WORLD TRADE ORGANIZATION

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Committee on Technical Barriers to Trade

Original: English

NOTIFICATION

The following notification is being circulated in accordance with Article 10.6

1.	**Notifying Member:** Brazil **If applicable, name of local government involved (Article 3.2 and 7.2):**
2.	**Agency responsible:** ANVISA - Brazilian Health Surveillance Agency **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**: National Institute of Metrology, Quality and Technology-INMETRO Telephone: +(55) 21 2563.2840 Telefax: +(55) 21 2563.5637 Email: barreirastecnicas@inmetro.gov.br Website: http://www.inmetro.gov.br/barreirastecnicas
3.	**Notified under Article 2.9.2 [** X **], 2.10.1 [ ], 5.6.2 [ ], 5.7.1 [ ], other:**
4.	**Products covered (HS or CCCN where applicable, otherwise national tariff heading. ICS numbers may be provided in addition, where applicable):** Medicines
5.	**Title, number of pages and language(s) of the notified document:** Draft Resolution nº 01, January 16th 2014 - Draft Resolution that defines rules to be adopted by register holders in order to establish the interchangeability between similar medicines and reference medicines (2 pages, in Portuguese)
6.	**Description of content:** This draft Resolution aims to define rules to be adopted by register holders in order to establish the interchangeability between similar medicines and reference medicines. According to this draft technical Resolution, interchangeable similar medicines are those which pharmaceutical equivalence/bioavailability, bioequivalence and biowaiver studies had already been presented, analysed and approved by Anvisa. Register holders of interchangeable similar medicines will have up to 90 (ninety) days to notify Anvisa of labelling adequacy and to require the entry price definition, in accordance to the defined in this draft Regulation. Changes in the packaging must be implemented in 180 (a hundred and eighty) days after the entry price is established.
7.	**Objective and rationale, including the nature of urgent problems where applicable:** Protection of human health or safety

8.	**Relevant documents:** (1) Brazilian Official Journal (Diário Oficial da União), January 17th 2014; Section 1, Draft Resolution (Consulta Pública) number 01, January 16th , 2014 (2) not Applicable; (3) Brazilian Official Journal; (4) Not Applicable
9.	**Proposed date of adoption:** } to be determined after the end of the consultation period. **Proposed date of entry into force:** } on the date of adoption
10.	**Final date for comments:** 24 February 2014
11.	**Text available from: National enquiry point [ ], 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 SIA, Trecho 5, Área Especial 57 Brasília ☐ DF / Brazil CEP: 71.205-050 Phone.: 55 61 3462-5402 E-mail: rel@anvisa.gov.br Websit http://portal.anvisa.gov.br/wps/wcm/connect/20ddca8042979c349ae8db1bb0036de1/Conuslta+P%C3%BAblica+n%C2%B0++1+DIMON+.pdf?MOD=AJPERES