PROPOSED PROCEDURE FOR END USERS AND NOOL IN HANDLING ALERTS

(pursuant to Directive 2001/83/EC of the European Parliament and of the Council, Directive 2011/62/EU and Commission Delegated Regulation (EU) 2016/161)

ver. 6.2

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List of abbreviations and terms

CZMVO = NOOL	Národní organizace pro ověřování pravosti léčiv, z.s.
CZMVS	Czech Medicines Verification System
OBP	On-boarding partner that enters data into the European hub
MAH	Marketing authorization holder
FMD	EU Directive 2011/62 / EU (falsified medicines directive)
Alert	Error notification (alert) from the CZMVS indicating a suspected falsified medicinal product
ATD	Anti-tampering device

1 Introduction

Pursuant to Directive 2001/83/EC of the European Parliament and of the Council, Directive 2011/62/EU and Commission Delegated Regulation (EU) 2016/161 – so-called **FMD** (**Falsified Medicines Directive**), individual Member States must create their national system for verification of the authenticity of medicinal products for human use and connect it to the European repositories system. For this purpose, the directive implements mandatory safety features that should allow identification of individual packs of select medicinal products and verification of their authenticity, using a unique identifier. The authenticity of the unique identifier should be verified by comparing the unique identifier against legitimate unique identifiers in the repositories system.

The National Medicines Verification System of the Czech Republic (CZMVS) is based on the technical solution of the company Solidsoft Reply. End users, i.e. all distributors and pharmacies, will have access to the national medicines verification system.
Národní organizace pro ověřování pravosti léčiv, z.s. (NOOL) was founded to create and operate the CZMVS and to provide individual entities with access to the CZMVS.

This document specifies the situations where a falsified medicinal product is suspected and a systematic alarm is generated and proposes operational and communication processes for a response to such events. The full text of the directive and regulation and other information about the project are available at NOOL's website: www.czmvo.cz/cs/

2 Medicinal Products

2.1 Safety features on medicinal products

Medicinal products that are released from production after 9 February 2019 and are subject to the Falsified Medicines Directive must bear safety features (i.e. the unique identifier (UI) as well as devices that allow verification of tampering with a medicinal product pack (ATD)).

2.1.1. Unique identifier

The unique identifier is a sequence of numeric or alphanumeric characters that is unique to a given pack of a medicinal product. It is one of the safety features that prescription-only medicinal products must bear. The data carrier for encoding the unique identifier is the two-dimensional symbol GS1 DataMatrix (hereinafter as 2D code), into which manufacturers will encode the unique identifier. The unique identifier consists of the data shown in Table 1.

Table 1 – Data in the 2D code

Abbreviation	Data
PC	Product code
LOT	Lot
EXP	Expiration date
SN	Serial number

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These data are also printed on the pack in human-readable format. All data are used in communication with the CZMVS.

If the 2D code printed on packaging is not in human-readable format (SN, PC), then the 2D code serves purposes other than verification of packaging based on the FMD. Medicinal product packaging can also be supplied, using a linear code. For examples of serialized products with the 2D code, see pictures in Section 2.4.

***Note**: If the 2D code and human-readable data cannot fit in the same place, the manufacturer can place them in a different place – anywhere on secondary packaging.*

2.1.2. Device to verify tampering with medicinal product packaging

Whether or not a medicinal product was tampered with is verified by a visual inspection of the integrity of the anti-tampering device (ATD) on outer packaging.

2.2 Difference between the 2D code (GS1 DataMatrix) and the QR code

Some medicinal products may also bear the QR code (see information in Section 2.1 and Articles 4 and 5 of the Commission Delegated Regulation). The QR code is visually and technically very similar to the 2D code, but its content is different. For the purposes of the directive, the structure of data in the 2D code is clearly defined, while data the QR code may include any information, e.g. medicinal product name, link to the manufacturer's website, etc. The GS1 DataMatrix code is explained in more detail on www.gs1cz.org.


QR code.


2D code (GS1 DataMatrix)

2.3 Impact of the effective date of the directive on release

Non-serialized medicinal products (without the 2D code) released from production prior to the effective date of the FMD (i.e. prior to 9 February 2019) do not require verification (even using the linear code), they are not subject to the FMD.

Serialized medicinal products (with the 2D code based on the specification), whether or not released from production prior to the effective date of the regulation (9 February 2018), must be verified upon their supply after 9 February 2019 (see e.g. the notification of the State Institute for Drug Control (SIDC) from 11 December 2018). The requirement is that the manufacturer of a medicinal product (MAH/OBP) enters relevant data into the system,

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otherwise it will be impossible to verify (and thus to supply) the medicinal product – an alert will be triggered (see down below).

Prior to the effective date of the FMD, it is possible to release even serialized medicinal products without verification (also using the linear code).

Medicinal products that are manufactured after 9 February 2019 and are subject to the FMD must bear safety features. When verifying safety features, manufacturers, distributors and entities authorized or entitled to supply medicinal products to the public will verify:

a) The authenticity of the unique identifier;
b) The integrity of the anti-tampering device.

The unique identifier (2D code) and human-readable data are described in Section 2.1. Verification of the authenticity of the unique identifier is a major step in ensuring the authenticity of a medicinal product bearing the unique identifier and should be based only on comparing reliable information about legitimate unique identifiers entered into the secured repositories system by verified users. For verification of ATD, see 2.1.2 above.

2.4 Examples of an actual medicinal product with the 2D code

Pic.1 – Examples 2D code

2.5 Code scanning

The 2D code is primarily scanned by a 2D barcode scanner. When a medicinal product is verified, two basic situations may occur:

a) **The 2D code is correctly read,** the information system will then process the information.
b) **The 2D code is not read.**

There may be several possible reasons for code unreadability:
- packaging and thus also the 2D code are physically damaged (unreadable due to mechanical reasons);
- print is of poor quality;
- the scanner is defective or incorrectly configurated.

Other reasons of failed verification and the recommended procedure for such situations are provided in Table 3.

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Re a): Even if the 2D code is read, it may not be necessarily further processed. It may be because the 2D code is not in the format required by the FMD (e.g. it is an OTC medicinal product that bears a 2D code with different information). It is a 2D code but based on its information, given software detects that the medicinal product is not subject to the FMD (IT SW of the end user will first check against the product catalog available from the CZMVS whether or not the medicinal product is subject to the FMD).

Re b): In the case that packaging is physically damaged, the medicinal product is returned to the distributor in compliance with current rules. With respect to other situations, it is necessary to test the functioning of technology (e.g. by reading another, already verified medicinal product).

2.6 Manual and repeated entry

In the case that the scanner cannot read the code, it is possible to enter human-readable data **manually**. **The number of repeated verifications of the status** ("verification" operation) **is not limited in any way**.

2.7 Medicinal product status

Table 2 shows and explains a list of every potential status of a supplied medicinal product.

A medicinal product can be supplied only if its status is "Active."

