OBP ON-BOARDING GUIDELINE – OBP PORTAL APPLICATION

Revision History

Version Date	Version	Author	Reason for Changes
18-MAR-2021	1.0	Tracy Slosse	Initial Request.
12-JUN-2024	2.0	Sabra Kapalanga	Update from EMVO Portal to OBP Portal Application

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/

Legal Notices

Copyright

Disclaimer

The information in this publication may change from time to time. You must always refer to the latest available version.

This document and the related PowerPoint presentation (altogether the "Guides") are provided "AS IS" by EMVO. They are provided for your information only and do not amount to professional advice or recommendations from EMVO. No warranty of any kind is made or given by EMVO with respect to these Guides or use thereof, including, but not limited to, as to the accuracy or the completeness thereof. Use of these Guides is at your own risks and perils. To the fullest extent permitted by applicable law, EMVO expressly disclaims all warranties of any kind, whether expressed or implied, including, but not limited to the warranties for hidden or latent defect, of merchantability, fitness for a particular purpose and non-infringement. EMVO shall not be liable for any direct or indirect damage, loss or claims, including loss of use, data, profits, benefits, data, business, opportunity, goodwill, clientele, for third party's claims, or for any other indirect, special, incidental or consequential damages of any kind in connection with or arising out of the use of any information disclosed hereunder, whether alleged as a breach of contract (including grave fault), tort, negligence (including gross negligence), hidden/latent defects, strict liability or any other legal theory, even if EMVO had been advised of the possibility of such damage. Nothing herein shall, however, operate to limit or exclude any liability for fraud or other liability that cannot be legally excluded. EMVO reserves the right to amend these Guides at any time without prior notice.

Translations

The English version of the EMVO documentation is the only official and binding version.

Trademarks

EMVO is the trade name of the European Medicines Verification Organisation A.S.B.L.

Other product or company names in this publication are trade names, trademarks, or registered trademarks of their respective owner.

Important

EMVO refers herein to the European Medicines Verification Organisation A.S.B.L., having its registered address at Rue du Commerce 123, B-1000 Brussels, in Belgium.

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 OBP Portal and submitting all requested information, including, but not limited, to the single point of contact information, billing details, the MAH and product information in accordance with the Guides as published by EMVO from time to time, and a valid and duly signed Participation Agreement.

- 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.

- Ensuring all information, data or other materials supplied through or in connection with EMVO's Onboarding Process are accurate, complete, and up to date.

EMVO validates the information, data, or other materials made available by the On-boarding Partners through EMVO's Onboarding Process only if and to the extent expressly documented in these Guides and in which case such validation is performed in accordance with the principles set out in these Guides. Any such validation does not waive or otherwise affect the ultimate responsibility of the On-boarding Partner for the content of the provided information, data or other material.

Table of Contents

List of abbreviations

AR	Authorized 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
EAEPC	European Association of Euro-Pharmaceutical Companies
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 Authorization
MAH	Marketing Authorization 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	Partner Portal, that includes the On-boarding module
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 the European and international levels. 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 Authorization 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 the pharmacy level). Medicines at higher risk of falsification should additionally be checked at the wholesaler level. To make this possible, a repository 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 Affordable Medicines Europe (the European Association of Euro-Pharmaceutical Companies).

Figure 1: EMVO Stakeholders – founding members

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

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

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 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:

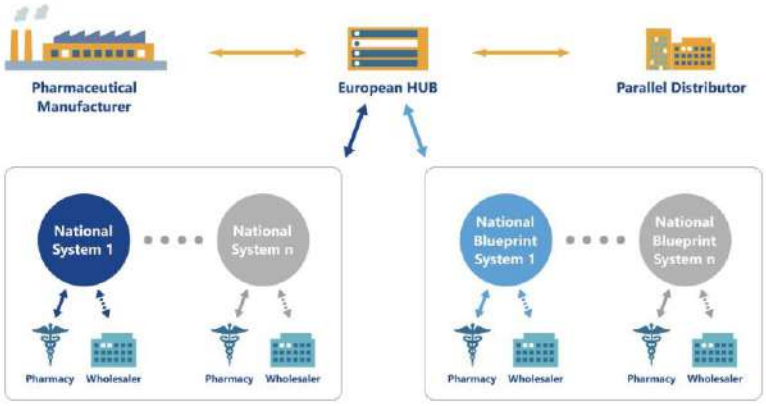

Figure 3: European Medicines Verification Landscape

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 operation 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 authorization 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 authorization 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 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 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 authorization 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 authorized to upload unique identifiers and other required information ('OBP Data') on behalf of Original Pack Manufacturers, holding a marketing authorization 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 authorization or a parallel distribution notice / import license and as long as the marketing authorization 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 the OBP and EMVO.

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

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

[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 authorization holder, a marketing authorization holder and an OBP at the same time.

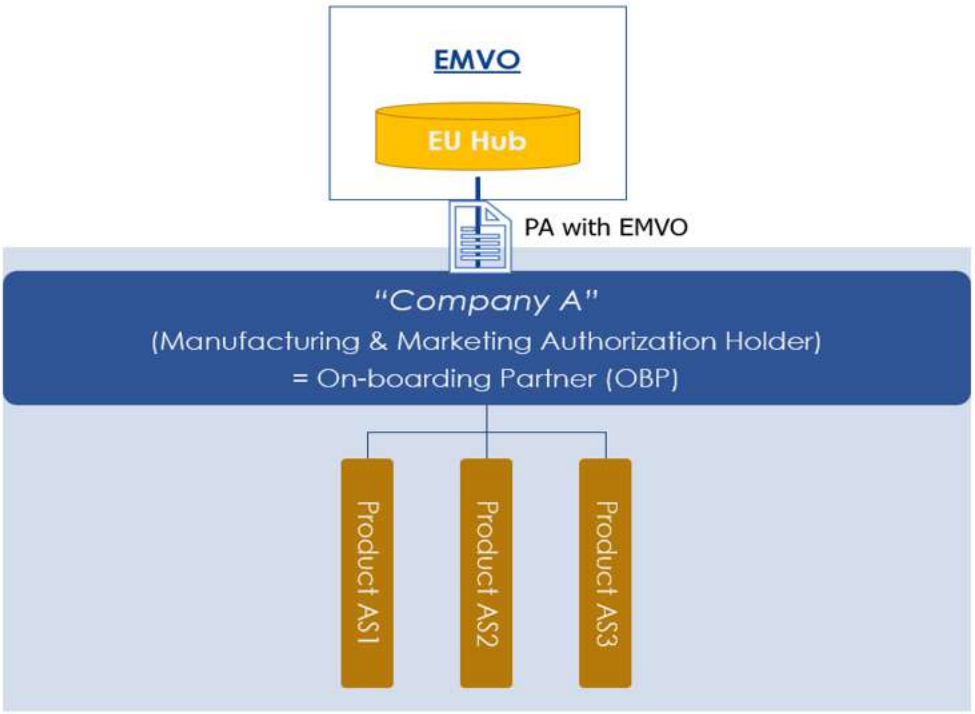

Figure 4: Relationship between the OBP and the EMVO – Example 1

Company A holds (a) manufacturing authorization(s) and (b) marketing authorization(s) to market its products in one or several countries in the European Economic Area. As Company A acts as an 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 authorization holder and marketing authorization holder are combined.

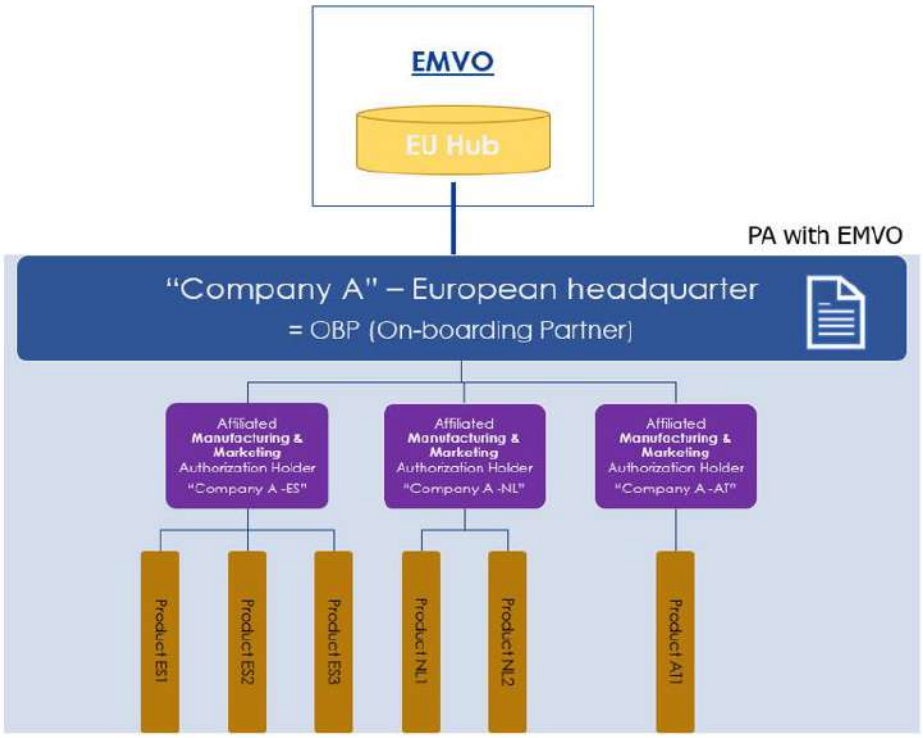

Figure 5: Relationship between the OBP and the EMVO – Example 2

The OBP is the European headquarter of the corporate group. The European Headquarter represents entities among the group that hold (a) manufacturing authorization(s) and (b) marketing authorization(s) to market their products in one or several countries of the European Economic Area. The legal entities with marketing and manufacturing authorizations 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 Authorization 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 authorization holders or marketing authorization holders or may combine both roles.
This example shows clearly that the Marketing Authorization Holder determines via which OBP the product data is uploaded to the EU Hub.

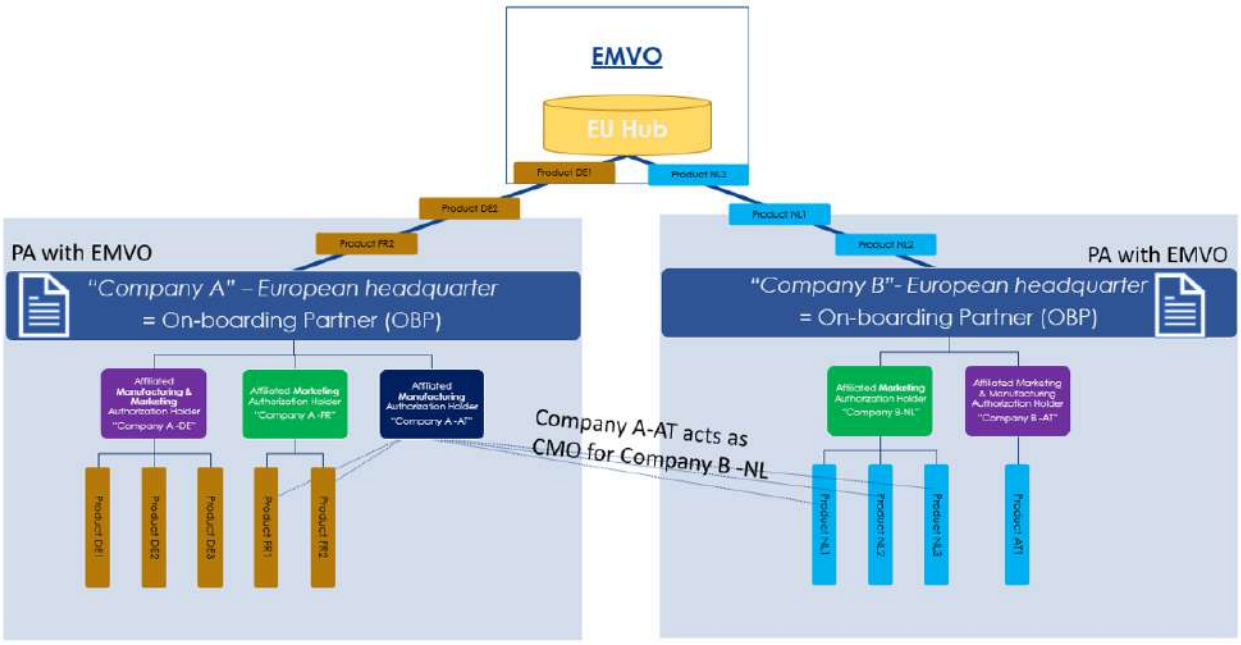

Figure 6: Relationship between the OBP and the EMVO – Example 3

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

The legal entities with Marketing Authorizations 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 Authorization 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 authorization lies (the parallel import authorization 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 authorization 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 authorization holder, Company A in France has the role of the marketing authorization 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 authorization 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 Authorization Holders. The Participation Agreement concluded with the OBP is also binding for these affiliated Marketing Authorization 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 " 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.

3.2 Steps of the On-boarding Process

As a first step of the registration process a company's representative visits the EMVO website and registers on the OBP Portal Application. 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 account will be deprecated once the SPOC account first accesses the OBP Portal.** From that moment, the person announced as the Single Point of Contact (SPOC) in sub-section "Contact Information" of the OBP Portal receives their credentials. This ensures 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, this can be indicated when filling in the contact information in the first section of the OBP Portal. The initial credentials can then be reused, and the role of the Initial Requester will be automatically changed to SPOC to make sure they can change inputted data (See Section 1: Provide Information, under 3.2.1.2.1).

