



22 November 2018

(18-7359)

Page: 1/2

Committee on Technical Barriers to Trade

Original: English

NOTIFICATION

The following notification is being circulated in accordance with Article 10.6

| |
|---|
| 1. Notifying Member: <u>BRAZIL</u> If applicable, name of local government involved (Article 3.2 and 7.2): |
| 2. Agency responsible: Institute of Metrology, Quality and Technology-INMETRO Telephone: +(55) 21 2563.2840 Telefax: +(55) 21 2563.5637 Email: barreirastecnicas@inmetro.gov.br Website: http://www.inmetro.gov.br/barreirastecnicas 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: Ministry of the Environment- MMA http://consultaspublicas.mma.gov.br |
| 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): Chapter 30 - Pharmaceutical products |
| 5. Title, number of pages and language(s) of the notified document: MMA - Ordinance 421, 12 November 2018 (Portaria 421, de 12 de Novembro de 2018), opening the consultation process of the proposed Decree for the implementation of a pharmaceutical reverse logistics system of medicines discarded by consumers. (5 page(s), in English) |
| 6. Description of content: Draft Decree that establishes the pharmaceutical reverse logistics activities for drugs discarded by consumers with the participation of importers, manufacturers, distributors and merchants, in accordance with the provisions of Law 12.305, 2 August 2010, which established the National Policy on Solid Waste and Decree 7.404, 23 December 2010. |
| 7. Objective and rationale, including the nature of urgent problems where applicable: Prevention of deceptive practices and consumer protection; Protection of human health or safety; Quality requirements |
| 8. Relevant documents: (1) Brazilian Official Journal (Diário Oficial da União) 235, 8 September 2017, section 3, page 139; (2) Law 12.305, 2 August 2010 and its amendments; Decree 7404, 23 December 2010 and its amendments; (3) Brazilian Official Journal; (4) Not informed. |

9. Proposed date of adoption: Upon publication in the Official Journal after receiving comments and approval of the new Decree by Congress.

Proposed date of entry into force: Upon publication in the Official Journal after receiving comments and approval of the new Decree by Congress.

10. Final date for comments: 19 December 2018

11. Texts available from: National enquiry point [X] or address, telephone and fax numbers and email and website addresses, if available, of other body:

<http://pesquisa.in.gov.br/imprensa/jsp/visualiza/index.jsp?data=16/11/2018&jornal=515&pagina=123>

<http://consultaspublicas.mma.gov.br/>

<http://consultaspublicas.mma.gov.br/medicamentos/wp-content/uploads/2018/10/DEC-LOGISTICA-REVERSA1.pdf>