

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

User Manual Applicant (Internet)

Version 1.0
Date Dec 26, 2023



Change Log

Version	Date	Comments
0.1	08/12/2023	First version
0.2	22/12/2023	Updated additional information
1.0	26/12/2023	Final version

Contents

Contents	3
HSA SHARE.....	4
1. System Overview	5
1.1 Abbreviations and Definitions	6
1.2 Application Statuses	6
1.3 IR Statuses and Trigger Points	6
2. Login	7
3. Dashboard	8
4. Creation Of New Application	9
4.1. Supporting Documents.....	13
4.2. Company Details.....	14
4.3. Application Details.....	20
4.4. Dealer’s Notice	23
4.5. Product Notification	25
4.6. Review	28
4.7. Declaration	29
5. Creation Of Update Application	30
6. Cancellation Of Dealer’s Notice or Product Notification.....	33
7. Withdrawal Of Products/Dealer Activities	39
8. Applications	41
9. Input Request	43
10. Products.....	45
11. Dealers.....	46
12. Search	47

HSA SHARE

SHARE (Singapore Health Product Access and Regulatory E-System) aims to deliver an integrated platform, elevating collaboration between Health Sciences Authority 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 CTGTP Class 1 Notification

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



Create a new CTGTP Dealer's Notice

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



Update Applications

To update on changes to the previous notice submitted.



Withdrawal of application

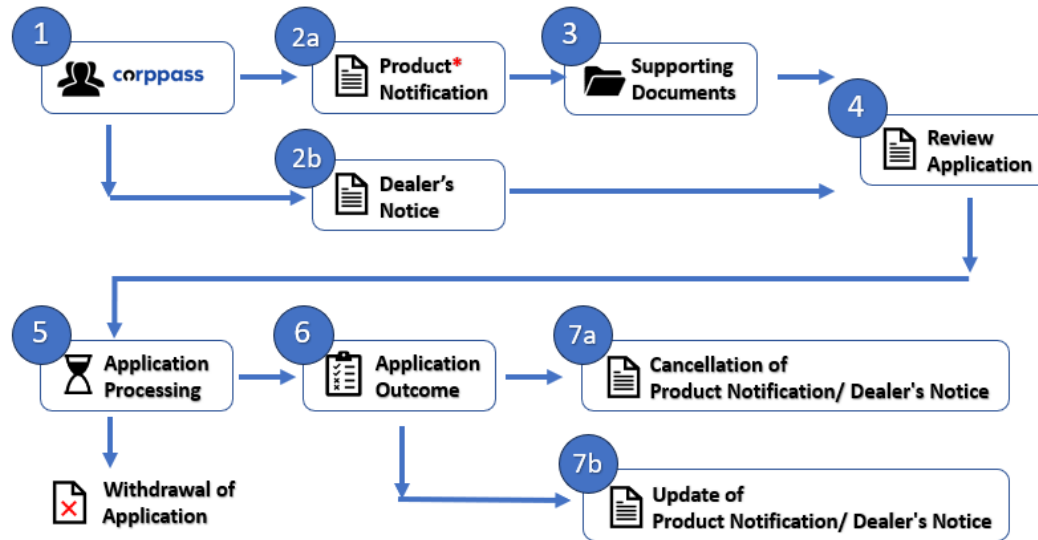
To withdraw any application before it is approved or rejected.



Submit cancellation notice for Notified Product(s)/ Known Dealer(s)

To notify HSA any cancellation of notified Class 1 CTGTP or Known Dealers

1. System Overview



*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 Application type and Submission type as (2a) Product Notification OR (2b) Dealer Notice
And 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 will be able to submit (7a) A new application for cancellation of product notification/ dealer's notice OR (7b) A new application for the update of product notification/ dealer's notice after the application has been closed.

