Guidelines for Managing Alerts During Verification and Decommissioning of Medicines after February 9th, 2019

The purpose of this document is to provide instructions to the participants in the medicines supply chain in Bulgaria in relation with the management of alerts under Art. 36(b) and 37(c) of Delegated Regulation (EU) 2016/161. The document has been coordinated with the national competent authorities and professional organizations of all stakeholders in the medicines supply chain in Bulgaria, namely the Association of the Research-Based Pharmaceutical Manufacturers in Bulgaria, the Bulgarian Generic Pharmaceutical Association, Bulgarian Association of Medicines Parallel Trade Development, Bulgarian Association of Pharmaceutical Wholesalers and Bulgarian Pharmaceutical Union.

According to Directive 2011/62/EC and Delegated Regulation (EU) 2016/161, all stakeholders in the legal medicines supply chain - manufacturers, wholesalers, parallel wholesale traders and pharmacies, as well as the National Medicines Verification Organization (BgMVO) and the National Competent Authorities (BDA) are responsible for fulfilling their obligations.

Technically, the Bulgarian Medicines Verification System has been in production and functioning since April 2018, however the use of such a large-scale system requires time to set up the computer systems of thousands of end-users. The period after February 9th, 2019 will be a period of smooth transition during which all stakeholders in the legal medicines supply chain are obliged to start using the new integrated European Medicines Verification System. Immediately after starting the wide use of the system, some technical difficulties might occur:

- Errors when manufacturers upload data for serialized packs of prescription medicines and omeprazole in the European hub;

- Errors when reading the codes on the packs with different types of barcode readers (scanners) by wholesale traders and pharmacies;

- Inaccuracies in the development of software applications by IT suppliers of pharmaceutical software.

The occurrence of technical errors during the initial period of operation of the new system should in no case be a barrier for the supply of medicines to patients or lead to problems in the normal supply of medicines in Bulgaria.

After February 9th, 2019, manufacturers are obliged to produce medicinal products with safety features. Initially, for a certain period of time, both serialized and non-serialized packs will be available in the legal supply chain. Some manufacturers may have produced serialized packs with no tamper-evidence before February 9th, 2019 or they may have not uploaded data for the serialized packs in the hub. Non-serialized packs, serialized packs which are not uploaded in the hub or packs without anti-tampering devices released before February 9th, 2019 may be supplied to patients until their expiry date.

Instructions to Manufacturers of Medicinal Products

Manufacturers of prescription medicines and omeprazole must ensure correct uploading of the data for serialized medicinal products (Product Master Data (PMD) and Product Pack Data (PPD)) into the European hub. It is recommended that data for serialized medicinal products produced before 9th February 2019 is uploaded retrospectively into the European hub. This will prevent getting alerts for missing system codes when verification of the product safety features by wholesalers and pharmacies takes place. In the event of failure to retrospectively upload the data, manufacturers should inform their trading partners in due time.

Instructions to Wholesale Traders

It is recommended that wholesale traders verify at least one pack of each batch of a serialized medicinal product to verify that the data has been uploaded by the manufacturer in the system before they deliver medicinal products. When receiving code-related alerts, wholesale traders should inform producers in good time.

It is recommended that wholesale traders verify the packs of medicinal products delivered to clients under Art. 23 of the Delegated Regulation (EU)2016/161.

The training to work with the medicines verification software should be provided by the IT supplier of the verification software. In case of problems with the use of warehouse software and scanners, wholesale traders must seek technical assistance from their IT suppliers or scanner providers.

Instructions to Pharmacies

It is recommended that pharmacies perform verification of serialized medicinal products at the time of their receipt from the wholesaler to prevent possible technical problems from happening in front of the patients.

The training for working with the medicines verification software should be provided by the IT supplier of the verification software. In case of problems with the use of pharmacy software and scanners, pharmacies must seek technical assistance from their IT suppliers or scanner providers.

Scanning recommendations

Example for a pack of a medicinal product with
Safety features – Two-dimensional bar code (2D Data Matrix code) and anti-tampering device

Safety features may be applied on a dark background. In these cases, it is necessary to adjust the settings of the scanner to recognize this format.

Safety features must not be tampered with, changed and/or covered by labels, stickers or otherwise.

Other types of bar codes that **must not** be scanned for verification and decommissioning in the system for medicines with safety features:

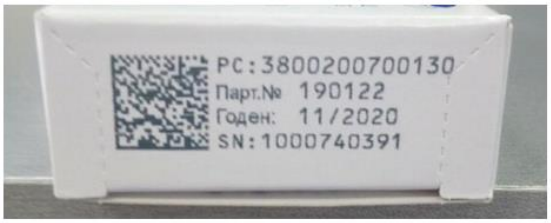
Linear Bar Code

QR Code
(it has squares in three of the angles)

Anti-tampering Device

In cases where serialized products have no tamper-evidence during the initial period, it can be assumed that they were produced before February 9th 2019 when the requirements of Delegated Regulation (EC) 2016/161 for the application of safety features on packs were not in force yet.

