16 July 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 06 to 12 July 2024.

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

Document Symbol	Notifying Member	Relevant Dates	Products Covered	Summary
G/TBT/N/ECU/525/Add.1	Ecuador	**Date of Distribution:** 12 July 2024 **Deadline for Comments:** Not indicated	Medicines in general and biological products - Addendum	The Republic of Ecuador communicates and announces Addendum 1 corresponding to the partial reform of Resolution ARCSA-DE-001-2019-JCGO through which the guidelines are issued to make notifications to the health registry of medicines in general and biological products. The regulations have been issued by Resolution No. ARCSA-DE-2024-030-DASP of July 3, 2024, issued by the National Agency for Health Regulation, Control and Surveillance - ARCSA, Doctor Leopoldo Izquieta Pérez. This regulation will come into force within a period of six (6) months from its subscription, without prejudice to its publication in the Official Registry.
G/TBT/N/RUS/163	Russian Federation	**Date of Distribution:** 12 July 2024 **Deadline for Comments:** 3 August 2024	Medical products	The draft Decision envisages updating the text of the Marketing Authorization and Assessment of Medicinal Products for Human Use, taking into account the experience of their enforcement, improving the classification of changes to the registration dossier of a medicinal product, detailing the requirements and number of documents submitted by the applicant as part of the amendment procedure; optimizing administrative procedures related to this procedure.
G/TBT/N/RUS/164	Russian Federation	**Date of Distribution:** 12 July 2024 **Deadline for Comments:** 7 August 2024	Medical products	The draft Decision provides for updating the text of the Requirements for the Medication Guide and Summary of Product Characteristics of Medicinal Products for Human Use taking into account the low enforcement practice of the Requirements concerning: - optimization of user's testing of the medication guide of medicinal products for human use, - updating templates for filling out the medication guide and summary of

				product characteristics of medicinal products for human use.
G/TBT/N/KOR/1217	Republic of Korea	**Date of Distribution:** 10 July 2024 **Deadline for Comments:** 8 September 2024	Medicinal products	The proposed amendments to the ”Regulation on Good Manufacturing Practices for Medicinal Products” are as follows: - Enhancement of the procedures for certification of GMP compliance and management system for validity period , etc.
G/TBT/N/KOR/1218	Republic of Korea	**Date of Distribution:** 10 July 2024 **Deadline for Comments:** 8 September 2024	Regulation on the registration of drug substance	The proposed amendments to the ”Regulation on the Registration of Drug Substance” are as follows: A. to clarify the expert in the medicine and pharmacy who reviewed translated documents for registration of drug substance and allow English translation of submitted documents written in other foreign languages. (Article 3 of the draft) B. to simplify the requirement for registration of drug substance by replacing Good Manufacturing Practice (GMP) inspection with submission of a GMP certificate and modify the relevant provisions (Article 4 and 5 of the draft and Annex 2)
G/TBT/N/KOR/1219	Republic of Korea	**Date of Distribution:** 10 July 2024 **Deadline for Comments:** 8 September 2024	Pharmaceuticals	The proposed amendments to the ”Regulation on Safety of Pharmaceuticals, etc.” are as follows: A. Simplification of submission for Good Manufacturing Practice (GMP) conformity assessment (Article 4, 48-bis of the draft, and attached Form 4) B. Simplification of API registration requirement (Article 15, 17 of the draft, attached Form 16 and 17) C. Improvement of verification • inspection for extension of GMP certificate validity (Article 48-quarter of the draft)

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