













EMVO ON-BOARDING

HOW TO CONNECT TO THE EU HUB? VERSION5.0 18 OCTOBER 2017

<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.



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ON-BOARDING PARTNER PORTAL



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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)



RESPONSIBILITIES OF THE SUPPLY CHAIN PARTNERS

Serialization by MAH

Risk based verification by Wholesalers

Verification and check-out at point of dispense

Safety features: Code ('unique identifier') + Tamper evidence

System set up and Governance by MAH together with other stakeholders

Oversight by competent authorities



Product #: S/N: Batch:	09876543210982 12345AZRQF1234567890 A1C2E3G4I5	
Expiry:	140531	



EMVO MEMBERS



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ORGANISATIONAL CHART

EMVO Board of Directors President: Hugh Pullen (EFPIA) Vice-President: Sonia Ruiz Morán (PGEU) Treasurer: Richard Freudenberg (EAEPC) Monika Derecque-Pois (GIRP) Adrian van den Hoven (Medicines for Europe)



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SYSTEM LANDSCAPE II



WHAT IS AN "OBP"?

- OBP means **On-Boarding Partner**. The OBP is the contracting party of EMVO; it concludes the Participation Agreement (PA).
- The OBP **represents the Marketing Authorization Holders (MAH)** on behalf of which it will upload data for in the European Hub. It has therefore to be legally authorized to conclude contracts on behalf of a MAH/a group of MAHs.
- The OBP has to be affiliated (*) to the MAH(s) on behalf of which it will upload data in the European Hub.
- The OBP should be located in the European Economic Area.
- The OBP can only upload product data for:
- its affiliated MAHs
- a manufacturer as long as the marketing authorization of the related products lies within the OBP corporation.

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



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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 GATEWAY PROVIDER?

- A third-party contractor engaged by the OBP, who assists the OBP entirely or partially with the development, the implementation, the provision, the use, and/or the operational phase related to the OBP interface to the EU Hub via a Gateway Connection,
- Every OBP Gateway Provider has to be promoted by at least one OBP in the On-boarding Process,
- **EMVO has then to validate and approve** the proposed Gateway Provider, if all requirements are fulfilled.

ON-BOARDING CONTRACT LANDSCAPE



- **EMVO:** European Medicines Verification Organization
- Solidsoft: IT Service Provider for implementation and operation of European HUB
- **OBP:** On-Boarding Partner
- **OBP CP:** IT Service Provider

- Gateway connection <

- Direct connection

ON-BOARDING PROCESS

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ON-BOARDING PARTNER PORTAL



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OBP PORTAL



HOW DOES THE ON-BOARDING WORK?

On-boarding Partner Portal

(Support software to guide the OBPs through the requirements to connect to the EU Hub)





HOW TO SPEED UP THE PROCESS RIGHT FROM THE START?

Collect Information:

- 1. Visit EMVO **Download Section** https://emvomedicines.eu/downloads/
- 2. Visit EMVO **Knowledge Data Base** https://emvomedicines.eu/faq/
- 3. Who will be the **On-Boarding Partner?**
- 4. What is my Company Registration number and VAT number?
- 5. Who can and will be the **Authorized Representative**?
- 6. Who can and will be the **Single Point of Contact**?
- 7. How many **MAHs** does the OBP represent?

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HOW TO REQUEST TO PARTICIPATE



2. Fill in User + Company details



3. You'll be directed to the confirmation screen



4. Check your email to validate your account



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HOW TO REQUEST TO PARTICIPATE

5. Your company portal will be created



7. Follow the instructions in your email to login to your Company portal

≅ L ↔ C ↑ ↓ = IRE MISSAGE	EMVO OBP Portal: Your new site details - Message (HTML)	
An 21/02/2017 14-22 noreply@emvs.com EMVO OBP Portal: Your new site details		
To Theorizzer, Willem	one with set in this message	
 Click here to download pictures, to help protect your privacy, Outlook prevented automatic download or so 	me pictures in this message.	
Hello Willem Theunissen,		
Welcome to the EMVO On-boarding Partner Portal (OBP Portal). Please follow all the in	structions below to logon to your personal OBP Portal area	
Your username: W.Theunissen-EMVO@emvo-portal.eu		
Temporary password: a9eTA_CB		
Click here to access your onboarding portal		
For help and support please email <u>helpdesk@emvo-medicines.eu</u> or visit <u>https://www.em</u>	wo-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		
Welcome to SharePoint Online Name Name Name Name Name Name Name Nam		

6. Your company portal is created



8. Your Company portal is ready to On board



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INITIAL REGISTRATION REQUESTER CREDENTIALS

IMPORTANT NOTE !

