

LETTER OF ANNOUNCEMENT Participation Agreement for Operational Phase

6 November 2018

Dear On-boarding Partner,

EMVO is pleased to announce that the new Participation Agreement ("**PA**") between EMVO and the Onboarding Partners for the Operational Phase is now available on the On-boarding Partner Portal ("**OBP Portal**"). The new PA governs your participation in the full-scale operational mode of the European Medicines Verification System ("**Operational Phase**") as well as the conditions for the grant of rights that are necessary for the transmission of your data to the National Medicines Verification Systems through the European Hub. This new Agreement follows the PA for the Implementation Phase, which expires the 9th February 2019, at 00:00 CET and covers the Operational Phase as well as a part of the Implementation Phase. Therefore, EMVO would like to draw your attention to the following important points:

- The On-boarding Partners that have not started their Onboarding process yet, will be requested to sign only the new Agreement (in Step 2 of the On-boarding process on the OBP Portal) as soon as possible and follow the steps indicated in the OBP Portal;
- The On-boarding Partners that already have a PA for the Implementation Phase in place with EMVO, are hereby requested to proceed with the signature of the new Agreement for the Operational Phase, which has been made available on the OBP Portal (in Step 5 of the On-boarding process on the OBP Portal); in order to ensure compliance with the contractual obligations set out in their existing Agreement, the On-boarding Partners of this category will need to have a signed (new) Agreement until end of December 2018 at the latest.

As already communicated in previous announcements and for the sake of facilitating the administration procedure, no PA hardcopy will have to be sent by the On-boarding Partners to EMVO. The On-boarding Partners will be requested to only upload a signed PA via their account on the OBP Portal and EMVO will exchange in the same way its countersigned scanned copy.

Finally, EMVO would like to request you to make sure that the details of the legal entity, the Authorised Representative¹ as well as the SPOC, which will be inserted in the new PA (either via Step 1.1 and 1.2 or Step 5 of the On-boarding process on the OBP Portal), are up to date. In case a change in the Authorised

¹OBP's Authorised Representative is (are) the person(s) who is (are) authorised to sign on behalf of and engage the company, e.g. the person who signed the PA for the Implementation Phase.

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Representative has occurred between execution of the current and the new PA, the OBP will be requested to provide EMVO with sufficient proof thereto by uploading such proof on the OBP Portal along with the copy of the signed PA.

Additional information and other explanatory details will be shared, in an Information Package, to enable smooth execution of the Agreement with EMVO.



Guiding Matrix for the operational PA

In the event of any question or uncertainty, please do not hesitate to contact our Helpdesk:

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E-Mail: helpdesk@emvo-medicines.eu

EMVO Team

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