1.1 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

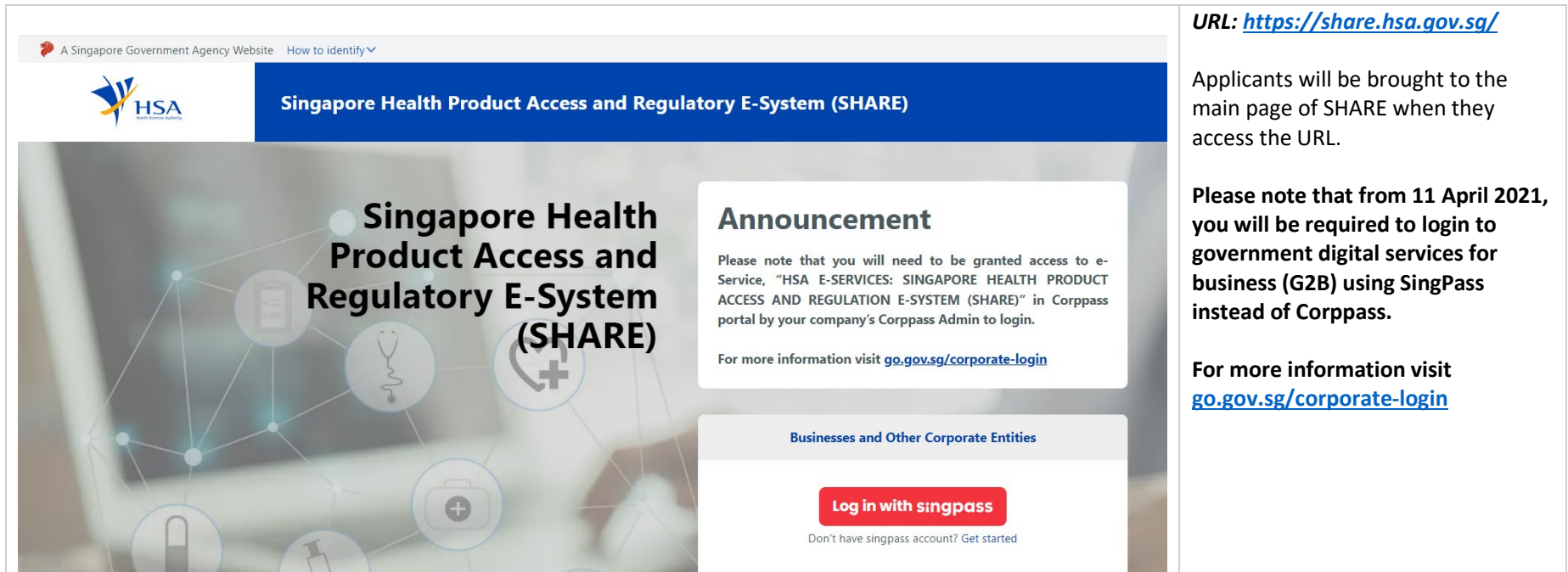
1.2 Application Statuses

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.

1.3 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 and applicant did not request for any IR extension and the IR has already past the due date.
Extension Requested	When an applicant requests for IR extension
Extended	When an IR extension has been granted
Expired	When IR has already been given extension and applicant has not provided any response

2. Login



The screenshot shows the Singapore Health Product Access and Regulatory E-System (SHARE) login page. The page header includes the HSA logo and the text "A Singapore Government Agency Website How to identify". The main content area features a large heading "Singapore Health Product Access and Regulatory E-System (SHARE)" and an "Announcement" section. The announcement states: "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 go.gov.sg/corporate-login". Below the announcement is a section for "Businesses and Other Corporate Entities" with a prominent red button labeled "Log in with singpass" and a link "Don't have singpass account? Get started".

