**LETTER OF ANNOUNCEMENT**
**Best practices for the On-boarding process and frequent errors**

Wednesday, the 10th of October 2018

Dear Future On-boarding Partner,

EMVO would like to support and assist you in starting and also completing the On-boarding process easily and in timely manner for the implementation of the Falsified Medicines Directive (FMD) in due time. Please see below the best practice and frequent errors related to important steps of the On-boarding process:

## A. Contractual On-boarding

- **Company Information** (Step 1.1)

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

*Frequent error: COMPANY TYPE - An OBP can only represent either (an) Original Pack Manufacturer/s or (a) Parallel Distributor/s. EMVO designed technically different interfaces with differences in the functionality for original pack manufacturers and parallel distributors. It is therefore strictly necessary to distinguish the type of company before applying to connect to the EU Hub.*

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

Please fill-in the information related to the person, among your OBP Company, who 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).

*Frequent error: Copy of proof of the Authorised Representative (AR) - The AR is to be explicitly named in the official register together with his/her senior management position and/or his/her explicit authorization to sign on behalf of the company. The full name of the AR shall be provided, without translation nor abbreviation, as it appears in the national register. Please consult the National Registers list for European countries on the EMVO website and check the validity of the document with respect to a potential expiration date.*

- **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.



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Those contact details may be updated at any time in step 5 'Maintenance'.

*Frequent error: Phone Number – The phone number shall be correct and working. Please check the digits of a phone number you are filling in.*

- **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.

*Frequent error: Contracts:*
*- Inconsistency between the named Authorised Representative in step 1.2. and the person that actually signed the contracts.*
*- No amendments will be accepted.*
*- Two (2) hardcopies have to be sent to EMVO via post. Both hardcopies have to be signed and both have to be original versions (not scanned).*
*- A scan of the Participation Agreement, checked and signed by the Authorised Representative, has to be uploaded in the portal.*

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

The Invoicing Information Form will allow EMVO to issue the invoice for the On-boarding Fee to be paid by your company. The amount of the On-boarding Fee depends on the number of MAHs your OBP company 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, in step 5 'Maintenance', you are requested to keep this information up to date and your company will be re-invoiced according to the updates.

*Frequent error: Inaccuracy of data – The Invoicing Information Form must be filled in accordingly. Please pay particular attention to a section where the full amount of MAHs, which you as an OBP represents, has to be filled in. Use the drop-down function in the Invoicing Information Form. Follow instructions described in all the 'notes'. Finally, you are requested to upload a PDF version of the completed Invoicing Information Form.*

- **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. This is sufficient to trigger the legitimacy check.



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**Later in the process, in step 5 'Maintenance', you will be requested to provide the full list of your MAHs.** Please note that the OBP and the MAH(s) it would like to represent and upload data for, have to be affiliates. The notion of affiliation has to be understood in the following sense: **"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".

*Frequent error: Number of MAHs filled in - A maximum of three MAHs and three products per MAH will be taken into account for the legitimacy check. Therefore, there is no need to fill in all MAHs in the Step 2.7. nor all products; one MAH and one product for that MAH is sufficient. Also, the "Marketing Authorisation Number" should reflect the number related to the product authorization from the national competent authority, according to the pack size, product form and strength filled in in the filed "Marketing Authorisation Name".*

## B. Technical On-boarding

- **Integrated Test Environment (ITE) (Step 4.2.2)**

A technical connection between the system of the OBP and the EU Hub needs to be established. If you use a Registered Gateway Provider , you are allowed to start immediately in the IQE environment. Therefore, you do not need to fill in information in Step 4.2.2 (ITE), unlike when you work with direct connection. In the latter case, the first step for the creation of your connection is to get your common name information for the creation of the CSR file in step "Information to create CSR" and then create your CSR file and private key. You will then upload the CSR file in the step "Upload CSR file". If you receive a failed message in this step it is most likely due to the common name information being wrong. After having downloaded the Client and the EU Hub Certificates, a Session Token will be automatically requested and then you will be able to access the ITE.

