



OBP On-Boarding Guideline

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On-boarding Guideline/Manual

for MAH

(without parallel distribution activity)

and

Parallel Distributors

(MAH with parallel distribution activity)



How to connect to the European Hub?

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

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

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List of abbreviations

AR	Authorised Representative
CEO	Chief Executive Officer
CER	Certificate
CFO	Chief Financial Officer
CIO	Chief Information Officer
CMO	Contract Manufacturing Organisation
CSR	Certificate Signing Request
DR	Delegated Regulation
EAEPCC	European Association of Euro-Pharmaceutical Companies
EFPIA	European Federation of Pharmaceutical Industries and Associations
EMVO	European Medicines Verification Organisation
EMVS	European Medicines Verification System
EU Hub	European Hub
FMD	Falsified Medicines Directive
GIRP	European Healthcare Distribution Association
IQE	Integrated Quality Environment
ITE	Integrated Test Environment
MAH	Marketing Authorisation Holder
NDA	Non-Disclosure Agreement
NMVO	National Medicines Verification Organisation
NMVS	National Medicines Verification System
OBP	On-boarding Partner
OBP Portal	On-boarding Partner Portal
PA	Participation Agreement
PD	Parallel Distributor
PGEU	Pharmaceutical Group of the European Union
PRD	Production Environment
RR	Registration Requester
SDK	Software Development Kit
SPOC	Single Point of Contact
SPOC	Single Point of Contact
UI	Unique Identifier



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1 Introduction

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

This guideline provides all manufacturers [marketing authorisation holders (MAH)] assistance in the upcoming implementation of the required measures for protection against falsification and describes in detail the On-boarding Process to the pan-European system against falsified medicines.

1.1 Falsified Medicines Directive

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

1.2 Delegated Regulation

The [Delegated Regulation \(EU\) 2016/161](#) detailing the characteristics of the safety features, how medicine authenticity should be verified, and by whom, was adopted on 2nd October 2015 and published, after scrutiny by the European Parliament and the Council, on 9th February 2016. The Delegated Regulation, and the new medicine verification system (repositories system) it specifies, will apply as of **9th February, 2019**¹. The key principle is to guarantee medicine authenticity by an end-to-end verification system supplemented by risk-based verifications by wholesalers: Medicines should be systematically verified at the point of supply to the public (e.g. at pharmacy level). Medicines at higher risk of falsification should

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



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additionally be checked at wholesaler level. To make this possible, a repositories system should be established and managed by stakeholders. As set out in the Delegated Regulation the main tasks of the repositories system are to store the information of the legitimate Unique Identifiers (UIs) and to allow the verification/decommissioning of UIs at any point of the supply chain.

1.3 European Medicines Verification System

The [European Medicines Verification Organisation \(EMVO\)](#) is a Belgian non-profit organisation representing stakeholders united in securing the legal supply chain from falsified medicines. EMVO has taken responsibility for advancing the formation of the European Medicines Verifications System (EMVS) in accordance with the Falsified Medicines Directive (Directive 2011/62/EU) and the delegated Regulation (EU) 2016/161 to ensure the implementation of a functioning, secure, interoperable and cost effective medicines verification system across Europe. Its founding members are EFPIA (the European Federation of Pharmaceutical Industries and Associations), Medicines for Europe (the European Generic and Biosimilar Medicines Association), PGEU (the Pharmaceutical Group of the European Union), GIRP (the European Healthcare Distribution Association) and EAEPCC (the European Association of Euro-Pharmaceutical Companies).



Figure 1: EMVO Stakeholder

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

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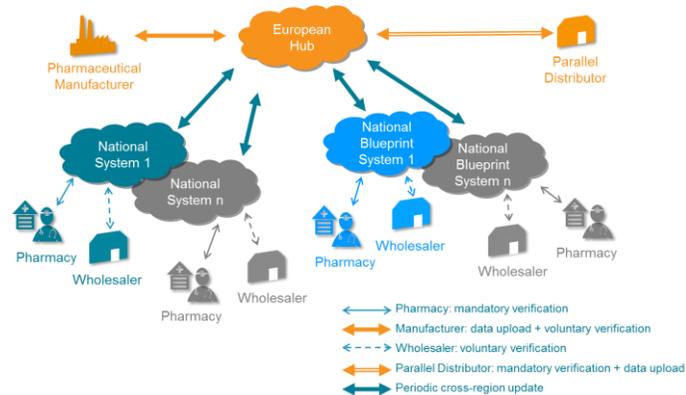


