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ON-BOARDING PRESENTATION

HOW TO CONNECT TO THE EU HUB? VERSION 13.0 MAY 2020

<u>www.emvo-medicines.eu</u> <u>helpdesk@emvo-medicines.eu</u>

Please check

www.emvo-medicines.eu

for the latest version of this Presentation and the On-boarding Guideline.



DISCLAIMER

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ON-BOARDING PARTNER PORTAL

General Information How does the On-boarding work?

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ON-BOARDING PARTNER PORTAL

General Information How does the On-boarding work?

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FMD LEGISLATION AND DELEGATED ACT



- Establish National Systems in 32 countries
- Connect many thousand Pharmacies and Wholesalers
- Serialise all affected pharmaceutical packs (10.5 bn)



FMD: Falsified Medicines Directive

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RESPONSIBILITIES OF THE SUPPLY CHAIN PARTNERS

Serialisation by MAH

Risk based verification by Wholesalers

Verification and check-out at point of dispense





Product #:	09876543210982
5/N:	12345AZRQF1234567890
Batch:	A1C2E3G4I5
Expiry:	135032



System set up and governance by MAH together with other stakeholders

Oversight by competent authorities



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ORGANISATION CHART



SYSTEM LANDSCAPE



SYSTEM LANDSCAPE II



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WHAT IS AN "OBP"?

- OBP means **On-boarding Partner**. The OBP is the contracting party of EMVO and enters into the Participation Agreement (PA) with EMVO.
- The OBP **represents the Marketing Authorisation Holders (MAHs)** on behalf of which it will upload data on the European Hub (EU Hub). The OBP has therefore to be authorised to do so by its MAH/a group of MAHs.
- The OBP has to be **affiliated (*) to its MAH(s)**.
- The MAHs should be located in the European Economic Area (EEA).
- The OBP can only upload product data for its affiliated MAHs as long as :
 - They are <u>either</u> original pack manufacturers <u>or</u> parallel distributors
 If the OBP would like to represent both types of MAHs, it will have to create two OBP accounts (**)
 - The Marketing Authorisation of the related products lies within the OBP group. Contract Manufacturing Organisations (CMOs) cannot upload their manufactured product data in the EU Hub.

(*) 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.

(**) Please contact the EMVO Helpdesk for further instructions if you represent both. (Contact details are provided at the end of this presentation.)

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The Marketing Authorisation Holder (MAH) is legally responsible for the quality, efficacy and safety throughout the entire life cycle of the product. Activities may be delegated, but overall responsibility is retained by the MAH.

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WHAT IS AN OBP CONNECTION PROVIDER?

- A third-party provider engaged by the OBP, who assists the OBP entirely or partially with the development, implementation, provision, use, and/or operation of the OBP interface to the EU Hub via a Gateway Connection,
- Every OBP Connection Provider has to be promoted by at least one OBP in the On-boarding Process,
- A registered OBP Connection Provider is a provider which signed the License Agreement with EMVO and a Support Contract with SolidSoft.



ON-BOARDING CONTRACT LANDSCAPE



- Direct connection

ON-BOARDING PROCESS



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ON-BOARDING PARTNER PORTAL

General Information How does the On-boarding work?

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HOW DOES THE ON-BOARDING WORK?

On-boarding Partner Portal (OBP Portal)

Webservice to guide the OBPs through the requirements to connect to the EU Hub.

Step 2: Detailed Information and P	articipation Agreement	
Step 3: Approvals		
Step 4: Technical On-boarding		
Step 5: Maintenance		
Private Policy	Terms of Use	Cookie

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HOW TO SPEED UP THE PROCESS?

Collect Information:

- 1. Visit the <u>EMVO Knowledge Database</u> for FAQs, Documents and Training Videos.
- 2. Who will be the **On-boarding Partner?**
- 3. What is my Company Registration number and VAT number?
- 4. Who can and will be the **Authorised Representative**?
- 5. Who can and will be the **Single Point of Contact** (SPOC) and its **Assistant** (SPOC Assistant)?
- 6. How many **MAHs** does the OBP represent?

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HOW TO REQUEST TO PARTICIPATE?

1. Via website – <u>link</u>



2. Fill in User + Company details



3. You'll be directed to the confirmation screen



4. Check your email to validate your companies account

I II ↔ C ↑ ↓ : RE MESSAGE	EMI/O OBP Portal: Request Registered - Message (HTML)		
ADD/DEFT MATE DOCPD/W@Emvs.com DocPD/W@Envs.com Comments Add Deft Request Registered Contracts, With Crick new to download pictures. To help protect your privacy. Outlook prevented automatic download of som	e pictures in this message.		
Iello Willem Theunissen. We've received your onboarding request. To validate your email address and complete registration please follow the link below.			
'alidate email address and continue onboarding			
Sind regards, MVO Team uropean Medicines Verification Organisation			
el. + 32 2 657 00 08 www.emo-medicines.eu sejodeskillernvo.medicines.eu			
emvo			



HOW TO REQUEST TO PARTICIPATE?

