



NOTICE FOR MANUFACTURE, IMPORT AND/OR WHOLESALE OF MINIMALLY MANIPULATED CELL, TISSUE AND GENE THERAPY PRODUCTS (CTGTP)

NOTES:

1. Your company must have a [CRIS](#) account with HSA and obtain a client code in order to submit this application.
2. This notice is not required if the company has obtained the corresponding CTGTP manufacturer's, importer's and wholesaler's licence(s) for dealing in CTGTP which are not minimally manipulated.
3. If there are changes to a notice previously submitted, please resubmit this form with the updated information. All previous notices will be superseded by the latest notice. There will be no fee charged for submission of update on changes to the previous notice submitted.
4. The 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 notice.
5. 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. Particulars of activities, CTGTP, premises
6. All entries shall be made in English. All the information required in the form should be supplied as far as they are applicable.
7. 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.
8. This completed form 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](#).
9. If the company intends to submit more than one notice, please submit this completed form in separate FormSG submissions, e.g. one submission for notice for import and another submission for the notice for wholesale.



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Section 1 - Company Particulars	
1.1 Name of Company:	
1.2 UEN and Client Code:	
1.3 Business Address of Company:	
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:	
Section 2 - Applicant Particulars	
2.1 Name (as in NRIC/FIN):	
2.2 Designation:	
2.3 Contact Number:	
2.4 Email Address:	
Section 3 - Purpose of notice <i>(Select one option below)</i>	
<input type="radio"/> This is a new notice <input type="radio"/> This notice is to update on changes to the previous notice submitted <input type="radio"/> This notice is to update that the company has ceased to import, wholesale and/or manufacture minimally manipulated CTGTP <i>(Skip sections 4, 5, 6 and 7, and proceed to fill in section 8)</i>	
Section 4 - Activities to be carried out <i>(multiple selection allowed)</i>	
<input type="checkbox"/> Manufacture <input type="checkbox"/> Import <input type="checkbox"/> Wholesale	

Section 5 - Particulars of CTGTP *(multiple selection allowed)*

- Class 1 Class 2 (only minimally manipulated)

Section 6 - Particulars of Premises *(attach additional sheet if necessary)*

6.1 Address 1

6.1.1 Postal Code:	
6.1.2 Block/House No:	
6.1.3 Level – Unit:	
6.1.4 Street Name:	
6.1.5 Building Name:	
6.1.6 Other Address:	

6.2 Address 2 *(if any)*

6.2.1 Postal Code:	
6.2.2 Block/House No:	
6.2.3 Level – Unit:	
6.2.4 Street Name:	
6.2.5 Building Name:	
6.2.6 Other Address:	

6.3 Address 3 *(if any)*

6.3.1 Postal Code:	
6.3.2 Block/House No:	
6.3.3 Level – Unit:	
6.3.4 Street Name:	
6.3.5 Building Name:	
6.3.6 Other Address:	

Section 7 - Particulars of Quality Management System Standard

My company will ensure, and maintain objective evidence to establish, that the manufacture, handling and storage (where applicable) of the CTGTP complies with the following standards:

(Please select at least one of the following.)

Manufacturer	Importer	Wholesaler
<input type="checkbox"/> Good Tissue Practice (Ministry of Health Tissue Banking Guidelines, Feb 2003)	<input type="checkbox"/> HSA Guidance Notes on Good Distribution Practice, <input type="checkbox"/> Singapore Standard for Good Distribution Practice for Medical Devices – Requirements (SS 620) <input type="checkbox"/> ISO 13485 (2016 edition)	<input type="checkbox"/> HSA Guidance Notes on Good Distribution Practice, <input type="checkbox"/> Singapore Standard for Good Distribution Practice for Medical Devices – Requirements (SS 620) <input type="checkbox"/> ISO 13485 (2016 edition)

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:

Submission Fee

Type of notice	Fee
Notice for manufacture of minimally manipulated CTGTP	\$90
Notice for import of minimally manipulated CTGTP	\$90
Notice for wholesale of minimally manipulated CTGTP	\$90

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.