

Singapore Health Product Access and Regulatory E-System (SHARE)

User Manual Applicant (Internet)

Version 2.1

Date 24 April 2026



Change Log

Version	Date	Comments
0.1	08 Dec 2023	First version
0.2	22 Dec 2023	Updated additional information
1.0	26 Dec 2023	Final version
1.1	03 Jun 2024	Updated Address Book section Updated Product Listing section
1.2	25 Sept 2024	Updated information on Class 2 CTGTP applications
1.3	03 Oct 2024	Updated version with Class 2 CTGTP applications
1.4	15 Oct 2024	Updated images with higher quality replacements
1.5	04 Feb 2025	Updated the guide to include information on Dealer Licence and Certificate applications
1.6	06 Feb 2025	Updated additional information
1.7	23 May 2025	Added SHARE DASH
1.8	25 June 2025	Added more context regarding the Overseas Entity flow
1.9	10 Dec 2025	Updated the guide to include information on CPP and FSC applications
2.0	24 Mar 2026	Updated the guide with information on the Update Company Details module
2.1	24 April 2026	Updated the guide with information on SAR applications

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HSA SHARE

SHARE (Singapore Health Product Access and Regulatory E-System) aims to deliver an integrated platform, elevating collaboration between Health Sciences Authority (HSA) and the industry. SHARE allows applicants to effectively apply for multiple products or dealer's notices in a single application. Similarly, applicants can also apply for dealer's licence and certificate within a single application. Applicants would be able to perform other application activities such as updating/amending, cancellation and withdrawal of applications on a single platform.

SHARE (Singapore Health Product Access and Regulatory E-System)

SHARE would allow applicants to

**Create a new Class 1 CTGTP Notification or Class 2 Registration application**

To notify HSA on the product and receive HSA's written acceptance of registration and notification before the product can be supplied in Singapore.

**Create a new Fulfilment of Approval Condition, Retention or Change of Registrant application**

To submit data to fulfill approval condition or to update change of registrant.

**Create a new CTGTP Dealer's Notice or Dealer's Licence/Certificate application**

To notify HSA before you import, wholesale or manufacture any CTGTP in Singapore.

**Create a Retention or Renewal application for products and licences respectively**

To extend the validity period of approved products and licences.

**Update/Amend Products, Licences and applications**

To make changes to products, licences and applications submitted.

**Withdrawal of application**

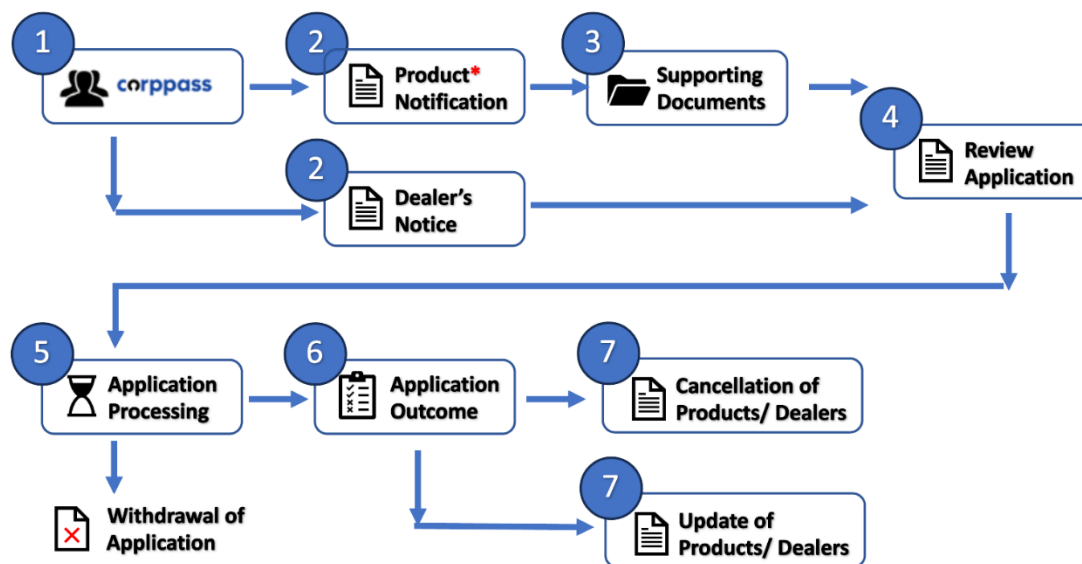
To withdraw any application, products or licences/certificates before it is approved or rejected.

**Submit cancellation notice for Notified and Registered Product(s), Known Dealer(s) or Approved Licence(s)**

To notify/request HSA of any cancellation of notified Class 1 CTGTP, registered Class 2 CTGTP, known dealers or approved licences.

1 System Overview

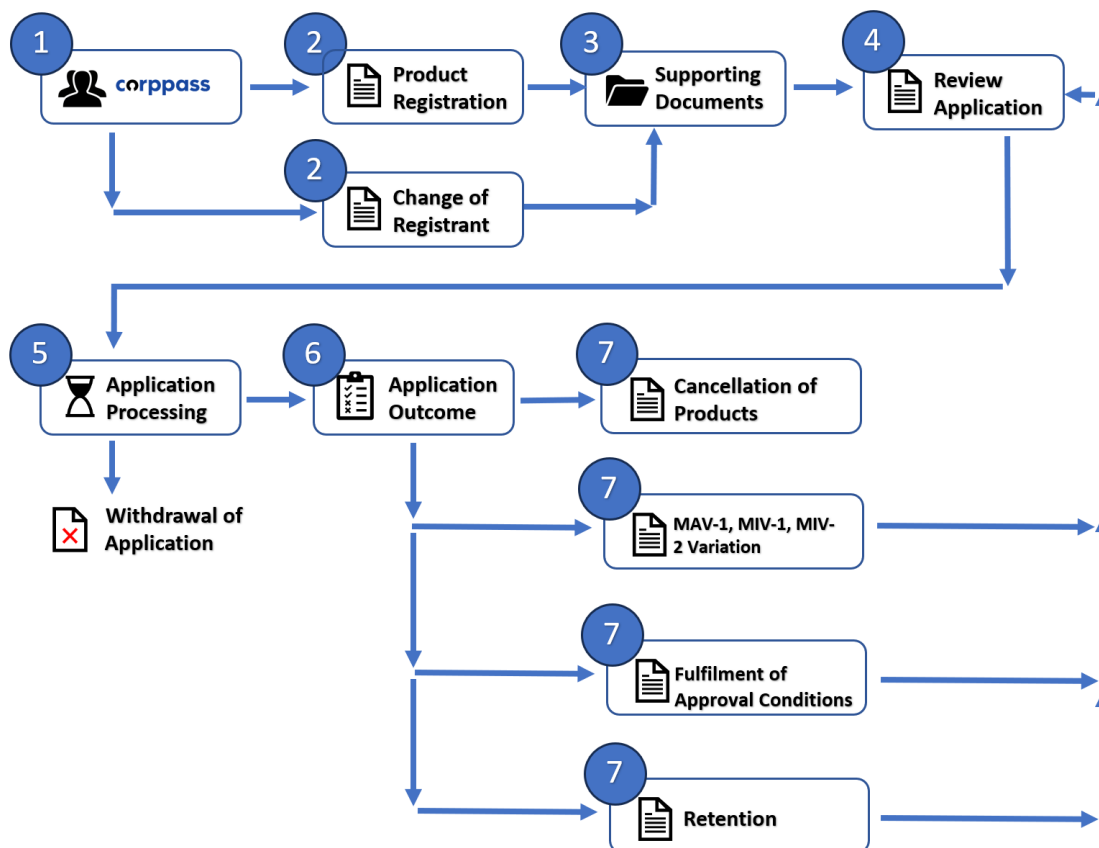
1.1 Class 1 CTGTP



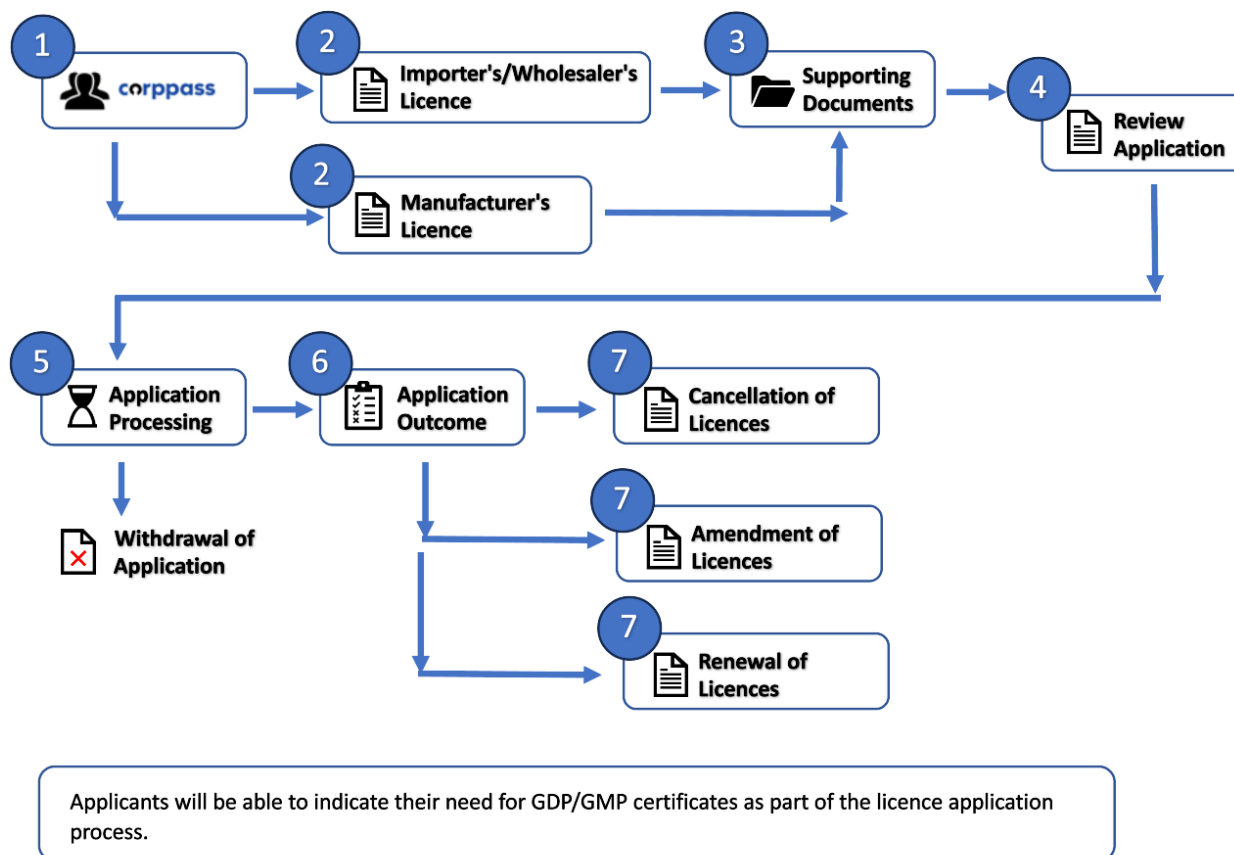
*You must be a known dealer to submit a Product Notification for Class 1 CTGTP. Applicants would need to submit a Dealer's Notice Application to notify HSA prior to your manufacturing, importing or wholesaling activity relating to Class 1 CTGTP.

1. Applicants log in via Corppass.
2. Applicants would be able to select the submission type and application type (Product Notification or Dealer's Notice)
 - i. Applicants would be required to populate the required fields in all the sections of the application (company details, application details, etc).
3. Applicants would be required to upload supporting documents for Class 1 CTGTP notification application.
4. Before the submission, applicants would be able to review the application. Applications can be saved as a draft and can be edited from the dashboard.
 - i. Before submission, applicants would be able to check for application information as well as payment breakdown. The applicant would have to check on the declaration section before submission of the application.
5. Once submitted, the application would be reviewed by the HSA officer. (Applicants would be able to withdraw the application during this stage).
6. After the application has been reviewed by the officer, applicants would be notified of the application outcome.
7. Applicants would be able to submit a new application for cancellation of products/ dealers or a new application for the update of products/dealers after the application has been closed.

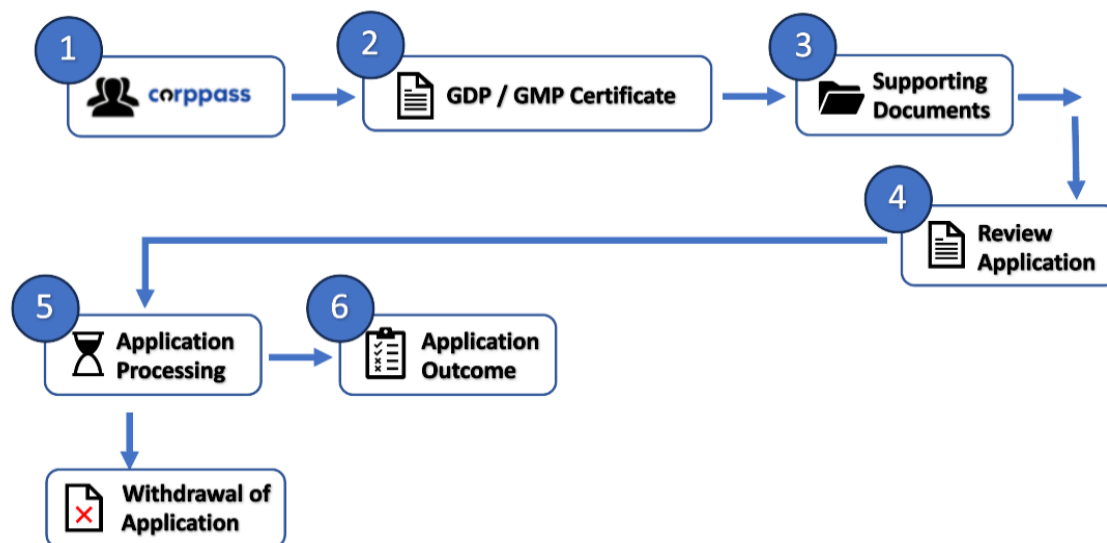
1.2 Class 2 CTGTP



1. Applicants log in via Corppass.
2. Applicants would be able to select the submission type and application type
 - i. Applicants would be required to populate the required fields in all the sections of the application (company details, application details, etc).
3. Applicants would be required to upload supporting documents for Class 2 CTGTP registration application and change of registrant application.
4. Before the submission, applicants would be able to review the application. Applications can be saved as a draft and can be edited from the dashboard.
 - i. Before submission, applicants would be able to check for application information as well as payment breakdown. The applicant would have to check on the declaration section before submission of the application.
5. Once submitted, the application would be reviewed by the HSA officer. (Applicants would be able to withdraw the application during this stage).
6. After the application has been reviewed by the officer, applicants would be notified of the application outcome.
7. Applicants would be able to submit a new application for cancellation of products, MAV-1, MIV-1, MIV-2 Variation for approved products, Fulfilment of Approval Conditions or Retention



1. Applicants log in via Corppass.
2. Applicants would be able to select the submission type and application type (Importer's/ Wholesaler's/ Manufacturer's Licence)
 - i. Applicants would be required to populate the required fields in all the sections of the application (company details, application details, etc).
3. Applicants would be required to upload supporting documents for the selected licence application.
4. Before the submission, applicants would be able to review the application. Applications can be saved as a draft and can be edited from the dashboard.
 - i. Before submission, applicants would be able to check for application information as well as payment breakdown. The applicant would have to check on the declaration section before submission of the application.
5. Once submitted, the application would be reviewed by the HSA officer. (Applicants would be able to withdraw the application during this stage).
6. After the application has been reviewed by the officer, applicants would be notified of the application outcome.
7. Applicants would be able to submit a new application for cancellation, amendment or renewal of licences after the application has been closed.



1. Applicants log in via Corppass.
2. Applicants would be able to select the submission type and application type (GDP/ GMP Certificate)
 - i. Applicants would be required to populate the required fields in all the sections of the application (company details, application details, etc).
3. Applicants would be required to upload supporting documents for Class 2 CTGTP certification application.
4. Before the submission, applicants would be able to review the application. Applications can be saved as a draft and can be edited from the dashboard.
 - i. Before submission, applicants would be able to check for application information as well as payment breakdown. The applicant would have to check on the declaration section before submission of the application.
5. Once submitted, the application would be reviewed by the HSA officer. (Applicants would be able to withdraw the application during this stage).
6. After the application has been reviewed by the officer, applicants would be notified of the application outcome.

1.3 Abbreviations and Definitions

Terms	Definition
CTGTP	Cell, Tissue and Gene Therapy Products
Corppass	Authorisation system for entities to manage digital service access of employees who need to perform corporate transactions
Dealer	The entity that performs the following activity – import, wholesale, or manufacture CTGTP products
HSA	Health Sciences Authority
IR	Input Request: a set of queries to seek clarification or request for additional data from the applicant regarding the application
Supporting Documents	Set of documents which are uploaded by an applicant to an application form

1.4 Application Statuses

Status	Description
Draft	When the application is not yet submitted by an applicant
Processing	When the application has been submitted by an applicant
Pending IR	When an applicant is yet to respond to an officer's IR
Closed	When the application has been closed by an officer
Withdrawn	All products/dealer activities listed in the application are withdrawn by the applicant

1.5 IR Statuses and Trigger Points

IR Statuses	Trigger Points
Fresh IR	New IR raised by the officer
Responded	When applicant responded to an IR
Overdue	When IR has not been responded, the applicant did not request for any IR extension, and the IR has already past the due date
Extension Requested	When an applicant requests for IR extension
Extended	When an IR extension has been granted
Expired	When IR has already been given extension and applicant has not provided any response

2 Login

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 **Singapore Health Product Access and Regulatory E-System (SHARE)**

Singapore Health Product Access and Regulatory E-System (SHARE)

Announcement

Please note that you will need to be granted access to e-Service, "HSA E-SERVICES: SINGAPORE HEALTH PRODUCT ACCESS AND REGULATION E-SYSTEM (SHARE)" in Corppass portal by your company's Corppass Admin to login.

For more information visit <https://go.gov.sg/corporate-login>

If you encounter technical issues with SHARE (e.g. unable to upload documents), please e-mail HSA_info@hsa.gov.sg with the screenshot of the error message for assistance.

Businesses and Other Corporate Entities

Log in with corppass

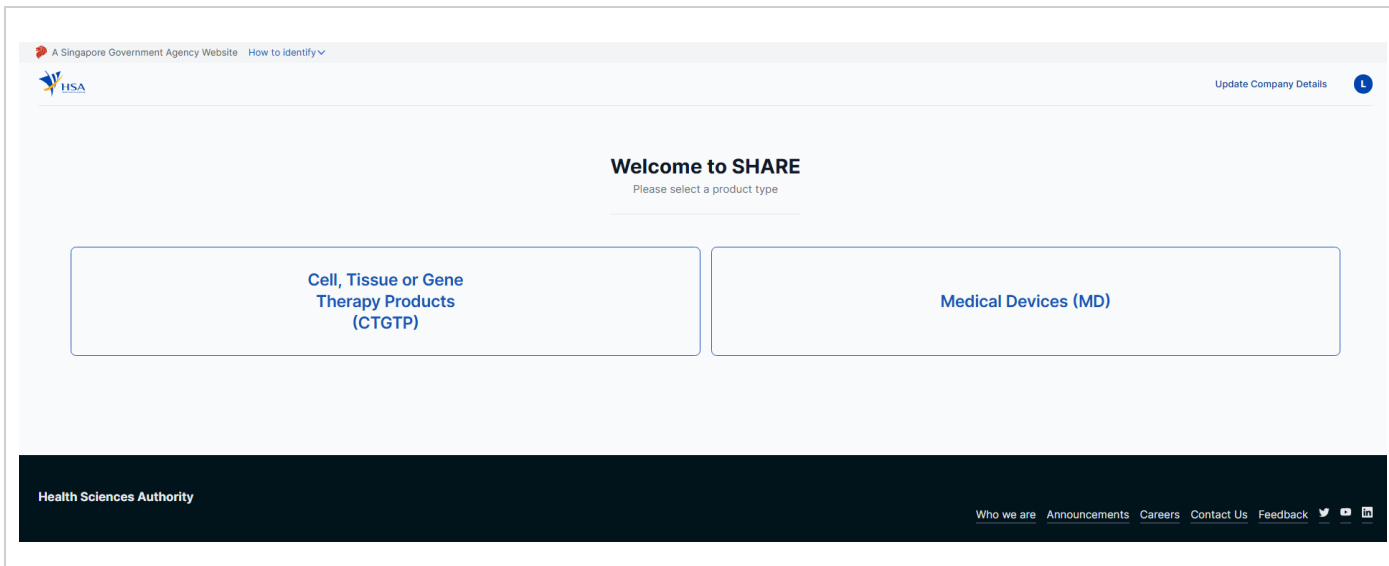
Don't have corppass account? [Get started](#)

URL: <https://share.hsa.gov.sg/>

Applicants will be brought to the main page of SHARE when they access the URL.

Please note that from 11 April 2021, you will be required to login to government digital services for business (G2B) using SingPass instead of Corppass.

For more information visit go.gov.sg/corporate-login



The screenshot shows the SHARE dashboard interface. At the top, there is a header with the HSA logo and a link to 'A Singapore Government Agency Website'. Below the header, the main content area displays 'Welcome to SHARE' with a prompt 'Please select a product type'. Two large buttons are presented: 'Cell, Tissue or Gene Therapy Products (CTGTP)' on the left and 'Medical Devices (MD)' on the right. A footer at the bottom contains the 'Health Sciences Authority' logo and a navigation menu with links for 'Who we are', 'Announcements', 'Careers', 'Contact Us', and 'Feedback', along with social media icons.

After login, select Cell, Tissue or Gene Therapy Products (CTGTP) to go to the DASH dashboard.

2.1 Update Company Details

The Update Company Details module is where you may submit an update request in the event that your company's registered name and/or address with ACRA has changed. Once the update request has been processed by the system, all Active Products/Licences/Applications associated with the company will have its company name/address details updated accordingly.

After login, select Update Company Details to go into the module.

Focused View

Company Details

CTGTP

MD

Declaration

Audit Trail

General Information

The company details reflected here is the latest information extracted from ACRA. No changes can be made to the company details from here. Do ensure that the latest company information has already been updated with ACRA.

This module is meant to make changes to the company details (name/address) displayed within the application forms and approved documents.

For billing address updates (where address is reflected in invoices, payment-related documents), please do it via the [Client Code](#) page.

Company Details

Company Name

UEN

Test Update 1.7

FirstTestUpdate

Company Address *

Postal Code *

Block / Number *

Level - Unit

Street Name *

Building Name

000007

007

07 - 07

Keagan Run 07

Texas 07

Cancel

Next >

Within the Company Details tab, the Company Details/Address will display the latest information extracted from ACRA.



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The CTGTP tab will display the list of Active Products/Licences/Applications that your company have under CTGTP, if any.

Suspended products and licences are also displayed within this list.

Focused View

Company Details

CTGTP

MD

Declaration

Audit Trail

Active Products/Licences/Applications

Any address change will apply to all the listed items

PRODUCTS

LICENCES

APPLICATIONS

Product Name

Product No.

Reset

Search

4 item(s) found

Product Name	Product No.	Class	Current Company Name	Current Company Address
Numquam minima fugit incididunt.	MDPR260303X0002	Class D	Test Update 1.7	007, Keagan Run 07, #07-07, Texas 07, Singapore 00... <a>Show More
Minus eligendi voluptatibus repudiandae quisquam f... <a>Show More	MDPR260303W0001	Class C	Test Update 1.7	007, Keagan Run 07, #07-07, Texas 07, Singapore 00... <a>Show More
Unde earum perferendis.	MDPN260302S0002	Class A	Test Update 1.7	007, Keagan Run 07, #07-07, Texas 07, Singapore 00... <a>Show More
Aspernatur dolorem magni laudantium illum esse rep... <a>Show More	MDPN260302R0001	Class A	Test Update 1.7	007, Keagan Run 07, #07-07, Texas 07, Singapore 00... <a>Show More

< Back

Next >

The MD tab will display the list of Active Products/Licences/Applications that your company have under MD, if any.

Suspended products and licences are also displayed within this list.

 HSA

Update Company Details 

Focused View 

Company Details

CTGTP

MD

Declaration

Audit Trail

Declaration

I, on behalf of my company, wish to confirm updating the company details for the above-mentioned products, licences and applications, refer to the total counts below.

Active CTGTP	: 6
Active CTGTP Licences	: 11
Pending/Draft CTGTP Applications	: 24
Active MD Product Listings	: 4
Active MD Licences	: 7
Pending/Draft MD Applications	: 8

[< Back](#)[Submit and Update !\[\]\(268d17a79f5913c36d8998dd535a8ce6_img.jpg\)](#)

Within the Declaration tab, a total count of each of the Active Products, Licences and Applications for CTGTP and MD will be displayed.

Click on the ‘Submit and Update’ button to have the company details of all the listed Products/Licences/Applications updated.

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 HSA

Update Company Details

Focused View

Company Details

CTGTP

MD

Declaration

Audit Trail

Audit Trail

MD

CTGTP

10 item(s) found

Changed On	Action	Items Changed
23-Mar-2026	Total Class BCD Updated: 2; Total Class A Updated:... Show More	View List
23-Mar-2026	Total Class BCD Updated: 2; Total Class A Updated:... Show More	View List
20-Mar-2026	Total Class BCD Updated: 2; Total Class A Updated:... Show More	View List
20-Mar-2026	Total Class BCD Updated: 2; Total Class A Updated:... Show More	View List
20-Mar-2026	Total Class BCD Updated: 2; Total Class A Updated:... Show More	View List
20-Mar-2026	Total Class BCD Updated: 2; Total Class A Updated:... Show More	View List

The Audit Trail tab displays details of when an update request was submitted as well as the items that have been updated for both CTGTP and MD.

