

12 December 2022

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 26 November to 02 December 2022.

Relative thereto, we respectfully invite stakeholders to comment on the three (3) notified draft technical regulations from three (3) WTO Members:

Document Symbol	Notifying Member	Relevant Dates	Products Covered	Summary
G/TBT/N/KOR/1117	Republic of Korea	Date of Distribution: 02 December 2022 Deadline for Comments: 31 January 2023	Pharmaceuticals	The proposed amendment to the Standard on Pharmaceutical Equivalence Test is as follows: 1) Add standards for designating Reference Listed Drugs in accordance with the expanded scope of drugs subject to pharmaceutical equivalence study; 2) Harmonize bioequivalence criteria for narrow therapeutic index drugs with international standards; 3) Strengthen management of excipient changes by taking into consideration the formulations of products; and 4) Recalibrate pharmaceutical equivalence study document requirements for cases when manufacturing procedures and sites are changed
G/TBT/N/THA/610/Ad d.1	Thailand	Date of Distribution: 28 November 2022 Deadline for Comments: Not Indicated	Medical oxygen - Addendum	This addendum is to inform that the ministerial regulation on medical oxygen (TIS 540-2564(2021)) to conform with the standard, B.E. 2565(2022). The regulation will enter into force on 7 August 2023.
G/TBT/N/UKR/227/Ad d.1	Ukraine	Date of Distribution: 02 December 2022	Medical devices, in vitro diagnostic	Ukraine informs that the draft Resolution of the Cabinet of Ministers of Ukraine "On Amendments to Some

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: Not Indicated	medical devices and active implantable medical devices - Addendum	Resolutions of the Cabinet of Ministers of Ukraine on the Recognition of Conformity Assessment Results" (G/TBT/N/UKR/227) was adopted on 25 November 2022 (Resolution No. 1317), published and entered into force on 30 November 2022
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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

