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THERAPEUTIC PRODUCTS GUIDANCE

IMPORT AND SUPPLY OF AN UNREGISTERED
THERAPEUTIC PRODUCT FOR PATIENTS' USE

TPB-GN-004-002



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1. INTRODUCTION

This guidance outlines the special access route under regulation 5(1)(b)(i) and 51 of the *Health Products (Therapeutic Products) Regulations* for the import of an unregistered therapeutic product, as well as its subsequent supply under regulation 58(1)(f) and (g) of the *Regulations*.

These regulations serve to facilitate access to life-saving therapies where there is an unmet medical need, such as in situations where treatment option is absent and the patient's health will be clinically compromised without treatment with the unregistered therapeutic product.

2. REQUIREMENTS FOR IMPORT AND SUPPLY OF UNREGISTERED THERAPEUTIC PRODUCTS FOR PATIENTS' USE

Under the special access route, an unregistered therapeutic product may be imported by any of the following:

- a) A licensed hospital or clinic¹ for use by a registered doctor or dentist practising at that hospital or clinic and for use in any patient under the care of that doctor or dentist;
- b) A licensed retail pharmacy² acting on behalf of a registered doctor or dentist pursuant to a valid prescription; or
- c) A company acting on behalf of a licensed hospital or clinic.

2.1 Importer's and Wholesaler's Licence

A company acting on behalf of a hospital or clinic is required to obtain a valid Therapeutic Products Importer's Licence (TPIL) prior to carrying out any import

¹ Hospital or clinic licensed under the *Private Hospitals and Medical Clinics Act (PHMCA) (Cap. 248)*

² Retail pharmacy licensed under *Health Products (Licensing of Retail Pharmacies) Regulations 2016*

activity. The company must appoint one or more persons as a responsible person to be named in the TPIL, and the responsible person must be a qualified pharmacist³.

The company is also required to hold a valid Therapeutic Products Wholesaler's Licence (TPWL) in order to supply the unregistered therapeutic product to the hospital or clinic.

A hospital or clinic importing an unregistered therapeutic product directly for use in a patient treated at that hospital or clinic is not required to hold TPIL. A retail pharmacy acting on behalf of a registered doctor or dentist may also import an unregistered therapeutic product that is intended for use a patient pursuant to a valid prescription without holding a TPIL.

In all cases, HSA's prior approval must be obtained for each consignment of the unregistered therapeutic product to be imported (see section 2.2).

2.2 Consignment Approval

Pursuant to regulation 51(3) of the *Regulations*, HSA's prior approval must be obtained for each consignment of the unregistered therapeutic product to be imported, and the amount imported must not exceed a total dosage of 3 months per patient based on the manufacturer's recommended dosing regimen. Any application requesting for quantity exceeding the specified amount must be accompanied by substantive justification.

The use of unregistered therapeutic products should only be reserved for situations where there is no alternative registered treatment available. **Clinicians are reminded to exercise discretion in their clinical decisions on using unregistered therapeutic products. These products are not evaluated by HSA for quality,**

³ a registered pharmacist under the *Pharmacists Registration Act* who holds a valid practising certificate and is in active practice, as defined in regulation 2 of the *Pharmacists Registration (Practising Certificates) Regulations 2008* (G.N. No. S 438/2008).

efficacy and safety, and that the clinicians are fully responsible for the use of such unregistered products in their patients.

The overall requirements are summarized in the table below:

Importer	Importer's Licence	Wholesaler's Licence	Consignment Approval
Licensed hospital or clinic	No	No	Yes
Licensed retail pharmacy	No	No	Yes
Company importing on behalf of a licensed hospital or clinic	Yes	Yes	Yes

To submit an application for consignment approval to import and supply an unregistered therapeutic product for patient's use, please complete the online application form ([click here](#) or scan the QR code for the application form).



QR code for the online application form

Applicants will require CorpPass to login and access the online application form.

Please refer to **Annex A** on Guidance Notes for the Submission of the Online Application form, and **Annex B** on Frequently Asked Questions (FAQs) on the Online Application Form.

2.3 Labelling Requirements

The package or container of any therapeutic product imported through the special access route must be labelled with all of the following information:

- a) the proprietary name of the therapeutic product
- b) the name and appropriate quantitative particulars of any active ingredient of the therapeutic product;
- c) an appropriate control number, such as a serial number, batch number or lot number;
- d) the expiry date of the therapeutic product;
- e) where the therapeutic product contains any of the following substances, *viz.* tartrazine, benzoic acid or sodium benzoate, the therapeutic product must be labelled with a statement declaring the presence of that substance.

All information must be legible, indelible and written in English.

