Bundesamt für Sicherheit im Gesundheitswesen
BASG

amvo
Austrian Medicines Verification Organisation

Information regarding the

Stabilisation Period

09/02/2019 to 08/02/2020

How to proceed within the context of dispensing or verifying medicinal products in Austria during the stabilisation period

Version 2.0

25/06/2019

Organisations involved

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1 Stabilisation period

The stabilisation period applies to Medicinal Products Subject to Serialisation in Austria in respect of error messages as listed in item 2.1 occurring in the period from 9 February 2019 until including 8 February 2020.

1.1 Purpose

The stabilisation period serves for the consolidation of the processes of the persons and organisations involved within the context of acts of Verification, Decommissioning or Recommissioning performed by the VDL as well as for the checking by the OBP, together with the RPC and MAH, of the error messages displayed by the AMVSystem, and also for coordination with AMVS GmbH and BASG.

The stabilisation period shall provide all involved persons and organisations with a shared opportunity to identify and correct process errors and operator errors.

2 Error messages and system check

2.1 Error messages

Error messages containing a Unique Alert ID, which are displayed by the AMVSystem within the context of an act of Verification, Decommissioning or Recommissioning performed by a VDL:

NMVS_NC_PC_01	The product code scanned/entered is not known. Stabilisation period - system check - VDL checks pack of medicinal product. Alert ID:AT-xxxxxx-xxxx-xxxx-xxxx-xxxxxxxxxxx
NMVS_NC_PC_02	The Serial Number scanned/entered is not known. Stabilisation period - system check - VDL checks pack of medicinal product. Alert ID:AT-xxxxxx-xxxx-xxxx-xxxx-xxxxxxxxxxx
NMVS_FE_LOT_03	The batch number scanned/entered was not found. Stabilisation period - system check - VDL checks pack of medicinal product. Alert ID:AT-xxxxxx-xxxx-xxxx-xxxx-xxxxxxxxxxx
NMVS_FE_LOT_12	The expiry date scanned/entered is different from the one stored in the system. Stabilisation period - system check - VDL checks pack of medicinal product. Alert ID:AT-xxxxxx-xxxx-xxxx-xxxx-xxxxxxxxxxx
NMVS_FE_LOT_13	The batch number scanned/entered is different from the one stored in the system. Stabilisation period - system check - VDL checks pack of medicinal product. Alert ID:AT-xxxxxx-xxxx-xxxx-xxxx-xxxxxxxxxxx
NMVS_NC_PCK_06	Recommissioning was not possible because the pack was decommissioned with a different status. Stabilisation period - system check - VDL checks pack of medicinal product. Alert ID:AT-xxxxxx-xxxx-xxxx-xxxx-xxxxxxxxxxx
NMVS_NC_PCK_19	The non-national pack has been decommissioned already. Stabilisation period - system check - VDL checks pack of medicinal product. Alert ID:AT-xxxxxx-xxxx-xxxx-xxxx-xxxxxxxxxxx
NMVS_NC_PCK_20	The time available for Recommissioning the non-national pack has been exceeded. Stabilisation period - system check - VDL checks pack of medicinal product. Alert ID:AT-xxxxxx-xxxx-xxxx-xxxx-xxxxxxxxxxx
NMVS_NC_PCK_21	Recommissioning a non-national pack can be performed only by the same user who did the Decommissioning. Stabilisation period - system check - VDL checks pack of medicinal product. Alert ID:AT-xxxxxx-xxxx-xxxx-xxxx-xxxxxxxxxxx
NMVS_NC_PCK_22	The pack has been decommissioned already. Stabilisation period - system check - VDL checks pack of medicinal product. Alert ID:AT-xxxxxx-xxxx-xxxx-xxxx-xxxxxxxxxxx
NMVS_NC_PCK_27	The status change cannot be carried out for the non-national pack. Stabilisation period - system check - VDL checks pack of medicinal product. Alert ID:AT-xxxxxx-xxxx-xxxx-xxxx-xxxxxxxxxxx

Error messages are displayed in German language. Translation above is for information only.

2.2 System check

If one of the error messages indicated above is displayed by the AMVSystem within the context of an act of Verification, Decommissioning or Recommissioning, VDL, OBP, RPC, MAH and AMVS GmbH have to perform a system check.

The Unique Alert ID displayed by the AMVSystem serves to identify the affected pack of medicinal product and as a reference for all further steps and as a unique identification number (incident number).

2.2.1 System information provided to AMVS GmbH and OBP

In the event of an error message, the system will automatically inform AMVS GmbH and the OBP; the message will contain the Unique Alert ID.

2.2.2 Ruling out technical errors and process errors

The MAH and RPC are informed by the OBP that an error message has occurred. In cases where the details of the RPC are not known to the OBP, the MAH shall inform the RPC of the error message. The following information has to be transmitted to the RPC by the OBP or MAH in any case:

- ✓ Contents of the error message
- ✓ Unique Alert ID
- ✓ Responsible person/department of the OBP and MAH in charge of investigating the error message, stating the name of the respective natural person, the respective department, the respective address, the respective telephone number and the respective e-mail address

OBP collaborates with MAH, RPC, AMVS GmbH and VDL in performing a system check.

AMVS GmbH provides support in coordinating VDL, OBP, RPC and MAH within the context of their respective responsibilities concerning the investigation of the error message, accessing the Audit Trail, if applicable.
The system check by OBP, RPC and MAH should address at least the following questions:

- Was the affected pack of medicinal product serialised correctly?
- Were the pack details uploaded completely and correctly to the EMVS?
- Is there any process error and/or operator error?

The system check performed by the VDL (together with its software supplier, if necessary) should address at least the following questions:

- Is there any fault in the interface translation between the AMVSystem and the VDL's system?
- Is there any process error and/or operator error?

If there are any process errors and/or operator errors on the part of the VDL, a clarification between VDL, RPC, MAH and AMVS GmbH must be carried out.

The RPC/MAH has to collect information as to the reason for triggering the error message and to what extent the fault or error has been corrected, and inform AMVS GmbH, with reference to the Unique Alert ID, of the outcome and details of the system check.

3 Distribution of medicinal products and obligation to notify on the part of VDL

During the stabilisation period, the error messages listed in item 2.1 will not be classified as potential incidents of falsification.

Regardless of the system check, the VDL shall check the pack of medicinal product affected by the error message for integrity and authenticity and decide about dispensing it based on the Legal Framework.

4 Appendixes

Appendix ./1	Cross-functional flow chart	1 page

5 List of abbreviations

AMG	Austrian Medicinal Products Act as amended
AMVO	Austrian Medicines Verification Organisation AMVS
AMVS	Austrian Medicines Verification System GmbH
BASG	Federal Office for Safety in Health Care
EMVO	European Medicines Verification Organisation
MAH	Marketing authorisation holder
OBP	Onboarding Partner EMVO
VDL	Verifying or Dispensing Location
RPC	Responsible pharmaceutical company

6 Revision History

Version	***Date***	***Reason For Changes***	***Description of changes made***
1.0	31/01/2019	Initial Document	-
2.0	25/06/2019	Resolution of AMVO Board	Extending the stabilisation period from 6 to 12 months