

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

User Manual Applicant (Internet)

Version 1.3
Date 03 Oct 2024



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

Contents

Contents	3
HSA SHARE.....	5
1 System Overview	6
1.1 Class 1 CTGTP.....	6
1.2 Class 2 CTGTP.....	7
1.3 Abbreviations and Definitions	8
1.4 Application Statuses	8
1.5 IR Statuses and Trigger Points	8
2 Login	9
3 Dashboard	10
4 Creation Of New Application	11
4.1 Supporting Documents.....	22
4.2 Company Details.....	23
4.3 Application Details.....	29
4.4 Dealer’s Notice	32
4.5 Product Notification	34
4.6 Product Registration.....	39
4.7 Review	46
4.8 Declaration	47
5 Creation of Update Application.....	48
6 Cancellation of Dealer’s Notice, Product Notification or Product Registration	53
7 Withdrawal of Products/Dealer Activities.....	62
8 Creation of Fulfilment of Approval Conditions Application	64
8.1 Fulfillment of Approval Condition	66
8.2 Review	66
8.3 Declaration	67
9 Creation of Change of Registrant Application	68
9.1 Product List.....	70
9.2 Supporting Documents.....	70
9.3 New Appointed IL/WL	71
9.4 Company Details.....	72
9.5 Application Details.....	73
9.6 Payment Details.....	74
9.7 Review	75

- 9.8 Declaration 76
- 10 Creation of Retention Application..... 77
 - 10.1 Product List 79
 - 10.2 Payment Details..... 80
 - 10.3 Review 81
 - 10.4 Declaration 82
- 11 Applications 83
- 12 Input Request 85
- 13 Products..... 87
- 14 Dealers 88
- 15 Search 89

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. Applicants would be able to perform other application activities such as updating, cancellation and withdrawal of applications in 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 Class 1 CTGTP Dealer's Notice

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



Update Products and applications

To update changes to products and applications submitted.



Withdrawal of application

To withdraw any application or products before it is approved or rejected.

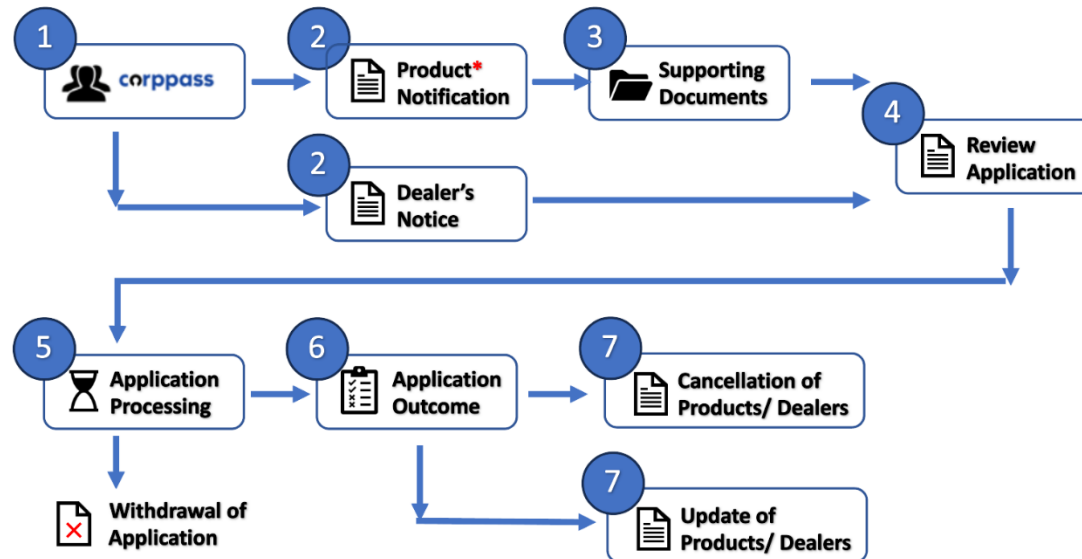


Submit cancellation notice for Notified Product(s), Registered Product(s) or Known Dealer(s)