5. Your OBP Portal will be created **\$\$\$**. **\$**\$\$. emvo emvo Thanks for registering Thanks for registering t whilst we prepare your Company On-Boarding Portal. Your Company On-Boarding Portal has now been created We have sent an email to the account you registered with containing further details. 7. Follow the instructions in your email to login to your OBP 8. Your company is ready to On-board Portal 🔤 🔒 🕤 ଓ 🕈 🎍 : FILE MESSAGE noreplv@emvs.com EMVO OBP Portal: Your new site details Step 1: Provide Initial Information Hello Willem Theunissen Step 2: Detailed Information and Participation Agreement Welcome to the EMVO On-boarding Partner Portal (OBP Portal). Please follow all the instructions below to logon to your personal OBP Portal area Your username: W.Theunissen-EMVO@ Temporary password: a9eTA_CB Click here to access your onboarding portal For help and support please email helpdetk@emyo-medicines.eu or visit https://www.emyo-medicines.eu Login Guide: Step 1: Follow the link to your site above Step 2: Log in using your new account and temporary password: a9eTA_CB Step 3: Update your password Step 4: Select Organisational account on the account selection screen Private Policy Terms of Use Welcome to SharePoint Online

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Microsoft account Sign is with the account

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6. Your OBP Portal is created

Cookie Policy

INITIAL REGISTRATION REQUESTER CREDENTIALS

IMPORTANT NOTE !

The SPOC and the SPOC Assistant are the only persons having the credentials to access the OBP Portal. However, in the event the Initial Registration Requester is the same person as the SPOC, they will be able to access the OBP Portal with the credentials received in the first place.



ON-BOARDING PARTNER PORTAL

Step 1: Provide Initial Information

Step 2: Detailed Information and Participation Agreement

Step 3: Approvals

Step 4: Technical On-boarding

Step 5: Maintenance

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1 PROVIDE INITIAL INFORMATION



1.1 COMPANY INFORMATION

Company Information		×
Company Name *		
Country of Registration *		
VAT Number *		
Company Registration Number * 🛭 📵		
Street *		
Number *		
Box		
Zip code *		
City *]
Country *]
Business Phone * 🚺]
Web Page]
Company Email Address *]
Parent Company information		
Company Type * 🚯	 Parallel Distributor Original Pack Manufacturer 	
	Note: The permissions given in the EU Hub will depend on the Company Type. Please check the information button and make sure the information is correct. Any error in the selection of the company type will bring the pursuit of the on-boarding at stake.	
Marketing Activity Status *	Start-upEstablished	
	Save]

Company Name:

✓ Make sure to provide the full official name of your company

Company identification numbers: VAT and Company Registration Number

- Make sure not to get confused between the OBP company, the parent company, and the MAHs information
- Make sure to include the full sequence of digits, with no typos, and the initial country identification letters in front, if necessary

Country name / Country of registration:

Make sure to provide the Country name, not the one of the county

Organisation (Company) Type:

The permissions given in the EU Hub will depend on the Organisation Type. Please check the information button and pay the greatest attention when filling this information that is of paramount importance! Any error in the selection of the organisation type will lead to incorrect authorisations for the OBP in the EU Hub and may result in <u>severe delays</u> in the On-boarding process and may result in an additional cost to be borne by the OBP.

ORGANISATION TYPE

IMPORTANT NOTE !

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

For the purpose of the FMD, which is addressed to 'Manufacturing Authorisation Holders', or 'Manufacturers', we have technically designed different interfaces for Original Pack Manufacturers and Parallel Distributors. Parallel Distributors base their master data partially on pack data previously issued by originator companies. It is therefore strictly necessary to distinguish the type of organisation before applying to connect to the EU Hub.

ORGANISATION TYPE

IMPORTANT NOTE !

For your Organisation Type, your organisation is requested to select either:

• **Parallel Distributor (PD)** which is an independent company purchasing medicines in one market and – after repackaging - placing these medicines on a different market (the market of destination) under a license obtained under its name from the National Competent Authority (NCA) of the destination market (parallel import license) or under comparable permits issued by the European Medicines Agency (EMA) for centrally approved medicines (EMA parallel distribution notice). Parallel distributors must repackage the product that they handle in order to comply with the labelling and other regulatory and trademark requirements of the destination market; this constitutes (partial) manufacturing and is subject to a manufacturing authorisation.