Any unregistered therapeutic product supplied to a hospital or a clinic must be accompanied by the package insert (PI) or product information. If the original PI accompanying the product is not written in English, an English-translated PI must be provided for each supply of the unregistered therapeutic product.

Any re-labelling of the product information for the purpose of fulfilling the requirements as described in this section can be carried out by the importing company without a Manufacturer's Licence.

2.4 Requirement for Other Licences/Approval for Specific Products

If the unregistered therapeutic product contains a controlled drug or a psychotropic substance, the following requirements will also apply:

- a) A Licence to Import Controlled Drugs under the Misuse of Drugs Regulations

[\(click here or scan the QR code to apply\).](#)



QR code for the application of licence to import controlled drug

b) Approval to import therapeutic products containing psychotropic substances

[\(click here or scan the QR code to apply\).](#)



QR code for the application of licence to import psychotropic substances

3. TRANSFER OF UNREGISTERED THERAPEUTIC PRODUCTS BETWEEN PHMCA-LICENSED HOSPITALS OR CLINICS

A hospital or clinic may transfer an unregistered therapeutic product imported under the special access route to another hospital or clinic for the treatment of a patient treated at that hospital or clinic, without additional approval or licensing requirement.

The transferring and receiving hospitals or clinics are required to keep records of the receipt and supply as described in Section 4 below.

4. DUTIES AND OBLIGATIONS OF IMPORTERS, WHOLESALERS AND SUPPLIERS (INCLUDING HOSPITALS, CLINICS AND RETAIL PHARMACIES)

4.1 Duties to Maintain Records of Receipt and Supply

Importers, including hospitals, clinics and retail pharmacies importing under regulation 51 of the *Regulations*, and wholesalers of unregistered therapeutic products must maintain records of every receipt and wholesale supply of the unregistered therapeutic products, respectively. The records must be retained for at least 2 years from the date of supply, and must be made available when requested by HSA.

Records of each receipt must contain the following information:

- a) the proprietary name or description of the therapeutic product, if the therapeutic product is supplied by a manufacturer, importer or wholesaler, as the case may be;
- b) the date on which the therapeutic product is received;
- c) the name and address of the company from which the therapeutic product is received;
- d) the quantity of the therapeutic product received; and
- e) the identification number (including the control number, lot number, batch number or serial number) of the therapeutic product received.

Records of each wholesale supply must contain the following information:

- a) the proprietary name or description of the therapeutic product;
- b) the date on which the therapeutic product is supplied;
- c) the name and address of the company to which the therapeutic product is supplied;
- d) the quantity of the therapeutic product supplied; and
- e) the identification number (including the control number, lot number, batch number or serial number) of the therapeutic product supplied.

In addition, the record keeping requirements under the *Misuse of Drugs Regulations* must be complied with if the unregistered therapeutic product contains one or more controlled drugs, in accordance with the form of Register as prescribed in the Fifth Schedule of the Regulations. The Register must be retained for at least 3 years from the date of which the last entry is made.

4.2 Duties to Maintain Records of Defects and Adverse effects

Importers, including hospitals, clinics and retail pharmacies importing under regulation 51 of the *Regulations*, of unregistered therapeutic products must maintain records of any defect or any adverse effect arising from the use of the therapeutic product. The records must be retained for at least 2 years after the expiry date of the therapeutic product and be made available when required by HSA.

The records must contain the following information:

- a) the proprietary name or description of the therapeutic product;
- b) the date on which the importer first became aware of the event or occurrence;
- c) the identification number (including the control number, lot number, batch number or serial number) of the therapeutic product; and
- d) the nature of the defect or adverse effect.

4.3 Duties to Report Defects and Serious Adverse Reactions

Importers, including hospitals, clinics and retail pharmacies importing under regulation 51 of the *Regulations*, and wholesalers of unregistered therapeutic products must report any defect or any serious adverse reactions arising from the use of the unregistered therapeutic product to HSA.

Any defects representing a serious threat to persons or public health must be reported to HSA within 48 hours of becoming aware of the defect. In all other cases, the defect must be reported within 15 calendar days.

Any serious adverse reactions arising from the use of the unregistered therapeutic product must be reported to HSA as soon as possible within 15 calendar days.

Please also refer to the *Guidance for Industry - Reporting and Recall of Defective Therapeutic Products* for details on reporting of product defects to HSA, and to the *Guidance for Industry – Post-marketing Vigilance Requirements for Therapeutic Products*.

4.4 Duties to Notify HSA Concerning Recall

Importers, including hospitals, clinics and retail pharmacies importing under regulation 51 of the *Regulations*, and wholesalers who intend to recall an unregistered therapeutic product must notify HSA of the intended recall as soon as possible within 24 hours before initiating the recall.

Please also refer to the *Guidance for Industry - Reporting and Recall of Defective Therapeutic Products*.

