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 (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:** Draft resolution number 1108, 18 August 2022;; (20 page(s), in Portuguese) |
| **6.** | **Description of content:** This Draft Resolution is regarded to a proposal for a Normative Instruction that establishes the modalities and criteria applied for the optimized analysis procedure, in which the evaluations conducted by the Equivalent Foreign Regulatory Authority (EFRA) are used to analyze the market authorization and post-market authorization petitions of medicines and biological products, and a letter of adequacy of active pharmaceutical ingredient (CADIFA), in national territory.According to the proposal, it is designated as Equivalent Foreign Regulatory Authority (EFRA), the institution that has similar measures and controls in relation to the regulatory process adopted by Anvisa and meets, among other requirements, the adoption of international standards and norms equivalent to those currently adopted by Anvisa applicable to active pharmaceutical ingredient, medicines and biological products and their active substances, in particular those established by the **International Council for Harmonisation** of Technical Requirements for Pharmaceuticals for Human Use (**ICH**) and the World Health Organization (WHO); |
| **7.** | **Objective and rationale, including the nature of urgent problems where applicable:** Starting the discussion about the specific criteria for taking advantage of analyzes carried out by an Equivalent Foreign Regulatory Authority in the context of Drug and Biological Products General Office (GGMED) of Anvisa, it being necessary to define, by product category or type of service, the guidelines, criteria and procedures necessary for the adoption of abbreviated or optimized regulatory paths. 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:** 14 October 2022 |
| **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/10181/6354042/CONSULTA+P%C3%9ABLICA+N+1108+GGMED.pdf/876bfc10-471d-464c-a8b6-7bfc0ea972de](http://antigo.anvisa.gov.br/documents/10181/6354042/CONSULTA%2BP%C3%9ABLICA%2BN%2B1108%2BGGMED.pdf/876bfc10-471d-464c-a8b6-7bfc0ea972de) Comment form: https://pesquisa.anvisa.gov.br/index.php/899929?lang=pt-BR |