

Date

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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: 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

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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.

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

Interministerial Ordinance no 701, August 31 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
- **8. Relevant documents:** 1) Brazilian Official Journal (Diário Oficial da União), September 2 2015; Section 1, p. 26; 2) Not stated; 3) Brazilian Official Journal; 4) Not stated.
- **9. Proposed date of adoption:** September 9 2015

September 9 2015

Proposed date of entry into force:

10. Final date for comments:

11. Texts available from: National enquiry point [] or address, telephone and fax numbers, e-mail and web-site addresses, if available of the other body:

Agency Responsible Brazilian Health Surveillance Agency - ANVISA SIA, Trecho 5, Área Especial 57

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