

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

User Manual Applicant (Internet)

Version 1.6
Date 6 Feb 2025



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

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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.
- 

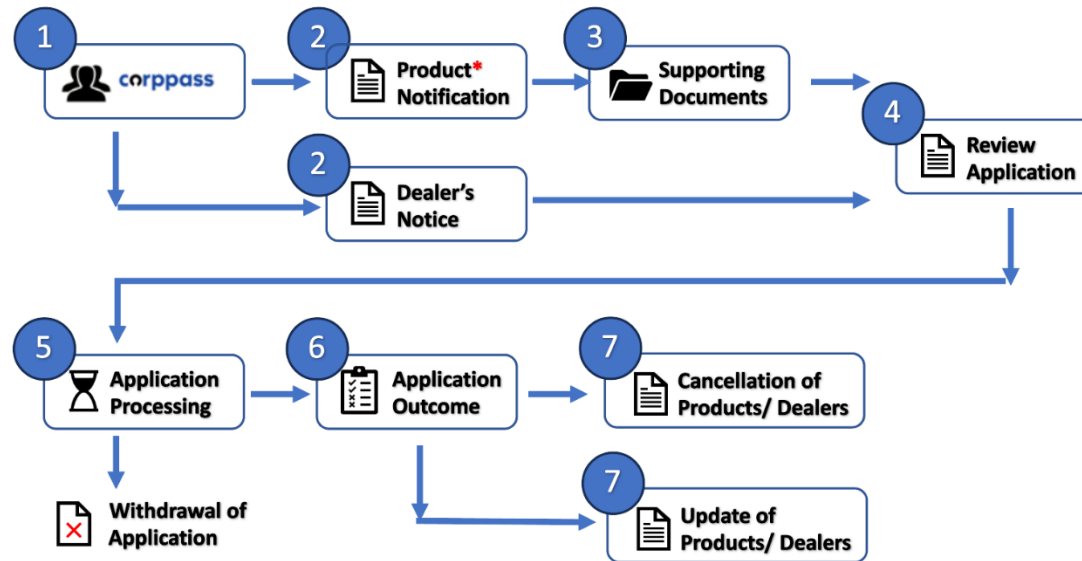
Update/Amend Products, Licences and applications
To make changes to products, licences and applications submitted.
- 

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

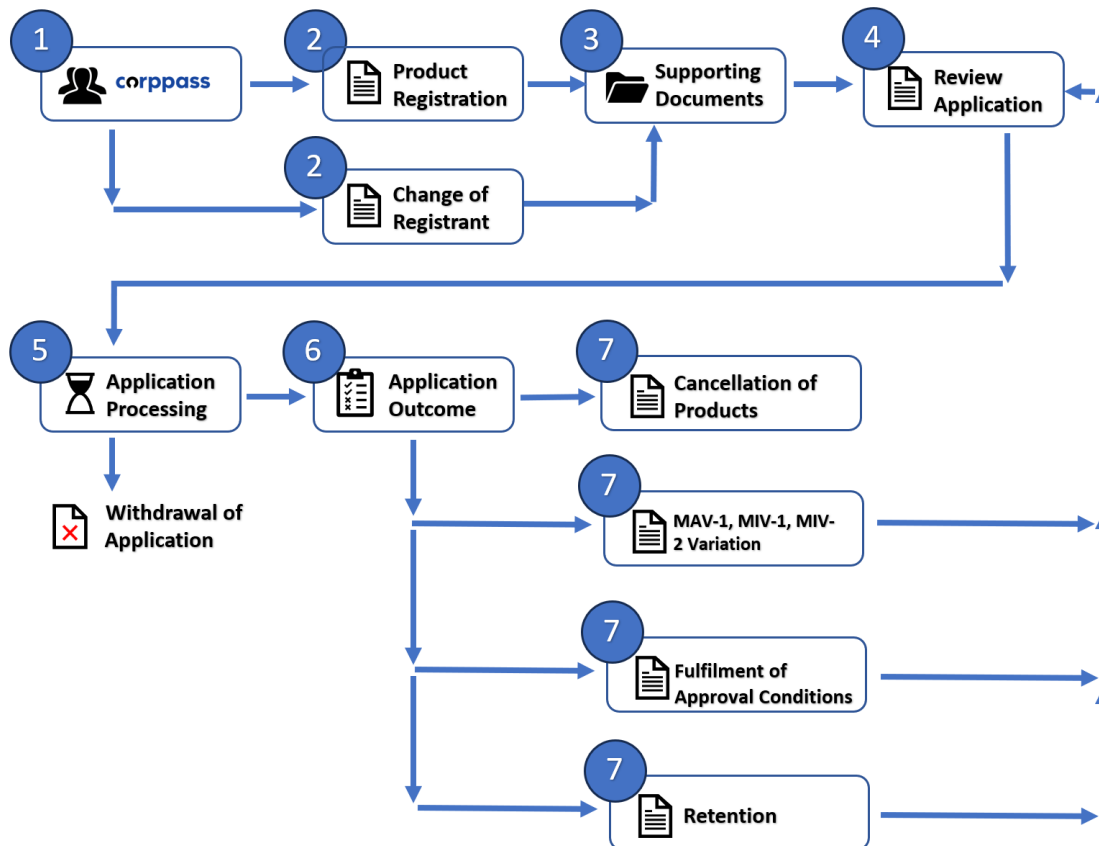
1.1 Class 1 CTGTP



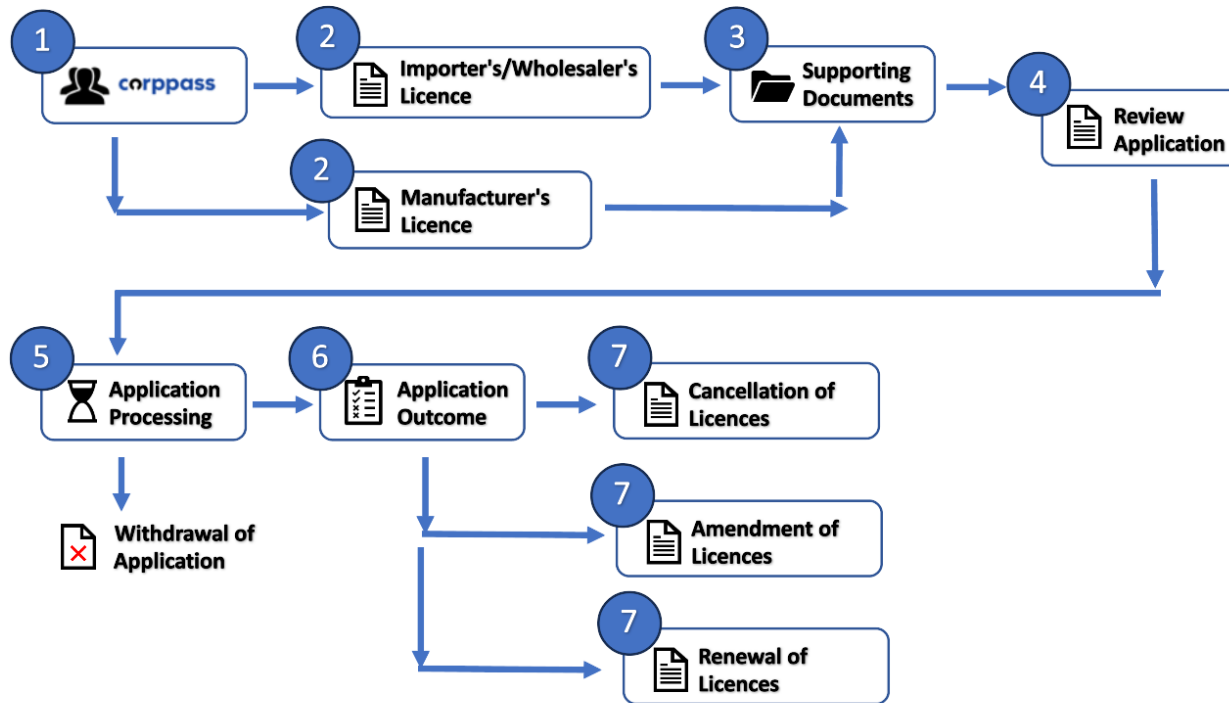
*You must be a known dealer to submit a Product Notification for Class 1 CTGTP. Applicants would need to submit a Dealer's Notice Application to notify HSA prior to your manufacturing, importing or wholesaling activity relating to Class 1 CTGTP.

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

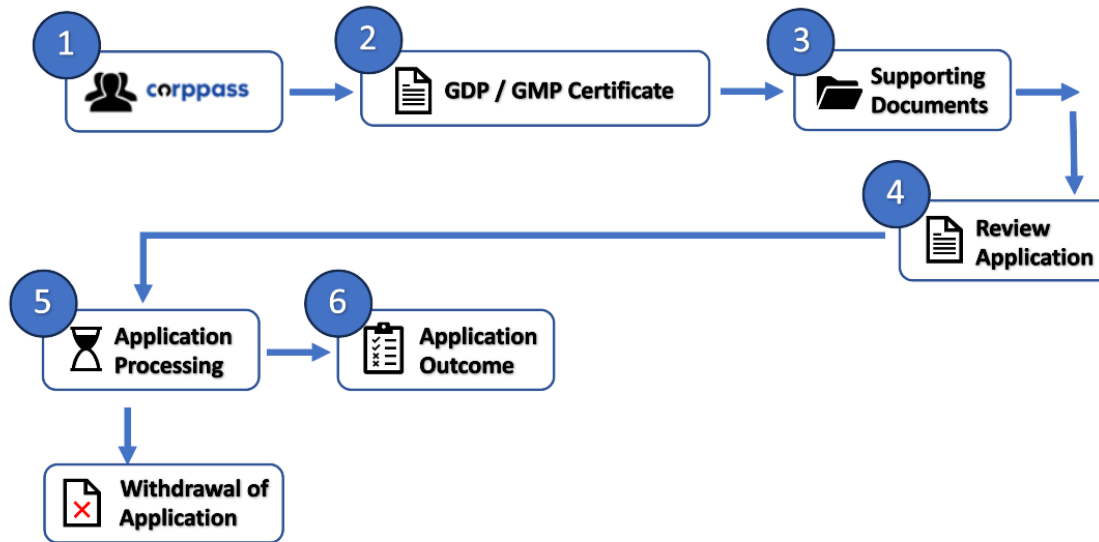


1. Applicants log in via Corppass.
2. Applicants would be able to select the submission type and application type
 - i. Applicants would be required to populate the required fields in all the sections of the application (company details, application details, etc).
3. Applicants would be required to upload 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



Applicants will be able to indicate their need for GDP/GMP certificates as part of the licence application process.

