



SOP – Measures to eliminate and prevent alerts

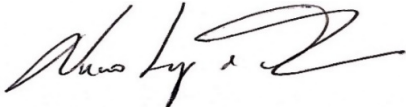
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1.0	25-Oct-2019	Initial document	N/A

THE SOLE FUNCTION OF THE ABOVE TEXT IS TO APPROVE THE VERSION OF DOCUMENT AND TO MAINTAIN THE REVISION HISTORY. IT IS NOT PART OF THE DOCUMENT ITSELF. NOTE THAT A SEPARATE HEADER AND FOOTER IS USED ON THIS FIRST PAGE.



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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 participating in the legal supply chain in order to eliminate and prevent alerts from being raised by the verification system.

The volume of alerts, as well the alerts/transactions ratio have been declining since the EMVS go-live in February 9th 2019. However, a significant number of alerts remain and must be eliminated from the system. Likewise, new alerts must be prevented from being raised.

The measures to be adopted by each type of entity results from the experience of having analysed all the Level 5 alerts generated since 9th February 2019 (approx. 2 million alerts), so that a root cause could be determined, and concrete actions could be defined and carried out by each entity.

Up until the moment of elaboration of this document, no real suspected falsification alerts were detected in Portugal.

2. Alerts generated by the verification system

The verification system has been designed to generate exceptions (alerts) when a given transaction is not possible to be completed. The alerts are categorized into levels 1 to 5. For example, level 1 alert is when the user has failed to login into the system because in incorrect password was used.

A Level 5 alert is generated when the NMVS detects a potential suspect falsified pack within the European Medicines Verification System (EMVS), which are escalated to end-users as well as NMVO's, National Competent Authorities (NCAs) and OBP / MAHs.

The Level 5 alerts are the following:

Alert message (Arvato NMVS)	Alert message (EU Hub)	Meaning	Alert code (Arvato NMVS)	Alert code (EU Hub)
Unknown product code	Product Not Found	The Product Number (GTIN) from the data matrix was not found.	NMVS_NC_PC_01	#A1
Failed to find a batch for the given data	Batch Not Found	The Batch Id from the data matrix was not found for the Product Number (GTIN) from the data matrix.	NMVS_FE_LOT_03	#A2
Expiry date does not match the date held in the NMVS	Expiry Date Mismatch	The Expiry Date from the data matrix does not match the batch expiry date submitted to the EMVS.	NMVS_FE_LOT_12	#A52



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Alert message (Arvato NMVS)	Alert message (EU Hub)	Meaning	Alert code (Arvato NMVS)	Alert code (EU Hub)
Unknown serial number	Pack Not Found	The Serial Number from the data matrix was not found for the Product Number (GTIN) from the data matrix.	NMVS_NC_PC_02	#A3
The batch ID does not match the serial number in the NMVS	Batch Number Mismatch	The Serial Number from the data matrix was found for the Product Number (GTIN) from the data matrix, but it does not belong to the Batch Id from the data matrix.	NMVS_FE_LOT_13	#A68
Property is already set on pack	Attempt to decommission an already decommissioned pack	Pack is already in requested state (applicable when an IMT is triggered).	NMVS_NC_PCK_19	#A7
Pack is already inactive	Attempt to decommission an already decommissioned pack	A decommissioning was attempted for a pack that is already inactive.	NMVS_NC_PCK_22	#A24
Defined timeframe between setting this property and the undo was exceeded	Time Limit Exceeded	Maximum delay (10 days) between decommissioning and undo was exceeded (applicable when an IMT is triggered).	NMVS_NC_PCK_20	#A4
Undo can only be executed by the same user who previously set the attribute	Undo can only be executed by the same user who previously set the attribute	Undo can only be executed at the same location (i.e. the same end user) where the original transaction occurred (applicable when an IMT is triggered).	NMVS_NC_PCK_21	#A5



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Alert message (Arvato NMVS)	Alert message (EU Hub)	Meaning	Alert code (Arvato NMVS)	Alert code (EU Hub)
Actual pack status doesn't match the undo transaction (set and undo status must be equivalent)	Attempt to decommission an already decommissioned pack	Undo transaction does not match pack status (e.g. Undo Dispense attempted for a pack in status SAMPLE).	NMVS_NC_PCK_06	#A24
Status change could not be performed	Attempt to decommission an already decommissioned pack	A decommissioning was attempted for a pack that is already inactive (applicable when an IMT is triggered).	NMVS_NC_PCK_27	#A24



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3. Eliminate and prevent alerts

All level 5 alerts raised by the PTMVS are analysed by PTMVO 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 that caused the alert in the system. The responsible entity for causing the alerts may or may not be the entity where the alerts were 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/PIAH, Wholesaler, Pharmacy or Hospital.

The most probable causes of the alerts and the measures to eliminate alerts presented in this document result from the experience of having analysed the alerts raised by PTMVS and the respective measures already implemented to eliminate the alerts from the system and from the experiences (analysis and solutions) shared within the European NMVO community.

