WORLD TRADE ORGANIZATION

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Date

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Committee on Technical Barriers to Trade Original:

NOTIFICATION

The following notification is being circulated in accordance with Article 10.6.

1.	**Notifying Member:** Brazil **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 [**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): 30022000 (Vaccines for human medicine)
5.	**Title, number of pages and language(s) of the notified document:** Resolution number 444, 10 December 2020. **Language(s):** Portuguese. **Number of pages:** 5. http://antigo.anvisa.gov.br/documents/10181/6134216/RDC_444_2020_.pdf/f23f3e74-e0da-4672-ac53-d24ffeb24a85
6.	**Description of content:** This resolution establishes temporary authorization of emergency use, experimentally, of Covid-19 vaccines the Public Health Emergency of National Concern due to the new coronavirus (SARS-CoV-2) pandemic.
7.	**Objective and rationale, including the nature of urgent problems where applicable:** Protection of human health. As there is no provision in the existing regulations on the emergency use of medicines or vaccines in cases of public health emergency and that there is an urgent and unmet need for vaccines for Covid-19, it is evident the need for the preparation of a Draft OF DRC by ANVISA that establishes minimum criteria for temporary authorization for emergency use of vaccines for the prevention of Covid-19 , with the objective of ensuring minimum requirements for safety, quality and efficacy, based even on the proper monitoring of these vaccines in the country. The authorization for emergency use will facilitate the availability and use of vaccines for Covid-19, allowing the use of vaccines not yet registered, but that meet minimum quality, safety and efficacy requirements.
8.	**Relevant documents:** 1) Brazilian Official Gazette 236-A on 10 December 2020, section 1 Extra A, page 1.

	https://www.in.gov.br/web/dou/-/resolucao-de-diretoria-colegiada-rdc-n-444-de-10-de-dezembro-de-2020-293481443
9.	**Proposed date of adoption:** On the day of its publication **Proposed date of entry into force:** On the day of its publication
10.	**Final date for comments:**
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