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=31454
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):** Medicinal products
5.	**Title, number of pages and language(s) of the notified document:** Draft Resolution n. 343, May 11 2017. 18 pages.
6.	**Description of content:** This Draft Resolution provides for good distribution and storage practices as well as good practices for the transport of medicinal products. It applies to companies that carry out the activities of distribution, storage or transport of medicines. This resolution does not apply to the distribution storage and transportation activities of raw materials, bulk drugs, labels, packaging or medicinal gases. All parties involved in the production, storage, distribution and transportation should be responsible for the quality and safety of the medicines. Shared responsibility covers recall actions, whether motivated by the health authority, the registrant or the distributor. Manufacturers must provide medicines only to companies authorized and licensed by competent the sanitary authority for distribution activities or delivery of medicines to patients. The companies involved in the distribution activity should only obtain supplies of medicines purchased directly from the companies that hold the registration and should only provide to companies authorized and licensed to delivery to patients. This resolution also establishes provisions regarding the organization and administration; staff; quality management system; storage areas installations; storage; expedition and receipt; transport and in-transit storage; vehicles and equipments; containers; documentation; complaints; withdraw; returns; adulterated, falsified, robbed or stolen

	medicines; subcontracted activities; self-inspections; qualifications and validations and thermolabile medicines. This resolution revokes the Ministerial Order nº 802 of October 8, 1198 and the Resolution – RDC nº 320 of November 22, 2002, and the article 3º of the Ministerial Order nº 2.814/GM/MS of May 29, 1998. This resolution comes into force on the date of its publication.
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 90, 12 May 2017, section 1, page 34/35; (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:** This resolution comes into force on the date of its publication.
10.	**Final date for comments:** July 10, 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/10181/2957539/CONSULTA+PUBLICA+N+343+GGFIS.pdf/2dbf8b62-68cf-43f9-8bfe-5dc55347718f