The SPOC Assistant role is an optional user that can support the SPOC activities, and will receive credentials from the moment the user is appointed in the sub-section Contact Information

Request to participate:

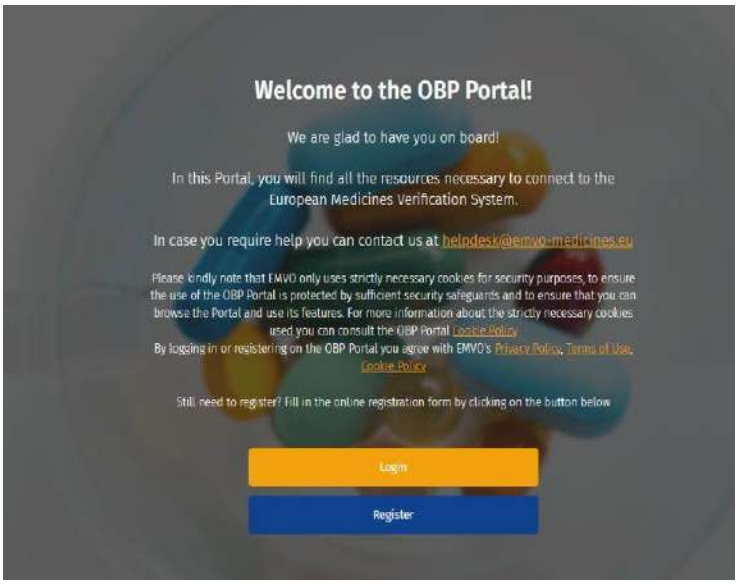

Figure 7: OBP Portal – Welcome Message

Complete user information:

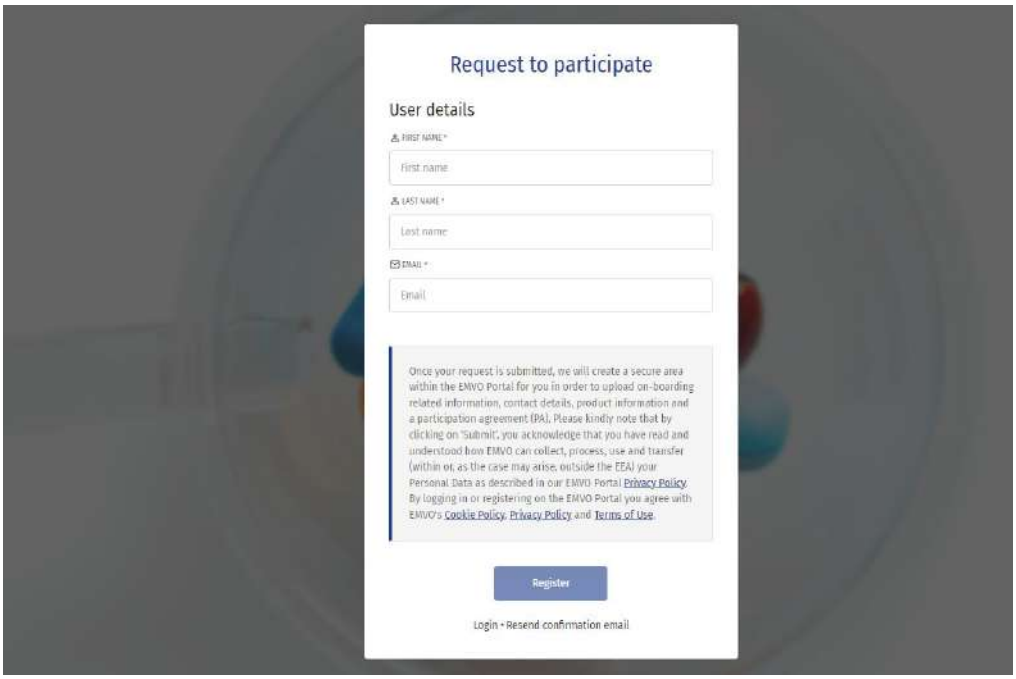

Figure 8: OBP Portal – Portal Registration

Once the registration request is submitted and the OBP confirms the registration by clicking on the link provided by email, EMVO creates a secured area for the OBP within the OBP Portal. The Initial Requester will receive two emails. The first email will contain a link to a dedicated area on the OBP Portal, where the user will be asked to set up their password. The second email will provide the user with a confirmation that his/her account has been properly set up.

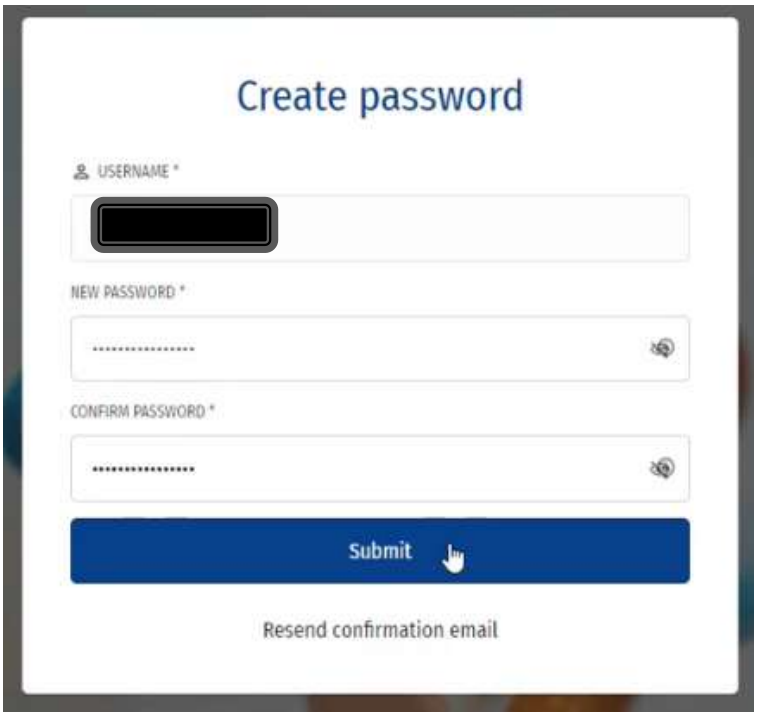

Figure 9: OBP Portal – Home Page

When the user logs in for the first time, they will be directed to the "Create new company" page, where they have to provide the initial company information:

- Name
- Country of Registration
- VAT number
- Company Type

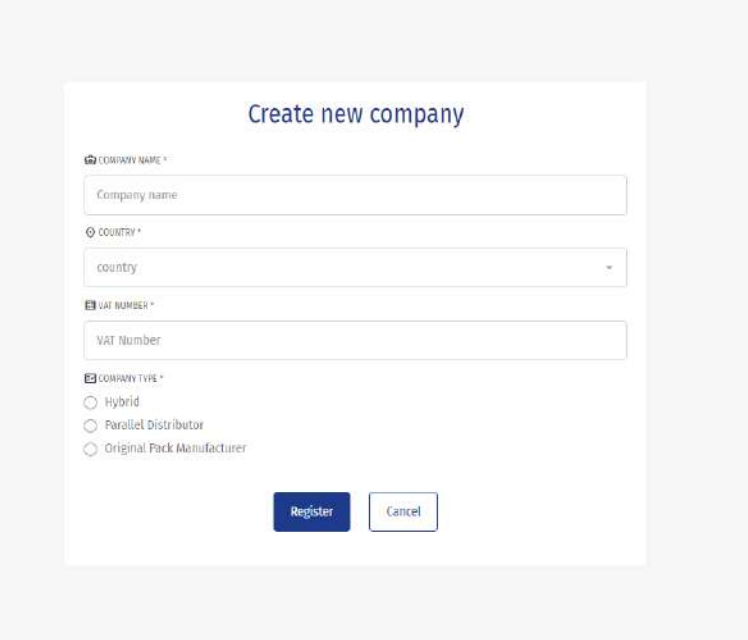

Figure 10: OBP Portal – Home Page

As soon as the account is created on the OBP Portal, the OBP automatically gets an identification number (Contract Partner Number: "CP *number*") made of three or four digits. This number will allow for a unique identification of the OBP company and will be reflected in the Participation Agreement which will be concluded with EMVO.

Note: if you are already a registered user for an OBP company and would like to create an account for another non-affiliated company, please check section 3.3.1.1.

Important Note:

An OBP concluding the On-boarding in the OBP Portal can represent either (an) Original Pack Manufacturer/s or (a) Parallel Distributor/s or both (*'Hybrid'* company type).

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

For the purpose of the FMD, which is addressed to "manufacturing authorization holders", or "manufacturers", technically different interfaces have been designed 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 authorization.

B) **Original Pack Manufacturer (or Manufacturer)** is a pharmaceutical company holding a marketing authorization (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. Please select the company type '*Original Pack Manufacturer*'.

2. If the MAH(s) is (are) parallel distributor(s) only, parallel distributors can choose one common OBP to represent/onboard them. Please select the company type '*Parallel Distributor*'.

3. If some MAH(s) are original pack manufacturers and some are parallel distributors, please select the *'Hybrid'* company type.

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, please select the '*Hybrid'* company type.

3.2.1 Section 1: Provide Information

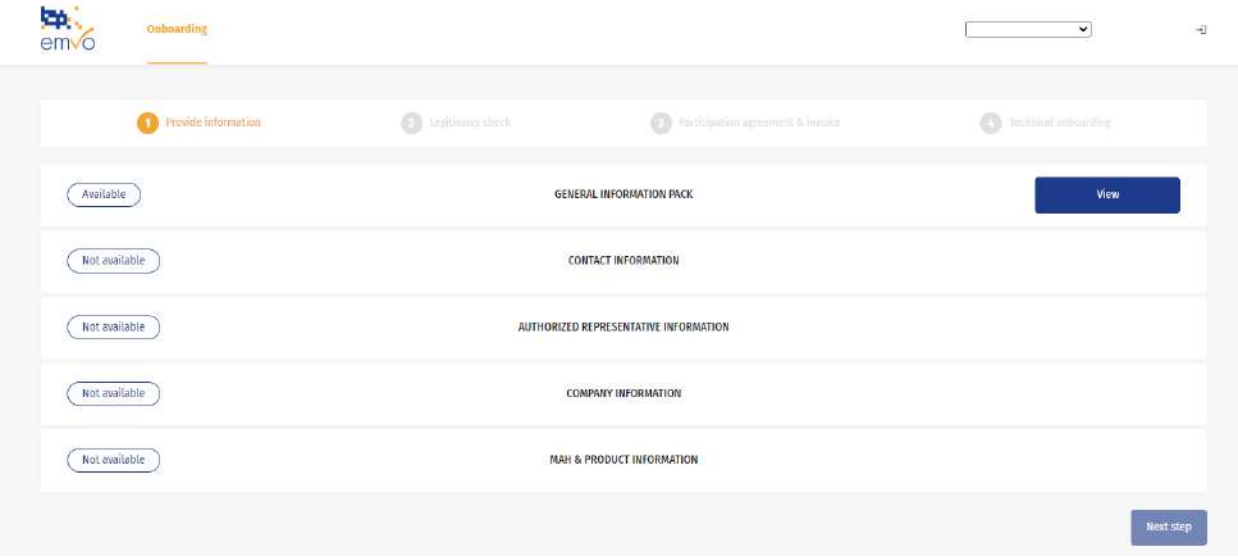

Figure 11: OBP Portal – Provide Information

3.2.1.1 General Information Pack

The *'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 00038 - EMVO Gateway User Manual
- EMVO 00122 - EMVS Master Data Guide
- EMVO 00127 - EMVO Gateway Templates
- EMVO-00955 - OBP On-boarding Guidelines (this document)
- EMVO-02771 - OBP On-boarding Presentation
- EMVO 02855 - SOP – New OBP Portal On-boarding Process

3.2.1.2 Contact Information

In this sub-section the OBP must appoint a Single Point of Contact (SPOC), optionally, a SPOC Assistant (for more information, please see below), and an Authorized Representative (AR).

3.2.1.2.1 SPOC & SPOC Assistant

The SPOC is the OBP's key contact person for EMVO and is authorized 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 SPOC validates their credentials and logs in the OBP Portal, **the access of the Initial Requester permissions will switch to read-only.** 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, the user can check the '*I am also the SPOC*' or '*I am also the SPOC Assistant*" box.

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, by checking the box '*Appoint SPOC Assistant*".

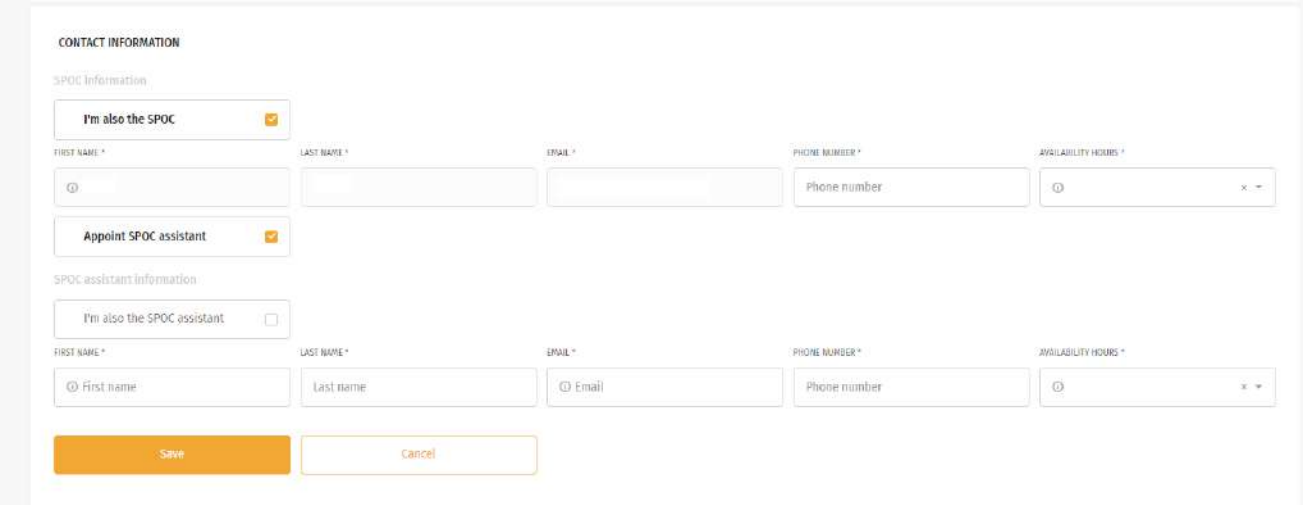

Figure 12: OBP Portal – Contact Information

Finally, the SPOC and the SPOC Assistant details may be changed either before the approval of the Legitimacy Check by EMVO or after successfully completing the Participation Agreement. When the SPOC or SPOC Assistant emails are modified, the new SPOC or SPOC Assistant will receive credentials in order to login. The old SPOC or SPOC Assistant account access is revoked only from the specific OBP account from which they were removed from and upon the successful login of the new SPOC or SPOC Assistant.

