Singapore Health Product Access and Regulatory E-System

(SHARE)

User Manual
Applicant (Internet)

Version	1.6
Date	6 Feb 2025

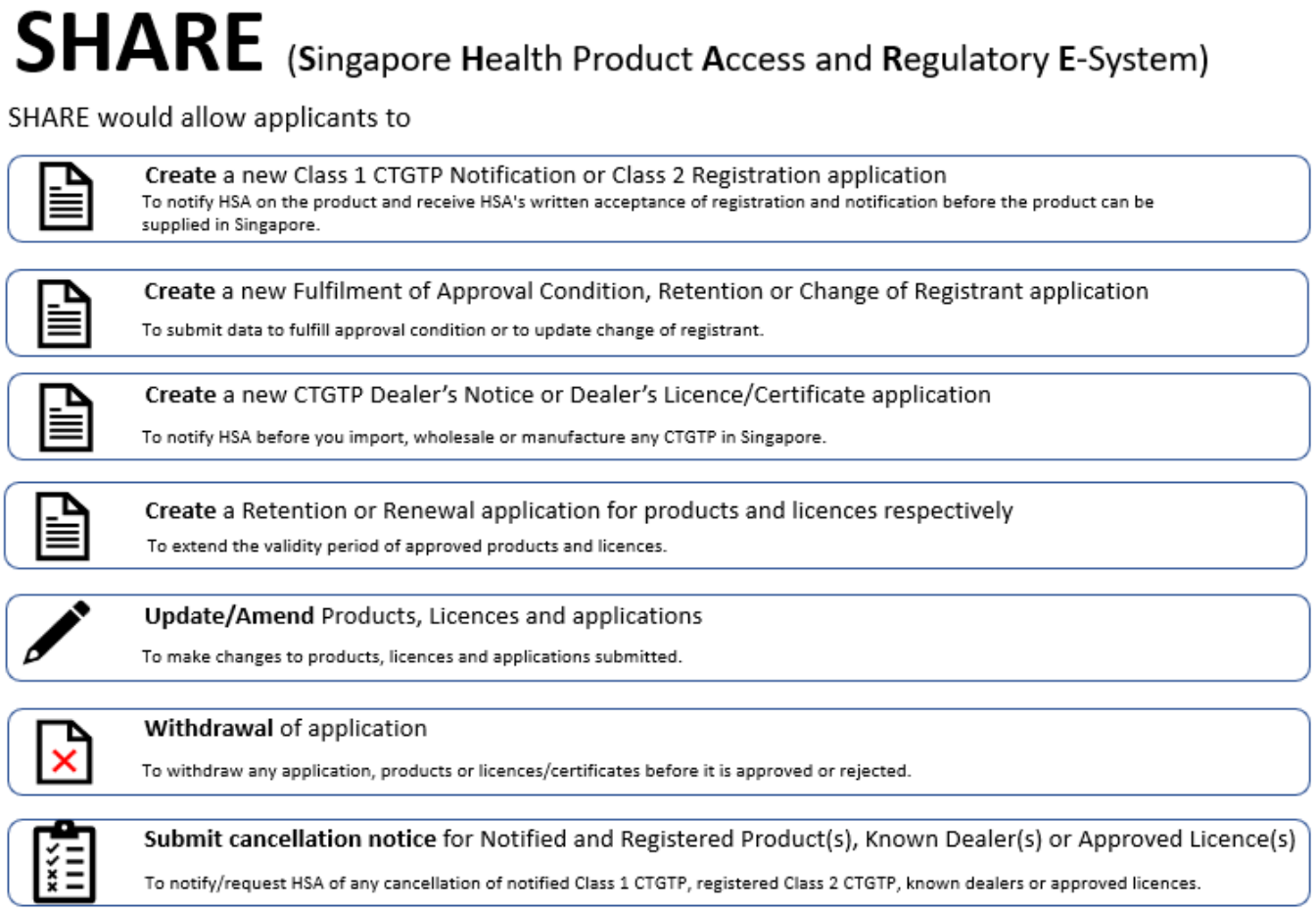
Change Log

Version	Date	Comments
0.1	08 Dec 2023	First version
0.2	22 Dec 2023	Updated additional information
1.0	26 Dec 2023	Final version
1.1	03 Jun 2024	Updated Address Book section Updated Product Listing section
1.2	25 Sept 2024	Updated information on Class 2 CTGTP applications
1.3	03 Oct 2024	Updated version with Class 2 CTGTP applications
1.4	15 Oct 2024	Updated images with higher quality replacements
1.5	04 Feb 2025	Updated the guide to include information on Dealer Licence and Certificate applications
1.6	06 Feb 2025	Updated additional information

Contents

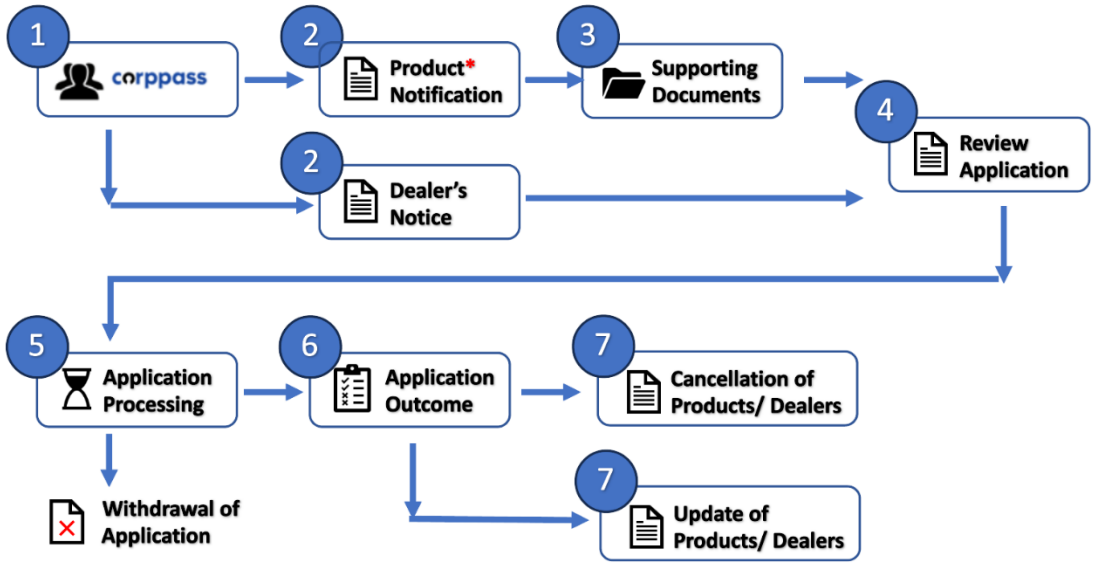
HSA SHARE

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



1 System Overview

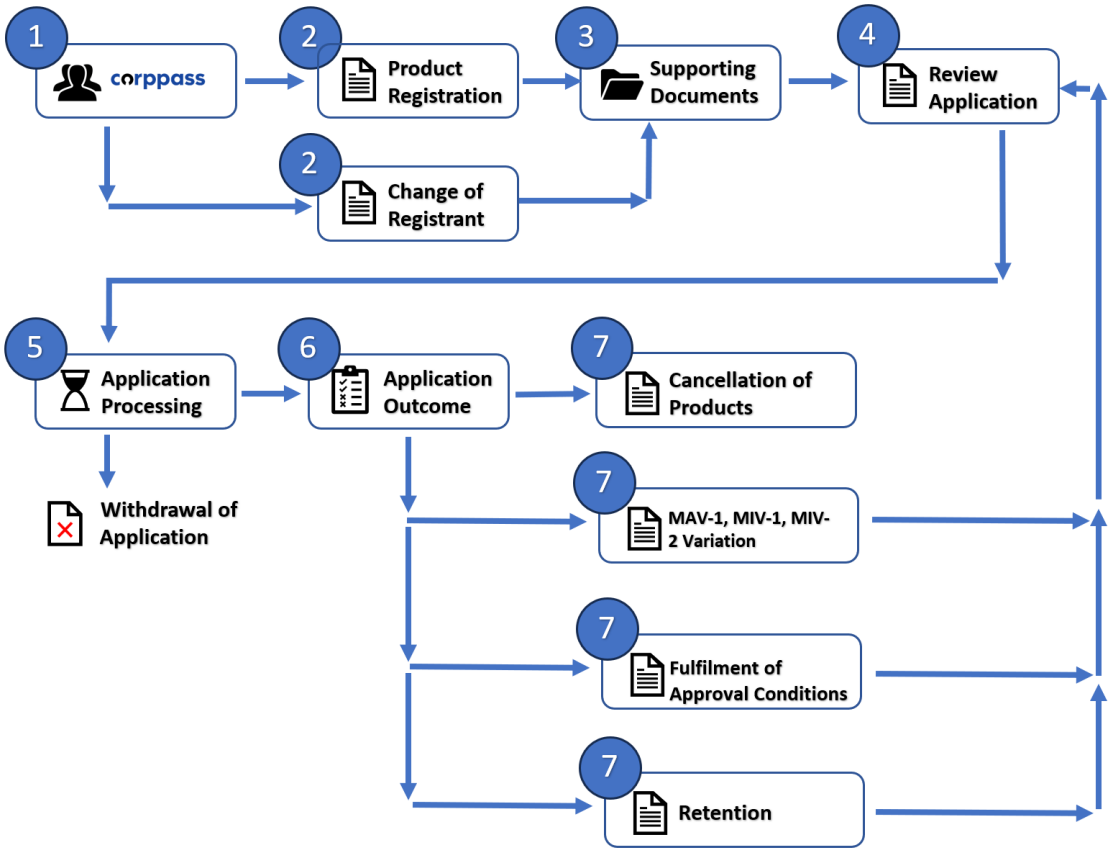
1.1 Class 1 CTGTP



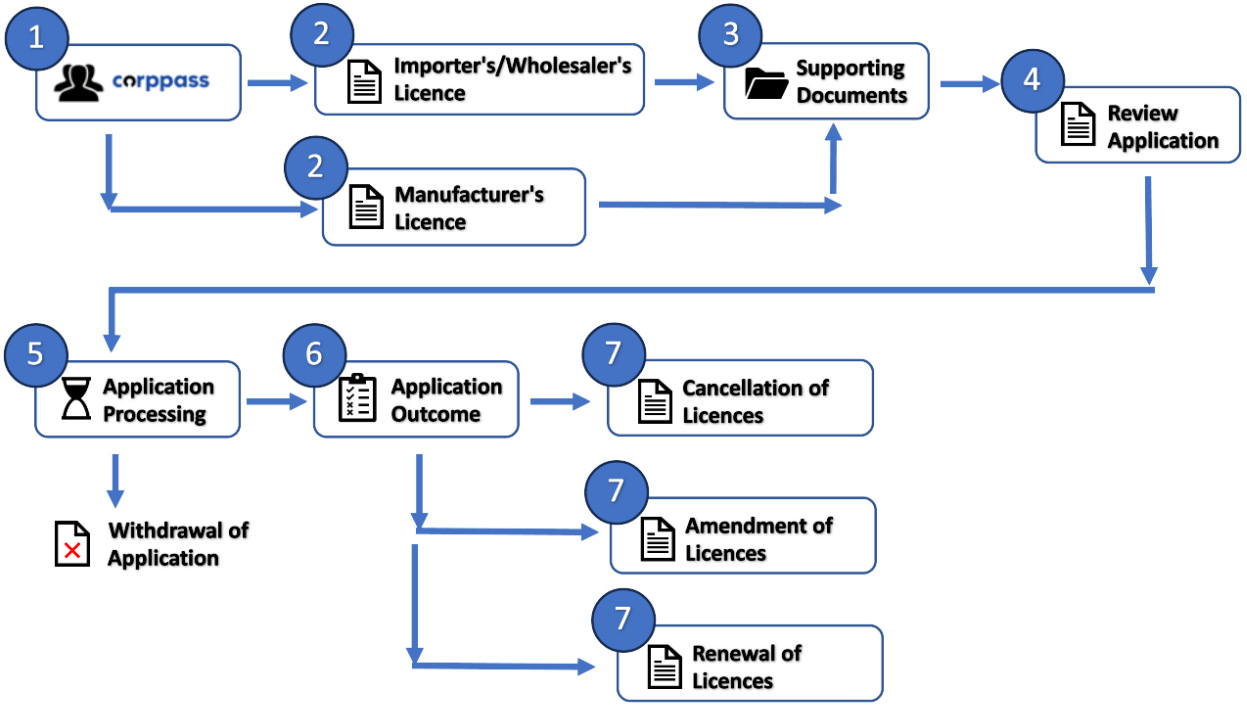
*You must be a known dealer to submit a Product Notification for Class 1 CTGTP.
Applicants would need to submit a Dealer's Notice Application to notify HSA prior to your manufacturing, importing or wholesaling activity relating to Class 1 CTGTP.

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

1.2 Class 2 CTGTP

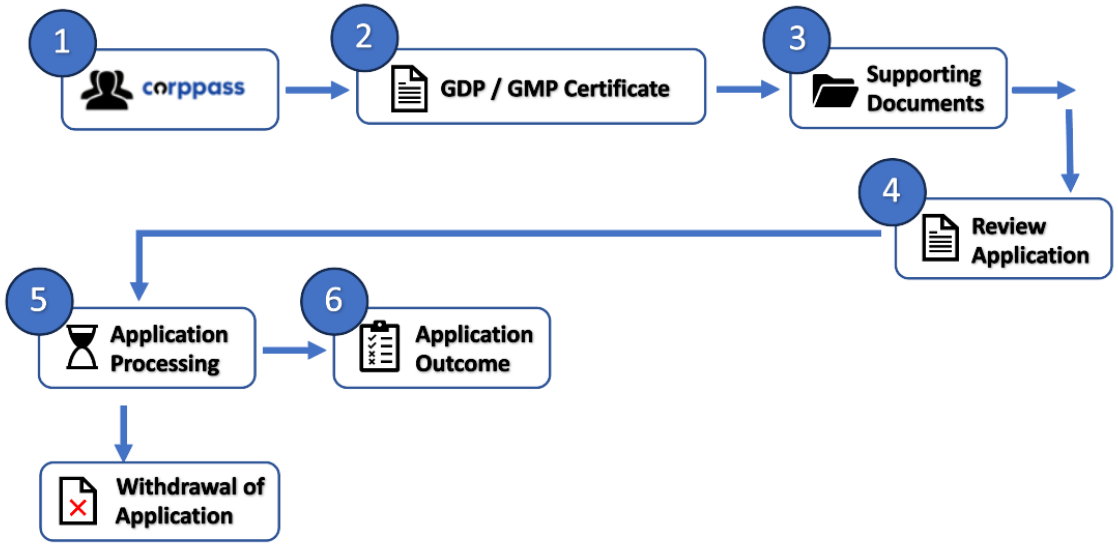


1. Applicants log in via Corppass.
2. Applicants would be able to select the submission type and application type
   i. Applicants would be required to populate the required fields in all the sections of the application (company details, application details, etc).
3. Applicants would be required to upload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



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

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



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

1.3 Abbreviations and Definitions

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

1.4 Application Statuses

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

1.5 IR Statuses and Trigger Points

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

2 Login

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

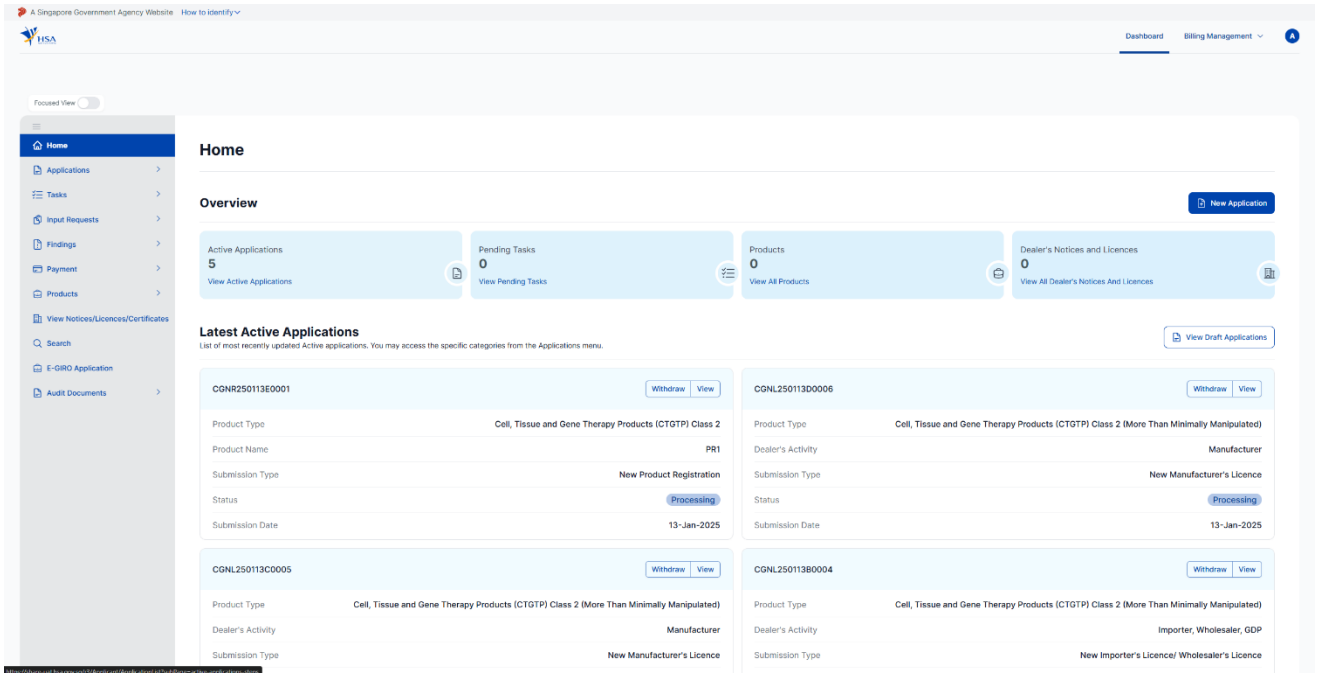
Applicants will be brought to the main page of SHARE when they access the URL.

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

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

3 Dashboard

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



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

Applications
Tasks
Input Requests
Findings
Payment
Products
View Notices/Licences/Certificates
Search
Audit Documents

Additionally, the blue cards serve the following functions:

Active Application:
Displays all applications submitted, pending HSA approval.

Pending Tasks:
Displays all tasks requiring action from the applicant.

Products:
Presents a list of products.

Dealer's Notice and Licences:
Presents a list of licences, certificates, notices.

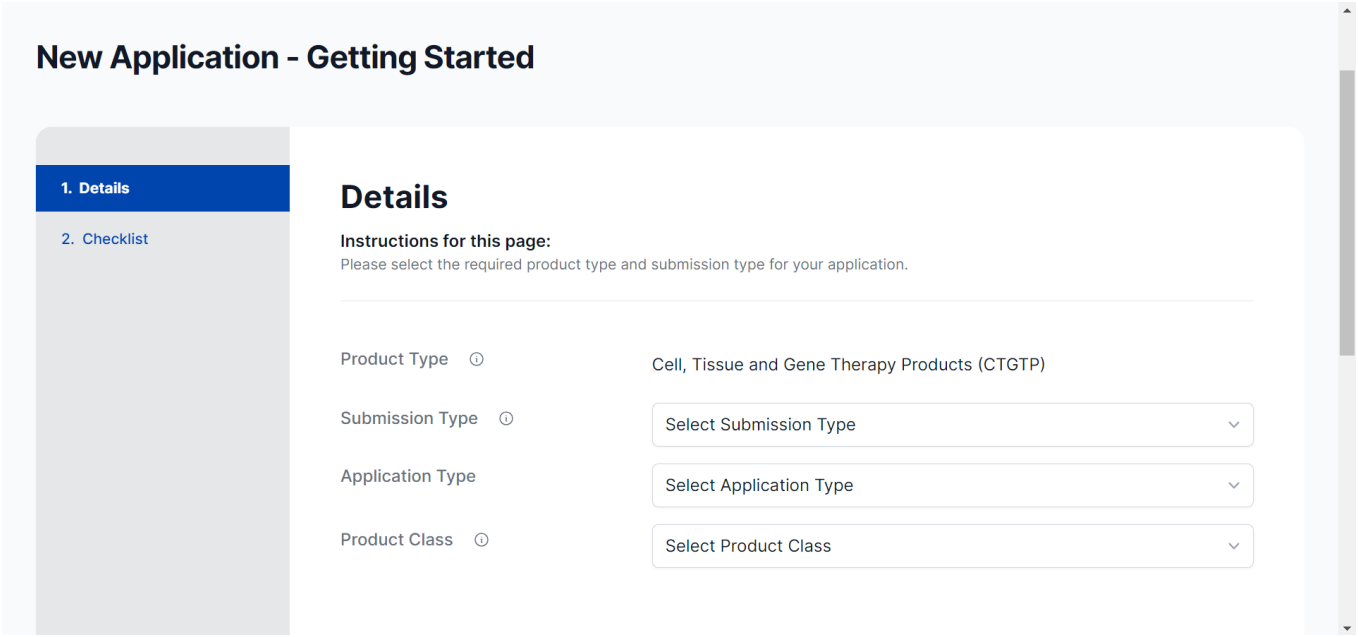
Applicants would be able to create a new application by clicking on the 'New Application' button.

4 Application Creation

4.1 Creation of New Application

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

New Application - Getting Started (i)



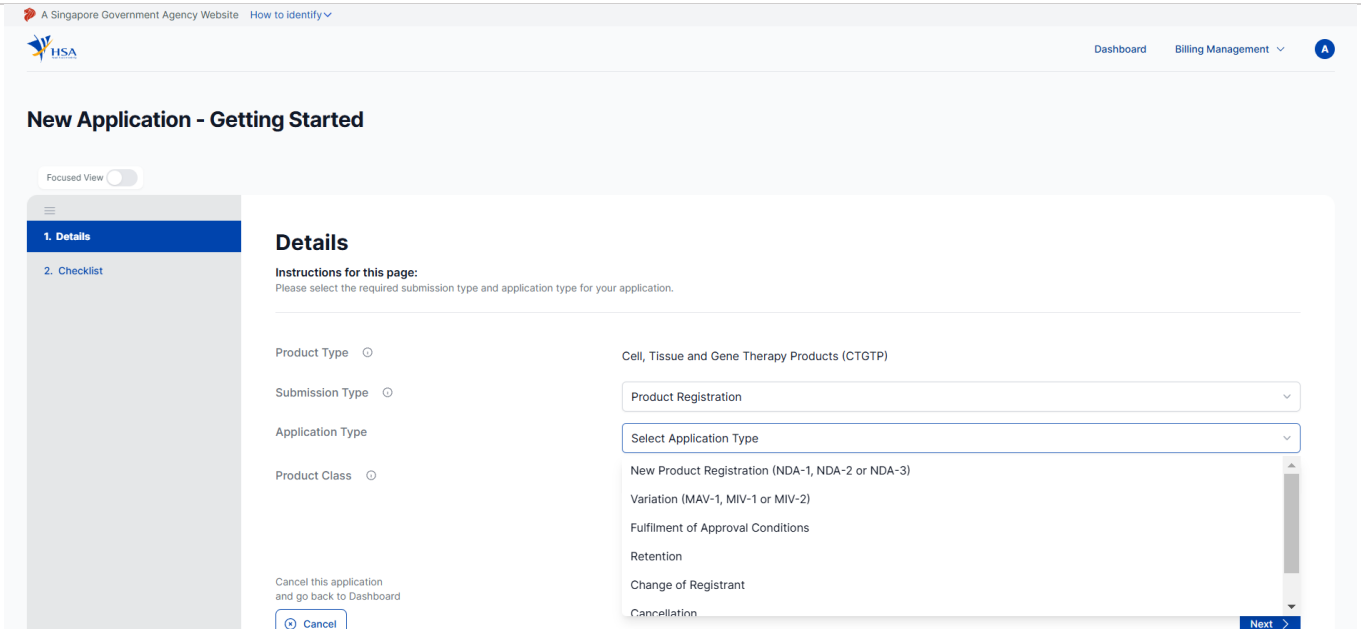
Applicants can select the type of application to be submitted.

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

Submission Type
- Dealer's Notice
- Product Notification
- Product Registration
- Importer's Licence/ Wholesaler's Licence
- Manufacturer's Licence
- GDP Certificate
- GMP Certificate

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

If **Product Notification** or **Dealer's Notice** is selected
- New
- Update
- Cancel



If **Product Registration** is selected

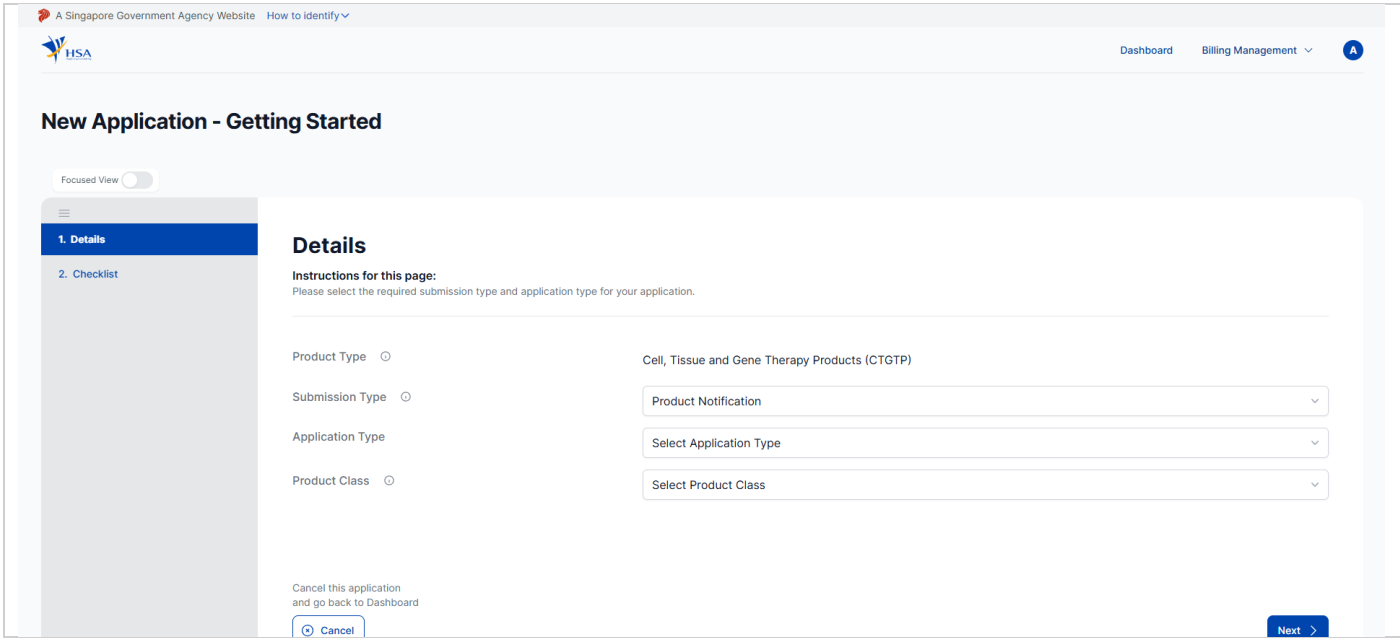
- New Product Registration (NDA-1, NDA-2 or NDA-3)
- Variation (MAV-1, MIV-1 or MIV-2)
- Fulfilment of Approval Conditions
- Retention
- Change of Registrant
- Cancellation
- Global Update of Importers

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

- New
- Amendment
- Cancel
- Renewal

If **GDP Certificate / GMP Certificate** is selected

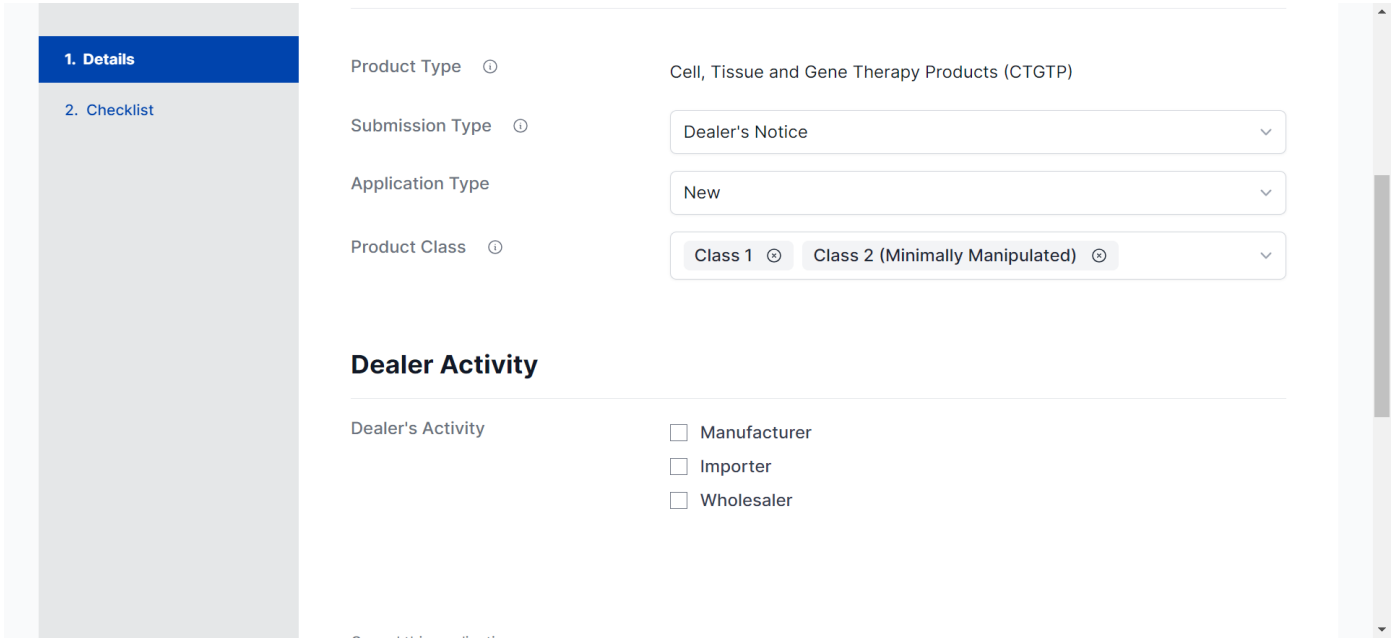
- New



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

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

New Application - Getting Started (ii)



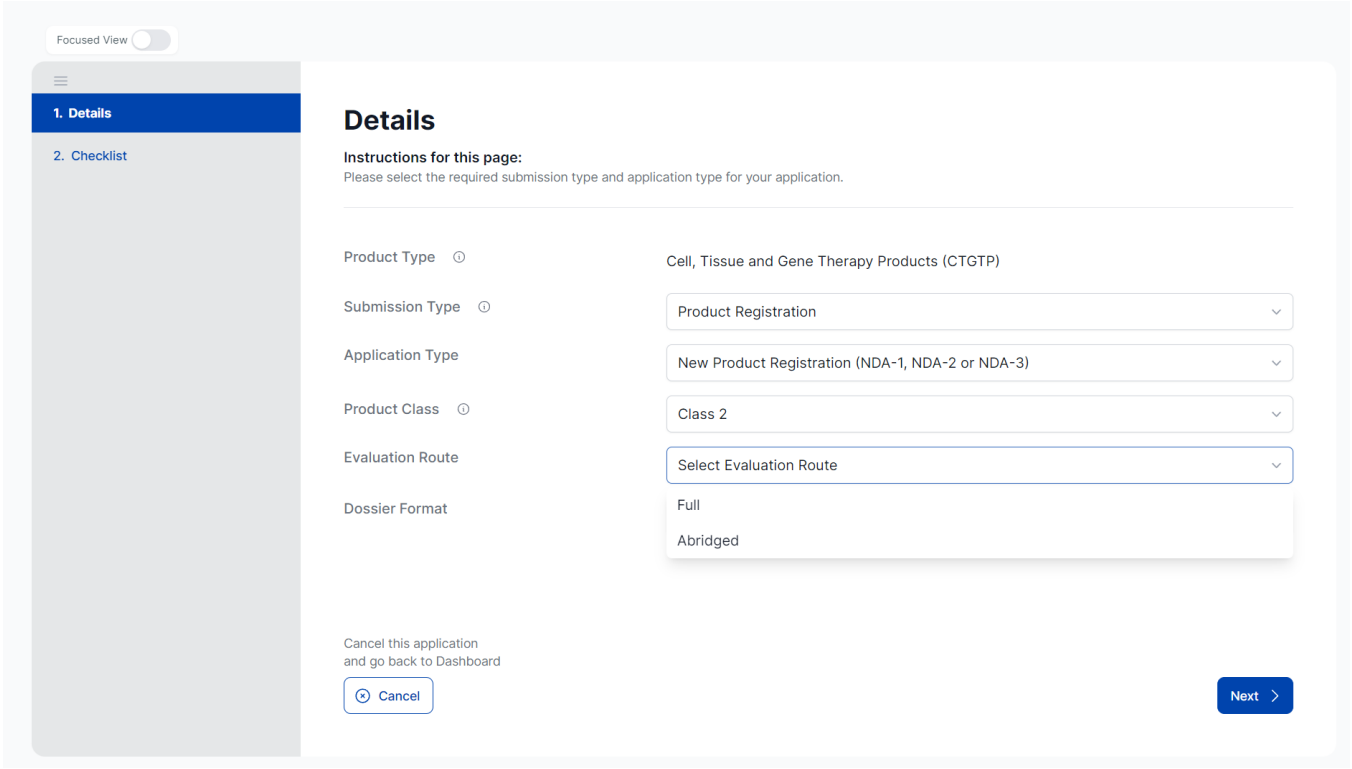
Dealer's Activity

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

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

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

New Application - Getting Started (iii)



Evaluation Route

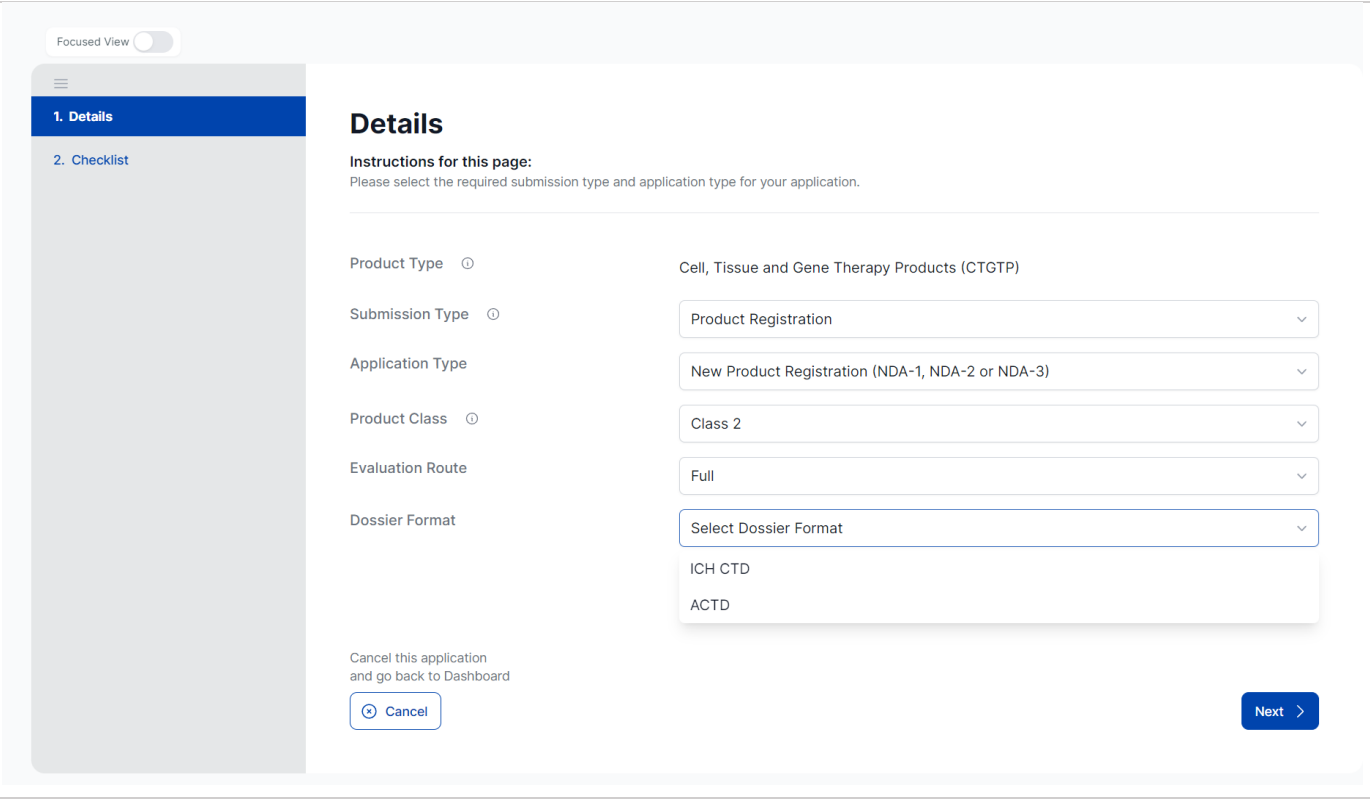
*(options in dropdown menu will only be shown **after selection of Submission Type, Application Type and Variation Type)***

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

OR

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

Applicants can select either full or abridged evaluation routes



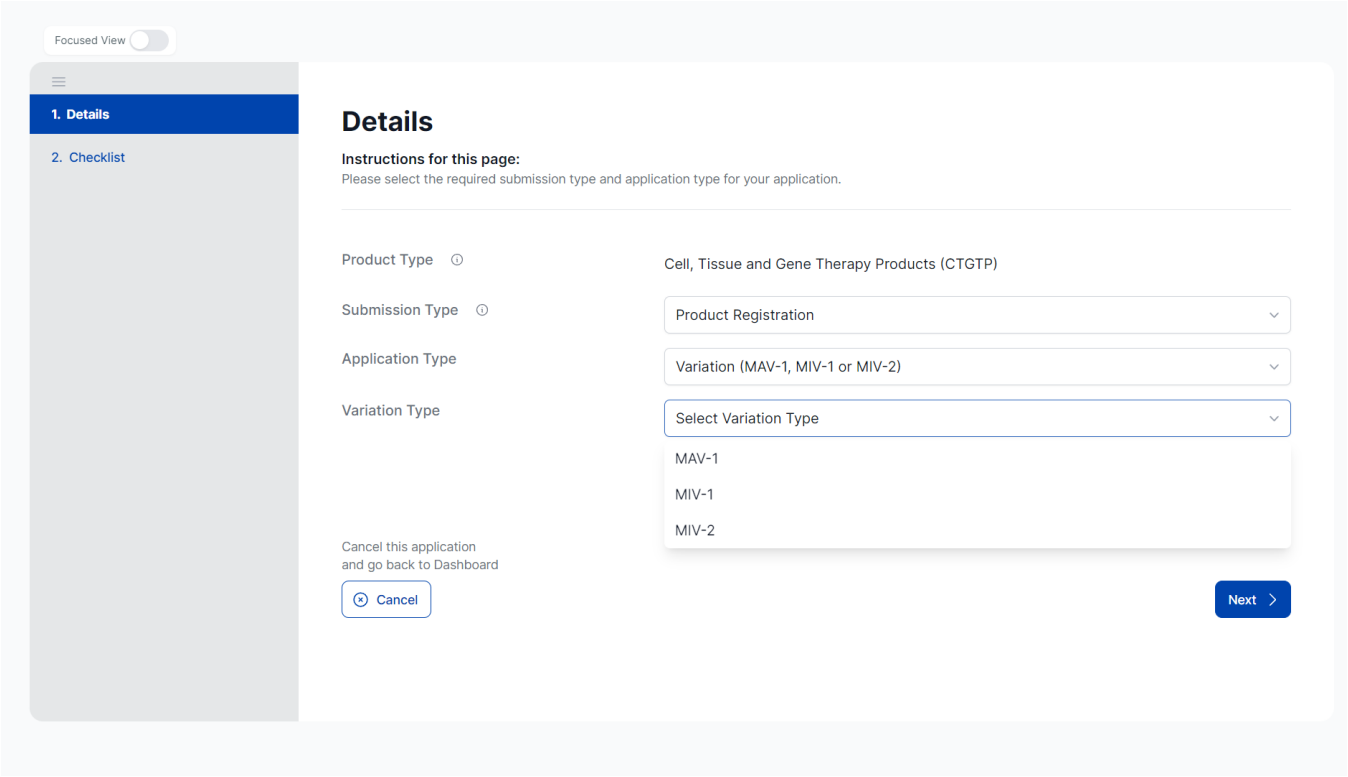
Dossier Format

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

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

Applicants can select either ICH CTD or ACTD dossier formats

New Application - Getting Started (iv)

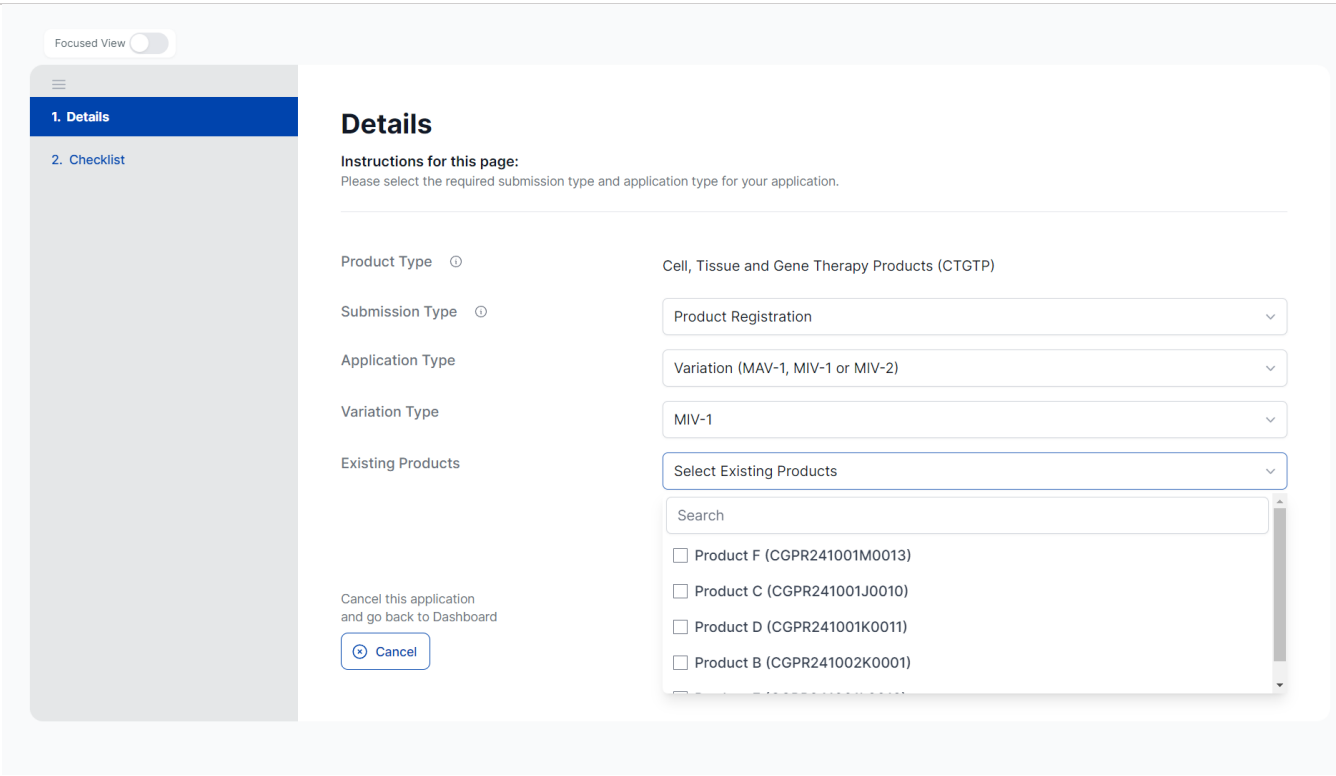


Variation Type

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

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

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



Existing Products

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

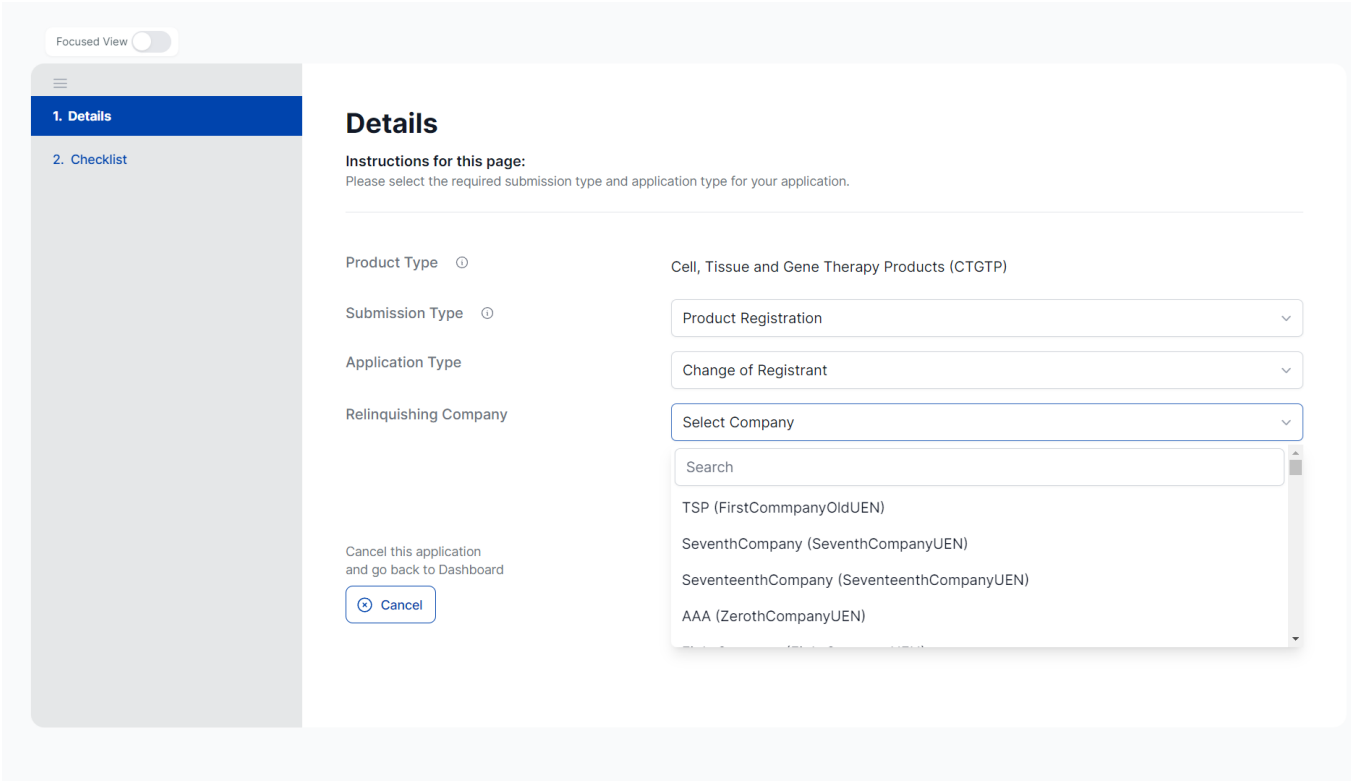
- Submission type = 'Product Registration'
- Application type = 'Variation (MAV-1, MIV-1 or MIV-2)'

Applicants can search for products using the search bar.

Multiple products can be selected.

For a continuation of MIV applications, visit the MIV section.

