Bundesamt für Sicherheit im Gesundheitswesen
BASG

amvo
Austrian Medicines Verification Organisation

Guidance on how to Proceed in the Event of (Suspected) Process Errors

("Guidance on Process Errors" for short)

within the context of Dispensing or Verifiying Medicinal Products in Austria

The German version of this document is authoritative.

The English version is for information only.

Version 1.0 - May 2021

Contents

Disclaimer

This Guidance serves as an aid to the OBP, the MAH and the VDL and does not relieve them of their responsibility and obligations under the relevant laws and regulations as amended from time to time.

The process errors referred to in this guidance are based on experience gathered during the stabilisation phase and the start phase operations. The organisations which participated in drawing up this guidance accept no liability or warranty for the information presented herein to be up-to-date, accurate and complete.

Whether a process error exists can only be determined on a case-by-case basis, with such decision having to be made exclusively by the OBP/MAH/RPC and the VDL.

As the organisation operating the repository, AMVS GmbH provides support in this context by exercising the coordination function assigned to it.

1 Organisations Involved

The following organisations cooperated in drawing up this guidance:

BASG - Federal Office for Safety in Health Care (*Bundesamt für Sicherheit im Gesundheitswesen*)
Traisengasse 5, A-1200 Vienna
Tel. + 43 50 555-36111
serialisierung@basg.gv.at
www.basg.gv.at

AMVO - Austrian Medicines Verification Organisation
Operngasse 6/6, 1010 Vienna
Tel. +43 1 40 60 290 0
office@amvo-medicines.at
www.amvo-medicines.at

AMVS - Austrian Medicines Verification System GmbH
Square plus – office building 1,
Leopold-Ungar-Platz 2, Entrance 1, Top 134, 1190 Vienna
Tel. +43 1 99 69 499 0
office@amvs-medicines.at
www.amvs-medicines.at

Austrian Chamber of Pharmacists (*Österreichische Apothekerkammer*)
Spitalgasse 31, P.O. box 87, 1091 Vienna
Tel. +43 1 404 14 100
info@apothekerkammer.at
www.apothekerkammer.at

Austrian Medical Chamber (*Österreichische Ärztekammer*)
Weihburggasse 10-12, 1010 Vienna
Tel. +43 1 51406 0
post@aerztekammer.at
www.aerztekammer.at

Austrian Generic Medicines Association (*Österreichischer Generikaverband,* OeGV)
c/o Gaisberg Consulting GmbH,
Lugeck 4, 1010 Vienna
Tel. +43 650 544 92 92
office@generikaverband.at
www.generikaverband.at

PHAGO – Austrian Association of Full-Line Pharmaceutical Wholesalers (*Verband der österreichischen Arzneimittel-Vollgroßhändler*)
Am Belvedere 8, 1100 Vienna
Tel. +43 1 71 72 8 794
office@phago.at
www.phago.at

PHARMIG - Association of the Austrian Pharmaceutical Industry (*Verband der pharmazeutischen Industrie Österreichs*)
Operngasse 6/6, 1010 Vienna
Tel. +43 1 40 60 290 0
office@pharmig.at
www.pharmig.at

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
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
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
Procedural Error	means a type of process error within the meaning of the Guidance
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 in accordance with this Guidance (technical correction or Recommissioning)
Guidance	means this 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
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	Process Errors are technical errors and Procedural errors within the meaning of this Guidance
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 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
Safety Features under the Delegated Regulation	means the Unique Identifier and the anti-tampering device (ATD)
Technical Error	means a type of Process Error within the meaning of this Guidance
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)
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 Scope

This document addresses the VDLs of the AMVSystem (in their roles as public pharmacy, hospital pharmacy, dispensing doctor, IVF centre or wholesaler) and the OBP, the MAH and the RPC.

4 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 Potential / Confirmed Incidents of Falsification**

- **Complaints Procedure Instruction**

5 Purpose of the Document

In the stabilisation phase and the start phase operations, technical errors or procedural errors during verification or decommissioning ("**Process Errors**", see Clause 6.) gave rise to different system messages occurring in day-to-day practice, in particular **level 5 system messages**.

