

AMVO-002-3.0	Appendix ./4
<i>Guidance on Potential / Confirmed Incident of Falsification within the context of Dispensing or Verifying Medicinal Products in Austria</i>	
Applicable as from: see section 7 – Entry into force	

Appendix ./4 Ruling out the Potential Incident of Falsification – 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

Alert Code		Description	Root cause analysis by OBP/MAH/VPU (questions to be considered in any case)
EU HUB	AMVSystem		
A2	NMVS_FE_LOT_03	The batch number was not found	Has the batch been uploaded correctly? Is there a suspected input / scanning error by the VDL? What is the correct batch number?
A3	NMVS_NC_PC_02	The serial number is not known	Has the serial number been uploaded correctly? Is there a suspected input / scanning error by the VDL? What scheme do you generally use for serial numbers (numerical/alphanumeric, number of digits)? In the event of an input / scanning 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?

AMVO-002-3.0	Appendix ./4
<i>Guidance on Potential / Confirmed Incident of Falsification within the context of Dispensing or Verifying Medicinal Products in Austria</i>	
Applicable as from: see section 7 – Entry into force	

A7	NMVS_NC_PCK_19	The pack is already in the requested status	Analysis by OBP/MAH/VPU required in the following cases: - Alarm was generated by OBP user (Market ID EU and Client ID of the OBP) - First decommissioning was performed by OBP - Request by AMVS / BASG for analysis Did the OBP carry out an unintentional decommissioning which triggered the alert message?
A24	NMVS_NC_PCK_22	The pack is already in a different decommissioned status	
	NMVS_NC_PCK_06	Recommissioning was not possible because the package was decommissioned with a different status	
	NMVS_NC_PCK_27	The non-national pack is already in a different decommissioned status	
A52	NMVS_FE_LOT_12	The expiry date is different from the one stored in the system	Has the expiry date been uploaded correctly? Is there a suspected input / scanning error by the VDL? What is the correct expiry date?
A68	NMVS_FE_LOT_13	The batch number is different from the one stored in the system	Analysis by OBP/MAH/VPU required upon request by AMVS / BASG Has the batch been uploaded correctly? Is there a suspected input / scanning error by the VDL?