FMD Principles (Falsified Medicines Directive)

(In the sense of the Directive 2001/83/EC of the European Parliament and of the Council and Commission Delegated Regulation (EU) 2016/161)

ver. 1.1

(Supersedes ver. 1.0 - changes:
- Chap. 4.7 – update of Table 1 – Medicinal product pack statuses)

May 22nd, 2025

- The alert resolution procedure is described in more detail in the document „PROCEDURE FOR HANDLING ALERTS FOR END USERS, MARKETING AUTHORIZATION HOLDERS AND PARALLEL IMPORTERS “, published on the CZMVO website in the individual sections of “System users” part.
- Answers to the most frequent questions related to FMD/NMVS/CZMVO/CZAMS can be found in the document „FREQUENTLY ASKED QUESTIONS IN REGARD TO FMD AND ALERTS WHEN USING CZMVS AND CZAMS “, published on the CZMVO website in the “Important information/Q&A” section.

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Shortcuts and abbreviations

CZMVO = NOOL	**Czech Medicines Verification Organisation -** Národní organizace pro ověřování pravosti léčiv, z.s.
CZMVS = NSOL	**Czech Medicines Verification System -** Národní systém pro ověřování pravosti léčiv
CZAMS	Czech alert management system
OBP	On-boarding partner – An entity uploading data into CZMVS on behalf of an MAH
MAH	Marketing authorisation holder
FMD	Falsified Medicines Directive - EU 2011/62/EU
Alert	An exception generated in CZMVS indicating a potential counterfeit suspect
UI	Unique identifier – an identifier that provides for authenticity verification and identification of a single pack of a medicinal product
ATD	Anti-tampering device – a means to prevent tampering with the outer packaging of a medicinal pack
2D code	Two-dimensional data matrix code (as per GS1)
Parallel importer	Distribution licence holder for medicinal products providing for a resale between countries
SIDC	State Institute for Drug Control
PC/GTIN	Product code/Global Trade Item Number – / a unique and internationally recognized product identifier
LOT/BATCH	Batch number
EXP	Expiry date
SN	Serial number
OTC	Over-the-counter – a medicine that can be sold without a prescription

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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 – the so-called **FMD** (**Falsified Medicines Directive**), individual Member States must set up national systems for verifying the authenticity of medicinal products for human use and connect them to the European repositories system (EMVS). For this purpose, the Directive implements mandatory safety features that will allow to identify individual packs of select medicinal products and to verify 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 Solidsoft Reply company. End users, i.e. all wholesalers and pharmacies, have access to the National Medicines Verification System.
The Czech Medicines Verification Organisation. (CZMVO) was founded to establish and operate CZMVS and to provide individual entities with access to CZMVS.

The full text of the Directive and Regulation and other information about the project are available at websites of CZMVO: www.czmvo.cz

2 Purpose

The objective of this document is to closely specify situations that result in cases of suspected counterfeits and alerts generated by the system, and to propose operational and communication processes responding to such alerts.

This document is based on the current state of CZMVS and the current setup of CZAMS.

The proposed processes may change in the future depending on the development of both systems and suggestions of their users.

3 Scope

This document includes the procedure for handling alerts, including responses generated in the CZMVS once a medicinal product verification request from an end user is received.

This document does not include obligations and procedures of individual companies distributing and supplying medicinal products related to quality defects or suspected counterfeits and are not generated in CZMVS.

4 Medicinal product

4.1 Safety features on medicinal products

Medicinal products **released from production** by a qualified person of the manufacturer of a medicinal product **after February 9, 2019** are subject to the Falsified Medicines Directive and must therefore bear **safety features** (i.e. the unique identifier (**UI**) as well as a device that allows detection of tampering with a medicinal product pack (**ATD**)).

