On-boarding Guideline/Manual
for Original Pack Manufacturers
and
Parallel Distributors

How to connect to the European Hub?

Please make sure that you have the latest version of the On-boarding Guideline/Manual. The latest version is always available for download on the EMVO website.

https://emvo-medicines.eu/knowledge-database/

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Without prejudice to any provision of the Delegated Regulation and/or the Participation Agreement, each On-boarding Partner is solely and exclusively responsible for:

- Timely registering on the EMVO OBP Portal and submitting all requested information, including, but not limited, to the single point of contact information, a valid and duly signed Participation Agreement, the requested invoicing information via the invoicing information form and the MAH and product information in accordance with the Guides as published by EMVO from time to time,

- Ensuring it has all rights and permissions necessary so that all information, data or other materials supplied through or in connection with EMVO's Onboarding Process can be stored, used, and made available by EMVO as set out in the Guides, including all necessary permissions from third parties when such information, data, or other materials originate from or relate to a third party,

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List of abbreviations

AME	Affordable Medicines Europe
AR	Authorised Representative
ATD	Anti-Tampering Device
CEO	Chief Executive Officer
CER	Certificate
CFO	Chief Financial Officer
CIO	Chief Information Officer
CMO	Contract Manufacturing Organisation
CSR	Certificate Signing Request
DR	Delegated Regulation
D&A	Divestiture and Acquisitions
EFPIA	European Federation of Pharmaceutical Industries and Associations
EMA	European Medicines Agency
EMVO	European Medicines Verification Organisation
EMVS	European Medicines Verification System
EU Hub	European Hub
FMD	Falsified Medicines Directive
GIRP	European Healthcare Distribution Association
IQE	Integrated Quality Environment
IR	Initial Requester
ITE	Integrated Test Environment
MA	Marketing Authorisation
MAH	Marketing Authorisation Holder
M&A	Mergers and Acquisitions
NCA	National Competent Authority
NMVO	National Medicines Verification Organisation
NMVS	National Medicines Verification System
OBP	On-boarding Partner
OBP Portal	On-boarding Partner Portal
OPM	Original Pack Manufacturer
PA	Participation Agreement
PC	Product Code
PD	Parallel Distributor
PGEU	Pharmaceutical Group of the European Union

PMD	Product Master Data
PPD	Product Pack Data
PRD	Production Environment
SDK	Software Development Kit
SKU	Stock Keeping Unit
SPOC	Single Point of Contact
UI	Unique Identifier

1 Introduction

Falsified medicines are a major threat to public health and safety. As falsifications become more sophisticated, the risk that falsified medicines reach patients in the EU increases every year. Falsified medicines represent a serious threat to global health and call for a comprehensive strategy both at European and international level. With the Falsified Medicines Directive and its supplementing Delegated Regulation (altogether 'FMD') the legislator has taken the necessary steps to prevent falsified medicines from entering the legal supply chain. One of the measures that is being undertaken to achieve this goal is to mandate pharmaceutical companies and parallel distributors of mainly prescription medicines to apply safety features to their outer packaging.

This guideline provides all manufacturers [Marketing Authorisation Holders (MAHs)] and Parallel Distributors with assistance in the upcoming implementation of the required measures for protection against falsification and describes in detail the On-boarding Process to the pan-European system against falsified medicines.

1.1 Falsified Medicines Directive

Following adoption by the Council and the European Parliament, the Falsified Medicines Directive (Directive 2011/62/EU) was published on 1 July 2011 in the Official Journal of the European Union and applies since 2 January 2013 in all EU Member States. The Directive introduces rules to improve the protection of public health with new harmonised, pan-European measures to ensure that medicines are safe. To this end, these new measures include obligatory safety features on the outer packaging of medicines. These safety features consist of a unique identifier and an anti-tampering device which allow the verification of the authenticity of medicinal products subject to the FMD requirement and protect patients and business alike from the risks of falsified medicines.

1.2 Delegated Regulation

The Delegated Regulation (EU) 2016/161 detailing the characteristics of the safety features, how medicine authenticity should be verified, and by whom, was adopted on 2nd October 2015 and published, after scrutiny by the European Parliament and the Council, on 9th February 2016. The Delegated Regulation, and the new medicine verification system (repositories system) it specifies, applied as of **9th February, 2019**[1]. The key principle is to guarantee medicine authenticity by an end-to-end verification system supplemented by risk-based verifications by wholesalers: Medicines should be systematically verified at the point of supply to the public (e.g. at pharmacy level). Medicines at higher risk of falsification should additionally be checked at wholesaler level. To make this possible, a repositories system should be established and managed by stakeholders. As set out in the Delegated Regulation the main tasks of the repositories system are to store the information of the legitimate Unique Identifiers (UIs) and to allow the verification/decommissioning of UIs at any point of the supply chain.

1.3 European Medicines Verification System

The European Medicines Verification Organisation (EMVO) is a Belgian non-profit organisation representing stakeholders united in securing the legal supply chain from falsified medicines. EMVO has taken responsibility for advancing the formation of the European Medicines Verifications System (EMVS) in accordance with the FMD to ensure the implementation of a functioning, secure, interoperable and cost-effective medicines verification system across Europe. Its founding members are EFPIA (the European Federation of Pharmaceutical Industries and Associations), Medicines for Europe (the European Generic and Biosimilar Medicines Association), PGEU (the Pharmaceutical Group of the European Union), GIRP (the European Healthcare Distribution Association) and AME (Affordable Medicines Europe).

Figure 1: EMVO Stakeholders – founding members

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[1]Belgium, Greece and Italy may defer the application of Articles 1-48 of the Delegated Regulation and have the option of deferring the application of the rules by an additional period of up to 6 years. Belgium has however formally renounced using this option and confirmed the application of the new rules as of 9th February 2019.

Affiliated members are HOPE (the European Hospital and Healthcare Federation) and EAHP (the European Association of Hospital Pharmacists).

Figure 2: EMVO Stakeholders – affiliated members

EMVO is setting up a pan-European infrastructure of repositories centred on an information and data router, the "European Hub (EU Hub)", which is currently fully operational. The following system landscape has been selected since it ensures effective protection of patient safety and allows the fulfilment of specific requirements in different countries:
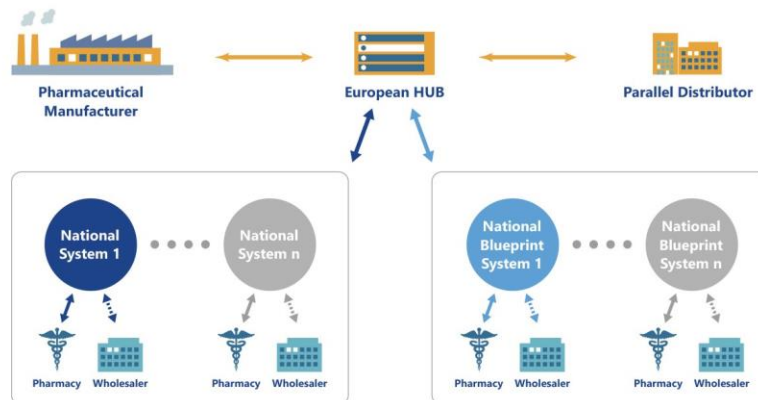

Figure 3: European Medicines Verification Landscape

The European Medicines Verification Landscape as depicted in the figure is composed of the European Hub and national systems (most of which will be hereinafter called national Blueprint systems i.e. built in accordance with a standard template specified by EMVO).

1.4 European Hub

The European Hub is the central element of the European Medicines Verification System (EMVS). It was created in 2014 and is currently in full operational mode.

The primary purposes for the European Hub are (i) to centralise the uploading of data by the manufacturers, MAHs and Parallel Distributors and thereby minimising the number of technical interfaces that have to be supported by them, (ii) to implement and maintain a set of standardised interfaces that in turn support the overall principles of system interoperability and (iii) to serve as a single, fundamentally secure entry point for all EMVS master data. The European Hub has robust processes to ensure that each party (e.g. MAHs, manufacturers, etc) connecting to the system has been verified and validated as a genuine connecting partner with valid reasons for injecting data in to the overall EMVS. By providing the European Hub with these primary attributes, the overall system cost can be minimised due to the centralised security process and the centralised and minimised number of interfaces that must be maintained.

The European Hub as the core component of the EMVS performs the following tasks:

- It provides a single-entry point for Original Pack Manufacturers holding the marketing authorisation for the FMD-affected product(s) and Parallel Distributors to upload their product serialisation data (for Parallel Distributors it concerns the subsequent upload of new product data of the repackaged products into the market).

- It provides a single access point from which national systems can obtain revised/new product serialisation data.

- It provides a centralised location for the storage of master data and master data regarding the connected national systems.

- It provides a means by which multi-market packs can be systematically marked as 'decommissioned' in all affected markets once a pack has been dispensed in one market.

- It provides a means to decommission packs by Original Pack Manufacturers holding the marketing authorisation for the FMD-affected product(s) and Parallel Distributors for already uploaded pack data from a source market.

- It provides a verification gateway for parallel distributors to access the repositories of the source markets for verification of authenticity.

- It provides a central point from where information concerning product recalls can be transmitted in addition to the established recall procedures.

- It provides a mechanism by which exported and imported products can be reconciled at a dose level as they are used by parallel distributors in repackaging / relabelling.

- It provides a central point from which alerts, that cannot be handled solely at the national level e.g. issues in different countries with multi-market packs, can be managed. This includes providing response e.g. to the appropriate company/regulatory authority etc.

- It provides a platform permitting cross-country inquiries, in accordance with Article 34(2) of the Delegated Regulation, in order to verify whether a UI that was not found in a national repository, is stored elsewhere in the repositories system.

1.5 National Medicines Verification Systems

The National Medicines Verification Systems (NMVS) are currently being established in all participating Member States. The main purpose of the National Medicines Verification Systems is to serve as the verification platforms that pharmacies or other registered users such as wholesalers, self-dispensing doctors or hospital pharmacies will connect to in order to check a medicinal product's 'authenticity'. All data necessary to perform this and other relevant transactions with respect to medicinal products intended to be placed on a particular market are stored in the respective NMVS.

The key tasks of a National Medicines Verification System are:

- Holding the relevant product serialisation data for its market.

- Receiving revised/new product serialisation data from the European Hub.

- Serving as the verification platform for pharmacies or other registered users such as wholesalers and hospitals to check for a product's authenticity in accordance with the FMD.

- Serving as the platform for wholesalers, to mark a product pack as decommissioned prior to handing it over to the patient in the case of application of Art 23 of the Delegated Regulation by Member States.

- Serving as the platform for wholesalers to mark a product pack as 'decommissioned' e.g. 'exported out of EU' in accordance with the FMD.

2 Connection of On-boarding Partners (OBP) to the European Hub

According to the Delegated Regulation, Original Pack Manufacturers holding a marketing authorisation for the FMD-affected product(s) and Parallel Distributors have to upload unique identifiers and related information to the repositories system before their medicinal products are released for sale or distribution. An On-boarding Partner (OBP) is a legal entity that is authorised to upload unique identifiers and other required information ('OBP Data') on behalf of Original Pack Manufacturers, holding a marketing authorisation for the FMD-affected product(s), and Parallel Distributors or on its own behalf and who concludes the Participation Agreement (PA) with EMVO.

