WORLD TRADE ORGANIZATION

G/TBT/N/BRA/707

22 February 2017

(17-1061)

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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: http://www.inmetro.gov.br/barreirastecnicas The comments to this Draft Regulation shall be sent to: http://portal.anvisa.gov.br/documents/10181/2724161/CONSULTA+P%C3%9ABLICA+N+311+DIGES.pdf/f7c69614-fa3c-4be5-961d-9f9a850221df
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. Pharmaceutical products (HS: 30)
5.	**Title, number of pages and language(s) of the notified document:** Draft Resolution No. 311, 15 February 2017 (7 pages, in Portuguese)
6.	**Description of content:** This Draft Resolution proposes the implantation of the National Medicine Control System (NMCS) and the mechanisms and procedures for medicine track and tracing, besides other measures. These mechanisms and procedures for medicine track and tracing is applicable throughout the national territory. The provisions of this proposal apply to all medicines registered at the Brazilian Health Regulatory Agency (ANVISA). It is not applicable to serum and vaccines that are part of the National Immunization Program; radiopharmaceuticals; non-prescription medicaments; medicines included on the Programs of medicines for free distribution and individualized delivery control of the Ministry of Health; specific medicines and phytomedicines; free samples. Medicine track and tracing system establishes mechanisms and procedures that allow to recovery the medicine history, identify its current location and the last known destination. The bidimensional bar code is the technology used to capture, store and comunicate events related to medicine track and tracing on the NMCS and the DATAMIX is the adopted standard as established on ISO/IEC 16022:2006. The owner of the medicine marketing authorization is responsible for the generation and inclusion of the Datamix on the comercial package, including data of the Unique Medicine Identificiation (UMI) and other provisions established at RDC Nº 71 from 22 December 2009 (available at http://bvsms.saude.gov.br/bvs/saudelegis/anvisa/2009/res0071_22_12_2009.html) and modified by the RDC Nº 26 from 16 June 2011 (available at http://bvsms.saude.gov.br/bvs/saudelegis/anvisa/2011/rdc0026_16_06_2011.pdf).

	Every transport package, from expedition at the marketing authorization owner, should have a unique identification code that allows identify the UMI inside it. Imported medicines may have the Datamix and serial code printed by the manufacture on the country of origin or by the owner of the authorization in Brazil. The option adopted should be informed to Anvisa at the process for the Import Licence. Each member at the medicine supply chain should store and transmit electronically the data regarding the events of the medicine under its responsibility. The technological specifications related to the NMCS procedures will be published as Normative Instruction before the end of the fourth month after the date of publishing of this technical regulation. This proposal revokes the Resolution RDC Nº 54 from 10 December 2013 (available at http://bvsms.saude.gov.br/bvs/saudelegis/anvisa/2013/rdc0054_10_12_2013.pdf) and the RDC Nº 114 from 29 September 2016 (available at http://portal.anvisa.gov.br/documents/10181/2718376/RDC_114_2016.pdf/823dbdb9-c11f-45fa-b313-220426e75fb0)
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) Nº 34, 16 February 2017, section 1, page 39; (2) Ordinance RDC Nº 54/2013 (Resolução da Diretoria Colegiada - RDC Nº, 54 de 10 de dezembro de 2013); (3) Brazilian Official Journal; (4) Not stated.
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 publication
10.	**Final date for comments:** 17 March 2017
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: http://www.anvisa.gov.br http://portal.anvisa.gov.br/documents/10181/2724161/CONSULTA+P%C3%9ABLICA+N+311+DIGES.pdf/f7c69614-fa3c-4be5-961d-9f9a850221df http://pesquisa.in.gov.br/imprensa/jsp/visualiza/index.jsp?data=16/02/2017&jornal=1&pagina=39&totalArquivos=96