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1. Purpose of this document

The purpose of this document is to describe the measures to be taken by each type of entity in the supply chain that is connected to the Swedish Medicines Verification System (SMVS) in order to eliminate and prevent alerts from being raised by the SMVS.
The volume of alerts, as well as the alerts/transactions ratio have been declining since the EMVS go-live on February 9th, 2019. However, a significant number of alerts remain and must be eliminated from the system. Likewise, alerts must be prevented from being raised when new organisations connect to SMVS or e.g. when new scanners or software are adopted by existing end-users.
The measures to be adopted by each stakeholder in the supply chain are based on the experience of analysis of all the Level 5 alerts (see explanation below) generated since 9th February 2019. The purpose with this document is to provide guidance on the root causes determined from this analysis and provide for concrete actions that could be carried out by each entity.

2. Alerts generated by the verification system

The verification system has been designed to trigger exceptions (alerts) when data from the four elements on a physical pack being scanned do not match the data uploaded into the SMVS or when a given transaction is not possible to complete. These levels reflect the classification and severity of the exception. Specifically, the escalation level defines the scope of communication of any notification. If the exception is critical, an alert is raised and the notification contains an Alert ID. The exceptions are categorised into levels 1 to 5. For example, level 1 exception is when the user has failed to login into the system because an incorrect password was used.
A Level 5 alert is triggered when the SMVS detects a potential suspect falsified pack within the European Medicines Verification System (EMVS), and is escalated to end-users as well as e-VIS, EMVO, Medical Products Agency (Läkemedelsverket) and OBP / MAHs.
Level 2 to 4 are exceptions where the initiator of the transaction is informed (and in some cases other system administrators) but these are not considered by default to be potential suspected falsified packs and these exceptions do not generate an Alert ID.

The Level 5 alerts are the following:

Alert message (SSR NMVS)	Alert message (EU Hub)	Meaning	Alert code/codes (SSR NMVS)	Alert code (EU Hub)
The product code is unknown.	Product Not Found	The Product Number (GTIN) from the data matrix was not found. This is not an alert but MAH/OBP may receive this error during upload and Wholesaler/Pharmacy when scanning a pack.	41020000	#A1 Please note that #A1 is not a level 5 exception.
The serial number is unknown. An alert has been raised.	Batch Not Found	The Batch Id from the data matrix was not found for the Product Number (GTIN).	41020001	#A2
The expiry date mismatches the recorded expiry date. An alert has been raised.	Expiry Date Mismatch	The Expiry Date from the data matrix does not match the batch expiry date submitted to the EMVS.	41020005	#A52
The serial number is unknown. An alert has been raised.	Pack Not Found	The Serial Number from the data matrix was not found for the Product Number (GTIN).	41020001	#A3

Alert message (SSR NMVS)	Alert message (EU Hub)	Meaning	Alert code/codes (SSR NMVS)	Alert code (EU Hub)
The batch identifier mismatches the recorded batch identifier. An alert has been raised.	Batch Number Mismatch	The Serial Number from the data matrix was found for the Product Number (GTIN), but it does not match with the Batch Id from the data matrix.	41020003	#A68
The pack cannot be supplied. An alert has been raised.	Pack Already in Requested State	Pack is already supplied in another location.	51220200	#A7
The pack was previously supplied at this location. Too many repeated attempts. An alert has been raised.	Pack Already in Requested State	Pack is already supplied at the same location.	51220201	#A7
The pack cannot be decommissioned. An alert has been raised.	Pack Already in Requested State	Pack is already decommissioned and in requested state.	51320300 51320400 51320500 51320600 51320700 51320800	#A7

Alert message (SSR NMVS)	Alert message (EU Hub)	Meaning	Alert code/codes (SSR NMVS)	Alert code (EU Hub)
The pack cannot be supplied. An alert has been raised.	Attempt to decommission an already decommissioned pack	A supply was attempted for a pack that is already inactive.	51220300 51220400 51220500 51220600 51220700 51220800 51220900	#A24
The pack cannot be supplied. An alert has been raised.		A decommissioning was attempted for a pack that is already supplied.	51320200	#A24
The pack cannot be decommissioned. An alert has been raised.	Attempt to decommission an already decommissioned pack	A decommissioning was attempted for a pack that is already inactive.	51320300 51320400 51320500 51320600 51320700 51320800 51320900	#A24
The pack cannot be reactivated. An alert has been raised.		A reactivation was attempted for a Checked-out pack.	51420900	#A24

