



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 (Articles 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 [], other:
4. Products covered (HS or CCCN where applicable, otherwise national tariff heading. ICS numbers may be provided in addition, where applicable): HS Code(s): 2941; 3003; 3004; 3005; 3006 (pharmaceutical products).
5. Title, number of pages and language(s) of the notified document: Resolution – RDC number 471, 23 February 2021. Language(s): Portuguese. Number of pages: 7.
6. Description of content: This resolution establishes criteria for prescription, exemption, control, packaging, and labelling of medicines based on substances categorized as antimicrobial for use under prescription, isolated or associated. They will be listed in a specific Normative Instruction.
7. Objective and rationale, including the nature of urgent problems where applicable: Protection of human health.
8. Relevant documents: 1) Brazilian Official Gazette 36 on 24 February 2021, section 1, page 85 2) Normative Instruction No. 83, 23 February 2021. https://www.in.gov.br/en/web/dou/-/resolucao-rdc-n-471-de-23-de-fevereiro-de-2021-304923190 http://antigo.anvisa.gov.br/documents/10181/6232328/IN_83_2021_.pdf/74dad76b-30ce-43d3-8c54-c0e2a3403c05
9. Proposed date of adoption: In the date of its publication. Proposed date of entry into force: In the date of its publication.
10. Final date for comments: Not applied.
11. Texts available from: National enquiry point [X] 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

http://antigo.anvisa.gov.br/documents/10181/6232328/RDC_471_2021_.pdf/a678704e-afb3-48bf-a33e-9b69c6270668