Figure 2: European Medicines Verification Landscape

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

1.4 European Hub

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

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

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

- It provides a single-entry point for MAH without parallel distribution activity and MAH with parallel distribution activity (Parallel Distributors) to upload their product serialisation data.
- It provides a single access point from which national systems can obtain revised/new product serialisation data.



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- It provides a centralised location for the storage of master data and master data regarding the connected national systems.
- It provides a means by which multi-market packs can be systematically marked as 'decommissioned' in all affected markets once a pack has been dispensed in one market.
- It provides a means to decommission packs by MAH without parallel distribution activity and MAH with parallel distribution activity (Parallel Distributors).
- It provides a verification gateway for parallel distributors to access the repositories of the source markets for verification of authenticity.
- It provides a central point from where information concerning product recalls can be transmitted in addition to the established recall procedures.
- It provides a mechanism by which exported and imported products can be reconciled at a dose level as they are used by parallel distributors in repackaging / relabelling.
- It provides a central point from which alerts, that cannot be handled solely at the national level e.g. issues in different countries with multi-market packs, can be managed. This includes providing response e.g. to the appropriate company/regulatory authority etc.
- It provides a platform permitting cross-country inquiries, in accordance with Delegated Regulation Article 34(2), in order to verify whether a UI that was not found in a national repository is stored elsewhere in the repositories system.

1.5 National Medicines Verification Systems

The National Medicines Verification Systems (NMVS) are currently being established in all participating Member States. The main purpose of the National Medicines Verification Systems is to serve as the verification platforms that pharmacies or other registered parties such as wholesalers, self-dispensing doctors or hospital pharmacies will use to check a product's 'authenticity'. All data necessary to perform this and other relevant transactions are stored in the respective NMVS.

The key tasks of the National Systems are:

- Hold the relevant product serialisation data for this market.
- Receiving revised/new product serialisation data from the European Hub.
- Serving as the verification platform for pharmacies or other registered parties such as wholesalers and hospitals to check for a product's authenticity.

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- Serving as the platform wholesalers in the case of member states application of Art 23 DR, to mark a product pack as decommissioned prior to handing it over to the patient.
- Serving as the platform for wholesalers to mark a product pack as 'decommissioned' e.g. 'exported out of EU'.

2 Connection of OBPs to the European Hub

According to the DR, MAH without parallel distribution activity and MAH with parallel distribution activity (Parallel Distributors) have to upload unique identifiers and related information to the repositories system before their medicinal products are released for sale or distribution. An OBP is a legal entity that is authorised to sign on behalf of MAHs without parallel distribution activity or MAHs with parallel distribution activity (Parallel Distributors) and conclude the Participation Agreement (PA) with EMVO.

