19 February 2024

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 03 to 09 February 2024.

Relative thereto, we respectfully invite stakeholders to comment on the four (4) notified draft technical regulations from Japan, Kenya, and United States:

Document Symbol	Notifying Member	Relevant Dates	Products Covered	Summary
G/TBT/N/JPN/797	Japan	**Date of Distribution**: 05 February 2024 **Deadline for Comments**: 04 April 2024	Pharmaceutical products	Under Paragraph 1 of Article 41 of the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices, the Japanese Pharmacopoeia, Eighteenth edition are to be revised.
G/TBT/N/KEN/1585	Kenya	**Date of Distribution**: 09 February 2024 **Deadline for Comments**: 08 April 2024	Mercurial sphygmomanometers	This National Workshop Agreement lays down the requirements for mercurial sphygmomanometers used for measuring arterial blood pressure of human beings.
G/TBT/N/KEN/1586	Kenya	**Date of Distribution**: 09 February 2024 **Deadline for Comments**: 08 April 2024	Dentistry : tooth powder	This Draft Kenya Standard prescribes requirements and the methods of sampling and test for tooth powders.
G/TBT/N/USA/1839/Add.1	United States	**Date of Distribution**: 05 February 2024 **Deadline for Comments**: Not Indicated	Medical devices - Addendum	The Food and Drug Administration (FDA, the Agency, or we) is issuing a final rule to amend the device current good manufacturing practice (CGMP) requirements of the Quality System (QS) regulation to harmonize and modernize the regulation. We are harmonizing to align more closely with the international consensus standard for devices by

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Membership:
- International Organization for Standardization (ISO)
- International Electrotechnical Commission (IEC)
- World Trade Organization (WTO) Technical Barriers to Trade (TBT)
  - National Enquiry Point (NEP)
  - National Notification Authority (NNA)

				converging with the quality management system (QMS) requirements used by other regulatory authorities from other jurisdictions (i.e., other countries). We are doing so by incorporating by reference an international standard specific for device quality management systems. Through this rulemaking we also establish additional requirements and make conforming edits to clarify the device CGMP requirements for such products. This action will continue our efforts to align our regulatory framework with that used by regulatory authorities in other jurisdictions to promote consistency in the regulation of devices and provide timelier introduction of safe, effective, high-quality devices for patients.

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,

Digitally signed by
Catajay Neil Pinuela

NEIL P. CATAJAY
Director