HEALTH SCIENCES AUTHORITY

REGULATORY GUIDANCE

**01 JUNE 2023**

# THERAPEUTIC PRODUCTS GUIDANCE

## APPLICATION TO IMPORT A THERAPEUTIC PRODUCT ON CONSIGNMENT BASIS

**TPB-GN-003-002**

HSA Health Sciences Authority

## REVISION HISTORY

Guidance Version (Publish Date)

TPB-GN-003-002 (Version 2; updated 01 June 2023)

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.

## 1. Conditions of the Approval on Consignment Basis

a) The therapeutic product to be imported must be in all respects the same as the product that is currently registered in Singapore:
   i. The chemistry, manufacturing, and controls (CMC) standards must be the same as the registered therapeutic product in Singapore; and
   ii. The package insert supplied with the product must be the same as that currently approved for the registered therapeutic product in Singapore.

b) The therapeutic product must not contain any controlled drug specified under the Misuse of Drugs Act and its Regulations.

c) Importation must be carried out within 6 months from the date of the approval of the application.

d) The approval is only valid if the therapeutic product continues to be registered in Singapore at the point of importation.

e) The imported batches may be subject to testing by HSA under the Product Quality Surveillance Programme; and failure to meet the CMC standards as approved by HSA for the registered therapeutic product will result in the cancellation of the approval for the special consignment.

f) 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).

g) The applicant company must hold a valid Therapeutic Product Importer's Licence and a Therapeutic Product Wholesaler's Licence.

## 2. Making an Application

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

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

## 3. Documentary Requirements

The list of supporting documents required are as below:

a) A colour scanned copy of the documentary evidence issued by the regulatory authority of the exporting country which confirms that the exporting company is licensed to carry out export business for pharmaceutical products in the exporting country.

b) Proof of approval of the therapeutic product in the exporting country:
   i. Approval letter issued by the drug regulatory authority of the exporting country; or
   ii. Reference to any register / listing published by the authority on its website. The information stated on the website must be in English and must allow the confirmation of the product's identity and product's ownership. Such proof of approval must be provided in the form of website screenshot and URL (of the website) for confirmation that the therapeutic product to be imported is registered in the exporting country.

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

d) A certificate of analysis (CoA) of the consignment batch to be imported issued by either:
   i. The finished product manufacturer of the therapeutic product to be imported; or
   ii. A testing laboratory accredited by the Singapore Accreditation Council

(SAC) to perform the specific test(s) in accordance with the accreditation scope as specified in the Schedule of Accreditation listed on the SAC website. The submitted test report should bear the SAC-SINGLAS logo; or

iii. An overseas testing laboratory that is accredited by the International Laboratory Accreditation Cooperation (ILAC) to perform the specific test(s) in accordance with the accreditation scope. The submitted test report should bear the ILAC mark alongside with logo of an accreditation body.

e) Documentary evidence that the therapeutic product to be imported is supplied with the same container closure system (CCS) as that approved for the registered product. Such evidence can be in the form of either:

i. Product label which states the type of CCS used; or

ii. Proof of approval from the exporting country which states the approved CCS information.

f) Documentary evidence that the therapeutic product to be imported has the same requirement for storage condition as that approved for the registered product. Such evidence can be in the form of either:

i. Product label which states the recommended storage condition of the product; or

ii. Proof of approval from the exporting country which states the approved storage condition of the product.

g) Documentary evidence that the therapeutic product to be imported has the same shelf-life as that approved for the registered product. Such evidence can be in the form of either:

i. The product's outer carton which reflects both the manufacturing and expiry dates of the imported product; or

ii. Proof of approval from the exporting country which states the approved shelf-life of the product.

iii. CoA issued by the finished product manufacturer which includes the manufacturing date and accompanied by the product's outer carton

which states the expiry date.

h) A declaration letter stating that the consignment product will be supplied with the Singapore approved package insert.

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

## 4. Fees and Target Turn-Around-Time

For the current fee chargeable, please refer to our website at: HSA | Import and supply of registered therapeutic product on consignment basis

**The application fee is paid at the point of application submission and is non-refundable.** The target turn-around-time is 14 working days from the date of submission of complete documents, excluding stop-clock time, i.e., the time taken by the applicant to respond to HSA's queries.

The applicant 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 for import, sale and/or supply of the therapeutic product to which the consignment approval relates, including the display of the assigned registration number on the product packaging 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

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