Instruction on

the Complaints Procedure in Connection with Process Errors

The German version of this document is authoritative.

The English version is for information only.

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Contents

Disclaimer

For ease of understanding, this instruction provides a shortened and simplified illustration of the steps that need to be taken when there is a complaint related to a process error. The groups of incidents and details referred to in this instruction are non-binding and based on experience gathered during the stabilisation phase and the start phase operations; who caused the error must in any case be evaluated on a case-by-case basis. The relevant stakeholders within the supply chain must establish which examinations to carry out and which measures to take under the complaints procedure instruction and implement them as applicable.

This instruction has been published by: AMVO - Austrian Medicines Verification Organisation

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1 Organisations Involved

The following organisations cooperated in drawing up this instruction:

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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
Instruction	means the present 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 in accordance with the Guidance on Process Errors (technical correction or Recommissioning).
Guidance on Process Errors	means the guidance on how to proceed in the event of (suspected) process errors in the context of dispensing or verifying medicinal products in Austria, including all its appendixes , as amended from time to time

Guidance on Potential / Confirmed Incidents of Falsification	means the Guidance on Potential / Confirmed Incidents of Falsification in 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
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
Process Error	means a technical error or a procedural error within the meaning of the Guidance on Process Errors.
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
Complaint	in accordance with this instruction, a complaint is deemed to exist if the criteria set out in 5.1. are met.
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
Safety Features under the Delegated Regulation	means the Unique Identifier and the anti-tampering device (ATD)
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**

- **Guidance on Potential / Confirmed Incidents of Falsification**

3.2 Scope of this Instruction

This complaints procedure instruction applies to medicinal products subject to serialisation in Austria.

Taking into account the legal and contractual bases (Clause 3.1), this instruction sets out standardised procedures applicable in the event that a level 5 system message is generated by the AMVSystem during an act of verification, decommissioning or recommissioning performed by a VDL, and in the event that a complaint within the meaning of Clause 4.1. exists and the medicinal product package can no longer be allocated to saleable stock pursuant to the Delegated Regulation.

The information provided here is to ensure that all stakeholders involved in the process will follow a uniform procedure when a complaint within the meaning of 4.1. arises. However, any pre-existing price and supply terms and conditions of the stakeholders involved in the process as well as applicable statutory regulations shall take precedence over this instruction.

4 Complaints

4.1 Definition

A complaint incident within the meaning of this information is deemed to exist if

1. the incident is not a confirmed incident of falsification within the meaning of the Delegated Regulation, and
2. the level 5 system message has been triggered by a process error within the meaning of the guidance on process errors, and
3. a corrective measure pursuant to the guidance on process errors has not been carried out successfully or in time, and
4. the person or entity causing the process error within the meaning of the guidance on process errors or causing the corrective measure pursuant to the guidance on process errors not to have been carried out has been identified.

4.2 Incident Groups

Starting point for incident groups 1-6 below
The AMVSystem displays a level 5 system message including a unique alert ID during an act of verification, decommissioning or recommissioning performed by a VDL. An incident of falsification has been ruled out.

Incident group 1

a. Cause for the level 5 system message: A batch has not been uploaded / only partially uploaded
For analysis/correction of the process error, see guidance on process errors Clause 8.1.2.

b. No corrective measure in accordance with the guidance on process errors is carried out: medicinal product package can no longer be allocated to saleable stock.

c. Caused by: OBP/MAH/RPC

Incident group 2

a. Cause for the level 5 system message: Data (batch, expiry date) incorrectly uploaded
For analysis/correction of the process error, see guidance on process errors Clause 8.1.3.

b. No corrective measure in accordance with the guidance on process errors is carried out: medicinal product package can no longer be allocated to saleable stock.

c. Caused by: OBP/MAH/RPC

Incident group 3

a. Cause for the level 5 system message: Unintentional decommissioning of the medicinal product package by the OBP
For analysis/correction of the process error, see guidance on process errors clause 8.2.1.

b. No corrective measure in accordance with the guidance on process errors is carried out: medicinal product package can no longer be allocated to saleable stock.

c. Caused by: OBP/MAH/RPC

Incident group 4

a. Cause for the level 5 system message: Technical error - incorrect data transfer (includes scanning errors)
For analysis/correction of the process error, see guidance on process errors Clause 8.1.1.

b. No corrective measure in accordance with the guidance on process errors is carried out: medicinal product package can no longer be allocated to saleable stock.

c. Caused by: The VDL that generated the incorrect data transfer - no complaint within the meaning of this instruction.

Incident group 5

a. Cause for the level 5 system message: Decommissioning by two different system users
For analysis/correction of the process error, see guidance on process errors Clause 8.2.2. and 8.2.3.

b. No corrective measure in accordance with the guidance on process errors is carried out: medicinal product package can no longer be allocated to saleable stock.

c. Caused by: unequivocal VDL identification not possible.
Clarification by the relevant VDL required

Incident group 6 – special case: Verification of an inactive medicinal product package by a VDL

- If a VDL verifies a medicinal product package with the status “inactive”, this will not trigger a level 5 system message.
- In cases of doubt, this VDL (“receiving VDL”) as well as the VDL that supplied the medicinal product package (“supplying VDL”) can prove, by providing a print-out of the data stored in its software for the relevant serial number, that it did not carry out a decommissioning.
- The receiving VDL that verified the medicinal product package has the right, at any time, to inquire in writing with AMVS GmbH whether or not it was the system user who decommissioned the medicinal product package in question.

Receiving VDL decommissioned the medicinal product package:
No complaint within the meaning of this instruction.

Supplying VDL decommissioned the medicinal product package:
In this case, the medicinal product package in question is considered a complaint within the meaning of this information.

a. No corrective measure in accordance with the guidance on process errors is carried out: medicinal product package can no longer be allocated to saleable stock.

b. Caused by: unequivocal identification not possible.
To be clarified between the receiving and the supplying VDL on a case-by-case basis.

The aforementioned applies mutatis mutandis to incidents where the decommissioning and the verification was carried out not by two VDLs, but by the OBP and a VDL.

4.3 Consequences of Identification of Causing Person or Entity

The procedure, the handling and the (economic) consequences of the complaint depend on the respective contractual and business relationship between the VDL and the person or entity unequivocally identified as having caused the incident, as well as on the applicable statutory regulations.

5 Not Covered by this Instruction

- **Potential / confirmed incidents of falsification**
  Incidents where the AMVSystem displays a level 5 system message and a potential or confirmed incident of falsification exists must be handled in accordance with the guidance on potential / confirmed incidents of falsification.

- **Medicinal product package is not ready for dispensing:**
  This information 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 the 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 instruction 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.

6 Entry into Force

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

7 Index of Changes

Version	Applicable as from	Reason for changes
1.0	Release date of the document: June 2nd 2021	New document

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

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