GUIDANCE ON THE VERIFICATION OF SAFETY FEATURES OF MEDICINAL PRODUCTS

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Slovak Medicines Verification Organization SOOL

for pharmacy, marketing authorisation holders for medicinal products and holders of authorisations for the wholesale distribution of medicinal products

Content

I. CHAPTER Basic information 4

Article I. Basic framework 4

Article II. General information guidelines 8

II. CHAPTER - Public Pharmacy 13

Article III. Connection to the Medicines Authentication System 13

Article IV. Procedure for verifying the authenticity of medicinal products and deactivating the unique packaging identifier of a medicinal product 14

Article V. Procedure in the event of an incident due to non-recognition of the packaging of the medicinal product in the authentication system 19

Article VI. Procedure for other packaging incidents in the Medicines Authentication System 21

Article VII. Incident Reporting Procedure 23

Article VIII. Procedure in case of technical problems not allowing verification of the authenticity of medicinal products and deactivation of the unique packaging identifier of the medicinal product at the time of dispensing 24

Article VIV. Verification of authenticity and deactivation of medicinal products in the provision of pharmaceutical care for outpatient health care facilities and institutional health care facilities 26

Article X. Verification of authenticity and deactivation of medicines in the provision of pharmaceutical care in a hospital pharmacy 27

III. CHAPTER - Wholesalers 28

Article XI. Connection to the Medicines Authentication System 28

Article XII. Procedure for verifying the authenticity of medicinal products and deactivating the unique packaging identifier of a medicinal product 29

Article XIII. Procedure in the event of an incident due to non-recognition of the packaging of the medicinal product in the authentication system 32

Article XIV. Procedure in the event of an incident due to inactive packaging of a medicinal product in the authentication system 33

Article XV. Incident Reporting Procedure 34

Article XVI. Procedure in case of technical problems not allowing verification of the authenticity of medicinal products and deactivation of the unique packaging identifier of the medicinal product at the time of dispensing 35

IV. CHAPTER - Marketing Authorisation Holders for Medicinal Products 36

Article XVII. Basic framework 36

Article XVIII. Connection to the Incident Management Portal.....36

Article XVIV. Procedure in the event of an incident by the holder 37

V. CHAPTER - General resolutions.....38

Article XX. Data protection and ownership.....38

Article XXI. Legal binding force.....39

Appendix No. 1..... 29

Appendix No. 2..... 30

I. CHAPTER Basic information

Article I. Basic framework

pursuant to the Commission Delegated Regulation (EU) 2016/161 of 2 October 2015 supplementing Directive 2001/83/EC of the European Parliament and of the Council with provisions concerning detailed rules on the safety features appearing on the packaging of medicinal products for human use (hereinafter referred to as the "Regulation") and pursuant to Act No. 362/2011 Coll. on medicinal products and medical devices and on amendments to certain acts, The following articles apply (the articles listed below are excerpts from the above legislation):

Article 20 Verification of the authenticity of the unique identifier by wholesale distributors

The wholesale distributor must verify the authenticity of the unique identifier on at least the following medicinal products in its physical possession:

a) *medicinal products which have been returned to him by persons authorised or authorised to supply medicinal products to the public or to other wholesale,*

b) *medicinal products which it obtains from a wholesale distributor who is neither a manufacturer nor a wholesale distributor with a marketing authorisation, nor a wholesale distributor authorised by a written contract by the marketing authorisation holder to store and distribute, on behalf of the holder, medicinal products covered by his marketing authorisation.*

Article 21 Exceptions to the provisions of Article 20(b)

Verification of the authenticity of the unique identifier of a medicinal product shall not be required under Article 20(b) in one of the following situations:

(a) there has been a change of ownership of the medicinal product, but the medicinal product remains physically owned by the same wholesaler.

(b) the medicinal product in question is distributed in the territory of a Member State between two warehouses belonging to the same wholesale distributor or legal entity without being sold.

Article 22 Deactivation of unique identifiers by wholesale distributors

The wholesale distributor must verify the authenticity of the unique identifier and deactivate it for the following medicinal products:

a) *medicinal products which it intends to distribute outside the territory of the Union;*

b) *medicinal products which have been returned to him by persons authorised or authorised to supply medicinal products to the public or to other wholesale distributors and which may not be returned to marketable stocks;*

c) *medicinal products that are intended for disposal;*

d) *medicinal products which are physically in his possession and which are requested by the competent authorities as a sample;*

e) *medicinal products which it intends to distribute to the persons or establishments referred to in Article 23 where required by national law, in accordance with the provisions of that Article.*

Article 24 Measures to be taken by wholesale distributors in the event of suspected tampering or counterfeiting

A wholesale distributor may not supply or export a medicinal product for which it has reason to believe that its packaging has been tampered with, or if verification of the safety features reveals that the medicinal product may not be genuine. It shall inform the competent authorities thereof without delay.

Article 25 Obligations of persons authorised or authorised to supply medicinal products to the public

1. *Persons who are authorised or authorised to supply medicinal products to the public must verify the safety features and deactivate the unique identifier of each medicinal product equipped with safety features that they supply to the public at the time of supply of the medicinal product to the public.*

2. *Without prejudice to paragraph 1, persons authorised or authorised to supply medicinal products to the public and who carry out their activities in a health establishment may carry out verification and deactivation at any time when the medicinal product is physically in the possession of the health establishment, provided that there is no sale between the delivery of the medicinal product to the health establishment and its supply to the public.*

3. *In order to verify the authenticity of the unique identifier of a medicinal product and to deactivate it, persons authorised or authorised to supply medicinal products to the public shall be required to connect to the registration system referred to in Article 31 through national or supranational registers serving the Member State in which they have been authorised or authorised.*

4. *They must also verify the safety features and deactivate the unique identifier for the following medicinal products equipped with safety features: (a) medicinal products that they physically possess and that cannot be returned to wholesale distributors or manufacturers; (b) medicinal products which are in their physical possession and which are requested as a sample by the competent authorities in accordance with national law; (c) medicinal products which they supply for the purpose of their subsequent use as authorised investigational medicinal products or authorised concomitant medicinal products as defined in Article 2(2), points (9) and (10), of Regulation (EU) No 536/2014.*

