Onboarding of Hospitals with MVO Portugal

Reference guide – version 2.0

October 2018

Author Signature

Name	Role	Date	Signature
Nuno Lages	Author	03-Oct-2018	

Approver Signatures

Name	Role	Date	Signature
Ricardo Valente	QA approver	03-Oct-2018	

Revision History

Version	Date	Reason for changes	Description of changes made
1.0	07-June-2018	Initial document	N/A
2.0	03-Oct-2018	Address change	MVOPT address change

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1. Purpose

The purpose of this document is to describe the onboarding process for Hospitals with MVO Portugal.

2. Scope

The scope of this document includes the information on the onboarding process for Hospitals with MVO Portugal. The onboarding process for Authorization Holders (Marketing Authorization Holders and Parallel Import Authorization Holders) and other end users with MVO Portugal is described in separate documents and thus out of the scope of this document. The onboarding process with EMVO is described in documents issued by EMVO and thus out of the scope of this document.

3. Definitions

Term/Acronym	Definition
MVO Portugal	Portuguese Medicines Verification Organisation
PTMVO	Portuguese Medicines Verification Organisation
PTMVS	Portuguese Medicines Verification System
MAH	Marketing Authorisation Holder
PIAH	Parallel Import Authorization Holders
NMVO	National Medicines Verification Organisation
NMVS	National Medicines Verification System
NCA	National Competent Authority – in Portugal is INFARMED
SOP	Standard Operating Procedure

4. Connection to PTMVS

The connection between the end user system and PTMVS is represented in Figure 1. The Hospital may engage an IT Service Provider to build a system that can connect to PTMVS. In order to establish this connection, Hospitals must follow PTMVO's on-boarding process which consists of the multiple steps set out in this document.

The IT Service Provider may represent a single Hospital or a group of Hospitals.
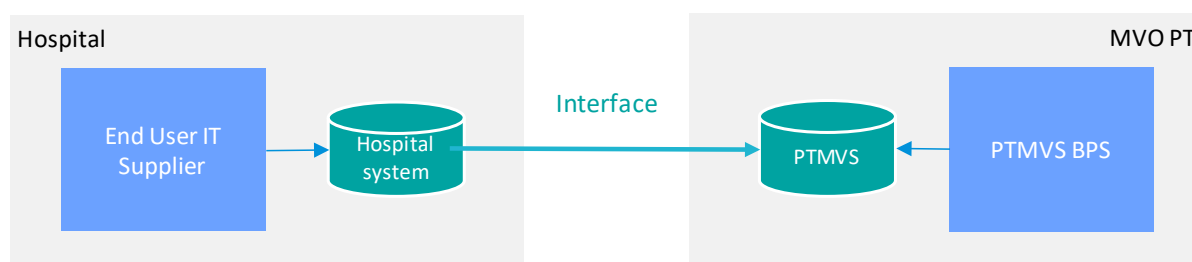
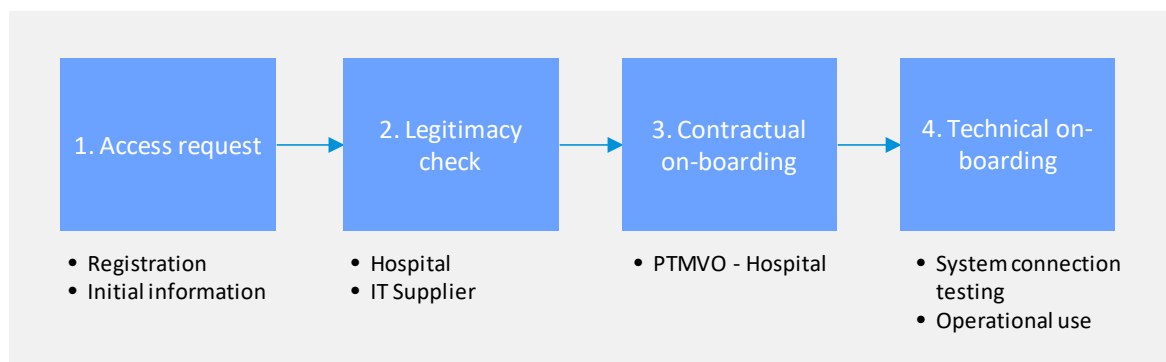**Figure 1.** Connection between the end user system and PTMVS.

5. Onboarding process

The onboarding process starts with the submission of the Access Request Form and ends with the connection of the Hospital system to the qualification environment (IQE), as set out in this document. Once the Hospital successfully accomplishes the onboarding with MVO Portugal, a notification will be issued to the Hospital.

