Bundesamt für Sicherheit im Gesundheitswesen
BASG

amvo
Austrian Medicines Verification Organisation

Guidance on Potential / Confirmed Incidents of Falsification

within the context of Dispensing or Verifying Medicinal Products in Austria

The German version of this document is authoritative.

The English version is for information only.

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Contents

1 Organisations involved

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
AMG	means the Austrian Medicinal Products Act (*Österreichisches Arzneimittelgesetz*) as amended from time to time
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
ATD	means the anti-tampering device pursuant to the Delegated Regulation 2016/161
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 Package Subject to Serialisation from the EU Hub and from the national repository (AMVSystem) as required under the Delegated Regulation. Via its Serial Number, the package is labelled as “inactive” in the system
Delegated Regulation	means 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
EC	means the European Commission
EMA	means the European Medicines Agency
EMVO	means the European Medicines Verification Organisation, A.S.B.L., a non-profit company, with its registered office at 1000 Brussels (Belgium), Rue du Commerce 123
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

GTIN	means the global trade identification number
Unique Identifier	means, pursuant to Article 3(2)(a) Delegated Regulation, the safety feature enabling the verification of the authenticity and the identification of an individual Medicinal Product Package by means of the AMVSystem in conjunction with the EU Hub
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
Corrective Measure	means a measure aimed at correcting a process error within the meaning of the Guidance on Process Errors.
Guidance	means the present guidance, 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
Medicinal Product Package Not Ready For Dispensing	means any medicinal product package that cannot be dispensed to patients due to a software system message or due to physical damage
NTIN	means the national trade identification number
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
OMCL	means the Official Medicines Control Laboratory (*Behördliches Arzneimittelkontrolllabor*) of BASG
Process Error	means a technical error or a procedural error within the meaning of the Guidance on Process Errors.
Audit Trail	pursuant to Article 35(1)(g) Delegated Regulation
Recommissioning	means the reverting of the status of a Unique Identifier after a Medicinal Product Package 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 package is reverted to an active status in the system, as set out in Article 13 Delegated Regulation.
Legal Framework	means Directive 2011/62/EU of the European Parliament and the Council of 8 June 2011 amending Directive 2001/83/EC creating a Community code relating to medicinal products for human use, as regards the prevention of the entry into the legal supply chain of falsified medicinal products, Official Journal No. L 174 of 1 July 2011,

	p. 74 and the related 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, and any and all related national legislation in the version applicable from time to time as well as the amendments enacted in relation to said legislation
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.
Serial Number	means, under Article 4(b)(ii) Delegated Regulation, a numeric or alphanumeric sequence of maximum 20 characters, generated by a deterministic or a non-deterministic randomisation algorithm
Safe Custody	means keeping a medicinal product safe and separate from any other goods and protecting it against unauthorised access.
Safety Features under the Delegated Regulation	means the Unique Identifier and the anti-tampering device (ATD)
PRO	means the public prosecutor's office
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 Bases & Scope

3.1 Legal and Contractual Bases

- **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** (*Österreichisches Arzneimittelgesetz*, AMG) including 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 Process Errors**

- **Complaints Procedure Instruction**

3.2 Scope of this Guidance

The present guidance applies to medicinal products subject to serialisation in Austria.

Together with the cross-functional flowchart in **Appendix ./1**, this guidance sets out the procedure to be followed, in compliance with the legal and contractual bases (chapter 3.1), if a potential or confirmed incident of falsification occurs within the context of the verification of the authenticity of a Unique Identifier by the VDL.

The Guidance shall not affect / limit any **measures or documentation obligations** related to emergency medical care.

Whenever a level 5 system message is displayed to the VDL in the course of decommissioning, verification or recommissioning, it must be assumed that a potential incident of falsification has occurred.

Potential incident of falsification upon display of the following level 5 system messages (**Appendix ./2)**:

In the course of verification
Product code (NTIN or GTIN) not available
Serial Number not available
Batch number not available or different
Expiry date not available or different

In the course of decommissioning the unique identifier
Serial Number not available
Batch number not available or different
Expiry date not available or different
Status INACTIVE (supplied, removed, blocked, destroyed, exported, stolen; sample for official use, or free medical sample)

In the course of recommissioning the unique identifier
Serial Number not available
Batch number not available or different
Expiry date not available or different
If the package status to be reverted to active status does not match the set status of the package

The guidance shall apply whenever the AMVSystem displays one of the above-mentioned level 5 system messages to the VDL.

