



OBP On-Boarding Guideline

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On-boarding Guideline/Manual

for MAH

(without parallel distribution activity)

and

Parallel Distributors

(MAH with parallel distribution activity)



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://www.emvo-medicines.eu/eu-hub-on-boarding/on-boarding-process/>



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List of abbreviations

AR	Authorised Representative
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
EAEPIC	European Association of Euro-Pharmaceutical Companies
EFPIA	European Federation of Pharmaceutical Industries and Associations
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
ITE	Integrated Test Environment
MAH	Marketing Authorisation Holder
NMVO	National Medicines Verification Organisation
NMVS	National Medicines Verification System
OBP	On-boarding Partner
OBP Portal	On-boarding Partner Portal
PA	Participation Agreement
PD	Parallel Distributor
PGEU	Pharmaceutical Group of the European Union
PRD	Production Environment
RR	Registration Requester
SDK	Software Development Kit
SPOC	Single Point of Contact
UI	Unique Identifier



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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](#) 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 prescription medicines to apply safety features to the outer packaging.

This guideline provides all manufacturers [marketing authorisation holders (MAH)] 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, will apply as of **9th February,**



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2019¹. 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 Falsified Medicines Directive (Directive 2011/62/EU) and the delegated Regulation (EU) 2016/161 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 EAEPIC (the European Association of Euro-Pharmaceutical Companies).



Figure 1: EMVO Stakeholder

EMVO is setting up a pan-European infrastructure of repositories centred on the “European Hub (EU Hub)” which is currently operational in a ramp-up mode. The following system landscape has been selected since

¹ Belgium, Greece and Italy may defer the application of Articles 1-48 of the Delegated Regulation by up to 6 years but Belgium has indicated that the earlier compliance deadline will be followed.

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it ensures effective protection of patient safety and allows the fulfilment of specific requirements in different countries:

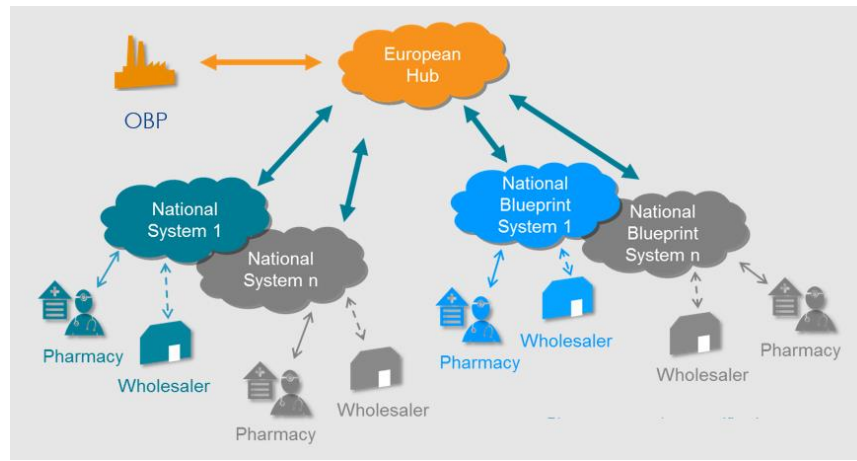


Figure 2: European Medicines Verification Landscape

The European Medicines Verification Landscape as depicted in the figure is composed of a central information and data router (European Hub) and national systems (most of these will be so-called national Blueprint systems i.e. built to a standard template specified by EMVO).

1.4 European Hub

The European Hub is the central element of the European Medicines Verification System (EMVS). The Hub has been operational since 2014 and is currently in ramp-up mode.

The primary purposes for the European Hub are to centralise the uploading of data thereby minimising the number of technical interfaces that have to be supported by all connecting clients, to implement and maintain a set of standardised interfaces that in turn support the overall principles of system interoperability and 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 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.



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

- It provides a single-entry point for MAH without parallel distribution activity and MAH with parallel distribution activity (Parallel Distributors) to upload their product serialisation data.
- 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 MAH without parallel distribution activity and MAH with parallel distribution activity (Parallel Distributors).
- 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 Delegated Regulation Article 34(2), 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 parties such as wholesalers, self-dispensing doctors or hospital pharmacies will use to check a product's 'authenticity'. All data necessary to perform this and other relevant transactions are stored in the respective NMVS.



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The key tasks of the National Systems are:

- Hold the relevant product serialisation data for this market.
- Receiving revised/new product serialisation data from the European Hub.
- Serving as the verification platform for pharmacies or other registered parties such as wholesalers and hospitals to check for a product's authenticity.
- Serving as the platform wholesalers in the case of member states application of Art 23 DR, to mark a product pack as decommissioned prior to handing it over to the patient.
- Serving as the platform for wholesalers to mark a product pack as 'decommissioned' e.g. 'exported out of EU'.



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

According to the DR, MAH without parallel distribution activity and MAH with parallel distribution activity (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 sign on behalf of MAHs without parallel distribution activity or MAHs with parallel distribution activity (Parallel Distributors) and 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 affiliated² to the entity acting as the OBP among the corporation. The OBP company will only be allowed to upload product data for its affiliated MAH(s) and for manufacturers (Contract Manufacturing Organisations) as long as the marketing authorisation of the related product(s) lies within the OBP corporation.

To upload these 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 the (contractual) on-boarding, even if they have not yet put in place any technical measures in their companies, or if the countries to which they supply their products do not yet have a NMVS in place.

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

² Affiliate shall mean, in relation to a Party, any other person affiliated with such Party within the meaning of Article 11 of the Belgian Code of Companies (it being understood, for the avoidance of doubt, that the definition set out in said Article 11 is agreed to also apply to non-Belgian persons).



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EMVO distinguishes three roles within a corporation:

- The OBP: uploads data on behalf of its affiliated marketing authorisation holders
- The manufacturing authorisation holder: holds the authorisation to manufacture a product
- 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 be applied.

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.

