NOTIFICATION

The following notification is being circulated in accordance with Article 10.6

|  |  |
| --- | --- |
| **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 [ ], 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 1288, 17 October 2024; (10 page(s), in Portuguese) |
| **6.** | **Description of content:** This Draft Resolution contains provisions on post-market-registration changes and cancellation of registration of medicines with synthetic and semi-synthetic active ingredients and establishes rules for the preparation, harmonization, updating, publication and availability of medication leaflets for patients and healthcare professionals. |
| **7.** | **Objective and rationale, including the nature of urgent problems where applicable:** This draft resolution seeks to ensure safe and effective access to essential health products.; 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:** 23 December 2024 |
| **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:  Draft: <https://antigo.anvisa.gov.br/documents/10181/6892593/CONSULTA+P%C3%9ABLICA+N%C2%BA+1288+GGBIO.pdf/30802d83-2788-4e5a-828f-7e122f229f29>  Comment form: <http://pesquisa.anvisa.gov.br/index.php/212154?lang=pt-BR>  <https://members.wto.org/crnattachments/2024/TBT/BRA/24_07153_00_x.pdf> |