Any other statuses mean that the medicinal product has already been supplied and its concrete packaging has been decommissioned from the repository or that the medicinal product cannot be supplied for any reason. These statuses are either permanent, i.e. cannot be changed (e.g. STOLEN), or can be changed within 10 days (EXPORT from EU) or can be changed without any time limitation (LOCKED). Table 2 on the next page shows statuses that can be changed (marked in yellow) or cannot be changed (marked in red).

Statuses marked in yellow can be changed in a defined way (on the same place, within 10 days or without any time limitation) and typically returned to their initial status. **However, not all statuses can be changed at verification workplaces** (e.g. the status "Export from EU" can be changed only by the distributor; the "LOCKED" status can be changed only by the manufacturer (MAH)).

Statuses marked in red are permanent and cannot be changed.

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Table 2 – Product status

Potential medicinal product status	Description
Active/Aktivní	The medicinal product can be supplied.
Supplied/Vydaný	The medicinal product with the given serial number has been supplied. The serial number has been decommissioned but **can be reactivated at the same place within 10 days** (without any limited number of reactivations).
Locked/Uzamčený	The medicinal product with the given serial number is **temporarily locked** for further investigation by the MAH or for another action. The serial number **can be reactivated** by the manufacturer **without any time limitation** (at the same place). A pack, a lot or an entire medicinal product can be locked.
Export from EU/Export z EU	The medicinal product with the given serial number has been exported from the EU. The serial number has been decommissioned but **can be reactivated at the same place within 10 days**.
Sample/Vzorek	The medicinal product with the given serial number has been provided as a sample to the supervisory authority. The serial number has been decommissioned but **can be reactivated at the same place within 10 days.**
Free Sample/Vzorek zdarma	The medicinal product with the given serial number has been provided as a free sample. The serial number has been decommissioned but **can be reactivated at the same place within 10 days**.
Expired/Exspirovaný	The medicinal product with the given serial number has expired. The serial numbers of the given lot has been **permanently decommissioned**.
Withdrawn/Stažený	**All medicinal product packs** are being withdrawn from the market. All serial numbers of the medicinal product (i.e. all lots of the given medicinal product as well) have been **permanently decommissioned**.
Recalled/Odvolaný	**The lot** with the given serial number has been recalled. The serial numbers of the entire lot has been **permanently decommissioned**.
Destroyed/Zničený	The medicinal product with the given serial number is to be destroyed. The serial number has been **permanently decommissioned**.
Stolen/Odcizený	The medicinal product with the given serial number has been stolen. The serial number has been **permanently decommissioned**.
Checked-out/Odregistrovaný	The medicinal product with the given serial number has been re-packed by the parallel importer. The serial number has been **permanently decommissioned**.

Legend:

It can be supplied
It can be supplied after a status change
It cannot be supplied at all

Note: *Reactivation = return to the active status (can be supplied again)*
Pack = a medicinal product in a pack with the unique identifier

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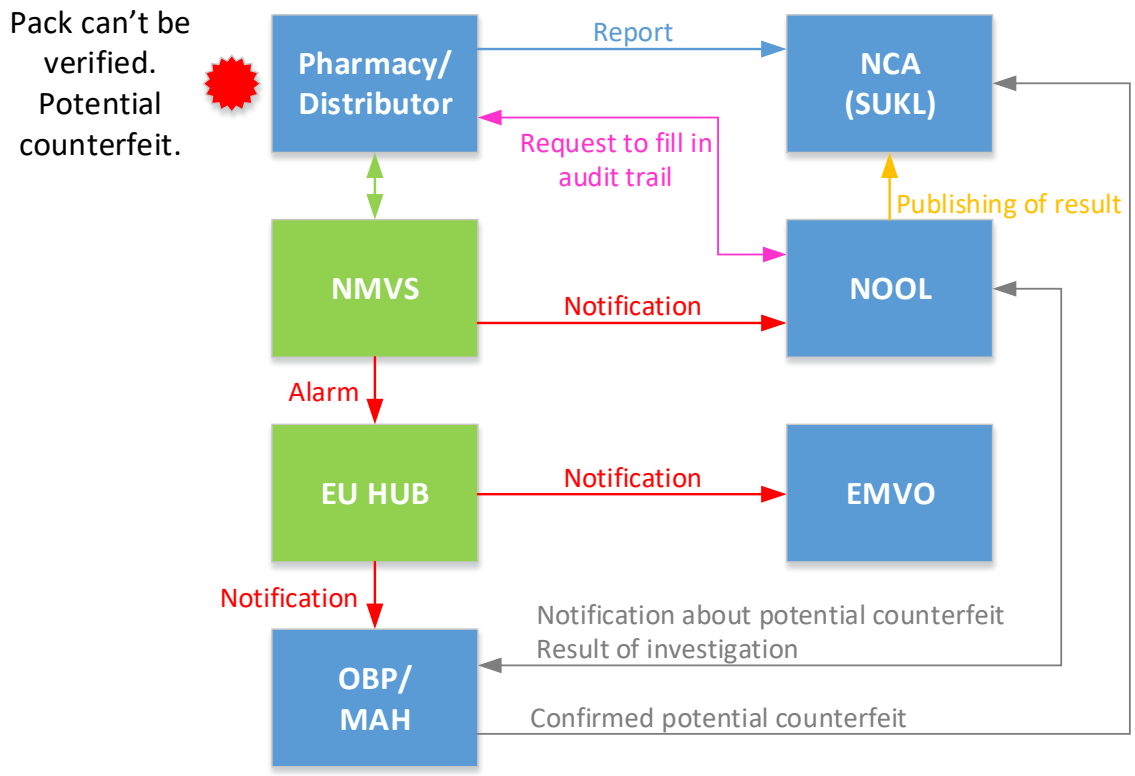
3 Processing of Situations upon the Supply of a Medicinal Product

The supply of a medicinal product and the flow of information in case of suspected falsification are shown in the picture below.

Pic.2 – Supply of a medicinal product and the flow of information in case of suspected falsification



Legend:

- Regular communication with the CZMVS (verification, decommissioning, etc.)
- Alert – suspected falsification indication (it is automatically generated by the CZMVS)
- Communication outside the CZMVS (e-mail, phone, etc.)
- Reporting of suspected falsification for the NCA (electronically, in writing)
- NOOL's information about confirmed falsification to the NCA, EMA and EC.

