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:** 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
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):** Clinical trials with medicines.
5.	**Title, number of pages and language(s) of the notified document:** Draft Resolution nº 65, August 1st 2014, that disposes about the clinical trials with medicines accomplished in Brazil. (20 pages, in Portuguese)
6.	**Description of content:** This draft technical resolution establishes the procedures and requirements to the accomplishment of clinical trials with medicines in Brazil, including the Dossier of a Medicine Clinical Development, which requires prior consent of ANVISA. This draft resolution is applicable to clinical trials with medicines, which will have all its clinical development, or part of it, in Brazil, in order to the registration by ANVISA. Post-commercialization clinical trials (phase IV) are not subject to this regulation, except for those involving vaccines and those which purpose is to evaluate efficacy and safety, necessary to the registration or revalidation, and which are considered phase III. This draft resolution is also not applicable to bioequivalence and relative bioavailability studies, clinical trials with cosmetics, medical devices, foods, gene therapy and stem cells, which must follow specific regulations. The non-compliance with the terms of this regulation will be considered sanitary infraction, according to Federal Law 6.437/77. This draft resolution revokes the following technical Resolutions: RDC n. 39/2008; RDC n. 36/2012; and items 1 and 1.1 of Section I of Chapter XXVI of RDC 81/2008.
7.	**Objective and rationale, including the nature of urgent problems where applicable:** Protection of human health or safety

8.	**Relevant documents:** Brazilian Official Journal (Diário Oficial da União), August 04th 2014; Section 1, p. 73, Draft Resolution (Consulta Pública) number 65, August 01th 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:** 11 September 2014
11.	**Texts available from: National enquiry point [ ] or address, telephone and fax numbers and email and website addresses, if available, of other body:** 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 Website: www.anvisa.gov.b http://portal.anvisa.gov.br/wps/wcm/connect/b60b380044fb0348bc87bcc5b6e3ae4b/Consulta+P%C3%BAblica+n%C2%B0+65+COPEM+GGMED.pdf?MOD=AJPERES