NEWSLETTER MVO PORTUGAL

ISSUE 4 – FEBRUARY 9TH, 2019

THE DELEGATED REGULATION ENTERED INTO FORCE TODAY

The Delegated Regulation 2016/161 of October 2nd, 2015 has entered into force. From this date the european medicines verification system is legally enforced.

ENTRY INTO FORCE OF THE DELEGATED REGULATION – MEASURES FOR THE TRANSITION PERIOD.

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 "[…] in the go-live, transition and stabilization period after the Delegated Regulation entered into force is necessary to ensure the normal activity of the market and the regular supply of medicines by all entities, without any interruptions, having into consideration the legal and deontological of all supply chain participants. 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. […]"

Following the publication of the abovementioned Informative Note, MVO Portugal prepared a guideline for the transition period. The guideline can be found in attach to this newsletter.

LIST OF HEALTHCARE INSTITUTIONS OBLIGED TO VERIFY AND DECOMMISSION UNIQUE IDENTIFIERS – AZORES AND MADEIRA

The regional authorities published the lists of entities obliged to verify and decommission the unique identifiers on the packs under their responsibility. The list concerning entities in Azores can be found here. The list concerning entities in Madeira can be found here.

ACCESS REQUEST TO PTMVS

To access the national medicines verification system (PTMVS) must initiate the process by sending the access request form to MVO Portugal. The access request form can be found here.

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DATA UPLOAD TO THE EUROPEAN HUB – DESIGNATED WHOLESALER

MVO Portugal sent a communication to Marketing Authorization Holders/OBPs on February 7th, concerning the need to upload the data related to the designated wholesalers.
The onboarding partners that have not yet loaded information concerning designated wholesaler (as part of the product master data upload) must proceed with the respective loading. In case of having already uploaded data into the system, the onboarding partners must check the data and proceed with the necessary corrections, so the data is correct and consistent. In addition and for more information on this subject, the onboarding partners and marketing authorization holders must consult the Informative Note 176/CD/100.20.200 issued by INFARMED, I.P. on December 17th 2018. More information can be found also in Appendix 5 of the master data guide. This document can be found on our website, as well as on EMVO's.

INSTABILITY OF THE EUROPEAN HUB

Some OBPs have been experiencing intermittent availability of the EU Hub. EMVO is conducting a root cause analysis of the issue behind this intermittent problem, and mode information can be found here.

VERIFICATION AND DECOMMISSIONING OF VACCINES

The verification and decommissioning of vaccines is to be performed as to any other serialized product under the obligation to bear safety features.

INFOMED DATABASE ALREADY INCLUDES INDICATION OF THE PRODUCTS TO BEAR SAFETY FEATURES

INFARMED, I.P. included in the INFOMED database (in table *emb*) the indication whether the medicinal products have to bear safety features.

GS1 GUIDES ON DATAMATRIX CODES

The GS1 guides concerning the datamatrix codes can be found here.

MANAGEMENT OF THE USERS IN THE NATIONAL MEDICINES VERIFICATION SYSTEM

When the accesses to the Quality and Production environment are granted, a user management procedure document is sent to the main contact person of the entity. This document describes how the End Users can configure and manage their users and respective roles. It includes the nomenclatures, rules and data to be inserted while creating and maintaining users and roles. It is critical that each Entity defines upfront the person(s) responsible(s) for this function within the organization.

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ASSOCIAÇÃO PORTUGUESA
DE VERIFICAÇÃO DE MEDICAMENTOS

Go-live of the national verification system – transition period

February 2019

Version 2.0

History of the document

Version	Date	Reason for changes	Description of changes
1.0	2019-02-04	Initial version	n.a.
2.0	2019-02-07	Clarifications	Included of examples of technical, procedural or pack handling problems; actions in case of anti-tampering device is compromised; actions in case of missing data concerning designated wholesalers.

Agenda

Context

Measures for the transition period

Context (1/2)

- The national verification system is an additional tool to control and monitor the legal supply chain, which has proved to be stable, secured and effective. There are no record of falsification incidents in the Portuguese legal supply chain.
- In the go-live, transition and stabilization period after the Delegated Regulation entered into force is necessary to ensure the normal activity of the market and the regular supply of medicines by all entities, without any interruptions, having into consideration the legal and deontological of all supply chain participants.
- 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. A generic message is showed to the user, confirming the transaction was recorded in the national system.
- The alerts generated by the national verification system will be monitored by MVO Portugal and INFARMED, I.P. The Marketing Authorization Holders will be notified of the alerts, via European hub, so investigation of the problems occurred, concerning the products under their responsibility, can be carried out.
- The detection of potentially falsified medicines in the legal supply chain is communicated to INFARMED, I.P. by MVO Portugal, after having verified that the alert is not explained by technical, procedural or pack handling problems[1]. The entities will be informed by MVO Portugal about the alerts concerning medicines that were in their possession. In case of need, and considering the already existing procedures, INFARMED, I.P. will immediately trigger the necessary investigations and actions to inform the entities and recall the products from the national market, so the public health of the Portuguese is not endangered.