Examples of different types of anti-tampering devices:



Receiving Alerts in the Bulgarian Medicines Verification System

Technical Errors

The occurrence of technical errors can lead to alerts in the Bulgarian Medicines Verification System. The technical errors are not an obstacle to supplying medicines to patients. According to Art. 29 of Delegated Regulation (EC) 2016/161, in case of technical problems, pharmacists can supply the relevant medicinal product to the public after they have recorded the Unique Identification Code (UIC) by scanning or by hand. In the case of manual input, it is sufficient to record the Product Code (PC) and the Serial Number (SN).

A specific example of possible technical errors is related to the reading of the bar code when the keyboard is in Cyrillic mode and the barcode reader is not configured by the scanner provider. In this case, the scanner provider must set the device or the IT supplier must set the reader by software for reading barcodes in Latin.

It is possible to receive **two main types of alerts** in the system:

I. Alerts due to errors in product data

The alerts that can be received in the system as a result of errors in the product data are as follows:

"The serial number is unknown. An alert has been raised."

"The batch identifier mismatches the recorded batch identifier. An alert has been raised."

"The expiry date mismatches the recorded expiry date. An alert has been raised."

The reason for receiving these alerts may be:

- Technical errors when medicinal product data is uploaded by the manufacturer onto the European hub;
- Encoding errors;
- Errors in the barcode scanner setup;
- Inaccuracies in the development of the pharmaceutical software by IT providers.

Manufacturers will receive an alert about the error via the European hub and will take action to remove the errors when releasing the next batches and, if possible, for the current batch. These technical errors should not prevent the supply of medicinal products to patients during the initial period of use of the system.

II. Alerts due to product status errors

The possible statuses of a pack in the system are as follows:

Pack Status	Description
Active	Active. A pack with this status can be supplied to a patient or decommissioned from the system as "Destroyed", "Sample", "Free Sample", "Stolen", "Locked", "Exported" or "Checked-out".
Supplied	The pack has been supplied to a patient.
Destroyed	The pack has been destroyed.
Sample	The pack has been provided as a sample to a regulatory body.
Free Sample	The pack has been provided as a sample to a medical doctor.
Stolen	The pack has been stolen.
Locked	The pack has been locked (quarantined).
Exported	The pack has been exported outside the EU.
Checked-out	The pack has been decommissioned for repackaging by a parallel wholesale trader.

Two types of messages are possible during decommissioning:
- ”Supplied” - only when the pack is supplied to a patient.
- ”Decommissioned” message is received in all other cases when the pack is decommissioned from the system.

Alerts that can be generated in the system due to errors in the product pack status are as follows:

*"The pack cannot be **supplied**. An alert has been raised."*

This alert is received when a pack is being supplied to a patient and its status in the system is not "Active".

"The pack cannot be decommissioned. An alert has been raised."

This alert is received when a pack is being decommissioned as "Destroyed", "Sample", "Free Sample", "Stolen", "Locked", "Exported" or "Checked-out" and its status in the system is not "Active".

"The pack was previously supplied at this location. Too many repeated attempts. An alert has been raised."

This alert is received when an attempt is made to supply a medicinal product more than 9 times on the same location. In case of frequent double clicks, the IT provider or scanner supplier must set up the barcode scanner.

In the case of an error made by the pharmacist when attempting to re-supply the pack on his/her location and receiving an alert from the system, the pack status can be reactivated within 10 days on the same location only. After re-activation, the pack may be dispensed.

When receiving alerts as a result of product status errors, the pharmacist must assess whether the alert is due to his/her error (for example, attempting to re-supply the pack on the same location) or that the alert is related to possible falsified medicinal products and then take a professional decision whether to supply the medicinal product to the patient. If there are frequent errors on that location, it is necessary to review the standard operating procedures for the activities on this location.

If the status of the product has been changed **on another location**, after receiving an alert, the pharmacist must inform the BDA and keep the pack in a safe place until further instructions from the competent authorities are obtained as the medicines supply chain has been disrupted and there is a suspicion of a falsified product.

When the integrity of the secondary packaging is compromised or the system gives notice that the pack has been decommissioned on another location, the pharmacy must not dispense the medicinal product to the patient and must record the Unique Pack Return Code (UPRC) and inform the BDA. In case of suspicion of falsification, the current legal requirements for pharmacovigilance must be applied.

In the period after February 9th, 2019, it is recommended that all manufacturers, parallel traders, wholesale traders, pharmacies and hospital pharmacies which have not connected to the medicines verification system should do so as soon as possible and start actively using it in order to set their computer systems and work processes without interrupting the supply of medicines for technical reasons.

For questions related to the Bulgarian Medicines Verification System, users of the System can send their inquiries to the following email address: office@bgmvo.org. Response to queries will be sent by email within one month.