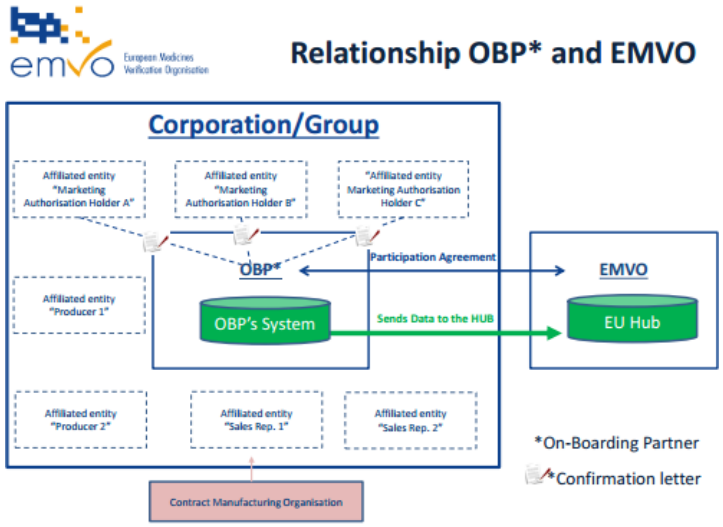
SUMMARY OF THE MOST IMPORTANT FAQs

Wednesday, the 10th of October 2018

Contractual part of the On-boarding process

1) What is an OBP? What is a MAH?

The concept of On-boarding Partner (OBP) has been defined in order to facilitate the On-boarding process for corporations to the EMVO. The OBP company represents the companies holding marketing authorization among its corporation. The Marketing Authorisation Holders the OBP represents and will upload data for in the EU Hub have to be the OBP's affiliates. A corporation can decide which legal entity will act as its OBP.



Definition of On-boarding Partner (OBP):

- The OBP is the contracting partner of EMVO and concludes the Participation Agreement.
- The OBP is legally authorized to sign on behalf of a MAH / a group of MAHs.
- The OBP has to be affiliated to a MAH / a group of MAHs.
- "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".
- OBP Affiliate(s) agree(s) in writing to be bound, jointly and severally with the OBP, by and to observe all terms, limitations and conditions applying to the OBP as set forth in the Participation Agreement.
- The group of MAHs represented by the OBP either consists of Original Pack Manufacturers or Parallel Distributors.

2) For whom can the OBP upload product data?

The OBP can upload data only for its affiliated MAHs.

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3) What is the difference between Original Pack Manufacturer and Parallel Distributor?

For the purpose of the FMD, which is addressed to "manufacturing authorization holders", or "manufacturers", we have designed technically different interfaces for original pack manufacturers and parallel distributors. Parallel distributors base their master data in part on pack data issued previously by originator companies. It is therefore strictly necessary to distinguish the type of company before applying to connect to the EU Hub.

The **Original Pack Manufacturer (OPM)** is a pharmaceutical company holding a marketing authorisation (MA) and is placing medicines on a given market. In the context of batch release the company uploads product codes and pack data into the EU Hub.

The **Parallel Distributor (PD)** or Parallel Import company is an independent company purchasing medicines in one market and – after repackaging - placing these medicines on a different market (the market of destination) under a license obtained under its name from the National Commitment Authority (NCA) of the destination market (parallel import license) or of comparable permits issued by European Medicines Agency (EMA) for centrally approved medicines (EMA parallel distribution notice).

Parallel distributors must repackage the product which they handle in order to comply with the labelling and other regulatory and trademark requirements of the destination market; this constitutes (partial) manufacturing and is subject to a manufacturing authorisation.

4) Why is the Company Type important and how to fill it in on the OBP Portal?

The connection of the Original Pack Manufacturer and Parallel Distributor differs (please see FAQ 2.05). As a result, an OBP company can either on-board Original Pack Manufacturer **OR** only Parallel Distributors. The OBP company is requested to provide EMVO with the information about the OBP, and the MAHs the OBP represents, company type in Step 1.1 'Company Information' in the OBP Portal.

This information is of paramount importance as it determines the authorisations in the EU-HUB, which differ between the OPM and the PD.

Consequently, there are 4 On-boarding cases:

a) If the MAH(s) is/are original pack manufacturer(s) only, it/they can choose one common OBP to represent/on-board it/them.
b) If the MAH(s) is/are parallel distributor(s) only, it/they can choose one common OBP to represent/on-board it/them.

c) If some MAH(s) is/are original pack manufacturers **AND** some are parallel distributors, each of the company type have to be represent by one OBP, respectively. The parallel distributors choose one common OBP to represent/on-board them AND the original pack manufacturers choose another common OBP to represent/on-board them.
d) If there is only one MAH which will on-board, but it is both an original pack manufacturer and a parallel distributor (Hybrid company), please contact the helpdesk for further guidance.

5) Who is a Designated Wholesaler? Is the Designated Wholesaler obliged to verify the authenticity of the unique identifier of medicinal products?

A Designated Wholesaler is a wholesaler designated by the marketing authorisation holder, by means of a written contract, to store and distribute the products covered by his marketing authorisation on his behalf. Consequently, a 'Designated Wholesaler' is neither the manufacturer, nor the Marketing Authorization Holder (MAH) nor a wholesaler buying from the manufacturer or MAH.