3 Dashboard

The Home Page is where you land when you log in and select CTGTP. The dashboard gives an overview of statuses of all the applications. It helps to navigate directly to the respective pages when clicked.

The screenshot displays the HSA Dashboard interface. On the left is a navigation sidebar with links: Home, Applications, Tasks, Input Requests, Findings, Payment, Products, View Notices/Licences/Certificates, Search, E-GIRO Application, and Audit Documents. The main content area is titled 'Home' and includes an 'Overview' section with four blue cards: 'Active Applications' (5), 'Pending Tasks' (0), 'Products' (0), and 'Dealer's Notices and Licences' (0). Below this is the 'Latest Active Applications' section, which lists four applications with details such as Product Type, Product Name, Submission Type, Status, and Submission Date. Each application card has 'Withdraw' and 'View' buttons. The top right of the dashboard shows 'Dashboard' and 'Billing Management' tabs, along with a user profile icon.

The left panel serves the purpose of aiding applicants in navigating through the following:

[Applications](#)
[Tasks](#)
[Input Requests](#)
[Findings](#)
[Payment](#)
[Products](#)
[Search](#)
[Audit Documents](#)

Additionally, the blue cards serve the following functions:

Active Application:

Displays all applications submitted, pending HSA approval.

Pending Tasks:

Displays all tasks requiring action from the applicant.

Products:

Presents a list of products.

Dealer's Notice and Licences:

Presents a list of licences, certificates, notices.

Applicants would be able to create a new application by clicking on the '[New Application](#)' button.

4 Application Creation

4.1 Creation of New Application

After applicant clicks on 'New Application' they will be brought to this page. The selection chosen by the applicant will determine the type of application form that the applicant would be able to complete and submit.

New Application - Getting Started (i)

Applicants can select the type of application to be submitted.

Product Type

- This is **fixed for all applications**. Cell, Tissue and Gene Therapy Products (CTGTP).

Submission Type

- Dealer's Notice
- Product Notification
- Product Registration
- Importer's Licence/
Wholesaler's Licence
- Manufacturer's Licence
- GDP Certificate
- GMP Certificate
- Certificate of a
Pharmaceutical Product
(CPP)
- Free Sale Certificate (FSC)
- Special Access Route

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HSA

Dashboard Billing Management

New Application - Getting Started

Focused View

1. Details

2. Checklist

Details

Instructions for this page:
Please select the required submission type and application type for your application.

Product Type Cell, Tissue and Gene Therapy Products (CTGTP)

Submission Type Product Registration

Application Type Select Application Type

Product Class

New Product Registration (NDA-1, NDA-2 or NDA-3)
Variation (MAV-1, MIV-1 or MIV-2)
Fulfilment of Approval Conditions
Retention
Change of Registrant
Cancellation

Cancel this application and go back to Dashboard

[Cancel](#) [Next](#)

Application Type

(options in dropdown menu will only be shown **after selection of Submission Type**)

If Product Notification or Dealer's Notice is selected

- New
- Update
- Cancel

If Product Registration is selected

- New Product Registration (NDA-1, NDA-2 or NDA-3)
- Variation (MAV-1, MIV-1 or MIV-2)
- Fulfilment of Approval Conditions
- Retention
- Change of Registrant
- Cancellation
- Global Update of Importers

If Importer's Licence/Wholesaler's Licence or Manufacturer's Licence is selected

- New
- Amendment
- Cancel
- Renewal

If GDP Certificate / GMP Certificate / Certificate of a Pharmaceutical Product (CPP) / Free Sale Certificate (FSC) is selected

- New

If Special Access Route is selected

- New
- Fulfilment of Approval Condition

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HSA

Dashboard

Billing Management

New Application - Getting Started

Focused View

1. Details

2. Checklist

Details

Instructions for this page:
Please select the required submission type and application type for your application.

Product Type

Cell, Tissue and Gene Therapy Products (CTGTP)

Submission Type

Product Notification

Application Type

Select Application Type

Product Class

Select Product Class

Cancel this application
and go back to Dashboard

Cancel

Next

(options in dropdown menu will only be shown **after selection of Submission Type**)

- Class 1 (*For Product Notification, Dealer's Notice, Free Sale Certificate (FSC)*)
- Class 2 Minimally Manipulated (*Only for Dealer's Notice*)
- Class 2 (*For Product Registration, Certificate of a Pharmaceutical Product (CPP), Special Access Route*)

New Application - Getting Started (ii)

1. Details

2. Checklist

Product Type ⓘ Cell, Tissue and Gene Therapy Products (CTGTP)

Submission Type ⓘ Dealer's Notice

Application Type New

Product Class ⓘ Class 1 ⓘ Class 2 (Minimally Manipulated) ⓘ

Dealer Activity

Dealer's Activity

☐ Manufacturer

☐ Importer

☐ Wholesaler

Dealer's Activity

(options in dropdown menu will only be shown **after selection of Submission Type and Application Type**)

- Submission Type = 'Dealer's Notice'
- Application Type = 'New'

Applicants can select the type of activity they would like to apply for by checking the boxes. Applicants would be able to submit multiple dealer's activities under one application.

New Application - Getting Started (iii)

Focused View ☐

1. Details
2. Checklist

Details

Instructions for this page:
Please select the required submission type and application type for your application.

Product Type ⓘ

Cell, Tissue and Gene Therapy Products (CTGTP)

Submission Type ⓘ

Product Registration

Application Type

New Product Registration (NDA-1, NDA-2 or NDA-3)

Product Class ⓘ

Class 2

Evaluation Route

Select Evaluation Route

Dossier Format

Full
Abridged

Cancel this application and go back to Dashboard

Cancel

Next >

Evaluation Route

(options in dropdown menu will only be shown **after selection of Submission Type, Application Type and Variation Type**)

- Submission type = 'Product Registration'
- Application type = 'New Product Registration (NDA-1, NDA-2 NDA-3)'

OR

- Submission type = 'Product Registration'
- Application type = 'Variation (MAV-1, MIV-1 or MIV-2)' **and** Variation Type = 'MAV-1'

Applicants can select either full or abridged evaluation routes

Focused View ☐

1. Details

2. Checklist

Details

Instructions for this page:
Please select the required submission type and application type for your application.

Product Type ⓘ

Cell, Tissue and Gene Therapy Products (CTGTP)

Submission Type ⓘ

Product Registration

Application Type

New Product Registration (NDA-1, NDA-2 or NDA-3)

Product Class ⓘ

Class 2

Evaluation Route

Full

Dossier Format

Select Dossier Format

ICH CTD

ACTD

Cancel this application
and go back to Dashboard

Cancel

Next >

Dossier Format

(options in dropdown menu will only be shown **after selection of Submission Type and Application Type**)

- Submission type = 'Product Registration'
- Application type = 'New Product Registration (NDA-1, NDA-2 or NDA-3'

Applicants can select either ICH CTD or ACTD dossier formats

New Application - Getting Started (iv)

Focused View ☐

1. Details

2. Checklist

Details

Instructions for this page:
Please select the required submission type and application type for your application.

Product Type ⓘ Cell, Tissue and Gene Therapy Products (CTGTP)

Submission Type ⓘ Product Registration

Application Type Variation (MAV-1, MIV-1 or MIV-2)

Variation Type

Select Variation Type

MAV-1

MIV-1

MIV-2

Cancel this application and go back to Dashboard

Variation Type

(options in dropdown menu will only be shown **after selection of Submission Type and Application Type**)

- Submission type = 'Product Registration'
- Application type = 'Variation (MAV-1, MIV-1 or MIV-2)'

Applicants can select among MAV-1, MIV-1 or MIV-2 variation types

Focused View ☐

1. Details
2. Checklist

Details

Instructions for this page:
Please select the required submission type and application type for your application.

Product Type ⓘ

Cell, Tissue and Gene Therapy Products (CTGTP)

Submission Type ⓘ

Product Registration

Application Type

Variation (MAV-1, MIV-1 or MIV-2)

Variation Type

MIV-1

Existing Products

Select Existing Products

- ☐ Product F (CGPR241001M0013)
- ☐ Product C (CGPR241001J0010)
- ☐ Product D (CGPR241001K0011)
- ☐ Product B (CGPR241002K0001)

Cancel this application and go back to Dashboard

Existing Products

(options in dropdown menu will only be shown **after selection of Submission Type and Application Type**)

- Submission type = 'Product Registration'
- Application type = 'Variation (MAV-1, MIV-1 or MIV-2)'

Applicants can search for products using the search bar.

Multiple products can be selected.

For a continuation of MIV applications, visit the [MIV section](#).

New Application - Getting Started (iv)

1. Details

2. Checklist

Details

Instructions for this page:
Please select the required submission type and application type for your application.

Product Type ⓘ Cell, Tissue and Gene Therapy Products (CTGTP)

Submission Type ⓘ Product Registration

Application Type Change of Registrant

Relinquishing Company Select Company

Search

TSP (FirstCompanyOldUEN)

SeventhCompany (SeventhCompanyUEN)

SeventeenthCompany (SeventeenthCompanyUEN)

AAA (ZerothCompanyUEN)

Cancel this application and go back to Dashboard

Cancel

Relinquishing Company

(options in dropdown menu will only be shown **after selection of Submission Type and Application Type**)

- Submission type = 'Product Registration'
- Application type = 'Change of Registrant'

Applicants can search for companies using the search bar.

For a continuation of Change of Registrant applications, visit the [Change of Registrant section](#).

Focused View ☐

1. Details
2. Checklist

Details

Instructions for this page:
Please select the required submission type and application type for your application.

Product Type ⓘ

Cell, Tissue and Gene Therapy Products (CTGTP)

Submission Type ⓘ

Importer's Licence/ Wholesaler's Licence

Application Type

Amendment

Approved Licences

Select Approved Licences

- CGWL250113D08
- CGIF241218P08
- CGWL241218I07
- CGWL250113A05

Cancel this application and go back to Dashboard

Approved Licences

(options in dropdown menu will only be shown **after selection of Submission Type and Application Type**)

- Submission type = 'Importer's Licence/ Wholesaler's Licence'
- Application type = 'Amendment'

OR

- Submission type = 'Manufacturer's Licence'
- Application type = 'Amendment'

Applicants can search for licences using the search bar.

For a continuation of Licence Amendment applications, visit the [Licence Amendment section](#).

New Application - Getting Started (v)

- Registered CPP

Focused View ☐

1. Details
2. Checklist

Details

Instructions for this page:
Please select the required submission type and application type for your application.

Product Type

Cell, Tissue and Gene Therapy Products (CTGTP)

Submission Type

Certificate of a Pharmaceutical Product (CPP)

Application Type

New

Product Class

Class 2

Is the product registered in Singapore?

Yes

Product Registration Number

Select Product Registration Number

Search
Seventh Product 3 (CGPR251205W0007)
Seventh Product 1 (CGPR251205V0006)
Seventh Product 2 (CGPR251205U0005)
Seventh Product 4 (CGPR251205T0004)

Cancel this application and go back to Dashboard
Cancel

- Unregistered CPP

Focused View ☐

1. Details
2. Checklist

Details

Instructions for this page:
Please select the required submission type and application type for your application.

Product Type

Cell, Tissue and Gene Therapy Products (CTGTP)

Submission Type

Certificate of a Pharmaceutical Product (CPP)

Application Type

New

Product Class

Class 2

Is the product registered in Singapore?

No

Manufacturer License/GMP Certificate Number

Select Manufacture Licence or GMP Certificate

Search
CGMZ50617Q01
CGMZ50131I02

Cancel this application and go back to Dashboard
Cancel

Next >

Product Registration Number OR Manufacturer License/GMP Certificate Number
(options in dropdown menu will only be shown **after selection of Submission Type, Application Type, Product Class, and “Is the product registered in Singapore?”**)

- Submission type = 'Certificate of a Pharmaceutical Product (CPP)'
- Application type = 'New'
- Product Class = 'Class 2'

If “Is the product registered in Singapore?” = Yes:

- Product Registration Number field shown

If “Is the product registered in Singapore?” = No:

- Manufacturer License/GMP Certificate Number field shown

Applicants can search for Product Registration number, licence number, or certificate number using the search bar.

New Application - Getting Started (vi)

Product Notification Application
*(options in dropdown menu will only be shown **after selection of Submission Type**)*

- Submission type = 'Free Sale Certificate (FSC)'

Applicants can search for companies using the search bar.

New Application - Getting Started (vii)

Special Access Route
*(options in dropdown menu will only be shown **after selection of Submission Type**)*

- Submission type = 'Special Access Route'

Applicants can select either Registered or Unregistered Class 2 CTGTP.

New Application - Getting Started (viii) – Dealer’s Notice

New Application - Getting Started

1. Details

2. Checklist

Checklist

Instructions for this page:
Review your selections and prepare for your application.

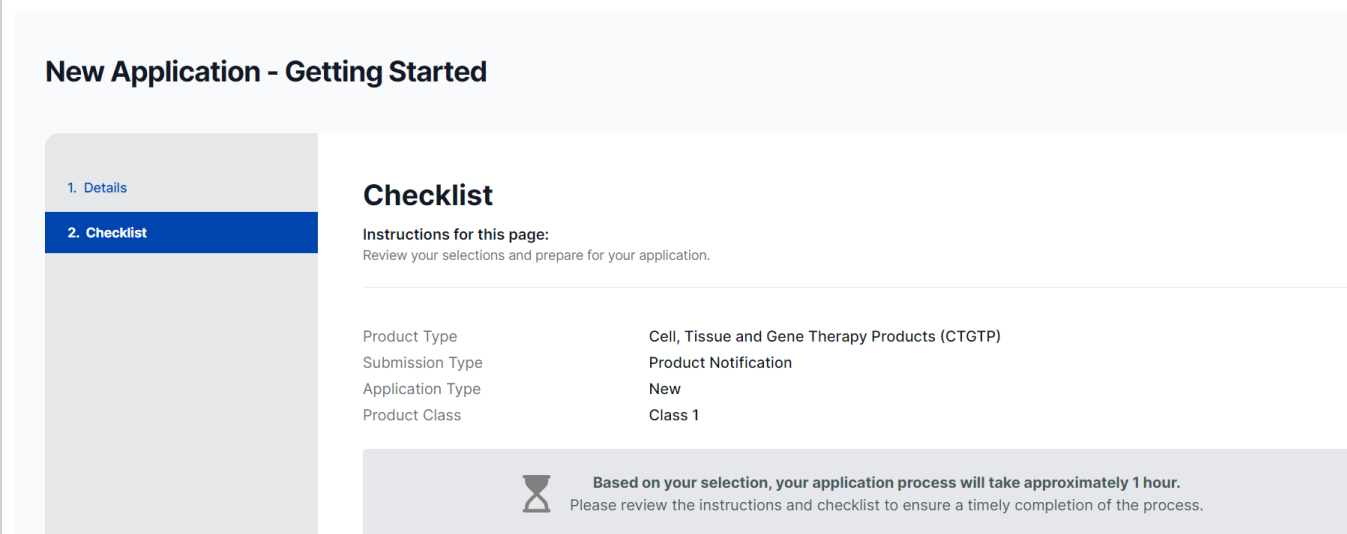
Product Type	Cell, Tissue and Gene Therapy Products (CTGTP)
Submission Type	Dealer's Notice
Application Type	New
Product Class	Class 1
	Class 2 (Minimally Manipulated)
Dealer's Activity	Manufacturer, Importer, Wholesaler



Based on your selection, your application process will take approximately 30 min.
Please review the instructions to ensure a timely completion of the process.

Applicants will be directed to the checklist page where there will be additional information regarding the application that the applicants are applying for.

Note: Information on this page may differ depending on the fields selected in [Creation of New Application](#).

New Application - Getting Started (viii) – Product Notification


New Application - Getting Started

1. Details
2. Checklist

Checklist

Instructions for this page:
Review your selections and prepare for your application.

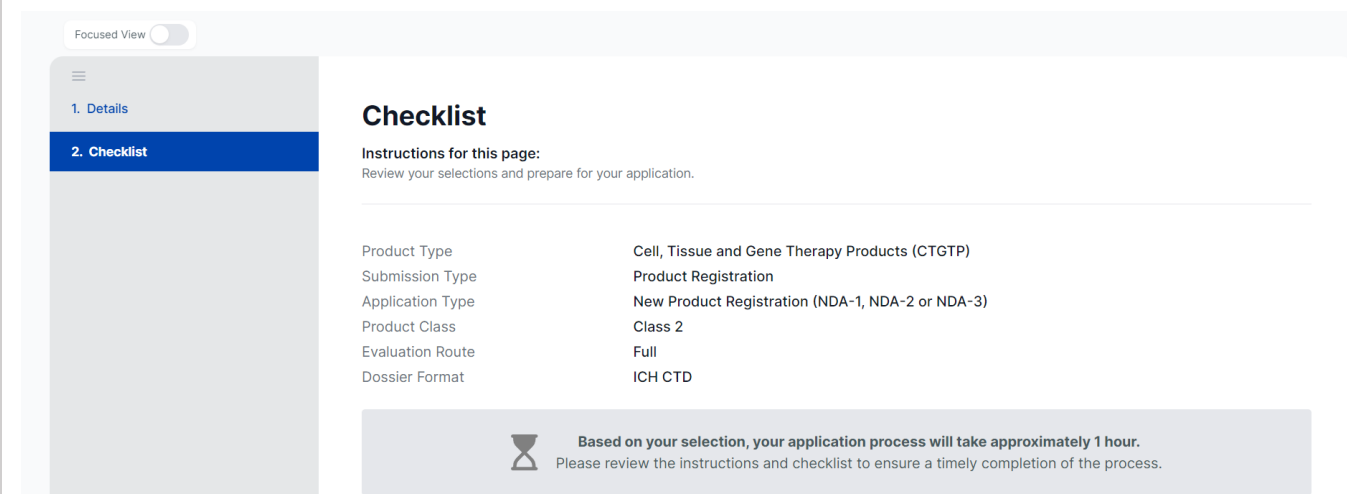
Product Type	Cell, Tissue and Gene Therapy Products (CTGTP)
Submission Type	Product Notification
Application Type	New
Product Class	Class 1



Based on your selection, your application process will take approximately 1 hour.
Please review the instructions and checklist to ensure a timely completion of the process.

Applicants will be directed to the checklist page where there will be additional information regarding the application that the applicants are applying for.

Note: Information on this page may differ depending on the fields selected in [Creation of New Application](#).

New Application - Getting Started (viii) – Product Registration


Focused View

1. Details
2. Checklist

Checklist

Instructions for this page:
Review your selections and prepare for your application.

Product Type	Cell, Tissue and Gene Therapy Products (CTGTP)
Submission Type	Product Registration
Application Type	New Product Registration (NDA-1, NDA-2 or NDA-3)
Product Class	Class 2
Evaluation Route	Full
Dossier Format	ICH CTD



Based on your selection, your application process will take approximately 1 hour.
Please review the instructions and checklist to ensure a timely completion of the process.

Applicants will be directed to the checklist page where there will be additional information regarding the application that the applicants are applying for.

Note: Information on this page may differ depending on the fields selected in [Creation of New Application](#).

New Application - Getting Started (viii) – Importer's Licence/ Wholesaler's Licence

The screenshot shows a web interface with a sidebar on the left containing a menu with '1. Details' and '2. Checklist'. The '2. Checklist' item is highlighted. The main content area is titled 'Checklist' and includes the following text:

Instructions for this page:
Review your selections and prepare for your application.

Product Type: Cell, Tissue and Gene Therapy Products (CTGTP)
 Submission Type: Importer's Licence/ Wholesaler's Licence
 Application Type: New
 Product Class: Class 2 (More Than Minimally Manipulated)

Based on your selection, your application process will take approximately 30 minutes.
 Please review the instructions and checklist to ensure a timely completion of the process.

Applicants will be directed to the checklist page where there will be additional information regarding the application that the applicants are applying for.

Note: Information on this page may differ depending on the fields selected in [Creation of New Application](#).

New Application - Getting Started (viii) – Manufacturer's Licence

The screenshot shows a web interface with a sidebar on the left containing a menu with '1. Details' and '2. Checklist'. The '2. Checklist' item is highlighted. The main content area is titled 'Checklist' and includes the following text:

Instructions for this page:
Review your selections and prepare for your application.

Product Type: Cell, Tissue and Gene Therapy Products (CTGTP)
 Submission Type: Manufacturer's Licence
 Application Type: New
 Product Class: Class 2 (More Than Minimally Manipulated)

Based on your selection, your application process will take approximately 30 minutes.
 Please review the instructions and checklist to ensure a timely completion of the process.

Applicants will be directed to the checklist page where there will be additional information regarding the application that the applicants are applying for.

Note: Information on this page may differ depending on the fields selected in [Creation of New Application](#).

New Application - Getting Started (viii) – GDP Certificate

The screenshot shows the 'Checklist' page for a GDP Certificate application. On the left is a sidebar with a 'Focused View' toggle and two menu items: '1. Details' and '2. Checklist', with '2. Checklist' selected. The main content area is titled 'Checklist' and includes instructions to review selections. It displays the following information: Product Type: Cell, Tissue and Gene Therapy Products (CTGTP); Submission Type: GDP Certificate; Product Class: Class 2 (More Than Minimally Manipulated). At the bottom, a grey box with an hourglass icon states: 'Based on your selection, your application process will take approximately 30 minutes. Please review the instructions and checklist to ensure a timely completion of the process.'

Applicants will be directed to the checklist page where there will be additional information regarding the application that the applicants are applying for.

Note: Information on this page may differ depending on the fields selected in [Creation of New Application](#).

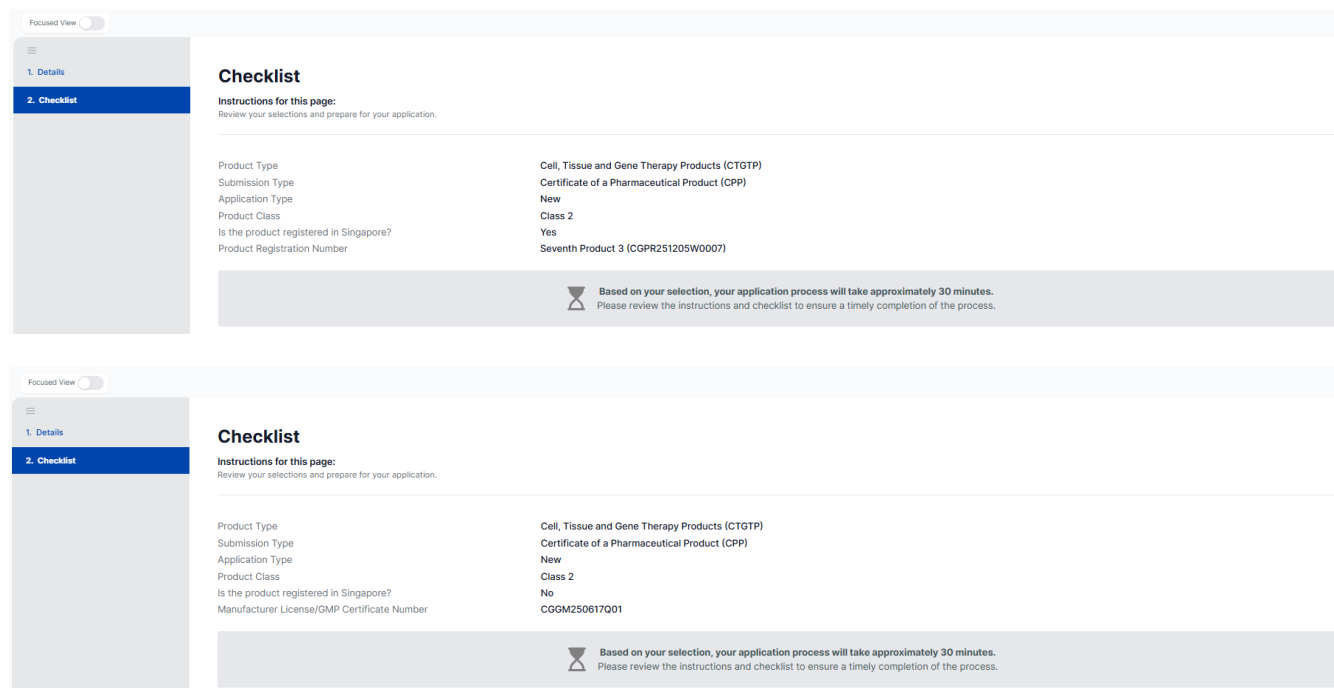
New Application - Getting Started (viii) – GMP Certificate

The screenshot shows the 'Checklist' page for a GMP Certificate application. The layout is identical to the GDP Certificate page, with the sidebar showing '2. Checklist' selected. The main content area displays: Product Type: Cell, Tissue and Gene Therapy Products (CTGTP); Submission Type: GMP Certificate; Product Class: Class 2 (More Than Minimally Manipulated). The bottom grey box with the hourglass icon contains the same 30-minute process time estimate and review instruction.

Applicants will be directed to the checklist page where there will be additional information regarding the application that the applicants are applying for.

Note: Information on this page may differ depending on the fields selected in [Creation of New Application](#).

New Application - Getting Started (viii) – Certificate of a Pharmaceutical Product (CPP)



Focused View ☐

1. Details

2. Checklist

Checklist

Instructions for this page:
Review your selections and prepare for your application.

