

28 March 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.tbims.wto.org) from 12-18 March 2022.

Relative thereto, we respectfully invite stakeholders to comment on the seven (7) notified draft technical regulations from five (5) WTO Member Countries:

Document Symbol	Notifying Member	Relevant Dates	Products Covered	Summary
G/TBT/N/BR/A/1310	Brazil	Date of Distribution: 15 March 2022 Deadline for Comments: not applied	Medical devices	This resolution contains provisions on technical attributes of medical devices selected for economic monitoring by Anvisa
G/TBT/N/BR/A/1311	Brazil	Date of Distribution: 15 March 2022 Deadline for Comments: not applied	Medical devices	This resolution contains provisions on the compassionate use of medical devices
G/TBT/N/BR/A/1312	Brazil	Date of Distribution: 15 March 2022 Deadline for Comments: not applied	Active pharmaceutical ingredients	This resolution defines the extraordinary and temporary criteria and procedures for the certification of good manufacturing practices for the purpose of market authorization and post-market authorization changes of active pharmaceutical ingredient, medicine and health products due to the international public health emergency of the new Coronavirus

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/EC U/512	Ecuador	Date of Distribution: 17 March 2022 Deadline for Comments: 16 May 2022	Bioequivalence and bioavailability in medicines for human use and consumption	This regulation is the Reform project to the Sanitary Technical Regulation that establishes the criteria and requirements to demonstrate bioequivalence and bioavailability, in medicines for human use and consumption
G/TBT/N/EG Y/318	Egypt	Date of Distribution: 17 March 2022 Deadline for Comments: 16 May 2022	Anaesthetic and respiratory equipment : breathing sets and connectors	Ministerial Decree No. 524 /2021 gives the producers and importers a six-month transitional period to abide by the Egyptian standard ES 6576/2021 which specifies basic requirements for breathing sets and breathing tubes intended to be used with anaesthetic breathing systems, ventilator breathing systems, humidifiers or nebulizers
G/TBT/N/KOR/1063	Republic of Korea	Date of Distribution: 15 March 2022 Deadline for Comments: 14 May 2022	Biological products	Pursuant to the amendment (July 16, Ordinance of the Prime Minister No. 1717) of The Rules on the Manufacturing and Sales management of biological products, etc, the regulation concerned is to determine the matters delegated in accordance with the Prime Minister Ordinance in relation to the procedures and methods required for storage and transportation, etc. of biological products, etc
G/TBT/N/PH L/282	Philippines	Date of Distribution: 17 March 2022 Deadline for Comments: 02 May 2022	Pharmaceutical products	This Circular aims to set guidelines on the License to Operate (LTO) application of drug establishments engaged in online pharmacy (E-Pharmacy) thereby ensuring the safety, health and welfare protection of the public

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,

NEIL P. CATAJAY
Director

