NOTIFICATION

The following notification is being circulated in accordance with Article 10.6

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| **1.** | **Notifying Member:** PHILIPPINES**If applicable, name of local government involved (Article 3.2 and 7.2):**  |
| **2.** | **Agency responsible:** Dr. Samuel A. ZacateDirector General Food and Drug AdministrationDEPARTMENT OF HEALTH**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:** Maria Cecilia C. MatienzoDirector IVCenter for Drug Regulation and ResearchFood and Drug AdministrationDEPARTMENT OF HEALTHEmail: cdrr.od@fda.gov.ph, cdrr.sds@fda.gov.ph; BPS@dti.gov.ph; BPS.SMD@dti.gov.ph[www.fda.gov.ph](http://www.fda.gov.ph)  |
| **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):** Pharmaceutics (ICS code(s): 11.120) |
| **5.** | **Title, number of pages and language(s) of the notified document:** Adoption and Implementation of the ASEAN Mutual Recognition Arrangement for Bioequivalence Study Reports of Generic Medicinal Products; (7 page(s), in English) |
| **6.** | **Description of content:** The policy adopts the ASEAN Mutual Recognition Arrangement for Bioequivalence Study Reports of Generic Medicinal Products and contains the general rules, regulations, and guidelines for the for the covered generic pharmaceutical products and listing of BE Centres in the ASEAN.  |
| **7.** | **Objective and rationale, including the nature of urgent problems where applicable:** This Order aims to officially adopt and implement the *"ASEAN MRA for BE Study Reports of Generic Medicinal Products"* to enable BE Study Reports issued by ASEAN-Listed BE Centres to be mutually recognized across Member States for review and assessment. Specifically, this Order aims to provide general rules, regulations, and guidelines for BE Study Reports of covered generic pharmaceutical products and listing of BE Centres in the ASEAN.The ASEAN Mutual Recognition Arrangement for Bioequivalence Study Reports of Generic Medicinal Products or Sectoral MRA was signed on 02 November 2017 in Manila, Philippines and entered into force at the same day. Philippines, as one of the signatories of the Sectoral MRA, is obliged to implement this arrangement. Article 10 of the Sectoral MRA states that the mutual recognition obligations referred to in Article 6 shall be implemented no later than 5 years after the entry of force of the Sectoral MRA. Article 6 states that Member States shall accept BE Study Reports issued by Listed BE Centres for review and assessment. The 5 years provision stated in the Sectoral MRA has already lapsed, and yet, the Philippines has not implemented the Sectoral MRA due to absence of administrative issuance that will regulate its local implementation. |
| **8.** | **Relevant documents:** * Republic Act No. 9711 "Food and Drug Administration (FDA) Act of 2009"
* Administrative Order No. 67 s. 1989 "Revised Rules and Regulations on Registration of Pharmaceutical Products"
* Administrative Order No. 2013-0021 "Adoption of the Association of Southeast Asian Nations (ASEAN) Common Technical Dossier (ACTD) and Common Technical Requirements (ACTR) for the Registration of Pharmaceutical Products for Human Use"
* ASEAN Mutual Recognition Arrangement for Bioequivalence Study Reports of Generic Medicinal Products
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| **9.** | **Proposed date of adoption:** To be determined**Proposed date of entry into force:** To be determined |
| **10.** | **Final date for comments:** 25 October 2024 |
| **11.** | **Texts available from: National enquiry point [ ] or address, telephone and fax numbers and email and website addresses, if available, of other body:** Mr. Neil P. CatajayDirectorBureau of Philippine StandardsDepartment of Trade and Industry3F Trade and Industry Building361 Sen. Gil Puyat AvenueMakati CityPhilippines1200Tel: (632) 751 4700; (632) 7913128Email: bps@dti.gov.phWebsite: <http://www.bps.dti.gov.ph><https://www.fda.gov.ph/90546-2/><https://members.wto.org/crnattachments/2024/TBT/PHL/24_06810_00_e.pdf> |