Bundesamt für Sicherheit im Gesundheitswesen
BASG

amvo
Austrian Medicines Verification Organisation

Guidance

on How to Use the

Alert Management System

The German version of this document is authoritative.

The English version is for information only.

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Contents

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The following organisations cooperated in drawing up this *Guidance*:

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2 Abbreviations and definitions

Dispensing location	means the person/entity authorised or entitled to supply medicinal products to the public. In Austria, this term includes public pharmacies, hospital pharmacies, dispensing doctors, and IVF centres
ADAM	means the AMVS Digital Alert Management System. VDLs, AMVS and BASG are connected to ADAM, which offers support for dealing with potential incidents of falsification.
Alert Management System	means the European Alert Management System, which ensures communications between the system participants during the processing and resolution of level 5 system messages. It consists of the AMS hub, the systems via which the OBPs are connected to the AMS hub, and the national alert management systems of the relevant Member States (in Austria: ADAM).
AMS hub	means the Alert Management System hub. The AMS hub is provided via the EU hub. OBPs, MAHs and RPCs can access and use the Alert Management System via the AMS hub. National alert management systems (in Austria: ADAM) are connected to the Alert Management System via the AMS hub.
AMVO	means the Austrian Medicines Verification Organisation. AMVO Österreichischer Verband für die Umsetzung der Verifizierung von Arzneimitteln, entered in the Central Register of Associations (*Zentrales Vereinsregister*, ZVR) with the Federal Ministry of the Interior under ZVR number 187087754
AMVS GmbH	means AMVS-Austrian Medicines Verification System GmbH, company register number 466094 h, Square plus – office building 1, Leopold-Ungar-Platz 2, Entrance 2, Top 134, 1190 Vienna, Austria. Organisation operating the Austrian national repository (AMVSystem) within the meaning of the Delegated Regulation
AMVSystem	means the Austrian Medicines Verification System. Austrian system in charge of the operations for the verification of medicinal products
BASG	means the Federal Office for Safety in Health Care (*Bundesamt für Sicherheit im Gesundheitswesen*).
Decommissioning	means decommissioning the unique identifier. Decommissioning of a medicinal product pack subject to serialisation from the EU hub and from the national repository (AMVSystem) as required under the Delegated Regulation. Via its serial number, the pack is flagged as “inactive” in the system
EMVS	means European Medicines Verification System. This is the European system for the verification of medicinal products, consisting of the EU hub and the national systems
EU hub	means the central information and data router as set out in Article 32(1)(a) Delegated Regulation The national and supranational repositories are connected to this European hub
Safe custody	means keeping a medicinal product safe and separate from any other goods and protecting it against unauthorised access.

Complaints Procedure Instruction	means the Instruction on the Complaints Procedure in Connection with Process Errors, including all its appendixes, as amended from time to time
Guidance on How to Use the Alert Management System	means this guidance, including all its appendixes, as amended from time to time
Guidance on Potential / Confirmed Incident of Falsification	means the Guidance on How to Proceed in the Event of a Potential/Confirmed Incident of Falsification within the Context of Dispensing or Verifying Medicinal Products in Austria, including all its appendixes, as amended from time to time
Guidance on Process Errors	means the Guidance on How to Proceed in the Event of (Suspected) Process Errors within the Context of Dispensing or Verifying Medicinal Products in Austria, including all its appendixes, as amended from time to time
Level 5 system message	means any message issued by the AMVSystem within the context of verification, decommissioning or recommissioning that has to be treated as a potential incident of falsification
MAH	means the marketing authorisation holder
OBP	means the onboarding partner, a legal entity having entered into an agreement with EMVO that regulates participation in the EMVS and, among other things, the uploading of the OBP's data and/or the data of marketing authorisation holders associated with the OBP to the national systems via the EU hub in accordance with the legal framework
Recommissioning	means reverting the status of a unique identifier after a medicinal product pack subject to serialisation has been decommissioned from the EU hub and from the national repository (AMVSystem) as required under the Delegated Regulation. Via its serial number, the pack is reverted to an active status in the system, as set out in Article 13 Delegated Regulation.
Medicinal product subject to serialisation	means any medicinal product for human use which is subject to prescription in Austria, with the exception of products featuring on the EU Commission's White List (Annex 1 to the Delegated Regulation as amended from time to time), as well as products featuring on the Black List (Annex 2 to the Delegated Regulation as amended from time to time) as well as products information on which is made available by the national competent authorities pursuant to Article 43 of the Delegated Regulation.
ADAM User Guide	means the description of the (operational) use of ADAM, including all its appendixes, as amended from time to time
Unique alert ID	means the unique identification number (incident number) of a potential incident of falsification
VDL	means the Verifying or Dispensing Location (*verifizierende oder abgebende Stelle* – VAS)
Verifying location	means any manufacturer, wholesaler and person authorised or entitled to supply medicinal products to the public that verifies the authenticity of the unique identifier pursuant to Article 10 Delegated Regulation by checking the unique identifier against the unique identifiers stored in the repositories system, verifies the