The SPOC is the only person having the credentials to access the portal. However, in the event the Initial Registration Requester is the same person as the SPOC, s/he will be able to access the portal with the credential received in the first place.



ON-BOARDING PARTNER PORTAL

Step 1: Provide Initial Information

Step 2: Participation Agreement + Detailed information

Step 3: Approvals

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STEP 1: PROVIDE INITIAL INFORMATION



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1.1 COMPANY INFORMATION

Company Information			×
Company Name *	EMVO		
Country of Registration *	Belgium		
VAT Number *	111111111		
Company Registration Number * 🧃			
Street *			
Number *			
Box			
Zip code *			
City *			
Country *			
Business Phone *			
Web Page			
Company Email Address *			
Are you part of a corporation? 🚺			
Do you represent? *	 Marketing Authorisation Holders (MAH) activity Marketing Authorisation Holders (MAH) Distribution activity 	with Parallel without Para	Distribution
		Save	Cancel

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, no typo, 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

1.2 AUTHORISED REPRESENTATIVE

Please provide the **information related to the Authorised Representative** together with a copy of proof attesting of the authorisation of that person to sign on behalf of the company.

Authorised representative information	×
First Name * 📵	
Last Name *	
Job Title *	
E-Mail *	
Business Phone *	
I confirm that I've uploaded at attachment which proves the authorized representative is entitled to sign on behalf of the company *	Ĵ ⊖Yes
Copy of Proof Attach file	Save

Note 1: The Authorised Representative (AR) is the person authorised to sign on behalf of the company. The AR will sign the Participation Agreement.

Mandatory in order to proceed with the further steps

Note 2:

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.

FRENQUENTLY COMMITTED ERRORS

Copy of proof of the Authorised Representative

<u>Purpose</u>: check the authorisation of your named Authorised Representative (AR) to sign on behalf of the company

- An official register (please consult the National Registers list for european countries on our website: <u>https://emvo-medicines.eu/wp-</u> <u>content/uploads/2017/06/National-Registers-for-obtaining-the-Copy-of-Proof.pdf</u>)
- The AR is to be explicitly named in the official register together with his/her senior management position and/or his/her explicit authorization
- Validity of the document with respect to a potential expiration date List of National Registers available on considered

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1.3 CONNECTION PROVIDER INFORMATION

Optional step:

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

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

Drop-down menu listing the Certified * Gateway Providers.

Making use of a certified Gateway Provider allows the OBP to start immediately a minicertification test in the Integrated Quality Environment (IQE).

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

<u>Note:</u> Only two connections are allowed per OBP.

ON-BOARDING PARTNER PORTAL

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STEP 2: DETAILED INFORMATION AND PARTICIPATION AGREEMENT



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2.1 GENERAL INFO PACK

General info pack - Pack Documents

Туре	Name	Modified	Modified By	Checked Out To
pdf	EMVO0038 - EMVO Gateway User Manual	2/20/2017 1:59 PM	Jamie Williams	
pdf	EMVO_0086_OBP On-Boarding Presentation	5/24/2017 2:01 PM	Willem Theunissen	
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	

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

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2.2 SINGLE POINT OF CONTACT

Single Point of Contact	 Note 1: The SPOC details
I am also the SPOC * SPOC First Name * SPOC Last Name * SPOC Email Address *	 By signing the PA the SPOC appoin The SPOC will be information in the When the SPOC of credentials via e- the portal, the initial
SPOC Phone Number * SPOC Availability Hours * Monday to Friday 09:00 to 16:00 CET	 If the SPOC is the Requester, (s)he credentials received.
Save	Note 2: • The second SPOC

Action:

A prefilled Participation Agreement will be generated

- will be **listed in the PA**.
- the Authorised Representative will confirm ement.
- the responsible for **providing all the required OBP** Portal.
- contact details will be listed, s/he will receive mail. At the moment of his/her first login in ial Registration Requester's credentials will
- same person as the Initial Registration vill be able to access the Portal with the red in the first place.
- contact details are optional.
- They will be used in case the first SPOC is not available.
- The second SPOC will not receive credentials.

