Bundesamt für Sicherheit im Gesundheitswesen
BASG

amvo
Austrian Medicines Verification Organisation

Information regarding the

Start Phase Operations

from 09/02/2020

How to proceed within the context of dispensing or verifying medicinal products in Austria during the start phase operations

Version 1.0

01/02/2020

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1 Start Phase Operations

The start phase operations applies to medicinal products subject to serialisation in Austria in respect of error messages as listed in item 3.1 occurring from February 9, 2020. The “Information regarding the Stabilisation Period 09/02/2019 to 08/02/2020” (Version 2.0 by 25/06/2019) thus expires by 08/02/2020.

As of February 9, 2020 “Information regarding the Start Phase Operations” as well as “Guidance - Potential / Confirmed Incident of Falsification within the context of Dispensing or Verifying Medicinal Products in Austria” become applicable.

1.1 Purpose

The start phase operations shall provide all involved organisations with the opportunity to correct process and operator errors as well as implementation errors that occurred during the stabilisation period.

The start phase operations shall ensure smooth operations to guarantee supply with medicinal products in Austria.

1.2 Process

On February 9, 2020 the stabilisation period ends and the start phase operations starts.

As of February 9, 2020 all VDL must perform verifications, decommissionings and recommissionings according to the legal and contractual provisions.

Disobedience of relevant duties by VDL, OBP, RPC and MAH will lead to sanctions by the respective competent bodies.

1.3 Competences

Ongoing evaluation of the start phase operations will be performed by the specifically established working group (shortly “working group”) that consists of representatives of all organisations involved in coordination with the supervisory and control board (AuKB) and the competent authority.

Based on this evaluation the working group in coordination with the AuKB and the competent authority will sequentially release error messages as listed in item 3.1 as potential incidents of falsification when occurring at the VDL premises in the context of verifications, decommissionings and recommissionings.

2 Implementation

During the start phase operations achievement of certain specified target figures will be evaluated on an ongoing basis by the working group. Next implementation steps will be determined in coordination with the AuKB and the competent authority.

3 Error messages and system checks

3.1 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 are:

NMVS_NC_PC_01	The product code scanned/entered is not known. Start phase operations - system check - VDL checks pack of medicinal product. (currently no Alert ID is generated)
NMVS_NC_PC_02	The Serial Number scanned/entered is not known. Start phase operations - system check - VDL checks pack of medicinal product. Alert ID:AT-xxxxxx-xxxx-xxxx-xxxx-xxxxxxxxxxxx
NMVS_FE_LOT_03	The batch number scanned/entered was not found. Start phase operations - system check - VDL checks pack of medicinal product. Alert ID:AT-xxxxxx-xxxx-xxxx-xxxx-xxxxxxxxxxxx
NMVS_FE_LOT_12	The expiry date scanned/entered is different from the one stored in the system. Start phase operations - system check - VDL checks pack of medicinal product. Alert ID:AT-xxxxxx-xxxx-xxxx-xxxx-xxxxxxxxxxxx
NMVS_FE_LOT_13	The batch number scanned/entered is different from the one stored in the system. Start phase operations - system check - VDL checks pack of medicinal product. Alert ID:AT-xxxxxx-xxxx-xxxx-xxxx-xxxxxxxxxxxx
NMVS_NC_PCK_06	Recommissioning was not possible because the pack was decommissioned with a different status. Start phase operations - system check - VDL checks pack of medicinal product. Alert ID:AT-xxxxxx-xxxx-xxxx-xxxx-xxxxxxxxxxxx
NMVS_NC_PCK_19	The non-national pack has been decommissioned already. Start phase operations - system check - VDL checks pack of medicinal product. Alert ID:AT-xxxxxx-xxxx-xxxx-xxxx-xxxxxxxxxxxx
NMVS_NC_PCK_20	The time available for Recommissioning the pack has been exceeded. Start phase operations - system check - VDL checks pack of medicinal product. Alert ID:AT-xxxxxx-xxxx-xxxx-xxxx-xxxxxxxxxxxx
NMVS_NC_PCK_21	Recommissioning a non-national pack can be performed only by the same user who did the Decommissioning. Start phase operations - system check - VDL checks pack of medicinal product. Alert ID:AT-xxxxxx-xxxx-xxxx-xxxx-xxxxxxxxxxxx
NMVS_NC_PCK_22	The pack has been decommissioned already. Start phase operations - system check - VDL checks pack of medicinal product. Alert ID:AT-xxxxxx-xxxx-xxxx-xxxx-xxxxxxxxxxxx
NMVS_PC_PCK_27	The status change cannot be carried out for the non-national pack. Start phase operations - system check - VDL checks pack of medicinal product. Alert ID:AT-xxxxxx-xxxx-xxxx-xxxx-xxxxxxxxxxxx

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

As there is currently no Unique Alert ID generated for the error message NMVS_NC_PC_01 all provisions of this document that are related to the Unique Alert ID do not apply for this error message.

3.2 System check

In case 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 must 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).

3.2.1 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.

3.2.2 Ruling out technical 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 about 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 must address the following questions at least:

- Was the affected pack of medicinal product serialised correctly?
- Have pack details been 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:

- Did an interface error between the AMVSystem and the VDL's system occur?
- 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 on why an error message was triggered and to what extent the fault or error has been corrected, and subsequently has to inform AMVS GmbH, with reference to the Unique Alert ID, of the outcome and details of the system check.

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

During the start phase operations, the error messages listed in item 3.1 will not be classified as potential incidents of falsification.

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

5 Appendixes

Appendix ./1	Cross-functional flow chart	1 page

6 List of abbreviations

AMG	Austrian Medicinal Products Act as amended
AMVO	Austrian Medicines Verification Organisation AMVS
AMVS	Austrian Medicines Verification System GmbH
AuKB	Supervisory and Control Board of AMVO
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