WORLD TRADE ORGANIZATION

G/TBT/N/UKR/328

9 January 2025

(25-0213)

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 Order of the Ministry of Health of Ukraine "On Approval of Amendments to Certain Regulatory Acts of the Ministry of Health of Ukraine"; (7 page(s), in Ukrainian)
6.	**Description of content:** The Draft Order proposes to approve amendments to: - the Procedure for the examination of registration materials for medicines submitted for state registration (re-registration), as well as the examination of materials on amendments to the registration certificate, approved by the Order of the Ministry of Health of Ukraine No. 426 of 26 August 2005 (as amended by the Order of the Ministry of Health of Ukraine No. 460 of 23 July 2015) - the Procedure for Prohibition (Temporary Prohibition) and Renewal of Circulation of Medicines in Ukraine, approved by the Order of the Ministry of Health of Ukraine No. 809 of 22 November 2011; - the Procedure for Termination of Registration Certificate for a Medicine, approved by the Order of the Ministry of Health of Ukraine No. 1801 of 08 August 2020. The provisions of the aforementioned Procedures will be aligned with Ukrtaine's legislation in the field of circulation of medicines and with each other in terms of introduction of updated requirements for the labelling of medicines, prohibition of the sale of medicines whose labelling does not meet the established requirements. At the same time, they will ensure the prevention of the unjustified withdrawal of medicines from circulation unrelated to their quality, and will ensure that the labelling of medicine packages contains reliable information about the medicine, its manufacturer, and/or the applicant, without any advertising elements. This will improve the processes of registration, re-registration of medicines, or amending registration materials, temporary suspension of the registration certificate for a medicine in case of violation of the requirements for labelling of medicines, and justified withdrawal of medicines from circulation in case of non-compliance with labelling requirements,

	taking into account a balanced approach to determining violations in the labelling of medicines.
7.	**Objective and rationale, including the nature of urgent problems where applicable:** Consumer information, labelling; Prevention of deceptive practices and consumer protection
8.	**Relevant documents:** Law of Ukraine No 123 of 04 April 1996 "On Medicinal Products" (as amended), Law of Ukraine No. 3860 of 16 July 2024 "On Amendments to Certain Laws of Ukraine on Parallel Import of Medicinal Products" (notified in document IP/N/1/UKR/30, IP/N/1/UKR/O/4), Law of Ukraine No. 3910 of 21 August 2024 "On Amendments to the Law of Ukraine "On Medicinal Products" on Labelling of Medicinal Products", Resolution of the Cabinet of Ministers of Ukraine No. 376 of 26 May 2005 "On Approval of the Procedure for State Registration (Reregistration) of Medicines and Fees for Their State Registration (Reregistration)" Referenced Notification(s): • G/TBT/N/UKR/316 • G/TBT/N/UKR/307 • G/TBT/N/UKR/300 • G/TBT/N/UKR/318
9.	**Proposed date of adoption:** To be determined **Proposed date of entry into force:** This Order shall enter into force on the date of its official publication, except for: paragraph 2 of sub-clause 2, paragraphs 2 and 3 of sub-clause 3 of clause 1 of the Amendments to Certain Regulatory Acts of the Ministry of Health of Ukraine approved by clause 1 of this Order, which will enter into force simultaneously with the entry into force of sub-clause 1 of clause 1 of section I of the Law of Ukraine No. 3860 of 16 July 2024 "On Amendments to Certain Laws of Ukraine on Parallel Import of Medicinal Products" (notified in document IP/N/1/UKR/30, IP/N/1/UKR/O/4); sub-clause 1, paragraphs 3 to 7 of sub-clause 2, paragraphs 4 to 6 of sub-clause 3 of clause 1, clause 2 and clause 3 of the Amendments to Certain Regulatory Acts of the Ministry of Health of Ukraine approved by clause 1 of this Order, which will enter into force simultaneously with the entry into force of the Law of Ukraine No. 3910 of 21 August 2024 "On Amendments to the Law of Ukraine "On Medicinal Products" on Labelling of Medicinal Products" (notified in G/TBT/N/UKR/307).
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:

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