

09 June 2023

### NOTICE TO RELEVANT STAKEHOLDERS

Dear Sir/Ma'am:

This refers to the draft regulations distributed through the World Trade Organization – Technical Barriers to Trade (WTO-TBT) website ([www.epingalert.org](http://www.epingalert.org)) from 27 May to 02 June 2023.

Relative thereto, we respectfully invite stakeholders to comment on the four (4) notified draft technical regulations from Russian Federation and Ukraine:

Document Symbol	Notifying Member	Relevant Dates	Products Covered	Summary
<a href="#">G/TBT/N/R/US/140</a>	Russian Federation	<b>Date of Distribution:</b> 31 May 2023  <b>Deadline for Comments:</b> 29 July 2023	Medicinal products	The draft amendments to the Rules for marketing authorization and assessment of medicinal products for human use provide for the updating of the Rules for marketing authorization and assessment of medicinal products for human use with account of the experience of law enforcement of these Rules on the procedure for marketing authorization of medicinal products and bringing the registration dossier in line with the requirements of the Eurasian Economic Union.
<a href="#">G/TBT/N/R/US/141</a>	Russian Federation	<b>Date of Distribution:</b> 31 May 2023  <b>Deadline for Comments:</b> 29 July 2023	Veterinary medicines	The draft provide for ensuring a phased transition to the implementation of the Requirements for the labeling of medicinal products for human use and veterinary medicinal products, approved by the Decision of the Council of the Eurasian Economic Commission dated November 3, 2016 No. 76, the Rules of Good Manufacturing Practice of the Eurasian Economic Union, approved by the Decision of the Council of the Eurasian Economic Commission dated November 3, 2016 No. 77 by establishing transitional periods for subjects of circulation of veterinary medicines.

#### BUREAU OF PHILIPPINE STANDARDS

#### Membership:

- International Organization for Standardization (ISO)
- International Electrotechnical Commission (IEC)
- World Trade Organization (WTO) Technical Barriers to Trade (TBT)
  - National Enquiry Point (NEP)
  - National Notification Authority (NNA)

<a href="#">G/TBT/N/R US/143</a>	Russian Federation	<b>Date of Distribution:</b> 31 May 2023  <b>Deadline for Comments:</b> 29 July 2023	Medicinal products	The draft decision envisages the updating of: a unified approach to the selection of a reference medicine; requirements for a bioequivalence based on a biopharmaceutical classification system taking into account 5 years of law enforcement practice, international experience and changes in bioequivalence research technologies for bioequivalence medicines
<a href="#">G/TBT/N/U KR/258</a>	Ukraine	<b>Date of Distribution:</b> 31 May 2023  <b>Deadline for Comments:</b> 29 July 2023	Medicinal products	At the beginning of the imposition of martial law, the Government of Ukraine has established that a conclusion about the quality of imported medicinal products, including registered medicinal products in foreign packaging manufactured for the needs of foreign markets, that do not comply with the approved registration documents, may be issued, inter alia, without the mandatory availability of a document confirming that the conditions of manufacture of medicinal products comply with the requirements for the manufacture of medicinal products in Ukraine, except for active pharmaceutical ingredients (substances).

To access the notification form, right click the document symbol to open the hyperlink. Should you have any queries on this matter or request for full text of draft regulation in English, please do not hesitate to email us at [BPS@dti.gov.ph](mailto:BPS@dti.gov.ph) copy [bps.smd@dti.gov.ph](mailto:bps.smd@dti.gov.ph).

Thank you.

Sincerely,

**NEIL P. CATAJAY**  
Director