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

1 System Overview

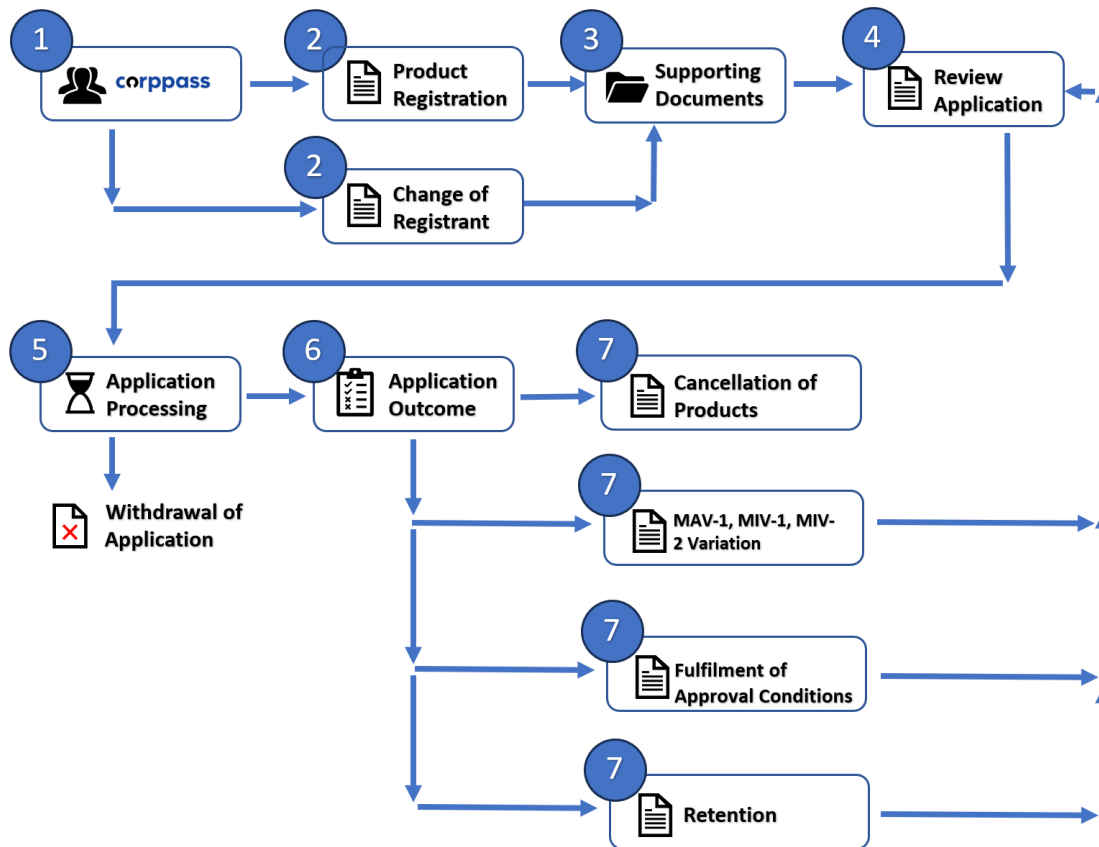
1.1 Class 1 CTGTP



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

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

1.2 Class 2 CTGTP



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

1.3 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

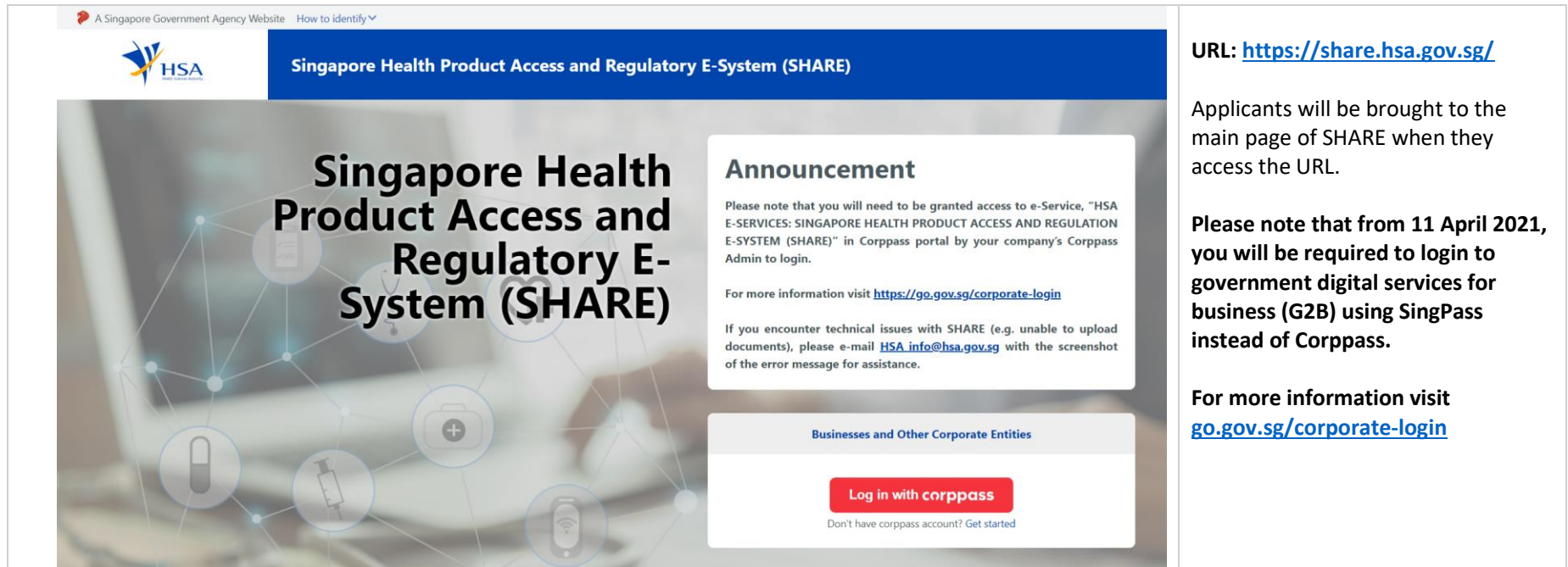
1.4 Application Statuses

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



A Singapore Government Agency Website How to identify

HSA

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

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

Announcement

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

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

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

Businesses and Other Corporate Entities

[Log in with corppass](#)

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

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

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

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

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

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.

Home

Overview [New Application](#)

- Active Applications: **9** [View Active Applications](#)
- Pending Input Requests: **1** [View Open IRs](#)
- Products: **10** [View all products](#)
- Dealer's Notice: **1** [View all dealer's notices](#)

Latest Active Applications [View Draft Applications](#)

List of most recently updated Active applications. You may access the specific categories from the Applications menu.

CGNR241003T0002	CGNR241002W0006
<p>Withdraw View</p> <p>Product Type: Cell, Tissue and Gene Therapy Products (CTGTP) Class 2</p> <p>Product Name: Product Z</p> <p>Submission Type: New Product Registration</p> <p>Status: Processing</p> <p>Submission Date: 03-Oct-2024</p>	<p>Withdraw View</p> <p>Product Type: Cell, Tissue and Gene Therapy Products (CTGTP) Class 2</p> <p>Product Name: Product A</p> <p>Submission Type: New Product Registration</p> <p>Status: Processing</p> <p>Submission Date: 02-Oct-2024</p>