Or

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

4 ON-BOARDING CASES

- 1. If the MAH(s) is/are Original Pack Manufacturer(s) only, the Original Pack Manufacturers can choose one common OBP to represent/On-board them.
- 2. If the MAH(s) is/are Parallel Distributor(s) only, Parallel Distributors can choose one common OBP to represent/On-board them.
- 3. If some MAH(s) are Original Pack Manufacturers and some are Parallel Distributors, the Parallel Distributors choose one common OBP to represent/On-board them AND the Original Pack Manufacturers choose another common OBP to represent/On-board them.
- 4. If there is only <u>one MAH/entity</u> which will On-board but it has <u>both organisation types</u> (i.e. it is an Original Pack Manufacturer and Parallel Distributor at the same time (Hybrid company)), <u>please contact the EMVO Helpdesk for further guidance</u>.

1.2 AUTHORISED REPRESENTATIVE

Please provide the information related to the Authorised Representative together with a Copy of Proof, attesting the authorisation of the person who can sign on behalf of the company.

Authorised representative information	×	Note 1: The Authorised
First Name * 1) Last Name * Job Title * E-Mail * Business Phone * 1)		(AR) is the person authorised to sign on behalf of the
I confirm that I've uploaded an attachment which proves the authorized representative is e Copy of Proof (Mandatory) Attach file	ntitled to sign on behalf of the company * 3 O Yes	company. The AR will sign the Participation Agreement (PA).
Mandatory in order to	Note 2:	

proceed to further steps

NUIE Z.

A document listing all the National Registers in Europe, where to find the relevant Copy of Proof for your company, is available on our website in its download section.

FREQUENTLY COMMITTED ERRORS

Copy of Proof of the Authorised Representative

- Check the authorisation of your named Authorised Purpose: Representative (AR) to sign on behalf of the company
- The AR is to explicitly appear in the official register together with their senior management position and/or their explicit power to sign on behalf of the company
- ✓ The full name of the AR shall be provided, without translation or abbreviation, as it appears in the national register
- Please consult the <u>National Registers list</u> for European countries on EMVO's Website
- List of National Registers available on EMVO Website The document needs to be valid in case it is of a limited duration \checkmark

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1.3 CONNECTION PROVIDER INFORMATION

Optional step:

If the choice concerning which type of connection will be used to connect to the EU Hub is already made, this field may be filled-in to provide this information and allow EMVO to start the On-boarding of the potential connection provider in parallel.

Select connection		×
Select connection #1	Edit	
Select connection #2	Edit	
Request new gateway provider		
	Save Cance	21

If the Connection Provider of your choice is not listed in the drop-down menu, please click the '*Request new gateway provider*' button to promote them.

Drop-down menu listing the registered* Connection Providers.

Making use of a registered Connection Provider allows the OBP to start immediately the tests in the Integrated Quality Environment (IQE).

<u>Note:</u>

Only two connections are allowed per OBP.

***registered Connection Provider** is a provider which signed the License Agreement with EMVO and a Support Contract with SolidSoft.

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ON-BOARDING PARTNER PORTAL

Step 1: Provide Initial Information

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2 DETAILED INFORMATION



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2.1 GENERAL INFO PACK

X General info pack - Pack Documents Type Name Modified Modified By Checked Out To pdf EMVO0038 - EMVO Gateway User Manual Jamie Williams 2/20/2017 1:59 PM pdf EMVO_0086_OBP On-Boarding Presentation Willem Theunissen 5/24/2017 2:01 PM pdf EMVO_0077_OBP On-boarding Guideline 3/10/2017 1:50 PM Willem Theunissen EMVO 0127 Gateway Templates 7/10/2017 2:34 PM André Geraldes 2

In that documentation you will find the explanation of **each Step** on the OBP Portal and the **corresponding requirements** as well as a user manual for the **EMVO Gateway**.



2.2 SINGLE POINT OF CONTACT AND ASSISTANT INFORMATION

Single Point of Contact		×
SPOC		I'M SPOC
First Name *		
Loot Nomo *		
Last Name		
Phone Number *		
Email *		
Availability Hours *	Monday to Friday 09:00 to 16:00 CE	
		CANCEL
	SODWIT	CANCEL
Action:		
A prefilled Part	icipation	
Agreement (PA	A) will be	
aenerated		
9011010100		

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Note 1:

- The Single Point of Contact (SPOC) details will be listed in the PA.
- By signing the PA, the **AR will confirm the SPOC appointment**.
- The SPOC will be the responsible for **providing all the required information** in the OBP Portal.
- When the SPOC contact details will be listed, they will receive credentials via e-mail. At the moment of their first login in the OBP Portal, the Initial Requester's (IR) credentials will be revoked.
- If the SPOC is the same person as the IR, they will be able to access the OBP Portal with the credentials received in the first place.
- The **SPOC can be changed** before the approval of the PA and after the Legitimacy Check (LC). The new user will receive credentials and **older user credentials will be revoked**.
- The SPOC shall be a natural person.

