


REPUBLIC OF SINGAPORE HEALTH SCIENCES AUTHORITY HEALTH PRODUCTS ACT CHAPTER 122D 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>	<input type="checkbox"/> 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 <input type="checkbox"/> 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 Number of patients: _____ Note: Clinical justification(s) must be provided.	
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		

<p>Supportive Evidence on the use of the Product in Named-Patient Applications (Tick the appropriate box)</p> <p>(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)</p>	<p><input type="checkbox"/> I will be submitting additional supportive evidence.</p> <p>List the references submitted:</p> <ol style="list-style-type: none"> 1. 2. 3. 4. 5. <p><input type="checkbox"/> I am not submitting any additional supportive evidence.</p>	
<p>Particulars of Doctor or Dentist</p>	<p>Name:</p>	<p>Registration Number: (MCR, DCR or PRN number)</p>
	<p>Department:</p>	
	<p>Name & Address of Hospital or Clinic:</p>	
	<p>Contact Number:</p>	<p>Email:</p>
<p>DOCTOR'S OR DENTIST'S DECLARATION</p>		
<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: _____</p>		<p>Date: _____</p>

Tick all boxes in the declaration.