


REQUEST FORM FOR IMPORT AND SUPPLY OF AN UNREGISTERED CLASS 2 CELL, TISSUE OR GENE THERAPY PRODUCT

REPUBLIC OF SINGAPORE HEALTH SCIENCES AUTHORITY HEALTH PRODUCTS ACT CHAPTER 122D APPLICATION FOR IMPORT AND SUPPLY OF AN UNREGISTERED CLASS 2 CELL, TISSUE OR GENE THERAPY PRODUCT			
<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>			
PRODUCT DETAILS			
Product Name <i>(including dosage form & strength):</i>		Requested Quantity:	Pack Size:
Name & Strength of Active Substance(s):		Name & Country of Manufacturer:	
PARTICULARS OF IMPORTER			
Name & Address of Importer:		Unique Entity No. (UEN): <i>(Applicable to companies importing on behalf of a healthcare institute)</i>	
Name of Applicant:		Client Code:	
Designation:		Wholesaler Licence:	
Email:	Tel. No.:		
IMPORTER'S DECLARATION <i>(All boxes should be checked)</i>			
<input type="checkbox"/>	I hereby declare that the aforementioned cell, tissue or gene therapy product is approved by Australia Therapeutic Goods Administration/ European Medicines Agency/ Health Canada/ United Kingdom Medicines and Healthcare products Regulatory Agency/ United States Food and Drug Administration.		
<input type="checkbox"/>	I hereby declare that the import of the unregistered cell, tissue or gene therapy product is pursuant to the instructions of the healthcare institution and/or doctor specified (attached) and all the information provided by me in this form is true and accurate.		
<input type="checkbox"/>	I hereby declare that the cell, tissue or gene therapy product is from the same registered manufacturer as approved.		
<input type="checkbox"/>	I hereby declare to submit the results of the approved release specifications of the aforementioned cell, tissue or gene therapy product.		
<input type="checkbox"/>	I declare that the aforementioned cell, tissue or gene therapy product will be shipped and handled in accordance with the storage condition specified in the approved package insert.		
<input type="checkbox"/>	I am fully aware that the aforementioned cell, tissue or gene therapy product requested in this application is not registered with HSA and has not been evaluated for its quality, safety and efficacy by the HSA.		
<input type="checkbox"/>	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: _____	

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SIGNED REQUEST <i>(To be completed by the requesting doctor or dentist)</i>	
Purpose	Named-patient Number of patients: _____
Product Name <i>(Including dosage form & strength)</i>	
Unit Quantity Required	
Dosage Regimen	
Indication	
Clinical justification of unmet medical needs & reason(s) <i>(Supportive evidence e.g. clinical practice guidelines or published papers should be submitted to support the use of the product, where appropriate)</i>	
Particulars of doctor/dentist	Name: _____ Registration No.: _____
	Department: _____
	Name & Address of Hospital/Clinic: _____
	Email: _____ Tel. No.: _____
DOCTOR'S OR DENTIST'S DECLARATION <i>(All boxes should be checked)</i>	
<input type="checkbox"/>	I am fully aware that the cell, tissue or gene therapy product requested in this application is not registered with HSA. I also declare that I will inform the patient/legal guardian that the aforementioned cell, tissue or gene therapy product is not registered with HSA and has not been evaluated for its quality, safety and efficacy.
<input type="checkbox"/>	I declare that the aforementioned cell, tissue or gene therapy product is required for the treatment of a patient under my care whose condition will be clinically compromised without the aforementioned cell, tissue or gene therapy product.
<input type="checkbox"/>	I am fully aware that consignment approval by HSA is not an endorsement of the clinical use by the Authority.
<input type="checkbox"/>	I declare that the use of the aforementioned cell, tissue or gene therapy product is in accordance with the instructions provided in the approved package insert.
<input type="checkbox"/>	I declare that the use of the aforementioned cell, tissue or gene therapy product is in compliance with Ministry of Health's allowable practice and applicable laws.
<input type="checkbox"/>	I undertake to maintain records of the patient who received the aforementioned cell, tissue or gene therapy product under my care and follow him/her for a period of 15 years (unless otherwise justified).
<input type="checkbox"/>	I undertake to collect data on patient safety, clinical outcomes and report serious adverse events.

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	I declare that the use of the aforementioned cell, tissue or gene therapy product is approved by the Clinical Ethics Committee and relevant professional board.
	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>Signature: _____ Date: _____</p>	

REVISION HISTORY

Form Version (Publish Date)

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