In the event of a potential/confirmed incident of falsification, BASG can, at any time, access the audit trail, decide to initiate separate investigations and involve the police and PRO, and issue instructions to proceed in a manner deviating from the present guidance.

4 Responsibilities

Chapter 4 describes the respective responsibilities of VDL, OBP, RPC, MAH, AMVS GmbH, BASG and AMVO under this guidance in dealing with a potential incident of falsification.

The responsibilities under the legal and contractual bases (chapter 3.1) apply without prejudice. In particular, the verification of the integrity of the anti-tampering device must be carried out irrespective of the provisions of this guidance within the scope of the safety feature verification (see Clause 6.).

4.1 Verifying or Dispensing Location (VDL)

- Immediately document and report any level 5 system message (suspicion of a potential incident of falsification) by e-mail (serialisierung@basg.gv.at) to BASG and AMVS GmbH, stating
  - ✓ Contents of the Level 5 System Message
  - ✓ Unique alert ID
  - ✓ VDL, providing the name of the natural person or legal entity, address, telephone number, e-mail address and responsible contact person

- Provide information to AMVS GmbH to the extent required for it to be able to fulfil its responsibilities.

- Keep the medicinal product package in safe custody and coordinate its further handling according to the instructions provided by BASG, and provide corresponding support.

- Cooperate with OBP, RPC, MAH and AMVS GmbH in investigating any potential incident of falsification.

- If it can be proven beyond any doubt that a process error occurred:
  - ➢ Immediately document and confirm this fact to AMVS GmbH, stating the reasons why it is certain beyond any doubt that a process error occurred and that an incident of falsification can be ruled out, making reference to the unique alert ID.

- Process error cannot be ruled out, reason to suspect incident of falsification:
  - ➢ Immediately document and report this fact to BASG and to AMVS GmbH, if the incident of falsification continues to exist, stating the reasons and making reference to the unique alert ID.

4.2 Onboarding Partner (OBP), Marketing Authorisation Holder (MAH) and Responsible Pharmaceutical Company (RPC)

- The OBP forwards the level 5 system message transmitted to the OBP via the EMVO interface to the MAH and the RPC, provided that the OBP is aware of the RPC's details, otherwise forwards the message to the RPC via the MAH.

- The following information has to be transmitted at the minimum:
  - ✓ Contents of the level 5 system message
  - ✓ Unique alert ID
  - ✓ Responsible person/department of the OBP in charge of investigating the potential incident of falsification, stating the name of the natural person, the department, address, telephone number and e-mail address

- Provide information to AMVS GmbH to the extent required for it to be able to fulfil its responsibilities.

- The OBP, RPC, MAH, AMVS GmbH and VDL cooperate to investigate a potential incident of falsification.

- RPC and MAH investigate the potential incident of falsification in coordination with BASG and, if applicable, in coordination with the police and PRO.

- If it can be proven beyond any doubt that a process error occurred:
  - Immediately document and confirm this fact to AMVS GmbH, stating the reasons why it is certain beyond any doubt that a process error occurred and that an incident of falsification can be ruled out, making reference to the unique alert ID.

- Potential incident of falsification cannot be ruled out, reason to suspect incident of falsification or confirmed incident of falsification:
  - Immediately document and report this fact to BASG and to AMVS GmbH, if the incident of falsification continues to exist, stating the reasons and making reference to the Unique Alert ID.

4.3 AMVS GmbH

- Ensure that potential incidents of falsification flagged in the AMVSystem are investigated, by:
  - Investigating the audit trail of a potential incident of falsification, if applicable.
  - Assisting in coordinating VDL, OBP, RPC, MAH, BASG and AMVO within the context of their respective responsibilities in investigating a potential incident of falsification.

- Provide information about the occurrence of a confirmed process error, by:
  - Notifying BASG and the VDL about the confirmed process error and about possible corrective measures provided for by the guidance on process errors.

- In the event of a confirmed incident of falsification, provide for the relevant alerting, by:
  - Notifying BASG, EMA and EC of such incident by forwarding the documentation made available by the RPC and/or MAH.

4.4 Authority (BASG)

- Access the AMVSystem for the purpose of investigating the potential incident of falsification.

- Investigate the potential incident of falsification in coordination with RPC and MAH and, if applicable, in coordination with the police and PRO.

- Provide information/instructions to the VDL concerning the further handling of the affected medicinal product package if a potential incident of falsification cannot be ruled out.

4.5 AMVO

- Supervise and control AMVS GmbH.

- Request the supervisory board of AMVO to intervene, if necessary.

5 Process Description

If the AMVSystem displays a level 5 system message during an act of verification, decommissioning or recommissioning by a VDL, the following process must be adhered to.