3.1 Market Authorization Holders (MAH) and Parallel Import Authorization Holders (PIAH)

In this sub-chapter are described the most probable causes of the alerts, when these are attributable to MAH or PIAH. If applied correctly, the measures presented to each case would 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 in the market. In case of need, contact MVO Portugal by email to alertas@mvoportugal.pt to request confirmation of successful data upload.



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#	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.	<p>For all batches released before 9th February 2019 bearing 2D matrix codes, upload product and pack data into the EU-Hub.</p> <p>For all batches released before 9th February 2019 bearing 2D matrix codes, and all non-FMD medicines (e.g. Indian packs) must be reported via the form MVOPT-0077 Non-FMD products released to the Portuguese market v1.0 and sent by email to alertas@mvoportugal.pt.</p>
3	Product Not Found	A1	<p>Wrong encoding of the 2D code elements (e.g. GTIN with less than 14 characters).</p> <p>Wrong separation of the elements in the 2D (e.g. not separating the serial number or batch Id from the NN).</p> <p>Wrong identification of the 2D elements (e.g. encode the NN as the GTIN).</p>	<p>Ensure correct data encoding into the 2D code.</p> <p>Ensure both master data and pack data are uploaded into the EMVS and that is done before the packs reach physically the market.</p> <p>Ensure the data encoded into the 2D code is identical to the data uploaded into the EMVS.</p> <p>Any encoding error must be communicated to MVO Portugal via the form MVOPT-0075 Report of problems by MAH PIAH v1.0 and sent by email to alertas@mvoportugal.pt.</p>
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.	<p>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.</p> <p>Any printing errors must be communicated to MVO Portugal via the form MVOPT-0075 Report of problems by MAH PIAH v1.0 and sent by email to alertas@mvoportugal.pt.</p>
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.	<p>Master data and pack data must be loaded into the system before the packs are placed in the market.</p> <p>In case of need, contact MVO Portugal by email to alertas@mvoportugal.pt to request confirmation of successful data upload.</p>



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#	Alert Type	Alert code	Most probable causes	Measures to eliminate and prevent alerts
6	Batch Not Found	A2	<p>Wrong encoding of the 2D code elements (e.g. misuse of upper case and lower case).</p> <p>Wrong separation of the elements in the 2D (e.g. not separating the serial number or batch Id from the NN).</p> <p>Wrong identification of the 2D elements (e.g. encode the NN as the GTIN).</p> <p>Data not identical in both the pack and the system.</p>	<p>Ensure correct data encoding into the 2D code.</p> <p>Ensure both master data and pack data are uploaded into the EMVS and that is done before the packs reach physically the market.</p> <p>Ensure the data encoded into the 2D code is identical to the data uploaded into the EMVS.</p> <p>Any encoding errors must be communicated to MVO Portugal via the form MVOPT-0075 Report of problems by MAH PIAH v1.0 and sent by email to alertas@mvoportugal.pt.</p>
7	Pack Not Found	A3	<p>Pack data was not uploaded into the EMVS at the moment the end-user performed the transaction that originated the alert.</p> <p>Packs physically released to the market but whose data was not uploaded into the EMVS (e.g. retained quality samples).</p>	<p>Master data and pack data must be loaded into the system before the packs are placed in the market.</p> <p>In case of need, contact MVO Portugal by email to alertas@mvoportugal.pt to request confirmation of successful data upload (specific serial numbers are not possible to confirm as the data is not accessible).</p>
8	Pack Not Found	A3	<p>Wrong encoding of the 2D code elements (e.g. misuse of upper case and lower case).</p> <p>Wrong separation of the elements in the 2D (e.g. not separating the serial number or batch Id from the NN).</p> <p>Wrong identification of the 2D elements (e.g. encode the NN as the GTIN).</p> <p>Data not identical in both the pack and the system.</p>	<p>Ensure correct data encoding into the 2D code.</p> <p>Ensure both master data and pack data are uploaded into the EMVS and that is done before the packs reach physically the market.</p> <p>Ensure the data encoded into the 2D code is identical to the data uploaded into the EMVS.</p> <p>Any encoding errors must be communicated to MVO Portugal via the form MVOPT-0075 Report of problems by MAH PIAH v1.0 and sent by email to alertas@mvoportugal.pt.</p>



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#	Alert Type	Alert code	Most probable causes	Measures to eliminate and prevent alerts
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 MVO Portugal via the form MVOPT-0075 Report of problems by MAH PIAH v1.0 and sent by email to alertas@mvoportugal.pt .
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 human readable expiry date has only month and year, then the expiry date in the 2D code should be YYMM00 (two zeros at the end). Any expiry date errors must be communicated to MVO Portugal via the form MVOPT-0075 Report of problems by MAH PIAH v1.0 and sent by email to alertas@mvoportugal.pt .



