Bundesamt für Sicherheit im Gesundheitswesen
BASG

amvo
Austrian Medicines Verification Organisation

Guidance - Potential / Confirmed Incident of Falsification

within the context of Dispensing or Verifying Medicinal Products in Austria

Version 1.0 – 20190125 (coordinated between BASG, AMVO & AMVS GmbH)

Contents

1 Organisations involved

The following organisations cooperated in drawing up this Guidance:

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2 Abbreviations and defined terms

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, and dispensing physicians
AMG	means the Austrian Medicinal Products Act 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, Garnisongasse 4/1/5, 1090 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. Removal of a pack of Medicinal Product 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 labelled as “supplied” 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 1040 Brussels (Belgium), Rue de la Loi 28
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 pack of a medicinal product by means of the AMVSystem in conjunction with the EU Hub
Guidance	means the present guidance, 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
Pack of Medicinal Product Not Ready For Dispensing	means any pack of medicinal product 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 the BASG
Audit Trail	pursuant to Article 35 (1)(g) Delegated Regulation
Recommissioning	means the reverting of the status of a Unique Identifier after a pack of Medicinal Product 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 labelled as "active" in the system again, pursuant to 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 that have been adressed 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
Safety Features under the Delegated Regulation	means the Unique Identifier and the anti-tampering device (ATD)
PRO	means the 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
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 having entered into an accession and service agreement to the AMVSystem with AMVS GmbH.

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 01 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

- **Cross-functional flow chart** Appendix ./1

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.

A potential incident of falsification must be assumed to have arisen at least if a Level 5 – System Message is displayed to the VDL in the course of Decommissioning, Verification or Recommissioning.

Potential incident of falsification upon the following Level 5 – System Messages:

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
Product code (NTIN or GTIN) not available
Serial Number not available
Batch number not available or different
Expiry date not available or different
Status INACTIVE (supplied, decommissioned, blocked, destroyed, exported, stolen; sample for official use, or free sample)

In the course of Recommissioning the Unique Identifier
Product code (NTIN or GTIN) not available
Serial Number not available
Batch number not available or different
Expiry date not available or different
If the pack status to be reverted to active status does not match the set status of the pack

The Guidance shall apply whenever the AMVSystem displays one of the above-described Level 5 - System Messages to the VDL.

In the event of a potential/confirmed incident of falsification, the Federal Office for Safety in Health Care (BASG) has access to the Audit Trail at any time, and may at any time decide to initiate separate investigations and call in the police and the prosecutor's office, and can at any time order to proceed in a manner deviating from the present Guidance.

4 Responsibilities

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

The responsibilities under the legal and contractual bases (chapter 3.1) apply independently of this.

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, 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
- ✓ Safely store the pack of medicinal product and coordinate its further handling according to the specification provided by BASG, and provide corresponding support
- ✓ Cooperate with OBP, RPC, MAH and AMVS GmbH in investigating any potential incident of falsification.

4.2 Onboarding Partner (OBP)

- Forward the Level 5 – System Message transmitted to the OBP by e-mail to the MAH and the RPC provided that the OBP is aware of the RPC's details.
- The following information has to be transmitted in any case:
  - ✓ 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 binding information whether the pack of medicinal product affected by the Level 5 – System Message has been uploaded to the EU Hub and/or disclose other reasons, if any, for the Level 5 – System Message having been triggered.
- Cooperate in the investigation of a potential incident of falsification together with the RPC, MAH, AMVS GmbH and VDL.

4.3 Responsible pharmaceutical company (RPC) and marketing authorisation holder (MAH)

- Forward to the RPC the Level 5 – System Message e-mailed by the OBP to the MAH.
- The following information has to be transmitted in any case:
  - ✓ 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
- Provide binding information whether the pack of medicinal product affected by the Level 5 – System Message has been uploaded to the EU Hub and/or disclose other reasons, if any, for the Level 5 – System Message having been triggered.
- RPC and MAH are to investigate the potential incident of falsification in coordination with BASG and, if applicable, in coordination with the police and the prosecutor's office.

- Potential incident of falsification can be ruled out:
  - Immediate documentation and immediate report to BASG and to AMVS GmbH, stating the reasons why the potential incident of falsification can be ruled out and making reference to the Unique Alert ID.
- Confirmed incident of falsification:
  - Immediate documentation and immediate report to BASG and to AMVS GmbH if the incident of falsification is confirmed, stating the reasons and making reference to the Unique Alert ID.

4.4 AMVS GmbH

- Provide for the investigation of potential incidents of falsification flagged in the AMVSystem, by:
  - Investigating the Audit Trail of a potential incident of falsification, if applicable.
  - Supporting coordination of VDL, OBP, RPC, MAH, BASG and AMVO within the context of their respective responsibilities concerning the investigation of a potential incident of falsification.
- In the event of a confirmed incident of falsification, provide for the relevant alert, by:
  - Notifying BASG, EMA and EC of such incident, forwarding the documentation made available by the RPC and/or MAH.

4.5 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 the prosecutor’s office.
- Inform VDL if incident of falsification was ruled out.
- Provide information/specification to VDL concerning the further handling of the affected pack of medicinal product.

4.6 AMVO

- Supervise and control AMVS GmbH.
- If necessary, request the Supervisory Board of AMVO to intervene.

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 shall 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 at the display unit and/or by means of a separate e-mail. The Unique Alert ID then serves to identify the affected packs of medicinal product and as a reference for all further steps and as a unique identification number (incident number).

5.2 Step I

5.2.1 System information provided to AMVS GmbH and OBP

In the event of a Level 5 – System Message, the system will automatically inform AMVS GmbH and the OBP, in addition to the VDL, by an e-mail message containing the Unique Alert ID.

