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 (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:** Resolution number 690, 13 May 2022; (6 page(s), in Portuguese) |
| **6.** | **Description of content:** This Resolution stablishes the Pilot for the Implementation of the Post-markt authorization Change Management Protocol for drugs with synthetic and semi-synthetic active principles, according to item 4 of the ICH Q12 guideline - Post-market Change Management Protocol (PACMP). |
| **7.** | **Objective and rationale, including the nature of urgent problems where applicable:** Protection of human health or safety |
| **8.** | **Relevant documents:**  Guideline ICH Q12 - Post-approval Change Management Protocol (PACMP). |
| **9.** | **Proposed date of adoption:** 1 June 2022  **Proposed date of entry into force:** 1 June 2022 |
| **10.** | **Final date for comments:** Not Applicable |
| **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:  <http://antigo.anvisa.gov.br/documents/10181/6322902/RDC_690_2022_.pdf/77a283b8-4e3f-4669-93a7-c60009a08dbc> |