NEWSLETTER MVO PORTUGAL

ISSUE 2 - NOVEMBER 2018

OUR WEBSITE IS LIVE

The website https://mvoportugal.pt/ is live and is a privileged channel for communication and information sharing.

It was built based on a logic of directing the relevant specific information for each group of entities impacted by the verification system (MAH/OBP, wholesalers, pharmacies and healthcare institutions), along with a logic of sharing information of general interest (verification system and safety features, about us, legislation and documentation, frequently asked questions, news and contacts).

The website is available is Portuguese. The English version will be released during the next month of December.

CONTACT US

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DATA UPLOAD TO THE EUROPEAN HUB – NATIONAL HEALTHCARE REIMBURSEMENT NUMBER (NHRN)

According to the Decree-Law 26/2018, the national healthcare reimbursement number (*número de registo*), granted by the National Competent Authority (INFARMED, I.P.) is part of the unique identifier. As such, it is mandatory the NHRN to be printed on the pack (as it already is today), encoded into the datamatrix and uploaded into the system via the European hub.

After analysing the data quality in our Production system, we verified that not all products were uploaded including the NHRN. The onboarding partners that have already uploaded data into the system are required to check the data and proceed with the necessary corrections.

DATA UPLOAD TO THE EUROPEAN HUB – DESIGNATED WHOLESALER

'Designated Wholesalers' are wholesalers who are designated by the marketing authorisation holder, by means of a written contract, to store and distribute the products covered by his marketing authorisation on his behalf. Likewise, the parallel importer/parallel distributor may designate a wholesaler, by means of a written contract, to store and distribute on his behalf the products covered by the parallel import authorisations/parallel distribution notices respectively.

Based on the logic of the end-to-end verification system, wholesalers that receive packs from a designated wholesaler are not obliged to verify the authenticity of such packs.

Being designated by the marketing authorisation and/or by the parallel importer/parallel distributor has a very significant impact on the wholesalers' operations. Furthermore, knowing who are the designated wholesalers is a critical information for all wholesalers in the supply chain.

After analysing the data quality in our Production system, we verified that not all products were uploaded including the information of who the designated wholesaler is. The onboarding partners that have already uploaded data into the system are invited to check the data and proceed with the necessary corrections so the data is correct and consistent.

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PARTICIPATION COSTS FOR 2019

The participation costs for 2019, to be borne by the marketing authorization holders and by the parallel import/distribution authorization holders, are still under approval process and will be published on our website as soon as possible. For budgeting purposes, the 2018 participation costs can be used. The participation costs will be equal or lower than those of 2018. The invoice will be issued in January.

LIST OF HEALTHCARE INSTITUTIONS OBLIGED TO VERIFY AND DECOMMISSION UNIQUE IDENTIFIERS

Following the established by article 23 of the Delegated Regulation, the National Competent Authority (INFARMED, I.P.) will publish a list containing the entities that are obliged to verify and decommission the unique identifiers against the national medicines verification system. As soon as the list is released, it will be published on our website.

SCANNER CONFIGURATION TO CORRECTLY READ 2D BARCODES

The scanners and the respective software to be used to verify and decommission unique identifiers must be apt to correctly read the datamatrix codes. The information encoded into the datamatrix (product code, serial number, batch, expiry date and NHRN) is separated by code initiators and finalizers permitting the scanner to interpret the codes. As such, the scanners and the respective software must by configured accordingly.

MVO PORTUGAL

MVO Portugal is a private not-for-profit organization, established on 4th August 2017, and is the responsible entity for the implementation and operation of the national medicines verification system, in accordance with the European and national legislation.

The members of MVO Portugal are the following:

- APIFARMA – Associação Portuguesa da Indústria Farmacêutica;
- APOGEN – Associação Portuguesa de Medicamentos Genéricos e Biossimilares;
- APIEM – Associação Portuguesa de Importadores e Exportadores de Medicamentos;
- ADIFA – Associação de Distribuidores Farmacêuticos;
- GROQUIFAR – Associação de Grossistas de Produtos Químicos e Farmacêuticos;
- AFP – Associação de Farmácias de Portugal;
- ANF – Associação Nacional de Farmácias;

More information can be found on our website https://mvoportugal.pt/pt/sobre-nos (English version to be released soon).

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