08 June 2022

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.tbtims.wto.org) from 21 to 27 May 2022.

Relative thereto, we respectfully invite stakeholders to comment on the eleven (11) notified draft technical regulations from six (6) WTO Member Countries:

Document Symbol	Notifying Member	Relevant Dates	Products Covered	Summary
G/TBT/N/BRA/1265/Add.1/Corr.1	Brazil	**Date of Distribution**: 25 May 2022 **Deadline for Comments**: Not indicated	Human immunoglobulin - Corrigendum	This is being circulated at the request of the delegation of Brazil
G/TBT/N/BRA/1384	Brazil	**Date of Distribution**: 25 May 2022 **Deadline for Comments**: Not indicated	Pharmaceutical goods	This Resolution contains provisions on the criteria for granting or renewing the Certification of Good Manufacturing Practices for Medical Devices
G/TBT/N/BRA/1385	Brazil	**Date of Distribution**: 25 May 2022 **Deadline for Comments**: Not indicated	Drugs with synthetic and semi-synthetic active principles	This Resolution stablishes the Pilot for the Implementation of the Post-markt authorization Change Management Protocol for drugs with synthetic and semi-synthetic active principles, according to item 4 of the ICH Q12 guideline - Postmarket Change Management Protocol (PACMP)

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/1386	Brazil	**Date of Distribution**: 25 May 2022 **Deadline for Comments**: Not indicated	Medicines and vaccines against COVID-19 to face the SARS-CoV-2 pandemic	This Resolution contains provisions on the procedures and requirements for the maintenance of authorizations already granted and for new requests for temporary authorization for emergency use (AUE), on an experimental basis, of medicines and vaccines against Covid-19 to face the SARS-CoV-2 pandemic
G/TBT/N/BRA/1395	Brazil	**Date of Distribution**: 25 May 2022 **Deadline for Comments**: Not indicated	Products with antimicrobial action used in critical and semi-critical articles	This Resolution contains provisions on products with antimicrobial action used in critical and semi-critical articles, and their market authorization
G/TBT/N/BRA/1396	Brazil	**Date of Distribution**: 25 May 2022 **Deadline for Comments**: Not indicated	Hospital disinfectant	This Resolution contains provisions on the indication for the use of sanitizing products in the "Sterilizing" category, for application in the form of immersion, the indication for the use of sanitizing products currently categorized as "Hospital Disinfectant for Semi-Critical Items
G/TBT/N/BWA/151	Botswana	**Date of Distribution**:	Refined petroleum jelly in two colour	This Botswana Standard specifies requirements for

		25 May 2022 **Deadline for Comments**: 24 July 2022	grades (white and yellow), intended for use in pharmaceutical and cosmetic applications	refined petroleum jelly in two colour grades (white and yellow), intended for use in pharmaceutical and cosmetic applications
G/TBT/N/CAN/653/Add.2	Canada	**Date of Distribution**: 23 May 2022 **Deadline for Comments**: Not indicated	Prescription drug list : brimonidine - Addendum	The purpose of this Notice of Amendment is to notify that, as a result of a scientific review and public consultation, Health Canada added a qualifier to brimonidine on the Prescription Drug List to enable sale of certain non-prescription products
G/TBT/N/RUS/133	Russian Federation	**Date of Distribution**: 24 May 2022 **Deadline for Comments**: 17 June 2022	Conduct of clinical trials and marketing authorization of medicinal products	Granting the right to drug manufacturers to submit data from the full preclinical development program on individual components of a drug from a combination of 2 active substances at any stage of development, while limiting themselves to short-term studies of the combination itself
G/TBT/N/UKR/162/Add.1	Ukraine	**Date of Distribution**: 23 May 2022 **Deadline for Comments**: 17 June 2022	Medical devices: personal protective equipment, medical devices, in vitro diagnostic medical	The amendments establish the possibility to recognize the results of conformity assessment of medical devices, in vitro diagnostic

			devices, active implantable medical devices - Addendum	medical devices, active implantable medical devices, carried out by foreign accredited bodies, appointed by conformity assessment bodies in Ukraine for the period of martial law
G/TBT/N/USA/1870	United States of America	**Date of Distribution**: 24 May 2022 **Deadline for Comments**: 22 August 2022	Certain medical gases	The Food and Drug Administration (FDA, the Agency, or we) is proposing new regulations that would amend the requirements concerning current good manufacturing practice (CGMP) and postmarketing safety reporting that apply to certain medical gases

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 Mrs. Catherine Antonio-Paguinto (CatherineAntonio@dti.gov.ph) and Ms. Jasmin E. Metre (JasminMetre@dti.gov.ph).

Thank you.

Sincerely,

FERDINAND L. MANFOSTE
Assistant Director