28 October 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) from 28 September to 04 October 2024.

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

Document Symbol	Notifying Member	Relevant Dates	Products Covered	Summary
G/TBT/N/UKR/285/Add.1	Ukraine	**Date of Distribution:** 4 October 2024 **Deadline for Comments:** Not indicated	Medicinal products- Addendum	Ukraine notifies the adoption of the Resolution of the Cabinet of Ministers of Ukraine No. 1121 "Some Issues of Safety and Verification of Medicinal Products" of 26 September 2024.The Resolution was published and entered into force on 03 October 2024.The Resolution also stipulates that Clauses 2, 5-8, 11, 12, 14-18
G/TBT/N/BRA/588/Add.3	Brazil	**Date of Distribution:** 1 October 2024 **Deadline for Comments:** Not indicated	Dental bleaching agents - Addendum	Resolution 6, 6 February 2015 - previously notified through G/TBT/N/BRA/588/Add.1 - which establishes criteria for packing and labelling of dental bleaching agents which are classified as medical devices, was revoked by Resolution 923, 19 September 2024. The final text is available only in Portuguese and can be downloaded at: https://antigo.anvisa.gov.br/documents/10181/6873945/RDC_923_2024_.pdf/92661e08-9622-4698-865e-e617a1c4363d
G/TBT/N/BRA/590/Add.2	Brazil	**Date of Distribution:** 1 October 2024 **Deadline for Comments:** Not indicated	In vitro diagnosis products - Addendum	Normative Instruction 3, 26 August 2015 - previously notified through G/TBT/N/BRA/590/Add.1 - which contains provisions on in vitro diagnosis products, was revoked by Normative Instruction 320, 19 September 2024.The final text is available only in Portuguese and can be downloaded at: https://antigo.anvisa.gov.br/documents/10181/6873945/IN_320_2024_.pdf/96dfb8b3-c781-4da3-b7d1-c3c2070e05f7
G/TBT/N/BRA/601/Add.3	Brazil	**Date of Distribution:** 1 October 2024 **Deadline for Comments:** Not indicated	Clinical trials with medical devices - Addendum	Draft Resolution 282, 09 December 2016 - previously notified through G/TBT/N/BRA/601/Add.2 - which contains provisions on inspection procedures for Good Clinical Practices on clinical trials of medical devices, was changed by Normative Instruction 321, 19 September 2024.The final text is available only in Portuguese and can be downloaded at: https://antigo.anvisa.gov.br/documents/10181/6873945/IN_321_2024_.pdf/3c702103-f01e-4d1a-82c5-ee2ed18e1ae4
G/TBT/N/BRA/607/	Brazil	**Date of Distribution:**	Labelling of medical	Resolution RDC nº 37, 26 August 2015 - previously notified through

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)

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Add.2		1 October 2024 **Deadline for Comments:** Not indicated	devices containing natural rubber latex - Addendum	G/TBT/N/BRA/607/Add.1 - which contains provisions on Labelling of Medical Devices Containing Natural Rubber Latex, was revoked by Resolution 924, 19 September 2024.The final text is available only in Portuguese and can be downloaded at: https://antigo.anvisa.gov.br/documents/10181/6873945/RDC_924_2024_.pdf/a39a49e9-faa5-47bb-8e42-16ad0bf46ff5
G/TBT/N/BRA/680/Add.2	Brazil	**Date of Distribution:** 1 October 2024 **Deadline for Comments:** Not indicated	Mercury thermometers and sphygmomanometers - Addendum	Resolution RDC nº 145, 21 March 2017 - previously notified through G/TBT/N/BRA/680/Add.1 - which prohibits throughout the national territory the manufacture, import and commercialization, as well as the use in health services, of thermometers and sphygmomanometers with a mercury column, was revoked by Resolution 922, 19 September 2024. The final text is available only in Portuguese and can be downloaded at: https://antigo.anvisa.gov.br/documents/10181/6873945/RDC_922_2024_.pdf/1e09cbf1-53db-4609-bea7-34afb7ce633c
G/TBT/N/BRA/758/Add.1	Brazil	**Date of Distribution:** 1 October 2024 **Deadline for Comments:** Not indicated	Hyperimmune Serum - Addendum	Resolution - RDC n. 187, November 8th, 2017 - previously notified through G/TBT/N/BRA/758 - which establishes the minimum requirements for the registration of Hyperimmune Serum in order to guarantee the quality, safety and efficacy of these products, was revoked by Resolution 914, 19 September 2024. The final text is available only in Portuguese and can be downloaded at: https://antigo.anvisa.gov.br/documents/10181/6873824/RDC_914_2024_.pdf/754dff2a-fbe5-4a89-81ad-476ea4b77ac3
G/TBT/N/BRA/770/Add.1	Brazil	**Date of Distribution:** 1 October 2024 **Deadline for Comments:** Not indicated	Industrialized allergen products - Addendum	Resolution - RDC n. 194, December 12th, 2017 - previously notified through G/TBT/N/BRA/770 - which provides for registration and post-registration changes of Industrialized Allergen Products, and makes other arrangements, was revoked by Resolution 915, 19 September 2024. The final text is available only in Portuguese and can be downloaded at: https://antigo.anvisa.gov.br/documents/10181/6873824/RDC_915_2024_.pdf/cdf5f193-5363-44d3-9af2-036e702cda53
G/TBT/N/BRA/842/Add.4	Brazil	**Date of Distribution:** 1 October 2024 **Deadline for Comments:** Not indicated	Medical devices - Addendum	Resolution 562, 1 September 2021 - previously notified through G/TBT/N/BRA/842/Add.2 - which disposes about requirements for manufacturing, trading, importing and exposure to the use of personalized medical devices, was revoked by Resolution 925, 19 September 2024. The final text is available only in Portuguese and can be downloaded at: https://antigo.anvisa.gov.br/documents/10181/6873945/RDC_925_2024_.pdf/19cc7d9c-f316-4666-9751-3649a98c65aa
G/TBT/N/BRA/885/Add.2	Brazil	**Date of Distribution:** 1 October	Medicines - Addendum	Resolution 317, 22 October 2019 - previously notified through G/TBT/N/BRA/885/Add.1 - which establishes criteria and deadlines for

