

10 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](http://www.epingalert.org)) from 24 to 30 September 2022.

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

Document Symbol	Notifying Member	Relevant Dates	Products Covered	Summary
<a href="#">G/TBT/N/BRA/928/Add.2</a>	Brazil	<b>Date of Distribution:</b> 26 September 2022  <b>Deadline for Comments:</b> Not Indicated	Medical devices - Addendum	The Draft resolution number 730, 14 October 2019 - previously notified through G/TBT/N/BRA/928 - which proposes the updating of the Resolution – RDC number 185, 22 October 2001, which establishes the risk classification, market authorization and technical requirements for labelling and usage instructions of medical devices, was adopted as Resolution - RDC number 751, 15 September 2022
<a href="#">G/TBT/N/BRA/1449</a>	Brazil	<b>Date of Distribution:</b> 26 September 2022  <b>Deadline for Comments:</b> 12 October 2022	New drugs for the treatment, diagnosis or prevention of rare diseases	This Draft Resolution proposes to establish a special procedure for the approval of clinical trials, certification of good manufacturing practices, and market authorization of new drugs for the treatment, diagnosis or prevention of rare diseases

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

#### 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)