New Application - Getting Started (iv)

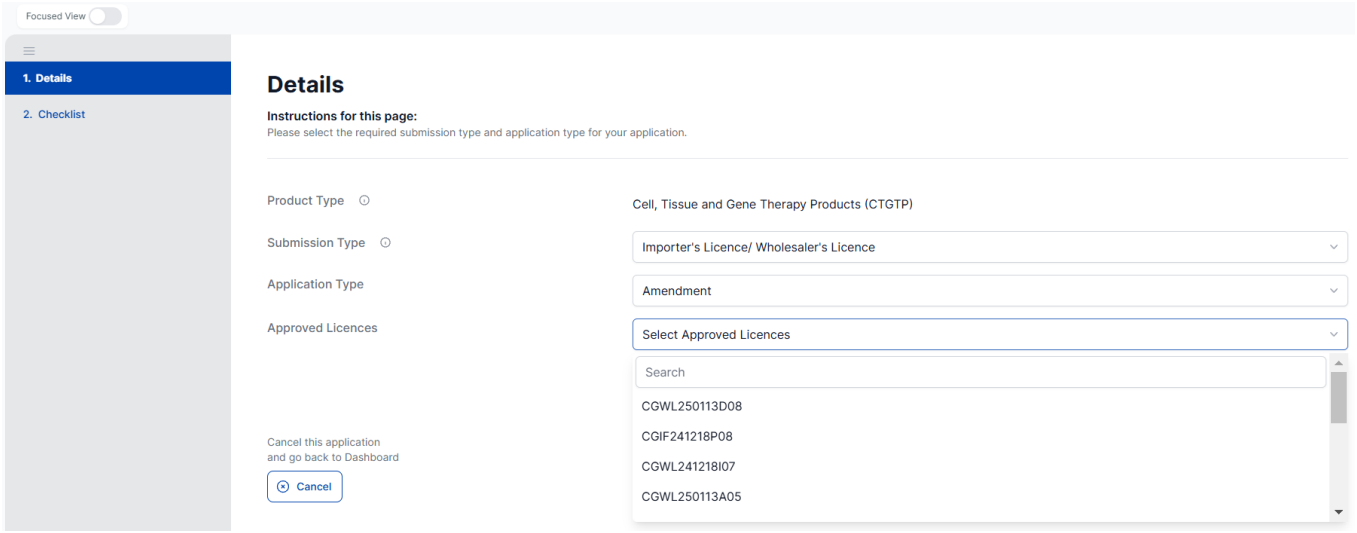


Relinquishing Company
*(options in dropdown menu will only be shown **after selection of Submission Type and Application Type**)*

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

Applicants can search for companies using the search bar.

For a continuation of Change of Registrant applications, visit the Change of Registrant section.



Approved Licences

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

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

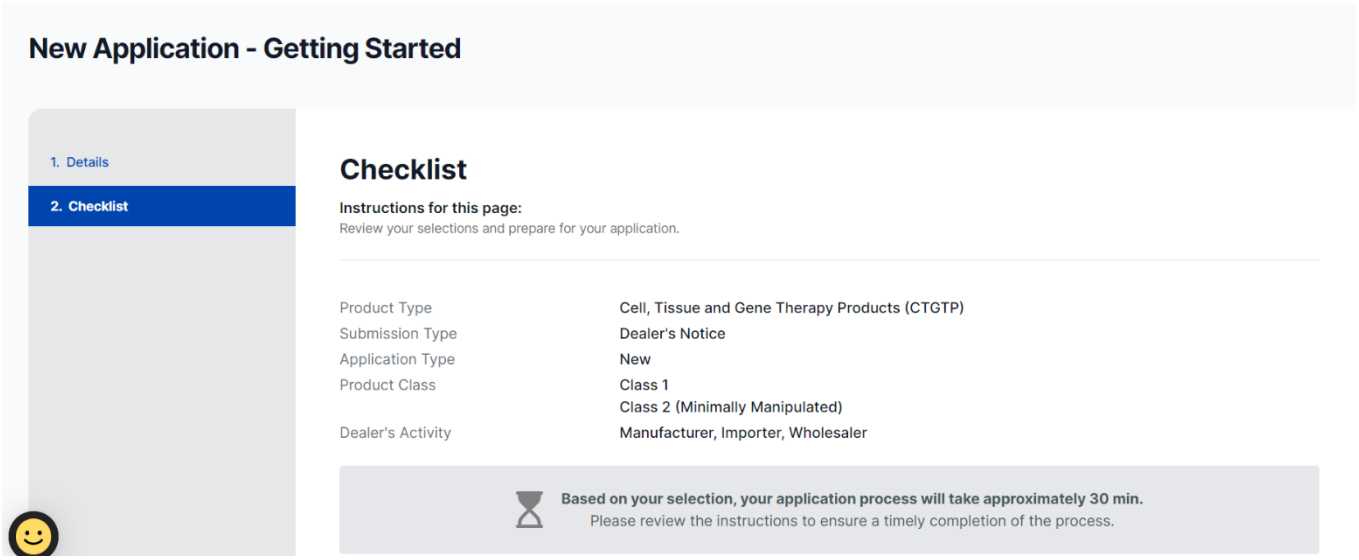
OR

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

Applicants can search for licences using the search bar.

For a continuation of Licence Amendment applications, visit the Licence Amendment section.

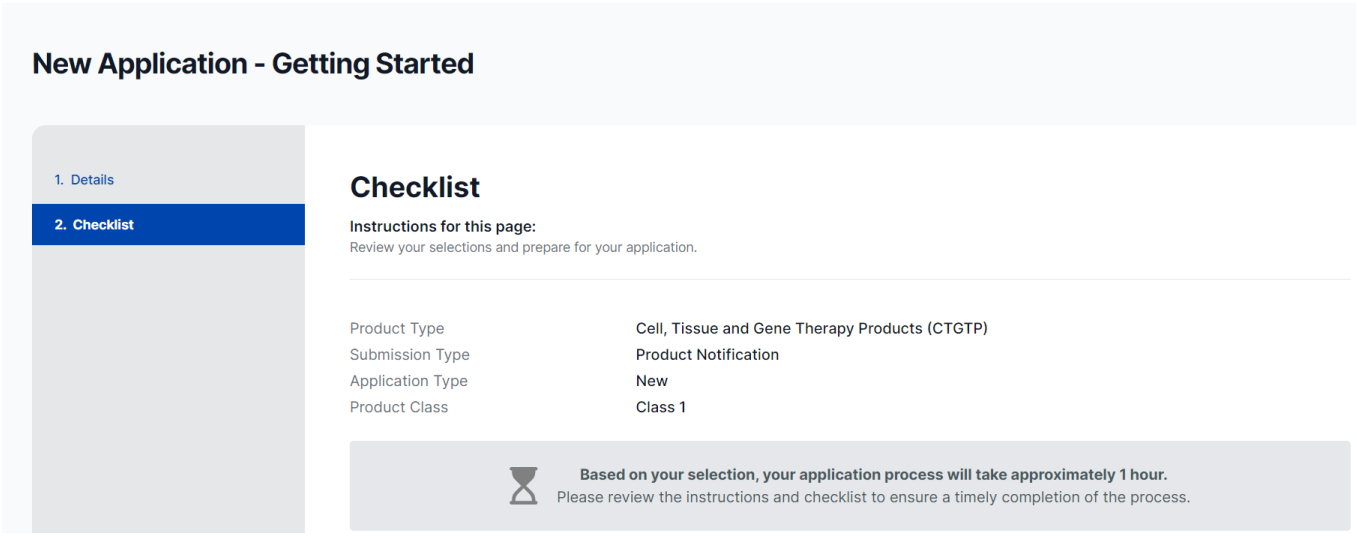
New Application - Getting Started (v) – Dealer's Notice



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.

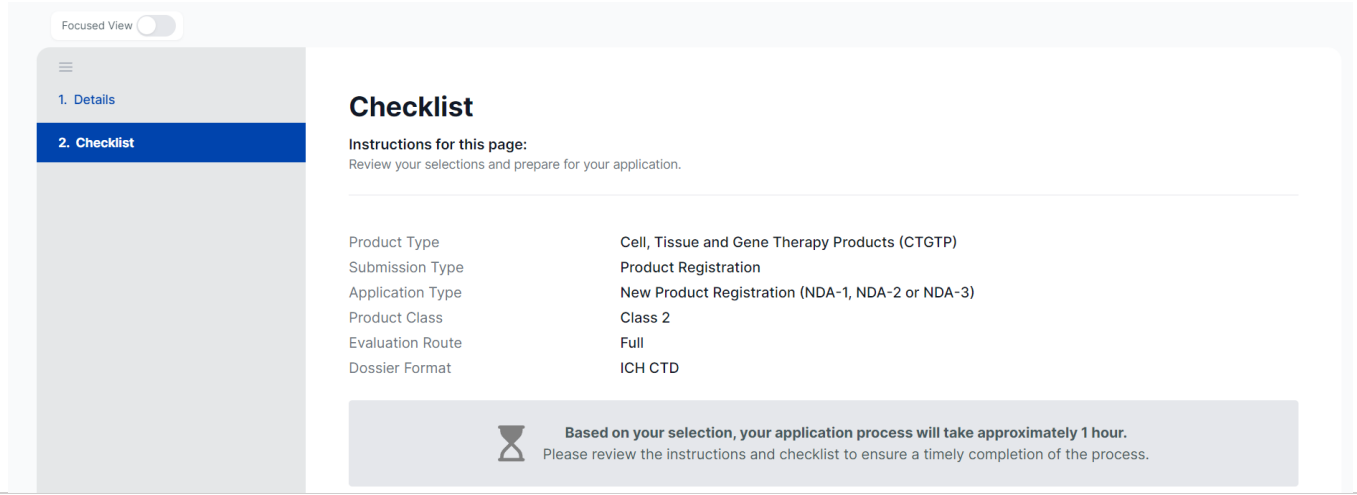
New Application - Getting Started (v) – Product Notification



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

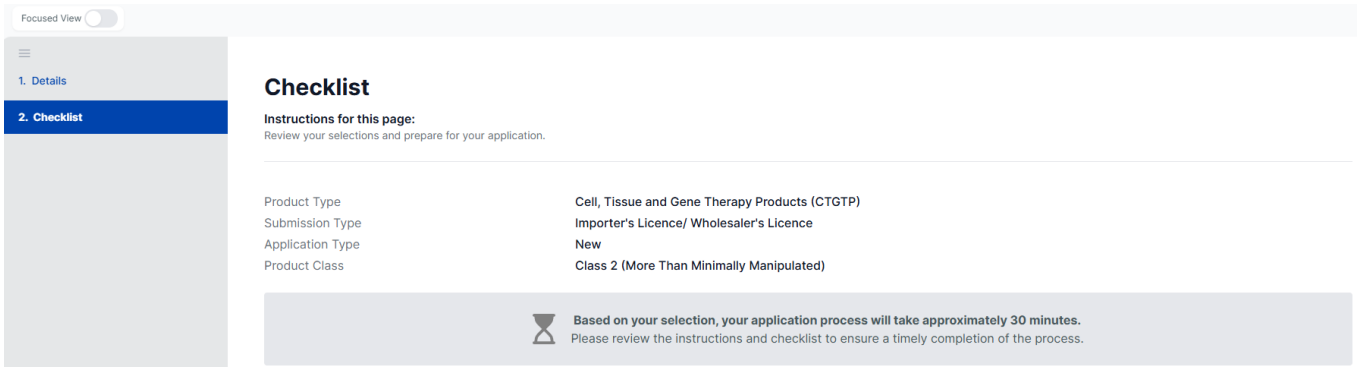
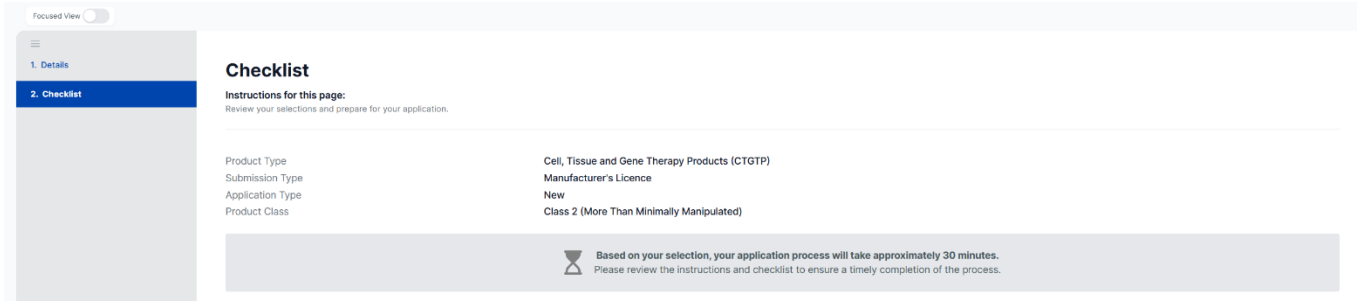
Note: Information on this page may differ depending on the fields selected in Creation of New Application.

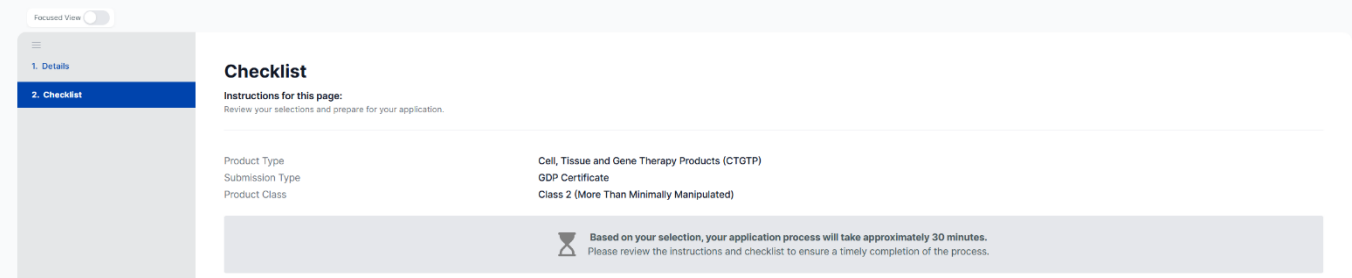
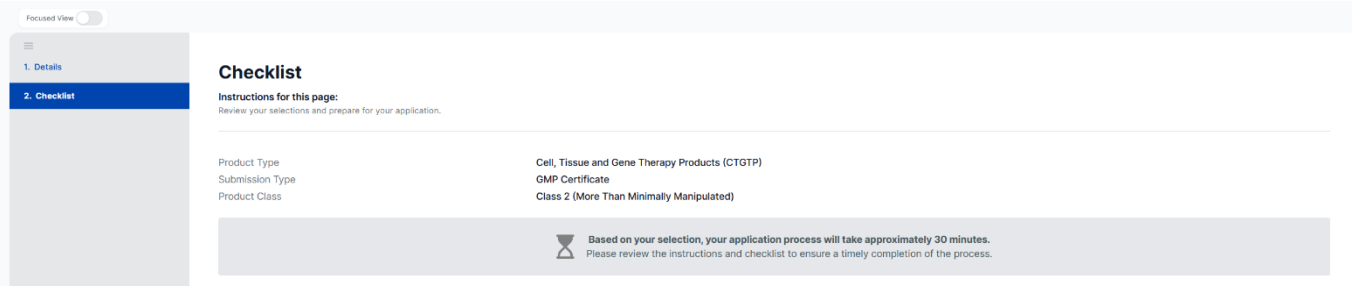
New Application - Getting Started (v) – Product Registration



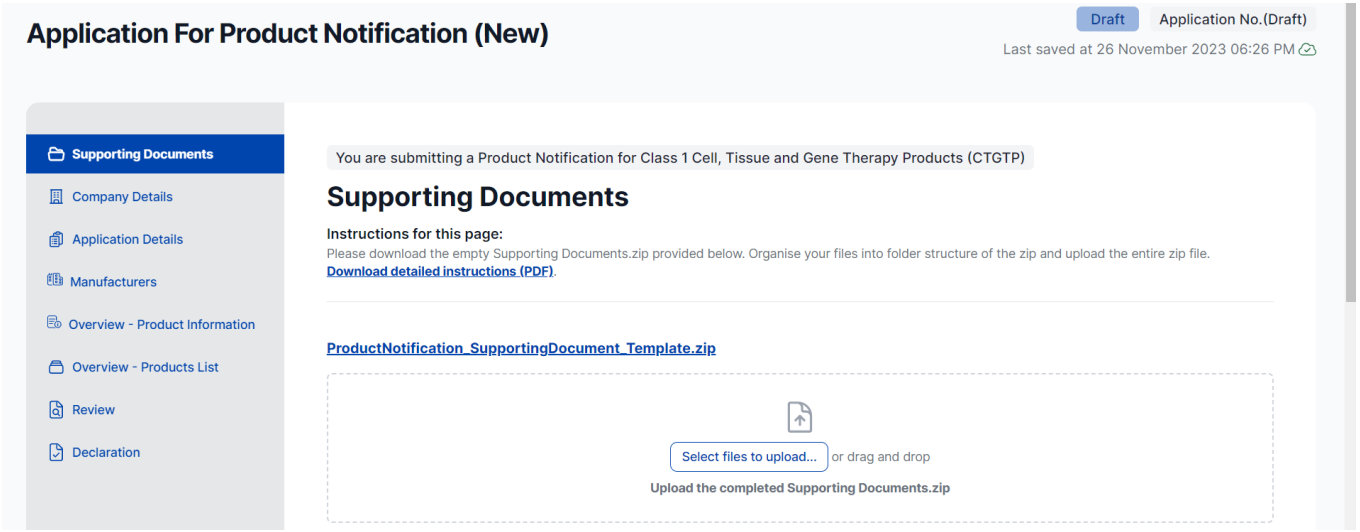
Applicants will be directed to the checklist page where there will be additional information regarding the application that the applicants are applying for.

Note: Information on this page may differ depending on the fields selected in Creation of New Application.

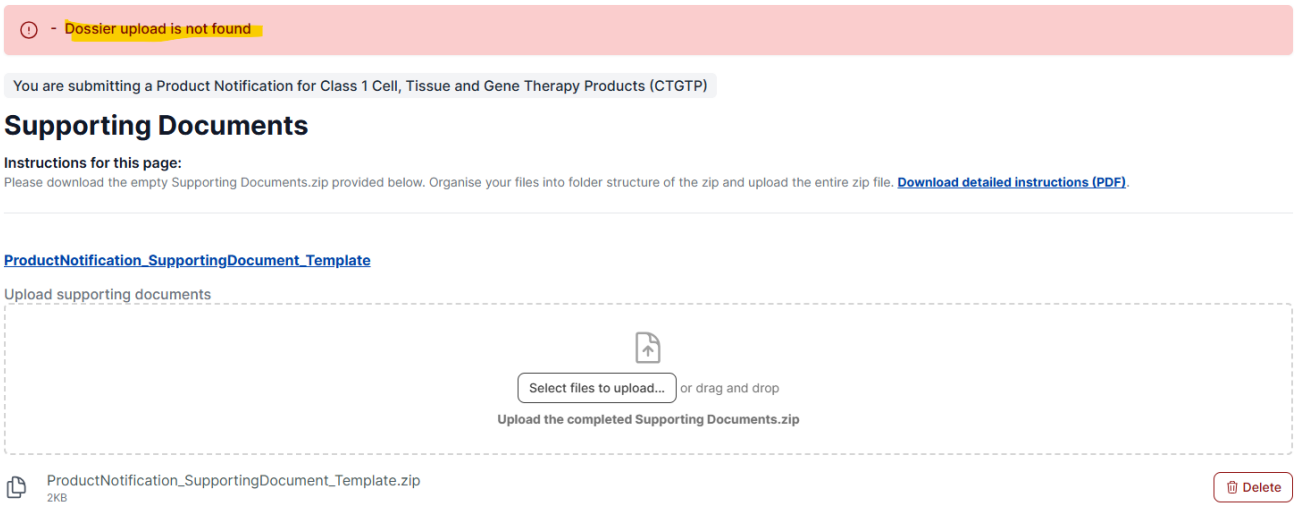
New Application - Getting Started (v) – Importer's Licence/ Wholesaler's Licence 	Applicants will be directed to the checklist page where there will be additional information regarding the application that the applicants are applying for. **Note:** Information on this page may differ depending on the fields selected in Creation of New Application.
New Application - Getting Started (v) – Manufacturer's Licence 	Applicants will be directed to the checklist page where there will be additional information regarding the application that the applicants are applying for. **Note:** Information on this page may differ depending on the fields selected in Creation of New Application.

New Application - Getting Started (v) – GDP Certificate 	Applicants will be directed to the checklist page where there will be additional information regarding the application that the applicants are applying for. **Note:** Information on this page may differ depending on the fields selected in Creation of New Application.
New Application - Getting Started (v) – GMP Certificate 	Applicants will be directed to the checklist page where there will be additional information regarding the application that the applicants are applying for. **Note:** Information on this page may differ depending on the fields selected in Creation of New Application.

4.1.1 Supporting Documents



Error messages that might appear:

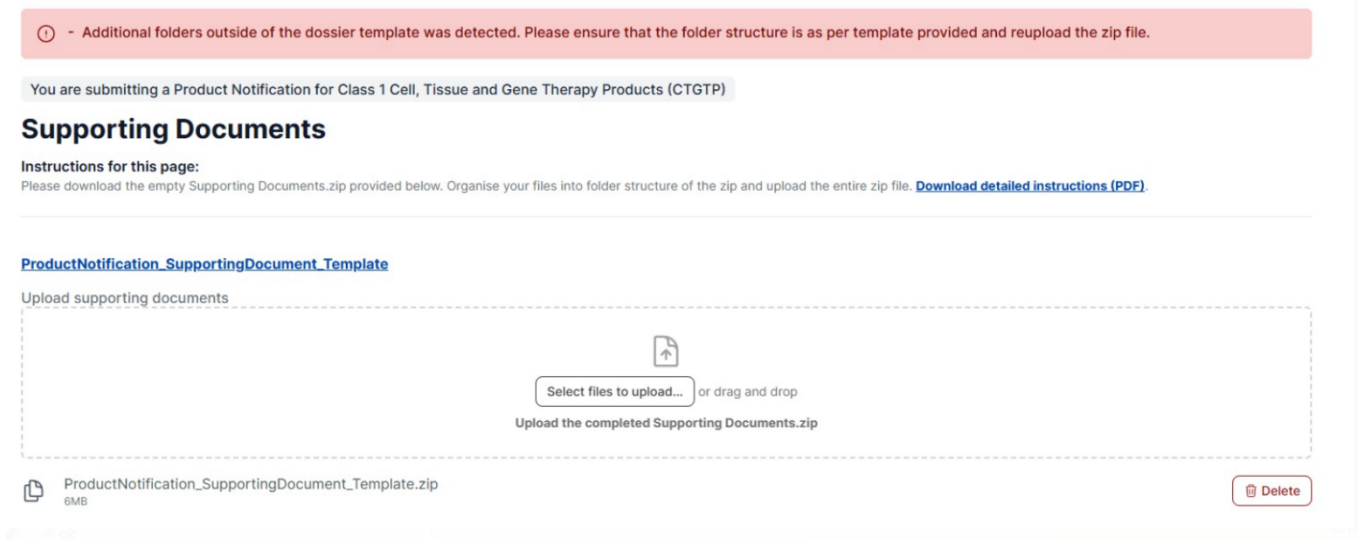


Applicants are required to download the template zip, upload the supporting documents to the respective template folders within the zip file, and then proceed with the upload. Detailed instructions for guidance can be downloaded for further assistance.

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

Error messages notes:

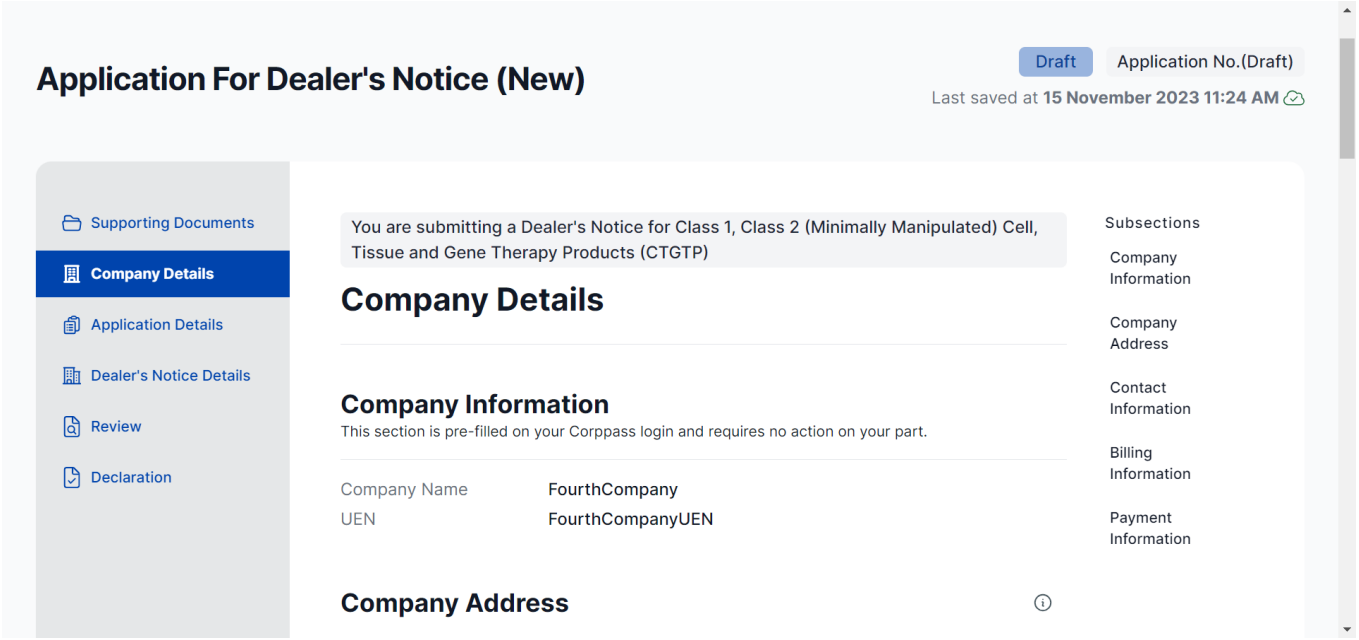
- 'Dossier upload is not found' error message will be shown when the dossier has been removed and then there is a network or communication issue that prevents the UI from retrieving the status. Please check your internet connection and try again.
- 'Additional folders outside of the dossier template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



or folders directly under the root folder.

4.1.2 Company Details

Company Information



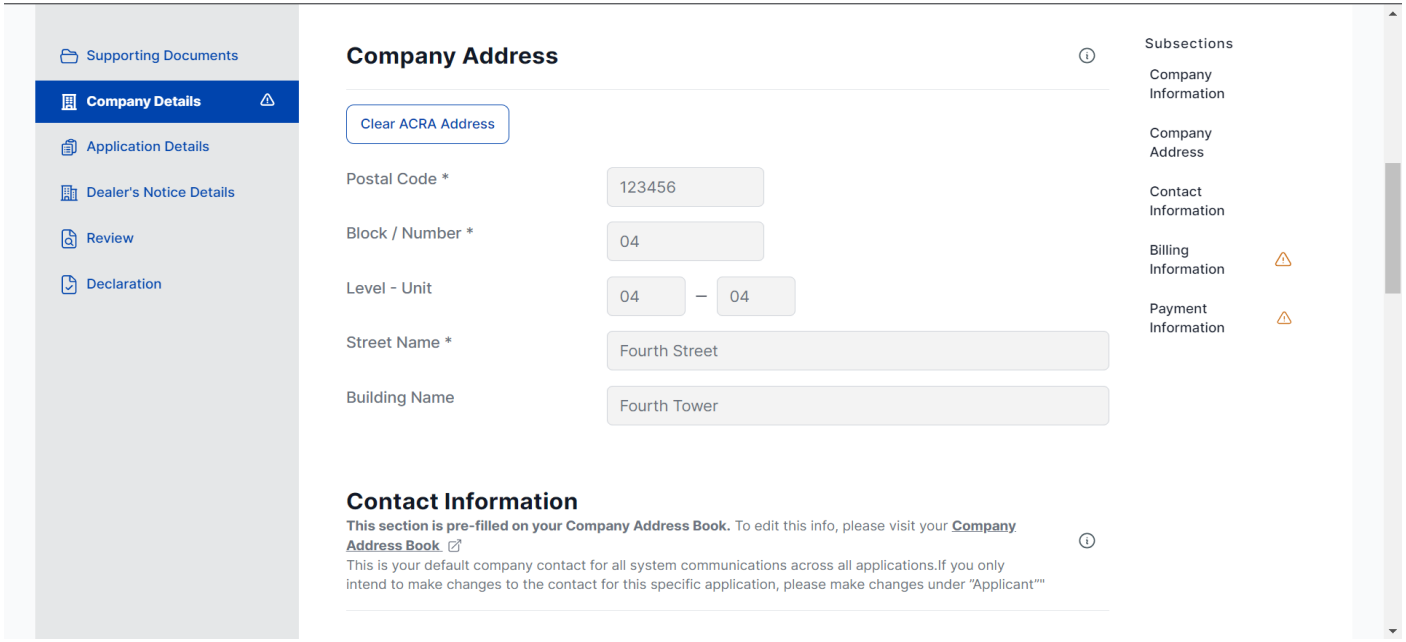
Applicants will first be directed to the application form – Company Details.

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

<u>Company Information</u>

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

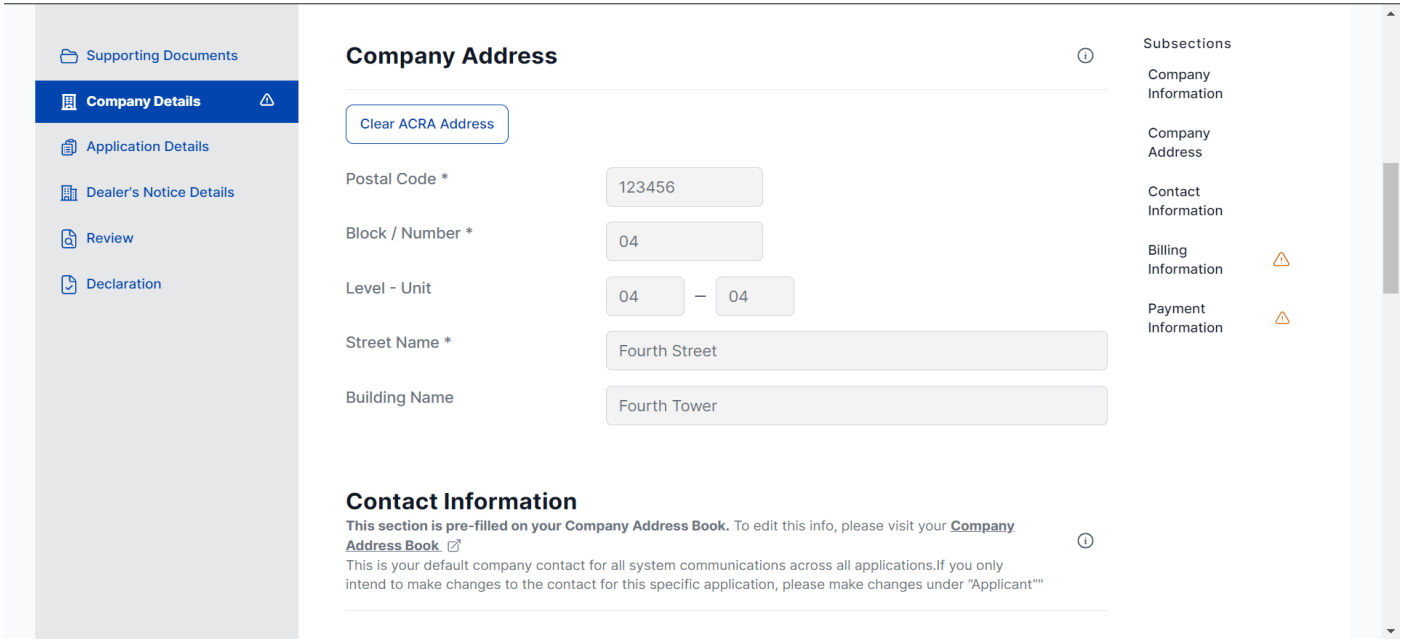
Company Address



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

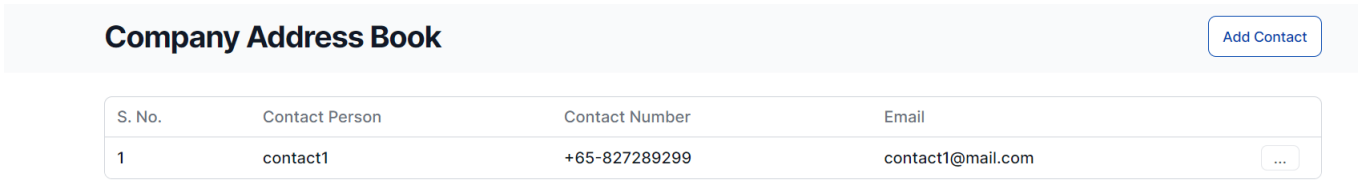
*Do note that changing the address field in the application form **does not change/update any address in ACRA.**

Contact Information



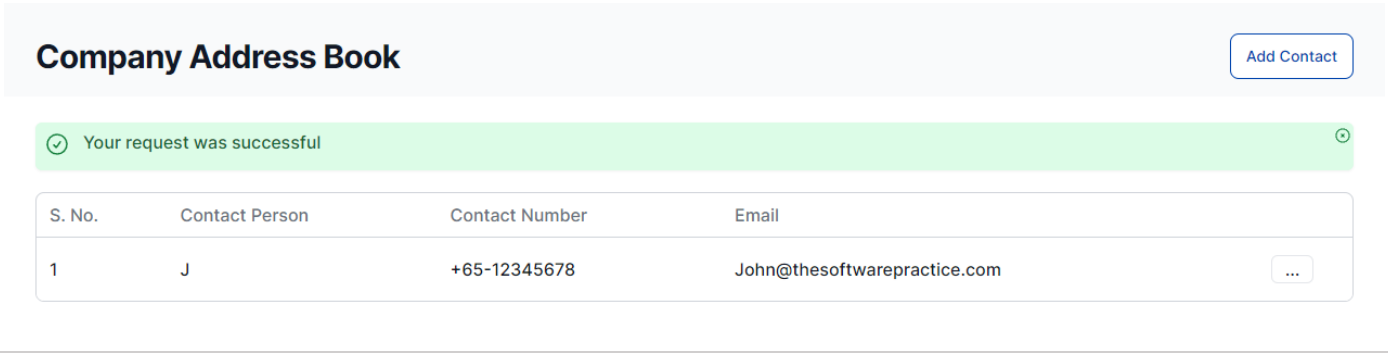
Applicants can click on the **company address book,** opening a new tab that allows them to update the company's address book.

Contact Information – Company Address Book



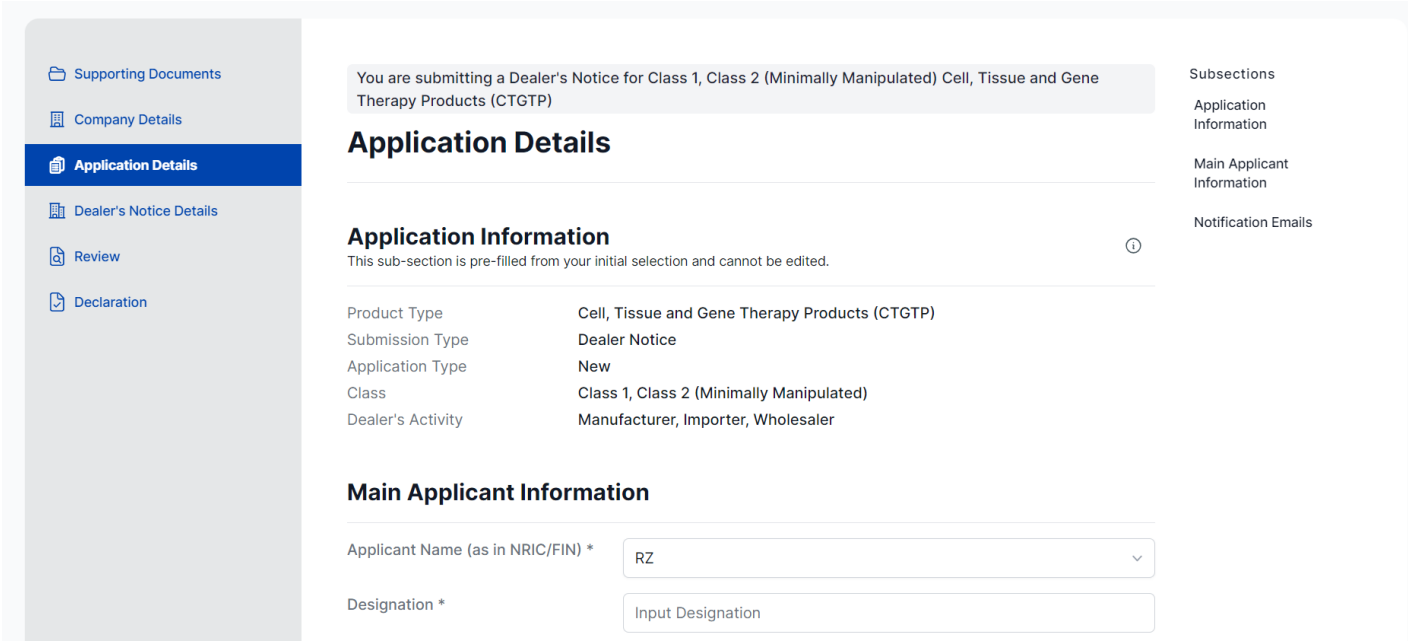
The new tab enables applicants to add new contact details by selecting '**Add Contact**' and filling in the necessary fields. Additionally, Applicants can **edit or delete** existing contact details in the company address book by clicking on the **three dots** on the right-hand side.

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

4.1.3 Application Details

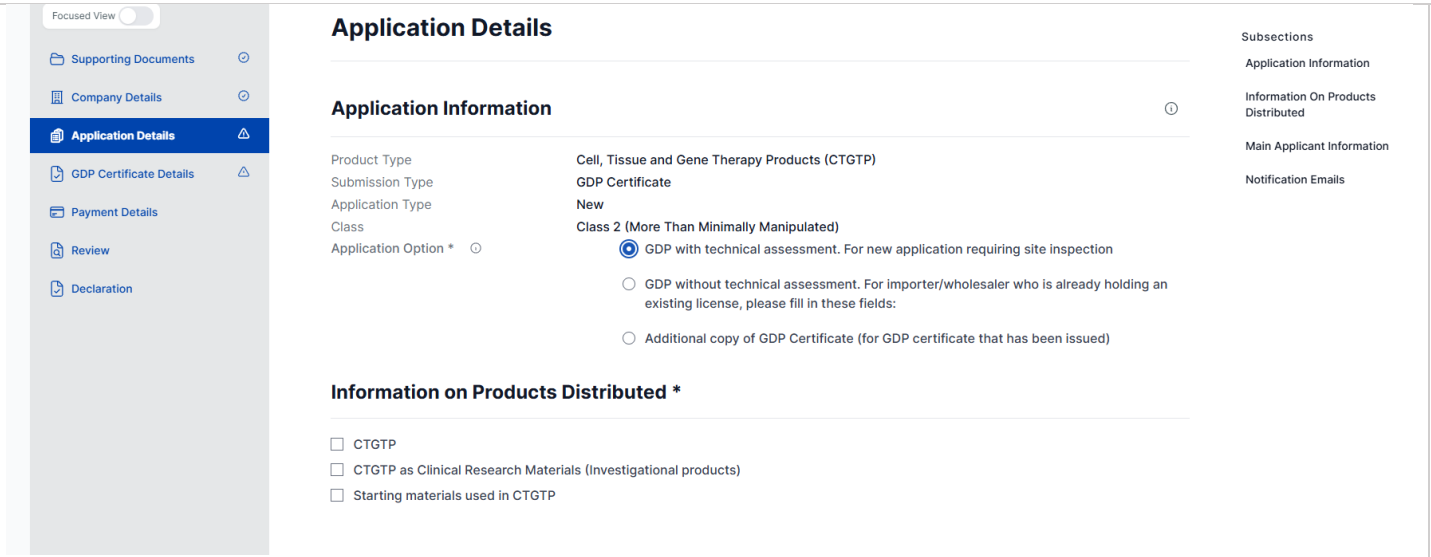
Application Information



The information displayed under 'Application Information' is based on the applicant's selections made during the application creation process. This includes details such as:

- Product Type
- Submission Type
- Application Type
- Class
- Dealer's Activity (Only relevant to Dealer's Notice)
- Evaluation Type (Only relevant to Product Registration)
- Dossier Format (Only relevant to Product Registration)
- Application Option (Only relevant to GDP Certificate & GMP Certificate)

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

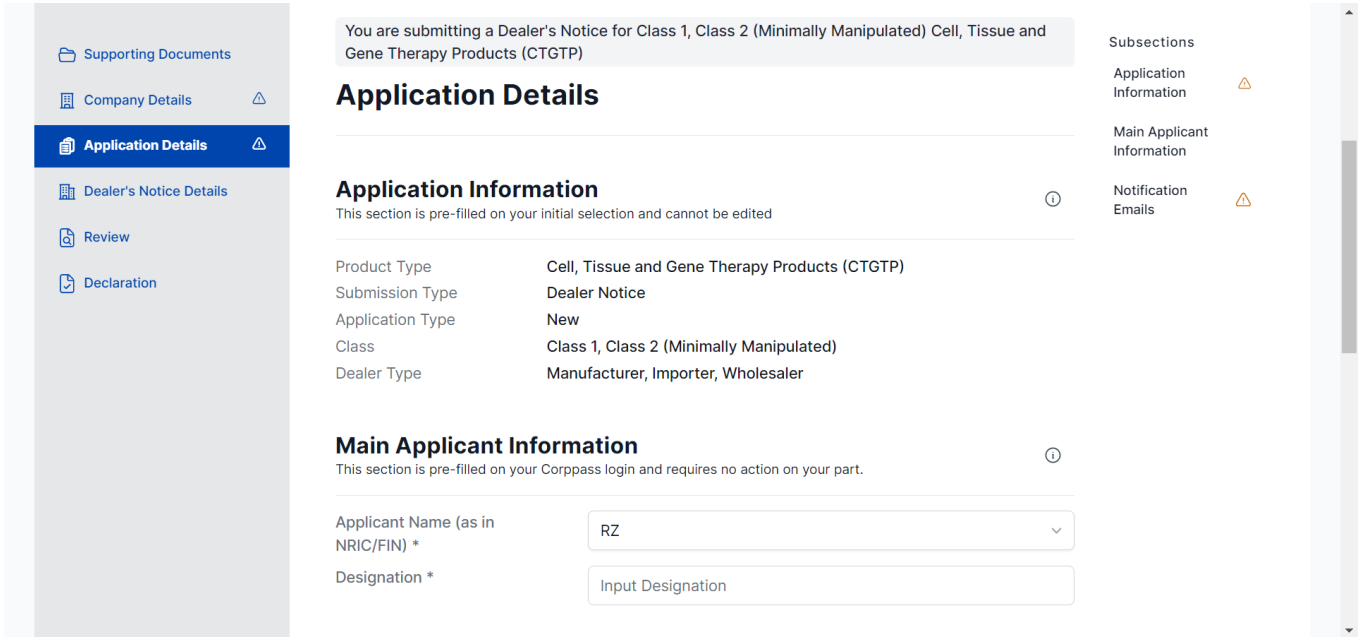


<u>Application Option</u>
Applicants should select one of the given options.

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

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

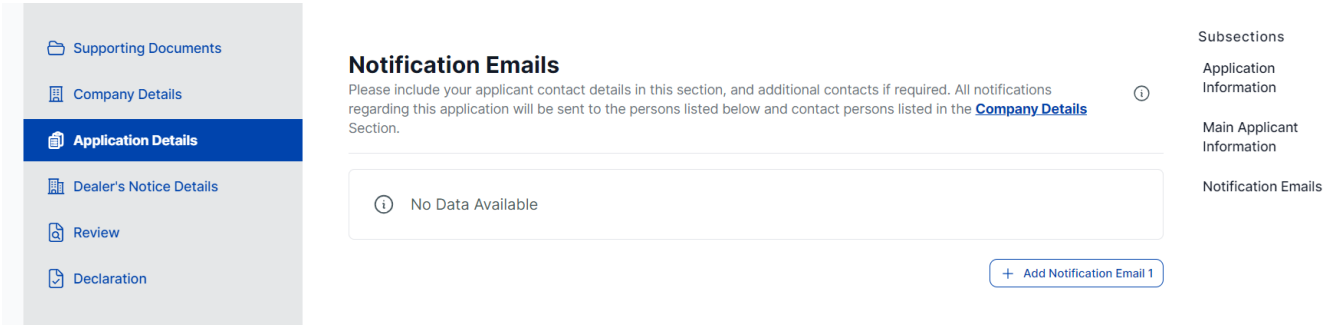
Main Applicant Information



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

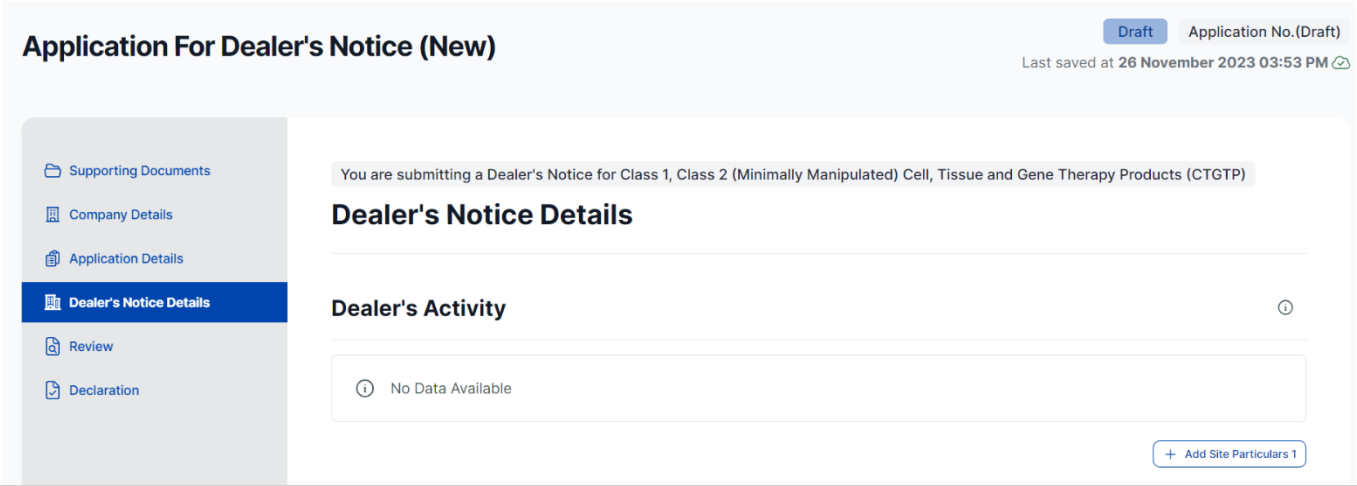


The applicant can update the notification email by selecting '**Add Notification Email**.'

