



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: Normative Instruction number 83, 23 February 2021. Language(s): Portuguese. Number of pages: 6.
6. Description of content: This normative instruction defines the list of substances categorized as antimicrobial for use under prescription, isolated or associated.
7. Objective and rationale, including the nature of urgent problems where applicable: Protection of human health. Complement the requirements of RDC No. 471 of 23 February 2021.
8. Relevant documents: 1) Brazilian Official Gazette 36 on 24 February 2021, section 1, page 86 2) RDC No. 471, 23 February 2021. https://www.in.gov.br/web/dou/-/instrucao-normativa-in-n-83-de-23-de-fevereiro-de-2021-304918127 http://antigo.anvisa.gov.br/documents/10181/6232328/RDC_471_2021_.pdf/a678704e-afb3-48bf-a33e-9b69c6270668
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:

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http://antigo.anvisa.gov.br/documents/10181/6232328/IN_83_2021_.pdf/74dad76b-30ce-43d3-8c54-c0e2a3403c05