



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=32938
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): HS 30 - Pharmaceutical products
5. Title, number of pages and language(s) of the notified document: Draft Resolution n. 393, September 13 th , 2017. (16 pages, Portuguese.)
6. Description of content: This Draft Resolution provides for activities involving the substance lenalidomide and the medicine containing it. Substances listed in Schedule C3 listed in Annex I of Portaria SVS 344/98 and its updates, with the exception of thalidomide, shall comply with the requirements set forth in this Resolution after evaluation and express determination of Anvisa. The market authorization holder of the lenalidomide medicine shall implement a supply, marketing, distribution and dispensation program to comply with the Pregnancy Prevention Plan (PPG) previously approved by Anvisa. The manipulation of the active pharmaceutical ingredient (API) lenalidomide, the medicinal product containing it or of formulas containing lenalidomide in pharmacies is prohibited. In addition to complying with the standards that regulate Good Manufacturing Practices for the production of API and medicines in the national territory, it is mandatory that companies provide individual and collective protection equipment that protects workers from exposure to the product and monitors their use in all stages of production the substance and the manufacture of the lenalidomide medicine. The presence of women on production and manufacturing lines is prohibited in any of the

<p>steps leading to product exposure.</p> <p>Distributors of the medicines must be previously qualified by the market authorization holder of the lenalidomide medicine for their regularity of health and technical and safety capability for the distribution of this medicine.</p> <p>Any movement of the lenalidomide substance, as well as the medicine containing it, even when sent for analytical or research purposes, must be carried out by issuing an Invoice or equivalent document.</p> <p>The importation and exportation of the substance lenalidomide or the medicine containing it shall comply with the requirements of Portaria SVS / MS no. 344/98, Portaria nº 6/99, RDC no. 99/2008, RDC 11/2013 or those that replace it.</p> <p>This Resolution also contains informations on teaching and research; registration; prescription; dispensation; bookkeeping and balance sheets; package; free sample; pharmacovigilance; refund; disposal; inspection.</p>
<p>7. Objective and rationale, including the nature of urgent problems where applicable: Protection of Human Health</p>
<p>8. Relevant documents: (1) Brazilian Official Journal (Diário Oficial da União) Nº 175, 12 September 2017, section 1, page 28; (2) Resolution RDC 61, 3 February 2016; Law 9.782, 26 January 1999; Decree 3.029, 16 April 1999; (3) Brazilian Official Journal; (4) Not applicable</p>
<p>9. Proposed date of adoption: to be determined after the end of the consultation period.</p> <p>Proposed date of entry into force: on the date of publication.</p>
<p>10. Final date for comments: September 30th, 2017</p>
<p>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:</p> <p>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</p> <p>http://portal.anvisa.gov.br/documents/10181/3351931/CONSULTA+PUBLICA+N+393+G+GMON.pdf/a509055f-53cd-434f-bdd9-b5ab6437587c</p>