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

Dealer’s Notice

Dealer’s Notice Details

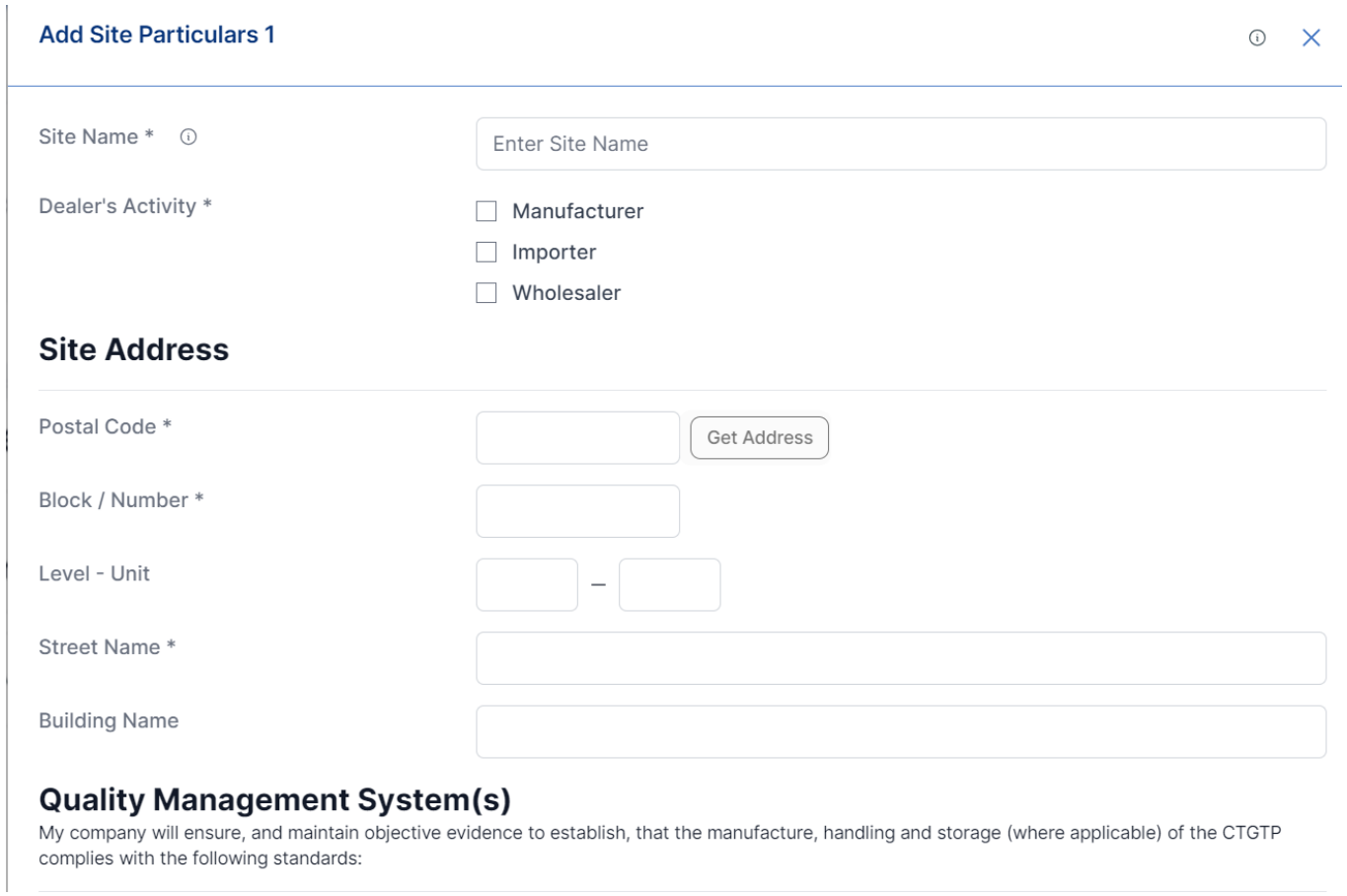


***This section is only applicable for Dealer’s Notice applications.**

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

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

Add Site Particular's

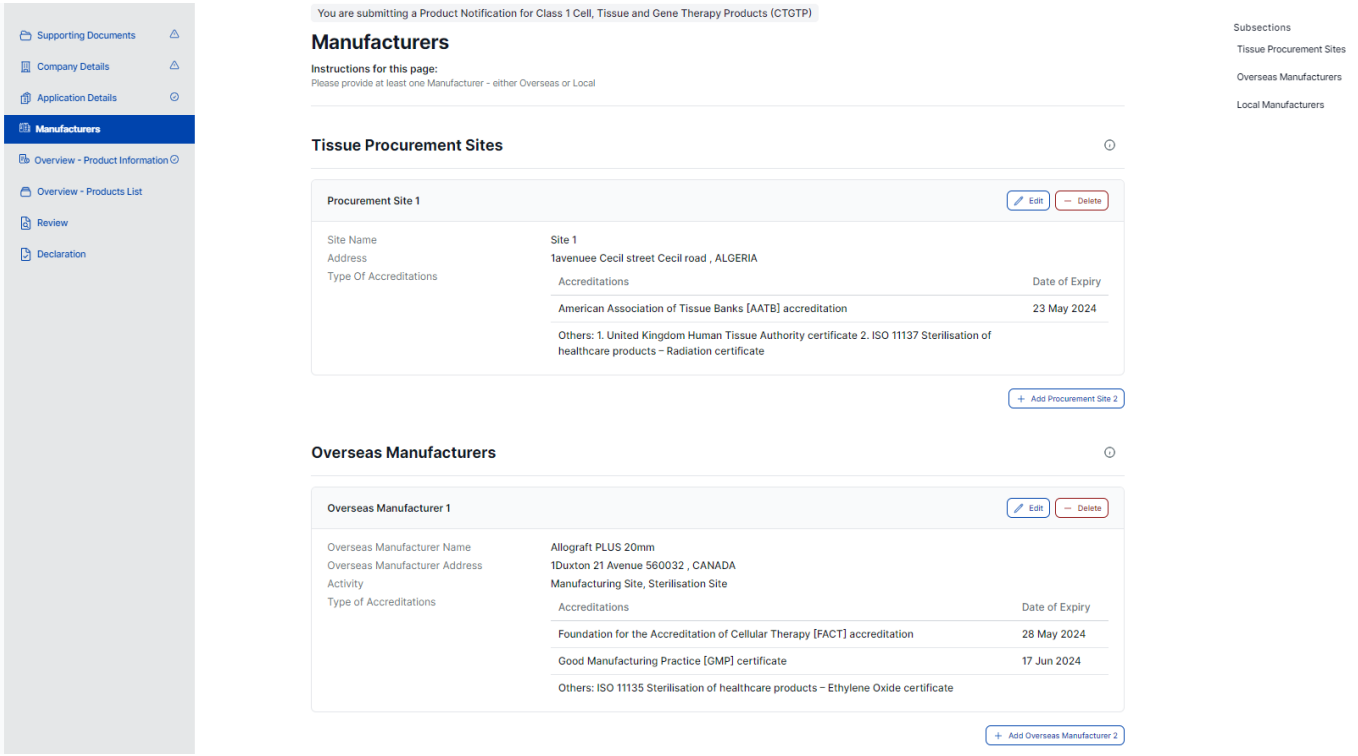


Applicants are required to complete all mandatory fields indicated by '*', and subsequently, they should choose the appropriate Quality Management System (QMS) for their respective sites.

For continuation of Dealer's Notice applications, please refer to Review section.

Product Notification

Manufacturers



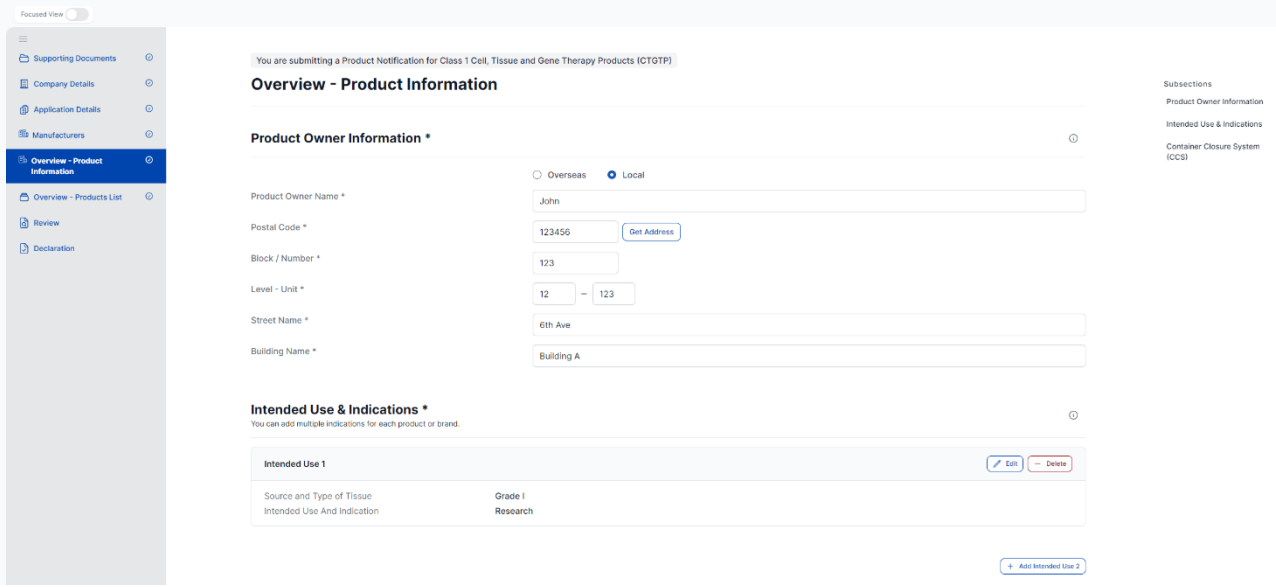
***This section is only applicable for Product Notification applications.**

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

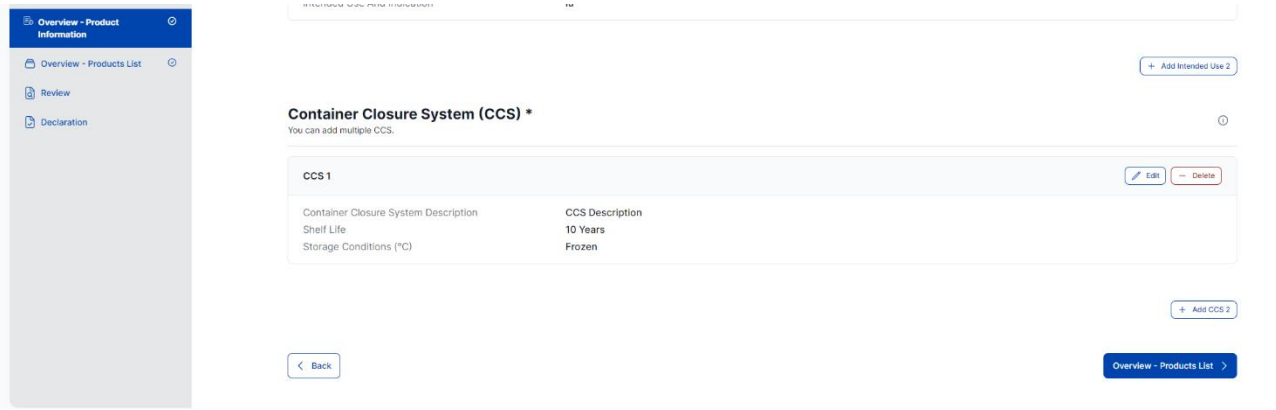


Product Information has three subsections:

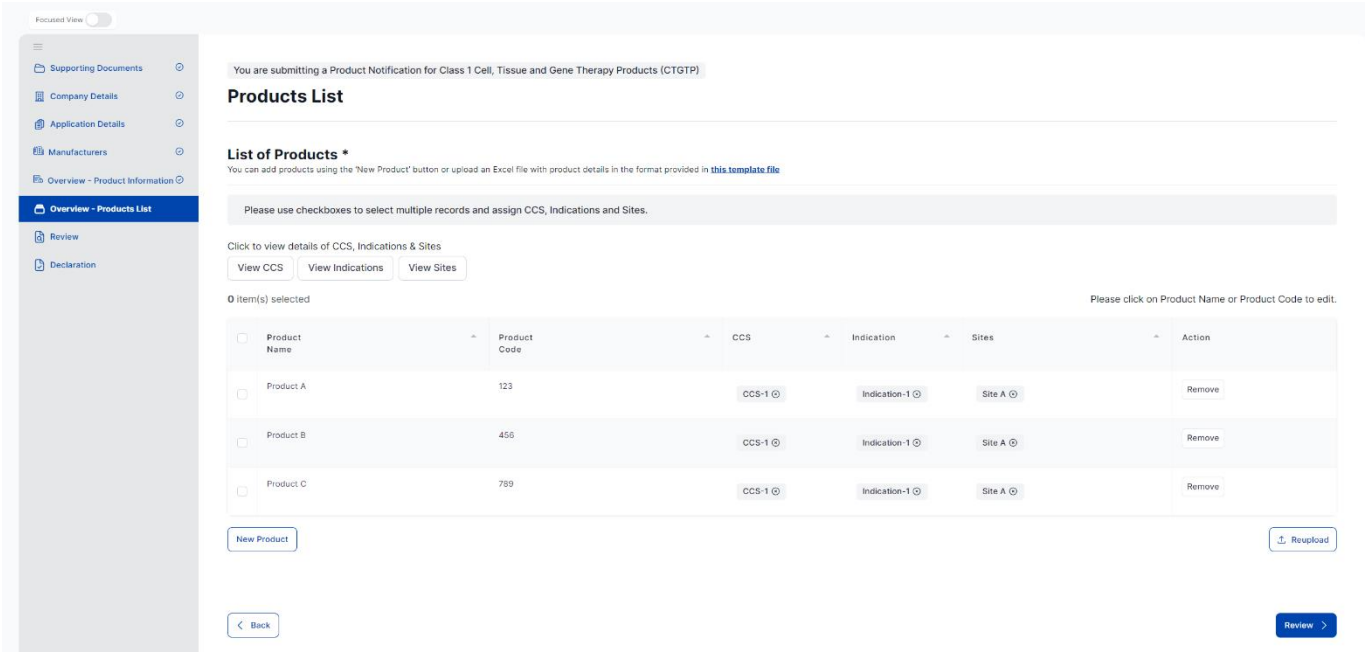
a. Product Owner Information
b. Intended Use and Indications.
c. Container Closure System (CCS)

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

Overview – Product Information



Overview – Product List



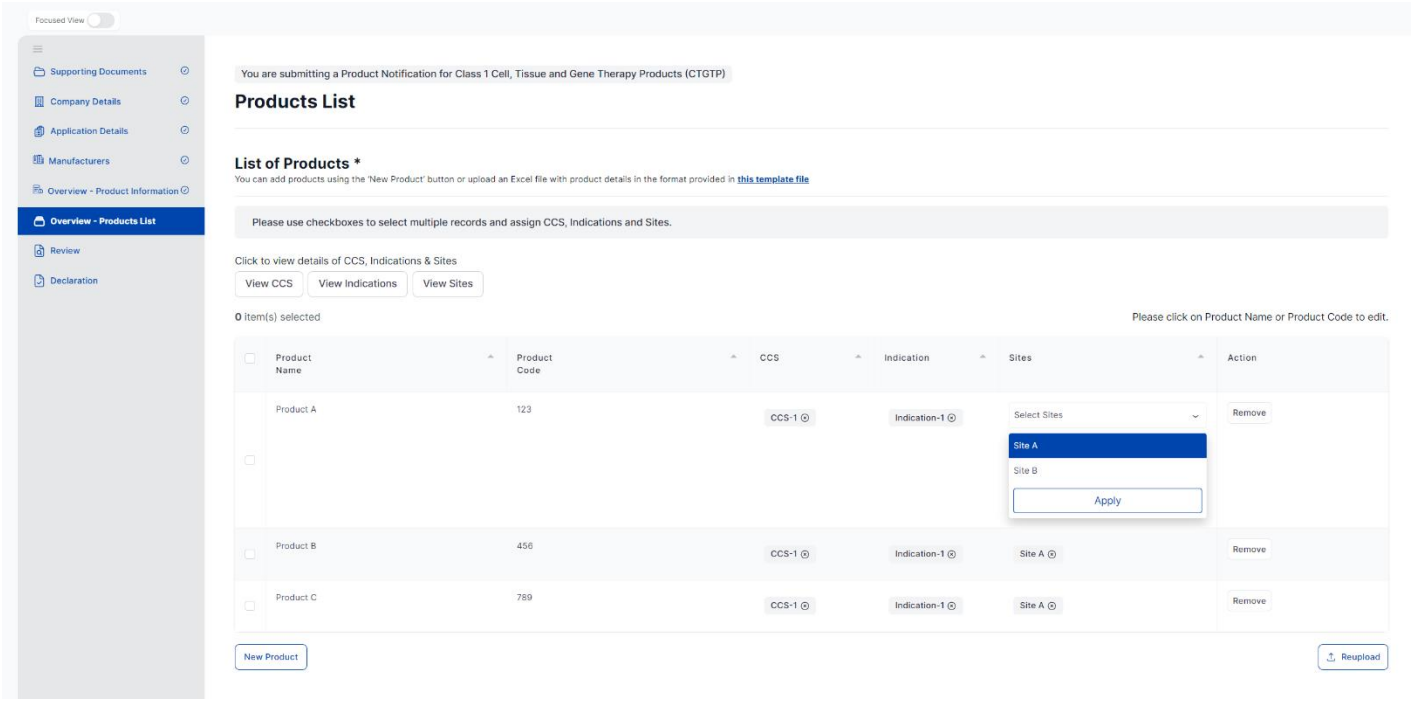
Applicants have the option to add products through two methods:

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.

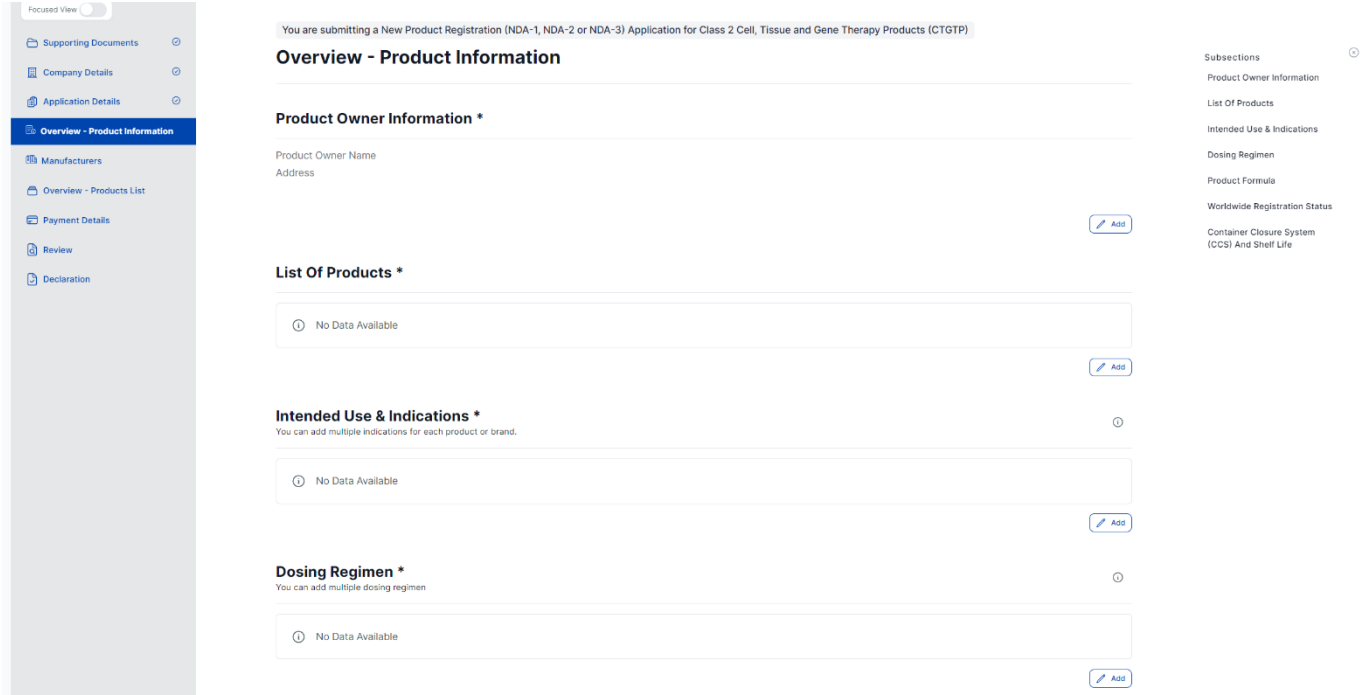
Overview – Product List



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

Product Registration

Overview – Product Information



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

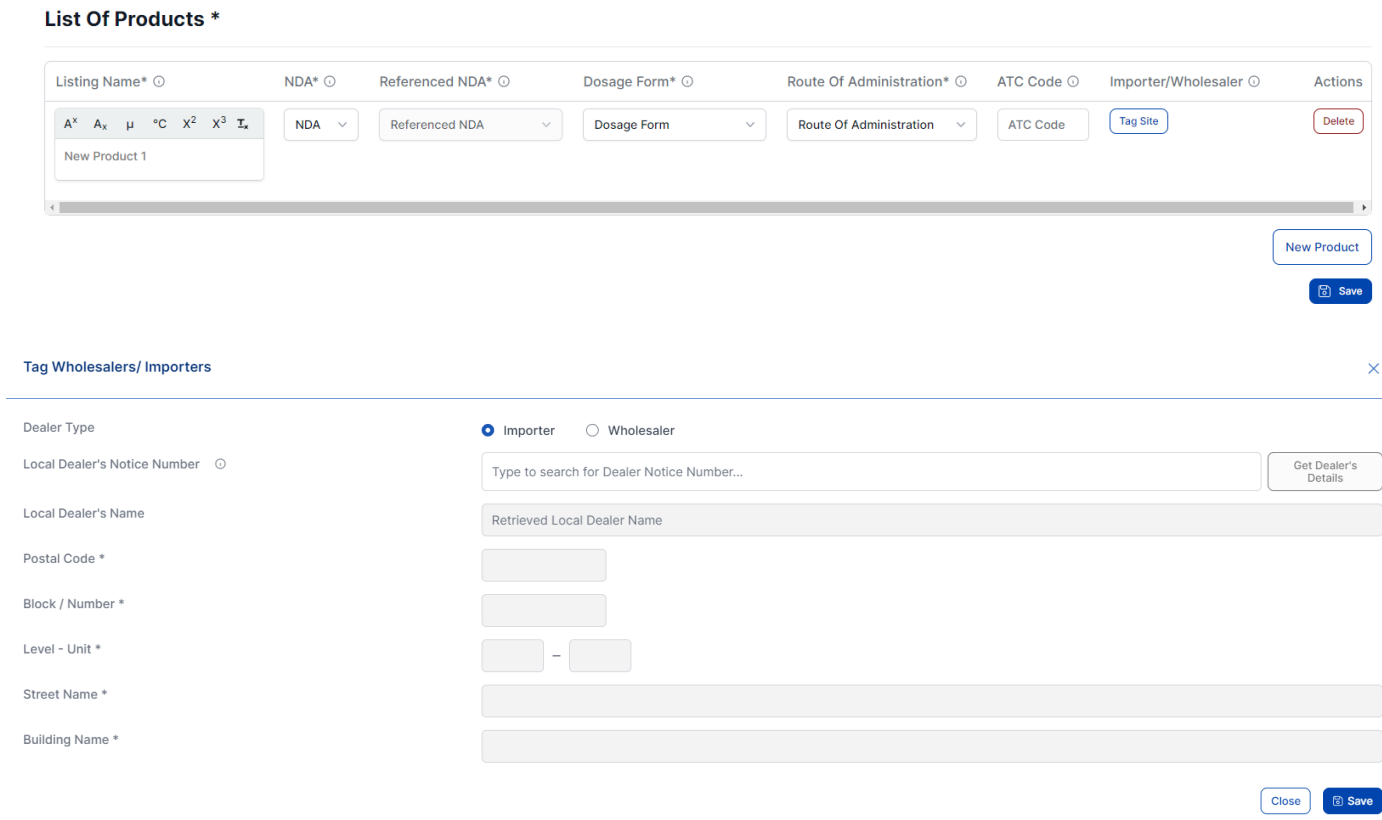
Overview - Product Information has seven subsections:

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

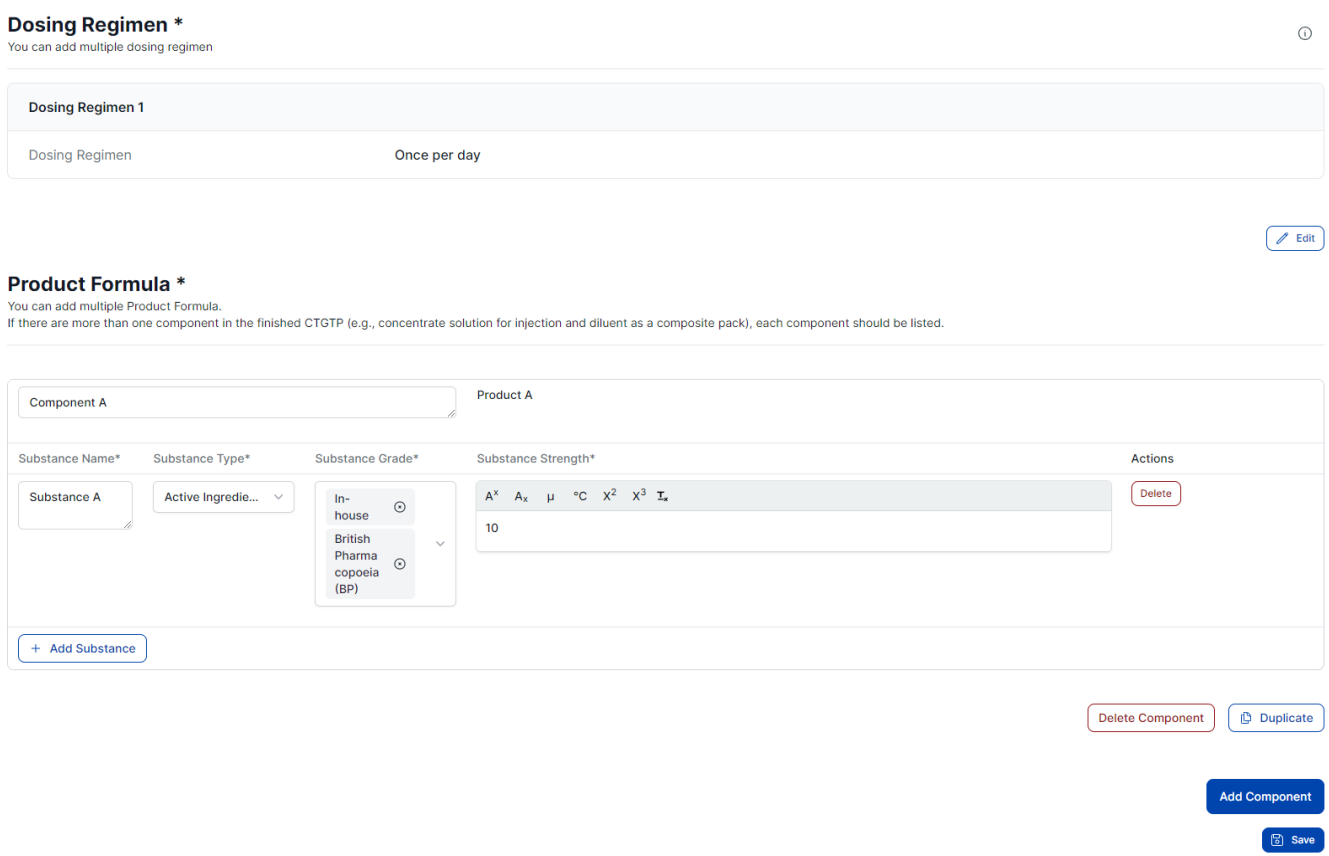


For the List of Products subsection, applicants can tag an importer or wholesaler to products (Click on the Save button after adding products before tagging sites).

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.

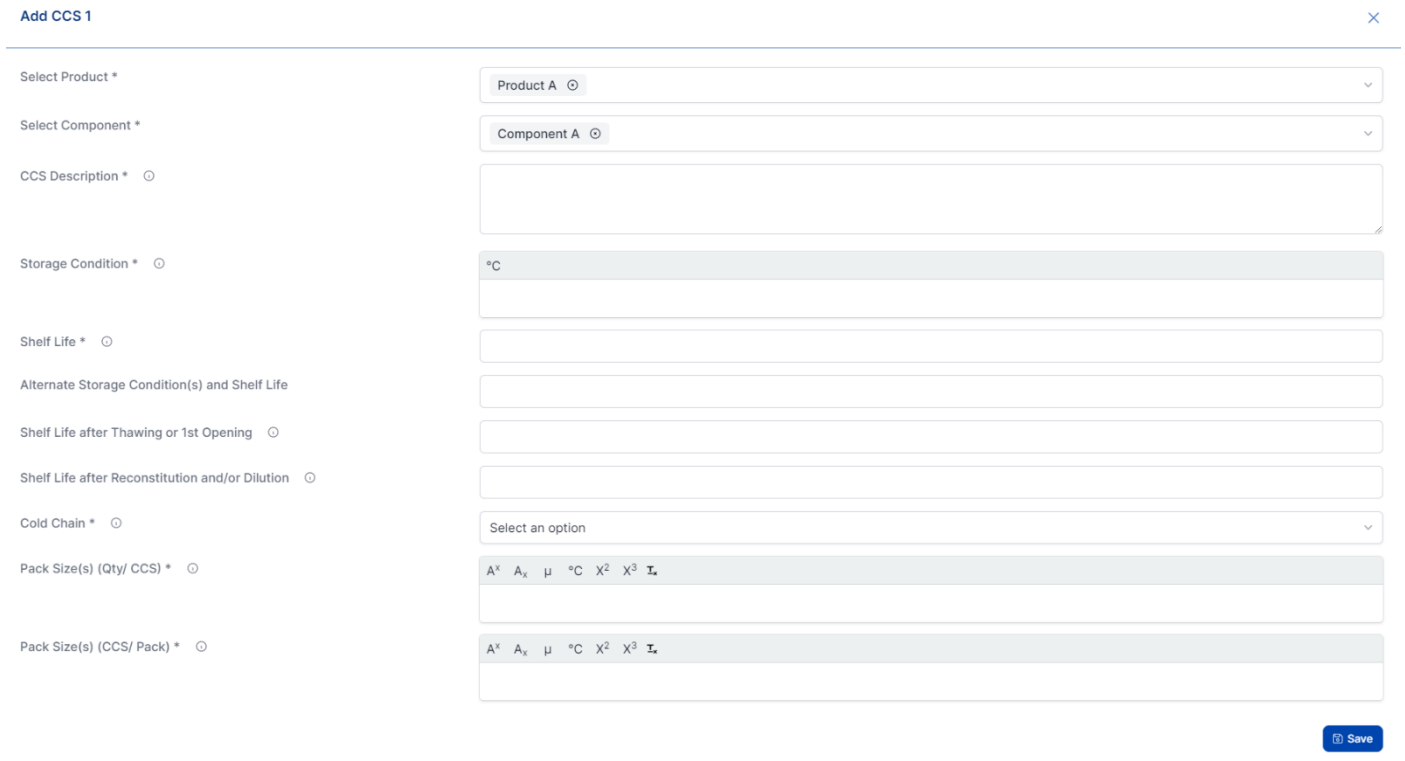
Overview – Product Information



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

Components can be duplicated by clicking on the 'Duplicate' button.

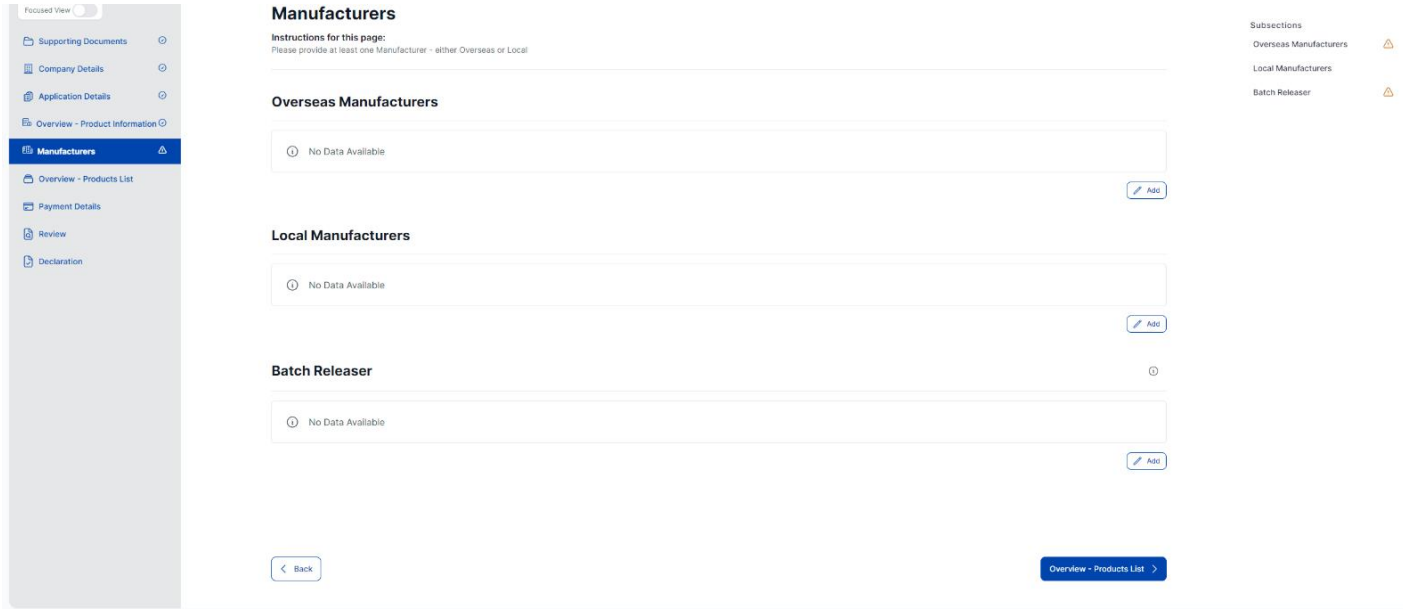
Overview – Product Information



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



***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.

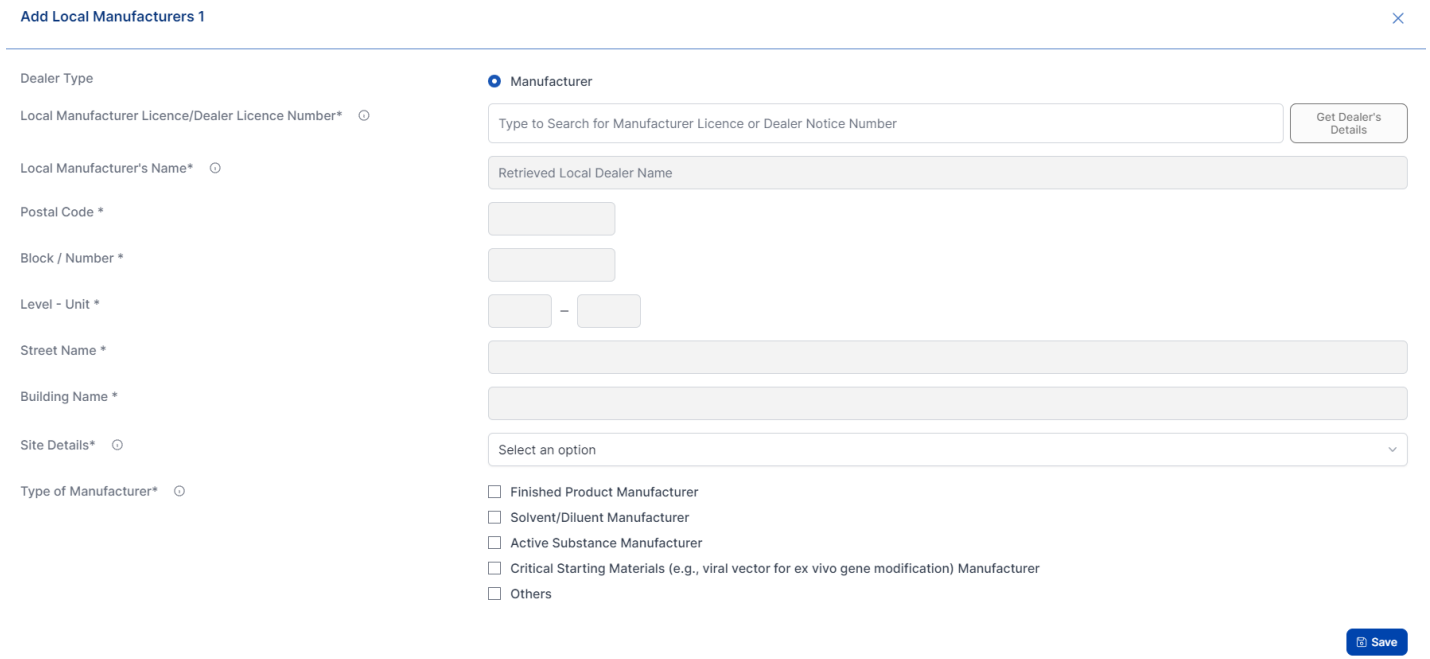
The subsections are not mandatory, but the following requirements must be met:

a. Each component must have at least one finished product manufacturer

b. Each active substance must have at least one active substance manufacturer

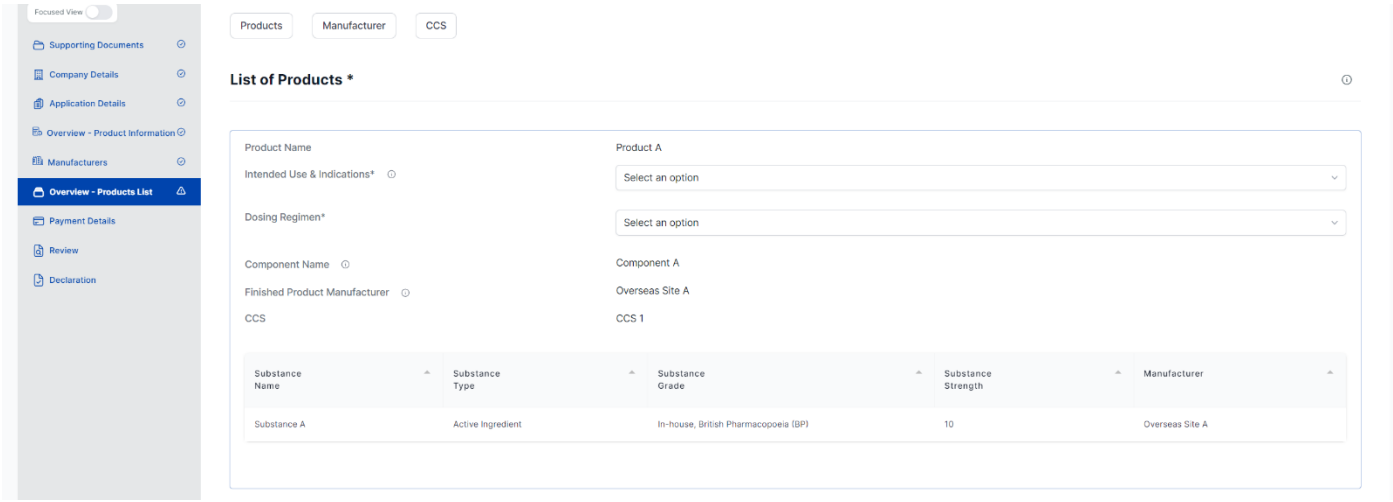
c. Each component must have at least one manufacturer with operation 'Bulk production'

d. Each product must have at least one batch releaser



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

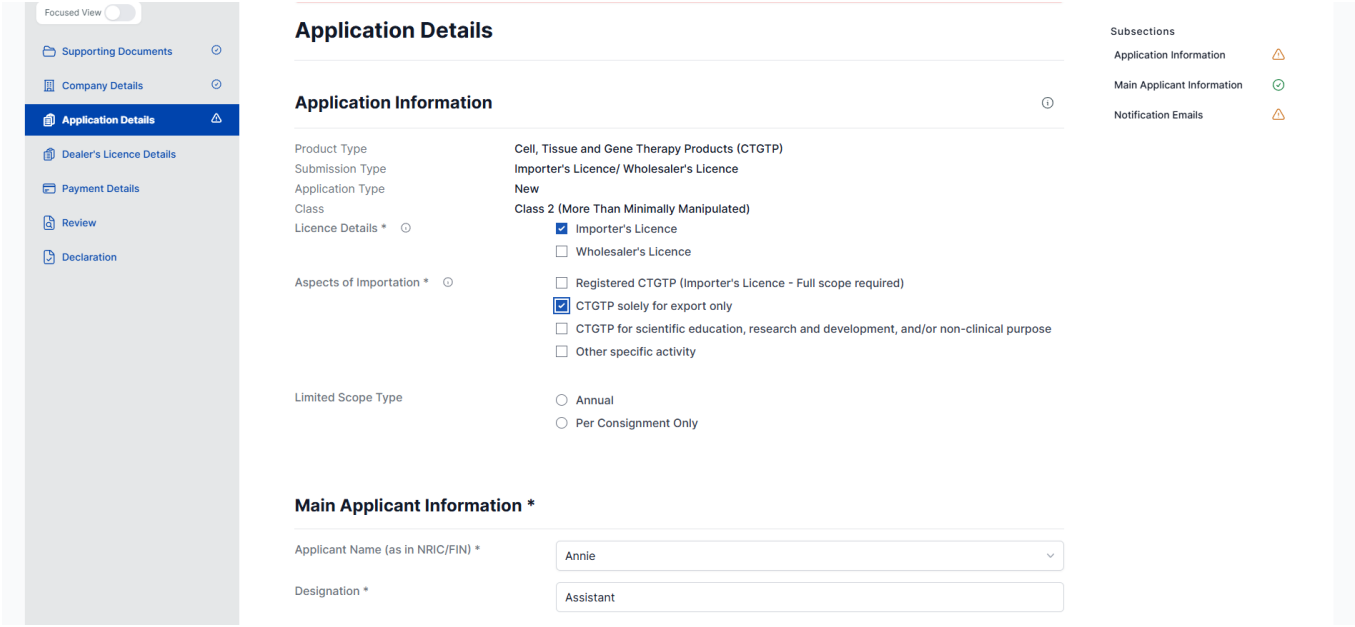
Overview – Products List



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

Importer's Licence/ Wholesaler's Licence

Application Details



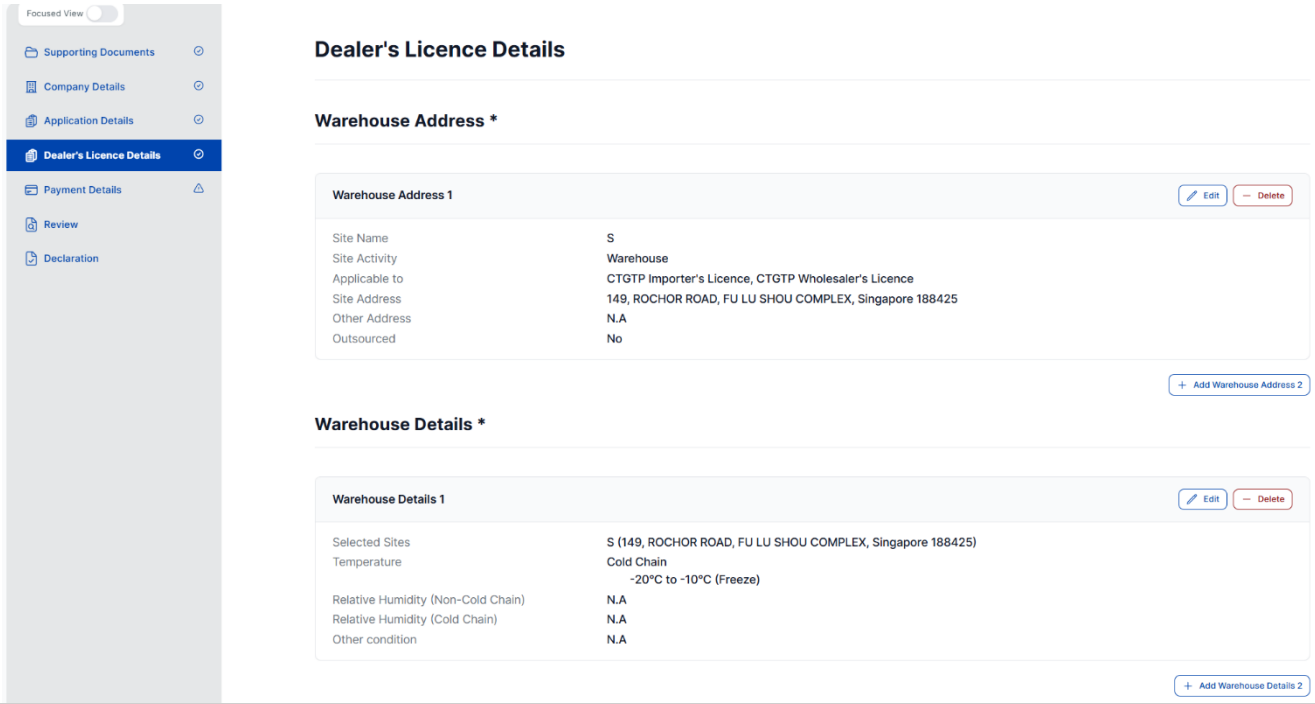
***This section is only applicable for importer's/ Wholesaler's licence applications.**

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

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

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

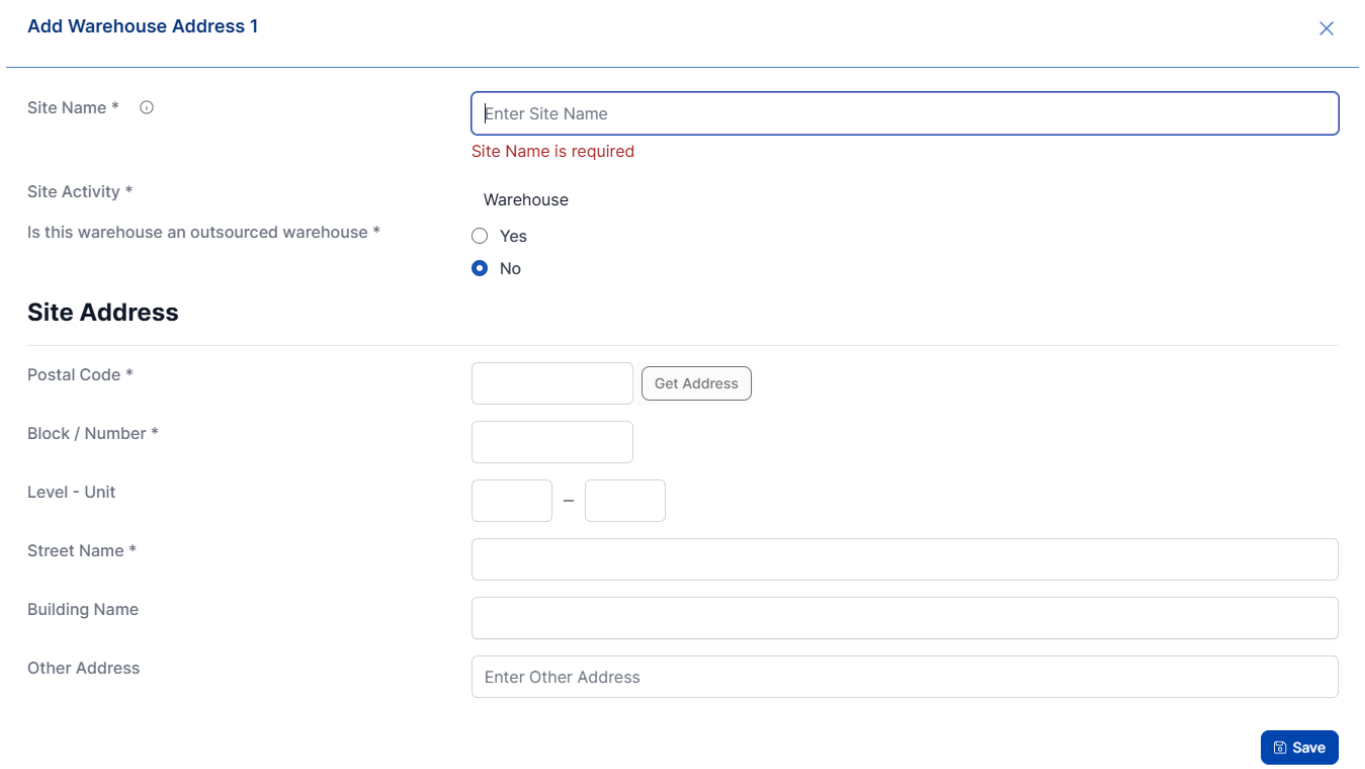
Dealer's Licence Details



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

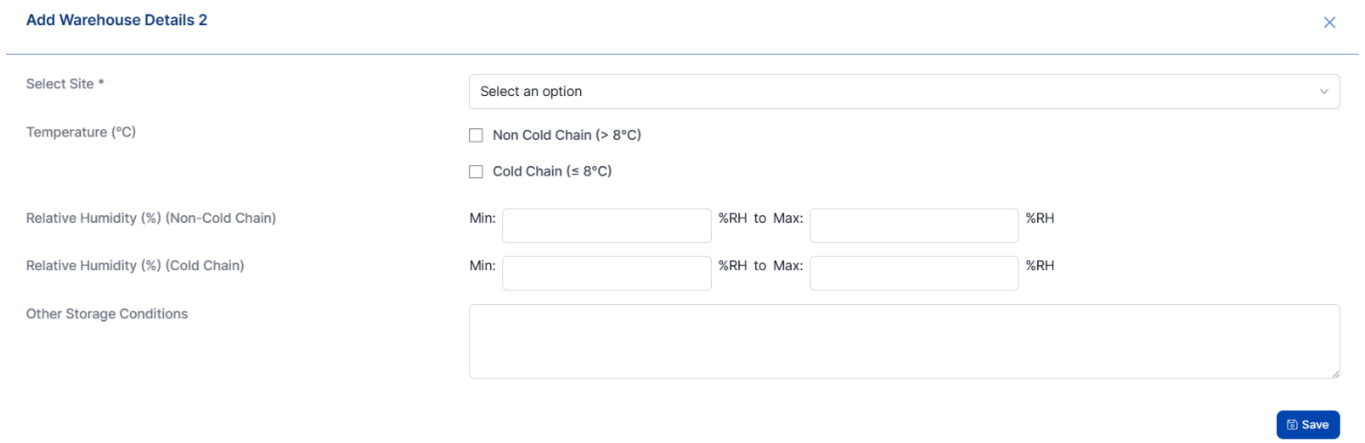
Applicants would be required to fill up the details of at least 1 site and 1 responsible person before proceeding with the application.

