HEALTH SCIENCES AUTHORITY

REGULATORY GUIDANCE

18 APRIL 2022

THERAPEUTIC PRODUCTS GUIDANCE

APPLICATION TO IMPORT A THERAPEUTIC PRODUCT ON CONSIGNMENT BASIS

TPB-GN-003-001

HSA Health Sciences Authority

REVISION HISTORY

Guidance Version (Publish Date)

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Importers who are **neither the registrants nor authorised** by the registrant and intend to import a registered therapeutic product under Regulation 5(1)(b)(vii) of the Health Products (Therapeutic Products) Regulations 2016 will need to apply for an approval for each consignment of the registered therapeutic product to be imported.

Conditions of the Approval on Consignment Basis

- The therapeutic product to be imported must be the same in all aspects as the product that is currently registered in Singapore.
- The batch of the therapeutic product to be imported must meet the approved release specifications of the product that is currently registered in Singapore.
- Importation must be carried out within one year from the date of the approval of the application.
- The approval is only valid if the therapeutic product is still registered in Singapore at the point of importation.
- The applicant company must be a business entity currently registered in Singapore with the Accounting and Corporate Regulatory Authority (ACRA) and has an active CRIS account with the Health Sciences Authority (HSA).
- The applicant company must hold a valid Importer's Licence and a Wholesaler's Licence.
- If the unregistered therapeutic product contains a controlled drug or a psychotropic substance, the applicant company must also apply for a licence to import and wholesale controlled drugs or import authorisation to import therapeutic products containing psychotropic substances, respectively.

Making an Application

Submit an application to import therapeutic products (on consignment basis) via Apply@PRISM.

A non-refundable application fee is applicable at the point of submission. For the current fee chargeable, please refer to our website at: HSA | Import and supply of registered therapeutic product on consignment basis

Each application is restricted to only one consignment of a specific batch of one therapeutic product (registration number specific).

You will need to submit the following documents as supporting documents in your application:

(i) A declaration by the exporting company stating that it is a licensed pharmaceutical dealer in the exporting country.

(ii) A colour scanned copy of the documentary evidence confirming that the therapeutic product to be imported is registered in the exporting country.

(iii) A copy of the supplier's invoice from the exporting country indicating the batch number of the therapeutic product to be imported.

(iii) A certificate of analysis of the consignment batch to be imported by the following:

  (a) The manufacturer of the therapeutic product to be imported, or

  (b) Any testing laboratory accredited by the Singapore Accreditation Council

(iv) The packaging labels and package insert of the following:

  (a) Therapeutic product to be imported; *and*

  (b) Locally-registered therapeutic product.

(v) A letter of undertaking for assuming responsibility for the quality, safety and efficacy of the consignment batch to be imported.

The target turn-around-time is 14 working days from the date of submission, excluding stop-clock time, i.e., the time taken by the applicant to respond to HSA's queries.

Your company will be notified of the outcome of the application via the preferred mode of contact selected in the application. For applications which are approved, an approval number with the format, SINnnnnnC (e.g. SIN00199C) will be issued.

Note: The applicant company must comply with all legal requirements relating to the import, sale and/or supply of the therapeutic product in this consignment approval, including the display of the registration number assigned to this approval on the product packaging, and all other labelling requirements as per APPENDIX 7 Points to Consider for Singapore Labelling, prior to supply of the product in Singapore.

HEALTH SCIENCES AUTHORITY

Health Products Regulation Group
Blood Services Group
Applied Sciences Group

www.hsa.gov.sg

Therapeutic Products Branch (TPB)
Medicinal Product Pre-Market Cluster
Health Products Regulation Group
Health Sciences Authority