
# ZAMRA

# Self- Service Portal

# Manual Contents

# 1 Introduction

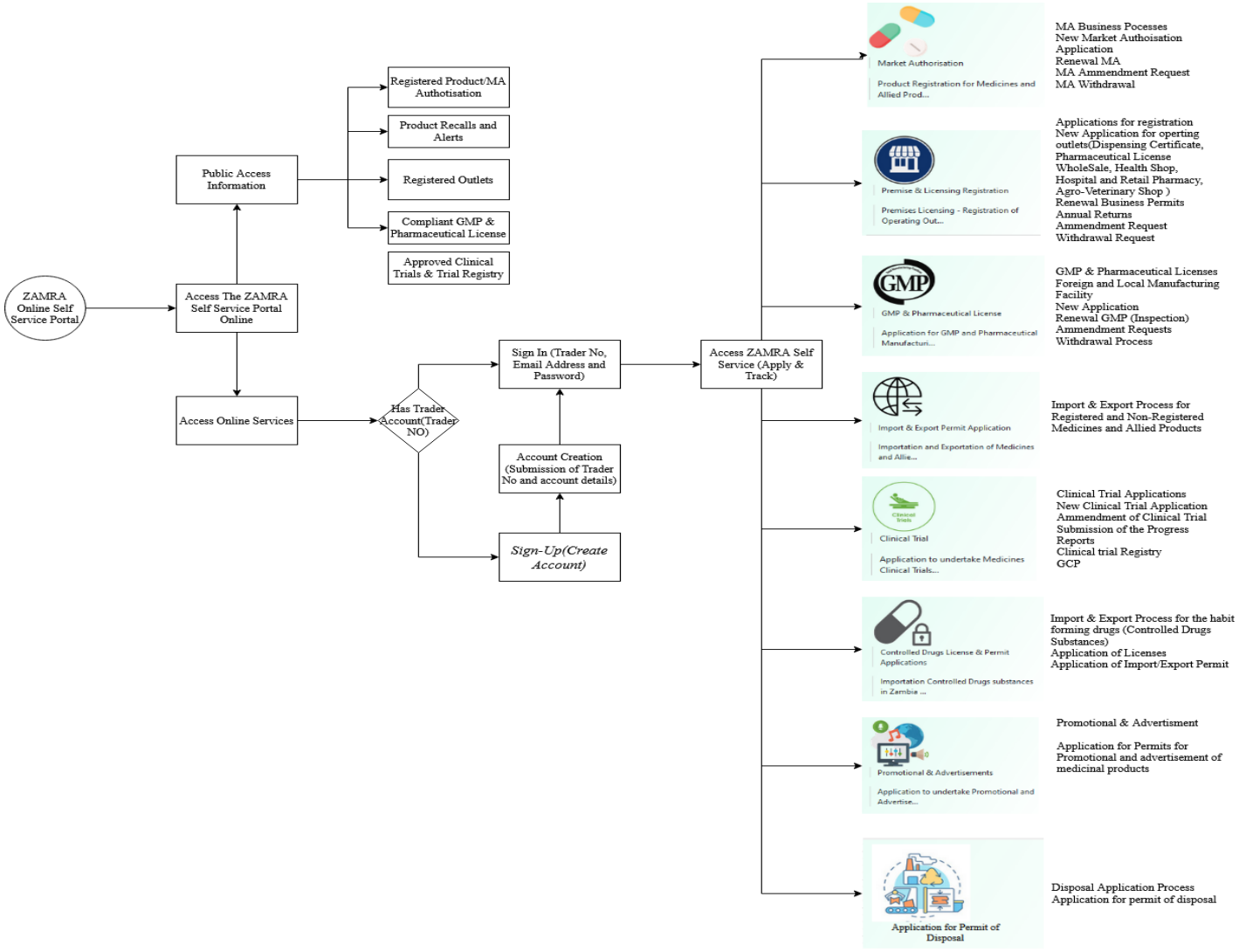
The ZAMRA self-service portal is an app, consisting of self-service and self-help functions that enable and empower our traders to request services, track applications, find information, register, and resolve issues. The service portal helps users address common needs efficiently and without outside help and thus complementing human service agents.

The Self-Service Portal incorporates a self-service portal where customers (traders) can submit a request for applications on various modules about the set workflow eliminating the physical submission of applications.

The portal acts as the link between the customers and the organization by handling all customer operations like:

- Application initialization and tracking of applications through the process flow
- Uploading and submission of requested dossiers and documents
- Responses to the request for additional information to queries
- Generation and printing of issued invoices, receipts, certificates, licenses, etc.

# 2 Getting Started



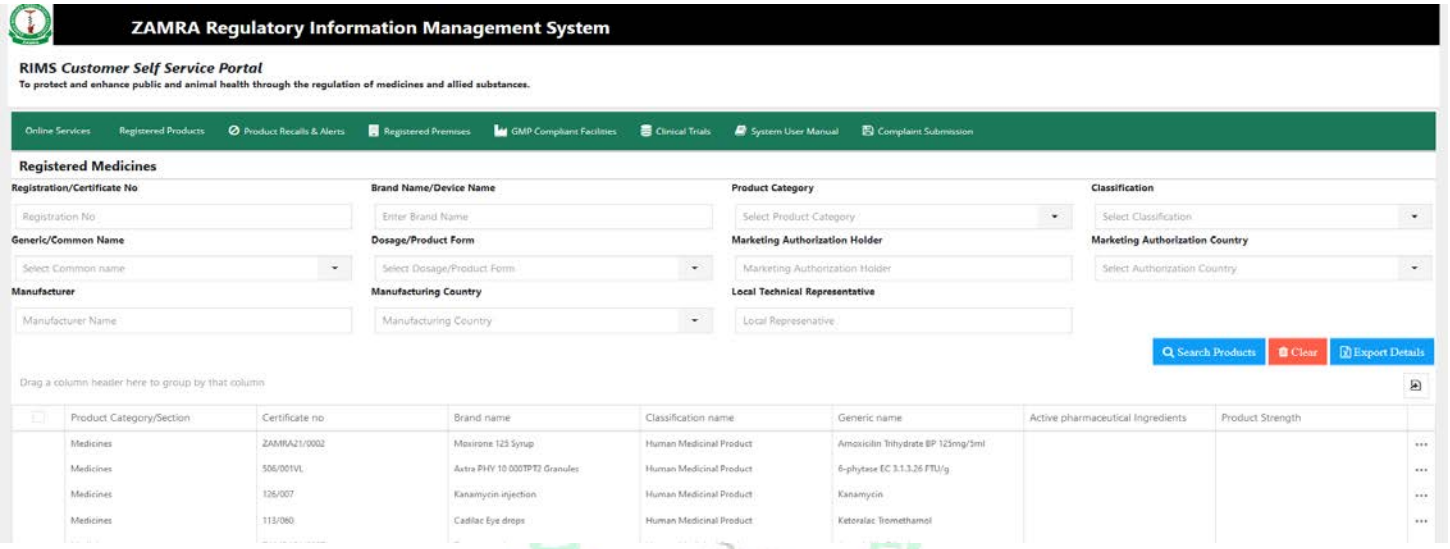

The self-service portal provides access to information to the public and allows access to services offered by ZAMRA.

# 3 Public Access Information

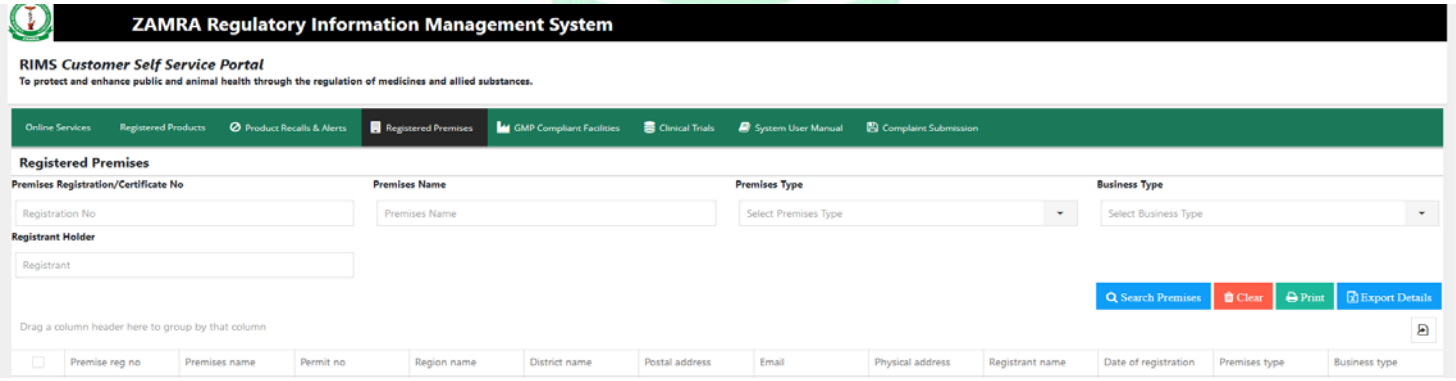
This provides access to registers for various applications as outlined below with extensive search (filter provision)

This includes:

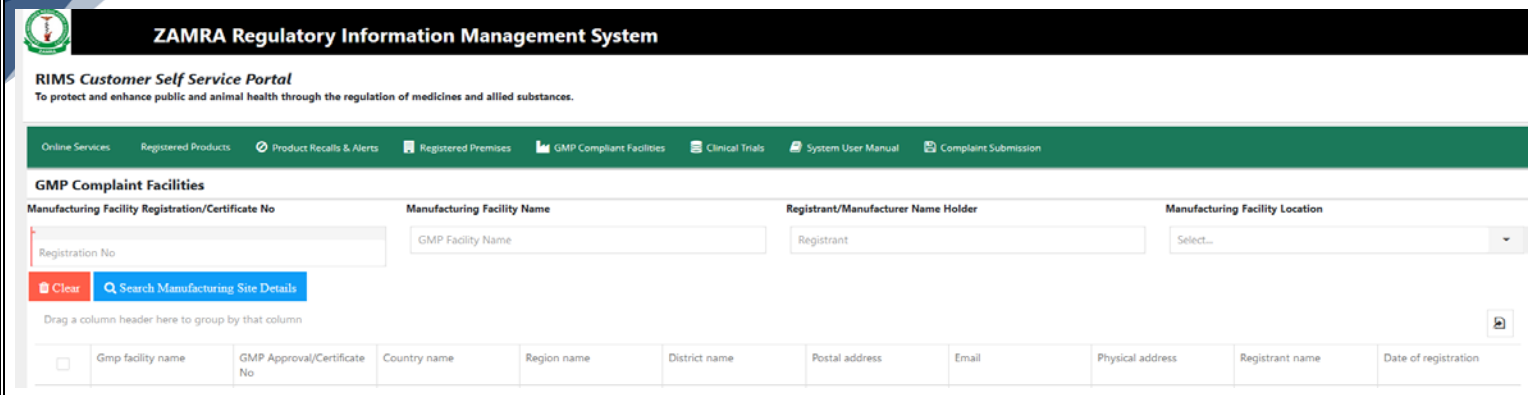
- Register for the approved Marketing Authorization in the country



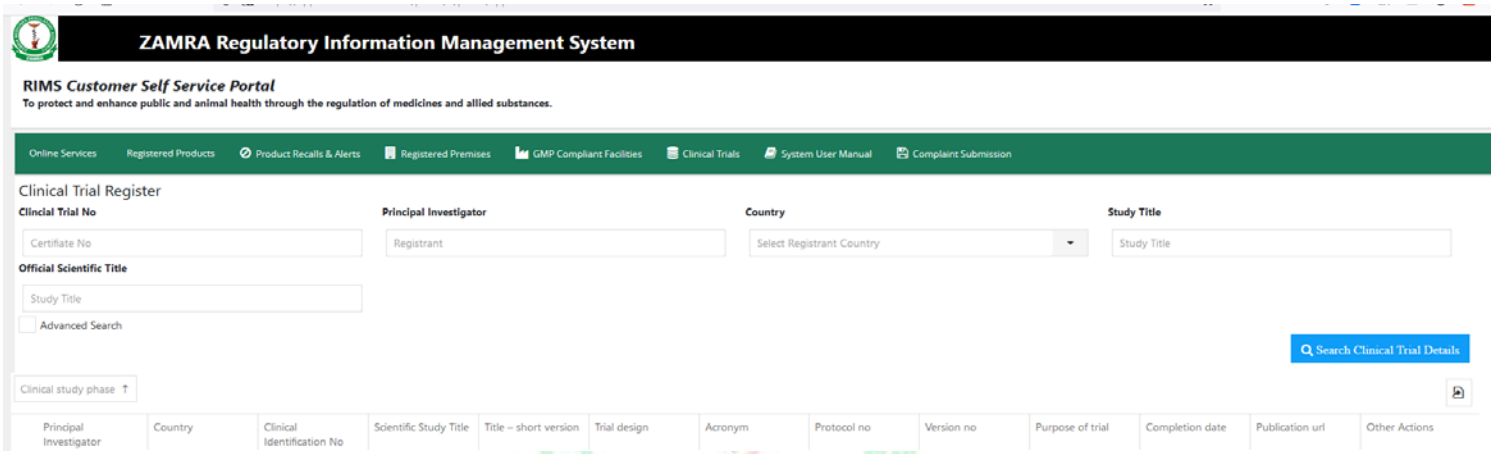

- Register for the Approved Business dealing with medicinal products




- Register for the Approved and Compliant GMP Facilities and Pharmaceutical Licenses




- Register for submission of the Clinical Trial information



# 4 Online Services

This system provides several services to the authorized traders who have an account with the organization. These Services includes:

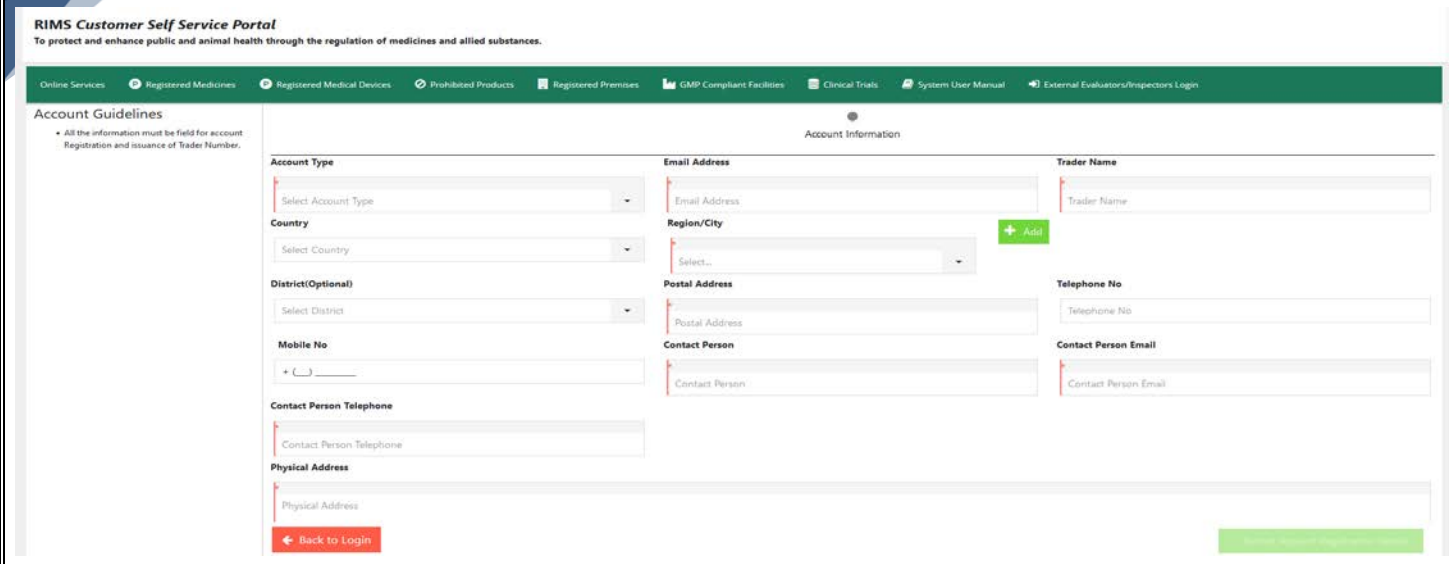
- Market Authorization
- Premise & Licensing Registration
- GMP & Pharmaceutical License
- Import & Export Permit Application
- Clinical Trial
- HFD License & Permit Applications
- Promotional & Advertisements
- Disposal Applications
- Automated Payment Remittance

To access this, the user has to have a valid account that can be registered by following the guidelines in the creation of the trader account section illustrated in the previous section.

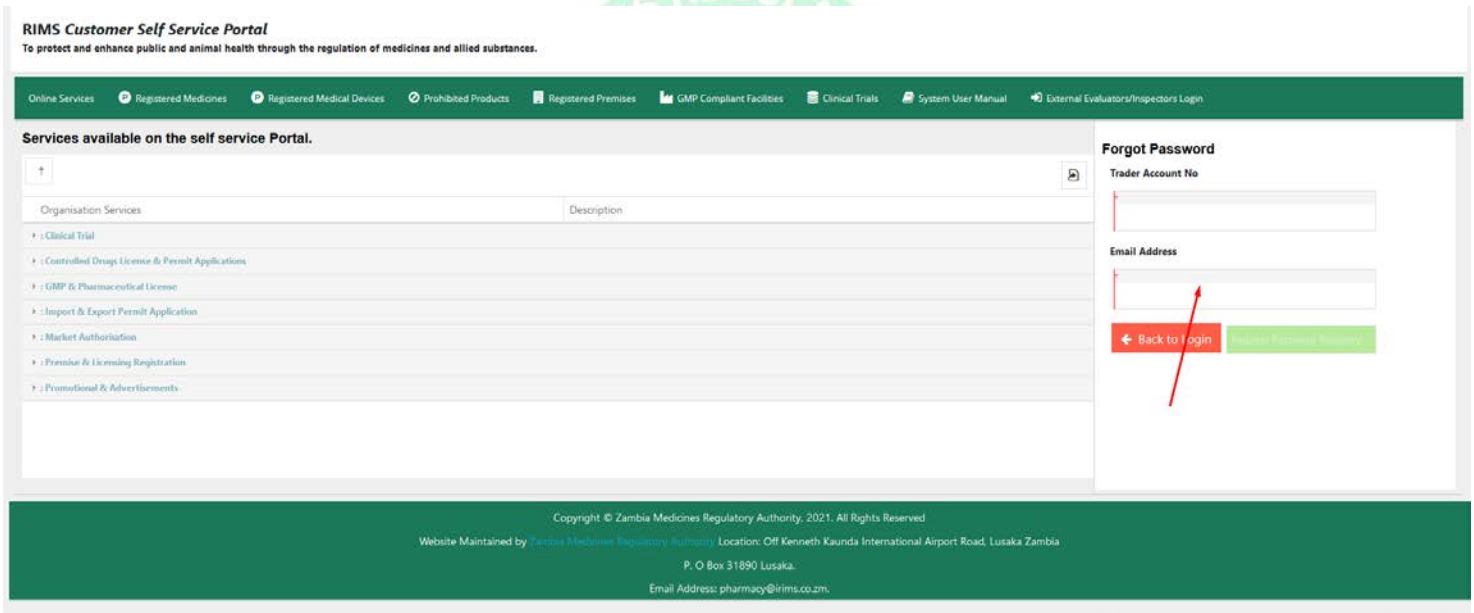
## 4.1 Creating a Trader Account

To create a trader account, the user first navigates to the online services page as illustrated below. A list of tabs describing the online services offered by the system is displayed on this page.


The user is required to click **Sign up(create trader account)** button located below the sign in button.
Once the button has been clicked, the window illustrated below is displayed. The user then enters all the required data into the fields provided.



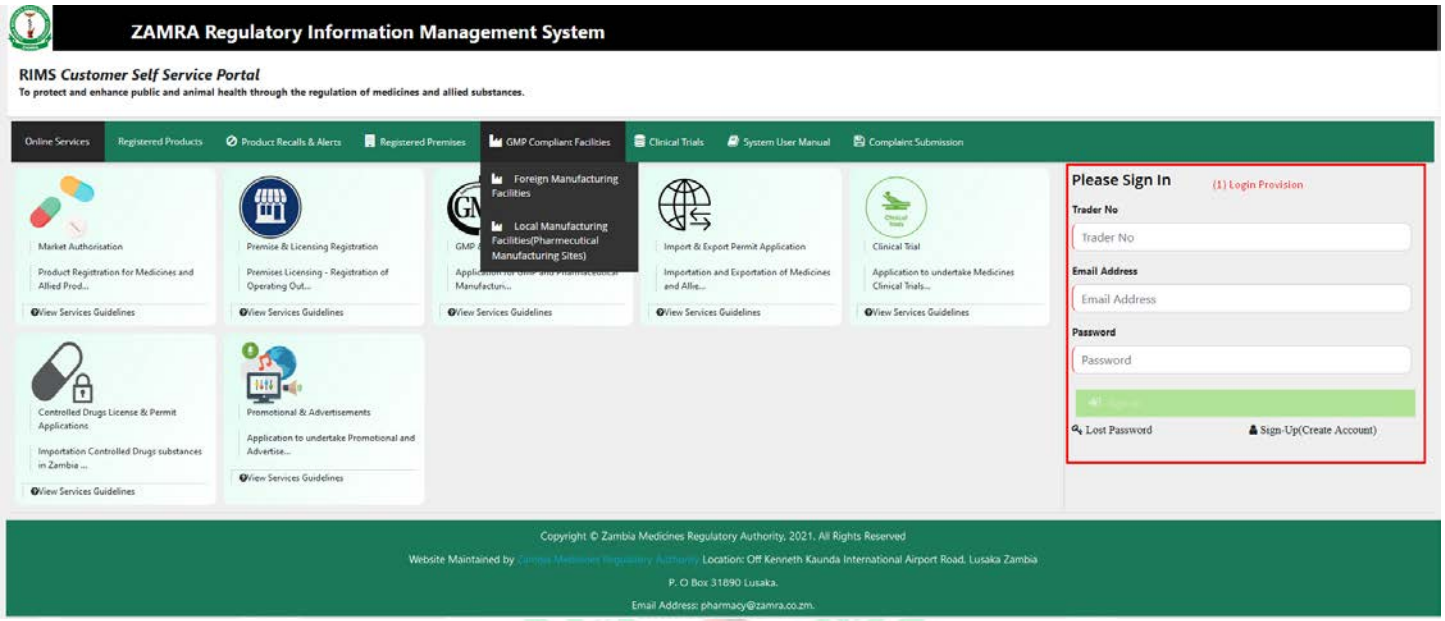

## 4.2 Forgot Password



## 4.3 Online service Login

The login section provides room for authentication to access the services offered by ZAMRA, and this is based on the information submitted during the Account Creation process which includes:

- Trader No: Unique Identification of a trader account
- Email Address: for purposes of communication and notification to the trader
- Password




On Successful Login: The system directs you to the Online Service Dashboard.

# 5 Online Services Dashboard

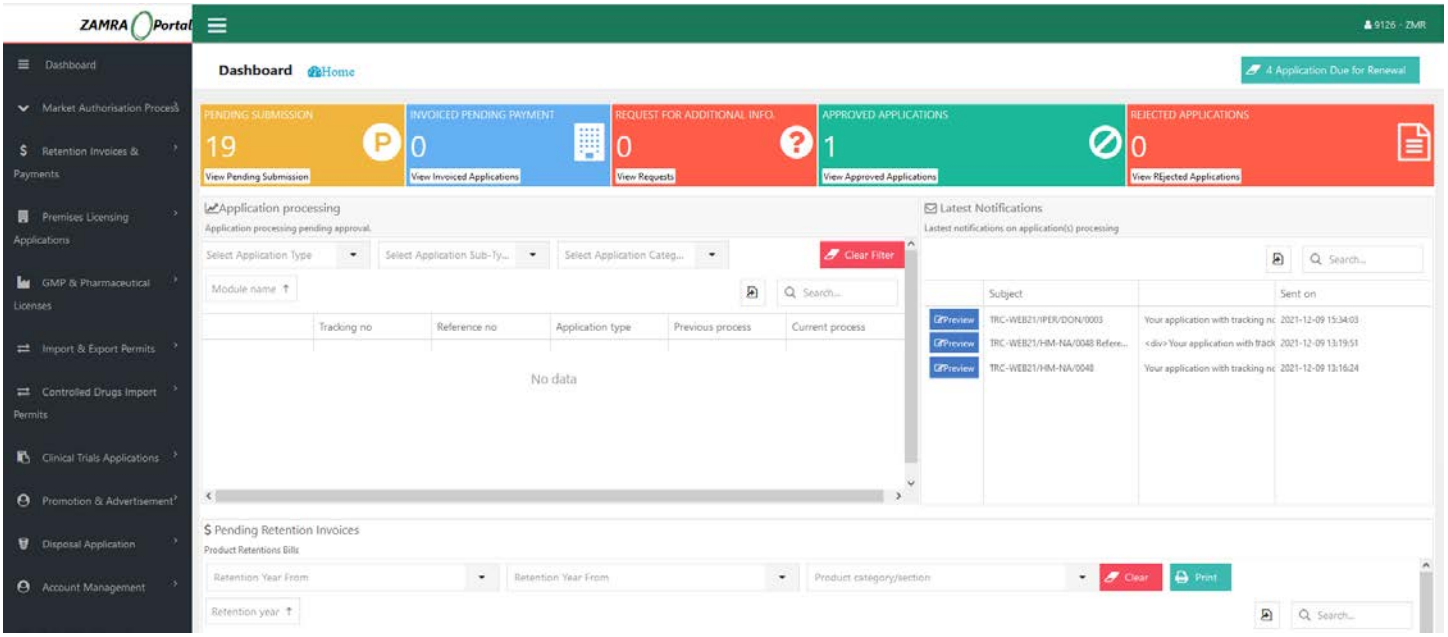
This is the main page/window displayed once the user has successfully logged into the system. It displays all the system modules on a navigation panel located on the left side of the window/page.

The window also provides the user with statistics on the:

• Number of Pending submissions invoiced pending payments, requests for additional information, approved and rejected applications.

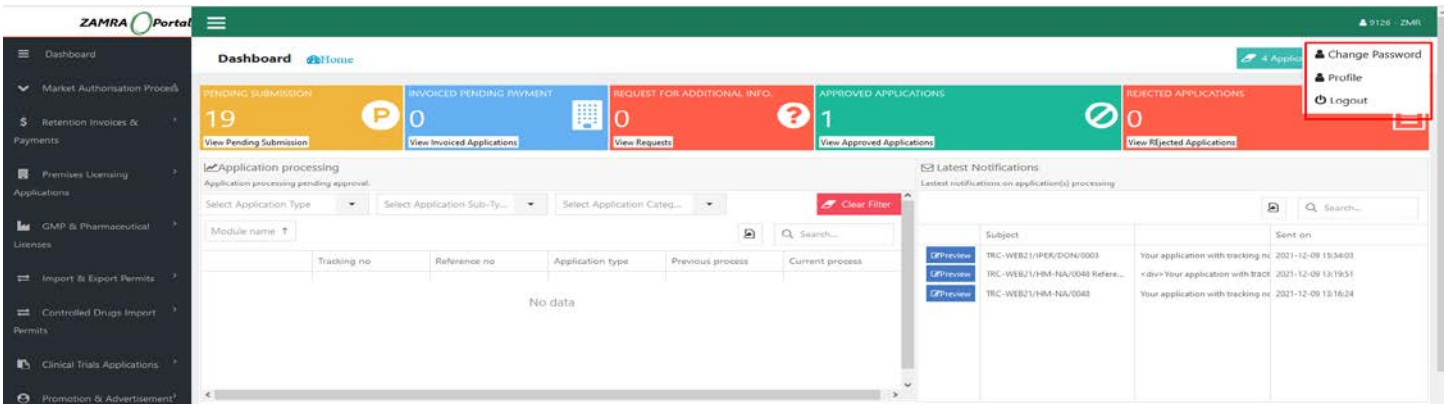
• Pending retention invoices, record of the applications will be displayed on the dashboard.

On the right-hand side of the dashboard is a list of all the latest notifications. All types of applications that have been approved will be listed here with the most recent located at the topmost of the notification list.

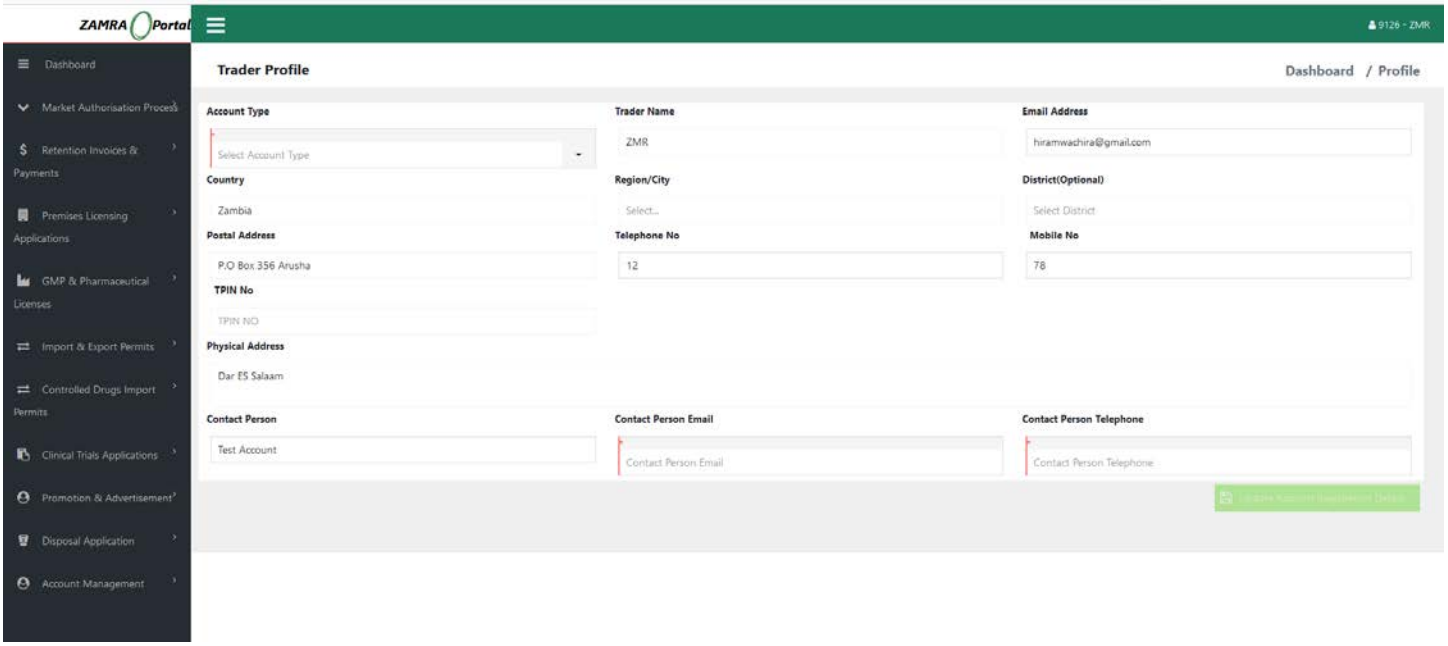


## 5.1 Account Profile Information

The user can also access the account information/configuration by clicking the user's name displayed at the top right of the window. Once clicked, a dropdown menu is displayed. It contains the change password button, the profile button, and the logout button as illustrated below.