The OBP represents the MAH(s) it will upload data for in the European Hub. Therefore, the MAH(s) has/have to be affiliated[2] to the OBP. The OBP will only be allowed to upload OBP Data for affiliated entities, holding a marketing authorisation or a parallel distribution notice / import license and as long as the marketing authorisation or parallel distribution notice / import license of the related product(s) lies within the OBP corporation. To upload OBP Data to the repositories system, OBPs have to connect their (IT) systems to the European Hub (see White Paper EMVS Data Upload). In order to establish this connection, OBPs have to follow EMVO's On-boarding Process which consists of multiple steps set out below.

OBPs can start with their (contractual) on-boarding to the European Hub, even if they have not put in place any technical measures in their affiliated companies yet, or if the countries to which they supply their products do not have a NMVS in place yet.

EMVO highly recommends that OBPs start as soon as possible with the (contractual) On-boarding to allow the exchange of information between OBP and EMVO.

EMVO distinguishes three roles within a corporation (group of companies):

1. The OBP uploads data on behalf of its affiliated marketing authorisation holders;
2. The manufacturing authorisation holder holds the authorisation to manufacture a product;
3. The marketing authorisation holder holds the authorisation to sell a product in a specific market.

Below we provide you with three examples to give you further insight about how these roles can apply.

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[2] 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.

Example 1:

In this example, "Company A" combines the three roles. It is a manufacturing authorisation holder, a marketing authorisation holder and an OBP at the same time.
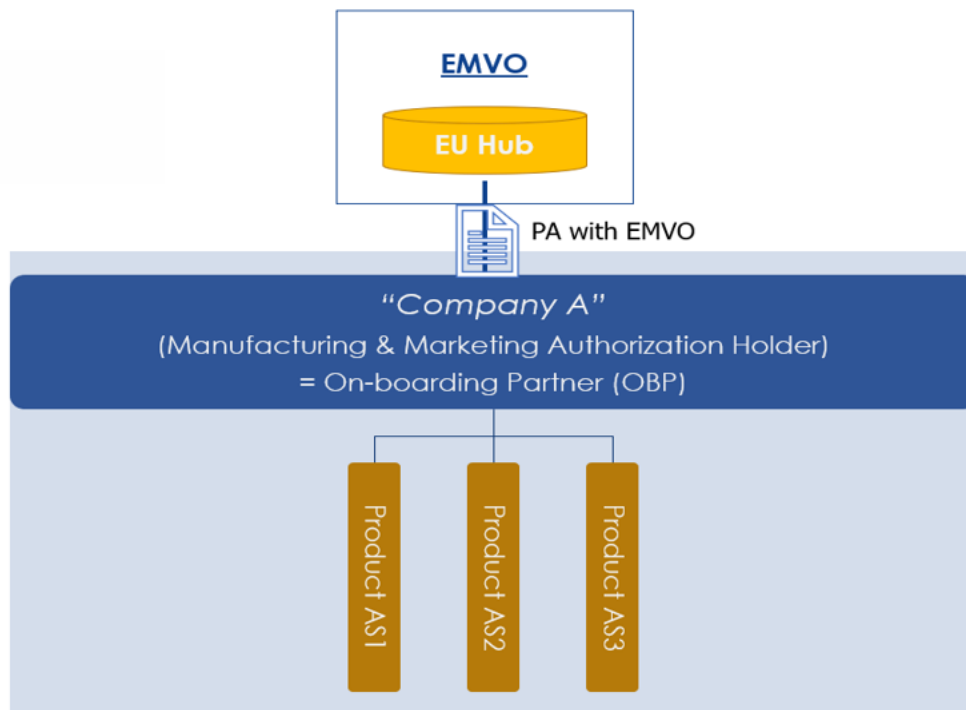

Figure 4: Relationship between the OBP and the EMVO – Example 1

Company A holds (a) manufacturing authorisation(s) and (b) marketing authorisation(s) to market its products in one or several countries in the European Economic Area. As Company A acts as OBP, Company A will conclude a Participation Agreement with EMVO, which will allow it to upload data in the EU Hub, for its own account. The OBP has a connection to the EU Hub and will upload data via that channel.

Example 2:

In this example, "Company A – European headquarter" takes on the role as OBP. In the three other affiliated legal entities, the roles of manufacturing authorisation holder and marketing authorisation holder are combined.
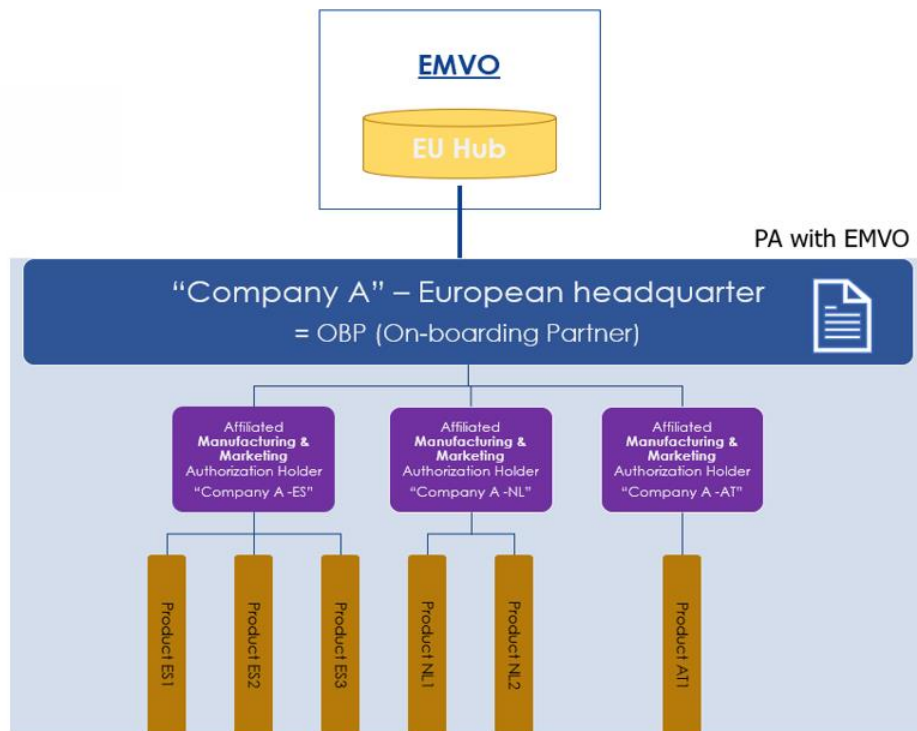
Figure 5: Relationship between the OBP and the EMVO – Example 2

The OBP is the European headquarter of the corporate group. The European Headquarter represents entities among the group that hold (a) manufacturing authorisation(s) and (b) marketing authorisation(s) to market their products in one or several countries of the European Economic Area. The legal entities with marketing and manufacturing authorisations have to be affiliated to the OBP in order to allow it to upload data on their behalf in the EU Hub. The Participation Agreement concluded with the OBP is also binding the affiliated Marketing Authorisation Holders as they are legally responsible for the quality, efficacy and safety throughout the entire life cycle of the product.

Example 3:

In this example we have 2 corporate groups. For each group, the role of OBP is taken on by the European headquarter. The other entities are either manufacturing authorisation holders or marketing authorisation holders or may combine both roles.

This example shows clearly that the Marketing Authorisation Holder determines via which OBP the product data is uploaded to the EU Hub.
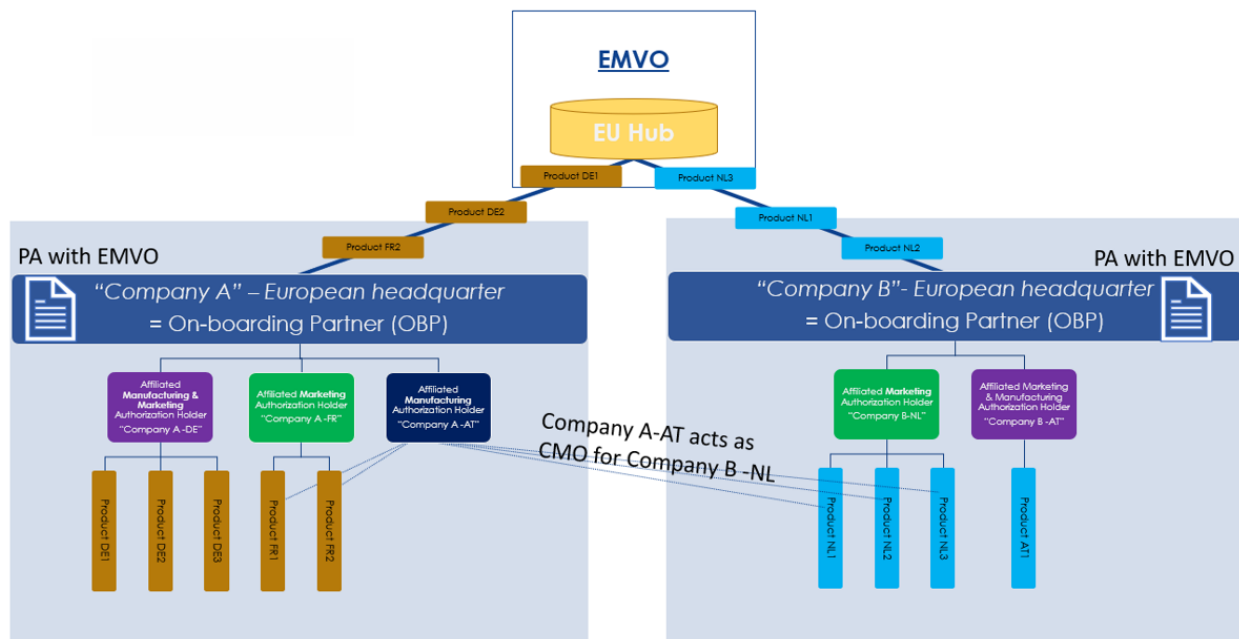

Figure 6: Relationship between the OBP and the EMVO – Example 3

For both entities, the European headquarter acts as OBP. The European Headquarter represents entities among the corporate group, that hold (a) manufacturing authorisation(s) and (b) marketing authorisation(s) to market their products in one or several countries of the European Economic Area.

The legal entities with Marketing Authorisations have to be affiliated to the OBP in order to allow it to upload data on their behalf in the EU Hub. The Participation Agreement concluded with the OBP is also binding for the Marketing Authorisation Holders as they are legally responsible for the quality, efficacy and safety throughout the entire life cycle of the product.

This example illustrates that if a manufacturer among a corporate group (Company A) acts as a contract manufacturing organisation (CMO) for another company being part of another corporate group (Company B), the company that will upload the data corresponding to those products is the legal entity among which the marketing authorisation lies (the parallel import authorisation or parallel distribution notice in the case of parallel distributors). In this example, as Company A in Austria acts as CMO for the Company B in the

Netherlands, the data corresponding to the products manufactured by Company A in Austria (as a CMO for Company B in the Netherlands) will be uploaded via the OBP representing Company B in the Netherlands because the marketing authorisation for those products is held by Company B in the Netherlands.

