

20 January 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 31 December 2022 to 06 January 2023.

Relative thereto, we respectfully invite stakeholders to comment on the thirteen (13) notified draft technical regulations from Brazil, Ecuador and Tanzania:

Document Symbol	Notifying Member	Relevant Dates	Products Covered	Summary
G/TBT/N/BRA/1024/Add.2	Brazil	Date of Distribution: 05 January 2023 Deadline for Comments: Not Indicated	Labelling of medicines - Addendum	The Resolution - RDC number 768, 12 December 2022 - previously notified through G/TBT/N/BRA/1024/Add.1 - which establishes the rules for drug labeling, was updated by Normative Instruction 199, 12 December 2022. The final text is available only in Portuguese and can be downloaded at: http://antigo.anvisa.gov.br/documents/10181/3426875/IN_199_2022_.pdf/e8304a48-03a2-444da1fb-29d6367f1519
G/TBT/N/BRA/1466	Brazil	Date of Distribution: 05 January 2023 Deadline for Comments: 06 March 2023	Drug inserts for patients and health professionals	This Draft Resolution contains provisions on rules for preparing, harmonizing, updating, publishing and making available drug inserts for patients and health professionals.
G/TBT/N/BRA/1467	Brazil	Date of Distribution: 05 January 2023 Deadline for Comments: 06 March 2023	Medicines	This Draft Resolution is regarded to a proposal to define the general guidelines for the pilot implementation of the optimized analysis procedure, based on risk criteria, to confirm the suitability of the documentation submitted to

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)

				Anvisa for marketing authorization and post-marketing authorization changes to medicines.
G/TBT/N/BRA/1468	Brazil	<p>Date of Distribution: 05 January 2023</p> <p>Deadline for Comments: 06 March 2023</p>	Active pharmaceutical ingredients, cannabis products for medicinal purposes, medicines and biological products	<p>This Draft Resolution is regarded to a regulatory proposal for the establishment of specific criteria and procedures for defining the Equivalent Foreign Regulatory Authorities of the sanitary inspection process of manufacturers of active pharmaceutical ingredients, Cannabis products for medicinal purposes, medicines and biological products. And the optimized Good Manufacturing Practices (GMP) Certification review process.</p> <p>The Regulatory Trust Building Program for the recognition of the equivalence of the health inspection processes of an AREE is applicable exclusively to regulatory authorities or member entities of the Pharmaceutical Inspection Cooperation Scheme (PIC/S) and the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH).</p>
G/TBT/N/ECU/514/Add.1	Ecuador	<p>Date of Distribution: 05 January 2023</p> <p>Deadline for Comments: Not Indicated</p>	Good manufacturing practices for pharmaceutical laboratories - Addendum	<p>The Republic of Ecuador communicates and publishes Addendum 1 corresponding to the Reform Partial to the Substitute Sanitary Technical Regulations for Good Manufacturing Practices for Pharmaceutical Laboratories. The regulations have been issued through Resolution No. ARCSA-DE2022-018-AKRG of December 5, 2022, by the National Agency for Regulation, Control and Sanitary Surveillance - ARCSA, Doctor Leopoldo</p>

				Izquieta Pérez, with the aim of facilitating trade.
G/TBT/N/TZA/450/Add.1	Tanzania	Date of Distribution: 04 January 2023 Deadline for Comments: Not Indicated	Intravenous fluids produced in hospital infusion units - Addendum	The aim of this addendum is to inform WTO Members that the Draft Tanzania Standard; CDC 16(5438) P3 Hospital based intravenous fluids - Good manufacturing practice (GMP) - Requirement for regulatory purposes notified in G/TBT/N/TZA/450 entered into force on 01 April 2022 as Tanzania Standard, TZS 2793:2021 Hospital based intravenous fluids - Good Manufacturing Practice (GMP) - Requirements for regulatory purposes. This specification can be purchased by contacting the TBT NEP through nep@tbs.go.tz
G/TBT/N/TZA/451/Add.1	Tanzania	Date of Distribution: 04 January 2023 Deadline for Comments: Not Indicated	Methylated spirit 70% for medical use - Addendum	The aim of this addendum is to inform WTO Members that the Draft Tanzania Standard; CDC 16(6638) P3 Methylated spirit 70% for medical use - Specification notified in G/TBT/N/TZA/451 entered into force on 01 April 2022 as Tanzania Standard, TZS 2794:2021 Methylated spirit 70% for medical use - Specification. This specification can be purchased by contacting the TBT NEP through nep@tbs.go.tz
G/TBT/N/TZA/452/Add.1	Tanzania	Date of Distribution: 04 January 2023 Deadline for Comments: Not Indicated	Sterilized dextrose intravenous infusion - Addendum	The aim of this addendum is to inform WTO Members that the Draft Tanzania Standard; CDC 16(6639) P3 Sterilized dextrose intravenous infusion notified in G/TBT/N/TZA/452 entered into force on 01 April 2022 as Tanzania Standard, TZS 2795:2021 Sterilized dextrose intravenous infusion. This specification can be purchased by contacting the TBT NEP through nep@tbs.go.tz