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

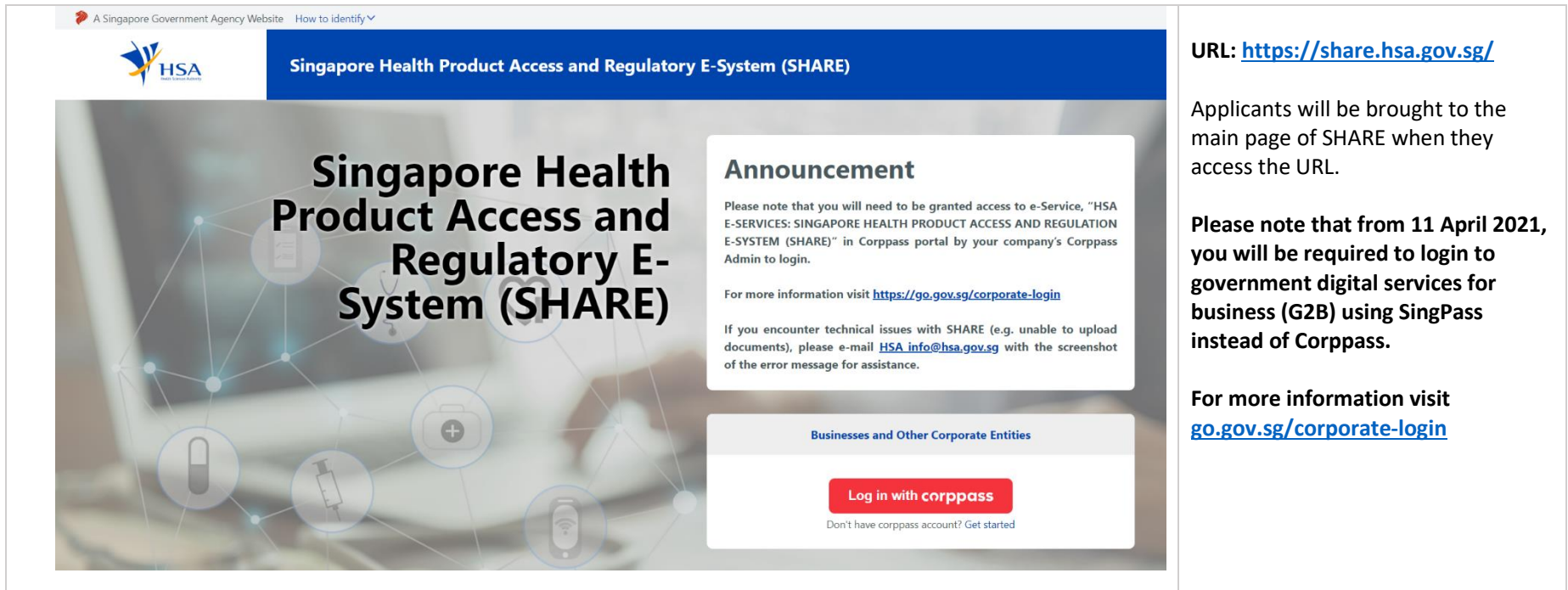
1.4 Application Statuses

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



The screenshot shows the SHARE website interface. At the top, there is a navigation bar with the HSA logo and the text "Singapore Health Product Access and Regulatory E-System (SHARE)". Below this, the main content area features a large heading "Singapore Health Product Access and Regulatory E-System (SHARE)" on the left. To the right of the heading is an "Announcement" box containing the following text: "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." Below the announcement is a section titled "Businesses and Other Corporate Entities" with a prominent red button labeled "Log in with corppass" and a link "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

3 Dashboard

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

The screenshot shows the HSA dashboard interface. On the left is a sidebar with navigation links: Home, Applications, Tasks, Input Requests, Findings, Payment, Products, View Notices/Licences/Certificates, Search, E-GRO Application, and Audit Documents. The main content area is titled 'Home' and features an 'Overview' section with four blue cards: 'Active Applications' (5), 'Pending Tasks' (0), 'Products' (0), and 'Dealer's Notices and Licences' (0). Below the overview is a 'Latest Active Applications' section displaying four application cards with details such as Product Type, Product Name, Submission Type, Status, and Submission Date.

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

[Applications](#)
[Tasks](#)
[Input Requests](#)
[Findings](#)
[Payment](#)
[Products](#)
[View Notices/Licences/Certificates](#)
[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)

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 ⓘ

Select Submission Type ▼

Application Type

Select Application Type ▼

Product Class ⓘ

Select Product Class ▼

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

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 is selected

- New

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 Notification

Application Type Select Application Type

Product Class Select Product Class

Cancel this application and go back to Dashboard

Product Class

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

- Class 1 (For both Product Notification and Dealer's Notice)
- Class 2 Minimally Manipulated *(only for Dealer's Notice)*
- Class 2 (only for Product Registration)

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 ⓘ

Application Type

Product Class ⓘ

Evaluation Route

Dossier Format

Cancel this application and go back to Dashboard

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 ⊙

Submission Type ⊙

Application Type

Product Class ⊙

Evaluation Route

Dossier Format

Cell, Tissue and Gene Therapy Products (CTGTP)

Product Registration

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

Class 2

Full

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

Search

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)

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

Submission Type

Application Type

Relinquishing Company

Search

- TSP (FirstComppanyOldUEN)
- SeventhCompany (SeventhCompanyUEN)
- SeventeenthCompany (SeventeenthCompanyUEN)
- AAA (ZerothCompanyUEN)

Cancel this application and go back to Dashboard

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

Search

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) – Dealer’s Notice

New Application - Getting Started

1. Details

2. Checklist

Checklist

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

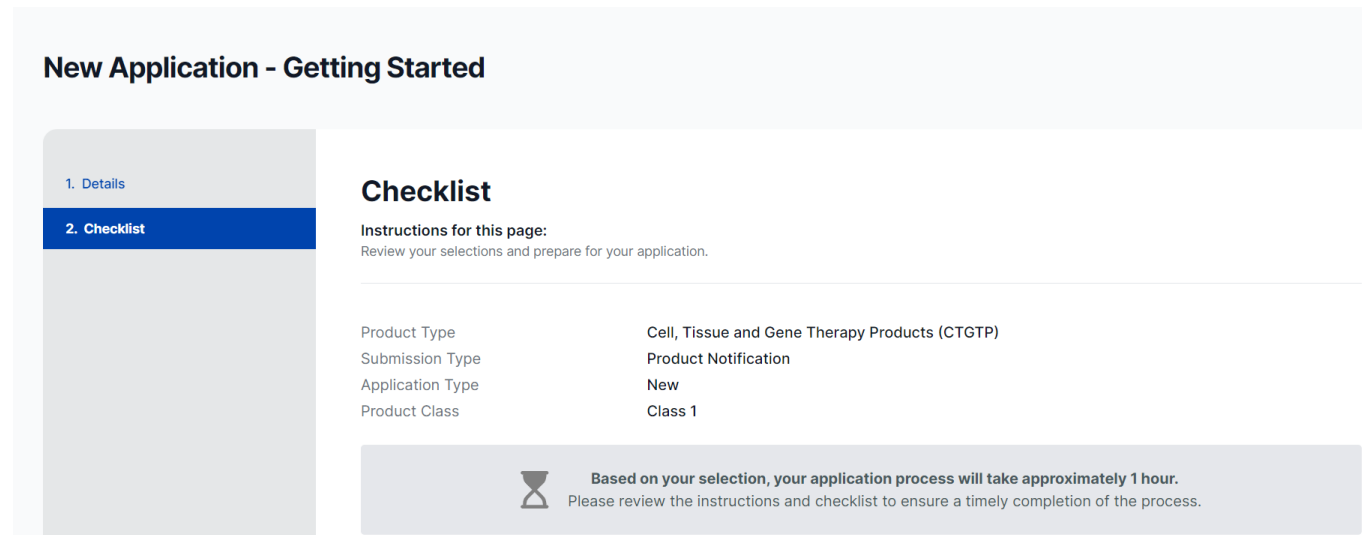
Product Type	Cell, Tissue and Gene Therapy Products (CTGTP)
Submission Type	Dealer's Notice
Application Type	New
Product Class	Class 1 Class 2 (Minimally Manipulated)
Dealer's Activity	Manufacturer, Importer, Wholesaler

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 (v) – Product Notification



New Application - Getting Started


1. Details

2. Checklist

Checklist

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

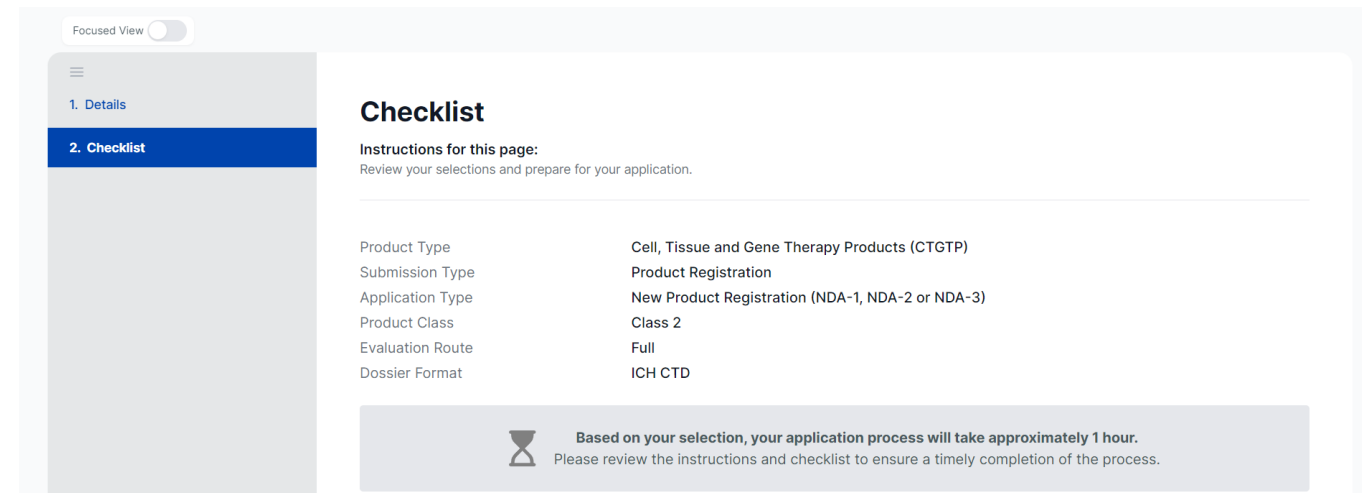
Product Type	Cell, Tissue and Gene Therapy Products (CTGTP)
Submission Type	Product Notification
Application Type	New
Product Class	Class 1