Home – Dashboard

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

[Applications](#)
[Input Requests](#)
[Products](#)
[Dealers](#)
[Search](#)

Additionally, the blue cards serve the following functions:

Active Application:

- Displays all applications submitted by the applicant pending HSA approval.

Pending Input Request:

- Allows applicants to click and assess all Input Requests that require their response.

Products:

- Presents a list of notified products.

Dealer's Notice:

- Presents a list of known dealers.

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

4 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 they want to submit.

Product Type

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

Submission Type

- Product Notification
- Dealer’s Notice
- Product Registration

Application Type
*(fields will be **shown only 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

Product Class

*(fields will be **shown only 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
 This will only be shown if applicants select:

- Submission type = "Dealer's Notice"
- Application type = "New"

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

New Application - Getting Started (iii)

Focused View

1. Details

2. Checklist

Details

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

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

Submission Type ⓘ Product Registration

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

Product Class ⓘ Class 2

Evaluation Route Select Evaluation Route

Dossier Format Full
Abridged

Cancel this application and go back to Dashboard

Evaluation Route

This will only be shown if applicants select:

- Submission type = “Product Registration”
- Application type = “New Product Registration (NDA-1, NDA-2 or NDA-3)” or Application type = “Variation (MAV-1, MIV-1 or MIV-2)” and Variation Type = “MAV-1”

