REPUBLIC OF SINGAPORE
HEALTH SCIENCES AUTHORITY

HEALTH PRODUCTS ACT
CHAPTER 122D

APPLICATION FOR CONSIGNMENT APPROVAL OF AN UNREGISTERED THERAPEUTIC PRODUCT FOR PATIENTS' USE

Please refer to the latest Guidance on HSA website before filling up the form. All applicants must comply with the Health Products Act (HPA) and its regulations.

SECTION A - PRODUCT DETAILS *(To be completed by Applicant)*

Product Name (*including dosage form & strength*):	Requested Quantity:
Name & Strength of Active Ingredient(s):	Pack Size:
	Route of Administration:
Name & Country of Manufacturer:	

SECTION B - PARTICULARS OF IMPORTER *(To be completed by Importer)*

Name & Address of Importer:	Name of Applicant:
	Designation:
Declaration 1. I hereby declare that the import of the unregistered therapeutic product is pursuant to the instructions of the healthcare institution and/or doctor specified in section D of this form, and all the information provided by me in this form is true and accurate. 2. I am fully aware that the therapeutic product requested in this application is not registered under the HPA and has not been evaluated for its quality, safety and efficacy by the HSA **3. I acknowledge that if any of the information provided by me in this form is false or inaccurate, I will be liable to prosecution for providing false information under the Penal Code.** _____ _____ Signature of Applicant Date	*Applicable to companies importing on behalf of a healthcare institute*: Importer's Licence No: Unique Entity No. (UEN): *Applicable to licensed retail pharmacies importing on behalf of a registered doctor or dentist pursuant to a valid prescription:* Pharmacy Licence No: Email Address: Tel No. : Fax No. :

SECTION C – APPROVAL FOR CONSIGNMENT *(To be completed by HSA)*

Approval No.:	**Date:**
This consignment approval is valid for 6 months from the date of approval. _____ *for Licensing Authority*	

SECTION D – UNREGISTERED THERAPEUTIC PRODUCT *(To be completed by the requesting doctor/dentist)*

Purpose *(Tick appropriate box)*	☐ Named-Patient Indicate the number of patients:_____	☐ Buffer Stock*
Full Name of Product# (including dosage form & strength)		
Unit Quantity Required (*Maximum 3 months*)		
Dosage Regimen		
Indication		
Clinical justification of unmet medical needs		
Reason(s) for not using current registered therapeutic products		
Doctor's/Dentist's Particulars & Declaration	Name: Registration No. : Department: Name of Hospital/Clinic: Address of Hospital/Clinic: Tel. No.: Email: <u>Declaration</u>: 1. I am fully aware that the therapeutic product requested in this application is not registered under the HPA and has not been evaluated for its quality, safety and efficacy by the HSA and I am fully responsible for its use on my patient. 2. I declare that the unregistered therapeutic product is required for the treatment of a patient under my care whose condition will be clinically compromised without the unregistered therapeutic product. 3. I am fully aware that consignment approval by HSA is not an endorsement of the clinical use by the Authority. 4. I declare that the use of the unregistered therapeutic product is in compliance with Ministry of Health's allowable practice and applicable laws. 5. I undertake to maintain records of the name, NRIC/identification document number and contact details of the patient who received the unregistered therapeutic product under my care. 6. **I hereby declare that all the information provided by me in this form is true and accurate. I acknowledge that if any of the information provided by me in this form is false or inaccurate, I will be liable to prosecution for providing false information under the Penal Code.** Signature:_____ Date: _____	

Applicable to healthcare institutions and clinics only.
#Please complete additional form for products containing methadone.

SECTION D – UNREGISTERED THERAPEUTIC PRODUCT *(To be completed by the requesting pharmacist)*

Purpose *(Tick appropriate box)*	☐ Buffer Stock*
Full Name of Product[#] (including dosage form & strength)	
Unit Quantity Required (***Maximum 3 months***)	
Dosage Regimen	
Indication	
Clinical justification of unmet medical needs	
Reason(s) for not using current registered therapeutic products	
Pharmacist's Particulars & Declaration	Name: Registration No. : Department: Name of Hospital/Clinic: Address of Hospital/Clinic: Tel. No.: Email: <u>Declaration</u>: 1. I am fully aware that the therapeutic product requested in this application is not registered under the HPA and has not been evaluated for its quality, safety and efficacy. The unregistered therapeutic product is requested pursuant to a prescription given by a doctor/dentist. 2. I undertake to maintain records of the name, NRIC/identification document number and contact details of the patient who received the unregistered therapeutic product. 3. **I hereby declare that all the information provided by me in this form is true and accurate. I acknowledge that if any of the information provided by me in this form is false or inaccurate, I will be liable to prosecution for providing false information under the Penal Code.** Signature: _____ Date: _____

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