Above all, this document describes:

- **Responsibilities for steps to take in the event of (suspected) process errors**
- **Ways to correct technical errors**
- **Ways to correct procedural errors**

The responsibilities under the legal and contractual bases apply irrespective of the provisions of this guidance. 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 9.).

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

6 What are Process Errors

The term **process errors** comprises **technical errors** and **procedural errors**.

6.1. Technical Errors

A level 5 system message is triggered because the data transmitted to the system by the VDL cannot be found. This can have any of the following reasons:

- Incorrect data transmission by the VDL during verification/decommissioning
- Upload of the entire product batch failed
- Upload of parts of a product batch failed
- Batch uploaded into the system with incorrect expiry date
- Parts of a batch or entire batch uploaded into the system with incorrect batch number

6.2. Procedural Errors

A level 5 system message is triggered because at the time of generation the status of the relevant medicinal product package is “inactive” already.

- Unintentional decommissioning by the OBP
- Decommissioning at two different VDL locations
- Unintentional decommissioning of an already decommissioned medicinal product package by the VDL
- Multiple decommissioning by the same VDLs

For any such incident to be classified as process error within the meaning of this guidance, it is necessary that the OBP/MAH/RPC/VDL has ruled out, beyond doubt, a potential / confirmed incident of falsification within the meaning of the guidance on potential / confirmed incidents of falsification.

7 Responsibilities and Procedure

In accordance with Clause 5.3.2. of the guidance on potential / confirmed incidents of falsification, AMVS GmbH shall inform BASG and, if applicable, the VDL about the confirmed process error it was made aware of, and about possible corrective measures pursuant to Clause 8. of this guidance.

Depending on the cause of the process error, the OBP/MAH/RPC and/or the VDL may carry out corrective measures in accordance with the procedure set out in Clause 8. of this guidance.

In the event of data having been uploaded incorrectly or not having been uploaded at all, the OBP/MAH/RPC shall inform AMVS GmbH if and when the technical error has been corrected. AMVS GmbH shall forward this information to BASG and the VDL.

Where a technical error occurred, a corrective measure, if any, shall be carried out immediately, in any case no later than within 10 calendar days, after the first level 5 system message was generated for the respective medicinal product package. If it is not possible to carry out corrective measures within 10 calendar days, the VDL may proceed in accordance with the complaints procedure instruction.

AMVS GmbH will provide support in this context by exercising its coordination function and may access the audit trail to the extent permitted by the legal framework.

If a (potential) incident of falsification cannot be ruled out, the further steps to be taken will not be governed by the present guidance, but by the guidance on potential / confirmed incident of falsification instead.

If a corrective measure can be carried out successfully, the medicinal product package can be reallocated to saleable stock.

If a corrective measure cannot be carried out (successfully), the medicinal product package must not be reallocated to saleable stock; if applicable, a complaint within the meaning of the complaints procedure instruction will be issued.

8 Corrective Measures

8.1 Correction of Technical Errors

The following error messages should be categorised as technical errors:

- Serial Number not found
- Batch number not found
- The batch number is different from the one stored in the system.
- The expiry date is different from the one stored in the system

In a first step, it must be clarified whether the technical error occurred due to an incorrect data transfer on the part of the VDL or due to the OBP's data having been uploaded incorrectly or not having been uploaded at all.

Procedure to be followed by the VDL:
The VDL compares the data it passed on to the system with the human readable data shown on the package. If these data do not match, the data transmission was faulty.
If these data do match, the OBP must check whether an error occurred during data upload.
The VDL informs AMVS GmbH about the result of the analysis and, if an error on the part of the OBP is suspected, sends a photo of the DataMatrix Code, making reference to the Unique Alert ID.

Procedure to be followed by the OBP/MAH/RPC:
On the basis of the information transmitted to the OBP via the EMVO interface, the OBP/MAH/RPC analyses the level 5 system message.

The OBP/MAH/RPC informs AMVS GmbH about the result of the analysis, making reference to the unique alert ID. The analysis should cover at least the following information:

In the event of "Batch number not found or batch number incorrect":

- Has the batch not been uploaded (correctly)?
- Did the VDL make an input error?
- What is the correct batch number?

In the event of "Expiry date wrong":

- Has the expiry date not been uploaded correctly?
- Did the VDL make an input error?
- What is the correct expiry date?