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#	Alert Type	Alert code	Most probable causes	Measures to eliminate and prevent alerts
11	Batch Number Mismatch	A68	<p>Wrong encoding of the 2D code elements (e.g. misuse of upper case and lower case in the batch ID).</p> <p>Wrong separation of the elements in the 2D (e.g. not separating the batch id from the NN).</p> <p>Wrong identification of the 2D elements (e.g. encode the NN as the GTIN).</p> <p>Wrong data encoded into the pack (e.g. encoding a valid serial number that belongs to another batch).</p> <p>Wrong data uploaded into the EMVS (valid batch id and valid serial number but serial number belongs to another batch).</p> <p>Data not identical in both the pack and the system.</p>	<p>Ensure correct data encoding into the 2D code.</p> <p>Ensure both master data and pack data are uploaded into the EMVS.</p> <p>Ensure the data encoded into the 2D code is identical to the data uploaded into the EMVS.</p> <p>Any encoding error must be communicated to MVO Portugal via the form MVOPT-0075 Report of problems by MAH PIAH v1.0 and sent by email to alertas@mvoportugal.pt.</p>



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3.2 Wholesalers

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

#	Alert Type	Alert code	Most probable causes	Measures to eliminate and prevent alerts
1	Unknown product code	NMVS_NC_PC_01	<p>Alerts caused by scanner misconfiguration (problems in the scanner device and/or in the associated software):</p> <p>Wrong identification of the 2D elements (e.g. consider the NN as the GTIN).</p> <p>Wrong separation of the elements in the 2D code (e.g. consider a GTIN with less/more than 14 digits).</p>	<p>Ensure correct scanner/software configuration (e.g. group separators). Involve scanner/software suppliers if necessary.</p> <p>The scanner/software must transfer the exact content of the 2D code read, with no interpretations. More information on scanner configuration can be found here.</p> <p>The identified problems must be communicated to MVO Portugal via the form MVOPT-0073 Report of problems by End Users v1.0 and sent by email to alertas@mvoptugal.pt.</p>



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#	Alert Type	Alert code	Most probable causes	Measures to eliminate and prevent alerts
2	Failed to find a batch for the given data	NMVS_FE_LOT_03	<p>Alerts caused by scanner misconfiguration (problems in the scanner device and/or in the associated software):</p> <p>Wrong interpretation of upper case/lower case (e.g. the batch id is "A1B2C3" but is read by the scanner as "a1b2c3").</p> <p>No read of special characters in batch id (e.g. the batch id "12345-B1" is read by the scanner as "12345B1").</p> <p>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).</p> <p>Wrong separation of the elements in the 2D code (e.g. consider a concatenation of the batch id and the NN as the batch id).</p>	<p>Ensure correct scanner/software configuration (e.g. character set conversion). Involve scanner/software suppliers if necessary.</p> <p>The scanner/software must transfer the exact content of the 2D code read, with no interpretations.</p> <p>The scanner/software must retrieve the exact content of the 2D code, with no interpretations.</p> <p>More information on scanner configuration can be found here.</p> <p>The identified problems must be communicated to MVO Portugal via the form MVOPT-0073 Report of problems by End Users v1.0 and sent by email to alertas@mvoportugal.pt.</p>



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#	Alert Type	Alert code	Most probable causes	Measures to eliminate and prevent alerts
3	Unknown serial number	NMVS_NC_PC_02	<p>Alerts caused by scanner misconfiguration (problems in the scanner device and/or in the associated software):</p> <p>Wrong interpretation of upper case/lower case (e.g. the serial number is "A1B2C3" but is read by the scanner as "a1b2c3").</p> <p>Unread special characters in the serial number (e.g. the serial number is "12345-B1" but is read by the scanner as "12345B1").</p> <p>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).</p> <p>Wrong separation of the elements in the 2D code (e.g. consider a concatenation of the serial number and the NN as the serial number).</p>	<p>Ensure correct scanner/software configuration (e.g. reverse printing). Involve scanner/software suppliers if necessary.</p> <p>The scanner/software must transfer the exact content of the 2D code read, with no interpretations. More information on scanner configuration can be found here.</p> <p>The identified problems must be communicated to MVO Portugal via the form MVOPT-0073 Report of problems by End Users v1.0 and sent by email to alertas@mvoportugal.pt.</p>



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#	Alert Type	Alert code	Most probable causes	Measures to eliminate and prevent alerts
4	Expiry date does not match the date held in the NMVS	NMVS_FE_LOT_12	<p>Alerts caused by scanner misconfiguration (problems in the scanner device and/or in the associated software):</p> <p>Read the expiry date in reverse order (i.e. instead of reading YYMMDD, the scanner reads DDMMYY).</p> <p>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).</p> <p>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).</p> <p>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).</p>	<p>Ensure correct scanner/software configuration (e.g. interface). Involve scanner/software suppliers if necessary.</p> <p>The scanner/software must retrieve the exact content of the 2D code, with no interpretations. More information on scanner configuration can be found here.</p> <p>The identified problems must be communicated to MVO Portugal via the form MVOPT-0073 Report of problems by End Users v1.0 and sent by email to alertas@mvoportugal.pt.</p>