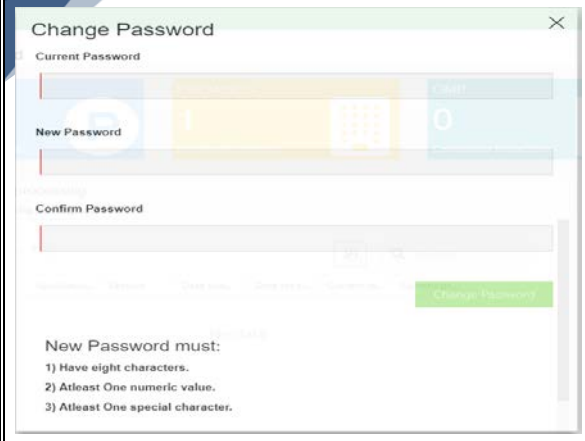



## 5.2 Profile




## 5.3 Change Password

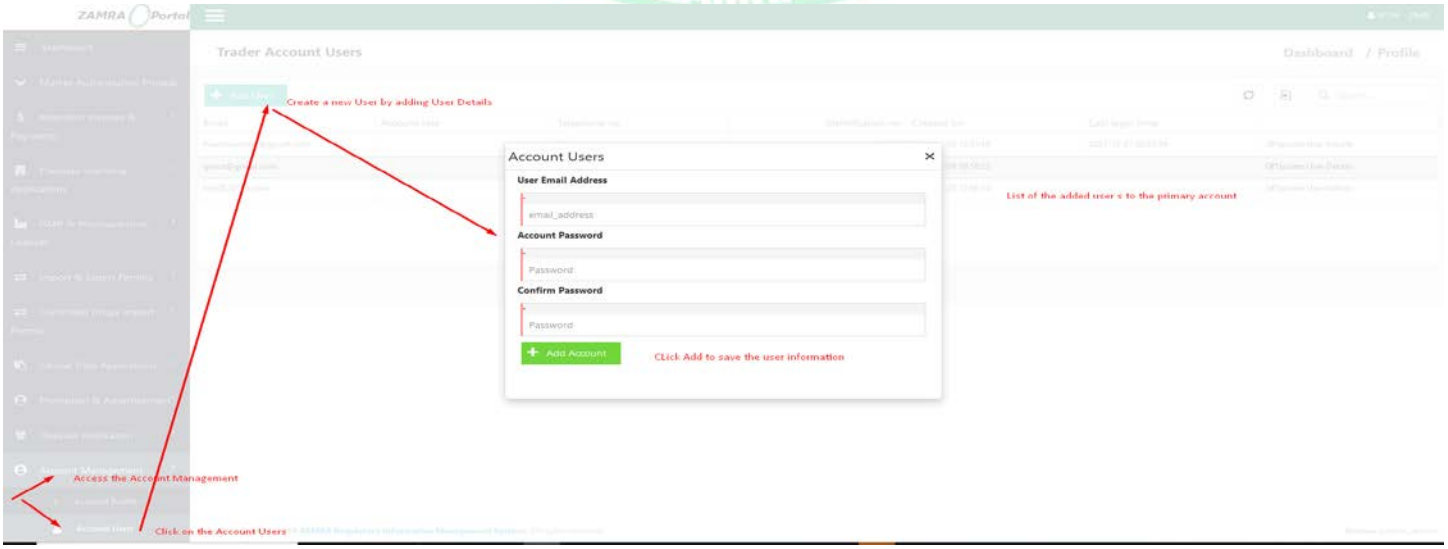
The change password section is used to change the user's current password to a new one. To do this, the user clicks the user's name displayed on the top right of the screen which opens the dropdown menu containing the "change password" button. Once clicked, the window illustrated below is displayed.




The user then enters his/her current password, then the new password and confirms it. The password must however have at least 8 characters, one special character, and one numeric value. After all, the requirements have been met and all the password details entered, then the "change password" button becomes active and the user can change the password by clicking it.

## 5.4 Account Users

This process provides the traders/Applicants with an option for adding more users to the primary account, this is to enable different persons under the same account to access the organization services I.e. The primary account registered under info@organ_name.com then the other accounts to the test1@ organ_name.com test2@organ_name.com, this is to allow scalability of services to the trader's department and further for tracking purposes of the initialization of applications by different personnel.



# 6 Marketing Authorization Application Process

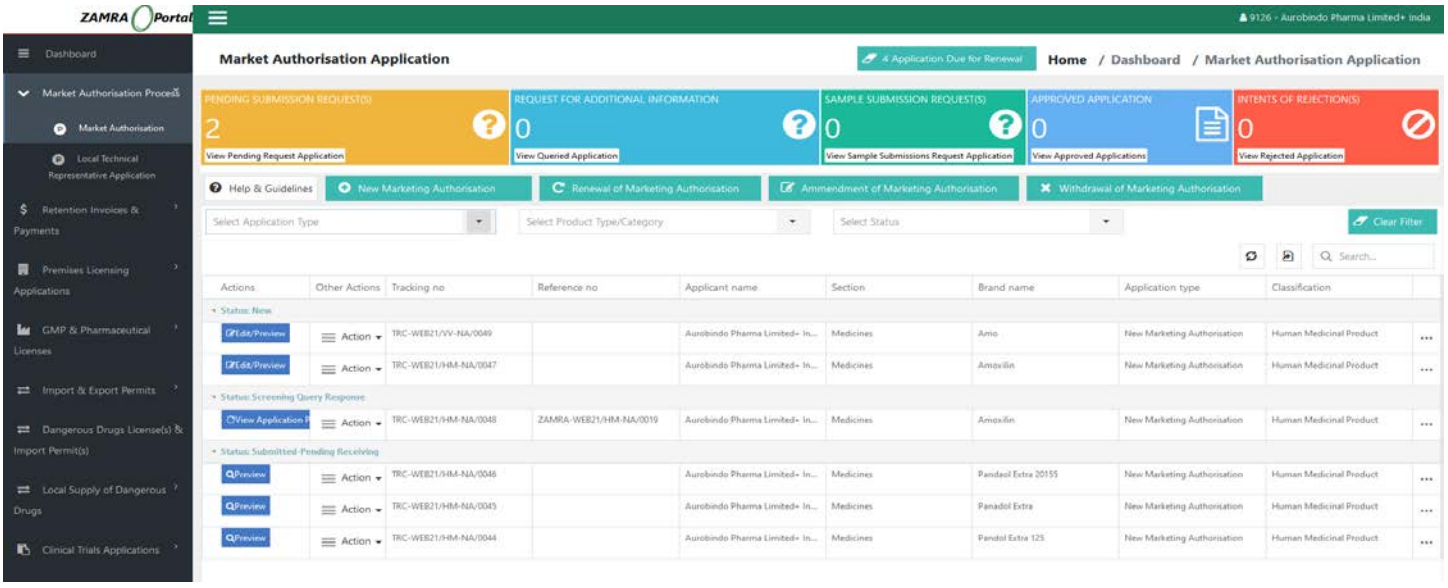
The Marketing Authorization business process provides for application for product registration of medicines and Allied Products in Zambia.

The following categories or Medicines are handled under the module

Note: The Required Product Information are distinct from one Product Type to the other and this guideline provides for the general overview of the required process which are uniform.

| Sn | Product Type | Product Categories | |
|---|---|---|---|
| 1 | Medicines Products | • Human Medicines<br>• Veterinary<br>• Biocidal Products | |
| 2 | Allied Substances | • Antiseptics, Disinfectants and Medicated Soap<br>• Medical Devices(In Vitro Diagnostic and Non-In Vitro Diagnostic) for Class A,B, C, D<br>• Cosmetics Products<br>• Condoms | • Acaricides are pesticides used to kill ticks and mites.<br>• Feed Addictive's<br>• Nutritional Supplements |

Marketing Authorization Dashboard



The dashboard provides for the following

- Analytics based on the submitted MA applications and based on a distinct status.
- Provision to initiate the following applications

1. New MA Application for the listed products types
2. Submission of renewal of Marketing Authorization
3. Submission of Amendment Requests for MA
4. Submission of withdrawal requests

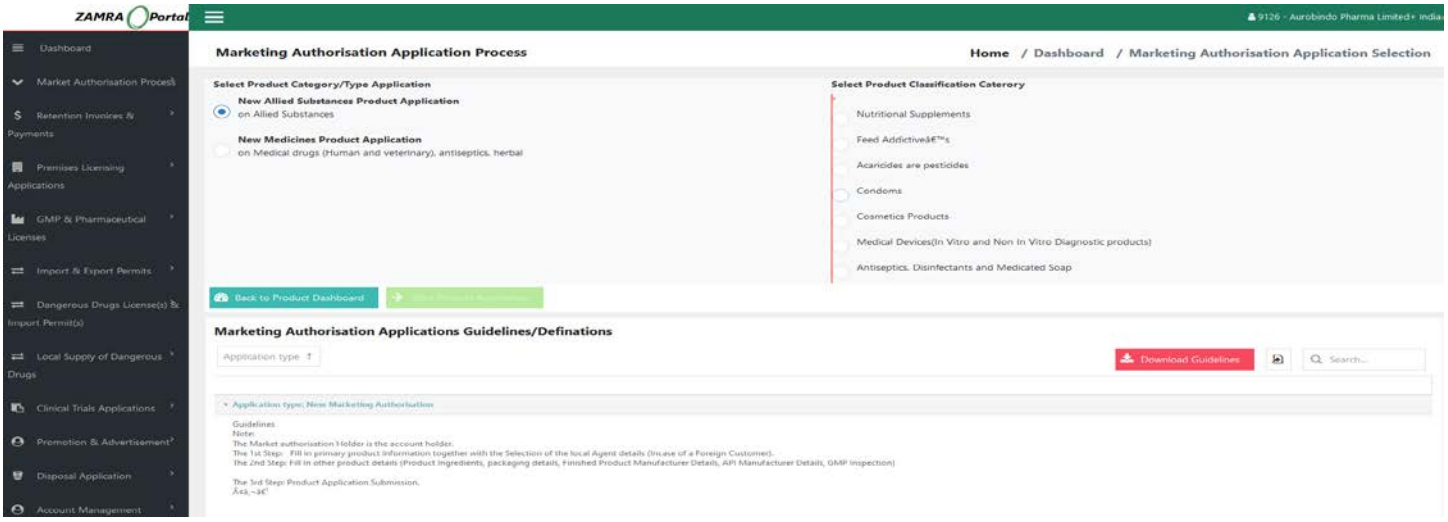
- List of the already initiated MA applications grouped under the distinct MA process

This also provides various actions on the initiated product application, this includes

1. Edit and Preview- Provision to continue with already initiated product application for submission under all the categories and processes
2. Preview: Preview already submitted MA application
3. Query Responses: Provision to Response to Request for Additional Information
4. Preview Invoice and Payments Details: Provision to preview and print proforma invoices and payments confirmations (receipt)
5. Print Options: Print MA Certificate, letter of rejection, request for additional information, etc.

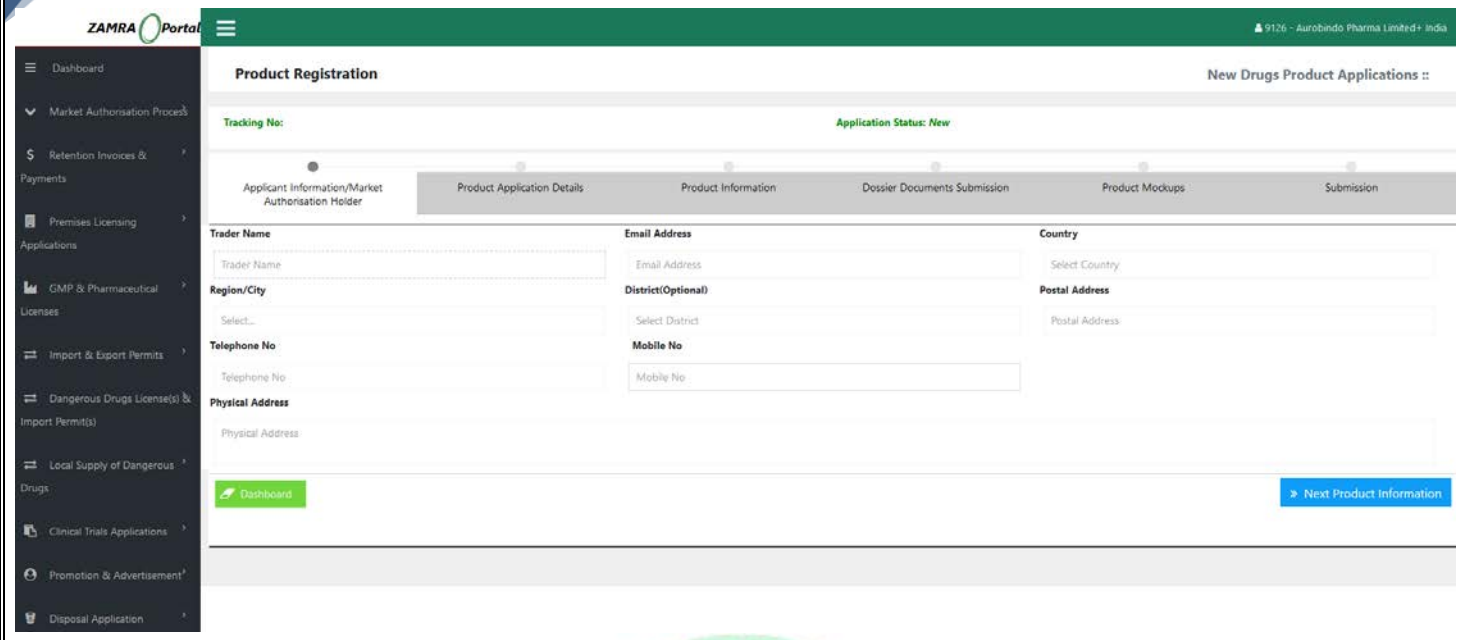
## 6.1 Initialization of New MA Application

- Step 1: Provision to select the Product type and category and then start the application process

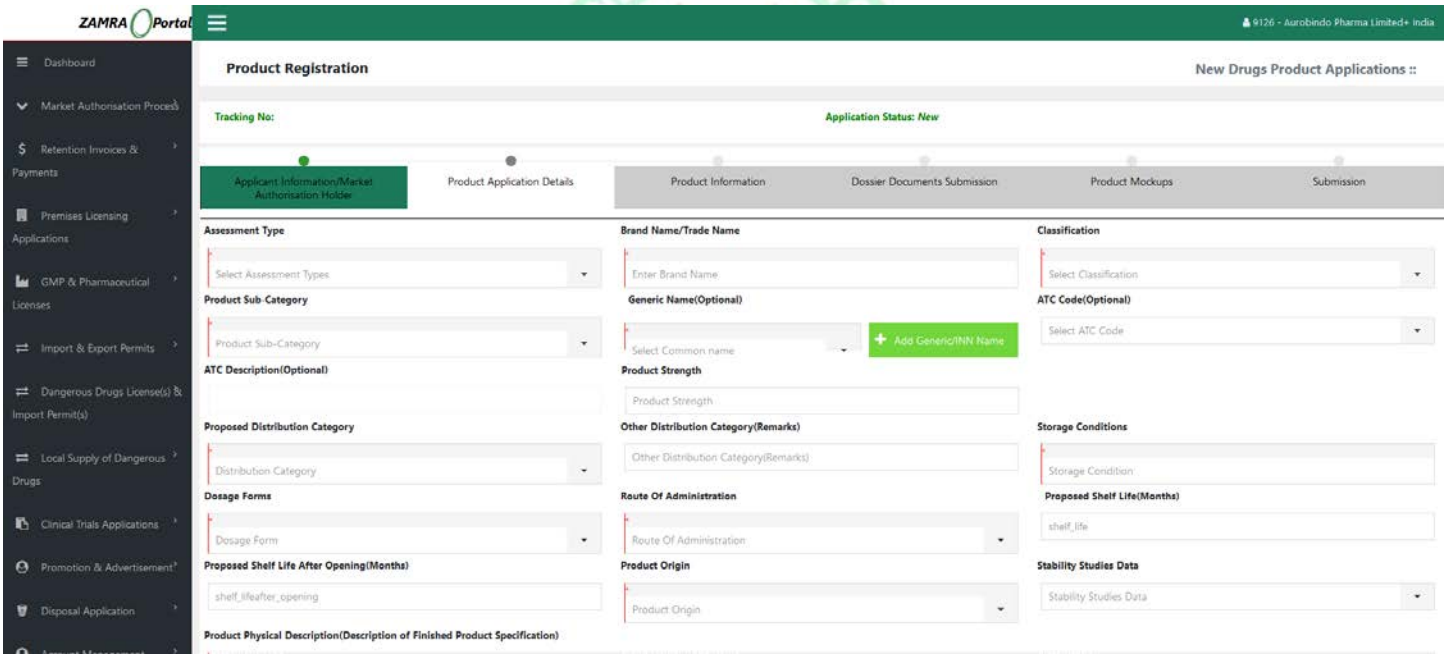



- Step 2: Fill in MA Application details

Step 1: Preview MA Holder's/Applicant Information

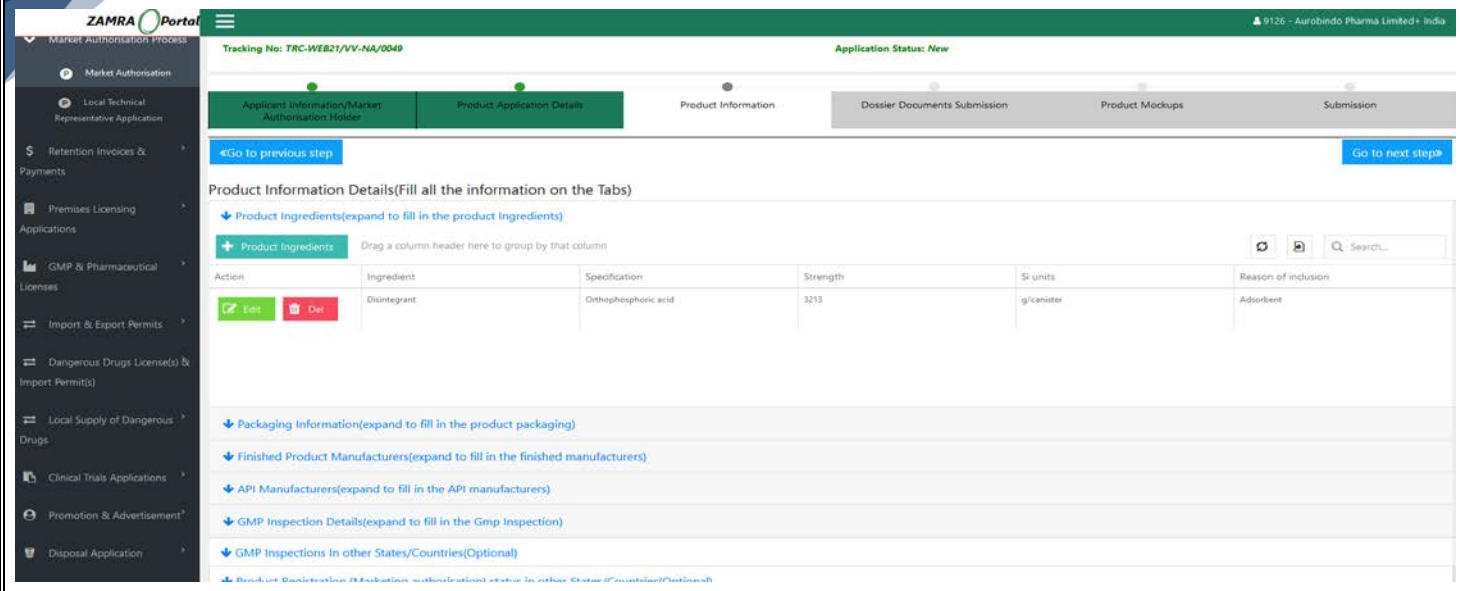



Step 2: Fill in Product General Product Information

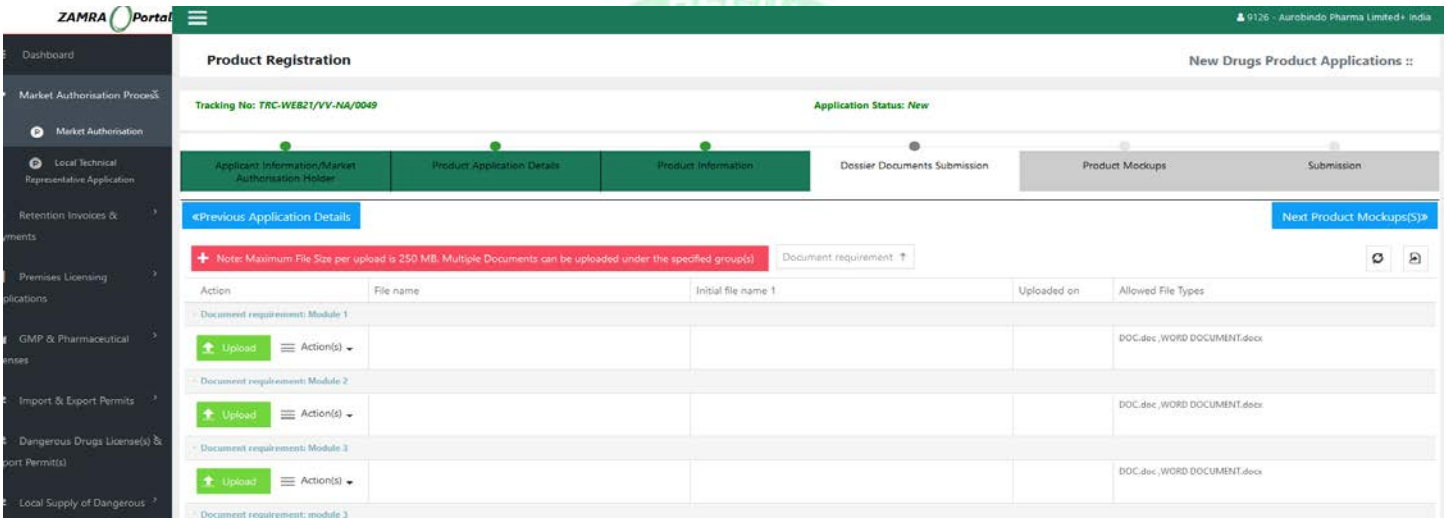



Step 3: Product Other Information

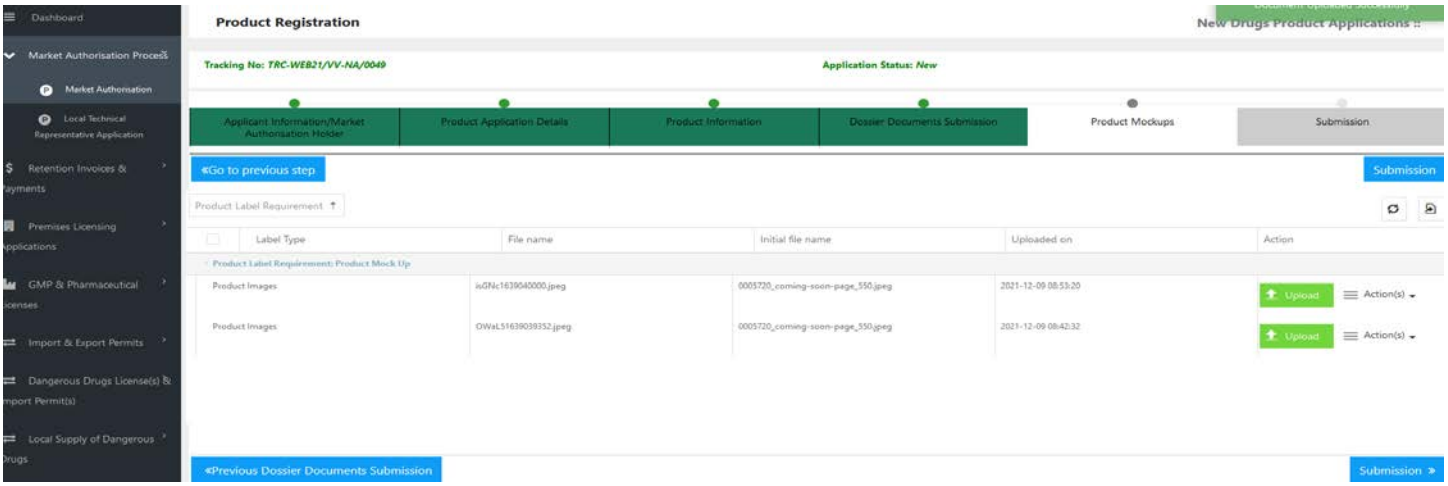
This includes the following information: Product API and other Ingredients details, Product Packaging Details, Finished Pharmaceutical Product Manufacturer(s), API Manufacturer and GMP Inspection Details



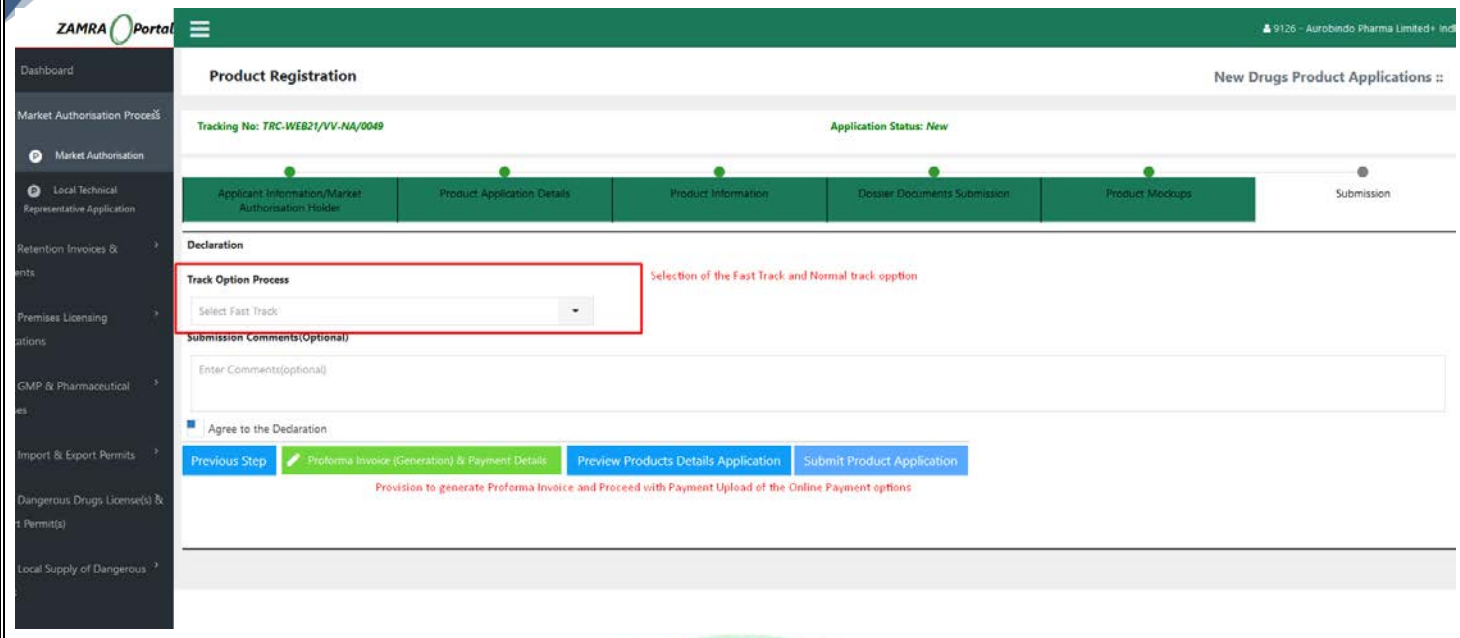

Step 4: Dossier Submission: Provision to upload the required documents and format the documents in CTD format which provides for upload of distinct section for processing



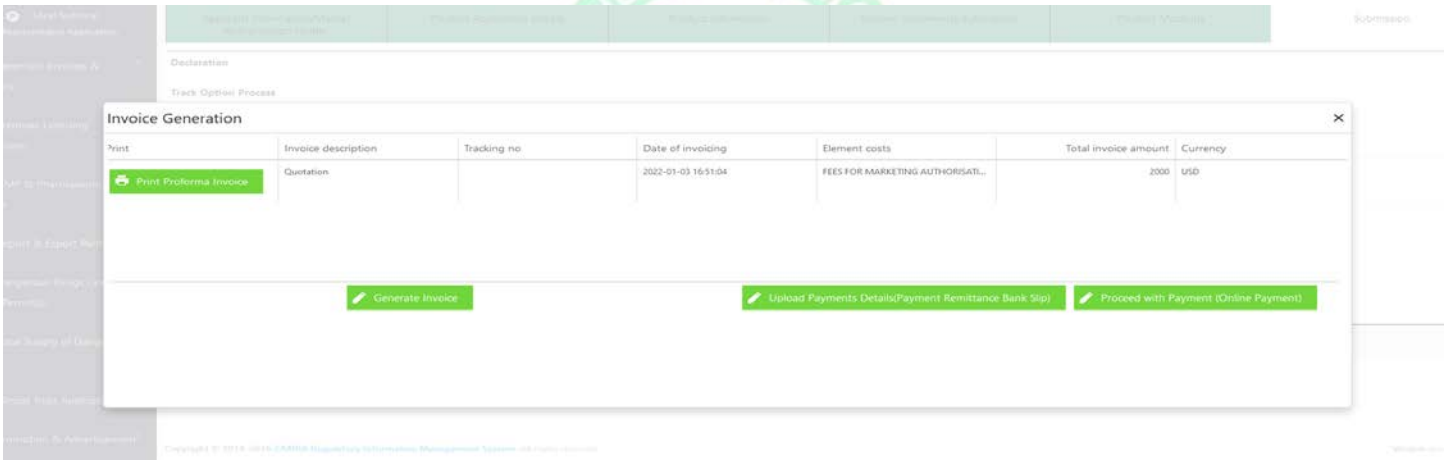

Step 5: Upload of the Products Mock-ups



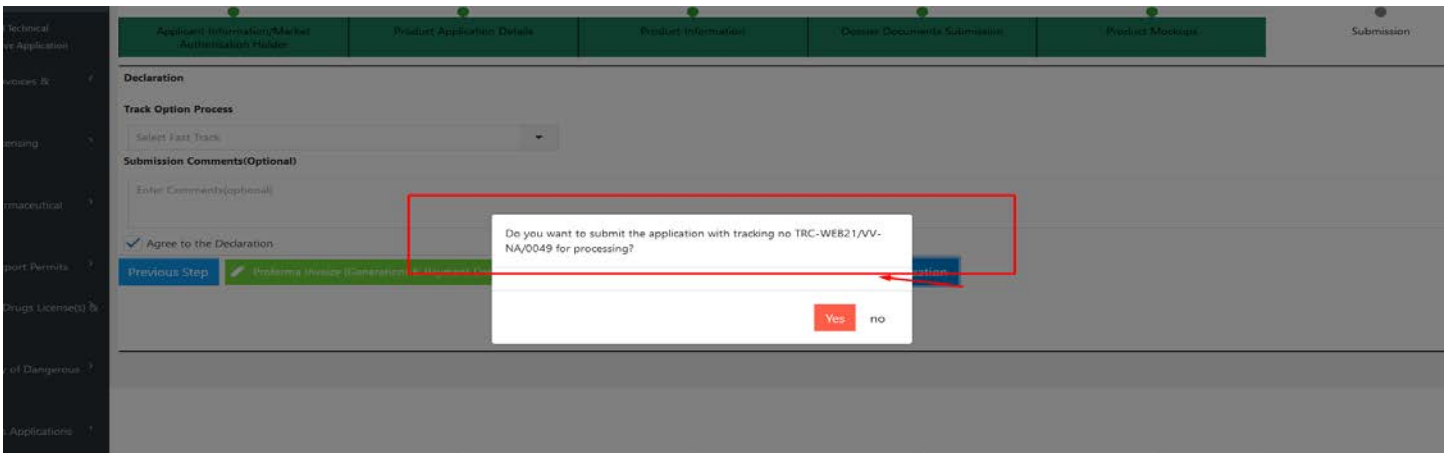
Step 6: Generation of the Proforma Invoice and Submission of the Application for processing




