REPUBLIC OF SINGAPORE
HEALTH SCIENCES AUTHORITY

HEALTH PRODUCTS ACT
CHAPTER 122D

APPLICATION FOR IMPORT AND SUPPLY OF AN UNREGISTERED CLASS 2 CELL, TISSUE AND GENE THERAPY PRODUCT (CTGTP)

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

SIGNED REQUEST *(To be completed by the requesting doctor or dentist)*	
No. of patients	
Product Name *(Including dosage form & strength)*	
Unit Quantity Required	
Dosage Regimen	
Indication *(To be aligned to indication approved by gulatory agency declared by importer)*	
Clinical Justification of Unmet Medical Needs & Reason(s) for not using Current Registered CTGTP or Therapeutic Products	☐ The patient(s) has/have tried registered therapies but there was inadequate or no response. Please list the registered therapies the patient(s) has/have tried: ☐ Other reasons, please specify:
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. This information would be used by HSA to assess the application and any failure in submission would result in a delay in approval timeline)*	*List the references submitted:* 1. 2. 3. 4. 5.

Particulars of doctor/dentist	**Name:**	**Registration No.:**
	Department:	
	Name & Address of Hospital/Clinic/Nursing Home:	
	Email:	**Tel. No.:**

DOCTOR'S OR DENTIST'S DECLARATION *(All boxes should be checked)*

☐	1. I hereby declare that I am fully aware that the CTGTP requested in this application is not registered with HSA and I am fully responsible for its use on my patient.
☐	2. I hereby undertake to obtain and document consent from the patient/legal guardian for the use of this CTGTP upon informing him/her that it has not been registered with or evaluated by HSA for its quality, safety and efficacy.
☐	3. I hereby declare that the CTGTP is required for the treatment of a patient under my care whose condition will be clinically compromised without this treatment.
☐	4. I hereby declare that I am fully aware that consignment approval by HSA is not an endorsement of clinical use by the Authority.
☐	5. I hereby declare that the use of the CTGTP is in accordance with the instructions provided in the approved package insert as approved by the regulatory agency declared under Importer's Declaration.
☐	6. I hereby declare that the use of the CTGTP is in compliance with Ministry of Health's allowable practice and applicable laws.
☐	7. I hereby undertake to maintain records of the name, NRIC/identification document number and contact details of the patient who received the CTGTP under my care and to follow him/her for a period of 15 years
☐	8. I hereby undertake to collect data on patient safety, clinical outcomes and report serious adverse events.
☐	9. I hereby declare that the use of the CTGTP is approved by the Clinical Ethics Committee and relevant professional board.
☐	10. 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:** _____

Form Version (Publish Date)

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