Article 26 Exceptions to the provisions of Article 25

1. *Persons authorised or authorised to supply medicinal products to the public shall be exempted from the obligation to verify the safety features and to deactivate the unique identifier of medicinal products, provided that they have obtained them as free samples in accordance with Article 96 of Directive 2001/83/EC.*

2. *Persons who are authorised or authorised to supply medicinal products to the public and who do not carry out their activities in a health establishment or pharmacy shall be exempted from the obligation to verify the safety features and to deactivate the unique identifier of medicinal products where such an obligation has been imposed on wholesale distributors under national law and in accordance with Article 23.*

3. *Without prejudice to Article 25, Member States may, where necessary to take account of the specific specificities of the supply chain in their territory, decide to exempt persons who are authorised or authorised to supply medicinal products to the public and who carry out their activities in a health establishment from the obligation to verify and deactivate the unique identifier, provided that: that the following conditions are met: (a) persons authorised or authorised to supply medicinal products to the public obtain a medicinal product bearing a unique identifier from a wholesale distributor who is part of the same legal entity as the health establishment in question; (b) the verification and deactivation of the unique identifier shall be carried out by the wholesale distributor supplying the medicinal products to the healthcare establishment concerned; (c) there is no sale of the medicinal product between the supplying wholesale distributor and the healthcare establishment concerned; (d) the medicinal product is supplied to the public within the health care establishment.*

Article 27 Obligations in the application of exceptions

Where the authentication and deactivation of the unique identifier within the meaning of Articles 23 or 26 are carried out earlier than referred to in Article 25(1), the integrity of the anti-tampering tool shall be verified at the time of delivery of the medicinal product to the public.

Article 28 Obligations for the supply of medicinal products in partial packs

Without prejudice to Article 25(1), persons authorised or authorised to supply medicinal products to the public shall, where they supply only part of a pack of a medicinal product with an active unique identifier, verify the safety features and deactivate the unique identifier at the moment when the package is opened for the first time.

Article 29 Obligations in the event of failure to verify the authenticity of a unique identifier and to deactivate it

Without prejudice to Article 25(1), persons authorised or authorised to supply medicinal products to the public shall, where technical problems do not allow them to verify the authenticity of a unique identifier and deactivate it at the time the medicinal product is supplied to the public, record that unique identifier and, as soon as the technical problems have been resolved, verify the authenticity of that unique identifier and deactivate it.

Article 30 Measures taken by persons authorised or authorised to supply medicinal products to the public in the event of suspicion of falsification

If persons authorised or authorised to supply medicinal products to the public have reason to believe that the packaging of the medicinal product has been tampered with, or if the verification of the safety features reveals that the medicinal product may not be genuine, those persons authorised or authorised to supply medicinal products to the public shall not supply the medicinal product and shall immediately inform the competent authorities thereof.

Article 48 Transitional measures

Medicinal products which have been released for sale or distribution without safety features in a Member State before the date of application of this Regulation in that Member State and which have not been repackaged or

relabelled after that date may be placed on the market, distributed and supplied to the public in that Member State until their expiry date.'

Article II. General information guidelines

1. A system for verifying the authenticity of medicinal products is established in order to prevent falsified medicinal products from entering the legal supply chain by requiring safety features consisting of the following on the outer packaging of selected medicinal products for human use for the purpose of their identification and authenticity verification:
    a) the unique identifier of the packaging of the medicinal product, and
    b) anti-tampering tool. If the selected medicinal product for human use does not consist of an outer packaging, the safety features shall be indicated on the immediate packaging.
2. The system for verifying the authenticity of medicinal products for human use is governed by Directive 2011/62/EU of the European Parliament and of the Council of 8 June 2011 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use as regards the prevention of the entry of falsified medicinal products into the legal supply chain and by Commission Delegated Regulation (EU) 2016/161 of 2 October 2015; supplementing Directive 2001/83/EC of the European Parliament and of the Council with provisions concerning detailed rules on the safety features to appear on the packaging of medicinal products for human use.
3. Verification of the authenticity and deactivation of medicinal products is obliged to be carried out by every pharmaceutical care provider and, in situations defined by the relevant legislation, also by the holder of a marketing authorisation for the wholesale distribution of medicinal **products for human use, from 9 February 2019** and before this date.
4. Pursuant to the provisions of Act No. 362/2011 Coll. on Medicinal Products and Medical Devices and on Amendments to Certain Acts, the holder of a marketing authorisation for the provision of pharmaceutical care, the holder of a marketing authorisation for the wholesale distribution of medicinal products for human use and the marketing authorisation holder for medicinal products for human use is obliged to comply with the obligations laid down in a special regulation, which is the Regulation by reference to the footnote. Pursuant to Act No. 362/2011 Coll. on Medicinal Products for Human Use, the holder of a marketing authorisation for medicinal products for human use commits another administrative offence if he fails to comply with the obligations set out in the Regulation, for which he or she may be fined in accordance with the said legislation.
5. The legal entity that establishes and administers the system of verification of the authenticity of medicinal products in the Slovak Republic is **the Slovak Organization for the Verification of Medicinal Products**.

Web address: **www.sool.sk**,

E-mail: **kancelaria@sool.sk**,

Phone number: **+421 2 2078 9464**.

6. Verification of authenticity and deactivation of medicinal products applies to:

a) medicinal products subject to medical prescription, with the exception of medicinal products included in the list set out in Annex 1 to this Guideline;

b) non-prescription medicinal products included in the list set out in Annex 2 to this Guideline.

