

AMVO-002-4.0	Appendix ./5
<i>Guidance on Potential / Confirmed Incident of Falsification within the context of Dispensing or Verifying Medicinal Products in Austria</i>	
Applicable as from: 09 February 2026	

## Appendix ./5 Ruling out the Potential Incident of Falsification – Information to be Made Available by the VDL

In the analysis of the Level 5 System Message by the VDL as stipulated in 5.3.1, at least the following aspects must be addressed, and information thereon be transmitted to AMVS GmbH within no more than 3 business days via e-mail sent to [office@amvs-medicines.at](mailto:office@amvs-medicines.at):

The analysis should cover at least the following information (which is already included in the automatically generated e-mail referred to in Appendix ./3):

Alert ID

Time stamp

Error code

Product code

Product name

Batch number retrieved

Expiry date retrieved

Serial number retrieved

Analysis of the Level 5 System Message:

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

In the event of “Expiry date wrong”:

In the event of “Serial number not found”:

- Do the human readable data shown on the package correspond to those transmitted to the system?

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. medical samples, supply for 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. reversal of a standard dispensing to medical sample?

If the analysis proves the existence of a process error beyond doubt and rules out an incident of falsification, the VDL must confirm this to AMVS GmbH within 3 business days in its report on the findings and inform AMVS GmbH about the situation and the respective details, making reference to the unique alert ID.