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 205, December 28th, 2017. 8 pages, Portuguese.
6.	**Description of content:** This Resolution establishes special procedure for approval of clinical trials, good manufacturing practices certification and registration of new medicines for treatment, diagnosis or prevention of rare diseases. This resolution applies to new medicines for rare diseases. The special procedure applies to: I – clinical trials authorization to be performed in Brazil for the evaluation of medicines for rare diseases; II - certification of good manufacturing practices of medicines for rare diseases; III – market authorization of new medicines for rare diseases. A medicine for a rare disease shall be considered a medicine intended to treat, diagnose or prevent a rare disease and: I - is used in a serious debilitating condition; II - proposes to change in a clinically significant way the disease evolution or to make

possible the remission of the disease.

The request of approval for clinical trials and registration of a new medicine for rare diseases is established in this Resolution.

If it is not confirmed during the technical analysis that the petitions for approval of clinical trials and registration of new medicine refers to rare disease, the petition will be rejected.

Submission of clinical medicine development dossier, specific clinical trial dossier, substantial modification by inclusion of protocol should be performed according to specific legislation regarding clinical trials in Brazil, added by the documentation established in this Resolution.

The request for registration of a new rare disease medicine must be carried out according to specific legislation for each regulatory category, added by the documentation described in this Resolution.

Supplemental data and additional evidence may be allowed after the registration has been granted, by means of a signature of an agreement between Anvisa and the company requesting registration. Failure to comply with the agreement may lead to cancellation of the registration.

Anvisa may permit the use of an international comparator medicine registered with another regulatory authority, under the terms set forth in this Resolution in the event of a request for registration of a rare disease medicine with the same registered medicine IFAs.

Companies that submit a request for registration of new medicine in accordance with this resolution must present a maximum price definition dossier concomitantly with the registration request

For applications for registration of new medicines for rare diseases, it does not apply the provisions of art. 2 of the Resolution of the Collegiate Board of Directors - RDC nº 20, of April 10, 2013.

This resolution changes the text of §2 of art. 47 of the Resolution of the Collegiate Board of Directors - RDC nº 9 of February 20, 2015.

7. **Objective and rationale, including the nature of urgent problems where applicable:** Protection of Human Health

8. **Relevant documents:** Resolution of the Collegiate Board of Directors - RDC nº 9 of February 20, 2015.

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.

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
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http://portal.anvisa.gov.br/documents/10181/2718376/RDC_205_2017_.pdf/996fc46e-216b-44ab-b8c8-2778151b786e