WORLD TRADE ORGANIZATION

G/TBT/N/UKR/285

2 February 2024

(24-0834)

Page: 1/3

Committee on Technical Barriers to Trade

Original: English

NOTIFICATION

The following notification is being circulated in accordance with Article 10.6

1.	**Notifying Member:** UKRAINE **If applicable, name of local government involved (Article 3.2 and 7.2):**
2.	**Agency responsible:** Ministry of Health of Ukraine **Name and address (including telephone and fax numbers, email and website addresses, if available) of agency or authority designated to handle comments regarding the notification shall be indicated if different from above:**
3.	**Notified under Article 2.9.2 [X], 2.10.1 [ ], 5.6.2 [X], 5.7.1 [ ], 3.2 [ ], 7.2 [ ], other:**
4.	**Products covered (HS or CCCN where applicable, otherwise national tariff heading. ICS numbers may be provided in addition, where applicable):** Medicines
5.	**Title, number of pages and language(s) of the notified document:** draft Resolution of the Cabinet of Ministers of Ukraine "Some Issues of Safety and Verification of Medicinal Products"; (22 page(s), in Ukrainian)
6.	**Description of content:** the draft Resolution of the Cabinet of Ministers of Ukraine "Some Issues of Safety and Verification of Medicinal Products" is developed in order to establish and ensure the effective operation of the national system of verification of medicinal products and to assure that manufacturers apply safety features to the packaging of the medicinal product. In order to approximate the EU legislation on preventing and combating the circulation of counterfeit medicines and to effectively prevent and combat the circulation of counterfeit medicines it is proposed to implement the verification of medicines - the 2D coding system for medicines. Thus, the draft Resolution provides for approval: 1) the Regulation on the national system of verification of medicinal products (hereinafter - the Regulation); and 2) the Procedure for application of safety features to the packaging of medicinal products and their use. The Regulation on the national system of verification of medicinal products defines the principles, procedure for the formation and functioning of the national system of verification of medicinal products. The purpose of the national system of verification of medicinal products is to facilitate control over the circulation of medicinal products exclusively for preventing and counteracting the circulation of counterfeit medicines. The Regulation is mandatory for the National agency for verification of medicinal products, state control body, owners and/or holders (managers) of information systems, registers, databases/data warehouses, all legal entities and individuals engaged in business activities in field of medical practice, production, import (except for APIs), wholesale,

	retail trade, including distance trade, utilisation and/or destruction of medicinal products that: 1) sold on prescription, except for medicinal products included in the list of prescription medicinal products for which safety features are are not mandatory; 2) sold without a prescription, included in the list of over-the-counter medicinal products for which safety features are mandatory; 3) contain safety features applied by manufacturers in accordance with the Procedure for application of safety features to the packaging of medicinal product and their use, approved by this Resolution, on a voluntary basis. The Procedure for application of safety features to the packaging of medicinal products and their use defines the characteristics of the safety features of medicinal products, the procedure for their application, means of verification, encryption requirements (if necessary), as well as the structure and format of information to be contained in the relevant safety features. Manufacturers shall apply safety features to medicinal products in accordance with the provisions of this Procedure. Safety features shall not be applied to medicinal products intended for export to countries outside the EU. The draft Resolution also stipulates that: the requirements of the Regulation in terms of establishing of National agency for verification of medicinal products and the national system of verification of medicinal products shall apply from the entry into force of this Resolution; the provisions of the Regulation, not specified above, as well as the Procedure for application of safety features to the packaging of medicinal products and their use shall be applied by business entities: - on a voluntary basis from 01 January 2026, but not before the availability of the relevant technical capability in the national system of verification of medicinal products. The technical capability of the national system of verification of medicinal products will be effective from the date of publication on the website of the National agency for verification of medicinal products of the information on the commissioning of the centralised data warehouse of the national system of medicinal products verification; - mandatory from 01 January 2028.
7.	**Objective and rationale, including the nature of urgent problems where applicable:** Consumer information, labelling; Prevention of deceptive practices and consumer protection; Protection of human health or safety
8.	**Relevant documents:** Law of Ukraine "On Medicines"; Commission Delegated Regulation (EU) 2016/161 of 2 October 2015 supplementing Directive 2001/83/EC of the European Parliament and of the Council by laying down detailed rules for the safety features appearing on the packaging of medicinal products for human use; Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use.
9.	**Proposed date of adoption:** To be determined **Proposed date of entry into force:** the Resolution will enter into force from the date of its publication, except for subparagraphs 2 and 3 of paragraph 2 of the Resolution, which will enter into force on 01 January 2026.
10.	**Final date for comments:** 60 days from notification

11. Texts available from: National enquiry point [X] or address, telephone and fax numbers and email and website addresses, if available, of other body:

Ministry of Economy of Ukraine
Department for Trade Agreements and Export Development
12/2 Hrushevskoho Str.
Tel: +(38 044) 596 6839
Fax: +(38 044) 596 6839
Email: ep@me.gov.ua
Website: https://www.me.gov.ua

https://moz.gov.ua/article/public-discussions/povidomlennja-pro-opriljudnennja-proektu-postanovi-kabinetu-ministriv-ukraini--dejaki-pitannja-bezpeki-ta-verifikacii-likarskih-zasobiv

https://members.wto.org/crnattachments/2024/TBT/UKR/24_00963_00_x.pdf
https://members.wto.org/crnattachments/2024/TBT/UKR/24_00963_01_x.pdf
https://members.wto.org/crnattachments/2024/TBT/UKR/24_00963_02_x.pdf