

04 June 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](http://www.epingalert.org)) from 25 to 31 May 2024.

Relative thereto, we respectfully invite stakeholders to comment on the notified draft technical regulations from Australia, Philippines, Ecuador and Egypt:

Document Symbol	Notifying Member	Relevant Dates	Products Covered	Summary
<a href="#">G/TBT/NA/US/169</a>	Australia	<b>Date of Distribution:</b> 31 May 2024  <b>Deadline for Comments:</b> 30 July 2024	Therapeutic goods	The Therapeutic Goods Administration (TGA) is Australia's regulatory authority for therapeutic goods. There are provisions under the Therapeutic Goods Act 1989 to establish quality standards for therapeutic goods. These standards, known as Therapeutic Goods Orders (TGOs), can specify particular labelling, packaging or other requirements.
<a href="#">G/TBT/N/PHL/333</a>	Philippines	<b>Date of Distribution:</b> 31 May 2024  <b>Deadline for Comments:</b> 15 June 2024	Clinical trials	These guidelines shall apply to Sponsors, Clinical Research Organizations (CROs), Investigators, and Research Ethics Committees (RECs), and other stakeholders involved in the approval, conduct, monitoring and inspection, in all phases of clinical trials for Investigational Pharmaceutical Products to ensure that the rights, safety, and well-being of study subjects have been protected, to ensure integrity of the scientific data collected and to assess adherence to the International Council on Harmonization of Good Clinical Practices (ICH-GCP) Principles.
<a href="#">G/TBT/NE/CU/527</a>	Ecuador	<b>Date of Distribution:</b> 30 May 2024  <b>Deadline for Comments:</b> 29 July 2024	Medications in general and biological medications	Partial Reform to Resolution No. ARCSA-DE-005-2018-JCGO Guidelines for issuance of the Certificate of Exclusivity of medicines in general and biological medicines.
<a href="#">G/TBT/NE/GY/3/Add.79</a>	Egypt	<b>Date of Distribution:</b> 30 May 2024  <b>Deadline for Comments:</b> Not indicated	Dentistry : operator's stool - Addendum	It should be noted that Ministerial Decree No. 423/2005 (25 pages, in Arabic) which was formerly notified in G/TBT/N/EGY/3 dated 14 December 2005 mandated among others the earlier version of this Standard and the draft of this standard was formerly notified in

### BUREAU OF PHILIPPINE STANDARDS

#### 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)

				G/TBT/N/EGY/3/Add.67 dated 11 March 2024. Worth mentioning is that standard is technically identical with ISO 7493/2006 (confirmed 2020). Producers and importers are kept informed of any amendments in the Egyptian standards through the publication of administrative orders in the official gazette.
<a href="#">G/TBT/N/EGY/3/Add.75</a>	Egypt	<b>Date of Distribution:</b> 29 May 2024  <b>Deadline for Comments:</b> Not indicated	Dentistry, stationary dental units and dental patient chairs : general requirements - Addendum	This addendum concerns the notification of the Ministerial Decree No.141/2024 (2 pages, in Arabic) that gives the producers and importers a six-month transitional period to abide by the Egyptian Standard ES 4761-1 for " dentistry - stationary dental units and dental patient chairs- part: 1 - general requirements "; (26 page(s), in Arabic) It should be noted that Ministerial Decree No. 423/2005 (25 pages, in Arabic) which was formerly notified in G/TBT/N/EGY/3 dated 14 December 2005 mandated among others the earlier version of this standard and the draft of this standard was formerly notified in G/TBT/N/EGY/3/Add.72 dated 4 April 2024.
<a href="#">G/TBT/N/EGY/3/Add.76</a>	Egypt	<b>Date of Distribution:</b> 29 May 2024  <b>Deadline for Comments:</b> Not indicated	Dentistry, stationary dental units and dental patient chairs : air, water, suction and wastewater systems - Addendum	This addendum concerns the notification of the Ministerial Decree No.141/2024 (2 pages, in Arabic) that gives the producers and importers a six-month transitional period to abide by the Egyptian Standard ES 4761-2 for " dentistry - stationary dental units and dental patient chairs- part: 2 - air, water, suction and wastewater systems "(41 page(s), in Arabic)

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](mailto:BPS@dti.gov.ph) copy [bps.smd@dti.gov.ph](mailto:bps.smd@dti.gov.ph).

Thank you.

Sincerely,

**NEIL P. CATAJAY**  
Director