NOTIFICATION

The following notification is being circulated in accordance with Article 10.6

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| **1.** | **Notifying Member:** Malaysia  **If applicable, name of local government involved (Article 3.2 and 7.2):** |
| **2.** | **Agency responsible:**  National Pharmaceutical Regulatory Agency (NPRA)  Ministry of Health  Lot 36, Jalan Universiti  46200 Petaling Jaya  Selangor  Phone: (+603)78835400  Fax: (+603)79581312  Email: [rosilawati.a@npra.gov.my](mailto:rosilawati.a@npra.gov.my)  Website: [www.npra.gov.my](http://www.npra.gov.my)  **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:** |
| **3.** | **Notified under Article 2.9.2 [****X], 2.10.1 [****], 5.6.2 [****], 5.7.1 [****], other:** |
| **4.** | **Products covered (HS or CCCN where applicable, otherwise national tariff heading. ICS numbers may be provided in addition, where applicable):** Drug‑Medical Device and Medical Device-Drug Combination products; (ICS: 11.040, 11.120). |
| **5.** | **Title, number of pages and language(s) of the notified document:** Guideline For Registration Of Drug-Medical Device And Medical Device-Drug Combination Products (33 page(s), in English; 3 page(s), in Malay) |
| **6.** | **Description of content:** This guideline serves as a guidance for the submission of registration application of drug-medical device/medical device-drug combination products.  Combination products which has not been registered :  - *Guideline For Registration Of Drug-Medical Device And Medical Device-Drug Combination Products* applicable for product registration application submitted on/after 1 July 2019.  Combination products registration application submitted before 1 July 2019 and still in evaluation :  - *Guideline For Registration Of Drug-Medical Device And Medical Device-Drug Combination Products* applicable during re-registration.  Combination products which has been registered and available in market :  - *Guideline For Registration Of Drug-Medical Device And Medical Device-Drug Combination Products* applicable during re-registration for product expired on/after 1 July 2019. |
| **7.** | **Objective and rationale, including the nature of urgent problems where applicable:** Protection of human health or safety; To ensure safety, quality, efficacy and performance of combination products. |
| **8.** | **Relevant documents:**   1. Sales of Drugs Act 1952 (Act 368) 2. Medical Device Act 2012 (Act 737) 3. Control of Drugs and Cosmetics Regulations 1984 4. Drug Registration Guidance Document (DRGD) Second Edition, September 2016, Revised July 2018 |
| **9.** | **Proposed date of adoption:** To be determined  **Proposed date of entry into force:** 1 July 2019 |
| **10.** | **Final date for comments:** 60 days from notification |
| **11.** | **Texts available from: National enquiry point [****X] or address, telephone and fax numbers and email and website addresses, if available, of other body:**  National Pharmaceutical Regulatory Agency (NPRA) Ministry of Health Lot 36, Jalan Universiti 46200 Petaling Jaya Selangor Phone: (+603)78835400 Fax: (+603)79581312 Email: [rosilawati.a@npra.gov.my](mailto:rosilawati.a@npra.gov.my) Website: [www.npra.gov.my](http://www.npra.gov.my)  Guideline for Registration of Drug-Medical Device and Medical Device-Drug Combination Products can be downloaded at this link:  <http://npra.moh.gov.my/images/Guidelines_Central/MDC/Garis_Panduan_13.3.17.pdf>  <https://members.wto.org/crnattachments/2018/TBT/MYS/18_5565_00_x.pdf>  <https://members.wto.org/crnattachments/2018/TBT/MYS/18_5565_01_e.pdf>  <https://members.wto.org/crnattachments/2018/TBT/MYS/18_5565_02_e.pdf> |