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

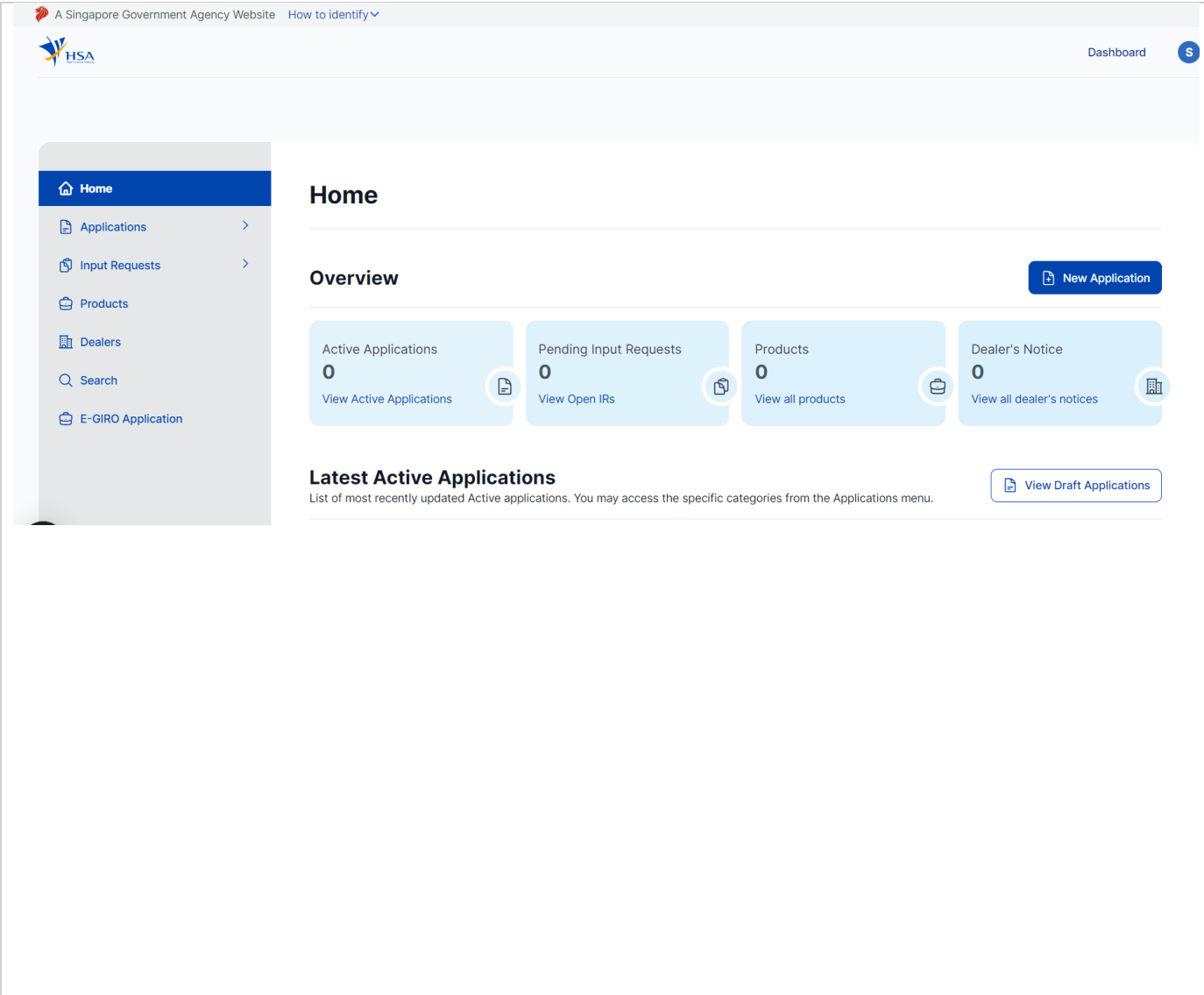
Applicants will be brought to the main page of SHARE when they access the URL.

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 login. The dashboard gives an overview of all the applicants status, it helps to navigate directly to the respective pages when clicked on it.



