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 |
| **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 (ICS code(s): 11.120.10) |
| **5.** | **Title, number of pages and language(s) of the notified document:** Draft resolution 1204, 14 September 2023; (5 page(s), in Portuguese) |
| **6.** | **Description of content:** This Draft Resolution contains provisions on the health requirements relating to non-clinical safety studies for the market authorization of industrialized medicines for human use.The non-clinical studies of medication safety of this draft resolution must follow guidelines from The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) |
| **7.** | **Objective and rationale, including the nature of urgent problems where applicable:** This draft resolution aims to maintain convergence with international standards.; Protection of human health or safety |
| **8.** | **Relevant documents:** - |
| **9.** | **Proposed date of adoption:** To be determined**Proposed date of entry into force:** To be determined |
| **10.** | **Final date for comments:** 6 November 2023 |
| **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.brThe final text is available only in Portuguese and can be downloaded at:Draft: [http://antigo.anvisa.gov.br/documents/10181/6654999/CONSULTA+P%C3%9ABLICA+N+1204+GGMED.pdf/f2ee27e8-8e79-44c7-992c-2042453a4ce5](http://antigo.anvisa.gov.br/documents/10181/6654999/CONSULTA%2BP%C3%9ABLICA%2BN%2B1204%2BGGMED.pdf/f2ee27e8-8e79-44c7-992c-2042453a4ce5) Comment form: <https://pesquisa.anvisa.gov.br/index.php/591814?lang=pt-BR> The comment form link is going to be available on 22 September 2023.<https://members.wto.org/crnattachments/2023/TBT/BRA/23_12452_00_x.pdf> |