 **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 (v) – Product Registration



Focused View


1. Details

2. Checklist

Checklist

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

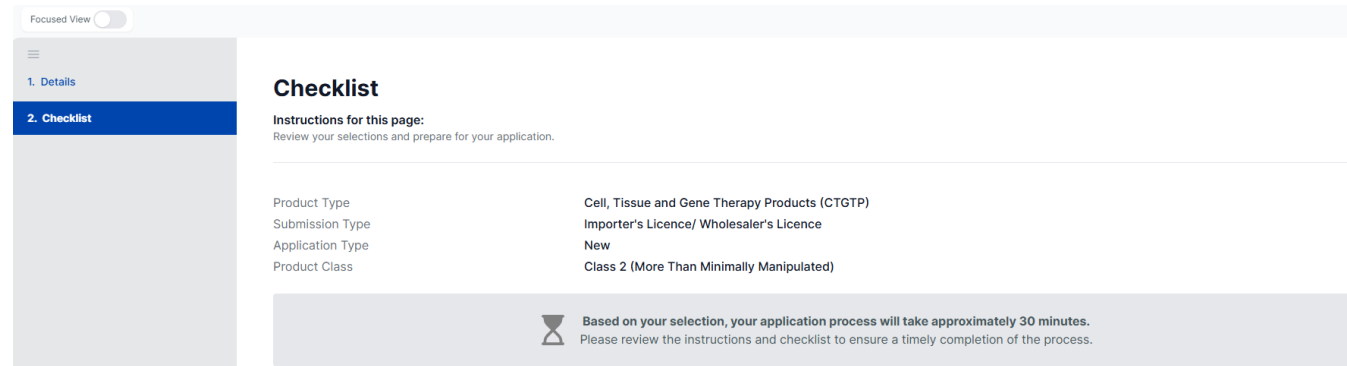
Product Type	Cell, Tissue and Gene Therapy Products (CTGTP)
Submission Type	Product Registration
Application Type	New Product Registration (NDA-1, NDA-2 or NDA-3)
Product Class	Class 2
Evaluation Route	Full
Dossier Format	ICH CTD

 **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 (v) – Importer's Licence/ Wholesaler's Licence



Focused View


1. Details

2. Checklist

Checklist

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

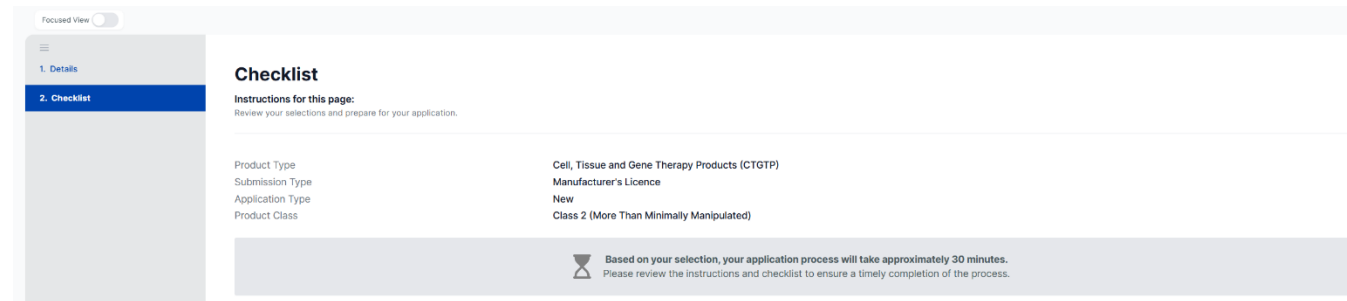
Product Type: Cell, Tissue and Gene Therapy Products (CTGTP)
 Submission Type: Importer's Licence/ Wholesaler's Licence
 Application Type: New
 Product Class: Class 2 (More Than Minimally Manipulated)

 **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 (v) – Manufacturer's Licence



Focused View


1. Details

2. Checklist

Checklist

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

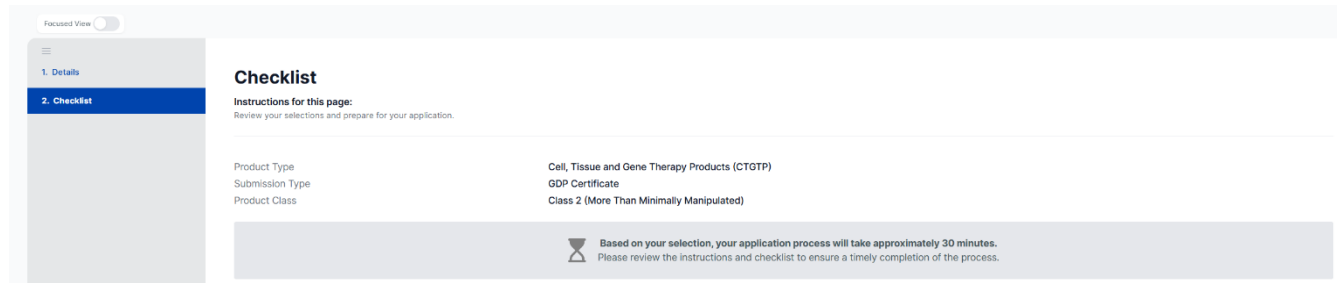
Product Type: Cell, Tissue and Gene Therapy Products (CTGTP)
 Submission Type: Manufacturer's Licence
 Application Type: New
 Product Class: Class 2 (More Than Minimally Manipulated)

 **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](#).

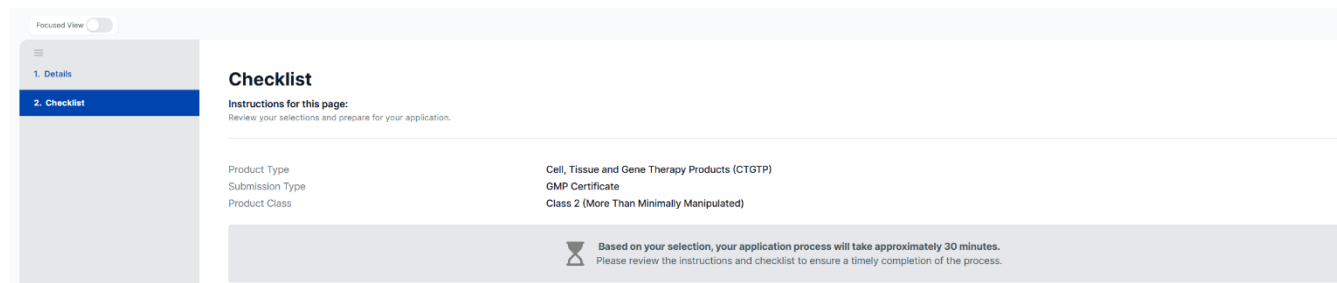
New Application - Getting Started (v) – GDP Certificate



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 (v) – GMP Certificate



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](#).

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

 - 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.


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
6MB  Delete

or folders directly under the root folder.

4.1.2 Company Details

Company Information

Application For Dealer's Notice (New) Draft Application No.(Draft)
Last saved at 15 November 2023 11:24 AM

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 will first be directed to the application form – Company Details.

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 *

Block / Number *

Level - Unit –

Street Name *

Building Name

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 *

Block / Number *

Level - Unit -

Street Name *

Building Name

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, 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) *

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)

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

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

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.

Main Applicant 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 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) *	<input style="width: 90%;" type="text" value="RZ"/>
Designation *	<input style="width: 90%;" type="text" value="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.

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.

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

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

Supporting Documents

Company Details

Application Details

Dealer's Notice Details

Review

Declaration

***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

Manufacturers

- 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)

Manufacturers

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

Tissue Procurement Sites

[Edit](#) [Delete](#)

Procurement Site 1	
Site Name	Site 1
Address	1avenue 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

[Edit](#) [Delete](#)

Overseas Manufacturer 1	
Overseas Manufacturer Name	Allograft PLUS 20mm
Overseas Manufacturer Address	1Duxton 21 Avenue 560032 , CANADA
Activity	Manufacturing Site, Sterilisation Site
Type of Accreditations	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

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

Overview - Product Information

Subsections
 Product Owner Information
 Intended Use & Indications
 Container Closure System (CCS)

Product Owner Information *

Overseas Local

Product Owner Name *

Postal Code * [Get Address](#)

Block / Number *

Level - Unit * -

Street Name *

Building Name *

Intended Use & Indications *

You can add multiple indications for each product or brand.

Intended Use 1		Edit	Delete
Source and Type of Tissue	Grade I		
Intended Use And Indication	Research		

[+ Add Intended Use 2](#)

- Product Information has three subsections:
- Product Owner Information
 - Intended Use and Indications.
 - 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

[+ Add Intended Use 2](#)

Container Closure System (CCS) *

You can add multiple CCS.

CCS 1		Edit	Delete
Container Closure System Description	CCS Description		
Shelf Life	10 Years		
Storage Conditions (°C)	Frozen		

[+ 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.