Generation of the Proforma Invoice




Submission: Submission of MA application for Processing

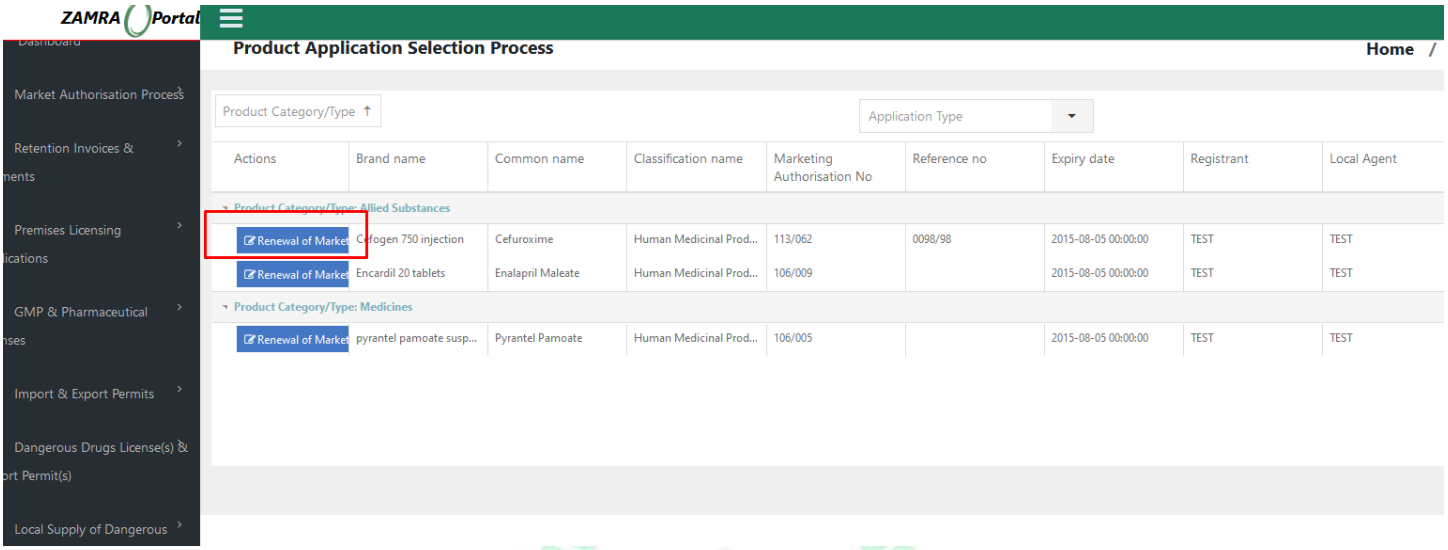


## 6.2 Request for Renewal of MA

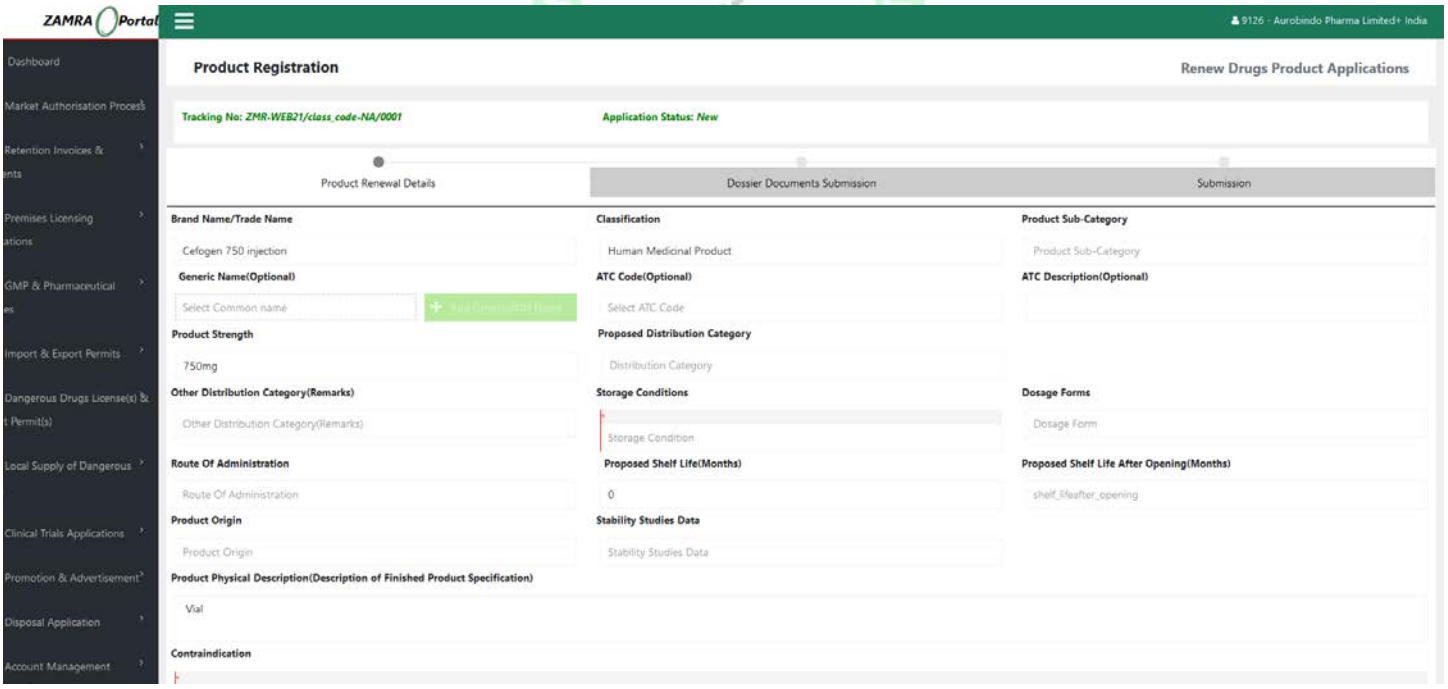
Provision to request for renewal of a registered Product or product issued with MA.

The system provides for

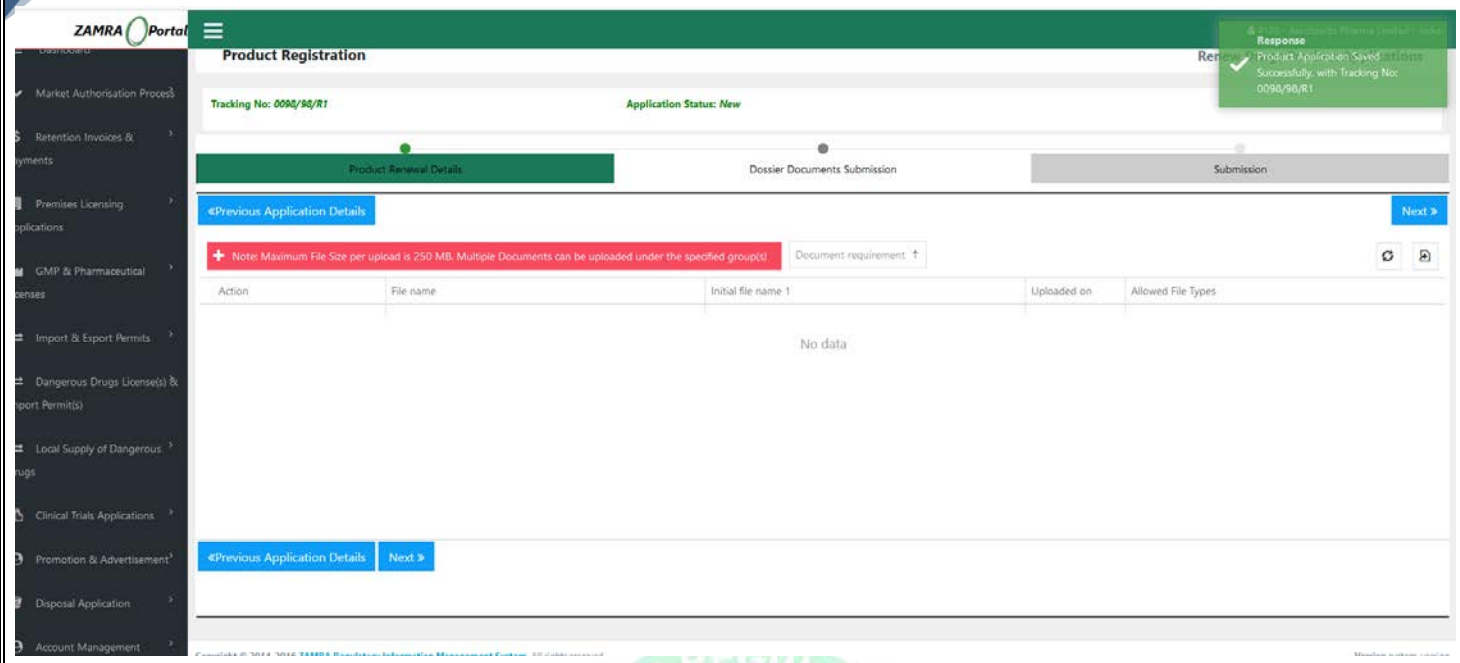
Step 1: Selection of application that is due for renewal




Step 2: Preview the registered product information

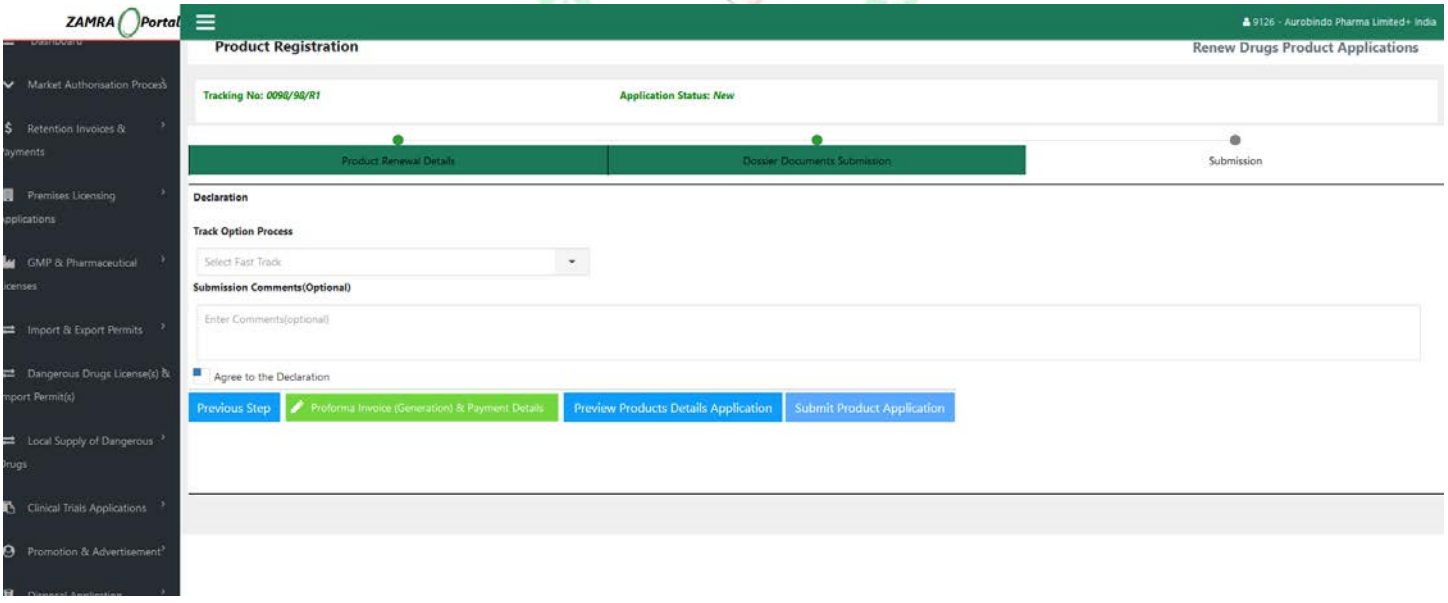


Step 4 : Provision to Upload the required documents (Dossier)

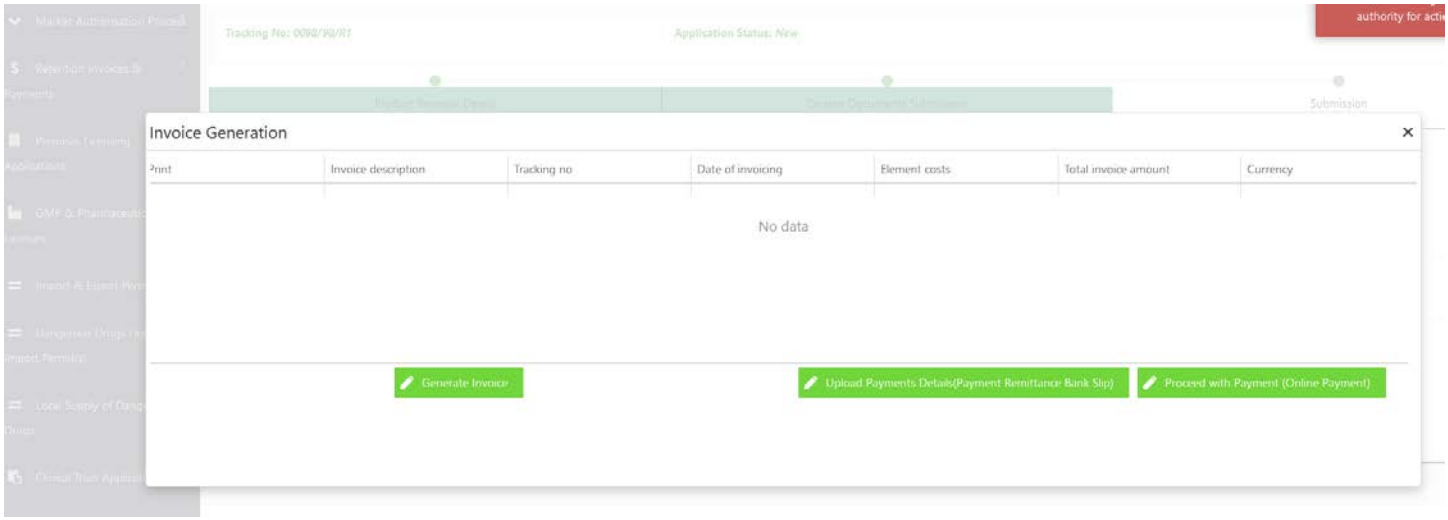



Step 5: Provision to Generate Proforma Invoice, payment process and submission of application for processing.

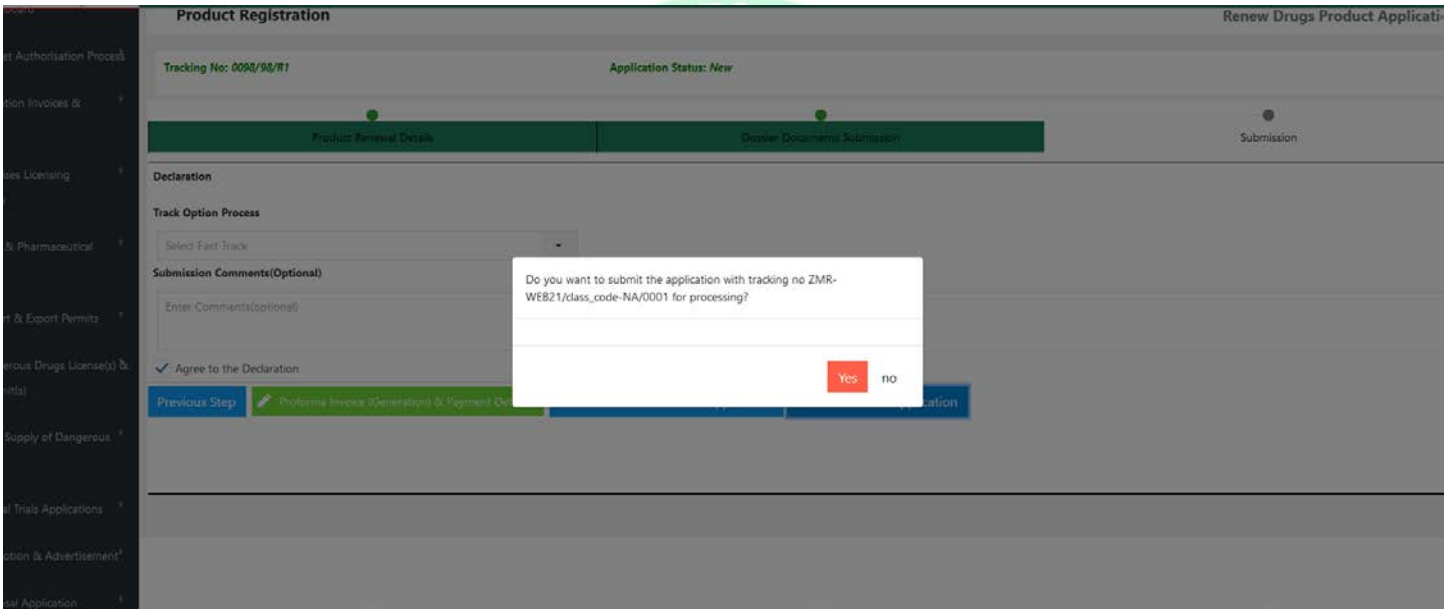
- Step 1 : Submission Stage



- Step 2: Generation of the Proforma Invoice and Submission of Proof of payments



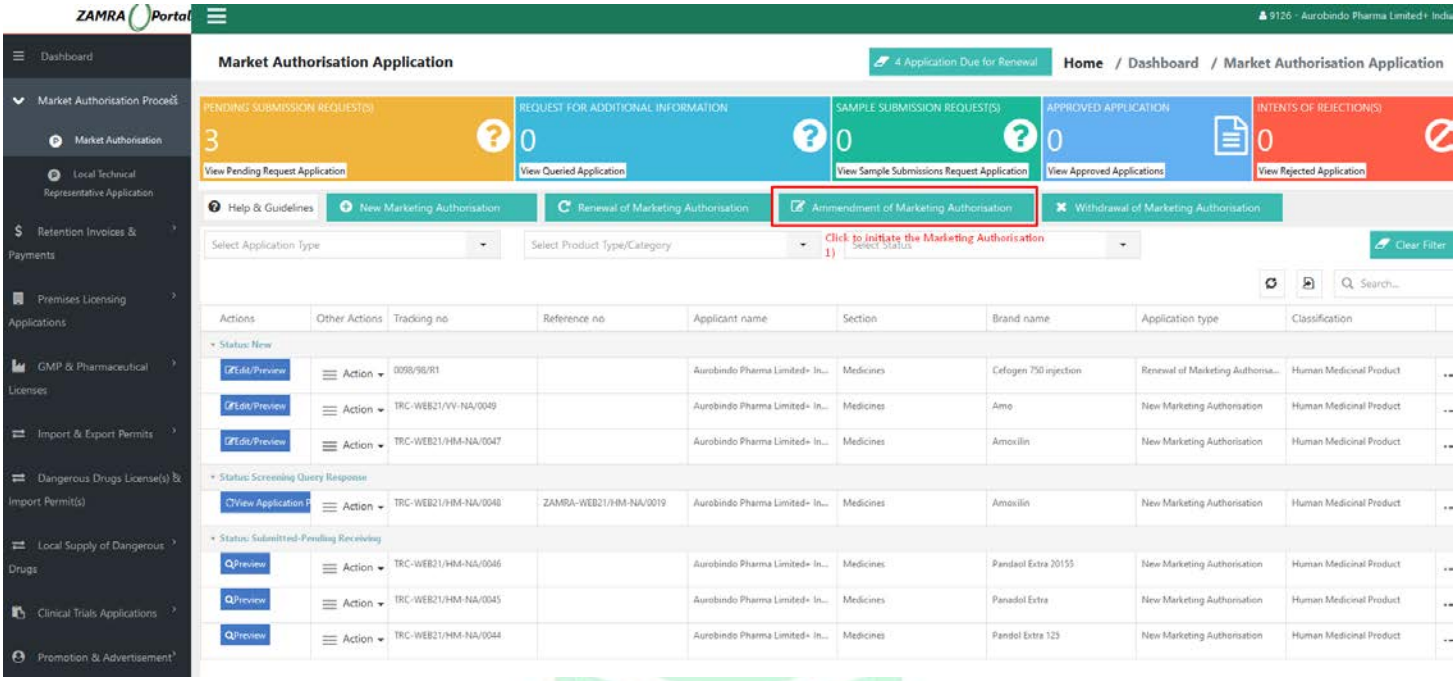

- Step 3: Provision to submit application for Processing by the Authority



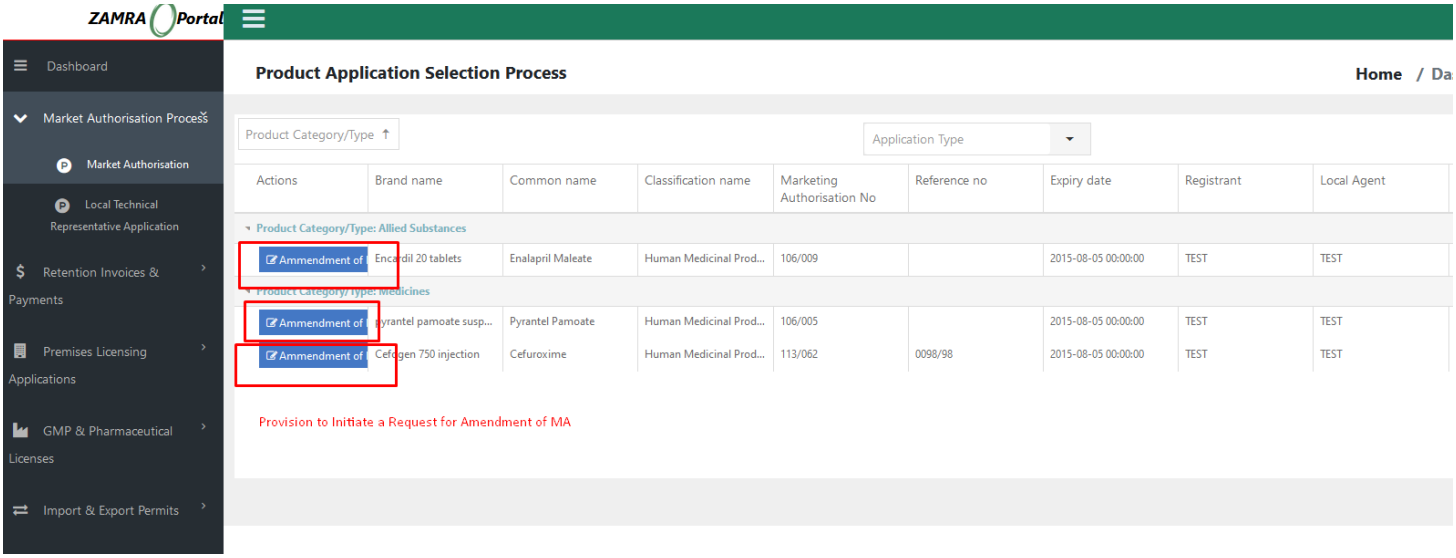
## 6.3 Request for Amendment of Registered Product Application/MA

The process provides for submission of amendment request for the Marketing Authorization (Registered Product)

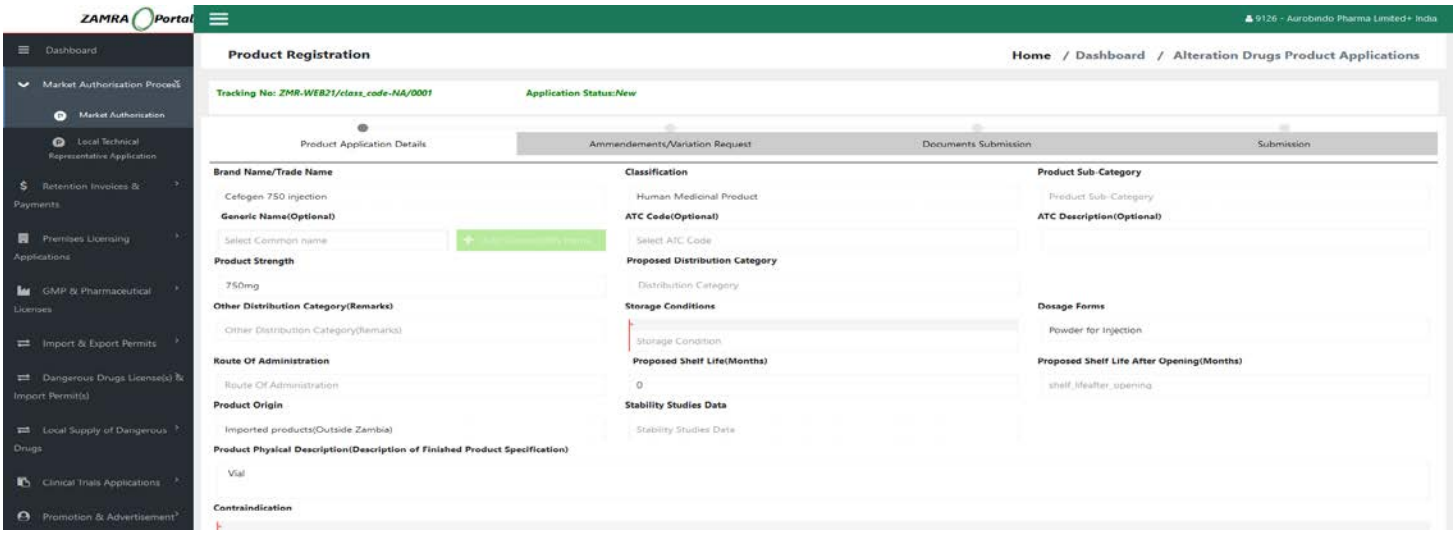
Step 1: Click on the Amendment of Marketing Authorization on the MA Dashboard which takes one to a list of registered products or products issued MA for one to select and initiate the Amendment Request.




Step 2: Selection of a registered MA application for initialization of request for amendment. Click on the Amendment Request and start the process.