ANNEX A

Guidance Notes on the Submission of the Online Application Form for Importation of a Consignment of Unregistered Therapeutic Product for Patients' Use

1. The online application form (Sections A to E) must be completed by the applicant who is the person importing the unregistered therapeutic product.
2. Each application is specific to a single product. The doctor, dentist, pharmacist or the healthcare institution who is requesting for the unregistered therapeutic product is referred to as the Requester.
3. Up to 3 requests for the same application type (Named-Patient or Buffer Stock) and for the same product can be submitted in one application. Each application must be accompanied by the respective Signed Request(s) which are completed and signed by each Requester. The Requester is required to sign a declaration that he or she assumes full responsibility for the use of the unregistered therapeutic product on the patient ([click here](#) or scan the QR code for the Signed Request form).



QR code for the Signed Request form

4. The application type is determined by the purpose of the request as follows:

Type of application	Purpose of the request
<p>Named-Patient application</p>	<p>(a) To import and supply an unregistered therapeutic product which presents a life-saving treatment option to the patient whose condition would be clinically compromised without the requested therapy, and that there is no effective alternative therapy registered in Singapore.</p> <p>OR</p> <p>(b) To import and supply a novel unregistered therapeutic product which offers a substantive clinical advantage over registered therapies and is expected to provide significant improvement in the patient's clinical outcome</p> <p><i>Important note:</i> <i>The application must be accompanied by the clinical justification(s) of unmet medical needs and reasons for not using current registered therapeutic products.</i></p>
<p>Buffer Stock application</p>	<p>To import and supply the unregistered therapeutic product which is a standard essential medicine, to be kept as stocks in hospitals or clinics to meet the critical needs of Singapore's healthcare system.</p> <p><i>Important note:</i></p>

	<p><i>Only medicines listed on the MOH Standard Drugs List or the Hospital Pharmacy and Therapeutics List are eligible for this category of application.</i></p>
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The applicant must ensure that the purpose of request as indicated by the Requester in the Signed Request, is correctly selected when making the application.

5. For an unregistered product which is imported by the applicant for the first time, the application must be accompanied by the outer and inner labels as well as package insert of the product.
6. For applications of an unregistered product containing methadone, an enclosure form which includes the following information must be submitted:
 - a. Patient's particulars;
 - b. Doctor's particulars;
 - c. Indication;
 - d. Dosage regimen; and
 - e. Quantity requested.

For applicants who require a copy of the enclosure form, please contact us at HSA_TP_SAR@hsa.gov.sg.

9. The target processing timeline is 14 working days from the date of receipt of the application, excluding stop-clock time. The stop-clock time starts when HSA requests for clarification or additional information, and ends upon receipt of a satisfactory response.

ANNEX B

Frequently Asked Questions (FAQs) on the Online Application Form

Q1: Can I still submit an application via fax using the current PDF application form?

A: You may submit an application via fax during the transition period from 2 September 2019 till 1 November 2019. However, fax submission will be discontinued from 2 November 2019. Applicants are strongly encouraged to switch to the online submission during the transition period.

Q2: Why can't I see the application form at the link provided?

A: Applicants have to login via CorpPass to access the online application form. For more information on CorpPass or to register for a CorpPass account, please click [here](#).

Q3: If I am importing a product on behalf of a Requester (e.g. doctor), does the Requester need to log in via CorpPass to submit the application too?

A: The Requester is not required to log in via CorpPass to access the application. However, you must obtain the Requester's Signed Request before submitting the online application (click [here](#) or scan the QR code to download the Signed Request form).



QR code for the Signed Request form

Q4: How will I know if my online application is received by TPB?

A: You will receive an email acknowledgment containing the application details and a unique reference number upon successful submission of your application. The unique reference number would serve to be the application number.

The unique reference number is a 24 alpha-numeric character, e.g. "Ref: 5d42d72a2779ec00138908c1"

For future correspondences with HSA regarding your application, please quote this application number.

Q5: Can I make changes to the application form after the submission?

A: Changes cannot be made to the application form once submitted. If you have made errors in your submission, you can withdraw the application and re-submit using a new application. To withdraw your application, please notify us at HSA_TP_SAR@hsa.gov.sg and quote the application number.

Q6: Is there a limit to the file size of the attachments?

A: You may attach files up to the maximum size up to 1 MB as specified in the respective fields in the application form. If you wish to submit multiple files, it is recommended to compress them into a zip folder prior to uploading.

Q7: How do I know if my application is approved?

A: You will be notified of the outcome of your application via email. For approved applications, the application number would also serve as your consignment approval number.

For enquiries, please contact us at: HSA_TP_SAR@hsa.gov.sg.

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