MEDICINES VERIFICATION - DIGITAL PROTECTION AGAINST FALSIFIED MEDICINES AND VACCINES IN THE COVID-19 PANDEMIC

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SOFIA, JANUARY 22, 2021
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• New elements in the legislative framework for medicines identification in Bulgaria: link between the national number and the product code

• Importance of the medicines verification system in the context of the COVID-19 pandemic for the protection of patients from falsified medicines and vaccines
MEDICINES VERIFICATION: 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

➢ Amendments made to the MPHMA in December 2020 by the National Health Insurance Fund Budget Act for 2021 in force since 1st January 2021
Art. 19

(4) (New, SG No. 67/2020, amended, SG No. 103/2020, effective 01.01.2021)

BDA has linked the national identification number under Art. 259\(^1\), para. 1 with the product code according to the provisions of art. 4 (b) (i) of Commission Delegated Regulation (EU) 2016/161 of 2 October 2015.

Art. 259\(^1\)

(1) The MP national identification number as per Art. 259, para. 1, item 12:

1. Ensures unambiguous identification of each MP and interoperability of all health information systems.
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
§ 20.

(1) Within 3 months of this Act coming into force, the BDA shall provide to the NCPRMP in electronic format and in a form approved by NCPRMP, information on the authorized and registered medicinal products on the territory of the Republic of Bulgaria and the MPs authorized for use under a centralized procedure pursuant to the provisions of Regulation (EC) 726/2004.

(2) NCPRMP shall authorize the template under para. 1 within 7 days of the Act coming into force.
§ 21.

(1) The identification numbers of MPs, included in the Positive Drug List, in the register of marginal prices and in the register of the maximum selling prices, shall be considered as a national identification number of the MP in the interpretation of Art. 259\(^1\), para. 1 of the MPHMA.

(2) Within 6 months of providing the information under § 20, para. 1, NCPRMP shall publish on its website the register according to Art. 259, para. 2, item 4 of the MPHMA.

(3) Within 3 months of this Act coming into force, the MAHs shall provide to the BDA through SESPA information on the product codes for all MPs.

(4) Within 3 months of this Act coming into force, the holders of permits for parallel import of MPs shall provide to the BDA through SESPA, information about the product codes.
Art. 284f. Those who fail to fulfill their obligation to provide the information under Art. 217b, para. 3, item 1, or fail to fulfill this obligation within the period specified in the Act, shall incur a fine in the amount of BGN 5,000 to 10,000, and in case of repeated violation - a fine in the amount of BGN 10,000 to 15,000.

Art. 284g. Those who provide information under Art. 217b, para. 3, item 1 with incomplete and/or inaccurate content shall incur a fine in the amount of BGN 3,000 to 5,000, and in case of repeated violation - a fine in the amount of BGN 5,000 to 10,000.
RISKS OF FALSIFIED MEDICINES AND VACCINES IN THE CONTEXT OF THE COVID-19 PANDEMIC
WARNINGS BY INTERPOL

• There is an increased supply of counterfeit medical devices and medicines: protective masks, disinfectants, antiviral and antimalarial drugs, vaccines and tests for COVID-19.
ON THE THREAT OF FALSIFIED VACCINES

• In December 2020, Interpol issued an orange code warning of the risk of increased organized criminal activity for counterfeiting, theft and illegal advertising of COVID-19 vaccines.

• INTERPOL Secretary General Jürgen Stock stated: “As governments are preparing to roll out vaccines, criminal organizations are planning to infiltrate or disrupt supply chains.”
THE EUROPEAN MEDICINES VERIFICATION SYSTEM (EMVS) CAN GUARANTEE PATIENT SAFETY

• The verification system provides a very high level of security, but **ONLY** when products are delivered in the legal supply chain in accordance with EU-FMD.

• All medicines, including COVID-19 vaccines, must be serialized and must have an anti-tampering device.

• The European Commission has granted a grace period for vaccines until the end of March 2021 as exception, due to the large number of people in the EU in need of vaccination in a short period of time.

• [SecuringIndustry.com](https://www.securingleaders.com/) - COVID vaccines 'a test of resilience' for FMD anti-counterfeiting
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
CONCLUSION

• The introduction of the European Medicines Verification System guarantees the origin and quality of prescribed medicines that patients receive.

• The legislative framework defining the rights and obligations of all participants in the drug supply chain, as well as the sanctions for violations was amended in December 2020 (by the 2021 NHIF Budget Act and amendments to MPHMA, December 2020).

• In the COVID-19 pandemic, the risk of supply of counterfeit medicines and vaccines has increased; an orange warning code has been issued by Interpol.

• Provided the drug supply is in compliance with the EU-FMD and MPHMA requirements, patients will be protected from falsified medicines and vaccines.
THANK YOU FOR YOUR ATTENTION!

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