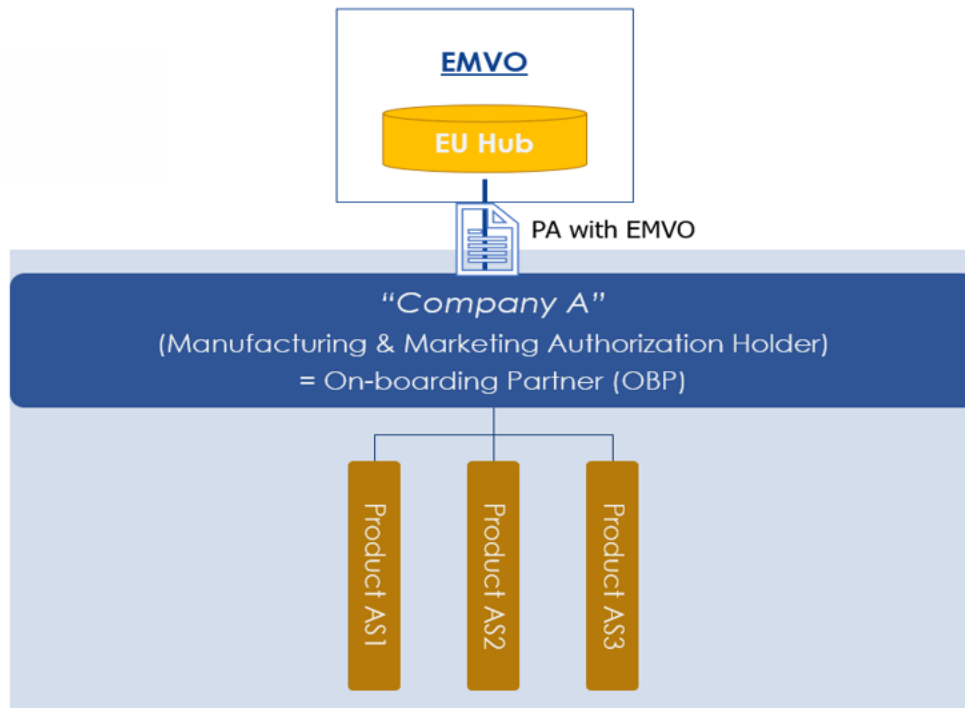


Figure 3: Relationship between the OBP and the EMVO – Example 1



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Company A holds (a) manufacturing authorisation(s) and (a) marketing authorisation(s) to market its products in one or several countries in the EU and/or 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 legal entities the roles of manufacturing authorisation holder and marketing authorisation holder are combined.

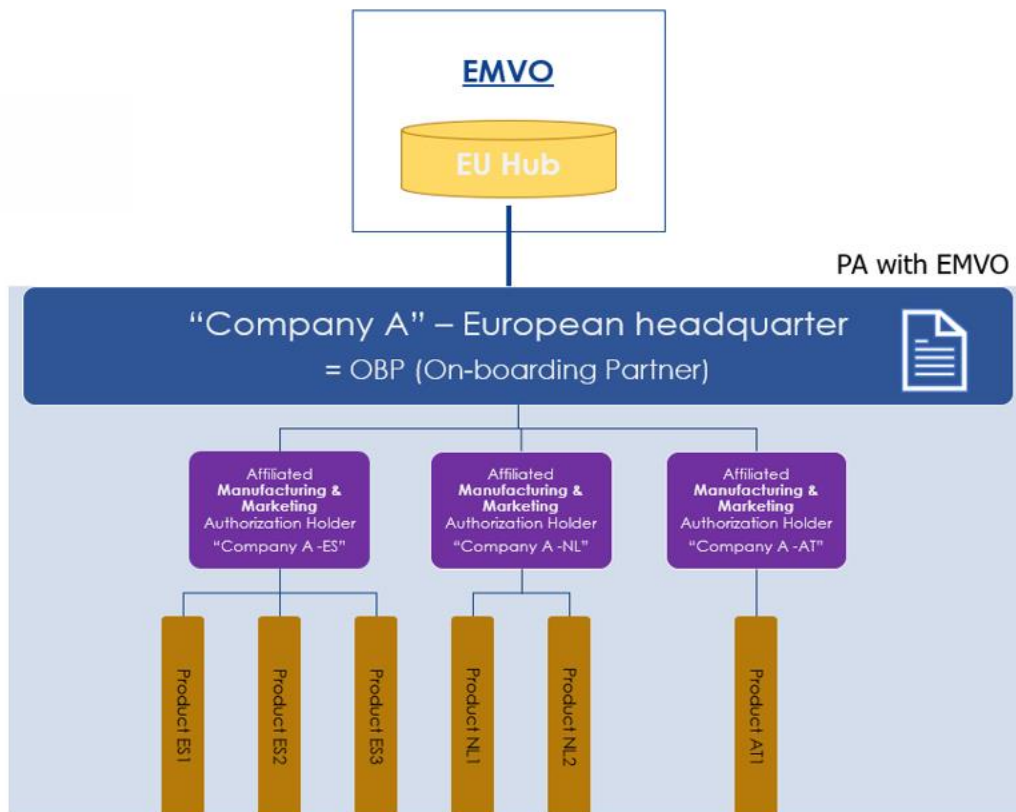


Figure 4: Relationship between the OBP and the EMVO – Example 2



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The OBP is the European headquarter of the corporation. The European Headquarter represents entities among the corporation that hold (a) manufacturing authorisation(s) and (a) marketing authorisation(s) to market their products in one or several countries in the EU and/or 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 by the OBP is also binding the 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 corporations. For each corporation, the role of OBP is taken on by the European headquarter. The other entities are either manufacturing authorisation holder or marketing authorisation holder, or 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.