In this example, Company A in Austria also manufactures products for Company A in France. Company A in Austria has the role of the manufacturing authorisation holder, Company A in France has the role of the marketing authorisation holder and Company A European headquarter has the role of the OBP. Company A in Austria will be allowed to generate the data concerning the products it manufactures for Company A in France and upload this data via the OBP Company A European headquarter, since the marketing authorisation holder of the manufactured products is affiliated to Company A European headquarter.

The OBP will conclude a Participation Agreement with EMVO, which will allow it to upload data in the EU Hub (via the connection it will maintain) on behalf of its affiliated Marketing Authorisation Holders. The Participation Agreement concluded with the OBP is also binding for these affiliated Marketing Authorisation Holders as they are legally responsible for the quality, efficacy and safety throughout the entire life cycle of the product.

3 On-boarding Partner Portal

3.1 Introduction

To facilitate the On-boarding Process to the EU Hub, EMVO provides a user-friendly web-based "EMVO On-boarding Partner Portal (OBP Portal)" that guides the user step by step through the process. The following instructions will help the OBPs to follow the On-boarding workflow.

As a first step of the registration process a company's representative visits the EMVO website and registers on the OBP Portal. Any delegate of the OBP can request access to the OBP Portal. That person is called "Initial Requester" (IR). The Initial Requester will receive personal login credentials for the OBP Portal. To be granted access, the Initial Requester has to provide basic information at the time of the first log-in. Please note that **the Initial Requester will have a 'read only'- view to the OBP Portal as soon as the Participation Agreement is approved** (Step 2.4 of the OBP Portal). As from that moment the person announced as the Single Point of Contact (SPOC) in Step 2.2 of the OBP Portal receives their credentials. This intends to ensure the security of the system and the accuracy of the information provided since it is the responsibility of the SPOC to confirm that the information provided on the OBP Portal is correct. If the Initial Requester and the SPOC are the same person, the initial credentials can be reused, and the role of the Initial Requester will be automatically changed to SPOC to make sure they can change inputted data.

When the Legitimacy Check has been successfully completed, the SPOC Assistant, which is appointed in Step 2.2 of the OBP Portal, will receive credentials to support the SPOC during the Technical On-boarding and the data maintenance. At the moment the Technical On-boarding is reached, the access of the Initial Requester will be revoked to make sure that only the SPOC and/or the SPOC Assistant will have access. For more information, please consult point 3.2.2.2.
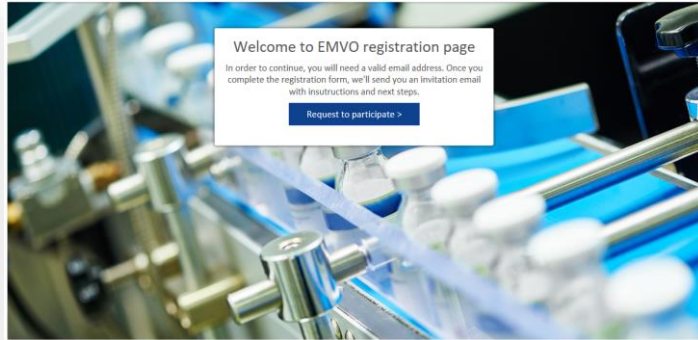
Moreover, if your company acts as an OBP and represents MAH(s) that is/are Original Pack Manufacturer(s) holding the marketing authorisation for the FMD-affected products and, at the same time, represents MAH(s) that is/are Parallel Distributor(s), please advise EMVO through the Helpdesk (helpdesk@emvo-medicines.eu).

• Request to participate	
• Complete company information	

Figure 7: EMVO OBP Portal – Portal Registration

3.2 Steps of the On-boarding Process

Once the registration request is submitted and the OBP confirms the registration by clicking on the link provided by e-mail, EMVO creates a secured area for the OBP within the OBP Portal. The Initial Requester will receive two e-mails. The first email will contain a link to an, dedicated to this company, area on the OBP Portal, where they will be asked to confirm their e-mail address. The second email will provide them with the credentials of the Initial Requester. While accessing the portal they will be shown the below screen with the 4 Steps of the On-boarding process during which they complete and upload (if requested) all necessary On-boarding information [e.g. company information, contact details, product information and a Participation Agreement (PA)]. Step 5 is used to collectively maintain all the OBP information after the OBP has fully On-boarded to the EU Hub.

Step 1: Provide Initial Information ⌄
Step 2: Detailed Information and Participation Agreement ⌄
Step 3: Approvals ⌄
Step 4: Technical On-boarding ⌄
Step 5: Maintenance ⌄

Private Policy   **Terms of Use**   **Cookie Policy**

Figure 8: EMVO OBP Portal – Dashboard

3.2.1 Step 1: Provide Initial Information

Figure 9: EMVO OBP Portal – Initial Information

3.2.1.1 Step 1.1: Company Information

The next step after registration, is for the Initial Requester to provide detailed company information. The following data is required:

1. Name of the company
2. Address of the company
3. VAT number
4. The company's registration or other equivalent identification number (as provided by e.g. chamber of commerce)
5. Company's phone number
6. Company's email address
7. Organisation (Company) type
   Whether the company represents (*)
   a. a Parallel Distributor(s) or
   b. a Original Pack Manufacturer(s)
8. Marketing Activity Status

(*) This choice is of major importance as it determines the functionalities the OBP can use within the EU Hub. An OBP concluding the On-boarding in the OBP Portal can only represent either (an) Original Pack Manufacturer/s or (a) Parallel Distributor/s.

Below we present the difference between the two organisation types and 4 On-boarding cases depending on the organisation type:

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

A) **Parallel Distributor** 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 Competent Authority (NCA) of the destination market (parallel import license) or under comparable permits issued by the European Medicines Agency (EMA) for centrally approved medicines (EMA parallel distribution notice). Parallel distributors must repackage the product that 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.

B) **Original Pack Manufacturer** 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.

1. If the MAH(s) is (are) original pack manufacturer(s) only, the original pack manufacturers can

   choose one common OBP to represent/onboard them.

2. If the MAH(s) is (are) parallel distributor(s) only, parallel distributors can choose one common OBP to represent/onboard them.

3. If some MAH(s) are original pack manufacturers and some are parallel distributors, the parallel distributors choose one common OBP to represent/onboard them AND the original pack manufacturers choose another common OBP to represent/onboard them. Indeed, with respect to technical requirements, both connections are different and therefore, both types of companies cannot be represented under the same OBP connection to the EU HUB.

4. If there is only one MAH/entity which will onboard but it has both organisation types (i.e. it is an original pack manufacturer and parallel distributor at the same time (Hybrid company)), please contact EMVO's Helpdesk for further guidance.

Please pay particular attention to the following elements:

- ✓ Provide the full name of your (OBP) company, as it is registered in official national registers.
- ✓ Make sure to include the full sequence of digits and no typos for your (OBP) company's registration number. Please do not forget to mention the initial country identification letters in front of the VAT Number of your OBP company.
- ✓ Make sure the address you share with us is the one appearing in the official national register.
- ✓ The permissions given in the EU Hub will depend on the organisation type. Any error in the selection of the organisation type may bring the pursuit of the Technical On-boarding at stake.

3.2.1.2   Step 1.2: Authorised Representative Information

In this Step, an Authorised Representative (AR) will be appointed by the OBP. The AR should be a senior officer who is authorised to sign on behalf of the company (for example "Prokurist" in Germany). It may be the person holding the position of CEO, CFO, CIO or a member of the board of Directors depending on each company's internal signatory policies. Only the named AR is able to sign the Participation Agreement (PA) in the name and on behalf of the OBP company. For the sake of consistency, the full name of the AR shall be provided, without translation nor abbreviation, as it appears in the national register. By signing the PA, the OBP also binds all the MAHs for which it will upload data in the EU Hub. At this Step, the OBP will be asked to prove the legitimacy of the Authorised Representative, by attaching a copy of an excerpt from a relevant national register, in order to certify their authorisation to sign on behalf of the OBP ('Copy of Proof'). The Copy of Proof may take the form of an excerpt form from a National Register, Chamber of Commerce, Trade Register, where the Authorised Representative's name will be expressly listed as an authorised person. For your convenience, the national registers providing such Copies of Proof are listed in our website download section (https://emvo-medicines.eu/downloads/) under the name of National Registers for obtaining the Copy of Proof. If you encounter any difficulty in obtaining that document, please advise us.

The Copy of Proof is a prerequisite for EMVO to allow the OBP to pursue with the next Steps of the process. The positive outcome of the Legitimacy Check that will be conducted on the OBP also depends on the provision of a valid Copy of Proof that leaves no doubt about the power of the named Authorised Representative to sign on behalf of the OBP and bind it. Therefore, please make sure that you provide a Copy of Proof meeting the below requirements:

- ✓ Is an excerpt from an <u>official register</u>
- ✓ Expressly lists the named Authorised Representative together with their authorisation and/or their position among the senior management
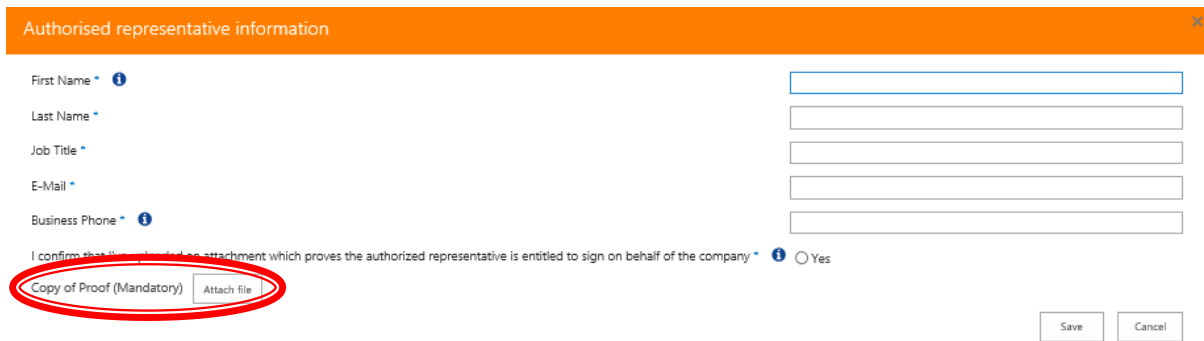- ✓ Is valid (in case it is of limited duration)

Figure 9.1: EMVO OBP Portal – Copy of Proof

The Authorized Representative will:

- sign the Participation Agreement (PA) to enable the OBP to obtain access to the EU Hub;
- confirm the appointment of the Single Point of Contact (SPOC), as a person who has the authority to manage the project for the OBP by signing the PA.

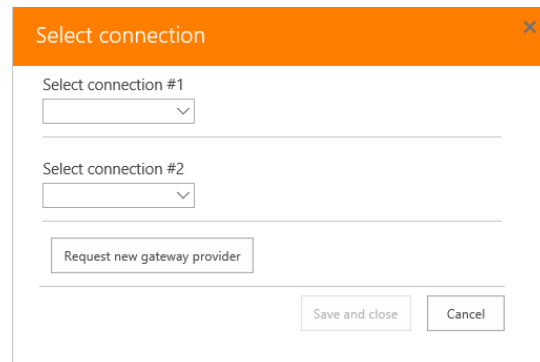### 3.2.1.3   Step 1.3: Pre-technical Connection Information

Figure 9.2: EMVO OBP Portal – Pre-technical Connection Information

If a decision has not been made yet, please note that this step is not mandatory and will be modifiable at any time during the process.

