



### 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 (Article 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, email and website 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: 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> Substances under special control.
<b>5. Title, number of pages and language(s) of the notified document:</b> Draft Resolution nº 66, August 6th 2014, that updates the Annex I, List of Narcotics, Psychotropic Drugs, Precursors and Other Substances under Special Control, of Ordinance SVS/MS 344/98. (25 pages, in Portuguese)
<b>6. Description of content:</b>  Draft Resolution nº 66, August 6 <sup>th</sup> 2014, that updates the Annex I, List of Narcotics, Psychotropic Drugs, Precursors and Other Substances under Special Control, of Ordinance SVS/MS 344/98.  This draft resolution establishes the following modifications:  Inclusion:  1.1. List "C1": Benzydamine  1.2. Inclusion of the addendum 7 in the list "C1"  According to this draft resolution, it is prohibited to import, manufacture, manipulate, acquire, sale and dispense systemic use BENZYDAMINE based medicines. BENZYDAMINE

<p>based medicines which pharmaceutical forms are extemporaneous preparation powder, gynaecological solution, spray, drops, mouthwash, toothpaste and gel are not subject to special control.</p> <p>The establishments that use the substance BENZYDAMINE will have a period of 30 days from the date of publication of this Resolution for adaptation to the requirements of the Ordinances SVS/MS 344/98 and 6/99. However, to obtain the Special Authorization this period will be of 180 days.</p>
<p><b>7. Objective and rationale, including the nature of urgent problems where applicable:</b> Protection of human health or safety</p>
<p><b>8. Relevant documents:</b> Brazilian Official Journal (Diário Oficial da União), August 7<sup>th</sup> 2014; Section 1, p. 40, Draft Resolution (Consulta Pública) number 66, August 6<sup>th</sup> 2014, issued by Brazilian Health Surveillance Agency – Anvisa. When adopted, it will be published at the Brazilian Official Journal. Available in Portuguese.</p>
<p><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> To be determined after the end of the consultation period.</p>
<p><b>10. Final date for comments:</b> 12 September 2014</p>
<p><b>11. Texts available from: National enquiry point [ ] or address, telephone and fax numbers and email and website addresses, if available, of other body:</b> Brazilian Health Surveillance 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/685421804503e6349e7cfeef4ebdb6ee/Consulta+P%C3%BAblica+n+66+GFARM.pdf?MOD=AJPERES">http://portal.anvisa.gov.br/wps/wcm/connect/685421804503e6349e7cfeef4ebdb6ee/Consulta+P%C3%BAblica+n+66+GFARM.pdf?MOD=AJPERES</a></p>