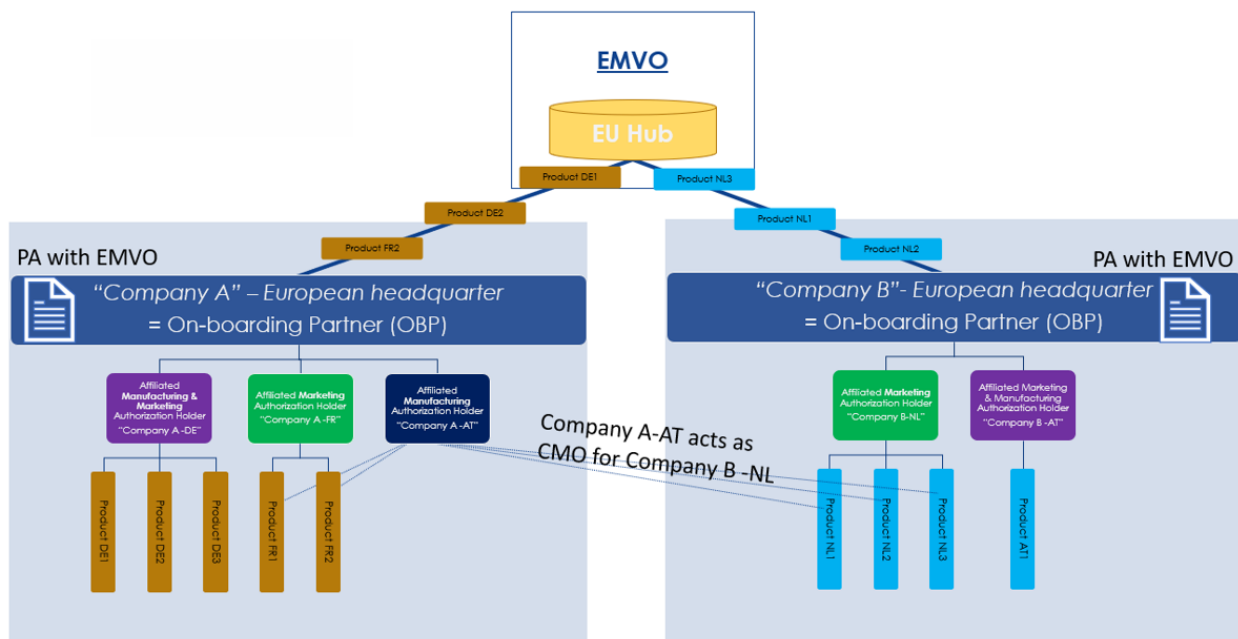


Figure 5: Relationship between the OBP and the EMVO – Example 3



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For both corporations, the European headquarter acts as OBP. The European Headquarter represents entities among the corporation, that hold (a) manufacturing authorisation(s) and (a) marketing authorisation(s) to market their products in one or several countries in the EU and/or 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 by 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 shows clearly that if a manufacturer among a corporation (company A corporation) acts as a contract manufacturing organisation (CMO) to another company being part of another corporation (company B corporation), the corporation that will upload the data corresponding to those products is the corporation among which the marketing authorisation lies. In this example the 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 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 manufacturing authorisation holder, company A in France has the role of marketing authorisation holder and company A European headquarter has the role of 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 the company A.

The OBP will conclude a Participation Agreement with EMVO, which will allow it to upload data in the EU Hub on behalf of its affiliated MAHs. The Participation Agreement concluded by 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. The OBP has a connection to the EU Hub and will upload data on behalf of its affiliated Marketing Authorisation Holders .



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3 On-boarding Partner Portal

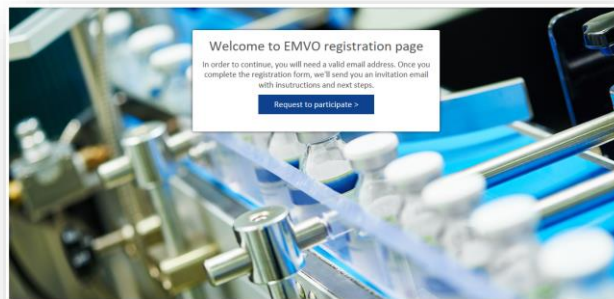
3.1 Introduction

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 representative visits the EMVO website and registers on the EMVO OBP Portal. Any delegate of the OBP is able to request access to the EMVO OBP Portal. That person is called a Registration Requester (RR). The Registration Requester will receive personal login data for the system portal. In order to be granted access, the user has to provide basic data at the time of the first log-in. Please note that **the credentials of the Registration Requester will be revoked when the SPOC contact details will be listed on the portal** (step 2.2), except if the Registration Requester and the SPOC are the same person. This intends to ensure that the security of the system and the accuracy of the information provided since it is the responsibility of the SPOC to confirm the information provided on the portal is correct.

Moreover, if your company represents Marketing Authorisation Holders with Parallel Distribution activities and Marketing Authorisation Holders without Parallel Distribution activities, please advise us through our Helpdesk (helpdesk@emvo-medicines.eu).

- Request to participate





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- Complete company information

Request to participate

User details

First Name
Last Name
e-mail

Company details

Company Name
Country of Registration
VAT Number

Type of Organization

Marketing Authorization Holders (MAH) with Parallel Distribution activity
 Marketing Authorization Holders (MAH) without Parallel Distribution activity

Once your request is submitted we will create a secure area within the EMVO Portal for you to upload all Company information, Contact Details, MAH and Product Information as well as a signed NDA and Participation Agreement.

Submit

Figure 6: EMVO OBP Portal – Portal Registration

3.2 Steps of the On-boarding Process

Once the registration request is submitted, EMVO creates a secured area for the OBP within the OBP Portal. The user will receive two e-mails. This first will contain a link to his OBP Portal area, where he will be asked to confirm his e-mail address. The second will provide him with the credentials of the Registration Requester. While accessing the portal he will be shown the below screen with the 4 steps of the on-boarding process during which he completes and uploads all necessary on-boarding information [e.g. company information, contact details, product information,) and a participation agreement (PA)].

Step 1: Provide initial information

Step 2: Detailed information and participation agreement

Step 3: Approvals

Step 4: Technical onboarding

Figure 7: EMVO OBP Portal – Dashboard



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3.2.1 Step 1: Provide initial information

Step 1: Provide initial information		Time to complete	Status
1.1	Company information ⓘ	5-7 min	Not Started
1.2	Authorised representative information ⓘ	5-7 min	Not Started
1.3	Pre-technical Connection Information ⓘ	5-7 min	

Figure 8: EMVO OBP Portal – Initial information

3.2.1.1 Step 1.1: Company information:

As a next step after registration, detailed company information needs to be provided by the Registration Requester. The following data should be provided:

1. Name of Company
2. Address of Company
3. VAT number
4. The company registration number (as provided by e.g. chamber of commerce)
5. Whether you are
 - a. a MAH without parallel distribution activity
 - or
 - b. a MAH with parallel distribution activity (Parallel Distributors)

NB:

A MAH without parallel distributing activity (e.g. manufacturer) is a producer of original packs/product, not sourced from a repacking operation.



