

NEWSLETTER

MVO PORTUGAL



ISSUE 5 – MAY 2019

TRANSITION PERIOD AND ALERT MONITORING

As defined in [Informative note 020CD100.20.200](#) published by INFARMED, I.P. on January 28, 2019, until further notice, there is a transition period during which the Delegated Regulation is fully in force, except with regard to procedures in the event of an alert (the operation must continue and the medicine be supplied, unless the anti-tampering device has been damaged).

Following what is defined in the referred note and in order to eliminate alerts related to system technical issues, MVO Portugal has monitored on a daily basis the alerts generated by the system and collaborated with MAHs, end users, scanner suppliers, software suppliers, EMVO and other NMVOs to solve the identified problems. It is essential that all those involved take the necessary actions so that the elimination of false alerts is achieved as quickly as possible.

Taking into account the information known to date and without prejudice of further instructions that may be issued by INFARMED, I.P., it is expected that the full stabilisation of the verification system will be achieved from the end of 2019 onwards.

To date, the alerts generated so far have in most cases had one of the following causes (arbitrary order):

- Incorrect reading or interpretation of data by scanners;
- Data on products, batches or packs not loaded into the system or loaded incorrectly;
- Technical problems in the end-user software.

FIRST THREE MONTHS AFTER GO LIVE

In the first 3 months after the entry into force of the Delegated Regulation, the stabilisation of the verification system has been occurring as expected. There has been a significant increase, week after week, both in the number of packs loaded into the national repository and in the number of transactions carried out (verify, decommissioning, etc.). Currently more than 75 million packs are registered in the repository and the average number of transactions per week is around 320,000. On the other hand, the volume of alerts has been falling steadily.

It is imperative that all entities (Wholesalers, Pharmacies and Hospitals) successfully complete the onboarding process, under risk of non-compliance with the provisions of the Delegated Regulation. Currently, 69 wholesalers, 2.788 pharmacies and 26 hospitals are connected to the national repository.

Whenever a pack bears a unique identifier (even if there is also a code 39), operations must be carried out on the basis of this identifier by reading its 2D code, and must proceed to verify and/or deactivate the pack in accordance with the rules defined in the Delegated Regulation.

PRODUCT MASTER DATA

For products data loaded via EU-HUB, there are still 646 products with no national registration number. The national registration number is mandatory. As of July 2019, it will not be possible to upload data to the EU-HUB without the respective national number.

Where the MAH is a distributor of its own products, it must indicate its name as the Designated Wholesaler (do not leave fields blank) when uploading the data to the EU-HUB. This information is critical for the logistical operation and thus it is clear to any entity on the market who is the designated wholesaler.

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SCANNER CONFIGURATION

In order to solve specific problems in the reading and interpretation of 2D codes, MVO Portugal contacted the three main manufacturers of scanners (Datalogic, Honeywell and Zebra), and in partnership were created modular configurations that allow solving the most common problems already detected: reading negative codes (printed in white on black background), definition of group separators, reading a specific code when there are several codes very close to each other and maintaining the character set (caps lock or lower case) of lots and serial numbers. Settings are available [here](#) and if specific settings are required, manufacturers are available to customize these same settings.

DATA LOADING - EXPIRY DATE

The information concerning the expiry date of batches loaded into the EU-HUB shall be identical to that encoded in the 2D codes printed on the packs. The expiry date format in the 2D code on the pack is "YYMMDD", where "YY" is the year, "MM" is the month and "DD" is the day. The information in the "DD" can be any day of the month in question or 00, even if the expiry date printed on the pack does not contain the information of the day.

2D CODES READINGS

The scanners as well as the end users' systems must be configured or developed to pass to the national repository the information of the 2D codes read, with exactly the same format and content that was read and that appears on the packs. In particular, the expiry date should be transmitted with the day read on the package, even if it is 00 and the character set (caps lock or lower case) of batches and serial numbers should be maintained.

EUROPEAN MEDICINES VERIFICATION SYSTEM INFORMATION (EVI)

EMVO provides a portal where all downtime situations, known issues and information concerning the European Hub and national repositories are published. It is also available the subscription to the EVI service that allows receiving the same information immediately by email. To access this portal, click [here](#).

CHANGING THE INTEGRATION SOFTWARE WITH THE NATIONAL REPOSITORY

At any time during the onboarding process or after the entry into production, if the end user (Wholesaler, Pharmacy or Hospital) decides to change the integration software with the national repository, it should be immediately communicated to MVO Portugal in order to define the necessary steps to validate and test the new solution. The onboarding process executed with the previous software will be ineffective from the indicated transition date.

INTERFACE VERSIONS WITH THE NATIONAL REPOSITORY

Currently two versions of interfaces with the national repository are available and working: Version 2 (V2) and Version 3 (V3). Although both are valid and working, V3 is the most up-to-date and includes corrections and improvements to V2, so we advise you to plan your upgrade to V3 in the coming months. In October this year, it will be mandatory to migrate to at least V3, as a new version will be available at this time (Version 4) and Version 2 will no longer be active. As for the future, all end-users will have to plan an integration version update with the national repository at least once a year in order to adopt the latest patches, improvements and new features made available.

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PRODUCT, BATCH AND PACK STATUS

The possible states for the products, batches and packs in the national repository are:



CONTACTS

For the purpose of communicating situations that should be clarified with MVO Portugal, they should be addressed to:



All telephone contacts should be made to the new number **+351 211 608 378**. The number +351 211 214 967 will soon be disconnected.

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