Add Warehouse Address



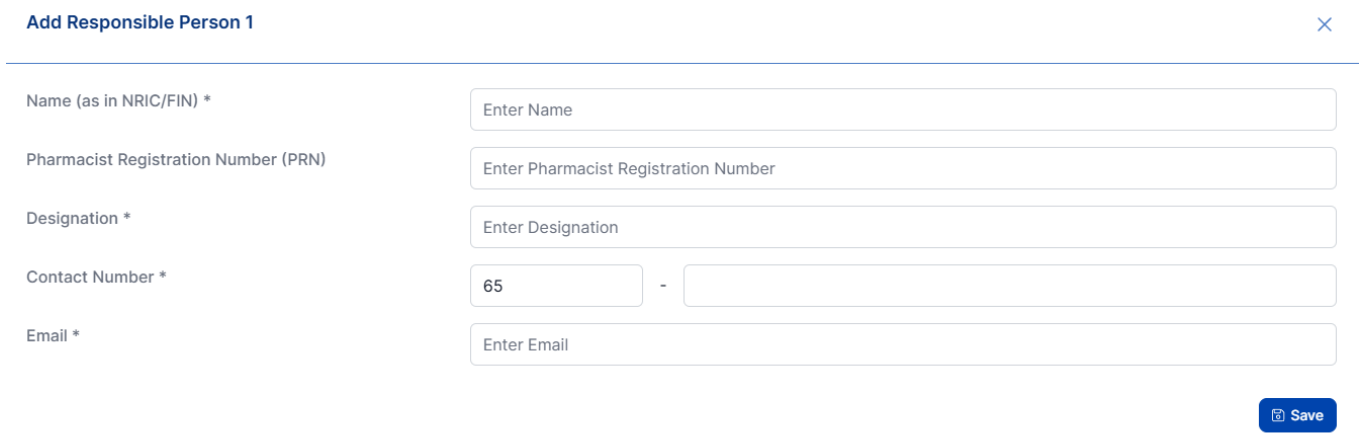
Applicants are required to complete all mandatory fields indicated by '*'.

Add Warehouse Details



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

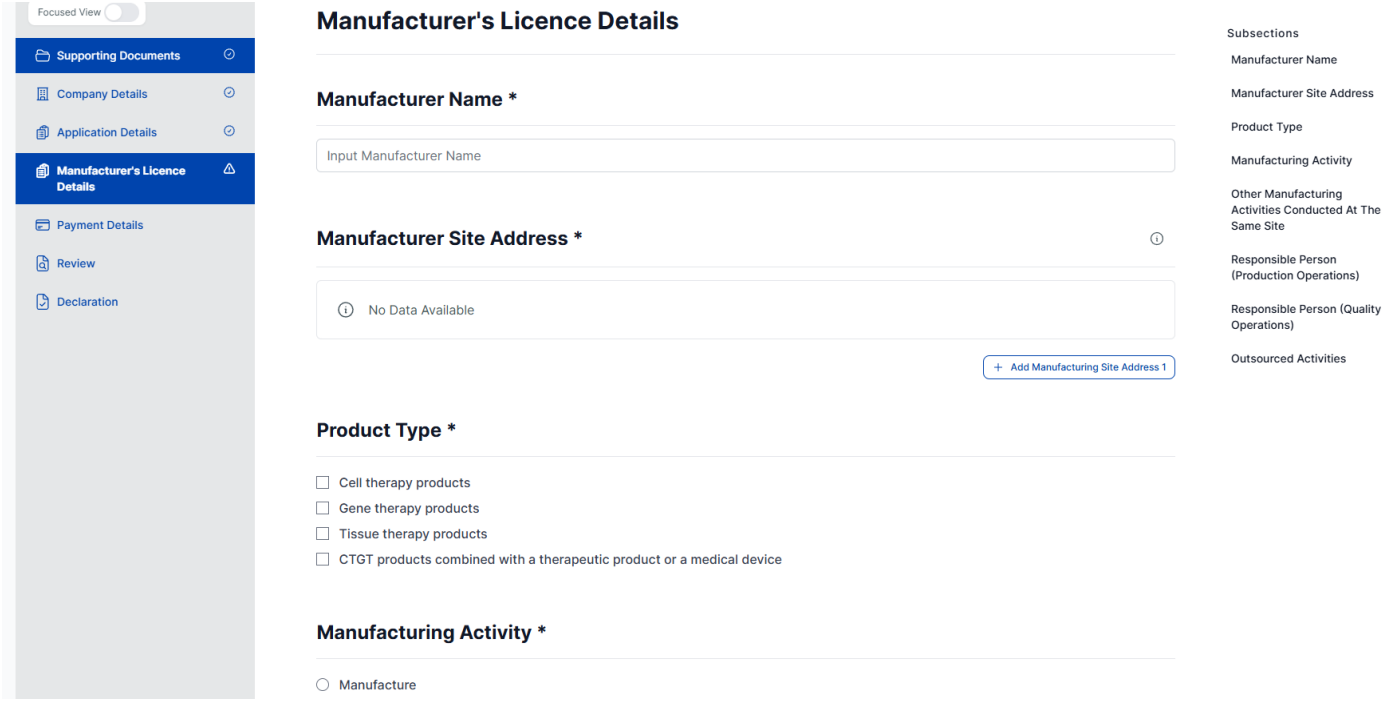
Add Responsible Person



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

Manufacturer's Licence

Manufacturer's Licence Details



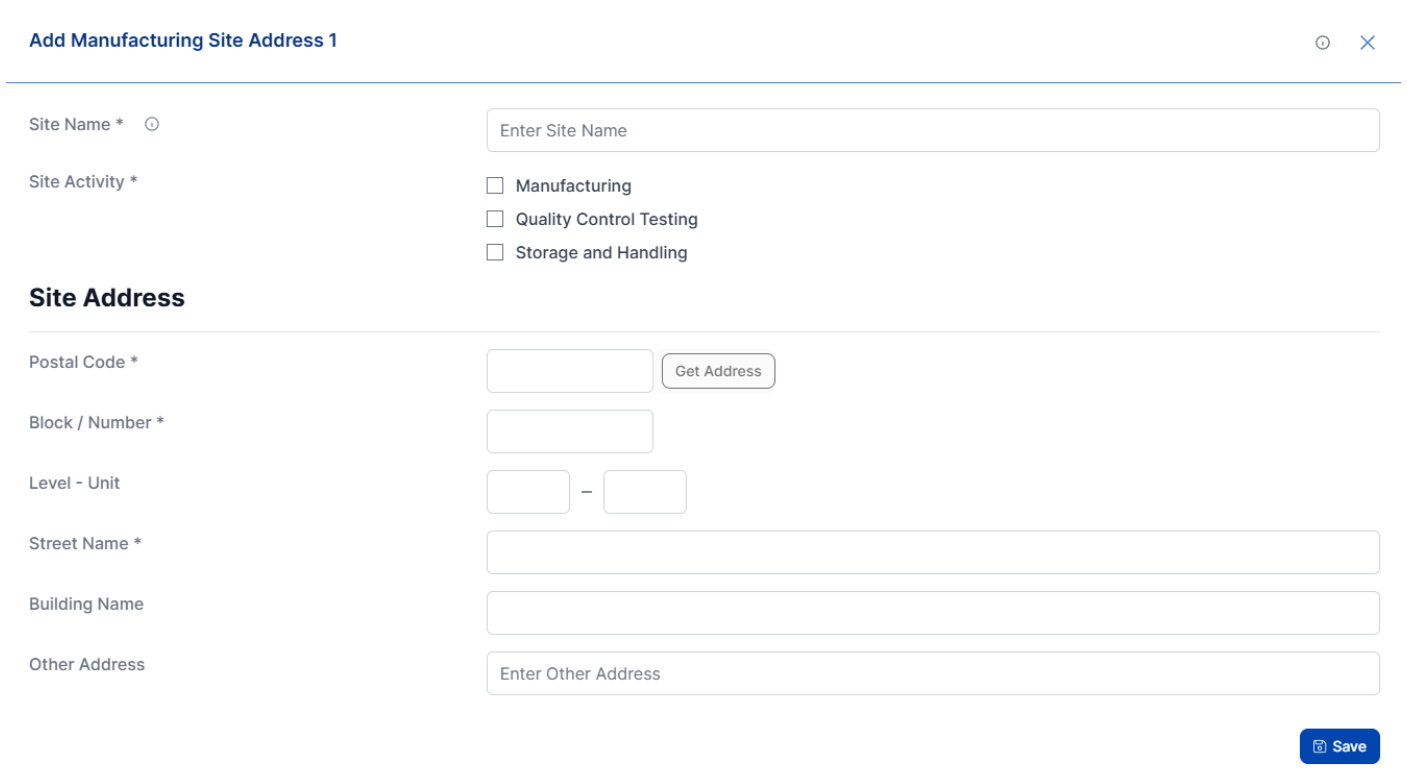
***This section is only applicable for Manufacturer's Licence applications.**

Manufacturer's Licence Details has eight subsections:

a. Manufacturer Name
b. Manufacturer Site Address
c. Product Type
d. Manufacturing Activity
e. Other Manufacturing Activities Conducted At The Same Site
f. Responsible Person (Production Operations)
g. Responsible Person (Quality Operations)
h. Outsourced Activities

All fields are mandatory.

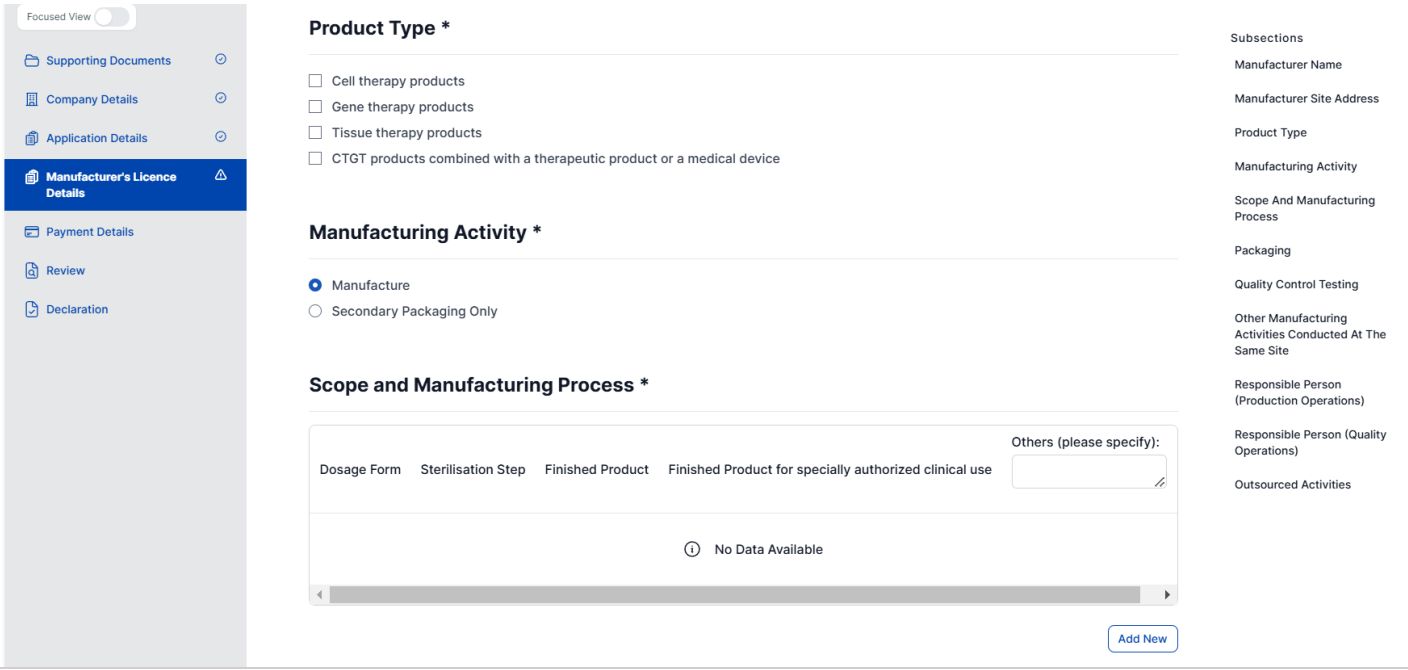
Manufacturer Site Address



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

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

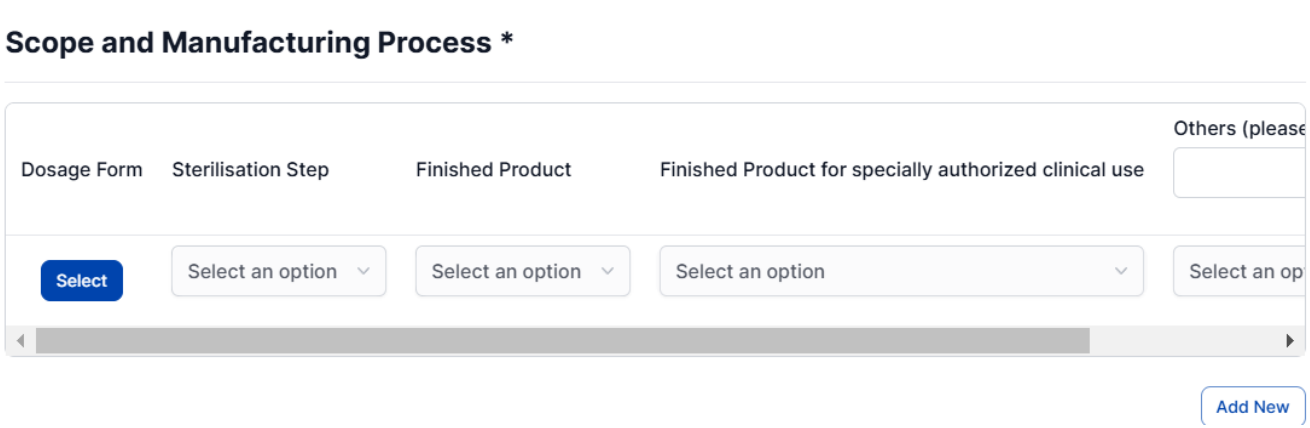
Product Type & Manufacturing Activity



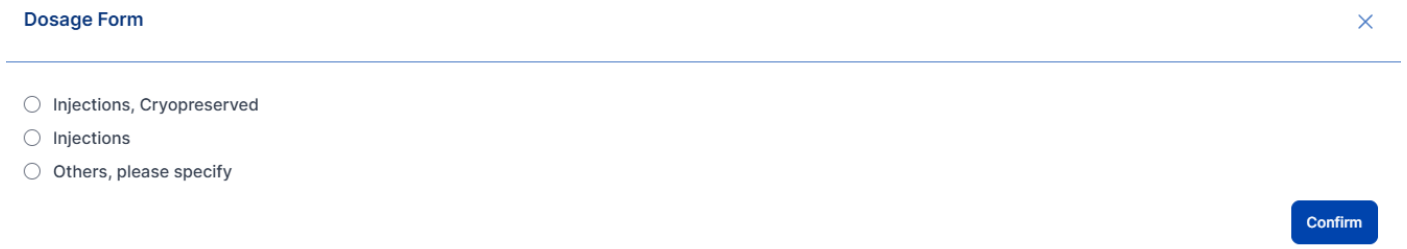
For the Product Type subsection, applicants must select at least one of the four given options, though multiple selections are permitted.

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

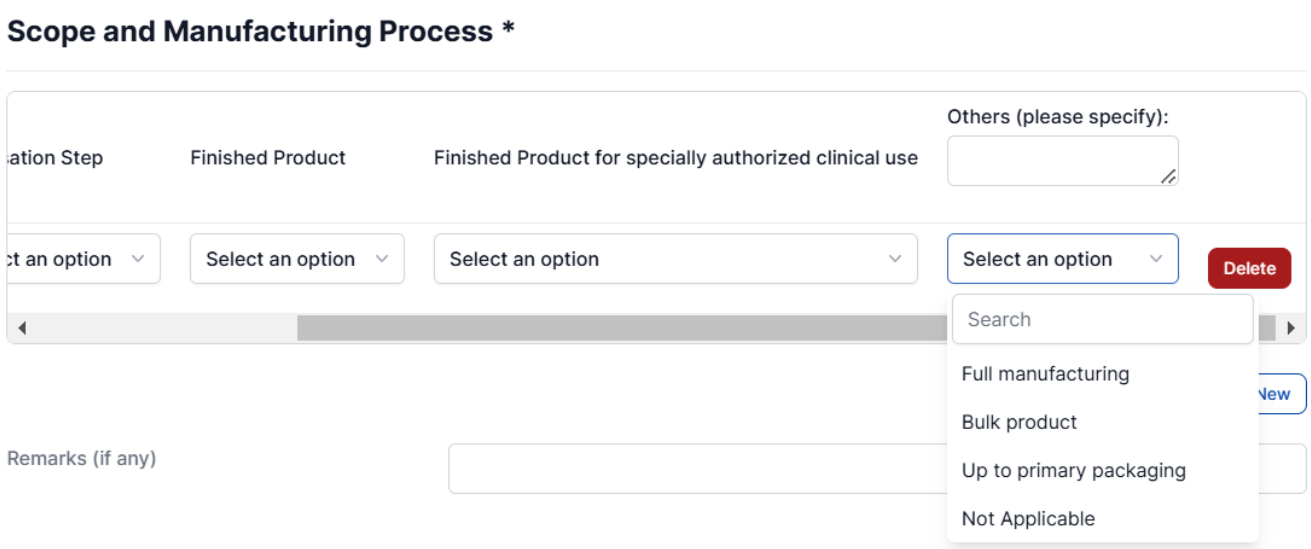
Scope and Manufacturing Process



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



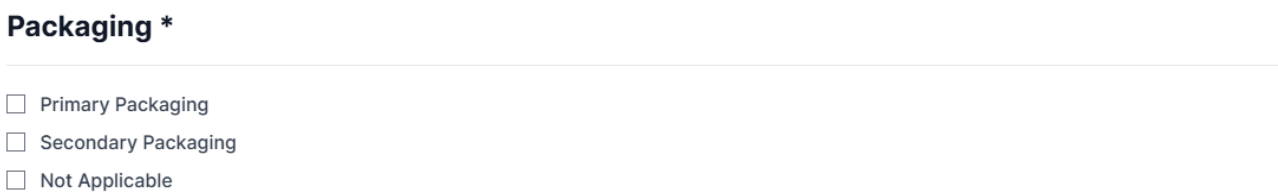
Under **Dosage Form**, applicants must click 'Select' and choose only one of the three available options.



For the fields **Sterilisation Step, Finished Product and Finished Product for specially authorized clinical use**, applicants are required to select one option from the dropdown lists.

In the case of **Others (please specify),** applicants must similarly select one of the given options if needed. Additionally, the text box must be filled up.

Packaging



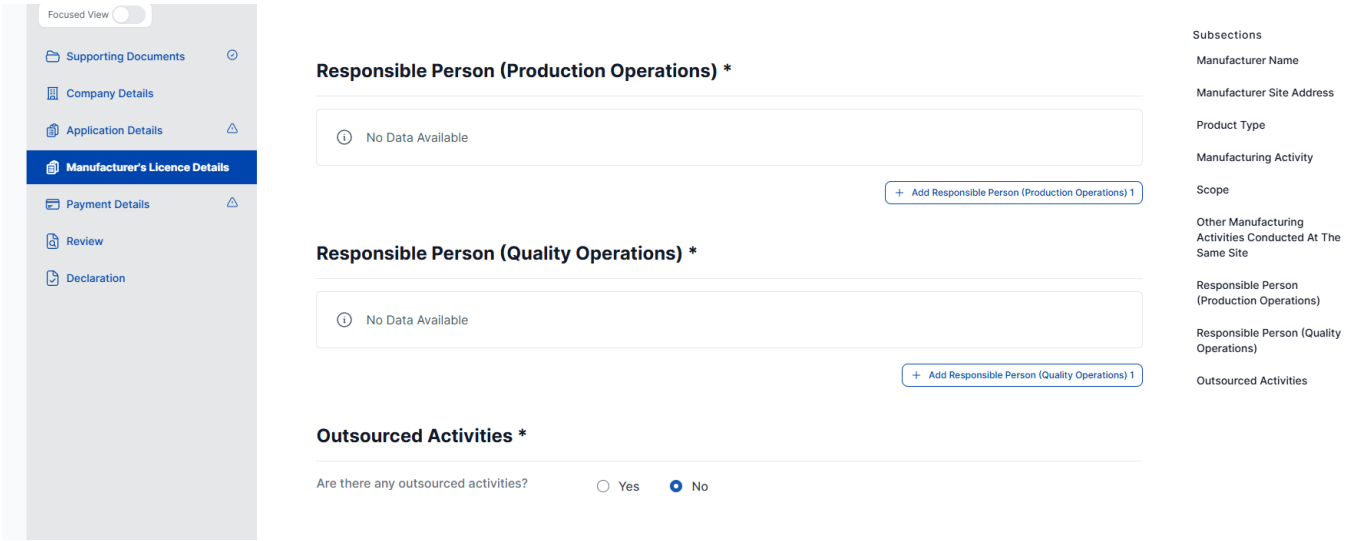
For the Packaging subsection, applicants must select one of the three given options. Multiple selections are permitted but if 'Not Applicable' is selected, it will automatically clear all other selections, and only 'Not Applicable' can be selected.

Quality Control Testing **Quality Control Testing *** ☐ Chemical / Physical ☐ Microbiological ☐ Biological ☐ Not Applicable Remarks (if any)	For the Quality Control Testing subsection, applicants must select one of the four given options. Multiple selections are permitted but if 'Not Applicable' is selected, it will automatically clear all other selections, and only 'Not Applicable' can be selected. The Remarks text box is not mandatory and can be left blank.

Scope **Scope *** ☐ Finished Product ☐ Finished product for specially authorized clinical use ☐ Others (please specify):	For the Scope subsection, applicants must select one of the three given options. Multiple selections are permitted. If 'Others' is selected, a mandatory text box will appear, which applicants must fill out.

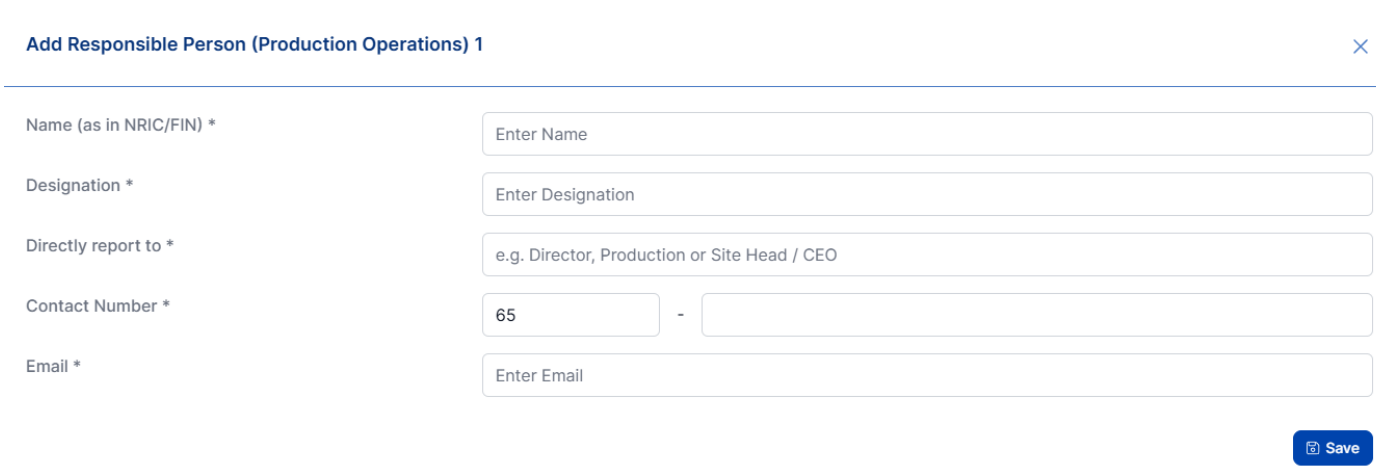
Other Manufacturing Activities Conducted at the Same Site **Other Manufacturing Activities Conducted at the Same Site *** ☐ Manufacture of investigational CTGT products ☐ Manufacture involving starting materials, viral vectors or viruses ☐ Manufacture of pathogenic organisms (biosafety level 3 and 4) ☐ Others (please specify): ☐ Not Applicable	For this subsection, applicants must select one of the five given options. Multiple selections are permitted but if 'Not Applicable' is selected, it will automatically clear all other selections, and only 'Not Applicable' can be selected. Additionally, if 'Others' is selected, a mandatory text box will appear, which applicants must fill out.

Responsible Person



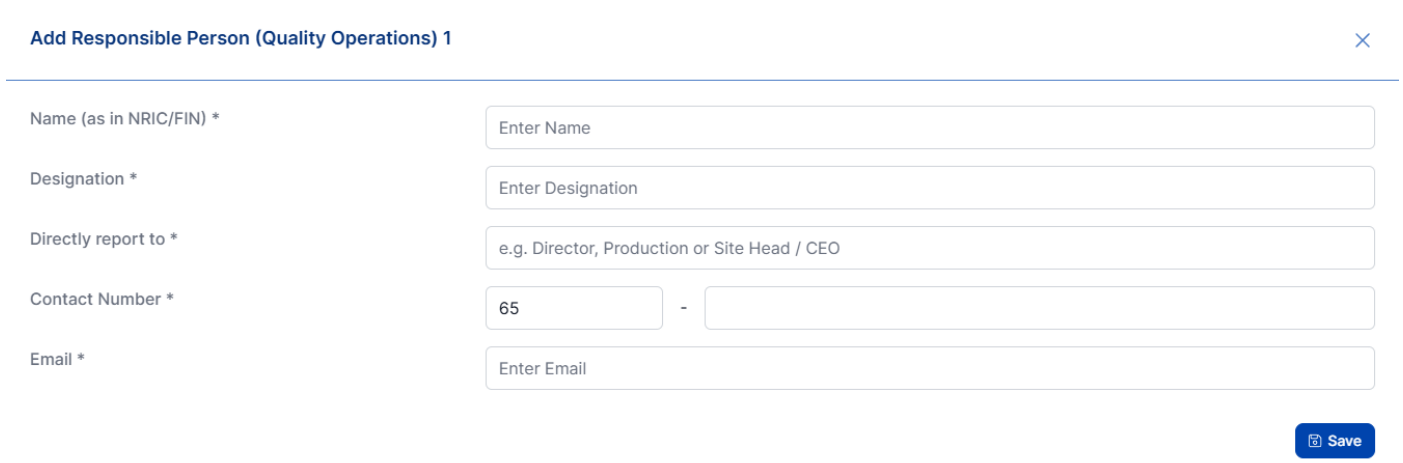
Applicants need to input the particulars of at least 1 responsible person each (for production operations and quality operations respectively) by clicking on **'+ Add Responsible Person (Production Operations)'** and **'+ Add Responsible Person (Quality Operations)'** buttons.

Add Responsible Person (Production Operations)



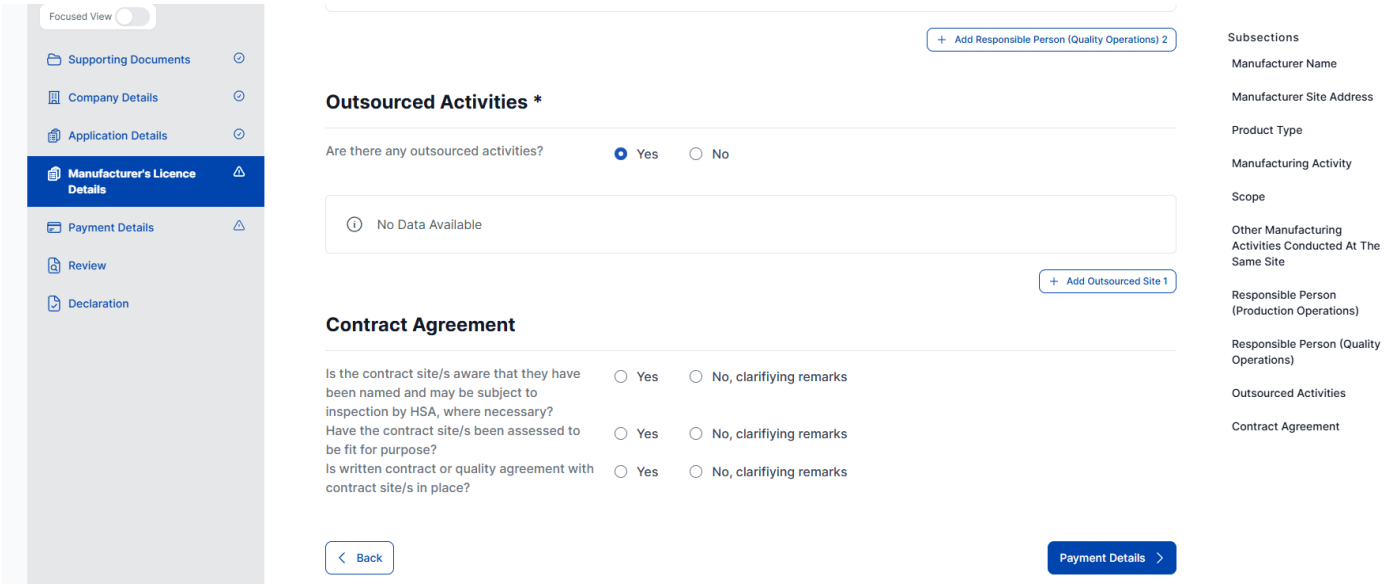
Applicants are required to complete all mandatory fields indicated by '*'.

Add Responsible Person (Quality Operations)



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

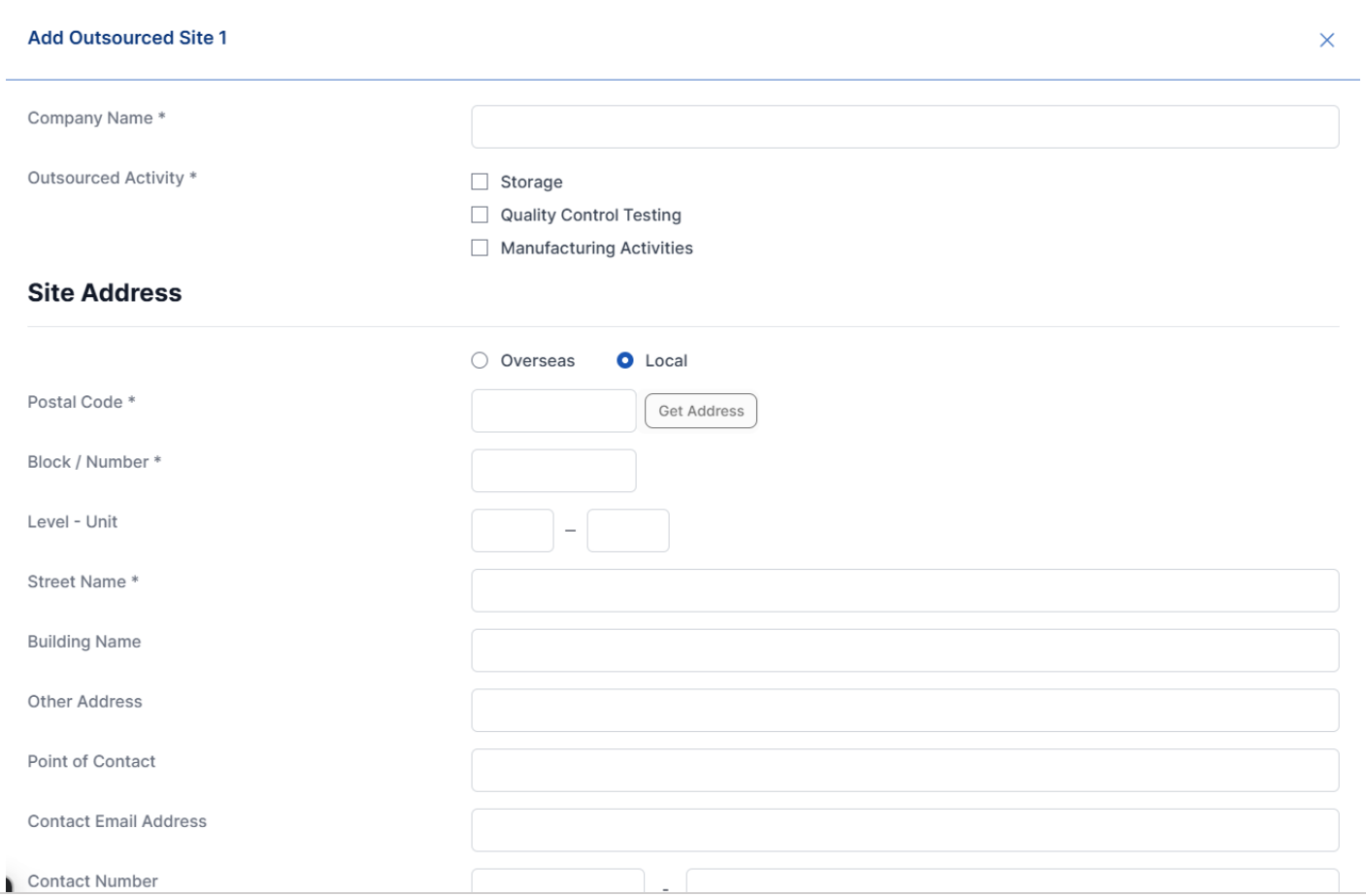
Outsourced Activities



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

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

Add Outsourced Site

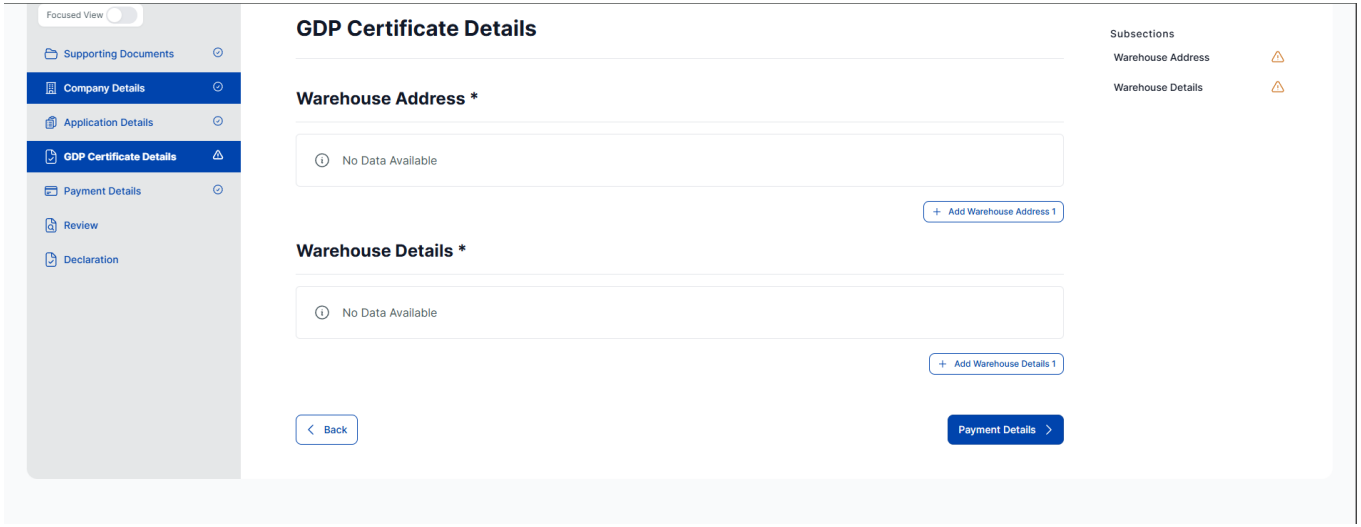


Applicants are required to complete all mandatory fields indicated by '*'.

For continuation of Manufacturer's Licence applications, please refer to Payment Details section.

GDP Certificate

GDP Certificate Details



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

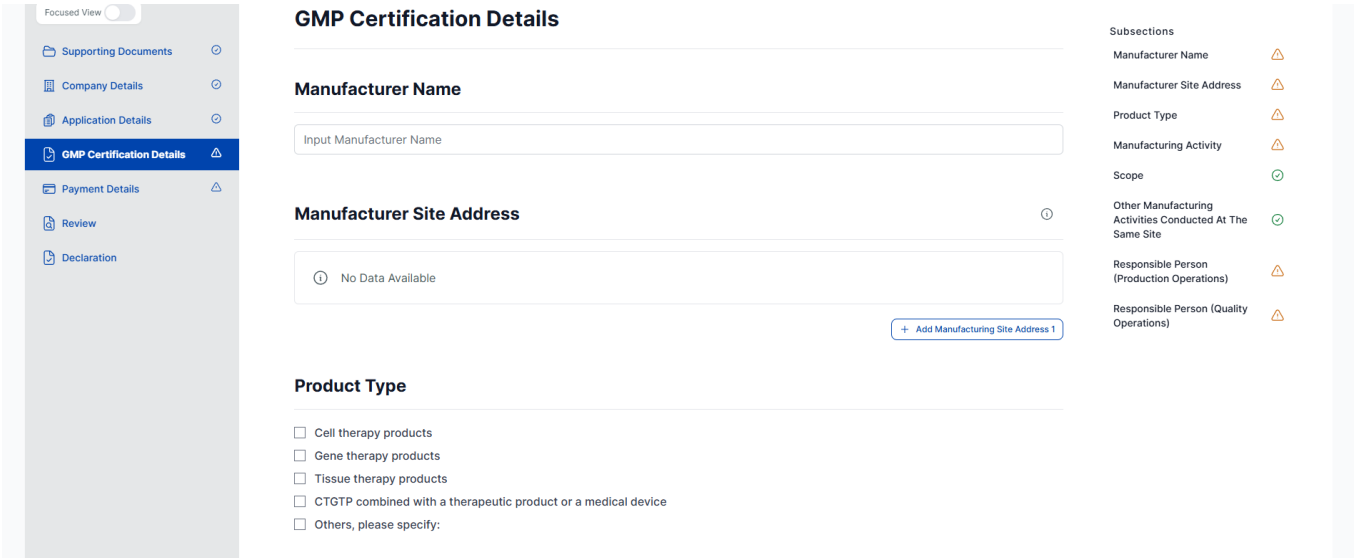
Applicants need to input site particulars for their GDP Certificate by clicking on **'+ Add Warehouse Address'** and **'+ Add Warehouse Details'** buttons.

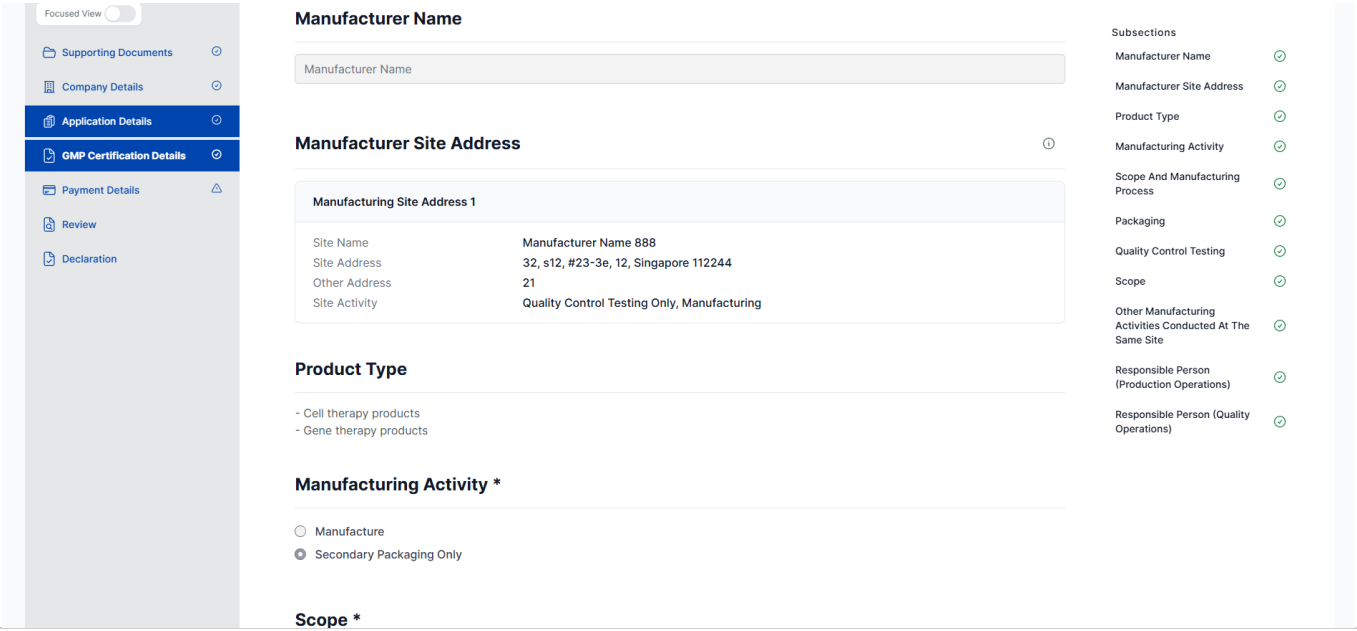
Applicants would be required to fill up the details of at least 1 site before proceeding with the application.

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

GMP Certificate

GMP Certificate Details





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

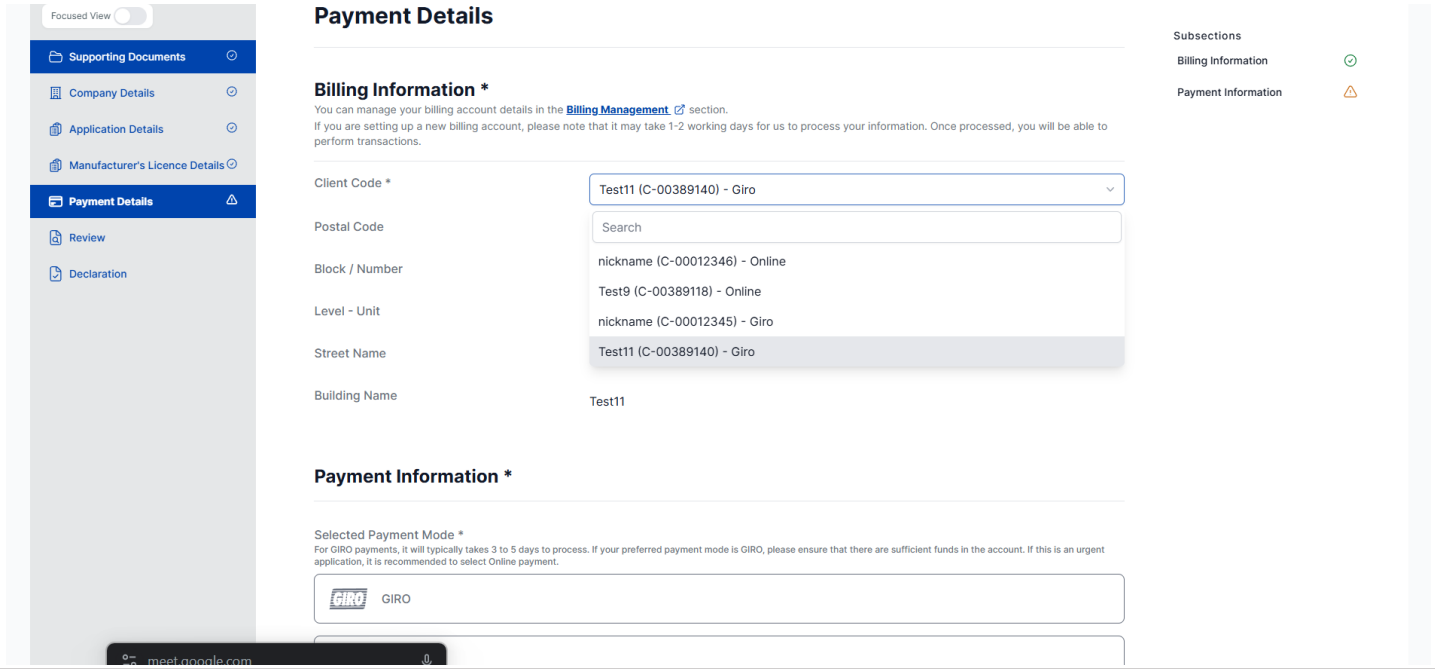
GMP Certificate Details has seven subsections:

a. Manufacturer Name
b. Manufacturer Site Address
c. Product Type
d. Manufacturing Activity
e. Other Manufacturing Activities Conducted At The Same Site
f. Responsible Person (Production Operations)
g. Responsible Person (Quality Operations)

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

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

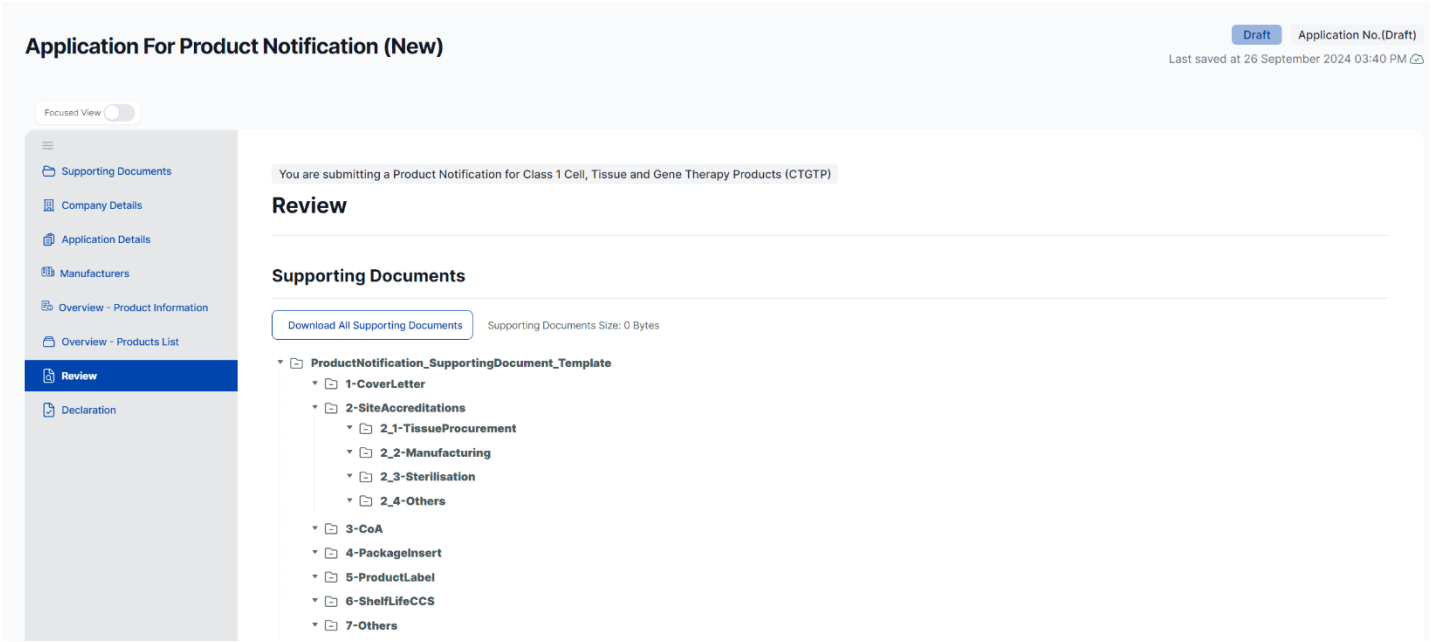
4.1.4 Payment Details



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

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

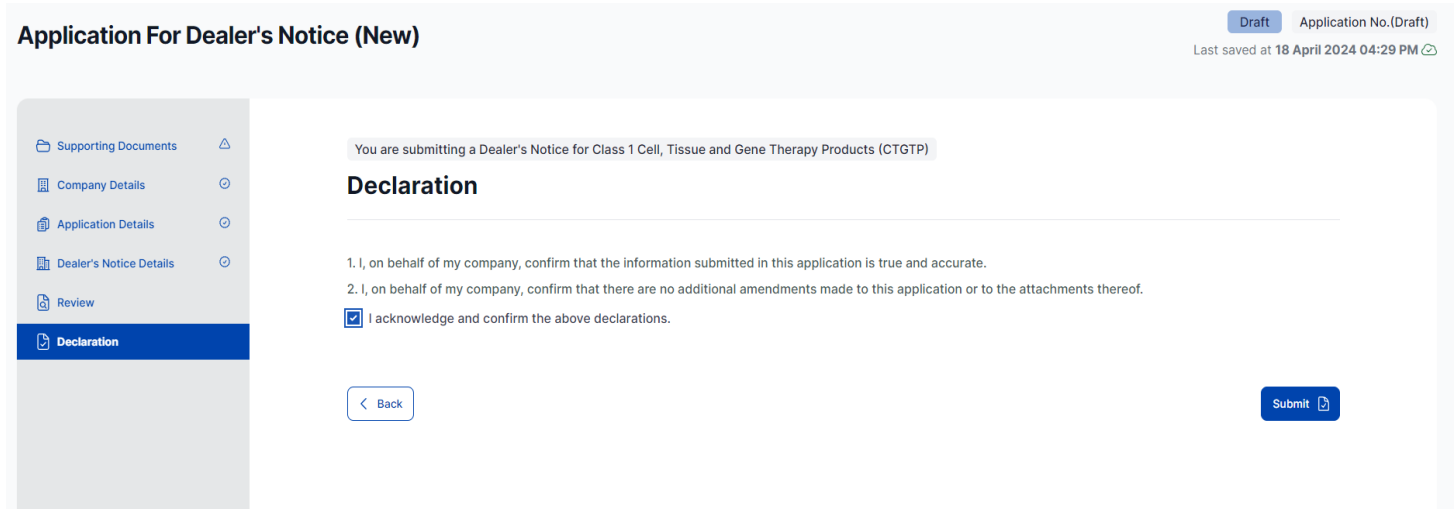
4.1.5 Review



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

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

4.1.6 Declaration



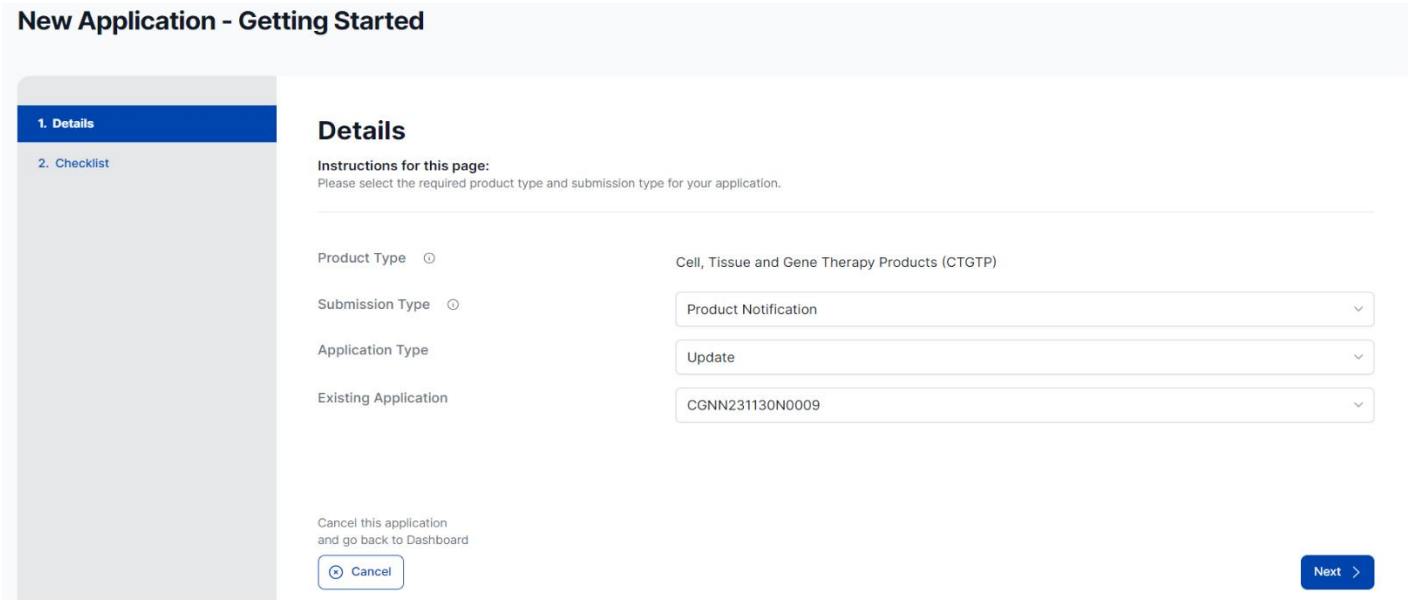
For all new and updated applications, Applicants would be required to complete the declaration before submission.

