WORLD TRADE ORGANIZATION

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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 [ ], 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): advanced therapy medicinal products
5.	**Title, number of pages and language(s) of the notified document:** Resolution – RDC number 453, 17 December 2020. **Language(s)**: Portuguese. **Number of pages(s)**: 2. Resolution: http://antigo.anvisa.gov.br/documents/10181/6164660/RDC_453_2020_.pdf/8c2f0043-942c-42cf-8751-39723140b371
6.	**Description of content:** This resolution changes the Resolution – RDC number 260, 21 December 2018, which establishes the technical requirements for the execution of clinical trials with advanced therapy medicinal products in Brazil and provides other measures.
7.	**Objective and rationale, including the nature of urgent problems where applicable:** Protection of human health. Because of the pandemic of the new coronavirus (Sars-Cov-2), some Researchers in Brazil and elsewhere have been testing treatments using advanced cell therapies in serious situations of the disease, with reports of improvement for some cases. Thus sponsors have been submitting to the Agency clinical studies dossiers with invesgatory products and the Agency has fulfilled its role promoting efficient and timely evaluation, with the necessary priority that requires the emergency situation. In this case, considering the innovative proposals in the covid-19, there is a need for an efficient evaluation of Anvisa prior to the clinical trials in Brazil quickly, focusing on safety, quality and the search for robust efficacy results. Among advanced therapy products, a specific type called by the RDC 260/2018 as Class I, defines products that have not been substantially handled but which promote innovation in its clinical use. In compliance with the situation of Covid-19, it is necessary to improve the classification and standard text to better understand the evaluation flow of these Class I

	products by the Agency. In addition, the proposed modifications will safeguard Anvisa and society in the face of other similar situations and contexts of prioritization and evaluation of investigative products in the emergency context, as well as improvement of the regulatory text. The amendment to the text will provide clarity of Anvisa's workflow and will be based on the harmonization of the Special communication (EC) concept that will apply to all types of products (Class I and Class II) and establishment of a 30-day period for the Agency's analysis for Class I products, taking into account the emergency involved in the Pandemic scenario, as well as other involving clinical trials with Class I advanced therapy products.
8.	**Relevant documents:** 1) Brazilian Official Gazette 245 on 23 December 2020, section 1, page 123 2) RDC 260, 21 December 2018 3) Justification for the resolution draft https://www.in.gov.br/web/dou/-/resolucao-de-diretoria-colegiada-rdc-n-453-de-17-de-dezembro-de-2020-295783509 http://antigo.anvisa.gov.br/documents/10181/3428326/RDC_260_2018_COMP.pdf/19994556-1ed3-4bb4-b3dd-37e66d354ae2
9.	**Proposed date of adoption:** 23 December 2020. **Proposed date of entry into force:** 23 December 2020.
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