Note: *The possibility to request data for completing an audit trail is established in Article 5 of the contract between NOOL and the end user. These data can be requested only if the MAH confirmed potential suspected falsification or requests data for an additional investigation.*

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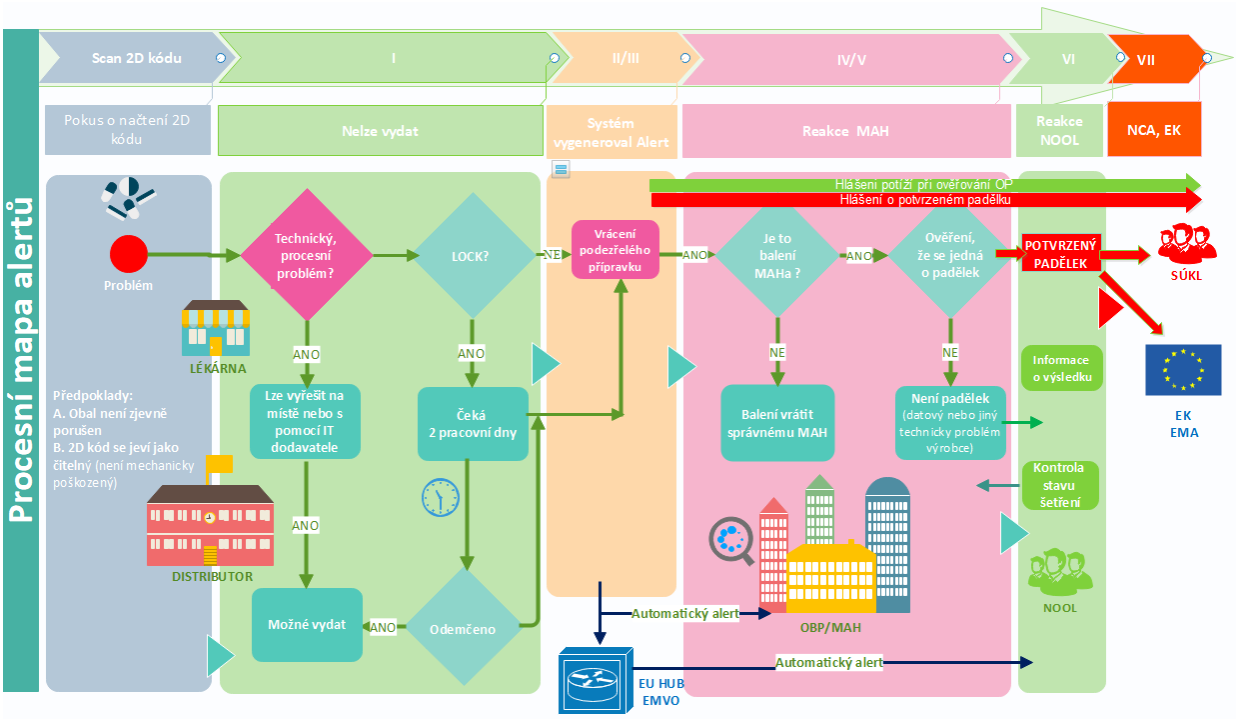
Pic. 3 – Alert workflow



The picture describes in detail the workflow and the activities performed by the individual participants of the entire process in case of suspected falsification or confirmed suspected falsification.

3.1 Recommendations of NOOL for end users

Tables 3 and 4 describe potential situations that can occur during verification of a medicinal product and the response to these situations in the CZMVS.
The column "Activity of End User – Pharmacy/Distributor" shows how the end user should proceed in case of a non-standard situation (**from the FMD's perspective**).

The tables do not show potential non-standard situations in hospital pharmacies caused by medicinal products returned from hospital wards (returned to another workplace, 10-day deadline lapsed, etc.). The CZMVS evaluates such situations as alerts and these situations will be handled based on standard processes. The tables do not include so-called bulk operations (i.e. the reading of several codes and their bulk sending to the CZMVS) either. In such situations, the basic error statuses are the same – there are only several additional situations (e.g. the same serial number of two medicinal products, etc.).

Note: An error code and an alert text will be displayed to the end user. The codes are designated mainly for the support of IT software providers. End users should see information about how to proceed in a given situation (it depends on how pharmacy or distributor software is implemented). More about error codes in Section 5.2.

Recommendation: In the case that a medicinal product is returned, **its packaging should be marked with information that the system generated during an alert!**

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We recommend printing these data generated by the CZMVS (but at least Alert ID):

Alert date and time
Error code
Alert unique identifier (so-called Alert ID)
Product code
Product name
Lot ID
Packaging serial number

The SW provider should ensure the display and printing of these data.

Recommendation: Used software should provide the user with information about whether or not the medicinal product is subject to the FMD.

3.1.1 Recommendations of NOOL for end users – pharmacies

Table 3 – Recommended activity of the end user–pharmacy (upon supply of medicinal products, from the FMD's perspective)

MP status			NMVS			Activity of end user - pharmacy
SCAN	Description		Status code	Displayed text	Alert	
User reads 2D code, 2D code is undamaged, mechanical feature is undamaged, there are no other apparent defects.	2D code cannot be read.	Scanner setup, defective scanner.	-	"Identifier is not readable – enter manually." "Contact IT support"	-	Enter numerical code manually (repeatedly, if necessary), or contact IT support
	2D code was not recognized.	2D code is read but not in the format to be processed.	-	Using their data sources, SW providers may notify end users prior to verification and supply that MP is not subject to the FMD or can exclude MP from FMD verification	-	Check before supply whether MP is subject to the FMD (2D code, ATD)
	2D code was recognized.	2D code is read and processed by the system.	-	Supply - text based on software providers	-	Supply
		2D code is read and processed by the system – Supply is not possible.	51220700	Verification. Locked. The pack cannot be supplied	-	Postpone – investigation in progress. Return to distributor if nor released within 14 days
			51320700	Supply. Locked. The pack cannot be supplied. Alert was generated.	YES	Postpone – investigation in progress. Return to distributor if nor released within 14 days
		2D code is read and is processed by the system. Supply is not possible. ID contains incorrect information or there are reasons shown in the text.	51221000	Lot expired. The pack cannot be supplied.	-	Standard procedure
			51321000		-	
			51221100	Lot was withdrawn. The pack cannot be supplied.	-	It cannot be released – return immediately to manufacturer (or distributor)
			41020000	Product code (GTIN) is unknown.	-	
			41020001	Serial number is unknown. Alert was generated.	YES	
			41020007			
			41020003	MP lot identifier does not correspond to the registered lot identifier. Alert was generated.	YES	
			41020005	MP expiration date does not correspond to the registered expiration date. Alert was generated.	YES	
			51220900	Checked-out. The pack cannot be supplied. Alert was generated.	YES	
			51220400	Destroyed. The pack cannot be supplied. Alert was generated.	YES	
			51320400			
			51220800	Export from EU. The pack cannot be supplied. Alert was generated.	YES	
			51320800			
			51220600	Free sample. The pack cannot be supplied. Alert was generated.	YES	
			51320600			
			51220500	Sample for supervisory authority. The pack cannot be supplied. Alert was generated.	YES	
			51320500			
			51220300	Stolen. The pack cannot be supplied. Alert was generated.	YES	
			51320300			
			51220200	The pack has been already supplied at this place. The pack cannot be supplied. Alert was generated.	YES	
			51320200			
			51220201	The pack has been already supplied at this place. Too many repeated attempts. Alert was generated.	YES	
			51221200	MP was withdrawn. The pack cannot be supplied.	YES	
			52120000	There are two pack identifiers. Alert was generated.		
			51420900	Checked-out (Export from EU). The pack cannot be reactivated. Alert was generated.	YES	
			51320900			

Recommendation: In case of returned medicinal products, we recommend their electronic transmission between the pharmacy and the relevant distributor, provided that the systems allow it.