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

4.2 Creation of Update Application

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

Update Application – Getting Started (i)

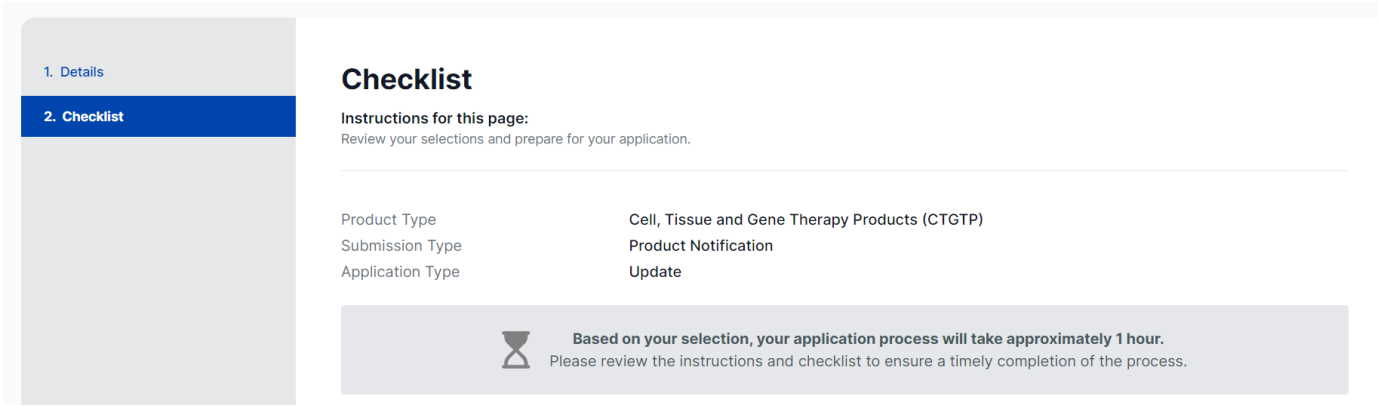


For all closed applications with submission type 'Product Notification' or 'Dealer's Notice', applicants can submit an update application. For closed application with submission type 'Product Registration', applicants can submit a variation application.

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')

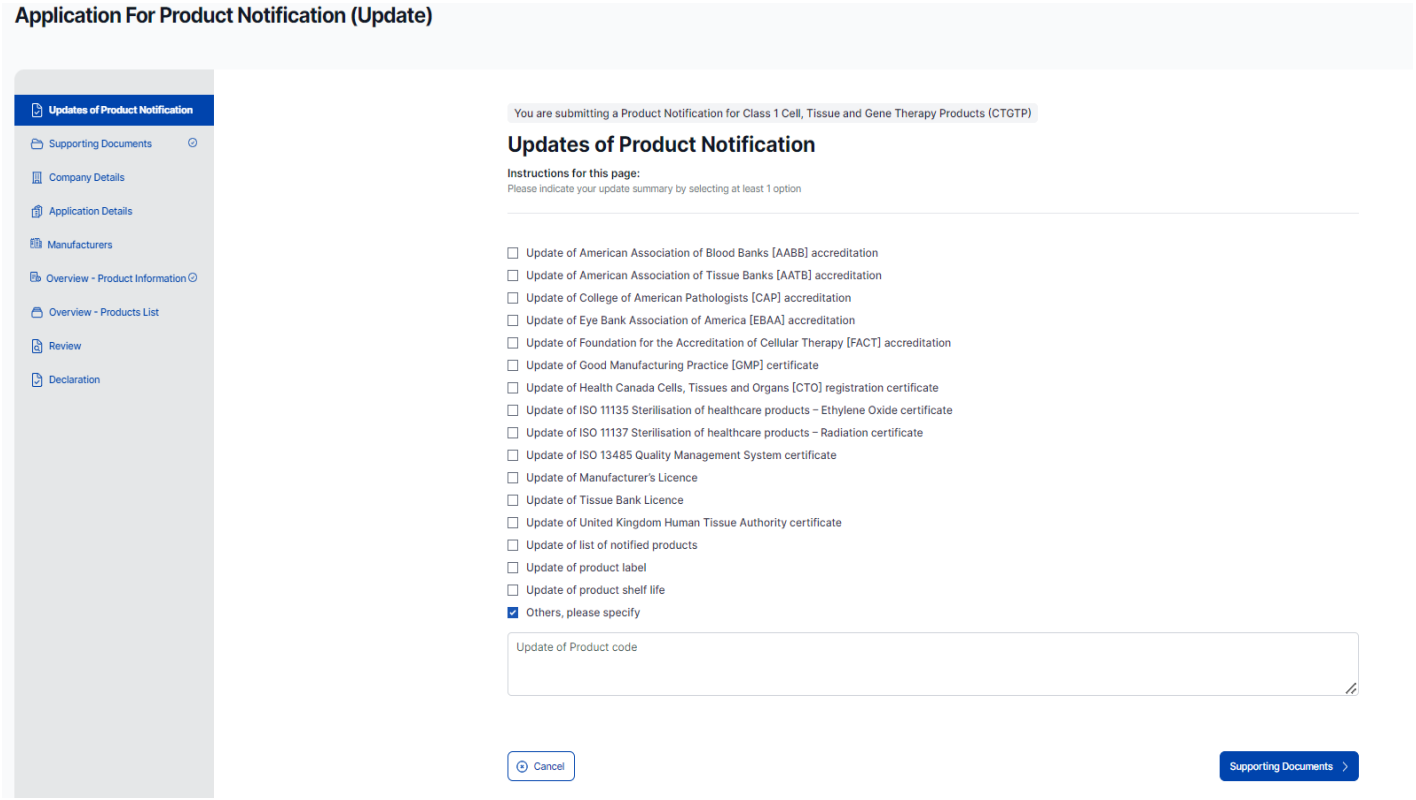
Update Application – Getting Started (ii)



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

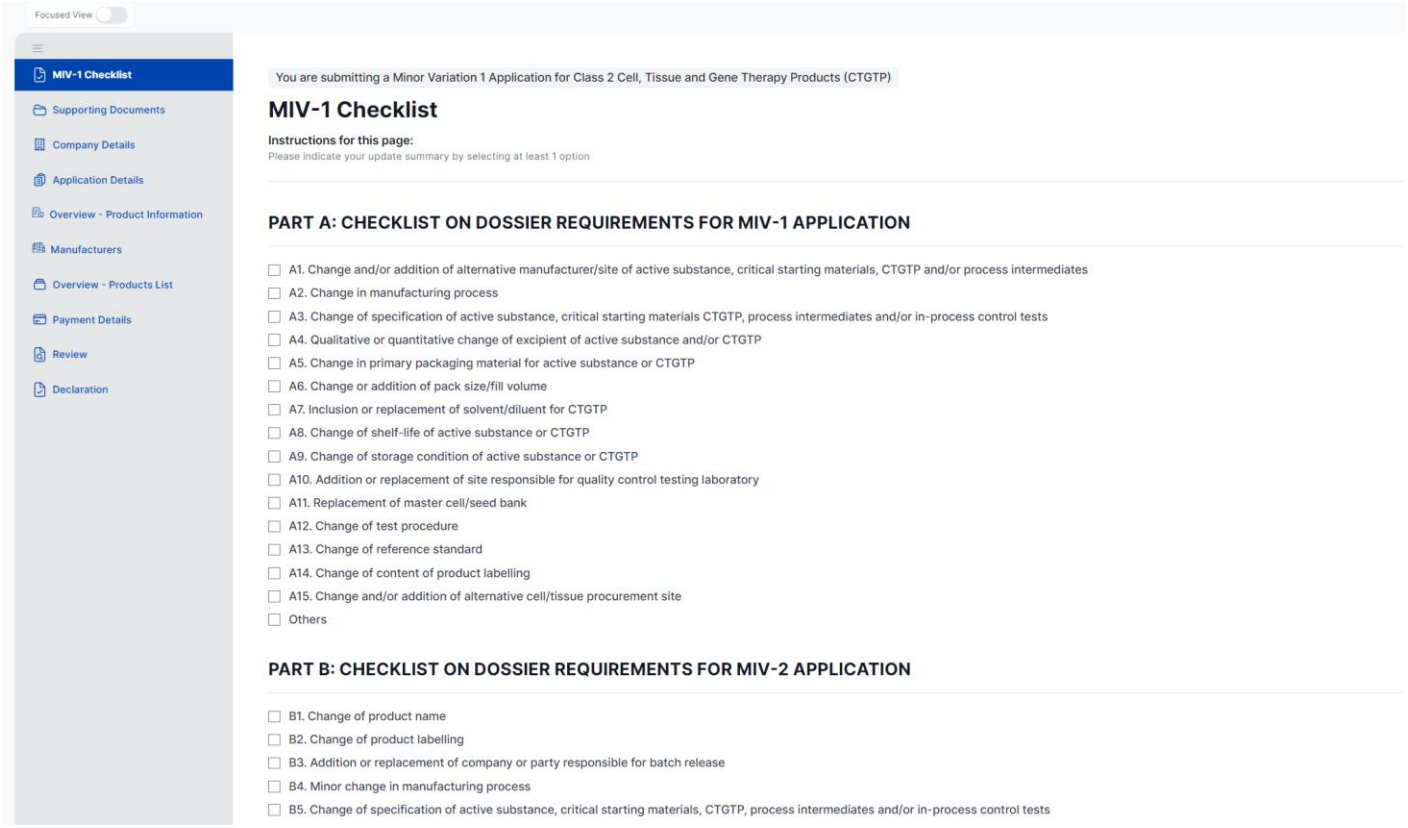


***This section is only applicable for Updates of Product Notification applications.**

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.

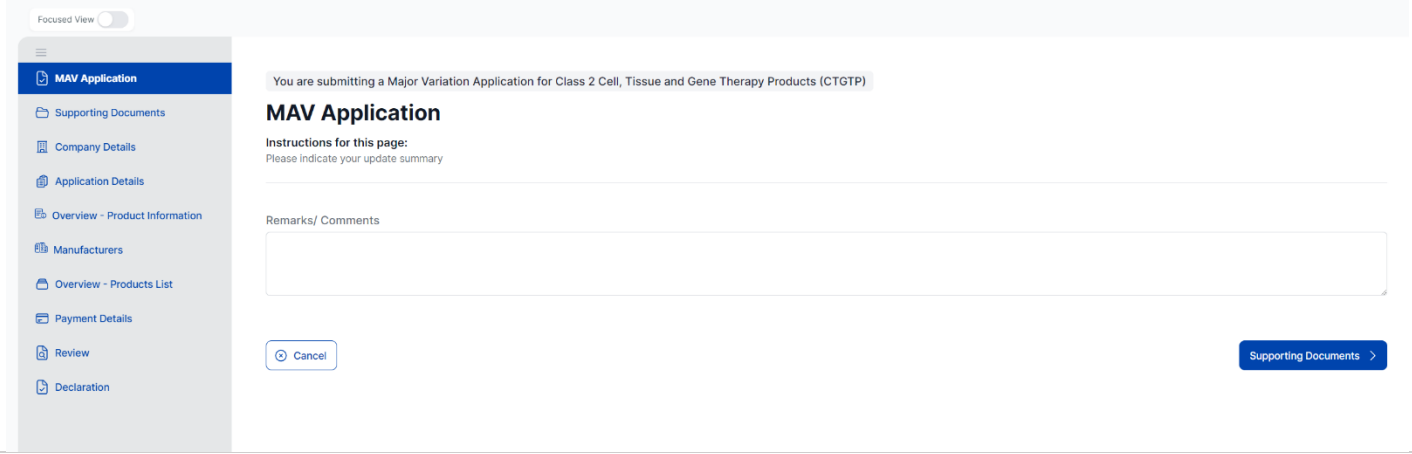
Variation Application

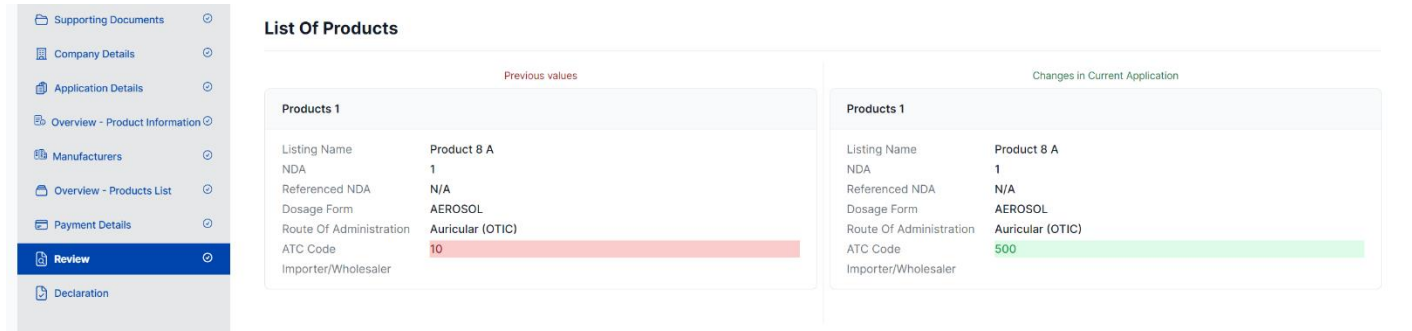


***This section is only applicable for variation applications for Product Registration applications.**

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.



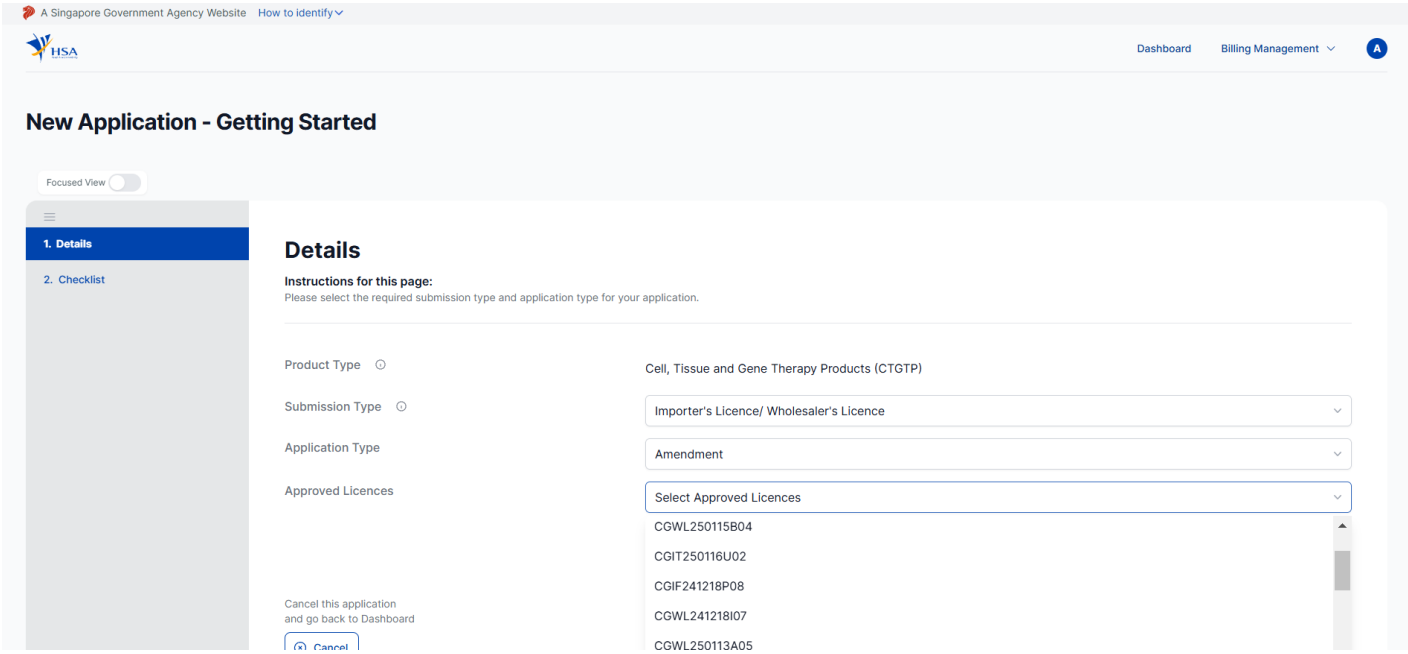


The review section will display the changes between the Previous values and changes in the variation application.

4.3 Creation of Amendment Application

For applicants that want to amend an approved licence.

Amendment Application – Getting Started (i)

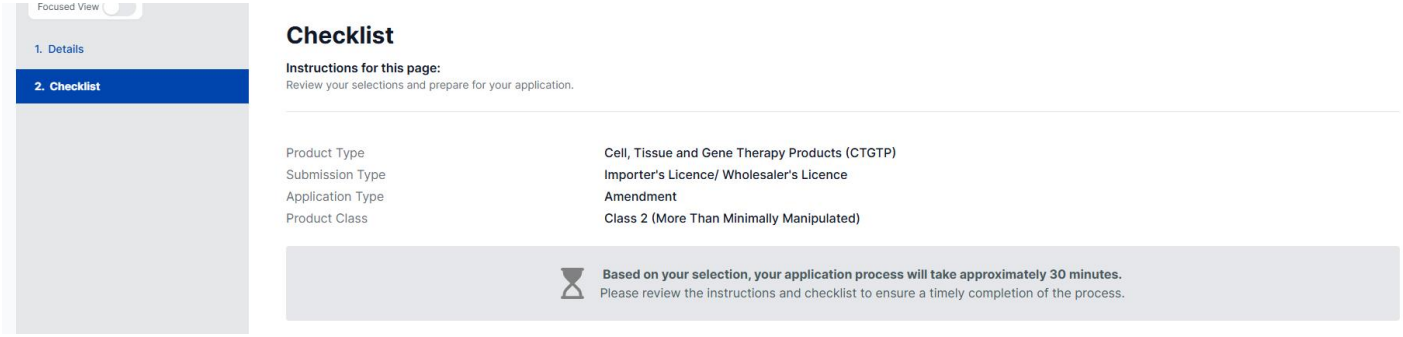


For all closed applications with submission type 'Importer's Licence/ Wholesaler's Licence' or 'Manufacturer's Licence', applicants can submit an amendment application.

Submission Type: Importer's Licence/ Wholesaler's Licence **OR** Manufacturer's Licence.
Application Type: Amendment

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

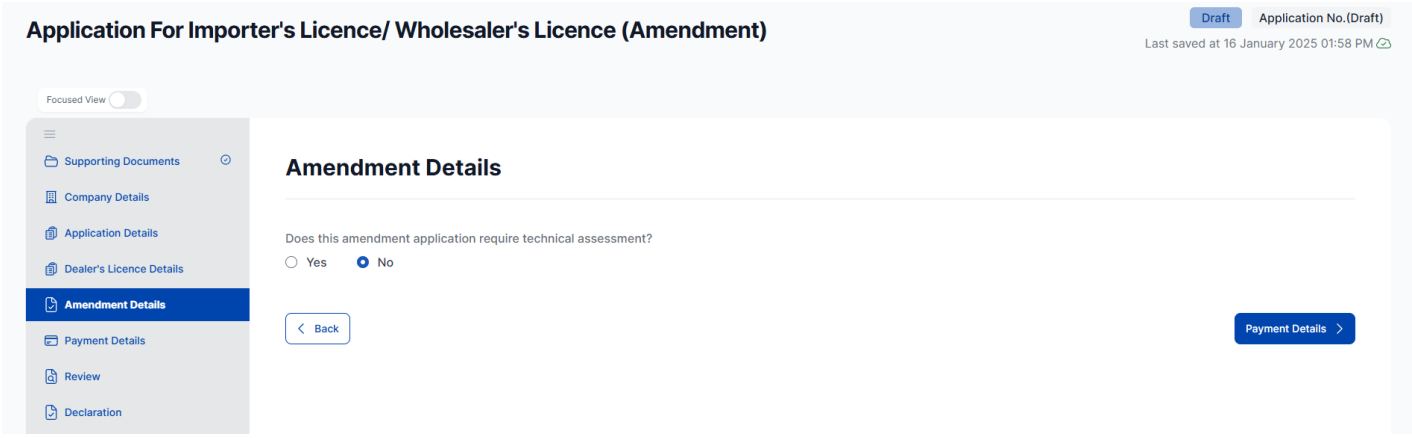
Amendment Application – Getting Started (ii)



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

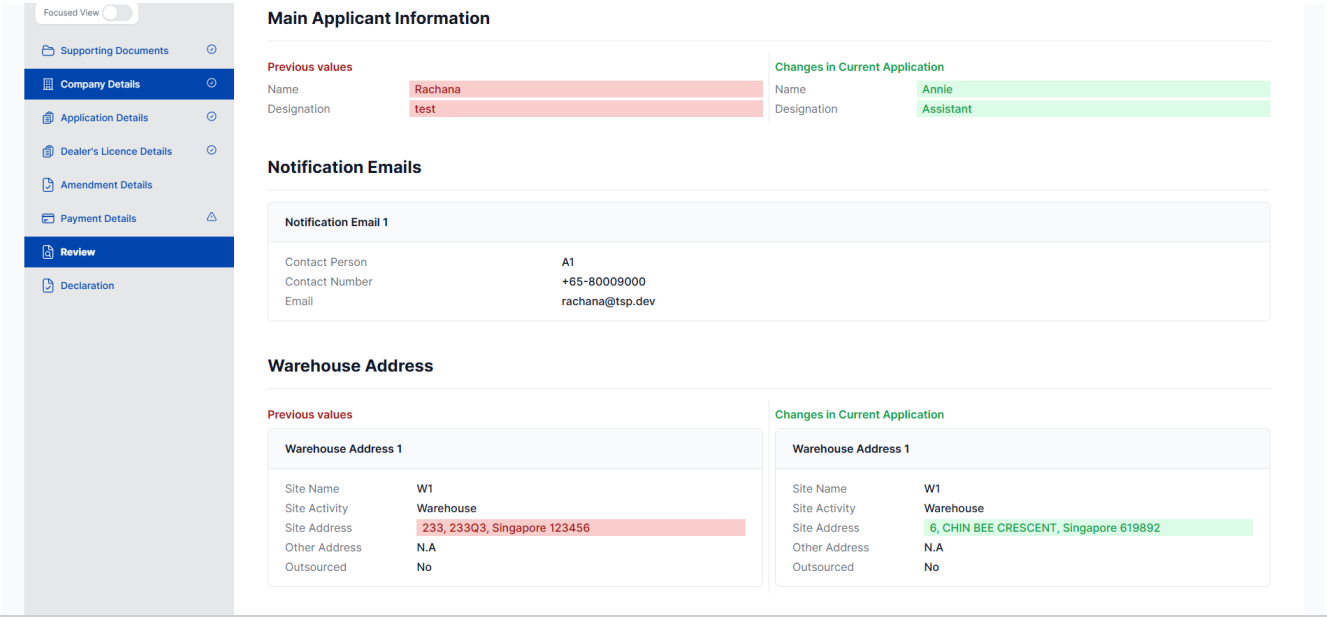
Note: Information on this page may differ depending on the Submission Type & Application Type selected by Applicants.

Amendment Details



Applicants will have to answer the question based on the changes they want to make for the application.

Note: The previous pages for both Importer's Licence/Wholesaler's Licence and Manufacturer's Licence remain consistent with the pages used during the creation of a new application.



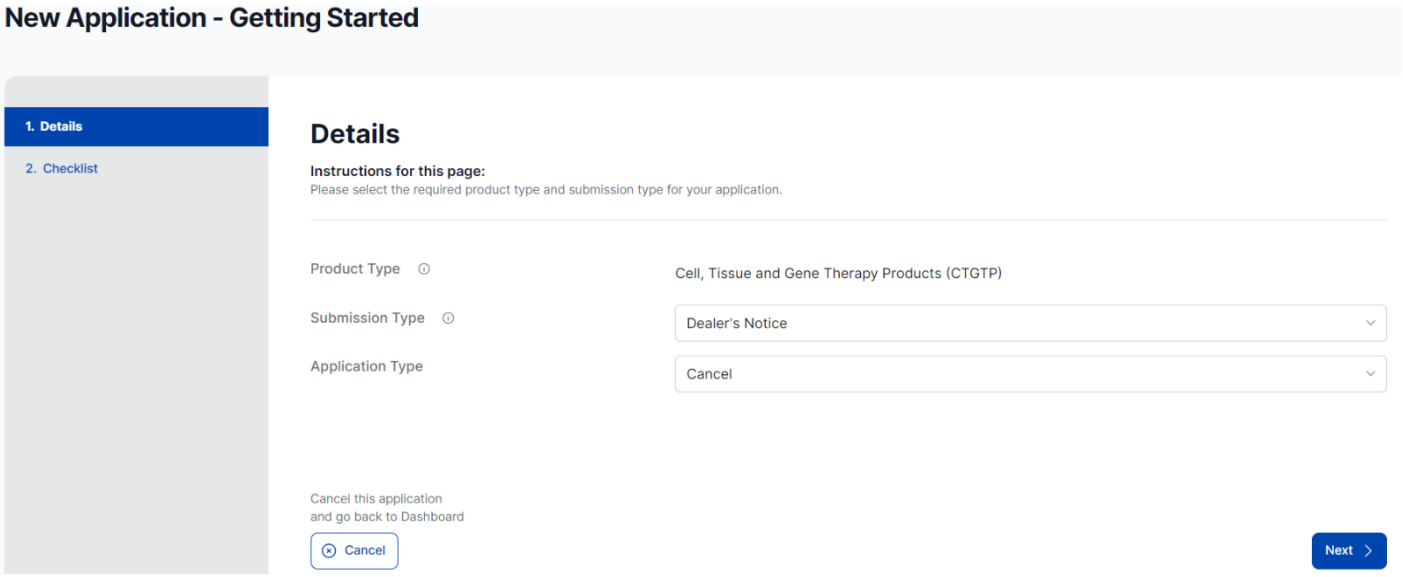
The review section will display the changes between the Previous values and changes in the amendment application.

5 Cancellation of Products, Licences, or Notices

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

Dealer's Notice

Cancel Dealer's Notice – Getting Started (i)

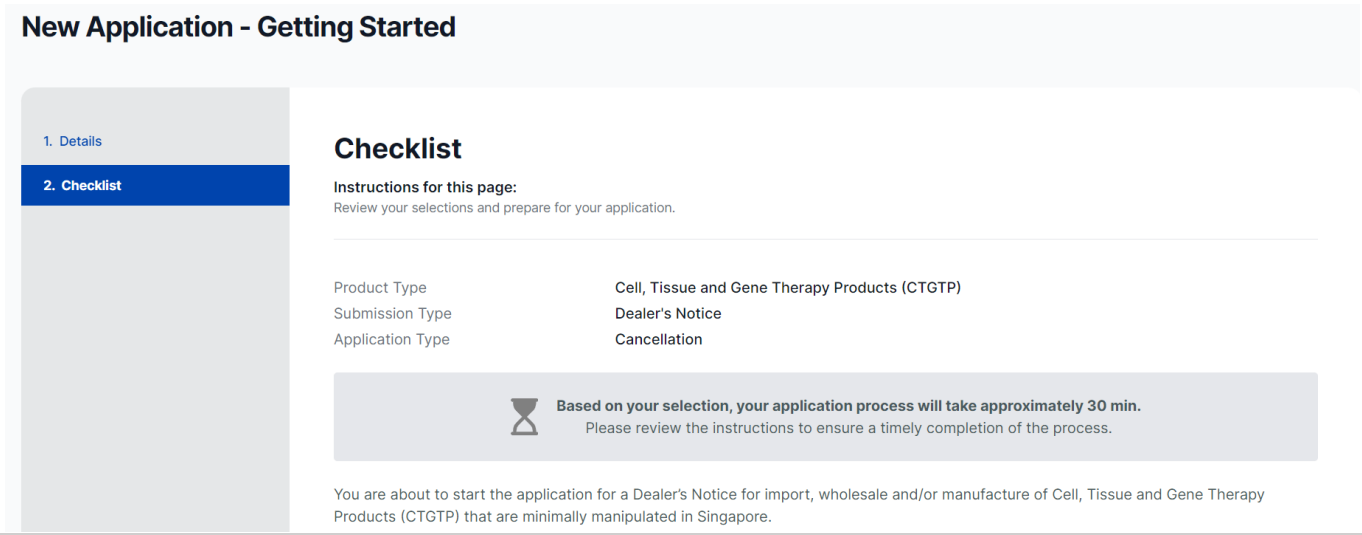


Applicants will populate the following fields in a manner similar to the process of creating a new application.

- Submission type
- Application type

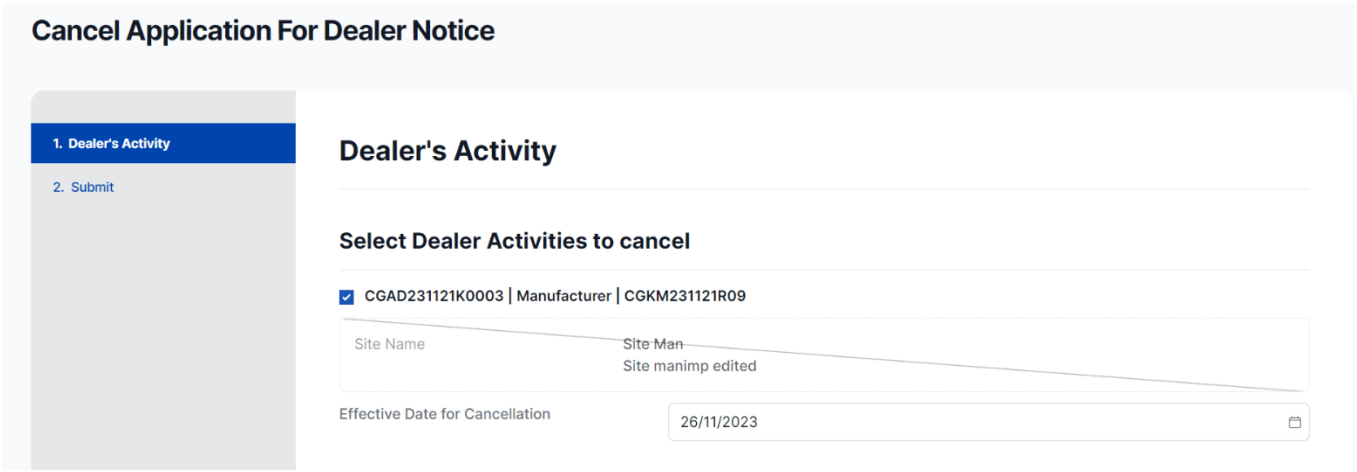
Choose the required submission type, application type(cancel) and click on Next, which redirects to checklist page

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.

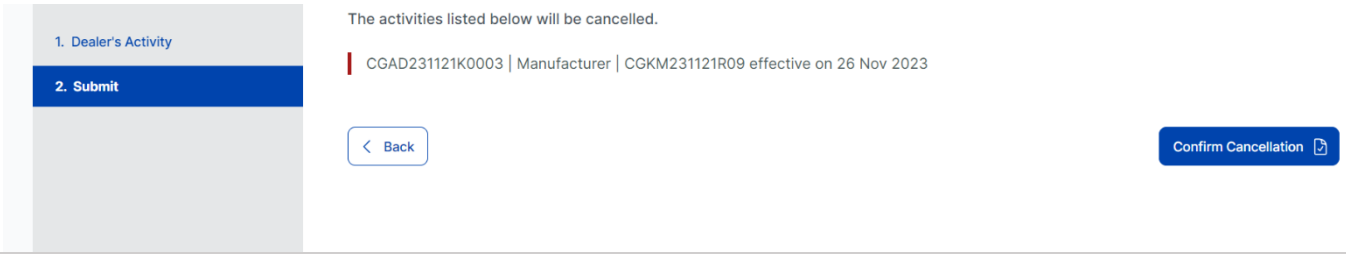


Applicants can choose the required Dealer's Activity they want to cancel.

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.

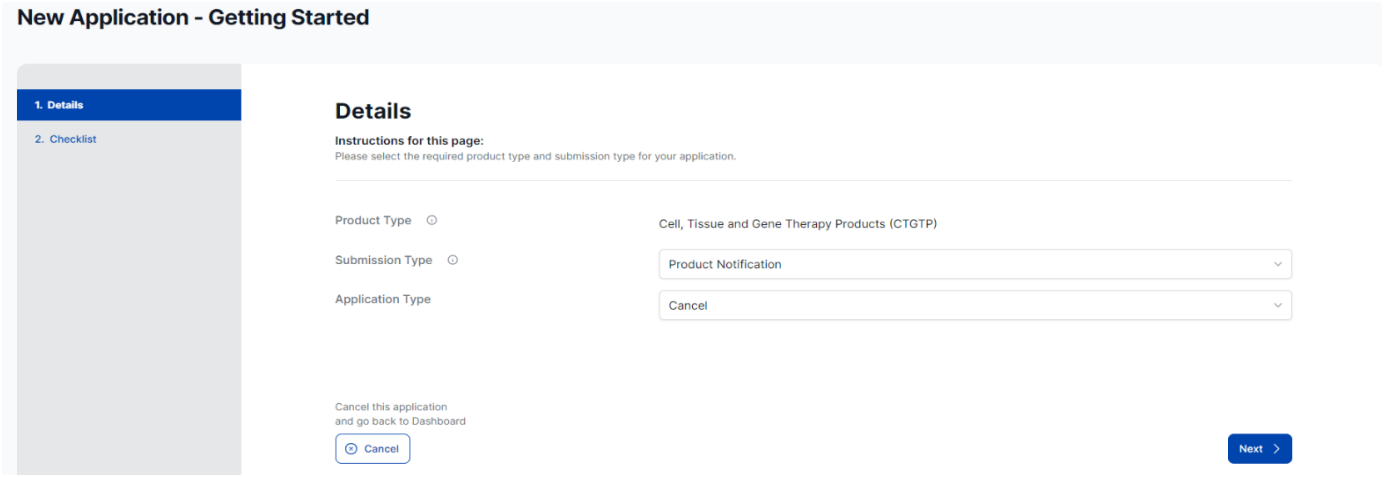
Cancel Dealer's Notice – Submit



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

Product Notification

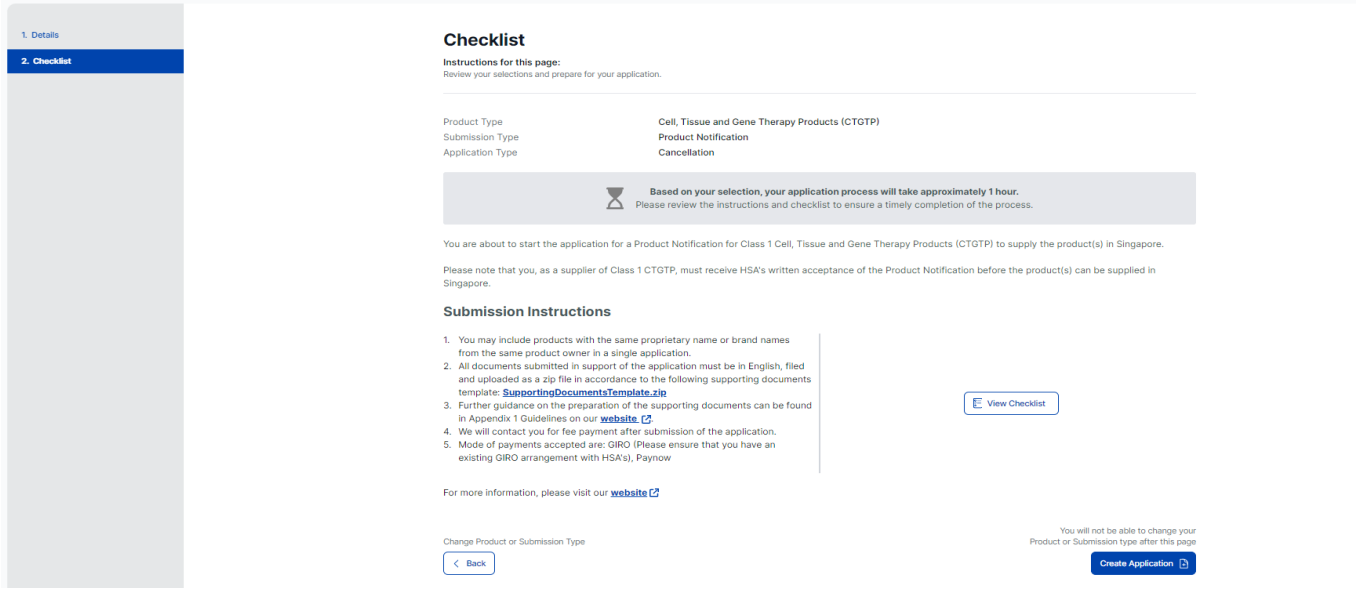
Cancel Product Notification – Getting Started (i)



Applicants will populate the following fields in a manner similar to the process of creating a new application.

- Submission type
- Application type

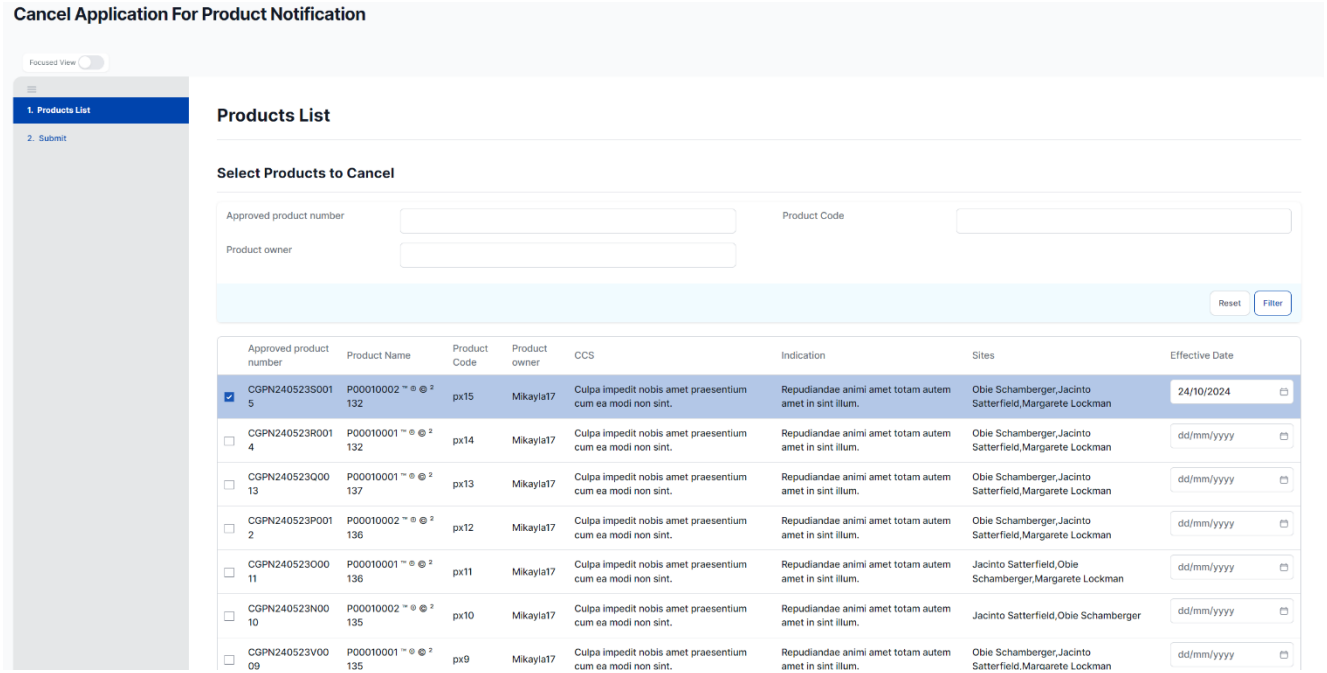
Choose the required submission type, application type(cancel) and click on Next, which redirects to checklist page



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

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

Cancel Product Notification – Getting Started (ii)

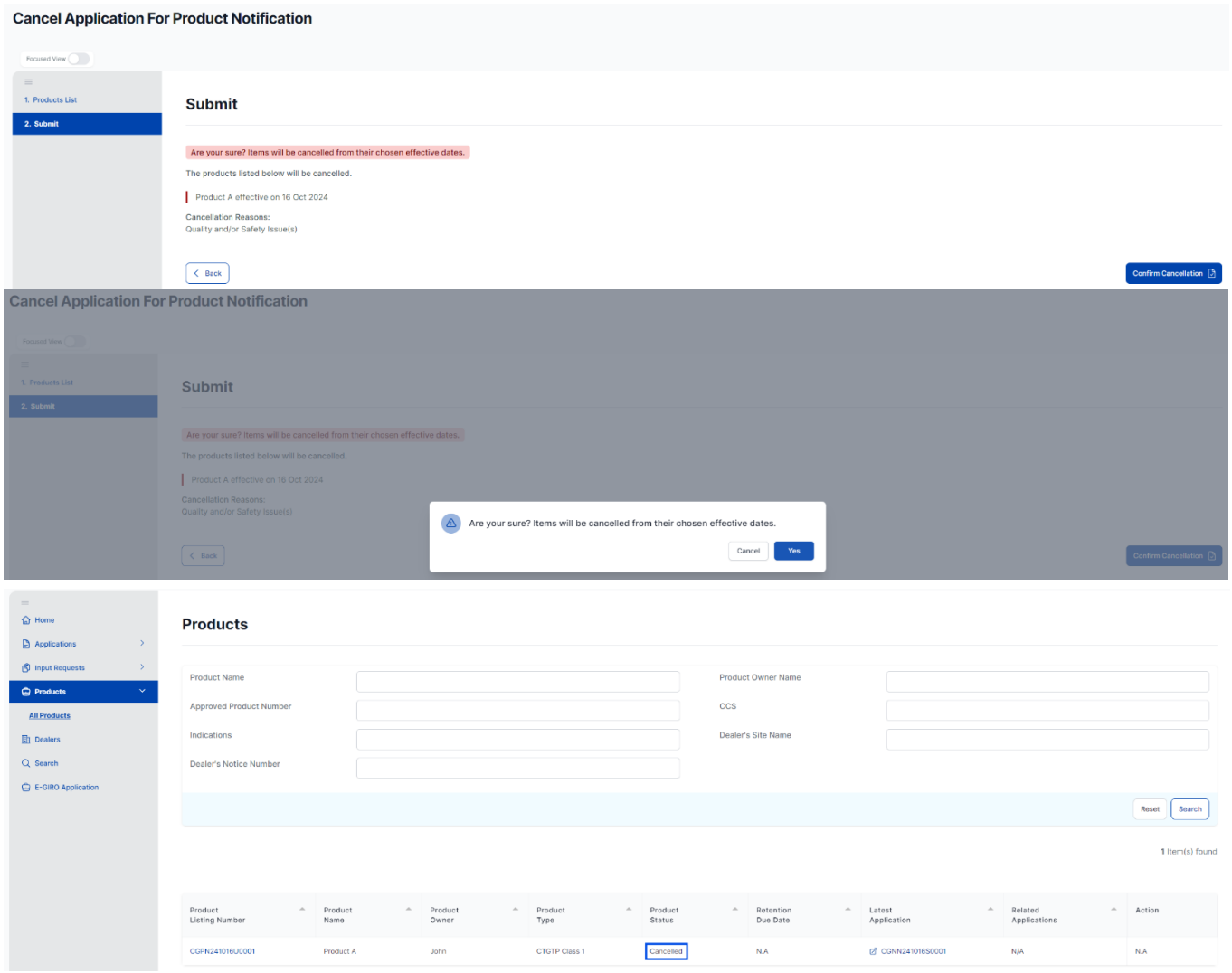


Applicants can choose the product(s) they want to cancel.

