



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 (Articles 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 2145.3817 Email: barreirastecnicas@inmetro.gov.br Web-site: www.inmetro.gov.br/barreirastecnicas
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): HS Code(s): 2941; 3003; 3004; 3005; 3006 (pharmaceutical products).
5. Title, number of pages and language(s) of the notified document: Draft Resolution number 875, July 22 nd , 2020. Language(s): Portuguese. Number of pages: 11. Draft: http://portal.anvisa.gov.br/documents/10181/5962542/CONSULTA+P%C3%9ABLICA+N+875+GGMED.pdf/406e2cb2-fc96-4e28-bd85-954b0973eb9a Comment form: http://formsus.datasus.gov.br/site/formulario.php?id_aplicacao=58219
6. Description of content: This draft resolution establishes the simplified procedure for the request of market authorization, post market authorization, and renewal of market authorization for medicines.
7. Objective and rationale, including the nature of urgent problems where applicable: Protection of human health. http://portal.anvisa.gov.br/documents/10181/5962542/Justificativa+regulat%C3%B3ria.pdf/aa1fc6e4-0fff-4f32-90df-ac5bba78dfb8
8. Relevant documents: 1) Brazilian Official Gazette N° 71, 29 July 2020, Section 1, Page 71
9. Proposed date of adoption: 60 days after the date of its publication. Proposed date of entry into force: 60 days after the date of its publication.
10. Final date for comments: October 5th, 2020

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

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