



## **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 [CRIS](#) 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 – [CTGTP Dealer's Submission](#). Corppass is required to access this FormSG. For more information, please visit the [Corppass website](#).



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

**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 Annual
  - Limited Scope Per Consignment Only
- 1.2  Wholesaler's Licence Only
- 1.3  Importer's and Wholesaler'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:

**Section 4 - Particulars on Premises** *(attach additional sheet if necessary)*

**4.1 Warehouse Address 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: \_\_\_\_\_

<b>4.3 Warehouse Address 2:</b>	
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:	
<b>4.4 Storage Condition of Warehouse 2:</b>	
<p>4.4.1 Temperature (<i>multiple selection allowed</i>)</p> <p><input type="checkbox"/> Non cold chain (Above 8°C)</p> <p><input type="checkbox"/> Cold chain (Not more than 8°C)</p> <p>4.4.1.1 Actual Temperature Range:</p> <p><input type="checkbox"/> 15 to 30°C (Room Temperature)</p> <p><input type="checkbox"/> 8 to 15°C (Cool)</p> <p><input type="checkbox"/> 2 to 8°C (Refrigerate, Do not freeze)</p> <p><input type="checkbox"/> -10 to -20°C (Freeze)</p> <p><input type="checkbox"/> Cryogenic storage temperature: _____ °C</p> <p><input type="checkbox"/> Others: _____</p> <p>4.4.2 Relative Humidity (Non-Cold Chain): Min% - Max%: _____</p> <p>4.4.3 Relative Humidity (Cold Chain): Min% - Max%: _____</p> <p>4.4.4 Other Storage Conditions: _____</p>	

**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)**

For Registered CTGTP, please fill in the Product Registration Number(s):

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

*(If the importer is not the product registrant, please submit an authorisation letter from the product registrant.)*

**5.3 Aspects of wholesale** *(multiple selection allowed):*

- Registered CTGTP
- CTGTP on a consignment basis
- Unregistered CTGTP for a named patient

<b>Section 6 - Responsible Person(s)</b> <i>(attach additional sheets if necessary)</i>	
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? <i>(multiple selection allowed)</i> <input type="checkbox"/> CTGTP Importer's Licence <input type="checkbox"/> 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? <i>(multiple selection allowed)</i> <input type="checkbox"/> CTGTP Importer's Licence <input type="checkbox"/> CTGTP Wholesale's Licence	
<b>Section 7 - Supporting Documents</b> <i>(multiple selection allowed)</i>	
<input type="checkbox"/> Authorisation letter from product registrant <input type="checkbox"/> Store layout plan <input type="checkbox"/> <i>Curriculum Vitae</i> (CV) of Responsible Person(s) <input type="checkbox"/> Other supporting documents	

**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**

<b>CTGTP Importer's and Wholesaler's Licence</b>	<b>Fee</b>
New Importer's Licence or Wholesaler's Licence (Full scope)	\$1,400
New Importer's & Wholesaler's Licence (bundled application)	\$2,500
New Importer's Licence (Limited scope <sup>#</sup> - annual)	\$210
New Importer's Licence (Limited scope <sup>#</sup> - per consignment)	\$110

<sup>#</sup>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.