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

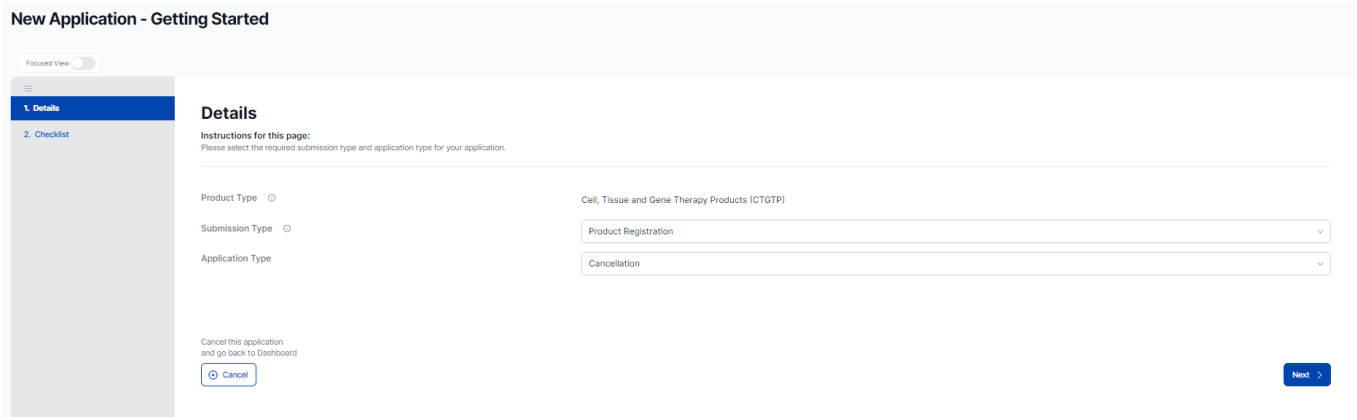
Cancel Product Notification - Submit



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

Product Registration

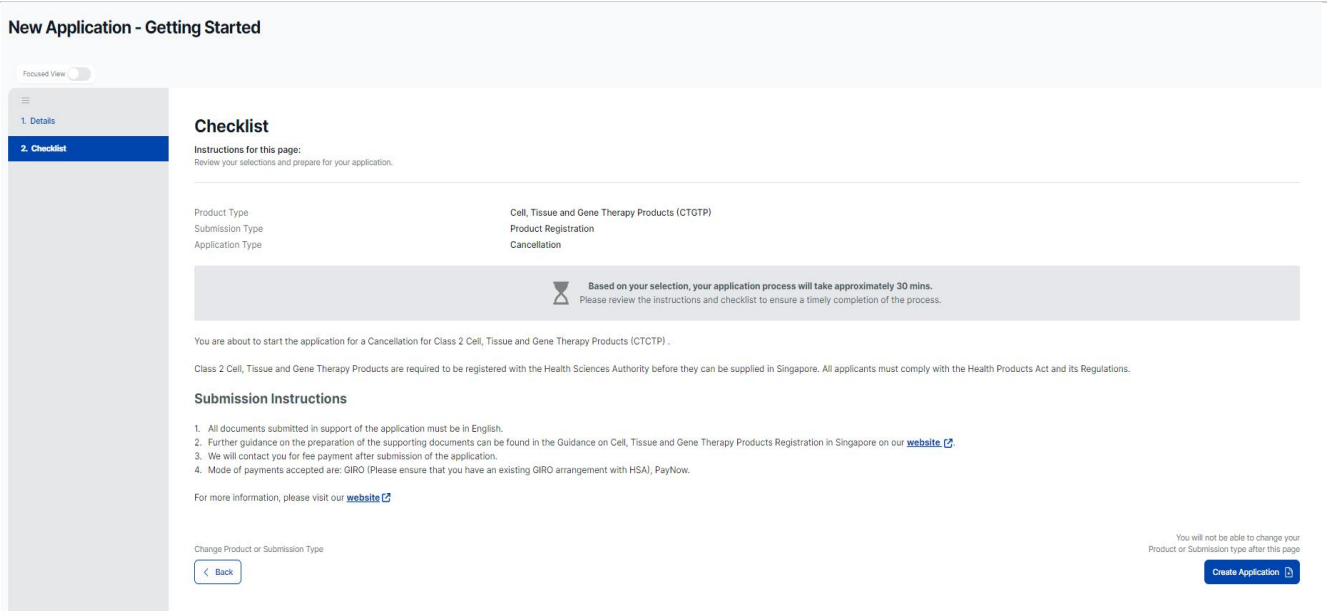
Cancel Product Registration – Getting Started (i)



Applicants will populate the following fields in a manner similar to the process of creating a new application.

- Submission type
- Application type

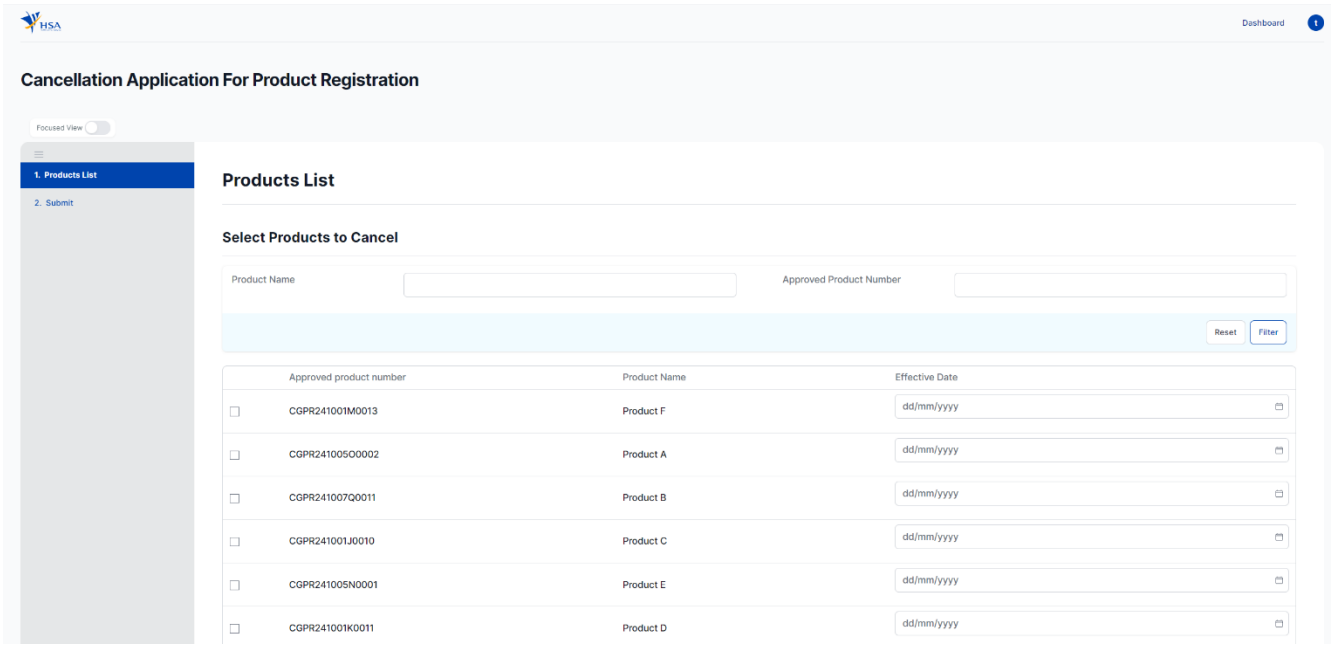
Choose the required submission type, application type(cancellation) and click on Next, which redirects to checklist page.



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

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

Cancel Product Registration – Getting Started (ii)

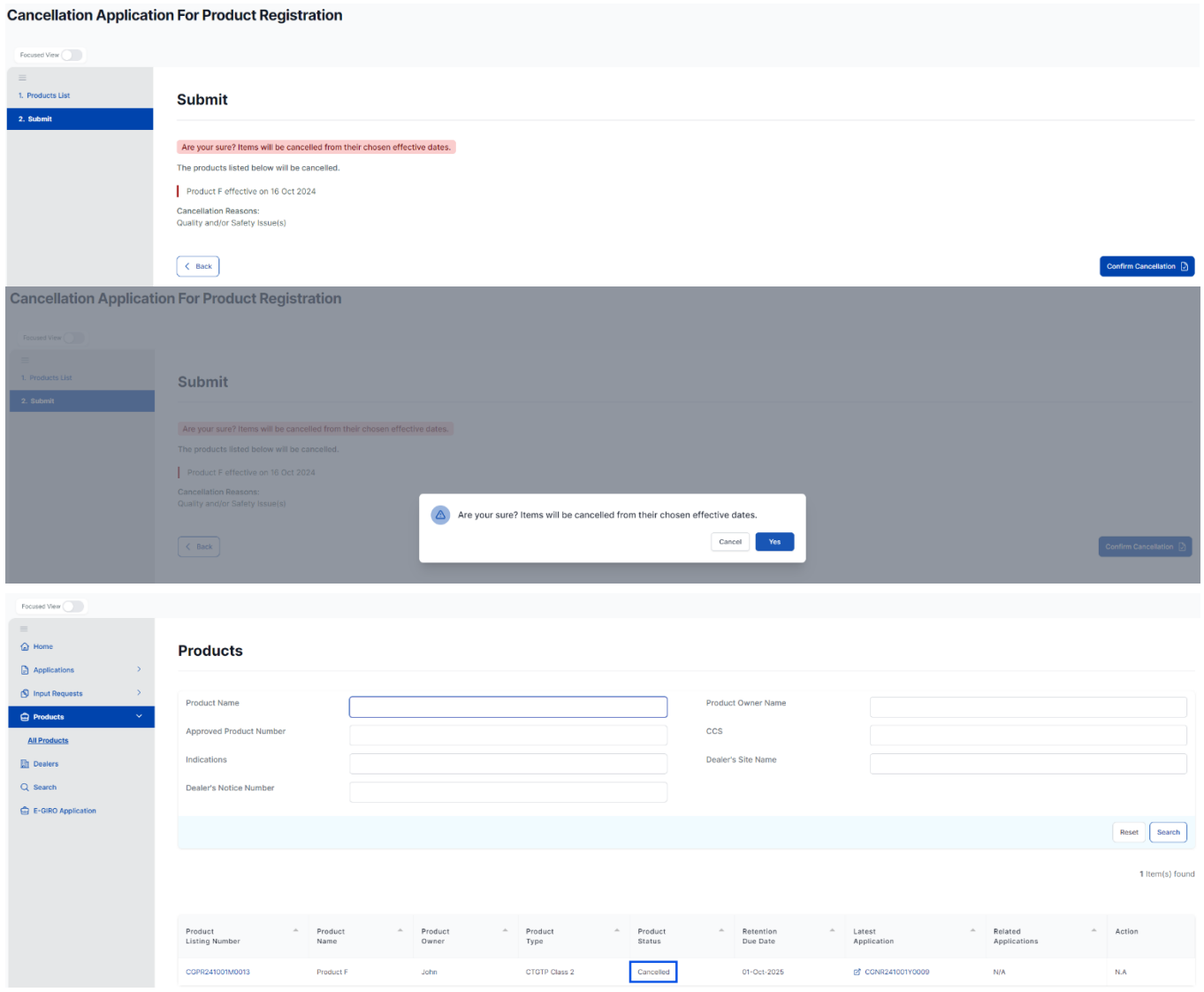


Applicants can choose the product(s) they want to cancel.

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.

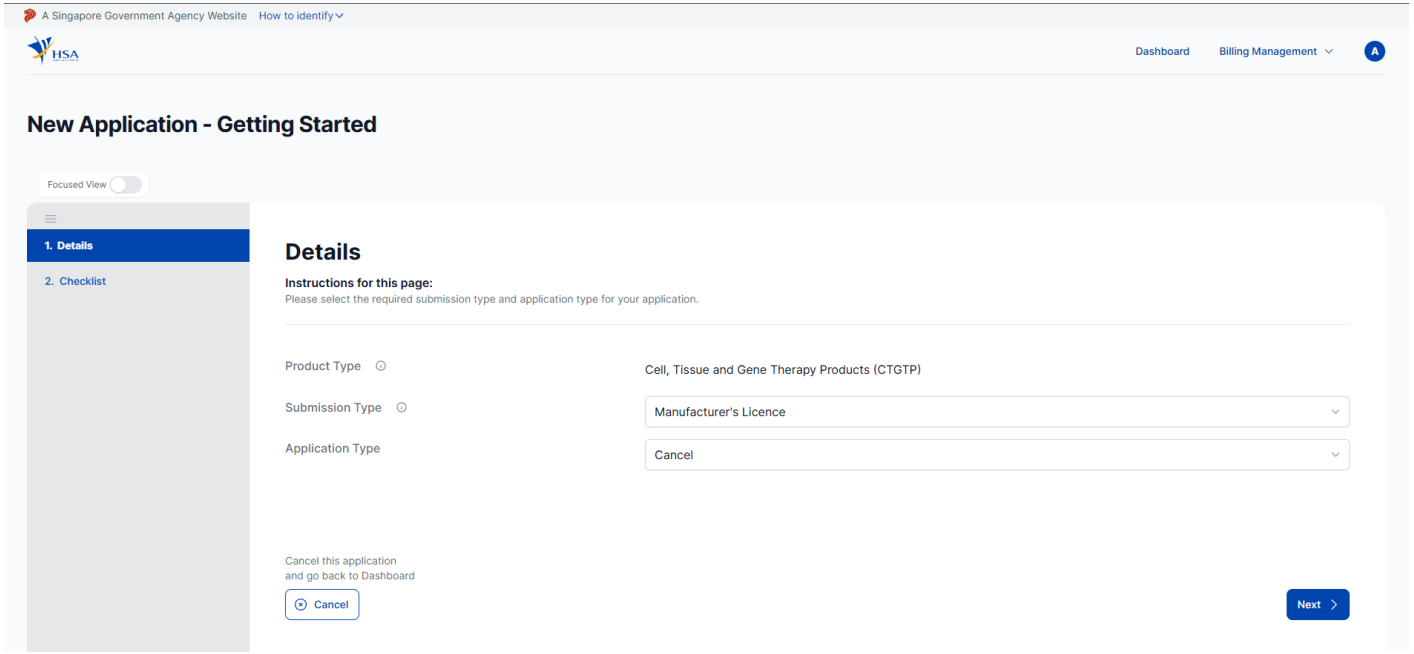
Cancel Product Registration - Submit



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

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

Licence Cancellation – Getting Started (i)

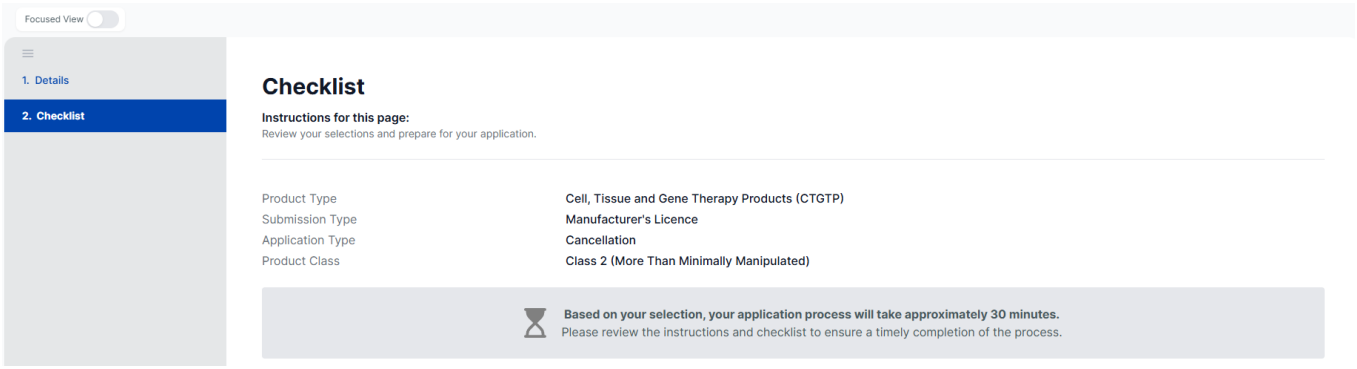


Applicants will populate the following fields in a manner similar to the process of creating a new application.

- Submission type
- Application type

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

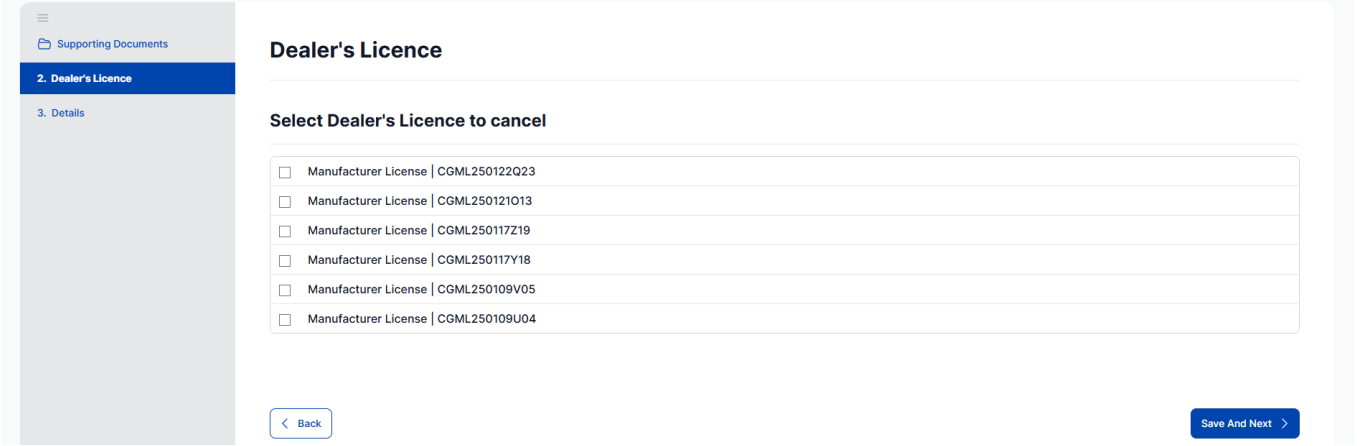
Licence Cancellation – Getting Started (ii)



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.

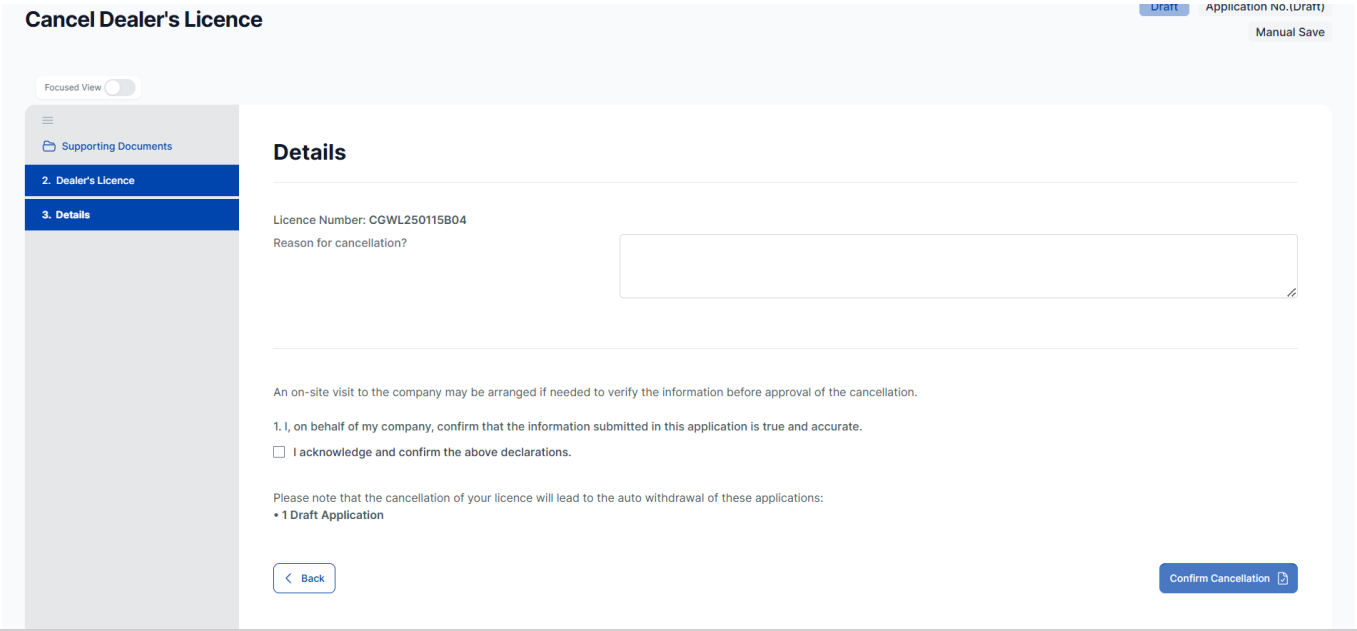
Dealer's Licence



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

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

Licence Cancellation – Details

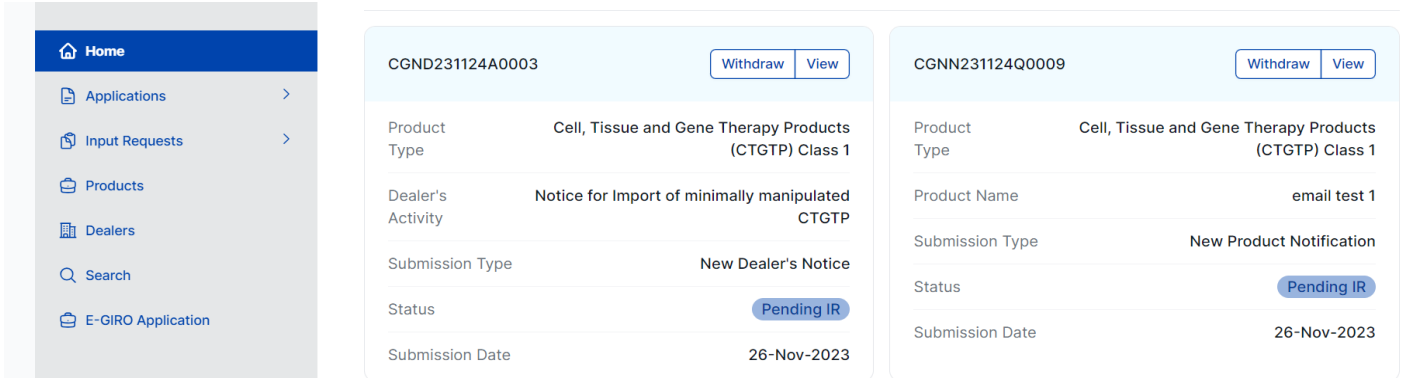


Applicants can input their reason for cancellation as well as complete the declaration to confirm cancellation.

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

6 Withdrawal of Products or Dealer Activities

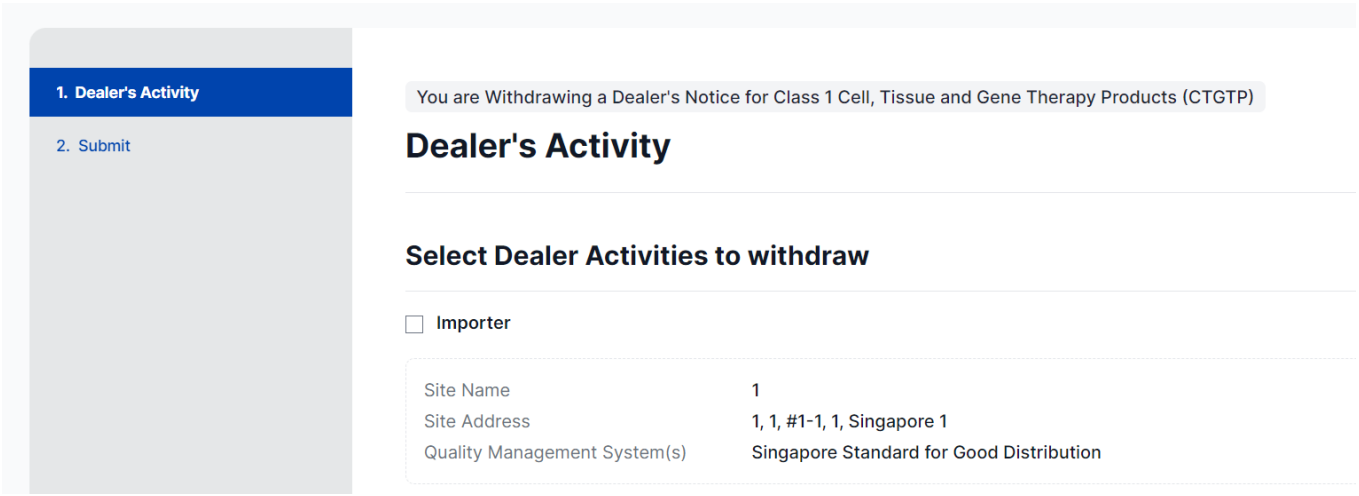
Applicants can withdraw the application before the application has been approved/accepted by an HSA officer.



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.

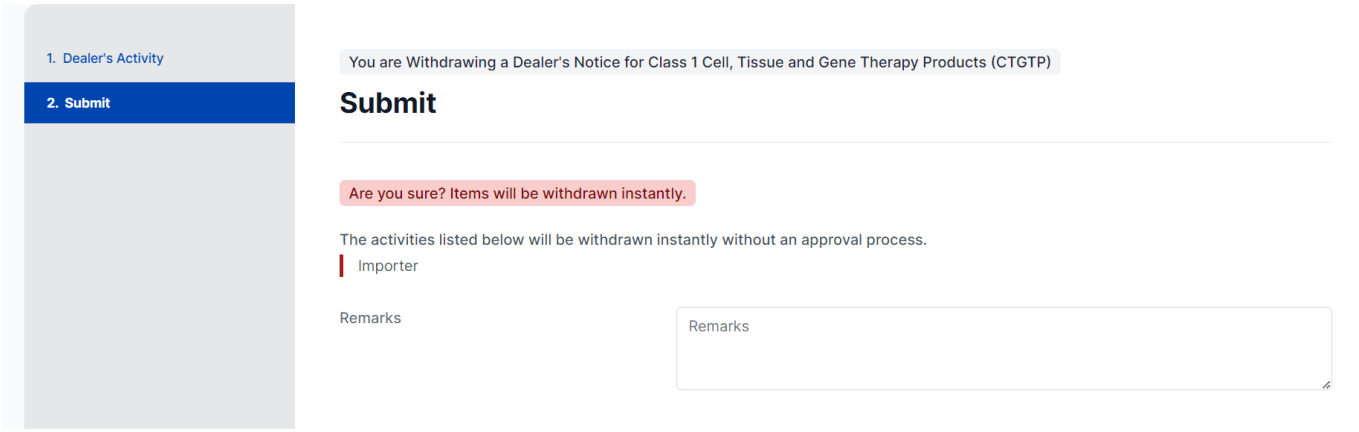
Withdrawal of Products/ Dealer's Activities



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

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

Withdrawal of Products/ Dealer's Activities – Submit



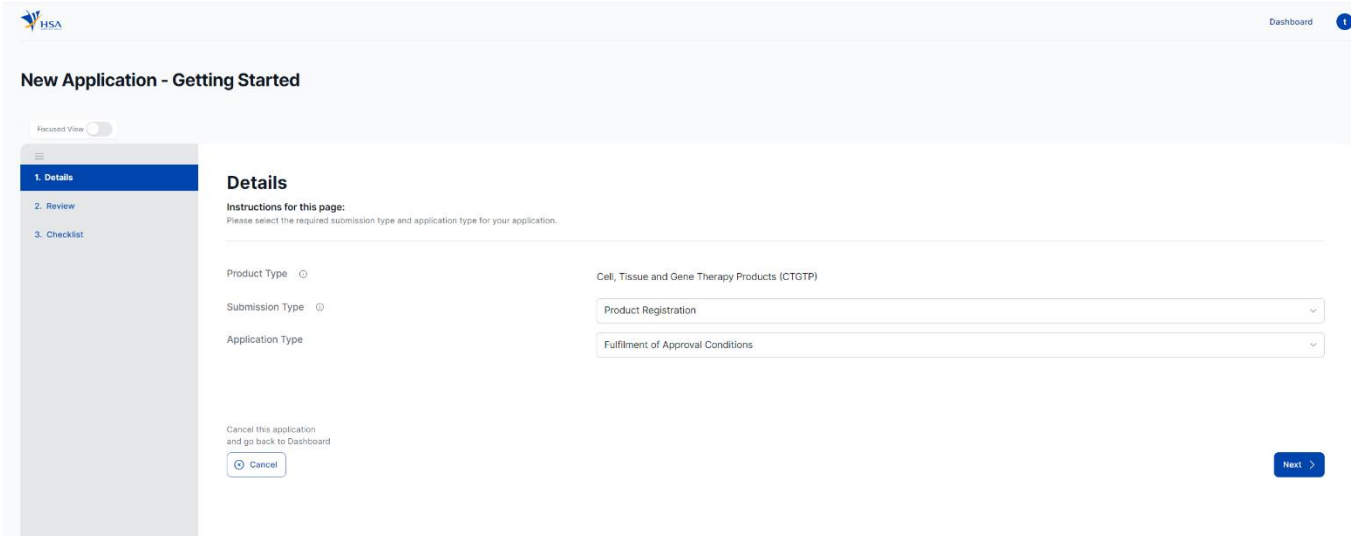
Applicants need to confirm the required Dealer's Activity/Product they want to withdraw.

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

7 Creation of Fulfilment of Approval Conditions Application

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

New Application - Getting Started (i)



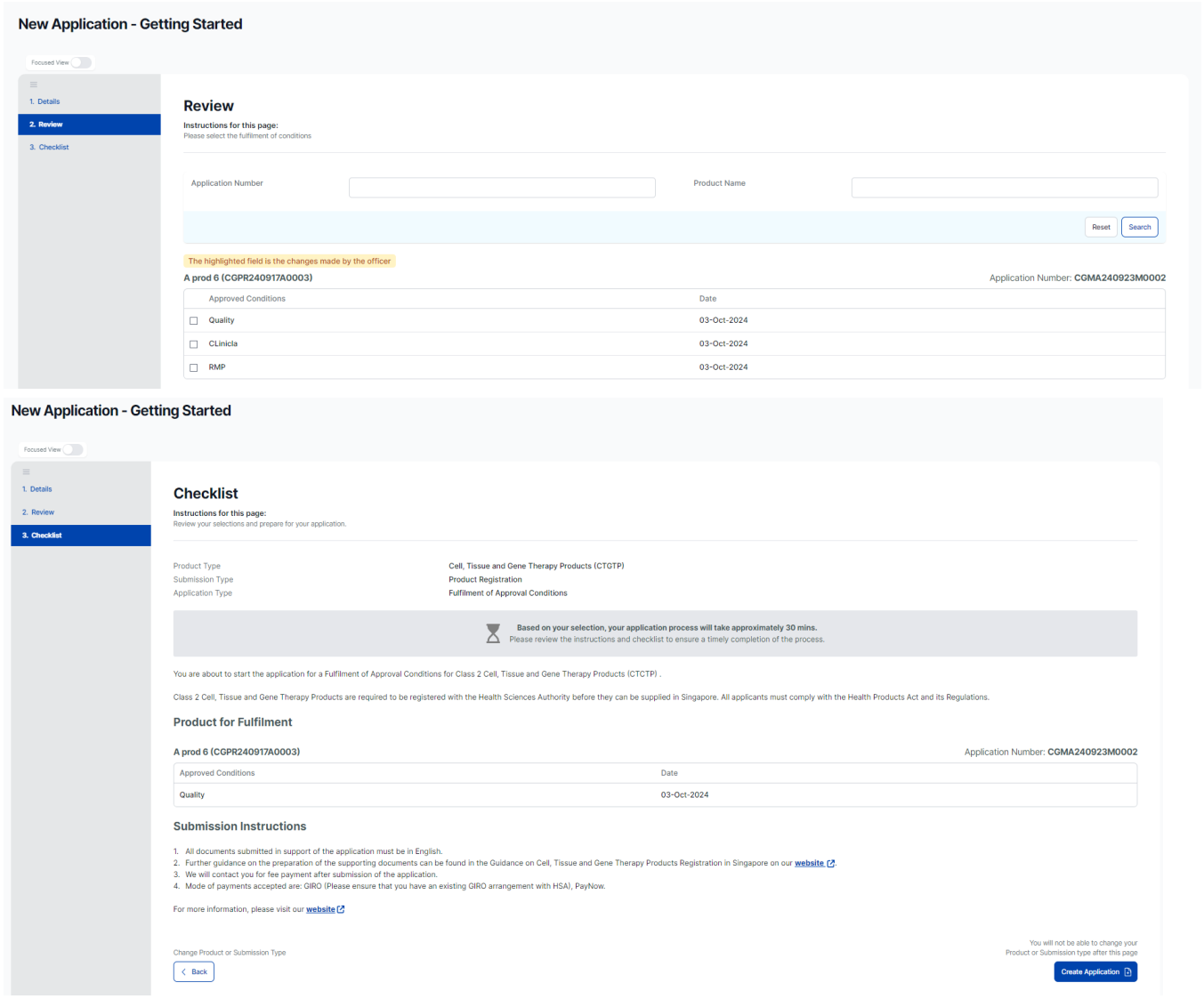
Applicants will populate the following fields in a manner similar to the process of creating a new application.

- 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.

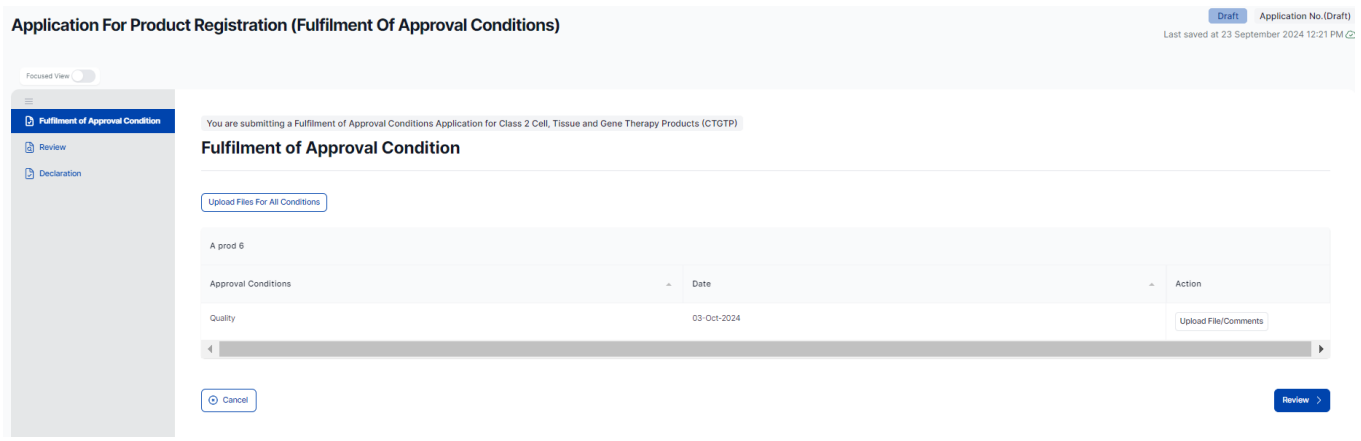
Applicants can also choose to select the approval conditions that need to have their due dates extended.



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.

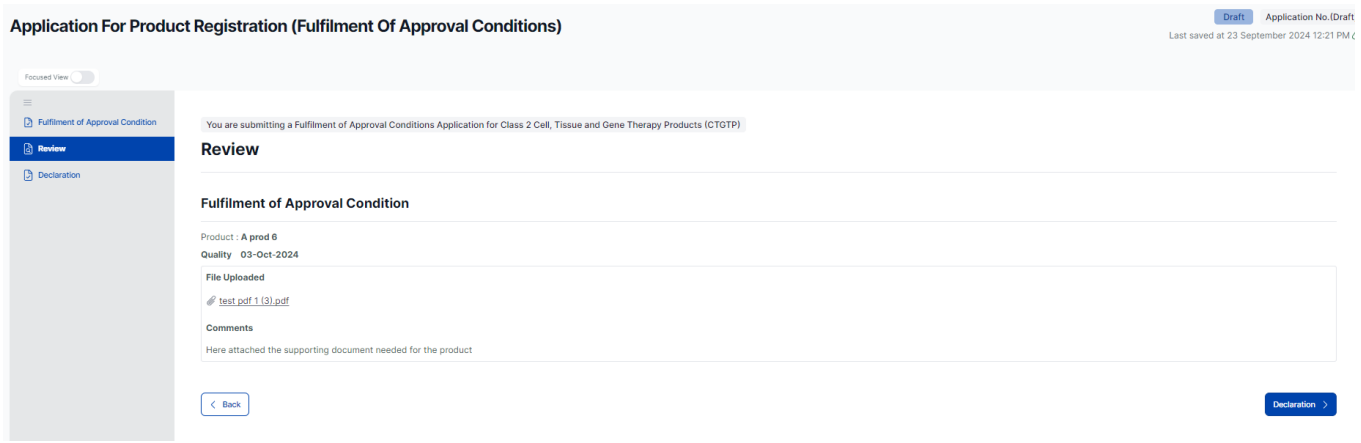
7.1 Fulfilment of Approval Condition



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

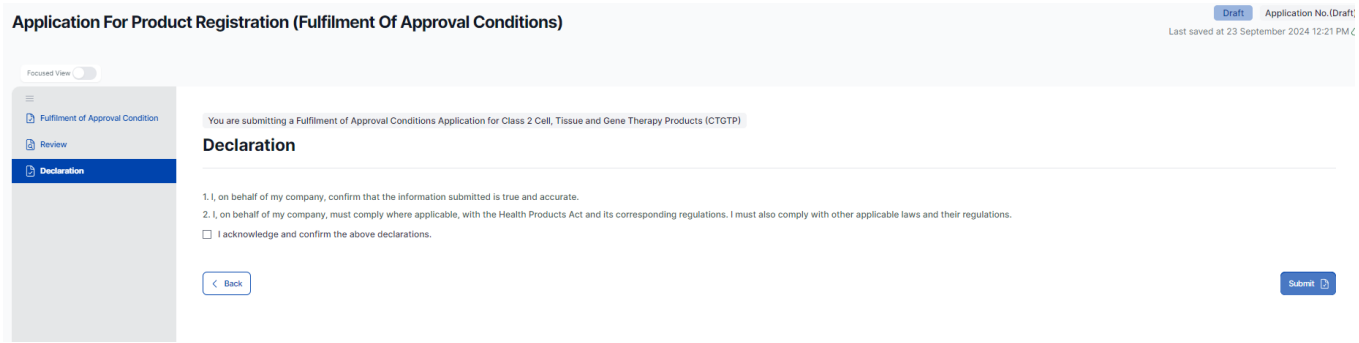
Each approval condition must have a file uploaded to proceed with the submission.

7.2 Review



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

7.3 Declaration

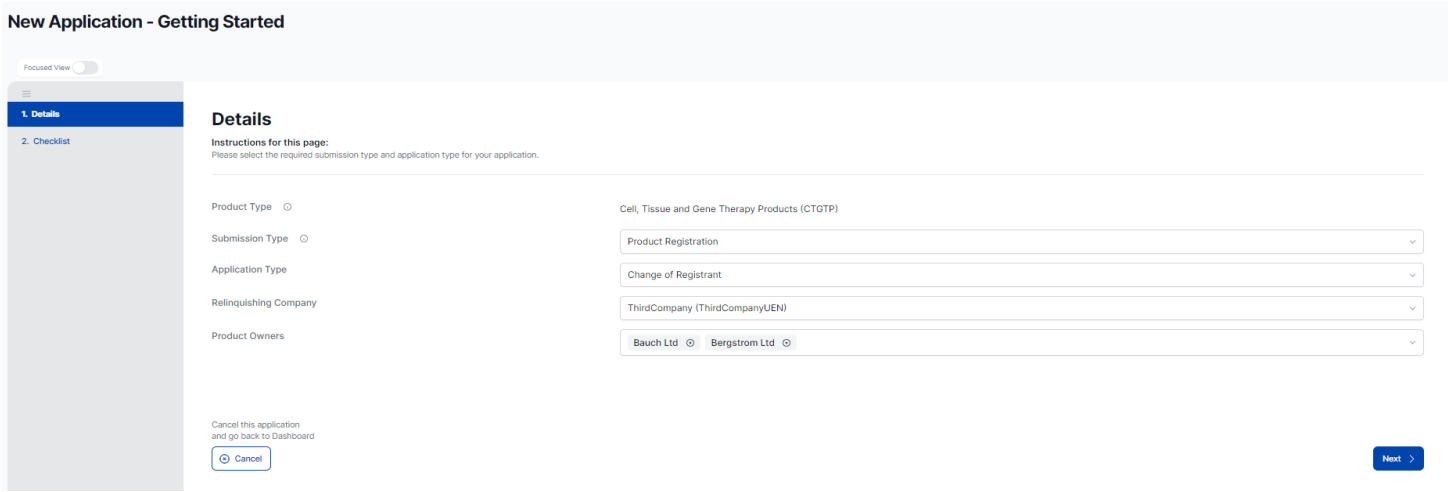


For all fulfilment of approval conditions applications, applicants are required to complete the declaration before submission.

8 Creation of Change of Registrant Application

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

New Application - Getting Started (i)



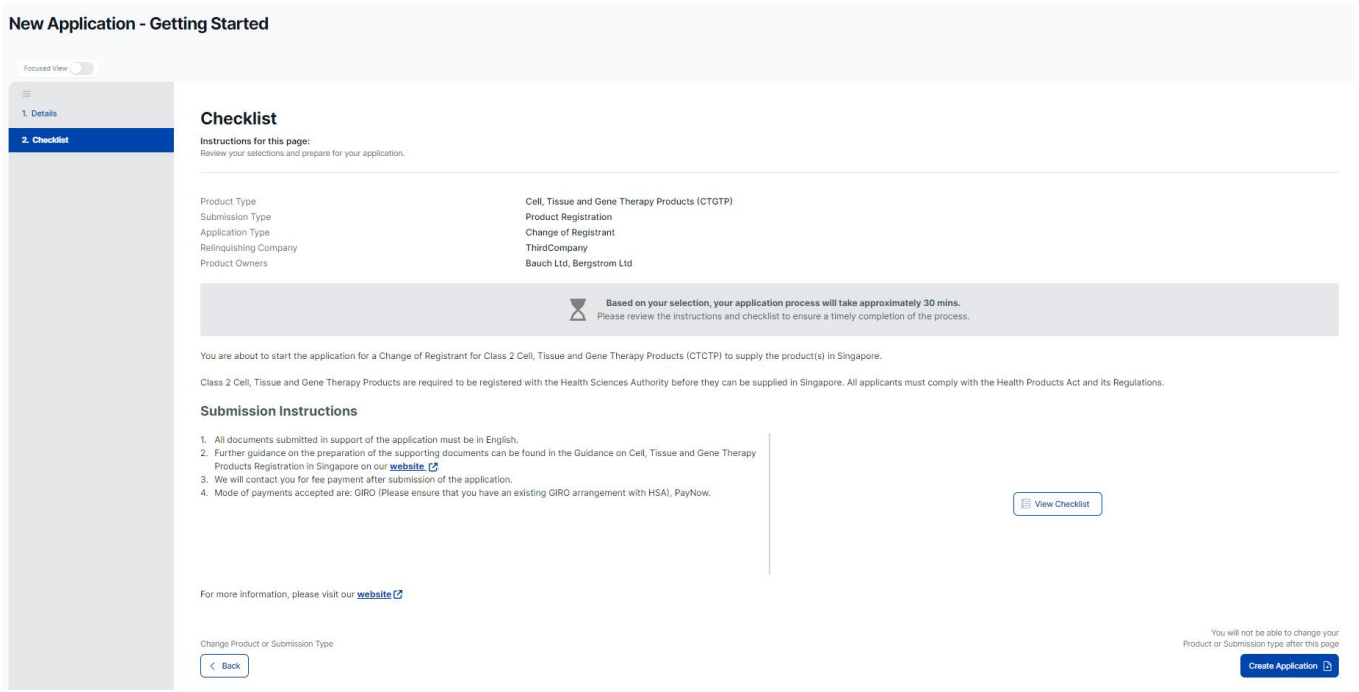
Applicants will populate the following fields in a manner similar to the process of creating a new application.

- Submission type
- Application type

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

- Relinquishing company
- Product owners

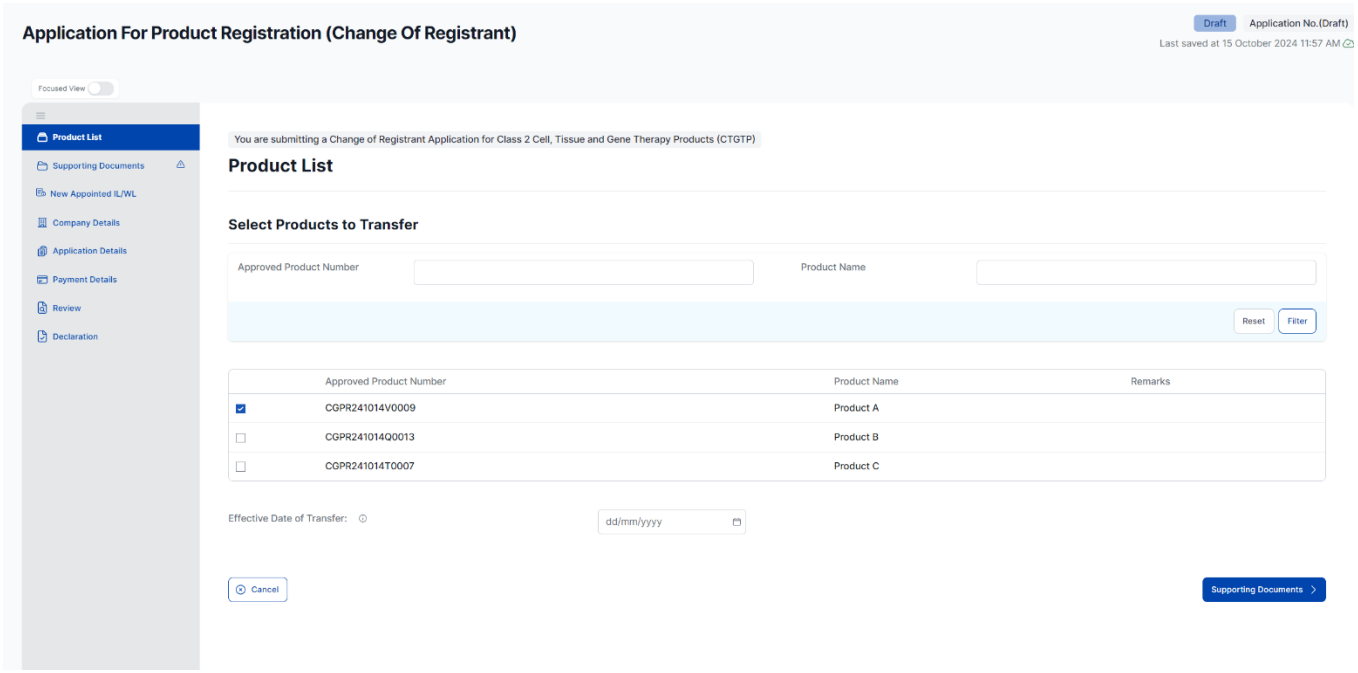
Choose the relevant relinquishing company, product owners and click on Next, which redirects to the checklist page.