		2024 **Deadline for Comments:** Not indicated		market authorization and notification of medicines; and provides other measures, was revoked by Resolution 912, 19 September 2024The final text is available only in Portuguese and can be downloaded at: https://antigo.anvisa.gov.br/documents/10181/6873824/RDC_912_2024_.pdf/6c82f302-9728-4f0e-9b39-bbdfb0bc5870
G/TBT/N/BRA/901/Add.2	Brazil	**Date of Distribution:** 1 October 2024 **Deadline for Comments:** Not indicated	Biological products - Addendum	Resolution 413, 20 August 2020 - previously notified through G/TBT/N/BRA/901/Add.1 - which which establishes post-market authorization alterations of biological products, was revoked by Resolution 913, 19 September 2024.The final text is available only in Portuguese and can be downloaded at: https://antigo.anvisa.gov.br/documents/10181/6873824/RDC_913_2024_.pdf/87bb2933-7638-4ef3-951a-5f4f596bedb8
G/TBT/N/BRA/1324/Add.2	Brazil	**Date of Distribution:** 1 October 2024 **Deadline for Comments:** Not indicated	Medicaments and medicines - Addendum	Resolution – RDC number 620, 09 March 2022 - previously notified through G/TBT/N/BRA/1324 - which contains provisions on the Certification of Good Practices for conducting Bioavailability/Bioequivalence studies of medicaments and defines which Bioavailability/Bioequivalence studies of medicines must be carried out in certified research centers, was revoked by Resolution 926, 20 September 2024. The final text is available only in Portuguese and can be downloaded at: https://antigo.anvisa.gov.br/documents/10181/6874029/RDC_926_2024_.pdf/448b8051-83fd-4b61-a18a-2351d5db9e36
G/TBT/N/BRA/1376/Add.2	Brazil	**Date of Distribution:** 1 October 2024 **Deadline for Comments:** Not indicated	Pharmaceutical equivalence centers - Addendum	Resolution – RDC number 621, 09 March 2022 - previously notified through G/TBT/N/BRA/1376- which contains provisions on petitions for license requests, license renewals, post-qualification modifications, testing outsourcing, suspensions and cancellations of Pharmaceutical Equivalence Centers, was revoked by Resolution 927, 20 September 2024. The final text is available only in Portuguese and can be downloaded at: https://antigo.anvisa.gov.br/documents/10181/6874029/RDC_927_2024_.pdf/63167a0c-94c3-48ea-b226-035dbad5b698
G/TBT/N/BRA/1417/Add.2	Brazil	**Date of Distribution:** 1 October 2024 **Deadline for Comments:** Not indicated	Veterinary drugs - Residues - Addendum	Normative Instruction number 162, 01 July 2022 - previously notified through G/TBT/N/BRA/1417 - which establishes the acceptable daily intake (ADI), the acute reference dose (DRfA) and maximum residue limits (MRL) for active pharmaceuticals ingredients (API) of veterinary drugs in foods of animal origin, was changed by Normative Instruction 317, 19 September 2024. The final text is available only in Portuguese and can be downloaded at: https://antigo.anvisa.gov.br/documents/10181/6870061/IN_317_2024_.pdf/b92930b4-679d-47af-a479-e181977c94dc

