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 2145.3817Telefax: +(55) 21 2563.5637Email: barreirastecnicas@inmetro.gov.brWeb-site: [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 [****], 3.2 [****], 7.2 [****],** **other****:**  |
| **4.** | **Products covered (HS or CCCN where applicable, otherwise national tariff heading. ICS numbers may be provided in addition, where applicable):** Medicaments (excluding goods of heading 30.02, 30.05 or 30.06) consisting of two or more constituents which have been mixed together for therapeutic or prophylactic uses, not put up in measured doses or in forms or packings for retail sale. (HS code(s): 3003); Medicaments (excluding goods of heading 30.02, 30.05 or 30.06) consisting of mixed or unmixed products for therapeutic or prophylactic uses, put up in measured doses (including those in the form of transdermal administration systems) or in forms or packings for retail sale. (HS code(s): 3004) |
| **5.** | **Title, number of pages and language(s) of the notified document:** Resolution number 688, 13 May 2022; (9 page(s), in Portuguese) |
| **6.** | **Description of content:** This Resolution contains provisions on the procedures and requirements for the maintenance of authorizations already granted and for new requests for temporary authorization for emergency use (AUE), on an experimental basis, of medicines and vaccines against Covid-19 to face the SARS-CoV-2 pandemic .The evaluation and authorization procedure through the EAU will only apply to new vaccines, provided that they are indicated by the Brazilian Ministry of Health as necessary to support the vaccination program in Brazil.For the purposes of this Resolution, it considers a listed regulatory authority to be the World Health Organization, regulatory authorities founding members and permanent members of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) and the Regulatory Agency for Medicines and Health Products of the United Kingdom. Kingdom (MHRA). |
| **7.** | **Objective and rationale, including the nature of urgent problems where applicable:** Protection of human health or safety |
| **8.** | **Relevant documents:** - |
| **9.** | **Proposed date of adoption:** 18 May 2022**Proposed date of entry into force:** 18 May 2022 |
| **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 57Brasília – DF / BrazilCEP: 71.205-050Phone.: +(55) 61 3462.5402Website: [www.anvisa.gov.br](http://www.anvisa.gov.br) The final text is available only in Portuguese and can be downloaded at:<http://antigo.anvisa.gov.br/documents/10181/6134216/RDC_688_2022_.pdf/22f4f571-e98d-49e6-9df7-9a39efe392e0> |