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:** 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, Quality and Technology (INMETRO) Telephone: +(55) 21 2563.2765 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=33294
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):** 3003 3004: Medicaments
5.	**Title, number of pages and language(s) of the notified document:** RDC Nº 204, December 27th, 2017. 6 pages, Portuguese.
6.	**Description of content:** This Resolution provides for the classification in the priority category, of registration petitions, post registration and prior consent in clinical trial of medicines. The criteria and procedures for framing on the priority category applications for registration, post-registration and prior consent in clinical trial for drugs are approved under the terms of this Resolution. In addition to the criteria established in arts. 3 and 4, Anvisa may classify as priority requests for registration and post-registration of medicines for sale under medical prescription, when the risk of market shortages that have an impact on public health is configured. The classification in the priority category should be made at the moment of the application of the petition regarding registration, post-registration alteration and prior consent in clinical trial. This resolution establishes the criteria for requests for registration of medicines and petitions for prior consent.

	The deadline for final decision regarding the analysis of petitions classified as priority will be: 120 (one hundred and twenty) days for drug registration applications and 60 (sixty) days for post-registration petitions. In order to be able to apply the criteria set forth in this resolution, the priority petition for registration, post-registration and prior consent in clinical trial must present all documentation required by the current resolution and current regulation, under penalty of rejection.
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) Nº. 248, 28 December 2017, section 1, page 88; (2) Law nº 9.782, 26 January 1999; RDC nº 20, de 10 April 2013 (3) Brazilian Official Journal; (4) Not applicable
9.	**Proposed date of adoption:** On the date of its publication. **Proposed date of entry into force:** 60 (sixty) days after the date of its publication. December 12th 2017.
10.	**Final date for comments:** Not applicable
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:** 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 Website: www.anvisa.gov.br http://portal.anvisa.gov.br/documents/10181/2718376/RDC_204_2017_.pdf/b2d4ae64-2d91-44e9-ad67-b883c752c094