3. Eliminate and prevent alerts

All level 5 alerts raised by the SMVS are analysed by e-VIS so a root cause (or at least a most probable cause) can be determined and corrective and/or preventive actions can be defined and carried out.
From the root cause analysis it is possible to determine the entity responsible for causing the alert in the system. The responsible entity may or may not be the entity where the alert was raised (e.g. an alert raised in a pharmacy may or may not have been caused by the pharmacy).
In the following sub-chapters, a description of the alerts, most probable causes and measures to eliminate the alerts is presented, organized by type of entity – MAH, Wholesaler, Pharmacy or Hospital.
The most probable causes of the alerts and the measures to eliminate alerts presented in this document are a result from the experience of analysing alerts raised by SMVS and the respective measures already implemented to eliminate alerts from the system as well as from the experiences (analysis and solutions) shared within the European NMVO community.
Please note that the following chapters also include 'Product Code Not Found', even if this exception is not classified as a level 5 alert.

3.1 Market Authorization Holders (MAH)

In this sub-chapter the most probable causes of the alerts are described, when these are attributable to MAH. If applied correctly, the measures presented to each case could eliminate the respective alerts.

#	Alert Type	Alert code	Most probable causes	Measures to eliminate and prevent alerts
1	Product Not Found	A1	Pack data was not uploaded into the EMVS at the moment the end-user performed the transaction that originated the alert.	Master data and pack data must be loaded into the system before the packs are physically placed on the market. In case of need, contact e-VIS on alerts@e-vis.se to request confirmation of successful data upload.

#	Alert Type	Alert code	Most probable causes	Measures to eliminate and prevent alerts
2	Product Not Found	A1	Non-FMD pack bearing a 2D matrix code.	For all batches released before 9th February 2019 bearing 2D matrix codes, upload product and pack data into the EU-Hub. For all batches released before 9th February 2019 bearing 2D matrix codes, and all non-FMD medicines (e.g. Indian packs) should be reported to e-VIS using info@e-vis.se.
3	Product Not Found	A1	Wrong encoding of the 2D code elements (e.g. GTIN with less than 14 characters). Wrong separation of the elements in the 2D (e.g. not separating the serial number or batch Id from the GTIN).	Ensure correct data encoding into the 2D code. Ensure both master data and pack data are uploaded into the EMVS and that is done before the packs physically reach the market. Ensure the data encoded into the 2D code is identical to the data uploaded into the EMVS. If product code cannot be corrected in the EMVS or on the printing of the physical packs this must communicated to the Swedish NCA and e-VIS on alerts@e-vis.se.
4	Product Not Found	A1	Wrong printing of the human readable elements (GTIN), if used in a manual transaction where the user inserts manually the GTIN.	Ensure correct printing of the human readable data. The human readable data must be identical to that uploaded into the EMVS and encoded into the 2D code. If printing cannot be corrected in the EMVS or on the printing of the physical packs this must communicated to the Swedish NCA and e-VIS on alerts@e-vis.se.

#	Alert Type	Alert code	Most probable causes	Measures to eliminate and prevent alerts
5	Batch Not Found	A2	Pack data was not uploaded into the EMVS at the moment the end-user performed the transaction that originated the alert.	Master data and pack data must be loaded into the system before the packs are placed in the market. In case of need, contact e-VIS using alerts@e-vis.se to request confirmation of successful data upload.
6	Batch Not Found	A2	Wrong encoding of the 2D code elements (e.g. misuse of upper case and lower case). Wrong separation of the elements in the 2D (e.g. not separating the serial number or batch Id from the GTIN). Data not identical in both the pack and the system.	Ensure correct data encoding into the 2D code. Ensure both master data and pack data are uploaded into the EMVS and that is done before the packs physically reach the market. Ensure the data encoded into the 2D code is identical to the data uploaded into the EMVS. If batch number cannot be corrected in the EMVS or on the printing of the physical packs this must communicated to the Swedish NCA and e-VIS using alerts@e-vis.se.
7	Pack Not Found	A3	Pack data was not uploaded into the EMVS at the moment the end-user performed the transaction that originated the alert. Packs physically released to the market but whose data was not uploaded into the EMVS (e.g. retained quality samples).	Master data and pack data must be loaded into the system before the packs are placed in the market. In case of need, contact e-VIS using alerts@e-vis.se to request confirmation of successful data upload of batch (specific serial numbers are not possible to confirm as the data is not accessible).