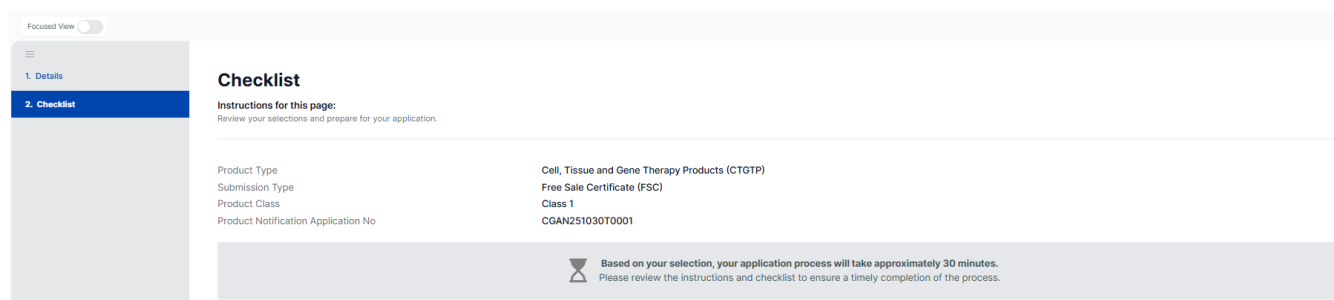
Product Type	Cell, Tissue and Gene Therapy Products (CTGTP)
Submission Type	Certificate of a Pharmaceutical Product (CPP)
Application Type	New
Product Class	Class 2
Is the product registered in Singapore?	Yes
Product Registration Number	Seventh Product 3 (CGPR251205W0007)

 Based on your selection, your application process will take approximately 30 minutes.
Please review the instructions and checklist to ensure a timely completion of the process.

Applicants will be directed to the checklist page where there will be additional information regarding the application that the applicants are applying for.

Note: Information on this page may differ depending on the fields selected in [Creation of New Application](#).

New Application - Getting Started (viii) – Free Sale Certificate (FSC)



Focused View ☐

1. Details

2. Checklist

Checklist

Instructions for this page:
Review your selections and prepare for your application.

Product Type	Cell, Tissue and Gene Therapy Products (CTGTP)
Submission Type	Free Sale Certificate (FSC)
Product Class	Class 1
Product Notification Application No	CGAN251030T0001

 Based on your selection, your application process will take approximately 30 minutes.
Please review the instructions and checklist to ensure a timely completion of the process.

Applicants will be directed to the checklist page where there will be additional information regarding the application that the applicants are applying for.

Note: Information on this page may differ depending on the fields selected in [Creation of New Application](#).

New Application - Getting Started (viii) – Special Access Route

Focused View

1. Details

2. Checklist

Checklist

Instructions for this page:
Review your selections and prepare for your application.

Product Type

Submission Type

Product Class

SAR Type

Cell, Tissue and Gene Therapy Products (CTGTP)

Special Access Route

Class 2

Registered Class 2 CTGTP

Based on your selection, your application process will take approximately 30 minutes.
Please review the instructions and checklist to ensure a timely completion of the process.

Focused View

1. Details

2. Checklist

Checklist

Instructions for this page:
Review your selections and prepare for your application.

Product Type

Submission Type

Product Class

SAR Type

Cell, Tissue and Gene Therapy Products (CTGTP)

Special Access Route

Class 2

Unregistered Class 2 CTGTP

Based on your selection, your application process will take approximately 30 minutes.
Please review the instructions and checklist to ensure a timely completion of the process.

Applicants will be directed to the checklist page where there will be additional information regarding the application that the applicants are applying for.

Note: Information on this page may differ depending on the fields selected in [Creation of New Application](#).



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4.1.1 Supporting Documents

Application For Product Notification (New)

Draft Application No. (Draft)

Last saved at 26 November 2023 06:26 PM

Supporting Documents

Company Details

Application Details

Manufacturers

Overview - Product Information

Overview - Products List

Review

Declaration

You are submitting a Product Notification for Class 1 Cell, Tissue and Gene Therapy Products (CTGTP)

Supporting Documents

Instructions for this page:

Please download the empty Supporting Documents.zip provided below. Organise your files into folder structure of the zip and upload the entire zip file. [Download detailed instructions \(PDF\).](#)

ProductNotification_SupportingDocument_Template.zip

Select files to upload... or drag and drop

Upload the completed Supporting Documents.zip

Error messages that might appear:

Dossier upload is not found

You are submitting a Product Notification for Class 1 Cell, Tissue and Gene Therapy Products (CTGTP)

Supporting Documents

Instructions for this page:

Please download the empty Supporting Documents.zip provided below. Organise your files into folder structure of the zip and upload the entire zip file. [Download detailed instructions \(PDF\).](#)

ProductNotification_SupportingDocument_Template

Upload supporting documents

Select files to upload... or drag and drop

Upload the completed Supporting Documents.zip

ProductNotification_SupportingDocument_Template.zip

2KB

Delete

Applicants are required to download the template zip, upload the supporting documents to the respective template folders within the zip file, and then proceed with the upload. Detailed instructions for guidance can be downloaded for further assistance.

Note: Criticality on this page may differ depending on the fields selected in Submission Type.

Error messages notes:

- 'Dossier upload is not found' error message will be shown when the dossier has been removed and then there is a network or communication issue that prevents the UI from retrieving the status. Please check your internet connection and try again.
- 'Additional folders outside of the dossier template was detected. Please ensure that the folder structure is as per template provided and reupload the zip file.' error message will be shown when there are folders or files that are inserted directly into the root folder. To solve this issue, make sure there is no other files


HSA
 Health Sciences Authority

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or folders directly under the root folder.

Company Information

Application For Dealer's Notice (New)

Draft

Application No.(Draft)

Last saved at 15 November 2023 11:24 AM

Supporting Documents

Company Details

Application Details

Dealer's Notice Details

 Review

 Declaration

You are submitting a Dealer's Notice for Class 1, Class 2 (Minimally Manipulated) Cell, Tissue and Gene Therapy Products (CTGTP)

Company Details

Company Information

This section is pre-filled on your Corppass login and requires no action on your part.

Company Name	FourthCompany
UEN	FourthCompanyUEN

Company Address

Subsections

Company Information

Company
Address

Contact Information

Billing Information

Payment Information

Applicants can navigate to other sections within the application form by clicking **the section name on the left panel**.

Company Information

- This information is **auto populated based on the Corppass login**. Applicants cannot edit any of the information for this section.

Company Address

Supporting Documents

Company Details

Application Details

Dealer's Notice Details

Review

Declaration

Company Address

Clear ACRA Address

Postal Code *

123456

Block / Number *

04

Level - Unit

04 - 04

Street Name *

Fourth Street

Building Name

Fourth Tower

Contact Information

This section is pre-filled on your **Company Address Book**. To edit this info, please visit your **Company Address Book**.

This is your default company contact for all system communications across all applications. If you only intend to make changes to the contact for this specific application, please make changes under "Applicant".

Subsections

Company Information

Company Address

Contact Information

Billing Information

Payment Information

This field is automatically populated based on the ACRA address. However, applicants can clear the pre-filled address and manually enter it if needed.

Do note that changing the address field in the application form **does not change/update any address in ACRA.*

Contact Information

Supporting Documents

Company Details

Application Details

Dealer's Notice Details

Review

Declaration

Company Address

Clear ACRA Address

Postal Code *123456

Block / Number *04

Level - Unit04 – 04

Street Name *Fourth Street

Building NameFourth Tower

Contact Information

This section is pre-filled on your **Company Address Book**. To edit this info, please visit your **Company Address Book**.

This is your default company contact for all system communications across all applications. If you only intend to make changes to the contact for this specific application, please make changes under "Applicant".

Subsections

Company Information

Company Address

Contact Information

Billing Information

Payment Information

Applicants can click on the **company address book**, opening a new tab that allows them to update the company's address book.

*Contact Information – Company Address Book***Company Address Book**[Add Contact](#)

S. No.	Contact Person	Contact Number	Email	
1	contact1	+65-827289299	contact1@mail.com	...

The new tab enables applicants to add new contact details by selecting '**Add Contact**' and filling in the necessary fields. Additionally, Applicants can **edit or delete** existing contact details in the company address book by clicking on the **three dots** on the right-hand side.

The company address book functions as a global update for the address book, ensuring synchronization across various applications submitted under the same company's UEN. All contacts listed under the company address book will receive notifications for ALL applications submitted under the same UEN.

Contact Information – Company Address Book

Company Address Book

Add Contact

✔ Your request was successful

S. No.	Contact Person	Contact Number	Email
1	J	+65-12345678	John@thesoftwarepractice.com

Successful message is displayed upon adding, deleting and editing the contact details.

4.1.3 Application Details

Application Information

Supporting Documents

Company Details

Application Details

Dealer's Notice Details

Review

Declaration

You are submitting a Dealer's Notice for Class 1, Class 2 (Minimally Manipulated) Cell, Tissue and Gene Therapy Products (CTGTP)

Application Details

Application Information

This sub-section is pre-filled from your initial selection and cannot be edited.

Product Type	Cell, Tissue and Gene Therapy Products (CTGTP)
Submission Type	Dealer Notice
Application Type	New
Class	Class 1, Class 2 (Minimally Manipulated)
Dealer's Activity	Manufacturer, Importer, Wholesaler

Main Applicant Information

Applicant Name (as in NRIC/FIN) *

RZ

Designation *

Input Designation

Subsections

Application Information

Main Applicant Information

Notification Emails

The information displayed under 'Application Information' is based on the applicant's selections made during the [application creation process](#).

This includes details such as:

- Product Type
- Submission Type
- Application Type
- Class
- Dealer's Activity (Only relevant to Dealer's Notice)
- Evaluation Type (Only relevant to Product Registration)
- Dossier Format (Only relevant to Product Registration)
- Application Option (Only relevant to GDP Certificate & GMP Certificate)
- Is the product registered in Singapore? (Only relevant to CPP)
- Product Registration Number (Only relevant to Registered CPP)
- Manufacturer Licence/GMP Certificate Number (Only relevant to Unregistered CPP)
- Product Notification Application Number (Only relevant to FSC)

Focused View

Supporting Documents

Company Details

Application Details

GDP Certificate Details

Payment Details

Review

Declaration

Application Details

Application Information

Product Type

Cell, Tissue and Gene Therapy Products (CTGTP)

Submission Type

GDP Certificate

Application Type

New

Class

Class 2 (More Than Minimally Manipulated)

Application Option *

☒ GDP with technical assessment. For new application requiring site inspection

☐ GDP without technical assessment. For importer/wholesaler who is already holding an existing license, please fill in these fields:

☐ Additional copy of GDP Certificate (for GDP certificate that has been issued)

Information on Products Distributed *

☐ CTGTP
 ☐ CTGTP as Clinical Research Materials (Investigational products)
 ☐ Starting materials used in CTGTP

Subsections

Application Information

Information On Products Distributed

Main Applicant Information

Notification Emails

- SAR Type (Only relevant to Registered and Unregistered SAR)

Note: For Application Details for Licences (Importer's, Wholesaler's), please refer to [the Importer's/ Wholesaler's Licence section.](#)

Application Option
Applicants should select one of the given options.

If 'GDP/GMP without technical assessment' is selected, applicants should choose an existing licence using the dropdown menu. Additionally, applicants should choose at least one of the given options under the Information on Products Distributed subsection.

If 'Additional copy of GDP/GMP Certificate' is chosen, applicants should select both an existing licence and how many additional copies of the licence they require from the dropdown menu.

Supporting Documents

Company Details

Application Details

Dealer's Notice Details

Review

Declaration

You are submitting a Dealer's Notice for Class 1, Class 2 (Minimally Manipulated) Cell, Tissue and Gene Therapy Products (CTGTP)

Application Details

Application Information

This section is pre-filled on your initial selection and cannot be edited

Product Type

Cell, Tissue and Gene Therapy Products (CTGTP)

Submission Type

Dealer Notice

Application Type

New

Class

Class 1, Class 2 (Minimally Manipulated)

Dealer Type

Manufacturer, Importer, Wholesaler

Main Applicant Information

This section is pre-filled on your Corppass login and requires no action on your part.

Applicant Name (as in NRIC/FIN) *

RZ

Designation *

Input Designation

Subsections

Application Information

Main Applicant Information

Notification Emails

The **applicant's name** is automatically populated based on the name retrieved from Corppass during [login](#).

The **designation field** is to be filled in by the applicant, reflecting their current position within the company.



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Notification Email

Supporting Documents

Company Details

Application Details

Dealer's Notice Details

Review

Declaration

Notification Emails

Please include your applicant contact details in this section, and additional contacts if required. All notifications regarding this application will be sent to the persons listed below and contact persons listed in the [Company Details](#) Section.

No Data Available

+ Add Notification Email 1

Subsections

Application Information

Main Applicant Information

Notification Emails

The applicant can update the notification email by selecting '**Add Notification Email.**'

The contact details entered under the notification email are specific to the application, and individuals listed under this email will receive notifications exclusively for updates related to the application.



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Dealer's Notice

Dealer's Notice Details

Application For Dealer's Notice (New)

Draft

Application No.(Draft)

Last saved at 26 November 2023 03:53 PM

Supporting Documents

Company Details

Application Details

Dealer's Notice Details

Review

Declaration

You are submitting a Dealer's Notice for Class 1, Class 2 (Minimally Manipulated) Cell, Tissue and Gene Therapy Products (CTGTP)

Dealer's Notice Details

Dealer's Activity

No Data Available

+ Add Site Particulars 1

***This section is only applicable for Dealer's Notice applications.**

Applicants need to input site particulars for the selected dealer's activity during the application creation process by clicking on ['+ Add Site Particulars'](#).

Applicants would be required to fill up at least 1 site before proceeding with the application.

*Add Site Particular's***Add Site Particulars 1**

Site Name * ⓘ

Enter Site Name

Dealer's Activity *

☐ Manufacturer☐ Importer☐ Wholesaler**Site Address**

Postal Code *

Get Address

Block / Number *

Level - Unit

Street Name *

Building Name

Quality Management System(s)

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:

Applicants are required to complete all mandatory fields indicated by '*', and subsequently, they should choose the appropriate Quality Management System (QMS) for their respective sites.

For continuation of Dealer's Notice applications, please refer to [Review section](#).

Product Notification

- Supporting Documents
- Company Details
- Application Details
- **Manufacturers**
- Overview - Product Information
- Overview - Products List
- Review
- Declaration

You are submitting a Product Notification for Class 1 Cell, Tissue and Gene Therapy Products (CTGTP)

Instructions for this page:
Please provide at least one Manufacturer - either Overseas or Local

Tissue Procurement Sites

Procurement Site 1

Edit

Delete

Site Name	Site 1	
Address	Tavenuee Cecil street Cecil road , ALGERIA	
Type Of Accreditations	Accreditations	Date of Expiry
	American Association of Tissue Banks [AATB] accreditation	23 May 2024
	Others: 1. United Kingdom Human Tissue Authority certificate 2. ISO 11137 Sterilisation of healthcare products – Radiation certificate	

+ Add Procurement Site 2

Overseas Manufacturers

Overseas Manufacturer 1		Edit	Delete								
Overseas Manufacturer Name	Allograft PLUS 20mm										
Overseas Manufacturer Address	1Duxton 21 Avenue 560032 , CANADA										
Activity	Manufacturing Site, Sterilisation Site										
Type of Accreditations	<table> <tr> <th>Accreditations</th><th>Date of Expiry</th></tr> <tr> <td>Foundation for the Accreditation of Cellular Therapy [FACT] accreditation</td><td>28 May 2024</td></tr> <tr> <td>Good Manufacturing Practice [GMP] certificate</td><td>17 Jun 2024</td></tr> <tr> <td colspan="2">Others: ISO 11135 Sterilisation of healthcare products - Ethylene Oxide certificate</td></tr> </table>			Accreditations	Date of Expiry	Foundation for the Accreditation of Cellular Therapy [FACT] accreditation	28 May 2024	Good Manufacturing Practice [GMP] certificate	17 Jun 2024	Others: ISO 11135 Sterilisation of healthcare products - Ethylene Oxide certificate	
Accreditations	Date of Expiry										
Foundation for the Accreditation of Cellular Therapy [FACT] accreditation	28 May 2024										
Good Manufacturing Practice [GMP] certificate	17 Jun 2024										
Others: ISO 11135 Sterilisation of healthcare products - Ethylene Oxide certificate											
		+ Add Overseas Manufacturer 2									

- Subsections
- Tissue Procurement Sites
- Overseas Manufacturers
- Local Manufacturers

***This section is only applicable for Product Notification applications.**

Manufacturers are categorised into three subsections:

- a. Tissue Procurement Sites
- b. Overseas Manufacturers
- c. Local Manufacturers

Applicants can add site details for any of the listed options. However, it is essential to provide site details on either overseas manufacturers or local manufacturers.

Note: For Local manufacturer, Applicants are required to enter the active dealer notice number, following which the details of the local manufacturer will be automatically populated.

Overview – Product Information

Focused View

Supporting Documents

Company Details

Application Details

Manufacturers

Overview - Product Information

Overview - Products List

Review

Declaration

You are submitting a Product Notification for Class 1 Cell, Tissue and Gene Therapy Products (CTGTP)

Overview - Product Information

Product Owner Information *

Product Owner Name *

John

Postal Code *

123456

Get Address

Block / Number *

123

Level - Unit *

12 - 123

Street Name *

6th Ave

Building Name *

Building A

Intended Use & Indications *

You can add multiple indications for each product or brand.

Intended Use 1

Source and Type of Tissue

Grade I

Intended Use And Indication

Research

Edit

Delete

+ Add Intended Use 2

Subsections

Product Owner Information

Intended Use & Indications

Container Closure System (CCS)

Product Information has three subsections:

- a. Product Owner Information
- b. Intended Use and Indications.
- c. Container Closure System (CCS)

Applicants are required to fill in the Product Owner's information and provide at least one Intended Use & Indication, as well as information on the Container Closure System; All **fields** are mandatory.

Overview – Product Information

Overview - Product Information

Overview - Products List

Review

Declaration

Container Closure System (CCS) *

You can add multiple CCS.

CCS 1

Container Closure System Description

Shelf Life

Storage Conditions (°C)

CCS Description

10 Years

Frozen

Edit

Delete

+ Add CCS 2

< Back

Overview - Products List >

Overview – Product List

Focused View ☐

Supporting Documents ☐

Company Details ☐

Application Details ☐

Manufacturers ☐

Overview - Product Information ☐

Overview - Products List

Review

Declaration

You are submitting a Product Notification for Class 1 Cell, Tissue and Gene Therapy Products (CTGTP)

Products List

List of Products *

You can add products using the 'New Product' button or upload an Excel file with product details in the format provided in [this template file](#)

Please use checkboxes to select multiple records and assign CCS, Indications and Sites.

Click to view details of CCS, Indications & Sites

0 item(s) selected Please click on Product Name or Product Code to edit.

☐	Product Name	Product Code	CCS	Indication	Sites	Action
☐	Product A	123	CCS-1	Indication-1	Site A	Remove
☐	Product B	456	CCS-1	Indication-1	Site A	Remove
☐	Product C	789	CCS-1	Indication-1	Site A	Remove

Applicants have the option to add products through two methods:

1. By uploading an Excel file.
Applicants can download the template file by clicking on '**this template file.**'
2. By uploading products individually via the '**New Products**' option, entering the details manually.

Once the product list has been populated, Applicants would be able to tag the products to Container Closure Systems (CCS), Indications, and Sites that were created in the previous sections.

Overview – Product List

Focused View

Supporting Documents

Company Details

Application Details

Manufacturers

Overview – Product Information

Overview – Products List

Review

Declaration

You are submitting a Product Notification for Class 1 Cell, Tissue and Gene Therapy Products (CTGTP)

Products List

List of Products *

You can add products using the 'New Product' button or upload an Excel file with product details in the format provided in [this template file](#)

Please use checkboxes to select multiple records and assign CCS, Indications and Sites.

Click to view details of CCS, Indications & Sites

View CCS

View Indications

View Sites

0 item(s) selected

Please click on Product Name or Product Code to edit.

☐	Product Name	Product Code	CCS	Indication	Sites	Action
☐	Product A	123	CCS-1	Indication-1	Select Sites Site A Site B Apply	Remove
☐	Product B	456	CCS-1	Indication-1	Site A	Remove
☐	Product C	789	CCS-1	Indication-1	Site A	Remove

New Product

Reupload

Applicants can select Indication and Sites from the drop-down list and click on apply.

Product Registration

Overview – Product Information

Focused View

Supporting Documents

Company Details

Application Details

Overview - Product Information

Manufacturers

Overview - Products List

Payment Details

Review

Declaration

You are submitting a New Product Registration (NDA-1, NDA-2 or NDA-3) Application for Class 2 Cell, Tissue and Gene Therapy Products (CTGTP)

Overview - Product Information

Product Owner Information *

Product Owner Name

Address

Add

List Of Products *

No Data Available

Add

Intended Use & Indications *

You can add multiple indications for each product or brand.

No Data Available

Add

Dosing Regimen *

You can add multiple dosing regimen

No Data Available

Add

Subsections

Product Owner Information

List Of Products

Intended Use & Indications

Dosing Regimen

Product Formula

Worldwide Registration Status

Container Closure System (CCS) And Shelf Life

***This section is only applicable for Product Registration applications.**

Overview - Product Information has seven subsections:

- a. Product Owner Information
- b. List Of Products
- c. Intended Use & Indications
- d. Dosing Regimen
- e. Product Formula
- f. Worldwide Registration Status
- g. Container Closure System (CCS) and Shelf Life

All **fields** are mandatory except for Worldwide Registration Status.

Ensure that the save button is clicked for each subsection upon completion.



Page 55 of 172

Overview – Product Information

List Of Products *

Listing Name* ⓘ	NDA* ⓘ	Referenced NDA* ⓘ	Dosage Form* ⓘ	Route Of Administration* ⓘ	ATC Code ⓘ	Importer/Wholesaler ⓘ	Actions
A* A_x μ °C X² X³ Σ New Product 1	NDA ▾	Referenced NDA ▾	Dosage Form ▾	Route Of Administration ▾	ATC Code	Tag Site	Delete

[New Product](#)
[Save](#)

For the List of Products subsection, applicants can tag an importer or wholesaler to products (Click on the Save button after adding products before tagging sites).

Depending on browser and zoom settings, applicants might have to scroll to the right to view the tag and delete buttons.

Select Importer or Wholesaler, enter the Dealer Notice Number and click on Get Dealer's Details to automatically fill up the fields with the information of that importer / wholesaler.

Tag Wholesalers/ Importers

Dealer Type ☒ Importer ☐ Wholesaler

Local Dealer's Notice Number ⓘ [Get Dealer's Details](#)

Local Dealer's Name

Postal Code *

Block / Number *

Level - Unit * -

Street Name *

Building Name *

[Close](#) [Save](#)

Overview – Product Information

Dosing Regimen *

You can add multiple dosing regimen

Dosing Regimen 1

Dosing RegimenOnce per day

Edit

Product Formula *

You can add multiple Product Formula.
If there are more than one component in the finished CTGTP (e.g., concentrate solution for injection and diluent as a composite pack), each component should be listed.

Component AProduct A

Substance Name*	Substance Type*	Substance Grade*	Substance Strength*	Actions
Substance A	Active Ingredie...	In-house British Pharma copoeia (BP)	A^x A_x μ °C X² X³ I_x 10	Delete

+ Add Substance

Delete Component

Duplicate

Add Component

Save

For the product formula subsection, applicants can add, edit and delete substances / components.

Components can be duplicated by clicking on the ‘Duplicate’ button.

Page 57 of 172

Overview – Product Information

Add CCS 1

Select Product *

Product A

Select Component *

Component A

CCS Description *

Storage Condition *

°C

Shelf Life *

Alternate Storage Condition(s) and Shelf Life

Shelf Life after Thawing or 1st Opening

Shelf Life after Reconstitution and/or Dilution

Cold Chain *

Select an option

Pack Size(s) (Qty/ CCS) *

A^x A_x μ °C X² X³ L_w

Pack Size(s) (CCS/ Pack) *

A^x A_x μ °C X² X³ L_w

Save

For the Container Closure System (CCS) and Shelf-Life subsection, the Component field is only visible after selecting a product in the 'Select Product' dropdown.

Components will only appear in the 'Select Component' dropdown if in the 'Product Formula' subsection, a substance strength for that product is entered.

Manufacturers

Manufacturers

Instructions for this page:
Please provide at least one Manufacturer - either Overseas or Local

Overseas Manufacturers

No Data Available

Local Manufacturers

No Data Available

Batch Releaser

No Data Available

Subsections

- Overseas Manufacturers
- Local Manufacturers
- Batch Releaser

Back Overview - Products List

***This section is only applicable for Product Registration applications.**

Manufacturers has three subsections:

- Overseas Manufacturers
- Local Manufacturers
- Batch Releaser

Ensure that the save button is clicked for each subsection upon completion.

The subsections are not mandatory, but the following requirements must be met:

- Each component must have at least one finished product manufacturer
- Each active substance must have at least one active substance manufacturer
- Each component must have at least one manufacturer with operation 'Bulk production'
- Each product must have at least one batch releaser

Add Local Manufacturers 1

Dealer Type

Local Manufacturer Licence/Dealer Licence Number* ⓘ

Local Manufacturer's Name* ⓘ

Postal Code *

Block / Number *

Level - Unit *

Street Name *

Building Name *

Site Details* ⓘ

Type of Manufacturer* ⓘ

Manufacturer

Type to Search for Manufacturer Licence or Dealer Notice Number

Retrieved Local Dealer Name

Select an option

☐ Finished Product Manufacturer

☐ Solvent/Diluent Manufacturer

☐ Active Substance Manufacturer

☐ Critical Starting Materials (e.g., viral vector for ex vivo gene modification) Manufacturer

☐ Others

Get Dealer's Details

Save

When adding Local Manufacturers, enter the Manufacturer Licence or Dealer Notice Number and click on Get Dealer's Details to automatically fill up the fields with the information of that local manufacturer.

Overview – Products List

Focused View

Supporting Documents

Company Details

Application Details

Overview - Product Information

Manufacturers

Overview - Products List

Payment Details

Review

Declaration

Products

Manufacturer

CCS

List of Products *

Product Name

Product A

Intended Use & Indications*

Select an option

Dosing Regimen*

Select an option

Component Name

Component A

Finished Product Manufacturer

Overseas Site A

CCS

CCS 1

Substance Name	Substance Type	Substance Grade	Substance Strength	Manufacturer
Substance A	Active Ingredient	In-house, British Pharmacopoeia (BP)	10	Overseas Site A

Each product in this section must contain an 'Intended Use & Indications' and a 'Dosing Regimen'.