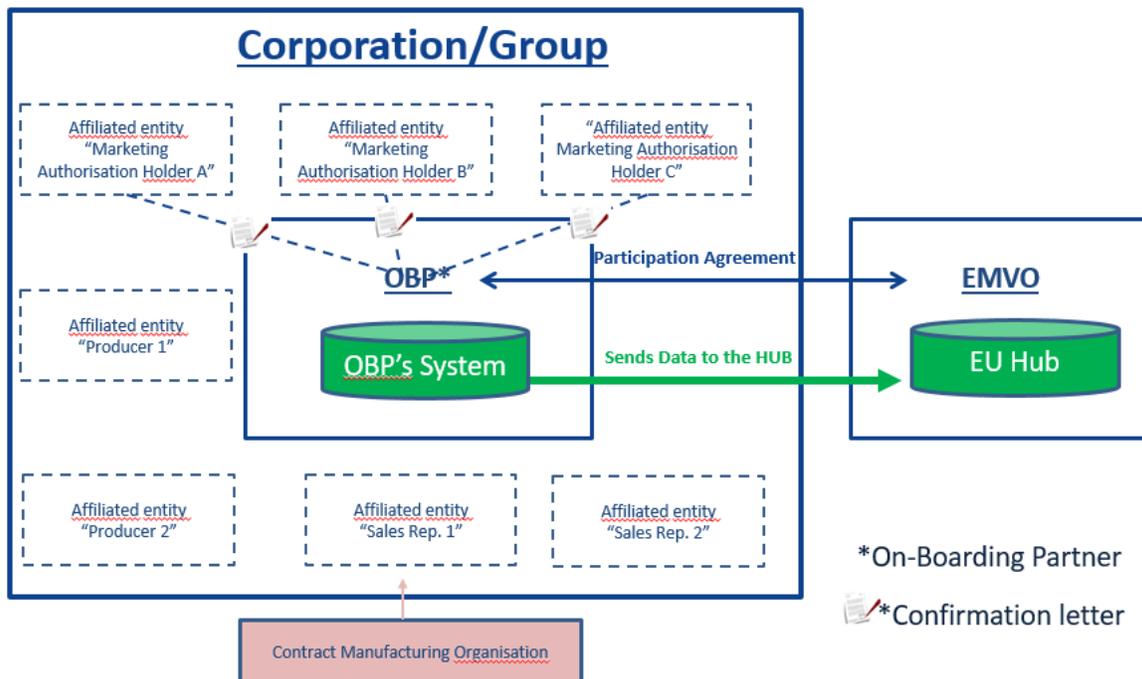


Figure 3: Relationship between the OBP and EMVO (This figure is also applicable to PDs)



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To upload these data to the repositories system, OBPs have to connect their (IT) systems to the European Hub (see [White Paper EMVS Data Upload](#)). In order to establish this connection, OBPs have to follow EMVO's On-boarding Process which consists of multiple steps set out below.

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

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

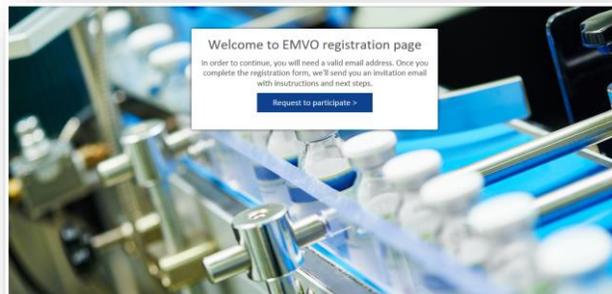
3 On-boarding Partner Portal

3.1 Introduction

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

As a first step of the registration process a company representative visits the EMVO website and registers for the EMVO OBP Portal. (Any delegate of the OBP is able to request access to the EMVO OBP Portal). This person is called a Registration Requester (RR). The Registration Requester will receive personal login data for the system portal. In order to be granted access, the user has to provide basic data during the first log-in.

- Request to participate





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- Complete company information

Request to participate

User details

First Name

Last Name

e-mail

Company details

Company Name

Country of Registration

VAT Number

Type of Organisation

Marketing Authorisation Holders (MAH) with Parallel Distribution activity

Marketing Authorisation Holders (MAH) without Parallel Distribution activity

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

Figure 4: EMVO OBP Portal – Portal Registration

3.2 Steps of the On-boarding Process

Once the registration request is submitted, EMVO creates a secured area for the OBP within the OBP Portal. The user will receive an email with a link to his OBP Portal area. He will be shown the below screen with the 5 steps of the on-boarding process during which he completes and uploads all necessary on-boarding information [e.g. company information, contact details, product information, non-disclosure agreement (NDA) and a participation agreement (PA)].

