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 2563.2840 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=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):** Medicinal products
5.	**Title, number of pages and language(s) of the notified document:** RDC Nº 200, December 26th, 2017. 5 pages, Portuguese.
6.	**Description of content:** The purpose of this Resolution is to establish the criteria and minimum documentation required to grant and renew the registration of medicinal products with synthetic and semi-synthetic active principles, classified as new, generic and similar, in order to guarantee the quality, safety and efficacy of these drugs. This Regulation applies to all medicines with synthetic and semi-synthetic active ingredient, classified as new, generic and similar, with the exception of those governed by specific legislation. Official documents in foreign languages used for registration purposes, issued by foreing health authorities, must be accompanied by a certified translation in accordance with the law. For the purposes of the provisions of these Resolutions, if there are specific legislation or guides, these should be fulfilled and the respective evidence must be presented. For the purpose of renewing the registration of the medicine in Anvisa, all companies must present the documents cited in this Resolution in the first half of the last year of the five-year period of validity of the registration already granted. The company that holds the registration or manufactures the drug may be inspected for

	on-site verification of data and information regarding the grant application and renewal of registration, at Anvisa's discretion. Anvisa may issue technical guidance on the applicability of this Resolution to specific cases of drug registration, such as the submission of data to prove safety and efficacy for incremental innovations, whenever necessary This Resolution revokes: - Resolution - RDC nº. 136, of May 29, 2003; - Resolution - RDC no. 16, dated March 02, 2007, with the exception of items 1 and 2, VI, of Annex I; - Resolution - RDC no. 17, dated March 2, 2007, with the exception of items 1 and 2, VI, of the Annex, arts. 1 and 4 of the Resolution - RDC nº. 210, dated September 2, 2004, and Section I and II of Chapter XVIII of Resolution-RDC No. 48 of October 6, 2009.
7.	**Objective and rationale, including the nature of urgent problems where applicable:** Protection of Human Health
8.	**Relevant documents:** Resolution RDC nº 31/2010; Resolution RDC nº 39/2013; Resolution RDC nº 20/2015; Resolution RDC nº 71/2009; Resolution RDC nº 17/2010 and Resolution RDC nº 45/2012.
9.	**Proposed date of adoption:** On the date of its publication. **Proposed date of entry into force:** On the date of its publication.
10.	**Final date for comments:**
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_200_2017.pdf/41a09070-4acd-4e34-8b0b-ba8e88295df0