

# The European Medicines Verification System (EMVS) explained:

## The European Medicines Verification Organisation (EMVO)





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## Glossary of key terms:

**OBP** – On-boarding partner. This is the legal entity, representing one or several MAHs from the same corporation which enters into a contract with EMVO and connects to the European Hub

**MAH** – Marketing Authorisation Holder. This is the entity which holds a license for the selling of a pharmaceutical product in a country. Parallel importers are considered MAHs in the context of EMVO based on their parallel import licenses.

**EMVO** – European Medicines Verification Organisation. EMVO is responsible for the European Hub and assists pharmaceutical companies in on-boarding to it.

**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.

**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.



## **1) Introduction to the EMVS**

The European Medicines Verification System (EMVS) is a new system of end-to-end verification of medicines, designed to ensure patient safety. This is done by preventing falsified medicines from entering the legal supply chain. Medicines should always be bought from legitimate pharmacies.

The EMVS is the first initiative of its kind that is stakeholder-driven. It is a multi-stakeholder undertaking; devised, funded and governed by the stakeholders of the pharmaceutical sector. The stakeholders of the pharmaceutical sector have been mandated by the European Commission to establish the EMVS based on the Falsified Medicines Directive (Directive 2011/62/EU) (FMD) and the associated Delegated Regulation (EU/2016/161) on safety features. The legislation dictates that a new system of verification for medicines be implemented; and thus introduced requirements for two new safety features on product packs. These features “allow the verification of the authenticity and the identification of each individual pack” in the supply chain of medicinal products in Europe. It is important to note that the EMVS covers mainly prescription medicines for human use, these are also known as RX products.

For more information on the FMD and the associated Delegated Regulation, please consult information released by the European Commission. A link to the FMD can be found [here](#) and one to the Delegated Regulation can be found [here](#).

According to the legislation, pharmaceutical manufacturers and parallel importers are required to print a Data Matrix code on the medicine pack. The code incorporates a Unique Identifier (UI). Pharmaceutical companies and parallel importers must also apply an anti-tampering device to the outer packaging for each individual sales package.

The UI consists of a random serial number unique to each pack and a product code. The Data Matrix also includes information about the batch number and expiry date.

At the point of dispense the medicine will be scanned, checked and verified for authenticity against a national (or supranational) repository. The UI may also have been checked at other points during the supply chain. Wholesale distributors following a risk-based approach are required to carry out verification checks of the UI when they receive packs from sources other than the marketing authorisation holders, manufacturers, or designated wholesalers. If the UI on the pack matches the UI in the repository, the pack is decommissioned and dispensed 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 then needs to determine whether the pack has been tampered with.

### **1.1) Structure and compliance**

The structure of the EMVS is divided into the European level, represented by the European Medicines Verification Organisation (EMVO), and the national level, represented by each National Medicines Verification Organisation (NMVO). Each Member State of the EU and EEA countries have their own NMVO. EMVO is responsible the European Hub and for assisting pharmaceutical companies and parallel importers in establishing their connection to the Hub. The NMVOs are responsible for establishing and operating a national system in their territory, which will connect to the Hub on one end, and to all the end-users (pharmacies, hospitals etc.) on the other end.

The main purpose of the European Hub is to serve as the principal location for the storage of master data and as a gateway for the transmission of pack related data to the national systems. Furthermore, data reconciliation on repackaging activities, i.e. maintaining a link between original and repackaged product batches, is exclusively performed on the European Hub.

All actors among the pharmaceutical supply chain have duties and responsibilities under the European legislation. Marketing Authorisation Holders (MAH), also referred to as On-boarding Partners (OBPs) (this distinction will be clarified later on in this text) have to proceed with an On-boarding process to the European Medicines Verification Organisation (EMVO) and develop their connection to the European Hub in order to be compliant with the FMD.



## **2) Entities within the EMVS**

### **2.1) European Medicines Verification Organisation (EMVO)**

EMVO is responsible for the European Medicines Verifications System (EMVS) in accordance with the Falsified Medicines Directive (Directive 2011/62/EU) and the Delegated Regulation (EU) 2016/161. EMVO's task is to ensure the implementation of a functioning, secure, interoperable and cost effective medicines verification system across Europe.