Source: Circular Informativa 020/CD/100.20.200, de 28 de Janeiro de 2019.
English version: Here.

(1)
- Examples of technical problems: incorrect or unstable functioning of software or hardware (i.e. scanners)
- Examples of procedural problems: no data uploaded, upload of wrong or incomplete data, wrong or incomplete data on the pack, packs sent to the wrong destination, packs sent with the wrong status (active/inactive)
- Examples of pack handling problems: damage to the packs by mishandling

Context (2/2)

- The medicine packs already in the market on the February 9th 2019 and that do not carry one or neither of the safety features, can continue to be supplied to all entities in the legal supply chain until expiry date. To preserve the normal supply of the market, all packs that do not carry one or neither of the safety features but with valid expiry date are to be considered to be released before February 9th 2019.

Source: Circular Informativa 020/CD/100.20.200, de 28 de Janeiro de 2019.
English version: Here.

Measures for the transition period

Actions on the packs

- Considering the established in the Informative Note 020/CD/100.20.200 published by INFARMED, I.P. the following is to be carried out:

Unique identifier on the pack?*	Anti-tampering device on the pack?	Action
Yes (with or without problems)	Yes (not corrupt)	Proceed (dispense to the public, etc)
Yes (with or without problems)	No	Proceed (dispense to the public, etc)
No	Yes (not corrupt)	Proceed (dispense to the public, etc)
No	No	Proceed (dispense to the public, etc)
Yes (with or without problems)	Yes, but corrupted	Do not proceed (do not dispense to the public, do not distribute, etc)**
No	Yes, but corrupted	Do not proceed (do not dispense to the public, do not distribute, etc)**

Note: by unique identifier with problems is understood data non-existent or wrong/incomplete in the system, coding errors on the pack, printing problems concerning the pack, etc.

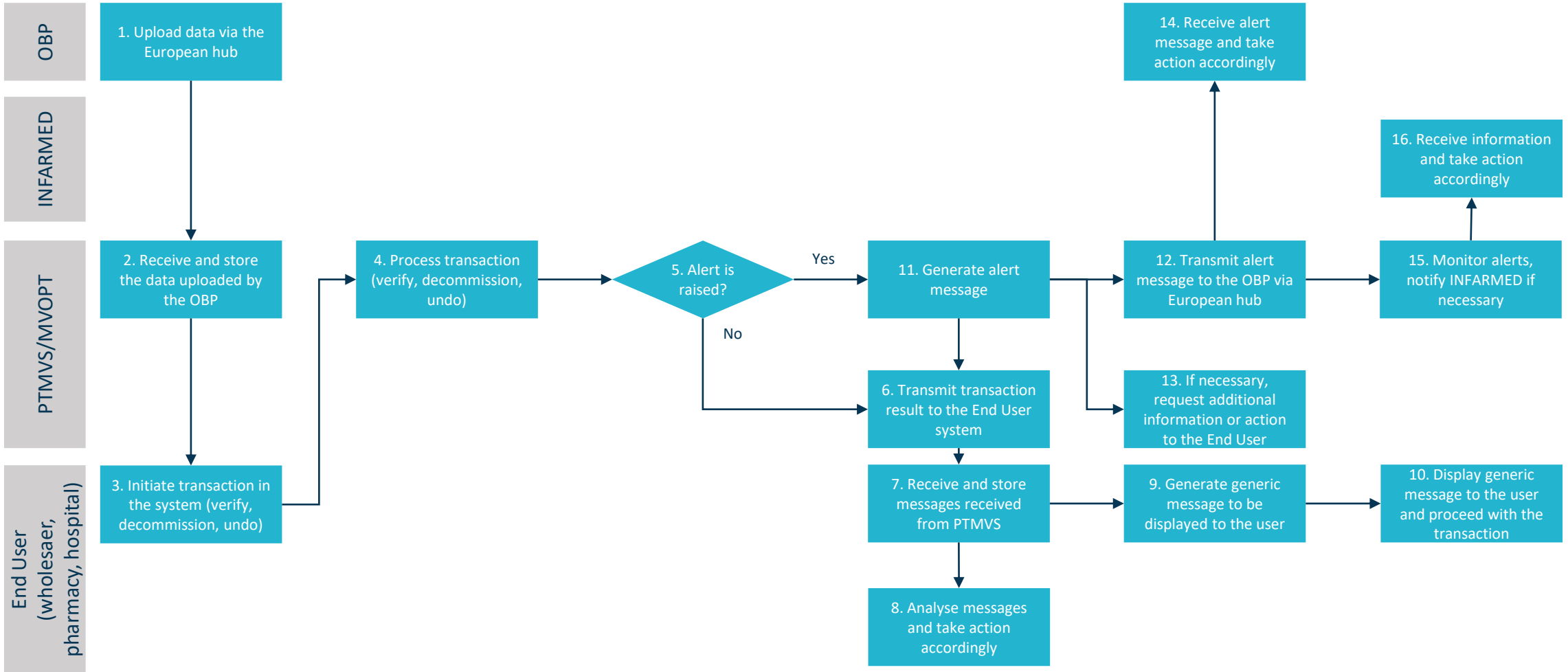
- All rules already existing still apply (GMP, GDP, applicable law, etc).