Importer's Licence/ Wholesaler's Licence

Application Details

Focused View

Supporting Documents

Company Details

Application Details

Dealer's Licence Details

Payment Details

Review

Declaration

Application Details

Application Information

Product Type
Cell, Tissue and Gene Therapy Products (CTGTP)

Submission Type
Importer's Licence/ Wholesaler's Licence

Application Type
New

Class
Class 2 (More Than Minimally Manipulated)

Licence Details *

☒ Importer's Licence
☐ Wholesaler's Licence

Aspects of Importation *

☐ 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

Limited Scope Type

☐ Annual
☐ Per Consignment Only

Main Applicant Information *

Applicant Name (as in NRIC/FIN) *
Annie

Designation *
Assistant

Subsections

Application Information

Main Applicant Information

Notification Emails

***This section is only applicable for importer's/ Wholesaler's licence applications.**

Under Licence Details, applicants should select whether they wish to apply for an importer, wholesaler or both licences.

If Importer's Licence is selected, a new field, Aspects of Importation will appear. Applicants should select at least one of the given options to specify the purpose of the products being imported. Multiple selections are permitted.

Applicants may be prompted to select whether they require a GDP Certificate and should indicate their preference accordingly.

Dealer's Licence Details

Focused View

Supporting Documents

Company Details

Application Details

Dealer's Licence Details

Payment Details

Review

Declaration

Dealer's Licence Details

Warehouse Address *

Warehouse Address 1

Edit

Delete

Site Name	S
Site Activity	Warehouse
Applicable to	CTGTP Importer's Licence, CTGTP Wholesaler's Licence
Site Address	149, ROCHOR ROAD, FU LU SHOU COMPLEX, Singapore 188425
Other Address	N.A
Outsourced	No

+ Add Warehouse Address 2

Warehouse Details *

Warehouse Details 1

Edit

Delete

Selected Sites	S (149, ROCHOR ROAD, FU LU SHOU COMPLEX, Singapore 188425)
Temperature	Cold Chain -20°C to -10°C (Freeze)
Relative Humidity (Non-Cold Chain)	N.A
Relative Humidity (Cold Chain)	N.A
Other condition	N.A

+ Add Warehouse Details 2

Applicants need to input site particulars for the selected dealer's activity during the application creation process by clicking on ['+ Add Warehouse Address'](#) and ['+ Add Warehouse Details'](#), as well as ['+ Add Responsible Person'](#) buttons.

Applicants would be required to fill up the details of at least 1 site and 1 responsible person before proceeding with the application.

Add Warehouse Address

Applicants are required to complete all mandatory fields indicated by '*'.

Add Warehouse Address 1



Site Name * 

Enter Site Name

Site Name is required

Site Activity *

Warehouse

Is this warehouse an outsourced warehouse *

☐ Yes

☒ No

Site Address

Postal Code *

Get Address

Block / Number *

Level - Unit

-

Street Name *

Building Name

Other Address

Enter Other Address

 Save

*Add Warehouse Details***Add Warehouse Details 2**

Select Site *

Select an option



Temperature (°C)

☐ Non Cold Chain (> 8°C)☐ Cold Chain (≤ 8°C)

Relative Humidity (%) (Non-Cold Chain)

Min: %RH to Max: %RH

Relative Humidity (%) (Cold Chain)

Min: %RH to Max: %RH

Other Storage Conditions

Save

Applicants are required to complete all mandatory fields indicated by '*', as well as indicate the temperature range associated with the site. For certain options, a text box will appear, which must also be filled out.

*Add Responsible Person***Add Responsible Person 1**

Name (as in NRIC/FIN) *

Enter Name

Pharmacist Registration Number (PRN)

Enter Pharmacist Registration Number

Designation *

Enter Designation

Contact Number *

65

-

Enter Email

Email *

Save

Applicants are required to complete all mandatory fields indicated by '*'.

Manufacturer’s Licence

Focused View

Supporting Documents

Company Details

Application Details

Manufacturer's Licence Details

Payment Details

Review

Declaration

Manufacturer's Licence Details

Manufacturer Name *

Input Manufacturer Name

Manufacturer Site Address *

No Data Available

+ Add Manufacturing Site Address 1

Product Type *

☐ Cell therapy products

☐ Gene therapy products

☐ Tissue therapy products

☐ CTGT products combined with a therapeutic product or a medical device

Manufacturing Activity *

☐ Manufacture

Subsections

Manufacturer Name

Manufacturer Site Address

Product Type

Manufacturing Activity

Other Manufacturing Activities Conducted At The Same Site

Responsible Person (Production Operations)

Responsible Person (Quality Operations)

Outsourced Activities

***This section is only applicable for Manufacturer’s Licence applications.**

Manufacturer’s Licence Details has eight subsections:

a. Manufacturer Name

b. Manufacturer Site Address

c. Product Type

d. Manufacturing Activity

e. Other Manufacturing Activities Conducted At The Same Site

f. Responsible Person (Production Operations)

g. Responsible Person (Quality Operations)

h. Outsourced Activities

All fields are mandatory.

Page 66 of 172

Manufacturer Site Address

Add Manufacturing Site Address 1



Site Name * ⓘ

Site Activity *

- ☐ Manufacturing
- ☐ Quality Control Testing
- ☐ Storage and Handling

Site Address

Postal Code *

Block / Number *

Level - Unit

 -

Street Name *

Building Name

Other Address

For the Manufacturer Site Address subsection, applicants need to input site particulars for the manufacturer by clicking on **'+ Add Manufacturing Address'** button.

Under Site Activity, applicants must select at least one of the three given options, though multiple selections are permitted.

Product Type & Manufacturing Activity

Focused View

Supporting Documents

Company Details

Application Details

Manufacturer's Licence Details

Payment Details

Review

Declaration

Product Type *

☐ Cell therapy products

☐ Gene therapy products

☐ Tissue therapy products

☐ CTGT products combined with a therapeutic product or a medical device

Manufacturing Activity *

☒ Manufacture

☐ Secondary Packaging Only

Scope and Manufacturing Process *

Dosage Form

Sterilisation Step

Finished Product

Finished Product for specially authorized clinical use

Others (please specify):

No Data Available

Add New

Subsections

Manufacturer Name

Manufacturer Site Address

Product Type

Manufacturing Activity

Scope And Manufacturing Process

Packaging

Quality Control Testing

Other Manufacturing Activities Conducted At The Same Site

Responsible Person (Production Operations)

Responsible Person (Quality Operations)

Outsourced Activities

For the Product Type subsection, applicants must select at least one of the four given options, though multiple selections are permitted.

For Manufacturing Activity, only one selection is allowed. If 'Manufacture' is selected, additional subsections titled [Scope and Manufacturing Process](#), [Packaging](#) and [Quality Control Testing](#) will appear. Otherwise, if 'Secondary Packaging Only' is selected, an additional mandatory subsection titled [Scope](#) will appear.

*Scope and Manufacturing Process***Scope and Manufacturing Process ***

Dosage Form	Sterilisation Step	Finished Product	Finished Product for specially authorized clinical use	Others (please specify)
Select	Select an option	Select an option	Select an option	Select an option

Applicants should click on the 'Add New' button to fill up relevant details. Upon doing so, they will be presented with the form shown.

Dosage Form

- ☐ Injections, Cryopreserved
☐ Injections
☐ Others, please specify

Under **Dosage Form**, applicants must click 'Select' and choose only one of the three available options.

Scope and Manufacturing Process * Manufacturing Step Finished Product Finished Product for specially authorized clinical use Others (please specify): Select an option Select an option Select an option Select an option Delete Remarks (if any) For the fields Sterilisation Step, Finished Product and Finished Product for specially authorized clinical use, applicants are required to select one option from the dropdown lists. In the case of Others (please specify), applicants must similarly select one of the given options if needed. Additionally, the text box must be filled up.
--

Packaging Packaging * ☐ Primary Packaging ☐ Secondary Packaging ☐ Not Applicable	For the Packaging subsection, applicants must select one of the three given options. Multiple selections are permitted but if 'Not Applicable' is selected, it will automatically clear all other selections, and only 'Not Applicable' can be selected.
---	--

*Quality Control Testing***Quality Control Testing ***

- ☐ Chemical / Physical
- ☐ Microbiological
- ☐ Biological
- ☐ Not Applicable

Remarks (if any)

For the Quality Control Testing subsection, applicants must select one of the four given options. Multiple selections are permitted but if 'Not Applicable' is selected, it will automatically clear all other selections, and only 'Not Applicable' can be selected.

The Remarks text box is not mandatory and can be left blank.

*Scope***Scope ***

- ☐ Finished Product
- ☐ Finished product for specially authorized clinical use
- ☐ Others (please specify):

For the Scope subsection, applicants must select one of the three given options. Multiple selections are permitted. If 'Others' is selected, a mandatory text box will appear, which applicants must fill out.

*Other Manufacturing Activities Conducted at the Same Site***Other Manufacturing Activities Conducted at the Same Site ***

- ☐ Manufacture of investigational CTGT products
- ☐ Manufacture involving starting materials, viral vectors or viruses
- ☐ Manufacture of pathogenic organisms (biosafety level 3 and 4)
- ☐ Others (please specify):
- ☐ Not Applicable

For this subsection, applicants must select one of the five given options. Multiple selections are permitted but if 'Not Applicable' is selected, it will automatically clear all other selections, and only 'Not Applicable' can be selected. Additionally, if 'Others' is selected, a mandatory text box will appear, which applicants must fill out.

Responsible Person

Focused View

Supporting Documents

Company Details

Application Details

Manufacturer's Licence Details

Payment Details

Review

Declaration

Responsible Person (Production Operations) *

No Data Available

+ Add Responsible Person (Production Operations) 1

Responsible Person (Quality Operations) *

No Data Available

+ Add Responsible Person (Quality Operations) 1

Outsourced Activities *

Are there any outsourced activities?

☐ Yes
☒ No

Subsections

Manufacturer Name

Manufacturer Site Address

Product Type

Manufacturing Activity

Scope

Other Manufacturing Activities Conducted At The Same Site

Responsible Person (Production Operations)

Responsible Person (Quality Operations)

Outsourced Activities

Applicants need to input the particulars of at least 1 responsible person each (for production operations and quality operations respectively) by clicking on ['+ Add Responsible Person \(Production Operations\)'](#) and ['+ Add Responsible Person \(Quality Operations\)'](#) buttons.

Add Responsible Person (Production Operations)

Add Responsible Person (Production Operations) 1

×

Name (as in NRIC/FIN) *

Enter Name

Designation *

Enter Designation

Directly report to *

e.g. Director, Production or Site Head / CEO

Contact Number *

65

-

Email *

Enter Email

Save

Applicants are required to complete all mandatory fields indicated by '*'.

Add Responsible Person (Quality Operations)

Add Responsible Person (Quality Operations) 1

Name (as in NRIC/FIN) *

Enter Name

Designation *

Enter Designation

Directly report to *

e.g. Director, Production or Site Head / CEO

Contact Number *

65

-

Email *

Enter Email

Save

Similarly, applicants are required to complete all mandatory fields indicated by '*'.

Outsourced Activities

Focused View

Supporting Documents

Company Details

Application Details

Manufacturer's Licence Details

Payment Details

Review

Declaration

+ Add Responsible Person (Quality Operations) 2

Outsourced Activities *

Are there any outsourced activities?

Yes

No

No Data Available

+ Add Outsourced Site 1

Contract Agreement

Is the contract site/s aware that they have been named and may be subject to inspection by HSA, where necessary?

Yes

No, clarifying remarks

Have the contract site/s been assessed to be fit for purpose?

Yes

No, clarifying remarks

Is written contract or quality agreement with contract site/s in place?

Yes

No, clarifying remarks

< Back

Payment Details >

Subsections

Manufacturer Name

Manufacturer Site Address

Product Type

Manufacturing Activity

Scope

Other Manufacturing Activities Conducted At The Same Site

Responsible Person (Production Operations)

Responsible Person (Quality Operations)

Outsourced Activities

Contract Agreement

If 'Yes' is selected under Outsourced Activities, additional fields will appear.

Applicants will need to input the site particulars of at least 1 site using the '+ Add Outsourced Site' button, as well as answer all questions under Contract Agreement.



Page 75 of 172

*Add Outsourced Site***Add Outsourced Site 1**

Company Name *

Outsourced Activity *

- ☐ Storage
- ☐ Quality Control Testing
- ☐ Manufacturing Activities

Site Address

☐ Overseas ☒ Local

Postal Code *

Block / Number *

Level - Unit

 -

Street Name *

Building Name

Other Address

Point of Contact

Contact Email Address

Contact Number

 -

Applicants are required to complete all mandatory fields indicated by '*'.

For continuation of Manufacturer's Licence applications, please refer to [Payment Details section](#).

GDP Certificate

GDP Certificate Details

GDP Certificate Details

Warehouse Address *

No Data Available

+ Add Warehouse Address 1

Warehouse Details *

No Data Available

+ Add Warehouse Details 1

< Back

Payment Details >

Subsections

Warehouse Address

Warehouse Details

***This section is only applicable for GDP Certificate applications.**

Applicants need to input site particulars for their GDP Certificate by clicking on ['+ Add Warehouse Address'](#) and ['+ Add Warehouse Details'](#) buttons.

Applicants would be required to fill up the details of at least 1 site before proceeding with the application.

Note: If 'GDP without technical assessment' or 'Additional Copies of GDP Certificate' is chosen under Application Option in [Application Details](#), these fields will be auto populated.

GMP Certificate

GMP Certificate Details

Focused View

Supporting Documents

Company Details

Application Details

GMP Certification Details

Payment Details

Review

Declaration

GMP Certification Details

Manufacturer Name

Manufacturer Site Address

No Data Available

+ Add Manufacturing Site Address 1

Product Type

☐ Cell therapy products
☐ Gene therapy products
☐ Tissue therapy products
☐ CTGTP combined with a therapeutic product or a medical device
☐ Others, please specify:

GMP Certification Details

Manufacturer Name

Manufacturer Site Address

Manufacturing Site Address 1

Site Name	Manufacturer Name 888
Site Address	32, s12, #23-3e, 12, Singapore 112244
Other Address	21
Site Activity	Quality Control Testing Only, Manufacturing

Product Type

☒ Cell therapy products
☐ Gene therapy products

Manufacturing Activity *

☐ Manufacture
☒ Secondary Packaging Only

Scope *

Subsections

Manufacturer Name

Manufacturer Site Address

Product Type

Manufacturing Activity

Scope

Other Manufacturing Activities Conducted At The Same Site

Responsible Person (Production Operations)

Responsible Person (Quality Operations)

***This section is only applicable for GMP Certificate applications.**

GMP Certificate Details has seven subsections:

- Manufacturer Name
- Manufacturer Site Address
- Product Type
- Manufacturing Activity
- Other Manufacturing Activities Conducted At The Same Site
- Responsible Person (Production Operations)
- Responsible Person (Quality Operations)

All fields are mandatory. All fields and forms in this section are identical to those in [Manufacturer's Licence Details](#). Please refer to that section for a detailed breakdown of each field.

Note: If 'GMP without technical assessment' or 'Additional Copies of GMP Certificate' is chosen under Application Option in [Application Details](#), these fields will be auto populated.

Certificate of a Pharmaceutical Product - Registered

Certificate Details

Information on Product Registration

Focused View ☐

- Supporting Documents
- Company Details
- Application Details
- Certificate Details**
- Payment Details
- Review
- Declaration

Certificate Details

Information on Product Registration

Name of Product *	Seventh Product 4
Brand Name For Foreign Country or Regional Authority	Brand Name
Registration Number *	CGPR251205T0004
Date of Issue *	05-Dec-2025
Name of Product Registrant *	SeventhCompany Modified
Address of Product Registrant *	07, Seventh Street, 07-07, Seventh Tower, 123456
For this product, what is the status of the product registrant? *	☐ Select an option
Dosage Form *	AEROSOL, POWDER
Is The Product on The Market in Singapore? *	☐ Yes ☐ No
Requesting Country or Regional Authority *	Select an option

***This section is only applicable for CPP - Registered applications.**

Registered CPP Certificate Details has five subsections:

- a. Information on Product Registration
- b. Product Formula
- c. Information on Manufacturers
- d. Documents To Append To Certificate
- e. Company Comments

Certain information from the associated PR application are extracted into the Registered CPP application form. Under Information on Product Registration, the following fields are extracted and non-editable:

- Name of Product
- Registraton Number
- Date of Issue
- Name of Product Registrant
- Address of Product Registrant

All other fields within this section is mandatory except 'Brand Name For Foreign Country or Regional Authority'.

Product Formula

Focused View

Supporting Documents

Company Details

Application Details

Certificate Details

Payment Details

Review

Declaration

Product Formula

C1

Email Test 1

Substance Name	Substance Type	Substance Grade	Substance Strength
S1	Active Ingredient	British Pharmacopoeia (BP), In-house	10

☐ Do not display excipients on the certificate

☐ Do not display substance grade on the certificate

Subsections

Information On Product Registration

Product Formula

Information On Manufacturers

Documents To Append To Certificate

Company Comments

The Product Formula displays information extracted from the associated PR application. This is not a mandatory section.

Applicants can choose to either one of the checkbox options and the information will accordingly be displayed on the certificate.

Information on Manufacturers

Focused View

Supporting Documents

Company Details

Application Details

Certificate Details

Payment Details

Review

Declaration

Information on Manufacturers

Overseas Manufacturers

Note: Only Finished Product Manufacturer and Solvent/Diluent Manufacturer will be displayed on the certificate.

Overseas Manufacturers 1

Overseas Manufacturer Name

Overseas Manufacturer Address

Type of Manufacturer

Active Substances

Finished Product Components

Active Substance -- Manufacturing Operations

Finished Products -- Manufacturing Operations

Helen,Durgan

42395 Dortha Passage, AFGHANISTAN

Finished Product Manufacturer, Active Substance Manufacturer

S1 (C1)

C1

Bulk Production

Primary Packaging

☐ Display this site on certificate

Local Manufacturers

Note: Only Finished Product Manufacturer and Solvent/Diluent Manufacturer will be displayed on the certificate.

There's no local manufacturers available.

Batch Releaser

Note: Only batch releaser name and site address will be displayed on the certificate.

Batch Releaser 1

Batch Releaser Name

Office Address

Site Address

Manufacturers

Products

Claudine20

883 Kutch Drive, AFGHANISTAN

43080 Anderson Bypass, AFGHANISTAN

Helen,Durgan

Email Test 1

☐ Display this site on certificate

Subsections

Information On Product Registration

Product Formula

Information On Manufacturers

Documents To Append To Certificate

Company Comments

The Information on Manufacturers section displays manufacturers and batch releasers extracted from the associated PR application. This is a mandatory section.

Applicants will have to select at least one overseas or local manufacturer to be displayed on the certificate. It is not mandatory to select a batch releaser to be displayed on the certificate.

Note: Only Finished Product Manufacturer and Solvent/Diluent Manufacturer will be displayed on the certificate even if the “Display this site on certificate” is checked for other manufacturer types.



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Documents To Append To Certificate

Focused View

- Supporting Documents
- Company Details
- Application Details
- Certificate Details**
- Payment Details
- Review
- Declaration

Documents To Append To Certificate

View PR Dossier

Do you have documents to append to the certificate? ☒ Yes ☐ No

Document Type	Select Document
Package Insert (PI)	Select an option
Patient Information Leaflet (PIL)	Select an option
Product Composition	Select an option
Others	Select an option

Subsections

- Information On Product Registration
- Product Formula
- Information On Manufacturers
- Documents To Append To Certificate
- Company Comments

Applicants are allowed to append certain documents to the Registered CPP certificate. These documents will have to come from either the PR dossier files or from folder 2 of the CPP dossier – ‘Documents requested to be included in the certificate’. It is not mandatory for applicant to append the document to the certificate.

CPP Dossier

Focused View

- Supporting Documents**
- Company Details
- Application Details
- Certificate Details
- Payment Details
- Review
- Declaration

Supporting Documents

Instructions for this page:
Please download the empty Supporting Documents.zip provided below. Organise your files into folder structure of the zip and upload the entire zip file.

CPP Dossier

Email Test 1 Dossier

Download All Supporting Documents

Supporting Documents Size: 0 Bytes

Delete All Documents

Upload .zip

CertificatePharmaceuticalProduct_Registered_SupportingDocument_Template

1-Recent local sales invoice

2-Documents requested to be included in the certificate

3-Other supporting documents

Cancel

Company Details

If applicant has selected ‘Yes’, it will be mandatory to select at least one file to be appended to the document. Applicants can select the file from a dropdown list.



HSA
Health Sciences Authority

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Certificate of a Pharmaceutical Product - Unregistered

Certificate Details

Product Information

Focused View ☐

- Supporting Documents
- Company Details
- Application Details
- Certificate Details**
- Payment Details
- Review
- Declaration

Certificate Details

Product Information

Name of Product *

Brand Name For Foreign Country or Regional Authority

Dosage Form *

Is The Product on The Market in Singapore? * ☐ Yes ☐ No

Requesting Country or Regional Authority *

Subsections

- Product Information
- Product Formula
- Information On Manufacturers
- Company Comments

***This section is only applicable for CPP - Unregistered applications.**

Unregistered CPP Certificate Details has four subsections:

- Product Information
- Product Formula
- Information on Manufacturers
- Company Comments

All fields within the Product Information subsection is mandatory except 'Brand Name For Foreign Country or Regional Authority'.

Product Formula

Focused View ☐

- Supporting Documents
- Company Details
- Application Details
- Certificate Details**
- Payment Details
- Review
- Declaration

Product Formula

You can add multiple Product Formula.
If there are more than one component in the finished CTGTP (e.g., concentrate solution for injection and diluent as a composite pack), each component should be listed.

Subsections

- Product Information
- Product Formula
- Information On Manufacturers
- Company Comments

Component 1

Substance Name*	Substance Type*	Substance Strength*	Actions
A<sup>x</sup> A<sub>x</sub>	Select an option	A<sup>x</sup> A<sub>x</sub> μ °C X<sup>2</sup> X<sup>3</sup> I<sub>x</sub>	Delete

Applicants are required to input at least one component for the product and its associated 'Substance Name', 'Substance Type' and 'Substance Strength'.

Information on Manufacturers

Focused View

Supporting Documents

Company Details

Application Details

Certificate Details

Payment Details

Review

Declaration

Information on Manufacturers

Manufacturer Site Address *

Manufacturing Site Address 1

Site NameShania Jakubowski test23

Site Address650, 73454 Rowe Bridge, #01-02, Juston Koss test, Singapore 454

Site Other Address368 Bechtelar Ridges

Site ActivityStorage And Handling Only

☐ Manufacturing of all steps of the finished pharmaceutical product (FPP)

☐ Manufacturing the bulk finished product

☐ Manufacturing of solvent and diluents

☐ Quality control of FPP

☐ Batch release of FPP

☐ Primary packaging of the dosage form

☐ Secondary packaging of the product

☐ Other(s):

Subsections

Product Information

Product Formula

Information On Manufacturers

Company Comments

The Information on Manufacturers subsection displays manufacturers extracted from the associated ML/GMP application. This is a mandatory section.

Applicants will have to select at least one activity for each manufacturing site.



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Free Sale Certificate

*Certificate Details**Requesting Country and Regional Authority*

***This section is only applicable for FSC applications.**

FSC Certificate Details has four subsections:

- a. Requesting Country or Regional Authority
- b. Product Owner Information
- c. List of Products
- d. Company Comments

‘Regional Country or Regional Authority’ is a mandatory subsection where applicants need to input at least one country. Up to five countries can be selected within one application.

Product Owner Information

The information within Product Owner Information subsection is extracted from the associated PN application and is not editable by applicants.

List of Products

Focused View

Supporting Documents

Company Details

Application Details

Certificate Details

Payment Details

Review

Declaration

List of Products *

☐ Display All On Certificate

Display On Certificate	Product Listing Number	Product Name	Product Code	Indication(s)
☐	CGPN250520N0003	E2E 20250520 3	E2E 20250520 3	Indication-1 (Source and Type of 1
☐	CGPN250520O0004	E2E 20250520 4	E2E 20250520 4	Indication-1 (Source and Type of 1
☐	CGPN250520M0002	E2E 20250520 2	E2E 20250520 2	Indication-1 (Source and Type of 1
☐	CGPN250520L0001	E2E 20250527 1 - Update	E2E 20250520 1	Indication-1 (Source and Type of 1

Subsections

Requesting Country Or Regional Authority *

Product Owner Information

List Of Products *

Company Comments

The information within List of Products subsection is extracted from the associated PN application and is not editable by applicants.

Applicants can select which products they would like to display on the certificate. At least one product will need to be selected.

Company Comments

Focused View

Supporting Documents

Company Details

Application Details

Certificate Details

Payment Details

Review

Declaration

Company Comments

Subsections

Requesting Country Or Regional Authority *

Product Owner Information

List Of Products *

Company Comments

***This section is applicable for CPP and FSC applications.**

Applicants can input any comments they might have regarding the application. This is not a mandatory subsection and comments entered will not be displayed on the certificate.

Special Access Route – Registered

Application Details

Licence Held by Importer

Focused View ☐

Supporting Documents

Company Details

Application Details

SAR Details

Manufacturer Information

Payment Details

Review

Declaration

Application Details

Application Information

Product Type	Cell, Tissue and Gene Therapy Products (CTGTP)
Submission Type	Special Access Route
Application Type	New
Class	Class 2
SAR Type	Registered Class 2 CTGTP

Licence Held by Importer *

☒ Licensed CTGTP wholesaler (on behalf of a licensed hospital, clinic or nursing home)

WL Number

Expiry Date

Subsections

- Application Information ☒
- Licence Held By Importer ☐
- Main Applicant Information ☐
- Notification Emails ☐

***This section is only applicable for SAR applications.**

Under Licence Held by Importer subsection for Registered SAR, applicants will have to select 'Licensed CTGTP wholesaler (on behalf of a licensed hospital, clinic or nursing home)' option and select a valid Wholesaler's Licence (WL) held by the company from a dropdown list.