In the event of "Serial Number not found":

- Has the serial number not been uploaded?
- Did the VDL make an input error?
- What scheme do you generally use for serial numbers (numerical/alphanumerical, number of digits)?
- In the event of an input error: Can you identify the error, e.g. serial number too short / too long (which digits are missing or have been added), upper/lower case error?
- Can you indicate the correct serial number?

In the event of data having been uploaded incorrectly or not having been uploaded at all, the OBP/MAH/RPC shall inform AMVS GmbH if and when the technical error has been corrected. AMVS GmbH shall forward this information to BASG and the VDL.
Based on the analyses performed, the following corrective measures are possible:

8.1.1 Incorrect Data Transfer by the VDL

An incorrect data transfer by the VDL can occur, among other things, due to an incorrect country-specific configuration of scanning devices or due to the incorrect interpretation of the data contents of the DataMatrix Code by the scanner or the software.

To see whether the scanner configuration is incorrect, you can, for example, use the Scanner Test Code provided by AMVS GmbH (can be downloaded via this link or ordered from a wholesaler under PZN 4474700).

A comparison of the data the VDL transferred to the system against the human readable data shown on the package may help to identify which data were transferred incorrectly.

The VDL must then correct the scanner/software error in cooperation with its IT support. As soon as the verification/decommissioning of the medicinal product package has been carried out successfully, the medicinal product package can be reallocated to saleable stock.

8.1.2 Batches Uploaded Partially or not at all

In the following cases, the OBP made an error during data upload:

- Upload of the entire product batch failed
- Upload of parts of a product batch failed

In both cases, the OBP can correct this by uploading the relevant data once again.
The data must be uploaded to the system without delay, in any case no later than within 10 calendar days after the first level 5 system message was generated for the respective medicinal product package.

8.1.3 Incorrectly Uploaded Data

In the following cases, the OBP made an error during data upload:

- Batch is uploaded into the system with incorrect expiry date
- Parts of a batch or entire batches are uploaded into the system with incorrect batch numbers

In both cases, the OBP can correct the relevant data.
The data must be corrected without delay, in any case no later than within 10 calendar days after the level 5 system message was generated for the respective medicinal product package.

8.2 Correction of Procedural Errors

Level 5 system messages triggered by a procedural error are generated if a status change (decommissioning or recommissioning) cannot be carried out.

Procedure to be followed by the OBP/MAH/RPC:
On the basis of the information transmitted to the OBP via the EMVO interface, the OBP/MAH/RPC analyses the level 5 system message.
The OBP/MAH/RPC informs AMVS GmbH about the result of the analysis, making reference to the unique alert ID. The analysis should cover at least the following information:

- Are the data transmitted by the VDL correct and have they been uploaded by the OBP?
- Did the OBP carry out an unintentional decommissioning which caused the level 5 system message?

Procedure to be followed by the VDL:
The VDL analyses the level 5 system message on the basis of the data transmitted to the AMVSystem:
In the event of “Package has already been decommissioned”:

- Did the VDL already decommission the package beforehand?
- Is it a temporary delivery from another VDL (e.g. pharmacy or hospital)?
- Is the package in question a package that must not be decommissioned by the VDL (e.g. free samples, supply of doctor’s offices, vaccines for regional authorities)?

In the event of “Status change not possible”:

- Does the action taken correspond to the status of the medicinal product package?
  e.g. Has an attempt been made to decommission a medicinal product package while its status was still “active”?
  Has an attempt been made to reverse a decommissioning that does not correspond to the status of the medicinal product package, e.g. recommissioning of a dispense for a free sample?

In addition, the VDL can, within the scope of its own inventory control system, check where the product was sourced and, if applicable, contact the location from which it received the medicinal product package to find out why a status change cannot be carried out.

The VDL that triggered the level 5 system message 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.

Based on the analysis referred to above, the level 5 system messages can be grouped as follows:

8.2.1 Unintentional Decommissioning by the OBP

Where an OBP unintentionally decommissions medicinal product packages into one of the statuses listed below, making them unfit for regular sale, these medicinal product packages will trigger a Level 5 System Message upon their being decommissioned by the VDL.

