


REPUBLIC OF SINGAPORE HEALTH SCIENCES AUTHORITY HEALTH PRODUCTS ACT 2007 APPLICATION FOR CONSIGNMENT APPROVAL OF AN UNREGISTERED THERAPEUTIC PRODUCT FOR PATIENTS' USE		
<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>		
SIGNED REQUEST FOR NAMED-PATIENT APPLICATION TYPE <i>(To be completed by the requesting doctor or dentist)</i>		
Purpose <i>(Tick only one box)</i>	To import and supply an unregistered therapeutic product which presents a life-saving treatment option to a patient under my care whose condition will be clinically compromised without the requested therapy, and that there is no effective alternative therapy registered in Singapore. OR 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 clinical outcome of a patient under my care. Note: Clinical justification(s) must be provided.	
Conditions of Using this Special Access Route <i>(Tick the box to indicate that you have read and agree to the conditions)</i>	<ol style="list-style-type: none"> 1. The use of the unregistered therapeutic product is in compliance with Ministry of Health's allowable practice and applicable laws. 2. The use of the unregistered therapeutic product is in compliance with the clinical practice allowed under the Singapore Medical or Dental Council's Ethical Code and Ethical Guidelines. 3. Informed consent from the patient for the use of this unregistered therapeutic product will be obtained and documented. <input type="checkbox"/> I have read and agree to the above conditions.	
Type of Application <i>(Tick only one box)</i>	New application	Repeat application
Number of Named-Patients <i>(Please indicate a number)</i>		
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 <i>(Tick only one box)</i>	<input type="checkbox"/> The patient(s) have failed or tried registered therapies but there was inadequate response. Please list the registered therapies the patient(s) have failed or tried: Other reasons, please specify:	
Supportive Evidence on the use of the Product in Named-Patient Applications <i>(Tick the appropriate box)</i> <i>(Supportive evidence e.g. clinical practice guidelines or scientific literature should be submitted to support the use of the product, where appropriate. HSA may request for these information to assess the application if they had not been submitted and this will lengthen the processing timeline of the application)</i>	<input type="checkbox"/> I will be submitting additional supportive evidence. <i>List the references submitted:</i> 1. 2. 3. <input type="checkbox"/> I am not submitting any additional supportive evidence.	
Particulars of Doctor or Dentist	Name:	Registration Number: <i>(MCR or DCR number)</i>
	Department:	
	Practicing address:	
	Contact Number:	Email:
DOCTOR'S OR DENTIST'S DECLARATION		
<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. <input type="checkbox"/> I am fully aware that the consignment approval by HSA for my hospital, clinic or nursing home ¹ to bring in the unregistered therapeutic product is not an endorsement of the clinical use by the Authority. <input type="checkbox"/> I hereby declare that I am fully responsible for the use of the unregistered therapeutic product. <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. <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.		
Signature: _____		Date: _____

Tick all boxes in the declaration.

¹ Specified healthcare service licensee under the Healthcare Services Act 2020; nursing home licensee under the Private Hospitals and Medical Clinics Act 1980.