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THERAPEUTIC PRODUCTS GUIDANCE

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

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HSA
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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.

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

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, clinic or nursing home[1] for use by a registered doctor or dentist practicing at that hospital, clinic or nursing home for use on any patient under the care of that doctor or dentist;

[1] *Specified healthcare service licensee under the Healthcare Services Act 2020.*

b) A licensed retail pharmacy[2] 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, clinic or nursing home.

The conditions for using the "named-patient" special access route are as follows:

a) The clinician must obtain and document informed consent from the patient or patient's guardian for the use of the unregistered therapeutic product on the patient;
b) The clinician must furnish a declaration that the use of the unregistered therapeutic product complies with the Ministry of Health's allowable practice and applicable law;
c) The clinician must furnish a declaration that the use of the unregistered therapeutic product complies with the clinical practice allowed under the Singapore Medical or Dental Council's Ethical Code and Ethical Guidelines.

2.1 Importer's and Wholesaler's Licence

A company acting on behalf of a hospital, clinic or nursing home is required to obtain a valid Therapeutic Products Importer's Licence (TPIL) prior to carrying out any import 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 pharmacist[3].

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, clinic or nursing home.

A hospital, clinic or nursing home importing an unregistered therapeutic product directly for use on a patient treated at that hospital, clinic or nursing home is not required to hold TPIL. A retail pharmacy acting on behalf of a registered doctor or

[2] Retail pharmacy licensed under Health Products (Licensing of Retail Pharmacies) Regulations 2016.
[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).

dentist may also import an unregistered therapeutic product that is intended for use on 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 2.3).

2.2 Documentary Requirements for Investigational Therapies

Any "named-patient" application seeking to import and / or supply an investigational therapeutic product that is still undergoing testing in clinical trials:

a) Which is not approved by any HSA's reference agency[4]; or
b) Which is rejected/ withdrawn/ pending deferral by any HSA's reference agency for safety or efficacy reasons; or
c) Where the clinician's intended use is not approved by any HSA's reference agency and not documented in established clinical guidelines that are recognised and adopted in local clinical practice,

The clinician is required to furnish documentary proof of professional consensus in accordance with Singapore Medical Council's (SMC) Ethical Code and Ethical Guidelines Section B6 paragraph 4 and SMC's Handbook on Medical Ethics Section B6.1 on the use of innovative therapies in a dire clinical situation. In accordance with SMC's guidance, professional consensus may be obtained from one or more local peer clinician(s) on the use of the innovative therapy in the specific context of the patients' clinical situation which may be in the form of email correspondence or other documentation. The requesting clinician must fulfil one of the following for obtaining professional consensus:

i. Consensus obtained from a multidisciplinary team or tumour board within the healthcare institution; or

[4] *HSA's reference agencies consist of the following: Australia Therapeutic Goods Administration, European Medicines Agency, Health Canada, Swissmedic, UK Medicines and Healthcare Products Regulatory Agency and US Food and Drug Administration.*

ii. Consensus obtained from one or more independent clinician(s) with the relevant medical specialty practising at a separate healthcare institution under a different Healthcare Services Act (HCSA) licence, and who are not directly involved in the patient's care. The clinician(s) providing professional consensus must declare that they do not have any conflict of interest.

2.3 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 validity period of the consignment approval is specified in **Annex A**. The overall requirements are summarized in the table below:

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

To submit an application for consignment approval to import and supply an unregistered therapeutic product for patient's use, please use the application form and Signed Request form for the respective application type in the table below).

Application Type	Application Form
Named-Patient	Please click here or scan the QR code below for the online application form. The application must be accompanied by the Signed Request form for Named-Patient use. Please click here to download the Signed Request form for Named-Patient application.
Buffer Stock	Please click here or scan the QR code below for the online application form. The application must be accompanied by the Signed Request form for Buffer Stock. Please click here to download the Signed Request form for Buffer Stock application.

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.

2.4 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, clinic or nursing home 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.

2.5 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 LICENSED HOSPITALS, CLINICS OR NURSING HOMES

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

The transferring and receiving hospitals, clinics or nursing homes 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, NURSING HOMES AND RETAIL PHARMACIES)

4.1 Duties to Maintain Records of Receipt and Supply

Importers, including hospitals, clinics, nursing homes 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, nursing homes 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, nursing homes and 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, nursing homes 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 hospital, clinic or nursing home who is requesting for the unregistered therapeutic product is referred to as the Requester.

3. Up to 2 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) for the relevant application type 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 for Named-Patient Application Type and the Signed Request for Buffer Stock Application Type).

QR code for the Signed Request forms

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

Type of application	Consignment approval validity	Purpose of the request
Named-Patient	6 months[#]	(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. OR (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 *Important notes:* *The application must be accompanied by the clinical justification(s) of unmet medical needs and reasons for not using current registered therapeutic products.* *Applications seeking to import/supply an investigational therapeutic product that is still*

		undergoing testing in clinical trial should be accompanied by documentary proof of professional consensus in accordance with Singapore Medical Councils' (SMC) Ethical Code and Ethical Guidelines Section B6 paragraph 4 and SMC's Handbook on Medical Ethics Section B6.1 on the use of innovative therapies in a dire clinical situation. In accordance with SMC's guidance, professional consensus may be obtained from one or more local peer clinician(s) on the use of the innovative therapy in the specific context of the patients' clinical situation which may be in the form of email correspondence or other documentation. The requesting clinician must fulfil one of the following for obtaining professional consensus: *i. Consensus obtained from a multidisciplinary team or tumour board within the healthcare institution; or* *ii. Consensus obtained from one or more independent clinician(s) with the relevant medical specialty practising at a separate healthcare*

		institution under a different Healthcare Services Act (HCSA) licence, and who are not directly involved in the patient's care. The clinician(s) providing professional consensus must declare that they do not have any conflict of interest.
Buffer Stock	12 months[#]	(a) To import and supply the unregistered therapeutic product which is a standard essential medicine listed on the **MOH Standard Drugs List**, to be kept as stocks in hospitals/ clinics/ or nursing homes to meet the critical needs of Singapore's healthcare system. OR (b) To import and supply the unregistered therapeutic product which is a standard essential medicine listed on the **Hospital Pharmacy and Therapeutics List**, to be kept as stocks in hospitals to meet the critical needs of the hospitals.

[#]The approved quantities may be imported in separate consignments within the validity period.

5. 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.

6. For medicines which are on both the MOH SDL and the Hospital P&T List, the MOH SDL option should be selected.

7. 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.

8. 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: How do I access the application form after clicking 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.

Q2: 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 for the relevant application type before submitting the online application (click here or scan the QR code to download the Signed Request form for Named-Patient Application Type and the Signed Request form for Buffer-Stock Application Type).

QR code for the Signed Request forms

Q3: How do I know if my online application is received by HSA?

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.

Q4: Can I make changes to the application form after the submission?

A: Changes cannot be made to the application form once it is submitted. If you wish to amend your submission, you can withdraw the application and re-submit a fresh application. To withdraw your application, please notify us using the following online application enquiry form.

QR code for the online application enquiry form

Q5: Is there a limit to the file size of the attachments?

A: You may attach files up to a maximum size of 3 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.

Q6: How do I know if my application is approved?

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

If the Requester would also like to be notified of the outcome of the application, please include the Requester's email address under the field "Contact Email".
For enquiries related to a submitted application, please contact us using the following online application enquiry form.



QR code for the online application enquiry form

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