7. Definitions:

a) **the system of verification of the authenticity of medicinal products** is an information system established and administered by the Slovak Organisation for the Verification of Medicinal Products and which is used to verify the authenticity of medicinal products, deactivate the unique identifier of the packaging of the medicinal product and other related requirements,

b) **A pack-specific identifier** is a security feature unique to a particular pack of a medicine that makes it possible to verify the authenticity and identify individual packs of a medicine and is indicated on the packaging of the medicine in the form of numeric or alphanumeric characters encoded in a two-dimensional code that can be read by a conventional two-dimensional code recognition scanning device.

c) **The anti-tampering tool** is a security feature that allows you to verify whether the packaging of the medicine has been tampered with and is placed on the packaging of the medicine, for example, as a transparent sticker or in another form,

d) **deactivation of the packaging identifier of a medicinal product** is an operation that changes the active state of the unique identifier of the packaging of a medicinal product stored in the system of authenticity of medicinal products to a state that prevents any further successful verification of the authenticity of that unique identifier of the packaging of the medicinal product,

e) **an active unique packaging identifier** is a unique packaging identifier for a medicinal product that has not been or is no longer deactivated;

f) **Active status** is the state of the active unique identifier of the packaging of a medicinal product stored in the system of verification of the authenticity of medicinal products, which allows such packaging to be dispensed to the patient after its subsequent deactivation and after verification of the integrity of the anti-tampering instrument.

g) **quarantine** is a reserved area in which a medicinal product will be stored until an instruction is issued pursuant to Article VI, point 4, Article VII, point 2, Article XIV, point 4, Article VX, point 2 of this Guideline.

8. Specific Pack Identifier:

a) means a sequence of numerical and alphanumeric characters that is unique for each package of a medicinal product up to one year from the expiry date or five years after the release of the package for sale, or whichever is later,

b) contains:

- **product code** (allows the identification of the name, common name, pharmaceutical form, strength of the product, package size and type of packaging of the product; indicated on the packaging as product code, (01), PC, GTIN or otherwise),
- **Serial number** (referred to on the packaging as serial number, (21), serial, SN, S.N., Sr. No. or otherwise),
- **batch number** (marked on the packaging as Batch No., (10), NO.Š., LOT, LN, L.N., Batch, Batch nr., B.N. and otherwise or is marked only in the form of alphanumeric characters);
- **Expiry date** (labelled as Ex, Expiry, (17) and otherwise on the packaging or indicated only in numerical characters)
- or other information, such as **the national code of the medicinal product** (the so-called NN number, which is not a condition for the inclusion on the packaging of medicinal products intended for the Slovak market),

c) it is encoded in a two-dimensional code placed on the packaging of the medicinal product by a readable standard two-dimensional code scanning device and is also readable by the naked eye in the form of an alphanumeric code containing the product code, serial number, batch number, expiry date and, where applicable, the national code of the medicinal product or other information, if the dimensions of the packaging allow,

d) A package of a medicinal product is considered genuine if the unique identifier of that package is present in the verification system.

Article III. Statuses of packaging, batch of medicinal product and product in the Pharmacovigilance System

1. The system for verifying the authenticity of medicines may include:

   a) Medicinal product as a product in the status:

      - active
      - Downloaded.

   b) Batch of the drug in status:

      - Active
      - Downloaded
      - expired.

   c) Packaging of the drug in status:

      - **An active** package is a package that can be dispensed to a patient. A specific identifier of a product packaging is in an active state if the product is in an active state and at the same time a batch of the product is in an active state and at the same time a specific package of the product is in an active state.
      - A package of a medicinal product that has been **exported** outside the territory of the European Union is exported. In this case, the Specific Packaging Identifier is deactivated.
      - A package of medicine that has been marked as **stolen** is stolen. In this case, the Specific Packaging Identifier is deactivated.
      - **A sample** is a package of a medicinal product that has been requested by the State Institute for Drug Control for the purpose of inspection or investigation. The requested package of the medicine is placed in the status of a sample by the pharmacy care provider or wholesale distributor. In this case, the Specific Packaging Identifier is deactivated.
      - **A free sample** is a package of a medicinal product that has been marked in that status by the marketing authorisation holder. In this case, the Specific Packaging Identifier is deactivated.
      - A package of a medicinal product that has been marked by the marketing authorisation holder is **locked**, for example, due to a suspicion of a quality deficiency or other reasons. In this case, the Specific Packaging Identifier is deactivated.

- A package of a medicine that is damaged and cannot be dispensed to a patient and has been designated for this status by a pharmacy provider or wholesale distributor is **destroyed**. In this case, the Specific Packaging Identifier is deactivated.
- A package of a medicinal product that has been designated as a status by a parallel distributor is deregistered from the register. In this case, the Specific Packaging Identifier is **deactivated**.
- The package of the medicine that was issued to the patient is dispensed. In this case, the Specific Packaging Identifier is **deactivated**.

II. CHAPTER - Public Pharmacy

Article III.
Connection to the Medicines Authentication System

1. A pharmaceutical care provider is obliged to connect to the drug verification system according to the instructions published on the website of the Slovak Medicines Verification Organization www.sool.sk in the **Information** section.
2. A pharmacy provider can implement a module of the drug authentication system:
    a) directly into your used information system through the supplier of the information system
    b) or implement a solution for connecting to a drug authentication system from another supplier of such a solution.
3. The provider of pharmaceutical care is obliged to
    a) Train each staff member who will perform authenticity verification and deactivation of specific identifiers of medicinal product packaging.
    b) ensure access to the PCS system at each site where the dispensing of medicines subject to verification of the authenticity of medicines takes place, and it is recommended to provide a two-dimensional code recognisable scanning device at each such point. Ensuring access to the verification system for the authenticity of medicinal products at the point where the receipt of medicinal products subject to verification of the authenticity of medicinal products from the supplier takes place is voluntary.

Article IV.
Procedure for verifying the authenticity of medicinal products and deactivating the unique packaging identifier of a medicinal product

When verifying the authenticity of medicinal products, persons authorised to carry it out must verify:

- **the authenticity** of the unique identifier of the packaging of the medicinal product;
- **integrity** of the anti-tampering tool.

