



PHARMACEUTICAL COMPANIES AFFECTED BY THE FMD

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WHO IS AFFECTED BY THE FALSIFIED MEDICINES DIRECTIVE?

All pharmaceutical companies holding marketing authorisations to supply prescription medicinal products to the European Economic Area (EEA) have to proceed with an on-boarding process to the European Medicines Verification Organisation (EMVO) and develop their connection to the European Medicines Verification System (EMVS) in order to meet their obligations under the Falsified Medicine Directive (FMD) and the Delegated Regulation (DR).

DIFFERENCE BETWEEN EMVO ON-BOARDING AND NMVO CONTRACTING

The European Medicines Verification Organisation (EMVO) On-boarding and the National Medicines Verification Organisations (NMVO) contracting are two distinct and separate processes and they both need to be executed in order to ensure compliance with the FMD and the DR.

In order to connect to the EMVS*, the Marketing Authorisation Holders (MAHs):

1. are requested to On-board with one of their affiliated pharmaceutical corporate entity (the On-boarding Partner) **to EMVO**. The On-boarding Partner represents its affiliated MAHs at EMVO level, proceeds to the on-boarding and signs the contract with EMVO on their behalf.

2. must contract with the relevant NMVO. All MAHs have to have a contract in place with each NMVO established in the territory they are active in.

*The whole EMVS includes the European Hub (EU Hub) and the National Medicines Verification Systems (NMVS). The master and product data is uploaded in the European Hub, established and managed by EMVO, and sent through to the relevant NMVS, established and managed by the NMVOs, where the data is stored and processed. The European Hub enables the interoperability between the different NMVSs.

EMVO ON-BOARDING

- Each pharmaceutical corporate entity will constitute an On-boarding Partner (OBP) of EMVO. This OBP represents the MAHs that are affiliated with it and is responsible for managing the upload of data and information about the MAH's concerned products into the EMVS via the EU Hub.
- The EMVO On-boarding process requires each OBP to successfully pass a legitimacy check and conclude a contract with EMVO. EMVO will charge the OBP a 'one-time' on-boarding fee according to the number of affiliated MAHs the OBP will 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 the technical On-boarding, contracting and fee payment, the OBP will be able to connect to the EMVS to upload master and pack data for its MAHs' in line with the FMD and DR requirements.

NMVO CONTRACTING

- Under the DR all NMVOs are required to set up their NMVS within their territories. Each NMVS develops an interface with the EU Hub and together with the EU Hub they form the EMVS.
- Each MAH which markets at least one product* within a national territory has to contract with the associated NMVO and in general pay 'one-time/entrance fee'** and an 'annual subscription fee'. In addition, wholesalers and supply chain dispensers, e.g. end-users, will have to connect to the relevant NMVS. This will enable the end-to-end verification and authentication of medicines within each NMVO's territory.

*Medicinal products subject to prescription (which) shall bear the safety features referred to in point (o) of Article 54 of the FMD, unless they have been listed in accordance with the procedure pursuant to point (b) of paragraph 2 of this Article. Medicinal products not subject to prescription shall not bear the safety features referred to in point (o) of Article 54 of the FMD, unless, by way of exception, they have been listed in accordance with the procedure pursuant to point (b) of paragraph 2 of this Article, after having been assessed to be at risk of falsification.

** Detailed NMVO's fee model description is available in EMVO [Knowledge database](#).

OVERVIEW OF FINANCING THE EMVS

The MAHs are the ones that finance the EMVS according to the DR.

- Due fees to EMVO:
 - ✓ one-time on-boarding fee
- Due fees to NMVO(s)*:
 - ✓ 'entrance fee' for each territory on which the MAH markets its product(s)
 - ✓ On-going annual subscription fee to each NMVO, relevant for the MAHs' marketed products which will cover the operational costs of the respective NMVS

* Detailed NMVO's fee model description is available on the EMVO website in the [Knowledge database](#).

In the event of any question or uncertainty, please do not hesitate to contact our Helpdesk:

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