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A MAH with parallel distributing activity (e.g. parallel distributor) is a manufacturer who produces own label packs/product where the content is sourced from a repacking process.

Please pay particular attention to the following elements:

- ✓ Provide the full name of your company, as it is registered in official national registers.
- ✓ Make sure to include the full sequence of digits and no typos for your company 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.

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), the person holding the position of CEO, CFO, CIO or a member of the management board. Only the named AR is able to sign the Participation Agreement (PA) in name and on behalf of the OBP company. By signing the PA, the OBP also engage all the MAHs for which it upload data in the EU Hub. At this step, the OBP will be asked to proof the legitimacy of the Authorised Representative, by attaching a copy of an excerpt from a relevant national register, in order to certify his/her authorisation to sign on behalf of the OBP. The copy of proof has to consist of an external document (an excerpt form from a National Register, Chamber of Commerce, Trade Register,..) where the Authorised Representative name will have to be expressly listed as authorised person. 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 to obtain that document, please advise us.

The copy of proof is an absolute necessity in order 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 company is also made conditional upon the provision of a valid document, a document that would leave no doubt about the authorisation of the named Authorised Representative to sign on behalf of the company. Therefore, please make sure that you provide the copy of proof meeting the above requirements:

- ✓ Is an excerpt from an official register: [National Register list available on the EMVO website](#)
- ✓ Expressly lists the named Authorised Representative together with his/her authorisation and/or his/her position among the senior management



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✓ Is valid with respect to a potential expiration date

Authorised representative information

First Name *

Last Name *

Job Title *

E-Mail *

Business Phone *

I confirm that I've uploaded an attachment which proves the authorized representative is entitled to sign on behalf of the company * Yes

Copy of Proof

Figure 8.1 : EMVO OBP Portal – Copy of Proof

The Authorized Representative will:

- make the official request for access to the EU Hub
- confirm that the SPOC is a legitimate person who has the authority to manage the project in name and on behalf of the OBP
- confirm that the details around the Marketing Authorisation Holders and products are correct
- sign the Participation Agreement (PA) to obtain access to the EU Hub



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3.2.1.3 Step 1.3: Pre-technical connection information

Select connection

Select connection #2
Direct Connection ▼ Edit

Technology Type
▼

Client Validation Status

Request new gateway provider

Save Cancel

Figure 8.2 : 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 Gateway Provider (a third-party contractor engaged by the OBP, who assists with the development, implementation, provision, use and/or operation of the OBP interface to the EU Hub. This assistance can be partial or total). You will then send your data to the Gateway Provider who sends it through to the European Hub.

The Gateway Provider also needs to fulfil special requirements. Therefore, it is important that EMVO is informed as early as possible on the Gateway Provider of your choice.

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

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

The *Select connection* field lists, in a drop-down menu, the Certified Gateway Providers. A Certified Gateway Provider is a provider which already went through the full certification.

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



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3.2.2 Step 2: Detailed information and Participation Agreement

Step 2: Detailed information and participation agreement		Time to complete	Status
2.1	General info pack i		
2.2	Single point of contact information i	5-7 min	Not Started
2.3	Participation Agreement i	1 min	
2.4	Upload Signed Participation Agreement i	1 min	Not Started
2.5	Invoicing Information Form	5 min	Available
2.6	Upload Invoicing Information Form	1 min	Not Started
2.7	MAH and product information i	60 min	Not Started

Figure 9: EMVO OBP Portal – Detailed information and participation agreement

3.2.2.1 Step 2.1: General info pack

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

This general info pack consists of the following documents:

- The On-boarding presentation
- The EMVO Gateway Manual

3.2.2.2 Step 2.2: Single point of contact information

In this step the OBP has to appoint a single point of contact (SPOC) and, optionally, a 'backup SPOC'. The SPOC is the key contact person for EMVO and is authorized by the AR to be in charge of the correspondence between the OBP and EMVO and therefore to be responsible for providing the requested information for the OBP on the On-Boarding Partner Portal in order to establish a connection with the EU Hub.



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Please note that as soon as the SPOC contact details will be listed in step 2.2. of the portal, **the SPOC will receive credentials via e-mail**. By the time the SPOC uses his/her credentials and effectively logs-in on the portal, **the credentials of the Registration Requester will be revoked**. The SPOC has the possibility to log-off from the account at any time. In the event the Initial Registration Requester is the same person as the SPOC, s/he will be able to access the portal with the credential received in the first place.

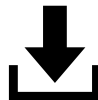
Furthermore, the possibility is offered to OBPs to provide two SPOCs contact details. Still, please keep in mind that **only the first SPOC listed in step 2.2. on the portal will receive credentials**. The second SPOC listed in the portal will only be contacted in the event the first one is not available, for the purpose of correspondence with EMVO and will not receive credentials.

Finally, **if the SPOC contact details need to be amended** because the SPOC person changes, EMVO kindly asks you to **request new credentials**, related to the new SPOC, via e-mail at our support service (helpdesk@emvo-medicines.eu). Credentials will then be generated for the new SPOC and will be shared via e-mail.

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 also the PA is based on the standard template that is strictly NON-NEGOTIABLE. Please follow the link 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 scan of the PA, checked and signed by the Authorised Representative, has to be uploaded in the portal and two signed original hardcopies of the PA have to be sent to the offices of EMVO in Brussels,



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one will be send back to you, double signed by EMVO only when the Legitimacy Check outcome will be successful. The address where the contract is to be sent is the following:

EMVO a.s.b.l
Rue de la Loi 28, box 21
B-1040 Bruxelles
Belgium

Please pay particular attention to the following elements :


- ✓ Consistency between the name Authorised Representative listed in step 1.2. and the person that actually signed the contract
- ✓ No amendments would be taken into account

Two (2) hardcopies have to be sent to EMVO. Both signed and in original versions (not scanned).

