



5 January 2023

(23-0140)

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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: 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 1137, 27 December 2022; (3 page(s), in Portuguese)
6. Description of content: This Draft Resolution contains provisions on rules for preparing, harmonizing, updating, publishing and making available drug inserts for patients and health professionals.
7. Objective and rationale, including the nature of urgent problems where applicable: Mitigating indirect impediment of generic/similar drugs on the market, when including indications for second use under patent protection.; 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/10181/6531822/CONSULTA+P%C3%9ABLICA+N+1137+GGMED.pdf/e5915d06-046e-4946-8be5-44c87b52f968> Comment form:

<https://pesquisa.anvisa.gov.br/index.php/173432?lang=pt-BR>