Step 1: Provide initial information

Step 2: Non-disclosure agreement

Step 3: Detailed information and participation agreement

Step 4: Approvals

Step 5: Technical onboarding

Figure 5: EMVO OBP Portal – Dashboard



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3.2.1 Step 1: Provide initial information

		Time to complete	Status
1.1	Company information ⓘ	5-7 min	Complete
1.2	Authorised representative information ⓘ	5-7 min	Complete
1.3	Connection provider information ⓘ	5-7 min	Complete

Figure 6: EMVO OBP Portal – Initial information

3.2.1.1 Step 1.1: Company information:

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

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

3.2.1.2 Step 1.2: Authorised Representative information

In this step an Authorised Representative (AR) needs to be appointed. The AR should be a senior officer, who is authorised to sign on behalf of the company (for example "Prokurist" in Germany) or the person holding the position of CEO, CFO, CIO or a member of the management board. Only the named AR is able to sign the non-disclosure agreement (NDA) and the participation agreement (PA) in name and on behalf of the OBP. Therefore, at this step, you will be asked to proof the legitimacy of the Authorised Representative by attaching a copy of the trade register excerpt, for example, in order to certify his/her authorisation to sign on behalf of the OBP.



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The Authorized Representative will:

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

3.2.1.3 Step 1.3: Pre-technical connection information

If, as OBP, you chose to make use of a Gateway connection to upload your data, you will need to sign a contract with a Gateway Provider (a third-party contractor engaged by the OBP, who assists with the development, implementation, provision, use and/or operation of the OBP interface to the EU Hub. This assistance can be partial or total). You will then send your data to the Gateway Provider who sends it through to the European Hub.

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

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

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

3.2.2 Step 2: Non-disclosure agreement

The screenshot shows a progress bar for 'Step 2: Non-disclosure agreement' which is marked as 'Complete'. It lists three tasks with their respective actions, time to complete, and status.

		Time to complete	Status
2.1	Non-disclosure agreement ⓘ View & Print	1 min	Available
2.2	Upload signed non-disclosure agreement ⓘ <input type="button" value="Upload PDF"/>	1 min	Approved
2.3	Two hardcopies sent to EMVO ⓘ View	21 days	Sent back on 02-03-2017



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Figure 7: EMVO OBP Portal – non-disclosure agreement

3.2.2.1 Step 2.1: Non-disclosure agreement

As soon as the information about the OBP and the associated Authorised Representative have been completed in the Portal, a pre-filled OBP non-disclosure agreement (NDA) will be generated and will become available in PDF-format. The NDA is based on a standard template. As EMVO expects to on-board more than 2500 OBP's, it is decided that this NDA is NON-NEGOTIABLE. The NDA ensures confidentiality and is an essential requirement for the provision of further information. Follow the link to view a sample of the standard template NDA:

OBP Non-Disclosure Agreement (SAMPLE)



[Non-Disclosure Agreement](#)

3.2.2.2 Step 2.2: Upload signed non-disclosure agreement

In this step, a scan of the NDA checked and signed by the Authorised Representative has to be uploaded in the OBP Portal (only PDF-format accepted).

3.2.2.3 Step 2.3: Two hardcopies sent to EMVO

After the OBP has signed the pre-filled NDA, the OBP has to send two original hardcopies of the NDA by regular postal services to the offices of EMVO in Brussels:

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

After receipt and approval by EMVO, a countersigned NDA will be uploaded in the OBP Portal and one countersigned hardcopy will be send back to the Authorised Representative by postal services.



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3.2.3 Step 3: Detailed information and participation agreement

			Time to complete	Status
3.1	General info pack ⓘ	Open		Available
3.2	Single point of contact information ⓘ	Modify	5-7 min	Complete
3.3	Participation Agreement ⓘ	View & Print	1 min	Available
3.4	Upload Signed Participation Agreement ⓘ	Upload PDF	1 min	Not Started
3.5	Invoicing information ⓘ	Add	5-7 min	Not Started
3.6	Additional company information ⓘ	Add	5-7 min	Not Started
3.7	MAH and product information ⓘ	Add	60 min	Not Started

Figure 8: EMVO OBP Portal – Detailed information and participation agreement

3.2.3.1 Step 3.1: General info pack

When the NDA is signed by the OBP, a general info pack will be available for download and an email will be sent to the Registration Requester. This general info pack consists of the following documents:

- The On-boarding presentation
- The EMVO Gateway Manual

3.2.3.2 Step 3.2: Single point of contact information

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

3.2.3.3 Step 3.3: Participation Agreement

After the completion of all requested information about the SPOC, a pre-filled OBP Participation Agreement (PA) will become available (step 3.3). Please be aware that also the PA is based on standard template that

