22 June 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 10 to 16 June 2023.

Relative thereto, we respectfully invite stakeholders to comment on the three (3) notified draft technical regulations from three (3) WTO Members:

Document Symbol	Notifying Member	Relevant Dates	Products Covered	Summary
G/TBT/N/ARM/94	Armenia	**Date of Distribution**: 14 June 2023 **Deadline for Comments**: 12 August 2023	Medicinal products	The draft amendments to the Rules for marketing authorization and assessment of medicinal products for human use provide for the updating of the Rules for marketing authorization and assessment of medicinal products for human use with account of the experience of law enforcement of these Rules on the procedure for marketing authorization of medicinal products and bringing the registration dossier in line with the requirements of the Eurasian Economic Union.
G/TBT/N/CHL/598/Add.2	Chile	**Date of Distribution**: 14 June 2023 **Deadline for Comments**: Not Indicated	Medical Devices Intended for Human Immunodeficiency Virus (HIV) Detection - Addendum	Modification of the content or scope of the notified measure and indication of where the text can be obtained1: Labeling update
G/TBT/N/KOR/1149	Republic of Korea	**Date of Distribution**: 12 June 2023 **Deadline for Comments**: 10 August 2023	In vitro diagnostic medical device	The proposed amendment to the Standards of in vitro diagnostic Medical Device Good Manufacturing Practices is as follows: 1) Complete transfer of KGMP audit authority to Korean private conformity assessment bodies for

				export-only in vitro diagnostic medical devices 2) Modification of required dossier for documentation review 3) Clarification of the KGMP audit procedure 4) Exemption of location change audit for in vitro diagnostic software manufacturers 5) Improvement of required dossier for in vitro diagnostic software manufacturers

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