Belgian Medicines Verification System

Incident management & Alert handling procedures

Technical implementation document for End Users and Software Suppliers

Version 3/08/2018

Reviewed by FAGG/AFMPS & BeMVO

Content

I.   PURPOSE

The objective of this document is to provide additional information and recommendations to the Software Suppliers (SWS) on how the management of incidents and potential falsification alerts can be handled in the end user's systems.

This document is focusing on
a) Incidents in terms of the return codes that are generated by the verification system, what is expected from the end users, SWS and BeMVO (see chapter IV)
b) Return codes that indicate a potential falsification, and the procedure that has been aligned with FAGG/AFMPS (see chapter V)

II.   SCOPE

Within the scope of this document are incidents caused by the return codes generated by the verification system. In this document we will focus on the return codes and messages generated by the system when submitting a query through the webservices.
Messages produced by the GUI are similar to the messages returned for the webservices, but are not further specified in this document.
Also to note that this version of the document is based on the current set up of the system and agreed procedures. The evolution of the system and future 'real life' practices might lead to updated versions of this document.

NOTE: this document was primary elaborated for the Belgian market, but the principles can also be applied in Luxembourg for the Luxembourg users.

III.   DEFINITONS

ATD	Anti-Tampering Device
BeMVO	Belgian Medicines Verification Organisation
BMVS/NMVS	The Belgian National verification system
EMVS	European verification system, EU Hub and all connected National systems
GUI	Graphical User Interface (User access through the internet browser)
NCA	National competent authorities (mainly FAGG/AFMPS)
SWS	Software Suppliers and internal IT departments
User	The end user

	Medicines Verification system		
	Medicines Verification system **Incident management & Alert handling procedures**		
BMVS_Incidents	SWS documentation	1/10/2018	FAGG/AFMPS - BeMVO

Belgian Medicines Verification Organisation

IV.   INCIDENTS Management

IV.1   Incidents handling

When submitting a webservice query to the BMVS, the XML response of the system is containing a return code and the corresponding message.

The expected, positive return code is "NMVS_SUCCESS" with the description "Successfully processed", indicating that the query could be processed as expected, providing additional information where appropriate (e.g. in case of a verification: provide the state of the pack).

However, BMVS can also provide a different message indicating that something went wrong. Examples are: login credentials of user invalid, technical issue with the system, …
Specific messages can also indicate that the pack is a potentially falsified pack. These messages will be discussed in chapter V on the Alerts.

BeMVO suggests that the return codes and messages are not shown as such to the user, but that FMD processes in the user's system are presented in a way that it is immediately clear for the user, allowing him to assess immediately what action (or no action) he should take. The 'technical terms' of the return codes and messages are not visible to the end user.

IV.2   Incidents classification

The messages to the user could be classified in 3 categories, with additional information shown in a 2nd level. The 3 categories are:

1. **YES, the pack can be delivered**
   In general this message should not be presented. To inform the user that no return messages implies that the process was executed correctly, except for a verification where the 2nd level can provide additional information: provide the state of the pack

2. **YES, But …**
   In this case the pack can be delivered, but the user (or the user's system) must be aware that an error message was provided which might request additional action from him, the SWS or BeMVO. An explanation text for the 'orange alert' can be provided in the 2nd level additional information.

3. **NO, the pack cannot be delivered**
   The pack cannot be delivered by the user and the 2nd level provides the reason.

In attachment A, the list of return codes and messages have been classified in the different categories.

	BeMVO Belgian Medicines Verification Organisation

	Medicines Verification system **Incident management & Alert handling procedures**		
BMVS_Incidents	SWS documentation	1/10/2018	FAGG/AFMPS - BeMVO

The different types of "YES, but…" related messages are:

a) BMVS issue

Meaning	A set of return codes indicating an issue with the BMVS.
Action	**User**: makes a judgment on the authenticity of the pack, verifies the ATD and can decide that it is safe to deliver the pack. The user stores the pack data and verification is done at a later moment when the system is running again. **SWS**: The user is informed. His system stores the pack information and submits it for verification and transaction at a later moment.

b) User access issue – Login/password

Meaning	A set of return codes indicating an issue with the user's login/password credentials.
Action	**User**: If the user or the user's system cannot resolve the issue immediately, then the user makes a judgment on the authenticity of the pack, verifies the ATD and can decide that it is safe to deliver the pack. Verification is done at a later moment when the login issue is solved. **SWS**: Update the user's password by running webservice G445 (see password renewal procedure).