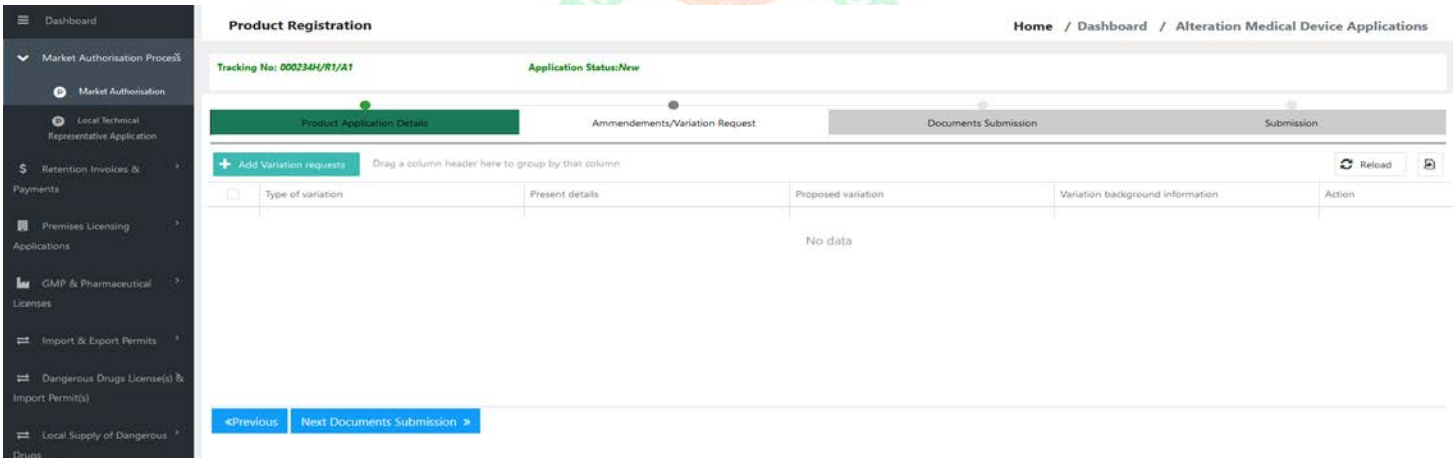


Step 3: Provision to preview the MA product general information and provision to proceed and enter the Amendment and Variation Request information



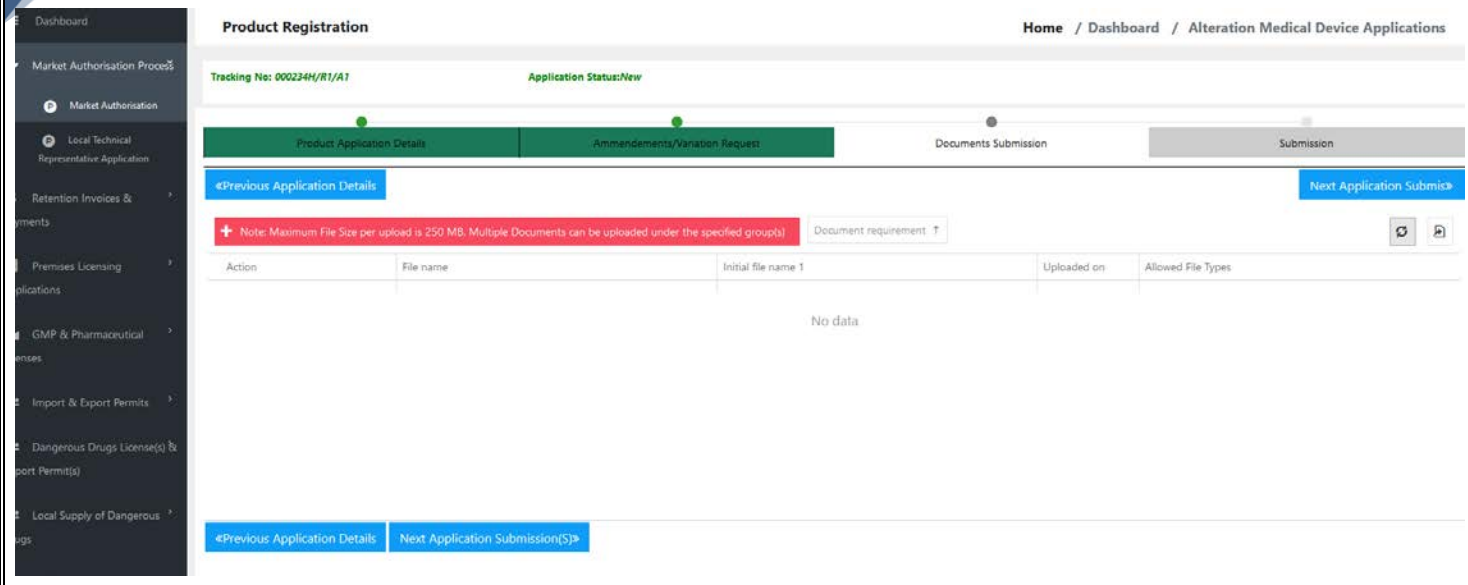

Step 4: Amendments/Variation Request: provision to enter the details for the amendment

Option 1: Preview the entered variation requests



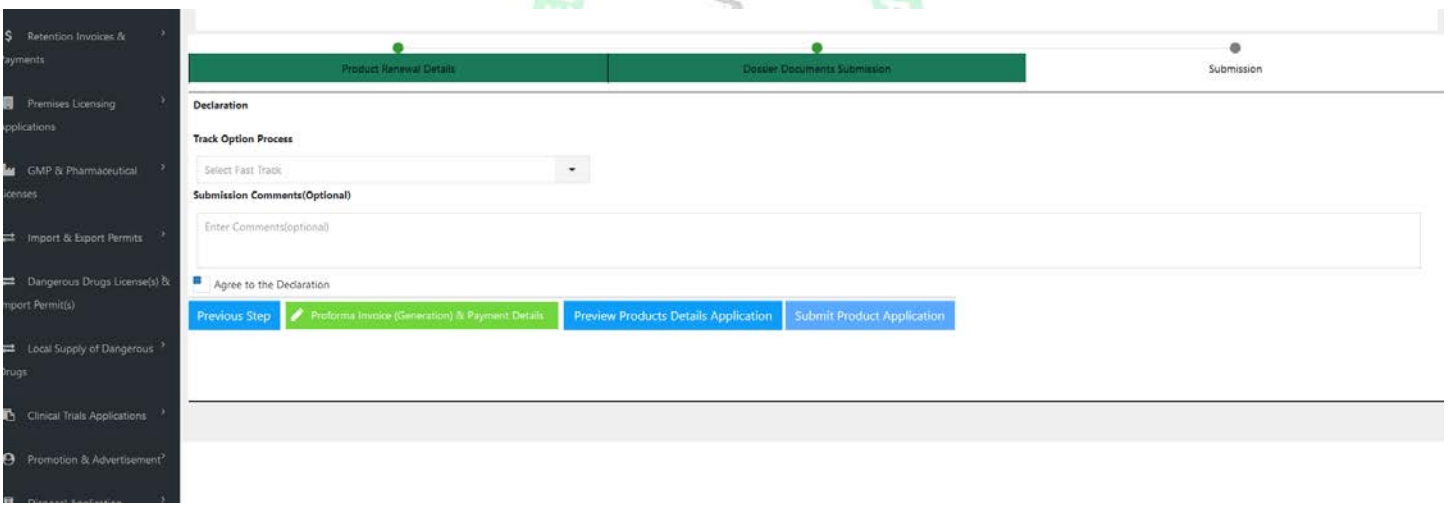

Option 2: Provision to enter the amendment Requests

Step 5: Enter the Amendment supporting Documents

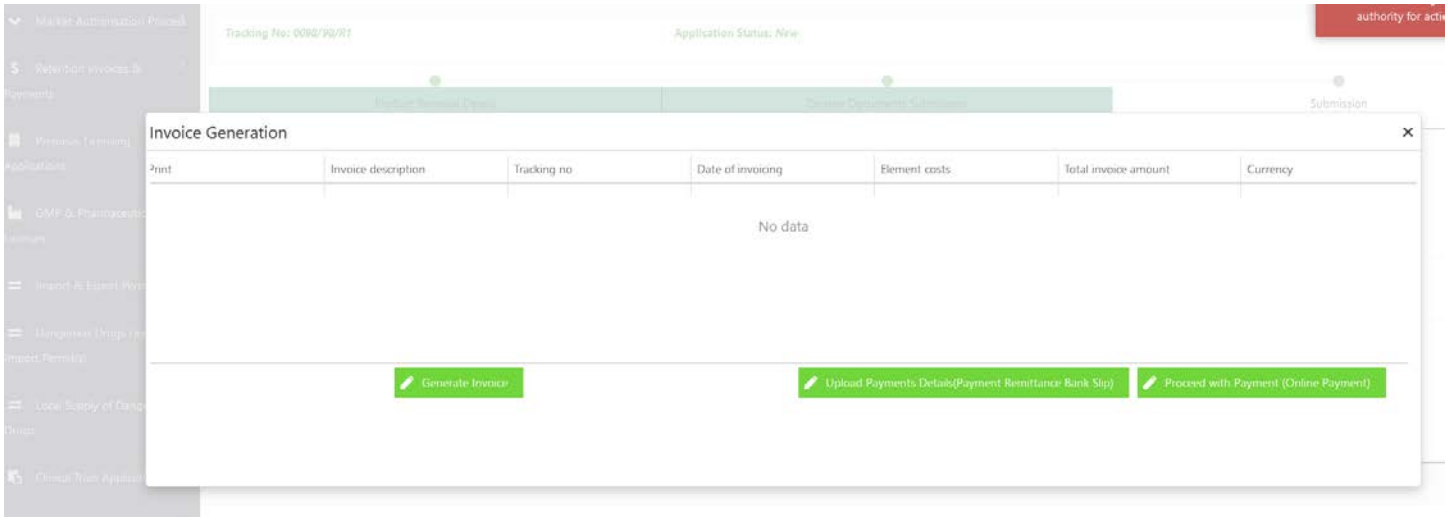



Step 6: Provision to Generate Proforma Invoice, payment process and submission of application for processing.

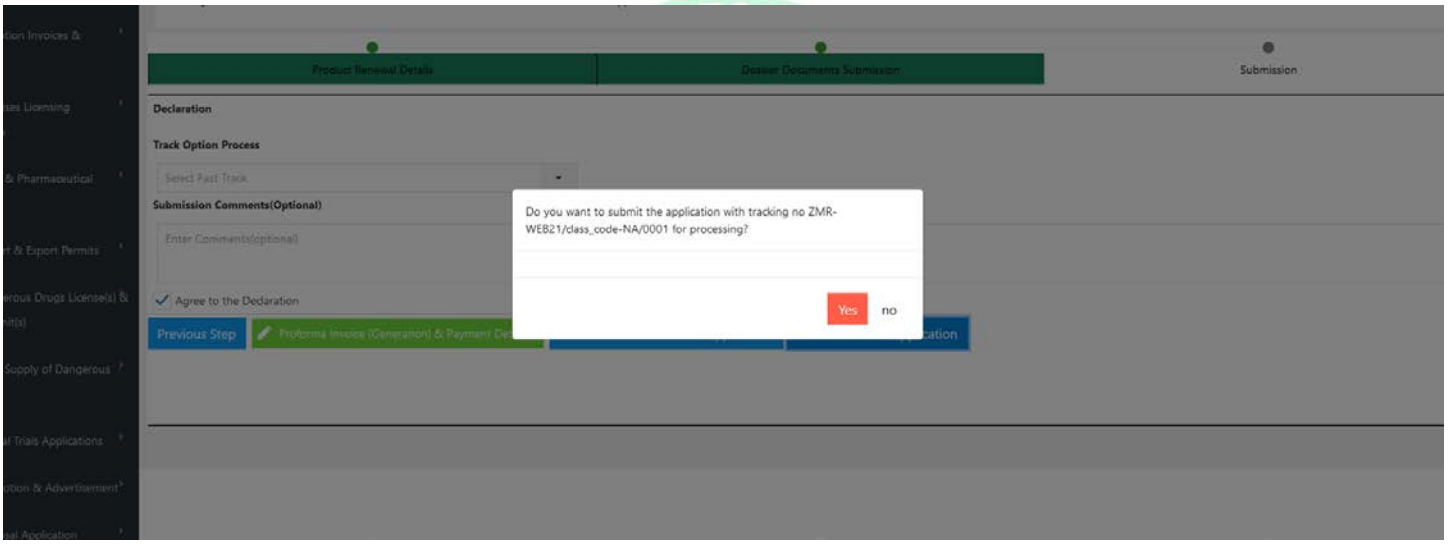
- Step 1 : Submission Stage



- Step 2: Generation of the Proforma Invoice and Submission of Proof of payments

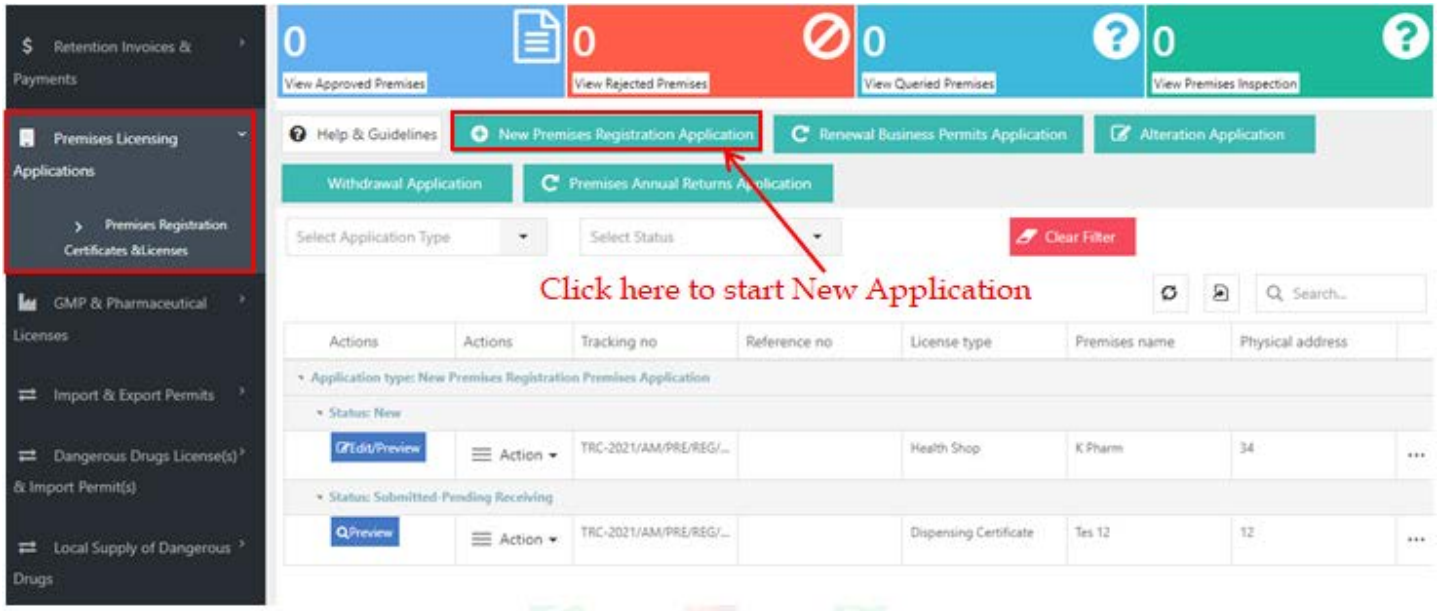



- Step 3: Provision to submit application for Processing by the Authority



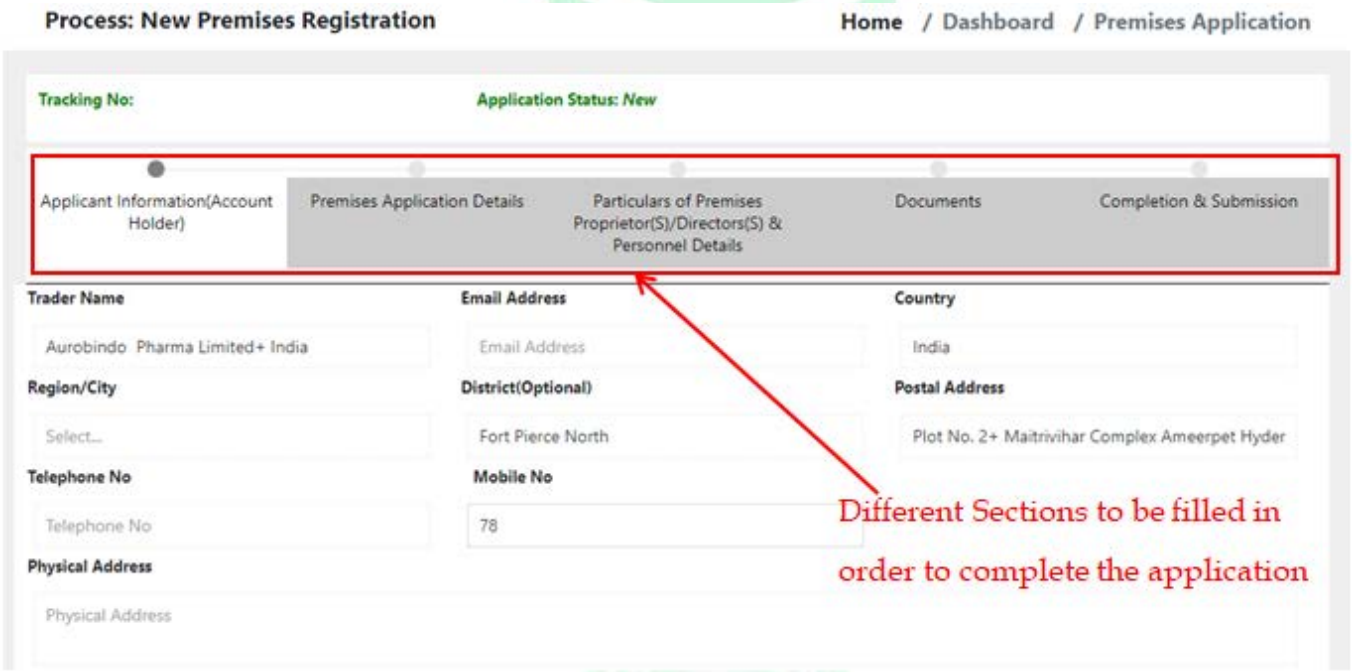
# 7 Premises Licensing Applications

The process provides the traders/Applicants with an option to make applications for premises registration certificates and licenses.




## 7.1 New premises Registration Application

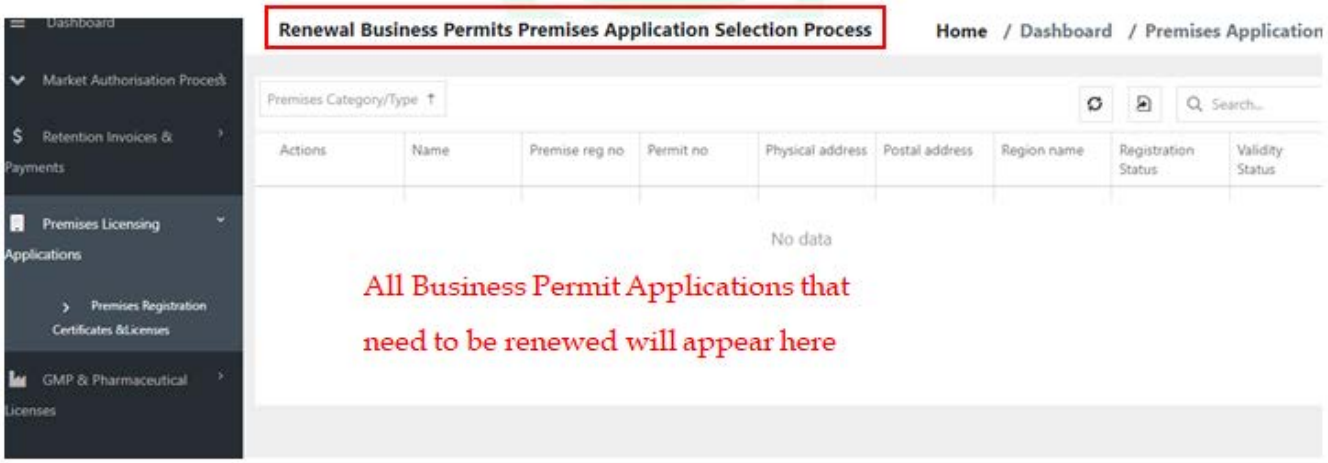
To make new premises Registration Application one is required to fill several sections with data after which the application is submitted to the next stage in the workflow.



## 7.2 Renewal Business Permits Application

This section is used to make an application for Business Permit renewal.

One is provided with a list of all Business Permits applications attached to the logged-in account which needs to be renewed where one can select the application which needs to be renewed.




## 7.3 Alteration Application

This section is used to make an application for premises alteration.

One is provided with a list of all Premises registration applications attached to the logged-in account from which one can select the ones that require alteration.

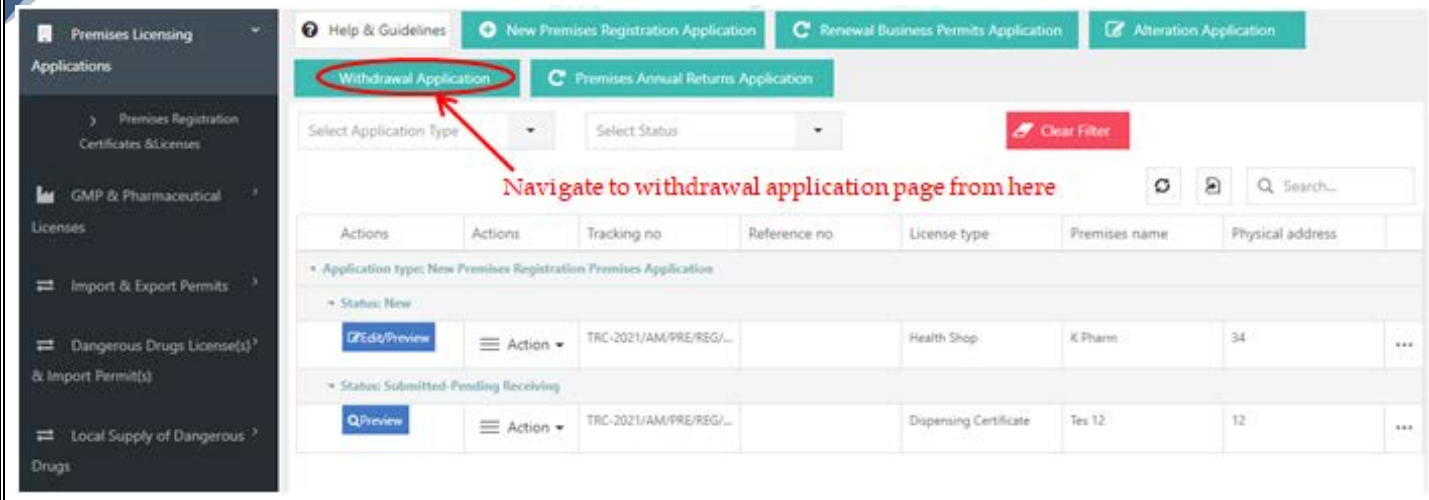
After selecting all the Premises that require alteration one should submit the alteration application to the next stage in the workflow.

## 7.4 Withdrawal Application

The process provides the traders/Applicants with an option to withdraw one or all Premises Registration Applications attached with the logged-in account.

To complete this, one is required to navigate to the Withdrawal application section and select the application that needs to be removed or withdrawn then submit the withdrawal application to the next stage in the

workflow.




## 7.5 Premises Annual Returns Application

This section is used to make an application for Premises Annual Returns.

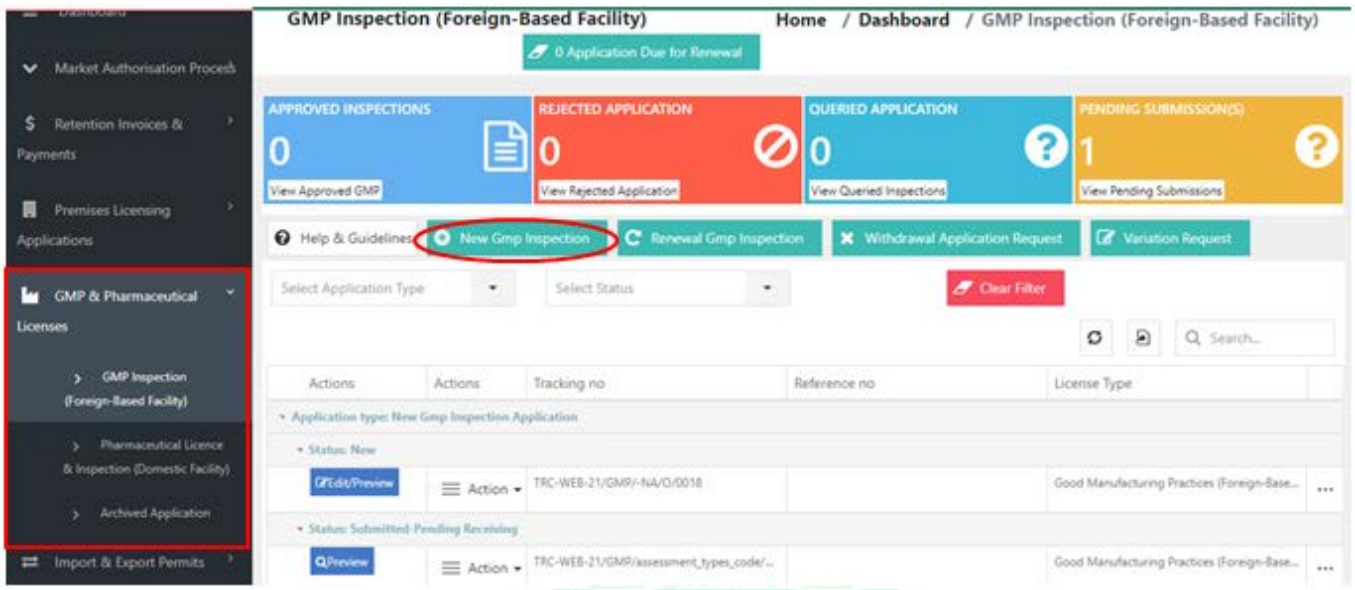
One is required to select the Premises Registration application that one is intending to make annual returns application for then on completing the application process submit the application to the next stage in the workflow.

# 8 GMP & Pharmaceutical Licenses

This section is meant for ensuring that products are consistently produced and controlled according to quality standards.

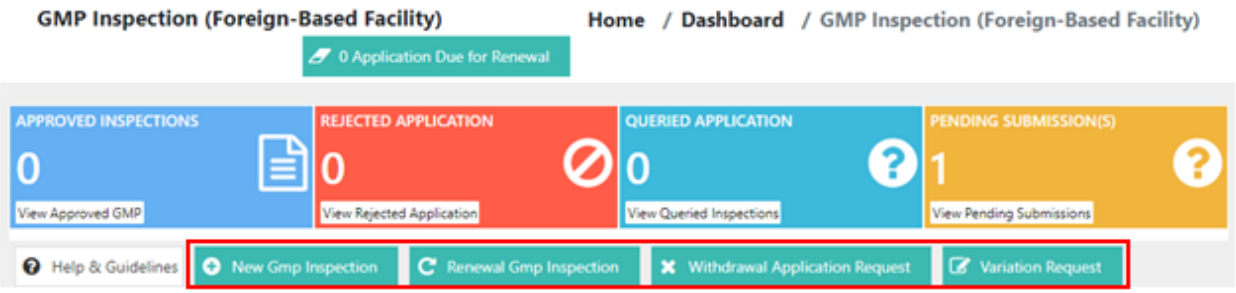
This section has three categories namely:

- GMP Inspection (Foreign-Based Facility).
- Pharmaceutical License & Inspection (Domestic Facility).
- Achieved Application.




## 8.1 GMP Inspection (Foreign-Based Facility)

This category deals with GMP & Pharmaceutical licensing of foreign-based facilities.

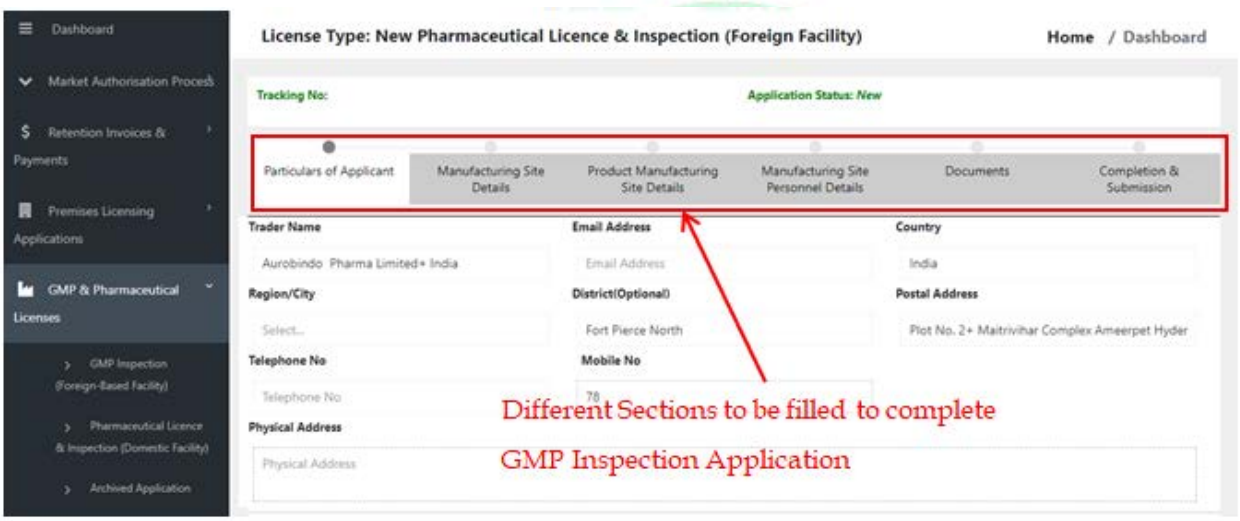


## 8.2 New Pharmaceutical license & Inspection (Foreign Facility)

To make a new GMP Inspection application Click the New GMP Inspection button from the GMP inspection (Foreign-Based Facility) dashboard then fill all sections provided and submit the application to the next stage in the workflow.

These sections include:

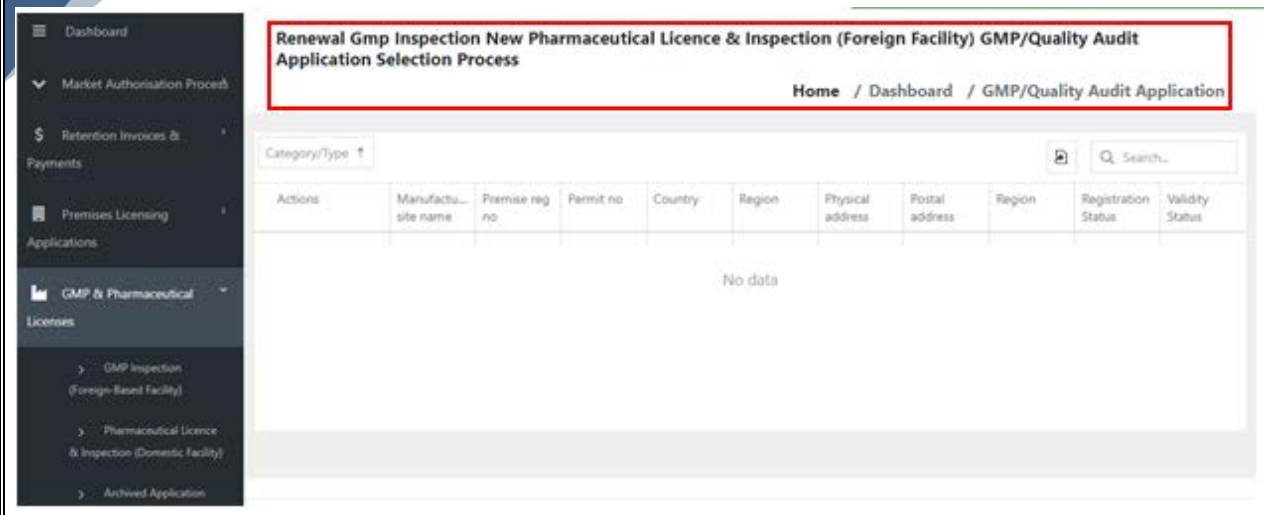
- Particulars of Applicant.
- Manufacturing Site Details.
- Product Manufacturing Site Details.
- Manufacturing Site Personnel Details.
- Documents.
- Completion & Submission.




## 8.3 Renewal GMP Inspection (Foreign-Based Facility)

This section is used to make an application for GMP Inspection (Foreign Facility) renewal.

One is provided with a list of all GMP Inspection applications attached to the logged-in account which needs to be renewed where one can select the application which needs to be renewed.




## 8.4 Withdrawal Application Request (Foreign-Based Facility)

The process provides the traders/Applicants with an option to withdraw one or all GMP Inspection Applications attached with the logged-in account.

To complete this, one is required to navigate to the Withdrawal application Request section and select the application that needs to be removed or withdrawn then submit the withdrawal application to the next stage in the workflow.

