

(24 - 4584)

20 June 2024

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Committee on Technical Barriers to Trade

Original: English

NOTIFICATION

The following notification is being circulated in accordance with Article 10.6

1. Notifying Member: <u>BRAZIL</u>

If applicable, name of local government involved (Article 3.2 and 7.2):

2. Agency responsible:

Brazilian Health Regulatory Agency (ANVISA)

Name and address (including telephone and fax numbers, email and website addresses, if available) of agency or authority designated to handle comments regarding the notification shall be indicated if different from above:

National Institute of Metrology, Quality and Technology (INMETRO) Telephone: +(55) 21 2145.3817 Telefax: +(55) 21 2563.5637 Email: <u>barreirastecnicas@inmetro.gov.br</u> Website: <u>www.inmetro.gov.br/barreirastecnicas</u>

- 3. Notified under Article 2.9.2 [X], 2.10.1 [], 5.6.2 [], 5.7.1 [], 3.2 [], 7.2 [], other:
- 4. Products covered (HS or CCCN where applicable, otherwise national tariff heading. ICS numbers may be provided in addition, where applicable): Health care technology (ICS code(s): 11)
- 5. Title, number of pages and language(s) of the notified document: Draft resolution 1263, 13 June 2024; (3 page(s), in Portuguese)
- **6. Description of content:** This draft resolution proposes a Normative Instruction that updates the composition of Covid-19 vaccines to be used in Brazil.
- 7. Objective and rationale, including the nature of urgent problems where applicable: This draft resolution seeks to maintain convergence with international standards.; Protection of human health or safety
- 8. Relevant documents:
- 9. Proposed date of adoption: To be determinedProposed date of entry into force: To be determined
- **10.** Final date for comments: 5 August 2024

11. Texts available from: National enquiry point [] or address, telephone and fax numbers and email and website addresses, if available, of other body:

Brazilian Health Regulatory Agency (Anvisa) SIA, Trecho 5, Área Especial 57 Brasília – DF / Brazil CEP: 71.205-050 Phone.: +(55) 61 3462.5402 Website: <u>www.anvisa.gov.br</u> Comment form: <u>https://pesquisa.anvisa.gov.br/index.php/872676?lang=pt-BR</u>

The final text is available only in Portuguese and can be downloaded at: $\frac{https://antigo.anvisa.gov.br/documents/10181/6770142/CONSULTA+PUBLICA+N\%C2}{\%BA+1263+GGBIO.pdf/ab070b32-d4d7-43bc-b542-2c0e6886041c}$

https://members.wto.org/crnattachments/2024/TBT/BRA/24_03843_00_x.pdf