The following data is required for the SPOC:

- First name
- Last name
- Email
- Business phone
- Availability hours referring to time zones.

The following information is required for the SPOC Assistant:

- First name
- Last name
- Email
- Business phone
- Availability hours referring to time zones.

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 email address. The successful user creation, user permission and access of the SPOC and SPOC assistant is based on the uniqueness of the email address. Therefore, it is of upmost importance to take this point into consideration while entering and maintaining the SPOC and SPOC Assistant contact information.
- 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 using a dedicated mailing list/inbox e.g. "serialisation@emvo.eu", as the email address of the SPOC Assistant account. However, please note that the email address needs to be linked to a registration of a contact person (first name & 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) notifications for the specific systems of interest.

3.2.1.2.2 Authorized Representative (AR)

The AR should be a senior officer who is authorized 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 AR, by attaching a copy of an excerpt from a relevant national register, in order to certify their authorization 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 Authorized Representative's name will be expressly listed as an authorized 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 Sections 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 AR 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 official register
- ✓ Expressly lists the named Authorized Representative together with their authorization and/or their position among the senior management
- ✓ Is valid (in case it is of limited duration)
- ✓ Is a pdf file

The following information is required for the AR:

1. First name
2. Last name
3. Email
4. Business phone
5. Job title
6. Copy of proof

The AR will sign the Participation Agreement (PA) to enable the OBP to obtain access to the EU Hub and might be contacted in case the provided SPOC details need confirmation.

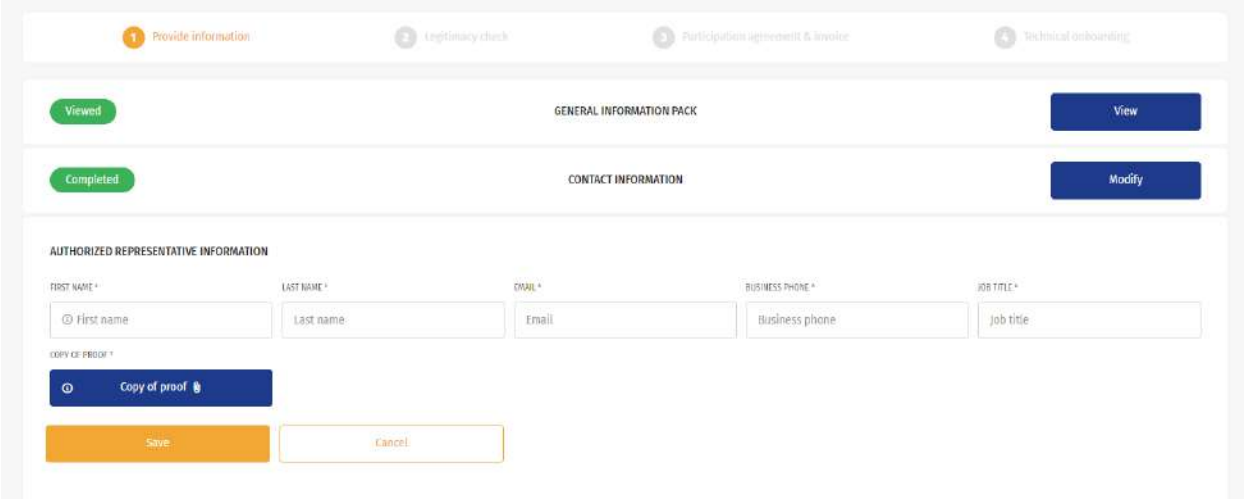

Figure 13: OBP Portal – Authorized Representative Information

3.2.1.2.3 Save all information

Once all information has been provided, the user needs to save the information to confirm, by clicking on the '*Save*' button.

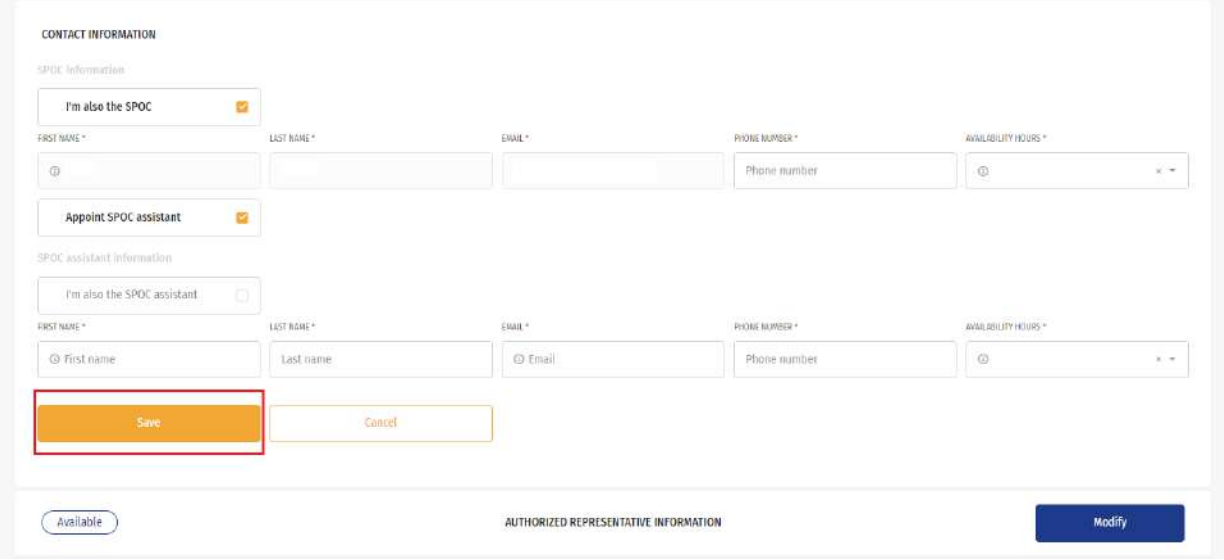

Figure 14: OBP Portal – Contact Information

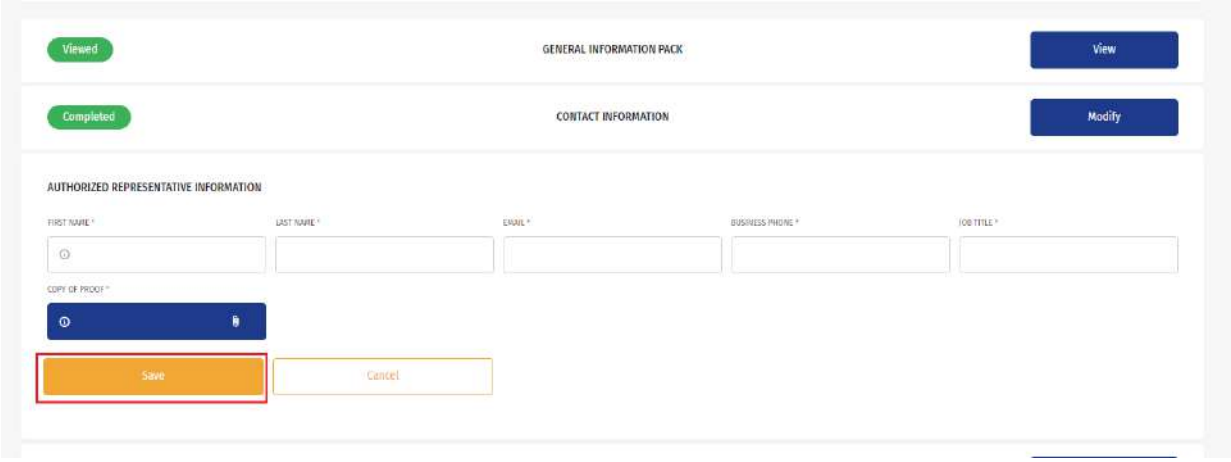

Figure 15: OBP Portal – Authorized Representative Information

3.2.1.3 Company Information

The next sub-section is for the user to provide detailed company information. The following data is required:

1. Company Name
2. Country of Registration

3. VAT ISO Code
4. VAT Number (if the company has no VAT number, the user can check the box *'I do not have any VAT Number'*)
5. Company Registration Number
6. Company Type (either *'Original Pack Manufacturer', 'Parallel Distributor',* or *'Hybrid'*)
7. Business Phone
8. Web Page
9. Company Email Address
10. Street
11. Number
12. Box
13. Zip Code
14. City
15. Country

If the billing entity is different from the OBP entity, the user can check the '*Different billing details'* box.

If the user wants to provide information on the Parent Company (not mandatory), the user can check the *'Parent company information'* box.

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.

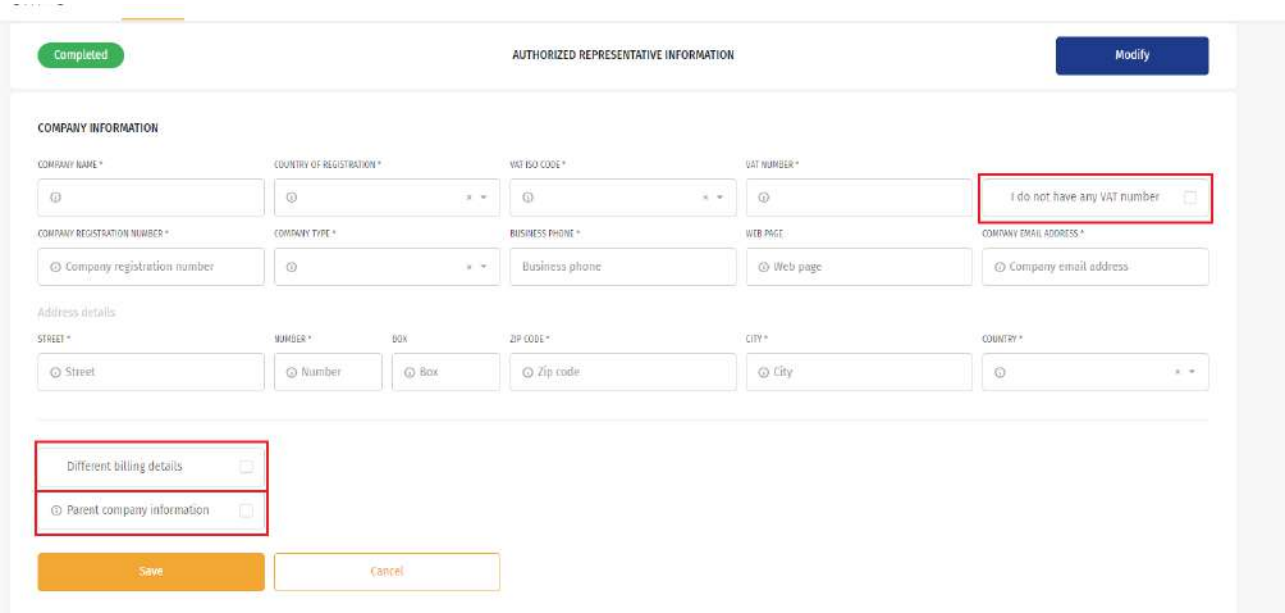

Figure 16: OBP Portal – Company Information

3.2.1.4 MAH & Product Information

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

The information on the MAH(s) 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.

For the purpose of the Legitimacy Check, the OBP will be asked to provide EMVO with one (1) MAH, as well as one (1) product for the MAH. Please note that once the Legitimacy Check has been approved and the Participation Agreement signed, the user can provide additional MAHs in this section (see point 3.3.4 '*Update MAHs & Products Information*').

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 **MAH Active in**, which are defined as the target countries/markets, for which the Marketing Authorization 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 Authorization 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 Authorization Number you provided.
- The **Marketing Authorization Number**, which is the licensed number related to the number of products the MAH received when applying for the Marketing Authorization to the relevant authority (following a decentralized or a centralized procedure).

- The **Marketing Authorization 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 Authorization Registration (e.g. centrally authorized), 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 authorized 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.

There are two possibilities to list MAH(s) on the OBP Portal:

1) By clicking on the button '*Add MAH*'.

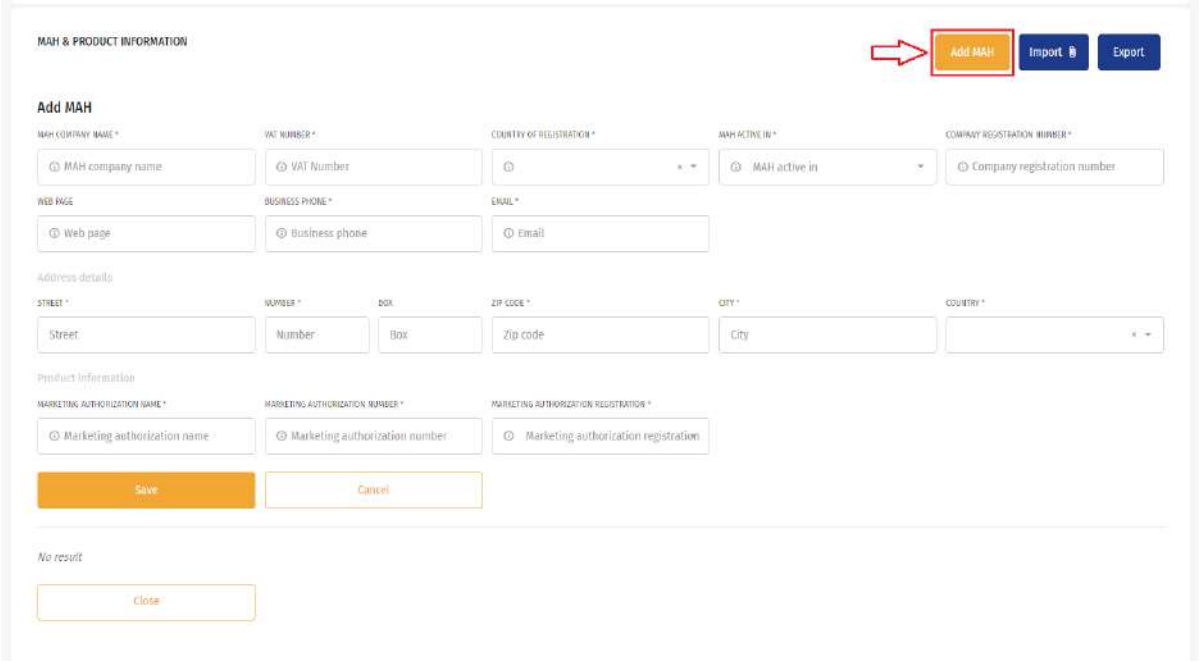

Figure 17: OBP Portal – MAH Information

2) By exporting the template, editing and report all the relevant information by clicking on the button '*Export*'.