<u>Note 2:</u>

- The SPOC Assistant contact details are optional.
- They will be used in case the first SPOC is not available.
- The **SPOC Assistant** will receive credentials from the moment the OBP has passed the LC successfully.
2.2 SINGLE POINT OF CONTACT AND ASSISTANT INFORMATION

IMPORTANT NOTE !

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

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

2.2 SINGLE POINT OF CONTACT AND ASSISTANT INFORMATION

IMPORTANT NOTE !

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

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

OBP CONTRACT WITH EMVO

The Participation Agreement (PA)

- Contractual framework for participation in the On-boarding project, e.g. use of the EMVO Gateway, SDK*, etc
 - Interface development
 - Connect to the EU Hub
- Includes a Non-Disclosure Agreement covering the provision of Confidential Information by EMVO, e.g on
 - EU Hub
 - EMVO Gateway

• Purpose: Execution of Technical On-boarding

EMVO will only countersign the PA and upload it on the OBP Portal when the Legitimacy Check has been passed successfully.

Upon request of EMVO the OBP can be obligated to sign a new PA. The SPOC and/or Assistant will be informed via email that a new PA will be available in Step 2.3 and/or Step 5.5.1 of the OBP Portal.

When a new PA is available in the OBP Portal, Step 2.4 and/or Step 5.5.2 becomes "deprecated" in order for the OBP to upload the new duly signed PA.

*Software Development Kit

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OBP CONTRACT WITH EMVO



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FREQUENTLY COMMITTED ERRORS

Contracts

- The name of the Authorised Representative listed in Step 1.2 of the OBP Portal needs to be the one of the person that actually signs the Participation Agreement;
- No amendments, modifications or other changes of the Participation Agreement are allowed;
- A scan of the Participation Agreement, checked and signed by the Authorised Representative, has to be uploaded on the OBP Portal in the relevant Step.



LETTER OF ADHESION

- Addressed by the MAH to the OBP
- Template shared by EMVO, 2 types for
 - (i) <u>EEA OBP</u> and
 - (ii) <u>NON-EEA OBP</u>
- Adhesion of the MAH to the Agreement between the OBP and EMVO
- The MAH is jointly and severally liable with the OBP vis-àvis EMVO
- The MAH confirms it duly authorised the OBP to upload its data onto the EU Hub on its behalf
- Termination of the Agreement leads to termination of the adhesion
- Additional conditions for non-EEA OBPs as set forth in Appendix 4 of the PA
- Signed letter to be sent to EMVO **only** upon request!





ON-BOARDING FEE

To cover connection costs, including, but not limited to, the cost of the Legitimacy Check, EMVO charges the OBPs with a one-time On-boarding Fee. The applicable one-time and non-refundable On-boarding Fee to be paid by the OBP to EMVO is calculated:

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

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

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

2.5 INVOICING INFORMATION FORM

		INVOICING INFORMATION FORM Please fill in the form and upload it in Step 2.6 / Step 5.6.2 of the OBP On-boarding Portal. Legal Entity Information: 1. Entity to which the invoice is billed	
	ΙΓ	*Legal Entity Name	
		* Address	
Mandatan		Contact name	
Manadiory		*E-mail address	
fields		Number of MAH's Please acted the number of MAH's Please select MAH number you are aked to fill in has to be fate total mamber of MAH's no tebuilt of which your OBP a going to updod data into the Thurspen Hikh Please use the drop- down mem. *VAT Number	
		Your PO number (framined)	
		Legal Entity Information: 2. Entity to which the services are provided (ad- remptes this section if different to perturbative)	
		*Legal Entity Name	
		Company Name/Department	
		Address	
		Contact name	
		E-mail address	
		Recipient of the invoice (only complex this section if the invoice is to be sent to an address other than above under section.)	
		Company Name/Department	
		Address	
		Contact name	
		E-mail address	
		* Randutery Comments :	

Number of MAHs

The OBP has to select the **total number of MAHs**, it will upload data for in the EU Hub, from a **drop-down menu**.

<u>Note</u>

A <u>sample of the Invoicing Information Form</u> (IIF) is available on our website in its download section.



Note 1

- Add MAH allows the OBP to add a new MAH into the list.
- **Export** allows the OBP to export an excel sheet with all the MAHs provided listed.
- **Import** allows the OBP to import the updated excel sheet in order to provide more than 1 MAH at the same time.

Note 2

- Edit MAH allows the OBP to edit an MAH.
- **Remove MAH** allows the OBP to remove an MAH from the list.
- **Show products** allows the OBP to provide the product information for the MAH.