Verification of the authenticity of the unique packaging identifier

1. When verifying the authenticity of the Packing Identifier of a medicinal product, persons authorised to carry it out shall compare the Packing Unique Identifier with the Packing Unique Identifier stored in the Medicines Authentication System using:
   a) reading the two-dimensional code of the unique identifier of the packaging of the medicinal product on the packaging of the medicinal product using a scanning device, or
   b) by manually entering the alphanumeric code of the product's unique packaging identifier into the system.
2. When manually verifying the Specific Packaging Identifier of a medicinal product, it is necessary to enter the product code and serial number into the system.
3. A product's unique packaging identifier is authentic if it is assessed as active by the Medicines Authentication System.

Verification of the integrity of the anti-tampering tool

1. When verifying the integrity of an anti-tampering tool, persons authorised to supply medicinal products to the public must visually check the integrity of such an instrument (for example, the integrity of the label on the packaging of the medicinal product).
2. In the event of a breach of the anti-tampering instrument or suspicion of tampering with the packaging, the medicine cannot be dispensed to the patient.

Operations that may be performed by a person authorised to supply medicinal products in the Medicines Authentication System

- **reading the information contained** in the two-dimensional code using a scanning device – this operation can be performed repeatedly,
- **verification (verification) of the authenticity** of the unique identifier of the packaging of the medicine – this operation can be performed repeatedly,
- **deactivation** of the unique packaging identifier of the medicinal product – marking the medicinal product as **dispensed**,
- **deactivation** of the unique packaging identifier – identification of the medicine as **a sample** intended for a national authority for inspection or investigation.
- **deactivation** of the product's unique packaging identifier – marking the product as **destroyed**;
- **change the status** of the unique packaging identifier of the medicinal product from **deactivated** to **active** within ten days after the deactivation of the unique identifier pursuant to paragraph 9 of this Article.

The process of verifying the authenticity of the medicine

1. **Verification** of the authenticity of the unique identifier of the packaging of the medicinal product can be carried out at any time and repeatedly, *provided that **the packaging of the medicinal product is physically present at the provider***.
2. **The deactivation** of the pack-specific packaging identifier **must be carried out**:
    a) at the time of dispensing the medicine to the patient;
    b) in the case of medicinal products which cannot be returned to wholesale distributors or manufacturers (except for expired medicinal products) and medicinal products which are requested by the competent authorities as a sample;
    c) in the case of use of the medicinal product in the preparation of an individually prepared medicinal product.
3. A medicine, subject to authenticity, **cannot be dispensed to a patient** without deactivating the unique identifier of the medicine pack (the medicine must be marked as dispensed in the system).
4. Persons who are authorised or authorised to supply medicinal products to the public and who carry out their activities in a healthcare establishment (hospital pharmacies) may carry out verification and deactivation at any time when the medicinal product is physically in the possession of the healthcare establishment, provided that there is no sale between the delivery of the medicinal product to the healthcare establishment and its dispensing to the public.

5. The authenticity of the unique identifier of the pack is verified using a scanning device by scanning a two-dimensional code. Subsequently, the Medicines Authentication System evaluates the authenticity of the Unique Packaging Identifier of the medicine. The system evaluates the unique identifier of the packaging of the medicine as genuine if it is present in the register and marked with the status "active". In the case of dispensing a medicine to a patient, it automatically deactivates it in the system and marks it with the status "dispensed". The exact technical progress depends on the supplier of the solution for connection to the drug authentication system.
6. Persons authorised to supply medicinal products **shall not dispense a medicinal product to a patient** unless the authenticity verification system evaluates the unique packaging identifier of the medicinal product as active at the time of dispensing. In such a case, it is necessary to proceed according to Article VIII.
7. In the event of failure to confirm the authenticity of the medicinal product (the unique identifier of the medicinal product packaging has not been evaluated in the system as active or the anti-tampering tool with the packaging is violated or there is another suspicion that the packaging of the medicinal product may not be genuine), the person authorised to dispense medicinal products shall proceed as follows:
    a) verifies the authenticity of another pack of the same medicine and dispenses the verified pack to the patient;
    b) if it is not possible to proceed in accordance with point (a), offer the patient the dispensing of a substitute human medicinal product,
    c) If it is not possible to proceed according to points (a) or (b), the patient will be advised to dispense the medicinal product to other pharmaceutical care providers or, after contacting the doctor, to consider the prescription of therapeutic replacement of the medicinal product.
8. If it is not possible to verify the authenticity of the unique packaging identifier of the medicinal product using a scanning device, it is necessary to verify the unique packaging identifier of the medicinal product manually using a format that is readable to the naked eye (the unreadable unique packaging identifier containing the product code, serial number, batch number, expiry date and, where applicable, other information such as the national product code must be on the outer or inner packaging of all medicinal products subject to verification of the authenticity of medicinal products, except for medicinal products for which the sum of the two longest dimensions of the outer packaging does not exceed 10 centimetres). When manually verifying the Specific Packaging Identifier of a

medicinal product, it is necessary to enter the product code and serial number into the system.

9. An already deactivated Pack-Specific Identifier can be returned to the active state under the following conditions:

   a) the person performing this operation has the same authorisation and works in the same premises as the person who deactivated the unique packaging identifier of the medicinal product;

   b) no more than 10 calendar days have elapsed since the deactivation of the unique packaging identifier of the medicinal product,

   c) the packaging of the medicine is not expired,

   d) the batch of the medicinal product is not withdrawn from the market, the packaging is not intended for disposal or stolen, and the person carrying out the change of status operation is not aware that it is a stolen package,

   e) The medicine pack has not been dispensed to the patient.

10. In the case of dispensing **only a part of the package of a medicinal product** that is subject to verification of the authenticity of medicinal products, the verification of the authenticity of the given packaging of the medicinal product and the deactivation of the unique identifier of the medicinal product packaging shall be carried out **only when** the given package of medicinal product is opened for the first time.

11. Medicinal products for disposal that have been dispensed to a patient and subsequently returned to the pharmacy are not subject to re-verification of the authenticity of the medicinal products and the reactivation of the unique packaging identifier of the medicinal product.

12. Medicinal products that have not been supplied to the public and that are intended for disposal **are subject to the deactivation** of the unique packaging identifier in the pharmacovigilance system before the medicinal product is handed over to the competent entity for disposal and must not be returned to marketable stocks.

