WORLD TRADE ORGANIZATION

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Date

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Committee on Technical Barriers to Trade

NOTIFICATION

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

1.	**Notifying Member:** BRAZIL **If applicable, name of local government involved (Articles 3.2 and 7.2):**
2.	**Agency responsible:** Brazilian Health Regulatory Agency (ANVISA) **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:** 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 **The comments to this Draft Regulation shall also be sent to** http://formsus.datasus.gov.br/admin/aplicacao_campo.php?id_aplicacao=10937.
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. HS: 30.0000
5.	**Title, number of pages and language(s) of the notified document:** Draft Resolution nº 10, April 2nd 2013 – Anvisa proposal for the implementation of the Brazilian System of Medicines control mechanisms and procedures for traceability of production, commercialization, dispensation and prescription of medicines. (6 pages, Portuguese)
6.	**Description of content:** This draft Technical Regulation establishes the implementation of the Brazilian System of Medicines control mechanisms and procedures for traceability of production, commercialization, dispensation and prescription of medicines. It is established, within the Brazilian System of Medicines Control, mechanisms and procedures for traceability of drugs though capture technology, electronic storage and transmission of data through all the chain that involves production, commercialization, import, dispensation and prescription and other types of movement provided by health controls. The provisions contained in this draft Technical Regulation applies to all medicines that

	must be registered at Anvisa to be commercialized in Brazil. This draft Technical Regulation revokes Resolution RDC 59, November 24th, 2009. According to article 23, it will be granted periods of 180 and 360 days from the date of entry into force of this Resolution for companies to promote the necessary adjustments to comply with this Technical Regulation.
7.	**Objective and rationale, including the nature of urgent problems where applicable:** Protection of Human Health
8.	**Relevant documents:** Brazilian Official Journal (Diário Oficial da União), April 3rd 2013; Section 1 Draft Resolution (Consulta Pública) number 10, April 2nd , 2013, issued by Brazilian Health Regulatory Agency – Anvisa; (2) Not Applicable; (3) Brazilian Official Journal; (4) Not Applicable
9.	**Proposed date of adoption:** **Proposed date of entry into force:** } to be determined after the end of the consultation period.
10.	**Final date for comments:** May 9, 2013.
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:** 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 http://portal.anvisa.gov.br/wps/wcm/connect/6726b5804f204d97b0cfbcc88f4b6a31/Consulta+P%C3%BAblica+n+10+GADIP.pdf?MOD=AJPERES