G/TBT/N/TZA/453/Add.1	Tanzania	Date of Distribution: 04 January 2023 Deadline for Comments: Not Indicated	Sterilized compound sodium lactate intravenous infusion (ringers-lactate solution for injection) - Addendum	The aim of this addendum is to inform WTO Members that the Draft Tanzania Standard; CDC 16(6640) P3 Sterilized compound sodium lactate intravenous infusion (Ringerslactate solution for injection) notified in G/TBT/N/TZA/453 entered into force on 01 April 2022 as Tanzania Standard, TZS 2796:2021 Sterilized compound sodium lactate intravenous infusion (Ringers – Lactate solution injection). This specification can be purchased by contacting the TBT NEP through nep@tbs.go.tz
G/TBT/N/TZA/454/Add.1	Tanzania	Date of Distribution: 04 January 2023 Deadline for Comments: Not Indicated	Sterilized sodium chloride intravenous infusion - Addendum	The aim of this addendum is to inform WTO Members that the Draft Tanzania Standard; CDC 16(6641) P3 Sterilized sodium chloride intravenous infusion notified in G/TBT/N/TZA/454 entered into force on 01 April 2022 as Tanzania Standard, TZS 2797:2021 Sterilized sodium chloride intravenous infusion. This specification can be purchased by contacting the TBT NEP through nep@tbs.go.tz
G/TBT/N/TZA/458/Add.1	Tanzania	Date of Distribution: 04 January 2023 Deadline for Comments: Not Indicated	Sterilized sodium chloride and dextrose intravenous infusion - Addendum	The aim of this addendum is to inform WTO Members that the Draft Tanzania Standard; CDC 16(6642) P3 Sterilized sodium chloride and dextrose intravenous infusion notified in G/TBT/N/TZA/458 entered into force on 01 April 2022 as Tanzania Standard, TZS 2798:202 Sterilized sodium chloride and dextrose intravenous infusion. This specification can be purchased by contacting the TBT NEP through nep@tbs.go.tz

G/TBT/N/TZA/473/Add.1	Tanzania	Date of Distribution: 05 January 2023 Deadline for Comments: Not Indicated	Surgical face masks - Addendum	The aim of this addendum is to inform WTO Members that the Draft Tanzania Standard; TDC 9(6784) P3 Textiles – Surgical face masks – Specification notified in G/TBT/N/TZA/473 entered into force on 01 April 2022 as Tanzania Standard, TZS 2871:2021 Textiles – Surgical face masks –Specification. This specification can be purchased by contacting the TBT NEP through nep@tbs.go.tz
G/TBT/N/TZA/474/Add.1	Tanzania	Date of Distribution: 05 January 2023 Deadline for Comments: Not Indicated	Reusable fabric face masks - Addendum	The aim of this addendum is to inform WTO Members that the Draft Tanzania Standard; TDC 9(6785) P3 Textiles – Reusable fabric face masks – Specification notified in G/TBT/N/TZA/474 entered into force on 01 April 2022 as Tanzania Standard, TZS 2870:2021 Textiles – Reusable fabric face masks – Specification. This specification can be purchased by contacting the TBT NEP through nep@tbs.go.tz

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