Home – Dashboard

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

- [Application](#)
- [Input Request](#)
- [Products](#)
- [Dealers](#)
- [Search](#)

Additionally, the blue cards serve the following functions:

Active Application:

- Displays all applications submitted by the applicant that are currently 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:

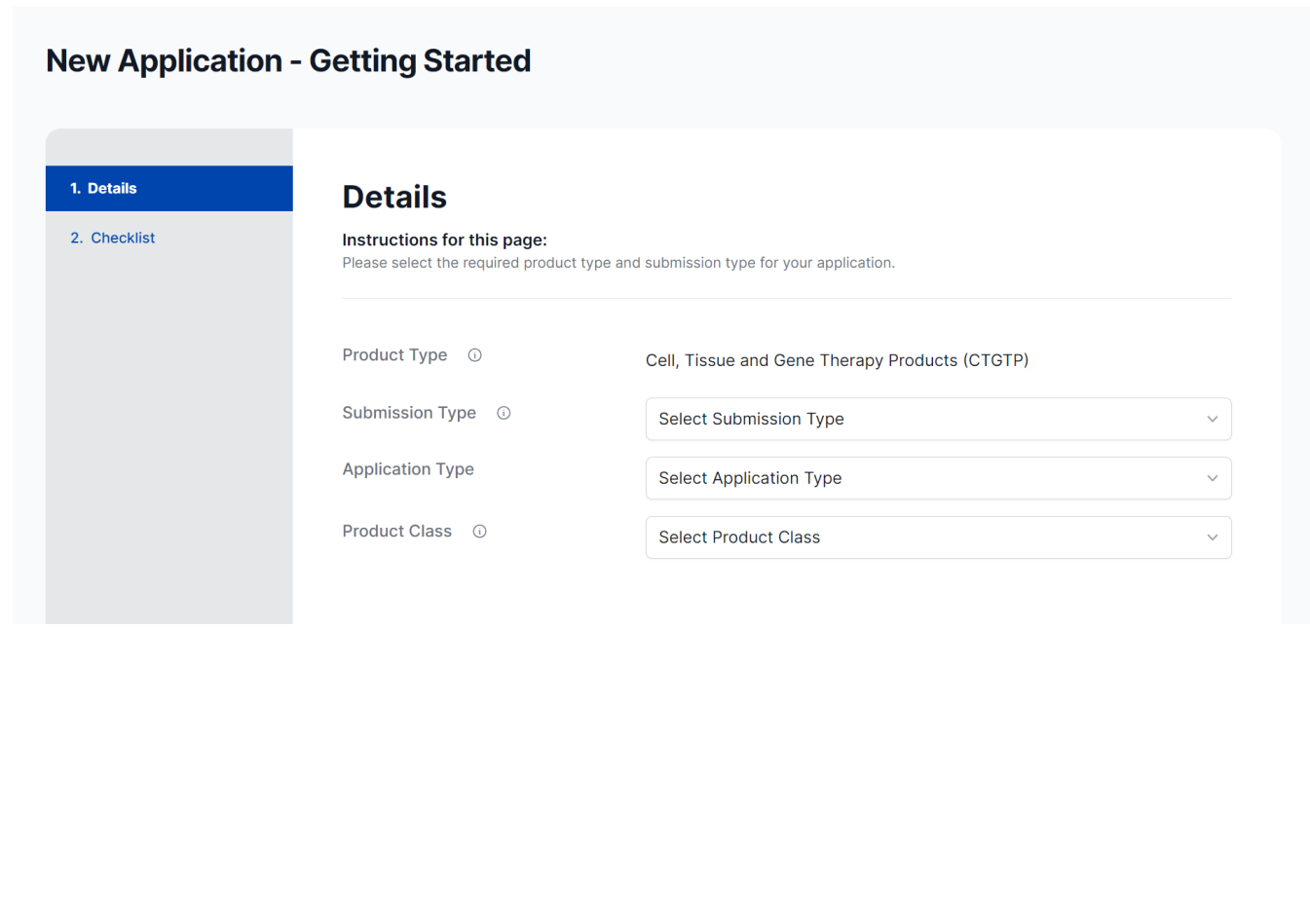
- Presents a list of known dealers.

