VERIFICATION OF MEDICINAL PRODUCTS - A DIGITAL INNOVATION FOR PATIENT SAFETY

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SAFETY FEATURES: SERIALIZATION (GTIN, SN) + ANTI-TAMPERING DEVICE

- The requirements for the matrix code are in line with GS1 standards
- Product code in GTIN format
- Example: 4 elements in Bulgaria

PC: (01) 07613421020088
SN: (21) 91121172533558
Batch №: (10) JE7675
Expiry date: (17) 07/2021
THE CONCEPT: Serialization of RX medicinal products by the manufacturer and verification by the pharmacy

Verification on receiving Rx and decommissioning on dispensing to patients
VERIFICATION OF MEDICINAL PRODUCTS: LEGISLATIVE FRAMEWORK


➢ Commission Delegated Regulation (EU) 2016/161 of 2 October 2015

➢ Medicinal Products in Human Medicine Act (MPHMA), State Gazette, Vol.67 of 28 July 2020
Art. 168

(8) On the secondary packaging (if there is no such - on the primary packaging) of the medicinal products, with the exception of radio-pharmaceutics, the following shall be placed:

1. **Unique identification code** as safety feature, which gives opportunity for the wholesale and retail traders to:
   a) Check the authenticity of the medicinal product;
   b) identify separate packages.

2. a **means to check if the package of the medicinal product has been tampered with.**
Art. 168a

(1) On the package of the medicinal product, which is prescribed by a doctor’s prescription, safety features shall be placed as per Art. 168, Para. 8 with the exception of cases, in which the medicinal product has been included in the list, determined by the European Commission by a delegated act under Art. 168b.

(2) On the package of a medicinal product, which does not need doctor’s prescription, no safety features shall be placed under Art. 168, Para. 8, with the exception of cases, in which the medicinal product is included in the list, determined by the European Commission by a delegated act under Art. 168b, after it has been assessed, that it may be put to a risk to be faked.
MAH / MANUFACTURERS OBLIGATIONS

➢ Perform the actions defined in DR (EU) 2016/161 (MPHMA art. 272b, para 1)

➢ Place on the secondary packaging, and if there is no such - on the primary packaging of the MP, defined in DR (EU) 2016/161, the safety features under Art. 168, para 8 - UIC and anti-tampering device (MPHMA, Art.160, para.11)

➢ The qualified person is responsible for ensuring that the safety features are placed on the packaging of the medicinal product (MPHMA, Art. 159, para. 4)

➢ Ensure the input of UIC for each package in the system of registers in accordance with DR (EU) 2016/161 (MPHMA art. 68a)

➢ The manufacturer shall inform the BDA immediately upon obtaining information that the MPs falling within the scope of their manufacturing authorization have been falsified or are suspected of being falsified (MPHMA art.160, para.1, item. 9)
OBLIGATIONS OF WHOLESALERS

➢ They perform the actions defined in DR (EU) 2016/161 (MPHMA art. 272b, para 1

➢ They verify that the MPs received from manufacturers, importers or wholesalers are not falsified, verifying their authenticity by the safety features in the cases specified in DR (EU) 2016/161 (MPHMA Art. 207, para 1, item 4a)
  - MPs received from another trader who is not the manufacturer or their contractual partner

➢ They check the safety indicators and decommission the UIC of a medicinal product before supplying this MP in the cases specified in the ordinance under Art. 198 (MPHMA Art. 207, para 1, item 4b)

➢ They immediately inform the BDA and the MAH when they have found or suspect that the medicinal product they have received or is being offered to them is falsified (MPHMA Art. 207, para 1, item 11).
OBLIGATIONS OF PHARMACIES

➢ They perform the actions defined in DR (EU) 2016/161 (MPHMA art. 272b, para 1)

➢ They check the authenticity of the MPs by the safety features and decommission the UIC in the system of registers (MPHMA art. 219, para 3)

The verification of the authenticity of the MP includes:

- UIC authenticity
- Integrity of the anti-tampering device

➢ The actions under para. 3 shall be carried out according to the provisions of Chapter VI of DR (EU) 2016/161 (MPHMA art. 219, para 4)
OBLIGATIONS AND RIGHTS OF THE COMPETENT AUTHORITIES

➢ The implementation of the measures under MPHMA, related to the prevention of the entry and spread of counterfeit MPs, is carried out by BDA and the customs authorities (MPHMA art.17, para 7)

