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 |
| **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):** HS (3003-3004) - Medicaments |
| **5.** | **Title, number of pages and language(s) of the notified document:** Draft Resolution number 1092, 03 May 2022; (9 page(s), in Portuguese) |
| **6.** | **Description of content:** This draft resolution proposes a review of Resolution – RDC number 98, 08 January 2016, which contains provisions on the criteria and procedures for classifying medicaments as non-prescription medicaments and reclassifying them as prescription medicaments and other measures. |
| **7.** | **Objective and rationale, including the nature of urgent problems where applicable:** Protection of human health or safety |
| **8.** | **Relevant documents:**  Resolution – RDC number 98, 08 January 2016  The final text is available only in Portuguese and can be downloaded at:  <http://antigo.anvisa.gov.br/documents/10181/2921766/%281%29RDC_98_2016_COMP.pdf/0b2f01fc-d66c-494d-a498-5c1861222bb0> |
| **9.** | **Proposed date of adoption:** To be determined after its publication  **Proposed date of entry into force:** To be determined after its publication |
| **10.** | **Final date for comments:** 25 June 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 57  Brasília – DF / Brazil  CEP: 71.205-050  Phone.: +(55) 61 3462.5402  Website: www.anvisa.gov.br    The comments form:  <https://pesquisa.anvisa.gov.br/index.php/645694?lang=pt-BR>  <http://antigo.anvisa.gov.br/documents/10181/6354796/%281%29CONSULTA+P%C3%9ABLICA+N+1092+GMESP+-+DOU.pdf/c747b9c0-6d66-4a83-a1c4-b66cd0ec41c7> |