Applicants can select either full or abridged evaluation routes

Dossier Format

This will only be shown if applicants select:

- 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

Focused View

- 1. Details
- 2. Checklist

Details

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

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

Submission Type Product Registration

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

Product Class Class 2

Evaluation Route Full

Dossier Format Select Dossier Format

- ICH CTD
- ACTD

Cancel this application and go back to Dashboard

New Application - Getting Started (iv)

Variation Type

This will only be shown if applicants select:

- 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

Existing Products

This will only be shown if applicants select:

- 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

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

New Application - Getting Started (iv)

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 (FirstCompanyOldUEN)
- SeventhCompany (SeventhCompanyUEN)
- SeventeenthCompany (SeventeenthCompanyUEN)
- AAA (ZerothCompanyUEN)

Cancel this application and go back to Dashboard

Relinquishing Company

This will only be shown if applicants select:

- Submission type = “Product Registration”
- Application type = “Change of Registrant”

Applicant can search for companies using the search bar.

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](#).

4.1 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

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](#). Submitting supporting documents is compulsory for product notification and product registration applications but not for dealer's notice applications.

4.2 Company Details

Company Information

Application For Dealer's Notice (New)

Draft Application No.(Draft)
Last saved at 15 November 2023 11:24 AM

- [Supporting Documents](#)
- Company Details**
- [Application Details](#)
- [Dealer's Notice Details](#)
- [Review](#)
- [Declaration](#)

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

Company Details

Company Information

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

Company Name	FourthCompany
UEN	FourthCompanyUEN

Company Address ①

- Subsections
- Company Information
- Company Address
- Contact Information
- Billing Information
- Payment Information

Note – Do make sure that the “Submission type” selected in “[Creation of New Application](#)” is “Dealer’s Activity”, “Product Notification” or “Product Registration”.

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.

Billing Information

Focused View

Supporting Documents

Company Details

Application Details

Dealer's Notice Details

Review

Declaration

Billing Information *

Client Code *

Postal Code -

Block / Number -

Level - Unit -

Street Name -

Building Name -

Choose Client code from the drop down and billing address would be pre-populated.

If your company has more than 1 Client Codes listed, please verify with your Finance Department which Client Code is relevant for your application.

Payment Information

Focused View

- Supporting Documents
- Company Details
- Application Details
- Dealer's Notice Details
- Review
- Declaration

Preferred Payment Mode *

GIRO

PayNow

Charge Code	Description	Price
CTGTNOTWS	Notice by a Wholesaler of CTGTP with minimal manipulation	\$95.00
CTGTNOTMFG	Notice by a Manufacturer of CTGTP with minimal manipulation	\$95.00
CTGTNOTIMP	Notice by a Importer of CTGTP with minimal manipulation	\$95.00
Subtotal		\$285.00
Tax		\$0.00
Total		\$285.00

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
Application Details >

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 and proceed to the application details section.

Note: For **product registration** the billing information is under a different section called "Payment Details".

4.3 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)

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) *

RZ

Designation *

Input Designation

Subsections

- Application Information
- Main Applicant Information
- Notification Emails

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

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

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.

4.4 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](#)

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](#).

4.5 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

Procurement Site 1 [Edit] [Delete]

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

Overseas Manufacturer 1 [Edit] [Delete]

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

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

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](#)

Container Closure System (CCS) ⓘ

You can add multiple CCS.

Subsections

Product Owner Information

Intended Use & Indications

Container Closure System (CCS)

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

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

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

Overview – Product Information

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

Container Closure System (CCS) *

You can add multiple CCS.

CCS 1		Edit	Delete
Container Closure System Description	ccs1-Test		
Shelf Life	12Years		
Storage Conditions (°C)	FROZEN		

+ Add CCS 2

< Back

Overview - Products List >

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

Overview – Product List

- 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 to assign CSS, Indications and Sites.

Click to view details of CSS, Indication & Sites

View CCS
View Indications
View 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"/>	P1	P001	CCS-1	Indication-1	SITE SINGAPORE	Remove

New Product
Reupload

Back
Review

*This section is only applicable for Product Notification applications.

