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 2563.2840 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=33367
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):**
5.	**Title, number of pages and language(s) of the notified document:** Draft Technical Resolution n. 372, 2nd August 2017. 7 pages, Portuguese.
6.	Description of content: This Draft Resolution provides for the classification in the priority category, of registration petitions, post-registration and prior consent in clinical research of medications. The criteria and procedures for framing an application for registration, post-registration and prior consent in clinical research for drugs in the priority category are stablished under the terms of this Resolution, according to public relevance, in order to guarantee or expand access to pharmaceutical assistance,. ANVISA may classify as priority the requests for registration and post-registration of medicines for sale under medical prescription, which are under risk of market shortages that have an impact on public health. Medications prioritized and registered according to the criteria of this Resolution should be marketed within a period of up to 120 days from the date of publication of the registration. New drugs in the priority category, as a result of the criteria established in this Resolution, will have a period of 30 days to submit the price proposal to ANVISA, counted from the first business day after the protocol of the priority petition.

	The classification in the priority category should be done at the moment of the protocol of the petition (registration, post registration alteration and previous consent in clinical research), which will be the object of prioritization. The deadline for final decision regarding the analysis of registration and post-registration requests for medicines classified as priority will be: I - 120 days for applications for registration of medication; II - 60 days for post-registration requests. In order to apply the criteria set forth in this Resolution, the priority petition for registration, post-registration and prior consent in clinical drug research must be instructed with all documentation required by current legislation and regulations.
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 148, 03 August 2017, section 1, page 112; (2) Law 9.782, 26 January 1999 (Lei nº 9.782, de 26 de janeiro de 1999); (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 its publication.
10.	**Final date for comments:** 8th October, 2017
11.	**Texts available from: National enquiry point [X] 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 Website: www.anvisa.gov.br http://portal.anvisa.gov.br/documents/10181/3488774/CONSULTA+PUBLICA+N+372+GGMED_integra.pdf/7867770b-68c6-4b18-b61a-646552948b19