#	Alert Type	Alert code	Most probable causes	Measures to eliminate and prevent alerts
8	Pack Not Found	A3	Wrong encoding of the 2D code elements (e.g. misuse of upper case and lower case). Wrong separation of the elements in the 2D (e.g. not separating the serial number or batch Id from the GTIN). Data not identical in both the pack and the system.	Ensure correct data encoding into the 2D code. Ensure both master data and pack data are uploaded into the EMVS and that is done before the packs physically reach the market. Ensure the data encoded into the 2D code is identical to the data uploaded into the EMVS. In case of need, contact e-VIS using alerts@e-vis.se to request confirmation of successful data upload of batch (specific serial numbers are not possible to confirm as the data is not accessible).
9	Pack Not Found	A3	Wrong printing of the human readable elements (serial number), if used in a manual transaction where the user inserts manually the GTIN.	Ensure correct printing of the human readable data. The human readable data must be identical to that uploaded into the EMVS and encoded into the 2D code. Any printing errors must be communicated to the Swedish NCA and e-VIS using alerts@e-vis.se.
10	Expiry Date Mismatch	A52	The expiry date loaded into the system is not identical to the expiry date encoded into the 2D code. Example: expiry date loaded into the system is 220122 (following the YYMMDD format), and the expiry date encoded into the 2D code is 220131.	Expiry date encoding into the 2D code must follow the format YYMMDD. Ensure the data encoded into the 2D code is identical to the data uploaded into the EMVS. Ensure the expiry date in the 2D code is identical to the human readable expiry date. If expiry date cannot be corrected in the EMVS or on the printing of the physical packs this must communicated to the Swedish NCA and e-VIS using alerts@e-vis.se.

#	Alert Type	Alert code	Most probable causes	Measures to eliminate and prevent alerts
11	Batch Number Mismatch	A68	Wrong encoding of the 2D code elements (e.g. misuse of upper case and lower case in the batch ID). Wrong separation of the elements in the 2D (e.g. not separating the batch id from the serial number). Wrong data encoded into the pack (e.g. encoding a valid serial number that belongs to another batch). Wrong data uploaded into the EMVS (valid batch id and valid serial number but serial number belongs to another batch). Data not identical in both the pack and the system.	Ensure correct data encoding into the 2D code. Ensure both master data and pack data are uploaded into the EMVS. Ensure the data encoded into the 2D code is identical to the data uploaded into the EMVS. If batch number cannot be corrected in the EMVS or on the printing of the physical packs this must communicated to the Swedish NCA and e-VIS on alerts@e-vis.se.

3.2 Pharmacies, Wholesalers and Health Care (End-users)

In this sub-chapter the most probable causes of the alerts are described, when these are attributable to end-users (pharmacies, wholesalers and health care). If applied correctly, the measures presented to each case could eliminate the respective alerts.

#	Alert Type	Alert code/codes	Most probable causes	Measures to eliminate and prevent alerts
1	The product code is unknown.	41020000	Alerts caused by scanner misconfiguration (problems in the scanner device and/or in the associated software): Wrong separation of the elements in the 2D code (e.g. consider a GTIN with less/more than 14 digits).	Ensure correct scanner/software configuration (e.g. group separators). Involve scanner/software suppliers if necessary. The scanner/software must transfer the exact content of the 2D code read, with no interpretations. If the problem is not due to technical problem in the scanner/software this should be communicated to the MAH and e-VIS using the form at reklameraläkemedel.se.
2	The product code is unknown.	41020000	Manual insertion of pack data of a non-serialized pack.	If the pack does not bear a 2D code, it is not under the Delegated Regulation and therefore it is not to be scanned for this purpose. If the problem is not due to technical problem in the scanner/software this should be communicated to the MAH and e-VIS using the form at reklameraläkemedel.se.