➢ BDA orders the blocking, withdrawal and destruction of falsified medicinal products and medicinal products of unknown origin, as well as medicinal products in the cases under Art. 24 and 30 of DR (EU) 2016/161 (MPHMA art. 272, para 1, item 5a)

➢ BDA participates in information campaigns about the danger of falsified medicinal products conducted by the European Commission and the EMA (MPHMA Art. 234b)

➢ The BDA, the Ministry of Health, the National Health Insurance Fund and the National Council on Prices and Reimbursement of MPs have the right to free access to the National Register (MPHMA Art. 272b, para 3).

➢ The access of competent authorities is via a portal designated for them and a package of standard reports, in strict compliance with the requirements for confidentiality of information.
MPHMA - SANCTIONS

➢ Anyone, who manufactures, imports, exports, keeps, sells or provides false medicinal products, as well as intermediates in selling and buying falsified medicinal products, shall be penalized with a fine of BGN 25,000 to BGN 50,000. (Art. 284а, para 1)

➢ In case of non-fulfillment of the obligation regarding the safety features of the MPs, defined in MPHMA or DR (EU) 2016/161, a penalty payment is imposed:

  • Any MAH, who fails to fulfill his/her obligation under Art. 160, shall be penalized with a penalty payment of BGN 5,000 to 10,000 and in case of a repeated violation – by a penalty payment of BGN 25,000 to 50,000 (Art. 284а, para 2).

  • Wholesale traders – BGN 5,000 to 10,000 and in case of a repeated violation – BGN 10,000 to 20,000 (Art. 284с, para 3)

  • For pharmacies - BGN 1,000 to 3,000 лв and in case of a repeated violation – BGN 5,000 -10,000. (Art. 288а)
FALSIFIED MEDICINES DIRECTIVE: IMPLEMENTATION IN EUROPE AND BULGARIA IN 2020
CONNECTED PHARMACIES BY COUNTRY AS OF 26.10.2020

Calendar Week 44 2020
EMVO MONITORING REPORT

(*)The information figuring hereunder was collected in Calendar Week 43 2020
In The Netherlands (NL) healthcare institutions are connected as pharmacies. Therefore, the On-boarding of healthcare institutions in NL is reflected in the overview on pharmacies connection.

In Norway (NO), hospital pharmacies are connected as pharmacies. The overview on healthcare institutions reflect only the number of hospitals that are connected.

(1) As of November 2019, dispensing doctors in Latvia have been added to the healthcare institutions report as legally they all are healthcare institutions.
PERCENTAGE OF DECOMMISSIONED RX MEDICINES BY MARKET SIZE

2020 Week 41

2020 Week 43

Calendar Week 44 2020
EMVO MONITORING REPORT
PERCENTAGE OF ALERTS IN RELATION TO THE NUMBER OF SCANS BY COUNTRY

(*The information figuring hereunder does not display the total of alerts in relation to the number of scans for Cyprus, Iceland, Liechtenstein and Malta as, due to IMT, the figures are not meaningful.)
PRACTICAL EXPERIENCE IN VERIFICATION IN PHARMACIES, HOSPITAL PHARMACIES AND WHOLESALERS

➢ Types of alerts in the verification system
➢ Examples of implementation cases
ALERTS RELATED TO PACKAGING CODES

A2 - Batch number is unknown. An alert has been raised.

A3 - Serial number is unknown. An alert has been raised.

A52 - The scanned expiry date does not match the expiry date in the system. An alert has been raised.

A68 - The scanned batch number does not match the batch number in the system. An alert has been raised.

Possible reasons and follow-up actions:

- Technical problem in a hospital pharmacy scanner and/or software: contact your IT provider to correct the problem.

- Technical issue in the MAH: BgMVO contact the MAH to eliminate the cause and notify the pharmacy when the packaging can be verified and dispensed.

NB! Packages with a problem in the matrix code for technical reasons with the MAH cannot be supplied before the technical problem is resolved.
ALERTS RELATED TO THE STATUS OF THE PACKS

A7 – The pack cannot be supplied/decommissioned. An alert has been raised.

This alert is received when an attempt is made to set a status identical to the status of the package in the system.

A24 - The pack cannot be decommissioned. An alert has been raised.

