

LETTER OF ANNOUNCEMENT
EMVO notice of the On-boarding on time

Monday, the 6th of August 2018

Dear Future On-boarding Partner,

EMVO contacts you with respect to the approaching deadline of the implementation of the Falsified Medicines Directive 2011/62/EU and the Delegated Regulation 2016/161 (altogether 'FMD') throughout Europe which is set for **the 9th of February 2019**. More than 2000 pharmaceutical companies 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.

Each pharmaceutical corporate entity will constitute an On-boarding Partner (OBP) of EMVO.

In January 2018, EMVO announced that the very last opportunity to on-board timely is June 2018. Any on-boarding after that date may entail a risk to the company's compliance with the FMD and consequently to the business too.

Indeed, the on-boarding process can take up to 6 months to be fully completed by an OBP. At the moment, only 131 working days remain before the Delegated Regulation comes into force.

EMVO currently counts 841 OBPs that have signed the required agreement, the Participation Agreement. 453 of them reached the Technical On-boarding and only 106 of them are connected to the Production environment of the EU Hub now. The Technical On-boarding is a challenging step in the whole On-boarding process and means that the OBPs have to connect their IT System to the EU Hub. An expertise from various departments of each company may be needed to complete the Technical On-boarding on time.

In case your company hasn't started the On-boarding process yet or if it has stopped at some of its steps and finds it difficult to complete, please consult the following information material, and initiate the process as soon as possible:

- [Detailed information](#) on which entity will be the EMVO On-boarding Partner.
- 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 proves 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 OBP On-boarding Guideline/Manual and the Participation Agreement.

EMVO also works in close collaboration with the [National Medicines Verification Organisations](#). Under the FMD, Marketing Authorisation Holders (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 relevant NMVO. For further details regarding the contractual on-boarding at a national level, please 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/>

It might be that your company has been/will be listed under another company acting as On-boarding Partner for your corporation. In case that your company is confident that an On-boarding Partner already listed/will list your company as a 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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