WORLD TRADE ORGANIZATION

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 2563.2821 Telefax: +(55) 21 2502.6542 Email: barreirastecnicas@inmetro.gov.br Web-site: www.inmetro.gov.br/barreirastecnicas The comments to this Draft Regulation shall be sent to http://formsus.datasus.gov.br/site/formulario.php?id_aplicacao=14777
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):** Medical devices, hygiene products, cosmetics, food and medicines
5.	**Title, number of pages and language(s) of the notified document:** Draft Normative Instruction nº 08, March 10th 2014 that adopts provisions on medical devices, hygiene products, cosmetics and food which manufacturing can be shared with medicines of human use, irrespective of previous authorization by ANVISA (4 pages, in Portuguese)
6.	**Description of content:** Draft Normative Instruction nº 08, March 10th 2014 that adopts provisions on medical devices, hygiene products, cosmetics and food which manufacturing can be shared with medicines of human use, irrespective of previous authorization by ANVISA. The shared manufacturing of products not listed in this draft normative instruction depends on previous authorization by ANVISA, which must be required by specific code and instructed with supporting documents. This documentation can be complemented by a sanitary inspection if it is necessary to the conclusion about the shared manufacturing request.

	The previous authorization of products listed in this draft normative instruction doesn´t exempt companies from presenting supporting documents whenever required.
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), March 12th 2014; Section 1, Draft Normative Instruction (Consulta Pública) number 08, March 10th 2014, issued by Brazilian Health Surveillance Agency – Anvisa (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:** 17 April 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/c0cb0c804341401ba056a188c37c37a1/Consulta+P%C3%BAblica+n%C2%B0+8+GGALI.pdf?MOD=AJPERES