This alert is received when attempting to supply or decommission a package that is not active and has one of the following statuses: "Destroyed", "Sample", "Free Sample", "Stolen", "Locked", "Exported" or “Checked-out”.

NB! If a pack is decommissioned at another site, the pack must be separated and stored in a safe place until further instructions from the competent authorities, as the supply chain has been broken and there is a suspicion of a falsified medicinal product.
# PACKAGE STATUSES IN THE SYSTEM

<table>
<thead>
<tr>
<th>PACK STATUS</th>
<th>DESCRIPTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Active</td>
<td>A pack with such a status can be supplied to a patient or decommissioned from the system.</td>
</tr>
<tr>
<td>Supplied</td>
<td>The pack has been supplied to a patient.</td>
</tr>
<tr>
<td>Destroyed</td>
<td>The pack has been destroyed.</td>
</tr>
<tr>
<td>Sample</td>
<td>The pack has been provided as a sample to the regulatory body.</td>
</tr>
<tr>
<td>Free Sample</td>
<td>The pack has been provided as a sample to a doctor.</td>
</tr>
<tr>
<td>Stolen</td>
<td>The pack was stolen.</td>
</tr>
<tr>
<td>Locked</td>
<td>The pack is locked (quarantined).</td>
</tr>
<tr>
<td>Exported</td>
<td>The pack has been exported outside the EU.</td>
</tr>
<tr>
<td>Checked-out</td>
<td>The pack has been checked-out from the system for repackaging by a parallel wholesaler.</td>
</tr>
<tr>
<td>Recalled</td>
<td>The batch has been recalled by the manufacturer.</td>
</tr>
<tr>
<td>Withdrawn</td>
<td>The medicinal product has been withdrawn.</td>
</tr>
</tbody>
</table>

*NB! Packs with a status other than "Active" must not be dispensed.*
If packages delivered under Ordinance 10 are intended for the European Union, the so-called inter-market transaction (IMT) is performed during verification, in which the data on the package are checked in another National System.

In the case of inter-market transactions, packages must be verified and supplied one at a time. Bulk verification cannot be used.

If alerts are received for packages under Ordinance 10 for no apparent technical reason from a scanner/software in the pharmacy, the responsible master pharmacist may contact the BgMVO for assistance.

A particularly relevant issue with regards to drugs and vaccines to treat COVID19.
The medicine verification system does not have a special status to write off packages for donation.

There was a case when the MAH provided to a hospital a donation of MPs which had been previously decommissioned in the System with the status "Trade Sample". This is in violation of the order for providing samples in the MPHMA.

Another MAH provided a hospital with a donation of packages that had previously been decommissioned by Wholesale Traders with the status “Supplied”.

In such cases, the Donor and the hospital pharmacy should discuss how the packages will be provided and who will decommission them in the Verification System:
- The donor decommissions the packages before delivering them, or
- The donor delivers active packages and the hospital pharmacy decommissions them.

In both cases, when attempting to supply the packages in the hospital pharmacies, A24 alerts are generated, as the MPs have already been decommissioned in the Medicines Verification System.

The goal is to avoid attempts to supply packages already decommissioned in the System and the "false" alerts generated as a result.
The status "Clinical Trials" is to be added to the Medicines Verification System at European level, however, currently there is no such status.

Questions by pharmacists about medicinal products intended for clinical trials.

- Should incoming packages for trials be checked

- Should such packages be decommissioned when supplied to a patient

Until there is a "Clinical Trials" status in the System, the wholesaler and the hospital pharmacy should discuss how the packages will be supplied and who will decommission them in order to avoid attempts to supply already decommissioned packages and "false" alerts generated as a result.
CONCLUSION

The introduction of the European Medicines Verification System guarantees the origin and quality of prescribed medicines that patients receive. The legislative framework defines the rights and obligations of all participants in the drug supply chain, as well as sanctions for violations (MPHMA, July 2020).

As of October 2020, the percentage of connected pharmacies in Bulgaria is 81% (83% for hospital pharmacies) and approx. 30% of the prescribed and supplied packages are decommissioned in the System.

The practical experience of pharmacists and other participants in solving specific cases with the application of the Verification System is increasing and the number of alerts generated due to technical problems with manufacturers and pharmacies is decreasing.
For more information: www.bgmvo.org

or

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THANK YOU FOR YOUR ATTENTION!

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