



26 September 2022

(22-7202)

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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 (excluding goods of heading 30.02, 30.05 or 30.06) consisting of two or more constituents which have been mixed together for therapeutic or prophylactic uses, not put up in measured doses or in forms or packings for retail sale. (HS code(s): 3003); Medicaments (excluding goods of heading 30.02, 30.05 or 30.06) consisting of mixed or unmixed products for therapeutic or prophylactic uses, put up in measured doses (including those in the form of transdermal administration systems) or in forms or packings for retail sale. (HS code(s): 3004)
5. Title, number of pages and language(s) of the notified document: Draft resolution number 1115, 15 September 2022; (3 page(s), in Portuguese)
6. Description of content: This Draft Resolution proposes to establish a special procedure for the approval of clinical trials, certification of good manufacturing practices, and market authorization of new drugs for the treatment, diagnosis or prevention of rare diseases. The text of this draft resolution was rectified. The rectified text is available only in Portuguese at: https://www.in.gov.br/en/web/dou/-/retificacao-431296155
7. Objective and rationale, including the nature of urgent problems where applicable: Suspending the obligation to hold a pre-submission meeting exclusively for clinical trial consent.; 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: 12 October 2022
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/10181/6491463/%281%29CONSULTA+P%C3%9ABLICA+N+1115+DIRE2.pdf/2fc6a739-1b81-4aa0-a177-1818422101f3 Comment form: https://pesquisa.anvisa.gov.br/index.php/531375?newtest=Y&lang=pt-BR