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 2145.3817Telefax: +(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 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 code(s): 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 code(s): 3004) |
| **5.** | **Title, number of pages and language(s) of the notified document:** Draft resolution 1282, 19 September 2024; (7 page(s), in Portuguese) |
| **6.** | **Description of content:** This Draft Resolution contains provisions on the execution of Terms of Commitment for the purposes of market registration or postmarket registration of medicines and biological products. |
| **7.** | **Objective and rationale, including the nature of urgent problems where applicable:** In view of constant scientific advances and health risk scenarios, such as that experienced during the COVID-19 pandemic, Anvisa has increasingly come across situations in which refusing to register a product can cause more harm than good to the population health. In this scenario, the signing of Terms of Commitment appears as an alternative to refusing market registration, allowing incomplete dossiers to be approved, as long as the missing documents are subsequently submitted.; 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:** 13 November 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 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:Draft: [https://antigo.anvisa.gov.br/documents/10181/5506254/CONSULTA+P%C3%9ABLICA+N%C2%BA+1282+GGBIO.pdf/65571112-661e-40ec-936d-d271f11b6273](https://antigo.anvisa.gov.br/documents/10181/5506254/CONSULTA%2BP%C3%9ABLICA%2BN%C2%BA%2B1282%2BGGBIO.pdf/65571112-661e-40ec-936d-d271f11b6273)Comment form: <http://pesquisa.anvisa.gov.br/index.php/694259?lang=pt-BR><https://members.wto.org/crnattachments/2024/TBT/BRA/24_06232_00_x.pdf> |