3.1.2 Recommendations of NOOL for end users – distributors

Table 4 – Recommended activity of the end user – distributor – upon supply of medicinal products, from the FMD's perspective

MP status			NMVS			Activity of end user - distributor
SCAN	Description		Status code	Displayed text	Alert	
User reads 2D code, 2D code is undamaged, mechanical feature is undamaged, there are no other apparent defects.	2D code cannot be read.	Scanner setup, defective scanner.	-	"Identifier is not readable – enter manually." "Contact IT support"	-	Enter numerical code manually (repeatedly, if necessary), or contact IT support
	2D code was not recognized.	2D code is read but not in the format to be processed.	-	Using their data sources, SW providers may notify end users prior to verification and supply that MP is not subject to the FMD or can exclude MP from FMD verification	-	Check before supply whether MP is subject to the FMD (2D code, ATD)
	2D code was recognized.	2D code is read and processed by the system.	-	Supply - text based on software providers	-	Supply
		2D code is read and processed by the system – Supply is not possible.	51220700	Verification. Locked. The pack cannot be supplied	-	Postpone – investigation in progress.
			51320700	Supply. Locked. The pack cannot be supplied. Alert was generated.	YES	Postpone – investigation in progress.
		2D code is read and is processed by the system. Supply is not possible. ID contains incorrect information or there are reasons shown in the text.	51221000	Lot expired. The pack cannot be supplied.	-	Standard procedure
			51321000		-	
			51221100	Lot was withdrawn. The pack cannot be supplied.	-	It cannot be released – return immediately to manufacturer (or distributor)
			41020000	Product code (GTIN) is unknown.	-	
			41020001	Serial number is unknown. Alert was generated.	YES	
			41020007			
			41020003	MP lot identifier does not correspond to the registered lot identifier. Alert was generated.	YES	
			41020005	MP expiration date does not correspond to the registered expiration date. Alert was generated.	YES	
			51220900	Checked-out. The pack cannot be supplied. Alert was generated.	YES	
			51220400	Destroyed. The pack cannot be supplied. Alert was generated.	YES	
			51320400			
			51220800	Export from EU. The pack cannot be supplied. Alert was generated.	YES	
			51320800			
			51220600	Free sample. The pack cannot be supplied. Alert was generated.	YES	
			51320600			
			51220500	Sample for supervisory authority. The pack cannot be supplied. Alert was generated.	YES	
			51320500			
			51220300	Stolen. The pack cannot be supplied. Alert was generated.	YES	
			51320300			
			51220200	The pack has been already supplied at this place. The pack cannot be supplied. Alert was generated.	YES	
			51320200			
			51220201	The pack has been already supplied at this place. Too many repeated attempts. Alert was generated.	YES	
			51221200	MP was withdrawn. The pack cannot be supplied.	YES	
			52120000	There are two pack identifiers. Alert was generated.		
			51420900	Checked-out (Export from EU). The pack cannot be reactivated. Alert was generated.	YES	
			51320900			

Recommendation:

To minimize the situations where the distributor sends a blocked product/lot to the pharmacy, we recommend that distributors verify one pack from each lot.

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4 Activity of NOOL

This section summarizes the general steps that arise from Directive 2001/83/EC, Regulation 2016/161/EU and EMVO's instructions and recommendations. These steps will be taken once the system generates an alert. These steps are now adapted to national conditions and are gradually modified and specified with respect to the amendment to the Pharmaceuticals Act and discussions with individual stakeholders.

Table 5 – NOOL's procedure in handling incidents

Step	Phase	Activity description
I.	Alert generation	**NOOL receives an alert (data report)–** and enters it in the Incident Database
II.		NOOL **verifies**: the completeness and correctness of the data report (CZMVS, EU-HUB)
		The NOOL Alert Center generates **a notification about the need to immediately start investigating the incident and with the request to provide the investigation outcome**, and sends it to the MAH.
III.	Investigation	In the case that the MAH **does not respond or does not resolve the problem within 10 workdays**, the NOOL Alert Center will contact the MAH and request again the investigation outcome. In the case that the MAH continues not to cooperate, the NOOL Alert Center will inform the SIDC.
		The MAH **itself can ask NOOL** for cooperation.
		NOOL will match data **upon request** – **incident localization** – and will inform the MAH.
IV.	Suspected falsification	**The MAH investigates the incident –** if suspected falsification is confirmed, the MAH will inform NOOL (once technical and data problems were eliminated).
V.		NOOL completes **the audit trail**.
VI.		NOOL informs **the SIDC, EMA and EC** about suspected falsification.
On a regular basis		NOOL regularly monitors the status of individual incidents and actively promotes their solving (closing).

4.1 NOOL's supervision over the CZMVS

Národní organizace pro ověřování pravosti léčiv, z.s. must continuously **monitor the behavior** of the CZMVS.
In case of **critical** incident flags (e.g. an unusually large number of alert notifications from one workplace, an unusually high frequency of queries coming from one workplace, etc.) that could jeopardize the stability of the entire CZMVS, NOOL can ask the end user to resolve such problems. The contract between NOOL and end users specifies the rights and obligations of both parties in using the CZMVS.

Note: *Article 5 of the Contract also explicitly specifies the obligation to use only certified software (approved by NOOL) to communicate with the CZMVS*.

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5 Annex:

5.1 Statuses after the 2D code is read/ not read

After an attempt to read the code and to compare it with data in the repository, the statuses shown in the two tables below can occur.

Table P.1 – Statuses that **do not indicate** "Suspected Falsification"

Product code (PC)	Lot (LOT)	Expiration (EXP)	Serial number (SN)	Action
Active	Active	Correct	Active	Operation can be performed.
Active	Active	**Expired**	x	Expired lot. It is proceeded based on current procedures.
Active	**Recalled**	x	x	Recalled lot. It is proceeded based on current procedures.
Withdrawn	x	x	x	Product is withdrawn. It is proceeded based on current procedures.

x – It makes no sense to verify
active – it can be supplied

The statuses in Table P.1 **do not indicate a falsified medicinal product but a medicinal product cannot be supplied** for other reasons. These statuses can be resolved by using current processes (returns, quality defect).

Note:

- Recalled – it is used when one lot or pack of a medicinal product is recalled
- Withdrawn – it is used when an entire medicinal product or all lots of a medicinal product are withdrawn

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Table P.2 describes situations where **falsification is suspected**, an alert can be generated and **the medicinal product must be verified**.

Table P.2 – Statuses that **indicate** "Suspected Falsification"

2D code	Product code (PC)	Lot (LOT)	Expiration (EXP)	Serial number (SN)	Description
Not read	x	x	x	x	Medicinal product is not marked or is marked incorrectly.
Read	**Not found**	x	x	x	Product code was not found.
Read	Active	**Not found**	x	x	Product lot was not found.
Read	Active	Active	**Different**	x	Expiration date does not match.
Read	Active	Active	Correct	**Inactive**	Serial number is not "Active" (see Tab 2).
Read	Active	Active	Correct	**Not found**	Serial number was not found.

