

HEALTH
SCIENCES
AUTHORITY

REGULATORY GUIDANCE

01 NOVEMBER 2016

THERAPEUTIC PRODUCTS GUIDANCE

**APPLICATION TO IMPORT A THERAPEUTIC
PRODUCT ON CONSIGNMENT BASIS**

TPB-GN-003-000



REVISION HISTORY

Guidance Version (Publish Date)

TPB-GN-003-000 (uploaded 23 Sep 2016)

1. This guidance is intended to assist you in your application to import a registered therapeutic product on consignment basis under Regulation 5(b)(vii) of the Health Products (Therapeutic Products) Regulations 2016.
2. Your company applying for importing a consignment of a registered therapeutic product 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). You may click on [CRIS@HSA](#) for more information about CRIS (Client Registration and Identification Service).
3. The application must be made online via [Apply@PRISM](#). Each application is restricted to ONE therapeutic product only. A separate application is required for each additional therapeutic product. The therapeutic product to be imported must be, in all respects, the same as the therapeutic product that is currently registered in Singapore.
4. In addition to the consignment approval, your company must obtain an Importer's Licence and a Wholesaler's Licence for the import and supply of the therapeutic product. If the therapeutic product contains a controlled drug or a psychotropic substance, the following requirements will also apply (as applicable):
 - (i) Licence to Import Controlled Drugs if the therapeutic product contains a substance controlled under the Misuse of Drugs Regulations ([click here to apply via PRISM](#)).
 - (ii) Approval for Therapeutic Product Containing Psychotropic Substances if the therapeutic product contains a psychotropic substance ([click here to apply via PRISM](#)).

5. If your company does not have an active Importer's Licence or an Importer's Licence with the relevant import activity, you will need to apply for the required licences via Apply@PRISM.
6. Please note that the batch of the therapeutic product to be imported must meet the approved release specifications of the corresponding registered therapeutic product to which your application relates.
7. You will need the following documents to support your application:
 - (i) A declaration by the exporting company indicating its status as a licensed pharmaceutical dealer in the exporting country.
 - (ii) Documentary evidence to show 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 therapeutic product batch to be imported from the following:
 - (a) The manufacturer of the therapeutic product to be imported, *or*
 - (b) Any testing laboratory accredited by the [Singapore Accreditation Council](#)
 - (iv) Packaging and labelling 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 therapeutic product batch to be imported.
8. Your company will be notified of the outcome of the application via the preferred mode of contact selected in the product registration.
9. Approval is granted to a single consignment of the specified batch(es) of the therapeutic product made in the application. Importation must be carried out within 1 year from the date of the approval, subject to the validity of the corresponding Importer's Licence.
10. Your company must comply with all legal requirements relating to the import, sale and/or supply of the therapeutic product to which the consignment approval relates, including the display of the registration number assigned to this approval on the product packaging, your company's name and address, and other labelling requirements, prior to any sale being made in Singapore.
11. For any enquiries, please contact the Therapeutic Products Branch (TPB) at email: HSA_TP_Enquiry@hsa.gov.sg

HEALTH SCIENCES AUTHORITY

Health Products Regulation Group
Blood Services Group
Applied Sciences Group

www.hsa.gov.sg

CONTACT INFORMATION

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