NOTIFICATION

The following notification is being circulated in accordance with Article 10.6

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| **1.** | **Notifying Member:** Brazil  **If applicable, name of local government involved (Article 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](mailto:barreirastecnicas@inmetro.gov.br)  Website: [www.inmetro.gov.br/barreirastecnicas](http://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):** Medicaments consisting of two or more constituents mixed together for therapeutic or prophylactic uses, not in measured doses or put up for retail sale (excl. goods of heading 3002, 3005 or 3006) (HS 3003); Medicaments consisting of mixed or unmixed products for therapeutic or prophylactic uses, put up in measured doses "incl. those for transdermal administration" or in forms or packings for retail sale (excl. goods of heading 3002, 3005 or 3006) (HS 3004); Pharmaceutical preparations and products of subheadings 3006.10.10 to 3006.60.90 (HS 3006) |
| **5.** | **Title, number of pages and language(s) of the notified document:** Resolution – RDC number 568, 29 September 2021. (2 page(s), in Portuguese) |
| **6.** | **Description of content:** This resolution disposes about, on an extraordinary and temporary basis, the permission of the use of medicines and biological products used in the treatment and prevention of Covid-19, from the remaining stock of clinical trials conducted or in progress in Brazil, due to the public health emergency resulting from 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 or safety |
| **8.** | **Relevant documents:** Not applicable |
| **9.** | **Proposed date of adoption:** 1 October 2021, on the date of its publication  **Proposed date of entry into force:** 1 October 2021, on the date of its publication |
| **10.** | **Final date for comments:** Not applicable |
| **11.** | **Texts available from: National enquiry point [** **]** **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](http://www.anvisa.gov.br)  <http://antigo.anvisa.gov.br/documents/10181/6332786/RDC_568_2021_.pdf/76df2c2d-49de-42c8-9431-23e228dce561> |