



Committee on Technical Barriers to Trade

NOTIFICATION

The following notification is being circulated in accordance with Article 10.6.

1. Notifying Member: BRAZIL 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, e-mail and web-site 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 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=33295
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): Medicines
5. Title, number of pages and language(s) of the notified document: Draft Technical Resolution n. 374, 2 nd August 2017. 40 pages, Portuguese.
6. Description of content: This Draft Resolution provides for claims of use for registration and notification of dynamised drugs. Determine the publication of the "Table of claims of use for registration and notification of dynamised drugs", in the form of the annex of this Normative Instruction and procedures for requests for change, inclusion or exclusion in the Table. The allegations of use in the Annex of this Normative Instruction were defined according the homeopathic, anthroposophical or antihomotoxic literature, since, for these associations, no clinical studies of efficacy were conducted.
7. Objective and rationale, including the nature of urgent problems where applicable: Protection of Human Health
8. Relevant documents: (1) Brazilian Official Journal (Diário Oficial da União) Nº 148, 03 August 2017, section 1, page 112; (2) Law 9.782, 26 January 1999 (Lei nº 9.782, de 26 de janeiro de 1999); (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 its publication.

10. Final date for comments: 8th October, 2017

11. Texts available from: National enquiry point [X] or address, telephone and fax numbers, e-mail and web-site addresses, if available of the other body:

Agency Responsible
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