REPUBLIC OF SINGAPORE
HEALTH SCIENCES AUTHORITY

HEALTH PRODUCTS ACT 2007

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.

SIGNED REQUEST FOR NAMED-PATIENT APPLICATION TYPE *(To be completed by the requesting doctor or dentist)*

Purpose *(Tick only one box)*	☐ 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 *(Tick the box to indicate that you have read and agree to the conditions)*	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. ☐ I have read and agree to the above conditions.	
Type of Application *(Tick only one box)*	☐ New application	☐ Repeat application
Number of Named-Patients *(Please indicate a number)*		
Product Name		
Dosage Form *(Film-coated tablet, capsule, injection etc.)*		
Strength *(mcg, mg, mg/ml etc.)*		
Required Quantity *(Indicate quantity and unit of measure e.g. 3 boxes, 3 vials, 3 syringes etc.)*		

<table>
<tr><td>Indication</td><td colspan="2"></td></tr>
<tr><td>Dosage Regimen</td><td colspan="2"></td></tr>
<tr><td>Reason for Requesting for Unregistered Therapeutic Product
(Tick only one box)</td><td colspan="2">☐ 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 state details :</td></tr>
<tr><td>Supportive Evidence on the use of the Product in Named-Patient Applications

(Supportive evidence e.g. clinical practice guidelines or scientific literature should be submitted to support the use of the product, where appropriate.)</td><td colspan="2">List the references submitted:
1.
2.
3.
4.
5.</td></tr>
<tr><td rowspan="4">Particulars of Doctor or Dentist</td><td>Name:</td><td>Registration Number:
(MCR or DCR number)</td></tr>
<tr><td colspan="2">Department:</td></tr>
<tr><td colspan="2">Practicing address:</td></tr>
<tr><td>Contact Number:</td><td>Email:</td></tr>
</table>

REQUESTER'S DECLARATIONS

☐ 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.

☐ I am fully aware that the consignment approval by HSA for my hospital/ clinic/ nursing home[1] to bring in the unregistered therapeutic product is not an endorsement of the clinical use by the Authority.

☐ I declare that I am fully responsible for the use of the unregistered therapeutic product.

☐ 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.

☐ I 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 .

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