

NEW APPLICATION FOR CELL, TISSUE AND GENE THERAPY PRODUCTS (CTGTP) IMPORTER'S LICENCE AND/OR WHOLESALER'S LICENCE

NOTES:

- 1. Your company must have a <u>CRIS</u> account with HSA and obtain a client code in order to submit this application.
- 2. This form should be completed by the applicant who is authorised by the company. The applicant will be the point of contact for all matters related to this application.
- 3. This form may take you 20 minutes to fill in. You will need the following information to fill in the form:
 - a. Company's details and applicant's details
 - b. Licence details including type of licence, premises, responsible person
 - c. Supporting documents (see section 7)
- 4. All entries shall be made in English. All the information required in the form should be supplied as far as they are applicable.
- 5. If the space provided in any section of this form is insufficient, the information pertaining to the affected section(s) may be submitted as an attachment together with this completed form as a PDF document. Please indicate the section numbers clearly in the attachment for ease of reference.
- 6. This completed form with its relevant supporting documents should be submitted as an attachment in the online FormSG <u>CTGTP Dealer's Submission</u>. CorpPass is required to access this FormSG. For more information, please visit the <u>CorpPass website</u>.

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Section 1 - Licence Type (Select either option 1.1, 1.2 or 1.3):			
1.1	☐ Importer's Licence Only (Select one option below)		
	 Full Scope 		
	 Limited Scope Ann 	ual	
	 Limited Scope Per 	Consignment Only	
1.2	☐ Wholesaler's Licence C	Pnly	
1.3	☐ Importer's and Wholesa	aler's Licences (bundled)	
Section 2 - Company Particulars			
2.1	Name of Company:		
2.2	UEN and Client Code:		
2.3	Company Address:		
	2.3.1 Postal Code:		
	2.3.2 Block/House No.:		
	2.3.3 Level - Unit:		
	2.3.4 Street Name:		
	2.4.5 Building Name:		
2.4	Billing Address (if different from Company Address):		
	2.4.1 Postal Code:		
	2.4.2 Block/House No.:		
	2.4.3 Level - Unit:		
	2.4.4 Street Name:		
	2.4.5 Building Name:		



Section 3 - Applicant Particulars			
3.1	Name (as in NRIC/FIN):		
3.2	Designation:		
3.3	Contact Number:		
3.4	Official Email Address:		
Sect	tion 4 - Particulars on Premises (attach additional sheet if necessary)		
4.1			
	4.1.1 Postal Code:		
	4.1.2 Block/House No:		
	4.1.3 Level - Unit:		
	4.1.4 Street Name:		
	4.1.5 Building Name:		
	4.1.6 Other Address:		
4.2	Storage Condition of Warehouse 1:		
	4.2.1 Temperature (multiple selection allowed):		
	□ Non cold chain (Above 8°C)		
	☐ Cold chain (Not more than 8°C)		
	4.2.1.1 Actual Temperature Range:		
	☐ 15 to 30°C (Room Temperature)		
	□ 8 to 15°C (Cool)		
	☐ 2 to 8°C (Refrigerate, Do not freeze)		
	□ -10 to -20°C (Freeze)		
	☐ Cryogenic storage temperature:°C		
	☐ Others:		
	4.2.2 Relative Humidity (Non-Cold Chain): Min% - Max%:		
	4.2.3 Relative Humidity (Cold Chain): Min% - Max%:		
	4.2.4 Other Storage Conditions:		



4.3	Warehouse Address 2:	
	4.3.1 Postal Code:	
	4.3.2 Block/House No:	
	4.3.3 Level - Unit:	
	4.3.4 Street Name:	
	4.3.5 Building Name:	
	4.3.6 Other Address:	
4.4	Storage Condition of Wareh	ouse 2:
	4.4.1 Temperature (multiple s	election allowed)
	☐ Non cold chain (Ab	ove 8°C)
	☐ Cold chain (Not mo	re than 8°C)
	4.4.1.1 Actual Ten	perature Range:
	☐ 15 to 3	60°C (Room Temperature)
	□ 8 to 15	°C (Cool)
	□ 2 to 8°	C (Refrigerate, Do not freeze)
	□ -10 to	-20°C (Freeze)
	□ Cryog	enic storage temperature:°C
	☐ Others	:
	4.4.2 Relative Humidity (Non-	Cold Chain): Min% - Max%:
	4.4.3 Relative Humidity (Cold	Chain): Min% - Max%:
	4.4.4 Other Storage Conditio	าร:



Secti	Section 5 - Licence Details (To be filled up where applicable):		
5.1	Aspects of importation (multiple selection allowed):		
		Registered CTGTP (Importer's Licence - Full scope required)	
		CTGTP solely for export only	
		CTGTP for scientific education, research and development, and/or non-clinical purpose	
		Other specific activity:	
5.2	Particulars of CTGTP to be imported (if full scope is applicable)		
		Registered CTGTP, please fill in the Product Registration Number(s):	
	,,,		
		e importer is not the product registrant, please submit an authorisation letter the product registrant.)	
5.3	Aspe	ects of wholesale (multiple selection allowed):	
		Registered CTGTP	
		CTGTP on a consignment basis	
		Unregistered CTGTP for a named patient	



Sect	Section 6 - Responsible Person(s) (attach additional sheets if necessary)		
6.1	Responsible Person		
	6.1.1 Name (as in NRIC/FIN):		
	6.1.2 Designation:		
	6.1.3 Email Address:		
	6.1.4 Contact Number:		
	6.1.5 This responsible person is applicable for? (multiple selection allowed) □ CTGTP Importer's Licence □ CTGTP Wholesale's Licence		
6.2	Responsible Person		
	6.2.1 Name (as in NRIC/FIN):		
	6.2.2 Designation:		
	6.2.3 Email Address:		
	6.2.4 Contact Number:		
	6.2.5 This responsible person is applicable for? (multiple selection allowed) □ CTGTP Importer's Licence □ CTGTP Wholesale's Licence		
Section 7 - Supporting Documents (multiple selection allowed)			
	Authorisation letter from product registrant Store layout plan Curriculum Vitae (CV) of Responsible Person(s) Other supporting documents		



Sect	Section 8 - Declaration		
	I, on behalf of my company, confirm that the information submitted in this application is true and accurate.		
	I, on behalf of my company, confirm that there are no additional amendments made to this application or to the attachments thereof.		
Name of applicant:		Signature and Date:	

Application Fee

CTGTP Importer's and Wholesaler's Licence	Fee
New Importer's Licence or Wholesaler's Licence (Full scope)	\$1,470
New Importer's & Wholesaler's Licence (bundled application)	\$2,630
New Importer's Licence (Limited scope# - annual)	\$220
New Importer's Licence (Limited scope# - per consignment)	\$116

^{*}Limited scope refers to importation of CTGTP for scientific education, research and development, non-clinical purpose or for export only.

An invoice for the applicable fee will be sent to the company. For companies on the GIRO scheme, the fee will be deducted from the GIRO-linked bank account. For companies not on the GIRO scheme, the fee can be made by bank transfer. More information will be provided on the invoice.