## 8.5 Variation Request (Foreign-Based Facility)

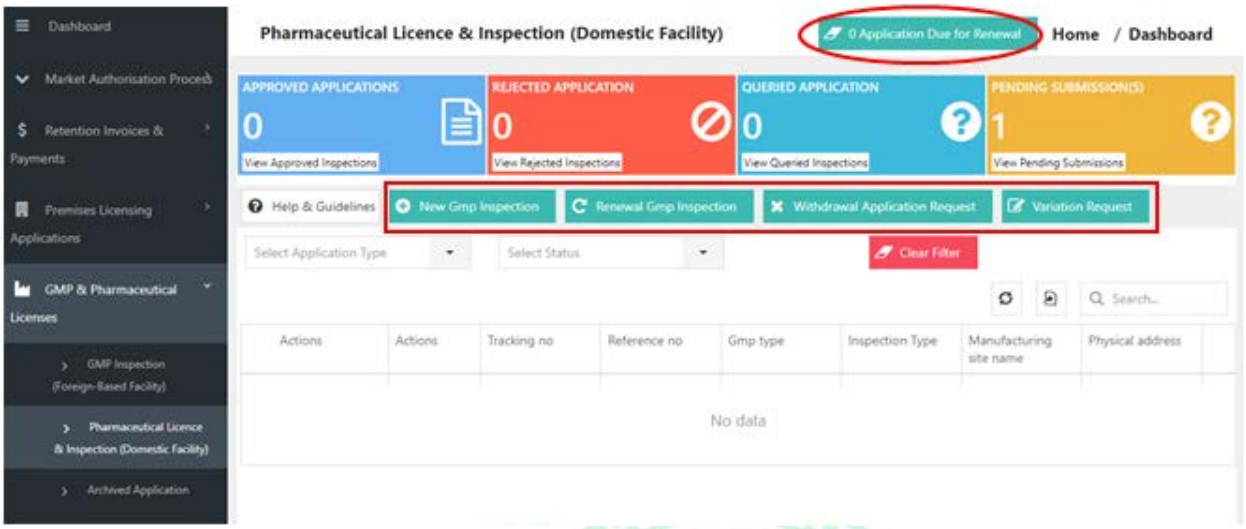
This section is used to make an application for GMP & Pharmaceutical License variation

One is provided with a list of all GMP Inspection applications attached to the logged-in account from which one can select the ones that require variation.

After selecting all the GMP Inspection & Pharmaceutical license applications that require variation one should submit the variation request to the next stage in the workflow.

## 8.6 Pharmaceutical License & Inspection (Domestic Facility)

This category deals with GMP & Pharmaceutical licensing of domestic-based facilities.



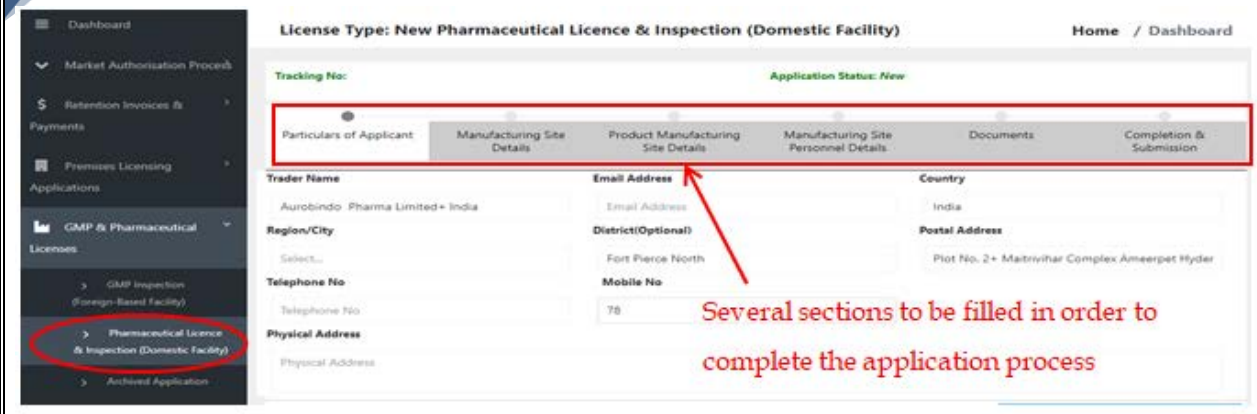

## 8.7 New GMP Inspection (Domestic Facility)

To make a new GMP Inspection application Click the New GMP Inspection button from the GMP Inspection (Domestic Facility) dashboard then fill all sections provided and submit the application to the next stage in the workflow.

These sections include:

- Particulars of Applicant.
- Manufacturing Site Details.
- Product Manufacturing Site Details.
- Manufacturing Site Personnel Details.
- Documents.

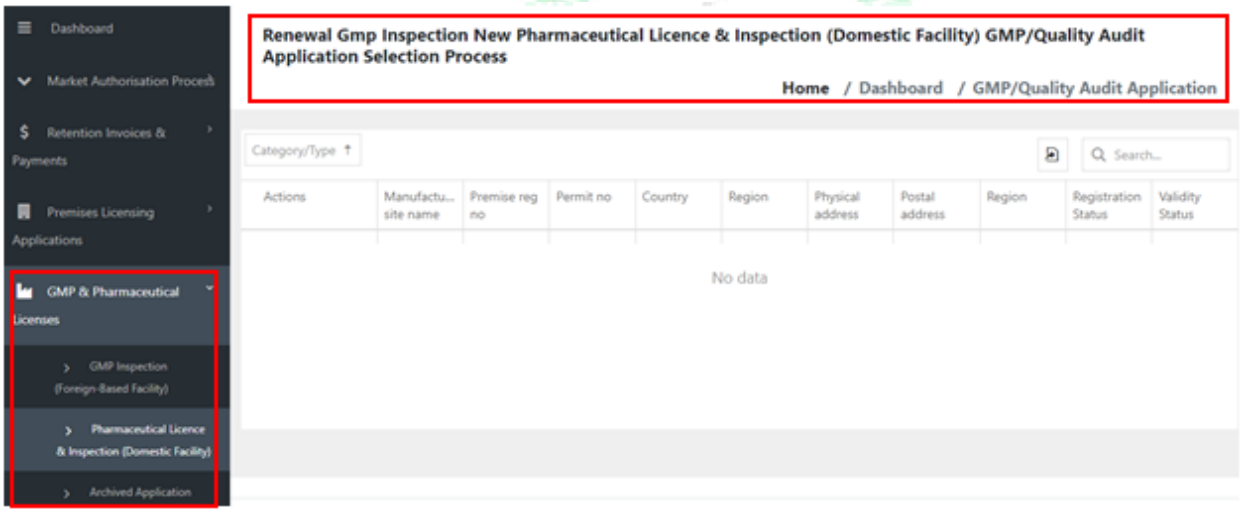
- Completion & Submission.




## 8.8 Renewal GMP Inspection (Domestic Facility)

This section is used to make an application for GMP Inspection (Domestic Facility) renewal.

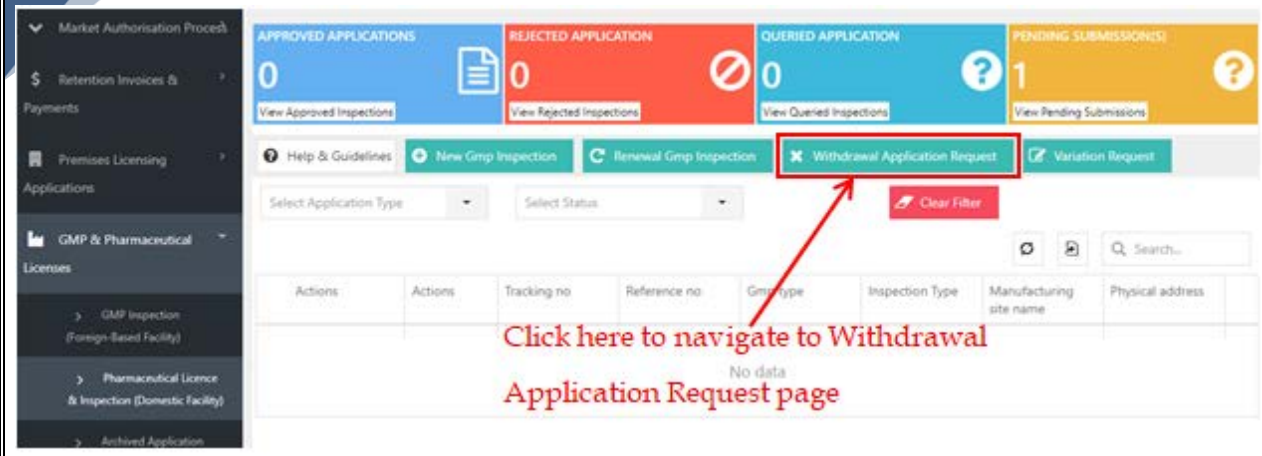
One is provided with a list of all GMP Inspection applications attached to the logged-in account which needs to be renewed where one can select the application which needs to be renewed.




## 8.9 Withdrawal Application Request (Domestic Facility)

The process provides the traders/Applicants with an option to withdraw one or all GMP Inspection Applications attached with the logged-in account.

To complete this, one is required to navigate to the Withdrawal application Request section and select the application that needs to be removed or withdrawn then submit the withdrawal application to the next stage in the workflow.




## 8.10 Variation Request (Domestic Facility)

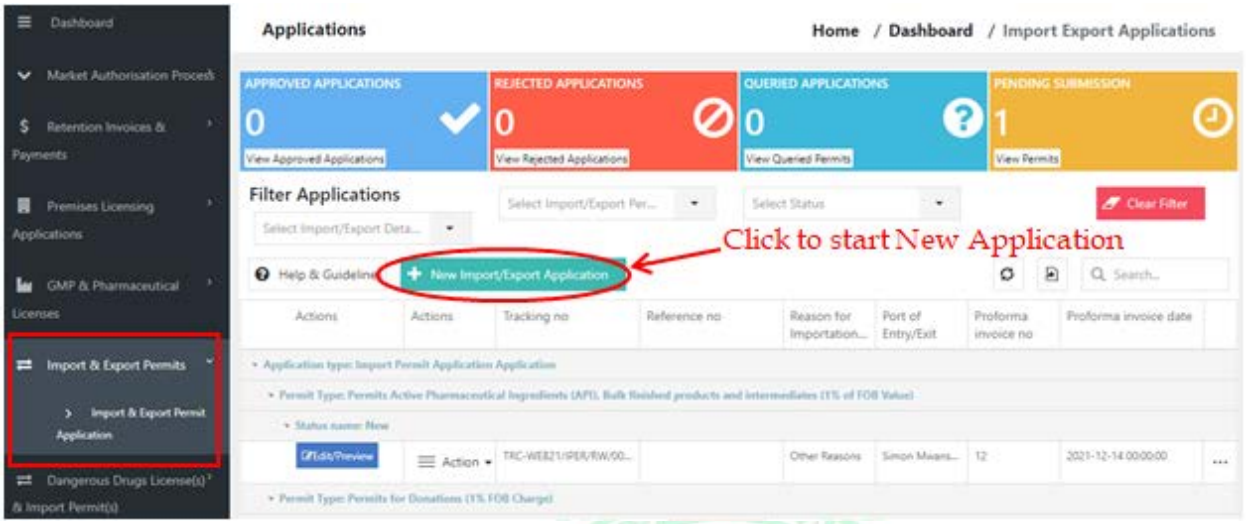
This section is used to make an application for GMP & Pharmaceutical License variation

One is provided with a list of all GMP Inspection applications attached to the logged-in account from which one can select the ones that require variation.

After selecting all the GMP Inspection & Pharmaceutical license applications that require variation one should submit the variation request to the next stage in the workflow.

# 9 Import & Export Permits

This section provides services related to Import & Export permit application including making new Import & Export Permit applications as well as editing already existing applications.




## 9.1 New Import/Export Permit Application

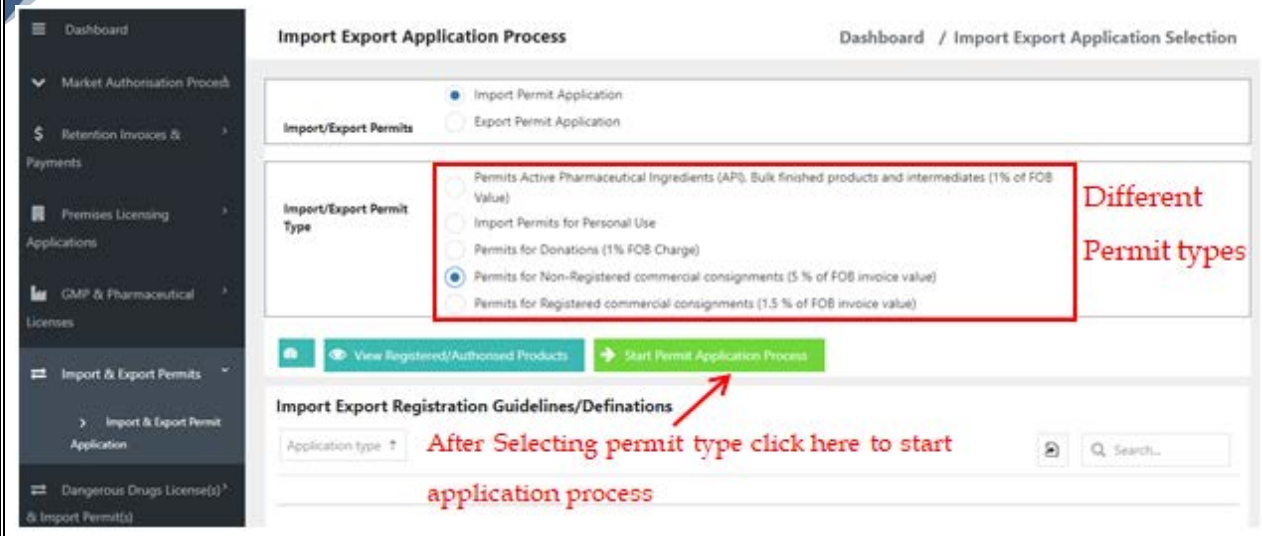
To make a new Import/Export application Click the New Import/Export Application button from the Import & Export Permit Application page to initialize the new application process.

Then one is required to choose between Import Permit Application and Export Application followed by the type of application.

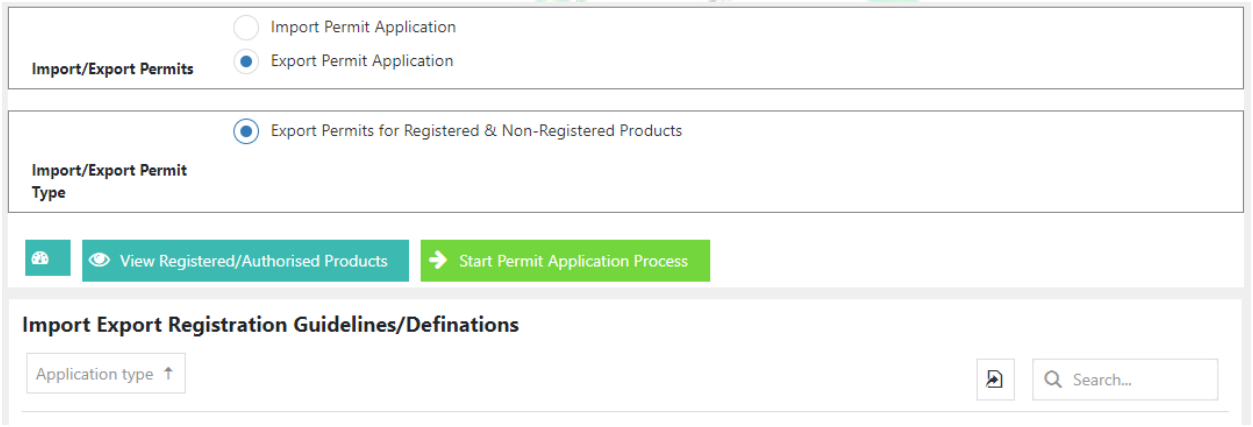
Several types of Import Permits are available under the Import Permit application to choose from which include:

- Permit Active Pharmaceutical Ingredients (API), Bulk finished products, and intermediates (1% of FOB value).
- Import Permit for Personal Use
- Permit for Donations (1% FOB Charge).
- Permit for Non-Registered commercial consignments (5% of FOB invoice value).

- Permit for Registered commercial consignment (1.5% of FOB invoice value).




On the other hand under the Export Permit application, we have only one permit type (Export Permit for Registered and Non-Registered products) which should be selected to continue with the Export Permit Application process.



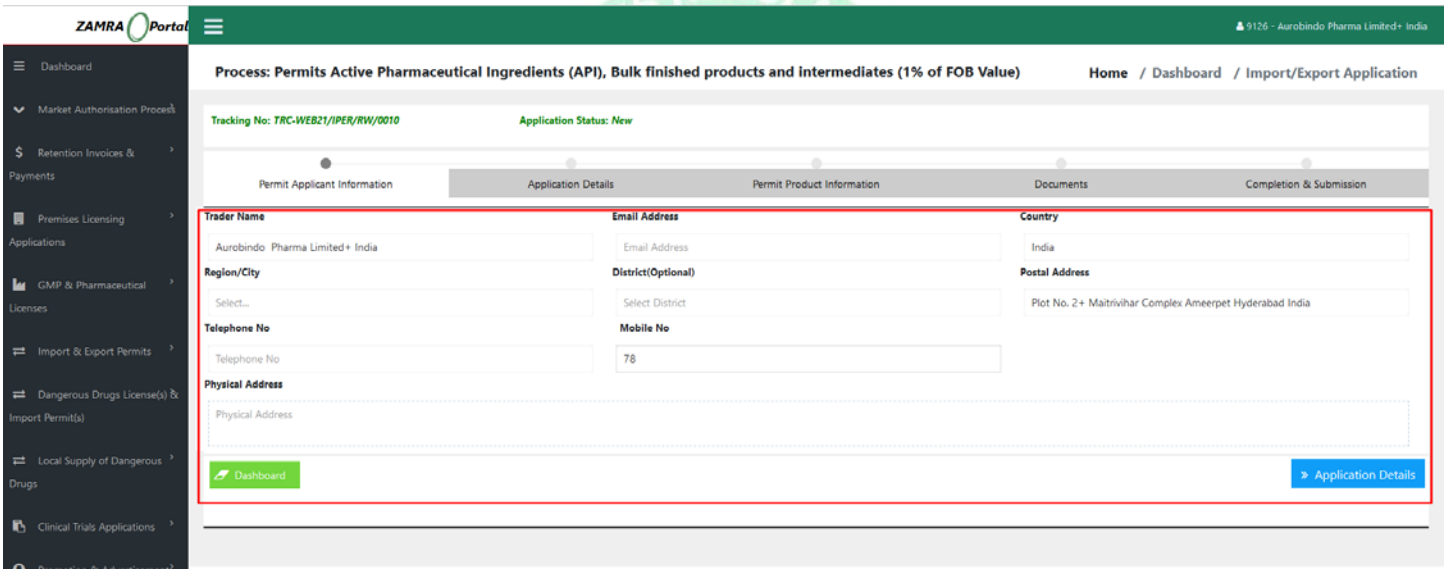

After selecting the permit type and clicking Start Permit Application Process one is provided with several options to be filled in to complete the application.

These sections include:

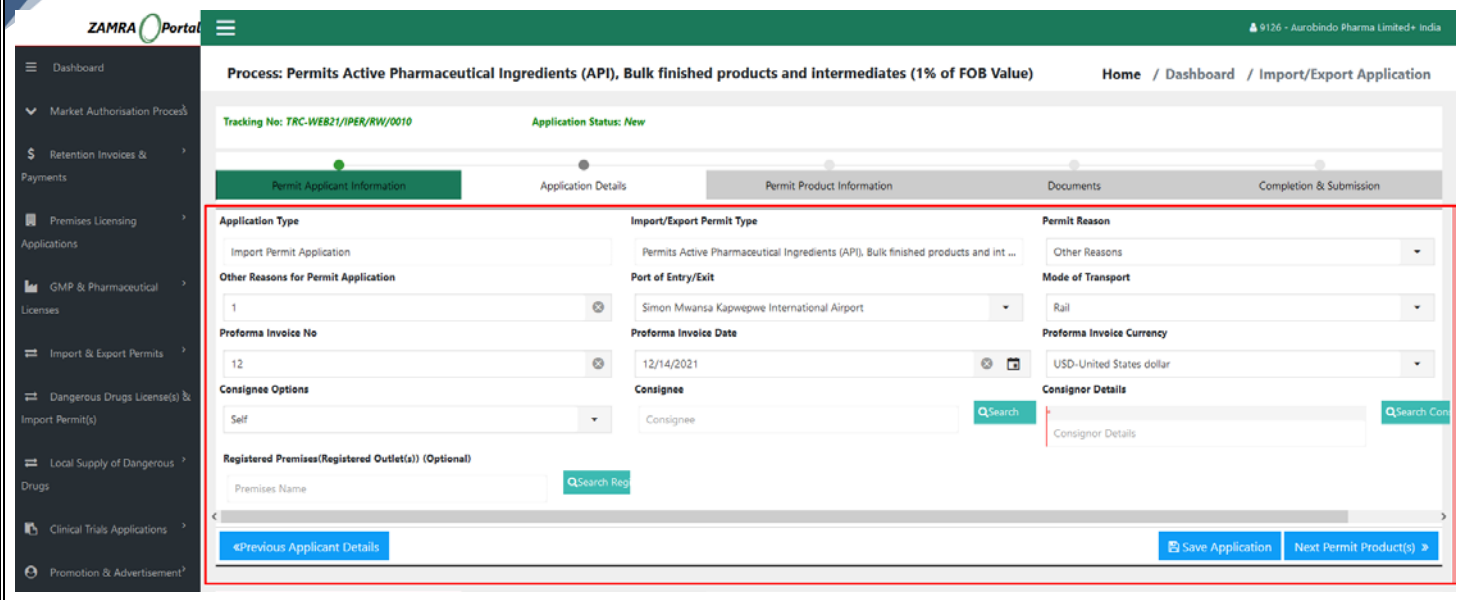
- Permit Applicant Information.
- Application Details.
- Permit Product Information.
- Documents.
- Completion & Submission.


## 9.2 Steps for the Import/Export Permit Application

1) Step 1: Preview Permit Applicant Details and click Next



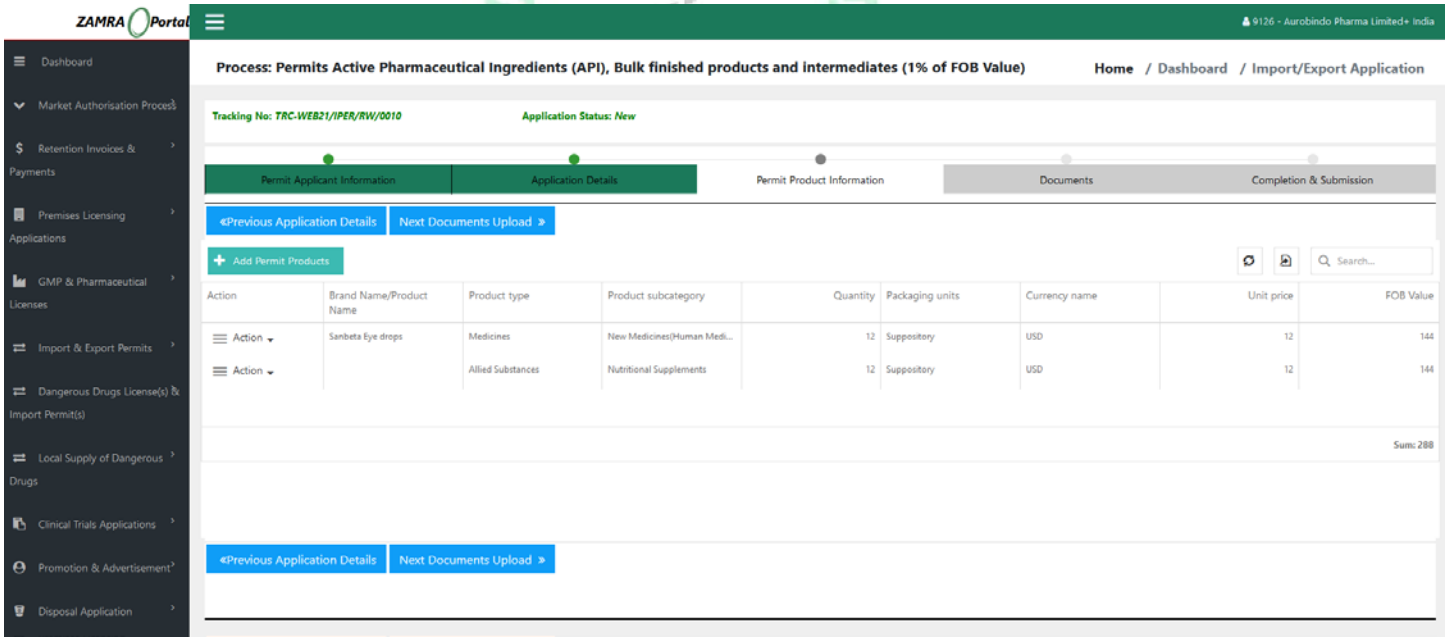
2) Step 2: Enter/Preview Permit General Information and save/update the details.



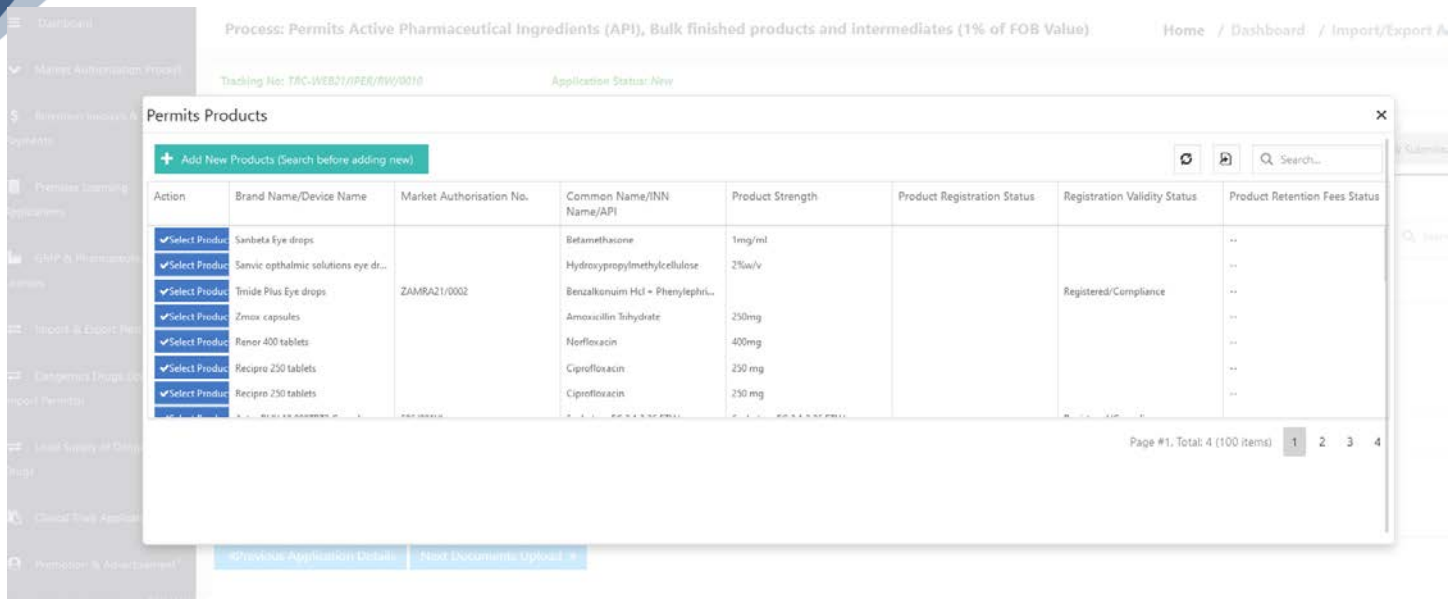

3) Step 3: Enter a list of Permits product details or preview the entered product information

This provides for

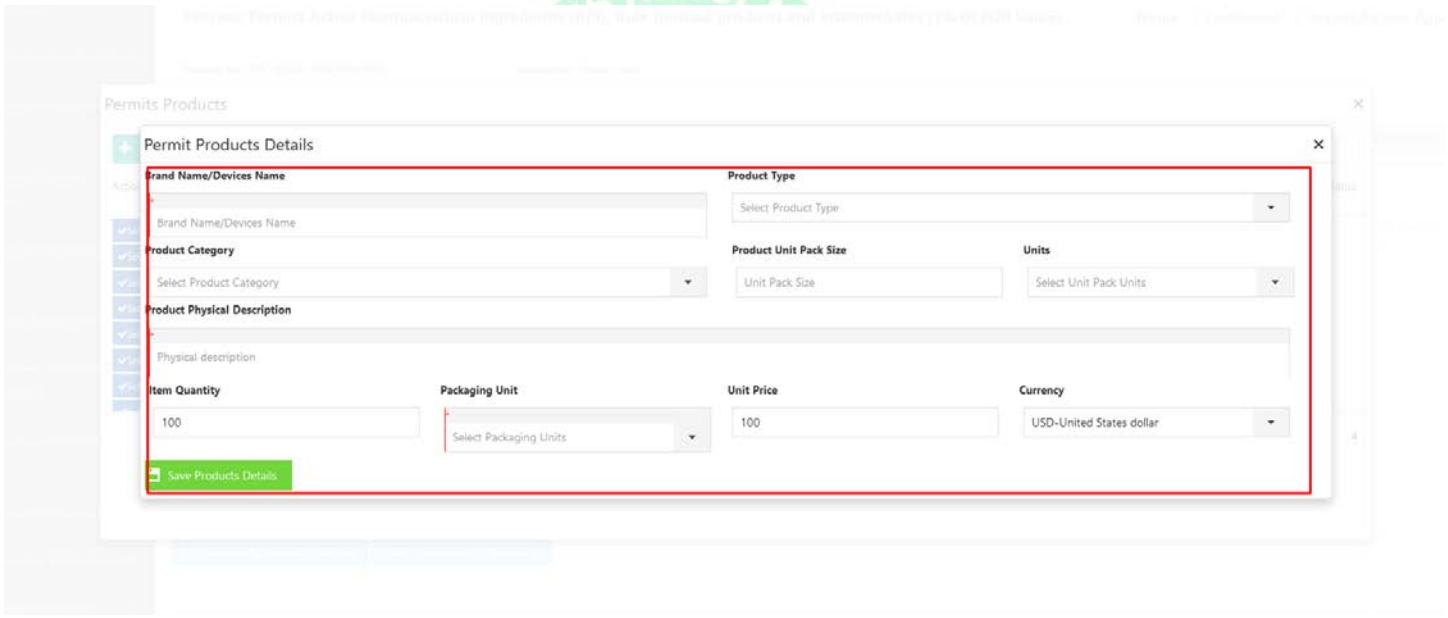
- Selection of the already registered Products or list of allowed products in the country
- Provision to enter new product information based on the Proforma Invoice



