pays for the EMVS?

The EMVS is entirely funded by the pharmaceutical industry. The EU and national governments – and therefore the public – nor any other supply chain actor will make any financial contribution to the technical set up and running of the system; however wholesalers and pharmacies do contribute to the governance cost of EMVO and of the national organisations.

Structure and roles

What is the role of the European Medicines Verification Organisation (EMVO)?

The European Medicines Verification Organisation (EMVO) is the organisation responsible for setting up and running the European Hub.

Ahead of EMVS going live on 9th February, EMVO has been assisting pharmaceutical manufacturers and parallel distributors (known as On-Boarding Partners (OBPs)) in connecting to the European Hub. This involves both a contractual on-boarding and a technical on-boarding. Once this has been completed, an OBP is able to upload the required data to the European Hub.

In addition, during the operational phase, EMVO will be responsible for ensuring that the system remains technically stable, ensuring that any issues encountered in its use are ironed out minimising any potential disruption for patients or the pharmaceutical supply chain, and establishing an effective alert handling mechanism.

What is the role of manufacturers and parallel distributors?

Once they have connected to the European Hub, pharmaceutical manufacturers and parallel distributors are responsible for uploading the Unique Identifiers via the Hub to the respective national systems. It is their responsibility to introduce the new safety features and to comply with the European legislation.

In order to be compliant with the legislation, On-Boarding Partners (OBPs) have to go through an on-boarding process to the EMVS, and to develop their connection to the European Hub. OBPs are set up in order to connect with and upload data to the EMVS on behalf of the MAH(s) that they represent.

Note that an OBP is a legal entity that can consist of either a single Marketing Authorisation Holder (MAH), or several MAHs. There are strict conditions under which a single OBP can on-board on behalf of more than one MAHs. There must be an affiliation between the MAHs of at least 50%. This means in practice that several MAHs cannot simply on-board collectively without belonging to the same economic undertaking.

In terms of the legal relationship that exists between EMVO and pharmaceutical manufacturers and parallel distributors, it is the OBP which is the contracting party, and it is the OBP that concludes an agreement with EMVO (known as the participation agreement). The OBP should be legally authorised to do this on behalf of the MAH(s) that it represents.

In addition to completing the on-boarding process with EMVO, MAHs must conclude a contract at the national level with the relevant National Medicines Verification Organisation (NMVO).

From a legal perspective, each Marketing Authorization Holder (MAH), or parallel distributor, is ultimately responsible for complying with the requirements set out in the Delegated Regulation. In this arrangement, an MAH chooses to delegate the task to uploading the data to the OBP. It is up to each respective OBP to ensure that proper documentation and processes are put in place amongst its MAHs to ensure that these tasks are dutifully carried and that ultimate responsibility rests with the respective MAHs.

What is the role of National Medicines Verification Organisations (NMVOs)?

Every EU Member State and EEA country has its own National Medicines Verification Organisation (NMVO). There is also some cooperation between countries, with Belgium and Luxembourg sharing the same NMVS, although both countries have their own NMVO.

Each NMVO is responsible for setting up and running the respective national medicines verification system. Furthermore, each NMVO is responsible for ensuring that their local pharmaceutical supply chain actors (i.e. wholesalers, pharmacists, hospitals) connect to the new system, and for connecting their national system to the European Hub. The actual verification of packs takes place at the national level with the NMVOs.

A full list of NMVOs can be found here.

What is the role of wholesalers?

The general principle for wholesalers is a risk -based verification, as set out in the legislation. More specifically this is the case when a wholesaler receives a pack if it is returned to from the pharmacy or hospital (or other customer). Furthermore, this would also be when they receive a pack from another wholesaler who is not the manufacturer/MAH or a wholesaler acting on behalf of the manufacturer/MAH.

A wholesaler also needs to decommission the pack under the following conditions:

- The pack is exported outside the EU
- The pack is returned to the wholesaler (from a pharmacy, hospital, …) and the pack cannot be placed into saleable stock
- The pack is intended for destruction
- The pack is provided to the authorities as a sample
- That it is required by national legislation in case where they supply to dispensing entities which are not operating within a healthcare institution (e.g. research institutions, prisons, dental practices – full list in Article 23).

What happens at pharmacy/hospital level?

