

**LETTER OF ANNOUNCEMENT  
MAH Country Listing**

18<sup>th</sup> December 2018

Dear OBP,

EMVO is contacting you to provide more detail on what information related to the MAH(s) it is necessary for OBPs to provide during the on-boarding process. Please pay close attention to this communication as some elements only serve as a reminder, while others are being communicated for the first time.

It is necessary for OBPs to fill-in information related to its MAH(s) in section 2.7 for the purpose of legitimacy check and in step 5.1. for maintenance. Maintaining the information up to date at all times in step 5.1 is an absolute requirement for all OBPs.

**What is required?**

**Step 2.7**

- In this step we need you to provide a minimum of 1 MAH and a minimum of 1 product marketing authorisation information owned by that MAH. If applicable, it is possible to provide more than this. This information will be checked during the legitimacy check.

**Step 5.1**

- The OBP is requested to fill in the full list of MAHs they represent. By default, the system needs an input in the product information section, which is not used for any purpose. Therefore, in order for the related step to be shown as completed, please fill in either one product marketing authorisation or "N/A". **It is important to note that it is a requirement to fill-in only an MAH and not add a product catalogue.**
- In this step, an additional element is requested: the information as where is the MAH active in. It is necessary for OBPs to explicitly indicate the country/countries of operations for each MAH. Indeed, it is not sufficient to indicate that the MAH owns a centralised authorisation; each country the MAH places products on the market in should be indicated in the related field. Also, it is not sufficient to indicate the ISO country code.

In addition to this, alongside providing a full list of the MAHs you wish to represent, you remain responsible for proving to EMVO that the MAHs are affiliated to your OBP company. The concept of affiliation has been detailed in previous EMVO communications. However, for the avoidance of doubt, here is the definition of affiliation as stated by EMVO: *"Affiliate means, in relation to a Party, any other entity Controlling, Controlled or under common Control with the Party. "Control" and its derivatives mean either the holding, directly or indirectly, of 50 % or more than 50% ownership interest or the statutory or de facto authority to exercise a decisive influence on the appointment of the majority of directors or managers or the orientation of policy provided it is, at EMVO's own absolute discretion, sufficiently proven"*.



## How should the information be provided?

There are two ways for you to provide us with the information we need.

- The first is by directly using the *Add MAH* function in the On-boarding Portal. For small to medium amount of MAHs, this allows you to fill-in the MAHs company information one by one.
- The second is by exporting an Excel sheet into the Portal, which contains the relevant information. However, please note that as soon as the Excel sheet is imported, all information which has already been provided in this step is overwritten. Also, please note that the portal will only allow you to upload the Excel sheet when all mandatory fields are filled in.

This information will always have to be maintained and can therefore be edited in the related step.

If you have any further questions, please be assured that EMVO's Helpdesk ([helpdesk@emvo-medicines.eu](mailto:helpdesk@emvo-medicines.eu)) remains at your disposal.

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)

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