



NOTIFICATION

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

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| 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 475, 10 March 2021. Language(s): Portuguese. Number of pages: 9. Resolution: http://antigo.anvisa.gov.br/documents/10181/6134216/RDC_475_2021_.pdf/a9edad40-f6de-4d2d-891b-be84e4ee4171 |
| 6. Description of content: This resolution establishes the procedure and technical requirements for the application for temporary market authorization on an emergency basis of medicines and vaccines for Covid-19 in experimental character to tackle the national public health emergency related to the outbreak of the new coronavirus (SARS-CoV-2) |
| 7. Objective and rationale, including the nature of urgent problems where applicable: Protection of human health. Anvisa has prepared RDC No. 444/20, as well as Guide No. 42/2020, which both deal with regulating the Temporary Authorization for Emergency Use of Vaccines. Still, the National Congress enacted Provisional Measure No. 1,026/2021, adding aspects to the Brazilian legal framework, with a direct impact on the regulatory framework then in force in the country. With the imposition of the sanction of The Conversion Bill No. 1/2021, coming from the Provisional Measure, it is necessary to advance in the regulation of the matter so that there is no normative vacuum that imposes additional challenges to the confrontation of the Pandemic. |
| 8. Relevant documents: 1) Brazilian Official Gazette 47-A on 11 March 2021, section 1, page 1 2) Legal Opinion - Exemption from Public Consultation and RIA |

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| <p>https://www.in.gov.br/web/dou/-/resolucao-rdc-n-475-de-10-de-marco-de-2021-307999666</p> <p>http://antigo.anvisa.gov.br/documents/10181/6134216/Parecer+-+Dispensa+de+AIR+e+CP/ac784dea-a8c6-4f45-bac2-e907fbd4be12</p> |
| <p>9. Proposed date of adoption: In the date of its publication.</p> <p>Proposed date of entry into force: In the date of its publication.</p> |
| <p>10. Final date for comments: Not applied.</p> |
| <p>11. Texts available from: National enquiry point [X] or address, telephone and fax numbers and email and website addresses, if available, of other body:</p> <p>http://antigo.anvisa.gov.br/documents/10181/6134216/RDC_475_2021_.pdf/a9edad40-f6de-4d2d-891b-be84e4ee4171</p> <p>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</p> |