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=33059
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
5.	**Title, number of pages and language(s) of the notified document:** Draft Technical Resolution n. 373, 2nd August 2017. 54 pages, Portuguese.
6.	**Description of content:** This Draft Resolution provides for registration, renewal of registration, post-registration changes and notification of industrialized dynamized drugs. The technical regulation that establishes the minimum requirements for registration, renewal of registration, post-registration changes and notification of industrialized dynamized drugs, in accordance with this Resolution, is hereby approved. This resolution applies to industrialized dynamized drugs. Homeopathic, anthroposophic and antihomotoxic medicines are considered as dynamized drugs, framed in specific categories according to the criteria set forth in art. 5 of this Resolution. For the purpose of framing the different categories of dynamized drugs, the following classification should be observed: I - are classified as homeopathic dynamized medicinal products those whose claim to use is defined based on the fundamentals of Homeopathy and that are elaborated according to homeopathic pharmacotechnical. II - are classified as anthroposophic dynamized drugs those prepared according to anthroposophic pharmacotechnics or those whose claim and use is defined based on the foundations of Anthroposophic Medicine, even if prepared according to homeopathic

	pharmacotechnics. III - anti-homotoxic drugs are defined as those that have their therapeutic indications defined according to the concepts of Homotoxicology and are elaborated in accordance with the homoeopathic or antihomotoxic pharmacotechnics. The addition of colorings, sweeteners, flavorings and essences to the formulation of energized medicinal products shall not be permitted. The claim of use of compounded dynamized medicinal products may be given considering the individual indication of each of the components of the drug and the rationale of the association must be proven. This notification also establishes provisions regarding the restriction on the sale of industrialized dynamized drugs; notification of medicinal products; drug registration; registration and notification; renewal of registration; labelling; medication package; post-registration changes; and final and transitional provisions. This resolution revokes the RDC nº 26, of March 30th 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) 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/10181/2959207/CONSULTA+PUBLICA+N+373+GGMED_integra.pdf/3a4a3ae1-20c7-4521-9a88-eb84f31337b2