13. In the case of sale of the medicinal product to another pharmaceutical care provider, the unique packaging identifier of the medicinal product must not be deactivated. It is possible to verify the authenticity of the specific identifier of the pack of the medicine at any time.

14. Medicines that do not have safety features on their packaging do not need to be verified.

15. All medicines manufactured and placed on the market after 9 February 2019 **are subject to verification of the authenticity of medicines**.

16. The pharmaceutical care provider must ensure that each package subject to verification is scanned and verified and must adapt its pharmacy information system accordingly.

Article V.
Procedure in the event of an incident due to non-recognition of the packaging of the medicinal product in the authentication system

1. **An incident in the Pharmacovigilance System** is a situation where the Medicines Authentication System evaluates the Specific Packaging Identifier of the medicinal product differently than the Active or Specific Packaging Identifier of the medicinal product is not recognised by the verification system.
2. Incidents in the verification system for medicinal products must be reported in accordance with Article VIII of this Guideline.
3. Incidents due to not recognizing the packaging of the medicine can be:
    a) **NMVS_NC_PC_01** – product code of the medicine pack not found
    b) **NMVS_FE_LOT_03** – the lot number assigned to the product code was not found,
    c) **NMVS_NC_PC_02** – the serial number assigned to the product code was not found,
    d) **NMVS_FE_LOT_12** – the expiry date of the specified package of the medicinal product does not coincide with the expiry date of the batch of the medicinal product,
    e) **NMVS_FE_LOT_13** - The serial number has been assigned to the product code, but it does not belong to the batch number listed.
4. In the event of an incident pursuant to paragraph 3 of this Article, the pharmaceutical care provider is obliged **to quarantine such packaging** and wait for instructions from the representative of the marketing authorisation holder responsible for the packaging in question or instructions from the Slovak Medicines Verification Organisation. The State Institute for Drug Control is automatically notified of the incident.
5. In the event that the reaction of the marketing authorisation holder of the packaging in question is awaited and the holder does not react to the incident **within 30 calendar days from the date of the evaluation pursuant to point 1 of this Article**, the pharmaceutical care provider has the right to return such packages to the holder as a complaint through the entity from which the package was purchased.
6. If there is a **serious suspicion** that it is a counterfeit packaging in any of the above incidents, it is necessary to report this fact to the State Institute for Drug Control via e-mail to **fmd.hlasenia@sukl.sk.**

7. In the event that the entity performing the verification has additional information that can help to close the incident, it can enter this information into the **PHARMACY** application on the website **https://lekaren.e-vuc.sk/** to the relevant incident.

Article VI.
Procedure for other packaging incidents in the Medicines Authentication System

1. It is necessary to proceed according to this article if the following incidents arise during the verification of the authenticity of medicinal products by a person authorised to supply medicinal products to the public, when verifying the unique identifier of the packaging of a medicinal product:

   a) the package of the medicine is **exported in the status**,

   b) the package of the medicine is **stolen in the status**,

   c) the packaging of the medicine is in **the status of a sample**,

   d) the package of the medicine is in **the status of a free sample**,

   e) the medicine package is **locked in the status**,

   f) the package of the drug is destroyed in the status,

   g) the package of the medicinal product is **deregistered from the registry** in the status,

   h) The package of the medicine is issued in the status.

In this type of incident, the system may display the following messages:

- **NMVS_NC_PCK_19** - The package is no longer active. You are trying to dispense an inactive package.
- **NMVS_NC_PCK_22** - The package is no longer active. You are trying to dispense an inactive package.

2. In the event of an incident pursuant to paragraph 1 of this Article of the Guideline, if the packaging of the medicinal product has not been listed in the specified status by the pharmaceutical care provider who performs the verification of the package, it is necessary to report the incident in the manner specified in Article VII of this Guideline, **to quarantine the packaging** and to wait for the instructions of the Slovak Organization for the Verification of Medicinal Products and/or the State Institute for Drug Control.

3. In the event that the reaction of the marketing authorisation holder of the packaging in question is awaited and the holder does not react to the incident **within 30 calendar days from the date of occurrence of the incident pursuant to point 1 of this Article**, the pharmaceutical care provider has the right to return such packages to the holder as a complaint through the entity from which the package was purchased.

4. If there is a **serious suspicion** that it is a counterfeit packaging in any of the above incidents, it is necessary to report this fact to the State Institute for Drug Control via e-mail to **fmd.hlasenia@sukl.sk.**

Article VII.
Incident Reporting Procedure

1. Incidents in the drug authentication system must be *reported* [1] to pharmacists in the **PHARMACY** application on **the https://lekaren.e-vuc.sk/** website.
2. In the event that the incident occurred unintentionally due to an error in the handling of the medicinal product or another technical problem, it is necessary to report such a fact via **the PHARMACY** application on the **https://lekaren.e-vuc.sk/ website,** where the user of the verification system writes a relevant note in the relevant incident, and then this fact is verified by the Slovak Medicines Verification Organization. If this is confirmed, the package of the drug can be dispensed to the patient.

[1] **Need to report** – When an incident occurs, the system automatically saves the incidents in the PHARMACY and DISTRIBUTOR application, and thus, to facilitate your work, these reports are automatically filed, and there is no need to report them additionally.