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

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

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

Products List

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

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

Click to view details of CCS, Indications & Sites

View CCS
View Indications
View Sites

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

	Product Name	Product Code	CCS	Indication	Sites	Action
<input type="checkbox"/>	Product Label1	PL001	CCS-1	Intention-1	<div style="border: 1px solid #ccc; padding: 2px; display: inline-block;"> Select Sites Site_J Overseas_company Apply </div>	Remove
<input type="checkbox"/>						

New Product
Reupload

Back
Review

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

4.6 Product Registration

Overview – Product Information

Focused View

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

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

Overview - Product Information

Product Owner Information *

Product Owner Name
Address

[Add](#)

List Of Products *

⊙ No Data Available

[Add](#)

Intended Use & Indications *

You can add multiple indications for each product or brand.

⊙ No Data Available

[Add](#)

Dosing Regimen *

You can add multiple dosing regimen

⊙ No Data Available

[Add](#)

Subsections

- Product Owner Information
- List Of Products
- Intended Use & Indications
- Dosing Regimen
- Product Formula
- Worldwide Registration Status
- Container Closure System (CCS) And Shelf Life

*This section is only applicable for Product Registration applications.

Overview - Product Information has seven subsections:

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

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

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

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 *

Select Component *

CCS Description *

Storage Condition *

Shelf Life *

Alternate Storage Condition(s) and Shelf Life

Shelf Life after Thawing or 1st Opening

Shelf Life after Reconstitution and/or Dilution

Cold Chain *

Pack Size(s) (Qty/ CCS) *

Pack Size(s) (CCS/ Pack) *

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

<div style="border: 1px solid #ccc; padding: 10px;"> <p>Add Local Manufacturers 1 ×</p> <hr/> <p>Dealer Type <input checked="" type="radio"/> Manufacturer</p> <p>Local Manufacturer Licence/Dealer Licence Number* ○ <input type="text" value="Type to Search for Manufacturer Licence or Dealer Notice Number"/> Get Dealer's Details</p> <p>Local Manufacturer's Name* ○ <input type="text" value="Retrieved Local Dealer Name"/></p> <p>Postal Code* <input type="text"/></p> <p>Block / Number* <input type="text"/></p> <p>Level - Unit* <input type="text"/> - <input type="text"/></p> <p>Street Name* <input type="text"/></p> <p>Building Name* <input type="text"/></p> <p>Site Details* ○ <input type="text" value="Select an option"/></p> <p>Type of Manufacturer* ○</p> <ul style="list-style-type: none"> <input type="checkbox"/> Finished Product Manufacturer <input type="checkbox"/> Solvent/Diluent Manufacturer <input type="checkbox"/> Active Substance Manufacturer <input type="checkbox"/> Critical Starting Materials (e.g., viral vector for ex vivo gene modification) Manufacturer <input type="checkbox"/> Others <p style="text-align: right;">Save</p> </div>	<p>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.</p>

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
Substance B	Excipient	In-house	20	

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

4.7 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.

4.8 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.

5 Creation of Update Application

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

Update Application – Getting Started (i)

New Application - Getting Started

1. Details

2. Checklist

Details

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

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

Submission Type Product Notification

Application Type Update

Existing Application CGNN231130N0009

Cancel this application and go back to Dashboard

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

Supporting Documents

Company Details

Application Details

Overview - Product Information

Manufacturers

Overview - Products List

Payment Details

Review

Declaration

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

MIV-1 Checklist

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

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

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

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

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

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

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

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

Focused View

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

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

MAV Application

Instructions for this page:
Please indicate your update summary

Remarks/ Comments

- 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	Product 8 A
NDA	1	1
Referenced NDA	N/A	N/A
Dosage Form	AEROSOL	AEROSOL
Route Of Administration	Auricular (OTIC)	Auricular (OTIC)
ATC Code	10	500
Importer/Wholesaler		

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

6 Cancellation of Dealer's Notice, Product Notification or Product Registration

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

Cancel Dealer's Notice – Getting Started (i)

New Application - Getting Started

1. Details

2. Checklist

Details

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

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

Submission Type Dealer's Notice

Application Type Cancel

Cancel this application and go back to Dashboard

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

<p>1. Dealer's Activity</p> <p>2. Submit</p>	<p>The activities listed below will be cancelled.</p> <p>CGAD231121K0003 Manufacturer CGKM231121R09 effective on 26 Nov 2023</p> <p>← Back</p> <p>Confirm Cancellation</p>	<p>Applicants need to confirm the required Dealer's Activity they want to cancel.</p>
---	--	---

