

20 December 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 09 to 15 December 2023.

Relative thereto, we respectfully invite stakeholders to comment on the nine (9) notified draft technical regulations from six (6) WTO Members:

Document Symbol	Notifying Member	Relevant Dates	Products Covered	Summary
G/TBT/N/B/DI/431	Burundi	Date of Distribution: 14 December 2023 Deadline for Comments: 11 February 2024	Ground ambulance	1.1 This Draft East African Standard establishes the requirements which a provider shall comply with when operating/providing ground ambulance services. 1.2 This standard specifies categories of ambulances based on increasing order of the level of treatment that can be carried out. 1.3 The standard is applicable to ambulances capable of referring at least one person on a stretcher. 1.4 It does not cover the requirements for approval and registration, this is the responsibility of the relevant authority/authorities in the country where the ambulance is to be registered.
G/TBT/N/B/DI/432	Burundi	Date of Distribution: 15 December 2023 Deadline for Comments: 12 February 2024	Emergency medical services : water ambulance	1.1 This Draft East African Standard establishes the requirements for water Ambulance Services. 1.2 The standard is applicable to ambulances capable of referring at least one person on a stretcher. 1.3 It does not cover the requirements for approval and registration, this is the responsibility of the relevant authority in the country where the water ambulance is to be registered.
G/TBT/N/B/RA/929/Add.2	Brazil	Date of Distribution: 15 December 2023 Deadline for Comments:	Medical devices for in vitro diagnosis - Addendum	The Draft resolution number 734, 22 October 2019 - previously notified through G/TBT/N/BRA/929 - which proposes the updating of the Resolution 36, 26 August 2015, which establishes the risk classification, control scheme of notification,

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)

		Not Indicated		registration, market authorization and technical requirements for labelling and usage instructions of medical devices for in vitro diagnosis, was adopted as Resolution 830, 6 December 2023.
G/TBT/N/BRA/1485/Add.2/Corr.1	Brazil	Date of Distribution: 15 December 2023 Deadline for Comments: Not Indicated	Surgical gloves and gloves for non-surgical procedures - Corrigendum	The Notification G/TBT/N/BRA/1485/Add.2 is identical to G/TBT/N/BRA/1485/Add.1, therefore G/TBT/N/BRA/1485/Add.2 should be considered null and void
G/TBT/N/CHL/666	Chile	Date of Distribution: 14 December 2023 Deadline for Comments: 11 February 2024	Sterile single-use hypodermic needles and sterile single-use hypodermic syringes	Updates the standards for sanitary control and verification of conformity of hypodermic, sterile and single-use needles and syringes; previously established in Exempt Decree No. 1887 of 27 December 2007 of Ministry of Health, issued for incorporation into the control system established by the Article 111 of the Sanitary Code and its regulations, approved by Decree No. 825 of 1998, of the Ministry of Health, of the indicated medical devices
G/TBT/N/ECU/522	Ecuador	Date of Distribution: 12 December 2023 Deadline for Comments: 09 February 2024	Pharmaceutical products containing new chemical entities	The purpose of the draft regulation is to establish the procedure by which the ARCSA will grant a period of data exclusivity or other undisclosed safety and efficacy information, the preparation of which involves considerable effort, for pharmaceutical products containing new chemical entities, in accordance with the provisions of the Organic Code of the Social Economy of Knowledge, Creativity and Innovation (COESCI)."
G/TBT/N/KOR/1185	Republic of Korea	Date of Distribution: 14 December 2023 Deadline for Comments: 22 February 2024	Pharmaceuticals	To implement the revision of the Act without difficulties by establishing specific criteria for the fine in the case of failure to report the reason for expiration of priority marketing authorization, which is responsible by the law, with the revision of [Pharmaceutical Affairs Act] (Act No, 19652, promulgation Date 16 Aug,2023, Enforcement Date 17, Feb,2024,), which includes that a person who obtained a priority marketing authorization that can market a medicine in priority to the identical medicine by receiving judgement or decision that means the

				medicine doesn't fall within the invalidity or the scope of patent right shall report it to the Minister of Ministry of Food and Drug Safety when a reason arises to the patent to expire.
G/TBT/N/UGA/1671/Add.1	Uganda	Date of Distribution: 11 December 2023 Deadline for Comments: Not Indicated	Reusable menstrual cup - Addendum	The aim of this addendum is to inform WTO Members that the Draft Uganda Standard; DUS 2381:2022, Reusable menstrual cup — Specification, First Edition; notified in G/TBT/N/UGA/1671 was adopted on 24 May 2023. The adopted Uganda Standard, US 2381:2023, Reusable menstrual cup — Specification First edition, can be purchased online through the link: https://webstore.unbs.go.ug/
G/TBT/N/UGA/1674/Add.1	Uganda	Date of Distribution: 11 December 2023 Deadline for Comments: Not Indicated	Tampon - Addendum	The aim of this addendum is to inform WTO Members that the Draft Uganda Standard; DUS 2863:2022, Tampon — Specification, First Edition; notified in G/TBT/N/UGA/1674 was adopted on 24 May 2023. The adopted Uganda Standard, US2863:2023, Tampon — Specification, First Edition, can be purchased online through the link: https://webstore.unbs.go.ug/

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