



Committee on Technical Barriers to Trade

NOTIFICATION

The following notification is being circulated in accordance with Article 10.6.

<b>1. Notifying Member:</b> BRAZIL <b>If applicable, name of local government involved (Articles 3.2 and 7.2):</b>
<b>2. Agency responsible:</b> Anvisa – Brazilian Health Regulatory Agency <b>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:</b>  National Institute of Metrology, Quality and Technology - INMETRO Telephone: +(55) 21 2563.2840 Telefax: +(55) 21 2563.5637 Email: <a href="mailto:barreirastecnicas@inmetro.gov.br">barreirastecnicas@inmetro.gov.br</a> Web-site: <a href="http://www.inmetro.gov.br/barreirastecnicas">www.inmetro.gov.br/barreirastecnicas</a>
<b>3. Notified under Article 2.9.2 [ X ], 2.10.1 [ ], 5.6.2 [ ], 5.7.1 [ ], other:</b>
<b>4. Products covered (HS or CCCN where applicable, otherwise national tariff heading. ICS numbers may be provided in addition, where applicable):</b> specific medicines
<b>5. Title, number of pages and language(s) of the notified document:</b> Ordinance Nº. 9, August 1 <sup>st</sup> 2016 (Instrução Normativa Nº 9, 1 Agosto 2016) (74 pages, Portuguese).
<b>6. Description of content:</b> Technical regulation regarding the standardization of leaflets on specific medicines and drugs.
<b>7. Objective and rationale, including the nature of urgent problems where applicable:</b> Protection of Human Health
<b>8. Relevant documents:</b> 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.
<b>9. Proposed date of adoption:</b> Upon publication in the Official Journal.  <b>Proposed date of entry into force:</b> Upon publication in the Official Journal.
<b>10. Final date for comments:</b> Not applicable
<b>11. Texts available from: National enquiry point [ ] or address, telephone and fax</b>

**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](http://portal.anvisa.gov.br/documents/10181/2718376/IN_9_2016.pdf/ffeca2b7-76ae-4b78-b858-24f394172878)