

## On-boarding of new Italian On-boarding Partners (OBPs) to the EU Hub & actions for existing OBPs

### Questions and Answers (Q&A) – Version 1.0

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This document is intended to support pharmaceutical companies in their onboarding process, focusing on non-technical aspects. It outlines the key questions and steps involved in the onboarding of Italian Onboarding Partners (OBPs) to the EU Hub, while also offering guidance for already connected OBPs planning to market products in this market. This version provides support with regards to data upload to the EU Hub.

The document will be updated as needed to address any additional questions or information brought to EMVO's attention.

Regularly consult EMVO's website and Knowledge Database ([here](#)) to follow up on the latest communication.

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## 1. General for Italy

### 1.1 How can the OBP sign a contract with the NMVO Italia?

**Answer:** OBPs can find the information of NMVO Italia to the NMVO Italia website [here](#) and LinkedIn page [here](#).

### 1.2 Are there any specifications defined for the National Reimbursement Number (NHRN)?

**Answer:** For Italy, the National Health Reimbursement Number (NHRN) corresponds to the AIC code, a 9-digit number, assigned by the **Italian Medicines Agency (AIFA)** for authorization to market in Italy. It is a mandatory field when uploading Product Master Data to the EU HUB. We recommend that clients review their Product Master Data Guide for submissions relating to the Italian market.

OBPs can find more information on the Data Matrix and NHRN on a dedicated section of the NMVO Italia website [here](#).

### 1.3 How can I get in contact with the Italian NMVO?

**Answer:** Please use the below contact detail to reach out the NMVO Italia:

- NMVO Italia at [onboarding@nmvo-italia.it](mailto:onboarding@nmvo-italia.it)

## 2. New Companies/On-Boarding Partners (OBPs) to the EU Hub

### 2.1 What is an On-boarding Partner (OBP) and what is Marketing Authorisation Holder (MAH)?

**Answer:** The concept of On-boarding Partner (OBP) has been defined in order to facilitate the On-boarding process for corporations to the EMVO. The OBP company represents the companies holding marketing authorization among its corporation. The Marketing Authorisation Holders (MAHs) the OBP represents and will upload data for in the EU Hub have to be the OBP's affiliates. A corporation can decide which legal entity will act as its OBP.

The OBP is therefore the contracting partner of EMVO and concludes the Participation Agreement. The OBP is legally authorized to sign on behalf of a MAH / a group of MAHs.

Please note that the OBP has to be affiliated to a MAH / a group of MAHs. *"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".*

OBP Affiliate(s) agree(s) in writing to be bound, jointly and severally with the OBP, by and to observe all terms, limitations and conditions applying to the OBP as set forth in the Participation Agreement.

The group of MAHs represented by the OBP either consists of Original Pack Manufacturers or Parallel Distributors.

## 2.2 What is the On-Boarding Portal and why do I need to connect?

**Answer:** To facilitate the On-boarding Process to the EU Hub, EMVO provides a user-friendly web-based “EMVO Onboarding Partner Portal (OBP Portal)” that guides the user step by step through the process. This multi-step procedure is required to establish the connection with the European Hub.

## 2.3 What are the on-boarding steps?

**Answer:** The On-boarding contains 4 main steps and starts with the creation of an account in the OBP Portal where the company is requested to provide detailed information about the organization. Then, a Legitimacy check follows which is part of EMVO’s mandatory security procedure ensuring that only users whose identity, role and legitimacy have been verified can connect to and upload data to the EU Hub. As soon as this step is finalised, the signature of the Participation Agreement (PA) (sample available [here](#)) takes place together with the invoicing. Please note that the PA can only be signed by the listed Authorised Representative (AR) who should be a senior officer authorised to sign on behalf of the company (it might be the person holding the position of a CEO, CFO, CIO or a member of the board of Directors depending on each company’s internal signatory policies).

The last step is the technical on-boarding that allows the OBP to test in a secured environment and connect to the EU Hub.

Please refer to EMVO’s On-Boarding Guide [here](#) which details each step and the required information from you. We also recommend you to have a look at our tutorial videos [here](#) aiming to provide a view on the portal and how to navigate effortlessly. You can start the on-boarding by following [this link](#) or alternatively, you can contact the EMVO’s Helpdesk to get information on the on-boarding process and timelines ([helpdesk@emvo-medicines.eu](mailto:helpdesk@emvo-medicines.eu)).

If you have any questions about the steps and the process, please contact the Helpdesk ([helpdesk@emvo-medicines.eu](mailto:helpdesk@emvo-medicines.eu)) or refer to EMVO’s Self Service Portal [here](#).

## 2.4 How long does it take to be a fully on-boarded OBP?

**Answer:** The timeline can vary depending on how quickly you respond to requests and how complete your required documents/materials are. Typically, if everything is in order, you can expect the on-boarding process to take approximately 3 weeks.

## 2.5 What would my responsibilities be as a new OBP?

**Answer:** As an OBP, you will have various responsibilities. Please refer to section **5. Rights and Obligations of the OBP** (pages 13-18) of the **OBP Participation Agreement sample** [here](#). Feel free to consult all the remaining points for further information.

In addition to signing the mandatory Participation Agreement (PA) with EMVO, Marketing Authorisation Holders (MAHs) are requested to conclude a contract at national level and pay an annual fee. The applicable fee model depends on each National Medicines Verification Organisation (NMVO). Please be reminded that the contract should be established in the countries in which the MAH is marketing their products. Therefore, please consult the latest version of the [NMVO Fee Models Overview Presentation](#) and the [NMVO Fee Models Overview Table](#) to identify the applicable fees.

In case you would need further details, please take direct contact with the relevant NMVO(s).

## 2.6 Are there any other documents that I should read before/while on-boarding?

**Answer:** We encourage you to get acquainted with the EMVS Master Data Guide available [here](#) and listening to the OBP Data Quality webinar available [here](#). You can consult many more documents which are uploaded on *EMVO's website* → *Recourses* → *Documents Overview or Videos* ([here](#)). And the Self-Service Portal ([here](#))

## 3. On-Boarding Partners (OBPs) already connected to the EU Hub

### 3.1 What would my responsibilities be as an already connected OBP which has been uploading data for other EU/EEA markets and will start marketing products in IT?

**Answer:** You should update the Marketing Authorisation Holder information in the OBP Portal account by including the new affiliated company your OBP is representing and uploading data for.

Please refer to question 4.2 to find out more about the data upload to the EU Hub.

## 4. Data upload

### 4.1 As an OBP, how can I add Italy to a PMD I have already uploaded to the EU HUB? Is a retrospective upload the correct approach?

**Answer:** A retrospective upload for adding new target markets is no longer available. To add Italy as new target markets, OBPs will need to create a new version of the PMD and include the new target markets.

### 4.2 Where can I read more about data upload to the EU Hub?

**Answer:** Please refer to **EMVO's Master Data Guide** available [here](#).