

# WORLD TRADE ORGANIZATION

G/TBT/N/BRA

Committee on Technical Barriers to Trade

Original: English

## NOTIFICATION

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

<b>1. Member to Agreement notifying: <u>BRAZIL</u> 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, Standardization and Industrial Quality-INMETRO  Telephone: +(55) 21 2563.2821 Telefax: +(55) 21 2502.6542 Email: barreirastecnicas@inmetro.gov.br Web-site: www.inmetro.gov.br/barreirastecnicas
<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> Pharmaceutical Products and Processes.
<b>5. Title, number of pages and language(s) of the notified document:</b> Draft Resolution nº 66, October 16 <sup>th</sup> 2012 – Anvisa's prior consent on patent concession . (3 pages, Portuguese)
<b>6. Description of content:</b>  This draft technical regulation amends Resolution RDC 45/08, that disposes about procedures for Anvisa's prior consent on requests of patent concession for pharmaceutical products and processes This draft technical regulation revokes art. 6 of Resolution RDC. 45, June 23, 2008.
<b>7. Objective and rationale, including the nature of urgent problems where applicable:</b> Protection of Human Health

<b>8.</b>	<b>Relevant documents:</b> Brazilian Official Journal (Diário Oficial da União), October 17, 2012; Section 1 p. 124 Draft Resolution (Consulta Pública) nº 66, October 16 2012, issued by Brazilian Health Regulatory Agency – Anvisa; When adopted, it will be published at the Brazilian Official Journal. Available in Portuguese.
<b>9.</b>	<b>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 adoption.
<b>10.</b>	<b>Final date for comments:</b> December 24, 2012.
<b>11.</b>	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: National enquiry point  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  <a href="http://portal.anvisa.gov.br/wps/wcm/connect/02857f004d1d5e66a350f74031a95fac/Consulta_Publica_n_66_COOPL.pdf?MOD=AJPERES">http://portal.anvisa.gov.br/wps/wcm/connect/02857f004d1d5e66a350f74031a95fac/Consulta_Publica_n_66_COOPL.pdf?MOD=AJPERES</a>