WORLD TRADE ORGANIZATION

G/TBT/N/BRA/808

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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 2563.2840 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=33294
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):** Nasal and oral inhalants medicines
5.	**Title, number of pages and language(s) of the notified document:** Draft Resolution 490, 26 March 2018 - criteria for acceptance of the in vitro and in vivo tests necessary to prove therapeutic equivalence for nasal and oral inhalants medicines. (10 page(s), in Portuguese)
6.	**Description of content:** Article 1 This Draft Resolution establishes the criteria for acceptance of the in vitro and in vivo tests necessary to prove therapeutic equivalence for the granting and renewal of registration and post-registration changes in nasal and oral inhalants medicines with synthetic active principles classified as new, generic and similar. Article 2 Single paragraph. In the case of new medicine products, the scope of this resolution is limited to medicine products containing active principles within the approved therapeutic range where therapeutic equivalence studies may replace clinical studies of Phase II and III, as defined by Resolution - RDC 60, 10 October 2014 and its updates. Article 4 All requirements for conducting the pharmaceutical equivalence study of nasal and oral inhalation medicines and for the preparation of reports shall meet the criteria established in this resolution, as well as in Resolution RDC 31, 11 August 2010, and its updates, which provides the Guide for Study Execution and Elaboration of the Pharmaceutical Equivalence Report and Dissolution Profile. Article 14 In addition to the requirements presented in this Resolution, pharmacokinetic studies for the purpose of proving the relative bioavailability/bioequivalence of nasal medicines products and oral inhalers should meet the criteria established in other regulations on the subject.

	Art 45 The relative bioequivalence/bioavailability study may be dispensed for other generic and new generic drug dosages, provided that the criteria for pharmacokinetic linearity and proportionality of the formulations are met, as determined by Resolution - RDC 37, 3 August 2011, which provides the Guide for Exemption and Substitution of Relative Bioavailability Studies/Bioequivalence Paragraph 1 The other dosages should use the same device as the dosage under study in vivo. Paragraph 2 The comparative performance tests between test drug and reference of the same dosage, as described in Section I of Chapter II of this Resolution, shall also be presented in the above exemption cases
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), 2 April 2018; Section 1, p. 94; 2) Resolution – RDC 60/2014; Resolution – RDC 31/2010; Resolution – RDC 37/2011;Resolution – RE 1170/06 and Resolution – RDC 27/12; 3) Brazilian Official Journal; 4) Not stated.
9.	**Proposed date of adoption:** On the date of its publication **Proposed date of entry into force:** On the date of its publication, after the end of the consultation period.
10.	**Final date for comments:** 7 June 2018
11.	**Texts available from: National enquiry point [ ] 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/10181/3178137/CONSULTA+P%C3%9ABLICA+N%C2%BA+490+GGMED.pdf/383ff9a9-1289-415e-9802-be4d411796ce