



15 April 2015

(15-2031)

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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: Anvisa – Brazilian Health Surveillance Agency 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 2563.2840 Telefax: +(55) 21 2563.5637 Email: barreirastecnicas@inmetro.gov.br Website: http://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=19987
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): Over-the-counter (OTC) drugs
5. Title, number of pages and language(s) of the notified document: Draft Technical Resolution n° 27, 6 April 2015, Regarding the Criteria and the Procedures to Define Medicines as Over-the-Counter (OTC) Drugs (7 pages, in Portuguese)
6. Description of content: Draft Technical Resolution n° 27, 6 April 2015, regarding the criteria and the procedures to define medicines as over-the-counter (OTC) drugs. This Draft Technical Resolution establishes the criteria to define over-the-counter medicines, and the procedures to request the category evaluation and the adequacy to the regulation. This Resolution revokes the Resolution RDC n° 138/2003.
7. Objective and rationale, including the nature of urgent problems where applicable: Protection of human health or safety
8. Relevant documents: 1) Brazilian Official Journal (Diário Oficial da União), 8 April 2015; Section 1, p. 48; 2) RDC 71/2009, RDC 47/2009; 3) Brazilian Official Journal; 4) Not Stated.
9. Proposed date of adoption: To be determined after the end of the consultation period Proposed date of entry into force: On the date of the publication
10. Final date for comments: 15 June 2015

11. Texts available from: National enquiry point [] or address, telephone and fax numbers and email and website addresses, if available, of other body:

Agency Responsible:

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