



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 682, August 12 th , 2019. Published on D.O.U, August 14th, 2019. Language(s): Portuguese. Number of pages: 41 Comment form: http://formsus.datasus.gov.br/site/formulario.php?id_aplicacao=49363
6. Description of content: This draft resolution proposes the establishment of the Dossier for Active Pharmaceutical Ingredient (API) and of the Adequacy Charter of the Dossier for Active Pharmaceutical Ingredient.
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), 14 August 2019, section 1, number 156; Page 73 2. Not stated; 3.Brazilian Official Journal; 4 Not stated.
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+682.pdf/36891e38-b30d-4648-b193-f5932314845f>