



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. 375, 2 <sup>nd</sup> August 2017. 34 pages, Portuguese.
<b>6. Description of content:</b> This Draft Resolution provides for the limits of potency for registration and notification of dynamized drugs and publishes the "Power Table for Registration and Notification of Medicaments", in the form of Annex I of this Normative Instruction.  This Resolution revokes the Normative Instruction nº 5, 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) Nº 148, 03 August 2017, section 1, page 113; (2) Law 9.782, 26 January 1999 (Lei nº 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.

**10. Final date for comments:** 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+375+G+GMED\\_integra.pdf/88223776-7a35-4b09-87cf-06b638b276a9](http://portal.anvisa.gov.br/documents/10181/2959207/CONSULTA+PUBLICA+N+375+G+GMED_integra.pdf/88223776-7a35-4b09-87cf-06b638b276a9)