



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 2563.2918 Telefax: +(55) 21 2563.5637 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): Biological products
5. Title, number of pages and language(s) of the notified document: Draft Normative Instruction number 686, August 12 th , 2019. Published on D.O.U, August 14 th , 2019. Language(s): Portuguese. Number of pages: 54.
6. Description of content: This draft resolution proposes an initiative for the revision of the Resolution – RDC number 49, September 20 th , 2011, which establishes post-market authorization alterations of biological products.
7. Objective and rationale, including the nature of urgent problems where applicable: Protection of Human Health
8. Relevant documents: RDC number 49, September 20th, 2011
9. Proposed date of adoption: To be determined after the end of the consultation period. Proposed date of entry into force: 120 days after the date of its publication.
10. Final date for comments: October 21st, 2019
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

<http://pesquisa.in.gov.br/imprensa/jsp/visualiza/index.jsp?data=14/08/2019&jornal=515&pagina=73>