	integrity of the anti-tampering device, or takes other permitted action
Verification	means verifying the authenticity of a unique identifier pursuant to Article 11 Delegated Regulation
RPC	means the responsible pharmaceutical company (*Verantwortliches Pharmazeutisches Unternehmen,* VPU) having entered into an agreement with AMVS GmbH on the accession to and use of the AMVSystem

3 Basis & scope

This document is intended for VDLs using the Alert Management System (in their capacity as public pharmacy, hospital pharmacy, dispensing doctor, IVF centre or wholesaler) to help them fulfil the responsibilities incumbent upon them under the legal and contractual bases set forth below, as well as for OBPs, MAHs and RPCs.

3.1 Legal and contractual basis

- **Directive 2011/62/EU** of the European Parliament and the Council of 8 June 2011 to amend Directive 2001/83/EC to create a Community code for medicinal products for human use to prevent falsified medicinal products from entering into the legal supply chain, OJ No. L 174 of 1 July 2011, p. 74, as amended from time to time.

- **Commission Delegated Regulation (EU) 2016/161** of 2 October 2015 supplementing Directive 2001/83/EC of the European Parliament and the Council by laying down detailed rules for the safety features appearing on the packaging of medicinal products for human use, as amended from time to time.

- Austrian **Medicinal Products Act** (*Arzneimittelgesetz*, AMG) including implementing regulations, as amended from time to time, as well as further provisions stipulated by law or by regulation

- **End User Agreement** relating to the Austrian Medicines Verification System

- **Accession and Service Agreement** governing accession of the Responsible Pharmaceutical Company to the Austrian Medicines Verification System

- **Guidance on Potential / Confirmed Incidents of Falsification Within the Context of Dispensing or Verifying Medicinal Products in Austria**

- **Guidance on Process Errors**

3.2 Other documentation for information purposes

- **Complaints Procedure Instruction**
- ***ADAM User Guide***

3.3 Purpose of the Guidance on How to Use the Alert Management System

The Guidance on Potential / Confirmed Incidents of Falsification provides VDLs, OBPs, MAHs, RPCs, AMVS GmbH, BASG and AMVO with instructions on how to deal with level 5 system messages within their respective areas of responsibility and in accordance with the applicable legal and contractual framework.

To simplify the operational handling of level 5 system messages displayed in the AMVSystem to indicate potential incidents of falsification, while in no way shifting the responsibilities imposed on the various actors under the legal and contractual framework, including, without limitation, the Guidance on Potential / Confirmed Incidents of Falsification,

- the VDLs, AMVS GmbH and BASG are requested to use ADAM,

  and

- the OBPs, RPCs and MAHs are requested to use the AMS hub.

Consequently, the purpose of the Guidance on How to Use the Alert Management System is to outline how the VDLs, OBPs, MAHs, RPCs, AMVS GmbH and BASG are to use the alert management system when level 5 system messages are displayed in the AMVSystem to indicate a potential incident of falsification.

