



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
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): Medicines
5. Title, number of pages and language(s) of the notified document: Resolution - RDC n. 191, December 11 th , 2017. Portuguese, 20 pages.
6. Description of content: This Resolution establishes mechanisms of control for the substance lenalidomide and lenalidomide-based medicine, and gives other measures. The supply, marketing, distribution and dispensation of lenalidomide-based medicine products is prohibited until the proper implementation by the holder of the registration of the respective PPP (Pregnancy Prevention Program) previously approved by Anvisa. The handling of the Active Pharmaceutical Intake (IFA) lenalidomide, as well lenalidomide-based medicine or formulas containing it is forbidden for pharmacies. Distributors of medicines products must be previously qualified by the holder of the lenalidomide medicine product registration for their regularity of health and technical and safety capability for the distribution of this medicine product, according to the particularities and needs of the PPP (Pregnancy Prevention Program) previously approved by Anvisa. The importation and exportation of the substance lenalidomide or medicine containing it should follow the provisions of Ministerial Ordinance SVS 344 of May 12, 1998; Ministerial Ordinance no. 6, dated February 1, 1999; Resolution - RDC No. 99, of December 24, 2008; Resolution - RDC No. 11, of March 6, 2013; Resolution - RDC No. 62, of February 11, 2016; Resolution - RDC No. 172, of September 8, 2017, or any that may replace them.

7. Objective and rationale, including the nature of urgent problems where applicable: Protection of Human Health
8. Relevant documents: Draft Resolution nº 393 of September 12 th 2017, notified as G/TBT/N/BRA/742; Ministerial Ordinance SVS 344 of May 12, 1998; Ministerial Ordinance no. 6, dated February 1, 1999; Resolution - RDC No. 99, of December 24, 2008; Resolution - RDC No. 11, of March 6, 2013; Resolution - RDC No. 62, of February 11, 2016; Resolution - RDC No. 172, of September 8, 2017; Resolution RDC nº 71, December 22 th 2009; Resolution RDC nº 47 September 8 th 2009; Resolution RDC nº 99, December 24 th 2008;
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: No 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/10181/3351931/RDC_191_2017_.pdf/a08ff846-09d0-4ee2-bc8f-1489f6f384da