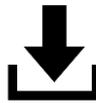


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is strictly NON-NEGOTIABLE for the same reason as why the NDA is non-negotiable. Please follow the link to view the standard template:

OBP Participation Agreement (SAMPLE):



[Participation Agreement](#)

3.2.3.4 Step 3.4: Upload signed Participation Agreement

In this step, a scan of the PA, checked and signed by the Authorised Representative, has to be uploaded in the portal and two original hardcopies of the PA have to be sent to the offices of EMVO in Brussels:

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

3.2.3.5 Step 3.5: Invoicing information

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



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

Figure 9: EMVO On-boarding fee

3.2.3.6 Step 3.6: Additional company information

In the following step, additional company information needs to be completed to allow verification of identity, role and legitimacy of the OBP. EMVO will carry out a multi-stage legitimacy check. To ensure that the check is as effective as possible, the individual parameters are strictly confidential and will not be published.

3.2.3.7 Step 3.7: MAH and product information

In this step, the OBP has to complete a full list of MAHs on whose behalf the upload of data to the EU Hub is performed. Only for MAHs that are listed in this step, the data upload to the European Hub is permitted. The list of MAHs will also be used to check the legitimacy of the OBP as it is required that the OBP and the MAHs are affiliated.

As soon as all required data are available in the OBP Portal and confirmed by the SPOC, the legitimacy check will be executed.



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3.2.4 Step 4: Approvals

Step 4: Approvals		Time to complete	Status
4.1	Legitimacy check status ⓘ	14 days	
4.2	Countersigned Participation Agreement send back to OBP ⓘ	21 days	
4.3	Invoice status(without logic) ⓘ		

Figure 10: EMVO OBP Portal – Approvals

3.2.4.1 Step 4.1: Legitimacy check status

After the legitimacy check is successfully completed, the process can proceed. In case the check was not successful, the OBP will be informed about the reason of rejection or in case of incorrect/missing information the OBP will be asked by email to correct or upload the missing data.

3.2.4.2 Step 4.2: Countersigned Participation Agreement sent back to OBP

In this step EMVO countersigns the PA, upload a scan and sends one hardcopy back to the SPOC. After completion of this process, the SPOC will receive login credentials for the portal. The account of the Registration Requester will be revoked automatically at this point.

As the SPOC is responsible for the data provided to the OBP Portal, all data already filled-in into the OBP Portal needs to be verified. All new requested information needs to be provided by the SPOC.

3.2.4.3 Step 4.3: Invoice status

After payment of the On-boarding fee, the Technical On-boarding process will be initiated.

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3.2.5 Step 5: Technical On-boarding