*Frequent errors: Following errors are relevant for all ITE, IQE and PRD!*

- *Issues with login to the OBP portal – Please be aware that as soon as you get access to Step 4, the Initial Requester account becomes obsolete. If you receive the following error messages "**access denied"** or "**request access"**, you are most likely using either the wrong account or the wrong link to the OBP Portal. For that reason, we recommend you to always refer to the login information you received in the e-mails sent by noreply@emvs.com to access your OBP Portal account.*
- *Creation of .CSR and .PFX file – The guideline on how to create a CSR file can be found in the Technical Info Pack (Step 4.1). You are requested to create the CSR file exactly according to the guideline otherwise you will not be able to upload the file to the EU Hub. After that you are requested to create a .PFX file. A common pattern is to combine the signed certificate and private key into a PFX file and then install that PFX onto machines that need to communicate with the EU Hub.*
- *Session Token – Please be aware that the waiting time for receiving the Session Token is usually 24 hours, but since it is manually provided it could take some more time. Please note that the Session Token will expire after 24 hours. If a new Session Token is generated while having an already*

*established connection, the connection will be broken and you need to make use of the new Session Token.*

- *Test Status Metrics – The OBP can test on different dimensions which require interaction with the EU Hub. Please be aware that once you performed the first test you will have 30 minutes to complete the other tests before submitting your tests results. The Portal only takes into account the last 30 minutes of testing. You can submit the tests as many times as you want. In case of the Test Status Metrics in IQE, please note these tests are manually reviewed and approved so it can take several days before your tests are passed. Passing these tests will give you the access to Production Environment.*

- **Integrated Quality Environment (IQE) (Step 4.2.3)**

In this Step, please create and upload CSR file and download Client and EU Hub Certificates to have access to the IQE. A session Token request will be automatically triggered.
If you are confident that your interface is ready for testing, you can execute tests from the test status metrics, by submitting these for EMVO approval. Then you can review in the 'Test status Metrics' if your related transactions have been successfully processed in the EU Hub. Currently only the first three test dimensions of the test metrics are required to be passed (Product Master Data, Product Pack Data, Product Pack Update).

If you selected the EMVO Gateway as a Gateway Provider, please send the following information to EMVO Helpdesk (helpdesk@emvo-medicines.eu):

- Company name
- CP Number - the number appearing on the OBP's account and in the Participation Agreement
- SPOC's First Name and Last Name
- SPOC's E-mail address
- Environment (IQE/PRD)

After having sent the requested information, EMVO will provide the credentials and URL to access IQE through the EMVO Gateway. The credentials and URL will be sent through the following email: noreply@meliorsolutions.com (please check your Junk folder). Then the EMVO team generates and uploads a Session Token in the OBP Portal for the requested connection. To be able to access the EMVO Gateway portal properly, SPOCs will be advised, via e-mail, on the next steps to complete the connection.

When the baseline tests have been passed, the OBP will be allowed to on-board to the EU Hub PRD.

*Frequent errors: Please see the frequent errors mentioned in the paragraph above 'Integrated Test Environment' (ITE) (Step 4.2.2).*

- **Production Environment (PRD) (Step 4.2.4)**

After having passed the baseline tests in the IQE, EMVO will grant you with access to the Production Environment (PRD). Please note that only internal validated systems are allowed to send data into the EU Hub. Following the same procedure, please create and upload CSR file and download Client and EU Hub Certificates to have access to the PRD. A session Token request will be automatically triggered. Then you will be able to upload the product data in the EU Hub.

*Frequent errors: Please see the frequent errors mentioned in the paragraph above 'Integrated Test Environment' (ITE) (Step 4.2.2).*

- **MAH information (Step 5.1)**

For the sake of proper OBP portal functioning, reporting and information consistency, the accuracy of the MAH information provided is paramount. In this step you **are requested to provide EMVO with the full list of the affiliated MAHs** on whose behalf the upload of data to the EU Hub is performed. But you don't have to list all related products information. Therefore, we recommend you disregard the sheet « MAH Product Data ». You can copy/paste existing data and export the existing MAH list to update it in Excel file. Please note that importing the Excel file will overwrite all existing MAH data in the OBP portal.

*Frequent error: Same MAH is listed several times or incomplete list of MAHs – To provide EMVO with inaccurate or incomplete MAH list is not in accordance with the signed contract and will lead to the termination of the contract.*

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

Tel. Helpdesk: +372 611 90 44

E-Mail: helpdesk@emvo-medicines.eu

**EMVO Team**

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