Article VIII.
Procedure in case of technical problems not allowing verification of the authenticity of medicinal products and deactivation of the unique packaging identifier of the medicinal product at the time of dispensing

1. In the event of technical problems that do not allow the verification of the authenticity of the medicinal product and the deactivation of the Unique Packaging Identifier at the time of dispensing the medicinal product to the patient, the person authorised to dispense the medicinal product shall read the Unique Packaging Identifier of the medicinal product into the Medicines Authentication System by means of a scanning device, which, after the technical problems have been resolved, shall verify the authenticity of the medicinal product and deactivate the Unique Packaging Identifier of the medicinal product automatically.
2. In the event of technical problems that do not allow the scanning device to read the unique packaging identifier of the medicinal product, the person authorised to supply medicinal products shall manually enter the alphanumeric value of the product-specific identifier (product code and serial number) into the medicine-authenticity verification system, which, once the technical problems have been resolved, shall verify the authenticity of the medicinal product and deactivate the product-pack unique identifier automatically.
3. In the event of technical problems that do not allow the scanning device to read the unique packaging identifier of the medicinal product and to manually enter the alphanumeric value of the unique packaging identifier (product code, serial number, batch number, expiry date and, where applicable, other information such as national product code) into the product authentication system, the person authorised to supply medicinal products shall record the alphanumeric value of the unique packaging identifier (product code and serial number). number), which, after eliminating technical problems, is entered manually into the drug authenticity verification system, which verifies the authenticity of the drug and deactivates the specific identifier of the drug packaging automatically.
4. In the event of a failure of the pharmacy module for verifying the authenticity of medicinal products, it is possible to verify the authenticity of the Unique Packaging Identifier of the medicinal product by manually entering the alphanumeric value of the Specific Packaging Identifier (product code and serial number) into the system on the **https://portal-prod-sk.nmvs.eu website**. It logs in to the system using the login details provided when

connecting to the Medicines Authentication System for the first time. Detailed instructions on how to verify the authenticity of a specific packaging identifier of a medicine through this website and possibly deactivate it can be found on **the www.sool.sk** website.

Article VIV.
Verification of authenticity and deactivation of medicinal products in the provision of pharmaceutical care for outpatient health care facilities and institutional health care facilities

In the event that a public pharmacy provides pharmaceutical care for an outpatient health care facility and an institutional health care facility, it proceeds with dispensing in the same way using the same procedures and technical equipment as in the case of dispensing medicinal products to the public.

Article X.
Verification of authenticity and deactivation of medicines in the provision of pharmaceutical care in a hospital pharmacy

A hospital pharmacy shall proceed in all steps in a manner similar to that of a public pharmacy, except that it does not have to proceed in accordance with Article V – Course of verification of the authenticity of a medicinal product, point 2(a) of this Guideline, where persons authorised or authorised to supply medicinal products to the public carrying out activities in a hospital pharmacy may carry out verification and deactivation at any time when the medicinal product is physically in the possession of the healthcare establishment, provided that: that there is no sale between the delivery of the medicinal product to the health care establishment and its supply to the public, and except where the medicinal products are not dispensed to the supply of medicinal products to the public, in which case the deactivation of the unique packaging identifier of the medicinal product is carried out by the department of supply of medicinal products to the public when the medicinal product is dispensed to the patient.

III. CHAPTER - Wholesalers

Article XI.
Connection to the Medicines Authentication System

1. The holder of an authorisation for the wholesale distribution of medicinal products for human use, hereinafter referred to as the 'wholesale distributor', who physically holds the products, trades in them and carries out the wholesale activities referred to in Articles 20 to 23 of Commission Delegated Regulation (EU) 2016/161 (for example, verification of returns or decommissioning for export), is obliged to connect to the verification system for medicinal products and carry out operations in it in accordance with the legislation, and according to the instructions published on the website of the Slovak Medicines Verification Organization www.sool.sk in the Information section.
2. A wholesale distributor can implement a drug authentication system module:
    a) directly into your used information system through the supplier of the information system
    b) or implement a solution for connecting to a drug authentication system from another supplier of such a solution.
3. A wholesale distributor is required
    a) Train each employee who will carry out the authentication and deactivation of the Unique Identifiers of the packaging of medicinal products.
    b) ensure access to the PCS system at each site where the distribution of medicines subject to verification of the authenticity of medicines takes place, and it is recommended to provide a two-dimensional code recognising scanning device at each such site.

Article XII.
Procedure for verifying the authenticity of medicinal products and deactivating the unique packaging identifier of a medicinal product

When verifying the authenticity of medicinal products, persons authorised to carry it out must verify:

- **the authenticity** of the unique identifier of the packaging of the medicinal product;
- **integrity** of the anti-tampering tool.

Verification of the authenticity of the unique packaging identifier

1. When verifying the authenticity of the Packing Identifier of a medicinal product, persons authorised to carry it out shall compare the Packing Unique Identifier with the Packing Unique Identifier stored in the Medicines Authentication System using:
   a) reading the two-dimensional code of the unique identifier of the packaging of the medicinal product on the packaging of the medicinal product using a scanning device, or
   b) by manually entering the alphanumeric code of the product's unique packaging identifier into the system.

Verification of the integrity of the anti-tampering tool

1. When verifying the integrity of an anti-tampering tool, authorised persons must visually check the integrity of such a tool (for example, the integrity of the label on the packaging of the medicinal product).
2. In the event of a breach of the anti-tampering tool or suspicion of tampering, the medicine cannot be distributed.

Operations that can be performed by an authorised person in the Medicines Authentication System

- **reading the information contained** in the two-dimensional code using a scanning device – this operation can be performed repeatedly,
- **verification (verification) of the authenticity** of the unique identifier of the packaging of the medicine – this operation can be performed repeatedly,

- **deactivation** of the unique packaging identifier of the medicinal product – marking the medicinal product as **dispensed**,
- **deactivation** of the product's unique packaging identifier – marking the product as **destroyed**;
- **deactivation** of the unique packaging identifier of the medicine – labelling the medicine as **a sample** intended for a national authority for inspection or investigation;
- **deactivation** of the unique identifier of the packaging of the medicinal product – marking the medicinal product as **exported**,
- **deactivation** of the unique identifier of the medicine – marking the medicine as **stolen**;
- **change the status** of the Pack Unique Identifier from **deactivated** to **active** within ten calendar days after the deactivation of the Pack Unique Identifier.