5.2.2 Pack shall not be supplied by VDL

Until the BASG has provided the specification regarding further handling, the affected pack shall not be supplied to the public, shall, in principle, be stored safely on the premises of the VDL and shall not leave the territory of Austria.

5.2.3 Information provided to BASG by VDL

Pursuant to the Delegated Regulation, the VDL shall immediately document, and inform the 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 required for clear identification (name of the natural person or legal entity, address, telephone number, e-mail address and responsible contact person).

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

5.3 Step II

5.3.1 Ruling out process faults

The MAH and RPC are 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 in any case:

- ✓ 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

OBP collaborates with MAH, RPC, AMVS GmbH and VDL in performing an examination to rule out any process fault.

AMVS GmbH provides support in coordinating VDL, OBP, RPC, MAH, BASG and AMVO within the context of their respective responsibilities concerning the investigation of the potential incident of falsification, accessing the Audit Trail, if applicable.

In the course of said examination, at least the following questions should be addressed:

- Was the affected pack of medicinal product serialised correctly?
- Were the pack details uploaded completely and correctly to the EMVS?
- Is there any fault in the interface translation between the AMVSystem and the VDL's system?
- Did the same VDL try more than four times to decommission the affected pack?

The OBP has to provide binding information whether the pack of medicinal product affected by the Level 5 – System Message has been uploaded to the EU Hub and/or disclose other reasons, if any, for the Level 5 – System Message having been triggered.

The ruling out of process faults has to be completed within **3 (three) working days**.

5.3.2 Potential incident of falsification can be ruled out due to process faults

If a process fault can be proven beyond doubt in the course of the examination and thus an incident of falsification can be ruled out, the RPC/MAH has to confirm this and inform BASG and AMVS GmbH of these facts and the respective details, making reference to the Unique Alert ID.

BASG shall then communicate to the VDL that no incident of falsification is present and provide the VDL with the instruction how to deal with the affected pack of medicinal product. In such a case, the BASG has to decide whether the affected pack

- ➢ has to be treated as a case for complaint within the supply chain;
- ➢ will be sampled by BASG;
- ➢ can, in cases where the OBP had not uploaded the data, be released for supply to the public after the required additional data were uploaded to the EMVS by the OBP.

5.3.3 Potential incident of falsification cannot be ruled out

If a process fault cannot be proven beyond doubt within 3 (three) working days, there is justified suspicion of an incident of falsification. In this case, continue with step III (chapter 5.4).

5.4 Step III

5.4.1 Information provided to BASG and AMVS GmbH

RPC/MAH immediately documents, and informs BASG and AMVS GmbH of, the fact that there is justified suspicion of 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 Information provided to VDL by BASG and specification for handling the pack

BASG informs VDL that there is justified suspicion of an incident of falsification and how to proceed.

BASG and/or the police/PRO instruct VDL how to proceed with handling the affected pack, and VDL has to implement this requirement. If this involves a process of returning products within the supply chain, it has to be ensured that the affected pack remains clearly identifiable by the Unique Alert ID, with any risk of confusion excluded, while being transmitted to the specified point and that the affected pack shall not leave the territory of Austria.

Packs of medicinal product purchased via an Austrian wholesaler shall be returned to him upon BASG's request, within 3 (three) working days, under a separate process during which they shall remain clearly identifiable by the Unique Alert ID, with any risk of confusion excluded.

Packs of medicinal product which were not purchased via Austrian wholesalers shall remain with the VDL until a notification how to proceed with the pack is issued by BASG within 3 (three) working days.

5.4.3 Further investigation of the potential incident of falsification

RPC/MAH 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 individually depend on the instructions given by the BASG and/or the police/PRO.

5.5 Step IV

5.5.1 Ruling out an incident of falsification

If an incident of falsification can be ruled out beyond doubt in the course of the further investigation, proceed as described in chapter 5.3.2.

5.6 Step V

5.6.1 Confirmation of an incident of falsification

If, in the course of the further investigation, an incident of falsification is confirmed or cannot be ruled out, the RPC/MAH shall immediately notify BASG and AMVS GmbH of this, making reference to the Unique Alert ID and stating the reasons.
Then AMVS GmbH shall provide for the alerting, as set out in Article 37 (d) Delegated Regulation, of the BASG, the European Medicines Agency (EMA) and the European Commission (EC) by notifying them of the confirmed incident of falsification and forwarding the information made available by the RPC and/or MAH.

6 Not covered by this Guidance

- **Pack of medicinal product is not ready for dispensing:**
  This Guidance does not cover those cases where the AMVSystem indicates that the pack cannot be supplied for reasons other than the defined Level 5 System Messages and this is NOT a potential incident of falsification. Other reasons preventing supply of the pack may include:

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

- **Technical issues of the VDL:**
  In this respect, refer to document AMVS-1006 (Guidance technical issues, "*Leitlinie technische Probleme"*) (available only in German)

- **Verification of the integrity of the anti-tampering device (ATD):**
  Under the provisions of the Delegated Regulation, also the integrity of the anti-tampering device of Medicinal Products Subject to Serialisation must be verified by the VDL. This Guidance does not cover the procedure to be followed in verifying 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 the BASG).

- **Regarding all cases already regulated:**
  Complaints, objections, quality defects, etc; in this respect, proceed in accordance with the instructions given so far.

- **Transitional provisions:**
  Medicinal products released already before 9 February 2019 for sale or distribution without the Safety Features, within the meaning of the transitional provisions.

7 Application

The present Guidance, as amended from time to time, shall apply as from 9 February 2019.

8 Appendixes

Appendix ./1	Cross-functional flow chart	1 page

9 Index of changes

Version	Applicable as from	Reason for changes
1.0	09 February 2019	New document