3.2.5.1 Introduction

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

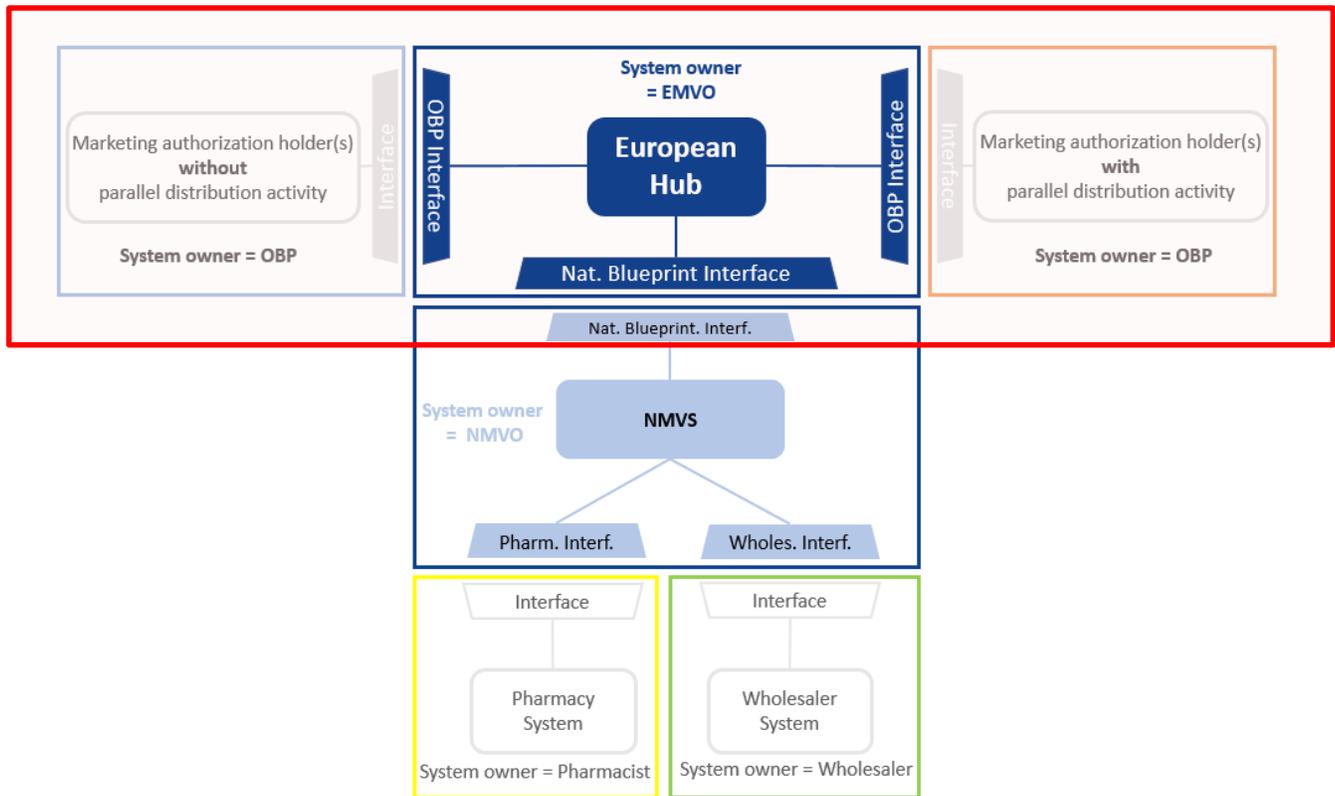


Figure 11: OBP's connection to the repositories system (EU Hub)

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3.2.5.2 EU Hub Environments

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

The first **Integrated Test Environment (ITE)** can be used as a sandbox² by the OBPs to perform the first development of the connection and do a first integration test³.

When the OBP feels confident enough he can use the **Integrated Quality Environment (IQE)** to perform the Quality & Certification test.

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

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



Figure 12: Available Environments for the OBP in the EU Hub

² 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.

³ Integration testing is a type of software testing performed as a first test of the integration or interfaces between the system of the OBP and the EU Hub.



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3.2.5.3 Step 5.1: Technical info pack

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

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

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

The technical info pack consists of following documents:

- Overview technical documentation
- How to create a Certificate Signing Request (CSR) file
- Software Development Kit (SDK) Documentation
 - a. EMVS SDK for MAH (without parallel distribution activity)
 - b. EMVS SDK for Parallel Distributors (with parallel distribution activity)
- On-boarding Process
 - a. On-boarding Process for OBP to EU Hub via Direct Connection
 - b. On-boarding Process for OBP to EU Hub via Gateway Connection
- Java Pack
 - a. Java SDK Installation Instructions
 - b. Java SDK Project Description
 - c. Java SDK_MAH
- .NET Pack
 - a. Code Samples
- Test Pack
 - a. Mini-Certification Test for EMVO Gateway Template
 - b. Template OBP Self Certification Checklist
 - c. OBP Self Certification Test Cases

3.2.5.4 Step 5.2: Connection client 1

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



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3.2.5.4.1 Step 5.2.1: Connection details

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

This details consist of the following data:

1. Client name
2. Type of Connection
 - a. Direct⁴
 - b. Gateway⁵
3. Type of technology
 - a. .NET
 - b. JAVA
4. Client validation Status
 - a. Validated
 - b. Non-Validated

3.2.5.4.2 Step 5.2.2: ITE – Information to create a CSR file

Only when the following dependencies are succeeded an account for the OBP to ITE of the EU Hub will be created:

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

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

- Organisation ID + Client ID
- Token

⁴ With a Direct Connection, the master data will be sent directly from the OBP's client to the EU Hub

⁵ With a Gateway Connection, the master data will be sent from the OBP's client to the Gateway provider, who sends the master data through to the EU Hub



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

The connection to the ITE is obligated for any OBP who desires a Direct Connection or a connection via a non-certified Gateway Provider⁶. This test environment can be used to develop the connection and to perform some integration testing.