Step 2: Detailed information and participation agreement		Time to complete	Status
2.1	General info pack ⓘ Open		Available
2.2	Single point of contact information ⓘ Modify	5-7 min	Completed
2.3	Participation Agreement ⓘ View Download	1 min	Available
2.4	Upload Signed Participation Agreement ⓘ Upload PDF	1 min	Awaiting approval

Figure 9.1 : 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 portal. However, the approval of the Participation Agreement is a prerequisite in order to access the Legitimacy Check.

			
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2.4 Upload Signed Participation Agreement ⓘ Upload PDF 1 min Approved

Figure 9.2 : EMVO OBP Portal – Detailed information and participation agreement approval by EMVO

3.2.2.5 Step 2.5: Invoicing information

To cover administrative connection costs, including the cost of the legitimacy check, EMVO charges a one-time On-boarding fee. The On-boarding fee varies between three-thousand and twenty-thousand Euro depending on the number of marketing authorisation holders in Europe (European Economic Area and Switzerland) the OBP represents and will upload data for in the EU Hub.

OBP Invoicing Information Form (SAMPLE):



[Invoicing Information Form](#)

The following table shows the On-boarding fee with regards to the number of MAHs:

	On-boarding Fee
OBPs with more than 12 MAHs in Europe	20,000 €
OBPs with 6 to 12 MAHs in Europe	10,000 €
OBPs with 3 to 5 MAHs in Europe	8,000 €
OBPs with 2 MAHs in Europe	6,000 €
OBPs with 1 MAH in Europe	3,000 €

Figure 9.3: EMVO On-boarding fee



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3.2.2.6 Step 2.6: Upload Invoicing Information Form

When the OBP completed the Invoicing Information Form, an invoice will be issued for the On-boarding fee. If any other document needs to be filled-in by EMVO for the OBP company internal process, this can be sent to our support service address (helpdesk@emvo-medicines.eu). The receipt of the payment of the On-boarding fee will be checked when a positive outcome will have been issued for the Legitimacy Check of the OBP.

The Invoicing Information Form will also have to be approved by EMVO on the basis of the completion of all mandatory fields.

Please note that the access to the Technical On-boarding is made conditional upon that payment.

3.2.2.7 Step 2.7: MAH and product information

In this step, the OBP has to complete a full list of MAHs on whose behalf the upload of data to the EU Hub is performed. Only for MAHs that are listed in this step, the data upload to the European Hub is permitted. The list of MAHs will also be used to check the legitimacy of the OBP as it is required that the OBP and the MAHs are affiliated. Please note that the products affected by the FMD are products subject to prescription, (Rx products) with a few exceptions. The Article 40 of the Delegated Regulation clearly states it; "*medicinal products subject to prescription are to bear the safety features while medicinal products not subject to prescription are not allowed to. [...] Member States may extend the scope of application of the safety features in accordance with Article 54a (5) of Directive 2001/83/EC.*"

In that section you will be asked to provide EMVO with information regarding the MAHs you will upload data for, as an OBP, and their products information. For the purpose of the Legitimacy Check the OBP will be asked to provide EMVO with a minimum of one and up to three MAH(s), and a minimum of one and up to three product(s) per MAH, up to three. Please note that in the end, the complete list of MAHs for which you will be willing to upload data in the European Hub will be requested, together with at least one related product information. Therefore, this step will always stay available for updates. The products information consist of the following elements:

- The **Marketing Authorisation Number** is the licensed number related to the number of the product that the MAH received when applying for Marketing Authorisation to the relevant entity (following a decentralized or a centralized procedure).



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- The **Marketing Authorisation Name**; together with the name, please 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 would provide.
- The **Marketing Authorisation Registration** refers to the country covered by the marketing authorization and may be centralized; covering the whole EU.

Please note that, for more convenience, the portal offers the possibility for the OBP to copy/paste an excel file 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 3.8.

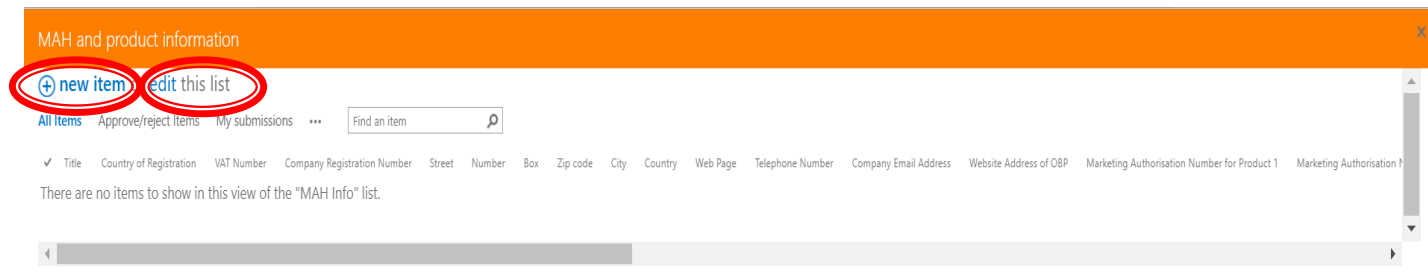


Figure 9.4 : EMVO OBP Portal – Step 2.8 MAH and product information

Indeed, by clicking on “Edit” this list, instead of “new item”, the OBP will have the possibility to copy/paste a file, internally prepared, listing the requested information concerning all its MAH, at once. This excel document has to be elaborated by the OBP following the exact sequence of the columns such as they appear in this section and the relevant information for each of them.

3.2.2.8 Step 2.9: Confirm

As soon as all required data are available in the OBP Portal, a ‘Confirm’ button will appear as step 3.9.

At that step the SPOC is asked to confirm the accuracy of the information provided and a legitimacy check will then be executed.