Cancel Product Notification – Getting Started

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

- Submission type
- Application type

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

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

Note: Information on this page may differ depending on the [Submission Type & Application Type](#) selected by Applicants

New Application - Getting Started

Cancel Product Notification – Getting Started (ii)

Cancel Application For Product Notification

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"/> CGPN231219T0005	New Product 5	np005	Larson	Quia debitis architecto eaque aperiam.	accusamus modi illum	mollitia accusantium inventore,ad maxime enim	21/12/2023 <input type="button" value=""/>
<input type="checkbox"/> CGPN231219S0004	New Product 4	np004	Larson	Quia debitis architecto eaque aperiam.	accusamus modi illum	mollitia accusantium inventore,ad maxime enim	dd/mm/yyyy <input type="button" value=""/>
<input type="checkbox"/> CGPN231219R0003	New Product 3	np003	Larson	Quia debitis architecto eaque aperiam.	accusamus modi illum	mollitia accusantium inventore,ad maxime enim	dd/mm/yyyy <input type="button" value=""/>
<input type="checkbox"/> CGPN231219Q0002	New Product 2	np002	Larson	Quia debitis architecto eaque aperiam.	accusamus modi illum	mollitia accusantium inventore,ad maxime enim	dd/mm/yyyy <input type="button" value=""/>

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

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.

New Product 5 effective on 21 Dec 2023

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

< Back
Confirm Cancellation

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.

New Product 5 effective on 21 Dec 2023

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

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

Cancel
Yes

< Back
Confirm Cancellation

- Home
- Applications >
- Input Requests >
- Products
- Dealers
- Search

Products

Product Name

Approved Product Number

Indications

Dealer's Notice Number

Product Owner Name

CCS

Dealer's Site Name

Reset Search

Product Listing Number	Product Name	Product Owner	Product Type	Product Status	Retention Due Date	Latest Application	Related Applications	Action
CGPN231219T0005	New Product 5	Larson	CTGTP Class 1	Cancelled	N/A	CGNN231219P0012	N/A	N/A

Cancel Product Registration – Getting Started

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

Focused View

1. Products List

2. Submit

Products List

Select Products to Cancel

Product Name Approved Product Number

Approved product number	Product Name	Effective Date
<input type="checkbox"/> CGPR240917F0008	B prod 1	<input type="text" value="dd/mm/yyyy"/>
<input type="checkbox"/> CGPR240917A0003	A prod 6	<input type="text" value="dd/mm/yyyy"/>
<input type="checkbox"/> CGPR240917E0007	B prod 3	<input type="text" value="dd/mm/yyyy"/>
<input type="checkbox"/> CGPR240917D0006	A prod 5	<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

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

A prod 2 effective on 05 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.

A prod 2 effective on 05 Oct 2024

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

[Back](#) [Confirm Cancellation](#)

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

[Cancel](#) [Yes](#)

Products

Product Name Product Owner Name

Approved Product Number CCS

Indications Dealer's Site Name

Dealer's Notice Number

[Reset](#) [Search](#)

0 Item(s) found

Product Listing Number	Product Name	Product Owner	Product Type	Product Status	Retention Due Date	Latest Application	Related Applications	Action
CGPR2409170001	A.prod 4	Welnher-Douglas	CTGTF Class 2	Cancelled	17-Jul-2024	CGPR24091700001	N/A	...

7 Withdrawal of Products/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 have the option to select various products or dealers within a given 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

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.

8 Creation of Fulfilment of Approval Conditions Application

Applicants required to fulfill 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)

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

Product for Fulfilment

A prod 6 (CGPR240917A0003) Application Number: CGMA240923M0002

Approved Conditions	Date
Quality	03-Oct-2024

Submission Instructions

- 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.

