

20 November 2015

Original: English

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Committee on Technical Barriers to Trade

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 (Article 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 2563.2840 Telefax: +(55) 21 2563.5637

Email: <u>barreirastecnicas@inmetro.gov.br</u>

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- 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): Monetary update on registration and GMP certification fees related to health products
- 5. **Title, number of pages and language(s) of the notified document:** Interministerial Ordinance no 701, 31 August 2015, regarding a monetary update on registration and GMP certification fees related to health products in Brazil (4 pages, in Portuguese)
- **6. Description of content:** Interministerial Ordinance no 701, 31 August 2015, regarding a monetary update on registration and GMP certification fees related to health products in Brazil.

This Ordinance promoted a monetary update on registration and GMP certification fees related to health products in Brazil. It was necessary once the values of ANVISA's fees were obsolete since its creation in 1999, with accumulated losses of 193.5% according to Brazilian official inflation rate. So it is considered not to be a tribute increase, but a currency value reconstitution.

- 7. Objective and rationale, including the nature of urgent problems where applicable: Protection of human health or safety
- **8. Relevant documents:** 1) Brazilian Official Journal (Diário Oficial da União), 2 September 2015; Section 1, p. 26; 2) Not stated; 3) Brazilian Official Journal; 4) Not stated.
- **9. Proposed date of adoption:** 9 September 2015

Proposed date of entry into force: 9 September 2015

10. Final date for comments: There is no final date for comments

11. Texts available from: National enquiry point [X] or address, telephone and fax numbers and email and website addresses, if available, of other body:

Agency Responsible Brazilian Health Surveillance Agency – ANVISA SIA, Trecho 5, Área Especial 57 Brasília – DF / Brazil

CEP: 71.205-050

Phone.: +(55) 61 3462.5402 Website: http://portal.anvisa.gov.br

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