


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

<p>REPUBLIC OF SINGAPORE HEALTH SCIENCES AUTHORITY</p> <p>HEALTH PRODUCTS ACT CHAPTER 122D</p> <p>APPLICATION FOR IMPORT AND SUPPLY OF A REGISTERED CLASS 2 CELL, TISSUE OR GENE THERAPY PRODUCT</p>		
<p><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></p>		
PARTICUARS OF IMPORTER		
Name of Importing Company:		
Address of Importing Company:		
Is Billing Address the same as the Company Address?	<p>Yes</p> <p>No, please specify:</p>	
Unique Entity No. (UEN):		
Client Code:		
Wholesaler Licence:		
APPLICANT PARTICULARS		
Name of Applicant:		
Designation:		
Email:		
Tel. No.:		
PRODUCT DETAILS		
Product Licence Number of the locally registered product:		
Product Name <i>(including dosage form & strength):</i>		
Name & Strength of Active Substance(s):		

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APPLICATION DETAILS	
Name of Active Substance Manufacturer:	
Active Substance Manufacturer Site Address:	
Name of CTGTP Manufacturer:	
CTGTP Manufacturer Site Address:	
Source of Import (Country):	
Pack size:	
Requested Quantity:	
Batch Number:	
Manufacturing date:	
Expiry date:	
APPLICANT'S DECLARATION	
	I confirm that the consignment batch is the same as the Singapore registered product in all quality aspects (including but not limited to formulation, container closure system, manufacturing process, quality and manufacturing controls, storage condition, shelf life, active substance and CTGTP manufacturing sites and specifications).
	I confirm that the product labels (i.e. outer carton, inner label) of the consignment product will contain the same content (information) as the approved labels of the Singapore-registered product at the point of supply to the healthcare institutions/pharmacies.
	I undertake to supply each unit of the consignment product with the Singapore approved package insert and/or patient information leaflet.
	I confirm that my company will take full responsibility for ensuring the quality, safety and efficacy of the consignment batch.
	I hereby declare that the information provided by me in this form is true and accurate. I acknowledge that if any of the information provided by me 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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