



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=28757
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. 285, January 16 2017. 1 page, Portuguese.
6. Description of content: This Draft Resolution establishes requirements for post-authorization procedures of notification, identification and qualification of degradation products in medicines established on the technical regulation (RDC) n. 53/2015.
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), January 17 2017, Section 1, p. 37; 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: February 22, 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

Brazilian Health Regulatory Agency (Anvisa)

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<http://portal.anvisa.gov.br/documents/10181/3192254/CONSULTA+PUBLICA+N+285+G+GMED.pdf/6000328d-c47f-4096-9f4b-6a8a7f4fd97e>