

30 October 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 12 to 18 October 2024.

Relative thereto, we respectfully invite stakeholders to comment on the notified draft technical regulations from: Japan, Brazil, Ecuador, and Philippines

Document Symbol	Notifying Member	Relevant Dates	Products Covered	Summary
G/TBT/N/JPN/839	Japan	Date of Distribution: 16 October 2024 Deadline for Comments: 15 November 2024	Radiopharmaceuticals-	The Minimum Requirements for Radiopharmaceuticals are to be partially amended to add the standards for a radiopharmaceutical to be newly approved.
G/TBT/N/BRA/955/Add.2	Brazil	Date of Distribution: 15 October 2024 Deadline for Comments: Not indicated	Pharmaceutical products - Addendum	Resolution 742, 10 August 2022 - previously notified through G/TBT/N/BRA/955/Add.1 - which establishes the minimal technical requirements for relative bioavailability and bioequivalence studies that supports dossier of consent for clinical research, market authorization or post-market authorization of medicines, in the terms of this resolution, was change by Resolution 931, 09 October 2024. The final text is available only in Portuguese and can be downloaded at: https://antigo.anvisa.gov.br/documents/10181/5740831/RDC_931_2024_.pdf/42c43a0e-99cd-4114-9fe1-d5b6421a68d1
G/TBT/N/BRA/1571	Brazil	Date of Distribution: 15 October 2024 Deadline for Comments: 28 November 2024	Veterinary medicinal products in foods of animal origin	This Draft Resolution contains provisions on the assessment of the risk to human health of veterinary medicinal products, the maximum residue limits (MRL) of veterinary medicinal products in foods of animal origin and the analysis methods for the purposes of conformity assessment. This draft resolution will also be notified to the SPS Committee
G/TBT/N/ECU/513/Add.2	Ecuador	Date of Distribution: 14 October 2024 Deadline for Comments: Not indicated	Medicines in general - Addendum	Draft Substitute Sanitary Technical Regulations for the sanitary registration, control and surveillance of medicines in general for human use. New deadline for comments on the draft Substitute Sanitary Technical Regulations for the sanitary registration, control and surveillance of medicines in general for human use.
G/TBT/N/PHL/337	Philippines	Date of Distribution: 14 October	Bioequivalence study reports of generic	The policy adopts the ASEAN Mutual Recognition Arrangement for Bioequivalence Study Reports of Generic Medicinal Products

BUREAU OF PHILIPPINE STANDARDS

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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)

		2024 Deadline for Comments: 25 October 2024	medicinal products	and contains the general rules, regulations, and guidelines for the for the covered generic pharmaceutical products and listing of BE Centres in the ASEAN.
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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

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