WORLD TRADE ORGANIZATION

G/TBT/N/BRA/780

11 January 2018

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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:** Brazilian Health Regulatory Agency (Anvisa) **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 2563.2765 Telefax: +(55) 21 2563.5637 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=28757
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):** HS CODE: 30 – pharmaceutical products
5.	**Title, number of pages and language(s) of the notified document:** Draft resolution (Consulta Pública) number 453, December 28th 2017. 28 pages, Portuguese. Republished on D.O.U, 2 January 2018, page 74.
6.	**Description of content:** Establishes the criteria for conducting Stability Studies of active pharmaceutical ingredients and medicines, other than biological, and makes other arrangements. It establishes the criteria for carrying out Stability Studies of active pharmaceutical inputs (IFAs), and of new, generic, similar, dynamised, specific, simplified notification, herbal and radiopharmaceutical medicines. This Resolution does not apply to biological medicines. The Stability Studies of the medicines and IFAs to be marketed and used in Brazil should be performed whenever required in regulation regarding registry or post-registration changes, and according to the parameters defined in this Resolution. Long-Term Stability Studies still in progress may be accepted at the petition application with results of at least 6 (six) months, provided they are accompanied by completed Accelerated Stability Studies. The completed Accelerated Stability Study should be submitted even though the Long-Term Stability Study is complete. Protocols, stability reports and raw data regarding stability should be made available

	whenever required by a competent health authority. ANVISA shall be immediately notified in the case of results outside the specification in Stability Studies, of approved condition. For simplified medicine notifications, studies that comply with the standards written in Art. 130 of this Resolution will be accepted if all of the following conditions are met: I - the study must have been finalized before the publication of this Resolution, while the respective notification to the Anvisa must have been made within 180 (one hundred and eighty) days as of the publication of this Resolution; or II - the study must have been started before the publication of this Resolution, while the respective notification to Anvisa must have been made up to 540 (five hundred and forty) days counted from the beginning of the study. This Resolution revokes: Resolution RE No 1 of 29 July 2005; Resolution RDC No. 45 of 9 August 2012; item 5.6.3 of Resolution - RDC No. 08 of 2 January 2001 and the Normative Instruction IN No. 4 of 11 April 2007.
7.	**Objective and rationale, including the nature of urgent problems where applicable:** Protection of Human Health
8.	**Relevant documents:** (1) Brazilian Official Journal (Diário Oficial da União) 249, 29 December 2017, section 1, page 118; (2) Law Nº 9.782, de 26 January 1999; (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:** To be determined after the end of the consultation period.
10.	**Final date for comments:** 19 April 2018
11.	**Texts available from: National enquiry point [X] or address, telephone and fax numbers and email and website addresses, if available, of 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 Website: www.anvisa.gov.br http://portal.anvisa.gov.br/documents/10181/3898778/CONSULTA+PUBLICA+N+453+GGMED.pdf/bb63a56f-9d2f-4776-9eee-93c239449e1b http://portal.anvisa.gov.br/documents/10181/3898778/RET_CP_453_2017.pdf/5ee841a3-254c-4380-b8e4-971400046b25