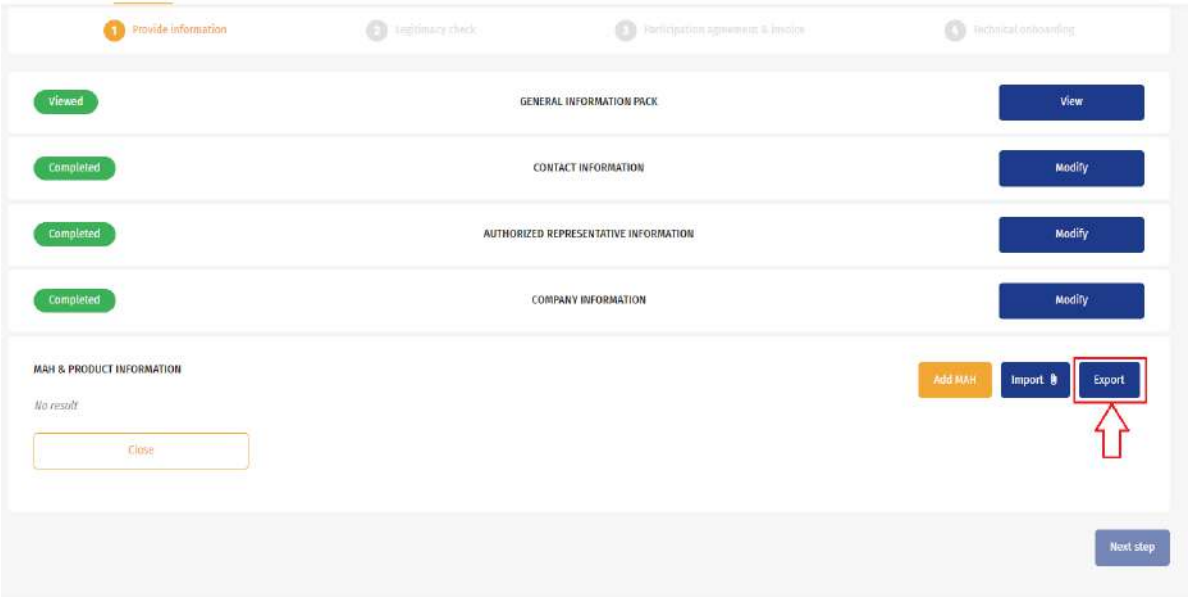

Figure 18: OBP Portal – MAH & Product Information

For reasons of convenience, an example is given on the first row to be used as a guide. Please press '*Enable Content*' on the yellow message that will appear with "Macros have been disabled", in order to be able to edit the content of the template.

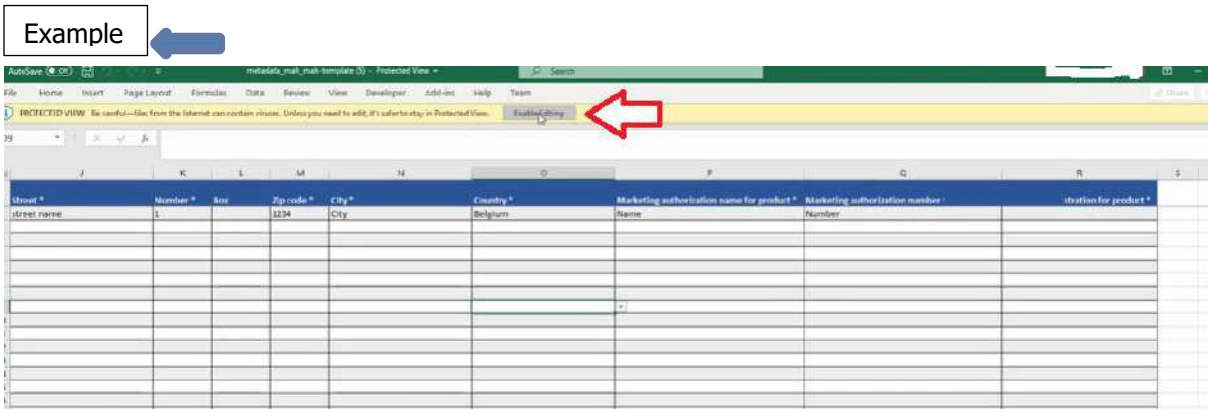

Figure 19: OBP Portal – MAH & Product Information Template

The user can check the countries MAH's of operations and save the excel file.

This file can be uploaded on the OBP Portal page by clicking the '*Import*' button.

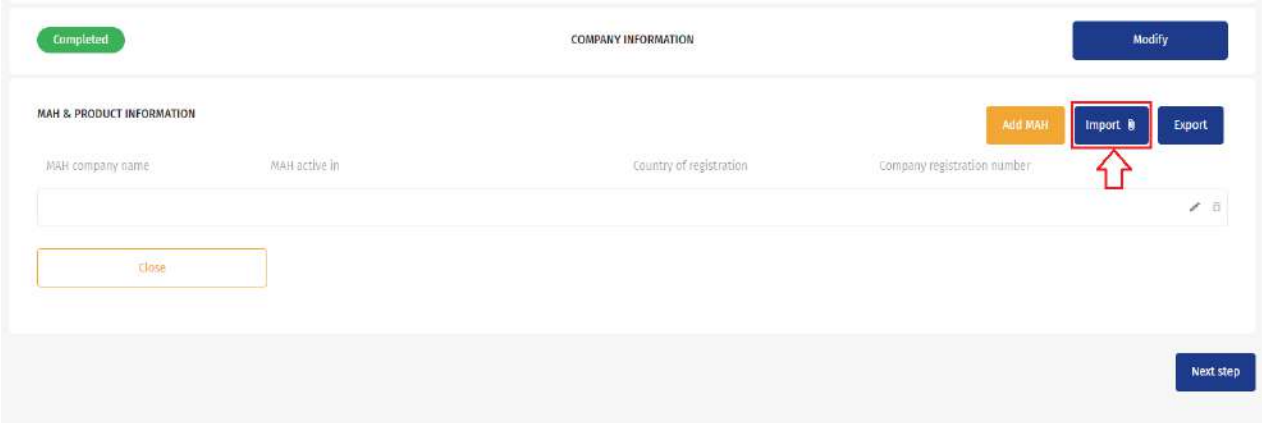

Figure 20: OBP Portal – MAH & Product Information Import

At least one MAH with one product needs to be provided.

The user can press the '*Next step*' button on the right bottom corner to continue.

Important Note: By importing the template file, all the previous MAH information is replaced by the excel file content.

3.2.2 Section 2: Legitimacy Check

Once the user has provided all necessary information in the '*Provide Information*' section, the user can trigger the Legitimacy Check for the OBP Company.

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 email to either correct it or to provide additional information via the OBP Portal as requested. In that case, EMVO will allow the OBP to go back to the "Provide Information" section 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 Section 2 will automatically be updated.

In order to trigger the Legitimacy Check, the user has to confirm the information provided as well as several elements:

- The company type indicated in section 1, sub-section '*Company Information*'
- The affiliation between the MAH(s) listed on the Portal and the OBP Company
- The system ownership and responsibilities
- The fee model

Once the user presses the *'Confirm'* button, the below window will appear to confirm all elements. It is also possible to change the company type, if necessary. The user then has to tick the box and click on the *'Accept'* button to proceed.

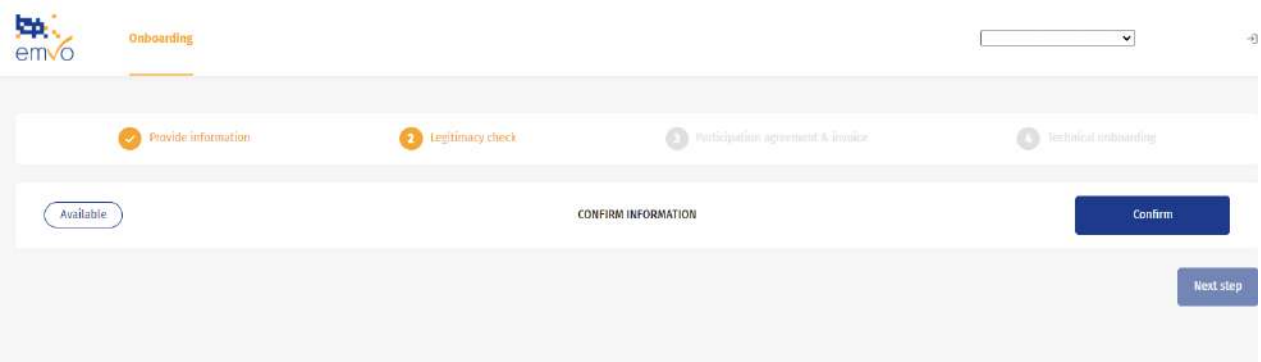

Figure 21: OBP Portal – Legitimacy Check

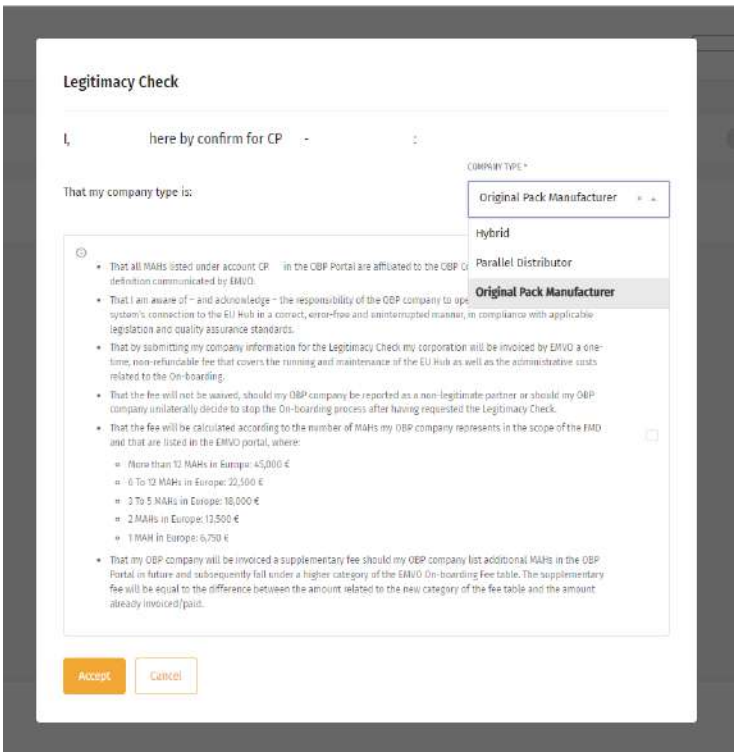

Figure 22: OBP Portal – Legitimacy Check

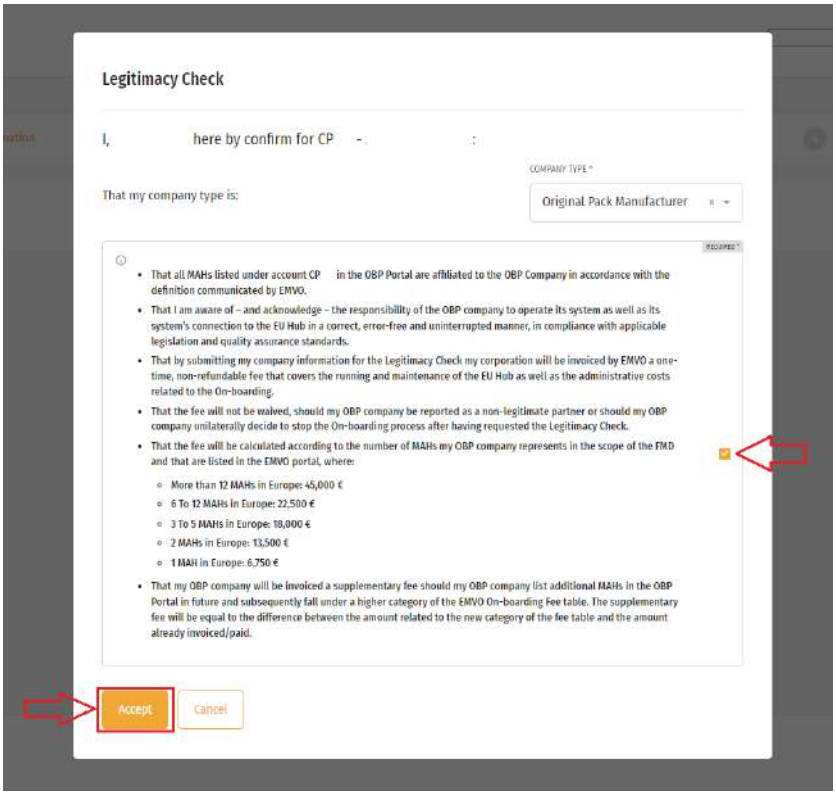

Figure 23: OBP Portal – Legitimacy Check

A notification will appear on the top right corner that '***Your request is currently reviewed by EMVO***'. While the status of the '*Confirm All Information*' sub-section is '*Reviewing*', it is not possible to change the Company, Contact or MAH & Product Information.

