



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: The 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: 30
5. Title, number of pages and language(s) of the notified document: Draft resolution (Consulta Pública) 657, 24 June 2019 (4 pages, Portuguese). Comment form: http://formsus.datasus.gov.br/site/formulario.php?id_aplicacao=48148
6. Description of content: This draft resolution establishes criteria and deadlines for market authorization and notification of medicines, and provides other measures.
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) 121, 26 June 2019, section 1, page 108; (2) Not informed (3) Brazilian Official Journal (Diário Oficial da União); (4) Not informed.
9. Proposed date of adoption: 90 days after the date of its publication Proposed date of entry into force: 90 days after the date of its publication
10. Final date for comments: 16 August 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: Brazilian Health Regulatory Agency (Anvisa) SIA, Trecho 5, Área Especial 57 Brasília – DF / Brazil

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<http://portal.anvisa.gov.br/documents/10181/2957412/CONSULTA+P%C3%9ABLICA+N+657+GGMED.pdf/9e62acb5-1399-4641-8d3c-e90683977c5a>