MAH and product information		· · · · · · · · · · · · · · · · · · ·
Test Company		EDIT MAH REMOVE MAH SHOW PRODUCTS (0)
MAH Company Name: Test Company	Country: Belgium	Zip Code: 1000
VAT Number: 5446415	City: Brussel	Company Email Address:
Countries of Operations: Belgium	Street: Teststreet	Web Page:
Registration Number: 1111111	Number: 1	Website Address of OBP:
Country Of Registration: Bulgaria	Box:	Telephone Number:
ADD MAH EXPORT 🛓 IMPORT 🛓 🚺		CLOSE



Note 3

- In Step 2.7 (For the purpose of the Legitimacy Check) the OBP has to provide a minimum of one MAH and a maximum of 3 MAHs. For each MAH the OBP represents, the OBP must provide the information of at least one, and a maximum of three, corresponding products.
- In Step 5 'Maintenance' of the OBP Portal, the OBP will have to provide the full list of MAHs for which it will upload data to the EU Hub for. No product information needs to be provided any more.

MAH and product information		×
Test Company		EDIT MAH REMOVE MAH SHOW PRODUCTS (0)
MAH Company Name: Test Company	Country: Belgium	Zip Code: 1000
VAT Number: 5446415	City: Brussel	Company Email Address:
Countries of Operations: Belgium	Street: Teststreet	Web Page:
Registration Number: 1111111	Number: 1	Website Address of OBP:
Country Of Registration: Bulgaria	Box:	Telephone Number:
ADD MAH EXPORT 🛓 IMPORT 🟦 🚯		CLOSE

Note 4

- Add Products allows the OBP to add a product of the related MAH
- Hide Products to go back to the MAH overview
- For the purpose of the Legitimacy Check the OBP has to provide at least 1 product information for each MAH.
- In Step 5 'Maintenance' of the OBP Portal, no product information needs to be provided any more.

MAH Information Management					×
lkj			ADD PRODUCT	HIDE PRODUCTS (0)	
Marketing Authorisation Name for product	Marketing Authorisation Number for product	Marketing Authorisation Registration for product			
Products not found					
ADD MAH EXPORT 🛓 IMPORT 🛓 🕯				CLOSE	

Note 5

Product Information:

- The **Marketing Authorisation Number** is the licensed number related to the number of products the MAH received when applying for the Marketing Authorisation.
- The **Marketing Authorisation Name**, together with the name, please also mention the strength, form and pack size of the product in order to allow EMVO to identify the exact product presentation linked to the Marketing Authorisation Number.
- The **Marketing Authorisation Registration** refers either to the specific country(ies)/market(s) covered by the marketing authorisation or to the entire EU.

NAH Information Management			
lkj			ADD PRODUCT HIDE PRODUCTS (0)
Marketing Authorisation Name for product	Marketing Authorisation Number for product	Marketing Authorisation Registration for product	
Products not found			
ADD MAH EXPORT 🛓 IMPORT 🟦 🚺			CLOS



IMPORTANT NOTE !

The type of Marketing Authorisation Registration (e.g. centrally authorised), does not automatically give an information about the country of operation of the MAH. A MAH with centrally approved MA/Product/s has the possibility to market the product in all granted markets, however an actual marketing of that product in all granted markets might not be the case. Ergo, (a) centrally authorised product(s), does not automatically mean an operation of that MAH in all target markets for that product/those products, hence the detailed information of the country(ies) of operation per MAH is necessary 'Country of Operation'.

Please provide the requested information using the drop-down menu of this field which consists of and allows a multiple selection of the target countries/markets.

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2.8 CONFIRM ALL INPUTTED INFORMATION

Step	2: Detailed Information and Participation Agreeme	ent Completed		^
			Time to complete	Status
2.1	General Info Pack 🚯	Open		Available
2.2	Single Point of Contact and Assistant Information	Verify	5-7 min	Completed
2.3	Participation Agreement	View Download	1 min	Available downloaded 11:03:2019 02:30
2.4	Upload signed Participation Agreement 🚯	Upload PDF	1 min	Approved (
2.5	Invoicing Information Form 🚺	View Download	5 min	Available downloaded 11:03:2019 02:30
2.6	Upload Invoicing Information Form	Upload PDF	1 min	Approved (
2.7	MAH and Product Information 🧃	Verify	60 min	Completed
2.8	Confirm all inputted Information 🚯	Confirm		

By clicking on the Confirm button, the SPOC **confirms the accuracy** of the information provided on the OBP Portal and the **On-boarding fee will be made due**, according to the EMVOs On-boarding fee model.

2.8 CONFIRM ALL INPUTTED INFORMATION

IMPORTANT NOTE !