The Guidance on How to Use the Alert Management System does not affect / limit any **measures or documentation obligations** related to emergency medical care.

4 Level 5 system message

A level 5 system message is any message issued by the AMVSystem within the context of verification, decommissioning or recommissioning that has to be treated as a potential incident of falsification.

5 How to use the alert management system

The alert management system is a web-based application designed to make the handling of level 5 system messages displayed in the AMVSystem to indicate potential incidents of falsification easier and more efficient.

In coordination with the other participating organisations, BASG grants, both by adopting and respecting the Guidance on How to Use the Alert Management System, its approval for the alert management system to be applied and used by VDLs, OBPs, MAHs, RPCs and by AMVS GmbH for easier and efficient handling of level 5 system messages displayed in the AMVSystem to indicate potential incidents of falsification.

The participating organisations recommend that VDLs, OBPs, MAHs, RPCs and AMVS GmbH apply and use the alert management system to handle level 5 system messages displayed in the AMVSystem to indicate potential incidents of falsification.

In cases where the alert management system is not used or cannot be used, it is mandatory to observe the Guidance on Potential / Confirmed Incidents of Falsification in conjunction with the Guidance on Process Errors (in particular with respect to responsibilities and process description steps), also if a potential incident of falsification is, or cannot be, conclusively resolved in spite of the alert management system being used.

6 Responsibilities

6.1 Verifying or dispensing location (VDL)

- Create the technical prerequisites for using ADAM (web-based application or system integration).
- Use ADAM in the event of level 5 system messages displayed in the AMVSystem to indicate potential incidents of falsification.
- Handle the potential incident of falsification in accordance with the rules and requirements of ADAM until the potential incident of falsification has been resolved.
- If the potential incident of falsification cannot be resolved completely or conclusively using ADAM, handle such incident in line with the Guidance on Potential / Confirmed Incidents of Falsification, in compliance with the responsibilities defined in such guidance.
- If not using ADAM, observe the Guidance on Potential / Confirmed Incidents of Falsification and the legal framework and handle the respective level 5 system messages accordingly.

6.2 Onboarding partner (OBP), marketing authorisation holder (MAH) and responsible pharmaceutical company (RPC)

- Create the technical prerequisites for using the AMS hub.
- Use the AMS hub in the event of level 5 system messages displayed in the AMVSystem to indicate potential incidents of falsification.
- Handle the potential incident of falsification in accordance with the rules and requirements of the AMS hub until the potential incident of falsification has been resolved.
- If the potential incident of falsification cannot be resolved completely or conclusively using the AMS hub, handle such incident in line with the Guidance on Potential / Confirmed Incidents of Falsification, respecting the responsibilities defined in such guidance.
- If not using the AMS hub, observe the Guidance on Potential / Confirmed Incidents of Falsification and the legal framework and handle the respective level 5 system messages accordingly.

6.3 AMVS GmbH

- Retain a system service provider to make ADAM available to VDLs, AMVS GmbH and BASG. The AMS hub, which is connected to ADAM, is made available to OBPs, MAHs and RPCs by EMVO.
- Provide support to VDLs in using ADAM.
- Bear the cost and expenses for making ADAM available (not including system integration at VDLs, MAHs or RPCs).

6.4 BASG

- Provide information/instructions to VDLs concerning the further handling of the relevant medicinal product pack if a potential incident of falsification cannot be ruled out.

7 Process description

7.1 Start

If an act of verification, decommissioning or recommissioning by a VDL causes the AMVSystem to generate a level 5 system message, this will be displayed on the VDL's reader (for instance, display unit at the counter, hand-held reader, etc).

To use ADAM, it is necessary to either launch the standard web browser (AMVS certificate stored in the browser) or the VDL's user software, provided that ADAM was integrated into such software by the VDL.

The OBP will receive the level 5 system message at the same time, and OBP, MAH and RPC will use the AMS hub to process the level 5 system message.