3.2.5.4.3 Step 5.2.3: ITE – Upload CSR file

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

3.2.5.4.4 Step 5.2.4: ITE – Certificate (CER)

The uploaded CSR file will be signed by EMVO and returned as an X.509 certificate for ITE. In this step the X.509 (.CER) file will be uploaded by EMVO.

Only when the X.509 certificate has been used to complete the certificate generation process will a PKCS #7 certificate, which includes the private key be generated. The OBP will require both the public and private keys from this certificate to access ITE.

In case the OBP requested a connection via a Gateway Provider, the full certificate, in the form of a PKCS #7 password protected file will need to be distributed to the Gateway Provider in order to establish the connection to ITE.

3.2.5.4.5 Step 5.2.5: ITE – Request access to IQE

After the OBP developed the connection in ITE and feels confident enough to start the self-certification test, he can request access to the IQE at any time.

3.2.5.4.6 Step 5.2.6: IQE – Information to create CSR file (*same procedure as step 5.2.2*)

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

- Client + Organisation ID
- Token

⁶ Certified Gateway Provider is a provider which for a first OBP already passed the full-certification test of the Gateway of this Gateway Provider



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

The connection to ITE can be skipped for the OBPs who desires a connection via a Certified Gateway Provider⁷. In this case the information to create the CSR file for IQE will be available immediately in order to perform the self-certification test.

3.2.5.4.7 Step 5.2.7: IQE – Upload CSR file *(same procedure as step 5.2.3)*

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

3.2.5.4.8 Step 5.2.8: IQE – Certificate (CER) *(same procedure as step 5.2.4)*

The uploaded CSR file will be signed by EMVO and returned as an X.509 certificate for IQE. In this step the X.509 (.CER) file will be uploaded by EMVO.

Only when the X.509 certificate has been used to complete the certificate generation process will a PKCS #7 certificate, which includes the private key be generated. The OBP will require both the public and private keys from this certificate to access IQE.

In case the OBP requested a connection via a Gateway Provider, the full certificate, in the form of a PKCS #7 password protected file will need to be distributed to the Gateway Provider in order to establish the connection to IQE.

3.2.5.4.9 Step 5.2.9: IQE – Upload Certification Test Results

At first the OBP will be asked to perform a first smoke⁸ & sanity⁹ check to make sure the connectivity and functionality within IQE works fine.

⁷ Certified Gateway Provider is a provider which for a first OBP already passed the full certification test of the Gateway of this Gateway Provider

⁸ Smoke Testing is a type of software testing performed after software build to ascertain that the critical functionalities of the program is working.

⁹ Sanity testing is a type of software testing performed after receiving a software build, with minor changes in code, or functionality, to ascertain that the bugs have been fixed and no further issues are introduced due to these changes.



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Full – Certification Test Results:

When the OBP has requested a direct connection or a connection via a non-certified Gateway Provider the OBP will be obligated to perform the Full-Certification Test. In step 5.2.9 the OBP will be asked to upload the test checklist with the test results.

Mini – Certification Test Results:

When the OBP has chosen for a Certified Gateway Provider¹⁰ only a Mini-Certification test is required. In step 5.2.9 the OBP can upload the test checklist with the test results.

Note: In case of the EMVO Gateway only the “Mini-Certification Test for EMVO Gateway Template” which can be found in the technical info pack need to be fulfilled and uploaded.

Feedback Certification Test Report

EMVO Operational Department will evaluate the test results provided by the OBP. If access is approved, EMVO Operational Department will grant access to PRD and upload the Feedback Certification Test Report in return.

