

**LETTER OF ANNOUNCEMENT**  
**The Risk of the Falsified Medicines Directive Non-Compliance for your Business**

Wednesday, the 10<sup>th</sup> of October 2018

Dear Manufacturer,

Dear Parallel Distributor,

We are writing you as the European Medicine Verification Organization (EMVO) managing the European Medicines Verification System (EMVS). In compliance with the legal provisions established in the EU Falsified Medicines Directive (FMD, 2011/62/EU) and the Delegated Regulation (DR, 2016/161), the EMVS is designed to prevent falsified medicines from entering the legal supply chain.

### **Do you know your responsibilities?**

Your company, as a member of the pharmaceutical supply chain, is obliged to comply with the FMD and the DR by the 9<sup>th</sup> of February 2019. Each Marketing Authorisation Holder (MAH) has to On-board directly as an On-boarding Partner (OBP) or indirectly via an affiliated company that acts as the OBP. The OBP should ensure that the product pack data are uploaded in the European Hub (EU Hub) in due time.

### **Take action now!**

Previous experiences have shown that it can take up to 6 months to fully complete the On-boarding process, mainly due to internal corporate regulations and procedures of the OBP. Therefore, we urge you to start your On-boarding to the EMVO without undue delay, in parallel with establishing your internal software strategy for the serialization. The On-boarding process consists of two main stages:

- Contractual On-boarding - completion of a registration request, provision of several information on the OBP and affiliated MAHs, legitimacy check, fee payment, Participation Agreement.
- Technical On-boarding - completion of a system connection, system testing and system operation.

### **Best Practice**

To start the On-boarding process effectively, you can consult the following information material:

- [Detailed information](#) on which entity will be the EMVO OBP.
- The On-boarding Partner Portal, directly accessible from the [EMVO Website](#).
- The On-boarding [Presentation](#) and [Guidelines](#).
- The On-boarding Partner Portal [Training Video](#).
- The EMVO [Knowledge Database](#).
- The National Medicines Verification Organisations' (NMVOs) contact details, available on the [EMVO website](#).



Although EMVO uses its best efforts to ensure a smooth and timely On-boarding for its OBPs, in no case shall it be responsible or liable for any late On-boarding or failure to On-board. As a general principle, EMVO does not assume and expressly disclaims any responsibility or liability for any OBP failing to complete its On-boarding successfully and on time or, more generally, failing to comply with any obligation applicable to it under the FMD, the DR, the OBP On-boarding Guideline/Manual and the Participation Agreement.

It might be that your company has been/will be listed under another company account, acting as an OBP for your corporation. If your company is confident that an OBP already listed/will list your company as an affiliated Marketing Authorisation Holder (MAH) it will represent and upload data for in the EU Hub, please disregard this letter.

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

Tel. Helpdesk: +372 611 90 44

E-Mail: [helpdesk@emvo-medicines.eu](mailto:helpdesk@emvo-medicines.eu)

## **EMVO Team**

### **European Medicines Verification Organisation**

[www.emvo-medicines.eu](http://www.emvo-medicines.eu)

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