G/TBT/N/BRA/1547/Add.1	Brazil	**Date of Distribution:** 1 October 2024 **Deadline for Comments:** Not indicated	Vaccines - Addendum	Draft resolution 1263, 13 June 2024 - previously notified through G/TBT/N/BRA/1547 - which proposes a Normative Instruction that updates the composition of Covid-19 vaccines to be used in Brazil, was adopted as Normative Instruction 316, 18 September 2024. The final text is available only in Portuguese and can be downloaded at: https://antigo.anvisa.gov.br/documents/10181/6770142/IN_316_2024_.pdf/a184142f-4c75-4f3c-b520-5b0e0d510832
G/TBT/N/BRA/1549/Add.1	Brazil	**Date of Distribution:** 1 October 2024 **Deadline for Comments:** Not indicated	Vaccines - Addendum	Draft Resolution 1262, 13 June 2024 - previously notified through G/TBT/N/BRA/1549 - which contains provisions on criteria for updating the composition of COVID-19 vaccines to be used in Brazil, was adopted as Resolution 905, 18 September 2024. The final text is available only in Portuguese and can be downloaded at: https://antigo.anvisa.gov.br/documents/10181/6770142/RDC_905_2024_.pdf/83622cba-e755-4e32-baee-5ab9e8696b1d
G/TBT/N/UKR/285/Add.1	Ukraine	**Date of Distribution:** 4 October 2024 **Deadline for Comments:** Not indicated	Medicinal products- Addendum	Ukraine notifies the adoption of the Resolution of the Cabinet of Ministers of Ukraine No. 1121 "Some Issues of Safety and Verification of Medicinal Products" of 26 September 2024.The Resolution was published and entered into force on 03 October 2024.The Resolution also stipulates that Clauses 2, 5-8, 11, 12, 14-18 of the Regulation on the National System of Verification of Medicinal Products shall be applied by state authorities and business entities from 03 October 20024; other clauses
G/TBT/N/BRA/588/Add.3	Brazil	**Date of Distribution:** 1 October 2024 **Deadline for Comments:** Not indicated	Dental bleaching agents - Addendum	Resolution 6, 6 February 2015 - previously notified through G/TBT/N/BRA/588/Add.1 - which establishes criteria for packing and labelling of dental bleaching agents which are classified as medical devices, was revoked by Resolution 923, 19 September 2024. The final text is available only in Portuguese and can be downloaded at: https://antigo.anvisa.gov.br/documents/10181/6873945/RDC_923_2024_.pdf/92661e08-9622-4698-865e-e617a1c4363d
G/TBT/N/BRA/590/Add.2	Brazil	**Date of Distribution:** 1 October 2024 **Deadline for Comments:** Not indicated	In vitro diagnosis products - Addendum	Normative Instruction 3, 26 August 2015 - previously notified through G/TBT/N/BRA/590/Add.1 - which contains provisions on in vitro diagnosis products, was revoked by Normative Instruction 320, 19 September 2024.The final text is available only in Portuguese and can be downloaded at: https://antigo.anvisa.gov.br/documents/10181/6873945/IN_320_2024_.pdf/96dfb8b3-c781-4da3-b7d1-c3c2070e05f7
G/TBT/N/BRA/601/Add.3	Brazil	**Date of Distribution:** 1 October 2024 **Deadline for**	Clinical trials with medical devices - Addendum	Draft Resolution 282, 09 December 2016 - previously notified through G/TBT/N/BRA/601/Add.2 - which contains provisions on inspection procedures for Good Clinical Practices on clinical trials of medical devices, was changed by Normative

		Comments: Not indicated		Instruction 321, 19 September 2024.The final text is available only in Portuguese and can be downloaded at: https://antigo.anvisa.gov.br/documents/10181/6873945/IN_321_2024_.pdf/3c702103-f01e-4d1a-82c5-ee2ed18e1ae4
G/TBT/N/BRA/607/Add.2	Brazil	**Date of Distribution:** 1 October 2024 **Deadline for Comments:** Not indicated	Labelling of medical devices containing natural rubber latex - Addendum	Resolution RDC nº 37, 26 August 2015 - previously notified through G/TBT/N/BRA/607/Add.1 - which contains provisions on Labelling of Medical Devices Containing Natural Rubber Latex, was revoked by Resolution 924, 19 September 2024.The final text is available only in Portuguese and can be downloaded at: https://antigo.anvisa.gov.br/documents/10181/6873945/RDC_924_2024_.pdf/a39a49e9-faa5-47bb-8e42-16ad0bf46ff5

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,

NEIL P. CATAJAY
Director