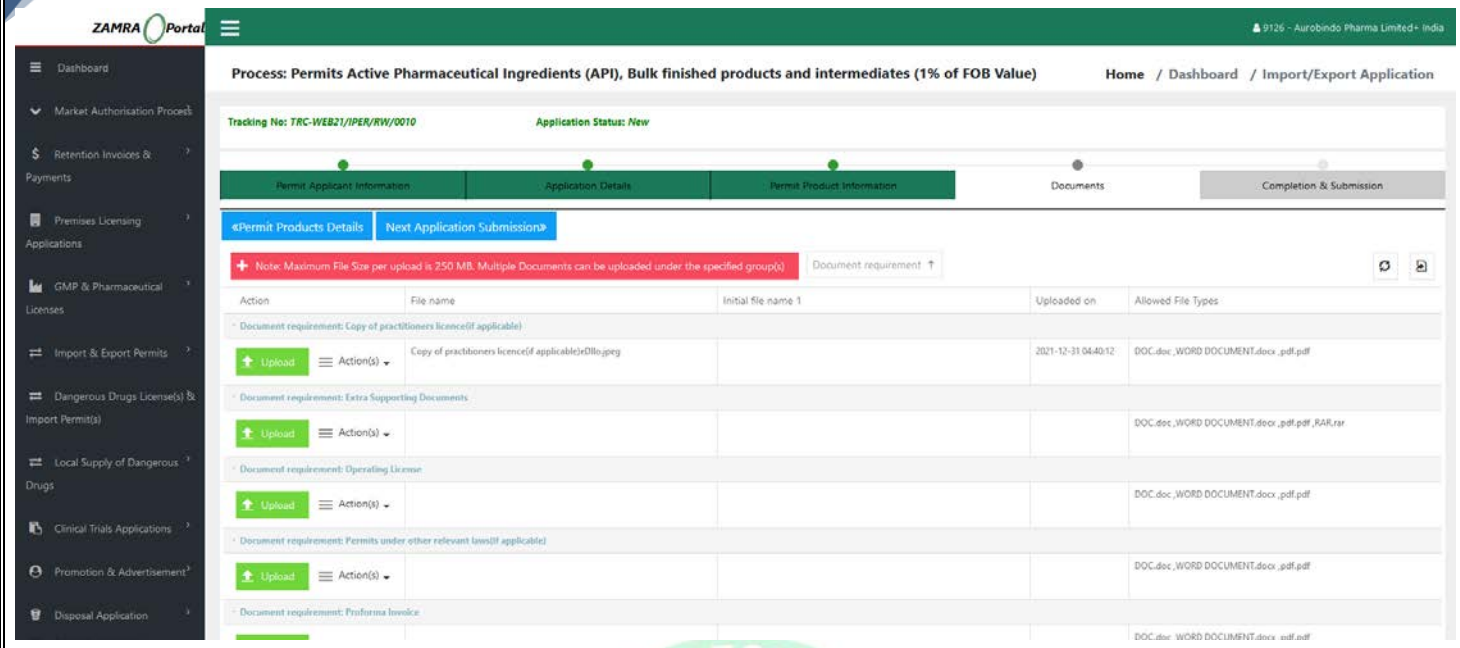

4) Step 4: Select Existing or registered products



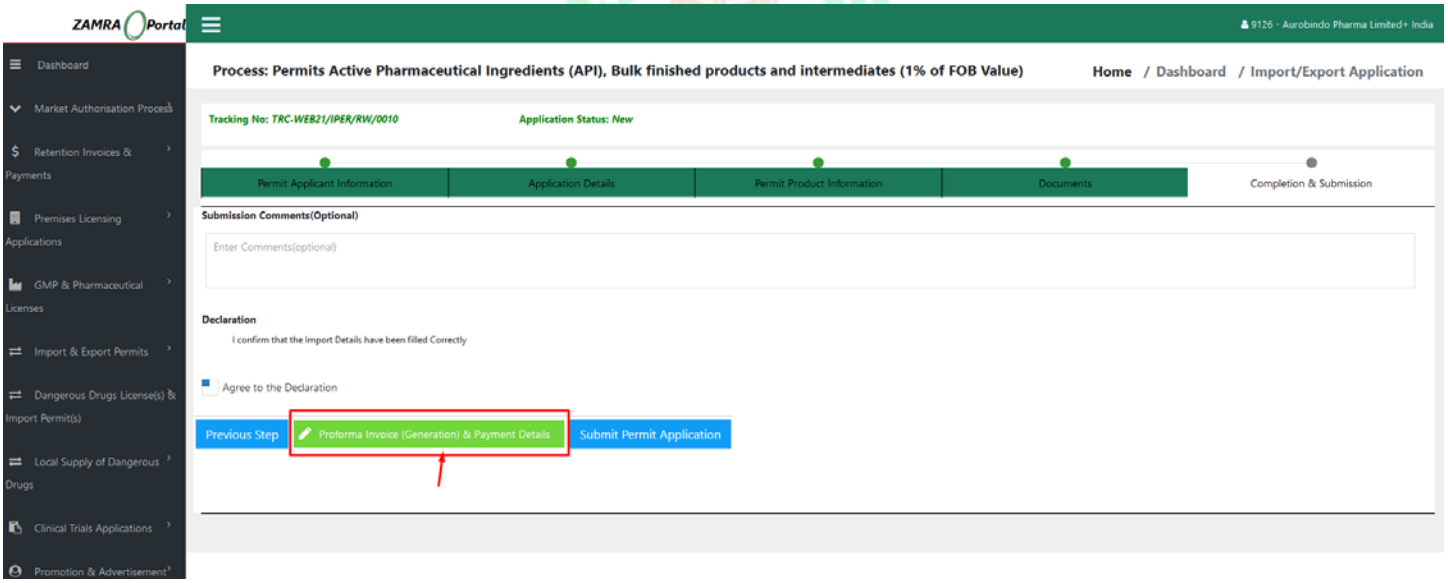

5) Step 5: Add permit Application Product Information: Note the products will be the basis for the calculation of the FOB value for invoice generation.



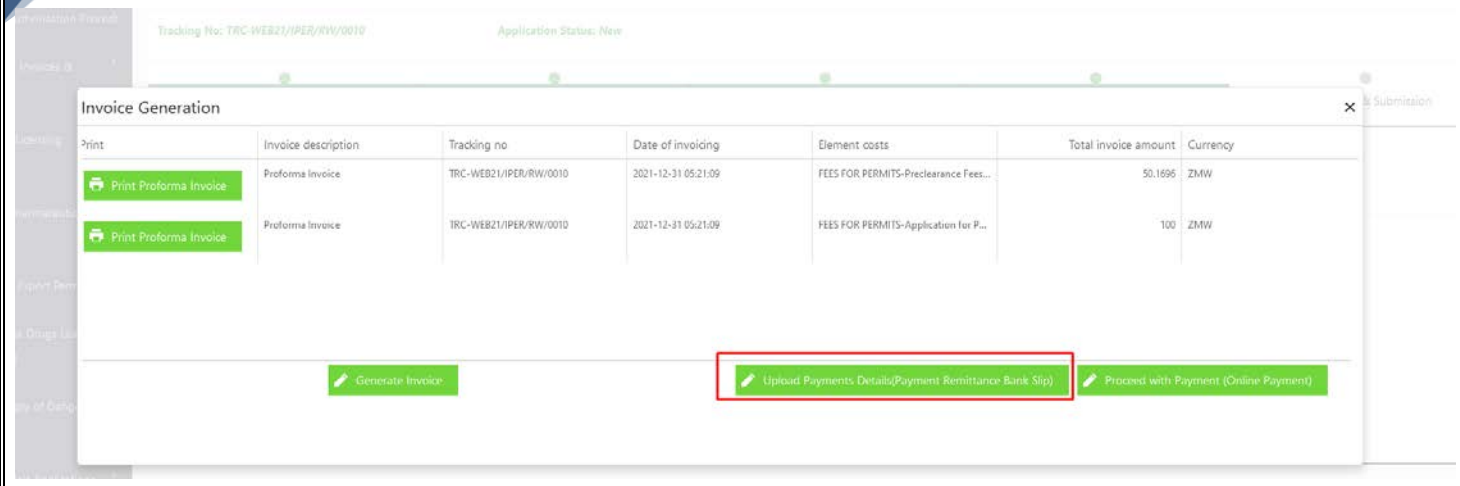
6) Step 6: Provision to Upload the required Permit Application Documents.



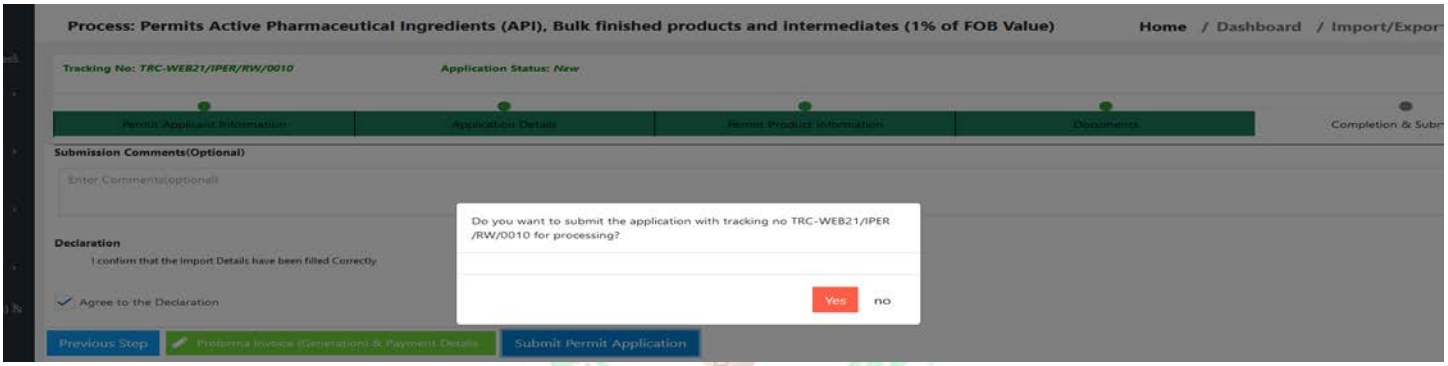

7) Step 7: Provision to generate and submit the permit application for processing



8) Step 8: Generate Proforma Invoice & Upload Evidence of payment details.




9) Step 9: Submit Permit Application for Processing

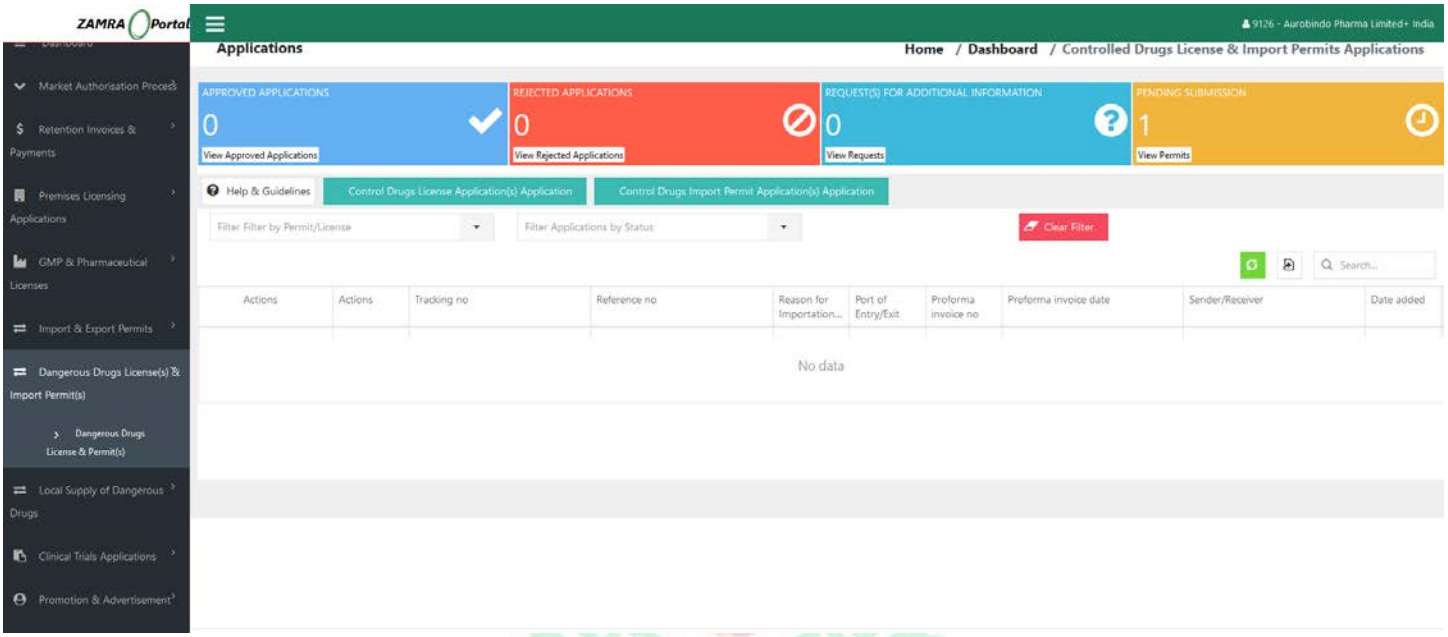


# 10 Dangerous Drugs License(s) & Import Permit(s)

This section provides services related to license and permit application for Dangerous Drugs

This provides for initialization of new application and provision to edit the already initiated permit and licenses application.

Note: the Process of Import Permit Application is similar to the Normal Import Permit Application process described above.



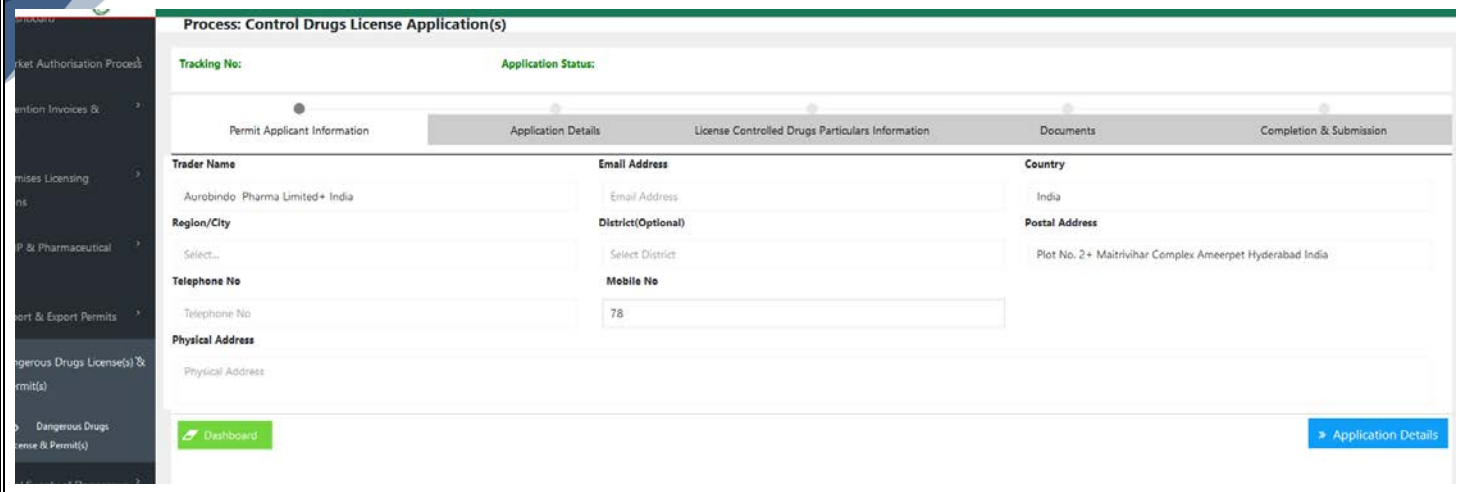

## 10.1 Dangerous Drugs License(s) Application

This provides the process to initiate a license application for dangerous drugs

After License Application Process one is provided with several options to be filled in to complete the application.

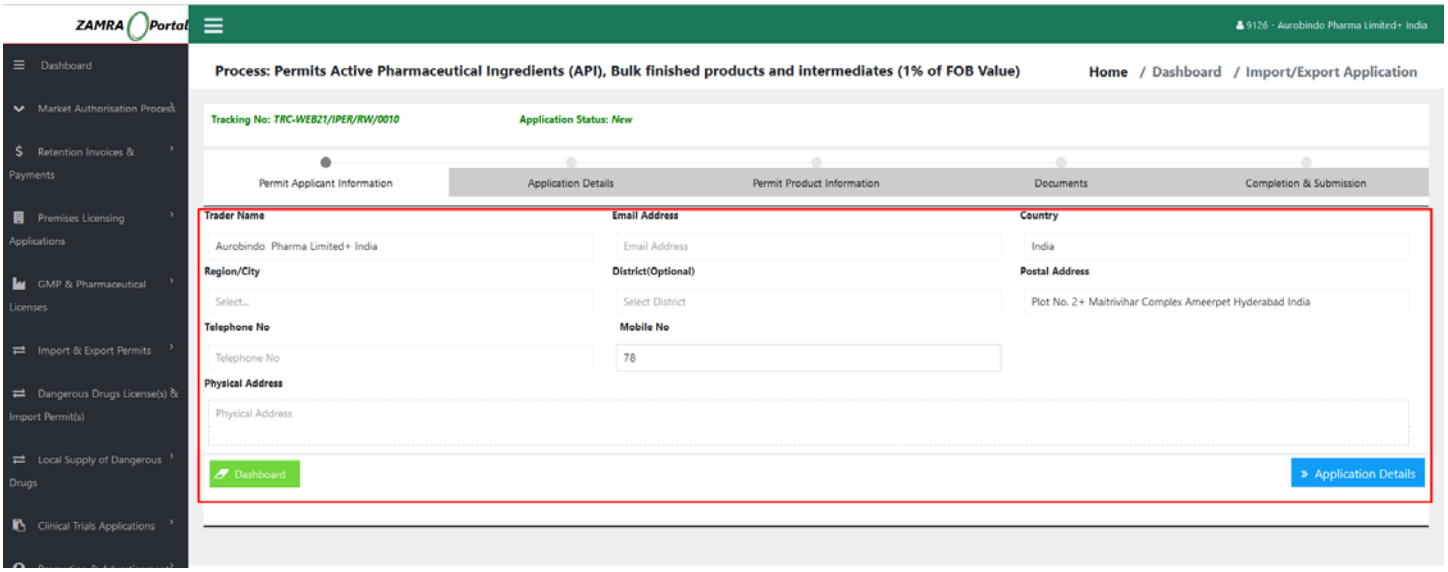
These sections include:

- Applicant Information.
- License Application Details.
- Permit Product Information.
- Documents.
- Completion & Submission.

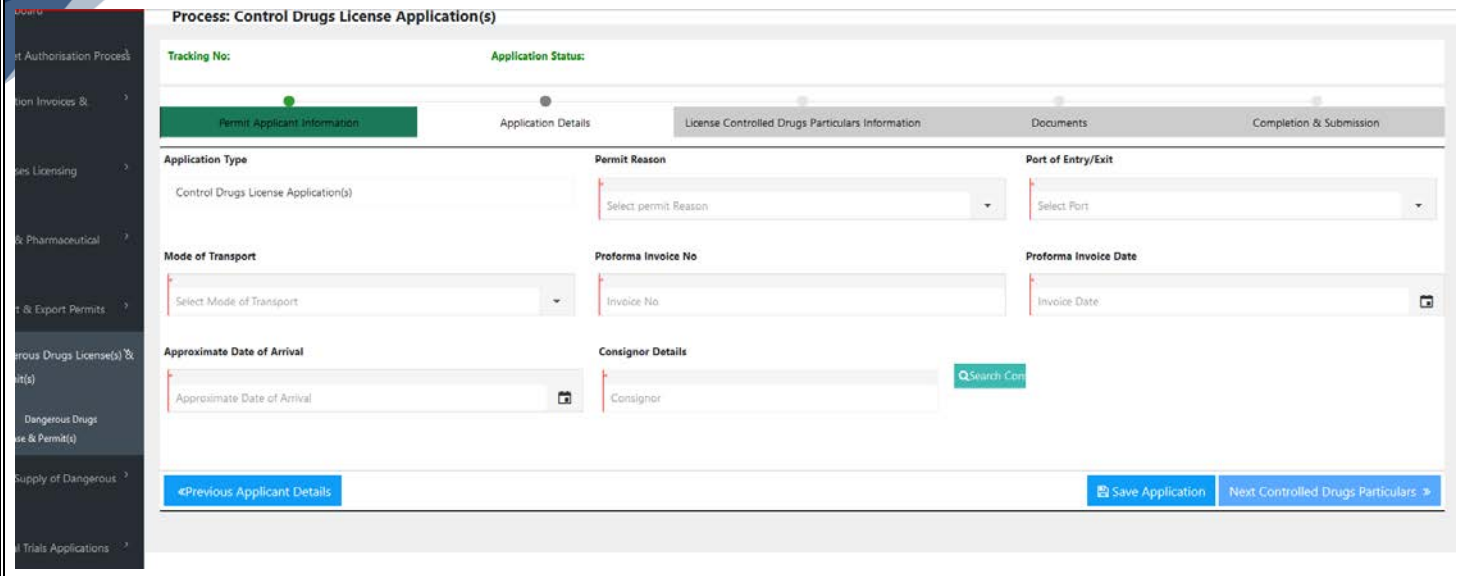



## 10.2 **Steps for the Import/Export Permit Application**

1) Step 1: Preview Applicant Details and click Next

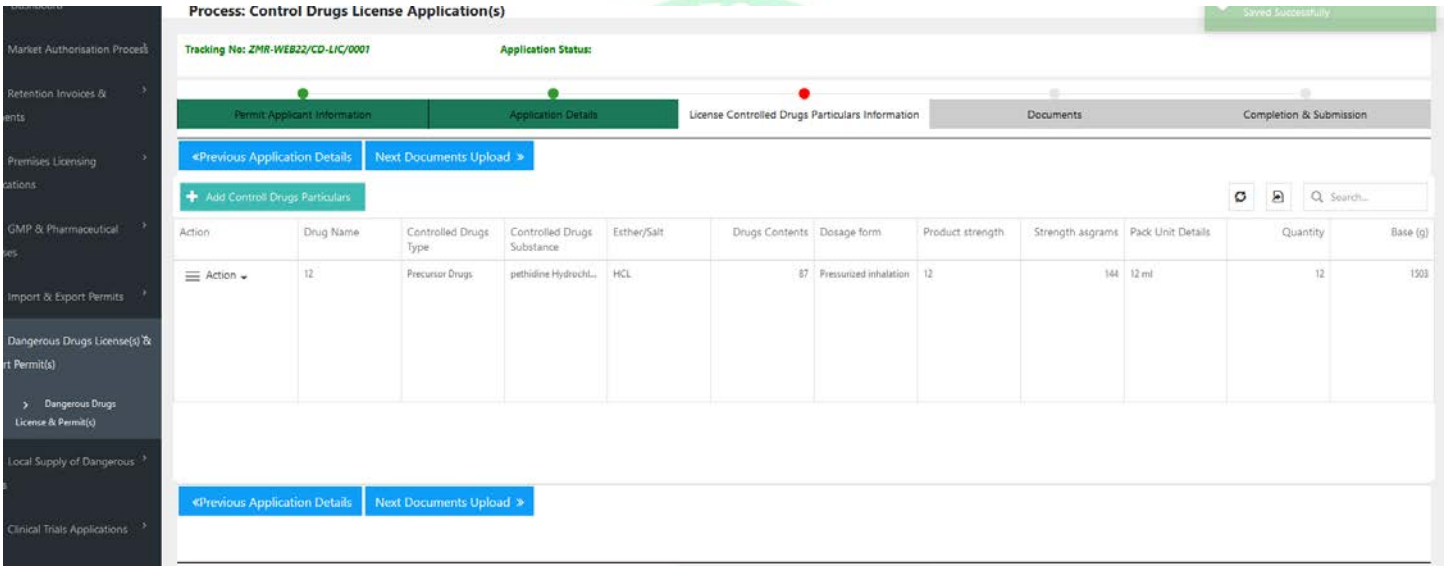



2) Step 2: Enter/Preview License General Information and save/update the details.



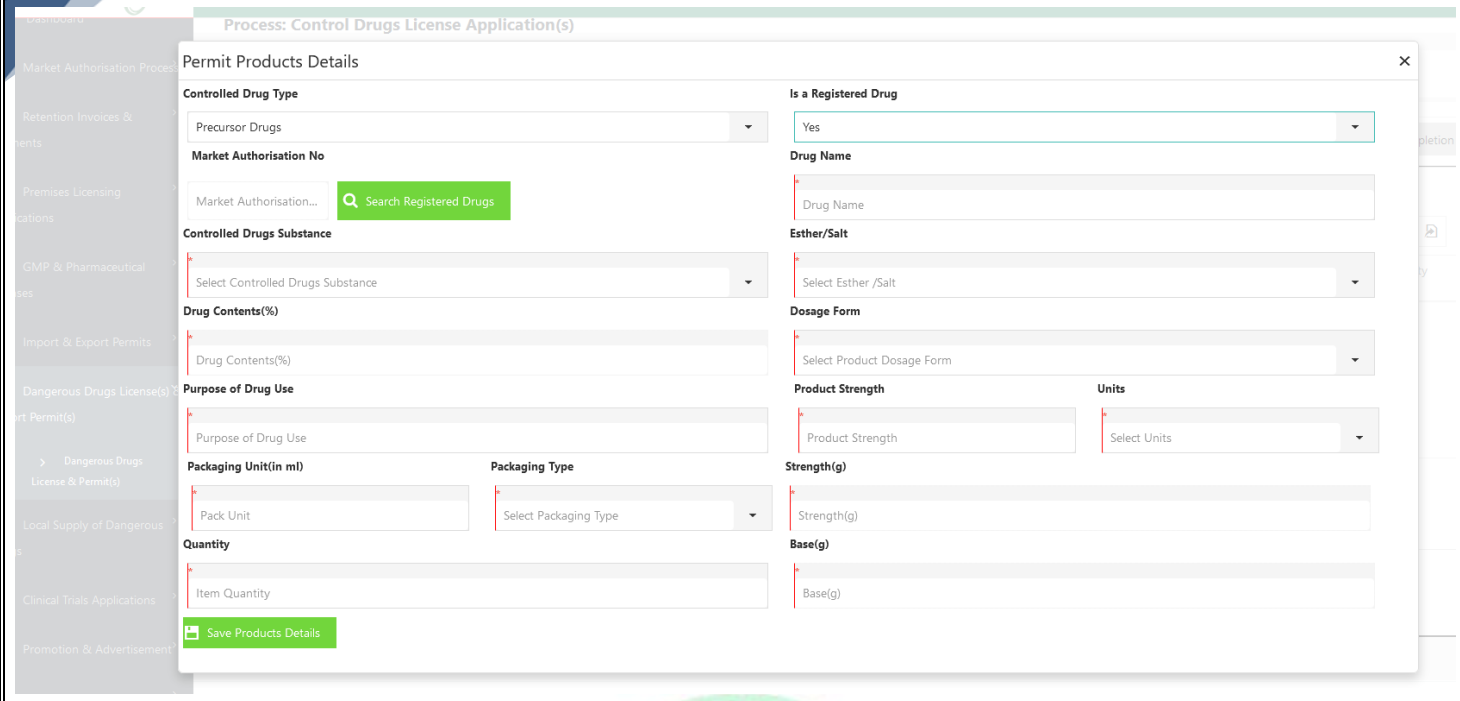

3) Step 3: Enter a list of Controlled Drugs details or preview the entered product information

This provides for

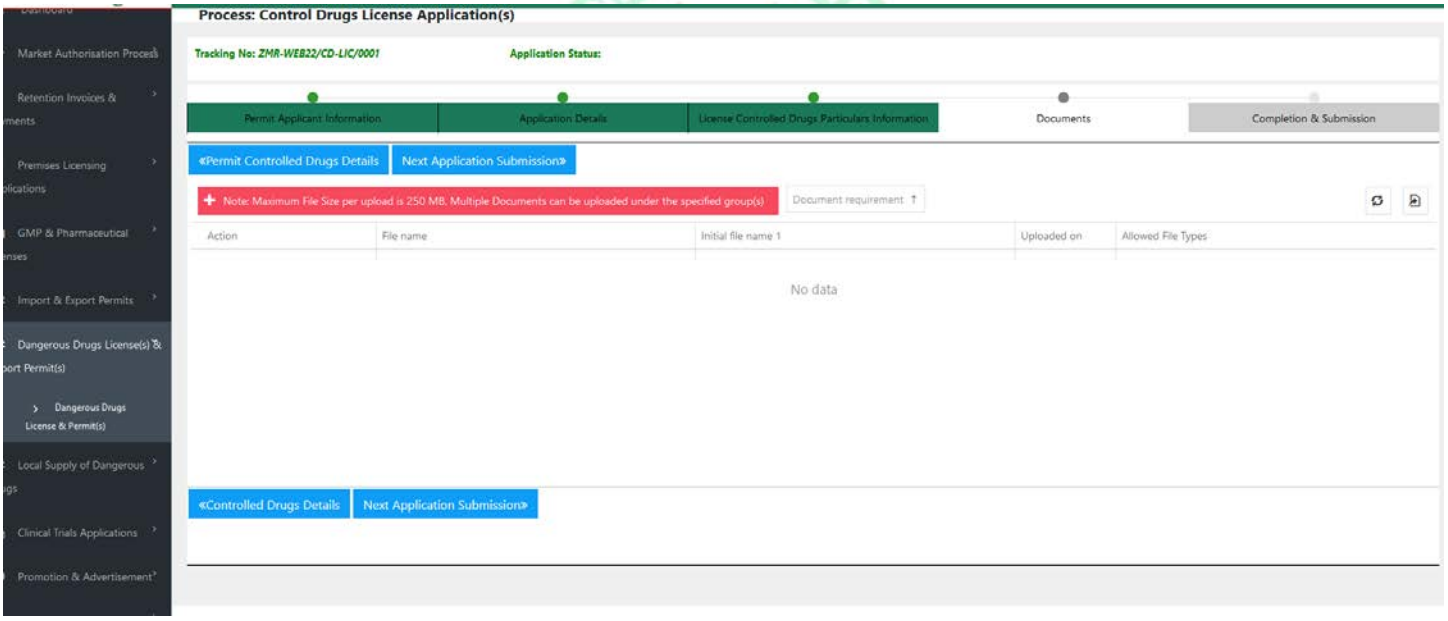



4) Step 4: Enter the Controlled Drugs Substance

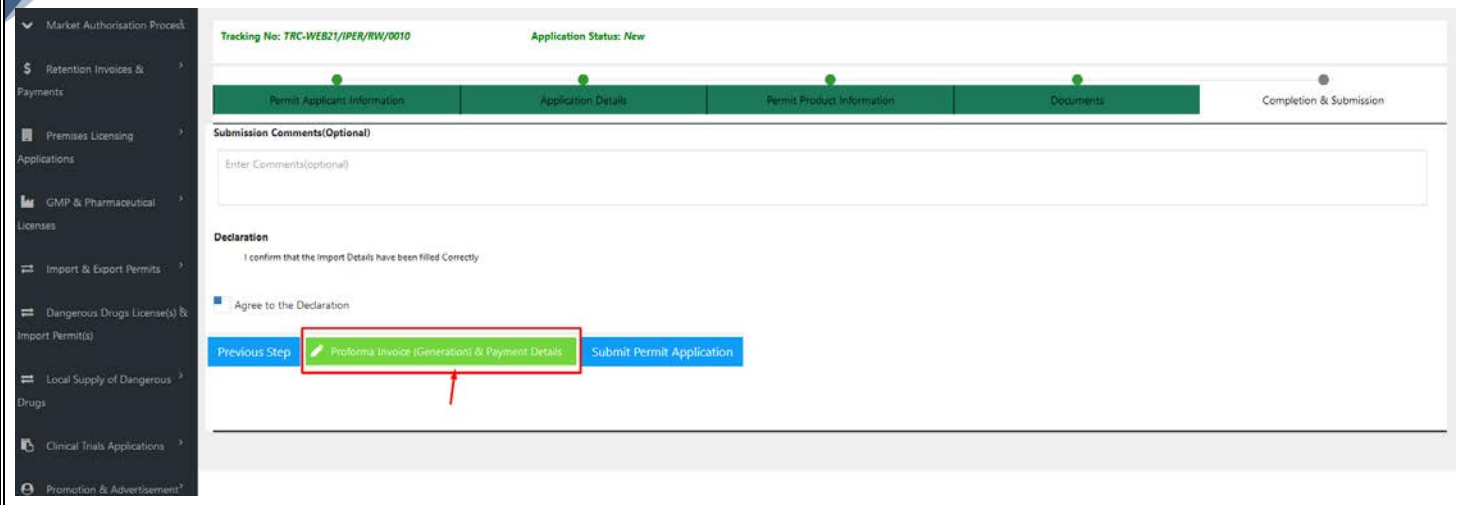
Note: The is provision to selected already issue MA or registered drugs by the authority based on the MA number.



