

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

Questions and Answers (Q&A) – Version 2.0

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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 Greek and Italian Onboarding Partners (OBPs) to the EU Hub, while also offering guidance for already connected OBPs planning to market products in these two markets. This updated version provides further 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 Greece

1.1 When can the OBP (MAH) sign a contract with the Greek NMVO (HMVO)?

Answer: You can sign a contract with the Hellenic Medicines Verification Organisation (HMVO) starting from mid-November 2024.

Every MAH or their designated representative is mandated to visit the official HMVO website, review the provided instructions (Instructions | HMVO), and subsequently proceed with the agreement applicable to all parties without exception.

1.2 Are there any Data Matrix specifications for HMVO?

Answer: There are no additional requirements/specifications than the four elements already included in the Data Matrix. Although the National Health Reimbursement Number (NHRN) is required from the Greek authorities, the NHRN will not be used as a fifth element in the Data Matrix. However, manufacturers will be required to provide it electronically during the Product Master Data (PMD) upload as required by the Greek authorities. This ensures that all necessary information is available for regulatory and reimbursement purposes.

1.3 How can I get in contact with the HMVO?

Answer: Please use the contact details below to reach out to respective NMVO:

- HMVO ticketing system: Ticketing System | HMVO – link [here](#)
- HMVO central contact email: hmvo@hmvo.gr

2. General for Italy

2.1 When can the OBP sign a contract with the NMVO Italia?

Answer: NMVO Italia will provide more details as soon as possible. Further information will be shared when available through NMVO Italia website [here](#) and LinkedIn page [here](#).

2.2 Are there are Data Matrix specifications for NMVO Italia?

Answer:

The Data Matrix and security-featured support (carta valori) specifications will be issued with specific Decrees from the competent authorities with the following timing:

Datamatrix - Decree of the Minister of Health – within 30 days from Decree approval (approved on 08/02/2025). By decree of the Minister of Health, to be adopted within thirty days from the date of entry into force of the legislative decree, the technical specifications and the procedures for affixing and verifying the unique identifier (so-called Datamatrix) shall be established.

2.3 How can I get in contact with the Italian NMVO?

Answer: Please use the below contact details to reach out to respective NMVO:

- NMVO Italia at onboarding@nmvo-italia.it

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

3.1 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.

3.2 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.

3.3 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 finalized, 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 authorized 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).

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

3.4 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.

3.5 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).

3.6 Can I on-board and become an OBP without uploading data?

Answer: Yes, you can start with the (contractual) on-boarding to the European Hub, even if you have not put in place any technical measures within the affiliated companies yet, or if the countries to which you will be supplying the products do not have a National Medicines Verification System (NMVS) in place yet. **EMVO highly recommends that OBPs start as soon as possible with the (contractual) On-boarding to allow for a timely exchange of information between the OBP and EMVO.** Please note that you will not have access to the Production Environment (PRD) of the EU Hub until you have provided the product and MAH information.

3.7 I am only marketing products in Greece/Italy. Can I already on-board and become an OBP before the connection of the Greek/Italian NMVO(s) to the EMVS?

Answer: Yes, we strongly recommend you to start the on-boarding to the European Hub as soon as possible. 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).

3.8 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* → *Knowledge Database* → *Documents Overview or Videos* ([here](#)).

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

4.1 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 GR and/or 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 5.4 to find out more about the data upload to the EU Hub.

5. Data upload

5.1 When can I start uploading data for the Greek/Italian market(s)?

Answer: You will be able to start uploading data as soon as the NMVOs have connected to the IQE & PRD Environment of the EU Hub and their systems are fully operational.

HMVO is fully connected to the EU Hub from 6 February 2025.

NMVO Italia is not connected yet. We will communicate as soon as we have any visibility on the connection date.

5.2 What will happen if I try uploading data for the Greek/Italian market(s) before the NMVOs' connection to the EMVS?

Answer: You will not be able to upload data for either of the markets as the EU Hub will respond with an A-16 data validation error (#A16). Consequently, the request will fail and you will be required to remove the invalid market(s) before proceeding further with the data upload for other markets.

5.3 What are the assumptions regarding the multi-market products under consideration in Cyprus and Greece?

Answer: The multi-market products under consideration are currently in Cyprus.

Some batches (or parts of batches) may currently be physically located in Greece, but their details were uploaded to Cyprus anyway.

Any products that are only intended for the Greek market will be treated as new products that should be uploaded as usual.

5.4 As an OBP, how can I add Greece and/or 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 Greece and Italy as new target markets, OBPs will need to create a new version of the PMD and include the new target markets.

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

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