EXPLANATION NOTE FOR MAKING AN APPLICATION FOR IMPORTER'S LICENCE AND/OR WHOLESALER'S LICENCE FOR THERAPEUTIC PRODUCTS

1. SCOPE

The purpose of this explanation note is to outline the requirements that must be fulfilled for making an application for licence(s) to import and/or wholesale therapeutic products in Singapore.

2. DEFINITIONS

2.1 Importer's Licence (IL) is a licence issued under the *Health Products (Therapeutic Products) Regulations 2016*.
2.2 Wholesaler's Licence (WL) is a licence issued under the *Health Products (Therapeutic Products) Regulations 2016*.
2.3 Therapeutic product (TP) means a health product defined in the First Schedule to the Health Products Act (Chapter 122D).

3. PRE-REQUISITES FOR SETTING UP A COMPANY TO IMPORT AND/OR WHOLESALE THERAPEUTIC PRODUCTS

3.1 PERSONNEL

3.1.1 The Importer and/or Wholesaler shall provide sufficient and competent personnel to carry out day-to-day operations. All personnel should receive proper training in relation to Good Distribution Practice (GDP) standards, operating procedures and safety issues.

3.1.2 A responsible person(s) (RP) must be named in the Importer's Licence (IL) and Wholesaler's licence (WL). The Importer and/or Wholesaler may have one or more RP named in the IL and WL. The RP is a person employed and appointed by the company to implement and maintain an effective quality system that meets HSA's Good Distribution Practice (GDP) Standards. For more information on the responsibilities of the RP, please refer to Guidance Notes on Duties of Responsible Persons Named in the Importer's Licence and Wholesaler's Licence.

3.2 QUALITY SYSTEM

The Importer and/or Wholesaler must maintain an effective quality system that complies with HSA's GDP Standards. This includes but is not limited to the areas such as personnel, premises and equipment, documentation on and handling of

products, etc. For more information on HSA's GDP Standards requirements, please refer to the HSA Guidance Notes On Good Distribution Practice.

3.3 DOCUMENTS REQUIRED

The following information/item(s) are required to be submitted when applying for Importer's Licence and/or Wholesaler's Licence:

- Current layout plan for the premise(s), specifying the storage area(s) (Mandatory)
- Authorisation Letter from Product Registrant (Mandatory for products not registered under your company. Applicable for a company who is an authorized agent to import the registered product and to list the product(s) in the IL)
- Pharmacist Practising Certificate (applicable for a Responsible Person who is a pharmacist registered with Singapore Pharmacy Council)
- Good Distribution Practice (GDP) Standard Operating Procedures
- Good Distribution Practice (GDP) Records or Recording Templates
- List of products to sell by wholesale
- Store Approval Letter

4. AUDIT

A Good Distribution Practice (GDP) audit of the Importer and/or Wholesaler will be arranged and conducted by auditors from Health Sciences Authority. During the audit, the Importer and/or Wholesaler will be assessed for compliance with the legal and GDP requirements, the availability of suitable equipment, storage facilities for the therapeutic products, and system for maintenance of records, procedures and other documentation relating to the operations.

Companies conducting for Restricted Activity(ies) only (i.e. importing TP solely for re-export, for non-clinical use, for vessel/aircraft use) will not be subject to routine GDP audits. However, these companies are expected to comply with the legal obligations and duties of maintaining records of receipt and supply/use, and such records shall be made available to HSA when requested. Please refer to section 6 below on the duties and obligations.

5. TARGET PROCESSING TIMELINE

New Importer's Licence (Full Scope) and Wholesaler's Licence will be issued within 10 working days from the date of the audit close-out (excluding any stop-clock time incurred by the applicant).

6. DUTIES AND OBLIGATIONS OF LICENSED IMPORTERS AND WHOLESALERS

You are reminded of your obligations to ensure the safety and authenticity of the products under the Health Products Act and its regulations. Records of receipt and supply for the traceability of the products are to be maintained and made available to HSA as and when required. Please refer to the regulations under Part 6 of the Health Products (Therapeutic Products) Regulations 2016 and the Health Products Act on the duties and obligations expected of the Importer and Wholesaler.

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