




Onboarding of Authorization Holders with MVO Portugal

Reference guide – version 2.0

October 2018

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Revision History

Version	Date	Reason for changes	Description of changes made
1.0	30-Abr-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 Authorization Holders (Marketing Authorization Holders and Parallel Import Authorization Holders) with MVO Portugal.

2. Scope

The scope of this document includes the information on the onboarding process for Authorization Holders (Marketing Authorization Holders and Parallel Import Authorization Holders) with MVO Portugal. The onboarding process for wholesalers and other end users with MVO Portugal is described in a separate document 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
Authorization Holders	The group composed by Marketing Authorisation Holders and Parallel Import Authorization Holders
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. Onboarding process

The onboarding process for Authorization Holders with MVO Portugal consists of the following steps:

- Sign the cooperation agreement;
- Pay the fees according to the rules and procedures described in this document and in the draft cooperation agreement.

Only after completing the steps above 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.

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4.1 Signature of the cooperation agreement

Authorization Holders will receive by email two versions of the cooperation agreement, one written in English and another written in Portuguese. Authorization Holders can use either as they are identical. In case of divergence, the draft written in Portuguese prevails.

The cooperation agreement can be signed by the Authorization Holder directly or by a legal representative. In case of signature by the Authorization Holder directly:

- The identification data in the contract draft (1ii) must identify correctly the Authorization Holder. For companies not registered in Portugal, the insertion of the information on share capital is not mandatory;
- The sentence “The Company is the representative of the Authorization Holders listed in Appendix 2 in Portugal” can be deleted;
- The Appendix 2 can be ignored;
- Proof of ability to bind the company by signature, must be presented (i.e. trade register extract). For Portuguese companies, the code to access the information on the website <https://bde.portaldocidadao.pt/evo/Services/Online/Pedidos.aspx?service=CCP> can be presented and would be sufficient;
- By default the draft has been prepared considering two signatures by the Authorization Holder. Authorization Holder can adjust if necessary. MVO Portugal binds itself with two signatures.


In case of signature by a legal representative:

- The identification data in the contract draft (1ii) must identify correctly the legal representative. For companies not registered in Portugal, the insertion of the information on share capital is not mandatory;
- The sentence “The Company is the representative of the Authorization Holders listed in Appendix 2 in Portugal” must be kept;
- In the Appendix 2 must be included the information to correctly identify the represented Authorization Holders – full legal name, address and fiscal/VAT number;
- Proof of ability to bind the company (the company acting as the legal representative) by signature, must be presented (i.e. trade register extract). For Portuguese companies, the code to access the information on the website <https://bde.portaldocidadao.pt/evo/Services/Online/Pedidos.aspx?service=CCP> can be presented and would be sufficient;
- A power of attorney must be presented to make proof of the ability of the legal representative to sign on behalf of the represented Authorization Holders;
- By default the draft has been prepared considering two signatures by the Authorization Holder. Authorization Holder can adjust if necessary. MVO Portugal binds itself with two signatures.

Once signed by the Authorization Holder of the legal representative, two signed hardcopies must be sent to:

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

One of the signed hardcopies will be sent to the Authorization Holder of the legal representative postal address.

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4.2 Payment of fees

The fees to be paid by Authorization Holders to MVO Portugal will support the setup, implementation and operation of the National Medicines Verification System.

The amount to be paid by each Authorization Holder is calculated in accordance with the following table:


Level	Criterion 1	Criterion 2	Amount
1	Up to 10 authorizations	Sales up to (and including) 1.000.000 EUR per year, per authorization	1.000 EUR + VAT per authorization
2	Up to 10 authorizations	Sales above 1.000.000 EUR per year, per authorization	10.000 EUR + VAT
3	More than 10 authorizations	n.a.	10.000 EUR + VAT

In addition to the information above:

- By “authorization” is meant the Marketing Authorization or Parallel Import Authorization granted by the authorities. For fee calculation purposes, a single authorization is given by the authorization number (*número de registo*) as per the information registered in the authorities;
- Only the authorizations with status “authorized” (*autorizado*) will be considered for fee calculation purposes;
- Only the authorizations whose products are marketed (*comercializado*) will be considered for fee calculation purposes;
- Only the products under the scope of the Delegated Regulation and national applicable legislation (if any) will be considered for fee calculation purposes;
- A single annual payment will apply, and no additional payments planned for 2018;
- No other fees apply (i.e. entrance fee, etc);
- When VAT is applicable, the 23% taxation will be applied.

In regard to invoicing and payment:

- The invoice can be issued to the Authorization Holder or to the legal representative. The Authorization Holder or the legal representative must inform MVO Portugal on the recipient of the invoice, by including the necessary information on the draft (Appendix 1);
- The annual payment can be done with more than one invoice. The Authorization Holder or the legal representative must inform MVO Portugal on the recipients of the invoice, by including the necessary information on the draft cooperation agreement (Appendix 1);
- Payments are to be made by bank transfer. MVO Portugal's IBAN is PT50-0033-0000-45522776576-05 and SWIFT code is BCOMPTPL. Bank document to make proof of the bank details, or other necessary documentation can be requested via the email address mvo.portugal@mvoportugal.pt;
- Once the payment is made, a proof of payment must be sent to the email address mvo.portugal@mvoportugal.pt to guarantee the correct identification of all payments.

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5. 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.

6. Reference documents

Document Identification	Title
MVOPT-0045	Cooperation agreement draft
MVOPT-0046	Cooperation agreement draft (PT)