



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: Anvisa – Brazilian Health Surveillance Agency 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=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, March 10 th 2015, regarding post-registration changes and cancellation of drugs registration (31 pages, Portuguese).
6. Description of content: Draft Technical Resolution nº 18, March 10 th 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 n. 11/2009.
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), March 11 th 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: April 15 th , 2015.	
11. Texts available from: National enquiry point [] or address, telephone and fax numbers, e-mail and web-site addresses, if available of the 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: www.anvisa.gov.br http://portal.anvisa.gov.br/wps/wcm/connect/67248e00479aafc58b5debfe096a5d32/CP+18-2015+-+Minuta.pdf?MOD=AJPERES	