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

Tuesday, the 11th of August 2018

Dear Manufacturer/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) and the Delegated Regulation (DR), 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 9th 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 serialization data are uploaded in the European Hub (EU Hub) in due time.

Take action now!

Previous experiences have shown that to fully complete the on-boarding process, mainly due to internal corporate regulations and procedures of the OBP, it can take up to 6 months. Therefore, you should start the EMVO on-boarding process now, in parallel with establishing your internal software strategy for the serialization. The on-boarding process consists of two main stages:

- Contractual on-boarding - a completion of a participation request, legitimacy check, fee payment, participation agreement.
- Technical on-boarding - a 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 acting as an OBP for your corporation. In case that 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:

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EMVO Team

European Medicines Verification Organisation

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