If, as OBP, you chose to make use of a Gateway Connection to upload your data, you will need to sign a contract with a Connection Provider (a third-party provider engaged by the OBP), who will assist with the development, implementation, provision, use and/or operation of the OBP interface to the EU Hub. You will then send your data to the Connection Provider who will then send it through to the European Hub.

The Connection Provider also needs to fulfil special requirements. Therefore, it is important that EMVO is informed as soon as possible about the Connection Provider of your choice.

In this step, you will be asked to submit the contact details of your Connection Provider if:

- you decided to connect via a Gateway Connection
- you already identified your Connection Provider

The *Select Connection* field lists, in a drop-down menu, the Registered Connection Providers. A Registered Connection Provider is a provider which already signed a contract with EMVO and SolidSoft Reply.

Finally, please note that a maximum of two connections will be allowed per OBP.

Figure 9.3: EMVO OBP Portal – Initial Information completed

3.2.2 Step 2: Detailed Information and Participation Agreement

Figure 10: EMVO OBP Portal – Detailed Information and Participation Agreement

3.2.2.1 Step 2.1: General Info Pack

Once Step 1 is completed, a general info pack will be available for download and an email will be sent to the Initial Requester.

This general info pack consists of the following documents:

- EMVO_0086_OBP On-boarding Presentation
- EMVO_0038_EMVO Gateway User Manual

3.2.2.2 Step 2.2: Single Point of Contact (SPOC) and Assistant Information

Figure 10.1: EMVO OBP Portal – Single Point of Contact and Assistant Information

In this step the OBP must appoint a Single Point of Contact (SPOC) and, optionally, a SPOC Assistant (for more information, please see below). The SPOC is the OBP's key contact person for EMVO and is authorised by the OBP via its AR to be in charge of any communication between the OBP and EMVO. Therefore, the SPOC (and the SPOC Assistant if applicable) is responsible, amongst others, for providing the requested information for the OBP on the OBP Portal to enable the establishment of a connection with the EU Hub, for receiving any announcements regarding the EMVS and the On-boarding project from EMVO and dispatching the information to the OBP for appropriate action (if needed). The appointment of a SPOC is mandatory for the OBP and any obligation of EMVO (included in the Participation Agreement or elsewhere) to notify or otherwise inform the OBP is fulfilled once EMVO communicates with the SPOC (and the Assistant) accordingly.

Please note that as soon as the Participation Agreement is approved by EMVO, **the SPOC will receive credentials via e-mail**. As soon as the SPOC uses their credentials and logs in the OBP Portal, **the credentials of the Initial Requester will be adapted to 'read only' mode.** The SPOC will have the possibility to log-off from the account at any time. In the event the Initial Requester is the same person as the SPOC or the Assistant, they will be able to access the OBP Portal with the initially received credentials.

Furthermore, the OBP may appoint an assistant ('SPOC Assistant') who can support the OBP during the Technical On-boarding and the maintenance of its data. The SPOC Assistant will receive their credentials in the moment, the OBP enters Step 4: Technical On-boarding.

Finally, the SPOC and the SPOC Assistant may be changed either before the approval of the Participation Agreement by EMVO or after successful completion of EMVO's Legitimacy Check over the OBP. When modified after the Legitimacy Check, the new SPOC will receive credentials in order to login and the old SPOC's credentials will be revoked.

Important Notes:

Due to quality reasons and communication purposes, it shall be avoided that the entered/appointed SPOC, SPOC Assistant or new persons assigned to the same role, share the same e-mail address. The successful user creation, user permission and access of the SPOC and SPOC assistant is based on the uniqueness of the e-mail address. Therefore, it is of upmost importance to take this point into consideration while entering and maintaining the SPOC and SPOC Assistant.

Please further note, that it may take several hours till the SPOC receives the credentials via e-mail after the Participation Agreement has been approved.

In case, an OBP would like to increase the number of recipients receiving communication from EMVO besides the SPOC & SPOC Assistant (if applicable), EMVO recommends to use a dedicated mailing list/inbox e.g. "serialisation@emvo.eu", as the e-mail address of the SPOC Assistant account. However please note that the e-mail address needs to be linked to a registration of a contact person (forename & last name).

Furthermore, to receive the information with regards to all known problems within the EMVS, EMVO strongly recommends subscribing to the EVI (European Medicines Verification System Information) Alerts for the specific systems of interest.

3.2.2.3 Step 2.3: Participation Agreement

After the completion of all requested information about the SPOC, a pre-filled OBP Participation Agreement (PA) will become available (Step 2.3). Please be aware that the PA is based on a standard template that has been negotiated within a dedicated working group comprised of representatives of the industry, and is strictly NON-NEGOTIABLE.

The OBP acknowledges and agrees that EMVO may amend or supplement the Participation Agreement at any time upon simple notification (typically, by making the updated document available on the EMVO OBP Portal and informing the OBPs via email). Please make sure that you always refer to, download, sign and upload on the Portal the latest Participation Agreement in effect. Please follow the link below to view the standard template.

OBP Participation Agreement (SAMPLE):

[Participation Agreement](#)

3.2.2.4   Step 2.4: Upload signed Participation Agreement

In this step, a scanned copy of the PA, duly completed and signed by the Authorised Representative, must be uploaded on the OBP Portal.

In order to upload the Participation Agreement, it is requested to tick two boxes whereby the OBP:

1) Confirms that the uploaded agreement has not been modified in any way;
2) Agrees that the Participation Agreement becomes effective upon its upload on the OBP Portal, which will be recognised equivalent to a signed original notify to EMVO

Figure 10.2: EMVO OBP Portal – Add Signed Participation Agreement

Please pay particular attention to the following:

- ✓ The name of the Authorised Representative listed in Step 1.2. needs to be the one of the person that actually signs the Participation Agreement[3];
- ✓ No amendments, modifications or other changes of the Participation Agreement are allowed and in case performed, the Agreement will be immediately rejected; the Agreement needs to be uploaded on the Portal duly signed but 'as is'.

Important Note: Appendix 4 of the Participation Agreement constitutes an Addendum applicable only to OBPs established outside the European Economic Area and forming part of the Participation Agreement. It sets out additional safeguards for the protection of the uploaded data. Therefore, only these OBPs are required to sign Appendix 4 of the Participation Agreement, upload it on the OBP Portal along with the Agreement and comply with the provisions therein.

The European Economic Area (EEA) unites the EU Member States, Iceland, Liechtenstein, and Norway. Therefore, countries like Switzerland, United States, Israel, Australia etc. do NOT belong to the EEA and the OBPs established in these countries are required to sign and upload on the OBP Portal Appendix 4.

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[3] In case a change in the Authorised Representative has occurred between execution of any previously signed Participation Agreement and the new Participation Agreement for the Operational Phase, 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 agreement.

Figure 10.3: EMVO OBP Portal – Detailed Information and Participation Agreement upload

The Participation Agreement will have to be approved by EMVO. In the meantime, the OBP will have the possibility to proceed with the next steps on the OBP Portal. However, the approval of the Participation Agreement is a prerequisite to trigger the Legitimacy Check.

Figure 10.4: EMVO OBP Portal – Detailed Information and Participation Agreement approval by EMVO

Upon request of EMVO, the OBP may have to sign a new Participation Agreement. The SPOC will be informed via email that a new Participation Agreement is available in Step 2.3. The already uploaded old Participation Agreement will be indicated as "Deprecated" in Step 2.4 of the OBP Portal then.

Figure 10.5: EMVO OBP Portal – Detailed Information and Participation Agreement deprecated

At this stage, it is also to be born in mind that the OBP needs to have in place a **Letter of Adhesion** with its MAH(s).

The Letter of Adhesion is a letter signed by each MAH and addressed to the OBP, it is represented by with regards to the data upload on the EU Hub.

It is a written statement, foreseen under section 4.6 of the Participation Agreement, with which the MAH adheres to the Agreement between EMVO and the OBP and agrees to be bound by the same obligations as and be jointly and severally liable with the OBP vis-à-vis EMVO.

Via this letter, the MAH also confirms it authorises the OBP to upload its data on the EU Hub on its behalf as well as that it is its affiliate in accordance with the relevant definition in the Participation Agreement. As a result, termination of the Agreement will lead to termination of the adhesion of the MAH (and the letter). For more information regarding affiliation, please consult the information in section '*2 Connection of On-boarding Partners (OBP) to the European Hub*' of this document.

Moreover, please note that there are **two types** of Letters of Adhesion: (i) one for OBPs located in the EEA and (ii) one for non-EEA OBPs.

Both letter types include the same requirements as described above while the non-EEA type includes additional safeguards for the protection of the data as described in Appendix 4 of the Agreement. They can be found on EMVO's Website.

[Letter of Adhesion for EEA OBP Affiliates](#)

[Letter of Adhesion for non-EEA OBP Affiliates](#)

These Letters of Adhesion need to be put in place between the OBPs and their MAHs but they should only be sent to EMVO **upon EMVO's request**. Please do not share with EMVO signed Letters of Adhesion unless requested to do so.

3.2.2.5 Step 2.5: Invoicing Information Form

To cover connection costs, including, but not limited to, the costs of the Legitimacy Check, EMVO charges the OBPs with a one-time On-boarding fee.

The applicable one-time and non-refundable On-boarding fee to be paid by the OBP to EMVO is calculated:

- In respect of the number of MAHs in Europe (European Economic Area and Switzerland) the OBP represents and announces in the Invoicing Information Form (IIF);
- In accordance with the table hereunder.

	PA Operational Phase[4] (Release of the PA for the Operational Phase, 2018/11/05)
OBPs with more than 12 MAHs in Europe	45,000 €
OBPs with 6 to12 MAHs in Europe	22,500 €
OBPs with 3 to 5 MAHs in Europe	18,000 €
OBPs with 2 MAHs in Europe	13,500 €
OBPs with 1 MAH in Europe	6,750 €

Figure 10.6: EMVO On-boarding fee

The Agreement will be considered valid provided all the following conditions are satisfied:

- All pages of the Agreement have been shared with EMVO using the OBP Portal as described above;
- No amendments, changes or other edits have been made to the Agreement;
- The individual(s) signing the Agreement is (are) the individual(s) duly authorised to sign on behalf of the OBP and provide(s) evidence to that respect as per the requirements EMVO has set and communicated to the OBP (3.2.1.2 Step 1.2: Authorised Representative Information)

The Invoicing Information Form will be considered valid, if all the mandatory fields are completed in the requested manner. For more information, please see point 3.2.2.6 below.

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[4] If the OBP has already paid the On-boarding fee under the previous Participation Agreement, it will not be required to pay again an On-boarding fee under the new Participation Agreement for the Operational Phase unless the OBP increases its number of MAHs by notifying EMVO accordingly and which may result in the OBP falling under a higher Onboarding fee category. Please note, that EMVO reserves the right to potentially apply an additional rise of the On-boarding fee.

