INTERFACE V5

Together with the **new release CORE 1.11** (5/10/2022) and the **new user interface V5** which is available since May 2022, a number of new features have been introduced in the FMD system. Hereby a short explanation on these new elements.

Highlights
• **New return code related to Brexit with "mandatory" switch to interface V5 !** • **New response fields when performing a verification on an inactive pack** • **New notification code when multiple scanning of the same pack** • **Additional product information related to the GTIN in the NMVS response** • **New return codes indication NO ALERT**

Brexit – Delegated Regulation 2022/315 & interface V5

On 17/12/2021 the EU Commission published an additional DR to cover the Brexit situation where the UK, with exception of Northern Ireland, is no longer part of the FMD-world.

This DR intents to solve the issue that UK packs continue to be distributed also in Northern-Ireland, Ireland, Cyprus and Malta. This issue is addressed by adding an additional message to the FMD users when a UK pack is scanned.

For BE/LU the **new return code NMVS_NC_PCK_04 "Pack sourced from outside the EU"** will need to be displayed to the user when he scans such UK pack (different message for the 4 countries mentioned above).

This return code is already **part of interface V5** but not yet active. It is planned to activate the return code with release 3.00 which is planned for October 2023. **Is therefor mandatory to switch to interface V5 before this date!**

If this new return code and the message is not visible for the end users (wholesalers and pharmacies) they can be considered not compliant to FMD by the authorities.

More detailed information regarding this new return code, e.g. how and when the return code is created, will follow as release 3.00 approaches.

Two additional response fields in the verification

50% of the alerts are caused by a user trying to deactivate a pack which is already inactive.
In order to help the user avoiding such alert, two additional fields are available in a response to a **"Verification" request.**

When the user executes a G110 Verify Single Pack, G112 Manual Verification of Single Pack, G115 Bulk Verify Packs and the pack is already inactive, then the system responds with the information if

the pack was previously deactivated by that same user and if this is the case, was the pack deactivated in the last 240 hours (10 days).

The addition fields are the following:

Attribute	Description
User Match	A flag indicating whether the same user decommissioned the pack before or if the initial decommissioning was done by another user
Undo Timeout	In case it is the same user, an indication whether the last decommission had occurred within the UNDO time limit (240 hours) – *if this information is available (which is not the case for a verification triggering an IMT)*

Maybe your FMD module is already doing a check in the users log before performing a decommissioning to avoid a 'double decommissioning' alert, but if not **then this function will be very useful when we move to the next phase of alert handling in the second half of 2023**.

Alert management: When a user has an alert of type "Pack is already inactive", the information that the pack was initially deactivated by himself or another user is very important. He might find such information in his log's, but with this feature he can see it immediately and know if he can reactivate the pack and deactivate for dispense while he has the patient in front of him. Or if the pack needs to go in quarantine (when we move to the full alert procedure) to investigate why the pack is in state 'inactive'.

As such, the main advantage of this new feature is that the user can avoid raising an alert when he scans the pack again for deactivation.
If the pack was deactivated by himself and that was within the last 240 hours, he can re-activate the pack with an 'Undo' operation (or his software can take care of it).

Warning on repeated transactions

Return Code	Description	Since Release
NMVS_NOTIFY_PCK_01	The limit of double action is reached. Performing the same transaction again will result in an alert.	CORE 1.10

This is also a feature to help the user avoiding alerts caused by multiple scanning of the same pack.

When a user is scanning and transmitting multiple time the same pack data, this does not automatically raise an alert of type NMVS_NC_PCK_19 "Property is already set on pack" or NMVS_NC_PCK_22 'Pack is already inactive". Depending on the country of origin of the pack, a parameter is allowing the user to scan the pack multiple times without immediately causing an "Alert".
Instead, the user is receiving return code NMVS_NC_PCK_23 "Re-setting of the property via double scan is registered" indicating that the data for the concerned pack have already been transmitted by that same user earlier.
New in interface V5 is that at the last scan before he reaches the number of multiple scans allowed by the parameter and generate an alert, he receives a notification NMVS_NOTIFY_PCK_01. As such the user can be aware that if he scans that same pack again, a FMD Alert will be raised that will need to be addressed and solved before the pack can be delivered.

Add Product Code Name in the local verification transactions

The **Product Name** and the **Product Common Name** (new) will be provided for each requested medicine, if the product is available in the local NMVS. The information for the product name and product common name are provided by the EU HUB via G510 Upload Product Master Data (product description from the MAH).

In case the product is not available in the local NMVS, an Intermarket Transaction (IMT) will be triggered. In that case the NMVS_NOTIFY_IMT_01 "Due to an IMT no product name could be return" will be displayed.

Displaying the product name allows the user to check if the GTIN transmitted really corresponds to the pack he has at hand or if the displayed product name is different which might indicate a falsification. This can be useful as far as another solution, e.g. GTIN/CNK look-up table, is not already present in the user's FMD module.

Attribute	Description
Product common name	Common Name of the product

```
        <ns1:Timestamp>2022-08-05T14:21:39.127+02:00</ns1:Timestamp>
    </ns1:Transaction>
  </ns1:Header>
  <ns1:Body>
    <ns1:Product>
       <ns1:ProductCode ns1:scheme="GTIN">05400581003646</ns1:ProductCode>
       <ns1:Name>Losartan Plus EG 50 mg/12,5 mg filmomhulde tabletten</ns1:Name>
       <ns1:CommonName>LOSARTAN POTASSIUM/HYDROCHLOROTHIAZIDE</ns1:CommonName>
       <ns1:Batch>
          <ns1:Id>03514</ns1:Id>
          <ns1:ExpDate>230831</ns1:ExpDate>
          <ns1:ExpDateNMVS>2023-08-31</ns1:ExpDateNMVS>
       </ns1:Batch>
    </ns1:Product>
    <ns1:Pack ns1:sn="FW59GAA9TT" ns1:state="INACTIVE" ns1:userMatches="false">
       <ns1:Reason>SUPPLIED</ns1:Reason>
    </ns1:Pack>
```

New return codes indicating NO ALERT

The following table contains a list of the return codes that have been added to the V5 interface. The full table with examples can be found in DOC-304007-14 Implementation Guideline NMVS CORE-1.11 on the Software Supplier Portal.

In interface V4, the system does not distinguish between level 5 alert return codes uniquely. This means that e.g. NMVS_NC_PCK_22 (Pack is already inactive) sometimes leads to an alert (e.g. set SUPPLIED on an EXPORTED pack) and sometimes it does not (e.g. set SUPPLIED on an EXPIRED or RECALLED pack). With the implementation of interface V5, this functional inconvenience is solved by splitting up the relevant return codes. For the case of NMVS_NC_PCK_22, this means that with the interface V5, this return code now always represents a L5 alert. If the transaction does not trigger an alert, the return code NMVS_NC_PCK_30 (Pack is already inactive (no alert)) will be returned.

Return Code	Description	Since Release
NMVS_FE_LOT_15	Failed to find a batch for the given data (no alert)	CORE 1.10
NMVS_FE_LOT_17	Expiry date does not match the date held in the NMVS (no alert)	CORE 1.10
NMVS_FE_LOT_18	The batch ID does not match the serial number in the NMVS (no alert)	CORE 1.10
NMVS_NC_PCK_28	Property is already set on pack (no alert)	CORE 1.10
NMVS_NC_PCK_30	Pack is already inactive (no alert)	CORE 1.10
NMVS_NC_PCK_31	Status change could not be performed (no alert)	CORE 1.10