



18 August 2017

(17-4434)

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Committee on Technical Barriers to Trade

Original: English

NOTIFICATION

The following notification is being circulated in accordance with Article 10.6

1. Notifying Member: <u>BRAZIL</u> If applicable, name of local government involved (Article 3.2 and 7.2):
2. Agency responsible: Brazilian Health Regulatory 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 2563.2765 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): Pharmaceutical Products
5. Title, number of pages and language(s) of the notified document: RDC N° 168, 8 August 2017 (3 page(s), in Portuguese)
6. Description of content: This Resolution provides for the administrative procedure related to Anvisa's prior consent for the granting of patents for pharmaceutical products and processes, regulated by Joint Ordinance ANVISA-INPI n° 01, of 12 April 2017. The prior consent procedure will begin with forwarding of the application by INPI to Anvisa, pursuant to art. 2 of Joint Ordinance No. 1, of 12 April 2017. Upon receipt of patent applications forwarded by INPI, Anvisa will analyze such requests in the light of public health and will conclude by consent or non-consent based on a technical evaluation by the competent organizational unit within ANVISA. The petitions and documents referred to in this Resolution will be received in accordance with Anvisa's specific protocol regulation. The provisions of this Resolution also apply to current patent applications and those who have closed the administrative instance within Anvisa . Resolutions RDC - n° 45, of 20 June 2008 and RDC - n° 21, of 10 April 2013 are revoked. This Resolution shall enter into force on the date of its publication.
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), 153, 10 August 2017; Section 1, p. 52; 2) Resolution RDC 61, 3 February 2016 (Resolução RDC Nº 61, de 3 de fevereiro de 2016); Law 9.782, 26 January 1999; 3) Brazilian Official Journal; 4) Not stated.
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: Not applicable
11. Texts available from: National enquiry point [X] or address, telephone and fax numbers and email and website addresses, if available, of other body: http://portal.anvisa.gov.br/documents/10181/3506177/RDC_168_2017_.pdf/793d53f7-2e00-460e-bf21-bedb722ac033