



3 January 2019

(19-0007)

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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: National Institute of Metrology, Quality and Technology (INMETRO) Telephone: +(55) 21 2563.2918 Telefax: +(55) 21 2563.5637 Email: barreirastecnicas@inmetro.gov.br Web-site: www.inmetro.gov.br/barreirastecnicas The comments to this Draft Regulation shall be sent to: http://formsus.datasus.gov.br/site/formulario.php?id_aplicacao=33294 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: Brazilian Health Regulatory Agency (Anvisa)
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): 11.120.10 Medicaments and biological products
5. Title, number of pages and language(s) of the notified document: Resolution - RDC 257, 20 December 2018 (1 page(s), in Portuguese)
6. Description of content: This present Resolution changes RDC 234 of 20 June 2018, regarding the outsourcing of production steps, quality control analysis, transportation and storage of medicaments and biological products, among other measures. Art.30 and art.31 of the RDC 234 (notified under the document G/TBT/N/BRA/700), 20 June 2018 are suspended for two years from the date of publication of this Resolution. The art.33 of RDC 234, 20 June 2018, is now in force with the following text: "Art.33. Article 52 of the RDC 17. April 16 th , 2010, and the RDC 25, March 29 th , 2007, are hereby revoked." This Resolution also changes art. 8, art. 9 and the subsection VIII of art. 10 of the RDC 10, 21 March 2011. This Resolution enter into force on the date of its publication.
7. Objective and rationale, including the nature of urgent problems where applicable: Protection of Human Health

8. Relevant documents: <ul style="list-style-type: none">• Resolution of the Collegiate Board of Directors - RDC 234 of 20 June 2018• Resolutions of the Collegiate Board of Directors - RDC 10, 21 March 2011• Draft Technical Resolution 273, 10 November 2016
9. Proposed date of adoption: On the date of its publication. Proposed date of entry into force: On the date of its publication.
10. Final date for comments: Not applicable
11. Texts available from: National enquiry point [] or address, telephone and fax numbers and email and website addresses, if available, of other body: <p>Agency Responsible 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://portal.anvisa.gov.br/documents/10181/5194604/RDC_257_2018_.pdf/dc743d7a-98dd-44ba-b683-ae2c593c31d2</p>