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4.1.1 Unique identifier

A unique identifier is a sequence of **alphanumeric characters** that is unique to a given medicinal product pack. It is one of the safety features that prescription-only medicinal products must bear, unless they are on the list of Annex I of Commission Delegated Regulation (EU) 2016/161 or are not subject to prescription and are on the list of Annex II of the Regulation. The data carrier for encoding the unique identifier is a two-dimensional symbol GS1 DataMatrix (hereinafter as 2D code), into which manufacturers encode the unique identifier. The unique identifier consists of data elements shown in Table 1.

Table 2 – Data in the 2D code

Abbreviation	Data element	Note
PC	**Product code**	GS1 format: GTIN, NTIN, PPN
LOT	**Lot number**	Allowed characters: based on GS1, chain length: 7 – 21 characters
EXP	**Expiry date**	Format: RRMMDD, where DD can also be "*00*"
SN	**Serial number**	Allowed characters: based on GS1, chain length: 7 – 21 characters

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

Other codes can also be printed on a packaging (e.g. QR code, EAN code); however, they include neither the UI nor the data elements in human-readable format (SN, PC) and thus are not used to verify the authenticity of medicinal products according to FMD directive, but probably serve other purposes (marketing information, link to the manufacturer's website, etc.). With respect to medicinal products required to have the UI in the form of the 2D code on their packaging, it is recommended to switch to the 2D code only and to limit the concurrence of the EAN code and the 2D code for the shortest possible time. In the case that medicinal product packaging contains only the EAN code or the QR code, such a medicinal product is probably not subject to the FMD.

For examples of serialized medicinal products bearing the 2D code, see the pictures in Section 4.4

Note: In case that a medicinal product pack includes a 2D code, the code must always be verified even if its packaging does not include the data elements in human-readable format (PC, LOT, SN, EXP).

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

SIDC (SÚKL) code

The SIDC code is used to distinguish each variant of a medicinal product for the purposes of record-keeping and possible identification when setting prices and reimbursements from public health insurance. SIDC codes are therefore unique identifiers for each variant of the product and are assigned not only to products registered nationally, through mutual recognition procedures, or centrally, but also to medicinal products permitted for use based on specific treatment programs (§ 49 of the Medicines Act), food for special medical purposes, and for simultaneous importation or distribution of the medicinal product, as well as when taking over the registration of the medicinal product.

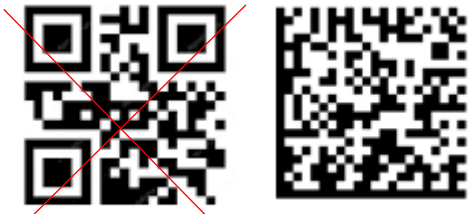
SIDC code is the fifth value of the unique identifier, which is not mandatory for the time being. However, for an easy identification of the medicinal product, we recommend that MAHs include this data in the master data when uploading to the repository.

4.1.2 A device to detect tampering with a pack of a medicinal product

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

4.2 Difference between a 2D code (GS1 DataMatrix) and a QR code

Some medicinal products may also bear the QR code. Even though the QR code is visually and technically very similar to the 2D code and it is also a 2D code, it is not permitted by the FMD. The QR code may include any information, e.g. medicinal product name, a link to the manufacturer's website, etc. The data elements and their structure in the 2D code are clearly defined for the purposes of the Directive. A detailed description of the 2D code is provided at www.gs1cz.org.



QR code 2D code

Picture 1 – The difference between a 2D code and a QR code

4.3 Impact of the effective date of the Directive on the supply of medicinal products

Non-serialized medicinal products (without the 2D code) released from production prior to the effective date of the FMD (February 9, 2019) may still be supplied without verification in CZMVS (based on the EAN code) since they are not subject to the FMD's requirements.