Figure 24: OBP Portal – Legitimacy Check Notification

When the Legitimacy Check has been performed by EMVO, the OBP will be informed by email whether the Legitimacy Check was successfully passed or if corrections are needed. (Below an image of an approved Legitimacy Check).

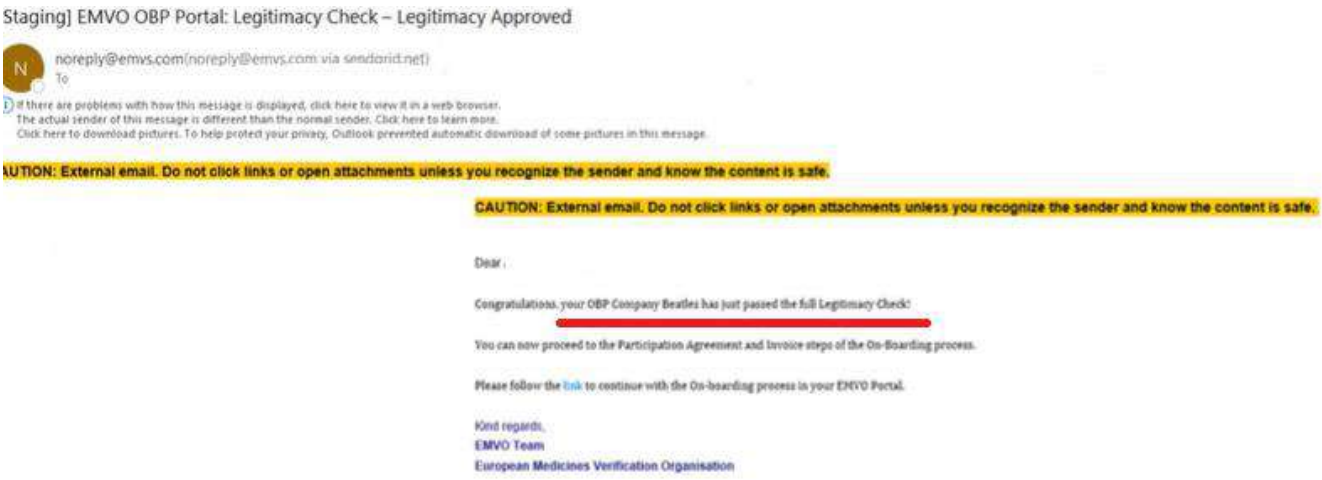

Figure 24: OBP Portal – Legitimacy Check Approval

If corrections are needed, the element(s) to be corrected will be indicated in the email, as well as the reason.

3.2.3 Section 3: Participation Agreement and Invoice

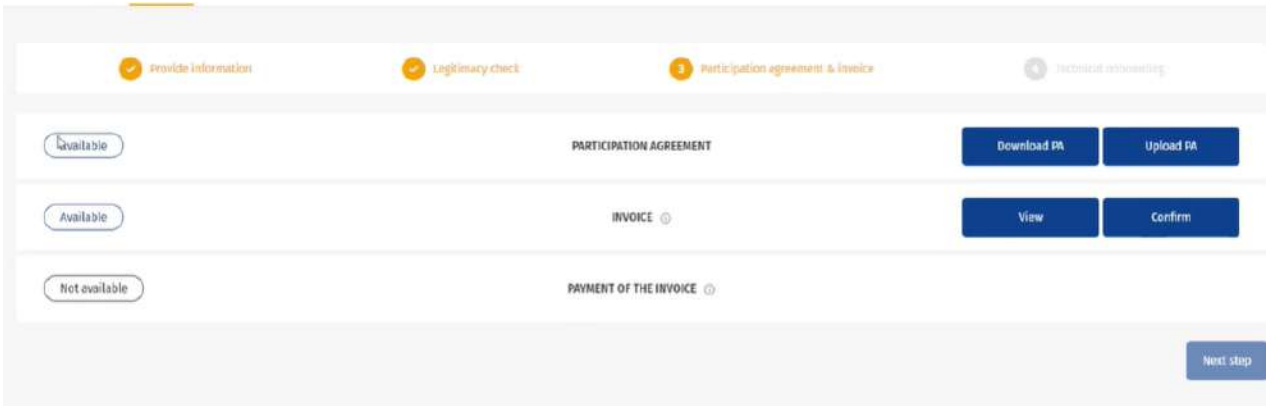

Figure 25: OBP Portal – Participation Agreement & Invoice

3.2.3.1 Participation Agreement (PA)

After the completion of the Legitimacy Check, a pre-filled OBP PA will become available. 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.

Figure 26: OBP Portal – Participation Agreement

The OBP acknowledges and agrees that EMVO may amend or supplement the PA at any time upon simple notification (typically, by making the updated document available on the 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

In the sub-section *'Participation Agreement'*, a scanned copy of the PA, duly completed and signed by the Authorized Representative, must be uploaded on the OBP Portal.

Figure 27: OBP Portal – Upload Participation Agreement

In order to upload the PA, 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 PA becomes effective upon its upload on the OBP Portal, which will be recognised equivalent to a signed original notify to EMVO

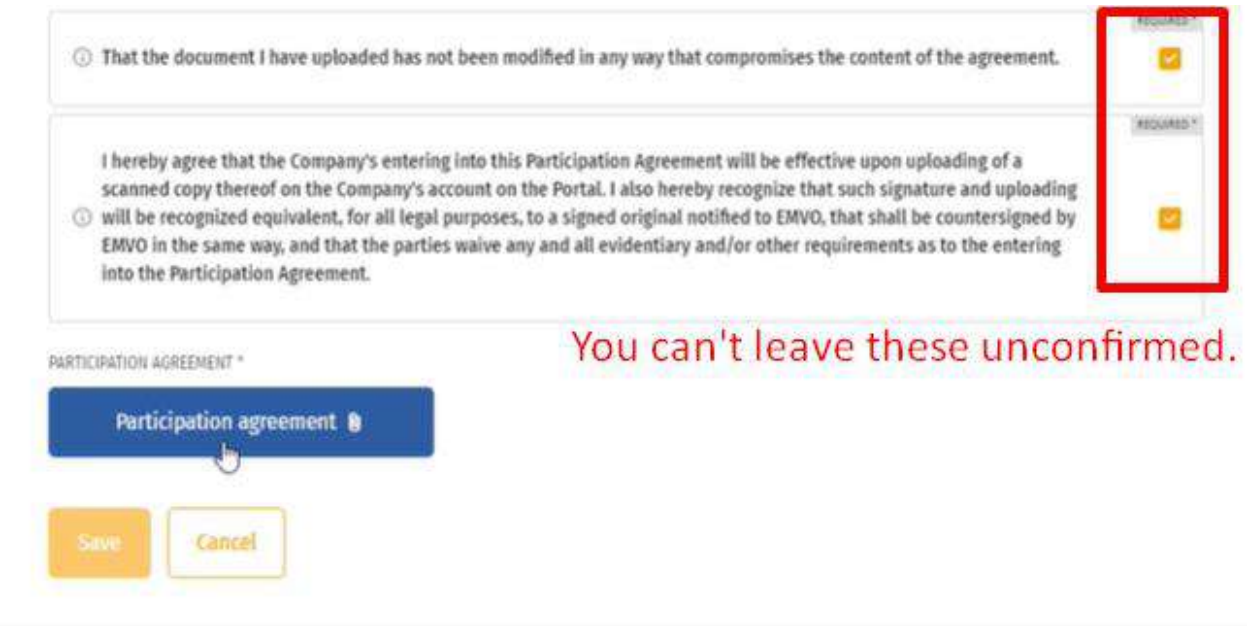

Figure 28: OBP Portal – Add Signed Participation Agreement

Please pay particular attention to the following:

- ✓ The name of the AR listed in section 1, sub-section *'Contact Information'*. needs to be the one of the person that actually signs the PA[3];
- ✓ No amendments, modifications or other changes of the PA 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 PA constitutes an Addendum applicable only to OBPs established outside the European Economic Area (EEA) and forming part of the PA. It sets out additional safeguards for the protection of the uploaded data. Therefore, only these OBPs are required to sign Appendix 4 of the PA, upload it on the OBP Portal along with the Agreement and comply with the provisions therein.

The EEA unites the EU Member States, Iceland, Liechtenstein, and Norway. Therefore, countries like Switzerland, the United Kingdom, the United States, Israel, Australia etc. do NOT belong to the EEA and the OBPs established in these countries are required to sign Appendix 4 of the PA.

[3] In case a change in the Authorized 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.

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 authorized 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(s)

Figure 29: OBP Portal – Detailed Information and Participation Agreement upload

Once EMVO has approved and countersigned the PA signed by the OBP, the countersigned copy will be automatically available on the OBP Portal.

Figure 30: OBP Portal – Detailed Information and Participation Agreement approval by EMVO

Upon request of EMVO, the OBP may have to sign a new PA. The SPOC will be informed via email that a new PA is available in section 3.

Figure 31: OBP Portal – Detailed Information and Participation Agreement deprecated

At this stage, 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 PA, 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 PA. 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.

3.2.3.2 Invoice

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, UK and Switzerland) the OBP represents;
- In accordance with the table hereunder.

Category	On-Boarding Fee
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 32: EMVO 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 number of MAHs for which the OBP will upload data in the EU Hub 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 not to mix up the number of Marketing Authorization Holders (MAHs) with the number of Marketing Authorizations (MAs).

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

It is possible to preview the invoice from the button *'View'* and examine the provided details e.g. VAT Number.

Then, the users need to press the '*Confirm*' button to trigger the invoicing. A disclaimer will pop-up on the screen. The first box must be ticked, which is the 'I confirm that I have provided all MAHs that my OBP is representing.' box. The '*Purchase Order Number'* box is ticked only when the OBP wishes to provide a Purchase Order Number.

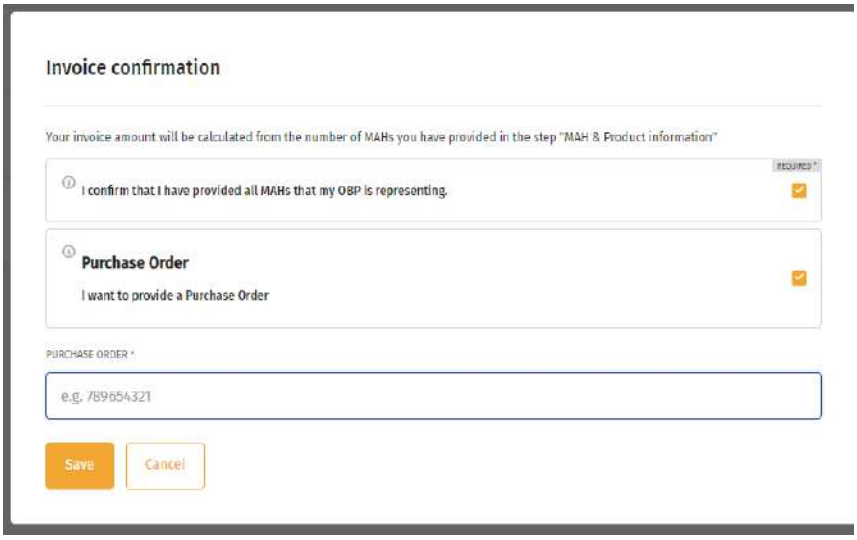

Figure 33: Invoice Confirmation

Note: After the OBP has pressed the '*Confirm*' button, EMVO checks the provided information and either approves the invoice or rejects it, should the provided information be incorrect. In case of rejection, the OBP is instructed to correct the information accordingly. After the invoice has been approved by EMVO, it can be downloaded by the OBP via the '*Download*' button.

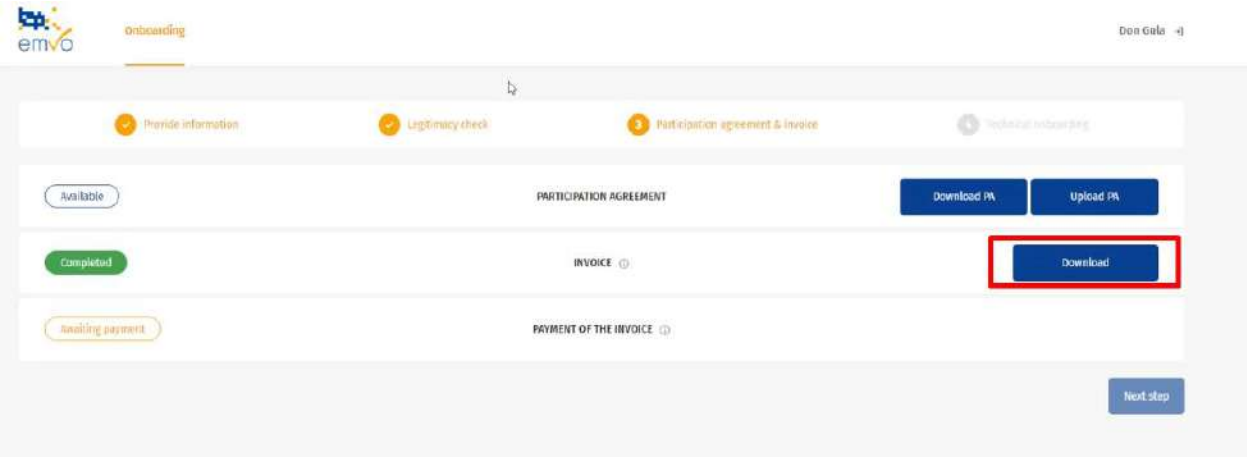

Figure 34: Invoive Download

3.2.3.3 Payment of the Invoice

The payment details will be provided together with the invoice. Please note that the bank transfer/payment of the invoice should always include the invoice number as reference.