Note:
The CZMVS verifies individual items in the order of the table columns from the left (to make it clear). In the case that an item is not found, is different or is inactive, then the data in the next columns to the right are no longer verified and the system generates an alert due to the reason shown the description.

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Table P.3 – Product status changes

Status setup	Who can change product status			Description
	Pharmacy	Distributor	MAH	
Active/Aktivní	-	-	YES	**Data entry and activation in EU HUB – the medicinal product can be supplied.**
Supplied/Vydaný	YES	YES	NO	The medicinal product with the given serial number has been decommissioned.
Reintroduce/Reaktivace Supplied/Vydaný - > Active/Aktivní	YES	YES	NO	The medicinal product has been reintroduced as "Active." It can be done if the conditions for reactivation exist (**at the same place within 10 days**) – without any limited number of reactivations.
Locked/Uzamčený	NO	NO	YES	The medicinal product with the given serial number **is temporarily locked** for further investigation or for another action. The serial number **can be reactivated by the manufacturer without any time limitation** (at the same place).
Reintroduce/Reaktivace Locked/Uzamčený - > Active/Aktivní	NO	NO	YES	Unlocked. The medicinal product has been reintroduced as "Active" from the status "Locked." No time limitation.
Export from EU/Export z EU	NO	YES	YES	The medicinal product has been exported from the EU. The serial number has been decommissioned.
Odvolání Exportu z EU Export from EU -> Active/Aktivní	NO	YES	YES	The medicinal product with the given serial number has been reintroduced as "Active" from the status "Exported from the EU." It can be done if the conditions for reactivation exist (at the same place within 10 days).
Sample/Vzorek	YES	YES	YES	The medicinal product with the given serial number has been provided as a sample to the supervisory authority. The serial number has been decommissioned.
Reintroduce/Reaktivace Sample/Vzorek - > Active/Aktivní	YES	YES	YES	The medicinal product has been reintroduced as "Active" from the status "Sample." It can be done if the conditions for reactivation exist (**at the same place within 10 days**) – without any limited number of reactivations.
Free Sample/Vzorek zdarma	NO	YES	YES	The medicinal product with the given serial number has been provided as a free sample.
Reintroduce/Reaktivace Free Sample/Vzorek zdarma - > Active/Aktivní	NO	YES	YES	The medicinal product has been reintroduced as "Active" from the status "Free Sample." It can be done if the conditions for reactivation exist (**at the same place within 10 days**) – without any limited number of reactivations.
Expired/Exspirovaný	NO	NO	YES	The lot with the given serial number has expired. The serial number (pack) has been **permanently decommissioned**.
Withdrawn/Stažený	NO	NO	YES	All medicinal product packs **are being withdrawn from the market. The serial number (pack) has been** permanently decommissioned**.**
Recalled/Odvolaný	NO	NO	YES	The lot **with the given serial number has been recalled. The serial number (pack) has been** permanently decommissioned**.**
Destroyed/Zničený	YES	YES	YES	The medicinal product with the given serial number is to be destroyed. The serial number (pack) has been **permanently decommissioned**.
Stolen/Odcizený	NO	YES	YES	The medicinal product with the given serial number has been stolen. The serial number (pack) has been **permanently decommissioned**.
Checked-out/Odregistrovaný	NO	YES	YES	The medicinal product with the given serial number has been re-packed by the parallel importer. The serial number (pack) has been **permanently decommissioned**.

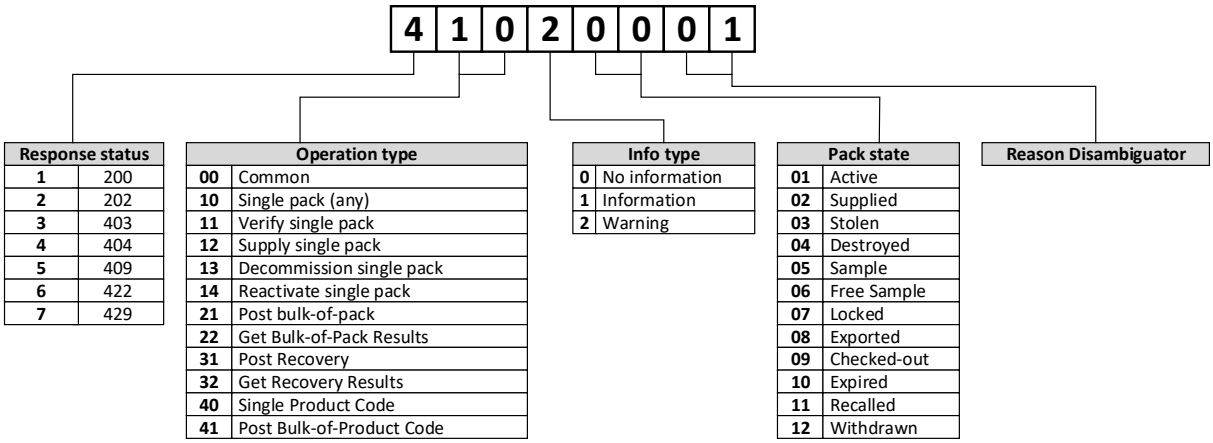
Note: *Some operations are technically possible in the CZMVS, but prohibited by national legislation. E.g.: Supplied – MAH is not authorized for supply.*

5.2 Operation codes - structure

The CZMVS sends back an operation code for each operation. The operation code consists of eight characters and contains encoded information about the operation outcome, medicinal product status, etc. The code structure is shown in the picture below.

***Note**: The API for version 1.4 used Integer, with the transition to API 1.5 being converted to String.*

Pic. P.1 – Operation code structure



The operation code includes a total of five sequences. Table 6 provides a list of code parts and their description.

Table P.4 – Code part description

Code part	Description
Response status	Re-entry code http.
Operation type	API operation type.
Info Type	Information type of the displayed text.
Pack state	Medical product state.
Reason Disambiguator	Distinction of reasons for codes with an otherwise identical response (it is usually a distinction of manual entries).

