



23 March 2015

(15-1625)

Page: 1/2

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 Web-site: 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=19731
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 nº 18, 10 March 2015, Regarding Post-Registration Changes and Cancellation of Drugs Registration (31 pages, in Portuguese)
6. Description of content: Draft Technical Resolution nº 18, 10 March 2015, Regarding Post-Registration Changes and Cancellation of Drugs Registration. This Draft Technical Resolution aims to classify post-approval changes in drugs, to establish the criteria and the minimum required documentation necessary to that, to provide direct responsibilities of companies and to establish the simplified procedure of post-approval changes for immediate implementation, in order to ensure quality, safety and efficacy of drugs. This Resolution revokes Resolution RDC n. 48/2009 and Normative Instruction Nº 11/2009.
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), 11 March 2015, Section 1, p. 78; 2) Law nº 6.437, 20 August 1977; 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: 30 days after the publication
10.	Final date for comments: 16 April 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 Anvisa – Brazilian Health Surveillance Agency SIA, Trecho 5, Área Especial 57 Brasília – DF/Brazil CEP: 71.205-050 Phone.: +(55) 61 3462.5402 Website: http://www.anvisa.gov.br http://portal.anvisa.gov.br/wps/wcm/connect/67248e00479aafc58b5debfe096a5d32/CP+18-2015+-+Minuta.pdf?MOD=AJPERES