



Stabilisation phase (09/02/2019 to 08/02/2020)

Cross-functional flow chart		Who?	What? / Duration	
Entire process	Start	<ul style="list-style-type: none"> Guidance for dealing with technical issues System generates error message System check 	<ul style="list-style-type: none"> Defined error message at VDL Unique Alert ID displayed to VDL at display unit Reference to stabilisation phase 	
	I	System information provided to AMVS, OB	Error message of the system generated automatically	
	II	<ul style="list-style-type: none"> VDL checks affected pack of medicinal product for integrity and authenticity If falsification is suspected, VDL is to proceed acc. to "Guidance - Potential / Confirmed Incident of Falsification" Examination of process errors and/or other faults or errors System check 	<ul style="list-style-type: none"> VDL OBP RPC/MAH/AMVS/VDL AMVS RPC/MAH 	<ul style="list-style-type: none"> OBP notifies RPC/MAH Examination by OBP collaborating with RPC/MAH/AMVS/VDL If applicable, inspection of Audit Trail by AMVS Supporting coordination by AMVS
	III	<ul style="list-style-type: none"> System error is corrected Information provided to AMVS 	RPC/MAH	
<p>BASG: No restriction of processes under the AMG. Has access to the Audit Trail at any time, may at any time decide to initiate separate investigations.</p>				

AMG	Austrian Medicinal Products Act (<i>Arzneimittelgesetz</i>)
AMVO	Austrian Medicines Verification Organisation
AMVS	Austrian Medicines Verification System GmbH
BASG	Federal Office for Safety in Health Care (<i>Bundesamt für Sicherheit im Gesundheitswesen</i>)
EMVO	European Medicines Verification Organisation
MAH	Marketing Authorisation Holder
OBP	Onboarding Partner EMVO
VDL	Verifying or Dispensing Location
RPC	Responsible pharmaceutical company (<i>Verantwortliches Pharmazeutisches Unternehmen</i>)