Important Note: The On-boarding fee is non-refundable. Once the OBP validates on the OBP Portal the number of MAHs it will upload data on behalf of and the Legitimacy Check is triggered, the amount of the On-boarding fee is then definitely calculated, and such amount will be invoiced by EMVO to the OBP. The OBP is solely responsible for ensuring that all information and other data provided to EMVO is accurate, complete, and up-to-date. Hence, as soon as the Legitimacy Check has been triggered, the On-boarding fee becomes definitive, due and non-refundable. Moreover, the OBP acknowledges and agrees that the amount of the On-boarding fee is calculated in accordance to the MAHs' number set out in the Invoicing Information Form which has been uploaded by the OBP and the fee application model described in this section. EMVO may under no circumstances amend, change, reimburse or otherwise refund in any way the amount that has been invoiced to and/or paid by the OBP even if there has been a change in the initial circumstances or a mistake from the OBP's side.

Please ensure to not mix up the number of Marketing Authorisation Holders (MAHs) with the number of Marketing Authorisations (MAs).

OBP Invoicing Information Form (SAMPLE):

[Invoicing Information Form](#)

3.2.2.6 Step 2.6: Upload Invoicing Information Form

When the OBP completes the Invoicing Information Form, an invoice for the On-boarding fee will be issued. If any other document needs to be filled-in by EMVO further to the OBP's internal processes, such request can be addressed to EMVO's Helpdesk (helpdesk@emvo-medicines.eu). The receipt of the payment of the On-boarding fee will be validated as soon as the Legitimacy Check of the OBP has been successfully passed.

The Invoicing Information Form will be also validated by EMVO in terms of the completion of all mandatory fields.

Please note that the access to the Technical On-boarding is conditional upon due payment of the On-boarding fee.

3.2.2.7 Step 2.7: MAH and Product Information

In this step, the OBP has to provide information about the MAHs on behalf of which it will upload data on the EU Hub as well as information about their product(s).

The information on the MAHs will be used to check the legitimacy of the OBP as it is required that the OBP and the MAHs are affiliated. For more information regarding affiliation, please consult the information in section '*2 Connection of On-boarding Partners (OBP) to the European Hub*' of this document.

Please note that, in principle, the products in scope of the Delegated Regulation are products subject to prescription (RX products), with a few exceptions. For more information, please see Article 40 of the Delegated Regulation.

The OBP will be asked to provide EMVO with a list of minimum one (1) and maximum three (3) MAH(s), as well as of minimum one (1) and maximum (3) three product(s) per MAH.

The MAH Information consists of:

- The **MAH Company Name**, which is the full name of the company as it appears in the relevant official national register.
- The **VAT Number**, corresponding to the specific MAH company.
- The **Country of Registration**, which is the country name of the country where the MAH is registered.
- The **Countries of Operation**, which are defined as the target countries/markets, for which the Marketing Authorisation Holder of a product/of products, holds a license for and markets a product/products actively, hence the MAH/OBP uploads data/SNs for the product(s) into the referring NMVS(') of that target market/country of operation. Please be aware that the drop-down menu of this field consists of and allows a multiple selection of the target countries/markets.
- The **Company Registration Number**, which is a unique combination of numbers, at times of numbers and letters. A unique company registration number is assigned as the company is registered on a certain register. The issuing entity differs from country to country. The company registration number can be found on the Certificate of Incorporation, on all official documentation received from the issuing entity or on the excerpts of the register.
- **Address Information** (Street, Number, Box, Zip code, City, Country) as well as Web Page, Company Email Address, Telephone Number and Website Address of OBP.

The Product Information consists of:

- The **Marketing Authorisation Number**, which is the licensed number related to the number of products the MAH received when applying for the Marketing Authorisation to the relevant authority (following a decentralized or a centralized procedure).
- The **Marketing Authorisation Name**, together with the name, please also mention the strength, form and pack size of the product in order to allow EMVO to identify the exact product presentation linked to the Marketing Authorisation Number you provided.
- The **Marketing Authorisation Registration**, which may refer either to the specific country(ies)/market(s) covered by the marketing authorization or to the entire EU.

Note: The type of Marketing Authorisation Registration (e.g. centrally authorised), does not automatically give an information about the country of operation of the MAH. A MAH with a centrally approved MA/Product/s has the possibility to market the product in all granted markets, however an actual marketing of that product in all granted markets might not be the case. Ergo, (a) centrally authorised product(s), does not automatically mean an operation of that MAH in all target markets for that product/those products, hence the detailed information of the country(ies) of operation per MAH is necessary *'Country of Operation'*. Please provide the requested information using the drop-down menu of this field which consists of and allows a multiple selection of the target countries/markets.

Figure 10.7: EMVO OBP Portal – MAH and Product Information overview

To add a product linked to an MAH, the OBP must click on the button '*Show Products'*. In this section product information can be added.

Figure 10.8: EMVO OBP Portal – MAH and Product Information add MAH

Please note that in Step 5: Maintenance, the complete list of MAHs for which the OBP will upload data in the EU Hub will be requested.

For your convenience, the OBP Portal provides the OBP with the possibility to export the existing MAHs list in excel in order to perform the necessary updates. In this way, the OBP can copy/paste existing data in order to avoid filling all new MAH information and product information in, one by one. This will require the OBP to respect the order of the columns listed in Step 2.7 of the OBP Portal. After updating the excel sheet, the OBP can import the updated list on the OBP Portal. Please note that importing the excel sheet will overwrite all existing MAH data in the OBP Portal.

Figure 10.9: EMVO OBP Portal – MAH Data Import Template

3.2.2.8   Step 2.8: Confirm

As soon as all required data is available on the OBP Portal, the '*Confirm*' button at Step 2.8 of the OBP Portal will be enabled.

EMVO will execute a Multi-Stage Legitimacy Check, as soon as the Single Point of Contact (SPOC) confirms all the information entered so far in the OBP Portal. This ensures that only users whose identity, role and legitimacy have been verified, get access to the repositories system.

Important Note: By clicking on the Button "Confirm", the On-boarding fee will be made due, according to the EMVOs On-boarding fee model.

Figure 10.10: EMVO OBP Portal – Detailed Information and Participation Agreement completed

3.2.3 Step 3: Approvals

Figure 11: EMVO OBP Portal – Approvals

3.2.3.1   Step 3.1: Legitimacy Check Status

According to the Delegated Regulation, EMVO has the obligation to put in place security procedures ensuring that only users whose identity, role and legitimacy has been verified can connect to and upload data to the EU Hub. This is fulfilled with the Legitimacy Check conducted by EMVO over the OBP.

Successful completion of this Check is a prerequisite for the OBP to access the next step of the On-boarding process, which is the Technical On-boarding. In case the results of the Check are not successful, the OBP will be informed about the rejection and the respective reasons.

If there is any incorrect or missing information, the OBP will be asked by e-mail to either correct it or to provide additional information via the OBP Portal as requested. In that case, EMVO will reopen the OBP's site on the OBP Portal and as soon as the modifications are performed, the OBP will be asked to confirm, once again, the provided information. This will trigger a second Legitimacy Check.

Upon successful completion of the Legitimacy Check, the OBP will be notified accordingly via the OBP Portal and the status in Step 3.1 will automatically be updated. As from this moment, the SPOC Assistant will receive credentials to the OBP Portal.

Note: It can take several hours till the SPOC Assistant receives the credentials via e-mail after the Legitimacy Check has been successfully passed.

3.2.3.2   Step 3.2: Countersigned Participation Agreement (uploaded on the OBP Portal by EMVO)

EMVO countersigns the copy of the signed by the OBP Participation Agreement found on the OBP Portal and uploads its countersigned scanned copy. This will automatically update the status of Step 3.2 in the OBP's site.

3.2.3.3   Step 3.3: Invoice Status

In order to grant to the OBP access to the Technical On-boarding, receipt of payment has to be confirmed by EMVO.

When the payment receipt is confirmed and the Legitimacy Check's results are successful, Step 4 will be enabled.

Please note that the status in Step 3.3 is updated once **every week**.

Figure 11.1: EMVO OBP Portal – Approvals completed

3.2.4 Step 4: Technical On-boarding

Figure 12: EMVO OBP Portal – Technical On-boarding

The OBP should be aware that as soon as it gets access to Step 4, the Initial Requester account becomes obsolete. As an addition to this Guide, EMVO has made available a video to walk you through the Technical On-boarding steps. Please consult the Knowledge DB on EMVO's Website.

3.2.4.1   Introduction

In order for Original Pack Manufacturers holding a marketing authorisation for the FMD-affected product(s) or for Parallel Distributors holding parallel import license issued by a national competent authority ('NCA') or the European Medicines Agency ('EMA') to upload master data into the EU Hub, a technical connection between the system of the OBP and the EU Hub needs to be in place. During this process, the OBP will get an Organisation ID and 1 or 2 Client ID(s). The Organisation ID reflects the OBP organisation whereas the Client ID's reflect the connections (1 or 2) of the OBP to the EU Hub.

To make this Technical On-boarding process as convenient as possible, Step 4 on the OBP Portal supports the OBP to obtain the necessary information to establish the technical connection.
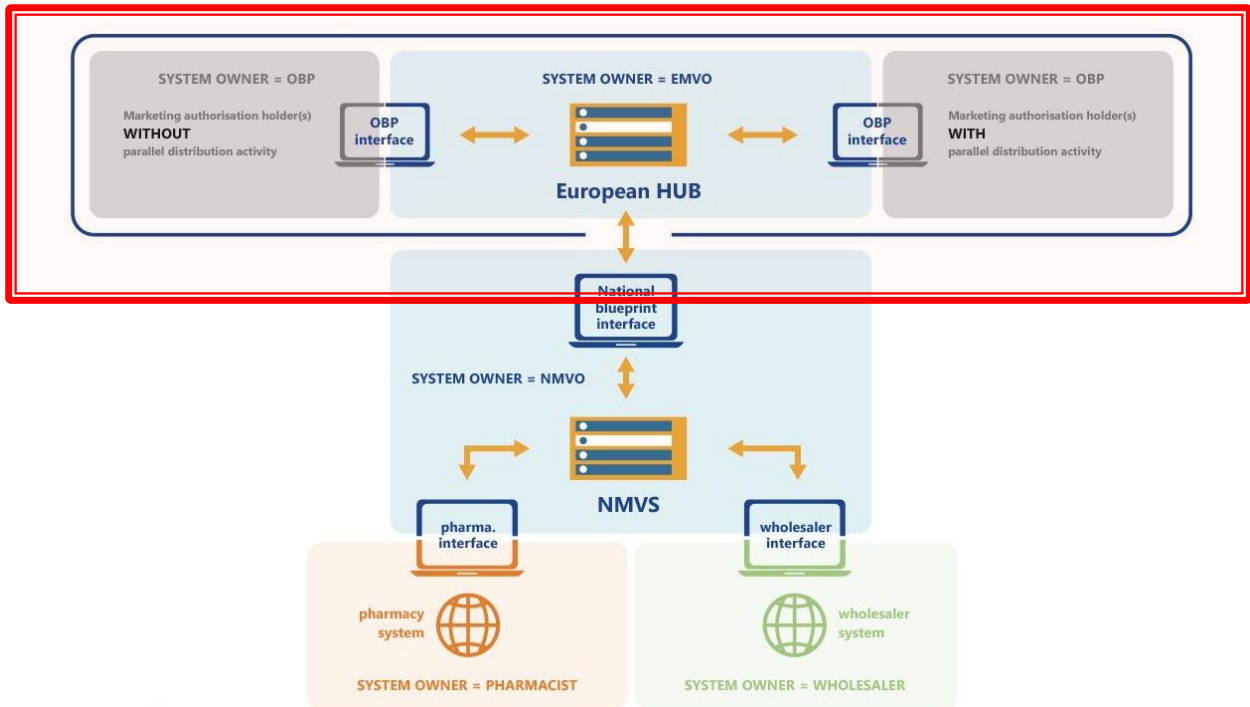
Figure 13: OBP's connection to the repositories system (EU Hub)

3.2.4.2   EU Hub Environments

In the EU Hub, there are three different environments available to make sure that the OBP is connected to the Production Environment (PRD) with a stable and technically qualified connection.

