AMVO-002-2.0	Appendix ./4
Guidance on Potential / Confirmed Incident of Falsification *within the context of Dispensing or Verifying Medicinal Products in Austria*	
Applicable as from: see section 7 – Entry into force	

Appendix ./4 Ruling out Process Errors – Information to be Made Available by OBP/MAH/RPC

In the analysis of the level 5 system message by RPC/MAH/OBP 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:

The analysis should cover at least the following information:
Alert ID
Time stamp
Error code
Product code
Product name
Batch number retrieved
Expiry date retrieved
Serial number retrieved

Root cause analysis:
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 "Package has already been decommissioned" or "Status change not possible":
- Are the data transmitted by the end user correct and have they been uploaded by the OBP?
- Did the OBP carry out an unintentional decommissioning which triggered the alert message?

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