



5 October 2023

(23-6676)

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: <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): Pharmaceutics in general (ICS code(s): 11.120.01); Medicaments (ICS code(s): 11.120.10)
5. Title, number of pages and language(s) of the notified document: Draft resolution 1206, 02 October 2023; (6 page(s), in Portuguese)
6. Description of content: This Draft Resolution contains provisions on complementary on the registration of biosimilars through the Comparability Development Pathway
7. Objective and rationale, including the nature of urgent problems where applicable: It is a process for reducing requirements, obligations, restrictions, requirements or specifications with the aim of reducing regulatory costs.; 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: 24 November 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:

<https://antigo.anvisa.gov.br/documents/10181/6511806/CONSULTA+PUBLICA+N%C2%BA+1206+GGBIO.pdf/4e02d017-f479-4c52-b4fc-f974eb843125> Comment form:

<https://pesquisa.anvisa.gov.br/index.php/124466?newtest=Y&lang=pt-BR> The comment form only will be available on 11 October 2023

https://members.wto.org/crnattachments/2023/TBT/BRA/23_12818_00_x.pdf