31 March 2023

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.epingalert.org) from 18 to 24 March 2023.

Relative thereto, we respectfully invite stakeholders to comment on the six (6) notified draft technical regulations from four (4) WTO Members:

Document Symbol	Notifying Member	Relevant Dates	Products Covered	Summary
G/TBT/N/BRA/1132/Add.1	Brazil	**Date of Distribution**: 23 March 2023 **Deadline for Comments**: Not Indicated	Veterinary products - Addendum	Ministry of Agriculture, Livestock and Food Supply – MAPA issued Ordinance No. 768, 21 March 2023, that extends the deadline for submission of studies that already started to redefine the grace period after alteration of Maximum Residue Limit (MRL).
G/TBT/N/BRA/1322/Add.1	Brazil	**Date of Distribution**: 24 March 2023 **Deadline for Comments**: Not Indicated	Ganglioside-based drugs - Addendum	The Resolution – RDC number 624, 09 March 2022 - previously notified through G/TBT/N/BRA/1322 - which contains provisions on the control by Brazilian Health Regulatory Agency (Anvisa) of the importation of raw materials, manufacture, distribution, commercialization, medical prescription and application of ganglioside - based drugs, was revoked by Resolution - RDC number 782, 17 May 2023.
G/TBT/N/BRA/1444/Add.1	Brazil	**Date of Distribution**: 24 March 2023 **Deadline for Comments**: Not Indicated	Medicines and biological products and their inputs - Addendum	Resolution - RDC number 750, 06 September 2022 - previously notified through G/TBT/N/BRA/1444 -, which 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, had its validity period extended until 31 March 2024 by Resolution- RDC number 781, 16 March 2023.
G/TBT/N/KGZ/51	Kyrgyz Republic	**Date of Distribution**: 21 March 2023 **Deadline for Comments**: 06 May 2023	Disinfectant, disinsectant and desacarizatio n products for veterinary	The draft provides for the Rules of regulation of circulation of disinfectant, disinsectant and desacarization products for veterinary use not directly coming into contact with animals (being used in vitro in veterinary medicine) in the customs territory of the Eurasian Economic Union.
G/TBT/N/TPKM/520	The Separate Customs Territory of Taiwan, Penghu, Kinmen and Matsu	**Date of Distribution**: 22 March 2023 **Deadline for Comments**: 20 May 2023	Medical equipment	As medical devices involve a variety of scientific fields, their types, items, and compositions are complex and rapidly changing. To clarify the scope of medical devices subject to management, we have reviewed the contents of the Annex to Article 4 of the "Regulations Governing the Classification of Medical Devices" and made appropriate revisions based on international management approaches and the current situation. It is recognized that medical device firms should be given a grace period to respond to the amendments, and Article 7 has been amended accordingly. The proposed amendments are as follows: (1) The date of entering into force for the new product items in Article 4. (Amendment to Article 7); (2) 64 product items have been added. (Amendment to the Annex to Article 4)

G/TBT/N/VNM/253	Viet Nam	**Date of Distribution**: 23 March 2023 **Deadline for Comments**: 01 April 2023	Medicaments : herbal ingredients	Amendments to regulations on export, import, registration of herbal ingredients, excipients, capsule shells, semi-finished herbal ingredients in Clause 1 Article 91, Article 93 of Decree No. 54 and point b Clause 47 Article 5 of Decree No. 155 to simplify administrative dossiers and procedures for export, import, registration of herbal ingredients, excipients, capsule shells, semi-finished herbal ingredients, creating more favourable conditions for enterprises, including allowing to replace "the Pharmacy Business License for enterprises supplying herbal ingredients, semi-finished herbal ingredients" with "Business license or equivalent documents with the trading scope in herbal ingredients", and allows to replace "Certificate of Good Manufacturing Practice (GMP) for herbal ingredients, semi-finished herbal ingredients" with "Manufacturing License or equivalent documents with Good Manufacturing Practice Certificate (GMP) within the scope of manufacture of herbal ingredients, semi-finished herbal ingredients".

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,

Catajay Neil Pinuela

NEIL P. CATAJAY
Director