

03 January 2024

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 16 to 22 December 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/NA/US/165	Australia	Date of Distribution: 18 December 2023 Deadline for Comments: 31 January 2024	Medicines	The Therapeutic Goods Administration (TGA) administers Australia's national system of controls for the quality, safety, efficacy and timely availability of therapeutic goods in Australia. There are provisions under the Therapeutic Goods Act 1989 to establish quality standards for therapeutic goods. These standards, known as TGOs, can specify things such as procedures to be carried out in the manufacture of the goods, labelling, or other requirements. Once approved, TGOs are registered as legislative instruments on the Federal Register of Legislation in Australia.
G/TBT/NB/RA/1466/A dd.2	Brazil	Date of Distribution: 21 December 2023 Deadline for Comments: Not Indicated	Drug inserts for patients and health professionals - Addendum	The Draft resolution number 1137, 27 December 2022 - previously notified through G/TBT/N/BRA/1466 - which contains provisions on rules for preparing, harmonizing, updating, publishing and making available drug inserts for patients and health professionals, was adopted as Resolution 831, 06 December 2023.
G/TBT/N/C/HE/284	Switzerland	Date of Distribution: 18 December 2023 Deadline for Comments: 22 March 2024	Medicinal products	The Therapeutic Products Act, which has been in force since 2002, is currently being revised. Topics which are affected: • Advanced therapy medicinal products (ATMPs) • Digitalisation in the prescription, dispensing and use of therapeutic products • Veterinary medicinal products
G/TBT/N/T/PKM/527/A dd.1	The Separate Customs Territory	Date of Distribution: 18 December 2023	Medical equipment - Addendum	The purpose of this notification is to provide the final texts of "Amendments on partial articles of Regulations Governing Issuance of Medical Device License,

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)

	of Taiwan, Penghu, Kinmen and Matsu	Deadline for Comments: Not Indicated		Listing and Annual Declaration as well as Appendix 1 of Article 5, Appendices 2 and 3 of Article 6" and relevant dates of its implementation. The draft texts notified in "G/TBT/N/TPKM/527" were adopted with minor changes.
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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