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Step 2: Detailed information and participation agreement		Complete		
			Time to complete	Status
2.1	General info pack ?	Open		Available
2.2	Single point of contact information ?	View	5-7 min	Completed
2.3	Participation Agreement ?	View Download	1 min	Available
2.4	Upload Signed Participation Agreement ?	Upload PDF	1 min	Approved
2.5	Invoicing Information Form	View Download	5 min	Available
2.6	Upload Invoicing Information Form	Upload PDF	1 min	Approved
2.7	MAH and product information ?	Verify	60 min	Completed
2.8	Confirm all inputted information ?	Confirm		

Figure 9.5 : EMVO OBP Portal – Detailed information and participation agreement completed

3.2.3 Step 3: Approvals

Step 3: Approvals			
		Time to complete	Status
3.1	Legitimacy check status ?	15 days	In Progress
3.2	Countersigned Participation Agreement send back to OBP ?	21 days	Awaiting Hardcopy
3.3	Invoice status ?		Awaiting payment

Figure 10 : EMVO OBP Portal Approvals

3.2.3.1 Step 3.1: Legitimacy check status

The access to the next step, e.g. Technical On-boarding, is made conditional upon the successful completion of a legitimacy check . In case the check is not successful, the OBP will be informed about the



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reason of rejection. The OBP may be informed of incorrect/missing information and will be asked by e-mail to correct and/or provide further proof of the veracity of the information filled-in on the OBP Portal. In that case, EMVO will reopen the site of the OBP on the portal and when the modifications will have been done, the OBP will be asked to confirm, once again, the information provided. This will trigger a reviewed legitimacy check.

When the legitimacy check will be reported as positive, this will be notified in the OBP portal and the status in step 3.1 will automatically be updated.

3.2.3.2 Step 3.2: Countersigned Participation Agreement sent back to OBP

In the event of a positive outcome of the legitimacy check, EMVO countersigns the Participation Agreement of the OBP. EMVO uploads a scanned copy of the countersigned PA in the Portal. This will automatically update the status of step 3.2 in the OBP site. EMVO then sends one hardcopy back to the OBP company, to the attention of the Authorised Representative.

3.2.3.3 Step 3.3: Invoice status

In order to grant 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 outcome is successful, step 4 will be opened for the OBP.

Step 3: Approvals		Complete	
		Time to complete	Status
3.1	Legitimacy check status	15 days	Passed
3.2	Countersigned Participation Agreement send back to OBP View	21 days	Sent on 27:06:2017
3.3	Invoice status		Payment Received

Figure 10.1 : EMVO OBP Portal – Approvals completed



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Please note that the status in step 3.3 will be updated **every two weeks**.

3.2.4 Step 4: Technical On-boarding

Step 4: Technical onboarding			Time to complete	Status
4.1	Technical InfoPack ?	Open	1 min	Not Started
4.2	Client Connection 1			
4.2.1	Connection Details ?	Add	1 min	Not Started
4.2.2	ITE ▼			
4.2.3	IQE ▼			
4.2.4	PRD ▼			
4.3	Client Connection 2			
4.3.1	Connection Details ?	Add	1 min	Not Started
4.3.2	ITE ▼			
4.3.3	IQE ▼			
4.3.4	PRD ▼			

Figure 11.1 : EMVO OBP Portal – Technical On-boarding



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3.2.4.1 Introduction

In order for MAHs without parallel distribution activity and MAHs with parallel distribution activity (Parallel Distributer) to upload master data into the EU Hub, a technical connection between the system of the OBP and the EU Hub need to be in place. To make this as convenient as possible, step four in the OBP Portal supports the OBP to obtain the necessary information to establish this technical connection.

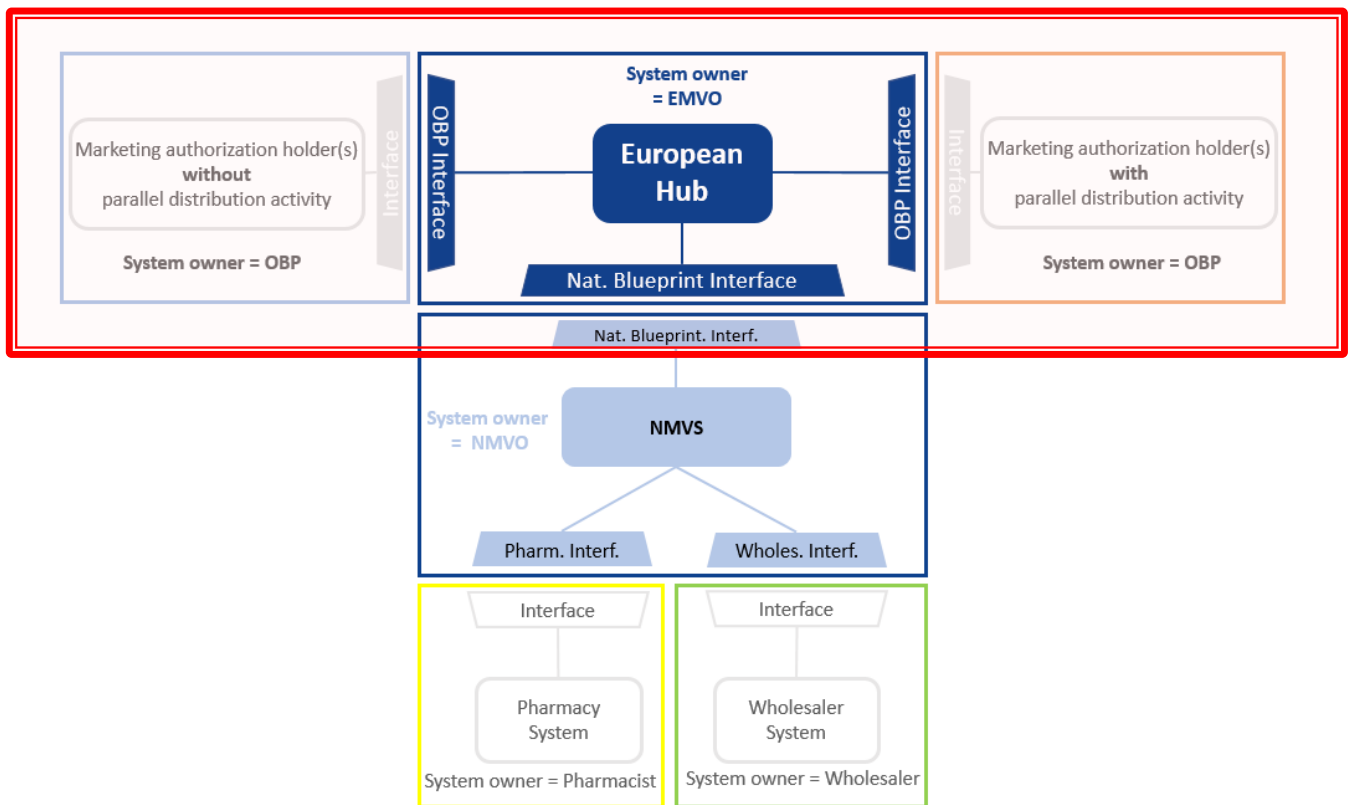


Figure 11.2 : OBP's connection to the repositories system (EU Hub)



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3.2.4.2 EU Hub Environments

In the EU Hub three different environments are utilized to make sure that the OBPs are connected to the Production Environment (PRD) with a stable and certified connection.