Firstly, the **Integrated Test Environment (ITE)** can be used as a sandbox[5] by the OBP to develop its connection for the first time and perform a first integration test[6].

When the OBP is confident that its interface is ready for testing, it can request access to the **Integrated Quality Environment (IQE)** to execute the test status metrics.

Once the OBP passes the Baseline tests (see below), access will be granted to the **Production Environment (PRD).** Note: Only internal validated systems are allowed to send data to the EU Hub.

From the moment the OBP reaches the PRD, it shall retain a single connection to each environment which can be used to ensure validation activities at any time in the event that a new software is released either by EMVO or the OBP.
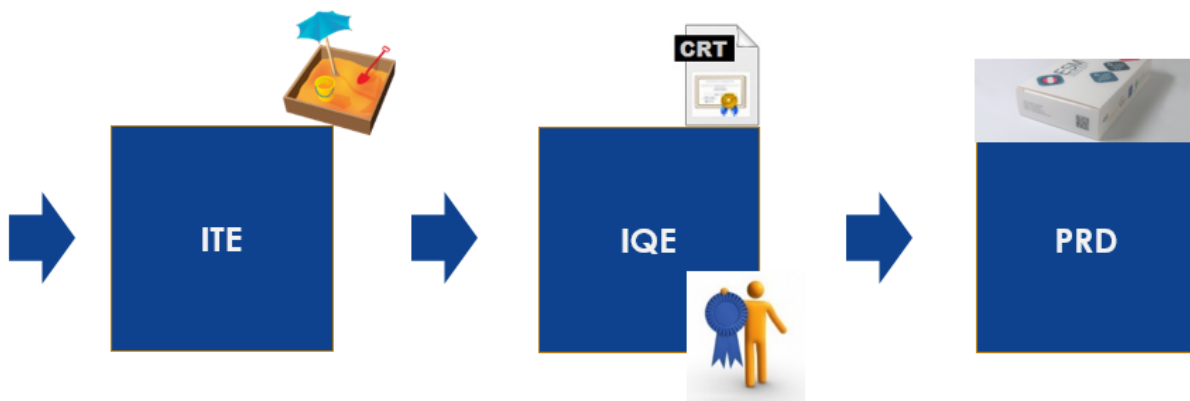
Figure 14: Available Environments for the OBP in the EU Hub

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[5] A sandbox is a type of software testing environment in which the execution, operation and processes of software development and testing is not affected by other running programs.

[6] Integration testing is a type of software testing performed as a first test of the integration or interfaces between the system of the OBP and the EU Hub.

3.2.4.3   Step 4.1: Technical Info Pack

Upon successful completion of the Legitimacy Check, a Technical Info Pack is made available and the OBP will be asked to provide EMVO with the details of the desired connection to the EU Hub.

The Technical Info Pack is a package of several files. In this step the OBP can download and review this Technical Info Pack to start its Technical On-boarding. To make sure the relevant information is used, an overview of the documentation can be found in the Technical Info Pack. Please check this folder regularly for new updated versions of the included documents.

The Technical Info Pack consists of the following documents:

1. Documentation JAVA

    •   20181 MAH SDK

    •   EMVS0787 - EMVS Java SDK Installation Instructions For OBPs

2. Documentation .NET

    •   EMVS0794 - EMVS OBPs .NET SDK Installation Guide

    •   C# SDK Code Sample

    •   .NET Callback

3. EMVO Gateway

    •   EMVO_0038_EMVO Gateway User Manual

4. On-boarding Steps

    •   EMVO_0117_Creating CSR Files

    •   EMVO_0270_Backwards Compatibility Design Note_EU Hub_OBPs

    •   Guidelines for Retrospective Upload as of SR 1.4

    •   EMVS0714 - EMVS SDK for OBPs

    •   EMVO_0077_OBP On-boarding Guideline

    •   EMVO_0086_OBP On-boarding Presentation

3.2.4.4   Step 4.2: Client Connection 1

The OBP can follow the required sub-steps to establish a first technical connection to the PRD environment of the EU Hub.

3.2.4.4.1   Step 4.2.1: Connection Details

Figure 15: EMVO OBP Portal – Connection Details

Once the OBP has reviewed the documentation in the Technical Info Pack, the SPOC should be able to provide EMVO with the details of the desired connection.

These details consist of the following data:

1. Type of Connection
   a. Direct[7]
   b. Gateway[8]
2. Type of technology
   a. .NET
   b. JAVA
3. Client validation Status
   a. Validated

---

[7] With a Direct Connection, the master data will be sent directly from the OBP to the EU Hub.

[8] With a Gateway Connection, the master data will be sent from the OBP to the Connection Provider, who will then send the master data through to the EU Hub.

3.2.4.4.2   Step 4.2.2.1: ITE – Information to create a CSR File

In case the Gateway Connection has been selected Step 4.2.2 (ITE) of the OBP Portal is not available.

Only when the following prerequisites have been met, a client to the ITE of the EU Hub will be created for the OBP:
- PA countersigned and uploaded on the OBP Portal by EMVO;
- Payment of the On-boarding fee received by EMVO;
- Successful completion of the Legitimacy Check;
- Connection details checked and approved by EMVO.

The connection to the ITE is mandatory for any OBP who wishes to have a Direct Connection to the EU Hub. This test environment can be used to develop the connection and to perform some integration testing. When creating a CSR file, a private key will be generated.

The guidelines on how to create a CSR file can be found in the Technical Info Pack (Step 4.1) in the document 'EMVO_0117_Creating CSR files'.

In this step the following information to create the CSR file for ITE will be made available: Organisation Type, Organisation ID, and Client ID.

3.2.4.4.3   Step 4.2.2.2: ITE – Upload CSR File

This step can be used to upload the CSR file. The file is automatically validated in the EU Hub. If the validation of the CSR is successful, step 4.2.2.3 will be available.

Please note that a .key file is generated at the moment of the CSR creation. The OBP should keep this file on a safe location.

3.2.4.4.4   Step 4.2.2.3: ITE – Certificate

In this step the OBP will have access to the following information:

1. Client certificate – downloadable .p7b file

2. Public Hub certificate for ITE Environment – downloadable .cer file

3. The Service Endpoints for the ITE Environment

To use the signed certificate to communicate with the EU Hub, a combination of the certificate itself (.cer) and the private key that was generated along with the CSR is needed. 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. There are a number of tools that can be used to create a PFX file, an example of which can be found in the 'EMVO_0117 Creating CSR Files' document.

3.2.4.4.5   Step 4.2.2.4 ITE – Session Token

After completing Step 4.2.2.3 – ITE – Certificate, the OBP Portal will automatically request a Session Token from EMVO. The OBP will be able to check the current Session Token in the Info Button, as soon as EMVO manually uploads it.

A new Session Token can be requested by clicking the button '*Request New*'. The new Session Token should be requested only if it is absolutely necessary. The OBP should be aware that if a new Session Token is generated while having an already established connection, this connection will be broken.
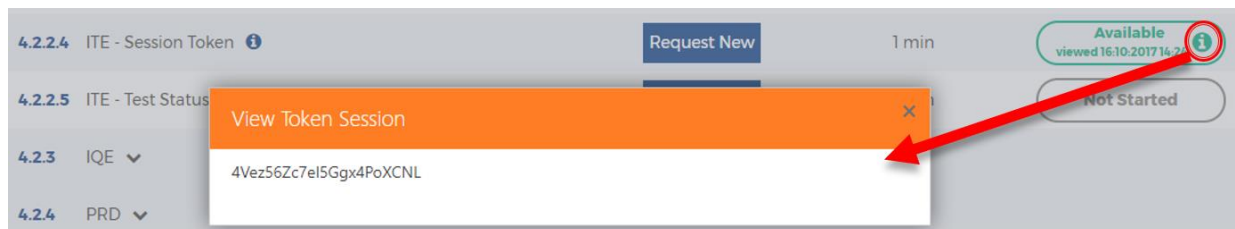
Figure 16: EMVO OBP Portal – View Session Token

3.2.4.4.6   Step 4.2.2.5 ITE – Test Status Metrics

The ITE Test Status Metrics in ITE is a pro-forma self-awareness tool which provides the OBP with a tool to test on dimensions which require interaction with the EU Hub and imparts a level of confidence that the OBP meets certain SDK requirements.

Please find bellow the different dimensions that can be tested in this step:

1. Product Master Data [Simply upload more successful master data payloads than failed attempts]
2. Product Pack Data [Simply upload more successful product pack data payloads than failed attempts]
3. Product Pack Update [Successfully amend the status for any given product/batch combination]
4. Product Pack Verification [Simply request a verification of at least one pack of any already loaded product/batch combination]
5. Batch Recall [Simply request Batch Recall]
6. Report Process [Simply request and successfully receive a report – e.g. product master data]
7. Acknowledgement – (EMVO will no longer support the Acknowledgement test via the OBP Portal)

Important Notes:

a. All tests of the test status metrics should use product data which is uploaded in the emulated markets (XX, XY and XZ).
b. A 30 minutes timeframe is available to execute and check the test results.
c. After the 30 minutes timeframe the status will automatically reset to 'Failed'.

Figure 17: EMVO OBP Portal – Test Status Metrics ITE

If technical support is needed, please fill in this form and sent it to the EMVO Helpdesk:

- **OBP Name**   -
- **Environment Name** - (EMVO ITE, IQE or Production or ISV Sandbox)
- **Connection Type**   - (Gateway/Direct)
- **Middleware used**   - (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 EU Hub)
- **Request Type**   - (e.g. Product Master Data Upload, Session Token Refresh, Report Request, Product Pack Data Upload)

3.2.4.4.7   Step 4.2.3.1: IQE – Information to create CSR File *(same procedure as step 4.2.2.1)*

The guidelines on how to create a CSR file can be found in the Technical Info Pack (Step 4.1) in the document 'EMVO_0117_Creating CSR files'.

In this step the following information to create the CSR file for IQE will be made available:
Organisation Type, Organisation ID, and Client ID

3.2.4.4.8   Step 4.2.3.2: IQE – Upload CSR File *(same procedure as step 4.2.2.2)*

This step can be used to upload the CSR file. The file is automatically validated in the EU Hub. If the validation of the CSR is successful, Step 4.2.3.3 will be available.

Please note that a .key file is generated in the moment of CSR creation. This file should be kept in safe location.