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

Please note that the amount of the On-boarding fee is calculated in accordance with the MAHs' number set out in the Invoicing Information Form which has been uploaded by the OBP and the fee application model described in section '*On-boarding Fee*'. Hence, as soon as the Legitimacy Check has been triggered, the On-boarding fee becomes definitive, due and non-refundable.

ON-BOARDING PARTNER PORTAL

Step 1: Provide Initial Information

Step 2: Detailed Information and Participation Agreement

Step 3: Approvals

Step 4: Technical On-boarding

Step 5: Maintenance

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3 APPROVALS



3 APPROVALS

Note 1

The outcome of the **Legitimacy Check** will be communicated to the OBP's SPOC via e-mail.

In the event that the Legitimacy Check is not successful, the OBP will have the possibility to modify the provided information.

Note 2

The Participation Agreement will be countersigned and uploaded to the OBP Portal by EMVO.

Note 3

Only when the Legitimacy Check is successful <u>and</u> the payment of the On-boarding fee has been received, the OBP will be granted **access to the Technical On-boarding**.

Step	3: Approvals Completed			^
			Time to complete	Status
3.1	Legitimacy Check Status 🚺		15 days	Passed ()
3.2	Countersigned Participation Agreement ()	View	21 days	Available 28:02:2019
3.3	Invoice Status 🚺			Payment received



ON-BOARDING PARTNER PORTAL

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4 TECHNICAL ON-BOARDING

Trigger Step 4: Step 3 completed

<u>Note</u>

If you make use of a Gateway Connection, the ITE environment is not necessary



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4 TECHNICAL ON-BOARDING

- ITE can be used as a sandbox by the OBPs to perform the first development of the connection and do a first integration test.
- When the OBP is confident that his interface is ready for testing, they can request access to the **IQE** to execute tests from the test status metrics.
- After the OBP passed the baseline tests, access will be granted for the PRD.

Note: Only internal validated systems are allowed to send data into the EU Hub.



4.1 TECHNICAL INFO PACK

The Technical Info Pack is a package of several files to download. It contains the following information in their last available versions:

- 1. Documentation JAVA
 - 20181 MAH SDK
 - EMVS0787 EMVS Java SDK Installation Instructions For OBPs
- 2. Documentation .NET
 - EMVS0794 EMVS OBPs .NET SDK Installation Guide
 - C# SDK Code Sample
 - .NET Callback
- 3. EMVO Gateway
 - EMVO_0038_EMVO Gateway User Manual
- 4. On-boarding Steps
 - EMVO_0117_Creating CSR Files
 - EMVO_0270_Backwards Compatibility Design Note_EU Hub_OBPs
 - Guidelines for Retrospective Upload as of SR 1.4
 - EMVS0714 EMVS SDK for OBPs
 - EMVO_0077_OBP On-boarding Guideline
 - EMVO_0086_OBP On-boarding Presentation



4.2.1 CONNECTION DETAILS

<u>Note</u>

This step is pre filled if you completed Step 1.3 of the OBP Portal already.

Select connection			×	
Select connection #1 Direct Connection Technology Type				→
Request new gateway provider				
	Save and close	Cancel		

If the Connection Provider of your choice is not listed in the drop-down menu, please click the '*Request new gateway provider*' button to promote them.

Drop-down menu listing the **registered* Connection Providers**. Making use of a registered Connection Provider allows the OBP to start immediately the tests in the Integrated Quality Environment (IQE).

***registered Connection Provider** is a provider which signed the License Agreement with EMVO and a Support Contract with SolidSoft.



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4.2.3 IQE

<u>Note</u>

When the OBP is confident that its interface is ready for testing, they can start testing in IQE.



European Medicines Verification Organisation

EMVO GATEWAY REQUEST

<u>Note</u>

This only applies if the OBP selected the EMVO Gateway in the Connection Details.

4.2.3.1 IQE - Information To Create CSR ()	Open	1 min	Completed
4.2.3.2 IQE - Upload CSR file 1	Upload	1 min	Completed
4.2.3.3 IQE - Certificate (CER) 1	Download	1 min	Completed downloaded 16:10:2017 14:33

As soon as Step 4.2.3.3 is finished, the following information should be sent to the EMVO Helpdesk (helpdesk@emvo-medicines.eu).

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

The credentials and URL will be sent through the following email: noreply@meliorsolutions.com (please be aware to check your Junk folder).

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4.2.2.5 IQE - TEST STATUS METRICS

X

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

This will send the current Test Results for EMVO's approval. If Product Master Data, Product Pack Data and Product Pack Update tests are passed, EMVO will allow access to PRD.

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<u>Note 1</u>

The OBP should verify and submit the Test Results of all positive transactions which are sent to the EU Hub in the last 30 minutes. The number of successful tests need to be higher than for failed tests.