The first **Integrated Test Environment (ITE)** can be used as a sandbox³ by the OBPs to perform the first development of the connection and do a first integration test⁴.

When the OBP is confident that his interface is ready for testing, (s)he can request access to the **Integrated Quality Environment (IQE)** to perform the Quality & Certification test.

After the OBP passed the Quality & Certification test (which is primarily a self-certification process), access will be granted for the **Production Environment (PRD)**. Only validated systems are allowed to send data into the EU Hub.

From the moment, the OBP reaches the PRD he will retain a single connection to each environment which can be used for recertification at any time in the event that new software is released either by EMVO or the OBP.

³ 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.

⁴ 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.

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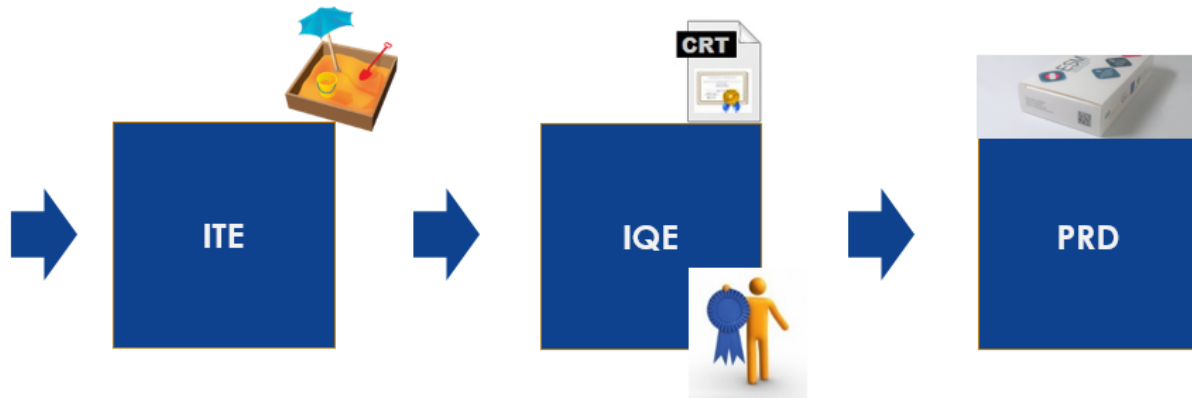


Figure 11.3 : Available Environments for the OBP in the EU Hub

3.2.4.3 Step 4.1: Technical info pack

When the outcome of the legitimacy check is positive, a technical info pack will be made available and the OBP will be asked to provide EMVO with the details of the desired connection to the EU Hub.

In this step the OBP can download and review this technical info pack to start the technical on-boarding. EMVO do not make a distinction between type of connection and type of organisation when the documentation is provided. This means not all documents in this info pack are relevant for every OBP.

To make sure the relevant information is used, an overview of the documentation can be found in the technical info pack.

The technical info pack consists of following documents, in their last available versions:

- 1) Documentation .NET
 - a. .Net Callback Service
 - b. .Net Hub 2.0 SDK
 - c. EMVS0794 - EMVS OBPs .NET SDK Installation Guide
- 2) Documentation JAVA
 - a. EMVS0787 - EMVS Java SDK Installation Instructions For OBPs
 - b. EMVS Java SDK_MAH_Hub_2.zip
- 3) On Boarding Steps
 - a. EMVO_0077_OBP On-boarding Guideline
 - b. EMVO_0086_OBP On-Boarding Presentation_
 - c. EMVO_0117_Creating CSR Files



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- d. EMVS0714 - EMVS SDK for OBPs
- e. EMVS0789 - EMVS SDK Quick Start Guide For OBPs

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 of the EU Hub.

3.2.4.4.1 Step 4.2.1: Connection details

Select connection

Select connection #2
Direct Connection ▼ Edit

Technology Type
▼

Client Validation Status

Request new gateway provider

Save Cancel

Figure 11.4 : EMVO OBP Portal – Connection details

After the OBP has reviewed the documentation in the technical info pack the SPOC should be able to provide EMVO the details of the desired connection.

This details consist of the following data:

1. Type of Connection



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- a. Direct⁵
- b. Gateway⁶
2. Type of technology
 - a. .NET
 - b. JAVA
3. Client validation Status
 - a. Validated

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

Only when the following prerequisites have been met, an account for the OBP to ITE of the EU Hub will be created:

- PA countersigned by EMVO
- On-boarding fee received
- Outcome legitimacy check positive
- Connection details checked and approved by EMVO

In this step of the OBP Portal the following information to create the CSR file for ITE will be made available:
Organisation ID + Client ID

The connection to the ITE is obligated for any OBP who desires a Direct Connection. This test environment can be used to develop the connection and to perform some integration testing.

3.2.4.4.3 Step 4.2.2.2: ITE – Upload CSR file

When the OBP is in the possession of the information to create the CSR file, the OBP can create the CSR file for ITE. During the creation of the CSR file a private key and an unsigned public key are generated. This step can be used to upload the CSR file.

⁵ With a Direct Connection, the master data will be sent directly from the OBP's client to the EU Hub

⁶ With a Gateway Connection, the master data will be sent from the OBP's client to the Gateway provider, who sends the master data through to the EU Hub



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3.2.4.4.4 Step 4.2.2.3: ITE – Certificate

The PFX (contains the private and public key), this is used with communications to the Hub along with the Hub certificate and CA certificates.

The PFX is created by the OBP using the client certificate (.cer) and the client private key.