c) User access issue – Certificate

Meaning	A set of return codes indicating an issue with the user's certificate.
Action	**User**: If the user or the user's system cannot resolve the issue immediately, then the user makes a judgment on the authenticity of the pack, verifies the ATD and can decide that it is safe to deliver the pack. Verification is done at a later moment when the certificate issue is solved. **SWS**: Update the user's certificate by running webservice G615 (see certificate renewal procedure).

d) User access issue – Infringement

Meaning	This is a specific return code indicating that the user is trying to perform a transaction that is not allowed for his role, eg a user with Role Pharmacy is trying to do transaction "Export". Such error should not occur is the verification solution has been implemented correctly at the user's level.
Action	**SWS**: The user should receive a message that he is not allowed to do this transaction and be invited to contact his SWS provider to report the error message. The SWS should check the software and make sure that the user's system cannot do not-allowed transactions.

e) User access issue – Locked

Meaning	A set of return codes indicating that the user's access is locked. This can happen when the user enters more than 3 time the wrong password.
Action	**User**: If the user or the user's system cannot resolve the issue immediately by contacting BeMVO to unlock the user, then the user makes a judgment on the authenticity of the pack, verifies the ATD and can decide that it is safe to deliver the pack. Verification is done at a later moment when the user is unlocked. The user contacts BeMVO who will check the user and un-lock the access.

f) Invalid query

Meaning	A set of return codes indicating that there is a content or format error in the XML query being submitted with the webservice.
Action	**User**: If the user or the user's system cannot resolve the issue immediately, then the user makes a judgment on the authenticity of the pack, verifies the ATD and can decide that it is safe to deliver the pack. The user should be invited to contact his SWS provider to report the error message. Verification is done at a later moment when the software issue is solved. **SWS**: investigate and correct the software to avoid these messages for the users.

g) No impact messages

Meaning	A set of return codes indicating that the user has started the wrong transaction type or providing additional information.
Action	**User**: If it concerns the wrong transaction started by the user, then the user has to do the correct transaction. **SWS**: display a clear message for the user.

IV.3   Potential falsification messages

Finally, attachment A contains a list of return codes and messages that indicate that the pack cannot be further processed or delivered because it concerns a potential falsification.

The processes related to that situation are addressed in **Chapter V. ALERTS.**

	Medicines Verification system		
	Incident management & Alert handling procedures		
BMVS_Incidents	SWS documentation	1/10/2018	FAGG/AFMPS - BeMVO

BeMVO — Belgian Medicines Verification Organisation

V. ALERTS management

**Hereafter the approach for ALERTS handling agreed in Belgium.**
For latest up to date information on Alerts handling in Belgium and Luxembourg, please consult the document FMD – Alerts Management on the website.

V.1 Background and system information

From a concept point of view, the data in the Verification system are organized in 3 levels: the product level, the batch information and the serialized pack codes.

Each of these levels have their proper status and it is only when the status of the 3 levels is set to "Active" that the verification on the specific pack will not return an "error message".

Schematic overview:
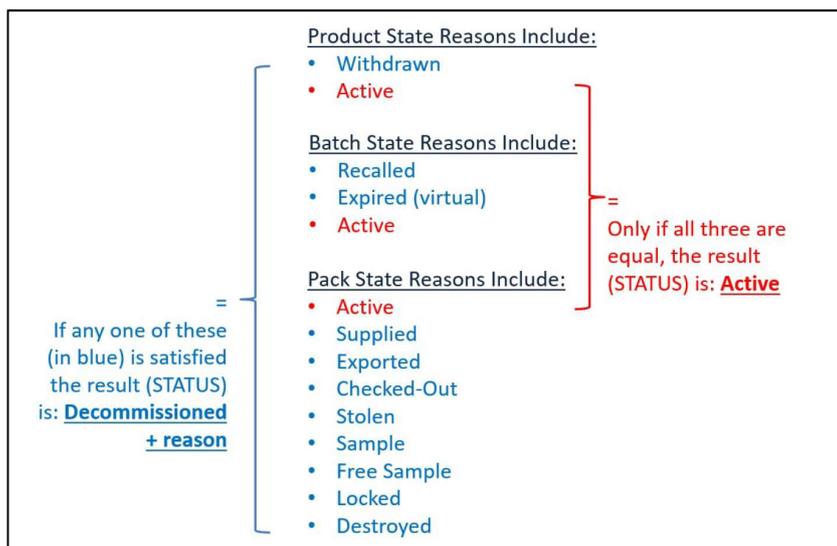
Based on this, following responses are possible when sending a verification query to the system:

