

LETTER OF ANNOUNCEMENT
MAH affiliation to the On-boarding Partner

Wednesday, the 10th of October 2018

Dear On-boarding Partner,

EMVO contacts you in order to remind you of an important aspect of the On-boarding to the European Hub through an On-boarding Partner (OBP) company.

The On-boarding Partner is a concept which has been designed in order to allow Marketing Authorisation Holder (MAH) belonging to the same corporate group, to on-board to the EU Hub all together through one account in the OBP Portal, by developing only one connection to the EU Hub.

An important element of the representation of a MAH company by an OBP is that both companies have to be affiliates. The concept of affiliation is defined as follows: ***“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”.***

The verification of the affiliation between the OBP company and the MAH(s) will be regularly performed. In the event no affiliation based on the required ownership threshold is found, the OBP will be requested to provide EMVO with additional proof to establish sufficient control between the two entities as per the above definition.

In case the OBP fails to sufficiently demonstrate, at EMVO’s discretion, such affiliation, it will not be allowed to upload data for the concerned MAH(s) .

Moreover, the affiliation between the OBP and its MAH(s) is a requirement explicitly set out in the Participation Agreement between the OBP and EMVO to be met by the OBP. Therefore, in the event that it comes into EMVO’s knowledge that the OBP uploads data on behalf of entities not affiliated to it as per the above definition, this will constitute a breach of the Agreement and will entitle EMVO to take appropriate action against the OBP, including, but not limited to, terminate the Agreement as well as require from the OBP to bear the financial impact of such breach. Finally this may result in disconnection of the OBP from the EU Hub and the initiation from the OBP of a completely new on-boarding process along with the payment of any associated costs with no liability of EMVO whatsoever.



Therefore, **the following three requirements must be met by the OBP:**

- All MAHs for which the OBP will upload data in the EU Hub have to be duly filled-in on the OBP Portal, in Step 5 – Maintenance. This list has to be maintained up-to-date by the OBP at all times.
- All MAHs for which the OBP will upload data for in the EU Hub have to be affiliated to the OBP as per the above definition.
- The OBP has to be able to sufficiently prove the affiliation between the OBP company and its MAHs companies.

In case of 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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