<input type="checkbox"/>	Product Name	Product Code	CCS	Indication	Sites	Action
<input type="checkbox"/>	Product A	123	<input type="button" value="CCS-1"/>	<input type="button" value="Indication-1"/>	<input type="button" value="Site A"/>	<input type="button" value="Remove"/>
<input type="checkbox"/>	Product B	456	<input type="button" value="CCS-1"/>	<input type="button" value="Indication-1"/>	<input type="button" value="Site A"/>	<input type="button" value="Remove"/>
<input type="checkbox"/>	Product C	789	<input type="button" value="CCS-1"/>	<input type="button" value="Indication-1"/>	<input type="button" value="Site A"/>	<input type="button" value="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

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

<input type="checkbox"/>	Product Name	Product Code	CCS	Indication	Sites	Action
<input type="checkbox"/>	Product A	123	CCS-1	Indication-1	Select Sites <div style="border: 1px solid #ccc; padding: 2px;"> Site A Site B <input type="button" value="Apply"/> </div>	<input type="button" value="Remove"/>
<input type="checkbox"/>	Product B	456	CCS-1	Indication-1	Site A	<input type="button" value="Remove"/>
<input type="checkbox"/>	Product C	789	CCS-1	Indication-1	Site A	<input type="button" value="Remove"/>

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

Product Registration

Overview – Product Information

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

List Of Products *

No Data Available

Intended Use & Indications *

You can add multiple indications for each product or brand.

No Data Available

Dosing Regimen *

You can add multiple dosing regimen

No Data Available

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.

Overview – Product Information

List Of Products *

Listing Name*	NDA*	Referenced NDA*	Dosage Form*	Route Of Administration*	ATC Code	Importer/Wholesaler	Actions
<input type="text" value="New Product 1"/>	<input type="text" value="NDA"/>	<input type="text" value="Referenced NDA"/>	<input type="text" value="Dosage Form"/>	<input type="text" value="Route Of Administration"/>	<input type="text" value="ATC Code"/>	<input type="button" value="Tag Site"/>	<input type="button" value="Delete"/>

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

Local Dealer's Name

Postal Code *

Block / Number *

Level - Unit * -

Street Name *

Building Name *

Overview – Product Information

Dosing Regimen *

You can add multiple dosing regimen



Dosing Regimen 1	
Dosing Regimen	Once 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 A Product 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 X ² X ³ 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.

Overview – Product Information

Add CCS 1 ✕

Select Product *	<input type="text" value="Product A"/>
Select Component *	<input type="text" value="Component A"/>
CCS Description *	<input type="text"/>
Storage Condition *	<input type="text" value="°C"/>
Shelf Life *	<input type="text"/>
Alternate Storage Condition(s) and Shelf Life	<input type="text"/>
Shelf Life after Thawing or 1st Opening	<input type="text"/>
Shelf Life after Reconstitution and/or Dilution	<input type="text"/>
Cold Chain *	<input type="text" value="Select an option"/>
Pack Size(s) (Qty/ CCS) *	<input type="text" value="A<sup>x</sup> A<sub>x</sub> μ °C X<sup>2</sup> X<sup>3</sup> I<sub>L</sub>"/>
Pack Size(s) (CCS/ Pack) *	<input type="text" value="A<sup>x</sup> A<sub>x</sub> μ °C X<sup>2</sup> X<sup>3</sup> I<sub>L</sub>"/>

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

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

Manufacturers

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

Overseas Manufacturers

No Data Available

[Add](#)

Local Manufacturers

No Data Available

[Add](#)

Batch Releaser

No Data Available

[Add](#)

[Back](#)
[Overview - Products List](#)

Subsections

- Overseas Manufacturers
- Local Manufacturers
- Batch Releaser

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

Manufacturers has three subsections:

- a. Overseas Manufacturers
- b. Local Manufacturers
- c. 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:

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

Add Local Manufacturers 1
✕

Dealer Type ● Manufacturer

Local Manufacturer Licence/Dealer Licence Number* ⊙ Get Dealer's Details

Local Manufacturer's Name* ⊙

Postal Code*

Block / Number*

Level - Unit* -

Street Name*

Building Name*

Site Details* ⊙

Type of Manufacturer* ⊙

- Finished Product Manufacturer
- Solvent/Diluent Manufacturer
- Active Substance Manufacturer
- Critical Starting Materials (e.g., viral vector for ex vivo gene modification) Manufacturer
- Others

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) *

Designation *

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

- Supporting Documents
- Company Details
- Application Details
- Dealer's Licence Details
- Payment Details
- Review
- Declaration

Dealer's Licence Details

Warehouse Address *

[Edit](#) [Delete](#)

Warehouse Address 1	
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 *

[Edit](#) [Delete](#)

Warehouse Details 1	
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
×

Add Warehouse Address 1

Site Name *
Site Name is required

Site Activity * Warehouse
 Is this warehouse an outsourced warehouse * Yes No

Site Address

Postal Code *

Block / Number *

Level - Unit -

Street Name *

Building Name

Other Address

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

<p><i>Add Warehouse Details</i></p> <p>Add Warehouse Details 2 ×</p> <hr/> <p>Select Site * <input type="text" value="Select an option"/></p> <p>Temperature (°C) <input type="checkbox"/> Non Cold Chain (> 8°C) <input type="checkbox"/> Cold Chain (≤ 8°C)</p> <p>Relative Humidity (%) (Non-Cold Chain) Min: <input type="text"/> %RH to Max: <input type="text"/> %RH</p> <p>Relative Humidity (%) (Cold Chain) Min: <input type="text"/> %RH to Max: <input type="text"/> %RH</p> <p>Other Storage Conditions <input style="width: 100%; height: 40px;" type="text"/></p> <p style="text-align: right;">Save</p>	<p>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.</p>
<p><i>Add Responsible Person</i></p> <p>Add Responsible Person 1 ×</p> <hr/> <p>Name (as in NRIC/FIN) * <input type="text" value="Enter Name"/></p> <p>Pharmacist Registration Number (PRN) <input type="text" value="Enter Pharmacist Registration Number"/></p> <p>Designation * <input type="text" value="Enter Designation"/></p> <p>Contact Number * <input type="text" value="65"/> - <input type="text"/></p> <p>Email * <input type="text" value="Enter Email"/></p> <p style="text-align: right;">Save</p>	<p>Applicants are required to complete all mandatory fields indicated by '*'.</p>

Manufacturer’s Licence

Manufacturer’s Licence Details

Focused View

- Supporting Documents
- Company Details
- Application Details
- Manufacturer’s Licence Details
- Payment Details
- Review
- Declaration

Manufacturer's Licence Details

Manufacturer Name *

Manufacturer Site Address *

①
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.

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				

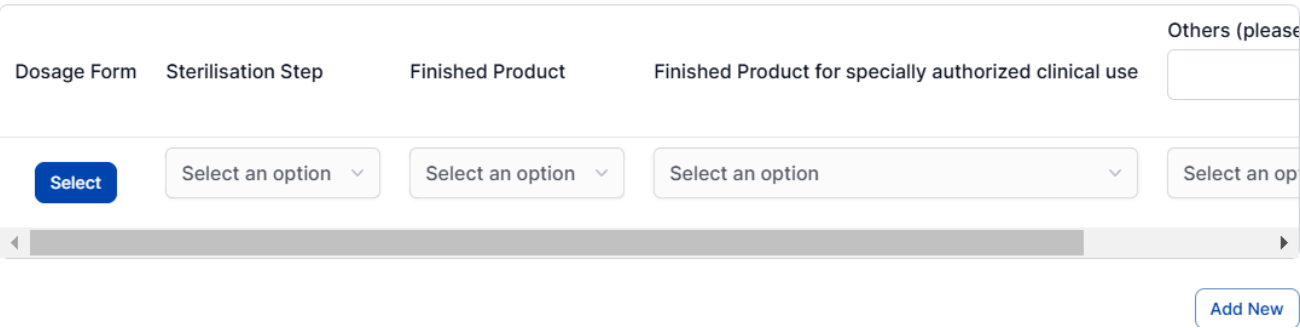
[Add New](#)

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.

<p><i>Scope and Manufacturing Process</i></p> <p>Scope and Manufacturing Process *</p> 	<p>Applicants should click on the 'Add New' button to fill up relevant details. Upon doing so, they will be presented with the form shown.</p>
<p>Dosage Form ×</p> <hr/> <p> <input type="radio"/> Injections, Cryopreserved <input type="radio"/> Injections <input type="radio"/> Others, please specify </p> <p style="text-align: right;">Confirm</p>	<p>Under Dosage Form, applicants must click 'Select' and choose only one of the three available options.</p>

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 ▼	<input style="width: 90%; height: 20px;" type="text"/>

Search

New

- Full manufacturing
- Bulk product
- Up to primary packaging
- Not Applicable

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

- 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) *

Designation *

Directly report to *

Contact Number * -

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.

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

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
- CTGTP combined with a therapeutic product or a medical device
- Others, please specify:

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:

- 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)

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.

Focused View

- Supporting Documents
- Company Details
- Application Details
- GMP Certification Details**
- Payment Details
- Review
- Declaration

Manufacturer Name

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 And Manufacturing Process ○
- Packaging ○
- Quality Control Testing ○
- Scope ○
- Other Manufacturing Activities Conducted At The Same Site ○
- Responsible Person (Production Operations) ○
- Responsible Person (Quality Operations) ○

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 *

Postal Code

Block / Number

Level - Unit

Street Name

Building Name

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.

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.

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

- I, on behalf of my company, confirm that the information submitted in this application is true and accurate.
- I, on behalf of my company, confirm that there are no additional amendments made to this application or to the attachments thereof.

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.