Only after completing all the steps set out in this document the onboarding with MVO Portugal will be complete. The completion of the onboarding process is necessary to be part of the Pilot phase of the implementation of the National Medicines Verification System.

The onboarding process for Hospitals has two main components, one legal/contractual and another technical:

- Legal/contractual: submit the access request and accept the Terms and Conditions
- Technical: make proof of minimum capacity to integrate with the PTMVS - perform the set of required tests and present evidence of having done so

Figure 2. The on-boarding process for Hospitals.

Hospitals will receive by email the following documents via email (note: the documents can be delivered in more than one email):

- MVOPT-0037 - Access Request Form_v3.0
- MVOPT-0039 - Access Request Form (PT)_v2.0
- MVOPT-0048_Services Agreement
- MVOPT-0049_Services Agreement (PT)
- NMVS – Hospital - Test Report Template v1

The documents MVOPT-0037 - Access Request Form_v2.0 and MVOPT-0039 - Access Request Form (PT) are identical in content. Hospitals can use either. Likewise, the documents MVOPT-0048_Services Agreement and MVOPT-0049_ Services Agreement (PT) are identical in content. Hospitals can use either. In case of divergence, the documents written in Portuguese prevail.

5.1 Access request

As a first step of the on-boarding process the Hospital representative fills in the Access Request Form (MVOPT-0037 - Access Request Form_v2.0 or MVOPT-0039 - Access Request Form (PT)) and returns it by email to mvo.portugal@mvoportugal.pt.

The Hospital representative must provide basic information regarding the company, the authorised representative of the company and the IT Service Provider of the company (if applicable).

5.1.1 Company information
The Hospital representative, in his/her role as requestor, provides the following information of the company:
- Company name
- Postal address
- E-mail address
- Phone number
- Type of end user (pharmacy, hospital pharmacy, Hospital, other entities authorized to dispense medicines)
- VAT number
- Registration number (*autorização de aquisição directa*)

5.1.2 Authorised representative information
An authorised representative must be appointed. He/she must be authorised to legally bind the company. Only the named representative is able to sign off contracts during the on-boarding process.

The requestor provides the following information of the authorised representative:
- Name
- Role within the Hospital company
- Contact details
- Evidence of authorization (trade register extract or copy of nomination decree)

5.1.3 IT Service Provider information

The IT Service Provider can be interpreted as the internal IT Department. If the Hospital decides to engage an IT Service Provider to develop the interface with PTMVS, a contract between the Hospital company and the IT Service Provider must be in place.

The requestor provides the following information of the contracted IT Service Provider:
- Company name
- Postal address
- E-mail address
- Business ID
- Contact person

5.1.4 Software identification

The requestor provides information on the software to be used to connect with the PTMVS, namely software name and version.

Once finished, the requestor shall sign and submit the Access Request Form via mvo.portugal@mvoportugal.pt.

5.2 Legitimacy check

Access to any confidential information within PTMVO may not be provided to unauthorized persons. Therefore, it must be verified that the access request is made by an authorised representative of a legitimate organization. The legitimacy check is performed by a designated PTMVO employee.

The legitimacy of Hospitals will be checked by reviewing License data provided by the authorised representative of the entity and verifying this information on the NCA webportal (http://extranet.infarmed.pt/LicenciamentoMais-fo/pages/public/listaECDPAD.xhtml). In case of private entities, the legitimacy of the authorized representative will be checked by comparing the reporte trade extract code with the information on https://bde.portaldocidadao.pt/evo/Services/Online/Pedidos.aspx?service=CCP.
In case of public entities, the legitimacy of the authorized representative will be checked by comparing the reported copy of nomination decree with the information on https://dre.pt/. In case of external company, the legitimacy of the IT Service Provider will be checked by comparing the reported trade register extract with the information available on https://bde.portaldocidadao.pt/evo/Services/Online/Pedidos.aspx?service=CCP.
In case of deviation, the Hospital will be contacted via the contacts provided in the Access Request Form.

5.3 Contractual on-boarding

After ensuring the legitimacy of the Hospital, the contractual on-boarding can start. This step encompasses the contractual arrangements between PTMVO and the Hospital. The contractual on-boarding can start even if the Hospital has not yet put in place any technical measures or selected an IT Service Provider.

The contractual framework between PTMVO and the Hospital consists of the Services Agreement sent to the end user via email. This contract also contains a confidentiality clause.

Once signed by the end user, two signed hardcopies must be sent to:

MVO Portugal – Associação Portuguesa de Verificação de Medicamentos
Torre de Monsanto
Rua Afonso Praça 30, 7°
1495-061 Algés, Portugal

One of the signed hardcopies will be sent to end user postal address.

