NEWSLETTER MVO PORTUGAL

NUMBER 7 – OCTOBER 2020

THE TRANSITION PERIOD IS STILL IN FORCE

In preparation for the entry into force of the Delegated Regulation, INFARMED, I.P. published the Informative Note 020/CD/100.20.200 (English version can be found here).

In this document can be read that "[…] As a precautionary measure and to support the need to ensure the continuity of supply with the known and usual quality, security and effectiveness, until further notice by INFARMED, I.P., the alerts of possible falsifications generated by the national verification system will not be visible to the user, so the supply of medicines can continue with no disturbance. […]".

The transition period is still in force. More information will be made available when possible.

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THE VERIFICATION SYSTEM IN PORTUGAL

Since the entry into force of the Delegated Regulation, the use of the verification system in Portugal has been progressively growing. On a monthly basis, the data corresponding to approximately 20 million packs is loaded in the system by the onboarding partners. In addition, the activity of wholesalers, pharmacies and hospitals has been growing and during September 2020 approximately 12 million packs were dispensed or decommissioned. There are around 394 million packs active in the system.

There are currently 238 connected wholesalers to the system (approximately 95% of the total). Furthermore, all pharmacies and 73 hospitals (nearly 60% of the total) have also finished the onboarding process. In addition, all MAHs initially identified have signed the contract with MVO Portugal.

Whenever packs are provided with a unique identifier (even if they have a 39 barcode), verification and deactivation operations must always be carried out in accordance with the rules defined in the Delegated Regulation.

ELIMINATION AND PREVENTION OF ALERTS

The alerts generated by the verification system are analysed by MVO Portugal in order to determine the most likely cause of each alert. Based on the results of the analysis, relevant entities are contacted for the resolution of registered alerts and prevention of future alerts.

In order to support the various stakeholders in the elimination of alerts from the verification system, MVO Portugal prepared a set of documents in which a description of the alerts, their most probable causes and ways of eliminating the alerts are described. Forms were also prepared for reporting the problems to MVO Portugal. The documents can be found in our website, here.

PARTICIPATION COSTS FOR 2021

The participation costs for 2021 will be communicated until the end of the current year. For budgeting purposes, the MAH and PIAH can consider for 2021 the amounts charged for 2020.

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NEW PT NMVS CORE RELEASE 1.08

The Portuguese National Repository (PT NMVS) will be upgraded to version 1.08 on the 28th October 2020. Between 20:00 on the 28th October and 06:00 on the 29th October, the PT NMVS may have unforeseen downtime periods and therefore MVO Portugal requests that all end-user make sure that their software message retry mechanisms are in place and fully operational during this period.

As previously communicated, the version 2 of the end-user interface will be removed in Core R1.08 and only version 3 (V3) and version 4 (V4) will be active.

VERSION 4 OF THE END-USER INTERFACE

All documentation for V4 is available in the SWS Portal under the technical documentation of R1.06. The changes from V3 to V4 are detailed in the chapter "Overview of changes V4 distributor interface" of the document "FD-002 Implementation Guideline NMVS BP" for Core R1.06 also available in the SWS Portal (here). When implementing the V4, all end-users should start sending the Portuguese NHRN (INFARMED I.P. AIM) read when scanning the 2D code in their requests to the PT NMVS. A new NHRN field is available in the requests, and although no validation between the NHRN and the GTIN will be done just after the go live of the R1.08, it is planned to activate this validation in medium term. The validation will compare the GTIN and NHRN read by the end users against the GTIN and NHRN uploaded by the MAHs/OBPs.

Summary of the V4 changes:

- Alert ID in a separate field in the responses from the PT NMVS
- NHRN as optional field in the request input data
- Mixed Bulk request with subUserId per transaction item and RefClientTrxId per item
- Pagination in G101 - download of product master data
- Soap WSSE Header supported in all G100 processes
- New return codes are available (see detailed list in the mentioned documentation)
- Two new sub return codes in the response output data structure.

END-USER CERTIFICATE RENEWALS

We are approaching the expiry dates of the initial quality and production certificates issued during the onboarding processes. These certificates are valid for 2 years. If your certificate is expiring, you will be receiving 60 days prior to its expiry date an email with a new "tan" and the instructions to download the new certificate. If you do not download and install the certificate 30 days prior to the expiry date, you will start receiving a daily email reminder to execute this activity.

In order to streamline the download and installation processes of the new certificates, there is a new endpoint in Core R1.08 which allows the certificates to be downloaded using only existing and valid credentials, without the new "Tan". The former endpoint to download the certificate with the new "tan" will continue to be available. The documentation is available in the SWS Portal in the document "FD-002 Implementation Guideline Preview NMVS" for Core R1.08 (here).

Please contact your software provider and request support in the renewal of your certificates.

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REPLACEMENT OF THE PT NMVS WILDCARD CERTIFICATE

To set up a secure connection to our website (using https://), MVO Portugal is currently using a 'wildcard certificate' (public key certificate) for every single environment. This wildcard certificate expires every two years and currently needs to be replaced by a new wildcard certificate.

This change is planned for the production environment on 19.10.2020 (before 08.00 CEST) and is downtime-free, so no issues or service degradations are expected. For the IQE Environment, the replacement of the wildcard certificate was already completed without any issues.

In some cases, End Users that are connected to a system that use a (wildcard ssl) certificate, store this certificate locally in their systems. In these cases, as soon the wildcard certificate will be replaced with a new one in the PT NMVS servers, the users will no longer be able to access the PT NMVS. MVO Portugal thereby requests all users to check that the PT NMVS wild card certificate is not stored in any of the End User systems and if so to correct this situation.

OBP STATIC IP ADDRESSES FOR THE EU HUB

Changes to the Outbound IP addresses (Hub to OBP) have occurred on Monday, 28th September 2020. OBP should have added the new IP address in their whitelist and firewall settings. Please contact your IT department or solution provider promptly to ensure you have the right configurations and to avoid any unwanted disruption to your daily operation and workflows. The new IP addresses are available here.

EMVS ALERTS & NOTIFICATIONS DOCUMENT

EMVO_0402_EMVS Alerts & Notifications is now available to OBPs. It can be found in the Technical Info Pack on the OBP Portal. The document describes alerts and notifications emanating from the European Medicines Verification System (EMVS). It can be used to help identify the triggers that cause the EMVS to issue alerts for Potential Suspect Falsification packs, and may assist with the design of processes and procedures for investigation and handling of potential suspect falsification packs and other scenarios where suspicious activity is detected.