04 May 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 22 to 28 April 2023.

Relative thereto, we respectfully invite stakeholders to comment on the two (2) notified draft technical regulations from Republic of Korea:

Document Symbol	Notifying Member	Relevant Dates	Products Covered	Summary
G/TBT/N/KOR/1138	Republic of Korea	**Date of Distribution**: 24 April 2023 **Deadline for Comments**: 22 June 2023	Medical device	The proposed amendments to the Regulation on medical device approval/report/review, etc. is as follows: 1) Recognition of real-world evidence when reviewing clinical trial data; 2) Introducing a custom classification procedure for newly developed medical devices such as digital health devices; 3) Preparation of grounds for multiple purposes description of combination medical devices according to its characteristics; 4) Easing double inspection when distributing used special medical equipment; 5) Expansion of expedited review including medical devices subject to production/import suspension reporting; 6) Increase test report accreditation body for biosafety data; 7) Minor change improvement
G/TBT/N/KOR/1139	Republic of Korea	**Date of Distribution**: 24 April 2023 **Deadline for Comments**: 22 June 2023	Medical devices	The proposed amendments to the Regulation on Stability Test Standard for Medical Devices is as follows: 1) Measurement period for stability test - For the measurement period, at least one time point, including the last time point, can be set for long-term preservation tests and accelerated aging tests of medical devices using raw materials without

				physical or chemical changes, such as metals, when the data at the start of the test is replaced. 2) Clarification of test items - Test items are divided into biological safety tests, performance tests, and other tests in accordance with the <Regulations on Medical Device Permission, Notification, Review, etc.> and <Regulation on In Vitro Diagnostic Medical Device Permission, Notification, Review, etc.>

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