Its founding members 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 EAEPIC (the European Association of Euro-Pharmaceutical Companies). HOPE (European Hospital and Healthcare Federation) and EAHP (European Association of Hospital Pharmacists) are also official EMVO stakeholders.

EMVO is primarily responsible for setting up and running the European Hub. As has already been explained this is where pharmaceutical companies upload the UI of each pack. The European Hub serves as the central database and router for the EMVS and connects all national systems together.

EMVO also assists On-Boarding Partners to connect to the European Hub. On-Boarding partners are pharmaceutical companies and parallel importers who connect to the European Hub to upload their data. The main purpose of the European Hub is to serve as a gateway for the transmission of manufacturer's and parallel distributor's data to the national systems.

It is important to note the difference between a Marketing Authorisation Holder (MAH) and an OBP. Under the architecture of the EMVS a Marketing Authorisation Holder (MAH), or a group of MAHs can connect to the European Hub via an On-boarding Partner (OBP). An OBP is a legal entity, set up in order to connect with and upload data to the European Hub, on behalf of a single/ more than one MAH(s).

Alongside completing the on-boarding process with EMVO, MAHs must conclude a contract at national level with the relevant NMVO and pay an entry and an annual fee. The fee model depends on each NMVO. Therefore, EMVO recommends consulting our most up to date Fee Models Presentation and Fee Models Table to identify the applicable fees. These can be found



on EMVO's [Knowledge Database](#). Any further details on this point must be taken up directly with the relevant NMVO(s).

## **2.2) National Medicines Verification Organisations (NMVOs)**

The EMVS is made up of two distinct (yet linked) levels. The European level has been explained above; with the national level serving as the verification platform that so called end users, i.e. pharmacies, hospitals, wholesalers or other registered parties can use to check a product's authenticity. Each NMVO is responsible for assisting with end user on-boarding.

Each country must implement its own National Medicines Verification System, set up and managed by the NMVO, a non-profit entity. The actual verification of the pack takes place at the national level.

A full list of NMVOs can be found [here](#).

## **2.3) What about pharmaceutical companies? What do they need to do?**

Each pharmaceutical company, whether they be a manufacturer or a parallel importer, is ultimately responsible for complying with the conditions set out by the FMD and Delegated Regulation. The EMVS provides a system under which each pharmaceutical company can be compliant with the legislation, however any failure to do so is the sole responsibility of that company.

An OBP provides a single entity from which national systems can obtain revised/new product serialisation data. In order to on-board to the European Hub, OBPs must pay an entrance fee directly to EMVO. It is very important to note that there are strict conditions under which a single OBP can on-board on behalf of more than one MAHs. For this to take place, there must be an affiliation between the MAHs of at least 50%. In other words, multiple MAHs cannot simply on-board collectively without their businesses already being closely associated.

In terms of the legal relationship that exists between EMVO and a pharmaceutical company, it is the OBP which is the contracting party and it is the OBPs which conclude an agreement with EMVO (the Participation Agreement). The OBP should be legally authorised to do this on behalf of the MAH(s) it represents.



Once this contractual on-boarding has been completed, EMVO then assists OBPs in the technical phase of on-boarding to the European Hub. Once this has been completed, then an OBP is able to upload the required data from its UIs to the European Hub.

### **3) Processes of the EMVS**

#### **3.1) How does the process of the EMVS work? What steps are taken to ensure a pharmaceutical product is not falsified?**

As was explained in the overview of the EMVS, the new features of the EMVS fall into two categories; safety features and the establishment of the EU Hub, where the Unique Identifier (UI) of each pack is uploaded and stored. In order to reach an understanding of how the processes of the EMVS work; they are described below.

#### **3.2) What does the End User (pharmacist, hospital, wholesaler) do?**

The pack is scanned by the end user at the point of dispense. When a pack is dispensed at a pharmacy, the pharmacist scans the data matrix on the pack. The information taken from the matrix is then compared to information that is held in the national system.