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#	Alert Type	Alert code	Most probable causes	Measures to eliminate and prevent alerts
5	The batch ID does not match the serial number in the NMVS	NMVS_FE_LOT_13	<p>Alerts caused by scanner misconfiguration (problems in the scanner device and/or in the associated software):</p> <p>Wrong interpretation of upper case/lower case (e.g. the batch id is "A1B2C3" but is read by the scanner as "a1b2c3").</p> <p>Unread special characters in batch id (e.g. the batch id "12345-B1" is read by the scanner as "12345B1").</p> <p>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).</p> <p>Wrong separation of the elements in the 2D code (e.g. consider a concatenation of the batch id and the NN as the batch id).</p>	<p>Ensure correct scanner/software configuration (e.g. character set configuration). Involve scanner/software suppliers if necessary.</p> <p>The scanner/software must retrieve the exact content of the 2D code, with no interpretations. More information on scanner configuration can be found here.</p> <p>The identified problems must be communicated to MVO Portugal via the form MVOPT-0073 Report of problems by End Users v1.0 and sent by email to alertas@mvoportugal.pt.</p>



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#	Alert Type	Alert code	Most probable causes	Measures to eliminate and prevent alerts
6	Pack is already inactive	NMVS_NC_PCK_22	Repetition of a decommissioning operation on an already decommissioned pack. The pack was initially decommissioned by the wholesaler itself or another wholesaler.	<p>Before performing the decommission operation, always perform a verify operation. If the pack is already inactive, do not try to decommission again.</p> <p>For bulk transactions, the end-user system must not allow a second call to the PTMVS before receiving the response to the first call.</p> <p>Retry mechanisms in the End User systems must be developed and configured so that they do not generate unnecessary retries:</p> <ul style="list-style-type: none"> • 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 and mixed bulk transactions: results should be requested with a minimum of 1 minute after the original transaction was requested. The original bulk transaction must not be retried if the result is not received, successful or return code unknown. <p>The identified problems must be communicated to MVO Portugal via the form MVOPT-0073 Report of problems by End Users v1.0 and sent by email to alertas@mvoportugal.pt.</p>



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#	Alert Type	Alert code	Most probable causes	Measures to eliminate and prevent alerts
7	Pack is already inactive	NMVS_NC_PCK_22	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.	<p>Ensure the packs are delivered in active state to pharmacies and hospitals.</p> <p>Correctly maintain the product and customer master data in order to identify which products and clients require decommission or not.</p> <p>The lists of hospitals that need to receive the packs in active state can be found here, here and here.</p> <p>The identified problems must be communicated to MVO Portugal via the form MVOPT-0073 Report of problems by End Users v1.0 and sent by email to alertas@mvoportugal.pt.</p>
8	Defined timeframe between setting this property and the undo was exceeded	NMVS_NC_PCK_20	<p>Undo transactions were performed after the 10 days immediately after the initial transaction.</p> <p>Undo operations can only be performed in the 10 days immediately after the initial transaction.</p>	<p>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.</p> <p>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.</p>



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#	Alert Type	Alert code	Most probable causes	Measures to eliminate and prevent alerts
9	Undo can only be executed by the same user who previously set the attribute	NMVS_NC_PCK_21	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.	<p>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.</p> <p>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.</p> <p>The identified problems must be communicated to MVO Portugal via the form MVOPT-0073 Report of problems by End Users v1.0 and sent by email to alertas@mvoportugal.pt.</p>
10	Input data does not match the XML schema definition	NMVS_TE_XM_02	Undo manual transactions performed without batch ID and the expiry date.	<p>The End User systems must request the batch ID and expiry date in the manual transactions, as these are mandatory fields for the undo transactions.</p> <p>The identified problems must be communicated to MVO Portugal via the form MVOPT-0073 Report of problems by End Users v1.0 and sent by email to alertas@mvoportugal.pt.</p>



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3.3 Pharmacies

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

#	Alert Type	Alert code	Most probable causes	Measures to eliminate alerts
1	Unknown product code	NMVS_NC_PC_01	Manual insertion of pack data of a non-serialized pack.	<p>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.</p> <p>In case the pack bears a 2D code, the End User must always read the 2D code and communicate it to the PtMVS.</p> <p>The identified problems must be communicated to MVO Portugal via the form MVOPT-0073 Report of problems by End Users v1.0 and sent by email to alertas@mvoportugal.pt.</p>



