OSMR
Organizația de Serializare a Medicamentelor din România

Alerts within the European Medicines Verification System

The European Medicines Verification System is designed as such that when a medicine pack is scanned at the point of dispense, it will be checked and verified for authenticity against a national repository.

If the Unique Identifier (UI) - which is encoded in a 2D data matrix holding information related to the pack - on the pack matches the UI in the repository, the pack is dispensed to the patient. At the same time, the status of the serial number of the pack is set to "decommissioned/supplied", enabling thus a record of the dispense of the pack to be kept, to check against potential future falsifications.

On the other hand, should the information taken from the UI differ from the information held in the system, the medicine pack's authenticity cannot be verified, and an alert will be raised.

An exception describes a situation where the normal operation of the EMVS is interrupted; as per EMVO User Requirements Specifications. Within EMVS - NMVS there are 5 levels of exceptions, going from level 1, in which the system can handle the situation by itself, to level 5, in which system administrators and external stakeholders are informed of the situation:

- Level 1: the system can handle the exception on its own. The deviation does not appear to the user in any way;
- Level 2: the initiator of a transaction/the operator is informed about the exception;
- Level 3: the system administrator (EU or national) is informed about the exception;
- Level 4: more than one system administrator is informed about the exception;
- Level 5: in addition to the initiator of a transaction/the operator and system administrators, disclosure of information to other stakeholders is required.
  The external stakeholders who are informed in the event of a level 5 alert are the NMVO, the OBP, EMVO and the National Competent Authority (NCA).

An alert describes the process of informing actors other than the one who was interacting with the system when the exception was triggered.

The information in EU Hub and NMVS is organized on 3 levels:

- Product Level;
- Batch Level;
- Pack Level.

Each level has a certain status in NMVS, and the decommissioning/verification operation can only be considered successful when the status is set as “Active” for all of them.

Thus, when interrogating NMVS, the following information should be received:

Product Status (Product Code, GTIN)

- Active;
- Recall;
- Product Code (PC) Unknown.

Batch Status (Batch):

- Active;
- Recall;
- Expired;
- Batch Unknown (when PC is unknown);
- Different expiry date (between the 2D data matrix on the pack and the information in NMVS);
- Different batch number (between the 2D data matrix on the pack and the information in NMVS).

Pack Status (Serial Number, SN):

- Active;
- Decommissioned;
- Unknown Serial Number.

It should be mentioned that the system is interrogated in a certain order: from PC level towards SN level, thus if the PC is unknown, NMVS cannot check the information on Batch, Expiry date or SN. Furthermore, if Batch in unknown, NMVS cannot verify Expiry date or SN.

There are 3 major transaction types in NMVS:

- **Verification** (the medicine’s status in NMVS is not modified);
- **Decommissioning** (the medicine’s status in NMVS is modified from Active to Inactive);
- **Undo decommissioning** (the medicine’s status in NMVS is modified from Inactive to Active).

Instances which do not raise an Alert in the NMVS:

- Batch Expired – the local procedures in place will be applied;
- Batch Recalled – the local procedures in place will be applied;
- Product Code Recalled – the local procedures in place will be applied.

In all the above-mentioned cases, the End User will be notified by the IT system which connects to the NMVS about the situation occurred.

Scenarios from the NMVS which can indicate an Alert:

- The Product Code cannot be identified in NMVS or EMVS;
- Batch not found;
- Expiry date differs from the information found in NMVS;
- Batch number differs from the Serial Number after interrogating NMVS;
- Serial Number inactive;
- Serial Number unknown;
- The scanner is not used/configured correctly, there are errors with the IT system of the End User;
- Medicines not in the scope of the FMD (no prescription);
- Medicines which are not manufactured in the EU/do not have packaging elements according to the EU legal requirements;
- Data on the product or the product batches have been incorrectly uploaded to the EU Hub, or the respective data is invalid;
- Errors generated by the EMVS when data is withdrawn by the NMVS, invalid data after uploading it to the EU Hub by the OBP/MAH.

Level 5 Alert Messages – 10 situations identified according to EMVO User Requirements Specifications:

- NMVS_NC_PC_01 – Unknown Product Code;
- NMVS_FE_LOT_03 – Failed to find a batch for the given data;
- NMVS_FE_LOT_12 – Expiry date does not match the date held in the NMVS;
- NMVS_FE_LOT_13 – The Batch ID does not match the Serial Number in the NMVS;
- NMVS_NC_PCK_22 – Pack is already Inactive;
- NMVS_NC_PCK_19 – Property is already set on pack;
- NMVS_NC_PC_02 – Unknown Serial Number;
- NMVS_NC_PCK_06 – Actual pack status doesn't match the undo transaction (set and undo status must be equivalent);
- NMVS_NC_PCK_20 – Defined timeframe between setting this property and undo was exceeded;
- NMVS_NC_PCK_21 – Undo can only be executed by the same user who previously set the attribute.

L5 Alerts may strongly suggest a potential falsified medicine.

Level 5 Alert message generated by NMVS is sent to the following recipients:

- The End User's IT system;
- EMVO, via the EU Hub;
- OBP/MAH via EU Hub (except for the cases where the product is unknown in NMVS, then the system cannot alert the OBP);
- OSMR (Romanian NMVO);
- ANMDM (The National Agency for Medicines and Medical Devices).

Level 5 Alerts contain the following information:

- The hour and the date when the alarm was generated (Time stamp);
- Unique Alert Identification Code (ID);
- Product Code;
- Batch Identification Code;
- Expiry Date;
- Serial Number;
- GTIN;
- NMVS and/or EU Hub Code corresponding to the product status at the moment the transaction had been undertaken by the End User;
- End User/Client Identification Number.