28 October 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.epingalert.org) from 15 to 21 October 2022.

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

Document Symbol	Notifying Member	Relevant Dates	Products Covered	Summary
G/TBT/N/ECU/515	Ecuador	**Date of Distribution**: 21 October 2022 **Deadline for Comments**: 19 December 2022	Homeopathic medicines	Project "Technical Sanitary Regulations Substitute for Sanitary Notification of Homeopathic Products or Medications, and of Good Practices of Manufacturing for Homeopathic Pharmaceutical Laboratories", whose purpose is to establish the parameters of quality, safety and efficacy, under which the notification will be granted healthcare to homeopathic products or medicines. In the same way set the criteria for carrying out the promotion, publicity, control, surveillance and sanction of said products.
G/TBT/N/MAC/20	Macao	**Date of Distribution**: 21 October 2022 **Deadline for Comments**: Not Applicable	Traditional chinese medicine	1. Law No. 11/2021 stipulates the technical requirements of Chinese medicine manufacturers and entities engaged in the import, export and wholesale activities of traditional Chinese medicines. It requires that the packaging, labelling and package insert of proprietary Chinese medicines to be written in at least Chinese or Portuguese. It also stipulates that all

				proprietary Chinese medicines must first be registered with the Pharmaceutical Administration Bureau before they can be circulated in the Macao SAR. 2. Administrative Regulation No. 46/2021 supplements Law No. 11/2021 with enforcement rules such as those on the information required to be displayed on the packaging or labelling of proprietary Chinese medicines.
G/TBT/N/UKR/216/Add.1	Ukraine	**Date of Distribution**: 18 October 2022 **Deadline for Comments**: Not Indicated	Medicines, active pharmaceutical ingredients - Addendum	Ukraine informs that the draft Order of the Ministry of Health of Ukraine "On Approval of the Medicines Quality Certification Procedure for International Trade and Confirmation for Exported Active Pharmaceutical Ingredients" (G/TBT/N/UKR/216) was adopted on 25 July 2022 (Order No. 1310), registered with the Ministry of Justice of Ukraine on 31 August 2022, published on 13 September 2022 and entered into force on 13 September 2022.
G/TBT/N/USA/1934	United States	**Date of Distribution**: 20 October 2022 **Deadline for Comments**: 06 December 2022	Medical devices subject to administrative destruction	Notice of Proposed Rulemaking - The Food and Drug Administration (FDA, Agency, or we) is proposing a regulation to implement its new authority to destroy a device valued at $2,500 or less (or such higher amount as the Secretary of the Treasury may set by regulation), that has been refused admission into the United States under the Federal Food, Drug, and Cosmetic Act (FD&C Act 21

				USC Ch. 9), by providing to the owner or consignee notice and an opportunity to appear and introduce testimony prior to the destruction

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