Applicants would be able to submit 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. Based on the selection chosen by the applicant, it 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

Application Type

*(fields will be **shown only after selection of Submission type**)*

- New
- Update
- Cancel

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)

New Application - Getting Started (ii)

1. Details

2. Checklist

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

Submission Type ⓘ

Application Type

Product Class ⓘ

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) – Dealer’s Notice

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

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.

New Application - Getting Started (iii) – 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](#).

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 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

- 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.”

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

Applicants could navigate themselves 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. Additionally, 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**, triggering 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.

Billing Information

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

Billing Information

Client Code *	<input type="text" value="Select Client Code"/>	
Postal Code	-	
Block / Number	-	
Level - Unit	-	
Street Name	-	
Building Name	-	

Subsections

- Company Information
- Company Address
- Contact Information
- Billing Information ▲
- Payment Information ▲

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

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

Payment Information

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

Payment Information

Preferred Payment Mode *

GIRO

Pay Now

Charge Code	Description	Price
CTGTNOTWS	Notice by a Wholesaler of CTGTP with minimal manipulation	\$90
CTGTNOTMFG	Notice by a Manufacturer of CTGTP with minimal manipulation	\$90
CTGTNOTIMP	Notice by a Importer of CTGTP with minimal manipulation	\$90
Subtotal		\$270
Tax		\$0
Total		\$270

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.

Subsections

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

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.

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)

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 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 SINGAPORE	
Address	1, 6TH AVE, #21, Singapore 128908	
Type Of Accreditations	Accreditations	Date of Expiry
	American Association of Blood Banks [AABB] accreditation	N/A
	American Association of Tissue Banks [AATB] accreditation	N/A

+ Add Procurement Site 2

Subsections

- Tissue Procurement Sites
- Overseas Manufacturers
- Local Manufacturers

Overseas Manufacturers ⊕

Overseas Manufacturer 1 ✎ Edit Delete

Overseas Manufacturer Name	Allograft PLUS™ 55mm by 20 mm	
Overseas Manufacturer Address	ABCD , INDONESIA	

*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

Subsections

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

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.

*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 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.

	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.

4.6. Review

You are submitting a Dealer's Notice 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-PackageInsert
 - 5-ProductLabel
 - 6-ShelfLifeCCS
 - 7-Others

Company Information

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.

4.7. Declaration

Application For Dealer's Notice (New)

Draft Application No.(Draft)
Last saved at 26 November 2023 05:29 PM

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

Declaration

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

[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, they would be able to submit an update application which allows to edit and make changes to their closed application.

Update Application – Getting Started (i)

For all closed applications, applicants can submit an update 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)

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

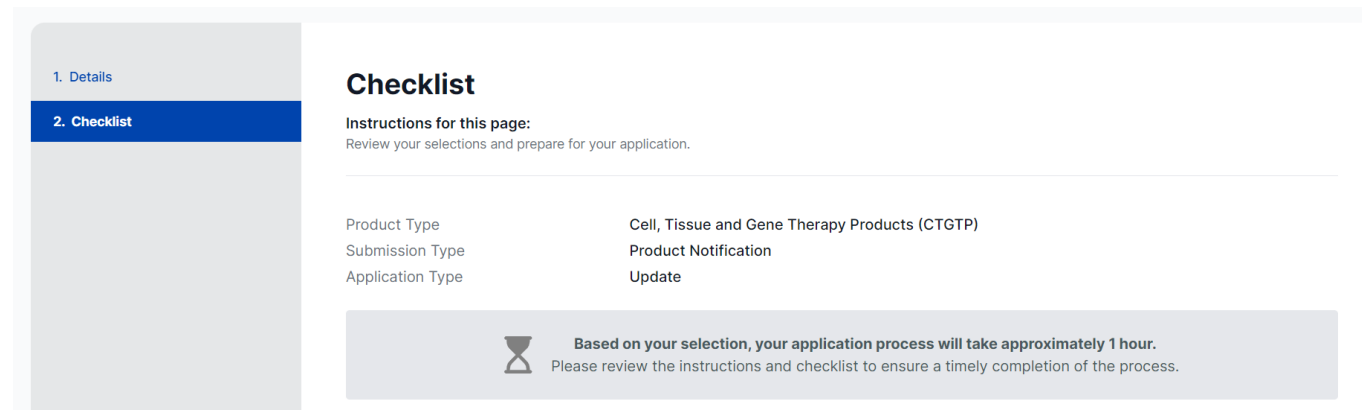
Submission Type

Application Type

Existing Application

Cancel this application and go back to Dashboard

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)