The Designated Wholesaler is not obliged to verify the authenticity of the unique identifier of medicinal products. As it is set out in the Delegated Regulation, wholesalers are not obliged to verify the authenticity of the unique identifier of products that they have received from the manufacturer, from the MAH, or a wholesaler properly designated under Article 20(b) Delegated Regulation ('Designated Wholesaler').

A detailed presentation related to Designated Wholesalers is available in our Documents Overview.

6) How to set up the coding for the different countries?

The product codes to be uploaded in the EU Hub have to follow the coding requirements of each country where the product is marketed. The list of coding requirements per country can be consulted from the EMVO website, in the Knowledge database section.

7) How to fill in the Product Master Data and Product Batch/Pack Data in the EU Hub? Which information to include?

Please consult the Master Data Guide, also available on EMVO website.

The key data fields have to be filled-in according to this guide (Product Code and Coding Scheme (in EMVS), Data Carrier Identifier (in SPOR) which is equivalent to the Product Code in EMVS, ISO Country Identifier for each market of intended sale).

In the Market Specific Master Data section, for each market within a multi-market pack the given table should be completed. For single market packs only one completed table is required.

Technical part of the On-boarding process

1) I have issues to access the OBP portal. What should I do?

If you receive the following error messages *access denied* or *request access*, you are most likely using either a wrong account or the wrong link to the OBP Portal. For that reason, we recommend you to always refer to the login information that you received in the e-mails sent by *noreply@emvs.com* to access your OBP Portal account. If, nevertheless, you still receive an error message of that kind, please try to access your account through a *Private/Incognito window* before contacting the Helpdesk. This could solve the issue since it is related with the cache stored in your browser.

Please make sure that you key in your OBP Portal account **with the right credentials (received from noreply@emvs.com) for the first time.** This will prevent many possible issues related to your connection to the OBP Portal in the future.

2) I have continuous problems with Product Data upload to the EU Hub. What should I do?

To expedite the troubleshooting with any issue related to the data upload or any transaction sent to the EU Hub, please fill in this form in the first place and send your request to our Helpdesk (helpdesk@emvo-medicines.eu).

- OBP Name
- Environment Name - EMVO ITE, IQE or Production or ISV Sandbox
- Schema used (2016 or 2018)
- Connection Type - Gateway/Direct
- Middleware (other systems) – e.g. SAP
- Common Name – e.g. M.1104.6
- Target Market
- SDK used - Java/.NET
- Timestamps - ideally within 24 hours
- Correlation ID - from message sent to the Hub
- Request Type - e.g. Product Master Data Upload, Session Token Refresh, Report Request, Product Pack Data Upload

3) What is the EMVO Gateway and how to access it?

Essentially the **EMVO Gateway** is an alternative means of connecting to the European Hub (alternate to developing a direct connection, or other Gateway Provider solutions). The direct connection will suit many OBP's however it is complex to realize. The EMVO Gateway provides an easier way to connect to the EU Hub using typically understood techniques and is aimed at those OBP's who want to participate in pilot programs but do not yet have a direct connection established or smaller OBP's who have no need for the direct connection because their volumes of batches are much lower. It's highly manual in operation so not well suited to automated processes, however it is a very effective means for connecting easily with the European Hub and wider EMVS.

In order to access the EMVO Gateway, the OBP will be asked to execute the following 3 steps:

a) After the OBP has decided to connect to the EU Hub via the EMVO Gateway and selected this option in either step 4.2 'Client Connection 1' or in step 4.3 'Client Connection 2' on the OBP Portal, the Single

Point of Contact (SPOC) can request access to the EMVO Gateway. To do so, he/she is requested to send an e-mail to the EMVO Helpdesk (helpdesk@emvo-medicines.eu) with following information:

- 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)

This action should be taken before the OBP reaches the step "Request session token" in IQE or PRD environment in Step 4 of the OBP Portal.

b) The credentials and URL to the EMVO Gateway portal will be sent to the SPOC through the following email: noreply@meliorsolutions.com (please be aware that it might appear in your Junk folder).

c) The SPOC receives the information pack to complete the EMVO Gateway connection. 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, the SPOC will be advised, via email, on the next steps to complete the connection.

4) What is Retrospective Upload and when should I use it?

In order to have the Product data properly linked to the Master Data, the OBPs have to use 'Retrospective Upload' functionality. The 'Retrospective Upload' functionality is only relevant for multi-market products where not all associated National Medicines Verification Systems (NMVS) are live yet. In this way, OBPs will be able to upload their serialized data to all National Medicines Verification Systems where their products are marketed. For further details on the 'Retrospective Upload', please consult the document uploaded on the OBP Portal, in the Technical Info Pack section. The document includes questions and answers and describes scenarios of uploads performed before and after the release 1.4 of the EU Hub.

5) How, as a Parallel Distributor, do I upload Pack Data in the EU Hub when no serial code is available in the physical pack?

For the particular case where a Parallel Distributor/Importer uses the EMVO Gateway and buys products which are not yet serialized, EMVO recommends to create a dedicated GTIN/NTIN/PPN owned by your OBP, as a placeholder to fill in the field "Original Product Code" for all Original products which are not yet serialized. Please be aware that this product code should not be used for any product you currently sell or will sell in the future.