

12 April 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) from 25 to 31 March 2023.

Relative thereto, we respectfully invite stakeholders to comment on the four (4) notified draft technical regulations from four (4) WTO Members:

Document Symbol	Notifying Member	Relevant Dates	Products Covered	Summary
G/TBT/N/BRA/910/Add.7	Brazil	Date of Distribution: 31 March 2023 Deadline for Comments: Not Indicated	Radiopharmaceuticals - Addendum	The RDC number 567, 29 September 2021 - previously notified through G/TBT/N/BRA/910/Add.2 - which contains provisions on the temporary and exceptional criteria and procedures for the importation of industrialized radiopharmaceuticals contained in Normative Instruction No. 81, of December 16, 2020, of ANVISA and its updates, due to the risk of shortages in the national territory, had its validity extended by Resolution 783, 29 March 2023.
G/TBT/NEU/963	European Union	Date of Distribution: 30 March 2023 Deadline for Comments: 28 May 2023	Unique device identifiers for contact lenses	The proposed Regulation is a Delegated measure adopted pursuant to Article 27 (10) (b) of Regulation (EU) 2017/745 whereby the Commission is empowered to amend Annex VI of that Regulation in light of international developments and technical progress in the field of Unique Device Identification. In order to resolve the implementation issue concerning the registration of UDI-DI data elements in Eudamed for highly individualised devices, and in particular contact lenses, the Commission is empowered to establish a specific UDI-DI assignment rule for such devices. This solution will allow a more effective implementation of the UDI system at European level.
G/TBT/N/KGZ/53	Kyrgyz Republic	Date of Distribution: 30 March 2023	Veterinary medicines	The draft provide for ensuring a phased transition to the implementation of the Requirements

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)

		Deadline for Comments: 28 May 2023		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.
G/TBT/N/KOR/1130	Republic of Korea	Date of Distribution: 27 March 2023 Deadline for Comments: 25 May 2023	Pharmaceuticals	The revision aims to provide reasonable support for proper pharmaceutical quality management by harmonizing standards and specifications in the Korean Pharmacopoeia and to distribute high-quality medicines by improving some of the general information that incorporated the development of pharmaceuticals and the demands of the pharmaceutical industry in line with the latest scientific level. A. Improvement and modernization of test method accuracy (Annex 3,4 of the revision) B. New establishment of analytical method for Alkyl Sulfonic Acid Esters and test method for Endotoxin with recombinant factor C (Annex 6 of the revision)

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 copy bps.smd@dti.gov.ph.

Thank you.

Sincerely,

NEIL P. CATAJAY
Director