Product level: return status of the GTIN/Product code (PC)
- Active
- Withdrawn
- PC not found

Batch level: return status of the Batch number (LOT) and Expiry date (EXP)
- Active
- Batch recalled
- Batch code not found (for the concerned PC)
- Expiry date (EXP) expired
- Expiry date different in the system from code in the query for the concerned PC/Batch

Pack level: return status of the serial number (SN) of the specific pack

- Active
- Decommissioned (for any reason) or Locked = Not Active
- SN not found

The system checks are done in a particular order. If the PC is not found, the system has no way of checking further the LOT, EXP or SN. If the batch code is not found, the EXP and SN cannot be checked, etc…

For latest up to date information on Alerts handling in Belgium and Luxembourg, please consult the document FMD – Alerts Management on the website.

Attachment A – Classified return codes

TD-014 List of Return Codes - Incidents management		
Return Codes	**01 BP Blueprint Description [ENG]**	**Comment**
GOOD CASE		
NMVS_SUCCESS	Successfully processed	The submitted transaction was successfully processed.
ACTION	**No action towards the user is required**	
NMVS SYSTEM ISSUE		
NMVS_ERROR	A general technical exception occurred	An unclassified internal technical system error occured
NMVS_TI_AU_01	The authentication process has failed due to technical reasons.	An unclassified error occured during the authentication process of the user.
NMVS_TI_TO_01	Process runtime exceeds max. configured runtime	The processing time of the submitted transaction exceeded an internal limit. The transaction was therefore stopped.
NMVS_TI_XM_01	Output data do not match the XML scheme definition.	An internal safety check has detected that the NMVS created a wrong XML structure. This message would to an error in the NMVS.
ACTION	**The issue will be picked up by NMVS** **The user needs to act as in the case the system is not accessible: store the codes and retry later.**	
USER ACCESS ISSUE		
NMVS_FE_AU_01	The entered user or password does not match	User id and password do not match
NMVS_FE_AU_06	The entered user or password does not match	User id and password do not match
NMVS_FE_AU_10	Entered password does not match the stored current password.	The password submitted is different from the password stored in NMVS
NMVS_FE_AU_11	The entered password is either expired or an initial password. Please renew your password.	The entered password is either expired or an initial password.
NMVS_FE_AU_17	Logindata is not valid, please contact your local NMVO.	The login or password is incorrect
NMVS_FE_PMS_02	The entered (new) password is the same as the stored password.	The new password submitted is the same as the previous password
NMVS_FE_PMS_03	Entered password cannot be used, new password matches one of last 20 passwords.	The new password submitted is not matching the required password policy, similar to a previously used password
NMVS_FE_PMS_04	The entered password does not meet the requirements of the password policy.	The new password submitted is not matching the required password policy
NMVS_NC_PMS_16	To many Password reset tries.	The user has execed the limit of password change trials
ACTION	**The login/password used in the webservices is not correct.** **Option might be to request a new password for the user with service G445** **In case of issues with password policy: display the policy to the user when he enters the 'new' password**	
NMVS_FE_PKI_01	Certificate has exceeded the maximum validity period.	Certificate is no longer valid
NMVS_FE_PKI_05	The user has no certificate.	The certificate for the user was not requested or is not installed
NMVS_FE_PKI_06	there is no valid certificate for this user.	The user either has an invalid certificate or no certificate at all.
NMVS_FE_PKI_07	There is no new certificate for this user.	No new certificate has been created for this user yet. It therefore cannot be downloaded.
ACTION	**Option might be to request a new certificate with service G615**	
NMVS_FE_AU_03	A general infringement was found.	The user does not have the access rights to execute this operation
ACTION	**Inform the user that he is trying to do an operation that is not allowed.** **Would in fact indicate that his software has been programmed with not-allowed functions. The SWS should fix this.**	
NMVS_FE_AU_02	The user is locked, login is not possible.	The user account is locked, no login possible
NMVS_FE_AU_05	Maximum number of failed login attempts reached. Account is blocked.	Maximum number of failed login attempts reached. Account is locked.
ACTION	**User is locked and need to contact BeMVO.** **BeMVO to check if user has still access right to system.**	