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Table P.5 – Operation codes

HTTP Status Code	API Operation	Info Type	Pack State	Reason Disambiguator	Alert	Operation Code	Display Text	Display Text
200	Verify Single Pack	Information	Active	0		11110100	The pack is available to be dispensed.	**Toto balení je aktivní.**
200	Verify Single Pack	Information	Supplied	0		11110200	The pack has been supplied.	**Toto balení bylo dodáno.**
200	Verify Single Pack	Information	Stolen	0		11110300	The pack is marked as stolen.	**Toto balení je označené jako ukradené.**
200	Verify Single Pack	Information	Destroyed	0		11110400	The pack is marked as destroyed.	**Toto balení je označené jako zlikvidované.**
200	Verify Single Pack	Information	Sample	0		11110500	The pack is marked as a sample.	**Toto balení je označené jako vzorek.**
200	Verify Single Pack	Information	Free Sample	0		11110600	The pack is marked as a free sample.	**Toto balení je označené jako vzorek zdarma.**
200	Verify Single Pack	Information	Locked	0		11110700	The pack is marked as locked.	**Toto balení je označené jako zablo kované.**
200	Verify Single Pack	Information	Exported	0		11110800	The pack is marked as exported from the EU.	**Toto balení je označené jako vyvezené z EU.**
200	Verify Single Pack	Information	Checked-Out	0		11110900	The pack has been re-packed.	**Toto balení bylo přebaleno.**
200	Verify Single Pack	Information	Expired	0		11111000	The batch has expired.	**Šarže po datu exspirace.**
200	Verify Single Pack	Information	Recalled	0		11111100	The batch has been recalled.	**Šarže byla stažena.**
200	Verify Single Pack	Information	Withdrawn	0		11111200	The product has been withdrawn.	**Tento přípravek byl stažen.**
200	Supply Single Pack	Information	Supplied	0		11210200	The pack has been supplied.	**Toto balení bylo dodáno.**
200	Supply Single Pack	Warning	Supplied	0		11220200	The pack was previously supplied at this location.	**Toto balení bylo již dodáno na toto místo.**
200	Supply Single Pack	Warning	Supplied	1		11220201	The pack was previously supplied at this location. The next attempt will be rejected.	**Toto balení již bylo na toto místo dodáno. Příští pokus bude zamítnut.**
200	Decommission Single Pack	Information	Stolen	0		11310300	The pack has been marked as stolen.	**Toto balení bylo označeno jako ukradené.**
200	Decommission Single Pack	Information	Destroyed	0		11310400	The pack has been marked as destroyed.	**Toto balení bylo označeno jako zlikvidované.**
200	Decommission Single Pack	Information	Sample	0		11310500	The pack has been marked as a sample.	**Toto balení bylo označeno jako vzorek.**
200	Decommission Single Pack	Information		0		11310600	The pack has been marked as a free sample.	**Toto balení bylo označeno jako vzorek zdarma.**
200	Decommission Single Pack	Information	Locked	0		11310700	The pack has been marked as locked.	**Toto balení bylo označeno jako zablokované.**

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200	Decommission Single Pack	Information	Exported	0		11310800	The pack has been marked as exported from the EU.	**Toto balení bylo označeno jako vyvezené z EU.**
200	Reactivate Single Pack	Information	Active	0		11410100	The pack has been reactivated.	**Toto balení bylo reaktivováno.**
200	Reactivate Single Pack	Warning	Active	0		11420100	The pack cannot be reactivated. It is already active.	**Toto balení nelze znovu aktivovat. Je již aktivní.**
200	Reactivate Single Pack	Warning	Recalled	0		11421100	The batch has been recalled in this market. The pack will be reactivated in any markets where the batch is not recalled.	**Skutečný počet balení neodpovídá uvedenému počtu.**
200	Reactivate Single Pack	Warning	Withdrawn	0		11421200	The product has been withdrawn in this market. The pack will be reactivated in any markets where the product is not withdrawn.	**Tento přípravek byl stažen.**
200	Get Bulk-of-Pack Results	No information provided		0		12200000		
200	Single Product Code					14000000		
200	Bulkof Product Code					14100000		
200	Get Report Job Status					15100000		
200	Delete a Report					15610000		
200	Request Report Types					15700000		
200	Request Report Metadata					15800000		
202	Post Bulk-of-Pack	No information provided		0		22100000		
200	Request a Report					25010000		
403	All operations	Warning		0		30020000	The client system is not authorised to perform this request.	**Klientský systém není oprávněn splnit tento požadavek.**
403	Single Product Code	Warning				30020000	The client system is not authorised to perform this request.	
403	Bulkof Product Code	Warning				30020000	The client system is not authorised to perform this request.	
403	Verify Single Pack	Warning		0		31120000	The pack cannot be verified. Too many verification attempts.	**Toto balení nelze ověřit. Příliš mnoho pokusů o ověření.**
403	Request a Report	Warning				35020000	not authorised to access requested report	
403	Retrieve a Report	Warning				35420000	not authorised to access requested report	
403	Delete a Report	Warning				35620000	not authorised to access requested report	

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403	Request Report Metadata	Warning				35820000	not authorised to access requested report type	
404	All Single Pack operations	No information provided		0		41000000		
404	All Single Pack operations	Warning		0		41020000	The product code is unknown.	**Kód produktu je neznámý.**
404	All Single Pack operations	Warning		1	Yes	41020001	The serial number is unknown. An alert has been raised.	**Sériové číslo je neznámé. Bylo vydáno upozornění.**
404	All Single Pack operations	Warning		2		41020002	The serial number is unknown.	**Sériové číslo je neznámé.**
404	All Single Pack operations	Warning		3	Yes	41020003	The batch identifier mismatches the recorded batch identifier. An alert has been raised.	**Identifikátor šarže neodpovídá zaznamenanému identifikátoru šarže. Bylo vydáno upozornění.**
404	All Single Pack operations	Warning		4		41020004	The batch identifier mismatches the recorded batch identifier.	**Identifikátor šarže neodpovídá zaznamenanému identifikátoru šarže.**
404	All Single Pack operations	Warning		5	Yes	41020005	The expiry date mismatches the recorded expiry date. An alert has been raised.	**Datum exspirace se neshoduje se zaznamenaným datem exspirace. Bylo vydáno upozornění.**
404	All Single Pack operations	Warning		6		41020006	The expiry date mismatches the recorded expiry date.	**Datum exspirace neodpovídá zaznamenanému datu exspirace.**
404	All Single Pack operations	Warning		0	Yes	41020007	Too many incorrect manual data entry attempts. An alert has been raised.	**Sériové číslo je neznámé. Bylo vydáno upozornění.**
404	Get Bulk-of-Pack Results	Warning		0		42220000	No results found. The results may have expired.	**Nebyly nalezeny žádné výsledky. Platnost výsledků možná vypršela.**
404	Single Product Code	Warning				44020000	The product code is unknown.	
404	Retrieve a Report	Warning				45420000	Report not found	
404	Delete a Report	Warning				45620000	Report not found	
404	Request Report Metadata	Warning				45820000	Unknown report type	
409	Supply Single Pack	Warning	Supplied	0	Yes	51220200	The pack cannot be supplied. An alert has been raised.	**Toto balení nelze dodat. Bylo vydáno upozornění.**
409	Supply Single Pack	Warning	Supplied	1	Yes	51220201	The pack was previously supplied at this location. Too many repeated attempts. An alert has been raised.	**Toto balení již bylo na toto místo dodáno. Příliš mnoho opakovaných pokusů. Bylo vydáno upozornění.**
409	Supply Single Pack	Warning	Stolen	0	Yes	51220300	The pack cannot be supplied. An alert has been raised.	**Toto balení nelze dodat. Bylo vydáno upozornění.**
409	Supply Single Pack	Warning	Destroyed	0	Yes	51220400	The pack cannot be supplied. An alert has been raised.	**Toto balení nelze dodat. Bylo vydáno upozornění.**

