17 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 05 to 11 August 2023.

Relative thereto, we respectfully invite stakeholders to comment on the eight (8) notified draft technical regulations from Brazil, Russian Federation, and Viet Nam:

Document Symbol	Notifying Member	Relevant Dates	Products Covered	Summary
G/TBT/N/BRA/1320/Add.1	Brazil	**Date of Distribution**: 10 August 2023 **Deadline for Comments**: Not Indicated	Medicaments : preparations containing the substance Lidocaine - Addendum	Resolution 626, 09 March 2022 - previously notified through G/TBT/N/BRA/1320 - which contains provisions on the prohibition of the use of preparations containing the substance Lidocaine, Brazilian Common Denomination (BCD) nº 05313, in the pharmaceutical form, oral solution for internal use, except in the pharmaceutical form spray for topical application on mucous membranes, provided that the applicator is equipped with a device that guarantees the exact dose of application, will be revoked by Resolution 802, 20 July 2023.
G/TBT/N/BRA/1417/Add.1	Brazil	**Date of Distribution**: 10 August 2023 **Deadline for Comments**: Not Indicated	Veterinary drugs - Residues - Addendum	Normative Instruction 162, 01 July 2022 - previously notified through G/TBT/N/BRA/1417 - which establishes the acceptable daily intake (ADI), the acute reference dose (DRfA) and maximum residue limits (MRL) for active pharmaceuticals ingredients (API) of veterinary drugs in foods of animal origin, was changed by Normative Instruction 241, 03 August 2023.

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)

G/TBT/N/BRA/1493	Brazil	**Date of Distribution**: 10 August 2023 **Deadline for Comments**: 28 August 2023	Synthetic and semi-synthetic drugs	This Draft Resolution contains provisions on health requirements for safety and efficacy for post-marketing registration alterations of synthetic and semi-synthetic drugs classified as new or innovative.
G/TBT/N/BRA/1494	Brazil	**Date of Distribution**: 10 August 2023 **Deadline for Comments**: 25 September 2023	Industrialized medicines for human use	This Draft Resolution contains provisions on the sanitary requirements for the market authorization of industrialized medicines for human use. It is important to highlight that, when the absence or incompleteness of national market authorization, andas long as there is no incompatibility, the adoption of guides and guidelines by the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH)
G/TBT/N/BRA/1495	Brazil	**Date of Distribution**: 10 August 2023 **Deadline for Comments**: 25 September 2023	Pandemic influenza vaccines	This draft resolution contains provisions on the conditions and procedures for registering pre-pandemic influenza vaccines, updating to a pandemic strain and authorization for the use, marketing and monitoring of pandemic influenza vaccines. It is important to highlight that, when the absence or incompleteness of national regulation, andas long as there is no incompatibility, the adoption of guides and guidelines by the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH)
G/TBT/N/BRA/1496	Brazil	**Date of Distribution**: 8 August 2023	Drugs containing synthetic and semi-synthetic active	This Draft Resolution establishes the criteria for carrying out Forced Degradation Studies on drugs containing synthetic and semi-

		Deadline for Comments: 18 October 2023	pharmaceutical ingredients	synthetic active pharmaceutical ingredients and defines the parameters for notification, identification and qualification of degradation products in these same products.
G/TBT/N/RUS/148	Russian Federation	**Date of Distribution**: 8 August 2023 **Deadline for Comments**: 3 September 2023	Pharmacopoeia	The draft amendments to the Pharmacopoeia of the Eurasian Economic Union provides for 46 general pharmacopoeia articles added, in terms of biological tests, biological medicinal products and radiopharmaceuticals.
G/TBT/N/VNM/215/Add.1	Viet Nam	**Date of Distribution**: 10 August 2023 **Deadline for Comments**: Not Indicated	Medicinal finished products and medicinal ingredients - Addendum	The Draft Circular amending some provisions in Circular No. 32/2018/TT-BYT dated 12 November 2018 of the Minister of Health guiding the registration of medicinal finished products and medicinal ingredients for circulation in Vietnam notified by G/TBT/N/VNM/215 has been published on 5 September 2022 under the name Circular No. 08/2022/TT-BYT guiding the registration of finished medical products and medicinal ingredients and entered into force from 20 December 2022.

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,

FERDINAND L. MANFOSTE
Officer-in-Charge