SAR Details

Product Information

Focused View

Supporting Documents

Company Details

Application Details

SAR Details

Manufacturer Information

Payment Details

Review

Declaration

Product Information *

Product

Prod 1 (CGPR260417C0008)

Product Name *

Prod 1

Registration Number *

CGPR260417C0008

Dosage Form *

AEROSOL

Active Substances *

Active Substance Name	Active Substance Strength
Sub 1	12
Sub 2	12

Source of Import (Location) *

Select Location

Pack Size *

A^{*} A_x μ °C X² X³ L_x

Requested Quantity *

A^{*} A_x μ °C X² X³ L_x

Batch Number *

Manufacturing Date

DD/MMM/YYYY

Expiry Date

DD/MMM/YYYY

Anticipated Product Import Date *

DD/MMM/YYYY

Subsections

Product Information

***This section is only applicable for SAR applications.**

Under SAR Details, applicants are required to provide information on the product.

Applicants can select the product from a dropdown list of all Class 2 CTGTP registered in Singapore.

Based on the product selection, the Product Name, Registration Number, Dosage Form and Active Substances fields will be autopopulated and is not editable by applicants.

The Active Substances fields will only display active substances and not excipients. These are autopopulated based on the Product selection and are not editable by applicants.

Other fields that are mandatory to fill for this section are Source of Import (Location), Pack Size, Requested Quantity and Batch Number.

Special Access Route – Unregistered

Application Details

Licence Held by Importer

Focused View

Supporting Documents

Company Details

Application Details

SAR Details

Manufacturer Information

Payment Details

Review

Declaration

Application Details

Application Information

Product Type

Submission Type

Application Type

Class

SAR Type

Cell, Tissue and Gene Therapy Products (CTGTP)

Special Access Route

New

Class 2

Unregistered Class 2 CTGTP

Licence Held by Importer *

☐ Licensed CTGTP wholesaler (on behalf of a licensed hospital, clinic or nursing home)

☐ Licensed hospital, clinic, or nursing home

☐ Licensed pharmacy

Subsections

Application Information

Licence Held By Importer

Main Applicant Information

Notification Emails

***This section is only applicable for SAR applications.**

Under Licence Held by Importer subsection, applicants could select one of the three options.

If 'Licensed CTGTP wholesaler (on behalf of a licensed hospital, clinic or nursing home)' is selected, applicants would have to select a valid Wholesaler's Licence (WL) held by the company from a dropdown list.

If 'Licensed hospital, clinic or nursing home' is selected, applicants would have to select one of the options from a dropdown list of licensed entities.

If 'Licensed pharmacy' is selected, applicants would have to key in the licensed pharmacy number into a text input box.

SAR Details

Product Information

Focused View

Supporting Documents

Company Details

Application Details

SAR Details

Manufacturer Information

Payment Details

Review

Declaration

SAR Details

Product Information *

Product Name *

A^x A_x μ °C X² X³ ℥_x

Dosage Form *

Dosage Form

Active Substances *

You can add multiple active substances per product

No Data Available

+ Add Active Substance

Requested Quantity *

A^x A_x μ °C X² X³ ℥_x

Pack Size *

A^x A_x μ °C X² X³ ℥_x

Anticipated Product Import Date *

DD/MMM/YYYY

Subsections

Product Information

Details Of Request

Approval By Other Regulatory Agencies

*This section is only applicable for SAR applications.

Under SAR Details, applicants are required to provide information on the product.

All fields in this section are mandatory.

Details of Request

Focused View

Supporting Documents

Company Details

Application Details

SAR Details

Manufacturer Information

Payment Details

Review

Declaration

Details of Request *

Number of Patients *

Unit Quantity Required * $\text{A}^\times$ A_x μ $^\circ\text{C}$ X^2 X^3 I_x

Name of Doctor / Dentist *

Registration Number of Doctor / Dentist *

Hospital / Clinic / Nursing Home

Name *

Department *

Address *

Contact Email *

Subsections

Product Information

Details Of Request

Approval By Other Regulatory Agencies

***This section is only applicable for Unregistered SAR applications.**

All fields under the Details of Request section is mandatory.

Approval by other Regulatory Agencies

Focused View

Supporting Documents

Company Details

Application Details

SAR Details

Manufacturer Information

Payment Details

Review

Declaration

Approval by other Regulatory Agencies *

I hereby declare that the aforementioned CTGTP is approved by: (Please tick where applicable)

☐ Australia Therapeutic Goods Administration
 ☐ European Medicines Agency
 ☐ Health Canada
 ☐ United Kingdom Medicines and Healthcare products Regulatory Agency
 ☐ United States Food and Drug Administration
 ☐ Others

I hereby declare that the CTGTP is from the same registered manufacturer as that approved by: (Please tick where applicable)

☐ Australia Therapeutic Goods Administration
 ☐ European Medicines Agency
 ☐ Health Canada
 ☐ United Kingdom Medicines and Healthcare products Regulatory Agency
 ☐ United States Food and Drug Administration
 ☐ Others

Subsections

Product Information

Details Of Request

Approval By Other Regulatory Agencies

***This section is only applicable for Unregistered SAR applications.**

‘Approval by other Regulatory Agencies’ is a mandatory subsection. Applicants will need to check at least one item for each of the declaration.

Special Access Route – Registered and Unregistered

Manufacturer Information

Supporting Documents

Company Details

Application Details

SAR Details

Manufacturer Information

Payment Details

Review

Declaration

Manufacturer Information

Active Substance Manufacturer *

Overseas Manufacturer

No Data Available

Add Overseas Manufacturer 1

Local Manufacturer

No Data Available

Add Local Manufacturer 1

CTGTP Manufacturer *

Overseas Manufacturer

No Data Available

Add Overseas Manufacturer 1

Local Manufacturer

No Data Available

Add Local Manufacturer 1

Back

Payment Details

Subsections

Active Substance Overseas Manufacturer

Active Substance Local Manufacturer

CTGTP Overseas Manufacturer

CTGTP Local Manufacturer

***This section is only applicable for both Registered and Unregistered SAR applications.**

In this section, applicant can input information about Active Substance Overseas Manufacturer, Active Substance Local Manufacturer, CTGTP Overseas Manufacturer, and CTGTP Local Manufacturer.

It is mandatory to provide at least one Active Substance Manufacturer, whether local or overseas.

It is also mandatory to provide at least one CTGTP Manufacturer, whether local or overseas. At least one of the CTGTP manufacturer will have to be a Finished Product Manufacturer.

Page 92 of 172

Add Overseas Manufacturer 1

Overseas Manufacturer Name* ⓘ

Location *

Select location

Address *

Type of Manufacturer* ⓘ

☐ Finished Product Manufacturer
☐ Solvent/Diluent Manufacturer
☐ Others

Save

Add Local Manufacturer 1

Dealer Type

Manufacturer

Local Manufacturer's Name * ⓘ

A* A_x μ °C X² X³ I_x

Postal Code *

Get Address

Block / Number *

Level - Unit *

-

Street Name *

Building Name *

Type of Manufacturer* ⓘ

☐ Finished Product Manufacturer
☐ Solvent/Diluent Manufacturer
☐ Others

Save

4.1.4 Payment Details

Focused View

Supporting Documents

Company Details

Application Details

Manufacturer's Licence Details

Payment Details

Review

Declaration

Payment Details

Billing Information *

You can manage your billing account details in the [Billing Management](#) section.
If you are setting up a new billing account, please note that it may take 1-2 working days for us to process your information. Once processed, you will be able to perform transactions.

Client Code *

Test11 (C-00389140) - Giro

Postal Code

Search

Block / Number

nickname (C-00012346) - Online

Test9 (C-00389118) - Online

nickname (C-00012345) - Giro

Test11 (C-00389140) - Giro

Level - Unit

Street Name

Building Name

Test11

Payment Information *

Selected Payment Mode *
For GIRO payments, it will typically takes 3 to 5 days to process. If your preferred payment mode is GIRO, please ensure that there are sufficient funds in the account. If this is an urgent application, it is recommended to select Online payment.

GIRO

GIRO

Subsections

Billing Information

Payment Information

Payment Details page allows applicants to select a Client Code using a drop-down menu under the Billing Information section.

In the Payment Information section, applications can choose their preferred payment method, either GIRO or Online Payment, and verify the cost of their application.

4.1.5 Review

Application For Product Notification (New)

Draft

Application No.(Draft)

Last saved at 26 September 2024 03:40 PM

Focused View

Supporting Documents

Company Details

Application Details

Manufacturers

Overview - Product Information

Overview - Products List

Review

Declaration

You are submitting a Product Notification for Class 1 Cell, Tissue and Gene Therapy Products (CTGTP)

Review

Supporting Documents

Download All Supporting Documents

Supporting Documents Size: 0 Bytes

ProductNotification_SupportingDocument_Template

1-CoverLetter

2-SiteAccreditations

2_1-TissueProcurement

2_2-Manufacturing

2_3-Sterilisation

2_4-Others

3-CoA

4-PackagelInsert

5-ProductLabel

6-ShelfLifeCCS

7-Others

Review page displays the summary of all the sections filled before the declaration.

Note: The view of the Review section depends on the Submission Type, selected by the applicant.



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4.1.6 Declaration

Application For Dealer's Notice (New)

Draft

Application No. (Draft)

Last saved at 18 April 2024 04:29 PM

Supporting Documents

Company Details

Application Details

Dealer's Notice Details

Review

Declaration

You are submitting a Dealer's Notice for Class 1 Cell, Tissue and Gene Therapy Products (CTGTP)

Declaration

1. I, on behalf of my company, confirm that the information submitted in this application is true and accurate.

2. I, on behalf of my company, confirm that there are no additional amendments made to this application or to the attachments thereof.

☒ I acknowledge and confirm the above declarations.

< Back

Submit

For all new and updated applications, applicants would be required to complete the declaration before submission.

Note: The view of Declaration section depends on the Submission Type, selected by applicant.



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4.2 Creation of Update Application

For applicants that would require to submit an update of any notified application or approved products, they are able to submit an update or variation application which allows to edit and update their closed application or products.

Update Application – Getting Started (i)

New Application - Getting Started

1. Details

2. Checklist

Details

Instructions for this page:
Please select the required product type and submission type for your application.

Product Type ⓘ

Cell, Tissue and Gene Therapy Products (CTGTP)

Submission Type ⓘ

Product Notification ▼

Application Type

Update ▼

Existing Application

CGNN231130N0009 ▼

Cancel this application and go back to Dashboard

Cancel

Next >

For all closed applications with submission type 'Product Notification' or 'Dealer's Notice', applicants can submit an update application. For closed application with submission type 'Product Registration', applicants can submit a variation application.

Applicants will populate the following fields in a manner similar to the process of [creating a new application](#).

- Submission type
- Application type
- Existing Applications (Shows a list of all closed applications, if submission type is 'Product Notification' or 'Dealer's Notice')
- Existing Products (Shows a list of all approved products, if submission type is 'Product Registration')

Update Application – Getting Started (ii)

1. Details

2. Checklist

Checklist

Instructions for this page:
Review your selections and prepare for your application.

Product Type

Submission Type

Application Type

Cell, Tissue and Gene Therapy Products (CTGTP)

Product Notification

Update



Based on your selection, your application process will take approximately 1 hour.
Please review the instructions and checklist to ensure a timely completion of the process.

Applicants will be directed to the checklist page where there will be additional information regarding the application that the Applicants are applying for.

Note: Information on this page may differ depending on the Submission Type & Application Type selected by Applicants.

Updates of Product Notification

Application For Product Notification (Update)

Updates of Product Notification

Supporting Documents

Company Details

Application Details

Manufacturers

Overview - Product Information

Overview - Products List

Review

Declaration

You are submitting a Product Notification for Class 1 Cell, Tissue and Gene Therapy Products (CTGTP)

Updates of Product Notification

Instructions for this page:
Please indicate your update summary by selecting at least 1 option

☐ Update of American Association of Blood Banks [AABB] accreditation

☐ Update of American Association of Tissue Banks [AATB] accreditation

☐ Update of College of American Pathologists [CAP] accreditation

☐ Update of Eye Bank Association of America [EBAA] accreditation

☐ Update of Foundation for the Accreditation of Cellular Therapy [FACT] accreditation

☐ Update of Good Manufacturing Practice [GMP] certificate

☐ Update of Health Canada Cells, Tissues and Organs [CTO] registration certificate

☐ Update of ISO 11135 Sterilisation of healthcare products – Ethylene Oxide certificate

☐ Update of ISO 11137 Sterilisation of healthcare products – Radiation certificate

☐ Update of ISO 13485 Quality Management System certificate

☐ Update of Manufacturer's Licence

☐ Update of Tissue Bank Licence

☐ Update of United Kingdom Human Tissue Authority certificate

☐ Update of list of notified products

☐ Update of product label

☐ Update of product shelf life

☒ Others, please specify

Update of Product code

Cancel

Supporting Documents

***This section is only applicable for Updates of Product Notification applications.**

Applicants will have to select the relevant checkboxes based on the changes they want to make for the application.

Note: The subsequent pages for both dealer's notice and product notification remain consistent with the pages used during the creation of a new application.

Variation Application

Focused View ☐

MIV-1 Checklist

Supporting Documents

Company Details

Application Details

Overview - Product Information

Manufacturers

Overview - Products List

Payment Details

Review

Declaration

You are submitting a Minor Variation 1 Application for Class 2 Cell, Tissue and Gene Therapy Products (CTGTP)

MIV-1 Checklist

Instructions for this page:
Please indicate your update summary by selecting at least 1 option

PART A: CHECKLIST ON DOSSIER REQUIREMENTS FOR MIV-1 APPLICATION

- ☐ A1. Change and/or addition of alternative manufacturer/site of active substance, critical starting materials, CTGTP and/or process intermediates
- ☐ A2. Change in manufacturing process
- ☐ A3. Change of specification of active substance, critical starting materials CTGTP, process intermediates and/or in-process control tests
- ☐ A4. Qualitative or quantitative change of excipient of active substance and/or CTGTP
- ☐ A5. Change in primary packaging material for active substance or CTGTP
- ☐ A6. Change or addition of pack size/fill volume
- ☐ A7. Inclusion or replacement of solvent/diluent for CTGTP
- ☐ A8. Change of shelf-life of active substance or CTGTP
- ☐ A9. Change of storage condition of active substance or CTGTP
- ☐ A10. Addition or replacement of site responsible for quality control testing laboratory
- ☐ A11. Replacement of master cell/seed bank
- ☐ A12. Change of test procedure
- ☐ A13. Change of reference standard
- ☐ A14. Change of content of product labelling
- ☐ A15. Change and/or addition of alternative cell/tissue procurement site
- ☐ Others

PART B: CHECKLIST ON DOSSIER REQUIREMENTS FOR MIV-2 APPLICATION

- ☐ B1. Change of product name
- ☐ B2. Change of product labelling
- ☐ B3. Addition or replacement of company or party responsible for batch release
- ☐ B4. Minor change in manufacturing process
- ☐ B5. Change of specification of active substance, critical starting materials, CTGTP, process intermediates and/or in-process control tests

***This section is only applicable for variation applications for Product Registration applications.**

Applicants will have to select the relevant checkboxes based on the changes they want to make for the application for MIV-1 and MIV-2 variation applications. For MAV-1 variation applications, applicants must enter a summary of the changes.

Note: The subsequent pages remain consistent with the pages used during the creation of a new application.

Focused View

MAV Application

Supporting Documents

Company Details

Application Details

Overview - Product Information

Manufacturers

Overview - Products List

Payment Details

Review

Declaration

You are submitting a Major Variation Application for Class 2 Cell, Tissue and Gene Therapy Products (CTGTP)

MAV Application

Instructions for this page:
Please indicate your update summary

Remarks/ Comments

Cancel

Supporting Documents

Supporting Documents

Company Details

Application Details

Overview - Product Information

Manufacturers

Overview - Products List

Payment Details

Review

Declaration

List Of Products

Previous values

Changes in Current Application

The review section will display the changes between the Previous values and changes in the variation application.

4.3 Creation of Amendment Application

For applicants that want to amend an approved licence.

Amendment Application – Getting Started (i)

A Singapore Government Agency Website

How to identify

HSA

Health Sciences Authority

Dashboard

Billing Management

New Application - Getting Started

Focused View

1. Details

2. Checklist

Details

Instructions for this page:

Please select the required submission type and application type for your application.

Product Type

Cell, Tissue and Gene Therapy Products (CTGTP)

Submission Type

Importer's Licence/ Wholesaler's Licence

Application Type

Amendment

Approved Licences

Select Approved Licences

CGWL250115B04

CGIT250116U02

CGIF241218P08

CGWL241218I07

CGWL250113A05

Cancel this application and go back to Dashboard

Cancel

For all closed applications with submission type 'Importer's Licence/ Wholesaler's Licence' or 'Manufacturer's Licence', applicants can submit an amendment application.

Submission Type: Importer's Licence/ Wholesaler's Licence

OR Manufacturer's Licence.

Application Type: Amendment

Additionally, applicants should select an approved licence to be amended from the dropdown menu.



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Amendment Application – Getting Started (ii)

Focused View

1. Details

2. Checklist

Checklist

Instructions for this page:
Review your selections and prepare for your application.

Product Type

Submission Type

Application Type

Product Class

Cell, Tissue and Gene Therapy Products (CTGTP)

Importer's Licence/ Wholesaler's Licence

Amendment

Class 2 (More Than Minimally Manipulated)

Based on your selection, your application process will take approximately 30 minutes.
Please review the instructions and checklist to ensure a timely completion of the process.

Applicants will be directed to the checklist page where there will be additional information regarding the application that the Applicants are applying for.

Note: Information on this page may differ depending on the Submission Type & Application Type selected by Applicants.



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Amendment Details Application For Importer's Licence/ Wholesaler's Licence (Amendment) Draft Application No.(Draft) Last saved at 16 January 2025 01:58 PM Focused View Supporting Documents Company Details Application Details Dealer's Licence Details Amendment Details Payment Details Review Declaration Amendment Details Does this amendment application require technical assessment? ☐ Yes ☒ No < Back Payment Details >	Applicants will have to answer the question based on the changes they want to make for the application. Note: The previous pages for both Importer's Licence/Wholesaler's Licence and Manufacturer's Licence remain consistent with the pages used during the creation of a new application.
Focused View Supporting Documents Company Details Application Details Dealer's Licence Details Amendment Details Payment Details Review Declaration Main Applicant Information Previous values Name Rachana Designation test Changes in Current Application Name Annie Designation Assistant Notification Emails Notification Email 1 Contact Person A1 Contact Number +65-80009000 Email rachana@tsp.dev Warehouse Address Previous values Warehouse Address 1 Site Name W1 Site Activity Warehouse Site Address 233, 233Q3, Singapore 123456 Other Address N.A Outsourced No Changes in Current Application Warehouse Address 1 Site Name W1 Site Activity Warehouse Site Address 6, CHIN BEE CRESCENT, Singapore 619892 Other Address N.A Outsourced No	The review section will display the changes between the Previous values and changes in the amendment application.

5 Cancellation of Products, Licences, or Notices

Applicants that would like to notify HSA of any cancellation of dealer's notice, notified products, approved products, or licences would be able to select the list of items, indicate the reason for cancellation and choose the date for cancellation.

Dealer's Notice

Cancel Dealer's Notice – Getting Started (i)

New Application - Getting Started

1. Details

2. Checklist

Details

Instructions for this page:
Please select the required product type and submission type for your application.

Product Type ⓘ

Cell, Tissue and Gene Therapy Products (CTGTP)

Submission Type ⓘ

Dealer's Notice ▼

Application Type

Cancel ▼

Cancel this application
and go back to Dashboard

Cancel

Next >

Applicants will populate the following fields in a manner similar to the process of [creating a new application](#).

- Submission type
- Application type

Choose the required submission type, application type(cancel) and click on Next, which redirects to checklist page

*Cancel Dealer's Notice – Getting Started (ii)***New Application - Getting Started**

1. Details

2. Checklist

Checklist**Instructions for this page:**

Review your selections and prepare for your application.

Product Type	Cell, Tissue and Gene Therapy Products (CTGTP)
Submission Type	Dealer's Notice
Application Type	Cancellation



Based on your selection, your application process will take approximately 30 min.
Please review the instructions to ensure a timely completion of the process.

You are about to start the application for a Dealer's Notice for import, wholesale and/or manufacture of Cell, Tissue and Gene Therapy Products (CTGTP) that are minimally manipulated in Singapore.

Applicants will be directed to the checklist page where there will be additional information regarding the application that the Applicants are applying for.

Note: Information on this page may differ depending on the Submission Type & Application Type selected by Applicants.

Cancel Application For Dealer Notice

1. Dealer's Activity

2. Submit

Dealer's Activity**Select Dealer Activities to cancel**
☒ CGAD231121K0003 | Manufacturer | CGKM231121R09

Site Name

Site Man

Site manip edited

Effective Date for Cancellation

26/11/2023



Applicants can choose the required Dealer's Activity they want to cancel.

Afterwards, the applicant can select the effective date of cancellation.

Note: Information on this page may differ depending on the Submission Type & Application Type selected by Applicants.

Cancel Dealer's Notice – Submit

1. Dealer's Activity

2. Submit

The activities listed below will be cancelled.

CGAD231121K0003 | Manufacturer | CGKM231121R09 effective on 26 Nov 2023

< Back

Confirm Cancellation

Applicants need to confirm the required Dealer's Activity they want to cancel.

Product Notification

Cancel Product Notification – Getting Started (i)

Applicants will populate the following fields in a manner similar to the process of [creating a new application](#).

- Submission type
- Application type

Choose the required submission type, application type(cancel) and click on Next, which redirects to checklist page

Applicants will be directed to the checklist page where there will be additional information regarding the application that the Applicants are applying for.

Note: Information on this page may differ depending on the Submission Type & Application Type selected by Applicants

New Application - Getting Started

1. Details
2. Checklist

Details

Instructions for this page:
Please select the required product type and submission type for your application.

Product Type

Cell, Tissue and Gene Therapy Products (CTGTP)

Submission Type

Product Notification

Application Type

Cancel

Cancel this application and go back to Dashboard

Cancel

Next

1. Details
2. Checklist

Checklist

Instructions for this page:
Review your selections and prepare for your application.

Product Type

Cell, Tissue and Gene Therapy Products (CTGTP)

Submission Type

Product Notification

Application Type

Cancellation

Based on your selection, your application process will take approximately 1 hour.

Please review the instructions and checklist to ensure a timely completion of the process.

You are about to start the application for a Product Notification for Class 1 Cell, Tissue and Gene Therapy Products (CTGTP) to supply the product(s) in Singapore.

Please note that you, as a supplier of Class 1 CTGTP, must receive HSA's written acceptance of the Product Notification before the product(s) can be supplied in Singapore.

Submission Instructions

- You may include products with the same proprietary name or brand names from the same product owner in a single application.
- All documents submitted in support of the application must be in English, filed and uploaded as a zip file in accordance to the following supporting documents template: [Supporting Documents Template.zip](#)
- Further guidance on the preparation of the supporting documents can be found in Appendix 1 Guidelines on our [website](#)
- We will contact you for fee payment after submission of the application.
- Mode of payments accepted are: GIRO (Please ensure that you have an existing GIRO arrangement with HSA's), Paynow

View Checklist

For more information, please visit our [website](#)

Change Product or Submission Type

< Back

You will not be able to change your Product or Submission type after this page

Create Application

Cancel Product Notification – Getting Started (ii)

Cancel Application For Product Notification

Focused View ☐

1. Products List
2. Submit

Products List

Select Products to Cancel

Approved product number

Product Code

Product owner

Reset Filter

Approved product number	Product Name	Product Code	Product owner	CCS	Indication	Sites	Effective Date
☒ CGPN240523S0015	P00010002 ~ @ 2 132	px15	Mikayla17	Culpa impedit nobis amet praesentium cum ea modi non sint.	Repudiandae animi amet totam autem amet in sint illum.	Obie Schamberger, Jacinto Satterfield, Margarete Lockman	24/10/2024
☐ CGPN240523R0014	P00010001 ~ @ 2 132	px14	Mikayla17	Culpa impedit nobis amet praesentium cum ea modi non sint.	Repudiandae animi amet totam autem amet in sint illum.	Obie Schamberger, Jacinto Satterfield, Margarete Lockman	dd/mm/yyyy
☐ CGPN240523Q0013	P00010001 ~ @ 2 137	px13	Mikayla17	Culpa impedit nobis amet praesentium cum ea modi non sint.	Repudiandae animi amet totam autem amet in sint illum.	Obie Schamberger, Jacinto Satterfield, Margarete Lockman	dd/mm/yyyy
☐ CGPN240523P0012	P00010002 ~ @ 2 136	px12	Mikayla17	Culpa impedit nobis amet praesentium cum ea modi non sint.	Repudiandae animi amet totam autem amet in sint illum.	Obie Schamberger, Jacinto Satterfield, Margarete Lockman	dd/mm/yyyy
☐ CGPN240523O0011	P00010001 ~ @ 2 136	px11	Mikayla17	Culpa impedit nobis amet praesentium cum ea modi non sint.	Repudiandae animi amet totam autem amet in sint illum.	Jacinto Satterfield, Obie Schamberger, Margarete Lockman	dd/mm/yyyy
☐ CGPN240523N0010	P00010002 ~ @ 2 135	px10	Mikayla17	Culpa impedit nobis amet praesentium cum ea modi non sint.	Repudiandae animi amet totam autem amet in sint illum.	Jacinto Satterfield, Obie Schamberger	dd/mm/yyyy
☐ CGPN240523V0009	P00010001 ~ @ 2 135	px9	Mikayla17	Culpa impedit nobis amet praesentium cum ea modi non sint.	Repudiandae animi amet totam autem amet in sint illum.	Obie Schamberger, Jacinto Satterfield, Margarete Lockman	dd/mm/yyyy

Applicants can choose the product(s) they want to cancel.

