



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 2563.2765 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=28756
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): Drugs
5. Title, number of pages and language(s) of the notified document: Draft Technical Resolution N° 273, 10 November 2016, regarding the outsourcing of manufacturing stages, analysis of quality control and storage of drugs. (7 pages, Portuguese.)
6. Description of content: Draft Technical Resolution N° 273, 10 November 2016, regarding the outsourcing of manufacturing stages, analysis of quality control and storage of drugs. The outsourcing petitions which were protocoled or accepted until the date of publication of this Resolution remain valid for 12 (twelve) months. This Draft Resolution revokes the Resolution RDC n. 25/2007 and the Resolution RDC n. 26/2013.
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), November 11 2016, Section 1, p. 59; 2) Not stated; 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 publication.

10. Final date for comments: December 19, 2016

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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<http://portal.anvisa.gov.br/documents/10181/3086248/CONSULTA+P%C3%9ABLICA+N+273+DIMON.pdf/5510c588-e531-4363-aff8-15f9a2d89f75>