



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 (Articles 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 2563.2918 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): HS CODE: 29; 30. (active pharmaceutical ingredients)
5. Title, number of pages and language(s) of the notified document: Draft Resolution number 683, August 12 th , 2019. Published on D.O.U, August 14 th , 2019. Language(s): Portuguese. Number of pages: 16 Comment form: http://formsus.datasus.gov.br/site/formulario.php?id_aplicacao=49362
6. Description of content: This draft resolution proposes the changing of the Resolution – RDC number 200, December 26 th , 2017, and of the RDC number 73, April 7 th , 2016, for the submission of the Dossier for Active Pharmaceutical Ingredient (API) in the market authorization and post-market authorization of medicines, respectively.
7. Objective and rationale, including the nature of urgent problems where applicable: Protection of Human Health
8. Relevant documents: Resolution – RDC number 200, December 26th, 2017 Resolution – RDC number 73, April 7th, 2016
9. Proposed date of adoption: To be determined after the end of the consultation period. Proposed date of entry into force: In the date of its publication.
10. Final date for comments: October 21st, 2019
11. Texts available from: National enquiry point [X] or address, telephone and fax

numbers and email and website addresses, if available, of other body:

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<http://portal.anvisa.gov.br/documents/10181/2961691/Consulta+Pu%C2%B4blica+683.pdf/8ef7f170-ecb3-4cf4-b160-fbc3ed430463>