

AMENDMENT APPLICATION FOR CELL, TISSUE AND GENE THERAPY PRODUCTS (CTGTP) IMPORTER'S 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 and applicant details
 - b. Details of the amendment to the licence(s)
 - c. Changes to premises, CTGTP imported and/or responsible person
 - d. Supporting documents to support the change in licence(s) details e.g. layout plan, authorisation letter from registrant. (see section 8)
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. Technical assessment requiring site inspection may be required for certain amendments. The following table shows examples of amendment details requiring administrative amendment (**AA**) / amendment with technical assessment (**ATA**):-

Examples of Amendment Details	Importer's Licence (Limited Scope) <u>only</u>	Wholesaler's Licence <u>only</u>	<u>Both Importer's Licence (Full Scope) & Wholesaler's Licences</u>	
			Importer's Licence (Full Scope)	Wholesaler's Licence
Addition of warehouse	AA	ATA	AA	ATA
Change in Responsible Persons (add or remove)	AA		AA	
Removal of Warehouse	AA		AA	

If in doubt, please clarify with the Audit & Licensing Division before submitting the application.

6. 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.
7. 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](#).
8. If the company intends to apply for amendment to both the importer's and wholesaler's licences of CTGTP, please submit this completed form in separate FormSG submission, one amendment application for importer's licence and another amendment application for wholesaler's licence.

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

Section 1 - Company Particulars	
1.1 Name of Company:	
1.2 UEN and Client Code:	
1.3 Company Address	
1.3.1 Postal Code:	
1.3.2 Block/House No.:	
1.3.3 Level – Unit:	
1.3.4 Street Name:	
1.3.5 Building Name:	
1.4 Billing Address <i>(if different from Company Address)</i>	
1.4.1 Postal Code:	
1.4.2 Block/House No.:	
1.4.3 Level – Unit:	
1.4.4 Street Name:	
1.4.5 Building Name:	
Section 2 - Applicant Particulars	
2.1 Name (as in NRIC/FIN):	
2.2 Designation:	
2.3 Contact Number:	
2.4 Official Email Address:	

Section 3 - Details of the amendment	
3.1 Licence number of importer's or wholesaler's licence to be amended:	
3.2 Does this amendment application require technical assessment? (Select one option)	
<input type="radio"/> Yes <input type="radio"/> No	
Section 4 - Particulars on Premises	
(Select one option)	
<input type="checkbox"/> No change (skip Section 4) <input type="checkbox"/> Amendment (complete the details below)	
4.1 Select type of change (Select one option):	
<input type="checkbox"/> Addition of warehouse (Fill in sections 4.1.1 and 4.1.2)	
<input type="checkbox"/> Change of storage condition of existing warehouse (Fill in sections 4.1.1 and 4.1.2)	
<input type="checkbox"/> Removal of warehouse (Fill in section 4.1.1 only)	
4.1.1 Warehouse Address:	
4.1.1.1 Postal Code:	
4.1.1.2 Block/House No:	
4.1.1.3 Level – Unit:	
4.1.1.4 Street Name:	
4.1.1.5 Building Name:	
4.1.1.6 Other Address:	

4.1.2 Storage Condition of Warehouse

4.1.2.1 Temperature (multiple selection allowed):

- Non-cold chain (Above 8°C)
- Cold chain (Not more than 8°C)

4.1.2.1.1 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: _____

4.1.2.2 Relative Humidity (Non-Cold Chain): Min% - Max%: _____

4.1.2.3 Relative Humidity (Cold Chain): Min% - Max%: _____

4.1.2.4 Other Storage Conditions: _____

4.2 Select type of change (Select one option):

- Addition of warehouse (Fill in sections 4.2.1 and 4.2.2)
- Change of storage condition of existing warehouse (Fill in sections 4.2.1 and 4.2.2)
- Removal of warehouse (Fill in section 4.2.1 only)

4.2.1 Warehouse Address

4.2.1.1 Postal Code:	
4.2.1.2 Block/House No:	
4.2.1.3 Level – Unit:	
4.2.1.4 Street Name:	
4.2.1.5 Building Name:	
4.2.1.6 Other Address:	

4.2.2 Storage Condition of Warehouse

4.2.2.1 Temperature (*multiple selection allowed*):

- Non-cold chain (Above 8°C)
- Cold chain (Not more than 8°C)

4.2.2.1.1 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: _____

4.2.2.2 Relative Humidity (Non-Cold Chain): Min% - Max% _____

4.2.2.3 Relative Humidity (Cold Chain): Min% - Max% _____

4.2.2.4 Other Storage Conditions: _____

Section 5 - Licence details

(Select one option)

- No change (skip Section 5)
- Amendment (complete the details below)

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 Aspects of wholesale (*multiple selection allowed*):

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

Section 6 - Particulars on CTGTP to be imported

(Select one option)

- No change (skip Section 6) Amendment (complete the details below)

6.1 Select type of change (Select one option):

- Addition of CTGTP
- Removal of CTGTP

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

(For addition of CTGTP, please submit an authorisation letter from the registrant if the importer is not the product registrant.)

6.2 Select type of change (Select one option):

- Addition of CTGTP
- Removal of CTGTP

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

(For addition of CTGTP, please submit an authorisation letter from the registrant if the importer is not the product registrant.)

Section 7 - Responsible Person (Attach additional sheets if necessary)

- No change (skip Section 7) Amendment (complete the details below)

7.1 Select type of change (Select one option):

- Addition of Responsible Person
- Removal of Responsible Person
- Change in information on existing Responsible Person

7.1.1 Name (as in NRIC/FIN):	
7.1.2 Designation:	
7.1.3 Email address:	
7.1.4 Contact number:	

<p>7.1.5 This responsible person is applicable for? <i>(multiple selection allowed)</i></p> <p><input type="checkbox"/> CTGTP Importer's Licence</p> <p><input type="checkbox"/> CTGTP Wholesaler's Licence</p>	
<p>7.2 Select type of change <i>(Select one option):</i></p> <p><input type="checkbox"/> Addition of Responsible Person</p> <p><input type="checkbox"/> Removal of Responsible Person</p> <p><input type="checkbox"/> Change in information on existing Responsible Person</p>	
7.2.1 Name (as in NRIC/FIN):	
7.2.2 Designation:	
7.2.3 Email address:	
7.2.4 Contact number:	
<p>7.2.5 This responsible person is applicable for? <i>(multiple selection allowed)</i></p> <p><input type="checkbox"/> CTGTP importer's Licence</p> <p><input type="checkbox"/> CTGTP wholesaler's Licence</p>	
<p>Section 8 - Supporting Documents</p>	
<p><input type="checkbox"/> Store layout plan (for changes in premises)</p> <p><input type="checkbox"/> Authorisation letter from product registrant (for new CTGTP to be imported)</p> <p><input type="checkbox"/> <i>Curriculum Vitae</i> (CV) of Responsible Person(s) (for new Responsible Person)</p> <p><input type="checkbox"/> Other supporting documents</p>	
<p>Section 9 - Declaration</p>	
<p><input type="checkbox"/> I, on behalf of my company, confirm that the information submitted in this application is true and accurate.</p> <p><input type="checkbox"/> I, on behalf of my company, confirm that there are no additional amendments made to this application or to the attachments thereof.</p>	
Name of applicant:	Signature and Date:



Application Fee

Amendment of CTGTP Importer's or Wholesaler's Licence(s)	Fee
Amendment with technical assessment	\$1,100
Administrative amendment	\$120

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.