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OBP CONTRACT WITH EMVO

The Participation Agreement (PA)

- Contractual framework for participation in the On-boarding project, e.g.
 - Use of the EMVO Gateway
 - Interface development
 - Connect to the HUB
 - SDK
- Includes a Non-Disclosure Agreement covering the provision of Confidential Information by EMVO, e.g on
 - European Hub
 - EMVO Gateway
 - Purpose: Execution of Technical On-Boarding

EMVO will only counter-sign the PA and send it back only when the legitimacy check will be successfully passed

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OBP CONTRACT WITH EMVO



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FRENQUENTLY COMMITTED ERRORS

Contracts

- Consistency between the named Authorised Representative in step 1.2. and the person that actually signed the contracts
- No ammendments
- Two (2) hardcopies have to be sent to EMVO via post
- Both hardcopies are signed and both are original versions (not scanned)



ON-BOARDING FEE

One-Time Fee per OBP

OBPs with more than 12 MAHs in Europe	20,000€
OBPs with 6 to12 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€

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2.5 INVOICING INFORMATION



INVOICING FORM Please fill in the form and return to helpdesk@envo-medicines.eu

Mandatory	/
fields	

Legal Entity information: 1. Entity to which the invoice is billed			
*Legal entity Name			
* Address			
Contact name			
*E-mail address			
*Number of MAH's Plaze note that the number of MAHs you are asked to fill in has to be the tool number of MAHs on behalf of which your OBP is going to upload data into the European Hub. Please use the drop- drom on one has the second second second second second the second se	1 MAH in Europe		
*VAT Number			
Your PO number (if required)			
Legal Entity information: 2. Entity to which the services are provided (Only complete this section if different to section above)			
*Legal entity Name			
Company Name/Department			
Address			
Contact name			
E-mail address			
Recipient of the invoice (Only complete this section if the invoice is to be sent to an address other than above under sction 1)			
Company Name/Department			
Address			
Contact name			
E-mail address			
* Mandatory Comments :			
EMVO (European Medicines Verification Organisation) asol Tus BF 0038 Shi 002	Permanent Office: Rue de la Loi 28. Bolle 21 B- 1040 Bruxelles	T: +32.2.667.00.06	Invoicing Information Version 1.0

In Number of MAHs the OBP has to chose from a **drop-down menu** the **total number of MAHs** it will upload data for in the European Hub.

Note:

A sample of this document is available on our website in its download section.

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2.7 MAH AND PRODUCT INFORMATION

<u>Note 1:</u>

- **New item** allows the OBP to add a new MAH into the list.
- **Edit** allows the OBP to copy paste an excel sheet with all its MAHs listed, using the exact same name and location of the columns as shown in that section.

Note 2:

For the purpose of the Legitimacy Check the OBP has to provide a minimum of one MAH and a minimum of one corresponding product information.

In the end, the OBP will have to fill-in the whole list of MAHs for which it will upload data in the European Hub.

MAH and product information								
Image: market with the second seco								
✓ Title Country of Registration VAT Number Company Registration Number There are no items to show in this view of the "MAH Info" list.	Street	Number	Box	Zip code	City	Country	Web Page	Telephone Number



2.7 MAH AND PRODUCT INFORMATION

MAH Info - New Item

MAH Company Name *		
Country of Registration *		
VAT Number *		
Company Registration Number * 🚯		
Street *		
Number *		
Box		
Zip code *		
City *		
Country *		
Web Page		
Telephone Number		
Company Email Address		
Website Address of OBP		
Marketing Authorisation Number for Product 1 * 🚯		
Marketing Authorisation Name for Product 1 * 🕚		
Marketing Authorisation Registration for Product 1 * 🔞	None	7
Marketing Authorisation Number for Product 2 🚯		
Marketing Authorisation Name for Product 2		
Marketing Authorisation Registration for Product 2 🚯	None	7
Marketing Authorisation Number for Product 3 🕚		
Marketing Authorisation Name for Product 3 🕚		
Marketing Authorisation Registration for Product 3 🕚	None	7
	[Save Cancel

Note:

Product information;

- The Marketing Authorisation Number is the licensed number related to the number of the product that the MAH received when applying for Marketing Authorisation
- The Marketing Authorisation Name; together with the name, please mention the strength and the pack size of the product in order to allow EMVO to identify the exact product presentation linked to the Marketing Autorisation Number.
- The Marketing Authorisation Registration refers to the country covered by the marketing authorization and may be centralized.