Draft Application No.(Draft)
Last saved at 26 November 2023 06:21 PM

- Updates of Product Notification
- Supporting Documents
- Company Details
- Application Details
- Manufacturers
- Overview - Product Information
- Overview - Products List
- Review

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

***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.

6. Cancellation Of Dealer's Notice or Product Notification

Applicants that would like to notify HSA of any cancellation of dealer's notice or notified 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

Cancel

Next >

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

- Submission type
- Application type

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

Cancel Dealer's Notice – Getting Started (ii)

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

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

New Application - Getting Started

- 1. Details
- 2. Checklist

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.

Cancel Application For Dealer Notice

- 1. Dealer's Activity
- 2. Submit

Dealer's Activity

Select Dealer Activities to cancel

CGAD231121K0003 | Manufacturer | CGKM231121R09

Site Name	Site Man Site manip edited
-----------	-------------------------------

Effective Date for Cancellation

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

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

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

Cancel Dealer's Notice – Submit

1. Dealer's Activity

2. Submit

The activities listed below will be cancelled.

CGAD231121K0003 | Manufacturer | CGKM231121R09 effective on 26 Nov 2023

< Back

Confirm Cancellation >

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

Cancel Product Notification – Getting Started

New Application - 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

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

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)

⚠

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

Page 38 of 47

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

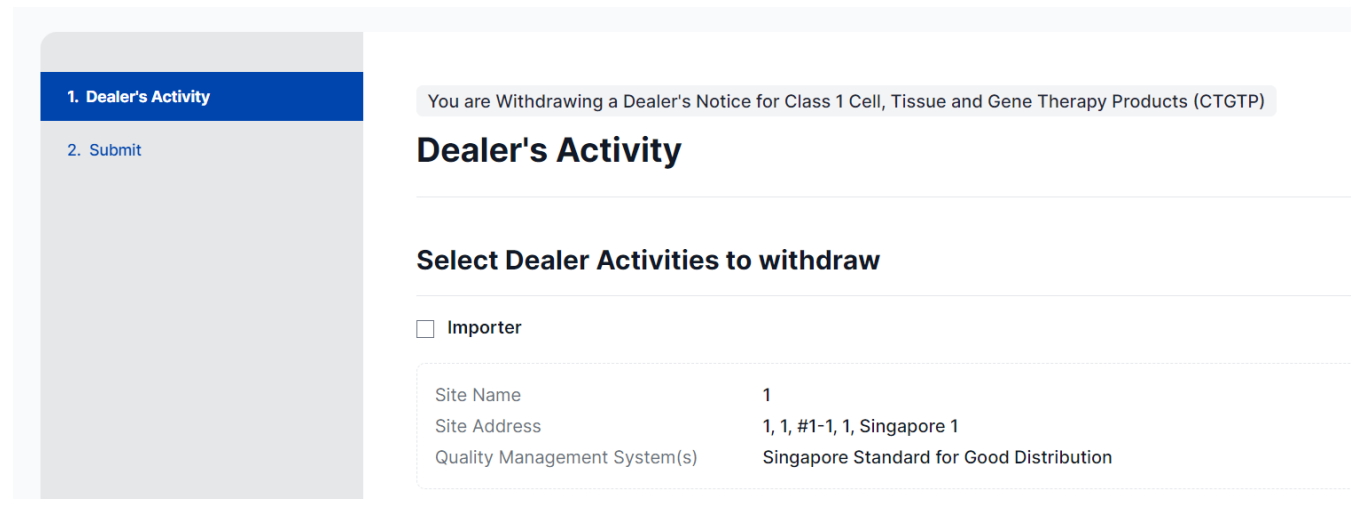
CGNN231124Q0009 Withdraw View

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 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