3.2.5.4.10 Step 5.2.10: PRD – Information to create CSR file (*same procedure as step 5.2.2*)

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

- Client + Organisation ID
- Token

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

3.2.5.4.11 Step 5.2.11: PRD – Upload CSR file (*same procedure as step 5.2.3*)

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

¹⁰ A Gateway Provider is certified when a first OBP passed the full certification test of the gateway of this Gateway Provider



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3.2.5.4.12 Step 5.2.12: PRD – Certificate (CER) *(same procedure as step 5.2.4)*

The uploaded CSR file will be signed by EMVO and returned as an X.509 certificate for PRD. In this step the X.509 (.CER) file will be uploaded by EMVO.

Only when the X.509 certificate has been used to complete the certificate generation process will a PKCS #7 certificate, which includes the private key be generated. The OBP will require both the public and private keys from this certificate to access PRD.

In case the OBP requested a connection via a Gateway Provider, the full certificate, in the form of a PKCS #7 password protected file will need to be distributed to the Gateway Provider in order to establish the connection to PRD.

3.2.5.5 Step 5.3: PRD – Connection client 2 (if applicable) *(same procedure as Step 5.2)*

The OBP is allowed to establish a second technical connection to the EU Hub with a maximum of two connections. Each client can only have 1 connection.

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

3.3 Timeline

Once the FMD effectiveness date comes into force on 9th February 2019, only serialised packs of medicine can be placed on the market. The schedule below shows that – assuming the usual project times – introduction for serialisation should begin as early as possible in order to be able to deliver all affected products at the start of February 2019. In any case, the complexity of the project involves a lot of imponderability's. On-boarding to the EU Hub is only a very small element of the overall manufacturer's/marketing authorisation holder's readiness, e.g.

- Identify products needing safety features
- Determine when to start supplying product with safety features
- Tamper evidence technology
- Plan for budget to cover cost of verification system
- Serialise Pack: AT-Line, carton and artwork, etc.
- Implement serialisation capability on packing lines/site
- Implement rework capability in warehouse/internal distribution
- Establish a Serialisation Data Repository



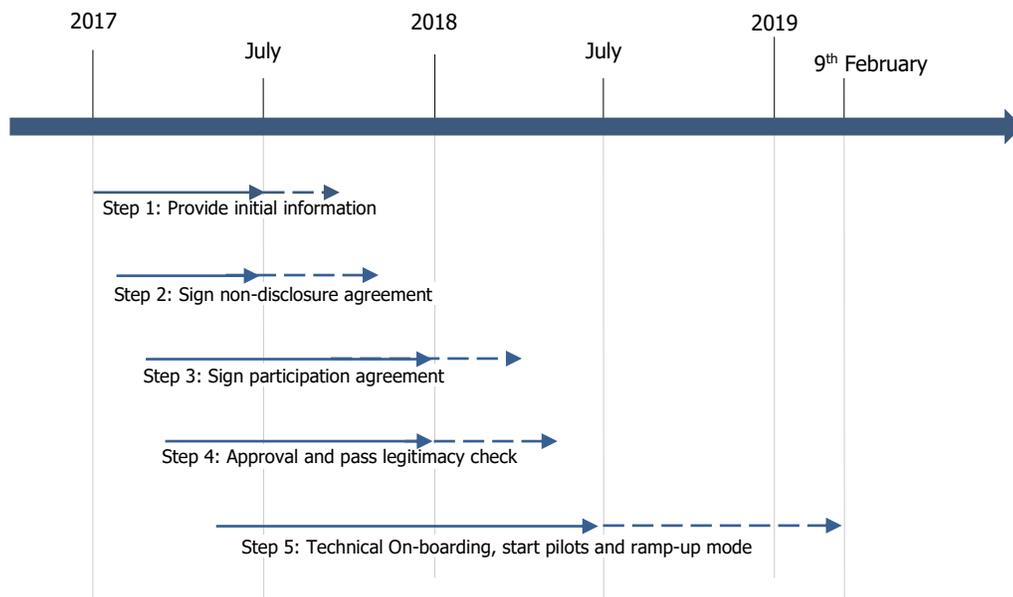
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- Choose an IT Service Provider
- Connection of Contract Manufacturing Organisations (CMOs)
- Validation
- Master Data Management

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

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





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4 Contact and support

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

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

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5 Appendix

1. Organisation chart



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