3.2.4.4.9   Step 4.2.3.3: IQE – Certificate *(same procedure as step 4.2.2.3)*

In this step the OBP will have access to the following information:

1. Client certificate – downloadable .p7b file

2. Public Hub certificate for IQE Environment – downloadable .cer file

3. The Service Endpoints for the IQE Environment

Organisation Type, Organisation ID, and Client ID

To use the signed certificate to communicate with the EU Hub, a combination of the certificate itself (.cer) and the private key that was generated along with the CSR is needed. 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. There are a number of tools that can be used to create a PFX file, an example of which can be found in the 'EMVO_0117 Creating CSR Files' document.

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

- Environment (IQE/PRD)
- Tenant / Company Name
- SPOC Name
- SPOC Email

After sending the above information, EMVO will provide the OBP with the credentials and the URL to access IQE through the EMVO Gateway. The credentials and the URL will be sent through the following email: noreply@meliorsolutions.com (please check your junk folder regularly).
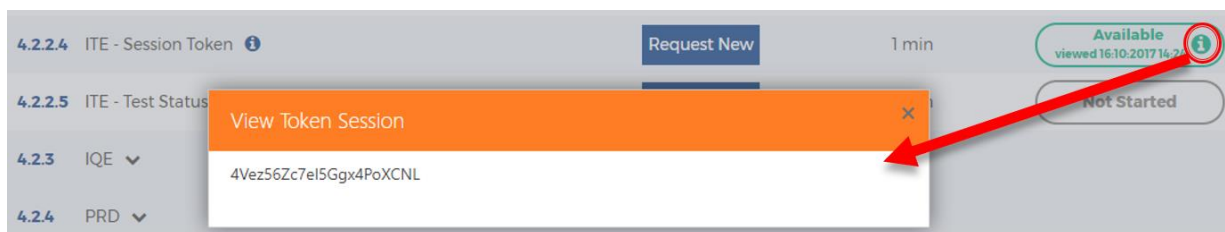
3.2.4.4.10 Step 4.2.3.4 IQE – Session Token

After completing Step 4.2.3.3 – IQE – Certificate, the OBP Portal will automatically request a Session Token from EMVO. The OBP will be able to check the current Session Token in the 'Info' Button, as soon as EMVO manually uploads it.

A new Session Token can be requested by clicking the button '*Request New*'. The new Session Token should be requested only if absolutely necessary. <u>The OBP should be aware that if a new Session Token is generated while having an already established connection, then this connection will be broken</u>.

3.2.4.4.11 Step 4.2.3.5 IQE Test Status Metrics

The IQE Test Status Metrics is a self-awareness tool which provides the OBP with a means to test on dimensions which require interaction with the EU Hub and provide a level of confidence that the OBP meets certain SDK requirements. These dimensions are merely confidence-based and having all test status metrics marked 'Passed' does not mean or imply that the OBP system has been certified or validated or otherwise checked by EMVO. Validation and compliance with the Delegated Regulation remains the responsibility of the OBP in its role as system owner and has to follow the procedures of the OBP's own Quality Management System. EMVO does not assume and expressly disclaims any responsibility and/or liability with respect to the connection of the OBP system and its function in general. The ultimate responsibility for the OBP is to guarantee that the system operates in a correct, error-free and uninterrupted manner, as well as being in compliance with applicable legislation.

Please note that the 'system' of the OBP consists of:

a) The system from which the OBP sends data to the EU Hub.

b) The system of the Gateway Provider (*in case of a Gateway connection*) which is used by the OBP to send data to the EU Hub (*). OBPs connecting via a Connection Provider must have a contract in place with such provider.

(*) With the exception of the EMVO Gateway, which is a system owned by EMVO. The Participation Agreement between the OBP and EMVO entitles the OBP to use the EMVO Gateway in accordance with the terms and conditions set out therein. Please note that EMVO reserves the right, in its own right and without any liability being due to the OBP, to review the provision of the EMVO Gateway in general and to either suspend or discontinue it or otherwise modify its terms by giving prior sufficient notice to the OBP. Moreover, the EMVO Gateway may come at a cost after May 2019.

To gain access to the EU Hub Production Environment (PRD) the first three test dimensions of the test metrics are mandatory to be passed. We refer to these 3 tests as the underlined baseline tests, which are comprised of the following 3 test dimensions:

1. Product Master Data [Simply upload more successful master data payloads than failed attempts]
2. Product Pack Data [Simply upload more successful product pack data payloads than failed attempts]
3. Product Pack Update [Successfully amend the status for any given product/batch combination]

Optional tests:

4. Product Pack Verification [Simply request a verification of at least one pack of any already loaded product/batch combination]
5. Batch Recall [Simply request Batch Recall]
6. Report Process [Simply request and successfully receive a report – e.g. product master data]
7. Acknowledgement – (Note: EMVO will no longer support the Acknowledgement test via the OBP Portal)

Important Notes:

a. All tests of the test status metrics should use product data which is uploaded in the emulated markets (XX, XY and XZ).
b. A 30 minutes timeframe is available to execute, check and submit the test results by clicking the button '*Submit*' in the OBP Portal.
c. After the 30 minutes timeframe the status will automatically reset to '*Failed*' even if the tests were passed and submitted.
d. When the baseline tests have been passed, the OBP will be allowed to on-board to the EU Hub PRD.

Figure 18: EMVO OBP Portal – Test Status Metrics IQE

If technical support is needed, please fill in this form and sent it to the EMVO Helpdesk:

- **OBP Name**   -
- **Environment Name**   - (EMVO ITE, IQE or Production or ISV Sandbox)
- **Connection Type**   - (Gateway/Direct)
- **Middleware used**   - (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 EU Hub)
- **Request Type**   - (e.g. Product Master Data Upload, Session Token Refresh, Report Request, Product Pack Data Upload)

3.2.4.4.12 Step 4.2.4.1: PRD – Information to create CSR File *(same procedure as step 4.2.2.1)*

In this step, the following information will be made available to create the CSR for PRD from the moment the test results of the self-qualification test are checked and approved by EMVO:

Organisation Type, Organisation ID, and Client ID

The guidelines on how to create a CSR file can be found in the Technical Info Pack in the document 'EMVO_0117_Creating CSR files'.

3.2.4.4.13 Step 4.2.4.2: PRD – Upload CSR File *(same procedure as step 4.2.2.2)*

This step can be used to upload the CSR file. The file is automatically validated in the EU Hub. If the validation of the CSR is successful, Step 4.2.4.3 will be available.

Please note that a .key file is generated in the moment of CSR creation. This file should be kept in a safe location.

3.2.4.4.14 Step 4.2.4.3: PRD – Certificate (CER) *(same procedure as step 4.2.2.3)*

In this step the OBP will have access to the following information:

1. Client certificate – downloadable .p7b file

2. Public Hub certificate for PRD Environment – downloadable .cer file

3. The Service Endpoints for the PRD Environment

To use the signed certificate to communicate with the EU Hub, the OBP will need a combination of the certificated itself (.cer) and the private key that was generated along with the CSR. 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. There are a number of tools that can be used to create a PFX file, an example of which can be found in the 'EMVO_0117_Creating CSR Files' document.

3.2.4.4.15 Step 4.2.4.4 PRD – Session Token

After completing Step 4.2.4.3 – PRD – Certificate (CER), the OBP Portal will automatically request a Session Token from the EU Hub. The OBP will be able to check the current Session Token in the '*Info*' Button, as soon as EMVO manually uploads it.

A new Session Token can be requested by clicking the button '*Request New*'. The new Session Token should be requested only if certain it is necessary. The OBP should be aware that if a new Session Token is generated while having an already established connection, this connection will be broken.

3.2.4.5 Step 4.3: Client Connection 2 (if applicable) *(same procedure as Step 4.2)*

The OBP is allowed to establish a second technical connection to the EU Hub. Connection 1 and 2 can be done at the same time. Each client can only have 1 connection.

This step can be used in case the OBP wants a second connection to the EU Hub. There is not difference with the Connection 1 and the OBP can Repeat the previous steps.

If this is desired and useful, this step can be used to establish this connection to the PRD of the EU Hub.

3.2.5 Step 5: Maintenance

When the Technical On-boarding is reached (Step 4), "Step 5: Maintenance" becomes available. This step can be used by the SPOC and/or the SPOC Assistant to update all relevant information which was gathered during the Contractual On-boarding (Steps 1/2/3 of the OBP Portal).

Figure 19: EMVO OBP Portal – Maintenance

Important Note: Please notify EMVO in good time as soon as your OBP, Company or MAH(s) face(s) one of the following scenarios.

1. MA transfers
2. MAH transfers
3. Divestiture and Acquisitions / Mergers and Acquisitions activities

Once uploaded to the HUB, Product Codes (PCs) are technically linked to the OBP which initially uploaded the PC.

A) This can lead to a technical blockage for the new Owner of a PC in case of D&A activities, such as Mergers, Acquisitions or MAH transfers. There are two applicable options for the described scenarios:

1. Change of the PC ownership

    -   The first interim workaround we could apply is to change the PC ownership in the EU Hub from the previous owner to the new owner. However, this would imply a responsibility for the future data uploaded by the new owner as well as for the already uploaded batch/pack data by the previous owner. Additionally, EMVO reserves the right to apply and invoice the resulting costs.. Please click here to consult the costs related to PC ownership changes. The invoice will be sent to the new PC owner.

2. Transferor OBP to continue uploading data and receiving alerts

    -   To address your needs during this period and to not obstruct the upload, we have prepared a letter based on the Participation Agreement that both OBPs have signed. This letter is to be signed by the new Transferor and the Acquirer and to be countersigned by EMVO and inserts a deviation from the upload rules set out in the Agreement. However, please refer to our Knowledge Database on our website where you can find D&A Guideline and the referring Side Letters.

B) **Important Note:** The described scenario might also lead to a technical blockage for the legitimate owner of a PC in case of an incorrectly uploaded PC by another party. In the event of an *#S10 error*, a PC ownership transfer is required. However, the incorrect PC owner will be held liable for any and all damages and/or other losses that may arise as a result of the above. Furthermore, the assignment costs will be borne by the incorrect owner. EMVO reserves the right to apply and invoice the resulting costs. Please click here to consult the costs related to PC ownership changes. The invoice will be sent to the illegitimate owner.

Please do so by contacting the EMVO Helpdesk (helpdesk@emvo-medicines.eu), providing the following information (if applicable).

- Which scenario do you face?
- How many entities are involved and which?
- Who is the Acquirer/New Owner & who is the Transferor/Old Owner?
- How many OBPs are involved and which?
- What is the planned timeframe? / When is the action taking place?
- How many SKUs/Product Codes (PC) are affected?
- Was data uploaded for the affected SKUs/Product Codes (PC)?
    - If yes, for which SKUs/PC?
    - If yes, Product Master Data (PMD) and Product Pack Data (PPD)?
- Who will be the responsible contact person(s)/representative(s) of both parties?

3.2.5.1 Step 5.1 MAH Information

In this step, the OBP can maintain its MAH Information. Here the OBP must provide EMVO with a full list of its affiliated MAHs on behalf of which it will upload data to the EU Hub.

