WORLD TRADE ORGANIZATION

G/TBT/N/BRA/1467

5 January 2023

(23-0139)

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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:** 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):** Medicaments (ICS code(s): 11.120.10)
5.	**Title, number of pages and language(s) of the notified document:** Draft resolution number 1136, 26 December 2022; (7 page(s), in Portuguese)
6.	**Description of content:** This Draft Resolution is regarded to a proposal to define the general guidelines for the pilot implementation of the optimized analysis procedure, based on risk criteria, to confirm the suitability of the documentation submitted to Anvisa for marketing authorization and post-marketing authorization changes to medicines.
7.	**Objective and rationale, including the nature of urgent problems where applicable:** Need to make the analyzes of marketing authorization and post-marketing authorization requests made by the Agency more adequate to its purpose, which is to guarantee access to products with quality, effectiveness and safety for the population, in such a way that the focus of the technical analyzes and the Agency decisions are based on risk criteria and not merely on the presence or absence of documents and information.; 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/10181/6531732/CONSULTA+P%C3%9ABLICA+N+1136+GGMED.pdf/b3039fc1-23d7-4501-a9b3-bd1658375afc Comment form: https://pesquisa.anvisa.gov.br/index.php/121997?lang=pt-BR