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#	Alert Type	Alert code	Most probable causes	Measures to eliminate alerts
2	Unknown product code	NMVS_NC_PC_01	Wrong manual insertion of the human readable elements.	<p>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 are to be used the least possible.</p> <p>In case of use of manual transactions, ensure that the insertion of the unique identifier elements (GTIN and serial number) are correctly inserted. The PtMVS provides 3 attempts to insert incorrect information before generating a L5 alert.</p> <p>The identified problems must be communicated to MVO Portugal via the form MVOPT-0073 Report of problems by End Users v1.0 and sent by email to alertas@mvoportugal.pt.</p>
3	Unknown product code	NMVS_NC_PC_01	<p>Alerts caused by scanner misconfiguration (problems in the scanner device and/or in the associated software):</p> <p>Wrong identification of the 2D elements (e.g. consider the NN as the GTIN).</p> <p>Wrong separation of the elements in the 2D code (e.g. consider a GTIN with less/more than 14 digits).</p>	<p>Ensure correct scanner/software configuration (e.g. group separators). Involve scanner/software suppliers if necessary.</p> <p>The scanner/software must transfer the exact content of the 2D code, with no interpretations. More information on scanner configuration can be found here.</p> <p>The identified problems must be communicated to MVO Portugal via the form MVOPT-0073 Report of problems by End Users v1.0 and sent by email to alertas@mvoportugal.pt.</p>



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#	Alert Type	Alert code	Most probable causes	Measures to eliminate alerts
4	Unknown product code	NMVS_NC_PC_01	Upon an unsuccessful manual transaction, the pharmacy software creates series of calls on the same pack which in turn create alerts for the same pack in fixed time intervals (e.g. every ten minutes).	<p>The development and/or configuration of the pharmacy software must be reviewed so the error is corrected.</p> <p>Retry mechanisms in the End User systems must be developed and configured so that they do not generate unnecessary retries: only known and configured return codes or return system messages should generate retry attempts. Time between retries should increase with the number of attempts.</p> <p>The identified problems must be communicated to MVO Portugal via the form MVOPT-0073 Report of problems by End Users v1.0 and sent by email to alertas@mvoportugal.pt.</p>



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#	Alert Type	Alert code	Most probable causes	Measures to eliminate alerts
5	Failed to find a batch for the given data	NMVS_FE_LOT_03	<p>Alerts caused by scanner misconfiguration (problems in the scanner device and/or in the associated software):</p> <p>Wrong interpretation of upper case/lower case (e.g. the batch id is "A1B2C3" but is read by the scanner as "a1b2c3").</p> <p>No read of special characters in batch id (e.g. the batch id "12345-B1" is read by the scanner as "12345B1").</p> <p>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).</p> <p>Wrong separation of the elements in the 2D code (e.g. consider a concatenation of the batch id and the NN as the batch id).</p> <p>The speed of the scanner reading is not adjusted. In cases of a sale with more than one pack, the scanner mixes the elements of the packs (e.g. in the same transaction, considers the GTIN of one pack and the batch id of another).</p>	<p>Ensure correct scanner/software configuration (e.g. character set conversion). Involve scanner/software suppliers if necessary.</p> <p>The scanner/software must transfer the exact content of the 2D code read, with no interpretations. More information on scanner configuration can be found here.</p> <p>The identified problems must be communicated to MVO Portugal via the form MVOPT-0073 Report of problems by End Users v1.0 and sent by email to alertas@mvoportugal.pt.</p>



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#	Alert Type	Alert code	Most probable causes	Measures to eliminate alerts
6	Unknown serial number	NMVS_NC_PC_02	<p>Alerts caused by scanner misconfiguration (problems in the scanner device and/or in the associated software):</p> <p>Wrong interpretation of upper case/lower case (e.g. the serial number is "A1B2C3" but is read by the scanner as "a1b2c3").</p> <p>No read of special characters in the serial number (e.g. the serial number is "12345-B1" but is read by the scanner as "12345B1").</p> <p>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).</p> <p>Wrong separation of the elements in the 2D code (e.g. consider a concatenation of the serial number and the NN as the serial number).</p> <p>The speed of the scanner reading is not adjusted. In cases of a sale with more than one pack, the scanner mixes the elements of the packs (e.g. in the same transaction, considers the GTIN of one pack and the batch id of another).</p>	<p>Ensure correct scanner/software configuration. Involve scanner/software suppliers if necessary.</p> <p>The scanner/software must transfer the exact content of the 2D code, with no interpretations. More information on scanner configuration can be found here.</p> <p>The identified problems must be communicated to MVO Portugal via the form MVOPT-0073 Report of problems by End Users v1.0 and sent by email to alertas@mvoportugal.pt.</p>



