


REPUBLIC OF SINGAPORE HEALTH SCIENCES AUTHORITY HEALTH PRODUCTS ACT CHAPTER 122D			
APPLICATION FOR IMPORT AND SUPPLY OF A REGISTERED CLASS 2 CELL, TISSUE AND GENE THERAPY PRODUCT (CTGTP)			
<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 Registration Number (Locally registered CTGTP):			
Product Name <i>(including dosage form & strength):</i>			
Name & Strength of Active Substance(s):			
PARTICULARS OF IMPORTER			
Name & Address of Importer:		Is Billing Address the same as the Company Address?	
		<input type="checkbox"/> Yes <input type="checkbox"/> No, please specify:	
Unique Entity No. (UEN): <i>(Applicable to companies importing on behalf of a healthcare institute)</i>			
Name of Applicant:		Client Code:	
Designation of Applicant:		Wholesaler Licence:	
Email:	Tel. No.:		

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>(All boxes should be checked)</i>	
<input type="checkbox"/>	1. 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).
<input type="checkbox"/>	2. 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.
<input type="checkbox"/>	3. I hereby undertake to supply each unit of the consignment product with the Singapore approved package insert and/or patient information leaflet.
<input type="checkbox"/>	4. I confirm that my company will take full responsibility for ensuring the quality, safety and efficacy of the consignment batch.
<input type="checkbox"/>	5. 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>	

Form Version (Publish Date)

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