Afterwards, the applicant can select the effective date of cancellation.

Note: Information on this page may differ depending on the Submission Type & Application Type selected by Applicants

Cancel Product Notification - Submit

Cancel Application For Product Notification

Focused View

1. Products List

2. Submit

Submit

Are your sure? Items will be cancelled from their chosen effective dates.

The products listed below will be cancelled.

Product A effective on 16 Oct 2024

Cancellation Reasons:
Quality and/or Safety Issue(s)

< Back

Confirm Cancellation

Cancel Application For Product Notification

Focused View

1. Products List

2. Submit

Submit

Are your sure? Items will be cancelled from their chosen effective dates.

The products listed below will be cancelled.

Product A effective on 16 Oct 2024

Cancellation Reasons:
Quality and/or Safety Issue(s)

< Back

Cancel

Yes

Confirm Cancellation

Home

Applications

Input Requests

Products

All Products

Dealers

Search

E-GIRO Application

Products

Product Name

Product Owner Name

Approved Product Number

CCS

Indications

Dealer's Site Name

Dealer's Notice Number

Reset

Search

1 Item(s) found

Product Listing Number	Product Name	Product Owner	Product Type	Product Status	Retention Due Date	Latest Application	Related Applications	Action
CGPN241016U0001	Product A	John	CTGTP Class 1	Cancelled	N/A	CGNN241016S0001	N/A	N/A

Applicants need to confirm the product(s) that they would like to cancel and indicate the reasons for cancellation

Page 110 of 172

Product Registration

Cancel Product Registration – Getting Started (i) New Application - Getting Started Focused View 1. Details 2. Checklist Details Instructions for this page: Please select the required submission type and application type for your application. Product Type Cell, Tissue and Gene Therapy Products (CTGTP) Submission Type Product Registration Application Type Cancellation Cancel this application and go back to Dashboard Cancel Next	Applicants will populate the following fields in a manner similar to the process of creating a new application. - Submission type - Application type Choose the required submission type, application type(cancellation) and click on Next, which redirects to checklist page.
New Application - Getting Started Focused View 1. Details 2. Checklist Checklist Instructions for this page: Review your selections and prepare for your application. Product Type Cell, Tissue and Gene Therapy Products (CTGTP) Submission Type Product Registration Application Type Cancellation Based on your selection, your application process will take approximately 30 mins. Please review the instructions and checklist to ensure a timely completion of the process. You are about to start the application for a Cancellation for Class 2 Cell, Tissue and Gene Therapy Products (CTGTP) . Class 2 Cell, Tissue and Gene Therapy Products are required to be registered with the Health Sciences Authority before they can be supplied in Singapore. All applicants must comply with the Health Products Act and its Regulations. Submission Instructions 1. All documents submitted in support of the application must be in English. 2. Further guidance on the preparation of the supporting documents can be found in the Guidance on Cell, Tissue and Gene Therapy Products Registration in Singapore on our website . 3. We will contact you for fee payment after submission of the application. 4. Mode of payments accepted are: GIRO (Please ensure that you have an existing GIRO arrangement with HSA), PayNow. For more information, please visit our website . Change Product or Submission Type Back You will not be able to change your Product or Submission type after this page Create Application	Applicants will be directed to the checklist page where there will be additional information regarding the application that the Applicants are applying for. Note: Information on this page may differ depending on the Submission Type & Application Type selected by Applicants

Cancel Product Registration – Getting Started (ii)



Dashboard

Cancellation Application For Product Registration

Focused View

1. Products List

2. Submit

Products List

Select Products to Cancel

Product Name

Approved Product Number

Reset

Filter

	Approved product number	Product Name	Effective Date
☐	CGPR241001M0013	Product F	dd/mm/yyyy
☐	CGPR241005O0002	Product A	dd/mm/yyyy
☐	CGPR241007Q0011	Product B	dd/mm/yyyy
☐	CGPR241001J0010	Product C	dd/mm/yyyy
☐	CGPR241005N0001	Product E	dd/mm/yyyy
☐	CGPR241001K0011	Product D	dd/mm/yyyy

Applicants can choose the product(s) they want to cancel.

Afterwards, the applicant can select the effective date of cancellation.

Note: Information on this page may differ depending on the Submission Type & Application Type selected by Applicants.

Applicants need to confirm the product(s) that they would like to cancel and indicate the reasons for cancellation.

Cancel Product Registration - Submit

Cancellation Application For Product Registration

Focused View

1. Products List

2. Submit

Submit

Are your sure? Items will be cancelled from their chosen effective dates.

The products listed below will be cancelled.

Product F effective on 16 Oct 2024

Cancellation Reasons:
Quality and/or Safety Issue(s)

< Back

Confirm Cancellation

Focused View

1. Products List

2. Submit

Submit

Are your sure? Items will be cancelled from their chosen effective dates.

The products listed below will be cancelled.

Product F effective on 16 Oct 2024

Cancellation Reasons:
Quality and/or Safety Issue(s)

< Back

Cancel

Yes

Confirm Cancellation

Focused View

Home

Applications

Input Requests

Products

All Products

Dealers

Search

E-GIRO Application

Products

Product Name

Product Owner Name

Approved Product Number

CCS

Indications

Dealer's Site Name

Dealer's Notice Number

Reset

Search

1 Item(s) found

Product Listing Number	Product Name	Product Owner	Product Type	Product Status	Retention Due Date	Latest Application	Related Applications	Action
CDPR241001M0013	Product F	John	CTGTP Class 2	Cancelled	01-Oct-2025	CDNR241001Y0009	N/A	N/A

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Importer's Licence / Wholesaler's Licence / Manufacturer's Licence

Licence Cancellation – Getting Started (i)

A Singapore Government Agency Website [How to identify](#)

HSA

Dashboard Billing Management

New Application - Getting Started

Focused View

- 1. Details
- 2. Checklist

Details

Instructions for this page:
Please select the required submission type and application type for your application.

Product Type Cell, Tissue and Gene Therapy Products (CTGTP)

Submission Type Manufacturer's Licence

Application Type Cancel

Cancel this application and go back to Dashboard

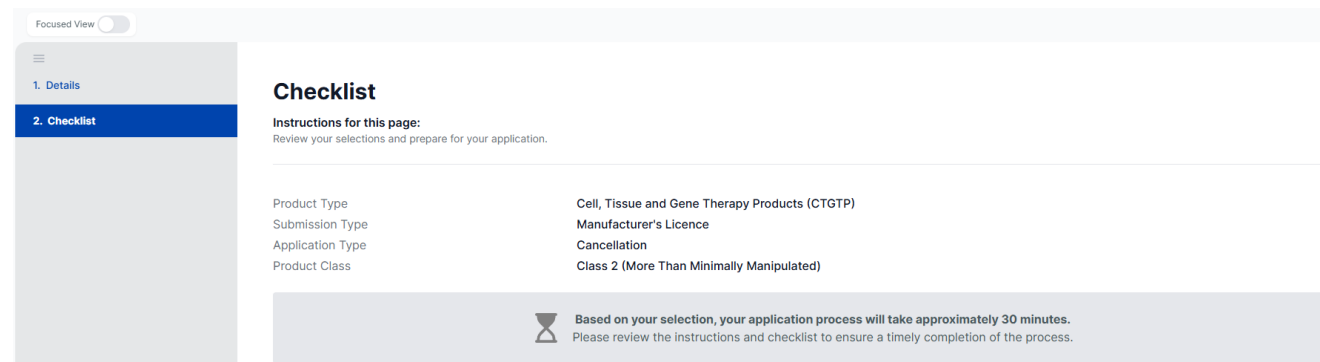
Cancel

Next >

Applicants will populate the following fields in a manner similar to the process of [creating a new application](#).

- Submission type
- Application type

Choose the required submission type, application type (cancel) and click on Next, which redirects to the checklist page

Licence Cancellation – Getting Started (ii)


Focused View ☐

1. Details

2. Checklist

Checklist

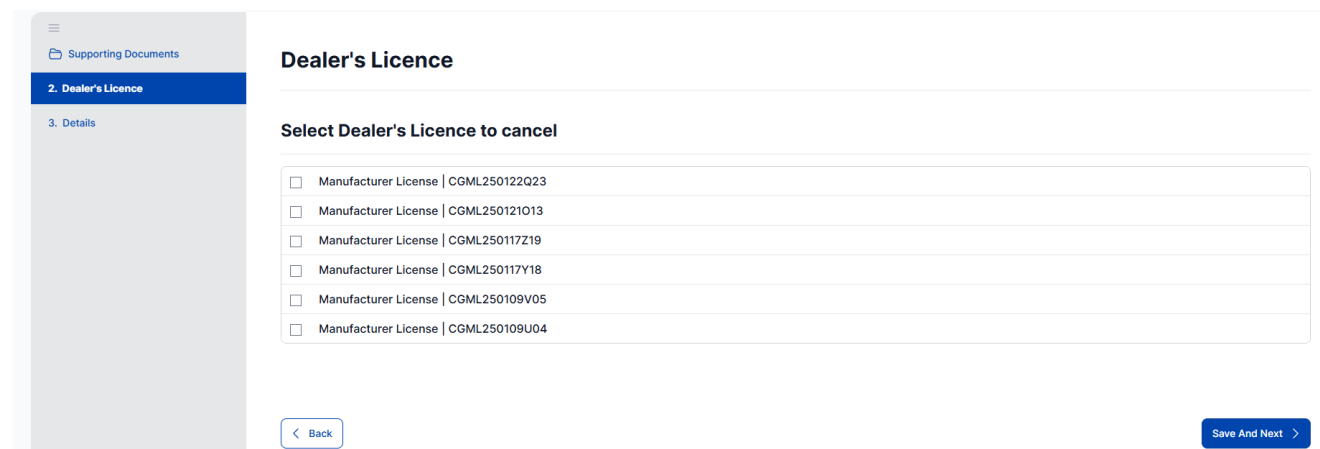
Instructions for this page:
Review your selections and prepare for your application.

Product Type	Cell, Tissue and Gene Therapy Products (CTGTP)
Submission Type	Manufacturer's Licence
Application Type	Cancellation
Product Class	Class 2 (More Than Minimally Manipulated)

 Based on your selection, your application process will take approximately 30 minutes.
Please review the instructions and checklist to ensure a timely completion of the process.

Applicants will be directed to the checklist page where there will be additional information regarding the application that the Applicants are applying for.

Note: Information on this page may differ depending on the Submission Type & Application Type selected by Applicants.

Dealer's Licence


Supporting Documents

2. Dealer's Licence

3. Details

Dealer's Licence

Select Dealer's Licence to cancel

☐	Manufacturer License CGML250122Q23
☐	Manufacturer License CGML250121O13
☐	Manufacturer License CGML250117Z19
☐	Manufacturer License CGML250117Y18
☐	Manufacturer License CGML250109V05
☐	Manufacturer License CGML250109U04

[< Back](#)

[Save And Next >](#)

Applicants can choose the required Dealer's Licence they want to cancel. Only one option can be selected.

Note: Information on this page may differ depending on the Submission Type & Application Type selected by Applicants.

Licence Cancellation – Details

Cancel Dealer's Licence

Draft

Application No. (Draft)

Manual Save

Focused View

Supporting Documents

2. Dealer's Licence

3. Details

Details

Licence Number: CGWL250115B04

Reason for cancellation?

An on-site visit to the company may be arranged if needed to verify the information before approval of the cancellation.

1. I, on behalf of my company, confirm that the information submitted in this application is true and accurate.

☐ I acknowledge and confirm the above declarations.

Please note that the cancellation of your licence will lead to the auto withdrawal of these applications:

• 1 Draft Application

< Back

Confirm Cancellation

Applicants can input their reason for cancellation as well as complete the declaration to confirm cancellation.

For cancellation of Manufacturer's licence, applicants will have a few more questions to answer before completing the declaration to complete the form.

6 Withdrawal of Products or Dealer Activities

Applicants can withdraw the application before the application has been approved/accepted by an HSA officer.

[Home](#)
[Applications](#)
[Input Requests](#)
[Products](#)
[Dealers](#)
[Search](#)
[E-GIRO Application](#)

CGND231124A0003

Withdraw View

Product Type	Cell, Tissue and Gene Therapy Products (CTGTP) Class 1
Dealer's Activity	Notice for Import of minimally manipulated CTGTP
Submission Type	New Dealer's Notice
Status	Pending IR
Submission Date	26-Nov-2023

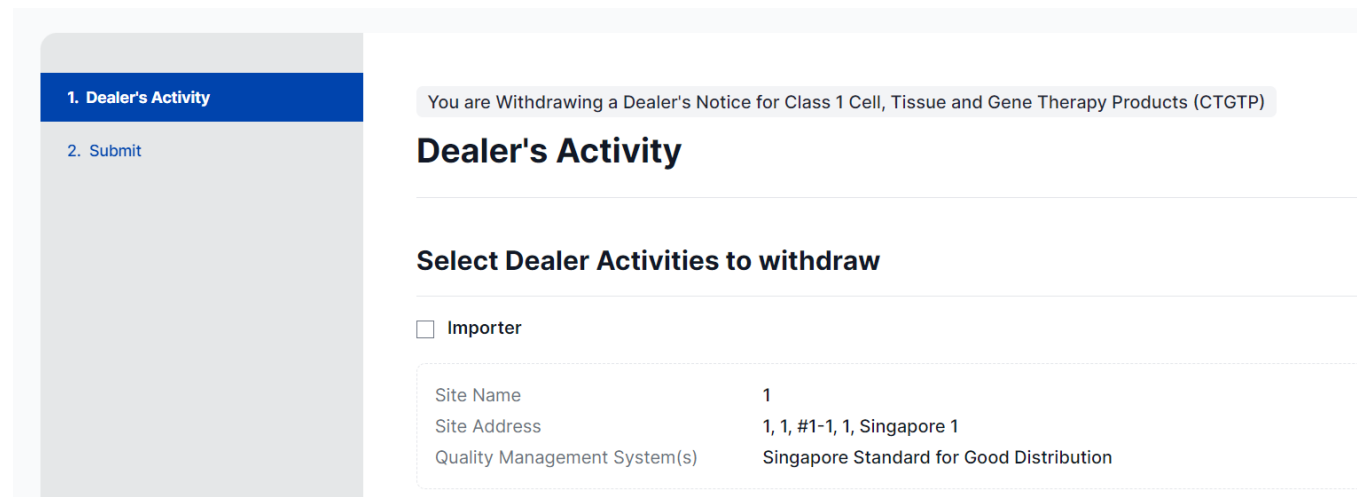
CGNN231124Q0009

Withdraw View

Product Type	Cell, Tissue and Gene Therapy Products (CTGTP) Class 1
Product Name	email test 1
Submission Type	New Product Notification
Status	Pending IR
Submission Date	26-Nov-2023

Applicants can select the **'Withdraw'** option to withdraw individual products or dealer activities while the application is pending HSA approval.

Note: If all products or dealer activities within an application are withdrawn, the entire application is considered withdrawn.

Withdrawal of Products/ Dealer's Activities


1. Dealer's Activity

2. Submit

You are Withdrawing a Dealer's Notice for Class 1 Cell, Tissue and Gene Therapy Products (CTGTP)

Dealer's Activity

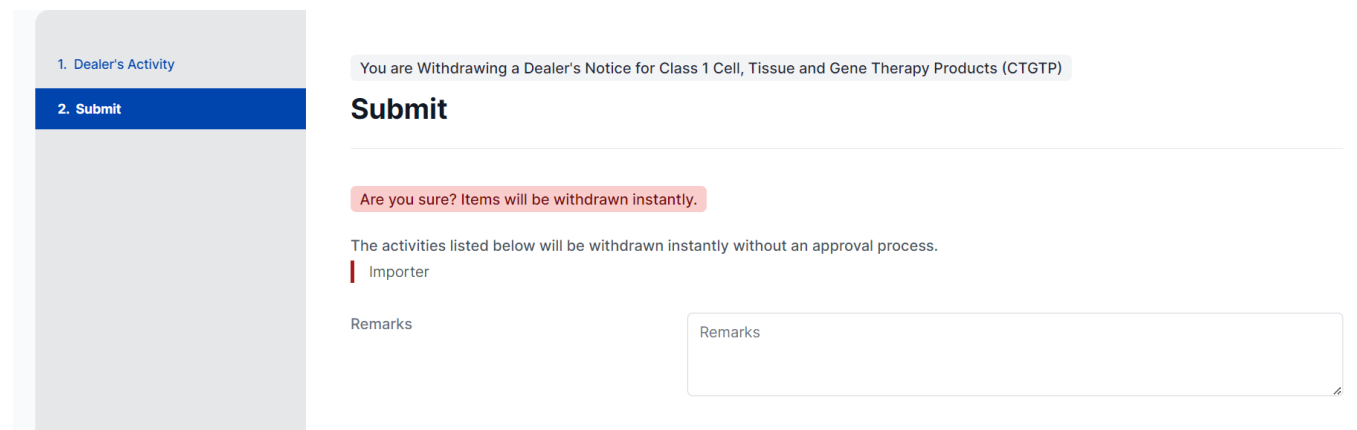
Select Dealer Activities to withdraw

☐ Importer

Site Name	1
Site Address	1, 1, #1-1, 1, Singapore 1
Quality Management System(s)	Singapore Standard for Good Distribution

Applicants also have the option to select various products or dealer's activity to withdraw within a given application. This will result in the withdrawal of those items only and not the whole application.

Note: The view is dependent on the type of application the applicant is withdrawing.

Withdrawal of Products/ Dealer's Activities – Submit


1. Dealer's Activity

2. Submit

You are Withdrawing a Dealer's Notice for Class 1 Cell, Tissue and Gene Therapy Products (CTGTP)

Submit

Are you sure? Items will be withdrawn instantly.

The activities listed below will be withdrawn instantly without an approval process.

Importer

Remarks

Remarks

Applicants need to confirm the required Dealer's Activity/Product they want to withdraw.

Applicants can choose the required products if an application has more than one product and submit for withdrawal.

7 Creation of Fulfilment of Approval Conditions Application

Applicants required to fulfil approval conditions for approved products can submit a fulfilment of approval conditions application that allows them to upload the required documents.

New Application - Getting Started (i)

New Application - Getting Started

Focused View ☐

1. Details

Details

Instructions for this page:
Please select the required submission type and application type for your application.

Product Type

Submission Type

Application Type

Cancel this application and go back to Dashboard

Applicants will populate the following fields in a manner similar to the process of [creating a new application](#).

- Submission type
- Application type

Submission Type

- Product Registration
- Special Access Routes

For application type, select Fulfilment of Approval Conditions and click on Next, which redirects to checklist page.

Applicants can choose which approval condition they want to fulfil in the 'Review' page.

Applicants can also choose to select the approval conditions that need to have their due dates extended.

Applicants will be directed to the checklist page where there will be additional information regarding the application that the Applicants are applying for.

Note: Information on this page may differ depending on the Submission Type & Application Type selected by Applicants.

New Application - Getting Started

Focused View

1. Details

2. Review

3. Checklist

Review

Instructions for this page:
Please select the fulfillment of conditions

Application Number

Product Name

Reset

Search

The highlighted field is the changes made by the officer

A prod 6 (CGPR240917A0003)

Application Number: CGMA240923M0002

Approved Conditions

Date

☐ Quality

03-Oct-2024

☐ CLINICA

03-Oct-2024

☐ RMP

03-Oct-2024

New Application - Getting Started

Focused View

1. Details

2. Review

3. Checklist

Checklist

Instructions for this page:
Review your selections and prepare for your application.

Product Type

Cell, Tissue and Gene Therapy Products (CTGTP)

Submission Type

Product Registration

Application Type

Fulfillment of Approval Conditions

Based on your selection, your application process will take approximately 30 mins.
Please review the instructions and checklist to ensure a timely completion of the process.

You are about to start the application for a Fulfilment of Approval Conditions for Class 2 Cell, Tissue and Gene Therapy Products (CTGTP) .

Class 2 Cell, Tissue and Gene Therapy Products are required to be registered with the Health Sciences Authority before they can be supplied in Singapore. All applicants must comply with the Health Products Act and its Regulations.

Product for Fulfilment

A prod 6 (CGPR240917A0003)

Application Number: CGMA240923M0002

Approved Conditions

Date

Quality

03-Oct-2024

Submission Instructions

1. All documents submitted in support of the application must be in English.

2. Further guidance on the preparation of the supporting documents can be found in the Guidance on Cell, Tissue and Gene Therapy Products Registration in Singapore on our [website](#) .

3. We will contact you for fee payment after submission of the application.

4. Mode of payments accepted are: GIRO (Please ensure that you have an existing GIRO arrangement with HSA), PayNow.

For more information, please visit our [website](#) .

Change Product or Submission Type

< Back

You will not be able to change your Product or Submission type after this page

Create Application



Page 120 of 172

Focused View

1. Details

2. Review

3. Checklist

healthcare institution where the materials are distributed, by the date of distribution of the materials. Every record must be retained for two years from the date of distribution.

☐ The product registrant must submit benefit-risk evaluation report in accordance with the timelines and intervals specified in Regulation 50 of the Health Products (Cell, Tissue and Gene Therapy Products) Regulations.

03-Apr-2025 Overdue

PR 31-12-1 (CGPR241231P0002) Application Number: CGNR241231W0001

Approved Conditions	Date
☒ Ongil	14-Feb-2025 Overdue
☐ Deep	30-Jan-2025 Overdue
☐ RMP	30-Jan-2025 Overdue

05 Feb 2 (CGPR250205R0003) Application Number: CGNR250205X0001

Approved Conditions	Date
☒ Deep	01-Aug-2025
☐ Pheyyen	07-Mar-2025 Overdue

[Request Extension](#)

Change Product or Submission Type

[< Back](#) [Next >](#)

Applicants may request for a due date extension for any applicable Fulfilment of Approval Conditions.

To do so, applicants should select one or more conditions from the list and click on the ‘Request Extension’ button.

Focused View

1. Details

2. Review

3. Declaration

Details

Instructions for this page:
Please select the fulfilment of conditions

The highlighted field is the changes made by the officer

05 Feb 2 (CGPR250205R0003) Application Number: CGNR250205X0001

Approved Conditions	Date
Deep	01-Aug-2025

Comment

Desired Due Date

dd/mm/yyyy

Cancel this application and go back to Dashboard

[Cancel](#) [Next >](#)

Thereafter, applicants should enter a justification in the comment field and propose a new due date under desired due date.

Once completed, click ‘Next’ to continue with the extension request submission.

7.1 Fulfilment of Approval Condition

Application For Product Registration (Fulfilment Of Approval Conditions)

Draft

Application No. (Draft)

Last saved at 23 September 2024 12:21 PM

Focused View

Fulfilment of Approval Condition

Review

Declaration

You are submitting a Fulfilment of Approval Conditions Application for Class 2 Cell, Tissue and Gene Therapy Products (CTGTP)

Fulfilment of Approval Condition

Upload Files For All Conditions

A prod 6

Approval Conditions	Date	Action
Quality	03 Oct-2024	Upload File/Comments

Cancel

Review

Applicants can upload files and add comments to each approval condition.

Each approval condition must have a file uploaded to proceed with the submission.

7.2 Review

Application For Product Registration (Fulfilment Of Approval Conditions)

Draft

Application No. (Draft)
Last saved at 23 September 2024 12:21 PM (UTC+8)

Focused View

Fulfilment of Approval Condition

Review

Declaration

You are submitting a Fulfilment of Approval Conditions Application for Class 2 Cell, Tissue and Gene Therapy Products (CTGTP)

Review

Fulfilment of Approval Condition

Product : A prod 6
Quality 03-Oct-2024
File Uploaded
test.pdf 1 (3).pdf
Comments
Here attached the supporting document needed for the product

< Back

Declaration >

The Review page displays the summary of all the sections filled before the declaration.

7.3 Declaration

Application For Product Registration (Fulfilment Of Approval Conditions)

Draft

Application No. (Draft)
Last saved at 23 September 2024 12:21 PM (UTC+8)

Focused View

Fulfilment of Approval Condition

Review

Declaration

You are submitting a Fulfilment of Approval Conditions Application for Class 2 Cell, Tissue and Gene Therapy Products (CTGTP)

Declaration

1. I, on behalf of my company, confirm that the information submitted is true and accurate.
2. I, on behalf of my company, must comply where applicable, with the Health Products Act and its corresponding regulations. I must also comply with other applicable laws and their regulations.
☐ I acknowledge and confirm the above declarations.

< Back

Submit

For all fulfilment of approval conditions applications, applicants are required to complete the declaration before submission.



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8 Creation of Change of Registrant Application

For applicants that want to transfer approved products, they can submit a change of registrant application that lets applicants choose the relinquishing company and the products to transfer.

New Application - Getting Started (i)

New Application - Getting Started

Focused View

1. Details

2. Checklist

Details

Instructions for this page:
Please select the required submission type and application type for your application.

Product Type

Cell, Tissue and Gene Therapy Products (CTGTP)

Submission Type

Product Registration

Application Type

Change of Registrant

Relinquishing Company

ThirdCompany (ThirdCompanyUEN)

Product Owners

Bauch Ltd Bergstrom Ltd

Cancel this application
and go back to Dashboard

Cancel

Next

Applicants will populate the following fields in a manner similar to the process of [creating a new application](#).

- Submission type

- Application type

Choose the product registration submission type, change of registrant application type and additional fields will appear.

- Relinquishing company

- Product owners

Choose the relevant relinquishing company, product owners and click on Next, which redirects to the checklist page.



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New Application - Getting Started

Focused View

1. Details

2. Checklist

Checklist

Instructions for this page:
Review your selections and prepare for your application.