If the information taken from the UI code matches the information held in the system, and additional criteria such as “product not decommissioned” are fulfilled, then the pack is dispensed to the patient. Simultaneously, the status of the serial number of the pack is set to “decommissioned/supplied”. This means that a record of the dispense of the pack to the patient will be kept; to check against potential future falsifications.

Should the information on the code differ from that in the repository (in particular “serial number does not exist in repository”) or the status of the serial number is already “Decommissioned”, the pack authenticity cannot be verified and an alert will be raised. Therefore, the pack must not be dispensed to the patient. This may, of course, be due to a process error in the supply chain; but it may of course also mean that there has been a falsification.

An investigation for the reason of the alert will be conducted involving different actors in the supply chain.

Wholesale distributors following a risk-based approach as laid down in the legislation carry out verification checks of the UI when they receive packs from sources other than the marketing authorisation holders, manufacturer, or designated wholesalers. In some countries, wholesaler





distributors are required by national legislation to decommission packs which they supply to dispensing entities which are not operating within a healthcare-institution(s) e.g. research institutions, prisons, dental practices, etc.

**3.3) Will all prescription medicines dispensed from 9<sup>th</sup> February 2019 include the new safety features?**

No. The change applies only to prescription medicines which are placed into the market after this date. As such, for some time after the deadline there will be medicine packs on the market without the data matrix. These medicines packages are still safe and have been produced under a regulatory framework which already prioritises the safety of patients. These medicines packages will no longer be produced from 9<sup>th</sup> February 2019 and will, over time, permanently leave the supply chain.

## **4) Alerts within the EMVS**

### **4.1) What is an alert? At what point is an alert triggered?**

An error describes a situation where the normal operation of the EMVS is interrupted; with every error being noticed by the system. Within the EMVS there are 5 levels of error; going from level 1, in which the system can handle the situation by itself, to level 5, in which system administrators and external stakeholders are informed of the situation.

An **error** is the term to describe the actual problem within the system. An **exception** describes the informing of the actor interacting with the system that there has been an error. An **alert** describes the process of informing actors other than the one who was interacting with the system when the error was detected. Thus, every alert is an error, but not every error causes an alert.

The external stakeholders who are informed in the event of a level 5 alert are the NMVO, the OBP, EMVO and the National Competent Authority (NCA).

### **4.2) What are some examples of an alert? What happens when a single alert is triggered?**

#### **4.2.1) End User scans a pack. A pack with the same Unique Identifier has already been dispensed in another pharmacy:**

As a first example, the End User (pharmacy, hospital or wholesaler) scans a pack. A pack with the same Unique Identifier has already been dispensed by another End User. This causes an exception to be raised by the national system to the end user. The national system then raises an alert to the end user, the NMVO of that country, and the EU Hub. The EU Hub then processes the alert and raises its own alert to the OBP, and to EMVO.

#### **4.2.2) Another example of an alert is in relation to an Inter-Market Transaction (IMT):**

The End User scans a pack, the information from the pack is then being sent to the respective national system for verification. This particular pack is not recognised by the national system, which then raises the error with the Hub to verify if the product exists in another national system and is available to sell. The Hub will then conduct the Inter-Market Transaction (IMT) and will check if the pack has been registered with another NMVS and can be dispensed to the patient.



Depending on the answer that is given back, the product is dispensed or not dispensed by the End User. However, if the Hub receives a response from an NMVS that the pack has already been dispensed in its market, this NMVS will raise its own alert, and not the initial alert.



## **5) EMVS key facts**

- 1- 9<sup>th</sup> February 2019 – the date that the EMVS enters its Operational Phase.
- 2- 28 European countries are participating in the EMVS. These 28 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 will be connected to the EMVS
- 4- 6,000 wholesale distribution authorization holders will be connected to the EMVS
- 5- 140,000 pharmacies will be connected to the EMVS
- 6- 5,000 hospital pharmacies and 2000 dispensing doctors will be connected to the EMVS.

**For more information on any of the points found here, please consult the Knowledge Database on our website. This includes all information that we release into the public domain and is regularly updated. If you require a more in-depth overview of the EMVS, it is possible to consult EMVO's URS Lite, which provides more technical details on the operation of the EMVS.**

**European Medicines Verification Organisation**

