

06 December 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 23 to 29 November 2024.

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

Document Symbol	Notifying Member	Relevant Dates	Products Covered	Summary
G/TBT/N/KO/R/1240	Republic of Korea	Date of Distribution: 29 November 2024 Deadline for Comments: 9 December 2024	Digital medical products	<p>The purpose of this Decree is to prescribe matters mandated by the Digital Medical Products Act for its enactment and enforcement. The matters are as follows:</p> <p>A. details necessary for establishment and implementation of a comprehensive plan for digital medical products</p> <p>B. facility standards for medicines combined with digital technology</p> <p>C. procedures and methods for designating institutions for fostering professional human resources, centers for regulatory support, and agencies for certification</p> <p>D. processing of sensitive information and personally identifiable information</p> <p>E. other matters</p>
G/TBT/N/KO/R/1241	Republic of Korea	Date of Distribution: 29 November 2024 Deadline for Comments: 9 December 2024	Digital medical products	<p>The purpose of this Rule is to prescribe matters mandated by the Digital Medical Products Act and the Enforcement Decree of that Act for its enactment and enforcement. The details are as follows:</p> <p>A. the scope of and classification standards for digital technology</p> <p>B. permission (certification and reporting) considering the characteristics of digital medical devices</p> <p>C. clinical trials (clinical performance tests)</p> <p>D. cancellation or correction order regarding confirmation/investigation of compliance with quality control standards</p> <p>E. labeling, follow-up management methods and procedures</p>

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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)

				<p>F. certification of excellent management systems</p> <p>G. manufacturing and import of medicines combined with digital technology</p> <p>H. impact assessment for supporting the development of digital medical products</p> <p>I. matters regarding fees for digital medical devices</p>
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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,

NEIL P. CATAJAY
Director

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