5.4 Technical on-boarding

In order for Hospitals to verify the authenticity of a medicinal product, a technical connection between the system of the Hospital and PTMVS needs to be in place. Therefore, the final step in the on-boarding process is to obtain the necessary information to establish this technical connection.

In order to establish the technical connection with the NMVS, the Hospital registers itself via the website https://sws-nmvs.eu/ (Software Supplier Portal). This step can be done at any moment (i.e. at the beginning of the process), but the approval will depend on the outcome of the legitimacy check (see section 5.2 of this document).

When the outcome of the contractual on-boarding is positive, a technical info pack (Distribution Package) will be made available to the Hospital or his IT Service Provider via the Software Supplier Portal.

The Distribution Package consists of the following documents/folders:
- FD-002 Implementation Guideline NMVO
- FD-006 Software Supplier Test Documentation - NMVS
- ID-004 Software Supplier Onboarding Guide
- TD-001 BP 1.0 Interface Description - G100 Distributor Transactions
- Csharp_Java_SoapUI_Examples
- NMVS - WSDL – XSD

In addition to the Distribution Package, the Hospital is provided a unique user ID and an initial password, which will have to be changed during the first login to the system. Likewise, a certificate is generated for installation by the Hospital. This certificate will be connected to the user ID enabling the Hospital to technically connect to PTMVS. Once the access to PTMVS is granted to the Hospital, it will be initially connected to the sandbox environment (see below).

In PTMVS three different environments are utilized to make sure that the users are connected to the Production Environment (PRD) with a stable and qualified connection:

- Sandbox: PTMVS test environment can be used as a sandbox by the Hospital or it's IT Service Provider to develop the connection and perform an initial integration test.

- Qualification (IQE): the qualification environment is connected to the qualification environment of the EMVS. Once the Hospital or it's IT Service Provider successfully runs the selected test scenarios (see below), access to qualification environment (IQE) will be granted to perform the quality test. The pilot phase will be run on IQE environment.

- Production (PRD): the live environment in which the system will be run. The production environment is connected to the production environment of the EMVS.
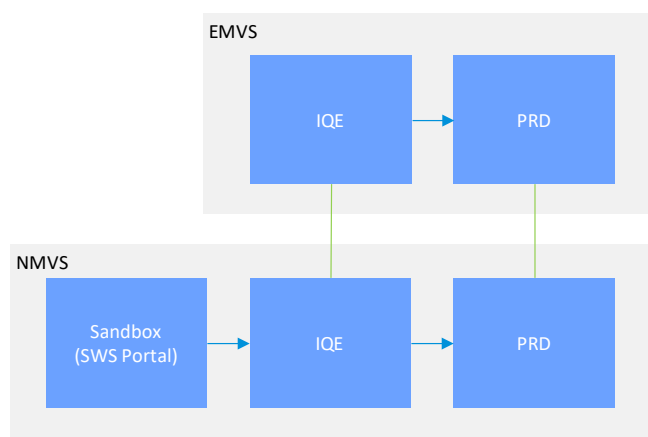
Figure 3. PTMVS and EMVS environments and connections.

Once the connection is set to the sandbox environment, the Hospital or the IT Service Provider must run a set of selected test scenarios to make proof of minimum readiness to connect to higher environments of the PTMVS. The relevant test scenarios are described in the document FD-006 Software Supplier Test Documentation – NMVS, available on the Software Supplier Portal.

The results of the tests will be documented on the template NMVS – Hospital - Test Report Template v1 and sent to MVO Portugal to mvo.portugal@mvoportugal.pt. MVO Portugal will review the contents of the submitted document and feedback will be provided to the Hospital or to the IT Service Provider. This review is intended only for verification of the minimum requirements to connect to qualification environment (IQE). No software certification is granted by MVO Portugal.

Upon successful testing, MVO Portugal will release a formal response and the Hospital will be granted access to the qualification environment (IQE). Once this stage is reached, the onboarding process is complete.

6. Communications

Communications with MVO Portugal will occur via the email address mvo.portugal@mvoportugal.pt, unless explicitly mentioned otherwise in this document. Authorization Holders can use this email address to request clarifications and/or face-to-face discussion.

7. Reference documents

Document Identification	Title
MVOPT-0037	Access Request Form_v3.0
MVOPT-0039	Access Request Form (PT)_v2.0
MVOPT-0048	Services Agreement
MVOPT-0049	Services Agreement (PT)
NMVS – Hospital - Test Report Template v1	NMVS – Hospital - Test Report Template v1