8.1 Fulfillment of Approval Condition

Application For Product Registration (Fulfilment Of Approval Conditions)

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

Focused View

- Fulfilment of Approval Condition
- Review
- Declaration

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

Fulfilment of Approval Condition

Upload Files For All Conditions

A prod 6

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

[Cancel](#)
[Review](#)

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

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

8.2 Review

Application For Product Registration (Fulfilment Of Approval Conditions)

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

Focused View

- Fulfilment of Approval Condition
- Review
- Declaration

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

Review

Fulfilment of Approval Condition

Product : A prod 6
Quality : 03-Oct-2024

File Uploaded

test.pdf 1 (3).pdf

Comments

Here attached the supporting document needed for the product

[Back](#)
[Declaration](#)

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

8.3 Declaration

Application For Product Registration (Fulfilment Of Approval Conditions) Draft Application No.(Draft) Last saved at 23 September 2024 12:21 PM,C

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.

9 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)

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

[Back](#)

[View Checklist](#)

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

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

9.2 Supporting Documents

Applicants must upload supporting documents before they can proceed. At least one file must be uploaded to each of the mandatory folders.

9.3 New Appointed IL/WL

Application For Product Registration (Change Of Registrant)

Draft Application No. (Draft) Last saved at 23 September 2024 11:40 AM

Focused View

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

New Appointed IL/WL

0 Item(s) selected

Product Name	IL and WL (Optional)	Action
<input type="checkbox"/> 33 TissueWaveX NAM25		Add Additional Site

< Back
Company Details >

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

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.

9.4 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/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)

Company Details

Company Information

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

Company Name	SecondCompany
UEN	SecondCompanyUEN

Company Address *


Clear ACRA Address

Postal Code *	123456
Block / Number *	02
Level - Unit *	02 - 02
Street Name *	Second Street
Building Name *	Second Tower

Subsections

- [Company Information](#)
- [Company Address](#)
- [Contact Information](#)
- [Billing Information](#)

The details of company details section can be found in [4.2. Company Details](#)



Page 72 of 89

9.5 Application Details

Application For Product Registration (Change Of Registrant)

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

Focused View

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

Subsections

- Application Information
- Main Applicant Information
- Notification Emails

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 *

Applicant Name: Afa

Designation: ASE

Notification Emails *

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

No Data Available

[+ Add Notification Email 1](#)

[← Back](#)
[Payment Details →](#)

The details of application details section can be found in [4.3. Application Details](#)

9.6 Payment Details

Application For Product Registration (Change Of Registrant)

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

Focused View ⌵

- [Product List](#)
- [Supporting Documents](#)
- [New Appointed IL/WL](#)
- [Company Details](#)
- [Application Details](#)
- [Payment Details](#)
- [Review](#)
- [Declaration](#)

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

Payment Details

Preferred Payment Mode *

GIRO

PayNow

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

Payment Instructions


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

← Back
Review →

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

Applicants will have two payment options, GIRO and PayNow.

Applicants must choose the required payment mode.



Page 74 of 89

9.7 Review

Application For Product Registration (Change Of Registrant)

Draft Application No.(Draft)
Last saved at 23 September 2024 11:54 AM

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

Review

Product List

Approved Product Number	Product Name	Remarks
CGPR240918F0007	33 TissueWaveX NAMZ5	

Effective Date of Transfer: N.A

Supporting Documents

Download All Supporting Documents
Supporting Documents Size: 2 MB

- Change of Registrant
 - 1. Relinquishing registrants authorisation documents
 - test.pdf 1 (3).pdf
999 KB | 23/09/2024 12:40
 - 2. Product owners authorisation documents
 - test.pdf 1 (2).pdf
999 KB | 23/09/2024 12:40

Remarks/Comments

No remarks or comments

New Appointed IL/WL

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

9.8 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 R/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)

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.

10 Creation of Retention Application

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

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 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.

10.1 Product List

Application For Product Registration (Retention)

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

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

Focused View

- Product List
- Payment Details
- Review
- Declaration

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

Product List

	Product	Product No	Current Retention Due Date	New Retention Due Date
<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

10.2 Payment Details

Application For Product Registration (Retention)

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

Focused View

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

Payment Details

Preferred Payment Mode *

GIRO

PayNow

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.

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.

10.3 Review

Application For Product Registration (Retention)

Draft Application No.(Draft)
Last saved at 23 September 2024 12:11 PM

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

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.

10.4 Declaration

Application For Product Registration (Retention) Draft Application No.(Draft)
Last saved at 23 September 2024 12:11 PM

Focused View

- Product List
- Payment Details
- Review
- Declaration**

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

Declaration

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

I acknowledge and confirm the above declarations.

