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)  Web-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 [****],** **other****:** |
| **4.** | **Products covered (HS or CCCN where applicable, otherwise national tariff heading. ICS numbers may be provided in addition, where applicable):** Active Pharmaceutical Ingredients (HS 3006); 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 number 606, 23 February 2022 (6 page(s), in Portuguese) |
| **6.** | **Description of content:** This resolution defines the extraordinary and temporary criteria and procedures for the certification of good manufacturing practices for the purpose of market authorization and post-market authorization changes of active pharmaceutical ingredient, medicine and health products due to the international public health emergency of the new Coronavirus.  The Foreign Regulatory Authorities, for the purposes of the actions described in the caput, are those members of:  I - PIC/S (Pharmaceutical Inspection Cooperation Scheme/Scheme for Cooperation in Pharmaceutical Inspection) for certifications related to medicines and pharmaceutical ingredients;  II - MDSAP (Medical Device Single Audit Program) for certifications related to medical devices; or  III - Programme to rationalize international GMP inspections of active pharmaceutical ingredients/active substance manufacturers for certifications related to pharmaceutical ingredients. |
| **7.** | **Objective and rationale, including the nature of urgent problems where applicable:** Protection of human health; Protection of human health or safety |
| **8.** | **Relevant documents:**  - |
| **9.** | **Proposed date of adoption:** 2 March 2022; On the date of its publication  **Proposed date of entry into force:** 2 March 2022; On the date of its publication |
| **10.** | **Final date for comments:** Not applied |
| **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)  The final text is available only in Portuguese and can be downloaded at:  <http://antigo.anvisa.gov.br/documents/10181/5809525/RDC_606_2022_.pdf/c70745b0-1f02-4cfa-ac9e-b418f93335c3>  <http://antigo.anvisa.gov.br/documents/10181/5809525/RDC_606_2022_.pdf/c70745b0-1f02-4cfa-ac9e-b418f93335c3> |