12 April 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 02 to 08 April 2022.

Relative thereto, we respectfully invite stakeholders to comment on the twelve (12) notified draft technical regulation from three (3) WTO Member Countries:

Document Symbol	Notifying Member	Relevant Dates	Products Covered	Summary
G/TBT/N/BRA/1313	Brazil	**Date of Distribution**: 04 April 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/BRA/1314	Brazil	**Date of Distribution**: 04 April 2022 **Deadline for Comments**: Not applied	Clinical trials with drugs	This Normative Instruction contains provisions on inspection procedures in Good Clinical Practice for clinical trials with drugs
G/TBT/N/BRA/1319	Brazil	**Date of Distribution**: 05 April 2022 **Deadline for Comments**: Not applied	Metered-dose inhalers that use chlorofluorocarbon-type propellant gas	This resolution contains provisions on the ban on the production and import of metered-dose inhalers that use chlorofluorocarbon-type propellant gas
G/TBT/N/BRA/1320	Brazil	**Date of Distribution**: 05 April 2022 **Deadline for Comments**: Not applied	Medicaments : preparations containing the substance Lidocaine	This resolution 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
G/TBT/N/BRA/1321	Brazil	**Date of Distribution**: 05 April 2022 **Deadline for Comments**: Not applied	Medicaments : implementation of the action of recalling drugs	This resolution contains provisions on minimum requirements related to the obligation, on the part of companies holding drug market authorizations, to communicate the implementation of the action of recalling drugs to the competent health authorities and consumers, in the event of sufficient evidence or proof of quality deviation that represent a risk, aggravation or health consequences, as well as in the event of deregistration related to safety and efficacy
G/TBT/N/BRA/1322	Brazil	**Date of Distribution**: 05 April 2022 **Deadline for Comments**: Not applied	Ganglioside-based drugs	This resolution contains provisions on the control by Anvisa of the importation of raw materials, manufacture, distribution, commercialization, medical prescription and application of ganglioside-based drugs
G/TBT/N/BRA/1324	Brazil	**Date of Distribution**: 05 April 2022 **Deadline for Comments**: Not applied	Medicaments and medicines	This resolution contains provisions on the Certification of Good Practices for conducting Bioavailability/Bioequivalence studies of medicaments and defines which Bioavailability/Bioequivalence studies of medicines must be carried out in certified research centers.
G/TBT/N/BRA/1326	Brazil	**Date of Distribution**: 05 April 2022 **Deadline for Comments**: Not applied	Seasonal influenza vaccines	This resolution contains provisions on the composition of seasonal influenza vaccines to be used in Brazil
G/TBT/N/CHN/1663	CHINA	**Date of Distribution**: 04 April 2022 **Deadline for Comments**: 03 June 2022	Medical electrical equipment: respiratory gas monitors	This document specifies particular requirements for the basic safety and essential performance of a respiratory gas monitor (RGM) and the requirements are listed as follows: • anaesthetic gas monitoring, • carbon dioxide monitoring, and • oxygen monitoring.

G/TBT/N/CHN/1664	CHINA	**Date of Distribution**: 05 April 2022 **Deadline for Comments**: 04 June 2022	Medical electrical equipment: respiratory high flow therapy equipment	This document specifies the basic safety and basic performance of high flow respiratory treatment equipment used in combination with accessories. Such medical devices are expected to be used for patients with spontaneous breathing
G/TBT/N/CHN/1665	CHINA	**Date of Distribution**: 05 April 2022 **Deadline for Comments**: 04 June 2022	Photodynamic therapy and photodynamic diagnosis equipment	This document applies to photodynamic therapy and photodynamic diagnosis equipment used to eliminate or alleviate disease, injury or disability
G/TBT/N/JPN/733	JAPAN	**Date of Distribution**: 05 April 2022 **Deadline for Comments**: 04 June 2022	Biological products: diphtheria toxin in the pneumococcal 13-valent conjugate vaccine adsorbed (mutated diphtheria CRM197 conjugate)	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)

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

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Director

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