10 July 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 24 to 30 June 2023.

Relative thereto, we respectfully invite stakeholders to comment on the seven (7) notified draft technical regulations from Uganda, China, Republic of Korea, and Philippines:

Document Symbol	Notifying Member	Relevant Dates	Products Covered	Summary
G/TBT/N/UGA/1801	Uganda	**Date of Distribution**: 28 June 2023 **Deadline for Comments**: 26 August 2023	Disposable bouffant cap	This Draft Uganda Standard specifies requirements, sampling and test methods for disposable bouffant caps also known as disposable hairnets, medical head caps, head covers and mobcaps.
G/TBT/N/CHN/1727	China	**Date of Distribution**: 26 June 2023 **Deadline for Comments**: 24 August 2023	Protective face mask for medical use	This document specifies the requirements, test methods, labels, instructions for use, packaging, transportation and storage of protective face mask for medical use (hereinafter referred to as mask). This document applies to non-powered filtering mask (half mask) used in medical environment to filter airborne particles, and provide barrier to droplets, blood, body fluids, secreta, etc. This document does not apply to masks used for protection against any chemical gases and vapours.
G/TBT/N/CHN/1728	China	**Date of Distribution**: 26 June 2023 **Deadline for Comments**: Not Indicated	Disposable protective clothing for medical use	This document specifies the requirements, test methods, marking, instructions for use, packaging and storage of disposable protective clothing for medical use. This document applies to disposable protective clothing for medical use (hereinafter

				referred to as protective clothing) worn by medical personnel that have potential exposure risks when they may have contact with infectious patients' blood, body fluids, secreta, airborne particulate matter, etc. while performing medical operations, infectious diseases prevention and control.
G/TBT/N/CHN/1733	China	**Date of Distribution**: 26 June 2023 **Deadline for Comments**: 24 August 2023	Medical devices	The document is to strengthen the quality management of medical device business, standardize the management behavior of medical device distribution, and ensure the safety and effectiveness of medical devices.
G/TBT/N/KOR/1150	Republic of Korea	**Date of Distribution**: 26 June 2023 **Deadline for Comments**: 24 August 2023	Biological Products	The proposed amendment to the Regulations on Approval and Review of Biological Products, including the following : 1) addition of new definition for drugs using microbiome 2) establishment of quality review requirements for the application of the QbD (Quality by Design) system 3) addition of mandatory submission of RMP (Risk Management Plan) for selfadministered injection recognized by the Minister of MFDS 4) establishment of assessment criteria for RNA and DNA vaccines
G/TBT/N/KOR/1152	Republic of Korea	**Date of Distribution**: 28 June 2023 **Deadline for Comments**: 26 August 2023	Orphan drug samples	To improve and complement the shortcomings of the current operating system including improvement of mandatory retention of orphan drug samples imported in small quantities and extension of period of validity of import permit for endangered wild fauna and

				flora in accordance with the Convention on International Trade in Endangered Species of Wild Fauna and Flora.
G/TBT/N/PHL/303	Philippines	**Date of Distribution**: 28 June 2023 **Deadline for Comments**: 7 July 2023	Leaflet of registered drug products	The proposed policy aims to provide guidelines to all Marketing Authorization Holders (MAHs) of drug products on the publishing of the package insert and patient information leaflet of registered drug products. This Circular shall also provide the healthcare professionals and consumers with the latest information on drug safety and use, through PI and PIL publication on the FDA Verification Portal System.

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