



EMVO ON-BOARDING / NMVO CONTRACTING

Dear On-boarding Partner,

The purpose of this letter is to provide you with further guidance regarding your on-boarding to the European Medicines Verification System (EMVS) and to clarify the difference between EMVO on-boarding and NMVO contracting, and the fees attached.

The European Medicines Verification System

All pharmaceutical companies holding marketing authorisations to supply prescription medicinal products¹ to the European Economic Area², are required to connect to the European Medicines Verification System in order to meet their obligations under the Falsified Medicine Directive (FMD) and the Delegated Regulation (DR). In order to connect to the EMVS, the pharmaceutical corporates have to on-board to the European Medicines Verification Organisation (EMVO), while their Marketing Authorisation Holders (MAHs) have to contract with the National Medicines Verification Organisations (NMVO). Those two processes are distinct and separate.

The EMVS includes the European Hub (EU Hub) and the National Medicines Verification Systems (NMVS). The master and product data are uploaded in the European Hub, owned by EMVO, and sent through to the relevant NMVSs where the data is stored and managed. The European Hub allows for interconnectivity between the different NMVSs.

The MAHs are the ones that finance the EMVS which means that, on the one hand, they finance the EU Hub and, therefore, on-board with their pharmaceutical corporate (the On-boarding Partner) and pay a one-time on-boarding fee to the EMVO – and on the other hand, they finance the NMVS and, therefore, have to contract with the relevant NMVO(s) and pay an annual fee to the NMVS.

EMVO Onboarding

Each pharmaceutical corporate entity will constitute an On-boarding Partner (OBP) to EMVO. This OBP is responsible to the EMVO for representing the MAHs that are affiliated with it and has the responsibility to manage the upload of data and information about the MAH's licensed products into the EMVS via the EU Hub. The OBP has been designed for security concerns, in order to manage fewer connections to the EU Hub.

¹ The safety features should only be applied on the packaging of the following medicinal products for human use:

(1) medicinal products subject to prescription which are not included in the list set out in Annex I to of Regulation (EU) No 2016/161;

(2) medicinal products not subject to prescription included in the list set out in Annex II of Regulation (EU) No 2016/161.

(3) medicinal products to which Member States have extended the scope of the unique identifier or the anti-tampering device to in accordance with Article 54a(5) of Directive 2001/83/EC.

² Switzerland is working on an agreement with the stakeholders, for a voluntary system implementation. The Swiss medicinal law (HMG, 17a) states, that the implementation of a system for the detection of counterfeit medicines is NOT mandatory but voluntary.



The EMVO on-boarding process requires each OBP to successfully pass a legitimacy check and conclude a contract with EMVO. Once contracting is complete, EMVO will charge the corporate entity a 'one-time' on-boarding fee ranging from € 3,000 to € 20,000 according to the number of MAHs the corporate will be willing to upload data for in the EU Hub. The OBP will then be allowed to access the technical part of the on-boarding.

Upon completion of a technical certification, contracting and fee payment, OBPs will be able to interface with EMVS to upload their master data and serialised pack information in line with the FMD requirements.

NMVO Contracting and Fee Payment

Under the FMD all National Medicines Verification Organisations (NMVOs) are required to set up a single NMVS within their territories.³ Each NMVS develops an interface with the EU Hub and together they form the EMVS.

Under the FMD, MAHs are required to fund the setup and operation of the EMVS, including the individual NMVSs. Each MAH which markets at least one product within a national territory has to contract with the associated NMVO. These costs are likely to include a 'one off' joining (e.g. entrance fee) for each territory on which the MAH is willing to market its product(s) and an ongoing annual subscription fee, which will pay for the operational costs of the NMVSs.

In addition, wholesalers and supply chain dispensers, e.g. end-users, will have to connect to the relevant NMVSs. This will enable the end-to-end verification and authentication of medicines within each NMVO's territory.

Summary

The EMVO On-boarding and NMVO Contracting processes are distinct and separate. Corporate entities, will contract once with the EMVO as an On-boarding Partner (OBP), on behalf of their MAHs. Then, each MAH operating within a national territory will contract with the associated NMVO of each national territory the MAH will market products in. Corporate entities (OBPs) have to pay one-off on-boarding fee to EMVO while their operational MAHs will pay annual fees to each NMVO relevant for their marketed products, under that NMVO's fee payment model.

For any further detail regarding the exact tasks that are taken over at the national level we invite you to contact the relevant NMVO(s). The NMVOs' contact details are available on our website at the following link: <https://emvo-medicines.eu/home/mission/emvs/>

Should you need any further information, our Helpdesk (helpdesk@emvo-medicines.eu) remains at your disposal.

³ Some NMVOs may collaborate with other countries and operate supranational systems – for further information please consult Article 32 of the DR.