

WORLD TRADE ORGANIZATION

G/TBT/N/BRA

Committee on Technical Barriers to Trade

Original: English

NOTIFICATION

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

1. Member to Agreement notifying: <u>BRAZIL</u> 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, Standardization and Industrial Quality-INMETRO Telephone: +(55) 21 2563.2821 Telefax: +(55) 21 2502.6542 Email: barreirastecnicas@inmetro.gov.br Web-site: www.inmetro.gov.br/barreirastecnicas
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): Pharmaceutical products.
5. Title, number of pages and language(s) of the notified document: Draft Resolution n° 01, January 7 th 2013 – Granting and renewal of registration of medicines with synthetic and semi-synthetic active ingredients classified as new, generic and similar (22 pages, Portuguese)
6. Description of content: This draft technical regulation establishes criteria and minimum documentation necessary for the granting and renewal of registration of medicines with synthetic and semi-synthetic active ingredients classified as new, similar and generic, in order to ensure the quality, safety and efficacy of these drugs. This draft technical regulation revokes Resolution RDC 136, May 29 th 2003; Resolution RDC 16, March 02 nd 2007 (excepting items 1 and 2, VI, of Annex I); Resolution RDC 17, March 02 nd 2007 (excepting items 1 and 2, VI, of Annex) and articles 1 and 4 of Resolution RDC 210, September 02 nd 2004.
7. Objective and rationale, including the nature of urgent problems where applicable: Protection of Human Health

8.	Relevant documents: Brazilian Official Journal (Diário Oficial da União), January 8 th 2013; Section 1 p. 35 Draft Resolution (Consulta Pública) number 01, January 7 th , 2013, issued by Brazilian Health Regulatory Agency – Anvisa; When adopted, it will be published at the Brazilian Official Journal. Available in Portuguese.
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 adoption.
10.	Final date for comments: April 15 th , 2013
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: National enquiry point Agency responsible Brazilian Health Regulatory Agency – ANVISA SIA, Trecho 5, Área Especial 57 Brasília – DF / Brazil CEP: 71.205-050 Phone.: 55 61 3462-5402 E-mail: rel@anvisa.gov.br Website: www.anvisa.gov.br http://portal.anvisa.gov.br/wps/wcm/connect/9885ae804e1b282fa1f5b3c09d49251b/Consulta+P%C3%ABblica+n%C2%B0+1+GGMED.pdf?MOD=AJPERES