



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 2563.2821 Telefax: +(55) 21 2502.6542 Email: barreirastecnicas@inmetro.gov.br 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.ap_aplicacao=11451">http://formsus.datasus.gov.br/site/formulario.php?id.ap_aplicacao=11451</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> Herbal medicines (HS:30.04)
<b>5. Title, number of pages and language(s) of the notified document:</b> Draft Ordinance nº 14, May 14 <sup>th</sup> 2013 – Draft Normative Instruction that determines the publication of the List of herbal medicines that requires simplified registration and the List of herbal medicines of traditional use that requires simplified registration at Anvisa. (13 pages, Portuguese)
<b>6. Description of content:</b>  This draft Normative Instruction determines the publication of the List of herbal medicines that requires simplified registration at Anvisa and the List of herbal medicines of traditional use that requires simplified registration at Anvisa to be commercialized in Brazil.  This Normative Instruction will enter into force on the date of its adoption. It will revoke Normative Instruction n. 5, December 11 <sup>th</sup> 2008.

<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), May 15 <sup>th</sup> 2013; Section 1 Draft Resolution (Consulta Pública) number 14, May 14 <sup>th</sup> , 2013, issued by Brazilian Health Regulatory Agency – Anvisa; (2) Not Applicable (3) Brazilian Official Journal (Diário Oficial da União); (4) Not Applicable; When adopted, it will be published at the Brazilian Official Journal. Available in Portuguese.
<b>9. Proposed date of adoption:</b>	} to be determined after the end of the consultation period. on the date of adoption.
<b>Proposed date of entry into force:</b>	
<b>10. Final date for comments:</b>	22 July 2013.
<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  Brazilian Health Regulatory Agency – ANVISA  SIA, Trecho 5, Área Especial 57  Brasília – DF / Brazil  CEP: 71.205-050  Phone.: 55 61 3462-5402  E-mail: rel@anvisa.gov.br  Website: www.anvisa.gov.br</p> <p><a href="http://portal.anvisa.gov.br/wps/wcm/connect/a5beee004fa126df932cf79a71dcc661/Consulta+P%C3%BAblica+n+14+SECOL.pdf?MOD=AJPERES">http://portal.anvisa.gov.br/wps/wcm/connect/a5beee004fa126df932cf79a71dcc661/Consulta+P%C3%BAblica+n+14+SECOL.pdf?MOD=AJPERES</a></p>