#	Alert Type	Alert code/codes	Most probable causes	Measures to eliminate and prevent alerts
3	The product code is unknown.	41020000	Wrong manual insertion of the human readable elements.	The manual insertion transactions were designed for fallback scenarios and therefore not to be used on a regular basis, as the probability of manual data insertions errors is very high. As such, manual transactions/entry are to be kept to a minimum. In case of use of manual transactions, ensure that the insertion of the unique identifier elements (GTIN and serial number) are correctly inserted. The SMVS provides 3 attempts to insert incorrect information before generating a level 5 alert.
3	Failed to find a batch for the given data	41020001	Alerts caused by scanner misconfiguration (problems in the scanner device and/or in the associated software): Wrong interpretation of upper case/lower case (e.g. the batch id is "A1B2C3" but is read by the scanner as "a1b2c3"). No read of special characters in batch id (e.g. the batch id "12345-B1" is read by the scanner as "12345B1"). Wrong identification of the 2D elements (e.g. the serial number is read by the scanner or transferred to the NMVS as being the batch id). Wrong separation of the elements in the 2D code (e.g. consider a concatenation of the batch id and the serial number as the batch id).	Ensure correct scanner/software configuration (e.g. character set conversion). Involve scanner/software suppliers if necessary. The scanner/software must transfer the exact content of the 2D code read, with no interpretations. The scanner/software must retrieve the exact content of the 2D code, with no interpretations. If the problem is not due to technical problem in the scanner/software this should be communicated to the MAH and e-VIS using the form at reklameraläkemedel.se.

#	Alert Type	Alert code/codes	Most probable causes	Measures to eliminate and prevent alerts
3	Unknown serial number	41020001	Alerts caused by scanner misconfiguration (problems in the scanner device and/or in the associated software): Wrong interpretation of upper case/lower case (e.g. the serial number is "A1B2C3" but is read by the scanner as "a1b2c3"). Unread special characters in the serial number (e.g. the serial number is "12345-B1" but is read by the scanner as "12345B1"). Wrong identification of the 2D elements (e.g. the serial number is read by the scanner or transferred to the NMVS as being the batch id). Wrong separation of the elements in the 2D code (e.g. consider a concatenation of the serial number and the batch id as the serial number).	Ensure correct scanner/software configuration (e.g. reverse printing). Involve scanner/software suppliers if necessary. The scanner/software must transfer the exact content of the 2D code read, with no interpretations. If the problem is not due to technical problem in the scanner/software this should be communicated to the MAH and e-VIS using the form at reklameraläkemedel.se.

#	Alert Type	Alert code/codes	Most probable causes	Measures to eliminate and prevent alerts
4	Expiry date does not match the date held in the NMVS	41020005	Alerts caused by scanner misconfiguration (problems in the scanner device and/or in the associated software): Read the expiry date in reverse order (i.e. instead of reading YYMMDD, the scanner reads DDMMYY). The scanner/software considers the date in which the transaction occurred and not the date encoded into the 2D code (e.g. the date in the 2D code is 220415, but the scanner/software retrieves 190901). The scanner/software converts the date in the 2D code into the last day of the month or the last day of the previous month (e.g. the date in the 2D code is 220415, but the scanner/software converts to 220430). The scanner/software converts the date in the 2D code into the first day of the month (e.g. the date in the 2D code is 220415, but the scanner/software converts to 220401).	Ensure correct scanner/software configuration (e.g. interface). Involve scanner/software suppliers if necessary. The scanner/software must retrieve the exact content of the 2D code, with no interpretations. If the problem is not due to technical problem in the scanner/software this should be communicated to the MAH and e-VIS using the form at reklameraläkemedel.se.

#	Alert Type	Alert code/codes	Most probable causes	Measures to eliminate and prevent alerts
5	The batch ID does not match the serial number in the NMVS	41020003	Alerts caused by scanner misconfiguration (problems in the scanner device and/or in the associated software): Wrong interpretation of upper case/lower case (e.g. the batch id is "A1B2C3" but is read by the scanner as "a1b2c3"). Unread special characters in batch id (e.g. the batch id "12345-B1" is read by the scanner as "12345B1"). Wrong identification of the 2D elements (e.g. the serial number is read by the scanner or transferred to the NMVS as being the batch id). Wrong separation of the elements in the 2D code (e.g. consider a concatenation of the batch id and the serial number as the batch id).	Ensure correct scanner/software configuration (e.g. character set configuration). Involve scanner/software suppliers if necessary. The scanner/software must retrieve the exact content of the 2D code, with no interpretations. If the problem is not due to technical problem in the scanner/software this should be communicated to the MAH and e-VIS using the form at reklameraläkemedel.se.