TD-014 List of Return Codes - Incidents management

Return Codes	01 BP Blueprint Description [ENG]	Comment
INVALID SYSTEM QUERY OR OTHER QUERY ISSUE		
NMVS_FE_TX_01	The entered transaction number does not match the transaction number of dispense.	In case of an undo transaction, the trx id of the initial transaction in the end user system ("client transaction id") has to be submitted as a reference. This way, the NMVS can double check that the right transaction was submitted for reversal. Note: The initial transaction is the one that needs to be
NMVS_FE_TX_02	Transaction Id unknown or the processing result is not yet available.	Unknown id when the end user requests the status of a previously submitted bulk transaction (G188 Request bulk transaction result).
NMVS_FE_TX_03	The entered transaction number does not match the transaction number of destruction.	In case of an undo transaction, the trx id of the initial transaction in the end user system ("client transaction id") has to be submitted as a reference. This way, the NMVS can double check that the right transaction was submitted for reversal. Note: The initial transaction is the one that needs to be
NMVS_FE_TX_05	Transaction number (reference from previous Set Property operation) is not valid for the undo operation.	Unknown id when the end user requests the status of a previously submitted bulk transaction (G188 Request bulk transaction result).
NMVS_TE_XM_01	The XML structure of input data is not valid.	The submitted XML structure is syntactically invalid.
NMVS_TE_XM_02	Input data do not match the XML scheme definition.	The submitted XML structure does not match the expected structure.
ACTION	**Issue with the user's system. User to contact the SWS.**	

Return Codes	01 BP Blueprint Description [ENG]	Comment
MESSAGES THAT DO NOT IMPACT DELIVERY		
NMVS_FE_LOT_06	The entered (old) expiry date does not match the stored expiry date	The MAH has extended the epxiry data of this batch. The submitted expiry date was identified as the original expiry date which is no longer valid.
NMVS_NC_PCK_04	Pack status is not dispensed	Undo transaction does not match the current pack status
NMVS_NC_PCK_05	The time frame between notification dispensed and reverse dispensed serial number exceeded the max. permissible limit.	Too much time has passed since the initial transaction, i.e. the 10 day limit was exceeded
NMVS_NC_PCK_06	Pack status is not destroyed	Undo transaction does not match the current pack status
NMVS_NC_PCK_07	Pack status is not exported	Undo transaction does not match the current pack status
NMVS_NC_PCK_13	The time frame between notification destroyed and reverse destroyed serial number exceeded the max. permissible limit.	Too much time has passed since the initial transaction, i.e. the 10 day limit was exceeded.
NMVS_NC_PCK_14	Pack status is not locked	Undo transaction does not match the current pack status
NMVS_NC_PCK_23	Re-setting of the property via double scan is registered.	Same transaction was submitted within a short timespan
ACTION	**Display the appropriate message to the user**	

Return Codes	01 BP Blueprint Description [ENG]	Comment
RISK: REQUIRE VERIFICATION BEFORE FURTHER PROCESSING _ NO DELIVERY		
NMVS_FE_GR_01	Invalid Productcode	A product code (code scheme GTIN) was submitted with a format error (e.g. wrong check digit). Can be a wrong, invamid product code on the pack (but can also be a user system issue)
NMVS_FE_GR_02	The check digit of the Pharmacy Central Number (PZN) is incorrect.	The product code format is wrong (code scheme PPN). Can be a wrong, invamid product code on the pack (but can also be a user system issue)
NMVS_FE_GR_04	Invalid Productcode	A product code (code scheme GTIN/PPN) was submitted with a format error (e.g. wrong check digit). Can be a wrong, invamid product code on the pack (but can also be a user system issue)
NMVS_FE_LOT_01	The associated batch of the entered serial number was recalled.	Batch id is in status "recalled"
NMVS_FE_LOT_02	Selected batch designation already exists with a different expiry date.	The submitted batch id exists but its expiry date is different from the expiry date that was submitted.
NMVS_FE_LOT_03	Selected batch designation does not exist.	The submitted batch id was not found although the product code exists.
NMVS_FE_LOT_04	Selected batch designation already exists with a different expiry date.	The submitted batch id exists but its expiry date is different from the expiry date that was submitted.
NMVS_FE_LOT_07	The expiry date contains incorrect date value	The format or value of the submitted expiry date is wrong
NMVS_FE_LOT_08	The associated product or batch of the entered serial number was recalled.	Batch id is in status "recalled"
NMVS_NC_PC_01	Unknown product code	This product code is not known.
NMVS_NC_PC_02	Unknown serial number	Product code was found, batch code was found, expiry date does match, but the serial number is unknown.
NMVS_NC_PCK_19	Property is already set on pack.	The pack is already in the status that was submitted.
NMVS_NC_PCK_22	Pack is already inactive.	Pack is no longer active as it was set to another status.
ACTION	**User to follow the ALERT procedures**	