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 ⌵

Application Type ⌵

Existing Application ⌵

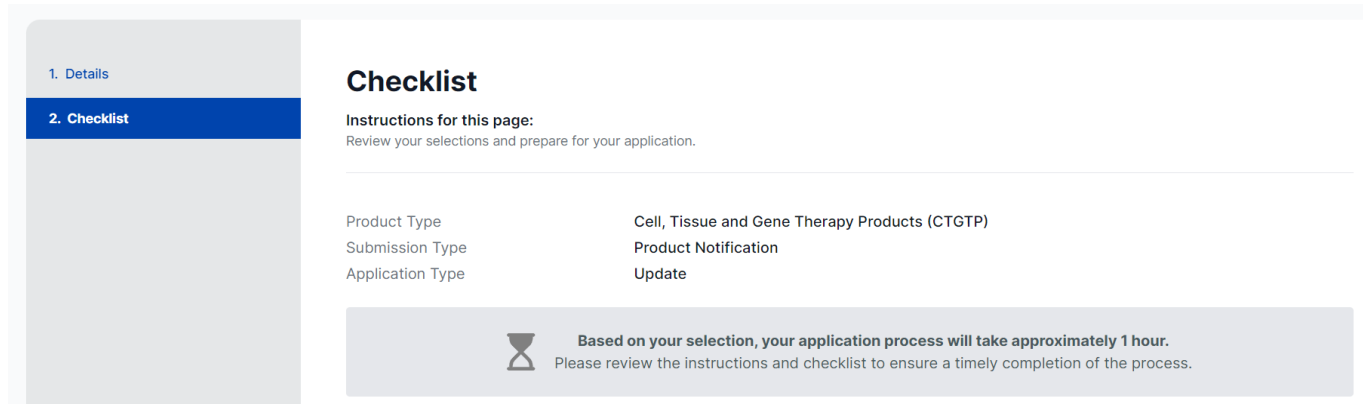
Cancel this application
and go back to Dashboard

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

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

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

Products 1

Listing Name	Product 8 A
NDA	1
Referenced NDA	N/A
Dosage Form	AEROSOL
Route Of Administration	Auricular (OTIC)
ATC Code	10
Importer/Wholesaler	

Products 1

Listing Name	Product 8 A
NDA	1
Referenced NDA	N/A
Dosage Form	AEROSOL
Route Of Administration	Auricular (OTIC)
ATC Code	500
Importer/Wholesaler	

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 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.

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	Cell, Tissue and Gene Therapy Products (CTGTP)
Submission Type	Importer's Licence/ Wholesaler's Licence
Application Type	Amendment
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.

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	Changes in Current Application
Name: Rachana	Name: Annie
Designation: test	Designation: Assistant

Notification Emails

Notification Email 1

Contact Person	A1
Contact Number	+65-80009000
Email	rachana@tsp.dev

Warehouse Address

Previous values	Changes in Current Application
Warehouse Address 1	Warehouse Address 1
Site Name: W1	Site Name: W1
Site Activity: Warehouse	Site Activity: Warehouse
Site Address: 233, 233Q3, Singapore 123456	Site Address: 6, CHIN BEE CRESCENT, Singapore 619892
Other Address: N.A	Other Address: N.A
Outsourced: No	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

The screenshot shows a web application interface for 'New Application - Getting Started'. On the left is a vertical navigation menu with two items: '1. Details' (highlighted in blue) and '2. Checklist'. The main content area is titled 'Details' and contains the following elements:

- Instructions for this page:** Please select the required product type and submission type for your application.
- Product Type:** A dropdown menu with the selected value 'Cell, Tissue and Gene Therapy Products (CTGTP)'.
- Submission Type:** A dropdown menu with the selected value 'Dealer's Notice'.
- Application Type:** A dropdown menu with the selected value 'Cancel'.
- Cancel button:** A button with a circular arrow icon and the text 'Cancel', with the instruction 'Cancel this application and go back to Dashboard' above it.
- Next button:** A blue button with the text '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

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)

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 >

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

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

1. You may include products with the same proprietary name or brand names from the same product owner in a single application.
2. 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](#)
3. Further guidance on the preparation of the supporting documents can be found in Appendix 1 Guidelines on our [website](#)
4. We will contact you for fee payment after submission of the application.
5. 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
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

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

Approved product number	Product Name	Product Code	Product owner	CCS	Indication	Sites	Effective Date
<input checked="" type="checkbox"/> 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 <input type="text"/>
<input type="checkbox"/> 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 <input type="text"/>
<input type="checkbox"/> 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 <input type="text"/>
<input type="checkbox"/> 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 <input type="text"/>
<input type="checkbox"/> 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 <input type="text"/>
<input type="checkbox"/> 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 <input type="text"/>
<input type="checkbox"/> 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 <input type="text"/>

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

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

Cancel Application For Product Notification

Focused View

- 1. Products List
- 2. Submit

Submit

Are you 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

Focused View

- 1. Products List
- 2. Submit

Submit

Are you 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)

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

< Back
Cancel Yes
Confirm Cancellation

- Home
- Applications
- Input Requests
- Products
- All Products
- Dealers
- Search
- E-GIRO Application

Products

Product Name

Approved Product Number

Indications

Dealer's Notice Number

Product Owner Name

CCS

Dealer's Site Name

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

Product Registration

Cancel Product Registration – 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(cancellation) 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

Cancel Product Registration – Getting Started (ii)

Cancellation Application For Product Registration

Products List

Select Products to Cancel

Product Name: Approved Product Number:

Approved product number	Product Name	Effective Date
<input type="checkbox"/> CGPR241001M0013	Product F	<input type="text" value="dd/mm/yyyy"/>
<input type="checkbox"/> CGPR241005O0002	Product A	<input type="text" value="dd/mm/yyyy"/>
<input type="checkbox"/> CGPR241007Q0011	Product B	<input type="text" value="dd/mm/yyyy"/>
<input type="checkbox"/> CGPR241001J0010	Product C	<input type="text" value="dd/mm/yyyy"/>
<input type="checkbox"/> CGPR241005N0001	Product E	<input type="text" value="dd/mm/yyyy"/>
<input type="checkbox"/> CGPR241001K0011	Product D	<input type="text" value="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 Registration - Submit

Cancellation Application For Product Registration

Focused View

- 1. Products List
- 2. Submit

Submit

Are you 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](#)

Cancellation Application For Product Registration

Focused View

- 1. Products List
- 2. Submit

Submit

Are you 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](#)

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

[Confirm Cancellation](#)

Focused View

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

Products

Product Name <input type="text"/>	Product Owner Name <input type="text"/>
Approved Product Number <input type="text"/>	CCS <input type="text"/>
Indications <input type="text"/>	Dealer's Site Name <input type="text"/>
Dealer's Notice Number <input type="text"/>	

1 item(s) found

Product Listing Number	Product Name	Product Owner	Product Type	Product Status	Retention Due Date	Latest Application	Related Applications	Action
CCNR241001M0013	Product F	John	CTG1P Class 2	Cancelled	01-Oct-2025	CCNR241001Y0009	N/A	N.A

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

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

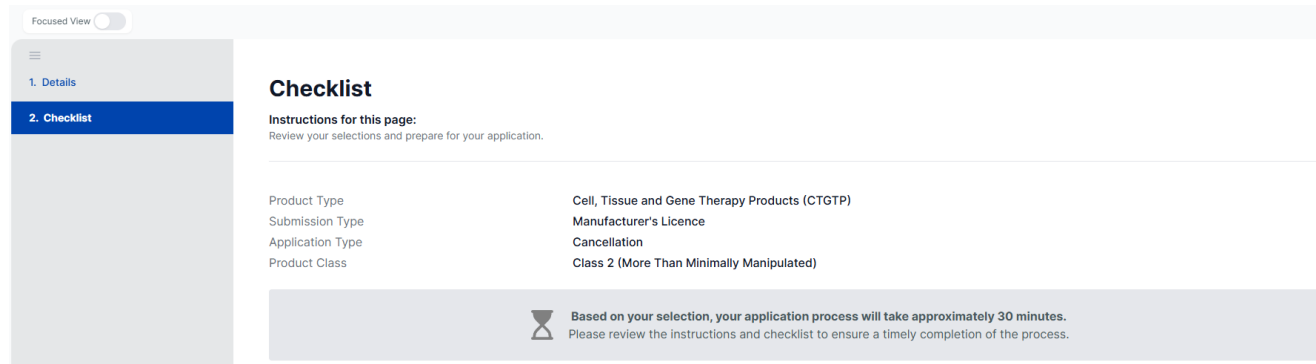
Cancel this application and go back to Dashboard

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.

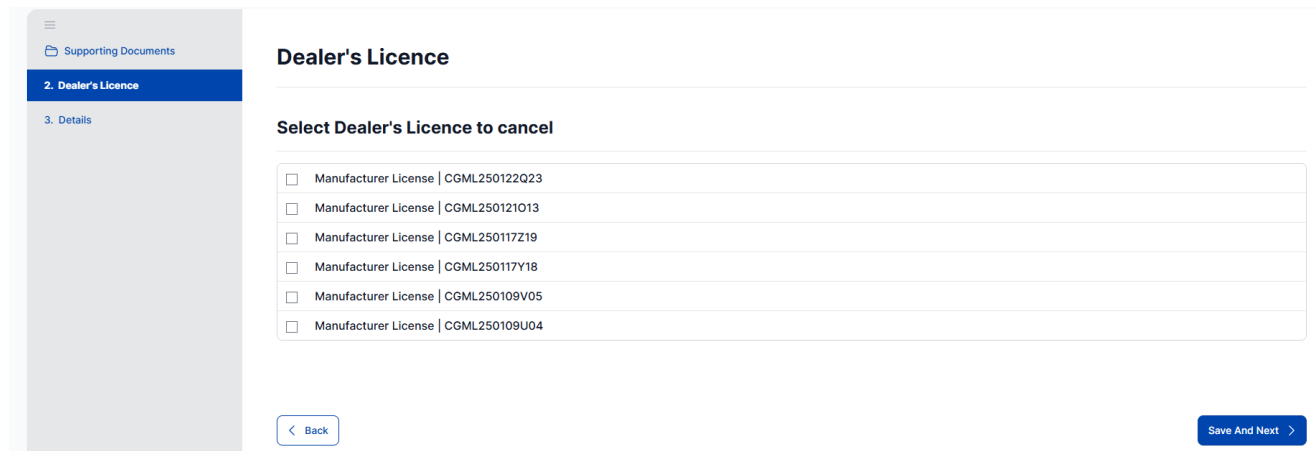
Product Type	Cell, Tissue and Gene Therapy Products (CTGTP)
Submission Type	Manufacturer's Licence
Application Type	Cancellation
Product Class	Class 2 (More Than Minimally Manipulated)

