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 up the form.
All applicants must comply with the Health Products Act (HPA) and its regulations.

PRODUCT DETAILS

Product Name *(including dosage form & strength)*:	**Requested Quantity:**	**Pack Size:**
Name & Strength of Active Substance(s):	**Name & Country of Manufacturer:**	
Anticipated product import date:		

PARTICULARS OF IMPORTER

Name & Address of Importer:	**Unique Entity No. (UEN):** *(Applicable to companies importing on behalf of a hospital, clinic or nursing home[1])*
Name of Applicant:	**Client Code:**
Designation of Applicant:	**Wholesaler Licence:**
Email: / **Tel. No.:**	

IMPORTER'S DECLARATION *(All boxes should be checked)*

☐	1. I hereby declare that the aforementioned CTGTP is approved by: *Please tick where applicable)* ☐ Australia Therapeutic Goods Administration ☐ European Medicines Agency ☐ Health Canada ☐ United Kingdom Medicines and Healthcare products Regulatory Agency ☐ United States Food and Drug Administration
☐	2. I hereby declare that the import of the unregistered CTGTP is pursuant to the instructions of the healthcare hospitals, clinics, nursing homes* and/or doctor specified *(Refer to Doctor's or Dentist's Declaration on Pages 2 and 3)* and all the information provided by me in this form is true and accurate.
☐	3. I hereby declare that the CTGTP is from the same registered manufacturer as that declared under point 1 above.
☐	4. I hereby declare to submit the certificate of analysis **within 14 days** upon import of the aforementioned CTGTP.
☐	5. I hereby declare that the aforementioned CTGTP will be shipped and handled in accordance with the storage condition specified in the approved package insert approved by HSA's comparable overseas regulator.
☐	6. I hereby declare that I am fully aware that the aforementioned CTGTP requested in this application is not registered with HSA and has not been evaluated for its quality, safety and efficacy by the HSA.
☐	7. I hereby 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.

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

SIGNED REQUEST *(To be completed by the requesting doctor or dentist)*		
Type of Application	☐ New application *Product labels including outer and inner labels as well as package insert must be submitted for first application.* *The labels must be in English and include the following details:* • *Proprietary name of the CTGTP.* • *Name and quantities of any active ingredient.* • *Appropriate control number, such as a serial number, batch number or lot number.* • *Expiry date.*	☐ Repeat application *Product labels, including outer and inner labels as well as package insert are not required for subsequent applications for the same product, unless there are changes to the product labels.*
Purpose	**Named-patient** Number of patients: _____	
Product Name *(Including dosage form & strength)*		
Unit Quantity Required		
Dosage Regimen		
Indication *(To be aligned to indication approved by regulatory 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[1]:	
	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 aforementioned CTGTP is required for the treatment of a patient under my care whose condition will be clinically compromised without the aforementioned CTGTP.
☐	4. I hereby declare that I am fully aware that consignment approval by HSA is not an endorsement of the clinical use by the Authority.
☐	5. I hereby declare that the use of the aforementioned 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 aforementioned 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 aforementioned 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 aforementioned 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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