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409	Supply Single Pack	Warning	Sample	0	Yes	51220500	The pack cannot be supplied. An alert has been raised.	**Toto balení nelze dodat. Bylo vydáno upozornění.**
409	Supply Single Pack	Warning	Free Sample	0	Yes	51220600	The pack cannot be supplied. An alert has been raised.	**Toto balení nelze dodat. Bylo vydáno upozornění.**
409	Supply Single Pack	Warning	Locked	0	Yes	51220700	The pack cannot be supplied. An alert has been raised.	**Toto balení nelze dodat. Bylo vydáno upozornění.**
409	Supply Single Pack	Warning	Exported	0	Yes	51220800	The pack cannot be supplied. An alert has been raised.	**Toto balení nelze dodat. Bylo vydáno upozornění.**
409	Supply Single Pack	Warning	Checked-Out	0	Yes	51220900	The pack cannot be supplied. An alert has been raised.	**Toto balení nelze dodat. Bylo vydáno upozornění.**
409	Supply Single Pack	Warning	Expired	0		51221000	The pack cannot be supplied. The batch has expired.	**Toto balení nelze dodat. Šarže má prošlé datum exspirace**
409	Supply Single Pack	Warning	Recalled	0		51221100	The pack cannot be supplied. The batch has been recalled.	**Toto balení nelze dodat. Šarže byla stažena.**
409	Supply Single Pack	Warning	Withdrawn	0		51221200	The pack cannot be supplied. The product has been withdrawn.	**Toto balení nelze dodat. Přípravek byl stažen.**
409	Decommission Single Pack	Warning	Supplied	0	Yes	51320200	The pack cannot be decommissioned. An alert has been raised.	**Toto balení nelze vyřadit. Bylo vydáno upozornění.**
409	Decommission Single Pack	Warning	Stolen	0	Yes	51320300	The pack cannot be decommissioned. An alert has been raised.	**Toto balení nelze vyřadit. Bylo vydáno upozornění.**
409	Decommission Single Pack	Warning	Destroyed	0	Yes	51320400	The pack cannot be decommissioned. An alert has been raised.	**Toto balení nelze vyřadit. Bylo vydáno upozornění.**
409	Decommission Single Pack	Warning	Sample	0	Yes	51320500	The pack cannot be decommissioned. An alert has been raised.	**Toto balení nelze vyřadit. Bylo vydáno upozornění.**
409	Decommission Single Pack	Warning	Free Sample	0	Yes	51320600	The pack cannot be decommissioned. An alert has been raised.	**Toto balení nelze vyřadit. Bylo vydáno upozornění.**
409	Decommission Single Pack	Warning	Locked	0	Yes	51320700	The pack cannot be decommissioned. An alert has been raised.	**Toto balení nelze vyřadit. Bylo vydáno upozornění.**
409	Decommission Single Pack	Warning	Exported	0	Yes	51320800	The pack cannot be decommissioned. An alert has been raised.	**Toto balení nelze vyřadit. Bylo vydáno upozornění.**
409	Decommission Single Pack	Warning	Checked-Out	0	Yes	51320900	The pack cannot be decommissioned. An alert has been raised.	**Toto balení nelze vyřadit. Bylo vydáno upozornění.**
409	Decommission Single Pack	Warning	Expired	0		51321000	The pack cannot be decommissioned. The batch has expired.	**Toto balení nelze vyřadit. Šarže má prošlé datum exspirace.**
409	Decommission Single Pack	Warning	Recalled	0		51321100	The pack cannot be decommissioned. The batch has been recalled.	**Toto balení nelze vyřadit. Šarže byla stažena.**

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409	Decommission Single Pack	Warning	Withdrawn	0		51321200	The pack cannot be decommissioned. Th e product has been withdrawn.	**Toto balení nelze vyřadit. Přípravek byl stažen.**
409	Reactivate Single Pack	Warning	Supplied	0		51420200	The pack cannot be reactivated. Time limit exceeded.	**Toto balení nelze znovu zavést do systému. Byl překročen časový limit.**
409	Reactivate Single Pack	Warning	Supplied	1		51420201	The pack cannot be reintroduced. It was supplied at another location.	**Toto balení nelze znovu zavést do systému. Bylo dodáno na jiné místo.**
409	Reactivate Single Pack	Warning	Stolen	0		51420300	The pack cannot be reactivated.	**Toto balení nelze znovu aktivovat.**
409	Reactivate Single Pack	Warning	Destroyed	0		51420400	The pack cannot be reactivated.	**Toto balení nelze znovu aktivovat.**
409	Reactivate Single Pack	Warning	Sample	0		51420500	The pack cannot be reactivated. It was decommissioned at another location.	**Toto balení nelze znovu aktivovat. Bylo vyřazeno na jiném místě.**
409	Reactivate Single Pack	Warning	Sample	1		51420501	The pack cannot be reactivated. Time limit exceeded.	**Toto balení nelze znovu aktivovat. Přípravek byl stažen.**
409	Reactivate Single Pack	Warning	Free Sample	0		51420600	The pack cannot be reactivated. It was decommissioned at another location.	**Toto balení nelze znovu aktivovat. Bylo vyřazeno na jiném místě.**
409	Reactivate Single Pack	Warning	Free Sample	1		51420601	The pack cannot be reactivated. Time limit exceeded.	**Toto balení nelze znovu aktivovat. Přípravek byl stažen.**
409	Reactivate Single Pack	Warning	Locked	0		51420700	The pack cannot be reactivated. It was decommissioned at another location.	**Toto balení nelze znovu aktivovat. Bylo vyřazeno na jiném místě.**
409	Reactivate Single Pack	Warning	Exported	0		51420800	The pack cannot be reactivated. It was decommissioned at another location.	**Toto balení nelze znovu aktivovat. Bylo vyřazeno na jiném místě.**
409	Reactivate Single Pack	Warning	Exported	1		51420801	The pack cannot be reactivated. Time limit exceeded.	**Toto balení nelze znovu aktivovat. Přípravek byl stažen.**
409	Reactivate Single Pack	Warning	Checked-Out	0	Yes	51420900	The pack cannot be reactivated. An alert has been raised.	**Toto balení nelze znovu aktivovat. Bylo vydáno upozornění.**
409	Reactivate Single Pack	Warning	Expired	0		51421000	The pack cannot be reactivated. The batch has expired.	**Toto balení nelze znovu aktivovat. Byl překročen časový limit.**
409	Reactivate Single Pack	Warning	Recalled	0		51421100	The pack cannot be reactivated. The batch has been recalled.	**Toto balení nelze znovu aktivovat. Šarže má prošlé datum exspirace.**
409	Reactivate Single Pack	Warning	Withdrawn	0		51421200	The pack cannot be reactivated. The product has been withdrawn.	**Toto balení nelze znovu aktivovat. Šarže byla stažena.**
409	Post Bulk-of-Pack	Warning		0	Yes	52120000	Duplicate serial numbers provided. An alert has been raised.	**Uvedeny dva identifikátory balení. Bylo vydáno upozornění.**
409	Get Bulk-of-Pack Results	Information		0		52210000	The request is still being processed.	**Požadavek se zpracovává.**
409	Bulkof Product Code	Warning				54120000	Duplicate product codes provided.	