The process steps represented in the cross-functional flowchart in **Appendix ./1** are described in chapters 5.1 to 5.6.

5.1 Start

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

In addition to every level 5 system message, the AMVSystem automatically creates a unique alert ID, which will be displayed to the VDL on the display unit and/or disclosed by means of a separate e-mail. The unique alert ID then serves to identify the affected medicinal product package and as a reference for further steps and as a unique identification number (incident number).

5.2 Step I

5.2.1 System Provides Information to AMVS GmbH and OBP

In the event of a level 5 system ,essage, the system will automatically inform the OBP via the EMVO interface, as well as AMVS GmbH and the VDL; the message will contain the unique alert ID.

5.2.2 Medicinal Product Package must not be Dispensed by VDL

In the event of a level 5 system message, the affected medicinal product package must not be supplied to the public, must, as a rule, be stored safely on the premises of the VDL and not leave the territory of Austria, (i) until a corrective measure has been carried out successfully and an incident of falsification has been ruled out, and/or (ii) until BASG has provided instructions for the further handling of the medicinal product package.

5.2.3 VDL Provides Information to BASG

Pursuant to the Delegated Regulation, the VDL must immediately document, and inform BASG of, the existence of a potential incident of falsification, by sending an e-mail to serialisierung@basg.gv.at, referring to the unique alert ID and stating the contents of the Level 5 System Message and its contact details to permit unambiguous identification (name of the natural person or legal entity, address, telephone number, e-mail address and responsible contact person). For this purpose, the VDL shall use the e-mail automatically generated by the AMVSystem after having checked it for completeness / having supplemented anything that was missing from the aforementioned data (for a template of the automatically generated e-mail see **Appendix ./3**). This information must also be provided to AMVS GmbH at office@amvs-medicines.at.

In addition, the provisions of the Austrian Medicinal Products Act shall be taken into account and complied with.

5.3 Step II

5.3.1 Rule out Process Errors

The MAH and RPC shall be informed by the OBP of the existence of a potential incident of falsification. In cases where the details of the RPC are not known to the OBP, the MAH shall inform the RPC of the existence of a potential incident of falsification. The following information has to be transmitted to the RPC by the OBP or MAH at the minimum:

- ✓ Contents of the level 5 system message
- ✓ Unique alert ID
- ✓ Responsible person/department of the OBP and MAH in charge of investigating the potential incident of falsification, stating the name of the respective natural person, the respective department, the respective address, the respective telephone number and the respective e-mail address.

The OBP shall collaborate with MAH, RPC, AMVS GmbH and VDL in performing an investigation to rule out any process error, as set out in the guidance on process errors.

Such investigation should address at least the following questions (for further details see Appendix ./4 (OBP/MAH/RPC) and Appendix ./5 (VDL):

- Was the affected medicinal product package serialised correctly? (*OBP*/*MAH*)
- Were the package details uploaded to the EMVS complete and correct? (*OBP*/*MAH*)
- Do the human readable data shown on the package correspond to those transmitted to the system? (VDL)
- Is there any error in the interface translation between the AMVSystem and the VDL's system? (VDL)
- Did the same VDL try more than four times to decommission the affected package? (VDL)

AMVS GmbH shall assist in coordinating OBP, RPC, MAH, BASG and AMVO within the context of their respective responsibilities in investigating the potential incident of falsification, accessing the Audit Trail, if applicable.

The OBP (and/or the MAH/RPC) must confirm, in a binding manner, that the medicinal product package to which the level 5 system message refers had been uploaded to the EU Hub and/or disclose to AMVS GmbH other reasons, if any, for the triggering of the level 5 system message so it can exercise its coordination function (template see **Appendix ./4**).

The ruling out of process errors must be completed within **3 (three) working days** after the occurrence of the level 5 system message.

5.3.2 Potential Incident of Falsification can be Ruled out due to Existence of Process Errors:

If the investigation proves the existence of a process error beyond doubt and rules out an incident of falsification, the entity having triggered the process error (OBP/RPC/MAH/VDL) must confirm this to AMVS GmbH and inform AMVS GmbH about the situation and the respective details, making reference to the unique alert ID (template for OBP/MAH/RPC see **Appendix ./4**, template for VDL see **Appendix ./5**).

AMVS GmbH shall inform BASG and, if applicable, the VDL about the process error confirmed in the manner stated above, and about possible corrective measures provided for by the guidance on process errors.

Process errors shall be handled in accordance with the guidance on process errors and complaints shall be handled in accordance with the complaints procedure instruction.

