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:

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.