Processing of the level 5 system message by the VDL or by OBP, MAH and RPC must be completed within 3 working days.

If a level 5 system message has been raised, the pack in question must no longer be supplied to the public.

7.2 Step I Investigation of the level 5 system message

7.2.1 VDL investigates the level 5 system message

In step I, the VDL will be shown instructions on how to investigate the alert.

Depending on the kind of level 5 system message, the system will ask questions the answers to which help to find the root causes of the level 5 system message.

7.2.2 OBP, MAH and RPC investigate the level 5 system message

OBP, MAH and RPC use the AMS hub to take, at a minimum, the following steps to investigate the level 5 system message:

- Set the overall alert status to "Under Investigation".
- Investigate the root causes of the level 5 system message; for examples of the issues to be considered in this context, refer to Appendix ./1.
- Save the outcome of the investigation as comment (External Message).
- Depending on the outcome of the investigation, pick an investigation status (OBP Investigation Status):
    - No Root Cause on my Side; or
    - Root Cause on my Side, and indicate whether and when corrective action will be taken.

7.3 Step II Outcome of the investigation of the level 5 system message

AMVS GmbH provides support in coordinating OBP, MAH, RPC, VDL and BASG. The outcome of the investigation will be processed based on the information supplied by OBP, MAH, RPC and VDL.

Once all the processing steps have been completed, ADAM will display the following message to the VDL:

- Investigation of level 5 system message completed:
- Investigation of level 5 system message not completed:

7.4 Step III Investigation “Closed”

Depending on the outcome of the investigation, the pack may be returned to saleable stock or further steps will be required (see Guidance on Process Errors and Guidance on Potential / Confirmed Incident of Falsification).

7.5 Step IV Investigation “Escalated”

If the investigation of the level 5 alert fails to confirm a process error or is not completed by the VDL and/or OBP, MAH and RPC within 3 working days, the outcome of the investigation will automatically be set to “Escalated”.

BASG will then be involved in the further investigation of the issue in conformity with the Guidance on Potential / Confirmed Incidents of Falsification.

7.6 ADAM User Guide

ADAM has been designed to provide a self-explanatory workflow of steps needed to deal with a potential incident of falsification.

For a detailed description of each of the steps to be carried out in ADAM, refer to the description in the ADAM User Guide as amended from time to time. The User Guide is available for download at https://amvs-medicines.at/infothek/alarm-management-adam/.

8 Out of scope of the Guidance on How to Use the Alert Management System

- **Medicinal product pack is not ready for dispensing**
  Cases where the AMVSystem indicates that the pack cannot be dispensed for reasons other than the defined level 5 system messages and this is not a potential incident of falsification are out of scope of the Guidance on How to Use the Alert Management System. Other reasons preventing dispensing of the pack may include:

  - Expiry date exceeded
  - Product withdrawn
  - Batch recalled

  As the above-mentioned cases are not level 5 system messages, no such message will be displayed.

- **Problems with technical infrastructure on site**

- **Verification of the integrity of the anti-tampering device (ATD):**
  Under the provisions of the Delegated Regulation, the VDL must also verify the integrity of the anti-tampering device of medicinal products subject to serialisation. The procedure to be followed to verify the integrity of the anti-tampering device (ATD) is out of scope of the Guidance on How to Use the Alert Management System. In this respect, proceed in accordance with the instructions given so far (reporting a quality defect to BASG).

9 Entry into force

The Guidance on How to Use the Alert Management System, as amended from time to time, shall enter into force as from the end of the start phase operations.

10 Appendixes

Appendix ./4 *Ruling out the Potential Incident of Falsification – information to be made available by OBP/MAH/RPC*

11 Change history

Version	Applicable as from	Reason for changes
1.0	Release date of the document: 13 February 2025	New document

Where this guidance refers to natural persons in the masculine form only, such references shall equally apply to all genders.

Legal notice

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The Guidance on How to Use the Alert Management System is available for download on the websites of AMVO and AMVS GmbH.