- The OBP sets the status to Dispensed or Free Sample
- The OBP sets the status to Locked
- The OBP sets the status to Destroyed, Stolen, Recalled or Withdrawn

The OBP/MAH/RPC confirms to AMVS GmbH that the OBP unintentionally decommissioned the medicinal product package and informs it whether or not a correction is possible (recommissioning of the medicinal product package).
AMVS GmbH forwards this information to the relevant VDL.

If a larger number of medicinal product packages in the same batch has been unintentionally decommissioned by the OBP and a correction of this error (recommissioning of the medicinal product package) is not possible, the OBP/MAH/RPC must immediately take out the relevant medicinal product packages from the market.

If the status of a medicinal product package is set to dispensed (dispensed to patients) or free sample, the OBP may carry out a recommissioning provided that the following prerequisites are met:
The system user who carried out the unintentional decommissioning can reverse it within 10 calendar days (240 hours) after such decommissioning.

If the status of a medicinal product package is set to locked, the OBP can recommission it at any time without any deadline, provided that the relevant prerequisites are met.

If the status is set to destroyed, stolen, recalled or withdraw, it is not possible to recommission the relevant medicinal product package.

8.2.2 Decommissioning at Two Different VDLs

It may happen that a medicinal product package is decommissioned by two different VDLs. In such a case, the second VDL's attempt will trigger a level 5 system message. The following scenarios occurred most frequently during the stabilisation phase and the start phase operations:

- Decommissioning by two different pharmacies
- Decommissioning by two different hospitals
- Decommissioning by dispensing doctor and pharmacy
- Decommissioning by public pharmacy and hospital pharmacy
- Decommissioning by wholesaler and public pharmacy, hospital pharmacy or dispensing doctor
- Decommissioning by wholesaler, public pharmacy or hospital pharmacy and IVF centre

Recommissioning is possible if the following prerequisites are met:
Where the status is dispensed (dispensed to patients) or free sample, the VDL that carried out the decommissioning can recommission it within 10 calendar days (240 hours) after such decommissioning.

After the expiry of 10 calendar days (240 hours) following decommissioning, correction (recommissioning) is no longer possible.

8.2.3 Unintentional Decommissioning of an Already Decommissioned Package by the VDL

It may happen that a VDL unintentionally decommissions an already decommissioned medicinal product package. If a VDL unintentionally decommissions an already decommissioned medicinal product package, such action will trigger a level 5 system message. The initial decommissioning may have been carried out either by a different VDL and by an OBP. The following scenarios occurred most frequently during the stabilisation phase and the start phase operations:

- Decommissioning of free samples
- Decommissioning of doctor's office supplies
- Decommissioning of Medicinal Product Packages decommissioned by the wholesaler for falling within the specific category defined in Article 23 of the Delegated Regulation (e.g. supplied to regional authorities, veterinarians' dispensaries, the Austrian Federal Army, prisons, rescue and medical facilities / full list see AMBO, section 3 (14))

If a Level 5 System Message was generated due to an unintentional Decommissioning, no correction is possible.

8.2.4 Multiple Decommissioning by the same VDL

It may happen that one and the same VDL repeatedly decommissions an already decommissioned medicinal product package.

Where one and the same VDL decommissions a medicinal product package placed on the Austrian market (uploaded into the AMVSystem) for the fifth time, this will trigger a level 5 system message.

Medicinal product packages uploaded into the system of another country will trigger a level 5 system message already upon the second decommissioning attempt.

Recommissioning is possible if the following prerequisites are met:
The VDL that carried out the decommissioning can reverse it within 10 calendar days (240 hours) after such decommissioning.

After the expiry of 10 days (240 hours) following decommissioning, correction (recommissioning) is no longer possible.

9 Not Covered by this Guidance

- **Potential / confirmed ncidents 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 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 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 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 concerning process errors, consult the complaints procedure instruction.

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

10 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.

11 Index of Changes

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

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

Legal Notice

Media owner and publisher: President of the Board Mag. Alexander Herzog,
Vice-President of the Board Dr. Wolfgang Andiel

AMVO - Austrian Medicines Verification Organisation

Operngasse 6/6, 1010 Vienna
Tel. +43 1 40 60 290 0
office@amvo-medicines.at
www.amvo-medicines.at
Association register number 187087754

Edited and designed by: DI Dr. Daniel Dangl

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