



24 April 2024

(24-3379)

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Committee on Technical Barriers to Trade

Original: English

### NOTIFICATION

The following notification is being circulated in accordance with Article 10.6

<b>1. Notifying Member:</b> <u>UKRAINE</u> <b>If applicable, name of local government involved (Article 3.2 and 7.2):</b>
<b>2. Agency responsible:</b> Ministry of Health of Ukraine <b>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:</b>
<b>3. Notified under Article 2.9.2 [X], 2.10.1 [ ], 5.6.2 [X], 5.7.1 [ ], 3.2 [ ], 7.2 [ ], other:</b>
<b>4. Products covered (HS or CCCN where applicable, otherwise national tariff heading. ICS numbers may be provided in addition, where applicable):</b> Medicinal products
<b>5. Title, number of pages and language(s) of the notified document:</b> Draft Order of the Ministry of Health of Ukraine "On Approval of Amendments to the Procedure for Confirmation of Compliance of Medicinal Products Manufacturing Conditions with the Requirements of Good Manufacturing Practice"; (3 page(s), in Ukrainian)
<b>6. Description of content:</b> The draft Order provides for the approval of amendments to the Procedure for Confirmation of Compliance of Medicinal Products Manufacturing Conditions with the Requirements of Good Manufacturing Practice, approved by the Order of the Ministry of Health of Ukraine No. 1130 of 27 December 2012.  The amendments to the Procedure will provide legislative regulation of the mechanism for extending the validity of the GMP Conclusion, as well as the possibility of extending the validity of the GMP certificate until the end of 2024 issued by the authorized body of an EU member state, the United Kingdom or a state that has a mutual recognition agreement with the EU or Ukraine.  Approval of the amendments to the Procedure will align it with EU requirements.
<b>7. Objective and rationale, including the nature of urgent problems where applicable:</b> Protection of human health or safety; Harmonization; Reducing trade barriers and facilitating trade
<b>8. Relevant documents:</b> Law of Ukraine "On Medicinal Products"
<b>9. Proposed date of adoption:</b> To be determined <b>Proposed date of entry into force:</b> From the date of its official publication

**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.  
Kyiv 01008  
Tel: +(38 044) 596 6839  
Fax: +(38 044) 596 6839  
Email: [ep@me.gov.ua](mailto:ep@me.gov.ua)  
Website: <https://www.me.gov.ua>

<https://moz.gov.ua/article/public-discussions/povidomlennja-pro-opriljudnennja--proektu-nakazu-ministerstva-ohoroni-zdorov%e2%80%99ja-ukraini-pro-zatverdzhennja-zmini-do-porjadku-provedennja-pidverdzhennja-vidpovidnosti-umov-virobnictva-likarskih-zasobiv-vimogam-nalezhnoi-virobnichoi-praktiki>

[https://members.wto.org/crnattachments/2024/TBT/UKR/24\\_02779\\_00\\_x.pdf](https://members.wto.org/crnattachments/2024/TBT/UKR/24_02779_00_x.pdf)

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