Deactivation of the Unique Packaging Identifier of a medicinal product by a wholesale distributor

1. On **the basis of the applicable legislation (Section 18 paragraph 19 of Act No. 362/2011 Coll. on Medicinal Products and Medical Devices and on Amendments to Certain Acts), the wholesale distributor must deactivate the specific identifier of the packaging of the medicinal product before the delivery of the medicinal product, if the medicinal product is supplied:**
   a) emergency medical service provider
   b) the armed forces and the armed forces;
   c) a veterinarian who provides professional veterinary activities,
   d) The Police Force and other state administration bodies that manage stocks of human medicines for the purposes of civil protection and disaster control,
   e) medical facility under the jurisdiction of the Ministry of Justice of the Slovak Republic.
2. On the basis of Act No. 362/2011 Coll. The Law on Medicinal Products and Medical Devices requires a wholesale distributor to supply medicinal products for human use to entities other than those referred to in point 1 of this Article, including:
   a) to another holder of an authorisation for the wholesale distribution of medicinal products for human use;

b) the holder of an authorisation to provide pharmaceutical care in a hospital pharmacy or a public pharmacy, even if the medicinal product for human use has been procured by a health insurance company;

c) an outpatient health care facility to the extent stipulated,

d) international humanitarian organization, if the Ministry of Health so decides.

3. The wholesale distributor is advised to verify the authenticity of the safety feature Unique Packaging Identifier of medicinal products supplied by the entities referred to in point 2(c) and (d) in the manner specified in the section "Deactivation of the Packaging Unique Identifier by the Wholesale Distributor.

Other voluntary operations of the wholesale distributor

4. According to Section 18 (1) (w) Pursuant to Article 362 of Act No. 362/2011 Coll. on Medicinal Products and Medical Devices and on Amendments to Certain Acts, the holder of an authorisation for the wholesale distribution of medicinal products is obliged to verify by checking the safety feature on the outer packaging that the supplied human medicinal products are not falsified;

5. The wholesale distributor is advised to verify the authenticity of the unique packaging identifier of the medicinal product for at least one package of each medicinal product in each batch that he has acquired.

6. In the event that the verification of the specific identifier of the packaging of the medicinal product pursuant to this Article reveals that it is not present in the system, it is necessary to suspend further distribution of the batch to which the package in question belongs, contact the representative of the marketing authorisation holder of the medicinal product in question, or the supplier of the batch to which the package in question, in order to remedy it, and only then continue with the distribution of the batch in question after the remedy has been made.

Article XIII.
Procedure in the event of an incident due to non-recognition of the packaging of the medicinal product in the authentication system

1. **An incident in the Pharmacovigilance System** is a situation where the Medicines Authentication System evaluates the Specific Packaging Identifier of the medicinal product differently than the Active or Specific Packaging Identifier of the medicinal product is not recognised by the verification system.
2. Incidents in the verification system for medicinal products must be reported in accordance with Article XVI of this Guideline.
3. Incidents due to not recognizing the packaging of the medicine can be:
    a) **NMVS_NC_PC_01** – The product code of the drug packaging was not found.
    b) **NMVS_FE_LOT_03** - The specified batch number associated with the product code could not be found.
    c) **NMVS_NC_PC_02** - The serial number associated with the product key could not be found.
    d) **NMVS_FE_LOT_12** – The expiry date of the specified package of the medicinal product does not coincide with the expiry date of the batch of the medicinal product.
    e) **NMVS_FE_LOT_13** - The serial number has been assigned to the product code, but it does not belong to the batch number listed.
4. In the event of an incident pursuant to paragraph 3 of this Article, the wholesale distributor is obliged **to quarantine such packaging** and wait for instructions from the representative of the marketing authorisation holder responsible for the packaging in question or instructions from the Slovak Medicines Verification Organisation. The State Institute for Drug Control is automatically notified of the incident.
5. In the event that the reaction of the marketing authorisation holder of the packaging in question is pending and the holder does not respond to the incident **within 30 calendar days**, the wholesale distributor has the right to return such packages to the holder as a complaint directly or through the entity from which the package was purchased.
6. If there is a **serious suspicion** that it is a counterfeit packaging in any of the above incidents, it is necessary to report this fact to the State Institute for Drug Control via e-mail to **fmd.hlasenia@sukl.sk.**

7. In the event that the entity performing the verification has additional information that can help close the incident, it can enter this information into the DISTRIBUTOR application on the website https://distributor.e-vuc.sk/ to the relevant incident.

Article XIV.
Procedure in the event of an incident due to inactive packaging of a medicinal product in the authentication system

1. It is necessary to proceed under this article if, during the verification of the authenticity of medicinal products by a person verifying the specific identifier of the packaging of the medicinal product, the following incidents occur, the primary cause of which is that the packaging of the medicinal product is not in an active state:
   a) the package of the medicine is **exported in the status**,
   b) the package of the medicine is **stolen in the status**,
   c) the packaging of the medicine is in **the status of a sample**,
   d) the package of the medicine is in **the status of a free sample**,
   e) the medicine package is **locked in the status**,
   f) the package of the drug is destroyed in the status,
   g) the package of the medicinal product is **deregistered from the registry** in the status,
   h) The package of the medicine is issued in the status.

For this type of incident, the system may display the following messages:

- **NMVS_NC_PCK_19** - The package is no longer active. You are trying to dispense an inactive package.
- **NMVS_NC_PCK_22** - The package is no longer active. You are trying to dispense an inactive package.

2. In the event of an incident pursuant to paragraph 1 of this Guideline, if the packaging of a medicinal product has not been listed in that status by the wholesale distributor who performs the verification of the package, it is necessary to report the incident in the manner specified in Article XVI of this Guideline, **to quarantine such packaging** and to wait for the instruction of the representative of the marketing authorisation holder responsible for

the packaging in question or the Slovak Medicines Verification Organisation, and/or the State Institute for Drug Control.

3. In the event that the reaction of the marketing authorisation holder of the packaging in question is awaited and the holder does not react to the incident **within 30 calendar days**, the wholesale distributor has the right to return such packages to the holder as a complaint directly to the holder or through the entity from which the package was purchased.

4. If there is a **serious suspicion** that any of the above incidents is counterfeit, it is necessary to report this fact to the State Institute for Drug Control via e-mail to **fmd.hlasenia@sukl.sk**.

