

06 November 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 19 to 25 October 2024.

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

Document Symbol	Notifying Member	Relevant Dates	Products Covered	Summary
<a href="#">G/TBT/N/BRA/1326/Add.1</a>	Brazil	<b>Date of Distribution:</b> 22 October 2024  <b>Deadline for Comments:</b> Not indicated	Seasonal influenza vaccines - Addendum	Resolution 616, 09 March 2022 - previously notified through G/TBT/N/BRA/1326 - which contains provisions on the composition of seasonal influenza vaccines to be used in Brazil, was changed by Resolution 933, 17 October 2024. The final text is available only in Portuguese and can be downloaded at: <a href="https://antigo.anvisa.gov.br/documents/10181/6892378/RDC_933_2024_.pdf/b71d8078-c680-45dd-8da9-ad8b00b5e0ad">https://antigo.anvisa.gov.br/documents/10181/6892378/RDC_933_2024_.pdf/b71d8078-c680-45dd-8da9-ad8b00b5e0ad</a>
<a href="#">G/TBT/N/BRA/1455/Add.2</a>	Brazil	<b>Date of Distribution:</b> 22 October 2024  <b>Deadline for Comments:</b> Not indicated	Influenza vaccines - Addendum	Normative Instruction 261, 25 October 2023 - previously notified through G/TBT/N/BRA/1455/Add.1 - which contains provisions on the composition of influenza vaccines to be used in Brazil in the year 2023, was revoked by Normative Instruction 330, 17 October 2024. The final text is available only in Portuguese and can be downloaded at: <a href="https://antigo.anvisa.gov.br/documents/10181/6892378/IN_330_2024_.pdf/987c2185-444d-415c-93f2-301dad0a5081">https://antigo.anvisa.gov.br/documents/10181/6892378/IN_330_2024_.pdf/987c2185-444d-415c-93f2-301dad0a5081</a>
<a href="#">G/TBT/N/BRA/1572</a>	Brazil	<b>Date of Distribution:</b> 22 October 2024  <b>Deadline for Comments:</b> 23 December 2024	Medicaments	This Draft Resolution contains provisions on post-market-registration changes and cancellation of registration of medicines with synthetic and semi-synthetic active ingredients and establishes rules for the preparation, harmonization, updating, publication and availability of medication leaflets for patients and healthcare professionals.
<a href="#">G/TBT/N/ISR/1359</a>	Israel	<b>Date of Distribution:</b> 22 October 2024  <b>Deadline for Comments:</b> 21 December 2024	Elastic properties of flat, non-adhesive, extensible fabric bandages	Revision of the Mandatory Standards SI X 1147, SI 1147 part 1, SI 1147 part 2 and SI 1147 part 3, dealing with bandages, to be replaced with SI 1147. This proposed standard adopts the British Standard BS 7505:1995, including its incorporating Corrigenda 1 and 2. This new standard differs significantly from the previous standards.
<a href="#">G/TBT/N/UKR/309</a>	Ukraine	<b>Date of Distribution:</b> 22 October 2024	Medicines	The draft Order of the Ministry of Health of Ukraine "On Approval of Amendments to the Procedure for Confirmation of Compliance of Manufacturing Conditions of Medicines with

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- World Trade Organization (WTO) Technical Barriers to Trade (TBT)
  - National Enquiry Point (NEP)
  - National Notification Authority (NNA)

		<b>Deadline for Comments:</b> 21 December 2024		the Requirements of Good Manufacturing Practice" has been developed pursuant to Article 9-1 "Peculiarities of state registration of medicines that may be procured by a person authorised to conduct procurement in the healthcare sector" of the Law of Ukraine "On Medicines", as well as to confirm compliance of manufacturing conditions with the requirements of good manufacturing practice for those medicines procured by a person authorized to conduct procurement in the healthcare sector.
<a href="#">G/TBT/N/UKR/310</a>	Ukraine	<b>Date of Distribution:</b> 22 October 2024  <b>Deadline for Comments:</b> 21 December 2024	Medicines	The draft Resolution of the Cabinet of Ministers of Ukraine "On Amendments to Clause 6 of the Procedure for State Quality Control of Medicines Imported into Ukraine" has been developed to deregulate the process of state control of radioactive and radiopharmaceutical medicines imported into Ukraine, as well as and to facilitate open electronic interaction between executive authorities and business entities.

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

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