In case of failed tests, the OBP should retry to upload the data and then contact the EMVO Helpdesk (helpdesk@emvo-medicines.eu) for further assistance.

When the transactions are passed, the OBP should click the **Submit** button.

Note 2

By default all statuses are marked as 'failed'. After passing and submitting the test results, statuses will reset to 'failed' after 30 minutes. Please await as EMVO has to approve your results.

4.2.4 PRD

Note 1

We only allow validated systems to connect to the PRD environment.

It is a prerequisite to have an approved test result.

Note 2

The OBP doesn't need to perform the Test Status Metrics in the PRD environment.

4.2.4.1 PRD - Information To Create CSR (1)	Open	1 min	Not Started
4.2.4.2 PRD - Upload CSR file 🚯	Upload	1 min	Not Started
4.2.4.3 PRD - Certificate (CER) (1)	Download	1 min	Not Started
4.2.4.4 PRD - Session Token (1)	Request New	1 min	Not Started



4.3 CONNECTION 2

Optional

This step can be used in case the OBP wants a second connection to the EU Hub. There is no difference with the Connection 1 and the OBP can repeat the previous steps.

4.3	Client Connection 2			
4.3.1	Connection Details ()	Add	1 min	Not Started
4.3.2	ITE 🗸			
4.3.3	IQE 🗸			
4.3.4	PRD 🗸			



ON-BOARDING PARTNER PORTAL

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5 MAINTENANCE

Trigger step 5: Step 4 reached

<u>Note:</u>

This step can be used by the SPOC or/and the SPOC Assistant to update all relevant information which was gathered during the Contractual On-boarding.



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5 MAINTENANCE: D&A

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. D&A / M&A activities

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

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

1. Change of the Product Code Ownership

- A change of the PC ownership in the EU Hub from the previous owner to the new owner.
- Implies a responsibility for the future data uploaded by new owner as well as for the already uploaded batch/pack data by the previous owner.
- EMVO reserves the right to apply and invoice the resulting costs. Please click <u>here</u> to consult the costs related to PC ownership changes. The invoice will be sent to the new PC owner.

5 MAINTENANCE: D&A/PC OWNERSHIP CHANGE

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

IMPORTANT NOTE !

B. 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 *#\$10 error*, a PC ownership transfer is required. EMVO reserves the right to apply and invoice the resulting costs. Please click <u>here</u> to consult the costs related to PC ownership changes. The invoice will be sent to the illegitimate PC owner.



5 MAINTENANCE

IMPORTANT NOTE !

- Please notify EMVO if you face one of the above scenarios by contacting the EMVO Helpdesk (<u>helpdesk@emvo-medicines.eu</u>), 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?

5.1 MAH INFORMATION

Note 1

The OBP can maintain its MAH information. The OBP Portal offers the option to export the existing MAH list as spreadsheet (.xlsm). After updating the spreadsheet, the OBP can import the updated list.

Importing the spreadsheet (file) will overwrite all existing MAH data in the OBP Portal!

Note 2

The OBP can still add a product which is linked to an MAH, but during maintenance this is not anymore required. To add a product linked to an MAH, the OBP has to click on the button 'Show Products'.

MAH and product information				
Test Company		EDIT MAH REMOVE MAH SHOW PRODUCTS (0)		
MAH Company Name: Test Company	Country: Belgium	Zip Code: 1000		
VAT Number: 5446415	City: Brussel	Company Email Address:		
Countries of Operations: Belgium	Street: Teststreet	Web Page:		
Registration Number: 1111111	Number: 1	Website Address of OBP:		
Country Of Registration: Bulgaria	Box:	Telephone Number:		
ADD MAH EXPORT 🛓 IMPORT 🛓 🚯		CLOSE		



5.2 COMPANY INFORMATION

All detailed company information, except for the organisation type, can be updated. The organisation type is used to create the account in the EU Hub and determines your permissions. Therefore, this information is not editable once an account is created during Technical On-boarding.

IMPORTANT NOTE !

As per the Participation Agreement in place with EMVO and before proceeding with the update under Step 5.2 of the OBP Portal, **the OBP must notify EMVO accordingly in advance**, by contacting the EMVO Helpdesk (<u>helpdesk@emvo-medicines.eu</u>).
5.3 SINGLE POINT OF CONTACT AND ASSISTANT

- In this Step access to the OBP Portal can be modified by the SPOC and/or the SPOC Assistant. If no SPOC Assistant had been assigned yet, the OBP can add one here.
- In case a user is filled in and saved, the credentials of the old user will be revoked and the new user will receive new credentials.



