NOTIFICATION

The following notification is being circulated in accordance with Article 10.6

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| **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 the Procedure for Confirmation of Compliance of Manufacturing Conditions of Medicines with the Requirements of Good Manufacturing Practice"; (5 page(s), in Ukrainian), (4 page(s), in English) |
| **6.** | **Description of content:** The draft Order of the Ministry of Health of Ukraine "On Approval of Amendments to the Procedure for Confirmation of Compliance of Manufacturing Conditions of Medicines with the Requirements of Good Manufacturing Practice" has been developed pursuant to Article 9-1 "Peculiarities of state registration of medicines that may be procured by a person authorised to conduct procurement in the healthcare sector" of the Law of Ukraine "On Medicines", as well as to confirm compliance of manufacturing conditions with the requirements of good manufacturing practice for those medicines procured by a person authorized to conduct procurement in the healthcare sector.  The draft Order provides for the regulation of the procedure for confirming the compliance of the manufacturing conditions of medicines registered by the competent authority of the United States of America, the Swiss Confederation, Japan, Australia, Canada, a Member State of European Union, or registered by the competent authority of European Union under a centralised procedure. This is intended for the purposes of procurement conducted by a person authorised to carry out procurement in the healthcare sector, in accordance with the requirements of Good Manufacturing Practice (GMP) issued by the competent authority of the USA, Switzerland, Japan, Australia, Canada, and EU Member State, based on the results of an inspection for compliance with GMP requirements. |
| **7.** | **Objective and rationale, including the nature of urgent problems where applicable:** Protection of human health or safety |
| **8.** | **Relevant documents:**  Law of Ukraine "On Medicines"  Referenced Notification(s):   * [G/TBT/N/UKR/294](https://eping.wto.org/en/Search/Index?viewData=G/TBT/N/UKR/294) * [G/TBT/N/UKR/294/Add.1](https://eping.wto.org/en/Search/Index?viewData=G/TBT/N/UKR/294/Add.1) |
| **9.** | **Proposed date of adoption:** To be determined  **Proposed date of entry into force:** 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/uk/povidomlennya-pro-oprilyudnennya-proyektu-nakazu-ministerstva-ohoroni-zdorov-ya-ukrayini-pro-zatverdzhennya-zmin-do-poryadku-provedennya-pidtverdzhennya-vidpovidnosti-umov-virobnictva-likarskih-zasobiv-vimogam-nalezhnoyi-virobnichoyi-praktiki>  <https://members.wto.org/crnattachments/2024/TBT/UKR/24_07161_00_e.pdf>  <https://members.wto.org/crnattachments/2024/TBT/UKR/24_07161_00_x.pdf>  <https://members.wto.org/crnattachments/2024/TBT/UKR/24_07161_01_x.pdf> |