[← Back](#) [Submit](#)

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

11 Applications

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

Draft

Applications New Application

Draft Applications

Draft	Expires June 17, 2024	Resume	Delete
Product Type	Cell, Tissue and Gene Therapy Products (CTGTP) Class 1		
Product Name	-		
Submission Type	New Product Notification		
Status	Draft		
Last Edited Date	20-Dec-2023		

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.

Whenever there is any inactive session for 30 minutes, a pop up will prompt the applicant if they would like to continue the session.

Inactivity session timeout

Application For Product Notification (New) Application No (Draft)
Last saved at 31 December 2023 09:24 AM (C)

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](#)

Idle Sign-out
The session would be terminated soon. Click 'Continue my session' to resume activity.

Continue My Session

Cancel Company Details

Active

Active applications are submitted by the applicant and under review.

This section displays Application number, Product type, Dealer’s activity, Submission Type, Status, Closure date, withdraw button and a view button.

Click on the withdraw button, enter the remarks and submit withdrawal. Application status changes to closed and this application cannot be used further.

Clicking on the view button displays the application details page.

Close

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

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

Clicking on the view button displays the application details page.

12 Input Request

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

Open IR

- 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

Input Requests (IR) 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:

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

Responded IR

Input Requests

Responded IRs

Application No.	Product Name / Dealer's Activity	Submission Type	Product Type	Milestone
CGNN231117P0006	Prod 1	Product Notification	Cell, Tissue and Gene Therapy Products (CTGTP) Class 1	First IR
#IR-012 1 Queries in this IR 0 Replied	Received 23 Nov 2023	Due 21 Dec 2023	Status Responded	View
#IR-008 1 Queries in this IR 0 Replied	Received 23 Nov 2023	Due 21 Dec 2023	Status Responded	View
#IR-006 2 Queries in this IR 0 Replied	Received 22 Nov 2023	Due 20 Dec 2023	Status Responded	View
#IR-005 1 Queries in this IR 0 Replied	Received 22 Nov 2023	Due 20 Dec 2023	Status Responded	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 with all the replied change logs.

13 Products

This section displays Product information such as product name, owner, type, status, listing number.

- [Home](#)
- [Applications](#)
- [Input Requests](#)
- [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"/>		

Product Listing Number	Product Name	Product Owner	Product Type	Product Status	Retention Due Date	Latest Application	Action
CGPN231117U0009	Herbal 3	overseas owner	CTGTP Class 1	Accepted	N/A	CGNN2311	Download PDF

System allows applicants to search and view the Product details.

For example: Enter Product name, Product owner name, Dealer's notice number, etc. and then click on the search button to retrieve data based on the parameters entered.

Clicking on the Application number redirects the applicant to the application page.

14 Dealers

This section displays Dealer's information such as product type, notice number, dealer's submission type, dealer's activity, status, renewal due date.

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

Dealers

Dealer's Activity

Dealer's Notice Number

Dealer's Site Name

1 Item(s) found

Dealer's Notice Number	Product Type	Dealer's Submission Type	Dealer's Activity	Status	Renewal Due Date	Latest Application	Action
CGKI231121M08	CTGTP Class 1	Notice	Importer	Accepted	N/A	CGND231121V0010	Download PDF

The system allows applicants to search and view the list of dealer's notices.

For example: Select dealer's activity, enter dealer's site name, dealer's notice number and then click on Search to retrieve data based on the parameters entered.

Dealer's details list is displayed, 'Download PDF' button is displayed for each item in the list. Click on Download PDF to download the PDF of the application.

15 Search

Search function allows applicant to retrieve the relevant application details by entering the required fields in the search filter.

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

Search

Application Number

Dealer's Activity

Submission Type

Submission Date -

Product Name

Payment Status

Milestone

1 Item(s) found

Application Number	Product Name / Dealer's Activity	Payment Status	Submission Type	Submission date	Milestone
CGNN231122H0002	Allograft PLUS™ 55mm by 2C	None	New Product Notification	22-Nov-2023	Submission

The system allows applicants to search the application using different parameters.

For example: Enter the Application number, Product name, Dealer's activity and then click on Search. Results will appear based on the parameters entered.

Clicking on the Application number redirects the applicant to the application page.