 **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

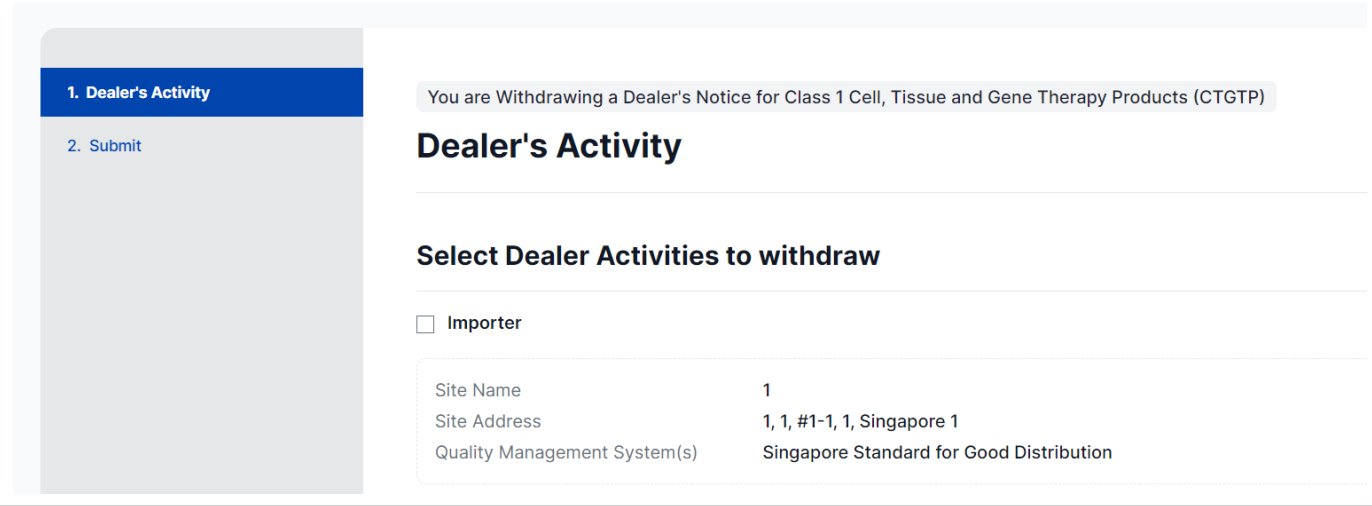
CGND231124A0003		Withdraw	View
Product Type	Cell, Tissue and Gene Therapy Products (CTGTP) Class 1		
Dealer's Activity	Notice for Import of minimally manipulated CTGTP		
Submission Type	New Dealer's Notice		
Status	Pending IR		
Submission Date	26-Nov-2023		

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

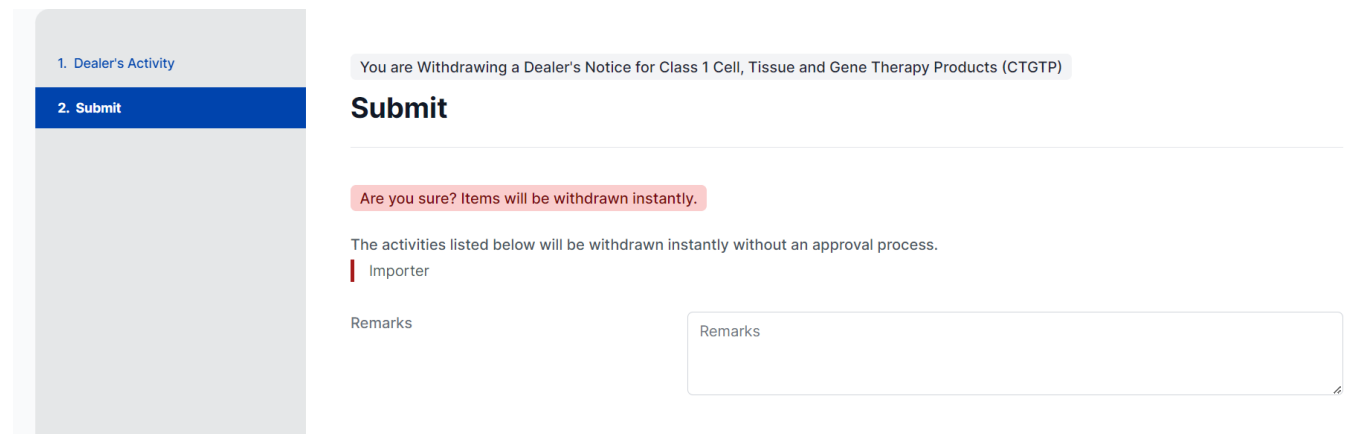
Importer

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)

The screenshot displays the 'New Application - Getting Started' page on the HSA portal. The interface includes a sidebar with navigation options: '1. Details' (selected), '2. Review', and '3. Checklist'. The main content area is titled 'Details' and provides instructions for selecting the submission and application types. The 'Product Type' dropdown is set to 'Cell, Tissue and Gene Therapy Products (CTGTP)'. The 'Submission Type' dropdown is set to 'Product Registration', and the 'Application Type' dropdown is set to 'Fulfilment of Approval Conditions'. A 'Cancel' button is located at the bottom left, and a 'Next >' button is at the bottom right.

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

- Submission type
- Application type

Choose product registration submission type, fulfilment of approval conditions application type 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.

New Application - Getting Started

Focused View

- 1. Details
- 2. Review**
- 3. Checklist

Review

Instructions for this page:
Please select the fulfilment of conditions

Application Number Product Name

The highlighted field is the changes made by the officer

A prod 6 (CGPR240917A0003) Application Number: CGMA240923M0002

Approved Conditions	Date
<input type="checkbox"/> Quality	03-Oct-2024
<input type="checkbox"/> CLinics	03-Oct-2024
<input type="checkbox"/> RMP	03-Oct-2024

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**

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 Fulfilment 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 (CTCTP).

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

- All documents submitted in support of the application must be in English.
- 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](#).
- 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), PayNow.

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

7.1 Fulfilment of Approval Condition

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

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

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.

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

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.

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	Change of Registrant
Relinquishing Company	ThirdCompany
Product Owners	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 (CTCTP) 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

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

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

Reset
Filter

	Approved Product Number	Product Name	Remarks
<input checked="" type="checkbox"/>	CGPR241014V0009	Product A	
<input type="checkbox"/>	CGPR241014Q0013	Product B	
<input type="checkbox"/>	CGPR241014T0007	Product C	

Effective Date of Transfer:

Cancel
Supporting Documents >

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

8.2 Supporting Documents

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

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 Get Dealer's Details

Local Dealer's 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/NL
- ☰ 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 Corpass login and requires no action on your part.

Company Name SecondCompany

UEN SecondCompanyUEN

Company Address *

Clear ACRA Address

Postal Code *

Block / Number *

Level - Unit * -

Street Name *

Building Name *

Subsections ⊕

Company Information ⊕

Company Address

Contact Information

Billing Information

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

8.5 Application Details

Application For Product Registration (Change Of Registrant)

Draft Application No. (Draft)
Last saved at 23 September 2024 11:51 AM

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

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) *

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](#)

[← Back](#)
[Payment Details →](#)

8.6 Payment Details

Application For Product Registration (Change Of Registrant)

Focused View

- Product List
- Supporting Documents
- New Appointed IL/WL
- Company Details
- Application Details
- Payment Details
- Review
- Declaration

Draft

Application No. (Draft)
Last saved at 23 September 2024 11:53 AM

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

Payment Details

Preferred Payment Mode *

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.

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 NAM25	

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.



Page 104 of 129

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/NL
- 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.

9 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

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	Cell, Tissue and Gene Therapy Products (CTGTP)
Submission Type	Product Registration
Application Type	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 (CTCTP) 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](#)

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.

9.1 Product List

Application For Product Registration (Retention) Draft Application No. (Draft)
Last saved at 23 September 2024 01:04 PM

Focused View

Product List

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

<input type="checkbox"/>	Product	Product No	Current Retention Due Date	New Retention Due Date
<input type="checkbox"/>	B prod 1	CGPR240917F0008	25-Sep-2024	25-Sep-2025
<input type="checkbox"/>	B prod 2	CGPR240917G0009	25-Sep-2024	25-Sep-2025

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

9.2 Payment Details

Application For Product Registration (Retention) Draft Application No. (Draft)
Last saved at 23 September 2024 12:10 PM

Focused View

Payment Details

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

Preferred Payment Mode*

Charge Code	Description	Price
CTGTRETPDT	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.

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.

9.3 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
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.

9.4 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.

10 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

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

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)

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.

10.1 Licence List

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.

10.2 Payment Details

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

Payment Details

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

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.

10.3 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

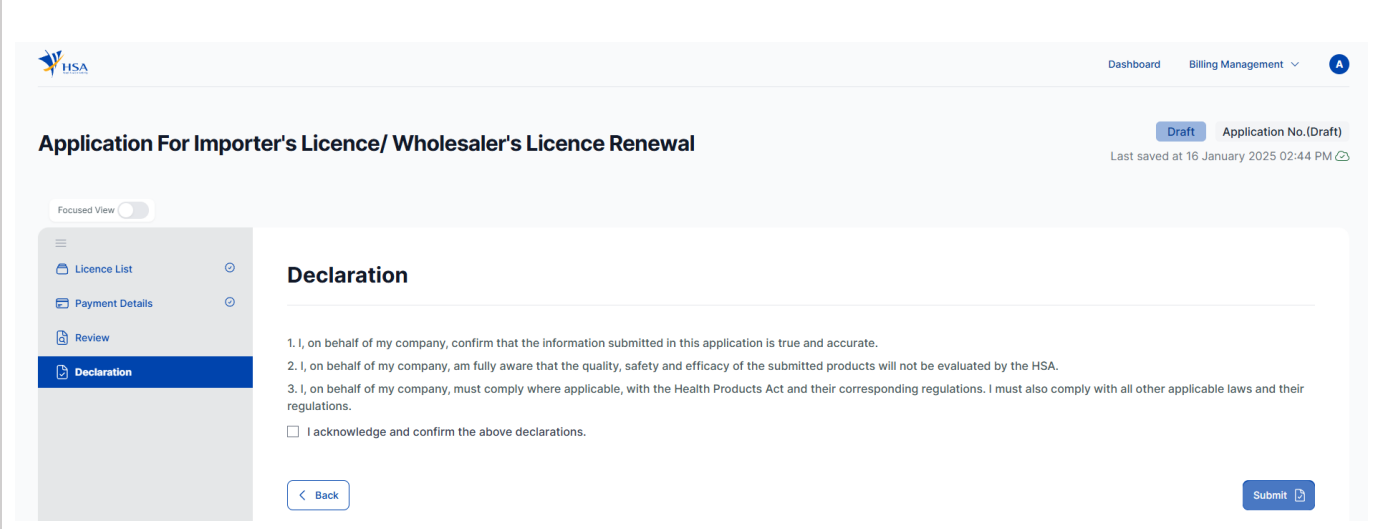
Selected Payment Mode

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.