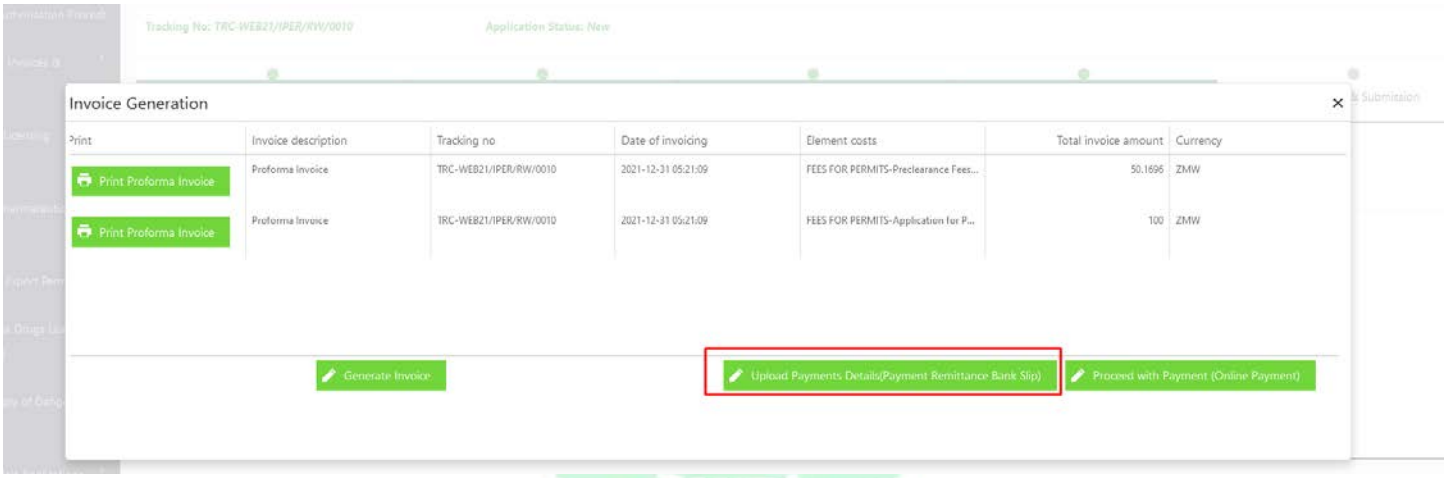

6) Step 5: Provision to Upload the required Permit Application Documents.



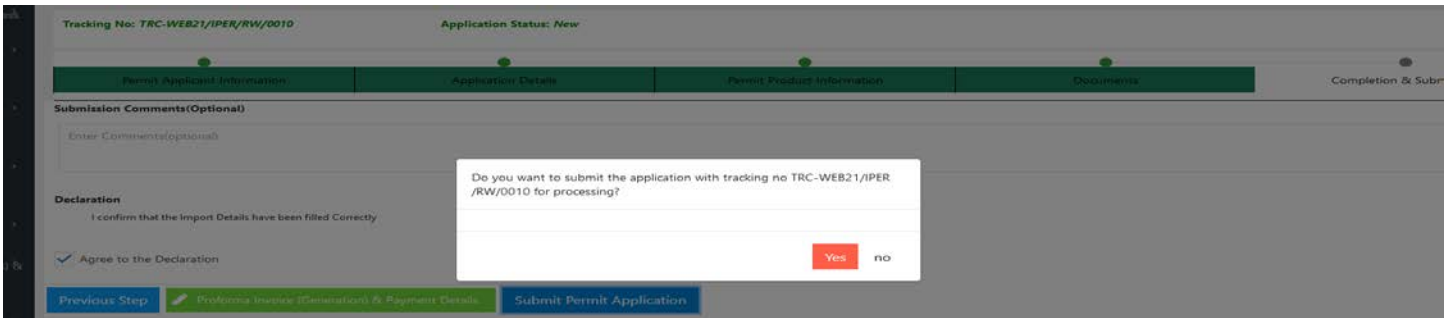
7) Step 6: Provision to generate and submit the permit application for processing




8) Step 8: Generate Proforma Invoice & Upload Evidence of payment details.




9) Step 9: Submit Permit Application for Processing



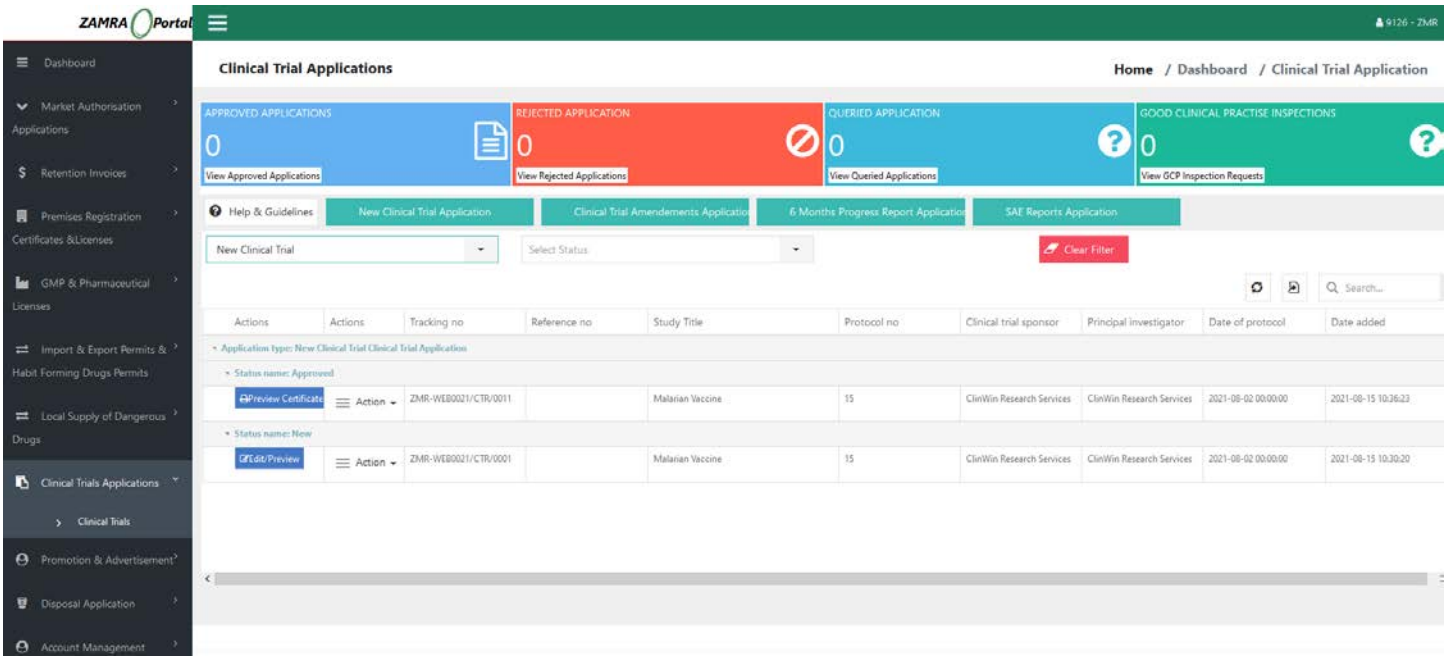
# 11 Clinical Trials Applications

This allows for the submission of clinical trial applications for the process by the authority

The Clinical Trial Dashboard provides for:

- List of already initiated clinical trial applications
- Statistics on summary of keys statuses of the applications
- Provision to start various clinical trial Applications and submission of requests

1) Initiate Application for new clinical trial
2) Initiate request for amendment of registered clinical trials
3) Submission of the Progress Clinical Trial Reports for review
4) SAE Reports Submission

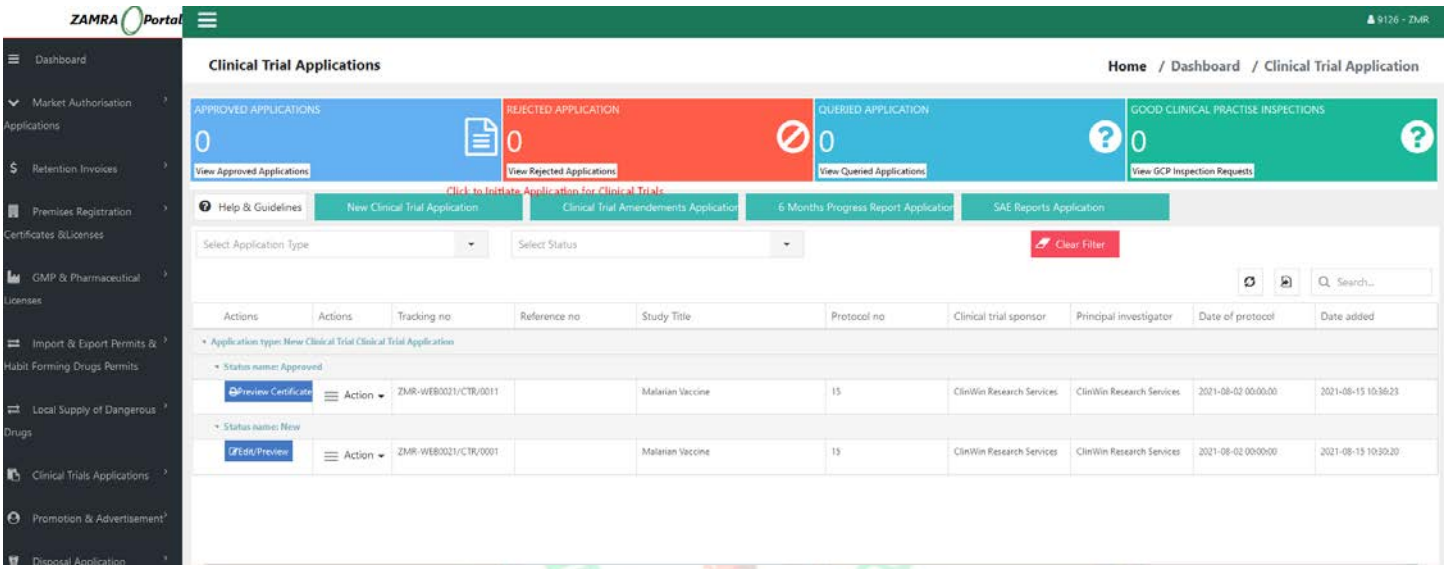


## 11.1 Initiating New Clinical Trial Application

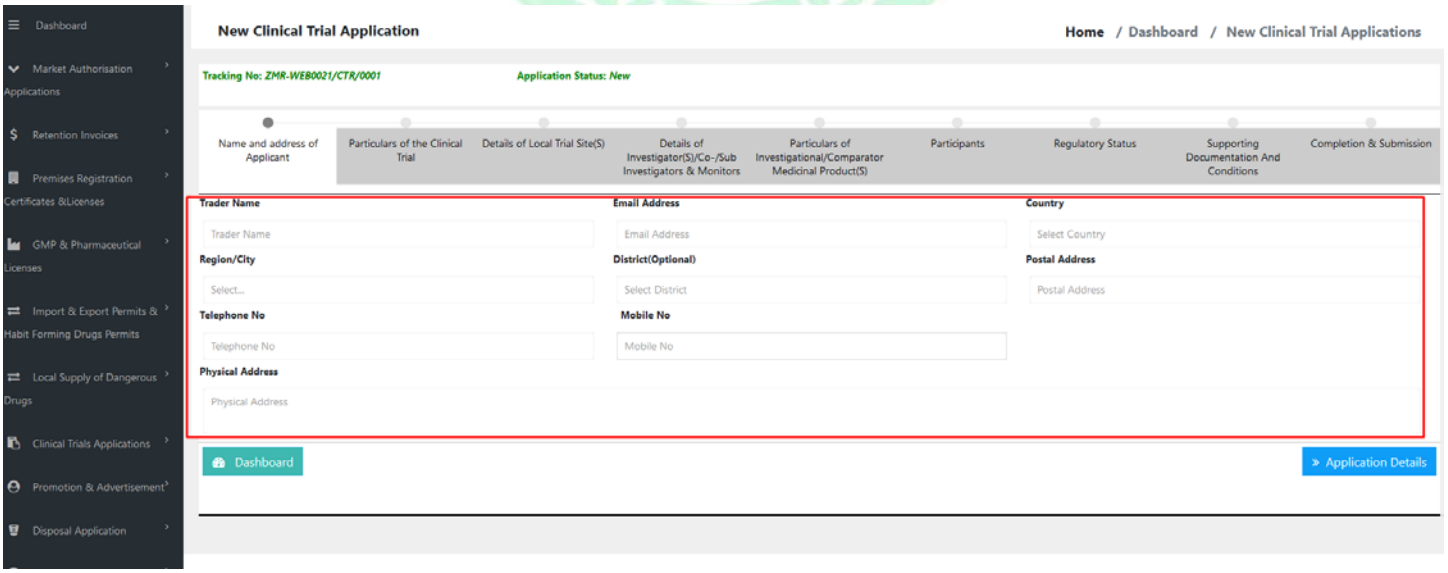
This allows for applicants/Principal Investigator or Institution to submit an application to undertake clinical trials in the country

The process involves submission of the Clinical Trial Information as described below

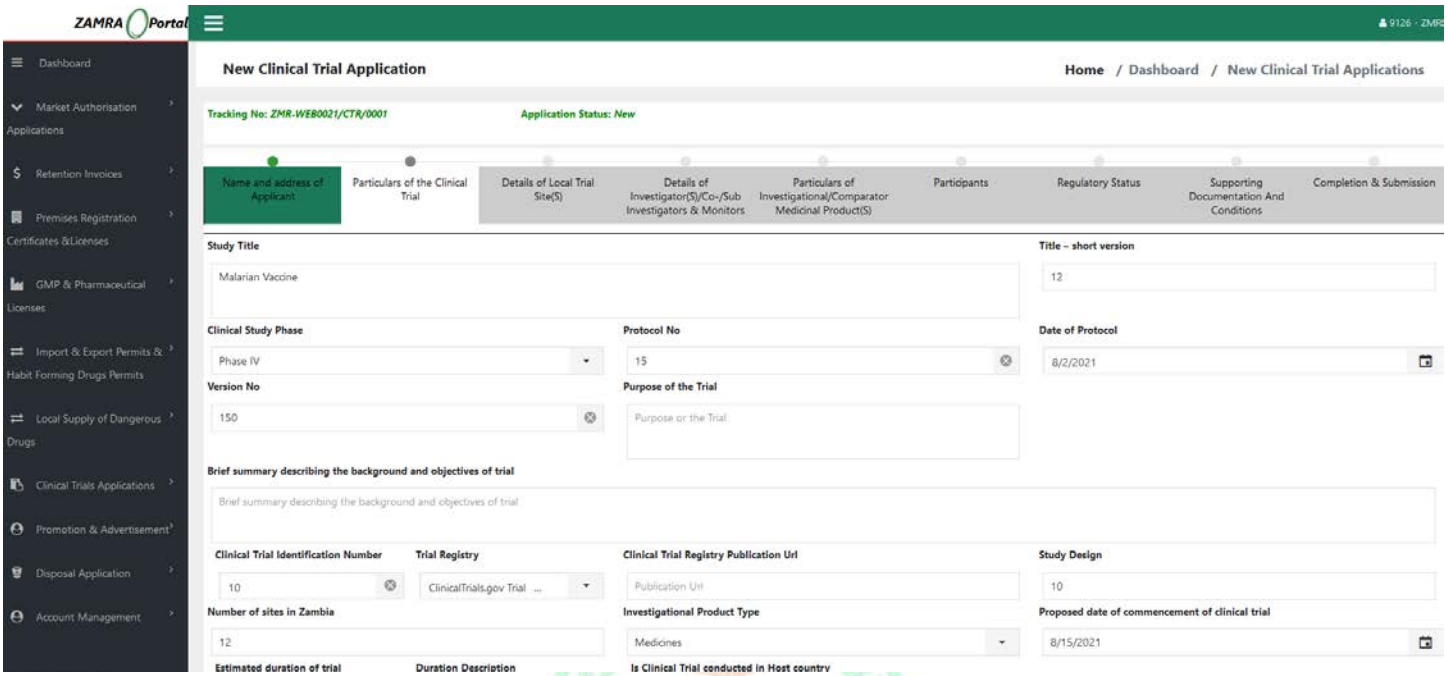
Step 1: Initiate Application for Clinical Trial by clicking the button described below thereby opening the section to fill in the clinical trial information.




Step 2: Preview the application applicant details

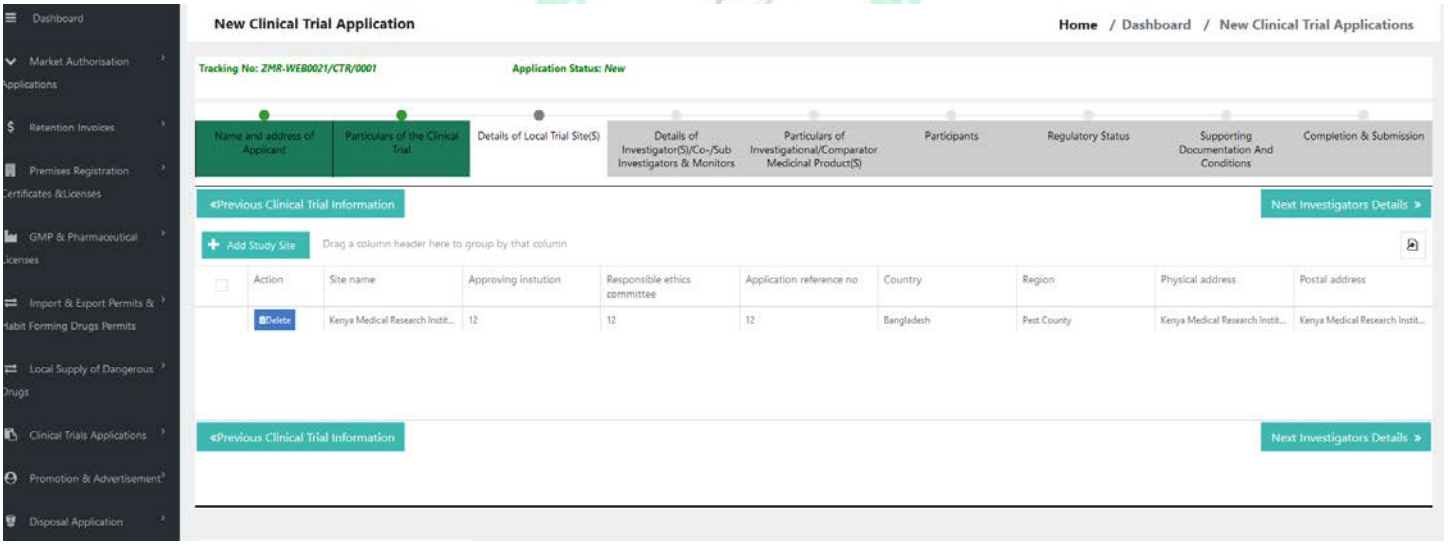


Step 3: Preview/Fill in the Clinical Trial General Information and save (a tracking number of Generated)

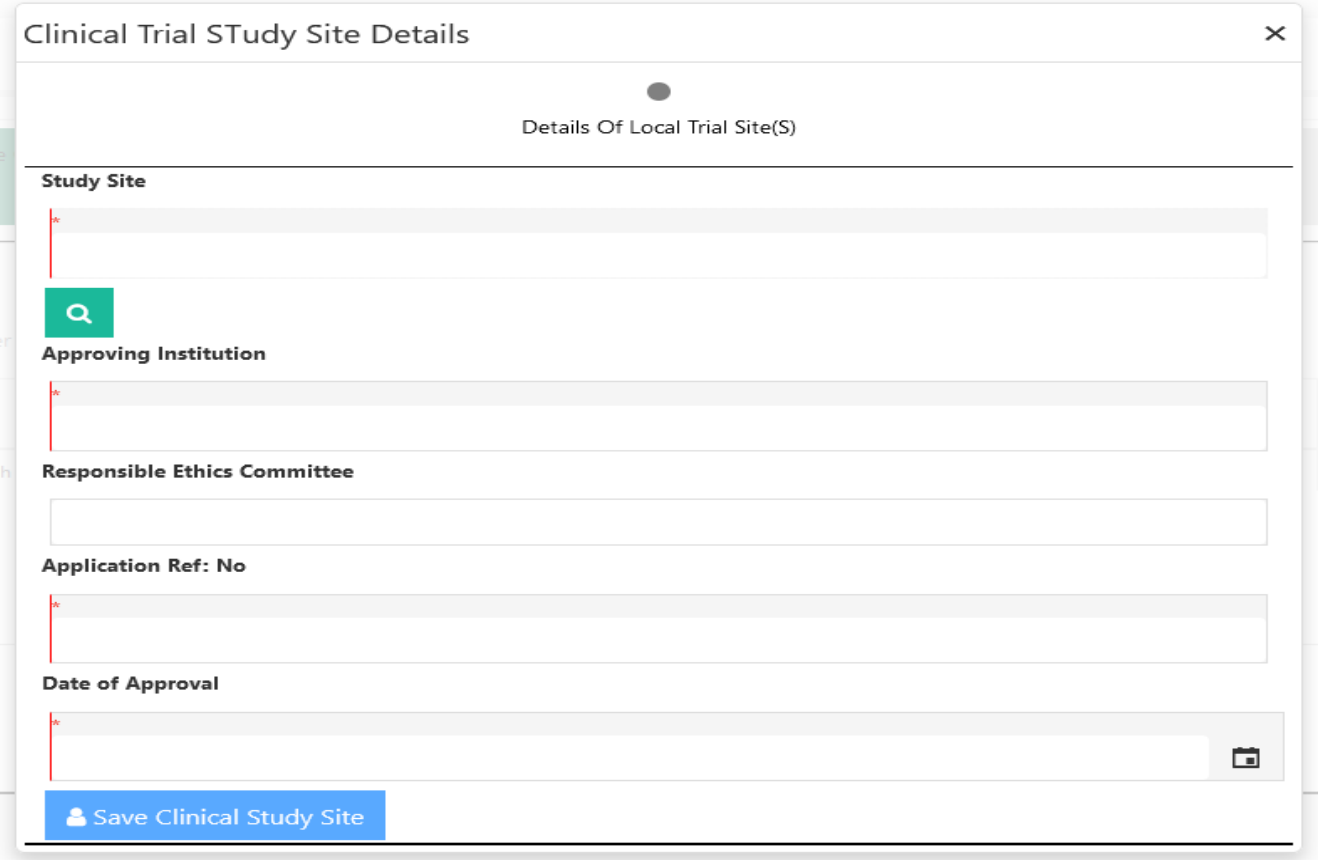



Step 4: Enter the Details of Local Trial Site(S)

