



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 Surveillance 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>The comments to this Draft Regulation shall be sent to</b> <a href="http://formsus.datasus.gov.br/site/formulario.php?id_aplicacao=19987">http://formsus.datasus.gov.br/site/formulario.php?id_aplicacao=19987</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> over-the-counter (OTC) drugs
<b>5. Title, number of pages and language(s) of the notified document:</b> Draft Technical Resolution nº 27, April 6 <sup>th</sup> 2015, regarding the criteria and the procedures to define medicines as over-the-counter (OTC) drugs (7 pages, Portuguese).
<b>6. Description of content:</b> Draft Technical Resolution nº 27, April 6 <sup>th</sup> 2015, regarding the criteria and the procedures to define medicines as over-the-counter (OTC) drugs.  This Draft Technical Resolution establishes the criteria to define over-the-counter medicines, and the procedures to request the category evaluation and the adequacy to the regulation.  This Resolution revokes the Resolution RDC nº 138/2003.
<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), April 8 <sup>th</sup> 2015; Section 1, p. 48; 2) RDC 71/2009, RDC 47/2009; 3) Brazilian Official Journal; 4) Not Stated.

<b>9. Proposed date of adoption:</b>	To be determined after the end of the consultation period.
<b>Proposed date of entry into force:</b>	On the date of the publication.
<b>10. Final date for comments:</b>	June 15 <sup>th</sup> , 2015.
<b>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:</b>	<p>Agency Responsible Anvisa - Brazilian Health Surveillance Agency SIA, Trecho 5, Área Especial 57 Brasília - DF / Brazil CEP: 71.205-050 Phone.: +(55) 61 3462.5402 Website: <a href="http://www.anvisa.gov.br">www.anvisa.gov.br</a></p> <p><a href="http://portal.anvisa.gov.br/wps/wcm/connect/8af4d78047f122ca9fa7bfbd15bfe28/Consulta+P%C3%BAblica+n%C2%B0+27+GGMED+SUMED.pdf?MOD=AJPERES">http://portal.anvisa.gov.br/wps/wcm/connect/8af4d78047f122ca9fa7bfbd15bfe28/Consulta+P%C3%BAblica+n%C2%B0+27+GGMED+SUMED.pdf?MOD=AJPERES</a></p>