

24 April 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 06 to 12 April 2024.

Relative thereto, we respectfully invite stakeholders to comment on the five (5) notified draft technical regulations from five (5) WTO Members:

Document Symbol	Notifying Member	Relevant Dates	Products Covered	Summary
G/TBT/N/BRA/1500/Add.1	Brazil	Date of Distribution: 10 April 2024 Deadline for Comments: Not Indicated	Medical equipment - Addendum	Draft resolution 1200, 01 September 2023 - previously notified through G/TBT/N/BRA/1500 - which contains provisions on the establishment of an optimized procedure for the analysis and decision of requests for registration of medical devices, through the use of analyzes carried out by an Equivalent Foreign Regulatory Authority, was adopted as Normative Instruction 290, 04 April 2024.
G/TBT/NECU/525	Ecuador	Date of Distribution: 12 April 2024 Deadline for Comments: 10 June 2024	Medicines in general and biological products	Partial reform project to "Resolution ARCSA-DE001-2019-JCGO through which the guidelines for making notifications are issued to the health registry of medicines in general and biological products"
G/TBT/N/JPN/804	Japan	Date of Distribution: 10 April 2024 Deadline for Comments: 09 May 2024	Biological products	The Minimum Requirements for Biological Products will be amended as follows: <ul style="list-style-type: none"> • GENERAL RULES Regarding the standard for "Nasally Live Attenuated Influenza Vaccine", the section of "Attenuation Assay" will be deleted. And the standard for "Purified Typhoid Vi Polysaccharide Vaccine" that is to be newly approved will be added. • STANDARDS The section of "Standard Antimeasles Serum" will be partially amended. The Public Notice on National Release Testing will be amended as follows: The criterion, fee, and quantity for "Purified Typhoid Vi Polysaccharide Vaccine" that is to be newly

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)

				approved will be added. And the criterion, fee, and quantity for "Human Serum Albumin" and "Freeze-dried Human Blood Coagulation Factor VIII Concentrate" will be partially amended. In addition, the criterion and fee for "Human Plasma Protein Fraction" will be partially amended.
G/TBT/N/R US/159	Russian Federation	Date of Distribution: 10 April 2024 Deadline for Comments: 04 May 2024	Labeling of medicinal products for human use and veterinary medicines	Updating the text of the Requirements for labeling medicinal products for human use and veterinary medicines, taking into account the experience of their enforcement in terms of variants of specifying the expiration date on the internal packaging of medicinal products
G/TBT/N/THA/733	Thailand	Date of Distribution: 11 April 2024 Deadline for Comments: 09 June 2024	Herbal pharmacopoeia	Amendments to the Notification of the Ministry of Public Health Re: Standard criteria, purity indicators or other essential characteristics for product quality in the Registration, Notification and Listing of Herbal Products B.E. 2564 (2020) are made to revise and implement the up-to-date version of pharmacopoeias on limits of contaminant test method and acceptance criteria as follows; - Microbial Contaminations; The British Pharmacopoeia 2021 Volume I – V, The Thai Herbal Pharmacopoeia 2021 and Supplements or The Tenth Edition of the European Pharmacopoeia and Supplements. - Heavy metals; The Thai Herbal Pharmacopoeia 2021 and Supplements, The Thai Herbal Preparation Pharmacopoeia 2022 or The Tenth Edition of the European Pharmacopoeia and Supplements.

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