WORLD TRADE ORGANIZATION

G/TBT/N/BRA/1468

5 January 2023

(23-0138)

Page: 1/2

Committee on Technical Barriers to Trade

Original: English

NOTIFICATION

The following notification is being circulated in accordance with Article 10.6

1.	**Notifying Member:** BRAZIL **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: barreirastecnicas@inmetro.gov.br Web-site: www.inmetro.gov.br/barreirastecnicas
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):** Pharmaceutics (ICS code(s): 11.120)
5.	**Title, number of pages and language(s) of the notified document:** Draft resolution number 1135, 23 December 2022; (6 page(s), in Portuguese)
6.	**Description of content:** This Draft Resolution is regarded to a regulatory proposal for the establishment of specific criteria and procedures for defining the Equivalent Foreign Regulatory Authorities of the sanitary inspection process of manufacturers of active pharmaceutical ingredients, Cannabis products for medicinal purposes, medicines and biological products. And the optimized Good Manufacturing Practices (GMP) Certification review process. The Regulatory Trust Building Program for the recognition of the equivalence of the health inspection processes of an AREE is applicable exclusively to regulatory authorities or member entities of the Pharmaceutical Inspection Co-operation Scheme (PIC/S) and the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH).
7.	**Objective and rationale, including the nature of urgent problems where applicable:** Establishing specific normative acts that define the Equivalent Foreign Regulatory Authorities (AREE) and the conditions for admitting analyzes carried out by these AREE in an optimized procedure, according to each type of health surveillance process or product category.; Protection of human health or safety
8.	**Relevant documents:** -

9.	**Proposed date of adoption:** To be determined **Proposed date of entry into force:** To be determined
10.	**Final date for comments:** 6 March 2023
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: www.anvisa.gov.br The final text is available only in Portuguese and can be downloaded at: Draft: http://antigo.anvisa.gov.br/documents/10181/6531690/CONSULTA+P%C3%9ABLICA+N+1135+GIMED.pdf/b683dddc-9016-4adc-978f-a8d557b95347 Comment form: https://pesquisa.anvisa.gov.br/index.php/575119?lang=pt-BR