* - The NHRN must be encoded on the pack, whether into the 2D datamatrix or into the code 39, otherwise the pack cannot be sold.

** - if the anti-tampering device is corrupted and that is not attributable to pack mishandling by the operator, the pack must be returned to the MAH and problem is to be treated as a defect/non-conformity of packing material. It is not necessary to notify INFARMED nor MVOPT.

Measures for the transition period

Main activities concerning the use of the system in the transition period



Non-exhaustive

Measures for the transition period

Description of activities (1/5)

#	Activity	Responsible	Description
1	Upload data via the European hub	OBP	The onboarding partner (OBP) proceeds with the data upload, via European hub, concerning the packs to be released to the market.
2	Receive and store the data uploaded by the OBP	PTMVS/MVOPT	The uploaded data concerning packs to the Portuguese market are received and stored into the national repository (PTMVS), being then available for use by the connected End Users (wholesalers, pharmacies and hospitals).
3	Initiate transaction in the system (verify, decommission, undo)	End User	The End User proceeds with the transactions on the packs under their possession. For the purpose of this document, End Users are the connected (PROD) wholesalers, pharmacies and hospitals. The information concerning designated wholesalers that has already been uploaded into the system by the onboarding partners do not yet have the necessary stability and quality. As such, for the products for which the designated wholesaler data has not yet been loaded into the system, the wholesaler does not have to proceed with the verification of the packs on reception, given that the packs are received from known and qualified suppliers.
4	Process transaction (verify, decommission, undo)	PTMVS/MVOPT	Once initialized by the End User, the transactions are transmitted to PTMVS and then processed.
5	Alert is raised?	PTMVS/MVOPT	If the transaction raises an alert of potential falsification, an alert message is generated by PTMVS (and not by the End User system or other). In case of alert message generation, the process continues to activity 11 - Generate alert message. Otherwise, the process continues to activity 6 - Transmit transaction result to the End User system.

Non-exhaustive

Measures for the transition period

Description of activities (2/5)

#	Activity	Responsible	Description
6	Transmit transaction result to the End User system	PTMVS/MVOPT	Once the transaction is processed, the PTMVS transmits the message to the system of the End User. Note that in this process no modifications were introduced. The messages to be sent are the same that would be sent if no transition period would be in place (e.g. messages confirming transaction success, alerts, etc).
7	Receive and store messages received from PTMVS	End User	The messages sent by PTMVS are received and stored by the End User system. The complete list of messages that can be generated by PTMVS can be found on the document TD-014 BP 1.3 ID - Catalog Translations, available in the software supplier portal (https://sws-nmvs.eu/).
8	Analyse messages and take action accordingly	End User	Without prejudice of the generic message to be displayed to the user, the End User still receives all messages from PTMVS and therefore can act accordingly, considering for example the Good Practices and applicable legislation. It is not necessary to notify MVOPT nor INFARMED (in the latter case as stated in the Informative Note 020/CD/100.20.200 or Here for english version). If necessary, MVOPT will contact the End User (see activity 13).
9	Generate generic message to be displayed to the user	End User	As stated in the Informative Note 020/CD/100.20.200 and Here, the supply must carry on with no disturbances. As such, all messages received from PTMVS (concerning alerts or not) are not to be displayed to the user. Instead, a generic message like “Transaction registered. Proceed.”, or similar. Note that despite the messages received from PTMVS are not displayed to the user, those messages are stored in the End User system.

