NEWSLETTER MVO PORTUGAL

ISSUE 3 - DECEMBER DE 2018

PARTICIPATION COSTS FOR 2019

The participation costs for 2019, to be borne by the Market Authorization Holders and by the Parallel Import Holders, were approved by the MVO Portugal General Assembly in December 2018.

The information concerning the participation costs for 2019 can be consulted in MVO Portugal's website, here.

NEW VERSION OF THE MASTER DATA GUIDE

EMVO recently issued an updated version of the master data guide. This document contains relevant information concerning the data upload to the European hub, as well as the designated wholesaler concept (appendix 5) and can be accessed in MVO Portugal's website or on the EMVO's website.

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ACCESS TO THE NATIONAL REPOSITORY BY WHOLESALE DISTRIBUTOR AUTHORISATION HOLDERS

As per the general principle, all holders of a wholesale distributor authorization (WDA) granted by the competent authority must connect to the national repository. To be able to do so, the WDA holders must complete the onboarding process with MVO Portugal, regardless of performing the logistics operations directly or via a third party:

	Onboard with MVOPT NO	Onboard with MVOPT YES
Logistics operation performed by the WDA holder itself		X
Logistics operation contracted to third parties (e.g. pre-wholesalers)		X*

On the other hand, virtually all marketing authorization holders are WDA holders as well. However, the marketing authorization holders will not connect to the national repository unless they perform directly the logistics operations:

	MAH to onboard with MVOPT as a wholesaler NO	MAH to onboard with MVOPT as a wholesaler YES
MAH contracts the logistics operation to third parties (e.g. pre-wholesalers)	X**	
MAH performs its own logistics operations		X

More information can be found on MVO Portugal's website, in the FAQs area, section 5.

- - in the onboarding process the WDA holder must identify it's logistics operator.

** - The market authorization holder must identify the designated wholesaler(s) in the master data to be uploaded into the european hub.

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DATA UPLOAD TO THE EUROPEAN HUB

INFARMED, I.P. recently issued the informative note N.º 176/CD/100.20.200, concerning data upload to the european hub. All verifications and decommissioning transactions on unknown pack to the system will raise alerts of possible falsification. As such, it is vital that the data upload to the European hub occurs before 9th February 2019, so unnecessary alerts and subsequent actions can be avoided. In this informative note is also included information concerning the verification and or correction of the data already uploaded, to be made by the marketing authorization holders or OBPs, including the mandatory upload of the NHRN to all products.

USE OF AGGREGATED CODES

SPMS, E.P.E. recently issued public tenders for centralized acquisition of medicines for the public hospitals. In these tenders was included references to "simultaneous decommissioning mechanisms of unique identifiers by the institutions of the National Healthcare Service". These mechanisms are unknown to MVO Portugal e these data transactions will occur outside the national verification system.

LIST OF HEALTHCARE INSTITUTIONS OBLIGED TO VERIFYAND DECOMMISSION UNIQUE IDENTIFIERS

INFARMED, I.P. recently issued a list of the public and private entities obliged to verify and decommission the unique identifiers. The list can be accessed in MVO Portugal's website and in INFARMED's website.

MEDICINAL PRODUCTS THAT MUST BEAR SAFETY FEATURES

As per article 54-A of the Directive 2001/83/CE, changed by the Directive 2011/62/EU, all medicinal products subject to prescription must bear safety features except those mentioned in annex I of the Delegated Regulation, as well as the medicinal products not subject to prescription mentioned in annex II of the Delegated Regulation. In addition, as per the Decree-Law 26/2018, of 24th April, the reimbursed medicinal products not subject to prescription whose dispense is exclusively done in community pharmacies (MNSRM-EF).

ONBOARDING PROCESS FOR USERS OF THE NATIONAL REPOSITORY

The test reports, for both sandbox and IQE, must contain the detail concerning the executed tests, including print screens of the applications used, requests/responses of the webservices and detail of the products, batches and serial numbers used. The review process would then be faster and more efficient.

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