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

Please note that the payment status is updated once **every week**.

3.2.4 Section 4: Technical On-boarding

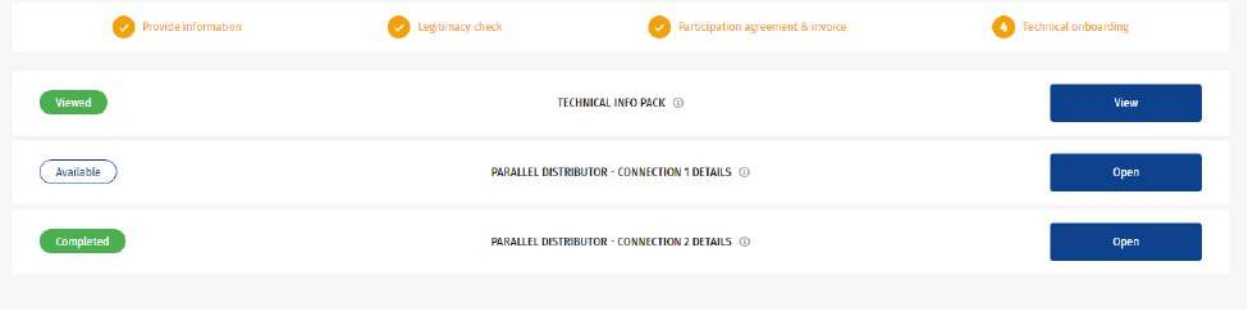

Figure 35: OBP Portal – Technical On-boarding

3.2.4.1 Introduction

In order for Original Pack Manufacturers holding a marketing authorization for the FMD-affected product(s) or for Parallel Distributors holding parallel import licenses 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 unique Organisation ID and the possibility of using 1 or 2 connections (hybrid OBPs have 2 Organisations IDs and a total of 4 connections, 2 for the Manufacturer designation and 2 for the Parallel Distributor designation). The Organisation ID is an unique identifier of the OBP in the EU Hub, whereas the Connections (1, 2, 3 or 4) are identified in the system through Client IDs. Each connection can host up to 3 Client IDs, one Client ID per EU Hub Environment (ITE, IQE and PRD).

To make this Technical On-boarding process as convenient as possible, the section *'Technical On-boarding'* on the OBP Portal supports the OBP to obtain the necessary information to establish the technical connection.

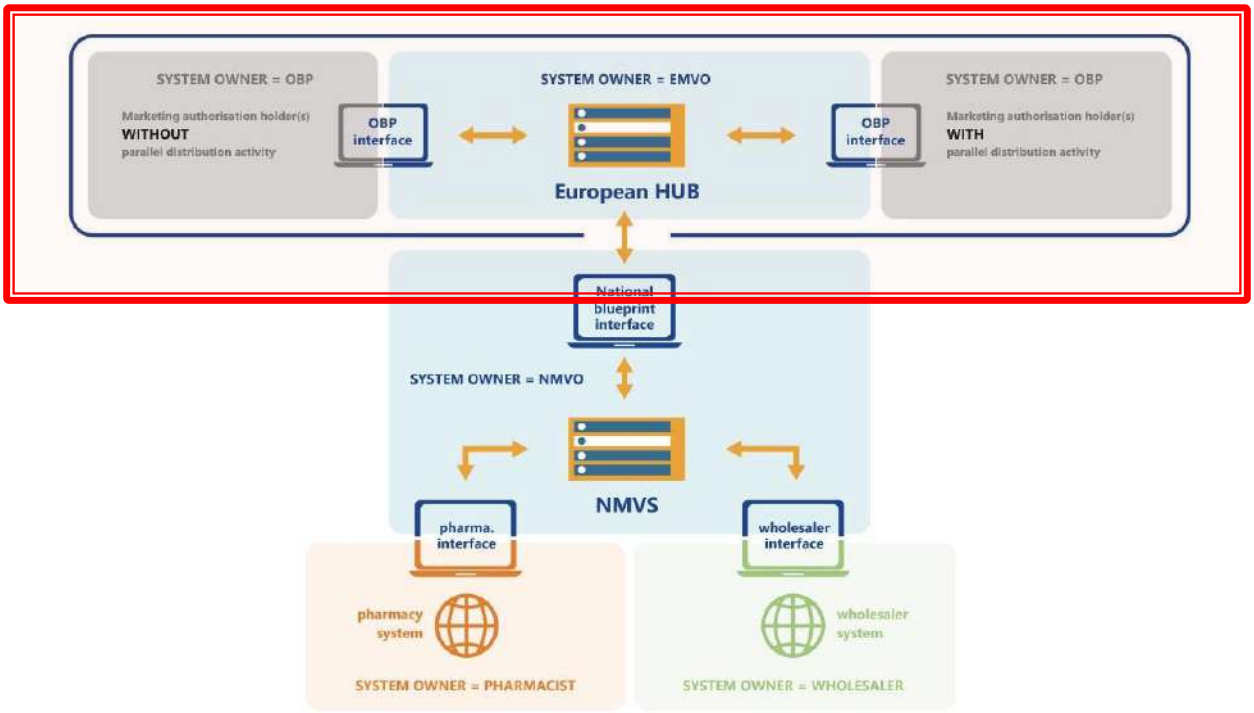

Figure 36: OBP's connection to the repositories system (EU Hub)

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[4] by the OBP to develop its connection for the first time and perform a first integration test[5].

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 internally 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.

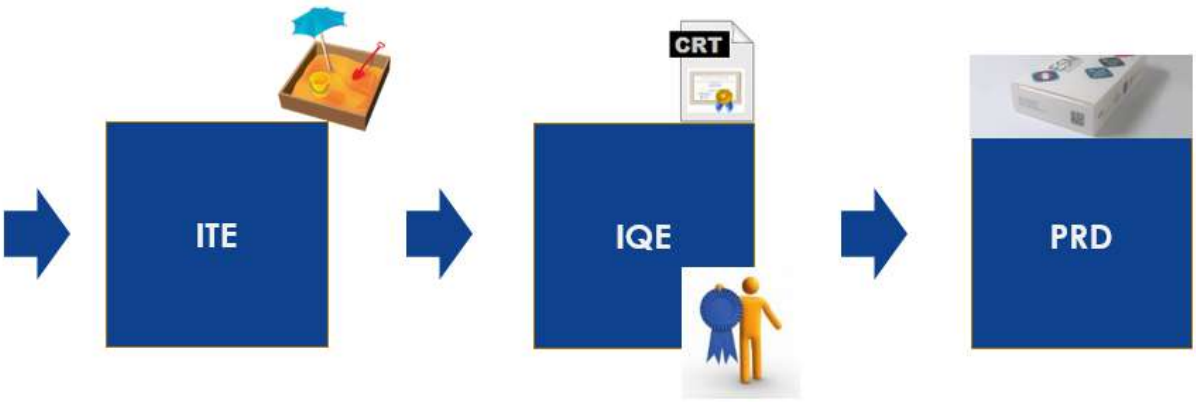

Figure 37: Available Environments for the OBP in the EU Hub

[4] 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.

[5] 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 Sub-section: Technical Info Pack

Upon successful completion of the PA and the payment of the Invoice has been received by EMVO, 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 sub-section 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
    - EMVO-01258_EMVS0787 - EMVS Java SDK Installation Instructions For OBPs
2. Documentation .NET
    - EMVO-02321_EMVS0794 - EMVS OBPs .NET SDK Installation Guide
    - C# SDK Code Sample
    - .NET Callback
3. EMVO Gateway
    - EMVO-00038_EMVO Gateway User Manual
4. On-boarding Steps
    - EMVO-00117_Creating CSR Files
    - EMVO-01614_EMVS0714 - EMVS SDK for OBPs
5. AMS documents
    - Alerts_Template_csv
    - AMS Declaration of Qualification
    - AMS On-boarding and Self-qualification Process
    - AMS Self-Qualification Booklet Template
    - EMVO-01376 EAMS Portal User Manual
    - EMVO-01963 EAMS OBP Terms and Conditions

- EMVO-00470 Alert Management System - AMS Hub and interfaces User Requirements Specification
- EMVO-00544 AMS Hub API Specifications
- EMVO-01392 EAMS Handbook for MAHs

6. Release Notes
7. Miscellaneous
    - EMVO-00270_Backwards Compatibility Design Note_EU HUB_OBPs
    - EMVO-00402_EMVS Alerts and Notifications
    - Master Data Maintenance - Versioning and Retrospective Upload
    - EMVO-00323 OBP Divestiture & Acquisition Guide
    - EMVO-00122 EMVS Master Data Guide

Figure 38: View Technical Info Pack

In case your organisation is a Hybrid, meaning that your organisation acts as both Manufacturer and Parallel Distributor designations, it's possible to have one Portal account for both activities. You will have access to 4 connections – 2 for the Manufacturing activities and 2 for the Hybrid activities.

3.2.4.4 Sub-sections Connection 1, 2, 3 and 4 Details (if applicable)

The OBP can follow the required sub-sections to establish a first technical connection to the PRD environment of the EU Hub. One connection per designation (Manufacturer and Parallel Distributor) is mandatory.

The OBP is also allowed to establish a second technical connection to the EU Hub per designation (Manufacturer and Parallel Distributor). Connection 1, 2, 3 and 4 can be done at the same time. Setting up a second connection per designation is optional.

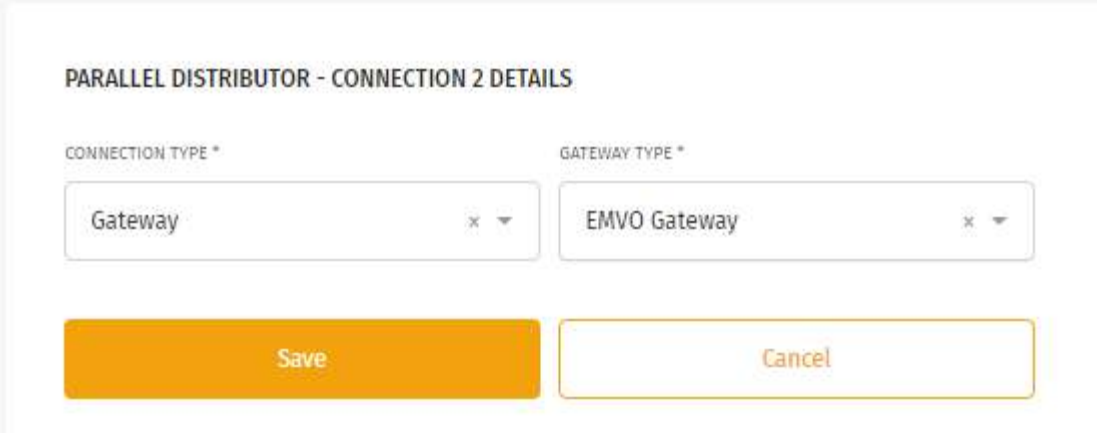

Figure 39: OBP Portal – Connection Details

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[6]
    b. Gateway[7]
2. Type of technology
    a. .NET
    b. JAVA
    c. SaaS

3.2.4.4.1 Sub-section ITE - Certificate Signing Request

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

Important Note: In case the Gateway Connection has been selected button ITE for that particular connection is not available.

The guidelines on how to create a CSR file can be found in the Technical Info Pack > '*EMVO-00117_Creating CSR files*' document.

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

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

In this sub-section the SPOC/SPOC Assistant can upload the CSR file. The file is automatically validated in the EU Hub. If the validation of the CSR is successful, this sub-section status will be *'Completed'*.

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

The following information to create the CSR file for ITE shall be available in the Certificate Signing Request modal box: Organisation Name, Organisation Type, Organisation ID, and Client ID, Common Name, Company Email, SPOC Name and SPOC Initials.

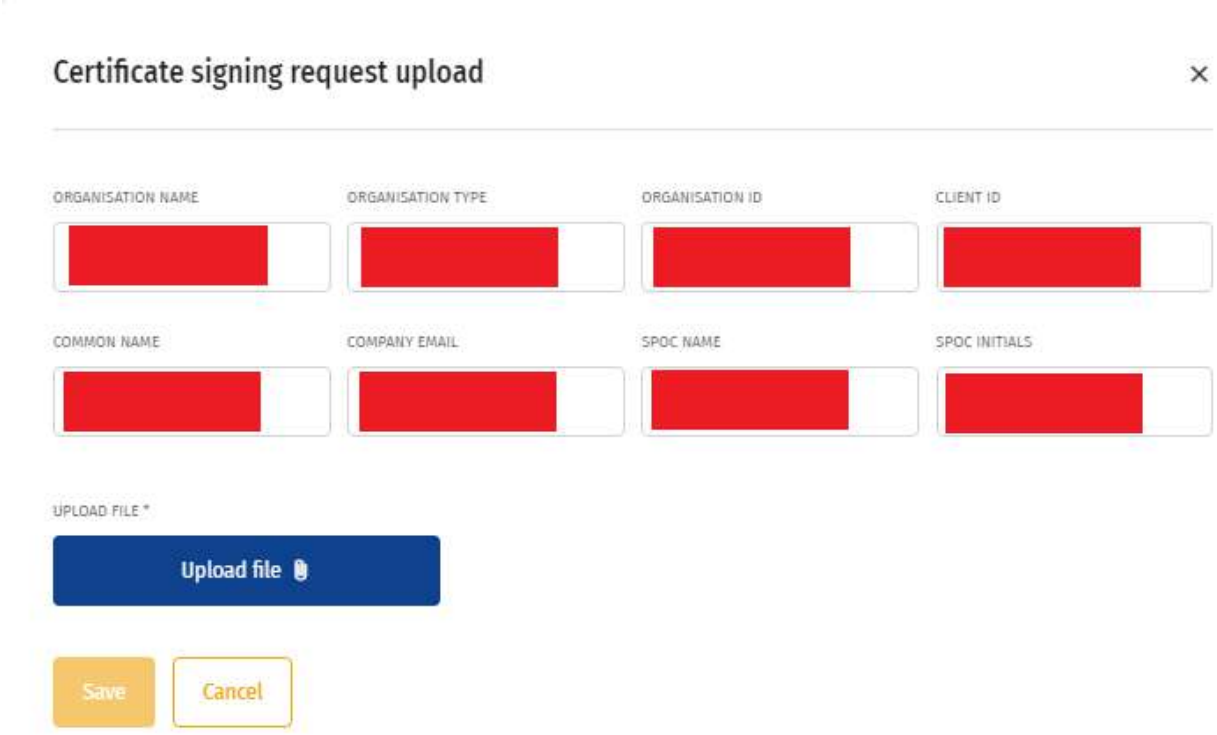

Figure 40: Certificate Signing Request

3.2.4.4.2 Sub-section ITE – Certificate(CER)

In this sub-section the OBP will have access to the following information:

1. Client certificate (Private Certificate) – downloadable .p7b file

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

3. The Service Endpoints document 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-00117 Creating CSR Files*' document.