Product Type

Submission Type

Application Type

Relinquishing Company

Product Owners

Cell, Tissue and Gene Therapy Products (CTGTP)

Product Registration

Change of Registrant

ThirdCompany

Bauch Ltd, Bergstrom Ltd

Based on your selection, your application process will take approximately 30 mins.
Please review the instructions and checklist to ensure a timely completion of the process.

You are about to start the application for a Change of Registrant for Class 2 Cell, Tissue and Gene Therapy Products (CTGTP) to supply the product(s) in Singapore.

Class 2 Cell, Tissue and Gene Therapy Products are required to be registered with the Health Sciences Authority before they can be supplied in Singapore. All applicants must comply with the Health Products Act and its Regulations.

Submission Instructions

1. All documents submitted in support of the application must be in English.

2. Further guidance on the preparation of the supporting documents can be found in the Guidance on Cell, Tissue and Gene Therapy Products Registration in Singapore on our [website](#).

3. We will contact you for fee payment after submission of the application.

4. Mode of payments accepted are: GIRO (Please ensure that you have an existing GIRO arrangement with HSA), PayNow.

For more information, please visit our [website](#).

Change Product or Submission Type

< Back

Create Application

You will not be able to change your Product or Submission type after this page

Create Application

Applicants will be directed to the checklist page where there will be additional information regarding the application that the Applicants are applying for.

Note: Information on this page may differ depending on the Submission Type & Application Type selected by Applicants.



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8.1 Product List

Application For Product Registration (Change Of Registrant)

Draft

Application No.(Draft)

Last saved at 15 October 2024 11:57 AM

Focused View

Product List

Supporting Documents

New Appointed IL/WL

Company Details

Application Details

Payment Details

Review

Declaration

You are submitting a Change of Registrant Application for Class 2 Cell, Tissue and Gene Therapy Products (CTGTP)

Product List

Select Products to Transfer

Approved Product Number

Product Name

Reset

Filter

	Approved Product Number	Product Name	Remarks
☒	CGPR241014V0009	Product A	
☐	CGPR241014Q0013	Product B	
☐	CGPR241014T0007	Product C	

Effective Date of Transfer:

dd/mm/yyyy

Cancel

Supporting Documents

Applicants are required to choose which products they would like to transfer to their company.

8.2 Supporting Documents

Application For Product Registration (Change Of Registrant)

Draft

Application No. (Draft)

Last saved at 23 September 2024 11:39 AM.

Focused View

Product List

Supporting Documents

New Appointed IL/WL

Company Details

Application Details

Payment Details

Review

Declaration

No files were detected in the mandatory folder. Please upload the relevant supporting document in this folder and re-submit.

You are submitting a Change of Registrant Application for Class 2 Cell, Tissue and Gene Therapy Products (CTGTP)

Supporting Documents

Instructions for this page:
Please download the empty Supporting Documents.zip provided below. Organise your files into folder structure of the zip and upload the entire zip file.

Download All Supporting Documents

Supporting Documents Size: 0 Bytes

Upload Zip

Change of Registrant

1. Relinquishing registrants authorisation documents

2. Product owners authorisation documents

Remarks/Comments

< Back

New Appointed IL/WL >

Applicants must upload supporting documents before they can proceed.

At least one file must be uploaded to each of the mandatory folders.

8.3 New Appointed IL/WL

Application For Product Registration (Change Of Registrant)

Draft

Application No. (Draft)

Last saved at 15 October 2024 11:59 AM.

Focused View

Product List

Supporting Documents

New Appointed IL/WL

Company Details

Application Details

Payment Details

Review

Declaration

You are submitting a Change of Registrant Application for Class 2 Cell, Tissue and Gene Therapy Products (CTGTP)

New Appointed IL/WL

0 item(s) selected

Product Name	IL and WL (Optional)	Action
Product A		Add Additional Site

< Back

Company Details >

Applicants can add a newly appointed importer license or wholesaler license to the product by entering the Dealer's Notice Number and click on Get Dealer's Details to automatically fill up the fields with the information of that importer / wholesaler.

Tag Wholesalers/ Importers

Dealer Type

☒ Importer ☐ Wholesaler

Local Dealer's Notice Number

Type to search for Dealer Notice Number...

Get Dealer's Details

Local Dealer's Name

Retrieved Local Dealer Name

Postal Code *

Block / Number *

Level - Unit *

-

Street Name *

Building Name *

Close

Save

8.4 Company Details

Application For Product Registration (Change Of Registrant)

Draft

Application No.(Draft)

Last saved at 23 September 2024 11:44 AM

Focused View

Product List

Supporting Documents

New Appointed IL/ML

Company Details

Application Details

Payment Details

Review

Declaration

You are submitting a Change of Registrant Application for Class 2 Cell, Tissue and Gene Therapy Products (CTGTP)

Company Details

Company Information

This sub-section is pre-filled from your Corppass login and requires no action on your part.

Company Name

SecondCompany

UEN

SecondCompanyUEN

Company Address *

Clear ACRA Address

Postal Code *

123456

Block / Number *

02

Level - Unit *

02 - 02

Street Name *

Second Street

Building Name *

Second Tower

Subsections

Company Information

Company Address

Contact Information

Billing Information

The details of company details section can be found in [Company Details](#).

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8.5 Application Details

Application For Product Registration (Change Of Registrant)

Draft

Application No. (Draft)

Last saved at 23 September 2024 11:51 AM

Focused View

Product List

Supporting Documents

New Appointed IL/WL

Company Details

Application Details

Payment Details

Review

Declaration

You are submitting a Change of Registrant Application for Class 2 Cell, Tissue and Gene Therapy Products (CTGTP)

Application Details

Application Information

This sub-section is pre-filled from your initial selection and cannot be edited.

Product Type

Cell, Tissue and Gene Therapy Products (CTGTP)

Submission Type

Product Registration

Application Type

Change Of Registrant

Class

Class 2

Main Applicant Information *

Applicant Name (as in NRIC/FIN) *

Afia

Designation *

ASE

Notification Emails *

Please include your applicant contact details in this section, and additional contacts if required. All notifications regarding this application will be sent to the persons listed below and contact persons listed in the [Company Details](#) Section.

No Data Available

+ Add Notification Email 1

Back

Payment Details

The details of application details section can be found in [Application Details](#).



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8.6 Payment Details

Application For Product Registration (Change Of Registrant)

Draft

Application No. (Draft)

Last saved at 23 September 2024 11:53 AM

Focused View

Product List

Supporting Documents

New Appointed IL/WL

Company Details

Application Details

Payment Details

Review

Declaration

You are submitting a Change of Registrant Application for Class 2 Cell, Tissue and Gene Therapy Products (CTGTP)

Payment Details

Preferred Payment Mode *

GIRO

GIRO

PayNow

Charge Code	Description	Price
CTGTADMCHGREG	App: Change of Registrant of CTGTP	\$158.00
	Subtotal	\$158.00
	Tax	\$0.00
	Total	\$158.00

Payment Instructions

The above fees will be processed by HSA upon successful submission of this application. If your preferred payment mode is GIRO, please ensure that there are sufficient funds in the account.

< Back

Review >

Once the applicant has created an application and filled in necessary details, the payment section is displayed.

Applicants will have two payment options, GIRO and PayNow.

Applicants must choose the required payment mode.



Page 130 of 172

8.7 Review

Application For Product Registration (Change Of Registrant)

Draft

Application No.(Draft)

Last saved at 23 September 2024 11:54 AM

Focused View

Product List

Supporting Documents

New Appointed IL/WL

Company Details

Application Details

Payment Details

Review

Declaration

You are submitting a Change of Registrant Application for Class 2 Cell, Tissue and Gene Therapy Products (CTGTP)

Review

Product List

Approved Product Number	Product Name	Remarks
CGPR240918F0007	33 TissueWaveX NAMZ5	

Effective Date of Transfer:

N.A

Supporting Documents

Download All Supporting Documents

Supporting Documents Size: 2 MB

Change of Registrant

1. Relinquishing registrants authorisation documents

test pdf 1 (3).pdf
999 KB 23/09/2024 12:40

2. Product owners authorisation documents

test pdf 1 (2).pdf
999 KB 23/09/2024 12:40

Remarks/Comments

No remarks or comments

New Appointed IL/WL

Review page displays the summary of all the sections filled before the declaration.

8.8 Declaration

Application For Product Registration (Change Of Registrant)

Draft

Application No. (Draft)

Last saved at 23 September 2024 11:54 AM

Focused View

Product List

Supporting Documents

New Appointed IL/ML

Company Details

Application Details

Payment Details

Review

Declaration

You are submitting a Change of Registrant Application for Class 2 Cell, Tissue and Gene Therapy Products (CTGTP)

Declaration

1. I, on behalf of my company, confirm that the information submitted is true and accurate.

2. I, on behalf of my company, must comply where applicable, with the Health Products Act and its corresponding regulations. I must also comply with other applicable laws and their regulations.

☐ I acknowledge and confirm the above declarations.

< Back

Submit

For all change of registrant applications, applicants are required to complete the declaration before submission.



Page 132 of 172

9 Global Update of Importers Application

For applicants that want to transfer approved products, they can submit a change of registrant application that lets applicants choose the relinquishing company and the products to transfer.

New Application - Getting Started (i)

A Singapore Government Agency Website [How to identify](#)

HSA Dashboard Billing Management

New Application - Getting Started

Focused View

- 1. Details
- 2. Checklist

Details

Instructions for this page:
Please select the required submission type and application type for your application.

Product Type ☐ Cell, Tissue and Gene Therapy Products (CTGTP)

Submission Type ☐ Product Registration

Application Type ☐ Global Update of Importers

Cancel this application and go back to Dashboard

Applicants will populate the following fields in a manner similar to the process of [creating a new application](#).

- Submission type
- Application type

Choose the product registration submission type, global update of importers application will appear.

Focused View

1. Details

2. Checklist

Checklist

Instructions for this page:
Review your selections and prepare for your application.

Product Type	Cell, Tissue and Gene Therapy Products (CTGTP)
Submission Type	Product Registration
Application Type	Global Update of Importers

Based on your selection, your application process will take approximately 1 hour.
Please review the instructions and checklist to ensure a timely completion of the process.

You are about to start the application for a Global Update of Importers for Class 2 Cell, Tissue and Gene Therapy Products (CTGTP) to supply the product(s) in Singapore.

Class 2 Cell, Tissue and Gene Therapy Products are required to be registered with the Health Sciences Authority before they can be supplied in Singapore. All applicants must comply with the Health Products Act and its Regulations.

Submission Instructions

1. All documents submitted in support of the application must be in English, filed and uploaded as a zip file in accordance to the following supporting documents template:
[SupportingDocumentsTemplate.zip](#)
2. Further guidance on the preparation of the supporting documents can be found in the Guidance on Cell, Tissue and Gene Therapy Products Registration in Singapore on our [website](#).
3. Mode of payments accepted are: GIRO (Please ensure that you have an existing GIRO arrangement with HSA), Paynow, Credit Card.
4. We will contact you regarding the fees in case of any issues during the payment processing

For more information, please visit our [website](#).

Change Product or Submission Type

You will not be able to change your Product or Submission type after this page

< Back

Create Application

Applicants will be directed to the checklist page where there will be additional information regarding the application that the Applicants are applying for.

Note: Information on this page may differ depending on the Submission Type & Application Type selected by Applicants.

9.1 Company Details

Application For Global Update Of Importer Tagging

Draft

Application No.(Draft)

Last saved at 27 May 2025 04:16 PM

Focused View

Company Details

Application Details

Importer Tagging

Review

Declaration

You are submitting a Global Update of Importers Application for Class 2 Cell, Tissue and Gene Therapy Products (CTGTP)

Company Details

Company Information

This sub-section is pre-filled from your Corppass login and requires no action on your part.

Company Name

FirstCompany

UEN

FirstCompanyUEN

Company Address *

Clear ACRA Address

Postal Code *

123456

Block / Number *

01

Level - Unit

01 - 01

Street Name *

First Street

Subsections

Company Information

Company Address

Contact Information

The details of company details section can be found in [Company Details](#).

9.2 Application Details

Focused View

Company Details

Application Details

Importer Tagging

Review

Declaration

You are submitting a Global Update of Importers Application for Class 2 Cell, Tissue and Gene Therapy Products (CTGTP)

Application Details

Application Information

This sub-section is pre-filled from your initial selection and cannot be edited.

Product Type

Cell, Tissue and Gene Therapy Products (CTGTP)

Submission Type

Product Registration

Application Type

Global Update Of Importers

Class

Class 2

Main Applicant Information *

Applicant Name (as in NRIC/FIN) *

Afia

Designation *

Input Designation

Notification Emails *

Please include your applicant contact details in this section, and additional contacts if required. All notifications regarding this application will be sent to the persons listed below and contact persons listed in the [Company Details](#) Section.

No Data Available

+ Add Notification Email 1

Subsections

Application Information

Main Applicant Information

Notification Emails

The details of application details section can be found in [Application Details](#).

9.3 Importer Tagging

Focused View

Company Details

Application Details

Importer Tagging

Review

Declaration

You are submitting a Global Update of Importers Application for Class 2 Cell, Tissue and Gene Therapy Products (CTGTP)

Importer Tagging

Select Products *

Cell culture 6 (CGPR250123P0002)

Product Name	NDA	Referenced NDA	Dosage Form	Route Of Administration	ATC Code	Importer
Cell culture 6	3	Cell culture 8	CEMENT	Auricular (OTIC)	12	Tag Importer

< Back

Review >

Focused View

Company Details

Application Details

Importer Tagging

Review

Declaration

Tag Importers

Local Importer Licence Number

Type to search for Dealer Notice Number...

Get Dealer's Details

Local Dealer's Name

Retrieved Local Dealer Name

Postal Code *

Block / Number *

Level - Unit *

-

Street Name *

Building Name *

Close

Save

Applicants should select the relevant product(s) from the dropdown menu under the Importer Tagging section. Multiple products may be selected if applicable.

After selecting a product, applicants should click on the ‘Tag Importer’ button to proceed. This will open a form where the importer’s details must be provided.

Applicants are required to fill in all mandatory fields, including the local importer licence number and address information, before clicking ‘Save’ to complete the tagging process.

9.4 Review

Focused View

Company Details

Application Details

Importer Tagging

Review

Declaration

You are submitting a Global Update of Importers Application for Class 2 Cell, Tissue and Gene Therapy Products (CTGTP)

Review

Company Information

Company Name

UEN

ThirdCompany

ThirdCompanyUEN

Company Address

Address

03, Third Street, #03-03, Third Tower, Singapore 123456

Contact Information

S. No.	Contact Person	Contact Number	Email
1	Elwin Kuvallis	+65-90213950	shafik+fakedata91650@tsp.dev

Application Information

Product Type

Submission Type

Application Type

Class

Cell, Tissue and Gene Therapy Products (CTGTP)

Product Registration

Global Update Of Importers

Class 2

Review page displays the summary of all the sections filled before the declaration.

9.5 Declaration

A Singapore Government Agency Website

How to identify

HSA

Health Sciences Authority

Dashboard

Billing Management

Application No.(Draft)

Last saved at 27 May 2025 04:50 PM

Application For Global Update Of Importer Tagging

Draft

Application No.(Draft)

Last saved at 27 May 2025 04:50 PM

Focused View

Company Details

Application Details

Importer Tagging

Review

Declaration

You are submitting a Global Update of Importers Application for Class 2 Cell, Tissue and Gene Therapy Products (CTGTP)

Declaration

1. I, on behalf of my company, confirm that the information submitted in this application is true and accurate.

2. I, on behalf of my company, must comply where applicable, with the Health Products Act and their corresponding regulations. I must also comply with all other applicable laws and their regulations.

☐ I acknowledge and confirm the above declarations.

< Back

Submit

For all change of registrant applications, applicants are required to complete the declaration before submission.



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10 Creation of Retention Application

For the payment of an annual retention fee to retain their product on the register, applicants can submit a retention application.

Retention Application - Getting Started (i)

New Application - Getting Started

Focused View ☐

1. Details

2. Checklist

Details

Instructions for this page:
Please select the required submission type and application type for your application.

Product Type ☐

Cell, Tissue and Gene Therapy Products (CTGTP)

Submission Type ☐

Product Registration

Application Type ☐

Retention

Cancel this application and go back to Dashboard

Cancel

Next

Applicants will populate the following fields in a manner similar to the process of [creating a new application](#).

- Submission type
- Application type

Choose the product registration submission type, application type (retention application) and click on Next, which redirects to the checklist page.

New Application - Getting Started

Focused View

1. Details

2. Checklist

Checklist

Instructions for this page:
Review your selections and prepare for your application.

Product Type

Submission Type

Application Type

Cell, Tissue and Gene Therapy Products (CTGTP)

Product Registration

Retention

Based on your selection, your application process will take approximately 30 mins.
Please review the instructions and checklist to ensure a timely completion of the process.

You are about to start the application for a Retention for Class 2 Cell, Tissue and Gene Therapy Products (CTGTP) to supply the product(s) in Singapore.

Class 2 Cell, Tissue and Gene Therapy Products are required to be registered with the Health Sciences Authority before they can be supplied in Singapore. All applicants must comply with the Health Products Act and its Regulations.

Submission Instructions

1. All documents submitted in support of the application must be in English.

2. Further guidance on the preparation of the supporting documents can be found in the Guidance on Cell, Tissue and Gene Therapy Products Registration in Singapore on our [website](#)

3. We will contact you for fee payment after submission of the application.

4. Mode of payments accepted are: GIRO (Please ensure that you have an existing GIRO arrangement with HSA), PayNow.

For more information, please visit our [website](#)

Change Product or Submission Type

< Back

Create Application

Applicants will be directed to the checklist page where there will be additional information regarding the application that the Applicants are applying for.

Note: Information on this page may differ depending on the Submission Type & Application Type selected by Applicants.



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10.1 Product List

Application For Product Registration (Retention)

Draft

Application No.(Draft)

Last saved at 23 September 2024 01:04 PM

Focused View

Product List

Payment Details

Review

Declaration

You are submitting a Retention Application for Class 2 Cell, Tissue and Gene Therapy Products (CTGTP)

Product List

☐	Product	Product No	Current Retention Due Date	New Retention Due Date
☐	B prod 1	CGPR240917F0008	25-Sep-2024	25-Sep-2025
☐	B prod 2	CGPR240917G0009	25-Sep-2024	25-Sep-2025

Cancel

Payment Details

Applicants are required to choose the products they want to retain.

10.2 Payment Details

Application For Product Registration (Retention)

Draft

Application No.(Draft)

Last saved at 23 September 2024 12:10 PM

Focused View

Product List

Payment Details

Review

Declaration

You are submitting a Retention Application for Class 2 Cell, Tissue and Gene Therapy Products (CTGTP)

Payment Details

Preferred Payment Mode *

GIRO

GIRO

PayNow

Charge Code	Description	Price
CTOTRETPDT	RET: CTGTP Product Retention	\$330.00
	Subtotal	\$330.00
	Tax	\$0.00
	Total	\$330.00

Payment Instructions

The above fees will be processed by HSA upon successful submission of this application. If your preferred payment mode is GIRO, please ensure that there are sufficient funds in the account.

Back

Review

Once the applicant has created an application and filled in necessary details, the payment section is displayed.

Applicants will have two payment options, GIRO and PayNow.

Applicants must choose the required payment mode.

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10.3 Review

Application For Product Registration (Retention)

Draft

Application No.(Draft)

Last saved at 23 September 2024 12:11 PM

Focused View

Product List

Payment Details

Review

Declaration

You are submitting a Retention Application for Class 2 Cell, Tissue and Gene Therapy Products (CTGTP)

Review

Product List

Product	Product No	Current Retention Due Date	New Retention Due Date
B prod 1	CGPR240917F0008	25-Sep-2024	25-Sep-2025

Payment Information

Preferred Payment Mode

GIRO

GIRO

PayNow

Charge Code	Description	Price
CTGTRETPDT	RET: CTGTP Product Retention	\$330.00
	Subtotal	\$330.00
	Tax	\$0.00
	Total	\$330.00

< Back

Declaration >

Review page displays the summary of all the sections filled before the declaration.



Page 143 of 172

10.4 Declaration

Application For Product Registration (Retention)

Draft

Application No. (Draft)

Last saved at 23 September 2024 12:11 PM

Focused View

Product List

Payment Details

Review

Declaration

You are submitting a Retention Application for Class 2 Cell, Tissue and Gene Therapy Products (CTGTP)

Declaration

1. I, on behalf of my company, confirm that the information submitted is true and accurate.
2. I, on behalf of my company, must comply where applicable, with the Health Products Act and its corresponding regulations. I must also comply with other applicable laws and their regulations.
☐ I acknowledge and confirm the above declarations.

< Back

Submit

For all retention applications, applicants are required to complete the declaration before submission.



Page 144 of 172

11 Renewal of Importer's Licence, Wholesaler's Licence or Manufacturer's Licence

For the payment of an annual renewal fee to retain their licence beyond the expiry date, applicants can submit a renewal application.

Licence Renewal - Getting Started (i)

A Singapore Government Agency Website [How to identify](#)

HSA

Dashboard Billing Management

New Application - Getting Started

Focused View

- 1. Details
- 2. Checklist

Details

Instructions for this page:
Please select the required submission type and application type for your application.

Product Type Cell, Tissue and Gene Therapy Products (CTGTP)

Submission Type Manufacturer's Licence

Application Type Renewal

Cancel this application and go back to Dashboard

Cancel

Next

Applicants will populate the following fields in a manner similar to the process of [creating a new application](#).

- Submission type
- Application type

Choose the dealer's licence submission type, application type (renewal application) and click on Next, which redirects to the checklist page.

Licence Renewal – Getting Started (ii)

Focused View

1. Details

2. Checklist

Checklist

Instructions for this page:
Review your selections and prepare for your application.

Product Type

Cell, Tissue and Gene Therapy Products (CTGTP)

Submission Type

Manufacturer's Licence

Application Type

Renewal

Product Class

Class 2 (More Than Minimally Manipulated)

Based on your selection, your application process will take approximately 30 minutes.
Please review the instructions and checklist to ensure a timely completion of the process.

Applicants will be directed to the checklist page where there will be additional information regarding the application that the Applicants are applying for.

Note: Information on this page may differ depending on the Submission Type & Application Type selected by Applicants.

11.1 Licence List

Application For Manufacturer's Licence Renewal

Draft

Application No.(Draft)

Last saved at 16 January 2025 02:26 PM

Focused View

Licence List

Payment Details

Review

Declaration

- Dealer License list for renewal is required

You are submitting a Renewal Application for Class 2 (More Than Minimally Manipulated) Cell, Tissue and Gene Therapy Products (CTGTP)

Licence List

Select Client Code

Select an option

Search

C-00661219

C-00389118

C-00661200

C-00389140

No Data Available

Cancel

Payment Details

Applicants should select a client code from the dropdown menu under the Licence List section. Once a client code is selected, the Licences subsection will automatically display licences that are eligible for renewal under that client code.

Applicants can then select the licences they wish to renew from the list displayed.

Page 146 of 172

Licence List

Select Client Code: C-00389140

Licences

Licences:

- ☐ CGML250122Q23
- ☐ CGML250117Y18

[Cancel](#) [Payment Details](#)

11.2 Payment Details

Payment Details

You are submitting a Renewal Application for Class 2 (More Than Minimally Manipulated) Cell, Tissue and Gene Therapy Products (CTGTP)

Selected Payment Mode *: Online

Charge Code	Description	Subtotal	Tax	Total
CTGTRENMFGSEC	Renew: CTGTP Manufacturer's Lic (secondary packaging)	\$3,780.00	\$0.00	\$3,780.00
Amount Payable				\$3,780.00

[< Back](#) [Review >](#)

Once the applicant has created an application and filled in necessary details, the payment section is displayed.

Applicants will have two payment options, GIRO and PayNow. Note that payment options may differ based on client code selected in [Licence List](#).

Applicants must choose the required payment mode.

11.3 Review

Focused View

Licence List

Payment Details

Review

Declaration

Review

Licence List

Client Code

C-00389140

Licences

Licence Type	Licence No.	Licence Start Date	Licence Expiry Date
Manufacturer	CGML250122Q23	N.A	N.A

Payment Information

Selected Payment Mode

Online

Charge Code	Description	Subtotal	Tax	Total
CTGTRENMFGSEC	Renew: CTGTP Manufacturer's Lic (secondary packaging)	\$3,780.00	\$0.00	\$3,780.00
Amount Payable				\$3,780.00

Review page displays the summary of all the sections filled before the declaration.

11.4 Declaration



DashboardBilling Management

Application For Importer's Licence/ Wholesaler's Licence Renewal

DraftApplication No.(Draft)
Last saved at 16 January 2025 02:44 PM

Focused View

Licence List

Payment Details

Review

Declaration

Declaration

1. I, on behalf of my company, confirm that the information submitted in this application is true and accurate.

2. I, on behalf of my company, am fully aware that the quality, safety and efficacy of the submitted products will not be evaluated by the HSA.

3. I, on behalf of my company, must comply where applicable, with the Health Products Act and their corresponding regulations. I must also comply with all other applicable laws and their regulations.

☐ I acknowledge and confirm the above declarations.

Back

Submit

For all renewal applications, applicants are required to complete the declaration before submission.

12 Overseas Entity Login

Local applicant is able to request overseas entity to submit additional documents to support his application. The request is done through an open IR. The applications that support this function are Product Registration (New) and Product Registration (Change Notification).

12.1 Requesting Access for Overseas Entity

A Singapore Government Agency Website [How to identify](#)

HSA

Dashboard Billing Management

Application For Product Registration

Pending IR Application No. CGNR250605I0001

Focused View

- IR Details
- Supporting Documents
- Company Details
- Application Details
- Overview - Product Information
- Manufacturers
- Overview - Products List
- Payment Details
- Review
- Input Requests
- All IRs

IR Details

[Request Upload Access To Third Party Entity](#)

Instructions for this page:
Please respond to all queries in this IR before submitting your response.

