



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> Brazilian Health Regulatory Agency (Anvisa) <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=33294">http://formsus.datasus.gov.br/site/formulario.php?id_aplicacao=33294</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> Medicines
<b>5. Title, number of pages and language(s) of the notified document:</b> Draft Technical Resolution n. 376, 2 <sup>nd</sup> August 2017. 9 pages, Portuguese.
<b>6. Description of content:</b> This Draft Resolution publishes the Reference List for safety and effectiveness evaluation of dynamized drugs and revokes the Normative Instruction n <sup>o</sup> 3, April 11 <sup>th</sup> 2007.
<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) N <sup>o</sup> 148, 03 August 2017, section 1, page 113; (2) Law 9.782, 26 January 1999 (Lei n <sup>o</sup> 9.782, de 26 de janeiro de 1999); (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 its publication.
<b>10. Final date for comments:</b> 8 <sup>th</sup> October, 2017

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

Agency Responsible  
Brazilian Health Regulatory Agency (Anvisa)  
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[http://portal.anvisa.gov.br/documents/10181/2959207/CONSULTA+PUBLICA+N+376+G+GMED\\_integra.pdf/0c265b1e-dae-4e1d-aba1-de6d7b81c0a6](http://portal.anvisa.gov.br/documents/10181/2959207/CONSULTA+PUBLICA+N+376+G+GMED_integra.pdf/0c265b1e-dae-4e1d-aba1-de6d7b81c0a6)