5.3 SINGLE POINT OF CONTACT AND ASSISTANT

- In case an OBP would like to increase the number of recipients receiving communication from EMVO besides the SPOC & SPOC Assistant (if applicable), EMVO recommends to use a dedicated mailing list/inbox e.g. "serialisation@emvo.eu", as the e-mail address of the SPOC Assistant account. However please note that the e-mail address needs to be linked to a registration of a contact person (forename & last name).
- Furthermore, to receive the information with regards to all known problems within the EMVS, EMVO strongly recommends subscribing to the EVI (European Medicines Verification System Information) Alerts for the specific systems of interest.

5.3 SINGLE POINT OF CONTACT AND ASSISTANT

IMPORTANT NOTE !

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

5.4 AUTHORISED REPRESENTATIVE INFORMATION

 In this Step the OBP can update the Authorised Representative Information, as soon as a new PA is available.



5.5 PARTICIPATION AGREEMENT

Note 1

The SPOC and/or the SPOC Assistant can view and/or download the latest PA by clicking on the particular button.

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

Note 2

- The new PA will have to be approved by EMVO, but during maintenance this does not impact the other Steps.
- EMVO will countersign the PA of the OBP and upload a scanned copy of the countersigned version in the OBP Portal. This will automatically update the status of Step 5.5.3 on the OBP Portal.





5.6 INVOICE MANAGEMENT

Note 1

- All relevant information concerning the Invoice Management can be consulted.
- In case more MAHs are registered in the OBP Portal than mentioned on the already approved Invoicing Information Form (IIF) or some other issues with the previous Invoice are encountered, the IIF will be rejected in order for you to restart the invoicing process.

Note 2

- The Invoicing Information Form can be viewed or downloaded.
- The payment status can be viewed in Step 5.6.3 of the OBP Portal. In case a new payment is required from the OBP, EMVO will manually adapt the Invoice Status to 'Awaiting Payment'.
- The payment status will be updated once every week.



CONTACT AND SUPPORT

In case of questions or uncertainty, the following information among others, is available to users on the Knowledge Data Base on <u>EMVO's website</u>:

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

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

CONTACT AND SUPPORT

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

- EMVO Helpdesk email address: <u>helpdesk@emvo-</u> <u>medicines.eu</u>
- EMVO Helpdesk phone number: +32 (0)2 657 00 08

• <u>Contact Form</u> on EMVO's website

IMPORTANT NOTE !

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

SIGN-OFF PAGE

Authored by:

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Quality Assurance Manager	Signature	Date

VERSION HISTORY

Version Date	Version	Author	Reason For Changes
2017/04/18	1.0	Stephan Theunissen	Initial Document
2017/05/03	2.0	Willem Theunissen	adapted:
			Slide 15: SDK moved to PA
			Slide 19: Client adapted to OBP's system
			Slide 21: Adapted client to OBP's system
2017/07/12	3.0	André Geraldes	Added step 3,7, 3.8, 3.9
			Added Technical On-boarding
2017/07/14	4.0	Benedikt M Fischer	Final review after adaption of new design by Jannik Jäger and the update of this Presentation for the implementation of the OBP Portal SR 3.0
2017/10/18	5.0	Fanny Trenteseaux	Update to OBP Portal SR 5.0 functionalities
2017/12/14	6.0	Fanny Trenteseaux	Updated: Slide 29 hyperlink - Updated with the adjusted On-boarding fee Slide 38
2018/01/29	7.0	Fanny Trenteseaux	Update of the Technical On-boarding, adding the Legal Notices, update section 3.2.2.2 Participation Agreement, Update the full document to align with OBP Portal SR 4.1
2018/04/10	8.0	Fanny Trenteseaux	Updated slides to align with OBP Portal SR 5.0
2018/08/20	9.0	Jannik Jäger/Francesca D' Agostino	Updated slides to align with OBP Portal SR 6.0
2018/10/26	10.0	Jannik Jäger	Updating information in Step 1, Step 2 and Step 5 according to the release of the operational Participation Agreement.
2019/05/20	11.0	Benedikt M. Fischer, Emmanouela Nikolakopoulou, Lorenzo Mari	Update of the full document to harmonize the information provided in the EMVO documentation and the Participation Agreement, design improvements, update of screenshots and improved process descriptions re OBP Portal SR 6.2, outdated information has been replaced due to the start of the EMVS Operational Phase on 2019/02/09, advice for D&A/M&A activity added, update of organisation chart
2019/10/21	12.0	Margarita Belichovska	Added relevant information in Step 5 on PC ownership change in case of D&A activities and incorrenct upload of PC(s) by another party. I incorporated the fee model accordingly. Updated the organisation chart.

2020/05/12



VERSION HISTORY

Version Date	Version	Author	Reason For Changes
2020/05/08	13.0	Margarita Belichovska	The fee model mentioned in Step 5 on PC ownership change was updated accordingly in order to illustrate the newly approved one. Additionally, a link indicating the service charges per PC was added. The organization chart was also updated.