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#	Alert Type	Alert code	Most probable causes	Measures to eliminate alerts
7	Unknown serial number	NMVS_NC_PC_02	Upon an unsuccessful manual transaction, the pharmacy software creates series of calls on the same pack which in turn create alerts for the same pack in fixed time intervals (e.g. every ten minutes).	<p>The development and/or configuration of the pharmacy software must be reviewed so the error is corrected.</p> <p>Retry mechanisms in the End User systems must be developed and configured so that they do not generate unnecessary retries: only known and configured return codes or return system messages should generate retry attempts. Time between retries should increase with the number of attempts.</p> <p>The identified problems must be communicated to MVO Portugal via the form MVOPT-0073 Report of problems by End Users v1.0 and sent by email to alertas@mvoportugal.pt.</p>



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#	Alert Type	Alert code	Most probable causes	Measures to eliminate alerts
8	Expiry date does not match the date held in the NMVS	NMVS_FE_LOT_12	<p>Alerts caused by scanner misconfiguration (problems in the scanner device and/or in the associated software):</p> <p>Read the expiry date in reverse order (i.e. instead of reading YYMMDD, the scanner reads DDMMYY).</p> <p>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).</p> <p>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).</p> <p>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).</p>	<p>Ensure correct scanner/software configuration (e.g. interface). Involve scanner/software suppliers if necessary.</p> <p>The scanner/software must transfer the exact content of the 2D code, with no interpretations. More information on scanner configuration can be found here.</p> <p>The identified problems must be communicated to MVO Portugal via the form MVOPT-0073 Report of problems by End Users v1.0 and sent by email to alertas@mvoportugal.pt.</p>



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#	Alert Type	Alert code	Most probable causes	Measures to eliminate alerts
9	The batch ID does not match the serial number in the NMVS	NMVS_FE_LOT_13	<p>Alerts caused by scanner misconfiguration (problems in the scanner device and/or in the associated software):</p> <p>Wrong interpretation of upper case/lower case (e.g. the batch id is "A1B2C3" but is read by the scanner as "a1b2c3").</p> <p>Unread special characters in batch id (e.g. the batch id "12345-B1" is read by the scanner as "12345B1").</p> <p>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).</p> <p>Wrong separation of the elements in the 2D code (e.g. consider a concatenation of the batch id and the NN as the batch id).</p> <p>The speed of the scanner reading is not adjusted. In cases of a sale with more than one pack, the scanner mixes the elements of the packs (e.g. in the same transaction, considers the GTIN of one pack and the batch id of another).</p>	<p>Ensure correct scanner/software configuration (e.g. character set configuration). Involve scanner/software suppliers if necessary.</p> <p>The scanner/software must transfer the exact content of the 2D code, with no interpretations. More information on scanner configuration can be found here.</p> <p>The identified problems must be communicated to MVO Portugal via the form MVOPT-0073 Report of problems by End Users v1.0 and sent by email to alertas@mvoportugal.pt.</p>
10	Pack is already inactive	NMVS_NC_PCK_22	<p>Repetition of a decommissioning operation on an already decommissioned pack. The pack was initially decommissioned by the pharmacy itself.</p>	<p>Before performing the decommission operation, always perform a verify operation. If the pack is already inactive, do not try to decommission again.</p> <p>The identified problems must be communicated to MVO Portugal via the form MVOPT-0073 Report of problems by End Users v1.0 and sent by email to alertas@mvoportugal.pt.</p>



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#	Alert Type	Alert code	Most probable causes	Measures to eliminate alerts
11	Defined timeframe between setting this property and the undo was exceeded	NMVS_NC_PCK_20	<p>Undo transactions was performed after the 10 days immediately after the initial transaction.</p> <p>Undo operations can only be performed in the 10 days immediately after the initial transaction.</p>	<p>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.</p> <p>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.</p> <p>The identified problems must be communicated to MVO Portugal via the form MVOPT-0073 Report of problems by End Users v1.0 and sent by email to alertas@mvoportugal.pt.</p>



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#	Alert Type	Alert code	Most probable causes	Measures to eliminate alerts
12	Undo can only be executed by the same user who previously set the attribute	NMVS_NC_PCK_21	<p>Undo transaction was performed by a user that did not perform the initial transaction.</p> <p>Undo transactions can only be performed by the same user that performed the initial transaction.</p>	<p>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.</p> <p>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.</p> <p>The identified problems must be communicated to MVO Portugal via the form MVOPT-0073 Report of problems by End Users v1.0 and sent by email to alertas@mvoportugal.pt.</p>
13	Input data does not match the XML schema definition	NMVS_TE_XM_02	<p>Undo manual transactions performed without batch ID and the expiry date.</p>	<p>The end user systems must request the batch ID and expiry date in the undo manual transactions, as these are mandatory fields for the undo transactions.</p> <p>The identified problems must be communicated to MVO Portugal via the form MVOPT-0073 Report of problems by End Users v1.0 and sent by email to alertas@mvoportugal.pt.</p>