Não exaustivo

Measures for the transition period

Description of activities (3/5)

<table>
<tr><th>#</th><th>Activity</th><th>Responsible</th><th>Description</th></tr>
<tr><td>10</td><td>Display generic message to the user and proceed with the transaction</td><td>End User</td><td>The generic message like “Transaction registered. Proceed.” or similar is displayed to the user. It could be the case that alert messages are displayed to the user (i.e. the implementation of the measures described in this document may have not been finished on time). If that occurs, the user must proceed with the transactions.</td></tr>
<tr><td>11</td><td>Generate alert message</td><td>PTMVS/MVOPT</td><td>If the transaction carried out by the End User raises an alert of possible falsification, an alert message is generated by PTMVS. Specifically, the messages concerning alerts of potential falsification are the following:
<table>
<tr><th>Condition</th><th>System Message Code</th><th>System Message Description</th><th>Hub Application Alert description</th></tr>
<tr><td>ALL</td><td>NMVS_NC_PCK_22</td><td>Pack is already inactive.</td><td>Status Change Could Not be Performed</td></tr>
<tr><td>ALL</td><td>NMVS_NC_PCK_06</td><td>Actual pack status doesn't match the undo transaction (set and undo status must be equivalent).</td><td>Status Change Could Not be Performed</td></tr>
<tr><td>ALL</td><td>NMVS_FE_LOT_12</td><td>Expiry date does not match the date held in the NMVS.</td><td>Expiry Date Mismatch</td></tr>
<tr><td>ALL</td><td>NMVS_FE_LOT_13</td><td>The batch ID does not match the serial number in the NMVS.</td><td>Batch Number Mismatch</td></tr>
<tr><td>ALL</td><td>NMVS_NC_PC_02</td><td>Unknown serial number.</td><td>Pack Not Found</td></tr>
<tr><td>ALL</td><td>NMVS_NC_PC_01</td><td>Unknown product code.</td><td>Product Not Found</td></tr>
<tr><td>ALL</td><td>NMVS_FE_LOT_03</td><td>Failed to find a batch for the given data.</td><td>Batch Not Found</td></tr>
<tr><td>IMT FLAG ON</td><td>NMVS_NC_PCK_19</td><td>Property is already set on pack.</td><td>Pack Already In Requested State</td></tr>
<tr><td>IMT FLAG ON</td><td>NMVS_NC_PCK_20</td><td>Defined timeframe between setting this property and the undo was exceeded.</td><td>Time Limit exceeded</td></tr>
<tr><td>IMT FLAG ON</td><td>NMVS_NC_PCK_21</td><td>Undo can only be executed by the same user who previously set the attribute.</td><td>Attempted Undo by Different Party</td></tr>
<tr><td>IMT FLAG ON</td><td>NMVS_NC_PCK_27</td><td>Status change could not be performed.</td><td>Status Change Could Not be Performed</td></tr>
</table>
</td></tr>
</table>

Não exaustivo

Measures for the transition period

Description of activities (4/5)

#	Activity	Responsible	Description
12	Transmit alert message to the OBP via european hub	PTMVS/MVOPT	The generated alert message is sent to the onboarding partner, via European hub. The content of the message will be the following (exemplificative): An alert was raised by the NMVS due to the identification of a suspicious pack. In this context, an alert-ID was generated and sent to the EU Hub. The following information is available for the affected suspicious pack: • Timestamp: 2019-01-31T18:27:59.910 • Alert ID: PT-e02be5c8-8561-49be-b7b2-b609eebc7493 • Productcode: 05713219413923 • Productcode Scheme: GTIN • Batch-ID: IFLSE00 • Batch-Expiry-Date: 220531 • Serialnumber: 160003864655 • Process ID (NMVS): 110 • External Transaction ID: Tutorial-Transaction • Returncode (NMVS): NMVS_FE_LOT_03 • Returncode Description (NMVS): Failed to find a batch for the given data. • Returncode (Hub): n/a

Não exaustivo

Measures for the transition period

Description of activities (5/5)

#	Activity	Responsible	Description
13	If necessary, request additional information or action to the End User	PTMVS/MVOPT	If necessary, MVOPT will contact the End User and request additional information and or action.
14	Receive alert message and take action accordingly	OBP	The onboarding partner (OBP) receives the alert message (see activity 12) and takes action accordingly. It is not necessary to notify MVOPT nor INFARMED (in the latter case as stated in the Informative Note 020/CD/100.20.200 and Here). If necessary, MVOPT will contact the onboarding partner or local affiliate.
15	Monitor alerts, notify INFARMED if necessary	PTMVS/MVOPT	MVOPT will monitor the alert generation and will share information with INFARMED.
16	Receive information and take action accordingly	INFARMED	INFARMED will take the actions considered adequate as the National Competent Authority.

Não exaustivo

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