

11 August 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 29 to 04 August 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/P/HL/308	Philippines	Date of Distribution: 4 August 2023 Deadline for Comments: 15 August 2023	Vaccines and biotherapeutic products for human use	The objectives of this Circular are: 1. To promulgate the revised requirements in instituting post-approval changes to registered biological products, incorporating the WHO and country-specific requirements; and. To provide the application process for post-approval changes.
G/TBT/NA/RE/584	United Arab Emirates	Date of Distribution: 4 August 2023 Deadline for Comments: 2 October 2023	Personal protective equipment	This GCC Technical Regulation lays down the mandatory requirements for the safety and electromagnetic compatibility of Personal Protective Equipment with which all Personal Protective Equipment must comply before it is placed on the market and allowed to move freely within the Member States markets, personal Protective Equipment within the scope of this regulation is specified in Annex 2, with the exclusion of the equipment mentioned in Annex 3 of this regulation.
G/TBT/N/USA/1260/R/ev.1/Add.1	United States	Date of Distribution: 2 August 2023 Deadline for Comments: 31 August 2023	Medical diagnostic equipment - Addendum	The Architectural and Transportation Barriers Compliance Board (hereafter, "Access Board" or "Board"), is extending the comment period for the Notice of Proposed Rulemaking on Standards for Accessible Medical Diagnostic Equipment published in the Federal Register on 23 May 2023. In that document, the Access Board requested comments by 24

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)

				July 2023. The Access Board is taking this action to allow interested parties additional time (until 31 August) to submit comments.
G/TBT/N/V NM/268	Viet Nam	Date of Distribution: 31 July 2023 Deadline for Comments: 28 September 2023	Toll manufactured medicines and technology transfer medicines	<p>This draft Circular provides general provisions on the registration of toll manufactured medicines and technology transfer medicines in Vietnam;</p> <p>This draft Circular also regulates the dossiers and procedures for granting, extending, amending, supplementing and withdrawing registration documents of toll manufactured medicines and technology-transferred medicines (pharmaceutical drugs, vaccines, biological products, herbal drugs) in Vietnam.</p> <p>This draft Circular shall amend, supplement or repeal some provisions of Circular 23/2013/TT-BYT and has been updated in accordance with the following legal texts in the field of pharmaceuticals, toll manufacturing and technology transfer</p>

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