23 September 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 10 to 16 September 2022.

Relative thereto, we respectfully invite stakeholders to comment on the seven (7) notified draft technical regulations from four (4) WTO Members:

Document Symbol	Notifying Member	Relevant Dates	Products Covered	Summary
G/TBT/N/AUS/145	Australia	**Date of Distribution**: 13 September 2022 **Deadline for Comments**: 11 October 2022	Medical devices	The Australian Government is undertaking a significant program of reform to the regulation of therapeutic goods in Australia. The reforms will continue to improve the safety, performance, and quality of medical devices in Australia and improve health outcomes for patients who require medical devices. As part of the Australian Government Department of Health and Aged Care, the Therapeutic Goods Administration (TGA) regulates therapeutic goods, and is responsible for implementing the Government's reforms, including the introduction of a unique device identification (UDI) system for medical devices supplied in Australia.
G/TBT/N/BRA/1165/Add.1	Brazil	**Date of Distribution**: 14 September 2022 **Deadline for Comments**: Not Indicated	Pharmaceutical products - Addendum	The Public Consultation No. 1044, 8 April 2021 - previously notified through G/TBT/N/BRA/1165 - which establishes the criteria for the exemption and substitution of relative bioavailability and bioequivalence studies, was adopted as Resolution - RDC number 749, 05 September 2022. The final text is available only in Portuguese and can be downloaded at:

				http://antigo.anvisa.gov.br/documents/10181/2695968/RDC_749_2022_.pdf/d8c6877a-b162-49e8-944b-e1e88f7ef6ef
G/TBT/N/BRA/1444	Brazil	**Date of Distribution**: 14 September 2022 **Deadline for Comments**: Not Applicable	Medicines and biological products	This Resolution establishes a temporary optimized analysis procedure, in which the analyzes conducted by an Equivalent Foreign Regulatory Authority are used for the verified analysis of the market authorization and post-market authorization petitions of medicines, biological products and their inputs, and the letter of adequacy of the pharmaceutical ingredient dossier active
G/TBT/N/BRA/1445	Brazil	**Date of Distribution**: 14 September 2022 **Deadline for Comments**: Not Applicable	Medicaments : caco-2 cells	This Resolution contains provisions on validation and permeability assays with Caco-2 cells
G/TBT/N/BRA/1448	Brazil	**Date of Distribution**: 14 September 2022 **Deadline for Comments**: 14 November 2022	Medical devices and in vitro diagnostic (IVD) medical devices	This Draft Resolution contains provisions on the essential safety and performance requirements applicable to medical devices and in vitro diagnostic (IVD) medical devices. The proposed Resolution will take as reference the document prepared by the International Medical Device Regulators Forum - IMDRF/GRRP WG/N47:2018 Essential Principles of Safety and Performance of Medical Devices and IVD Medical Devices.
G/TBT/N/EU/922	European Union	**Date of Distribution**: 13 September 2022 **Deadline for Comments**: 11 November 2022	Nicotinamide riboside chloride	This draft Commission Delegated Regulation concerns the authorisation of the addition of nicotinamide riboside chloride, as a source of niacin to foods in line with EFSA's relevant scientific opinion
G/TBT/N/UKR/227	Ukraine	**Date of Distribution**:	Medical devices, in vitro	At the beginning of Russia's military aggression against Ukraine, there was a risk of

		13 September 2022 **Deadline for Comments**: 12 October 2022	diagnostic medical devices and active implantable medical devices	complicating the work of designated bodies for conformity assessment of products with the requirements of technical regulations. The possible suspension of their work would have to a delay or blockage of imports to Ukraine of certain groups of goods that were subject to the conformity assessment procedure with the requirements of Ukrainian technical regulations with the involvement of designated conformity assessment bodies.

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,

FERDINAND L. MANFOSTE
Officer-in-Charge