Article XV.
Incident Reporting Procedure

1. Incidents in the drug authentication system must be *reported*[2] in the **DISTRIBUTOR** application on **the https://distributor.e-vuc.sk/ website.**

2. In the event that the incident was caused by an unintentional error in the handling of the medicinal product or other technical problem, it is necessary to report such a fact via **the DISTRIBUTOR** applications on the **https://distributor.e-vuc.sk/ website,** where the user of the verification system writes a relevant note in the relevant incident, and then verifies this fact to the Slovak Medicines Verification Organization. If this is confirmed, the medicine pack may be distributed.

[2] **Note** – When an incident occurs, the system automatically stores the incident in the registers specified in this point (**https://lekaren.e-vuc.sk/** and **https://distributor.e-vuc.sk/**) and thus the obligation to report the incident is automatically implemented and there is no need to report the incident manually.

Article XVI.
Procedure in case of technical problems not allowing verification of the authenticity of medicinal products and deactivation of the unique packaging identifier of the medicinal product at the time of dispensing

1. In the event of technical problems that do not allow the verification of the authenticity of the medicinal product and the deactivation of the Unique Packaging Identifier of the medicinal product in time, the person shall read the Specific Packaging Identifier of the medicinal product into the Medicines Authentication System by means of a scanning device, which, after the technical problems have been resolved, shall verify the authenticity of the medicinal product and deactivate the Specific Packaging Identifier of the medicinal product automatically.
2. In the event of technical problems that do not allow the scanning device to read the unique packaging identifier of the medicinal product, the authorised person manually enters the alphanumeric value of the unique packaging identifier of the medicinal product (product code and serial number) into the medicines authentication system, which, after eliminating technical problems, verifies the authenticity of the medicinal product and deactivates the unique packaging identifier of the medicinal product automatically.
3. In the event of technical problems that do not allow the scanning device to read the unique packaging identifier of the medicinal product and to manually enter the alphanumeric value of the product's unique packaging identifier (product code, serial number, batch number, expiry date and, where applicable, other information such as national product code) into the medicines authentication system, the authorised person shall note the alphanumeric value of the unique identifier of the packaging of the medicinal product (product code and serial number), which, after eliminating technical problems, is entered manually into the Medicines Authentication System, which verifies the authenticity of the medicine and deactivates the Specific Packaging Identifier of the medicine automatically.
4. In the event of a failure of the software for verifying the authenticity of medicines, it is possible to verify the authenticity of the unique identifier of the packaging of the medicine by manually entering the alphanumeric value of the unique identifier of the packaging of the medicine (product code and serial number) into the system on the **https://portal-prod-sk.nmvs.eu website**. It logs in to the system using the login details provided when connecting to the Medicines Authentication System for the first time. Detailed instructions

on how to verify the authenticity of a specific packaging identifier of a medicine through this website and possibly deactivate it can be found on **the www.sool.sk** website.

IV. CHAPTER - Marketing Authorisation Holders for Medicinal Products

Article XVII.
Basic framework

1. Marketing authorisation holders for medicinal products for human use (hereinafter referred to as the "Holder") are obliged to comply with the Commission Delegated Regulation (EU) 2016/161 of 2 October 2015 supplementing Directive 2001/83/EC of the European Parliament and of the Council with provisions concerning detailed rules on safety features appearing on the packaging of medicinal products for human use and pursuant to Act No. 362/2011 Coll. on Medicinal Products and Medical Devices and on Amendments to Certain Acts.
2. Holders connect to the verification system via the European Hub (EU HUB), where they upload the necessary data to the verification system.

Article XVIII.
Connection to the Incident Management Portal

1. A holder who has signed a contract with the Slovak Medicines Verification Organization has the right to access the Incident Management Portal located at the following address: **https://mah.sk-nmvs.sk/**

   Access data to the portal are sent automatically to the holder's contact person within 10 working days of signing the contract.

Article XVIV.
Procedure in the event of an incident by the holder

1. Each holder is informed about the occurrence of an incident via the Incident Management Portal or via the European Hub (EU HUB).
2. The holder has the opportunity to communicate about the manner of resolving the incident through the Incident Management Portal. The holder has the option to respond to incidents that are in the category of unrecognized packaging of the medicinal product[3] in the authentication system (in the status of Waiting for resolution of the MAH).
3. In the event that the holder has a serious suspicion of potential counterfeit packaging, he must immediately report such a fact:
    a) ŠUKL via e-mail to **the address fmd.hlasenia@sukl.sk**
    b) SOOL via e-mail to **kancelaria@sool.sk**
4. In the event that the holder does not react to the incident that has been assigned to him within 30 calendar days of the occurrence of the incident, the pharmacy care provider or wholesale distributor has the right to return the package to the holder of the package through the distribution chain as a product complaint.

[3] The category of unrecognized packages of a medicinal product contains the following incidents: NMVS_NC_PC_01 – The product code of the medicinal product packaging was not found; NMVS_FE_LOT_03 – The specified batch number assigned to the product code was not found; NMVS_NC_PC_02 – The serial number assigned to the product code could not be found; NMVS_FE_LOT_12 – The expiry date of that package of the medicinal product does not coincide with the expiry date of the batch of the medicinal product; NMVS_FE_LOT_13 – The serial number has been assigned to the product code, but it does not belong to the batch number listed.

V. CHAPTER - General resolutions

Article XX.
Data protection and ownership

1. Pharmaceutical care providers, wholesale distributors and holders of medicinal products for human use are responsible for all data generated by them when they use the Medicines Authentication System.
2. In the event of suspected cases of falsification of medicinal products for the purpose of investigating such falsification, access to this data will be available to the Slovak Medicines Verification Organization and the State Institute for Drug Control.

Article XXI.
Legal binding force

All of the above procedures are exclusively of a recommendatory and informative nature, taking into account the current state of legislation and the availability of all relevant documents.

The document was prepared in cooperation with the State Institute for Drug Control, the Slovak Chamber of Pharmacists, the Association of Wholesale Distributors, the Association of Innovative and Pharmaceutical Industry - AIFP and the GENAS Association for Generic and Biosimilar Drugs.

In Bratislava in April 2025

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