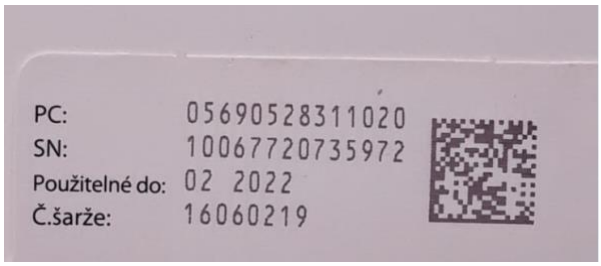
Serialized medicinal products (with the 2D code based on the specification) must be verified in CZMVS upon supply to public after February 9, 2019. The manufacturer or the marketing authorization holder (MAH)/on-boarding partner (OBP) is required to upload the relevant data into the system, otherwise it will be impossible to verify (and thus supply) the medicinal product – and an alert will be generated (see below). In case that a medicinal product was released from production prior to February 9, 2019 and the data were not subsequently uploaded into the repositories system, it will be still possible to dispense such a medicinal product to a patient despite the generated alert. However, CZMVS does not track the date of release from production and therefore does not provide this information to end users.

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

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

The UI, the 2D code and other human-readable data elements are described in Section 0.1. Verification of the UI is a major step in ensuring the authenticity of the pack of a medicinal product, hence the UI should be matched only against the legitimate unique identifier uploaded into the secured repository by verified users. For verification of the ATD, see Section 4.1.2.

4.4 Examples of real medicinal products carrying the 2D code



Picture 2 – Examples of 2D codes on medicinal products

4.5 2D code scanning

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

a) **The 2D code is correctly read;**
b) **The 2D code is not read.**

Ad a)

In case the 2D code is correctly read, the information system will further process the information.

Even if the 2D code is read, the information in the code might not be processed further because of the following reasons:

- The code is not in the format required by the FMD (e.g. the QR code of the medicinal product includes different information).
- The code is not a 2D code.
- One or several control characters are missing in the code.
- The pharmacy's software detects, by the information in the 2D code, that the medicinal product is not subject to the FMD (e.g. it is an OTC medicinal product, or it is not a medicinal product).

Ad b)

There are several potential reasons why the 2D code might not be properly read:

- 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.

In case the packaging is physically damaged, or the print is of poor quality, the medicinal product is returned to the wholesaler in compliance with the current rules. Otherwise, it is necessary to test the functioning of technological devices (e.g. by scanning another, already verified, medicinal product or by using the check scan available on the CZMVS websites).

Other reasons for a failed verification, and the recommended procedure for such situations are described in the document „ALERT RESOLUTION PROCEDURE FOR END USERS, MARKETING AUTHORIZATION HOLDERS AND PARALLEL IMPORTERS", Section 5.1. The process of verification of a medicinal product and the flow of information in case of a suspected counterfeit are described in detail in the same document.

4.6 Manual and repeated entry

In case the scanner cannot read the 2D code, it is possible to enter the human-readable data elements **manually**. **The number of repeated pack status verifications** ("verification" transaction) **is limited to 10 attempts**.

4.7 Medicinal product pack statuses

Table 2 shows a list of all potential statuses of a medicinal product. The status is marked yellow or red, depending on whether it can be changed, or not.

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

All other statuses indicate that the medicinal product has already been either supplied and the pack has been decommissioned from the repository or that the medicinal product cannot be supplied for some reason. These statuses are either permanent, i.e. they cannot be changed (e.g. STOLEN), or they can be changed within 10 days (EXPORT from the EU) or they can be changed without any time limitation (LOCKED) – this concerns only MAHs/OBPs and marketing authorization holders in the role of parallel distributors):

- Marked in yellow are pack statuses that can be changed under defined conditions (at the same location, within 10 days or without any time limitation), i.e. they can be returned to the initial status – i.e. ACTIVE. **However, a change of state can only be applied by a party authorized to perform that particular change of state.** (e.g. the "Export from the EU" status can be changed by marketing authorization holders (parallel distributors or MAHs) and the "Locked" status can be changed by MAHs/OBPs only.
- Marked in red are pack statuses that are permanently decommissioned and cannot be changed, i.e. the medicinal product pack can no longer return to the ACTIVE status (be reactivated).