3.2.4.4.3 Sub-section ITE – Session Token

After completing sub-section ITE – Certificate(CER), the SPOC/SPOC Assitant is able to request a Session Token from EMVO.

Figure 41: Session Token Available

Figure 42: Session Token Under Review

Once EMVO has provided a session token, the OBP will be able to check the current Session Token in the button *'View'*.

Figure 43: Session Token Completed

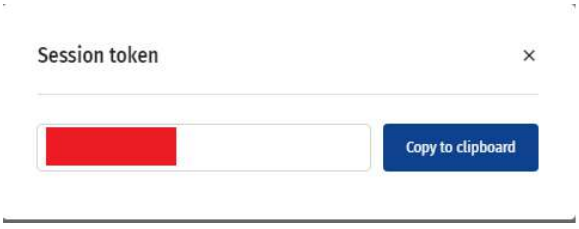

Figure 44: View Session Token

A new Session Token can be requested at any given moment by clicking the button '*Request*'. 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.

3.2.4.4.4 Sub-section ITE – Test Status Metrics

The 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]

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 45: 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** - (Company's 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** - (Country eg. BE)
- **SDK used** - (Java/.NET)
- **Timestamps** - (ideally within 24 hours)
- **Correlation ID** - (from message sent to the EU Hub)
- **Response file** - (Response xml/json file sent from the EU HUB to the OBP system)
- **Request file** - (Request xml/json file sent to the EU HUB)
- **Request Type** - (e.g. Product Master Data Upload, Session Token Refresh, Report Request, Product Pack Data Upload)

3.2.4.4.5 Sub-section IQE – Certificate Signing Request *(same procedure as sub-section ITE* – Certificate Signing Request*)*

The guidelines on how to create a CSR file can be found in the '*Technical Info Pack*' > '*EMVO-00117_Creating CSR files*' document.

In this sub-section the SPOC/SPOC Assistant can upload the CSR file. The file is automatically validated in the EU Hub. If the validation of the CSR is successful, this sub-section status will be *'Completed'*.

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

The following information to create the CSR file for IQE shall be available in the Certificate Signing Request modal box: Organisation Name, Organisation Type, Organisation ID, and Client ID, Common Name, Company Email, SPOC Name and SPOC Initials.

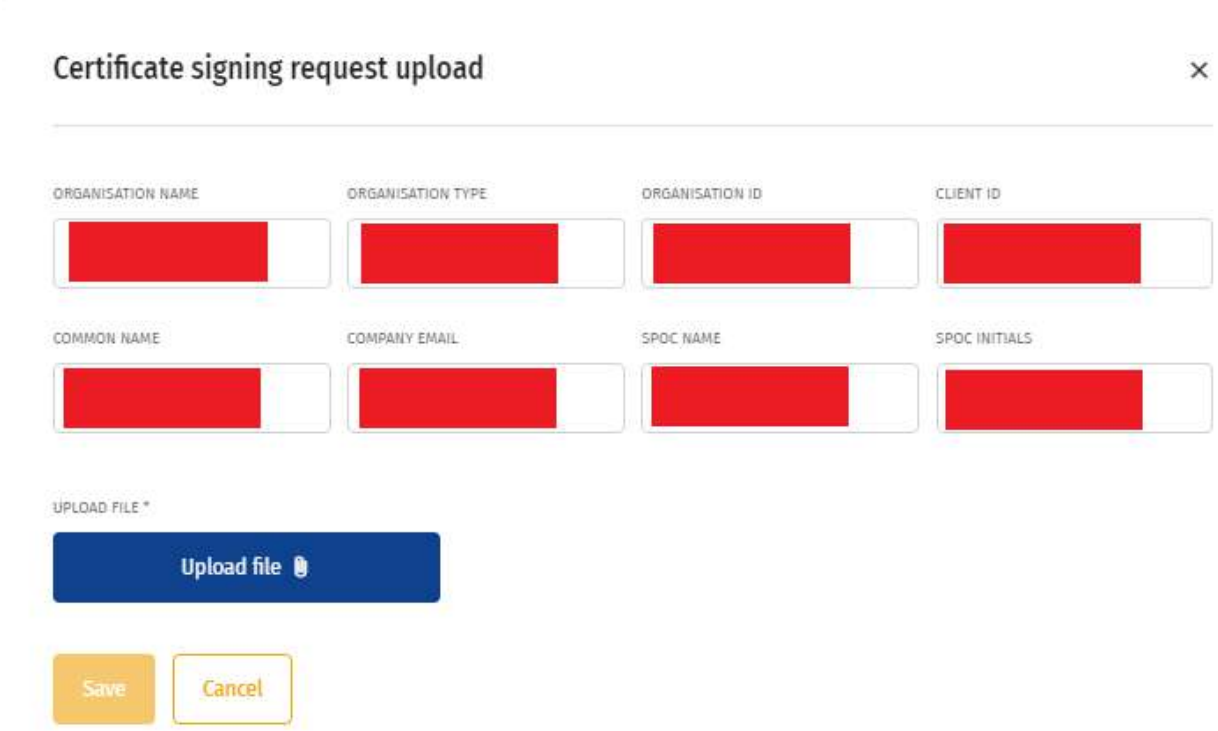

Figure 46: Certificate Signing Request IQE

3.2.4.4.6 Sub-section IQE – Certificate(CER) *(same procedure as Sub-section ITE – Certificate(CER)*

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

1. Client certificate (Private Certificate) – downloadable .p7b file

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

3. The Service Endpoints document for the IQE 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-00117 Creating CSR Files*' document.

If you selected the EMVO Gateway as your 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).

3.2.4.4.7 Sub-section IQE – Session Token *(same procedure as sub-section ITE – Session Token)*

After completing the sub-section '*IQE – Certificate(CER)*', the SPOC/SPOC Assistant is able to request a Session Token from EMVO.

Figure 47: Session Token Available

Figure 48: Session Token Under Review

Once EMVO has provided a session token the OBP will be able to check the current Session Token in the button *'View'*.

Figure 49: Session Token Completed

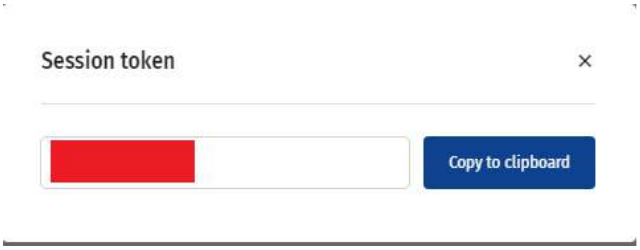

Figure 50: View Session Token

A new Session Token can be requested at any given moment by clicking the button '*Request*'. 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.

3.2.4.4.8 Sub-section 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 '*Completed*' 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.

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.

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 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]

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 minute timeframe is available to execute, check and submit the test results by clicking the button '*Submit*' in the EMVO 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 51: 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 and Response file**
- **Request Type** - (e.g. Product Master Data Upload, Session Token Refresh, Report Request, Product Pack Data Upload)

3.2.4.4.9 Sub-section PRD – Certificate Signing Request *(same procedure as sub-section ITE* – Certificate Signing Request*)*

The guidelines on how to create a CSR file can be found in the '*Technical Info Pack*' > '*EMVO-00117_Creating CSR files*' document.

In this sub-section the SPOC/SPOC Assistant can upload the CSR file. The file is automatically validated in the EU Hub. If the validation of the CSR is successful, this sub-section status will be *'Completed'*.

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

The following information to create the CSR file for PRD shall be available in the Certificate Signing Request modal box: Organisation Name, Organisation Type, Organisation ID, and Client ID, Common Name, Company Email, SPOC Name and SPOC Initials.

3.2.4.4.10 Sub-section PRD – Certificate (CER) *(same procedure as* Sub-section *ITE – Certificate(CER)*

In this sub-section, the OBP will have access to the following information:

1. Client certificate (Private Certificate) – downloadable .p7b file

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

3. The Service Endpoints document 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-00117_Creating CSR Files*' document.

3.2.4.4.11 Sub-section PRD – Session Token

After completing the sub-section *'PRD – Certificate(CER)'*, the SPOC/SPOC Assistant is able to request a Session Token from EMVO.

Figure 52: Session Token Available

Figure 53: Session Token Under Review

Once EMVO has provided a session token the OBP will be able to check the current Session Token in the button *'View'*.

Figure 54: Session Token Completed

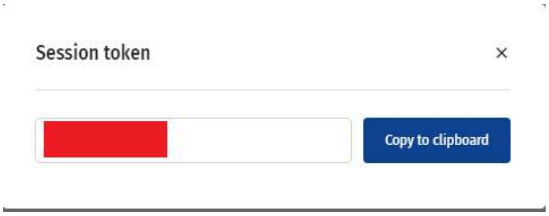

Figure 55: View Session Token

A new Session Token can be requested at any given moment by clicking the button '*Request'*. 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.

3.3 Information Maintenance

3.3.1 Logging into the OBP Portal

To access your account, go to the OBP Portal and click on the Login button and insert your log in details (see **Figure 57: OBP Portal Login Page).**

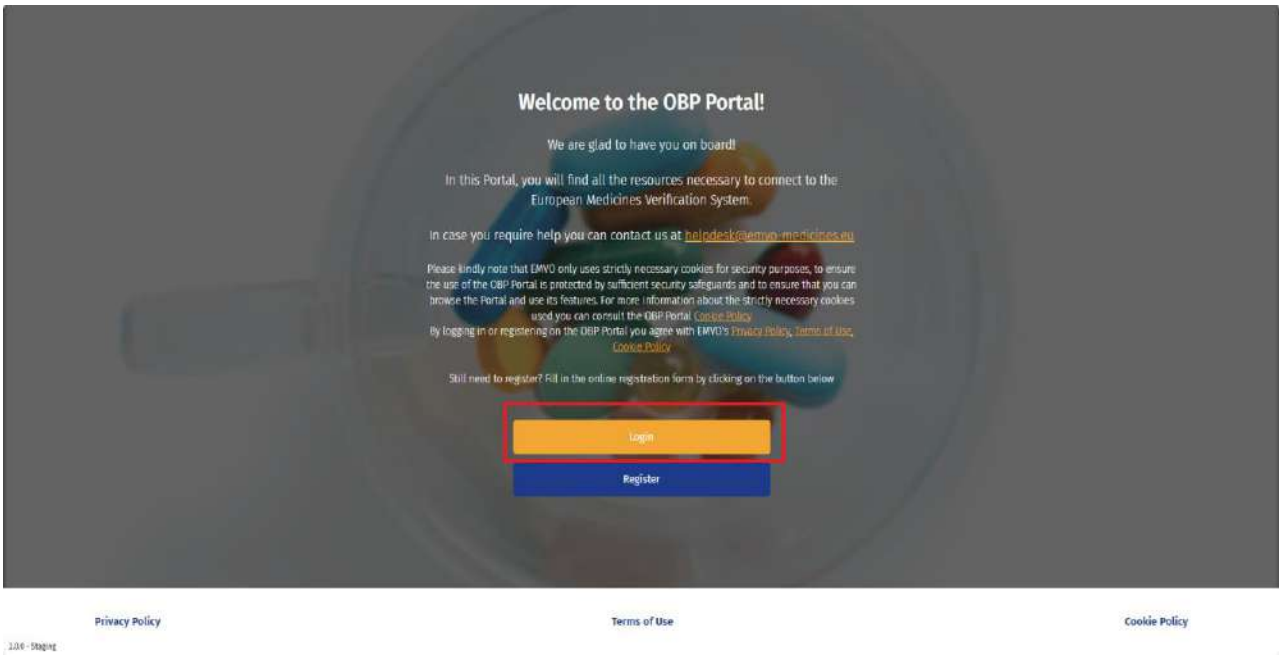

Figure 56: OBP Portal Home Page Login Highlight

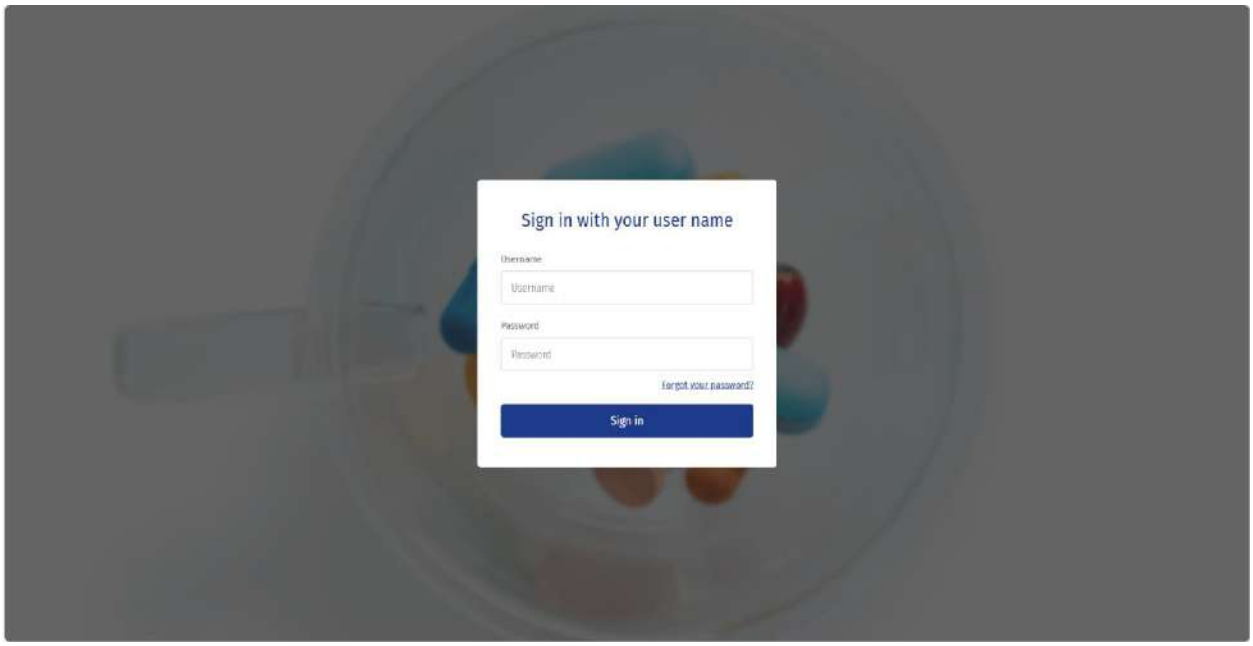

Figure 57: OBP Portal Login Page

Note: **Input your email address into the username field.**

3.3.1.1 Creating a new OBP Portal account as an existing user

If you are an existing user (either as a SPOC or SPOC Assistant), and you are required to commence the onboarding for a different, non-affiliated company, you are required create a new account for the new company. To do so, find the dropdown menu on the top right corner of the portal, next to your name, and select it:

Figure 58: OBP Portal Account Highlight

A dropdown list of your companies will appear, including an entry named "Create new company". Click on this latter entry to start the new registration process:

Figure 59: OBP Portal Account List

Once you select this option, you will be redirected to the "Create new company" page, where you can start the onboarding process for the new company. Please refer to Section 3.1 – Introduction - Figure 10: OBP Portal Home Page and follow the described steps.

3.3.1.2 Switching between OBP Portal Accounts

If your user account is linked to at least 2 different OBP accounts, you can switch between these accounts at any moment during the onboarding process. To do so, find the dropdown menu on the top right corner of the portal, next to your name:

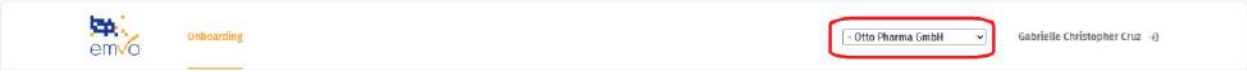

Figure 60: OBP Portal Dropdown

Once you click on the dropdown link, and you will find a list of your companies, including the most recently created one(s). You can select another company besides the currently selected one:

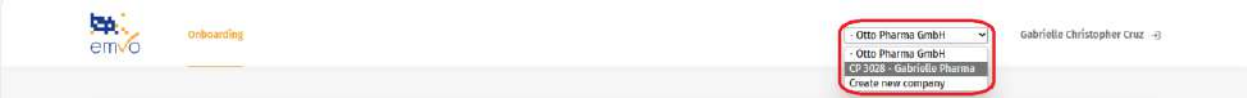

Figure 61: OBP Portal Updated Account List

By selecting another company, you will be redirected on the onboarding page of the selected company allowing you to proceed with the remaining steps:

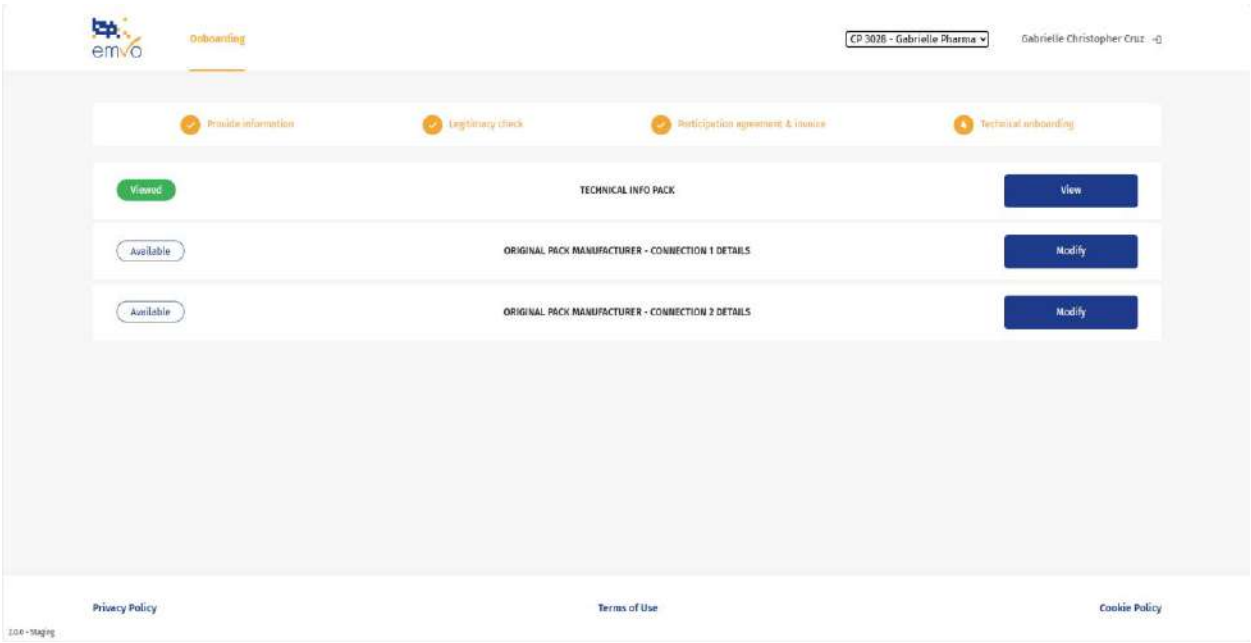

Figure 62: OBP Portal Selected Company Onboarding Page

3.3.2 Update Company Information

The SPOC/SPOC Assistant can update the Company Information at any given point after the signature of the PA, in the sub-section *'Company Information'* by clicking on the button *'Modify'*. The company type cannot be modified.

Figure 63: Update Company Information

Note: As per the PA in place with EMVO, the OBP is required to inform us **in advance** via email (helpdesk@emvo-medicines.eu) as soon as any of the following information is modified:

- OBP Company Name
- OBP Company Address
- OBP Company Registration Number

3.3.3 Update Contact Information

The SPOC/SPOC Assistant can update the Contact Information at any given point after the signature of the Participation Agreement, in the sub-section *'Contact Information'* by clicking on the button *'Modify'*.

Figure 64: Update Contact Information

If no SPOC Assistant had been assigned yet to the OBP, a SPOC Assistant can be added in this step.

If the SPOC or SPOC Assistant emails are modified, the new SPOC or SPOC Assistant will receive credentials in order to login. The old SPOC or SPOC Assistant account access is revoked only from the Specific OBP account from which they were removed from and upon the successful login of the new SPOC or SPOC Assistant.

If the AR has changed, a new Copy of Proof has to be uploaded.

3.3.4 Update MAHs & Products Information

The SPOC/SPOC Assistant can update the MAHs & Products Information at any given point after the signature of the PA, in the sub-section '*MAHs & Products Information*' by clicking on the button *'Modify'*.

Figure 65: Update MAHs & Products Information

While only one MAH is requested for the Legitimacy Check, the OBP should later provide EMVO with a full list of its affiliated MAHs on behalf of which it will upload data to the EU Hub.

The definition of all fields of the MAHs & Product Information is available in section 3.2.1.4 *'MAH & Product Information'* of this document.

Note: The type of Marketing Authorization Registration (e.g. centrally authorized), 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. Thus, (a) centrally authorized 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.

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

How to add and/or modify MAH & Product Information has been described in section 3.2.1.4 *'MAH & Product Information'* of this document.

Please make sure that every single MAH is listed only **once**.

3.3.5 Update Participation Agreement

The countersigned PA can be downloaded at any moment in the sub-section '*Participation Agreement'*.

Figure 66: Update Participation Agreement

Upon request of EMVO, the OBP may have to sign a new PA. The SPOC and/or the SPOC Assistant will be informed via email that a new PA is available.

Note: the following changes do **not** require an update of the PA:

- OBP Company Name Change
- OBP Company Address Change
- Authorized Representative Change
- SPOC/SPOC Assistant Change

In these cases, please inform EMVO before you execute the changes, so that EMVO can prepare an amendment to the PA.

For any further information regarding the PA, please refer to section 3.2.3 '*Section 3: Participation Agreement and Invoice*' of this document.

3.3.6 Update Invoice

Important Note: As per the PA 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.

In case the OBP has to update its list of affiliated MAHs in order to add new MAHs on the OBP Portal, and the total number of which is higher than the total number of MAHs for which the OBP has already paid the On-boarding fee, a new invoicing process will be launched.

To generate a new invoice, the SPOC/SPOC Assistant can go to the sub-section '*Invoice*' and first click on the button '*View*' to make sure than the information are correct. A draft of the invoice will be generated.

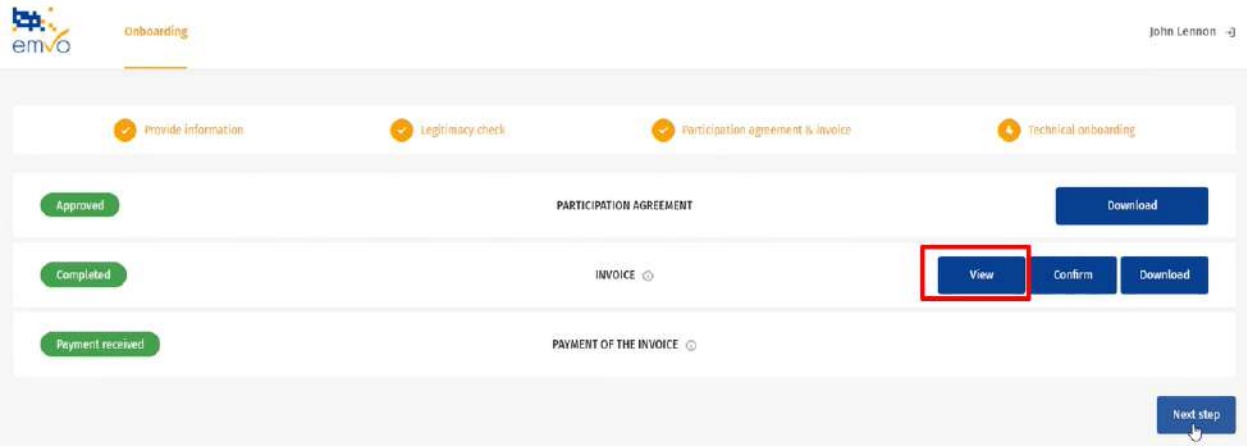

Figure 67: View Invoice

Then the SPOC/SPOC Assistant needs to click on the button '*Confirm*' to trigger the approval process.

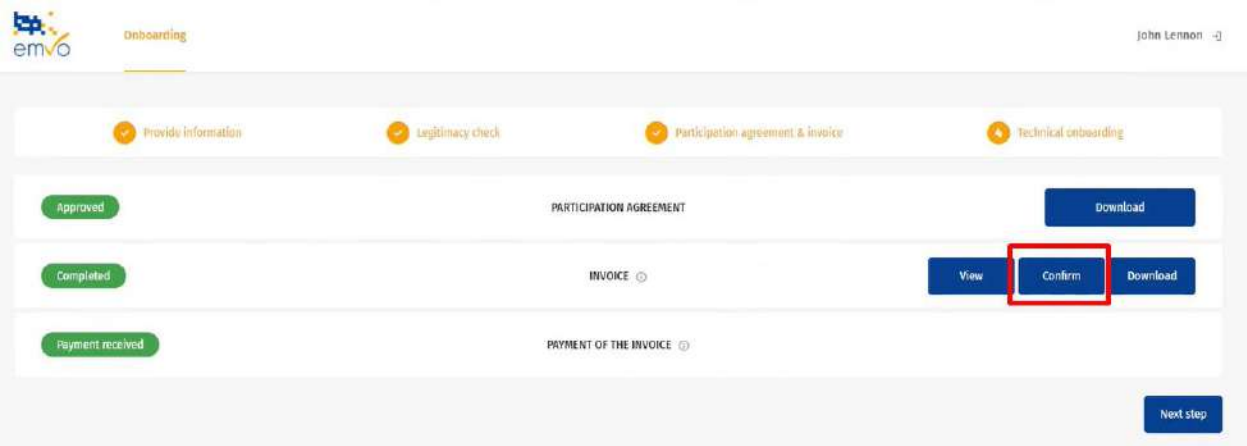

Figure 68: Confirm Invoice

The OBP shall contact the EMVO Helpdesk (helpdesk@emvo-medicines.eu) for that purpose. The payment status is updated once **every week**.

3.3.7 Divestiture and Acquisitions

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

In addition, please find here the OBP Divestiture and Acquisitions Guide.

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 Data upload correction 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 a data upload correction. 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?

3.4 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 authorization 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. Self-Service Portal
2. Frequently Asked Questions (FAQ)
3. Documents Overview
4. 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) notifications 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. Self-Service chat: https://help.emvo-medicines.eu/en/
2. EMVO's Service Desk – email address: helpdesk@emvo-medicines.eu
3. EMVO's Service Desk – phone number: +32 (0)2 657 00 08

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