

21 November 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 11 to 17 November 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/C/HL/663	Chile	Date of Distribution: 17 November 2023 Deadline for Comments: 15 January 2024	Pharmaceuticals	The purpose of this technical standard is to establish the requirements and documentation to be submitted to apply for sanitary registration and also, provide elements for the surveillance of blood products for human use to ensure the safety of the quality, safety and efficacy of these products, reinforce the importance of good manufacturing practices, as well as incorporate comprehensive and up-to-date definitions that serve as a guide for regulators and regulated in order to provide transparency and greater with
G/TBT/NE/CU/325/Ad d.3	Ecuador	Date of Distribution: 17 November 2023 Deadline for Comments: Not Indicated	Medical Devices - Addendum	Partial reform of the Substitute Technical Sanitary Regulations for the sanitary registration and control of medical devices for human use, and the establishments in which they are manufactured, they import, dispense, dispense and market.
G/TBT/N/NI/C/178	Nicaragua	Date of Distribution: 15 November 2023 Deadline for Comments: 20 January 2024	Medical Devices	It sets out the requirements and provisions for the Granting of sanitary registration of medical devices for human use. This standard Applies to natural or legal persons who manufacture, repower, reprocess, reesterilize or import medical devices, for distribution and marketing.
G/TBT/N/R/US/154	Russian Federation	Date of Distribution:	Medicinal products	The draft decision envisages updating the text of the Rules for Marketing Authorisation and

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)

		14 November 2023 Deadline for Comments: 13 December 2023		Assessment of Medicinal Products for Human Use, taking into account the practice of enforcement of the Rules on the procedure for making amendments to the registration dossier of a medicinal product
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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