State	The party authorized to change the state of the pack				Description
	Pharmacy	Wholesaler	Parallel Importer	MAH/OBP	
Active	YES	YES	YES	YES	The default pack state that allows to supply the pack/change the pack state
Supplied	YES	YES	YES	YES	The pack of a medicinal product with the given specific serial number has been marked as Supplied. The serial number can however be re-activated within 10 days at the same location (without limits in regard to the count of re-activations).
Change of the Supplied state - Re-introduction/Re-activation	YES	YES	YES	NO	A pack return. The pack of a medicinal product has been marked as Supplied, but can be re-activated (within 10 days at the same location - without limits in regard to the count of re-activations).
Expired	NO	NO	YES	YES	The batch for the given serial number has expired. The serial number is **permanently decommissioned.**
Withdrawn	NO	NO	YES	YES	The medicinal product (of the same product code) has been withdrawn from the market. The serial number is **permanently decommissioned.**
Recalled	NO	NO	YES	YES	The batch for the given serial number has been recalled. The serial number is **permanently decommissioned.**
Locked	NO	YES	YES	YES	The pack of a medicinal product with the given serial number has been temporarily locked for further investigation. The serial number can be **re-activated without any time limits** (provided the condition of the same location is preserved).
Destroyed	YES	YES	YES	YES	The medicinal product with the given serial number has been decommissioned as Destroyed. The serial number is **permanently decommissioned.**
Stolen	NO	YES	YES	YES	The medicinal product with the given serial number has been decommissioned as Stolen. The serial number is **permanently decommissioned.**
Export from EU	NO	YES	YES	YES	The medicinal product with the given serial number has been decommissioned as Exported. The serial number has been decommissioned, but **can be re-activated within 10 days at the same location.**
Undo Export from EU	NO	YES	YES	YES	Undo export. The medicinal product with the given serial number has been decommissioned as Exported. The serial number has been decommissioned, but **can be re-activated within 10 days at the same location.**
Sample	YES	YES	YES	YES	The medicinal product with the given serial number has been provided as a sample to the respective authorities. The serial number has been decommissioned, but **can be re-activated within 10 days at the same location.**
Free Sample	NO	YES	YES	YES	The medicinal product with the given serial number has been provided as a free sample. The serial number has been decommissioned, but **can be re-activated within 10 days at the same location.**
Checked-out	NO	NO	YES	NO	The medicinal product with the given serial number has been re-packed by a parallel importer. The serial number is **permanently decommissioned**.
Master data upload (via EU HUB)			YES	YES	
Pack data upload (via EU HUB)			YES	YES	
Report request	YES	YES	YES	YES	

Table 3 – Medicinal product pack statuses

Legend:

Active - the pack can be decommissioned
Decommissioned, but possible to re-activate
Decommissioned permanently
Change of state

***Note**.: Re-activation - the state of pack is returned to Active (the pack can be Supplied after a successful verification)*
Pack = 1 „packet" of a medicinal product secured with a UI; states defined in Table 1 relate to 1 pack of a medicinal product (except Recalled batch (the state applies to the whole batch) or (withdrawal of a medicinal product (the state applies to the medicinal product))
Medicinal product - 1 product code (PC)
Recalled = applicable to the whole batch of a medicinal product
Withdrawn = applicable to the medicinal product (includes all batches)
Parallel importer is a distribution licence holder for medicinal products having a special role within FMD as per the specific activities and rights to perform state changes of medicinal packs