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3.4 Hospitals

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

#	Alert Type	Alert code	Most probable causes	Measures to eliminate alerts
1	Unknown product code	NMVS_NC_PC_01	Manual insertion of pack data of a non-serialized pack.	<p>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.</p> <p>In case the pack bears a 2D code, the End User must always read the 2D code and communicate it to the PtMVS.</p> <p>The identified problems must be communicated to MVO Portugal via the form MVOPT-0073 Report of problems by End Users v1.0 and sent by email to alertas@mvoptugal.pt.</p>



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#	Alert Type	Alert code	Most probable causes	Measures to eliminate alerts
2	Unknown product code	NMVS_NC_PC_01	Wrong manual insertion of the human readable elements.	<p>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 are to be used the least possible.</p> <p>In case of use of manual transactions, ensure that the insertion of the unique identifier elements (GTIN and serial number) are correctly inserted. The PtMVS provides 3 attempts to insert incorrect information before generating a L5 alert.</p> <p>The identified problems must be communicated to MVO Portugal via the form MVOPT-0073 Report of problems by End Users v1.0 and sent by email to alertas@mvoportugal.pt.</p>
3	Unknown product code	NMVS_NC_PC_01	<p>Alerts caused by scanner misconfiguration (problems in the scanner device and/or in the associated software):</p> <p>Wrong identification of the 2D elements (e.g. consider the NN as the GTIN).</p> <p>Wrong separation of the elements in the 2D code (e.g. consider a GTIN with less/more than 14 digits).</p>	<p>Ensure correct scanner/software configuration (e.g. group separators). Involve scanner/software suppliers if necessary.</p> <p>The scanner/software must transfer the exact content of the 2D code, with no interpretations.</p> <p>More information on scanner configuration can be found here.</p> <p>The identified problems must be communicated to MVO Portugal via the form MVOPT-0073 Report of problems by End Users v1.0 and sent by email to alertas@mvoportugal.pt.</p>



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#	Alert Type	Alert code	Most probable causes	Measures to eliminate alerts
4	Failed to find a batch for the given data	NMVS_FE_LOT_03	<p>Alerts caused by scanner misconfiguration (problems in the scanner device and/or in the associated software):</p> <p>Wrong interpretation of upper case/lower case (e.g. the batch id is "A1B2C3" but is read by the scanner as "a1b2c3").</p> <p>No read of special characters in batch id (e.g. the batch id "12345-B1" is read by the scanner as "12345B1").</p> <p>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).</p> <p>Wrong separation of the elements in the 2D code (e.g. consider a concatenation of the batch id and the NN as the batch id).</p> <p>The speed of the scanner reading is not adjusted. In cases of a sale with more than one pack, the scanner mixes the elements of the packs (e.g. in the same transaction, considers the GTIN of one pack and the batch id of another).</p>	<p>Ensure correct scanner/software configuration (e.g. character set conversion). Involve scanner/software suppliers if necessary.</p> <p>The scanner/software must transfer the exact content of the 2D code read, with no interpretations. More information on scanner configuration can be found here.</p> <p>The identified problems must be communicated to MVO Portugal via the form MVOPT-0073 Report of problems by End Users v1.0 and sent by email to alertas@mvoportugal.pt.</p>



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#	Alert Type	Alert code	Most probable causes	Measures to eliminate alerts
5	Unknown serial number	NMVS_NC_PC_02	<p>Alerts caused by scanner misconfiguration (problems in the scanner device and/or in the associated software):</p> <p>Wrong interpretation of upper case/lower case (e.g. the serial number is "A1B2C3" but is read by the scanner as "a1b2c3").</p> <p>No read of special characters in the serial number (e.g. the serial number is "12345-B1" but is read by the scanner as "12345B1").</p> <p>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).</p> <p>Wrong separation of the elements in the 2D code (e.g. consider a concatenation of the serial number and the NN as the serial number).</p> <p>The speed of the scanner reading is not adjusted. In cases of a sale with more than one pack, the scanner mixes the elements of the packs (e.g. in the same transaction, considers the GTIN of one pack and the batch id of another).</p>	<p>Ensure correct scanner/software configuration. Involve scanner/software suppliers if necessary.</p> <p>The scanner/software must transfer the exact content of the 2D code, with no interpretations. More information on scanner configuration can be found here.</p> <p>The identified problems must be communicated to MVO Portugal via the form MVOPT-0073 Report of problems by End Users v1.0 and sent by email to alertas@mvoportugal.pt.</p>



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#	Alert Type	Alert code	Most probable causes	Measures to eliminate alerts
6	Expiry date does not match the date held in the NMVS	NMVS_FE_LOT_12	<p>Alerts caused by scanner misconfiguration (problems in the scanner device and/or in the associated software):</p> <p>Read the expiry date in reverse order (i.e. instead of reading YYMMDD, the scanner reads DDMMYY).</p> <p>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).</p> <p>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).</p> <p>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).</p>	<p>Ensure correct scanner/software configuration (e.g. interface). Involve scanner/software suppliers if necessary.</p> <p>The scanner/software must transfer the exact content of the 2D code, with no interpretations. More information on scanner configuration can be found here.</p> <p>The identified problems must be communicated to MVO Portugal via the form MVOPT-0073 Report of problems by End Users v1.0 and sent by email to alertas@mvoportugal.pt.</p>