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

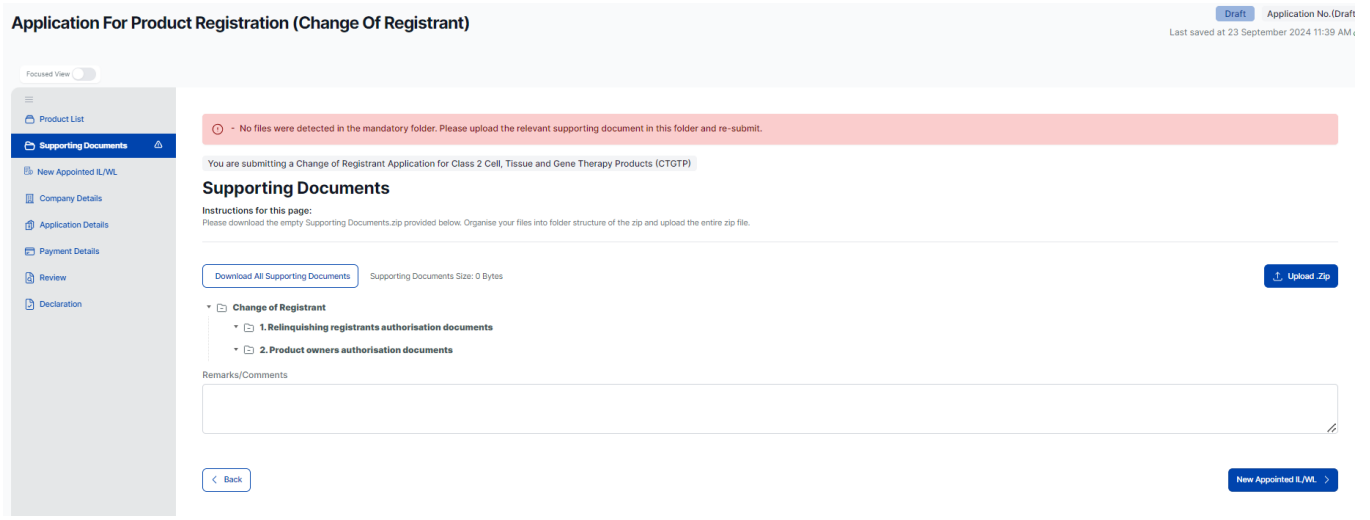
Note: Information on this page may differ depending on the Submission Type & Application Type selected by Applicants.

8.1 Product List



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

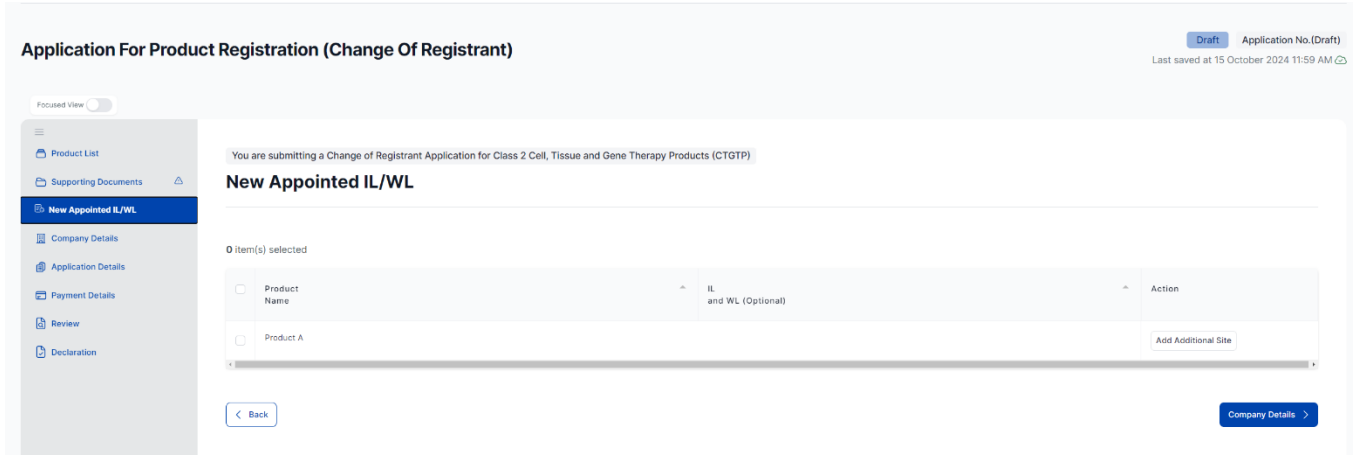
8.2 Supporting Documents



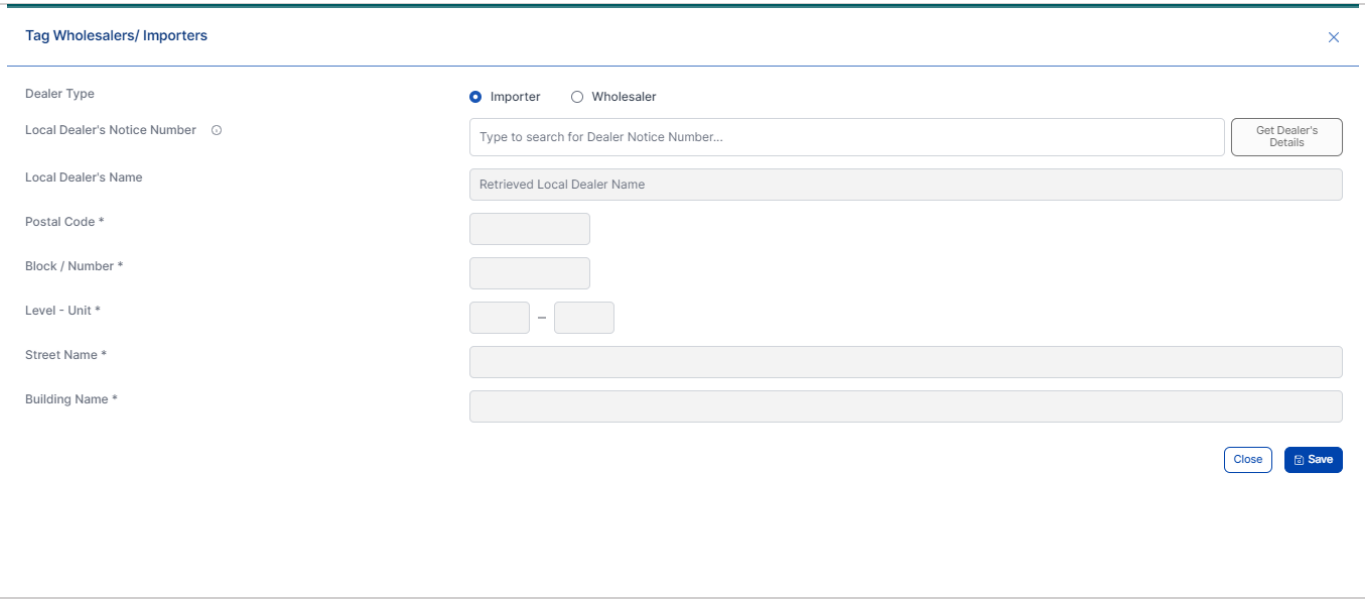
Applicants must upload supporting documents before they can proceed.

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

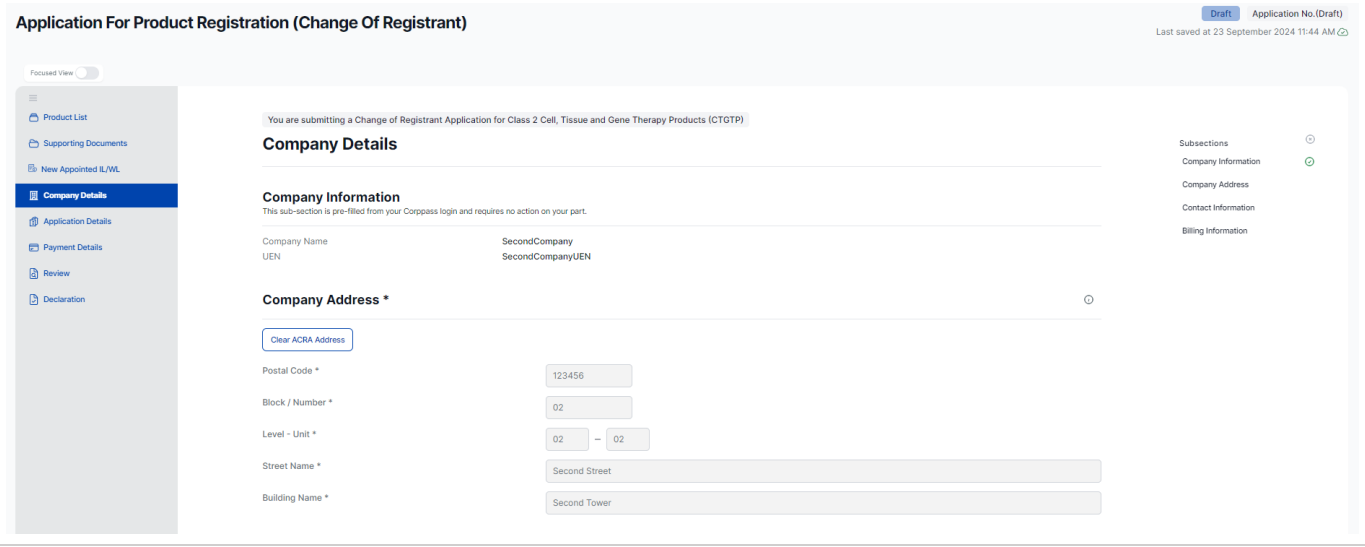
8.3 New Appointed IL/WL



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

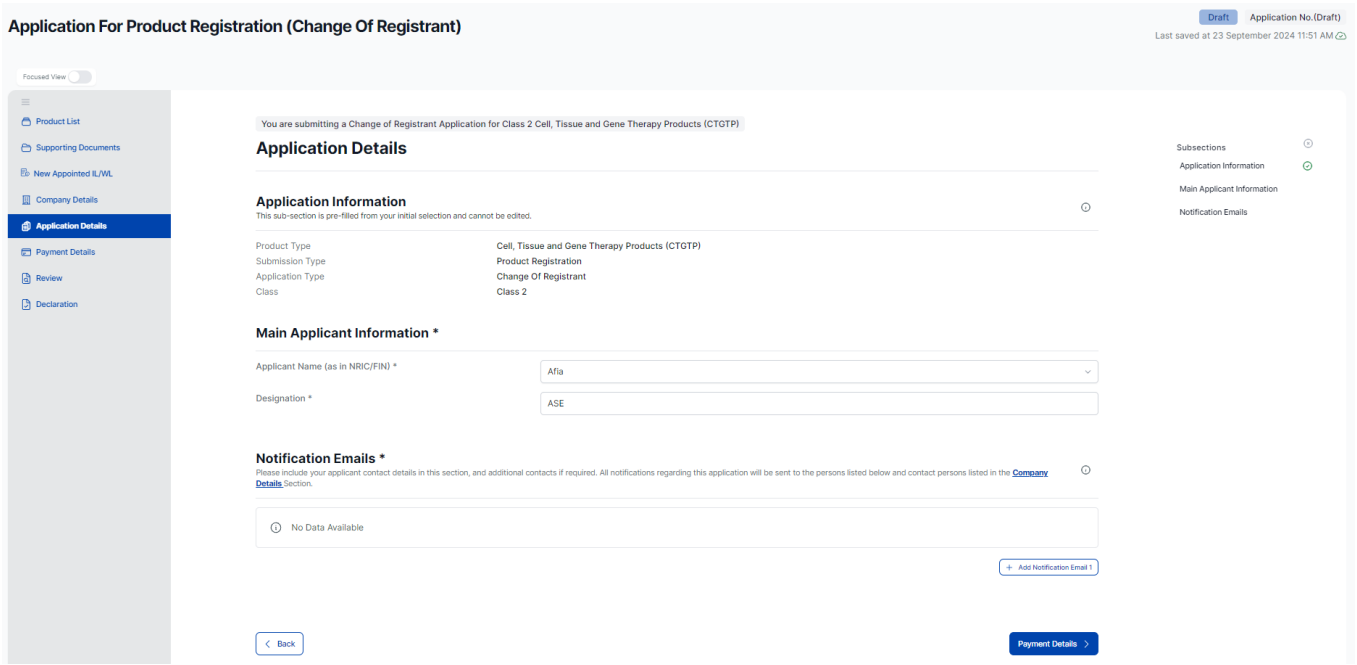


8.4 Company Details



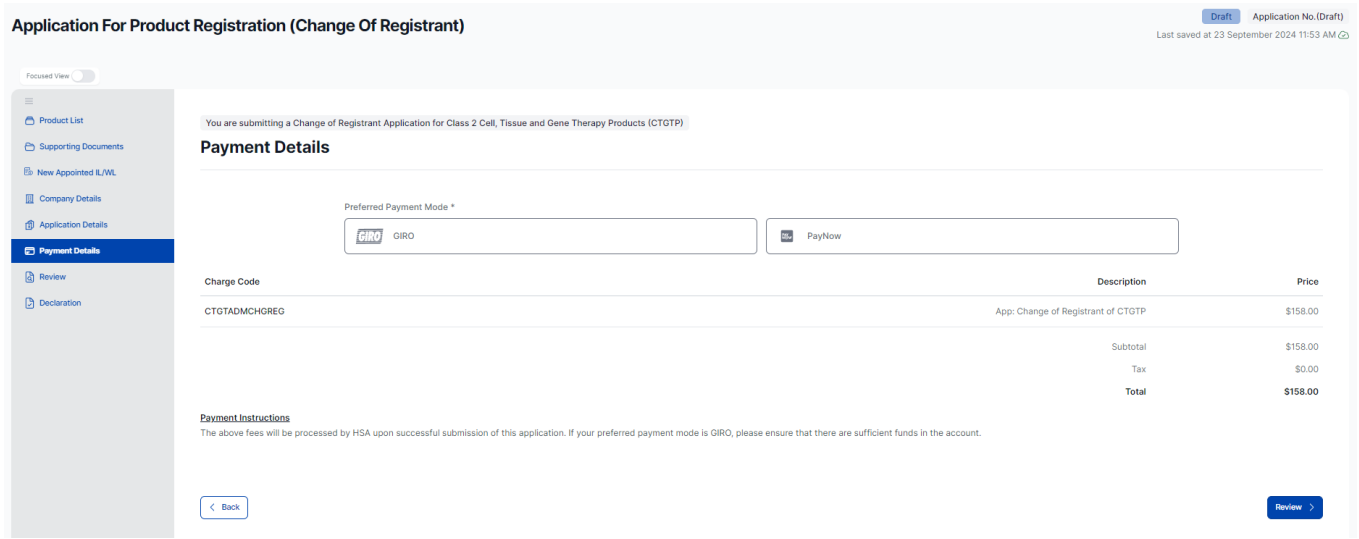
The details of company details section can be found in Company Details.

8.5 Application Details



The details of application details section can be found in Application Details.

8.6 Payment Details

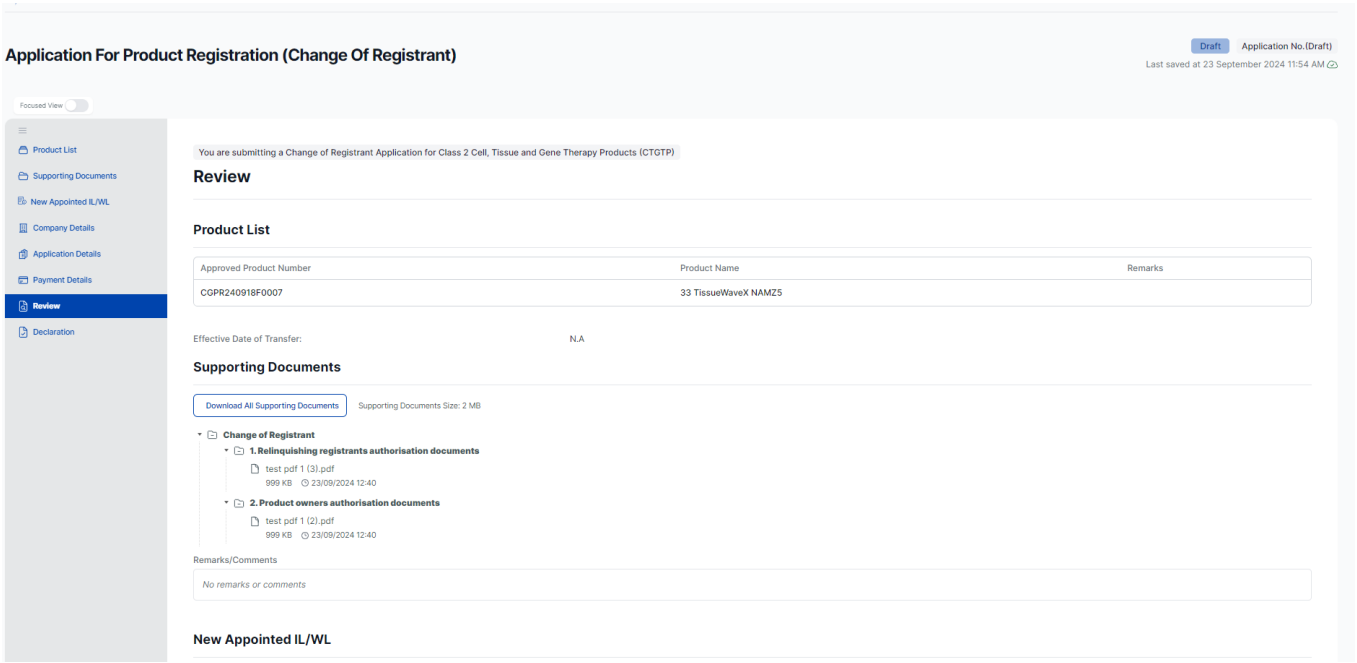


Once the applicant has created an application and filled in necessary details, the payment section is displayed.

Applicants will have two payment options, GIRO and PayNow.

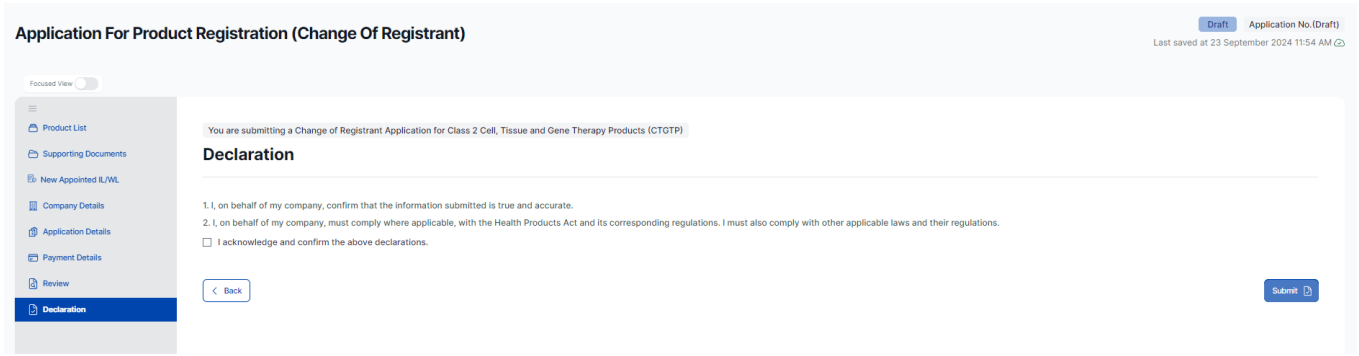
Applicants must choose the required payment mode.

8.7 Review



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

8.8 Declaration

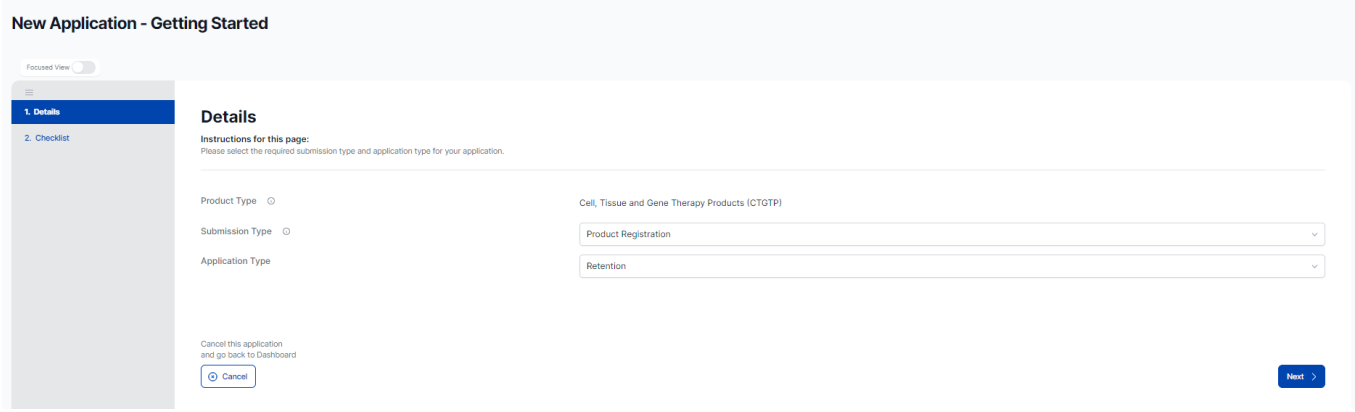


For all change of registrant applications, applicants are required to complete the declaration before submission.

9 Creation of Retention Application

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

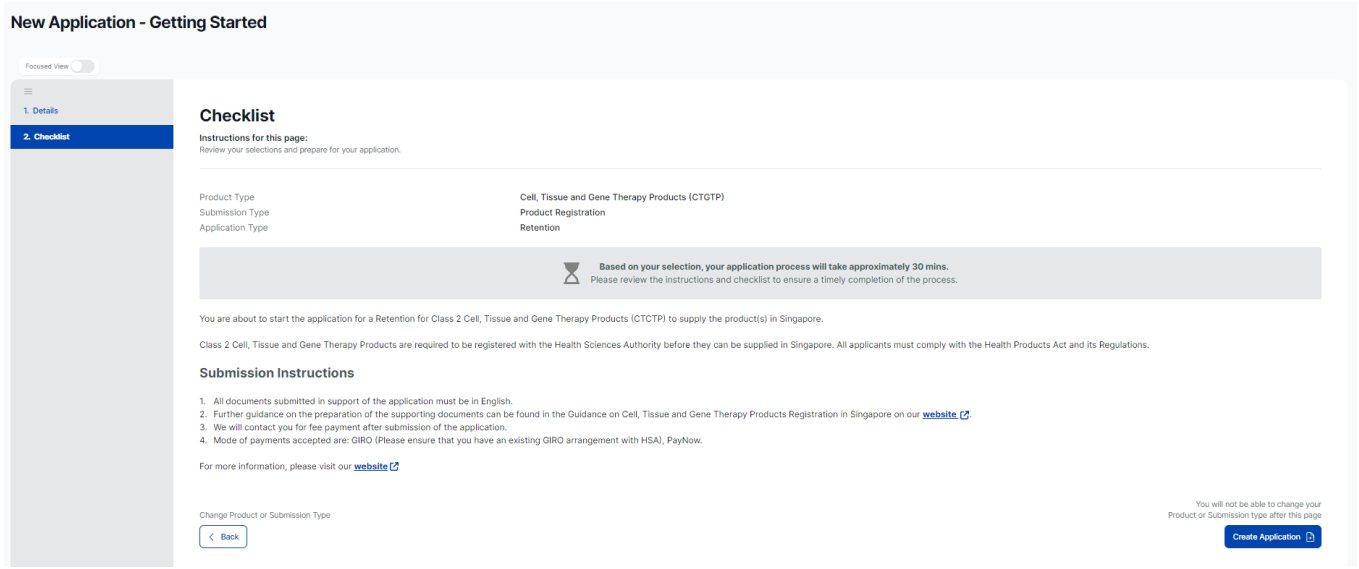
Retention Application - Getting Started (i)



Applicants will populate the following fields in a manner similar to the process of creating a new application.

- Submission type
- Application type

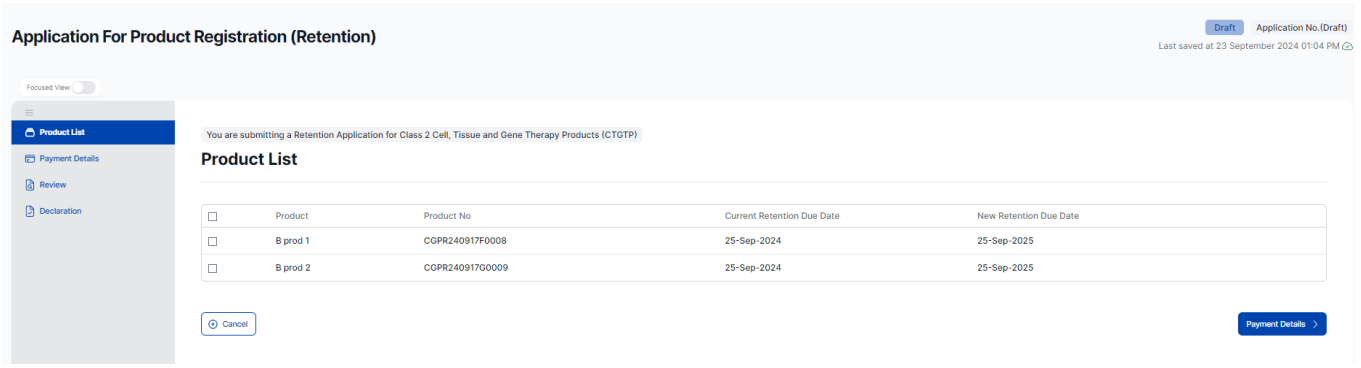
Choose the product registration submission type, application type (retention application) and click on Next, which redirects to the checklist page.



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

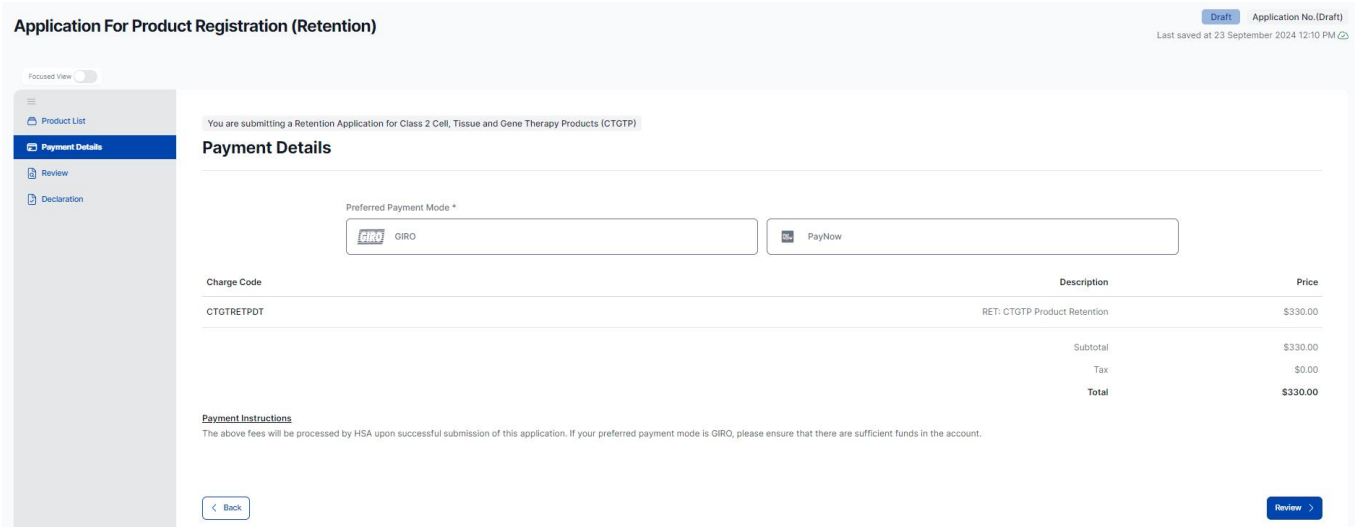
Note: Information on this page may differ depending on the Submission Type & Application Type selected by Applicants.

9.1 Product List



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

9.2 Payment Details

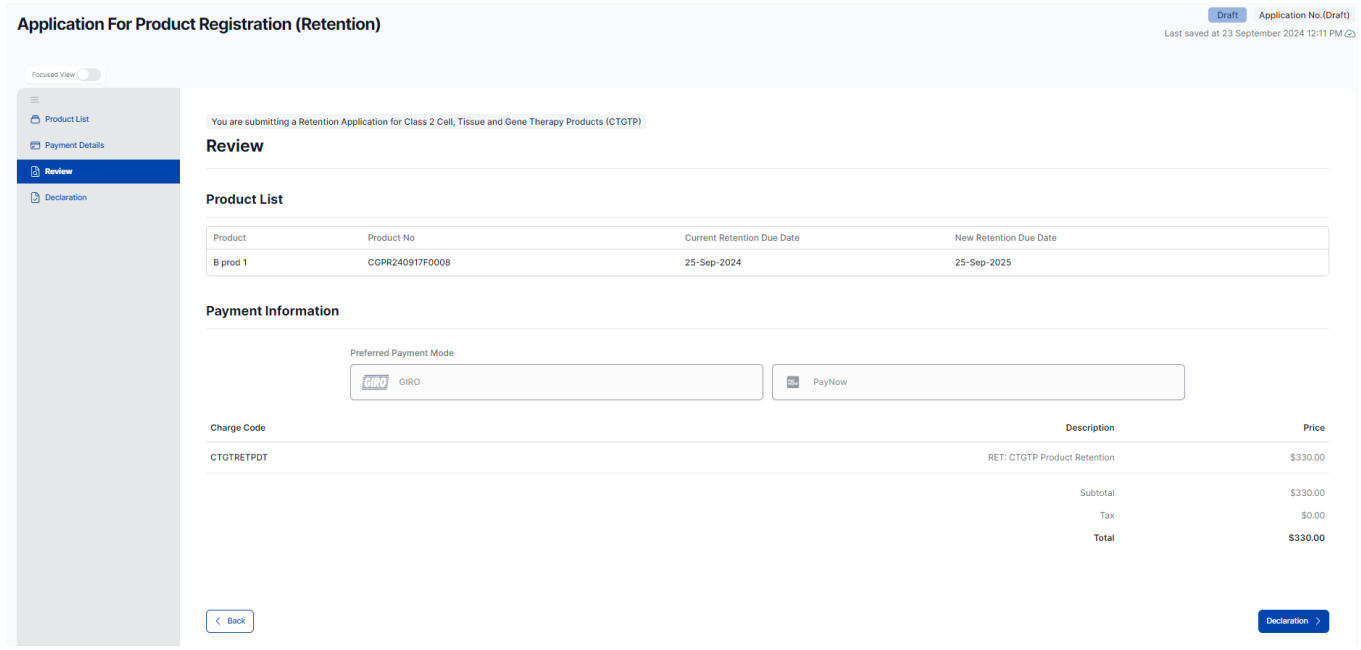


Once the applicant has created an application and filled in necessary details, the payment section is displayed.

Applicants will have two payment options, GIRO and PayNow.

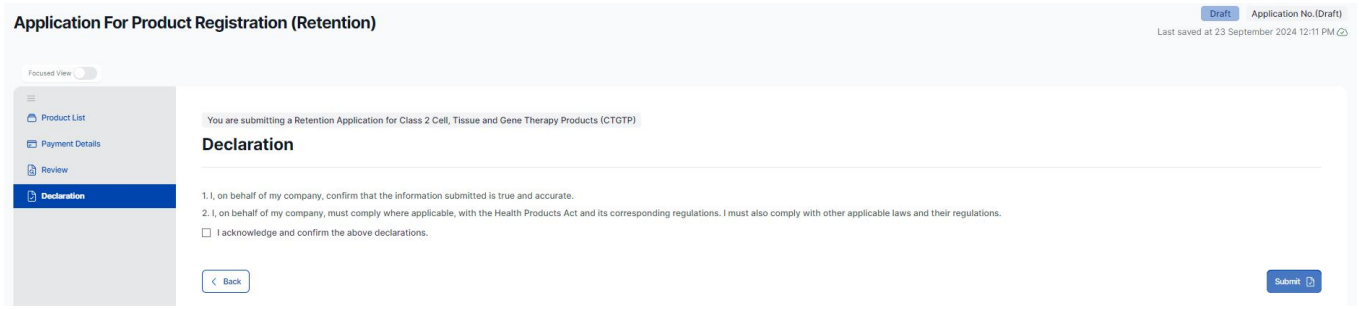
Applicants must choose the required payment mode.

9.3 Review



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

9.4 Declaration

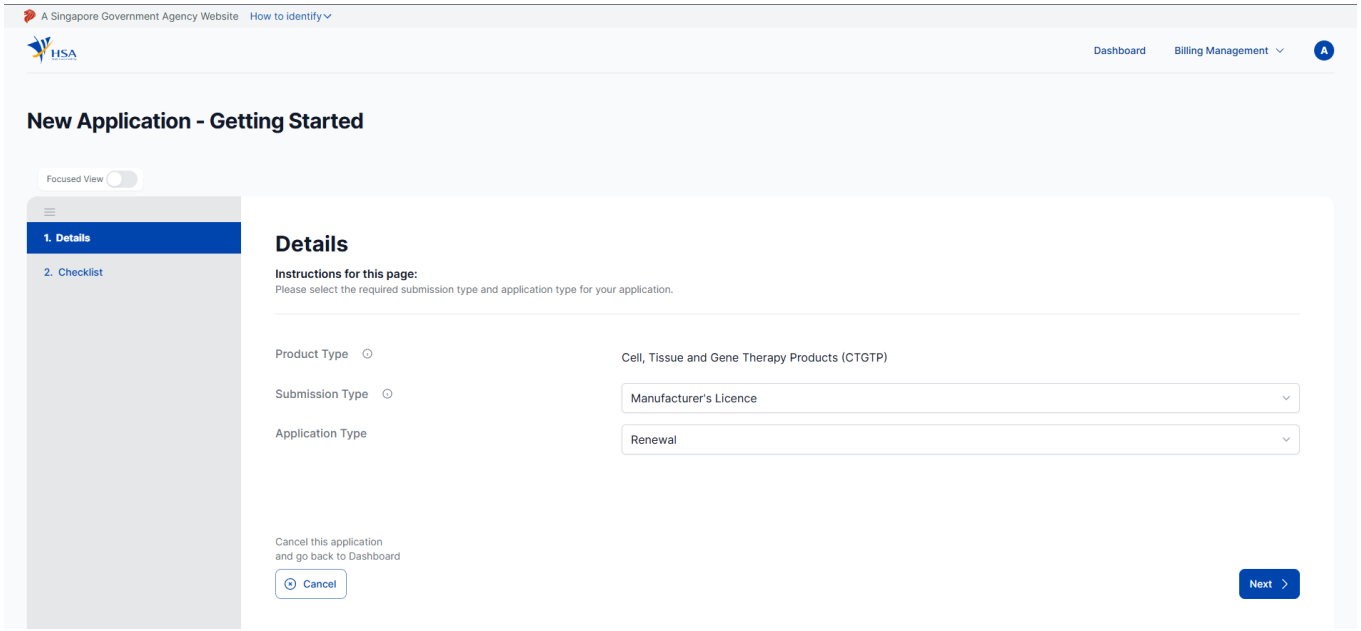


For all retention applications, applicants are required to complete the declaration before submission.

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

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

Licence Renewal - Getting Started (i)

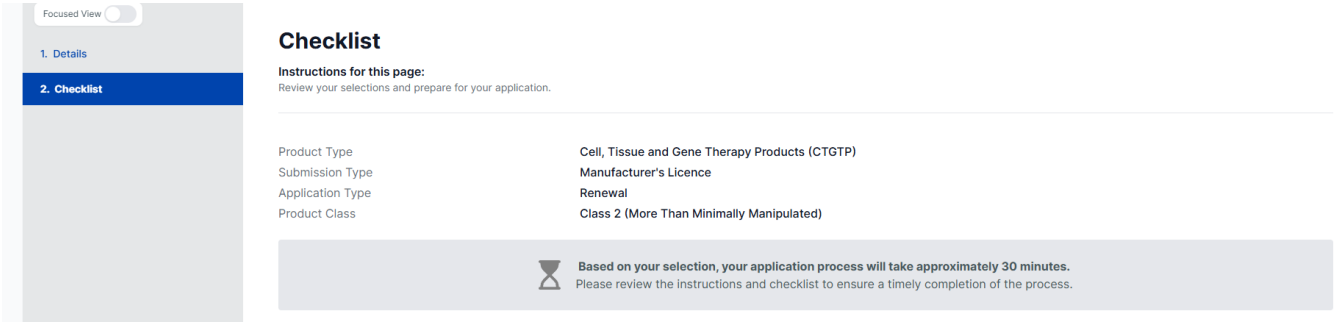


Applicants will populate the following fields in a manner similar to the process of creating a new application.

- Submission type
- Application type

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

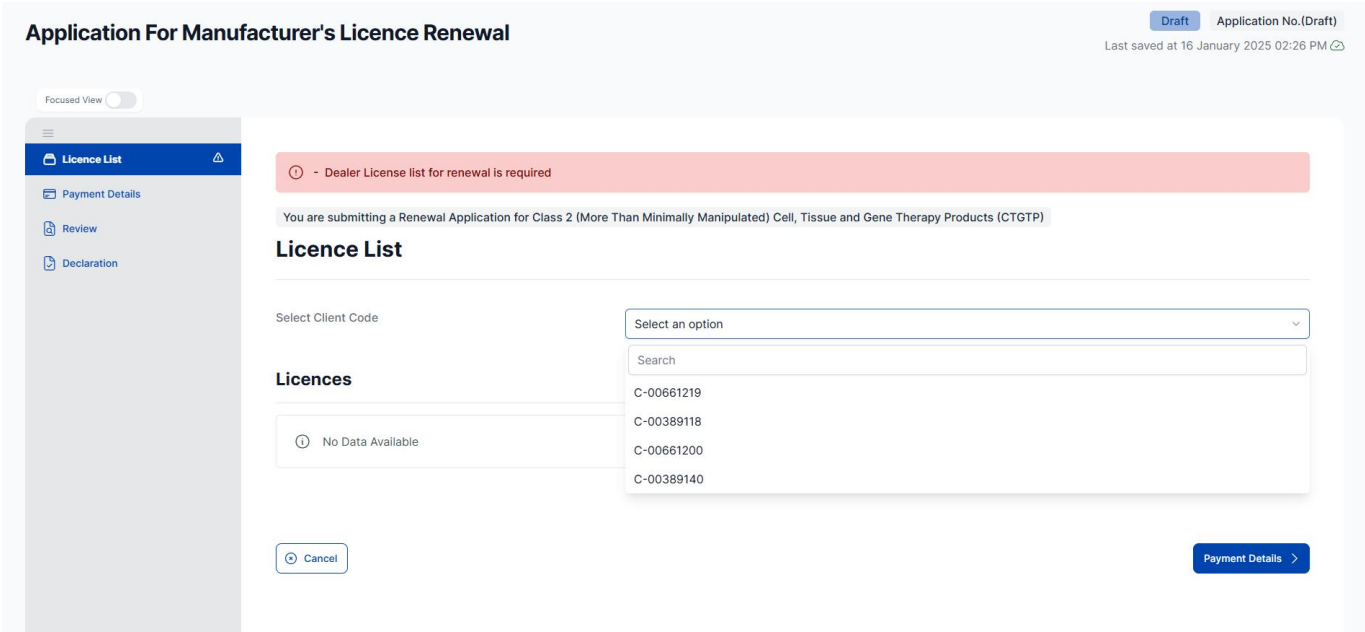
Licence Renewal – Getting Started (ii)



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

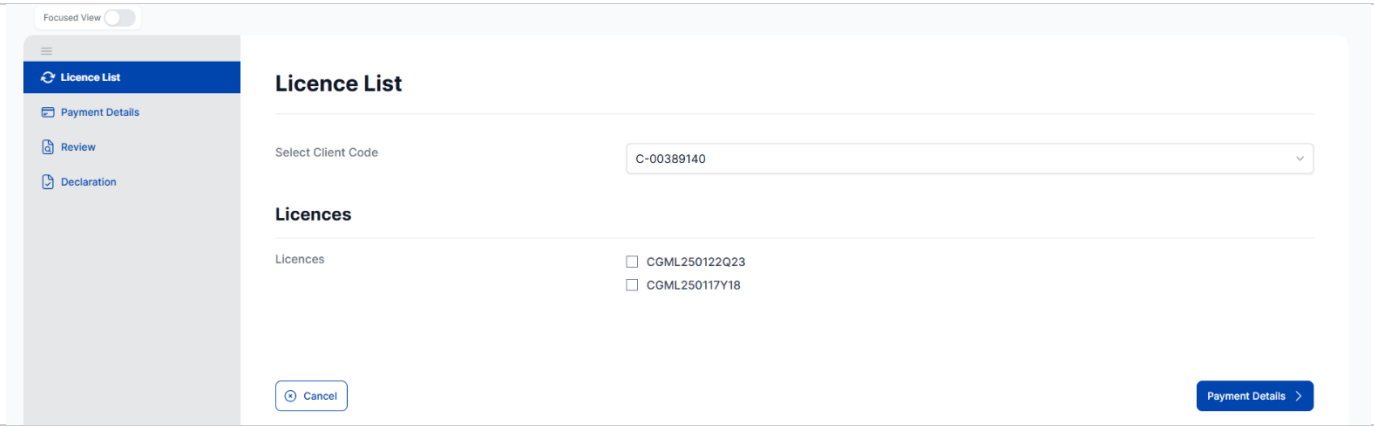
Note: Information on this page may differ depending on the Submission Type & Application Type selected by Applicants.

10.1 Licence List

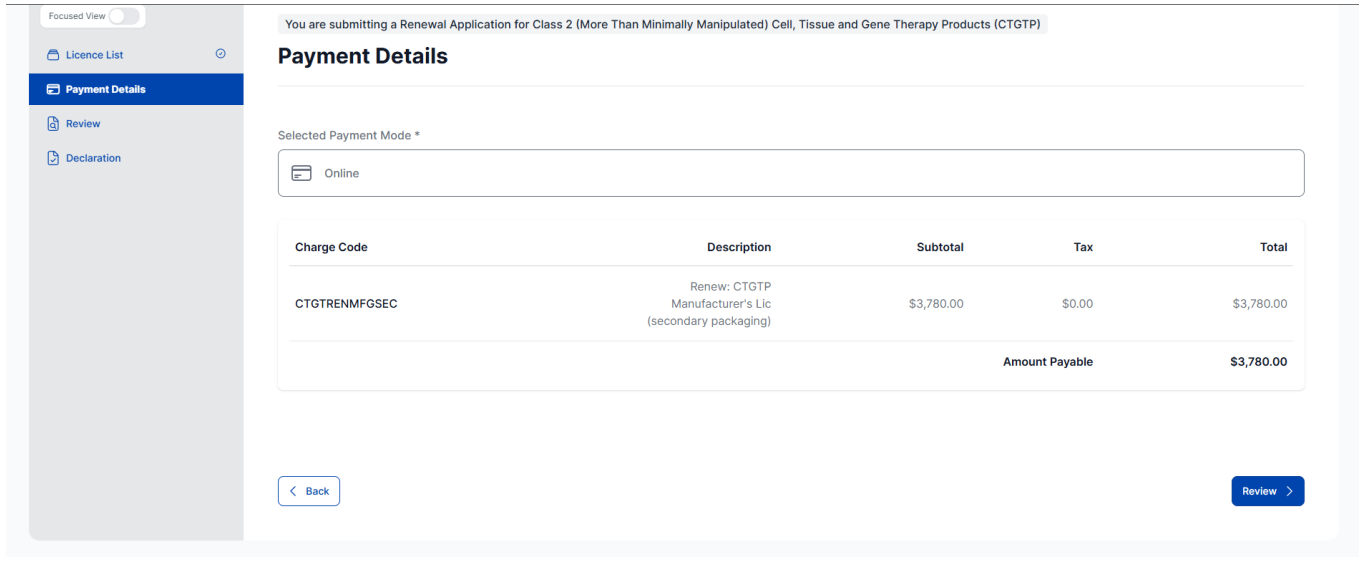


Applicants should select a client code from the dropdown menu under the Licence List section. Once a client code is selected, the Licences subsection will automatically display licences that are eligible for renewal under that client code.

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



10.2 Payment Details

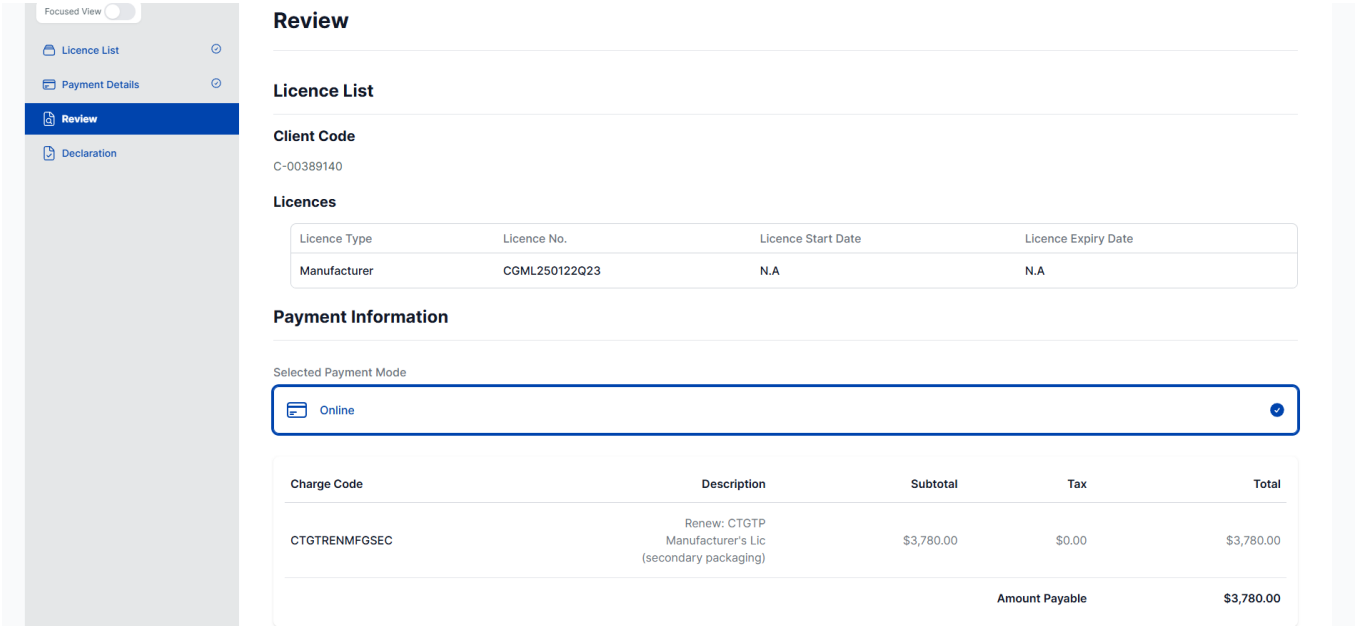


Once the applicant has created an application and filled in necessary details, the payment section is displayed.

