



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: Anvisa – Brazilian Health Regulatory Agency 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 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): specific medicines
5.	Title, number of pages and language(s) of the notified document: Ordinance Nº. 9, August 1 st 2016 (Instrução Normativa Nº 9, 1 Agosto 2016) (74 pages, Portuguese).
6.	Description of content: Technical regulation regarding the standardization of leaflets on specific medicines and drugs.
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) Nº 148, 3 August 2016; Section 1, p. 33; 2) Ordinance RDC Nº 47/2009 and updates (Resolução - RDC Nº 47/2009 e suas atualizações); 3) Brazilian Official Journal; 4) Not stated.
9.	Proposed date of adoption: Upon publication in the Official Journal. Proposed date of entry into force: Upon publication in the Official Journal.
10.	Final date for comments: Not applicable
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
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http://portal.anvisa.gov.br/documents/10181/2718376/IN_9_2016.pdf/ffeca2b7-76ae-4b78-b858-24f394172878