

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 Telefax: +(55) 21 2563.5637 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): 2941; 300220; 3003; 3004; 3005; 3006 (pharmaceutical products and vaccines for human medicine).
5. Title, number of pages and language(s) of the notified document: Resolution – RDC number 476, 10 March 2021. Language(s): Portuguese. Number of pages: 12. Resolution: http://antigo.anvisa.gov.br/documents/10181/6240597/RDC_476_2021_COMP.pdf/6c077803-fc71-4120-90a7-73c609156e76
6. Description of content: This resolution establishes the procedure and technical requirements for the submission of temporary and exceptional market authorization application for the import and distribution of medicines and vaccines for Covid-19 to tackle the national public health emergency related to the outbreak of the new coronavirus (SARS-CoV-2) in accordance with the Law number 14.124, 10 March 2021.
m Objective and rationale, including the nature of urgent problems where applicable: Protection of human health.
8. Relevant documents: 1) Brazilian Official Gazette 47-A on 11 March 2021, section 1, page 2 2) Law No. 14124, 10 March 2021. https://www.in.gov.br/web/dou/-/resolucao-rdc-n-476-de-10-de-marco-de-2021-307999746 http://www.planalto.gov.br/ccivil_03/ato2019-2022/2021/lei/L14124.htm
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: http://antigo.anvisa.gov.br/documents/10181/6240597/RDC_476_2021_COMP.pdf/6c077803-fc71-4120-90a7-73c609156e76 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