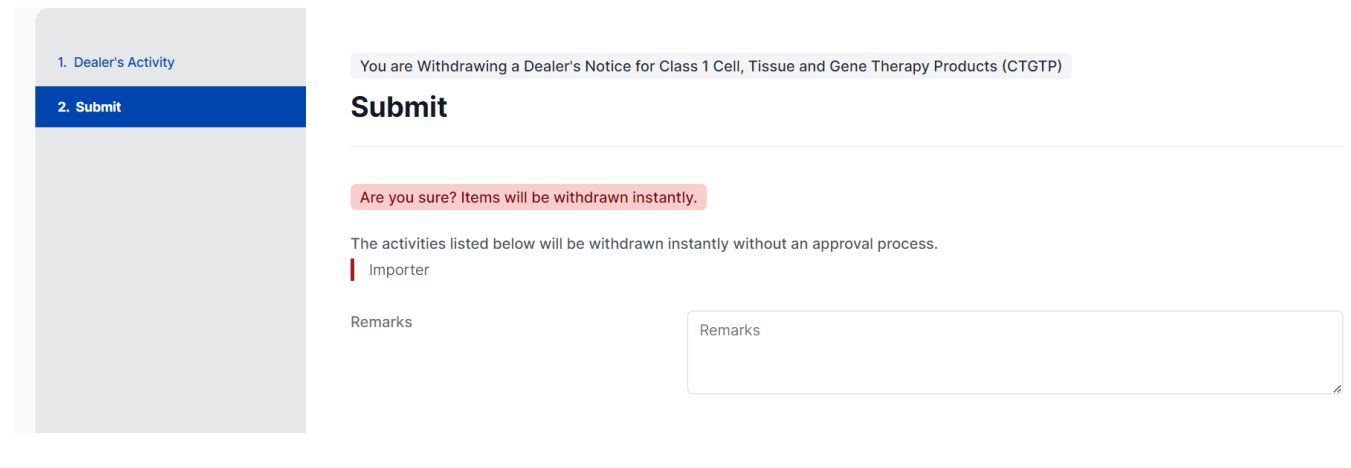
Importer

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 Activities – Submit



1. Dealer's Activity

2. Submit

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

Submit

Are you sure? Items will be withdrawn instantly.

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

- Importer

Remarks

Remarks

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

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

8. Applications

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

Draft

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 applicant click on next section.

Following buttons are displayed:

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

Inactivity session timeout

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

Active

Applications New Application

Active Applications

CGNN231122H0002	Withdraw View
Product Type	Cell, Tissue and Gene Therapy Products (CTGTP) Class 1
Product Name	Allograft PLUS™ 55mm by 20 mm
Submission Type	New Product Notification
Status	Processing
Submission Date	23-Nov-2023

CGAD231121L0004	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	Update Dealer's Notice
Status	Processing
Submission Date	23-Nov-2023

Active applications are submitted by the applicant but pending officer's withdrawal.

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 withdraw](#). Application status changes to closed and this application cannot be used further.

Clicking on the view button displays the application details page.

Closed

Applications New Application

Closed Applications

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

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

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.

9. 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
Application No.	Product Name / Dealer's Activity	Submission Type	Product Type	Milestone
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 initiated by officers seeking additional information and awaiting the applicant's response.

Open IRs (Input Request) 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

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

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.

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.

10. 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

Approved Product Number

Indications

Dealer's Notice Number

Product Owner Name

CCS

Dealer's Site Name

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 will allow applicants to search and view the list of Product details.

For example: Enter Product name, Product owner name, Dealer's notice number, etc. and 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.

11. 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 will allow 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 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.

12. 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

System will allow applicants to search the application using different parameters.

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

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