



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: The Brazilian Health Regulatory Agency 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 [], 2.10.1 [X], 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): 29, 2936, 2937, 2941, 30, 3001, 3002, 3003, 3004, 3005, 3006. (pharmaceutical products, active pharmaceutical ingredients, and healthcare products)
5.	Title, number of pages and language(s) of the notified document: Resolution – RDC number 346, March 12 th , 2020. Language(s): Portuguese. Number of pages: 4.
6.	Description of content: This Resolution establishes extraordinary and temporary criteria and procedure for Good Manufacture Practice Guidelines for market authorization and post-market registration amendments of Active Pharmaceutical Ingredients, medicines, and healthcare products due to the international public health emergency of the new coronavirus (Covid-19).
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) 50, 13 March 2020, section 1, page 66; (2) Not applicable; (3) Brazilian Official Journal; (4) Not applicable.
9.	Proposed date of adoption: In the date of its publication. Proposed date of entry into force: In the date of its publication.
10.	Final date for comments: Not applied.
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://portal.anvisa.gov.br/documents/10181/5809525/RDC_346_2020_.pdf/2bd739f9-283d-44ba-a627-db72d0d0999a