10.4 Declaration



The screenshot displays the HSA application portal interface. At the top left is the HSA logo. The top right navigation bar includes 'Dashboard' and 'Billing Management' with a dropdown arrow and a user profile icon. The main header area shows the title 'Application For Importer's Licence/ Wholesaler's Licence Renewal' and a 'Draft' status indicator. Below the title, it says 'Application No.(Draft)' and 'Last saved at 16 January 2025 02:44 PM'. A 'Focused View' toggle is visible. On the left, a sidebar menu contains 'Licence List', 'Payment Details', 'Review', and 'Declaration', with 'Declaration' selected. The main content area is titled 'Declaration' and contains three numbered statements for the applicant to confirm. Below the statements is a checkbox for acknowledgment. At the bottom of the content area are 'Back' and 'Submit' buttons.

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

Draft Application 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.

11 Applications

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

Draft

The screenshot shows the 'Applications' dashboard. On the left is a navigation menu with 'Applications' selected. The main area is titled 'Applications' and contains a 'New Application' button. Below this is a section for 'Draft Applications'. Two draft application cards are displayed, each with a 'Resume' and 'Delete' button. The cards show the following details:

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:

- Resume – allows applicant to resume the application and submit.
- Delete – allows applicant to delete the application.

Inactivity session timeout

The screenshot shows the HSA dashboard with a 'Session Expiry' pop-up window. The pop-up contains the following text:

Session Expiry
The session would be terminated soon. You can re-login or continue your Session
[Continue My Session](#)

The background dashboard shows the 'Home' page with an 'Overview' section. It displays 'Active Applications: 20', 'Pending Input Requests', 'Products', and 'Dealer's Notice: 4'. There is also a 'Latest Active Applications' table with columns for application ID, product type, and actions (Withdraw, View).

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

<p><i>Active</i></p>	<p>Applications New Application</p> <p>Active Applications</p> <div style="display: flex; justify-content: space-around;"> <div style="border: 1px solid #ccc; padding: 5px; width: 45%;"> <p>CGNN231122H0002 Withdraw View</p> <p>Product Type: Cell, Tissue and Gene Therapy Products (CTGTP) Class 1</p> <p>Product Name: Allograft PLUS™ 55mm by 20 mm</p> <p>Submission Type: New Product Notification</p> <p>Status: Processing</p> <p>Submission Date: 23-Nov-2023</p> </div> <div style="border: 1px solid #ccc; padding: 5px; width: 45%;"> <p>CGAD231121L0004 Withdraw View</p> <p>Product Type: Cell, Tissue and Gene Therapy Products (CTGTP) Class 1</p> <p>Dealer's Activity: Notice for Import of minimally manipulated CTGTP</p> <p>Submission Type: Update Dealer's Notice</p> <p>Status: Processing</p> <p>Submission Date: 23-Nov-2023</p> </div> </div>
----------------------	--

12 Tasks

12.1 Open Input Requests

Open IRs

Home

Applications >

Input Requests ▾

Open IRs

Responded IRs

Products

Dealers

Search

E-GIRO Application

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.

12.2 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
Focused View

- Home
- Applications
- Tasks 79
- Open IRs
- Open Finding(s) 3
- Pending Payments 75
- Pending Importer Tagging 1
- Input Requests
- Findings
- Payment
- Products
- View Notices/Licences/Certificates
- Search
- Audit Documents

Tasks

Open Finding(s)

Audit No.	Dealer's Activity	Audit Type	Product Type	
Audit_00133	Manufacturer, GMP	New Audit	More Than Minimally Manipulated	Export
<div style="display: flex; justify-content: space-between; align-items: flex-start;"> <div style="width: 20%;"> <p>#FD-002</p> <p>2 Queries in this FD</p> <p>0 Replied</p> </div> <div style="width: 20%;"> <p>Received</p> <p>22 Jan 2025</p> </div> <div style="width: 20%;"> <p>Due</p> <p>05 Mar 2025</p> </div> <div style="width: 20%;"> <p>Status</p> <p>Open</p> <p>22 working days left</p> </div> <div style="width: 10%; text-align: right;"> <p>Respond</p> </div> </div>				
Audit_00044	Importer, Wholesaler, GDP	New Audit	More Than Minimally Manipulated	Export
<div style="display: flex; justify-content: space-between; align-items: flex-start;"> <div style="width: 20%;"> <p>#FD-002</p> <p>1 Queries in this FD</p> <p>0 Replied</p> </div> <div style="width: 20%;"> <p>Received</p> <p>24 Dec 2024</p> </div> <div style="width: 20%;"> <p>Due</p> <p>05 Feb 2025</p> </div> <div style="width: 20%;"> <p>Status</p> <p>Open</p> <p style="background-color: #c00000; color: white; padding: 2px;">Request for Extension</p> </div> <div style="width: 10%; text-align: right;"> <p>Respond</p> </div> </div>				
<div style="display: flex; justify-content: space-between; align-items: flex-start;"> <div style="width: 20%;"> <p>#FD-001</p> <p>1 Queries in this FD</p> <p>0 Replied</p> </div> <div style="width: 20%;"> <p>Received</p> <p>24 Dec 2024</p> </div> <div style="width: 20%;"> <p>Due</p> <p>05 Feb 2025</p> </div> <div style="width: 20%;"> <p>Status</p> <p>Open</p> <p style="background-color: #c00000; color: white; padding: 2px;">Request for Extension</p> </div> <div style="width: 10%; text-align: right;"> <p>Respond</p> </div> </div>				

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.

12.3 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

- [Home](#)
- [Applications](#)
- [Tasks 79](#)
- [Open IRs](#)
- [Open Finding\(s\) 3](#)
- [Pending Payments 75](#)
- [Pending Importer Tagging 1](#)
- [Input Requests](#)
- [Findings](#)
- [Payment](#)
- [Products](#)
- [View Notices/Licences/Certificates](#)
- [Search](#)
- [Audit Documents](#)

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.

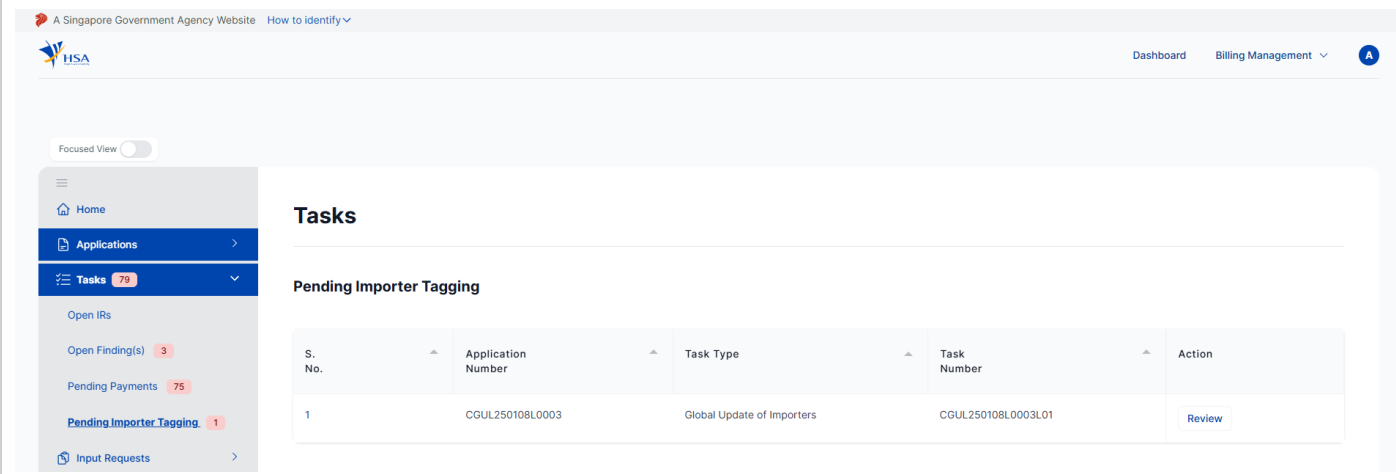
Applicants can click on the application number to view the application details for the specific application.

To proceed with payment, they can click the 'Pay' button, which redirects them to the payment page.

12.4 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 page header includes 'A Singapore Government Agency Website' and 'How to identify'. The HSA logo is in the top left, and 'Dashboard' and 'Billing Management' are in the top right. A sidebar on the left contains navigation options: Home, Applications, Tasks (79), Open IRs, Open Finding(s) (3), Pending Payments (75), Pending Importer Tagging (1), and Input Requests. 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

Review Importer Tagging

Focused View

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: FirstCompany
 UEN: FirstCompanyUEN

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.

13 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

- [Home](#)
- [Applications](#)
- [Tasks 79](#)
- [Input Requests](#)
- [Open IRs](#)
- [Responded IRs](#)
- [Findings](#)
- [Payment](#)
- [Products](#)
- [View Notices/Licences/Certificates](#)
- [Search](#)
- [Audit Documents](#)

Input Requests

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
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.

14 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.

