


<p>REPUBLIC OF SINGAPORE HEALTH SCIENCES AUTHORITY</p> <p>HEALTH PRODUCTS ACT CHAPTER 122D</p> <p>APPLICATION FOR CONSIGNMENT APPROVAL OF AN UNREGISTERED THERAPEUTIC PRODUCT FOR PATIENTS' USE</p>	
<p><i>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.</i></p>	

SIGNED REQUEST FOR BUFFER STOCK APPLICATION TYPE <i>(To be completed by the requesting doctor, dentist or pharmacist)</i>	
Purpose	<input type="checkbox"/> 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. Only medicines listed on the MOH Standard Drugs List or the Hospital Pharmacy and Therapeutics List are eligible for this category of application.
The medicine is listed on the following list(s) <i>(Tick only one box)</i>	<input type="checkbox"/> MOH Standard Drug List OR <input type="checkbox"/> Hospital Pharmacy and Therapeutic List Note: If the drug is listed on both the MOH Standard Drug List and the Hospital Pharmacy and Therapeutic List, please tick MOH Standard Drug List only.
Product Name	
Dosage Form <i>(Film-coated tablet, capsule, injection etc.)</i>	
Strength <i>(mcg, mg, mg/ml etc.)</i>	
Required Quantity <i>(Indicate quantity and unit of measure e.g. 3 boxes, 3 vials, 3 syringes etc.)</i>	
Indication	
Dosage Regimen	

Clinical Justification of Unmet Medical Needs and Reason(s) for not Using Current Registered Therapeutic Products		
Particulars of Doctor, Dentist or Pharmacist	Name:	Registration Number: <i>(MCR, DCR or PRN number)</i>
	Department:	
	Name & Address of Hospital or Clinic:	
	Contact Number:	Email:
COMPLETE THIS DECLARATION IF THE REQUESTER IS A DOCTOR OR DENTIST		
<p><input type="checkbox"/> 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.</p> <p><input type="checkbox"/> 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.</p> <p><input type="checkbox"/> I am fully aware that consignment approval by HSA is not an endorsement of the clinical use by the Authority.</p> <p><input type="checkbox"/> I declare that the use of the unregistered therapeutic product is in compliance with Ministry of Health's allowable practice and applicable laws.</p> <p><input type="checkbox"/> 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.</p> <p><input type="checkbox"/> 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.</p> <p>Signature: _____ Date: _____</p>		
COMPLETE THIS DECLARATION IF THE REQUESTER IS A PHARMACIST		
<p><input type="checkbox"/> 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.</p> <p><input type="checkbox"/> I undertake to maintain records of the name, NRIC/identification document number and contact details of the patient who received the unregistered therapeutic product.</p> <p><input type="checkbox"/> 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.</p> <p>Signature: _____ Date: _____</p>		

Tick all boxes in the applicable declaration.