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

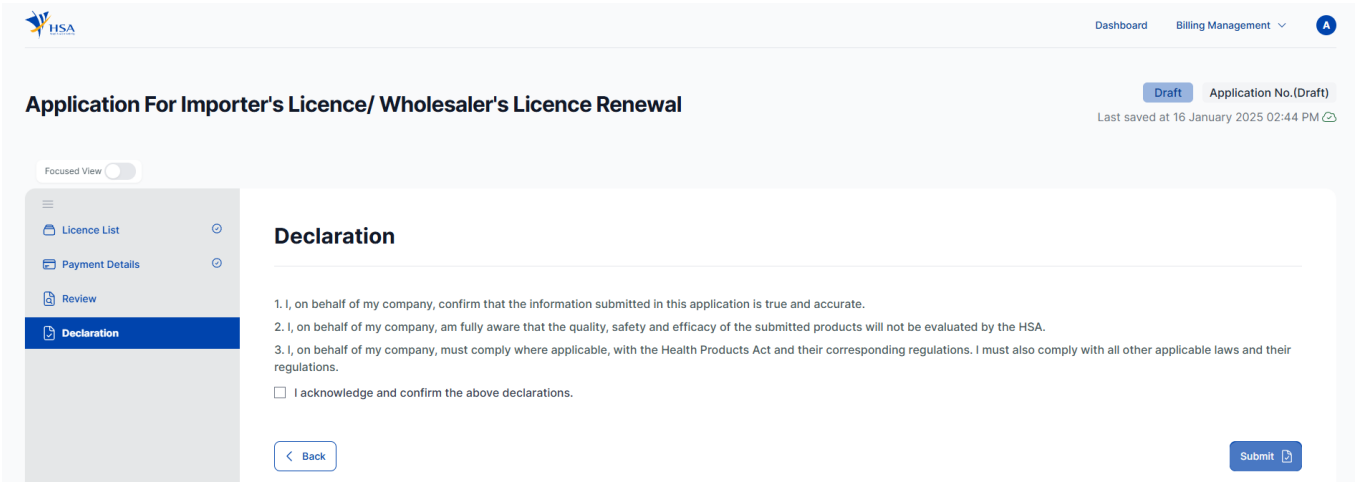
Applicants must choose the required payment mode.

10.3 Review



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

10.4 Declaration

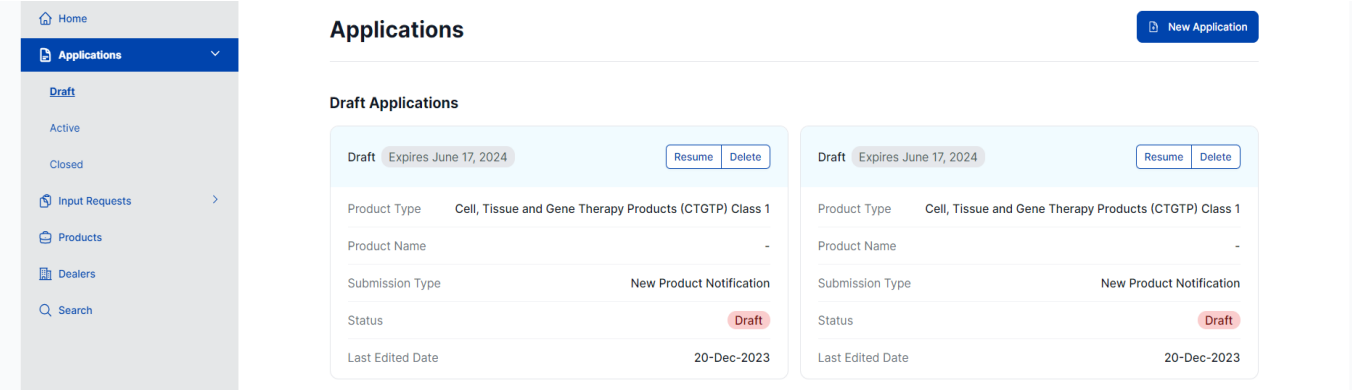


For all renewal applications, applicants are required to complete the declaration before submission.

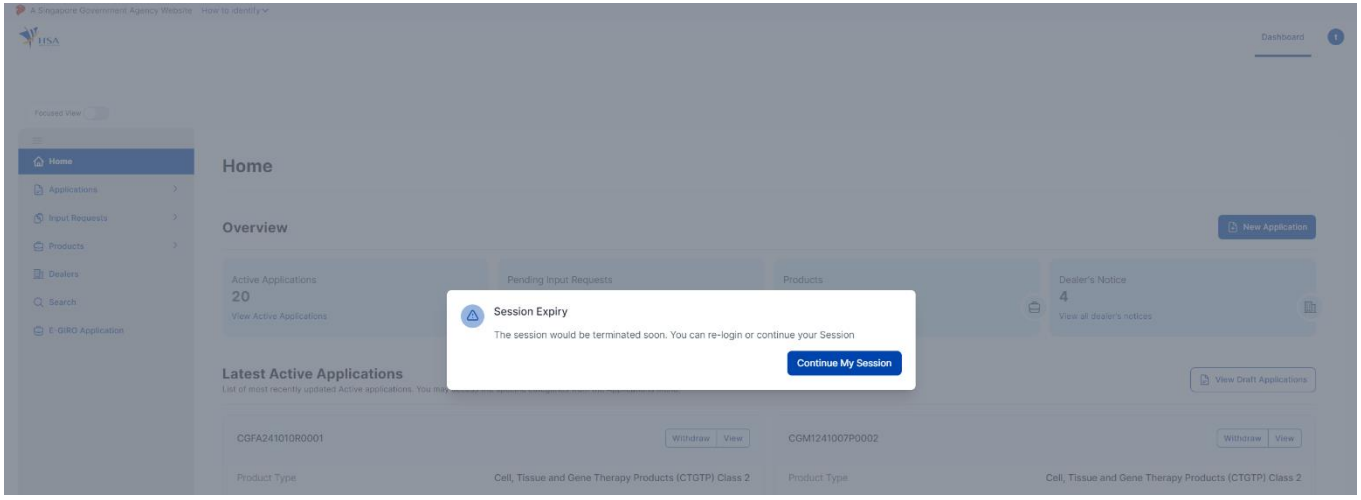
11 Applications

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

Draft



Inactivity session timeout



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

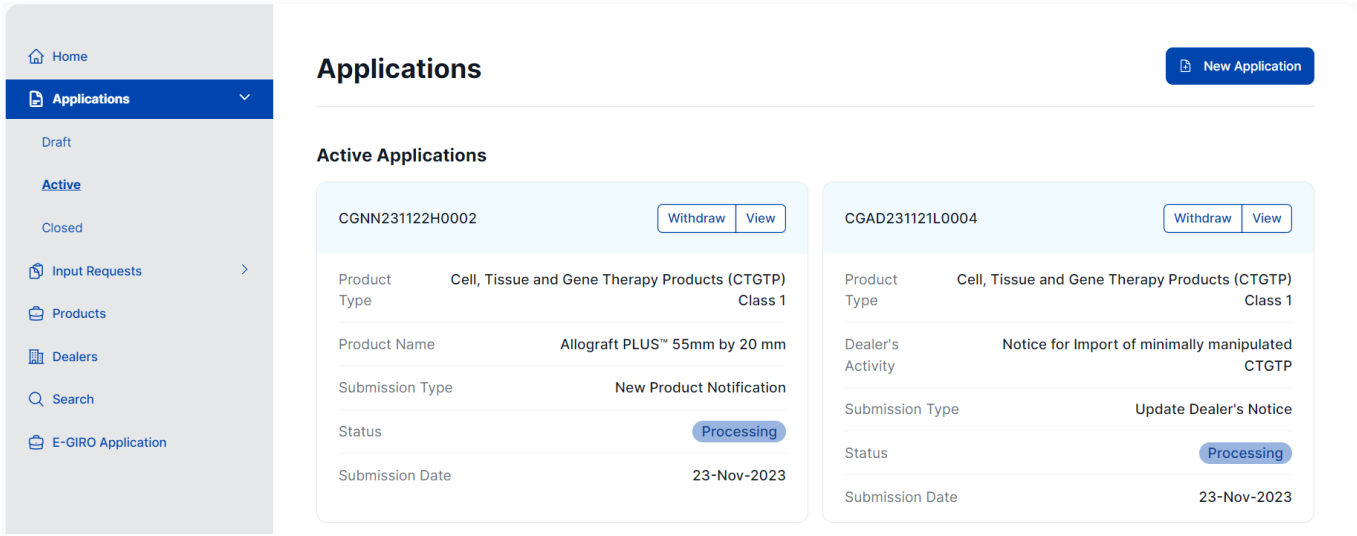
The application will be autosaved every few minutes and will also be saved whenever the applicant clicks on the next section.

The following buttons are displayed:

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

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

Active



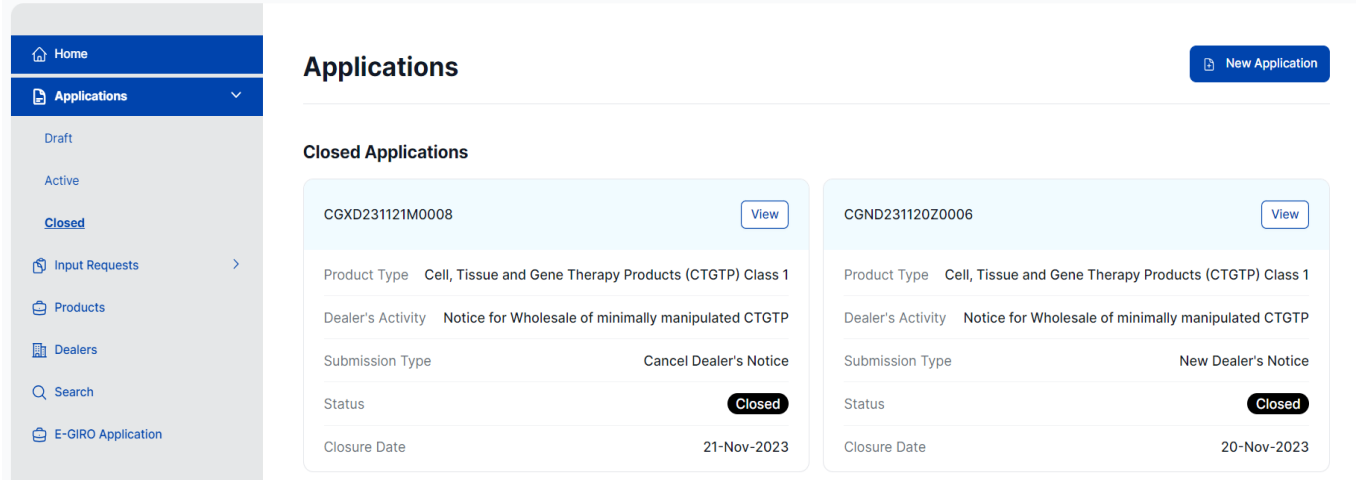
Active applications are submitted by the applicant and under review.

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

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

Clicking on the view button displays the application details page.

Closed



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

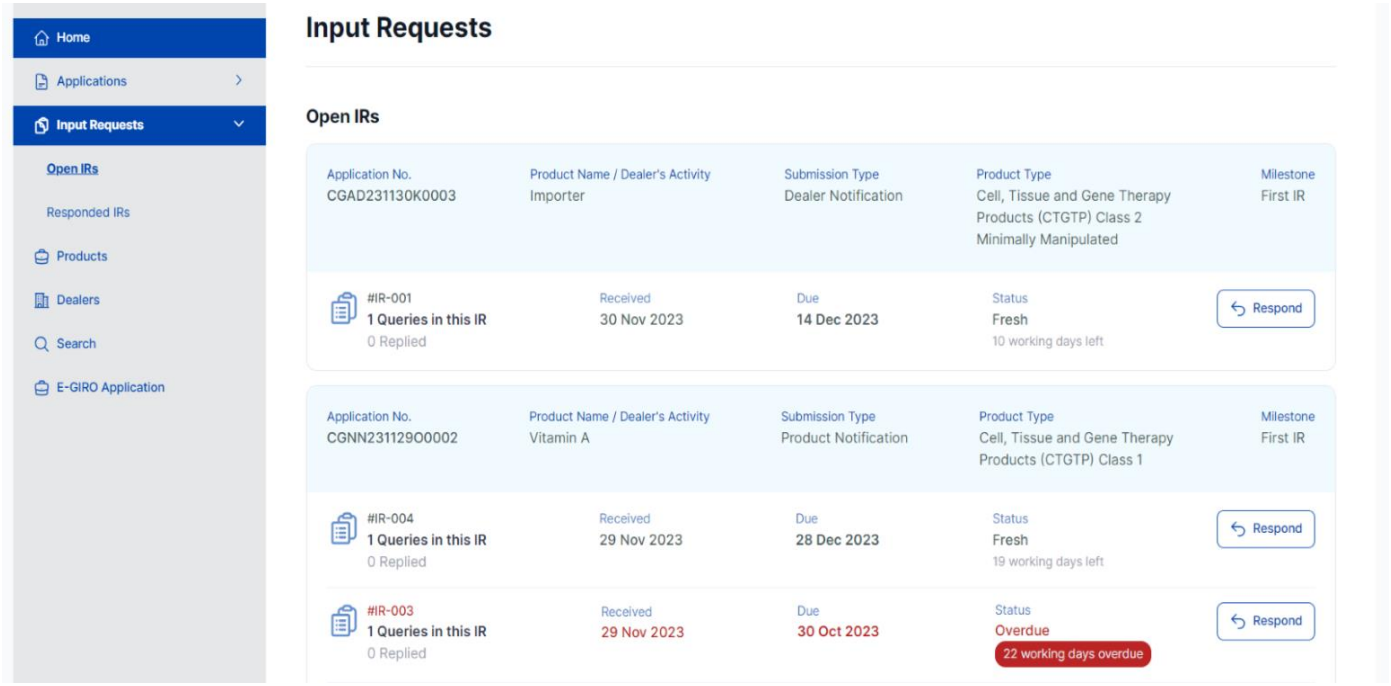
This section displays Application number, Product type, Product name/Dealer's activity, Submission type, Status, Closure date and a view button.

Clicking on the view button displays the application details page.

12 Tasks

12.1 Open Input Requests

Open IRs



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

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

Applicants would be able to:

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

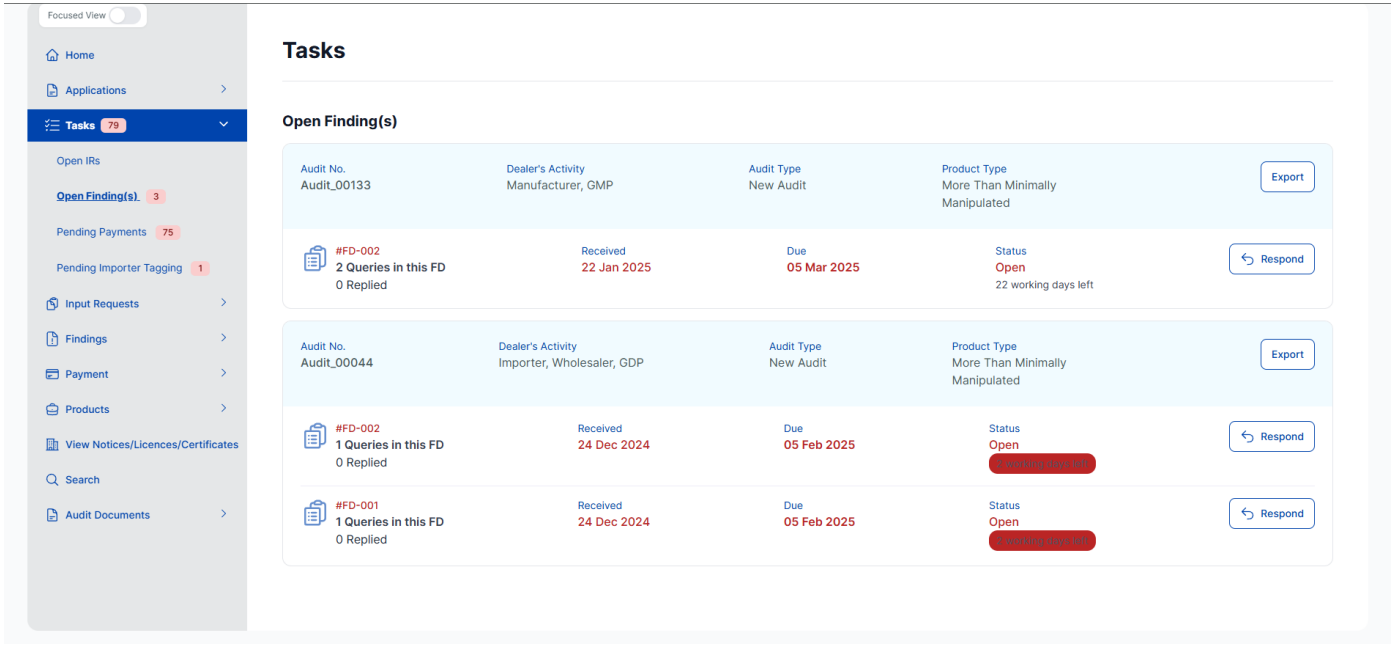
b) Export queries – downloads the IR queries.

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

12.2 Open Findings

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

Open Findings



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

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

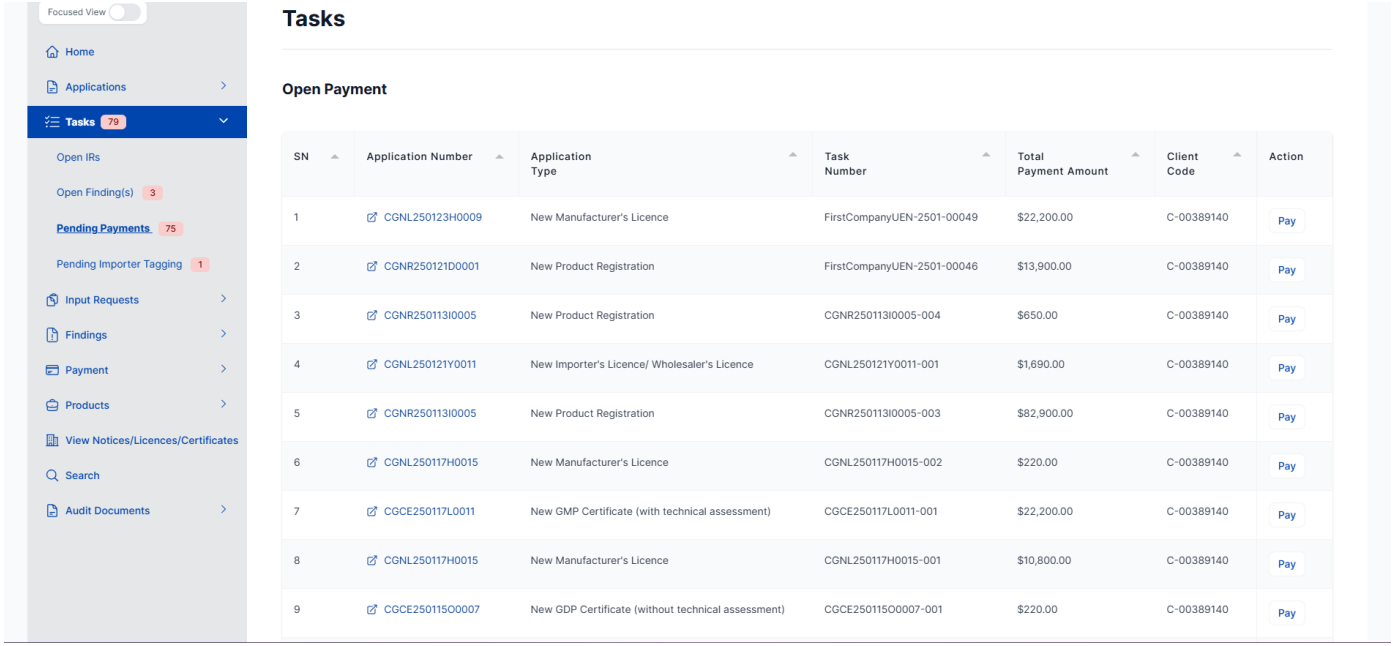
Applicants would be able to:

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

12.3 Pending Payments

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

Pending Payments



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

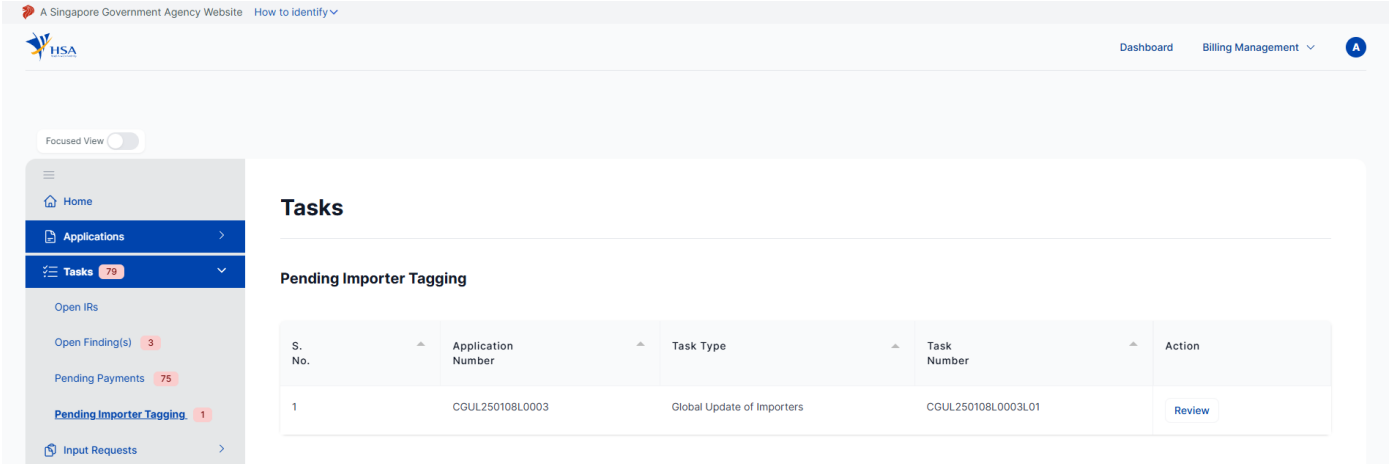
Applicants can click on the application number to view the application details for the specific application.

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

12.4 Pending Importer Tagging

Pending Importer Tagging displays applications where applicants i.e. authorised importer(s) must review and confirm importer details before approval. This process is triggered by Product Registrant when they authorise licensed importer(s) to import their registered products. The nominated licensed importer(s) would use this module to acknowledge their status as authorised importer(s).

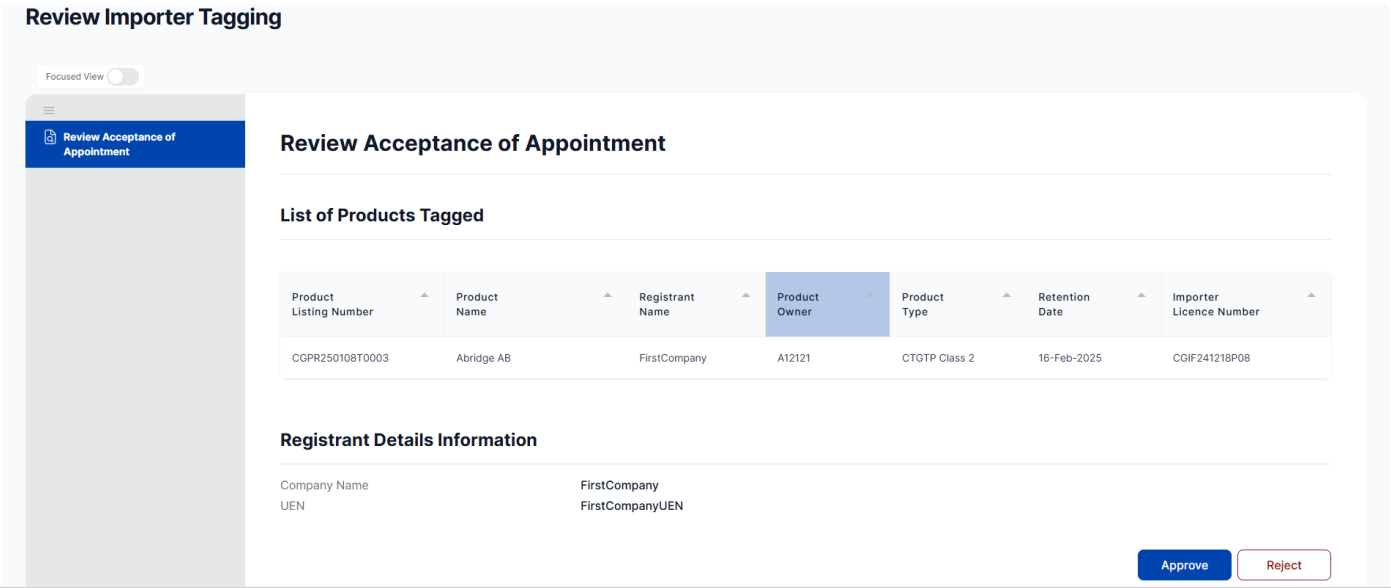
Pending Importer Tagging



The Pending Importer Tagging page lists applications requiring importer tagging. It includes the application number, task type, task number, and an 'Review' button.

Clicking on 'Review' directs applicants to the Review Importer Tagging page.

Review Importer Tagging



The Review Importer Tagging page displays product details, registrant information, and importer licence number.

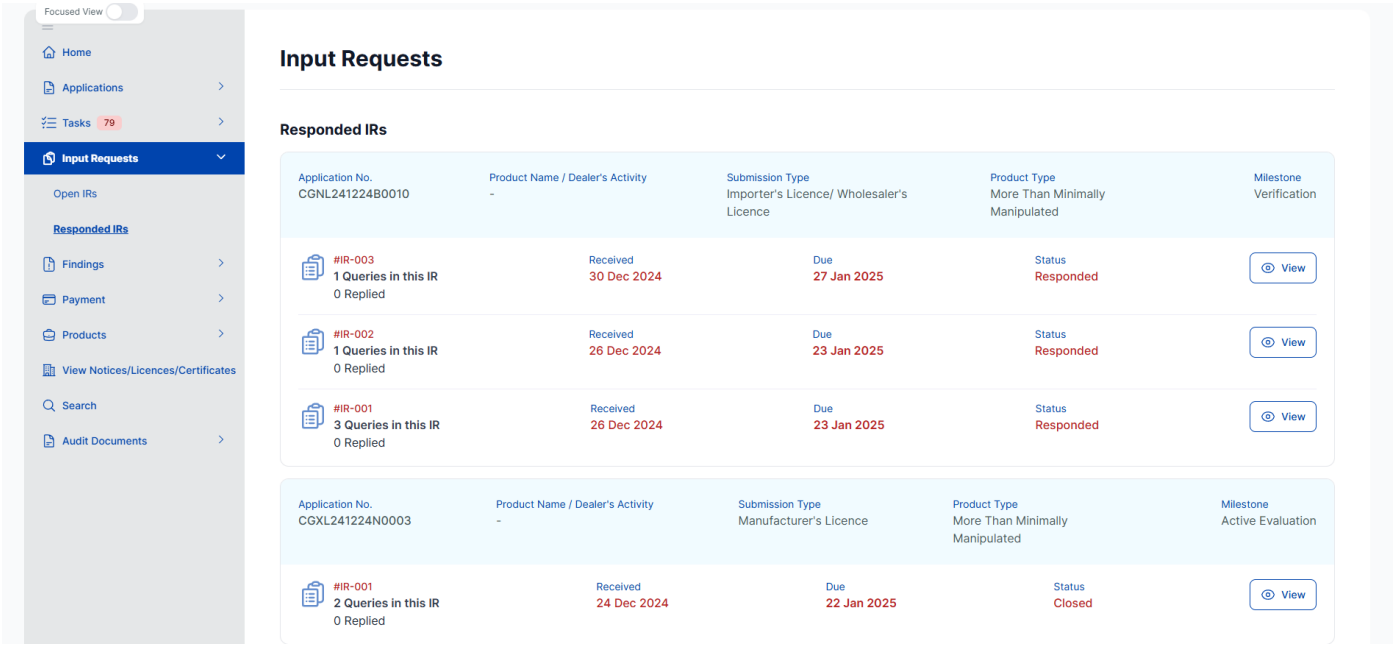
Applicants can approve the tagging request, confirming themselves as the authorised importer for the product. Alternatively, the applicant can reject the request and the registered product will not be tagged to the importer's licence.

13 Input Requests

The Input Requests section consists of two subsections: Open IRs and Responded IRs. Open IRs displays input requests from officers that require the applicant's response, while Responded IRs lists input requests that the applicant has already addressed.

The Open IRs page is identical to the page accessed via Tasks > Open IRs.

Responded IRs



Input Requests initiated by officers to which the applicant has already responded are displayed here.

The Responded IRs list displays the number of queries in the IR, received date, due date, status, and a 'View' button.

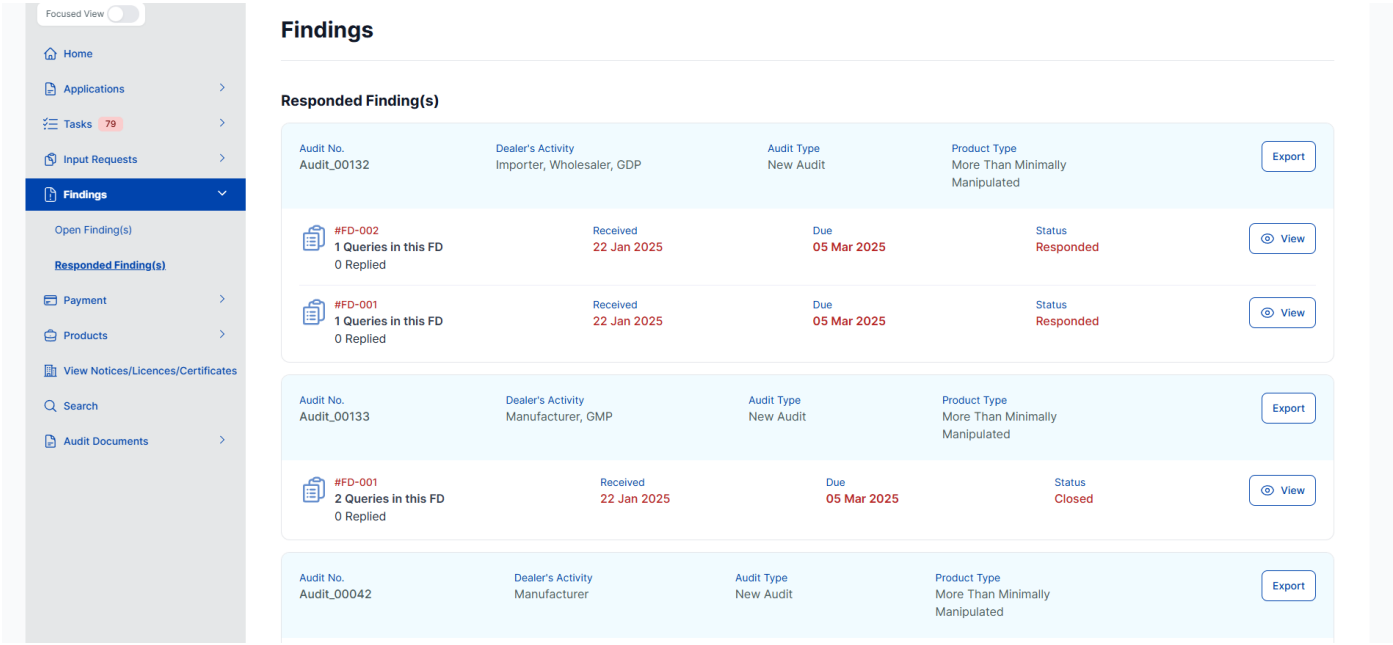
Clicking on the 'View' button redirects to the IR details page where all replied change logs are displayed.

14 Findings

The Findings section consists of two subsections: Open Findings and Responded Findings. Open Findings displays findings from officers that require the applicant's response, while Responded Findings lists findings that the applicant has already addressed.

The Open Findings page is identical to the page accessed via Tasks > Open Findings.

Responded Findings



Findings that have already been addressed by the applicant are displayed here.

The Responded Findings list includes details such as the audit number, dealer's activity, audit type, product type, received date, due date, status, and a 'View' button.

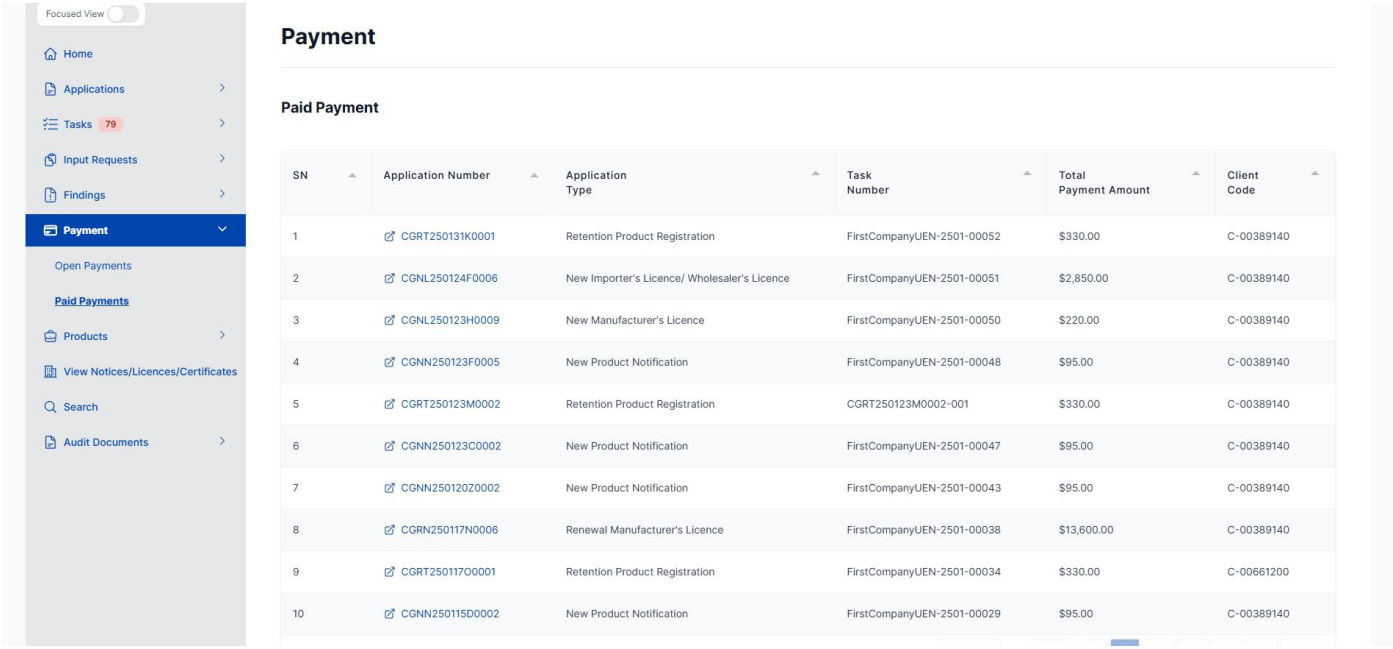
Clicking on the 'View' button redirects to the Respond to Finding(s) page where all responded queries are displayed.

15 Payment

The Payment section consists of two subsections: Open Payments and Paid Payments. Open Payment lists pending payments that require action from the applicant, while Paid Payments displays records of completed transactions.

The Open Payments page is identical to the page accessed via Tasks > Pending Payments.

Paid Payments



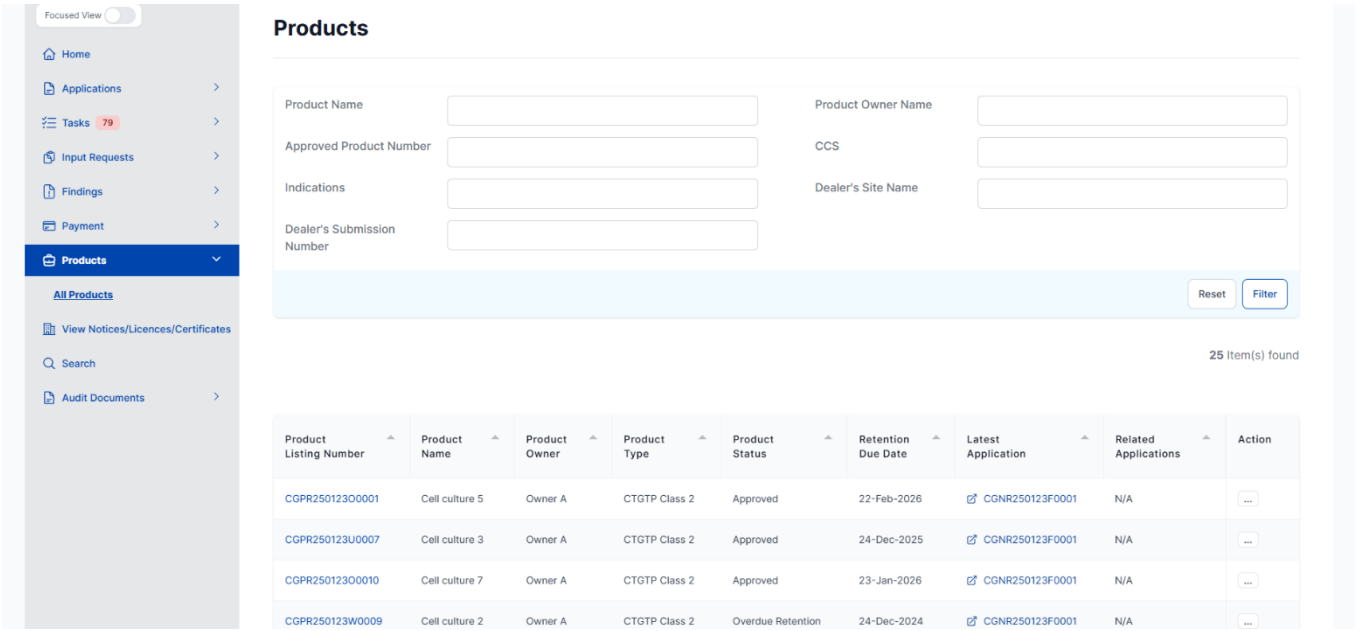
SN	Application Number	Application Type	Task Number	Total Payment Amount	Client Code
1	CGRT250131K0001	Retention Product Registration	FirstCompanyUEN-2501-00052	$330.00	C-00389140
2	CGNL250124F0006	New Importer's Licence/ Wholesaler's Licence	FirstCompanyUEN-2501-00051	$2,850.00	C-00389140
3	CGNL250123H0009	New Manufacturer's Licence	FirstCompanyUEN-2501-00050	$220.00	C-00389140
4	CGNN250123F0005	New Product Notification	FirstCompanyUEN-2501-00048	$95.00	C-00389140
5	CGRT250123M0002	Retention Product Registration	CGRT250123M0002-001	$330.00	C-00389140
6	CGNN250123C0002	New Product Notification	FirstCompanyUEN-2501-00047	$95.00	C-00389140
7	CGNN250120Z0002	New Product Notification	FirstCompanyUEN-2501-00043	$95.00	C-00389140
8	CGRN250117N0006	Renewal Manufacturer's Licence	FirstCompanyUEN-2501-00038	$13,600.00	C-00389140
9	CGRT250117O0001	Retention Product Registration	FirstCompanyUEN-2501-00034	$330.00	C-00661200
10	CGNN250115D0002	New Product Notification	FirstCompanyUEN-2501-00029	$95.00	C-00389140

The Paid Payments lists records of payments that have been successfully completed. Applicants can view details such as the application number, application type, task number, payment amount, client code, and payment status.

Clicking on the application number redirects applicants to the Application Details page.

16 Products

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



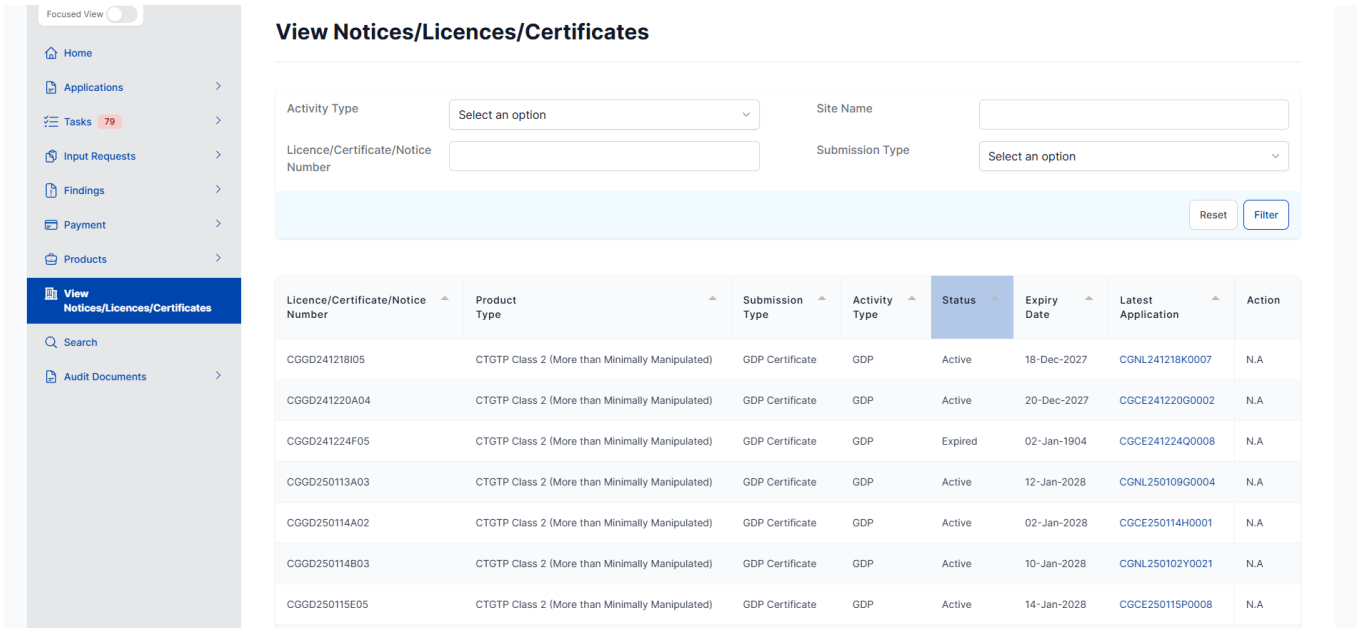
Applicants can search for specific product by selecting filters such as product name, owner name, product number, dealer's submission number, indications, CCS, or dealer's site name.

Clicking on the Application number redirects the applicant to the application page while clicking on the Product Listing Number redirects applicants to a page where they can download product-related files.

The Action column contains an ellipsis menu, which provides additional actions that applicants can take for the corresponding product.

17 View Notices/Licences/Certificates

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

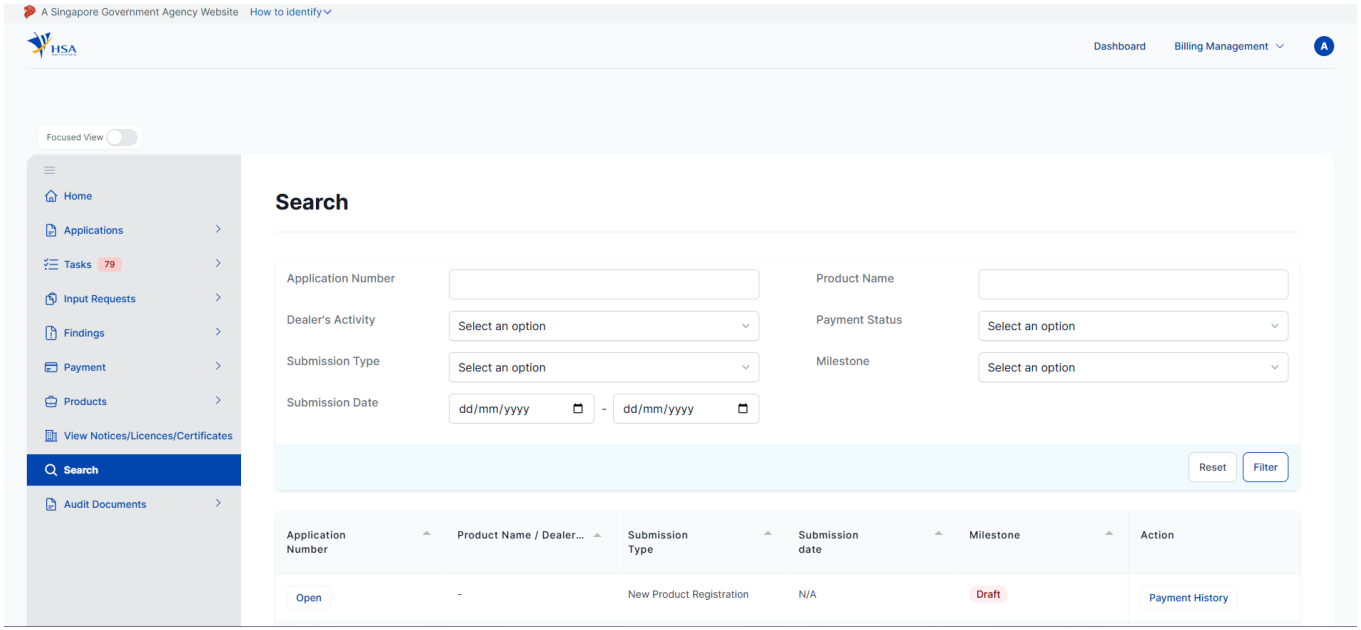


Applicants can search for specific records by selecting filters such as activity type, site name, submission type, and notice/licence/certificate number.

Once the relevant applications are displayed, they can click on the application number to view the details of the corresponding application.

18 Search

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

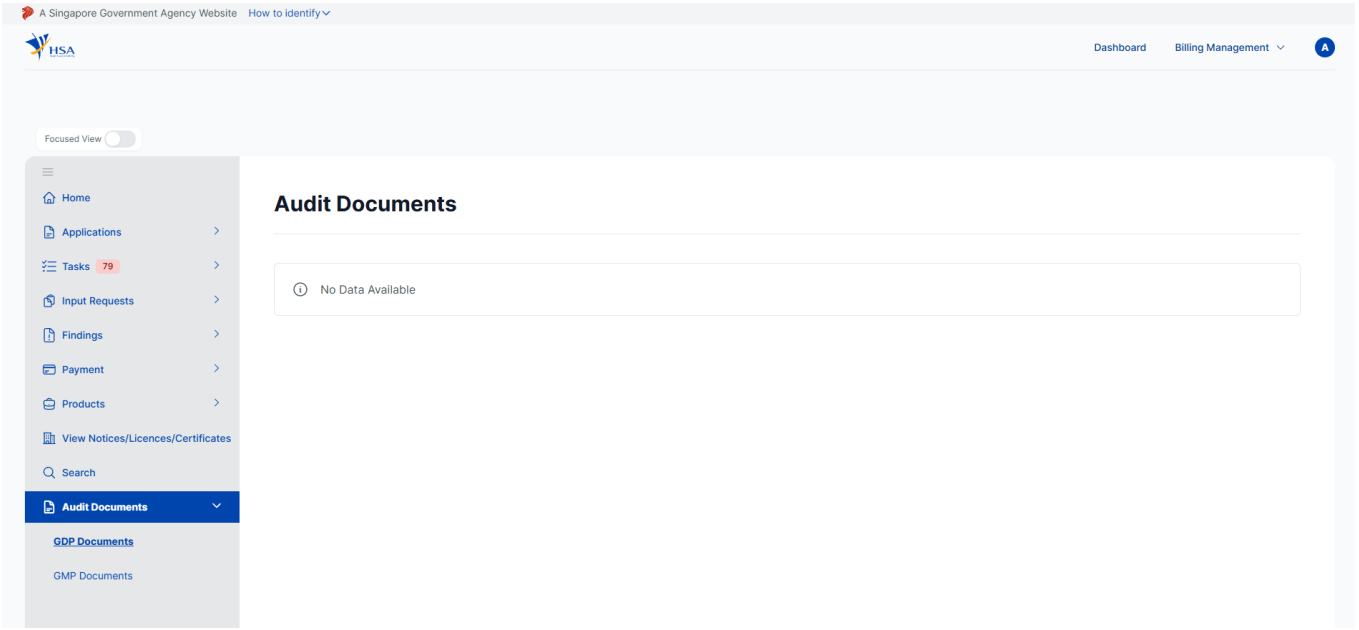


Applicants can search for specific records by selecting filters such as application number, product name, dealer's activity, payment status, milestone, submission type, or submission date.

Clicking on the Application number redirects the applicant to the application page, while Payment History leads to the Payment Details page.

19 Audit Documents

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



This section displays all documents associated with the audit case, if available.

Applicants can view the listed documents under their respective subsections.