2.8 CONFIRM ALL INPUTTED INFORMATION

Step 1: Provide initial information Complete				~
Step	2: Detailed information and participation agreement	Complete		^
			Time to complete	Status
2.1	General info pack ()	Open		Available
2.2	Single point of contact information 0	View	5-7 min	Completed
2.3	Participation Agreement ()	View Download	1 min	Available
2.4	Upload Signed Participation Agreement	Upload PDF	1 min	Approved
2.5	Invoicing Information Form	View Download	5 min	Available
2.6	Upload Invoicing Information Form	Upload PDF	1 min	Approved
2.7	MAH and product information	Verify	60 min	Completed
2.8	Confirm all inputted information	Confirm		

By clicking on the *Confirm* button the SPOC **confirms the accuracy** of the information provided on the portal.

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STEP 3: APPROVALS



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STEP 3: APPROVALS

Step	1: Provide initial information Complete			~
Step	2: Detailed information and participation agreement	Complete		~
Step	3: Approvals Complete			~
			Time to complete	Status
3.1	Legitimacy check status 🚯		15 days	In Progress
3.2	Countersigned Participation Agreement send back to OBP 🚯	View	21 days	Awaiting Hardcopy
3.3	Invoice status 🟮			Awaiting payment
Stop	4. Technical enhanding			

Please note that EMVO is going to check the reception of the payment and update those status every two weeks.

<u>Note 1:</u>

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

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

Note 2:

If and only if the Legitimacy Check outcome is successful, the Participation Agreement will be **countersigned by EMVO** and one hardcopy will be sent back to the OBP by post.

<u>Note 3:</u>

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 Onboarding**.

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ON-BOARDING PARTNER PORTAL

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STEP 4: TECHNICAL ON-BOARDING



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4.1 TECHNICAL INFO PACK

The Technical Info Pack contains the following information in their last available versions:

- 1. Documentation .NET
 - .Net Callback Service
 - .Net Hub 2.0 SDK
 - EMVS0794 EMVS OBPs .NET SDK Installation Guide
- 2. Documentation JAVA
 - EMVS0787 EMVS Java SDK Installation Instructions For OBPs
 - EMVS Java SDK_MAH_Hub_2
- 3. On Boarding Steps
 - EMVO_0077_OBP On-boarding Guideline
 - EMVO_0086_OBP On-Boarding Presentation
 - EMVO_0117_Creating CSR Files
 - EMVS0714 EMVS SDK for OBPs
 - EMVS0789 EMVS SDK Quick Start Guide For OBPs

4.2.1 CONNECTION DETAILS

<u>Note:</u>

This step is pre filled if you completed step 1.3

Select connection		×
Select connection #1	Edit	
Request new gateway provider	Save Cancel	_

Drop-down menu listing the **Registered * Gateway Providers**.

Making use of a Registered Gateway Provider allows the OBP to start immediately a selfcertification test in the Integrated Quality Environment (IQE).

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

4.2.2 ITE



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4.2.3 IQE

Note:

When the OBP is confident that its interface is ready for testing, (s)he can start testing in IQE



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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		
	E		

This will send the current Test Results for EMVO's approval. If everything is fine EMVO will allow access to PRD.

<u>Note:</u>

The OBP should verify and submit the Test Results of all positive transactions which are sent to the EU Hub for the last 30 minutes and will cover the basic requirements.

In the current version of the EU Hub SR 1.3, Batch Recall and Acknowledgments can be skipped as these functions are not implemented yet.

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

4.2.4 PRD

<u>Note:</u>

We only allow validated systems to connect to the Production environment. It is a prerequisite to have an approved test result.

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.

Repeat 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 🗸			