The client certificate is created by submitted the CSR file to the portal. This returns the .p7b file containing the .cer and the CA certificates.

The CSR file is generated by the private key. The reason for this is to keep the private key safe and avoid sending it to the server.

The Service Endpoints will also be available in this step, for the ITE environment.

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 to EMVO. You will be able to check the current Session Token in the Info Button, as soon as EMVO uploads it.

If necessary, a new session token can be requested by clicking Request New.

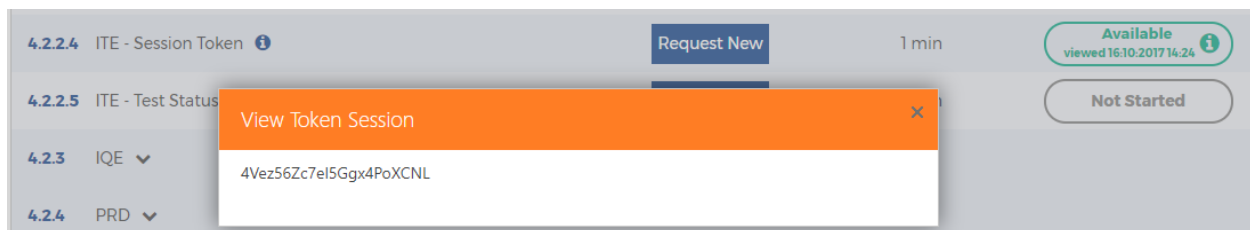


Figure 11.5 : EMVO OBP Portal – View Session Token

3.2.4.4.6 Step 4.2.2.5 ITE – Test Status Metrics

(Optional) In this Step the OBP can verify the results of all the data sent to the HUB in the last 30 minutes.



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Test results for 'ITEHub'×

Environment	ITEHub
Test Time Period	60 minutes
Organisation ID	1673
Client ID	1
Product Master Data	Failed
Product Pack Data	Failed
Product Pack Update	Failed
Product Pack Verification	Failed
Batch Recall	Failed
Report Process	Failed
Acknowledgements	Failed

CLOSE

Figure 11.6 : EMVO OBP Portal – Test Status Metrics ITE

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

In this step, again the following information will be made available to create the CSR for IQE from the moment the OBP request access to IQE:

Organisation ID + Client ID

The guidelines on how to create a CSR file can be found in the technical info pack in document EMVO_0117_Creating CSR files



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The connection to ITE can be skipped for the OBPs who desire a connection via a Gateway Provider⁷. In this case, OBP should contact their gateway provider to request a connection to their dedicated ITE. The information to create the CSR file for IQE will be available immediately in order to perform the self-certification test.

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

When the OBP is in the possession of the information to create the CSR file, the OBP can create the CSR file for IQE. During the creation of the CSR file a private key and an unsigned public key are generated. This step can be used to upload the CSR file.

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

The PFX (contains the private and public key), this is used with communications to the Hub along with the Hub certificate and CA certificates.

The PFX is created by the OBP using the client certificate (.cer) and the client private key.

The client certificate is created by submitted the CSR file to the portal. This returns the .p7b file containing the .cer and the CA certificates.

The CSR file is generated by the private key. The reason for this is to keep the private key safe and avoid sending it to the server.

The Service Endpoints will also be available in this step, for the IQE environment.

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 to EMVO. You will be able to check the current Session Token in the Info Button, as soon as EMVO uploads it.

If necessary, a new session token can be requested by clicking Request New.



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For OBP's using the EMVO Gateway, at this point the PFX Certificate and Session Token should be sent to the Helpdesk (helpdesk@emvo-medicines.eu). EMVO will then provide the Credentials and URL to access IQE through the EMVO Gateway.

3.2.4.4.11 Step 4.2.3.5 IQE Test Status Metrics

In this Step the OBP should verify and submit the results of the positive transactions which are sent to the EU Hub for the last 30 minutes and will cover the basic requirements. In the current version SR 1.3 of the HUB, Batch Recall and Acknowledgments tests can be skipped as these features are not implemented in the HUB. All the other basic transactions should be passed in order to have access to PRD. As soon as the required Tests are passed, the OBP should click 'Submit' so that EMVO can approve the received Test Results.

Test results for 'IQEHub' ✕

Environment	IQEHub
Test Time Period	60 minutes
Organisation ID	1673
Client ID	3
Product Master Data	Failed
Product Pack Data	Failed
Product Pack Update	Failed
Product Pack Verification	Failed
Batch Recall	Failed
Report Process	Failed
Acknowledgements	Failed

SUBMIT CLOSE

Figure 11.7 : EMVO OBP Portal – Test Status Metrics IQE



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3.2.4.4.12 Step 4.2.4.1: PRD – Information to create CSR file *(same procedure as step 5.2.2.1))*

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

The guidelines on how to create a CSR file can be found in the technical info pack.

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

When the OBP is in the possession of the information to create the CSR file, the OBP can create the CSR file for PRD. During the creation of the CSR file a private key and an unsigned public key are generated. This step can be used to upload the CSR file.

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

The PFX (contains the private and public key), this is used with communications to the Hub along with the Hub certificate and CA certificates.

The PFX is created by the OBP using the client certificate (.cer) and the client private key.

The client certificate is created by submitted the CSR file to the portal. This returns the .p7b file containing the .cer and the CA certificates.

The CSR file is generated by the private key. The reason for this is to keep the private key safe and avoid sending it to the server.

The Service Endpoints will also be available in this step, for the PRD environment.

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 to EMVO. You will be able to check the current Session Token in the Info Button, as soon as EMVO uploads it.

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.

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



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3.3 Timeline

Once the FMD effectiveness date comes into force on 9th February 2019, only serialised packs of medicines can be placed on the market. The schedule below shows that – assuming the usual project times – introduction for serialisation should begin as early as possible in order to be able to deliver all affected products at the start of February 2019. 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. 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.



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4 Contact and support

In case of questions, the following information are available to users:

1. Frequently Asked Questions (FAQ) on the [EMVO website](#)
2. Frequently Asked Questions (FAQ) of [European Commission](#)
3. EMVO-helpdesk: helpdesk@emvo-medicines.eu

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5 Appendix

1. Organisation chart