5.3.3 Potential Incident of Falsification cannot be Ruled out:

If the existence of a Process Error cannot be proven beyond doubt within 3 (three) working days, there are reasonable grounds to suspect an incident of falsification. The next step to take in such a case is step III (chapter 5.4).

5.4 Step III

5.4.1 Provide Information to BASG and AMVS GmbH

The RPC/MAH and/or VDL shall immediately document, and inform BASG and AMVS GmbH of, the fact that there are reasonable grounds to suspect an incident of falsification. Both the information provided to BASG and AMVS GmbH and the documentation shall make reference to the Unique Alert ID.

5.4.2 BASG provides Information and Instructions for Package Handling to VDL

BASG shall inform the VDL that there are reasonable grounds to suspect an incident of falsification and how to proceed further.

BASG and/or the police/PRO shall instruct the VDL how to proceed with handling the affected package, and the VDL shall implement these instructions accordingly. If this involves returning products within the supply chain, it has to be ensured that, during transfer to the specified location, the affected package remains clearly identifiable based on the unique alert ID, with any risk of confusion excluded, and that the affected package does not leave the territory of Austria.

Medicinal product packages purchased via an Austrian wholesaler shall, at BASG's written request, be returned to said wholesaler within 3 (three) working days, in a separate transfer during which they shall remain clearly identifiable based on the unique alert ID, with any risk of confusion excluded.

Medicinal product packages which were not purchased via Austrian wholesalers shall remain with the VDL until a notification on what to do with the package is issued by BASG within 3 (three) working days.

5.4.3 Further Investigation of the Potential Incident of Falsification

OBP/RPC/MAH/VDL shall further investigate the potential incident of falsification in coordination with BASG and, if applicable, in coordination with the police/PRO.

No time limit is set for step III in this guidance, as any investigation and any action taken will in each case depend on the instructions given by BASG and/or the police/PRO.

5.5 Step IV

5.5.1 Rule out an incident of falsification

If an incident of falsification can be ruled out beyond doubt in the course of further investigation, the OBP/RPC/MAH/VDL must confirm this fact to, and inform BASG and AMVS GmbH about, the situation and the respective details, making reference to the unique alert ID.

If applicable, BASG shall then communicate to the VDL that no incident of falsification has occurred and provide the VDL with instructions on how to deal with the relevant medicinal product package.

Complaints shall be handled in accordance with the complaints procedure instruction.

5.6 Step V

5.6.1 Confirm an Incident of Falsification

If, in the course of further investigation, an incident of falsification is confirmed or cannot be ruled out, the OBP/RPC/MAH/VDL shall immediately notify BASG and AMVS GmbH thereof, making reference to the unique alert ID and stating the reasons.

Then AMVS GmbH shall, as set out in Article 37 (d) Delegated Regulation, provide for the alerting of BASG, EMA and EC by notifying them of the confirmed incident of falsification and forwarding the information made available by the OBP/RPC/MAH/VDL.

6 Not Covered by this Guidance

- **Medicinal product package is not ready for dispensing:**
  This guidance does not cover cases where the AMVSystem indicates that the package cannot be dispensed for reasons other than the defined level 5 system messages and this is NOT a potential incident of falsification. Other reasons preventing dispensing of the package may include:

  - Expiry date exceeded
  - Product was withdrawn
  - Batch was recalled

- **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. This guidance does not cover the procedure to be followed to verify the integrity of the anti-tampering device (ATD). In this respect, proceed in accordance with the instructions given so far (reporting a quality defect to BASG).

- **For all cases already subject to regulation:**
  Objections, quality defects, etc; in this respect, proceed in accordance with the instructions given so far.
  With regard to complaints, the complaints procedure instruction shall apply.

- **Transitional provisions:**
  Applicable to medicinal products released for sale or distribution without the Safety Features before 9 February 2019.

7 Entry into Force

The present guidance, as amended from time to time, shall enter into force as from the end of the start phase operations.

8 Appendixes

Appendix ./1 Cross-functional flow chart
Appendix ./2 List of Level 5 System Messages
Appendix ./3 VDL notification about the contents of the Level 5 System Message
Appendix ./4 Ruling out Process Errors – information to be made available by OBP/MAH/RPC
Appendix ./5 Ruling out Process Errors – information to be made available by the VDL

9 Index of changes

Version	Applicable as from	Reason for changes
1.0	9 February 2019	New document
2.0	Release date of the document: June 2nd 2021	Revised version, in particular with regards to process errors and complaints

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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This Guidance is available for download on the websites of AMVO and AMVS GmbH.