Committee on Technical Barriers to Trade

Original: English

NOTIFICATION

The following notification is being circulated in accordance with Article 10.6

1.	**Notifying Member:** Brazil **If applicable, name of local government involved (Article 3.2 and 7.2):**
2.	**Agency responsible:** Brazilian Health Surveillance Agency - ANVISA **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 Website: 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):** Medicines
5.	**Title, number of pages and language(s) of the notified document:** Draft Resolution nº 44, June 18th 2014, that disposes about the Certification of Good Practices in Bioavailability/Bioequivalence of medicines. (6 pages, in Portuguese)
6.	**Description of content:** Draft Resolution to the revision of the Resolution nº 103/2003 that disposes about the Certification of Good Practices in Bioavailability/Bioequivalence in medicines. This draft resolution establishes the requirements and administrative procedures to be attended to the Certification of Good Practices in Bioavailability/Bioequivalence of medicines and defines the studies of Bioavailability/Bioequivalence of medicines which must be realized in certified research centers. According to this draft resolution, the studies of bioavailability/bioequivalence for purposes of registration and post registration of medicines must be realized in certified research centers. All stages of the study must be realized in research centers which are certified by the Brazilian Health Surveillance Agency – ANVISA. The concession of the certification will depend on the verification of the effective fulfillment of the requirements preconized by the Good Practices of Bioavailability/Bioequivalence of Medicines, through inspection, documented in a report, in the respective research center which is the object of certification, and through a favorable technical opinion issued by ANVISA.

	The certification of Good Practices of Bioavailability/Bioequivalence can be suspended or canceled in cases when it is proved by the competent sanitary authority the non-fulfillment of the requirements preconized by the current regulation of Good Practices of Bioavailability/Bioequivalence. The solicitation of a new certification must be realized through a specific formulary of petition and the documents specified in it, available in the site of ANVISA. The new certification will be valid for 2 (two) years from the expiration of the previous certificate.
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), June 20th 2014; Section 1, p. 87, Draft Resolution (Consulta Pública) number 44, June 18th 2014, issued by Brazilian Health Surveillance 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:** To be determined after the end of the consultation period.
10.	**Final date for comments:** 25 August 2014
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 Brazilian Health Surveillance 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 Websit http://portal.anvisa.gov.br/wps/wcm/connect/b9020500447118068d749f81581d3b02/Consulta+P%C3%BAblica+n+44+COBIO.pdf?MOD=AJPERES