Responded Findings

Focused View

- [Home](#)
- [Applications](#)
- [Tasks 79](#)
- [Input Requests](#)
- [Findings](#)
- [Open Finding\(s\)](#)
- [Responded Finding\(s\)](#)
- [Payment](#)
- [Products](#)
- [View Notices/Licences/Certificates](#)
- [Search](#)
- [Audit Documents](#)

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
<div style="display: flex; justify-content: space-between; align-items: flex-start; padding: 5px;"> <div style="width: 20%;"> #FD-002 1 Queries in this FD 0 Replied </div> <div style="width: 20%;"> Received 22 Jan 2025 </div> <div style="width: 20%;"> Due 05 Mar 2025 </div> <div style="width: 20%;"> Status Responded </div> <div style="width: 10%; text-align: right;"> View </div> </div>				
<div style="display: flex; justify-content: space-between; align-items: flex-start; padding: 5px;"> <div style="width: 20%;"> #FD-001 1 Queries in this FD 0 Replied </div> <div style="width: 20%;"> Received 22 Jan 2025 </div> <div style="width: 20%;"> Due 05 Mar 2025 </div> <div style="width: 20%;"> Status Responded </div> <div style="width: 10%; text-align: right;"> View </div> </div>				
Audit No. Audit_00133	Dealer's Activity Manufacturer, GMP	Audit Type New Audit	Product Type More Than Minimally Manipulated	Export
<div style="display: flex; justify-content: space-between; align-items: flex-start; padding: 5px;"> <div style="width: 20%;"> #FD-001 2 Queries in this FD 0 Replied </div> <div style="width: 20%;"> Received 22 Jan 2025 </div> <div style="width: 20%;"> Due 05 Mar 2025 </div> <div style="width: 20%;"> Status Closed </div> <div style="width: 10%; text-align: right;"> View </div> </div>				
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.

15 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

Focused View

- [Home](#)
- [Applications](#)
- [Tasks 79](#)
- [Input Requests](#)
- [Findings](#)
- Payment**
- [Open Payments](#)
- Paid Payments**
- [Products](#)
- [View Notices/Licences/Certificates](#)
- [Search](#)
- [Audit Documents](#)

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.

16 Products

This section allows applicants to search and view approved product information.

Focused View

- [Home](#)
- [Applications](#)
- [Tasks 79](#)
- [Input Requests](#)
- [Findings](#)
- [Payment](#)
- [Products](#)
- [All Products](#)
- [View Notices/Licences/Certificates](#)
- [Search](#)
- [Audit Documents](#)

Products

Product Name

Approved Product Number

Indications

Dealer's Submission Number

Product Owner Name

CCS

Dealer's Site Name

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.

17 View Notices/Licences/Certificates

This section allows applicants to search and view notices, licences, and certificates associated with their dealer activities.

Focused View

- [Home](#)
- [Applications](#)
- [Tasks 79](#)
- [Input Requests](#)
- [Findings](#)
- [Payment](#)
- [Products](#)
- [View Notices/Licences/Certificates](#)
- [Search](#)
- [Audit Documents](#)

View Notices/Licences/Certificates

Activity Type

Licence/Certificate/Notice Number

Site Name

Submission Type

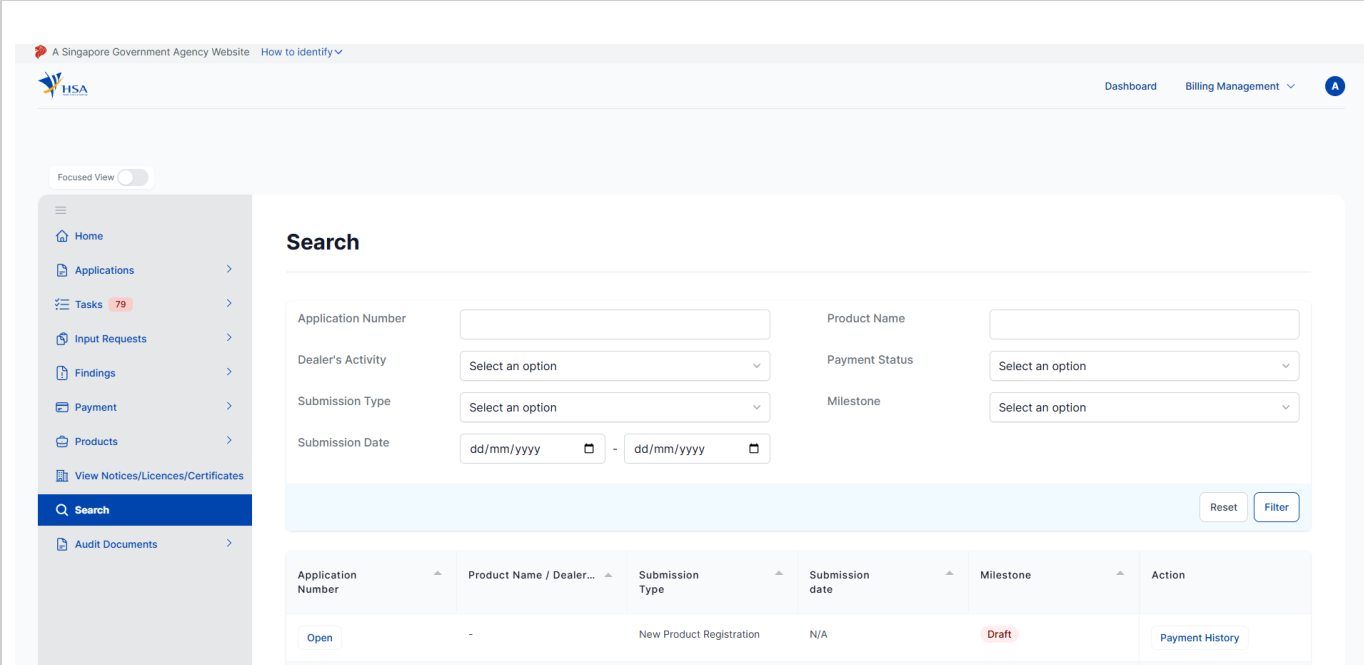
Licence/Certificate/Notice Number	Product Type	Submission Type	Activity Type	Status	Expiry Date	Latest Application	Action
CGGD241218I05	CTGTP Class 2 (More than Minimally Manipulated)	GDP Certificate	GDP	Active	18-Dec-2027	CGNL241218K0007	N.A
CGGD241220A04	CTGTP Class 2 (More than Minimally Manipulated)	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.

18 Search

This section allows applicants to search and retrieve relevant applications for ease of navigation.



The screenshot displays the HSA Search interface. On the left is a navigation menu with options: Home, Applications, Tasks (79), Input Requests, Findings, Payment, Products, View Notices/Licences/Certificates, Search (highlighted), and Audit Documents. The main content area is titled "Search" and contains several filter fields: Application Number (text input), Dealer's Activity (dropdown), Submission Type (dropdown), Submission Date (date range), Product Name (text input), Payment Status (dropdown), and Milestone (dropdown). Below the filters are "Reset" and "Filter" buttons. The search results are shown in a table with columns: Application Number, Product Name / Dealer..., Submission Type, Submission date, Milestone, and Action.

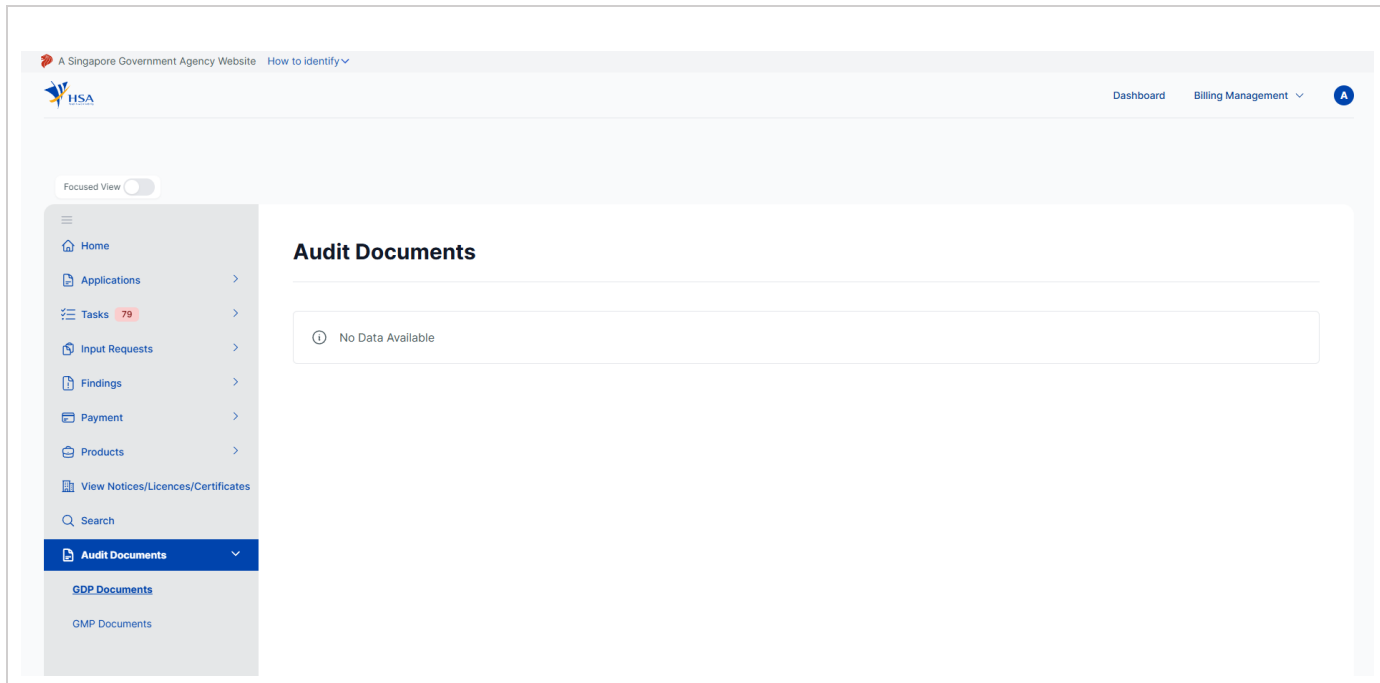
Application Number	Product Name / Dealer...	Submission Type	Submission date	Milestone	Action
Open	-	New Product Registration	N/A	Draft	Payment History

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.

19 Audit Documents

This section contains two subsections: GDP documents and GMP Documents.



The screenshot displays the HSA (Health Science Authority) web interface. At the top, there is a navigation bar with the HSA logo, a 'Dashboard' link, and a 'Billing Management' dropdown menu. Below the navigation bar, a sidebar menu is visible with options: Home, Applications, Tasks (79), Input Requests, Findings, Payment, Products, View Notices/Licences/Certificates, Search, Audit Documents (selected), GDP Documents, and GMP Documents. The main content area is titled 'Audit Documents' and contains a message: '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.