



**LETTER OF ANNOUNCEMENT**  
**Complete your Contractual On-boarding in a timely manner!**

Thursday, the 2<sup>nd</sup> of August 2018

Dear On-boarding Partner,

EMVO would like to support you and assist you reaching the legitimacy check step in your On-boarding process. A successful legitimacy check will allow you to start the Technical On-boarding part in a timely manner for the implementation of the FMD in due time.

EMVO encourages you to read the below best practice, allowing you to complete your Contractual On-boarding easily and in time.

In your contractual on-boarding process, you now have to complete at least one of the following steps:

- **Company Information** (Step 1.1)

You are requested to provide EMVO with basic company information (VAT number, postal address, etc.). Those information have to reflect the information officially registered in the national register of your company's country of registration.

- **Authorised Representative Information** (Step 1.2)

Please fill-in the information related to the person, among your OBP Company, that will sign the Participation Agreement with EMVO. In order to certify that this person is authorized to sign and engage the company, EMVO requests you to attach a Copy of Proof (typically an excerpt from the national register, where that person and his/her position and/or explicit authorization to sign are mentioned).

- **Single point of contact information** (Step 2.2)

EMVO kindly requests the contact details of the Single Point of Contact you would like to appoint for the On-boarding process. You also have the possibility to appoint a SPOC Assistant as a back-up. Those contact details may be updated at any time in step 5 'Maintenance'.



- **Participation Agreement** (Step 2.3 – 2.4)

In the steps related to the Participation Agreement, you are requested to download the pre-filled Participation Agreement for your company, make it sign by the Authorised Representative named in step 1.2., and upload it back on the Portal. EMVO also kindly asks you to send two, signed, original, hardcopies to the EMVO offices. Both will be countersigned and one will be sent back to you by postal services.

- **Invoicing Information Form** (Step 2.5 – 2.6)

The Invoicing Information Form will allow EMVO to issue your On-boarding Fee. The amount of the On-boarding Fee depends on the number of MAHs your OBP will represent and upload data for in the EU Hub. At this stage, we easily understand that you may not have an exhaustive list of those MAHs. This is why, at this stage, we ask for your best guess. Later in the process, at step 5 'Maintenance', you will be allowed to keep this information up to date and your company will be invoiced accordingly.

- **MAH and product information** (Step 2.7)

At that step, and for the purpose of the legitimacy check, EMVO requests you to fill-in a minimum of one MAH and a minimum of one product this MAH holds the marketing authorization for. It is sufficient to trigger the legitimacy check. Still, a maximum of three MAHs and three products per MAH will be taken into account for the legitimacy check. Later in the process, at step 5 'Maintenance', you will be requested to fill the full list of your MAHs in. Please note that the MAH(s) the OBP would like to represent and upload data for has/have to be its affiliate(s). The notion of affiliation has to be understood in the following sense: "Affiliate" means any other entity Controlling, Controlled or under common Control with the OBP company. "Control" and its derivatives mean the holding, directly or indirectly, more than 50% ownership interest.

Having filled-in those information, your OBP company is requested to click on the "Confirm" button in step 2.8. This will trigger the legitimacy check for your company. This step is crucial and may take some time, this is why EMVO strongly recommends you to reach that step as soon as possible. Indeed, not completing your Contractual On-boarding in a very near-future will put the whole FMD implementation in your company at risk. You're almost reaching this milestone, keep on going!



In order not to be behind the schedule, EMVOs' informative tools and support team remain at your disposal to make your on-boarding successful in due time.

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**

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