#IR-002	Received	Due	Status
1 Queries in this IR 0 Replied	05 Jun 2025	03 Jul 2025	Fresh 10 working days left

[Request Extension](#)

Sender: Verification Officer 10 (PR-Quality)
Phone: +65-6866 0000
Email: rachana+verificationofficerpr_quality_10@tsp.dev

1 Queries [Export Queries](#)

Verification Officer 10 (PR-Quality) @ 5 Jun 1 IR edit (Editable by Applicant) @ 05 Jun 2025

Sent in #IR-002

A

[View Thread](#) [Reply](#) [Go To Section](#)

In the application IR Details page.

Applicants would be able to request access for overseas entity by clicking on the 'Request upload access to Third Party Entity' button.

Request upload access to Third Party Entity

Email

Remarks

Queries

Select	Section	Created on	Query
☐	5 Jun 1 IR edit	2025-06-05	A

Request Access

Applicants would be able to fill in the details of the request, which include email, remarks, as well as selecting related IR queries by using the checkbox.

Thereafter, they can submit the request by clicking on the ‘Save’ button.

Focused View

IR Details

Supporting Documents

Company Details

Application Details

Overview - Product Information

Manufacturers

Overview - Products List

Payment Details

Review

Input Requests

All IRs

Application Admin

Audit Trail

IR Details

Instructions for this page:

Please respond to all queries in this IR before submitting your response.

For third party entity access please share the following link with your third party entity: [here](#)

#IR-002

Received

Due

Status

Request Extension

1 Queries in this IR

05 Jun 2025

03 Jul 2025

Fresh

10 working days left

1 Replied

Sender

Phone

Email

Verification Officer 10 (PR-Quality)

+65-6866 0000

rachana+verificationofficerpr_quality_10@tsp.dev

1 Queries

Export Queries

Verification Officer 10 (PR-Quality)

Sent in #IR-002

A

Afia

Request access to nicko_toh@thesoftwarepractice.com

re

Submit Response to IR

After officers grant access to the overseas entity, applicants will need to copy the link and share it with the overseas entity for access the system. Applicants also need to provide the application number to the overseas entity for their verification process.

Note: A new IR will be generated for the query pending input from the overseas entity. Once the overseas entity has responded, the IR will be marked as “Responded” and no action is required from the applicants. The applicants may continue addressing the rest of the queries concurrently.



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12.2 Overseas Entity Access



The screenshot shows the 'Third Party Entity Log In' page of the Singapore Health Product Access and Regulatory E-System (SHARE). The page features a blue header with the HSA logo and the system name. The main content area has a background image of a person using a laptop with medical icons overlaid. A login form is centered on the page, containing two input fields: 'Email' and 'Application Reference Number'. A 'Send OTP' button is located at the bottom right of the form. A blue circle with the number '1' is next to the 'Email' field, and a blue circle with the number '2' is next to the 'Send OTP' button.

URL:

<https://share.hsa.gov.sg/mop/thirdparty/login>

As the system does not require a login, the overseas entity must verify their email address through a two-factor authentication process for secure access.

To do so, the overseas entity must enter the correct email address and application number, then click 'Send OTP' to receive a one-time password to log in to the application.

Note: The OTP is only valid for 1-hour. A new OTP can be requested after 10 minutes, which will invalidate the previous one.

View Application

A Singapore Government Agency Website

How to identify



Dashboard

View Application

Focused View

All IRs

All IRs

#IR-012

2 Queries in this IR

0 Replied

Sender

Verification Officer 2 (PR-Quality)

Received

03 Jul 2025

Due

31 Jul 2025

Status

Fresh

20 working days left

Respond

#IR-007

1 Queries in this IR

0 Replied

Sender

Verification Officer 2 (PR-Quality)

Received

03 Jul 2025

Due

31 Jul 2025

Status

Fresh

20 working days left

Respond

#IR-002

1 Queries in this IR

1 Replied

Sender

Verification Officer 2 (PR-Clinical)

Received

27 Jun 2025

Due

25 Jul 2025

Status

Responded

View

The overseas entity will only have access to their assigned IRs within the application and will not be able to view other application details.

They can view the list of assigned IRs, access each IR’s details and queries, and refer to the Supporting Documents section as needed.



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Singapore Government Agency Website

[How to Identify](#)

[Dashboard](#)

View Application

Focused View

IR Details

Supporting Documents

Input Requests

All IRs

IR Details

Instructions for this page:
Please respond to all queries in this IR before submitting your response.

#IR-007 1 Queries in this IR 0 Replied	Received 03 Jul 2025	Due 31 Jul 2025	Status Fresh 20 working days left
Sender Verification Officer 2 (PR-Quality)	Phone +65-6866 0000	Email rachana+verificationofficerpr_quality_2@sso.dev	

1 Queries

Export Queries

Verification Officer 2 (PR-Quality)

Application Details

03 Jul 2025

Sent in #IR-007

test

yi_shen@thesoftwarepractice.com

Application Details

03 Jul 2025

Test reply

Edit Reply

Submit Response to IR

In order to submit the response, a reply is mandatory.

The overseas entity may also upload files by navigating to the Supporting Documents section.

View Application - Supporting Documents

A Singapore Government Agency Website

How to identify

HSA

Health Sciences Authority

Dashboard

View Application

Focused View

IR Details

Supporting Documents

Input Requests

All IRs

Supporting Documents

Instructions for this page:

Organise your files into folder structure of the zip and upload the entire zip file. Your files will be scanned for viruses and might take a while. Please refresh your page a few times after uploading to see updated status.

Supporting Documents Size: 0 Bytes

Supporting Documents

Third Party Entity Supporting Documents

Add Document

Create Folder

In the Supporting Documents section, the overseas entity can only view the Third-Party Entity Supporting Documents folder and their own uploaded files.

The overseas entity can manage supporting documents by uploading, editing, or deleting folders and files as needed.

Once ready, they can reply to the queries and submit their IR responses through the system.



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13 Applications

The applicant can save a draft while creating the application and resume it from the dashboard.

Home

Applications

Draft

Active

Closed

Input Requests

Products

Dealers

Search

Applications

Draft Applications

Draft

Expires June 17, 2024

Resume

Delete

Product Type

Cell, Tissue and Gene Therapy Products (CTGTP) Class 1

Product Name

-

Submission Type

New Product Notification

Status

Draft

Last Edited Date

20-Dec-2023

Draft

Expires June 17, 2024

Resume

Delete

Product Type

Cell, Tissue and Gene Therapy Products (CTGTP) Class 1

Product Name

-

Submission Type

New Product Notification

Status

Draft

Last Edited Date

20-Dec-2023

At any stage, an application can be saved as a draft before submission. All the drafts are listed in the dashboard.

The application will be autosaved every few minutes and will also be saved whenever the applicant clicks on the next section.

The following buttons are displayed:

a) Resume – allows applicant to resume the application and submit.

b) Delete – allows applicant to delete the application.

Whenever there is any inactive session for 10 minutes, a pop up will prompt the applicant if they would like to continue the session.

Home

Applications

Input Requests

Products

Dealers

Search

IR Application

Home

Overview

Active Applications

20

View Active Applications

Latest Active Applications

CGFA241010R0001

Withdraw

View

CGM1241007P0002

Withdraw

View

Session Expiry

The session would be terminated soon. You can re-login or continue your Session

Continue My Session

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Active

Applications [New Application](#)

Active Applications

Application Number	Product Type	Product Name	Submission Type	Status	Submission Date
CGNN231122H0002	Cell, Tissue and Gene Therapy Products (CTGTP) Class 1	Allograft PLUS™ 55mm by 20 mm	New Product Notification	Processing	23-Nov-2023
CGAD231121L0004	Cell, Tissue and Gene Therapy Products (CTGTP) Class 1	Notice for Import of minimally manipulated CTGTP	Update Dealer's Notice	Processing	23-Nov-2023

Active applications are submitted by the applicant and under review.

This section displays Application number, Product type, Product name/Dealer's activity, Submission type, Status, Submission date, a withdraw and a view button.

Click on the withdraw button to submit withdrawal. The application status changes to closed and this application cannot be used further.

Clicking on the view button displays the application details page.

Closed

Applications [New Application](#)

Closed Applications

Application Number	Product Type	Dealer's Activity	Submission Type	Status	Closure Date
CGXD231121M0008	Cell, Tissue and Gene Therapy Products (CTGTP) Class 1	Notice for Wholesale of minimally manipulated CTGTP	Cancel Dealer's Notice	Closed	21-Nov-2023
CGND231120Z0006	Cell, Tissue and Gene Therapy Products (CTGTP) Class 1	Notice for Wholesale of minimally manipulated CTGTP	New Dealer's Notice	Closed	20-Nov-2023

Applications which have been closed by HSA or Withdrawn by applicant are displayed here.

This section displays Application number, Product type, Product name/Dealer's activity, Submission type, Status, Closure date and a view button.

Clicking on the view button displays the application details page.

13.1 Document Publication

For certain application types, documents related to the closed application might be published by the officers. To access these, navigate to the specific closed applications and to the Document Publication tab.

Closed Applications

The screenshot displays the 'Application For Certificate Of A Pharmaceutical Product (CPP)' interface. At the top right, it indicates the application is 'Closed' with 'Application No. CGNC251205S0001'. A 'Focused View' toggle is present. On the left, a sidebar menu lists various sections: 'Supporting Documents', 'Company Details', 'Application Details', 'Certificate Details', 'Payment Details', 'Review', 'Input Requests' (with 'All IRs' sub-item), 'Application Admin' (with 'Audit Trail' sub-item), and 'Document Publication' (highlighted in blue). The main content area is titled 'Document Publication' and shows a message: 'No Data Available' with a circular icon containing an 'i'.

Application Submission Types that might have documents published through such a route includes the following:

- a) Importer's Licence/
Wholesaler's Licence
- b) Manufacturer's Licence
- c) GDP Certificate
- d) GMP Certificate
- e) Certificate of a
Pharmaceutical Product
(CPP)
- f) Free Sale Certificate (FSC)

Documents that have been published by officers are downloadable while those that have been unpublished will not longer be downloadable.

14 Tasks

14.1 Open Input Requests

Open IRs

Input Requests

Open IRs

Application No.	Product Name / Dealer's Activity	Submission Type	Product Type	Milestone
CGAD231130K0003	Importer	Dealer Notification	Cell, Tissue and Gene Therapy Products (CTGTP) Class 2 Minimally Manipulated	First IR
#IR-001 1 Queries in this IR 0 Replied	Received 30 Nov 2023	Due 14 Dec 2023	Status Fresh 10 working days left	Respond
CGNN231129O0002	Vitamin A	Product Notification	Cell, Tissue and Gene Therapy Products (CTGTP) Class 1	First IR
#IR-004 1 Queries in this IR 0 Replied	Received 29 Nov 2023	Due 28 Dec 2023	Status Fresh 19 working days left	Respond
#IR-003 1 Queries in this IR 0 Replied	Received 29 Nov 2023	Due 30 Oct 2023	Status Overdue 22 working days overdue	Respond

Open Input Requests (IRs) are raised by officers seeking additional information and awaiting applicant's response.

The Open IRs list displays the number of queries in the IR, received date, due date, status, and a respond button. Clicking on the respond button redirects to the IR details page with all the change logs.

Applicants would be able to:

- Request for Extension - request for additional time to respond to the Input Request.
- Export queries – downloads the IR queries.

An IR contains queries requested by HSA Officers for additional information from an applicant.

14.2 Open Findings

Findings are raised by officers when deficiencies, recommendations or comments are identified during inspections. These deficiencies, also termed Non-Conformities (NCs), must be addressed by companies before obtaining their licence or certificate, or during routine inspection in relation to approved licence(s).

Open Findings

Tasks

Open Finding(s)

Audit No.	Dealer's Activity	Audit Type	Product Type	Export
Audit_00133	Manufacturer, GMP	New Audit	More Than Minimally Manipulated	Export
#FD-002	Received	Due	Status	Respond
2 Queries in this FD	22 Jan 2025	05 Mar 2025	Open	↶ Respond
0 Replied			22 working days left	
Audit_00044	Importer, Wholesaler, GDP	New Audit	More Than Minimally Manipulated	Export
#FD-002	Received	Due	Status	Respond
1 Queries in this FD	24 Dec 2024	05 Feb 2025	Open	↶ Respond
0 Replied			Waiting for reply	
#FD-001	Received	Due	Status	Respond
1 Queries in this FD	24 Dec 2024	05 Feb 2025	Open	↶ Respond
0 Replied			Waiting for reply	

Open Findings are findings that the applicant have yet to respond to.

The Open Findings list displays the number of queries in each finding, received date, due date, status, and a 'Respond' button. Applicants can click 'Respond' to access the Respond to Finding(s) page and submit their replies.

Applicants would be able to:

- a) Request for Extension - request for additional time to respond to the Finding.

14.3 Pending Payments

Pending Payments display all outstanding payments that the applicant has yet to complete. This section allows applicants to track the status of their payments and take the necessary actions to complete them.

Pending Payments

Focused View

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Tasks

Open Payment

SN	Application Number	Application Type	Task Number	Total Payment Amount	Client Code	Action
1	CGNL250123H0009	New Manufacturer's Licence	FirstCompanyUEN-2501-00049	\$22,200.00	C-00389140	Pay
2	CGNR250121D0001	New Product Registration	FirstCompanyUEN-2501-00046	\$13,900.00	C-00389140	Pay
3	CGNR250113I0005	New Product Registration	CGNR250113I0005-004	\$650.00	C-00389140	Pay
4	CGNL250121Y0011	New Importer's Licence/ Wholesaler's Licence	CGNL250121Y0011-001	\$1,690.00	C-00389140	Pay
5	CGNR250113I0005	New Product Registration	CGNR250113I0005-003	\$82,900.00	C-00389140	Pay
6	CGNL250117H0015	New Manufacturer's Licence	CGNL250117H0015-002	\$220.00	C-00389140	Pay
7	CGCE250117L0011	New GMP Certificate (with technical assessment)	CGCE250117L0011-001	\$22,200.00	C-00389140	Pay
8	CGNL250117H0015	New Manufacturer's Licence	CGNL250117H0015-001	\$10,800.00	C-00389140	Pay
9	CGCE250115O0007	New GDP Certificate (without technical assessment)	CGCE250115O0007-001	\$220.00	C-00389140	Pay

The Pending Payments list shows details such as the application number, application type, task number, total payment amount, and client code.

Applicants can click on the application number to view the application details for the specific application.

To proceed with payment, they can click the 'Pay' button, which redirects them to the payment page.

14.4 Pending Importer Tagging

Pending Importer Tagging displays applications where applicants i.e. authorised importer(s) must review and confirm importer details before approval. This process is triggered by Product Registrant when they authorise licensed importer(s) to import their registered products. The nominated licensed importer(s) would use this module to acknowledge their status as authorised importer(s).

Pending Importer Tagging

The screenshot shows the 'Pending Importer Tagging' page. The sidebar on the left has a 'Tasks' menu item with a red badge showing '79'. Below it, 'Pending Importer Tagging' has a red badge showing '1'. The main content area is titled 'Tasks' and 'Pending Importer Tagging'. It contains a table with the following data:

S. No.	Application Number	Task Type	Task Number	Action
1	CGUL250108L0003	Global Update of Importers	CGUL250108L0003L01	Review

The Pending Importer Tagging page lists applications requiring importer tagging. It includes the application number, task type, task number, and an 'Review' button.

Clicking on 'Review' directs applicants to the [Review Importer Tagging](#) page.

Review Importer Tagging

Focused View

Review Acceptance of Appointment

Review Acceptance of Appointment

List of Products Tagged

Product Listing Number	Product Name	Registrant Name	Product Owner	Product Type	Retention Date	Importer Licence Number
CGPR250108T0003	Abridge AB	FirstCompany	A12121	CTGTP Class 2	16-Feb-2025	CGIF241218P08

Registrant Details Information

Company Name

UEN

FirstCompany

FirstCompanyUEN

Approve

Reject

The Review Importer Tagging page displays product details, registrant information, and importer licence number.

Applicants can approve the tagging request, confirming themselves as the authorised importer for the product. Alternatively, the applicant can reject the request and the registered product will not be tagged to the importer’s licence.

15 Input Requests

The Input Requests section consists of two subsections: Open IRs and Responded IRs. Open IRs displays input requests from officers that require the applicant’s response, while Responded IRs lists input requests that the applicant has already addressed.

The [Open IRs](#) page is identical to the page accessed via Tasks > Open IRs.

Responded IRs

Focused View

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Input Requests

Open IRs

Responded IRs

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Responded IRs

Application No.	Product Name / Dealer's Activity	Submission Type	Product Type	Milestone
CGNL241224B0010	-	Importer's Licence/ Wholesaler's Licence	More Than Minimally Manipulated	Verification
#IR-003 1 Queries in this IR 0 Replied	Received 30 Dec 2024	Due 27 Jan 2025	Status Responded	View
#IR-002 1 Queries in this IR 0 Replied	Received 26 Dec 2024	Due 23 Jan 2025	Status Responded	View
#IR-001 3 Queries in this IR 0 Replied	Received 26 Dec 2024	Due 23 Jan 2025	Status Responded	View

Application No.	Product Name / Dealer's Activity	Submission Type	Product Type	Milestone
CGXL241224N0003	-	Manufacturer's Licence	More Than Minimally Manipulated	Active Evaluation
#IR-001 2 Queries in this IR 0 Replied	Received 24 Dec 2024	Due 22 Jan 2025	Status Closed	View

Input Requests initiated by officers to which the applicant has already responded are displayed here.

The Responded IRs list displays the number of queries in the IR, received date, due date, status, and a 'View' button.

Clicking on the 'View' button redirects to the IR details page where all replied change logs are displayed.

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16 Findings

The Findings section consists of two subsections: Open Findings and Responded Findings. Open Findings displays findings from officers that require the applicant's response, while Responded Findings lists findings that the applicant has already addressed.

The [Open Findings](#) page is identical to the page accessed via Tasks > Open Findings.

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Findings

Responded Finding(s)

Audit No. Audit_00132	Dealer's Activity Importer, Wholesaler, GDP	Audit Type New Audit	Product Type More Than Minimally Manipulated	Export
#FD-002 1 Queries in this FD 0 Replied				
Received 22 Jan 2025		Due 05 Mar 2025		Status Responded
View				
#FD-001 1 Queries in this FD 0 Replied				
Received 22 Jan 2025		Due 05 Mar 2025		Status Responded
View				
Audit No. Audit_00133	Dealer's Activity Manufacturer, GMP	Audit Type New Audit	Product Type More Than Minimally Manipulated	Export
#FD-001 2 Queries in this FD 0 Replied				
Received 22 Jan 2025		Due 05 Mar 2025		Status Closed
View				
Audit No. Audit_00042	Dealer's Activity Manufacturer	Audit Type New Audit	Product Type More Than Minimally Manipulated	Export

Findings that have already been addressed by the applicant are displayed here.

The Responded Findings list includes details such as the audit number, dealer's activity, audit type, product type, received date, due date, status, and a 'View' button.

Clicking on the 'View' button redirects to the Respond to Finding(s) page where all responded queries are displayed.

17 Payment

The Payment section consists of two subsections: Open Payments and Paid Payments. Open Payment lists pending payments that require action from the applicant, while Paid Payments displays records of completed transactions.

The [Open Payments](#) page is identical to the page accessed via Tasks > Pending Payments.

Paid Payments

Payment						
Paid Payment						
SN	Application Number	Application Type	Task Number	Total Payment Amount	Client Code	
1	CGRT250131K0001	Retention Product Registration	FirstCompanyUEN-2501-00052	\$330.00	C-00389140	
2	CGNL250124F0006	New Importer's Licence/ Wholesaler's Licence	FirstCompanyUEN-2501-00051	\$2,850.00	C-00389140	
3	CGNL250123H0009	New Manufacturer's Licence	FirstCompanyUEN-2501-00050	\$220.00	C-00389140	
4	CGNN250123F0005	New Product Notification	FirstCompanyUEN-2501-00048	\$95.00	C-00389140	
5	CGRT250123M0002	Retention Product Registration	CGRT250123M0002-001	\$330.00	C-00389140	
6	CGNN250123C0002	New Product Notification	FirstCompanyUEN-2501-00047	\$95.00	C-00389140	
7	CGNN250120Z0002	New Product Notification	FirstCompanyUEN-2501-00043	\$95.00	C-00389140	
8	CGRN250117N0006	Renewal Manufacturer's Licence	FirstCompanyUEN-2501-00038	\$13,600.00	C-00389140	
9	CGRT250117O0001	Retention Product Registration	FirstCompanyUEN-2501-00034	\$330.00	C-00661200	
10	CGNN250115D0002	New Product Notification	FirstCompanyUEN-2501-00029	\$95.00	C-00389140	

The Paid Payments lists records of payments that have been successfully completed. Applicants can view details such as the application number, application type, task number, payment amount, client code, and payment status.

Clicking on the application number redirects applicants to the Application Details page.

18 Products

This section allows applicants to search and view approved product information.

Focused View ☐

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Products

Product Name

Approved Product Number

Indications

Dealer's Submission Number

Product Owner Name

CCS

Dealer's Site Name

Reset

Filter

25 Item(s) found

Product Listing Number	Product Name	Product Owner	Product Type	Product Status	Retention Due Date	Latest Application	Related Applications	Action
CGPR25012300001	Cell culture 5	Owner A	CTGTP Class 2	Approved	22-Feb-2026	CGNR250123F0001	N/A	...
CGPR250123U0007	Cell culture 3	Owner A	CTGTP Class 2	Approved	24-Dec-2025	CGNR250123F0001	N/A	...
CGPR25012300010	Cell culture 7	Owner A	CTGTP Class 2	Approved	23-Jan-2026	CGNR250123F0001	N/A	...
CGPR250123W0009	Cell culture 2	Owner A	CTGTP Class 2	Overdue Retention	24-Dec-2024	CGNR250123F0001	N/A	...

Applicants can search for specific product by selecting filters such as product name, owner name, product number, dealer's submission number, indications, CCS, or dealer's site name.

Clicking on the Application number redirects the applicant to the application page while clicking on the Product Listing Number redirects applicants to a page where they can download product-related files.

The Action column contains an ellipsis menu, which provides additional actions that applicants can take for the corresponding product.

19 Special Access Route

This section allows applicants to search and view their SAR licences.

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Special Access Routes

SAR Licence Number

Application Number

Product Name

SAR Type

Effective Date

Status

Expiry Date

dd/mm/yyyy

dd/mm/yyyy

dd/mm/yyyy

dd/mm/yyyy

Select an option

Select an option

Reset

Filter

SAR Licence Number	Application Number	Product Name	SAR Type	Effective Date	Status	Expiry Date	Action
CGSU260326A0001 Extension Requested	CGSA260326Z0001	YYPQ Drug	Unregistered New	27-Mar-2026	Active	N/A	
CGSR260326Y0002 Extension Requested	CGSA260326A0002	P1	Registered New	27-Mar-2026	Active	N/A	

Applicants can search for specific records by selecting filters such as SAR licence number, application number, product name, SAR type, effective date, expiry date and status.

Applicants can also download the relevant approval documents via the Download button under the Action column.

20 View Notices/Licences/Certificates

This section allows applicants to search and view notices, licences, and certificates associated with their dealer activities.

Focused View ☐

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View Notices/Licences/Certificates

Activity Type

Site Name

Licence/Certificate/Notice Number

Submission Type

Reset

Licence/Certificate/Notice Number	Product Type	Submission Type	Activity Type	Status	Expiry Date	Latest Application	Action
CGGD241218I05	CTGTP Class 2 (More than Minimally Manipulated)	GDP Certificate	GDP	Active	18-Dec-2027	CGNL241218K0007	N/A
CGGD241220A04	CTGTP Class 2 (More than Minimally Manipulated)	GDP Certificate	GDP	Active	20-Dec-2027	CGCE241220G0002	N/A
CGGD241224F05	CTGTP Class 2 (More than Minimally Manipulated)	GDP Certificate	GDP	Expired	02-Jan-1904	CGCE241224Q0008	N/A
CGGD250113A03	CTGTP Class 2 (More than Minimally Manipulated)	GDP Certificate	GDP	Active	12-Jan-2028	CGNL250109G0004	N/A
CGGD250114A02	CTGTP Class 2 (More than Minimally Manipulated)	GDP Certificate	GDP	Active	02-Jan-2028	CGCE250114H0001	N/A
CGGD250114B03	CTGTP Class 2 (More than Minimally Manipulated)	GDP Certificate	GDP	Active	10-Jan-2028	CGNL250102Y0021	N/A
CGGD250115E05	CTGTP Class 2 (More than Minimally Manipulated)	GDP Certificate	GDP	Active	14-Jan-2028	CGCE250115P0008	N/A

Applicants can search for specific records by selecting filters such as activity type, site name, submission type, and notice/licence/certificate number.

Once the relevant applications are displayed, they can click on the application number to view the details of the corresponding application.

Applicants can also download the relevant approval documents via the Download button under the Action column.

21 Search

This section allows applicants to search and retrieve relevant applications for ease of navigation.

A Singapore Government Agency Website

How to Identify

HSA

Health Sciences Authority

Dashboard

Billing Management

A

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Search

Application Number

Product Name

Dealer's Activity

Payment Status

Submission Type

Milestone

Submission Date

dd/mm/yyyy

dd/mm/yyyy

Reset

Filter

Application Number	Product Name / Dealer...	Submission Type	Submission date	Milestone	Action
Open	-	New Product Registration	N/A	Draft	Payment History

Applicants can search for specific records by selecting filters such as application number, product name, dealer’s activity, payment status, milestone, submission type, or submission date.

Clicking on the Application number redirects the applicant to the application page, while Payment History leads to the Payment Details page.

22 Audit Documents

This section contains two subsections: GDP documents and GMP Documents.

A Singapore Government Agency Website

How to identify

HSA

Health Sciences Authority

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Audit Documents

GDP Documents

GMP Documents

Audit Documents

No Data Available

This section displays all documents associated with the audit case, if available.

Applicants can view the listed documents under their respective subsections.