#	Alert Type	Alert code/codes	Most probable causes	Measures to eliminate and prevent alerts
6	Pack is already supplied	51220300 51220400 51220500 51220600 51220700 51220800 51220900	Repetition of a decommissioning operation on an already supplied pack. The pack was initially supplied by the end user itself or another end user.	Before performing the decommission operation, always perform a verify operation. If the pack is already inactive, do not try to decommission again. For bulk transactions, the end-user system must not allow a second call to SMVS before receiving the response to the first call. Retry mechanisms in the End User systems must be developed and configured so that they do not generate unnecessary retries: • Single transactions: only known and configured return codes or return system messages should generate retry attempts. Time between retries should increase with the number of attempts. • Bulk transactions: The original bulk transaction must not be retried if the result is not received, successful or return code unknown. If the problem is not due to technical problem in the scanner/software this should be communicated to the MAH and e-VIS for investigation using the form at reklameraläkemedel.se.

#	Alert Type	Alert code/codes	Most probable causes	Measures to eliminate and prevent alerts
7	Pack is already decommissioned	51320300 51320400 51320500 51320600 51320700 51320800 51320900	The pack was delivered in the inactive state in the point of dispense (pharmacies or hospitals). The pack must be delivered in the active state.	Ensure the packs are delivered in active state to pharmacies and hospitals. Correctly maintain the product and customer master data in order to identify which products and clients require decommission or not.
8	Defined timeframe between setting this property and the undo was exceeded	**Not level 5 alert** 51420002 51420200 51420501 51420601 51420801	Undo transactions were performed after the 10 days immediately after the initial transaction. Undo operations can only be performed in the 10 days immediately after the initial transaction.	The end-user must keep track of the initial transaction performed (in case it was performed by the End User itself, including date and nominated User), so the 10 days' timeframe can be managed, and the alert can be avoided. Before performing the undo operation, always verify if the pack was transacted by the End User, the type of transaction performed and then execute a verify operation to know the current pack status. If the pack is in a status different from last status generated by the End User and the date is not known, do not try to perform the undo operation.

#	Alert Type	Alert code/codes	Most probable causes	Measures to eliminate and prevent alerts
9	Undo can only be executed by the same user who previously set the attribute	**Not L5 alert** 51420001 51420201 51420500 51420600 51420700 51420800	Undo transaction was performed by a user that did not perform the initial transaction. Undo transactions can only be performed by the same user that performed the initial transaction.	The end-user must keep track of the initial transaction performed (in case it was performed by the End User itself, including date and nominated user), so the alert can be avoided. Before performing the undo operation, always verify if the pack was transacted by the End User, the type of transaction performed and then execute a verify operation to know the current pack status. If the pack is in a status different from last status generated by the End User and the nominated user that performed the initial transaction is not known, do not try to perform the undo operation.

4. Contacts

For the purpose of communicating with e-VIS regarding alerts, the following points of contact are to be used:

- Email regarding alerts related questions: alerts@e-vis.se
- Email regarding general questions: info@e-vis.se

5. Definitions

Term/Acronym	Definition
EMVS	European Medicines Verification System. The European system for medicines verification consisting of the European Hub, the NMVS, the interface between those two, and the interfaces to the manufacturer / parallel distributor systems and to the End User systems.
EU Hub	The subsystem of the European Medicines Verification System that serves as a gateway for the transmission of manufacturer and parallel importer data to the national systems. Furthermore, data reconciliation on repackaging activities is performed on the EU Hub.
End User	End User shall mean any wholesaler, pharmacy, hospital or other person authorized or entitled to supply medicinal products to the public as foreseen under the EU Directive on Falsified Medicines and the Delegated Regulation.
IQE	Integrated Quality Environment
ITE	Integrated Test Environment
IT Service Provider	The service provider that delivers the interface between the End User system and SMVS. Is contracted by the End User.
MAH	Marketing Authorisation Holder.
NCA	National Competent Authority (In Sweden, Medical Products Agency i.e. Läkemedelsverket).
e-VIS	e-Verifikation i Sverige
SMVS	Swedish Medicines Verification System. A system in the European Medicines Verification landscape that serves as the verification platform for Sweden. The End Users registered (Pharmacies, Wholesalers, Hospitals or Other kind of End Users in the Swedish context) check the authenticity of a product using a connection to this system.
User	A specific person that has authorized access to the End User system.