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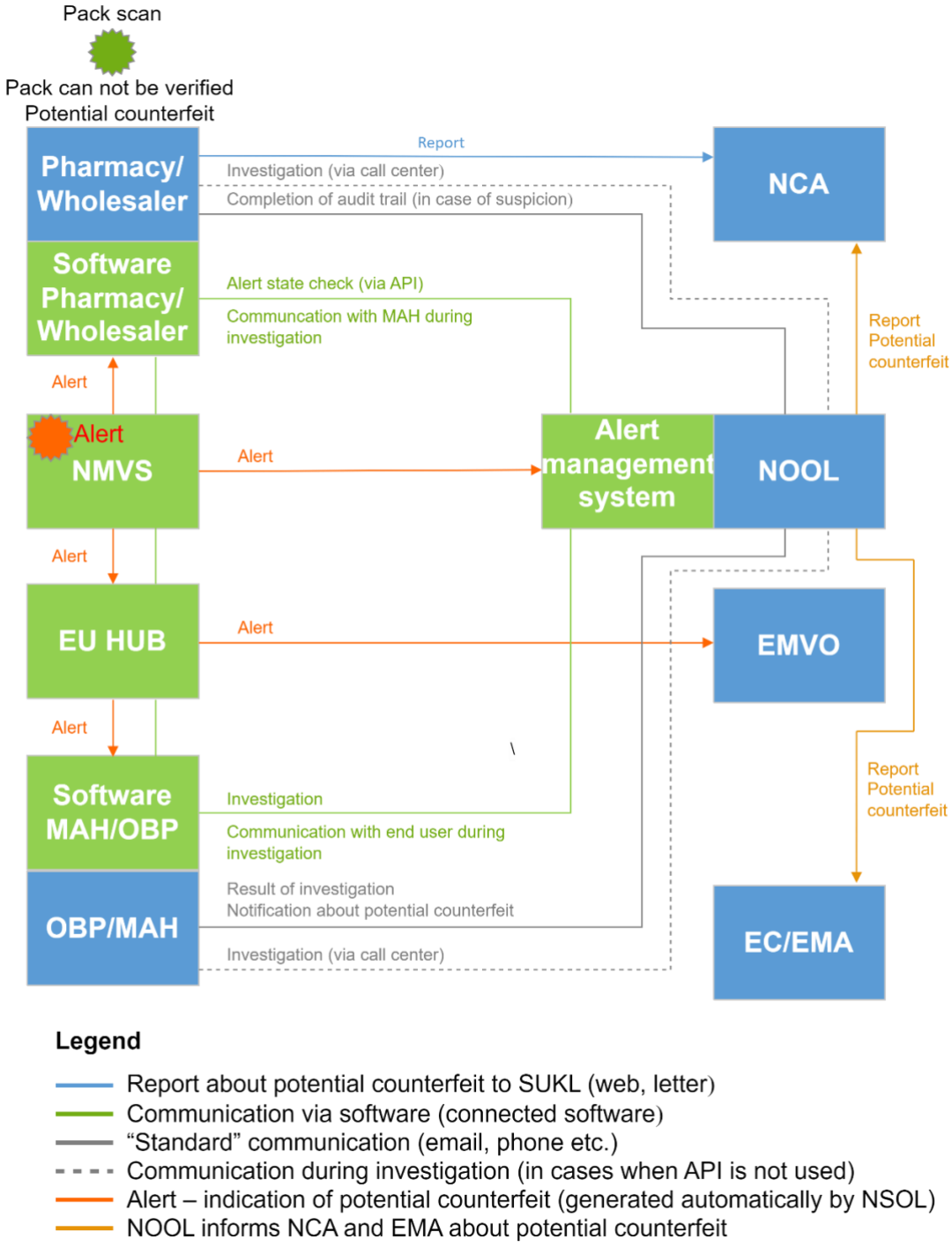
5 Handling of medicinal product verification situations

5.1 Medicinal product verification process and information flow upon detection of a counterfeit suspect



Picture3 – pack verification process and information flow in case of potential counterfeit

Note.: *The option to request data to complete the audit trail is anchored in Chapter 5 of the contract between CZMVO and the end user. This information will be requested only in case the MAH confirms a potential counterfeit suspect or requests information for further investigation.*