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#	Alert Type	Alert code	Most probable causes	Measures to eliminate alerts
7	The batch ID does not match the serial number in the NMVS	NMVS_FE_LOT_13	<p>Alerts caused by scanner misconfiguration (problems in the scanner device and/or in the associated software):</p> <p>Wrong interpretation of upper case/lower case (e.g. the batch id is "A1B2C3" but is read by the scanner as "a1b2c3").</p> <p>Unread special characters in batch id (e.g. the batch id "12345-B1" is read by the scanner as "12345B1").</p> <p>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).</p> <p>Wrong separation of the elements in the 2D code (e.g. consider a concatenation of the batch id and the NN as the batch id).</p> <p>The speed of the scanner reading is not adjusted. In cases of a sale with more than one pack, the scanner mixes the elements of the packs (e.g. in the same transaction, considers the GTIN of one pack and the batch id of another).</p>	<p>Ensure correct scanner/software configuration (e.g. character set configuration). Involve scanner/software suppliers if necessary.</p> <p>The scanner/software must transfer the exact content of the 2D code, with no interpretations. More information on scanner configuration can be found here.</p> <p>The identified problems must be communicated to MVO Portugal via the form MVOPT-0073 Report of problems by End Users v1.0 and sent by email to alertas@mvoportugal.pt.</p>
8	Pack is already inactive	NMVS_NC_PCK_22	<p>Repetition of a decommissioning operation on an already decommissioned pack. The pack was initially decommissioned by the pharmacy itself.</p>	<p>Before performing the decommission operation, always perform a verify operation. If the pack is already inactive, do not try to decommission again.</p> <p>The identified problems must be communicated to MVO Portugal via the form MVOPT-0073 Report of problems by End Users v1.0 and sent by email to alertas@mvoportugal.pt.</p>



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#	Alert Type	Alert code	Most probable causes	Measures to eliminate alerts
9	Defined timeframe between setting this property and the undo was exceeded	NMVS_NC_PCK_20	<p>Undo transactions was performed after the 10 days immediately after the initial transaction.</p> <p>Undo operations can only be performed in the 10 days immediately after the initial transaction.</p>	<p>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.</p> <p>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.</p> <p>The identified problems must be communicated to MVO Portugal via the form MVOPT-0073 Report of problems by End Users v1.0 and sent by email to alertas@mvoportugal.pt.</p>



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#	Alert Type	Alert code	Most probable causes	Measures to eliminate alerts
10	Undo can only be executed by the same user who previously set the attribute	NMVS_NC_PCK_21	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.	<p>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.</p> <p>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.</p> <p>The identified problems must be communicated to MVO Portugal via the form MVOPT-0073 Report of problems by End Users v1.0 and sent by email to alertas@mvoportugal.pt.</p>
11	Input data does not match the XML schema definition	NMVS_TE_XM_02	Undo manual transactions performed without batch ID and the expiry date.	<p>The end user systems must request the batch ID and expiry date in the undo manual transactions, as these are mandatory fields for the undo transactions.</p> <p>The identified problems must be communicated to MVO Portugal via the form MVOPT-0073 Report of problems by End Users v1.0 and sent by email to alertas@mvoportugal.pt.</p>



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4. Contacts

For the purpose of communicating with MVO Portugal regarding alerts, the following points of contact are to be used:

- Email: alertas@mvoportugal.pt;
- Phone number: +351 211 608 378.



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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, to the wholesaler systems and to the pharmacy 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 PTMVS. Is contracted by the End User.
MAH	Marketing Authorisation Holder.
NCA	National Competent Authority (In Portugal, INFARMED I.P.).
NN	National Reimbursement Number (also known as NHRN).
PIAH	Parallel Import Authorisation Holder.
PTMVO or MVOPT	Portuguese Medicines Verification Organisation.
PTMVS	Portuguese Medicines Verification System. A system in the European Medicines Verification landscape that serves as the verification platform for Portugal. The End Users registered (Pharmacies, Wholesalers, Hospitals or Other kind of End Users in the Portuguese context) check the authenticity of a product using a connection to this system.
SOP	Standard Operational Procedure.
User	A specific person that has authorized access to the End User system.



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6. Related documents

Document Identification	Title
MVOPT-0072	Medidas para eliminação e prevenção de alertas
MVOPT-0073	Report of problems by End Users
MVOPT-0074	Reporte de problemas por Utilizadores Finais
MVOPT-0075	Report of problems by MAH_PIAH
MVOPT-0076	Reporte de problemas por TAIM_AIP
MVOPT-0077	Non-FMD products released to the Portuguese market
MVOPT-0078	Reporte de lotes serializados que não se encontram ao abrigo do Regulamento Delegado