NOTIFICATION

The following notification is being circulated in accordance with Article 10.6

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| **1.** | **Notifying Member:** Singapore **If applicable, name of local government involved (Article 3.2 and 7.2):**  |
| **2.** | **Agency responsible:** Health Sciences Authority (HSA)**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:** Health Sciences Authority of Singapore 11 Biopolis Way #11-00, Singapore 138667 Email: HSA\_Intl\_Office@hsa.gov.sg |
| **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):** Therapeutic products which may include products covered under HS code 30, such as 3006 for finished therapeutic products, and 3002 for biologic products (e.g. vaccines) |
| **5.** | **Title, number of pages and language(s) of the notified document:** [1] Health Products (Therapeutic Products) Regulations – Presentation of Therapeutic Products regulations 19 and 20 (5 pages including the schedules referenced; in English) [2] Guidance on Therapeutic Product Registration in Singapore: Applicable labelling requirements in Appendix 7 on Points to consider for Singapore Labelling (2 pages; in English) |
| **6.** | **Description of content:** Therapeutic products in Singapore are subject to labelling requirements that are either legislated by law or mandated as HSA's administrative requirements. Legislated labelling requirements, under the Health Products (Therapeutic Products) Regulations, are subject to HSA's surveillance programme. Administrative labelling requirements, specified in the Guidance on Therapeutic Product Registration in Singapore, are included as part of product registration application. |
| **7.** | **Objective and rationale, including the nature of urgent problems where applicable:** The labelling requirements are in line with international best practices for labelling of pharmaceuticals to protect human health and safety |
| **8.** | **Relevant documents:** Health Products Act - available online at http://statutes.agc.gov.sg/ |
| **9.** | **Proposed date of adoption:** 1 November 2016**Proposed date of entry into force:** 1 November 2016 |
| **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:** Health Sciences Authority of Singapore 11 Biopolis Way #11-00, Singapore 138667 Email: HSA\_Intl\_Office@hsa.gov.sg<https://members.wto.org/crnattachments/2021/TBT/SGP/21_5464_00_e.pdf><https://members.wto.org/crnattachments/2021/TBT/SGP/21_5464_01_e.pdf> |