When a pack is dispensed at a pharmacy, the pharmacist scans the data matrix on the pack. The information from this data matrix is then compared to information that is held in the national system.

If the information taken from the data matrix matches the information held in the system, and if the product has also not been decommissioned at any stage of the supply chain, then the pack is dispensed to the patient. Once the pack has been dispensed, its status in the system is changed to "decommissioned/supplied", meaning that there is a record of it being dispensed to the patient that can be checked against potential future falsifications.

If the information taken from the data matrix does not match the information held in the system, or if the status of the serial number is already "decommissioned", then the pack authenticity cannot be verified, and an alert will be raised. As a result, the pack will not be dispensed to the patient. This could, of course, be because of a process error in the supply chain; but it could also mean that there has been a falsification. An investigation into the reason for the alert will be carried out, involving different actors in the supply chain under control and in cooperation with the National Competent Authority.

Alert system

What is an alert and when is one triggered?

Three relevant terms are used to describe the process by which an alert is triggered:

- An error is the term used to describe an actual problem within the system, meaning that the normal operation of the EMVS is interrupted. Every error is noticed by the system. Under the EMVS, there are five levels of errors. These go from level 1, in which the system itself can handle the situation, to level 5, in which system administrators and external stakeholders are informed about the situation.
- An exception describes the process by which an actor interacting with the system is informed about an error.
- An alert describes the process by which actors other than the one interacting with the system are notified about an error.

As a result, every alert is an error, but not every error causes an alert.

The external stakeholders that are notified in the case of a level 5 alert are: the NMVO, the OBP, EMVO and the National Competent Authority (NCA).

Examples of an alert being triggered

Example 1: End-user scans a pack that has an already decommissioned UI

A pharmacist scans a pack, but the UI has already been decommissioned. As a result, an exception is flagged by the national system to the end-user. The national system then alerts the end-user, the NMVO of the country that the pharmacist is in, and the EU Hub. The EU Hub processes the alert to the OBP for the product, and to EMVO.

Example 2: Inter-Market Transaction (IMT) is used to check whether a pack is registered with another NMVS – Note: an IMT is when a pack from a country e.g. the Netherlands is scanned in any other country than e.g. the Netherlands

A pharmacist scans a data matrix, but the UI is not recognised by the national system. The national system therefore flags the error to the European Hub to verify whether the UI exists in another national system and whether it is available to dispense. The Hub will then conduct the IMT and check whether the UI has been registered with another NMVS and can be decommissioned. Depending on the answer, the product is either dispensed or not dispensed by the end-user. If the NMVS in which the UI is stored informs the Hub that the pack has already been decommissioned in that NMVS, it will raise its own alert.

Patients and the EMVS

What does the EMVS mean for patients?

Patients across Europe will benefit from this system, and can rest assured that the EMVS improves patient access to safe medicines. Once the EMVS is fully operational, patients should notice no difference as the new data matrix is scanned by the pharmacist/hospital pharmacist at the point of sale/point of dispense, after checking the anti-tampering device. Information is sent to the European Hub in a matter of seconds to confirm that the pack is safe to be dispensed to the patient.

Glossary

EMVS: European Medicines Verification System. This term denotes all actors within it across all participating countries.
NMVS: National Medicines Verification System. This term refers to all participating actors within one participating country of the EMVS.
EMVO: European Medicines Verification Organisation. EMVO is responsible for the European Hub and assists pharmaceutical companies in on-boarding to it.
End-user: This describes a pharmacy, hospital or wholesaler.
European Hub: The centralised database and router holding the information from all Unique Identifiers across the EMVS and to which the national systems are connected.
FMD: The Falsified Medicines Directive (Directive 2011/62/EU) (FMD) and the associated Delegated Regulation (EU/2016/161) on safety features dictate that a new system of verification for pharmaceutical products was needed and introduced requirements for two new safety features on product packs.
MAH: Marketing Authorisation Holder. This is the authorisation holder of a pharmaceutical product in a country.
NMVO: National Medicines Verification Organisation. Each Member State of the European Union (EU), European Economic Area (EEA) and Switzerland has its own NMVO. NMVOs are responsible for end user on-boarding and for the operation of the national systems.
OBP: On-boarding partner. This is the legal entity which enters into a contract with EMVO and connects to the European Hub.