



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 [], 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): 300220 (Vaccines for human medicine).
5. Title, number of pages and language(s) of the notified document: Normative Instruction number 77, 17 November 2020. Language(s): Portuguese. Number of pages: 4. Normative http://antigo.anvisa.gov.br/documents/10181/6118549/IN_77_2020_.pdf/54b561e4-bfba-4f87-9fd6-c71862bf69dd Instruction:
6. Description of content: This Normative Instruction establishes the procedure for the continuous submission of technical data for the registration of vaccines for Covid-19.
7. Objective and rationale, including the nature of urgent problems where applicable: Protection of human health.
8. Relevant documents: 1) Brazilian Official Gazette 220 on 18 November 2020, section 1, page 205 https://www.in.gov.br/en/web/dou/-/instrucao-normativa-in-n-77-de-17-de-novembro-de-2020-288986932
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