01 August 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 July 2023.

Relative thereto, we respectfully invite stakeholders to comment on the eight (8) notified draft technical regulations from six (6) WTO Members:

Document Symbol	Notifying Member	Relevant Dates	Products Covered	Summary
G/TBT/N/BOL/22	Plurinational State of Bolivia	**Date of Distribution**: 24 July 2023 **Deadline for Comments**: 21 September 2023	Veterinary products	Establishes the registration and control of product companies veterinarians and their technical managers, regarding the modifications of the registrations, the suspension and cancellation and renewal of the same and the obligations of companies, as well as the registration and control of veterinary products. In addition, establishes the foundations and requirements of the quality management systems of the veterinary products companies (Good Manufacturing Practices GMP, Good GLP Laboratory Practices, GAP Good Storage Practices and requirements biosafety and bioprotection).
G/TBT/N/COL/266	Colombia	**Date of Distribution**: 26 July 2023 **Deadline for Comments**: 23 September 2023	Evidential breathalyzers, breathalyzers or breathalyzers	Taking into account the OIML R126:2021 recommendation, "Evidential Breath Analyzers" (Evidential Breathalyzers), of the Organization International Legal Metrology - OIML, the technical requirements and metrology that measuring instruments called analyzers must comply with of evidential breath, in order to guarantee the quality of the measurements they provide. International standard that was updated in 2021 and

				constitutes the foundation of this metrological technical regulation.
G/TBT/N/GBR/64	United Kingdom	**Date of Distribution**: 26 July 2023 **Deadline for Comments**: 26 September 2023	Medical devices	The amendments seek to introduce clearer, risk proportionate Post-market Surveillance (PMS) requirements. This will help to improve the ability of both the manufacturer and the MHRA to identify issues with Medical Devices placed onto the Great Britain market and where necessary, take appropriate action to safeguard public health.
G/TBT/N/JPN/777	Japan	**Date of Distribution**: 26 July 2023 **Deadline for Comments**: Not Applicable	Substances with probable effects on the central nervous system	Proposal for the additional designation of 2 substances as Shitei Yakubutsu, and their proper uses under the Act.
G/TBT/N/JPN/778	Japan	**Date of Distribution**: 26 July 2023 **Deadline for Comments**: 24 August 2023	Pharmaceutical products : recombinant respiratory syncytial virus vaccine	The Minimum Requirements for Biological Products will be amended as follows: The standard for "Recombinant Respiratory Syncytial virus Vaccine" that is to be newly approved will be added. In addition, in regard to the standard for "pH4-Treated Normal Human Immunoglobulin (Subcutaneous injection)", the section of "Test for immunoglobulin G content" and "Test for freedom from aggregated immunoglobulin G" will be partially amended and the section of "Test for pH, Storage and expiry date" will be deleted. The Public Notice on National Release Testing will be amended as follows: The criterion, fee and quantity for "Recombinant Respiratory

				Syncytial virus Vaccine" that is to be newly approved will be added. In addition, the criterion and quantity for "pH4-Treated Normal Human Immunoglobulin (Subcutaneous injection)" will be partially amended.
G/TBT/N/KOR/1156	Republic of Korea	**Date of Distribution**: 24 July 2023 **Deadline for Comments**: 21 September 2023	Pharmaceuticals	A. Expansion of recognition range of DMF submission (Article 15 of the draft, No 16 of form) Data to be submitted on the manufacturing site of the drug substance for DMF are data complying with the drug substance GMP. This amendment is to accept data approved by the Minister of Food and Drug Safety as manufacturing certificate or the data corresponds to the certificate. B. Establishment of regulations, such as procedures and methods for approval of the use of overseas investigational drugs for therapeutic purposes (Article 28-2 of the draft) As the range of investigational drugs for approval of the use for therapeutic purposes has been expanded to include overseas investigational drugs, regulations such as application procedures and dossier were prepared. C. Enactment of regulations for matters other than minor matters that does not require GMP determination of conformance to change (Article 48-3 of the draft) As the subject of minor changes has been very limited and the subject of conformance to Change has been wide, significant changes that may affect the quality of pharmaceuticals were designated as matters other

				than minor and subject to conformance to change. D. Preparation of regulations such as labeling and standards for medicines and quasidrugs for the visually/hearing-impaired (Article 71-2, 75-2, and 75-3 of the draft) As displaying braille and audio/sign language conversion codes on medicines and quasidrugs prescribed by the Minister of Food and Drug Safety for the visually/hearing impaired has been mandatory requirements, relevant indication methods and standards were established and regulation such as compliance on-site inspection and evaluation contents and methods were prepared. E. Establishment of regulations such as methods and procedures for online monitoring of illegal medicine sales (Article 71-3 of the draft) As the legal basis for entrusting online monitoring of illegal medicine sales has been established, regulations such as monitoring methods and procedures were prepared.
G/TBT/N/KOR/1159	Republic of Korea	**Date of Distribution**: 27 July 2023 **Deadline for Comments**: 04 September 2023	Pharmaceuticals	Pharmaceutical Affairs Act' was revised (Act No. 19359, promulgated on Apr 18, 2023, enforced on Oct 19, 2023) with the matter concerning establishing periodic monitoring system for illegal sale, advertisement of pharmaceuticals online and requesting the provider to take a measure on the violation. The revision aims to compensate the inadequacies of the current operating system including preparing the entrust ground for reporting

				production·export·import performance of pharmaceutical, etc. while determining matters entrusted by law and matters necessary for their implementation including prescribing measures to notify consumers of illegal sales advertisement and designating monitoring agency and organization.
G/TBT/N/RUS/147	Russian Federation	**Date of Distribution**: 28 July 2023 **Deadline for Comments**: 17 August 2023	Medicinal products	The draft amendments to the Nomenclature of dosage forms updates the names of dosage forms and their definitions, taking into account the experience of regulation enforcement and their unification in accordance with the Pharmacopoeia of the Eurasian Economic Union.

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