17 October 2022

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 01 to 07 October 2022.

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

Document Symbol	Notifying Member	Relevant Dates	Products Covered	Summary
G/TBT/N/BRA/1094/Add.3	Brazil	**Date of Distribution**: 07 October 2022 **Deadline for Comments**: Not Indicated	New and innovative synthetic and semisynthetic medicines - Addendum	The Draft Normative Instruction number 931, 13 October 2020 - previously notified through G/TBT/N/BRA/1094 - which establishes new codes for the administrative request of market authorization for new and innovative synthetic and semisynthetic medicines, was adopted as Normative Instruction number 184, 28 September 2022.
G/TBT/N/BRA/1095/Add.3	Brazil	**Date of Distribution**: 07 October 2022 **Deadline for Comments**: Not Indicated	Medicines with synthetic and semisynthetic active principles for human use - Addendum	The Draft Resolution number 932, 13 October 2020 - previously notified through G/TBT/N/BRA/1095 - which establishes criteria for the concession of market authorization for medicines with synthetic and semisynthetic active principles for human use categorized as new, innovative, generic, and similar, was adopted as Resolution - RDC number 753, 28 September 2022
G/TBT/N/BRA/1412/Corr.1	Brazil	**Date of Distribution**: 07 October 2022 **Deadline for Comments**:	Industrialized dynamized drugs - Corrigendum	Resolution - RDC number 721, 01 July 2022 The Resolution - RDC number 721, 01 July 2022 - previously notified through G/TBT/N/BRA/1412 - contains provisions on marketing

		Not Indicated		authorization, renewal of marketing authorization, post-marketing authorization changes and notification of industrialized dynamized drugs., was republished
G/TBT/N/KOR/1106	Republic of Korea	**Date of Distribution**: 06 October 2022 **Deadline for Comments**: 04 December 2022	Pharmaceuticals	To organize the matters entrusted by the Act, such as the GMP compliance determination subject, documents for GMP compliance determination application, GMP inspection procedure and GMP training, requirements for designation of training institutions, and designation application document and designation procedure, and matters necessary for its implementation, as the Pharmaceutical Affairs Act was revised (Act No. 18970, Notification Date June 10, 2022, Enforcement Date December 11, 2022), which intends to provide a basis for taking measures such as GMP compliance determination, GMP inspection and cancellation of the determination in case of violation and for implementing training for GMP inspectors.

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, BPS