22 February 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 01 January - 04 February 2022.

Relative thereto, we respectfully invite stakeholders to comment on the five (5) notified draft technical regulations from four (4) WTO Member Countries:

Document Symbol	**Notifying Member**	**Relevant Dates**	**Products Covered**	**Summary**
G/TBT/N/EU/866	European Union	**Date of Distribution**: 18 January 2022 **Deadline for Comments**: 18 March 2022	Products without an intended medical purpose listed in Annex XVI of Regulation (EU) 2017/745 on medical devices.	The common specifications (CS) for each of the groups of products listed in Annex XVI of Regulation (EU) 2017/745 on medical devices address the application of risk management, in respect of certain general safety and performance requirements set out in Annex I of that Regulation.
G/TBT/N/JPN/724	Japan	**Date of Distribution**: 20 January 2022 **Deadline for Comments**: 20 February 2022	Pharmaceutical Products	(1) To establish the standard for manufacturing process, properties, quality, storage and others of pharmaceuticals to which special attention must be paid for the attainment of public health and sanitation (Biological products). (2) To stipulate Biological products as subject to National Release Testing, as well as fee, criterion and quantity for the testing.
G/TBT/N/KOR/1051	Republic of Korea	**Date of Distribution**: 10 January 2022 **Deadline for Comments**: 10 March 2022	Pharmaceuticals	The Amendment to the Regulation on Designation, and Approval Procedure and Method of Pharmaceutical Products for National Lot Release

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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/KOR/1053	Republic of Korea	**Date of Distribution**: 26 January 2022 **Deadline for Comments**: 26 March 2022	Medical Device	The "Standards of Medical Device Good Manufacturing Practices" is being amended by the Ministry of Food and Drug Safety (MFDS) as follows: GMP change audit exemption of location changes for Software as Medical Devices (SaMD) Manufacturers.
G/TBT/N/TPKM/477	Separate Customs Territory of Taiwan, Penghu, Kinmen and Matsu	**Date of Distribution**: 6 January 2022 **Deadline for Comments**: 6 March 2022	Medical devices; Medical equipment (ICS 11.040)	The Food and Drug Administration (FDA) is proposing to draft the "Medical Device Product Items That Shall Accord Specification, Testing Method and Performance." The regulation is intended to develop a complete management mechanism for medical devices, to request the quality of medical devices and protect the safety and well-being 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,

Catajay Neil Pinuela

NEIL P. CATAJAY
Director