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409	Retrieve a Report	Warning				55420000	Report not ready	
500	Retrieve a Report	Warning				55420000	Error Creating Report	
422	All Single Pack operations	Warning		0		61020000	A batch identifier is required.	**Požaduje se identifikátor šarže.**
422	All Single Pack operations	Warning		1		61020001	A product code is required.	**Požaduje se kód produktu.**
422	All Single Pack operations	Warning		2		61020002	A product code scheme is required.	**Požaduje se schéma kódu produktu.**
422	All Single Pack operations	Warning		3		61020003	A serial number is required.	**Požaduje se sériové číslo.**
422	All Single Pack operations	Warning		4		61020004	An expiry date is required.	**Požaduje se datum exspirace.**
422	All Single Pack operations	Warning		5		61020005	The {0} product code scheme is not supported.	**Schéma kódu produktu {0} není podporováno.**
422	All Single Pack operations	Warning		6		61020006	The batch identifier is invalid.	**Identifikátor šarže je neplatný.**
422	All Single Pack operations	Warning		7		61020007	The expiry date is invalid.	**Datum exspirace je neplatné.**
422	All Single Pack operations	Warning		8		61020008	The product code is invalid.	**Kód produktu je neplatný.**
422	All Single Pack operations	Warning		9		61020009	A requested state is required.	**Je nutné uvést požadovaný stav.**
422	All Single Pack operations	Warning		10		61020010	The requested state is invalid.	**Požadovaný stav je neplatný.**
422	All Single Pack operations	Warning		11		61020011	The serial number is invalid.	**Sériové číslo je neplatné.**
422	All Single Pack operations	Warning		12		61020012	The emvs-data-entry-mode header is required.	**Požaduje se návěští režimu pro zadávání údajů.**
422	All Single Pack operations	Warning		13		61020013	The emvs-data-entry-mode header is invalid.	**Návěští režimu pro zadávání údajů emvs je neplatné.**
422	All Single Pack operations	Warning		14		61020014	The request body is invalid.	**Text požadavku je neplatný.**
422	Post Bulk-of-Pack	Warning		1		62120001	The actual number of packs does not match the stated number.	**Skutečný počet balení neodpovídá uvedenému počtu.**
422	Post Bulk-of-Pack	Warning		2		62120002	The request body is invalid.	**Text požadavku je neplatný.**
422	Post Bulk-of-Pack	Warning		3		62120003	Too many packs in bulk request. A maximum of {0} packs will be accepted.	**Hromadný požadavek se týká příliš mnoha balení. Bude akceptováno nejvýše {0} balení.**
422	Post Bulk-of-Pack	Warning		4		62120004	The emvs-data-entry-mode header is required.	**Požaduje se návěští režimu pro zadávání údajů.**
422	Post Bulk-of-Pack	Warning		5		62120005	The emvs-data-entry-mode header is invalid.	**Návěští režimu pro zadávání údajů emvs je neplatné.**
422	Post Bulk-of-Pack	Warning		6		62120006	Manually entered bulk of pack requests are not supported.	**Manuální zadávání hromadných požadavků není podporováno.**
422	Post Bulk-of-Pack	Warning		7		62120007	The requested state is invalid	**Požadovaný stav je neplatný.**
422	Single Product Code	Warning		0		64020000	A product code is required.	
422	Single Product Code	Warning		1		64020001	A product code scheme is required.	
422	Single Product Code	Warning		2		64020002	The product code scheme not supported.	

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422	Single Product Code	Warning		3		64020003	The product code invalid.	
422	Bulkof Product Code	Warning		0		64120000	The request body is invalid.	
422	Bulkof Product Code	Warning		1		64120001	Too many product codes in bulk request. A maximum of {0} product codes will be accepted.	
422	Request a Report	Warning		0		65020000	Unknown report type	
422	Request a Report	Warning		1		65020001	Invalid report parameters	
429	Bulkof Product Code	Warning				70000000		
429	All operations	Warning		0		70020000	The National System is handling an unusually high volume of requests. Please resend the request later.	**Národní systém zpracovává neobvykle velký objem požadavků. Odešlete prosím požadavek později znovu.**

Resource: Confluence database (SolidSoft Reply portal).

Note: *The operating code system responds to current process requirements - it is not a fixed set, but rather a relatively dynamically evolving set of return sequences*

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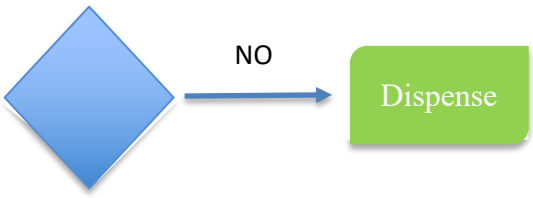
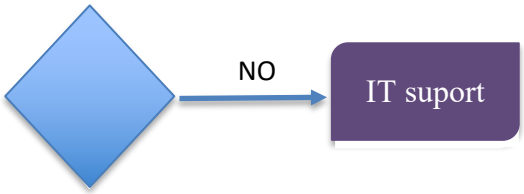
5.3 Proposed standard checklist for end users

In case of a problem with dispensing a medicinal product – VERIFY:

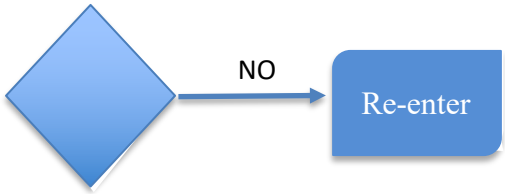
Is the medicinal product subject to the FMD?
Software that will check in the internal database whether or not the medicinal product is subject to the Falsified Medicines Directive could help with this decision.



Does the barcode scanner work correctly? Are data sent to the NMVS correct?
The user can check whether the scanner works correctly by comparing the scanned code with printed information. The user can also try to verify a completely different medicinal product and check whether scanned data are identical with printed codes. Such verification of a completely different product can also help to find out whether the problem is caused by some other problem in the user system, e.g. the FMD module generates wrong codes in the inquiry sent to the NMVS verification database.



In case of manually entered data - were they entered correctly, were there any typos?
The user should verify the manually entered code. The user can re-enter the code and check whether an alert is still generated. The FMD software module in the user's system should check the so-called control code that is a part of the product code to make sure that the product code is not entered incorrectly (this is also recommended in case of scanning).



Did the user make an invalid transaction?
This can happen e.g. in the case that the user scans and tries to dispense an already dispensed pack. In such a case, the alert message will display whether or not the user has already decommissioned the pack. In the case that the pack has been decommissioned by the user, the alert should not be escalated.

(In the case that the user decommissioned the pack at the same workplace less than 10 days ago and the pack was not decommissioned because it was destroyed or stolen, the user can cancel - withdraw the decommissioning if necessary, it can be reactivated).