IMPORTANT NOTE: While only the On-Boarding Partner needs to enter into a contractual relationship with EMVO, the respective MAHs must have a contract in place with the NMVOs in the markets of which the product(s) in question is(are) actively being marketed/sold. For example, if an MAH markets/sells products in scope both in Austria and in Belgium, the MAH needs to have a contract in place both with the Austrian and Belgian NMVOs.

The definition of all fields of the MAH and Product Information is available in section '*3.2.2.7 Step 2.7: MAH and Product Information*' of this document.

Note: The type of Marketing Authorisation Registration (e.g. centrally authorised), does not automatically give an information about the country of operation of the MAH. A MAH with a centrally approved MA/Product/s has the possibility to market the product in all granted markets, however an actual marketing of that product in all granted markets might not be the case. Ergo, (a) centrally authorised product(s), does not automatically mean an operation of that MAH in all target markets for that product/those products, hence the detailed information of the country(ies) of operation per MAH is necessary '*Country of Operation*'. Please provide the requested information using the drop-down menu of this field which consists of and allows a multiple selection of the target countries/markets.

MAH and product information

ADD MAH   EXPORT ⬇   IMPORT ⬆   ⓘ   CLOSE

Figure 19.1: EMVO OBP Portal – Step 5.1 MAH and Product Information

The OBP can still add a product which is linked to an MAH, but during maintenance this is not anymore required. The product information was only used during the Legitimacy Check.

To add a product linked to an MAH, the OBP has to click on the button '*Show Products*'. In this section product information can be added.

Please, make sure that every MAH is listed only once.

MAH and product information

Test Company   EDIT MAH   REMOVE MAH   SHOW PRODUCTS (0)

MAH Company Name: Test Company	Country: Belgium	Zip Code: 1000
VAT Number: 5446415	City: Brussel	Company Email Address:
Countries of Operations: Belgium	Street: Teststreet	Web Page:
Registration Number: 1111111	Number: 1	Website Address of OBP:
Country Of Registration: Bulgaria	Box:	Telephone Number:

ADD MAH   EXPORT ⬇   IMPORT ⬆   ⓘ   CLOSE

Figure 19.2: EMVO OBP Portal - Product Information

For your convenience, the OBP Portal provides the OBP with the possibility to export the existing MAHs list in excel in order to perform the necessary updates. In this way, the OBP can copy/paste existing data in order to avoid filling all new MAH information and product information in, one by one. This will require the OBP to respect the order of the columns listed in Step 5.1. After updating the excel sheet, the OBP can import the updated list on the OBP Portal. Please note that importing the excel sheet will overwrite all existing MAH data in the OBP Portal.

3.2.5.2   Step 5.2: Company Information

At this step, all detailed company information, except for the organisation type, can be updated. The organisation type is used to create the account in the EU Hub and gives you the required permissions in the EU Hub, therefore, this information is not editable once an account is created during the Technical On-boarding.

You can update all data included for the first time under *Step 1.1: Company Information*, except for point 7, which refers to the organisation type.

Important Note: As per the Participation Agreement in place with EMVO and before proceeding with the update under Step 5.2 of the OBP Portal, the OBP must notify EMVO accordingly **in advance,** by contacting the EMVO Helpdesk (helpdesk@emvo-medicines.eu).

3.2.5.3   Step 5.3: Single Point of Contact and SPOC Assistant Information

In this step access to the OBP Portal can be modified by the SPOC and/or the SPOC Assistant. If no SPOC Assistant had been assigned yet to the OBP, a SPOC Assistant can be added in this step.

In case a user is filled in and saved, the credentials of the old user will be revoked, and the new user will receive unique credentials.

Important Notes:

Due to quality reasons and communication purposes, it shall be avoided that the entered/appointed SPOC, SPOC Assistant or new persons assigned to the same role, share the same e-mail address. The successful user creation, user permission and access of the SPOC and SPOC assistant is based on the uniqueness of the e-mail address. Therefore, it is of upmost importance to take this point into consideration while entering and maintaining the SPOC and SPOC Assistant.

In case, an OBP would like to increase the number of recipients receiving communication from EMVO besides the SPOC & SPOC Assistant (if applicable), EMVO recommends to use a dedicated mailing list/inbox e.g. "serialisation@emvo.eu", as the e-mail address of the SPOC Assistant account. However please note that the e-mail address needs to be linked to a registration of a contact person (forename & last name).

Furthermore, to receive the information with regards to all known problems within the EMVS, EMVO strongly recommends subscribing to the EVI (European Medicines Verification System Information) Alerts for the specific systems of interest.

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3.2.5.4 Step 5.4: Authorised Representative Information

In this step the OBP can update the Authorised Representative Information which has been initially provided in Step 1.2 of the OBP Portal.

3.2.5.5 Step 5.5: Participation Agreement

Figure 19.3: EMVO OBP Portal – Participation Agreement

The latest Participation Agreement can be viewed in Step 5: Maintenance.

3.2.5.6   Step 5.5.1: Participation Agreement

In this step the SPOC and/or the SPOC Assistant can view and/or download the latest Participation Agreement.

Upon request of EMVO, the OBP may have to sign a new Participation Agreement. The SPOC and/or the SPOC Assistant will be informed via email that a new Participation Agreement is available in Step 5. The already uploaded old Participation Agreement will be indicated as "Deprecated" in Step 5.5.2 of the OBP Portal then.

Figure 19.4: EMVO OBP Portal – Participation Agreement deprecated

For any further information regarding the Participation Agreement, please refer to the point about *Step 2.3: Participation Agreement*.

3.2.5.7   Step 5.5.2: Upload signed Participation Agreement

For any further information regarding the upload of the signed Participation Agreement, please refer to the point about *Step 2.4: Upload signed Participation Agreement*.

The Participation Agreement will have to be approved by EMVO but during maintenance this does not impact the other steps.

3.2.5.8   Step 5.5.3: Countersigned Participation Agreement

EMVO countersigns the copy of the signed by the OBP Participation Agreement found on the OBP Portal and uploads its countersigned scanned copy. This will automatically update the status of Step 5.5.3 in the OBP's site.

3.2.5.9 . Step 5.6: Invoice Management

In this step all relevant information concerning the Invoice Management can be consulted.

Important Note: As per the Participation Agreement in place between the OBP company and EMVO, it is the OBP's obligation to always maintain a complete and updated list of affiliated MAHs and to upload in the EU Hub data only on behalf of these MAHs.

Therefore, and in case the OBP has to update its list of affiliated MAHs in order to add new MAHs on the OBP Portal, the total number of which is higher than the total number of MAHs for which the OBP has already paid the On-boarding fee following the respective invoice or in case the Invoicing Information Form contains inaccurate or invalid OBP information, then the Form will be rejected and a new invoicing process will be launched in Step 5 of the OBP Portal. It is very important that the OBP populates the Invoicing Information Form with the requested information that shall be complete, accurate and correct so that EMVO can proceed with invoicing the OBP accordingly.

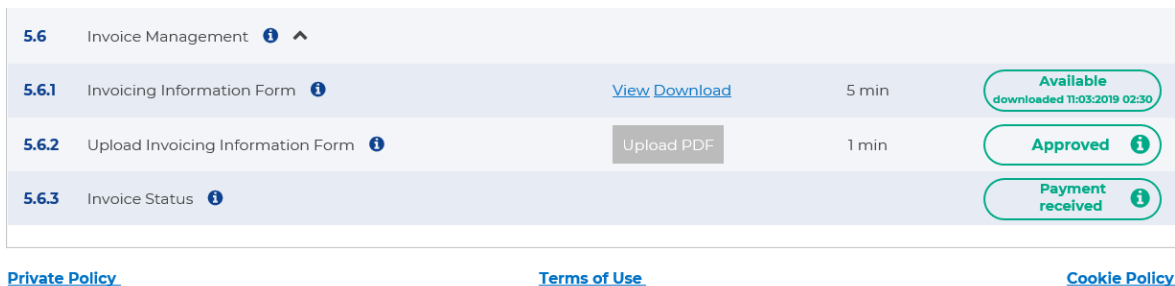The OBP shall contact the EMVO Helpdesk (helpdesk@emvo-medicines.eu) for that purpose.

Figure 19.5: EMVO OBP Portal - Invoice Management

3.2.5.9.1 Step 5.6.1: Invoicing Information Form

In this step the Invoicing Information Form can be viewed or downloaded.

For any further information regarding the upload of the signed Participation Agreement, please refer to the above point about *Step 2.5: Invoicing Information*.

3.2.5.10 Step 5.6.2: Upload Invoicing Information Form

For any further information regarding the upload of the Invoicing Information Form, please refer to the above point about *Step 2.6: Upload Invoicing Information Form.*

3.2.5.11 Step 5.6.3: Invoice Status

The payment status can be viewed here. In case a new payment is required from the OBP, EMVO will manually adapt the Invoice Status to '*Awaiting Payment*'.

Please note that the status in Step 5.6.3 of the OBP Portal will be updated once **every week.**

3.3 Timeline

As the Delegated Regulation entered into force on the 9th February 2019, only serialised packs of medicines falling under the FMD can be placed on the market. The schedule below shows that – taking usual project timeframes into account – introduction for serialisation should begin as early as possible in order to be able to deliver all affected products. In any case, the complexity of the project involves a lot of imponderability's. On-boarding to the EU Hub is only a very small element of the overall manufacturer's/marketing authorisation holder's readiness, e.g.

- Identify products needing safety features

- Determine when to start supplying product with safety features

- Tamper evidence technology

- Plan for budget to cover cost of verification system

- Serialise Pack: AT-Line, carton and artwork, etc.

- Implement serialisation capability on packing lines/site

- Implement rework capability in warehouse/internal distribution

- Establish a Serialisation Data Repository

- Choose an IT Service Provider

- Connection of Contract Manufacturing Organisations (CMOs)

- Validation

- Master Data Management

It should be noted carefully that this process can take more than one year to progress. Any late On-boarding may entail a risk to the company's business. On-boarding to the EU Hub and the internal project to take advantage of the connection, should be set up in parallel. Non-compliance with the FMD legislation or an inability to exchange data with the EMVS puts sales at risk and shortages could then arise. Small companies may be handicapped when it comes to the external services needed (i.e. upgrade of production lines). Finally, there is a danger that a bottleneck will occur if all companies are On-boarding at the same time.

Should this occur, applicants will be dealt with in a very strict, first come, first served basis to ensure fairness to all parties.

4   Contact and Support

In case of questions or uncertainty, the following information, among others, is available on the Knowledge Data Base of EMVO's website:

1. Frequently Asked Questions (FAQ)
2. Documents Overview
3. Video Section

EMVO wants to ensure that all OBPs receive the most accurate and up to date information in the most efficient way. To receive the information with regards to all known problems within the EMVS, EMVO strongly recommends subscribing to the EVI (European Medicines Verification System Information) Alerts for the specific systems of interest.

In case of questions, problems, comments or other uncertainty, requests should be addressed to the following support channels:

1. EMVO's Helpdesk – email address: helpdesk@emvo-medicines.eu
2. EMVO's Helpdesk– phone number: +32 (0)2 657 00 08
3. Contact Form on EMVO's website

Important Note: OBPs should always notify EMVO as soon as they become aware of any issues or problems during their On-boarding process.

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5 Appendix

Organisation Chart