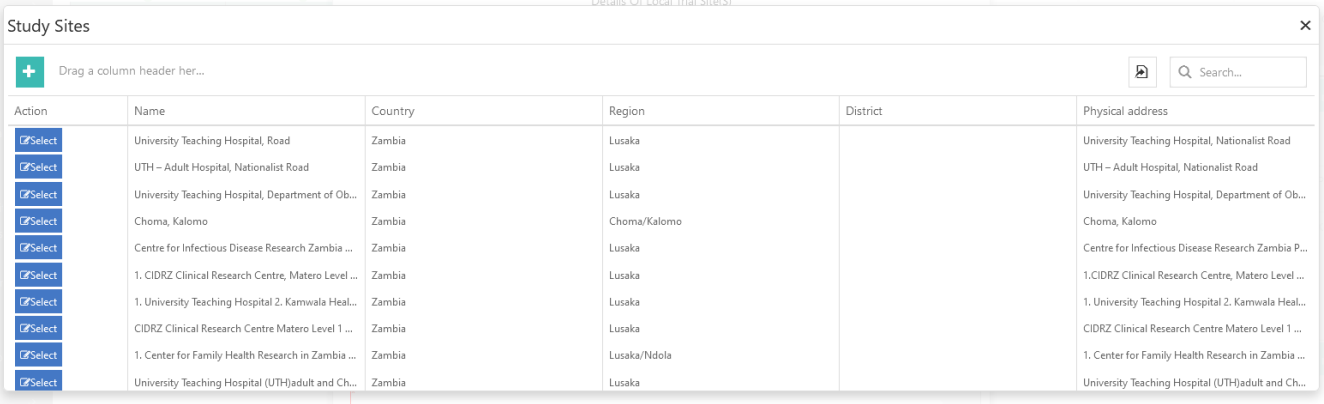
List of Entered Trial Sites



Provision to add clinical trial Sites

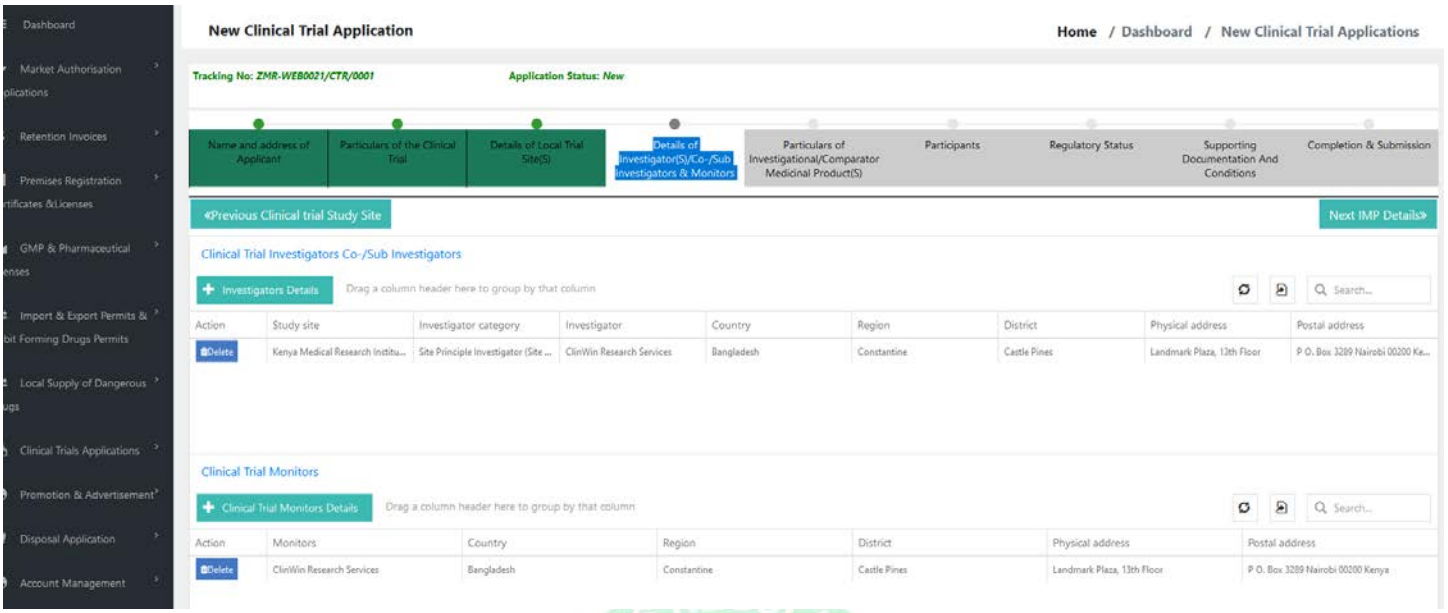



Provision to select A list of Clinical Trial Sites

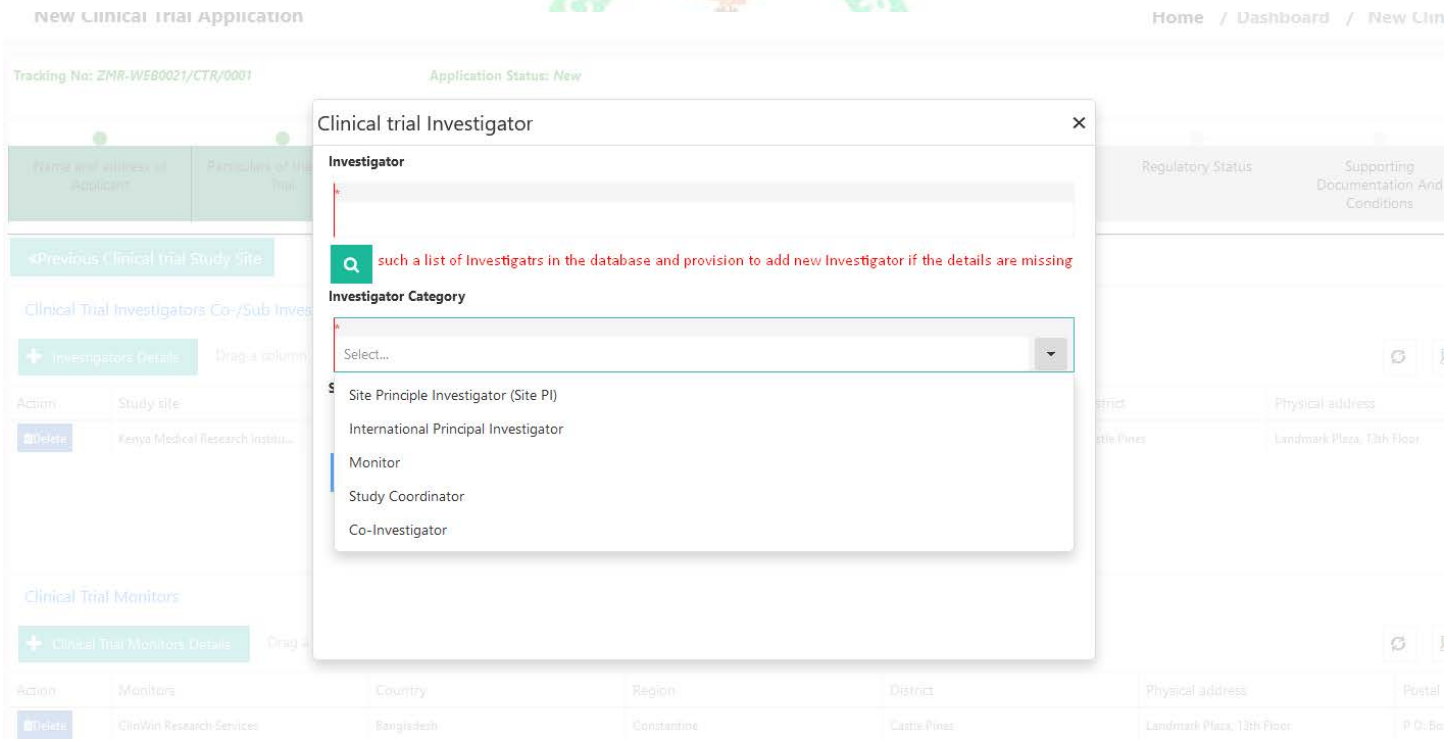


Step 5: Details of Investigator(S)/Co-/Sub Investigators & Monitors

Provision to Preview the already submitted investigators details

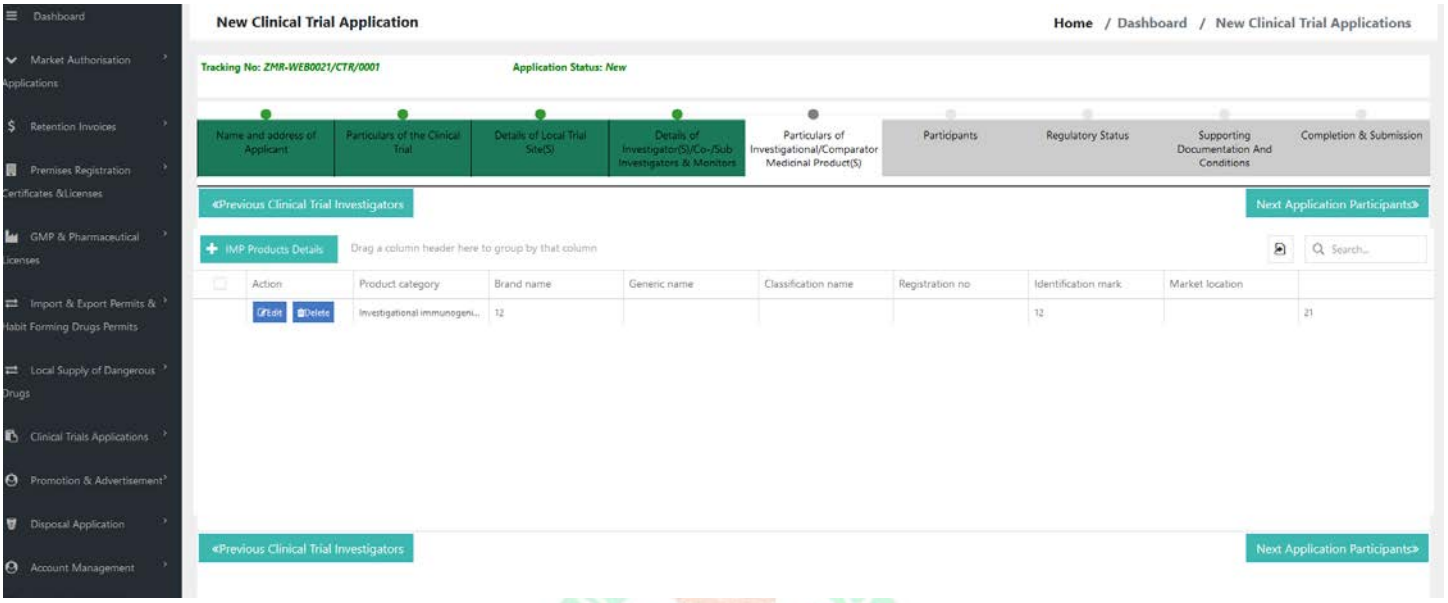



Provision to Add Investigator Details

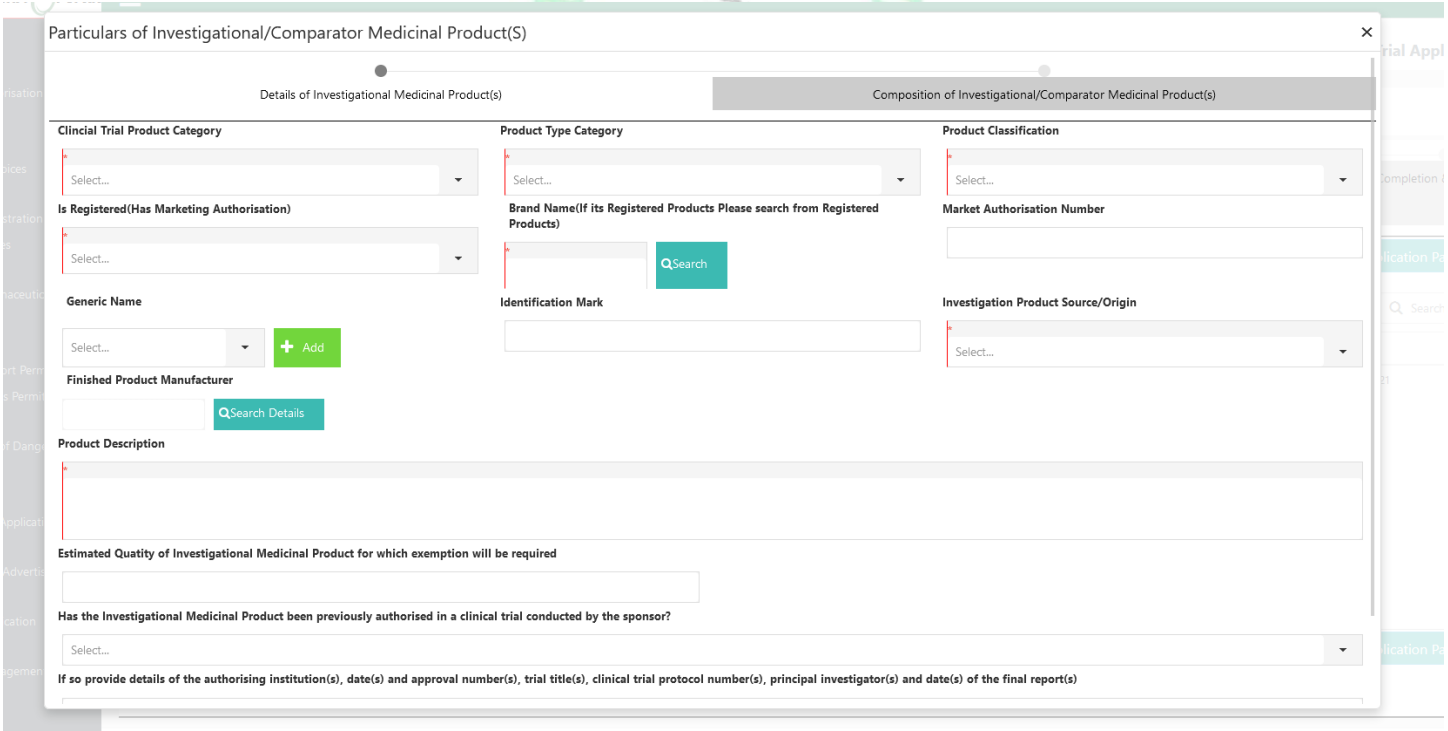


Step 6: Particulars of Investigational/Comparator Medicinal Product(S)

Provision to enter the Investigational Product information and the other Products Categories which include (Comparator product)

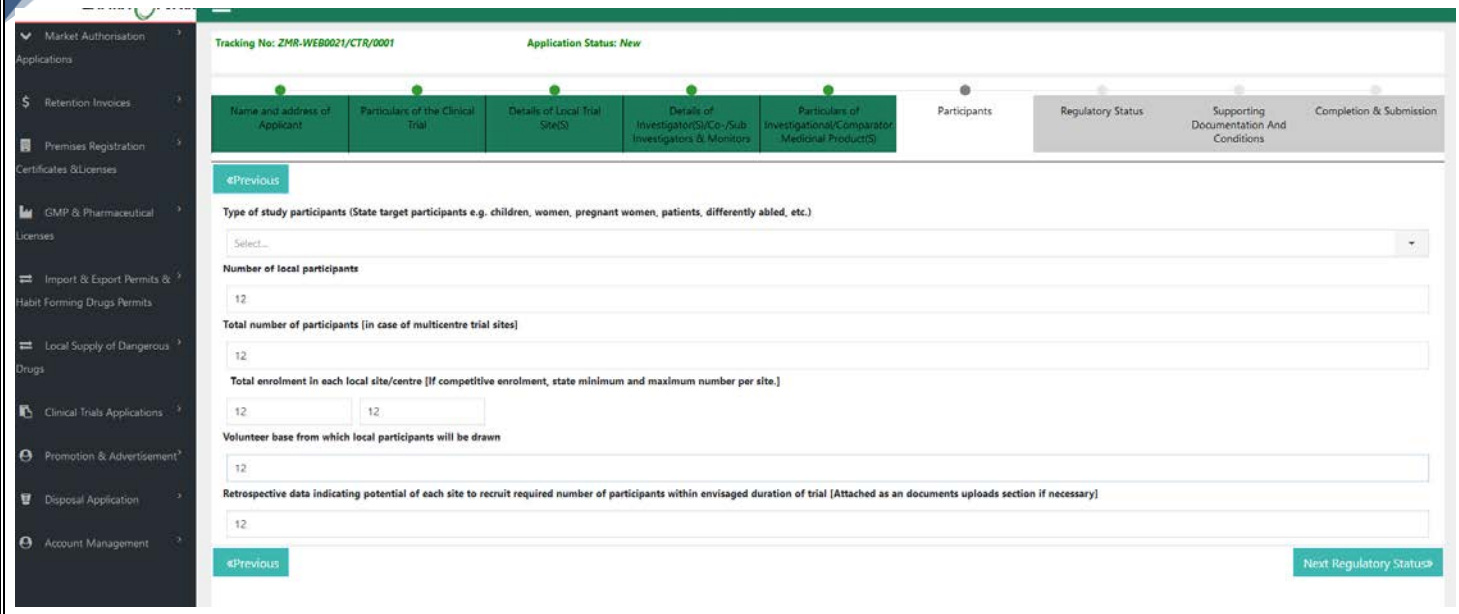



Provision to enter details of the investigation/comparator product



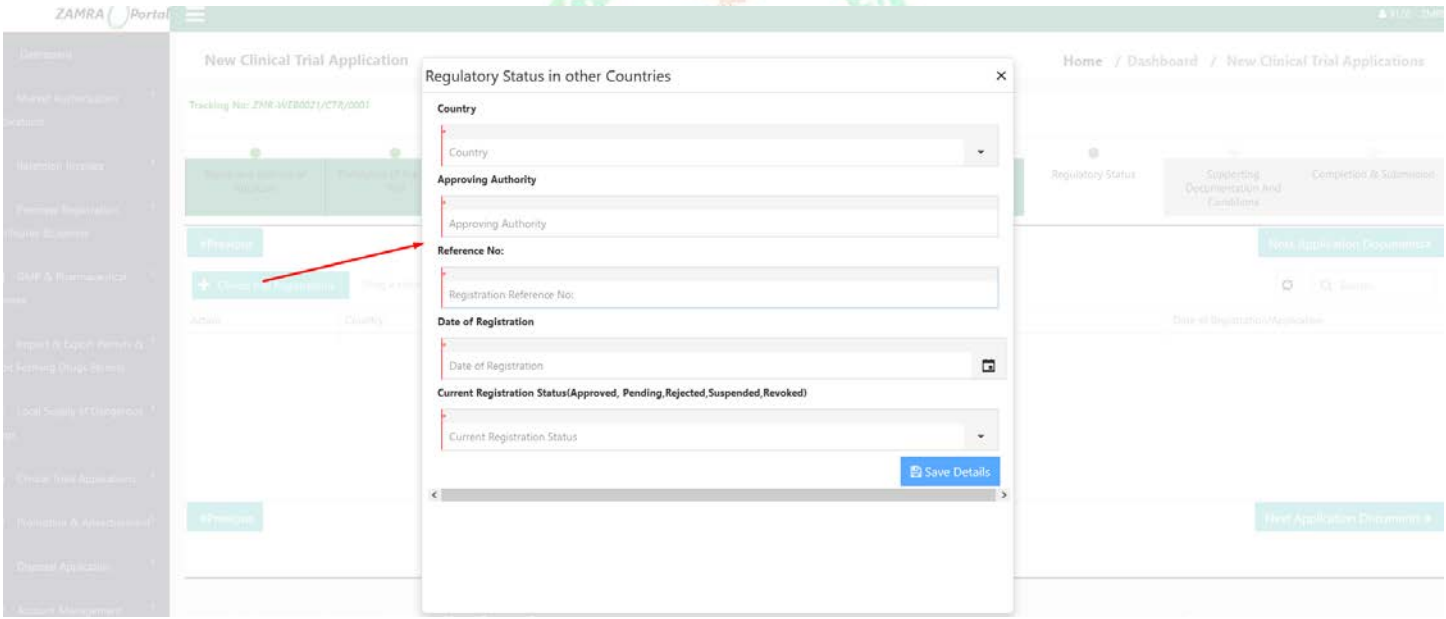

Step 7: Participants

Provision to enter information of the clinical trial participants



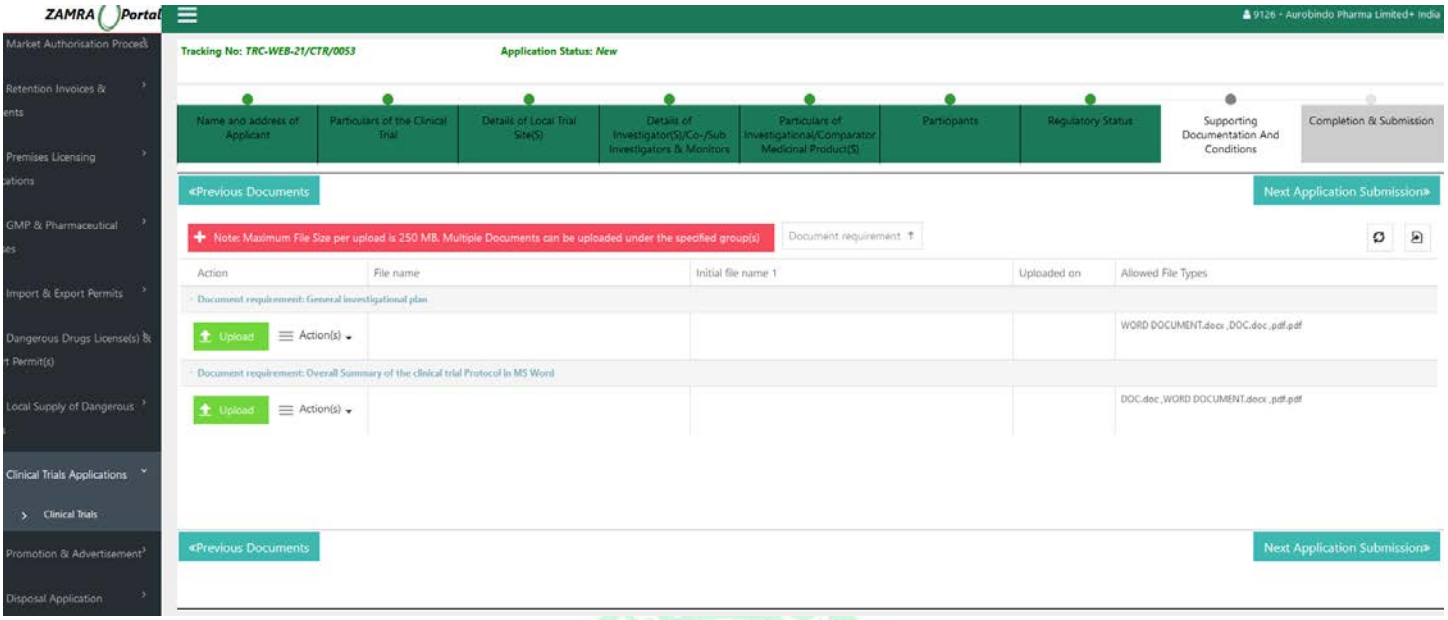

Step 8: Regulatory Status

Provision to enter regulatory status of the clinical trials in other countries



Step 9: Supporting Documentation and Conditions

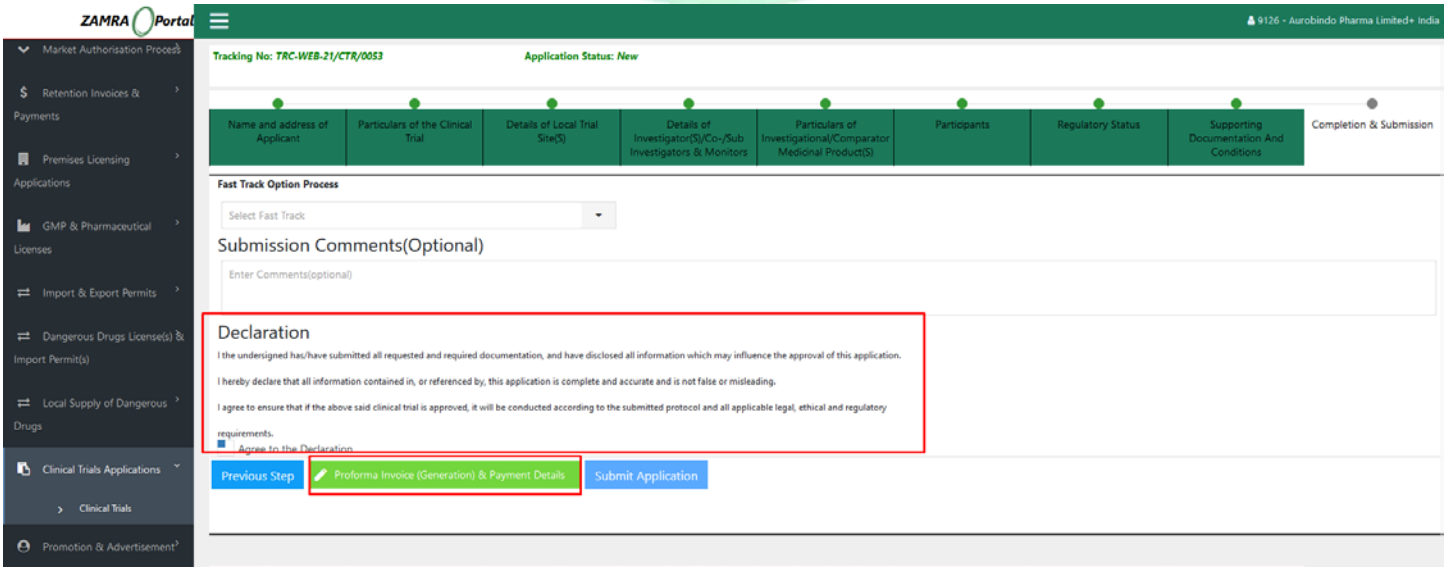
Provision to upload the required documents based on regulation



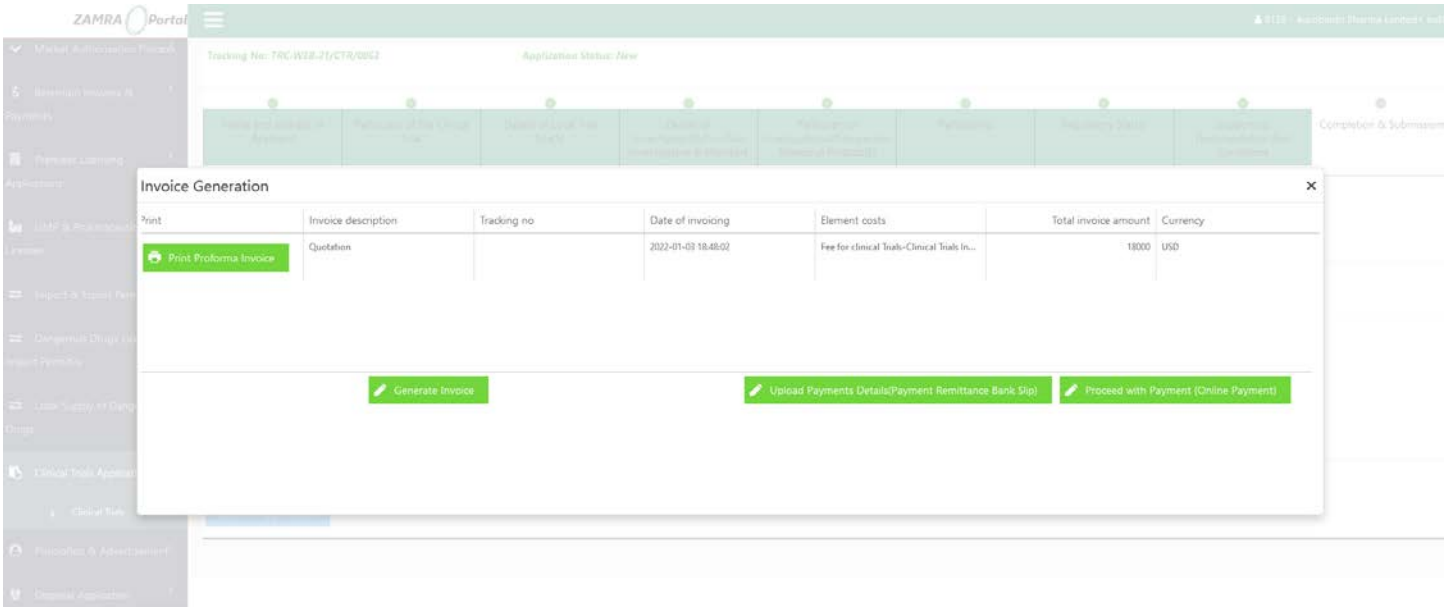

Step: 10: Submission Clinical trial Applications

The following provides for preview of the terms and conditions an set declarations and, provision for generation of the proforma invoice and upload of the proof of payments and submission of the application for processing by the authority.

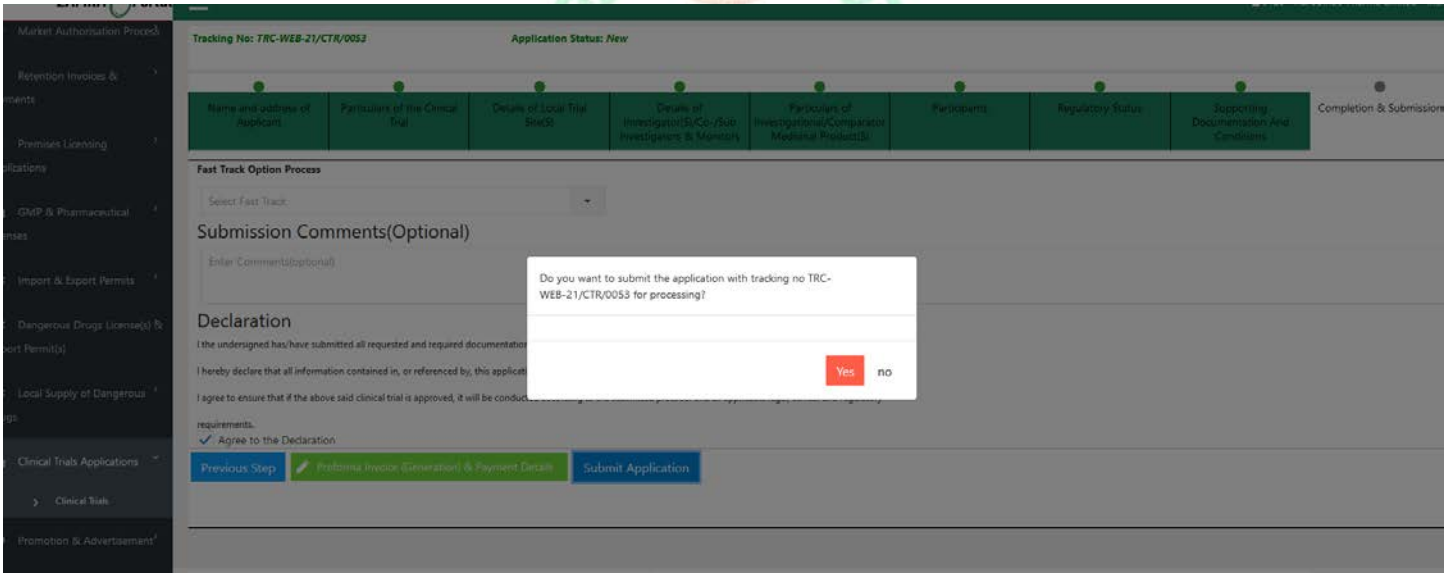
- Sub-Step: Submission Process



- Sub Step: Provision for generation of the Proforma Invoice and upload of the proof of payment




- Sub- Step: Submission of the clinical trial applications for processing by the authority

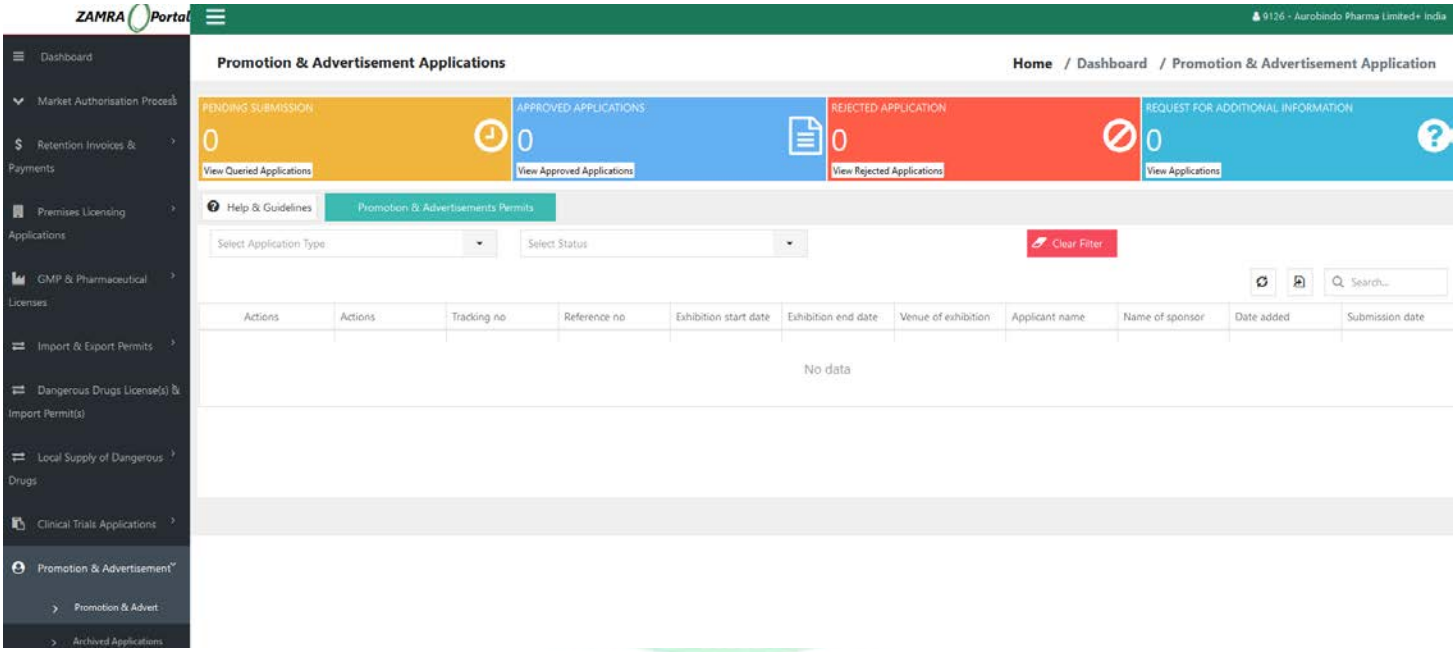


# 12 Promotion & Advertisement

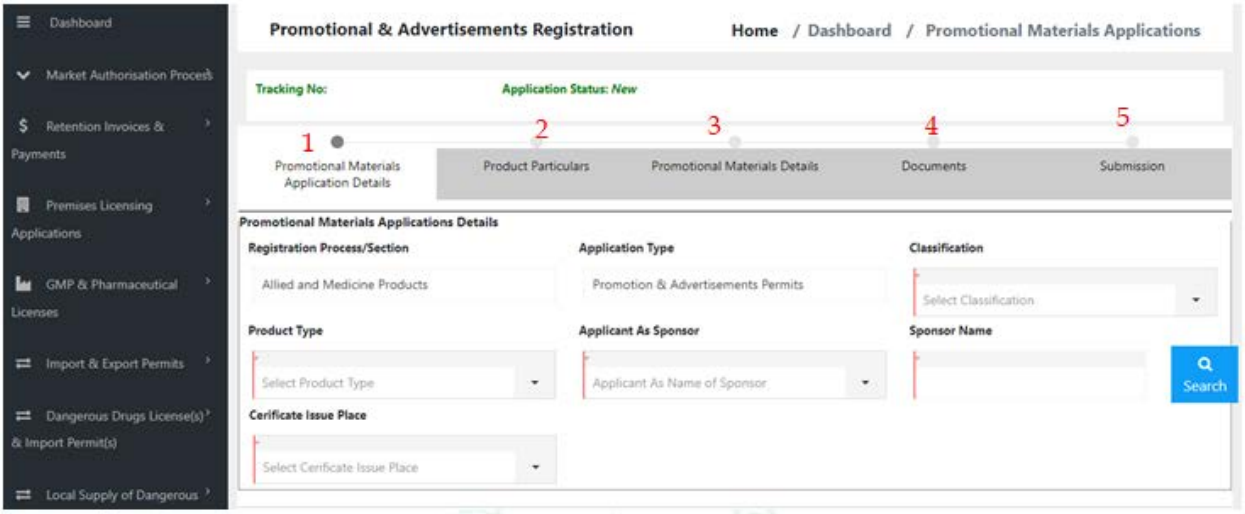
This allows for the submission of applications to undertake promotional and advertisement on medical products

The Promotional & advertisement Dashboard provides for:

- List of already initiated applications
- Statistics on summary of keys statuses of the applications
- Provision to initiate various application to undertake promotional and advertisement



## 12.1 Initiating Request to Undertake promotional and Advertisement




To complete Promotion & Advertisement Registration one is required to follow several steps.

These steps include:

1: Providing Promotional Materials Application Details

2: Filling details on Product Particulars

3: Providing Promotional Materials Details

4: Documents upload

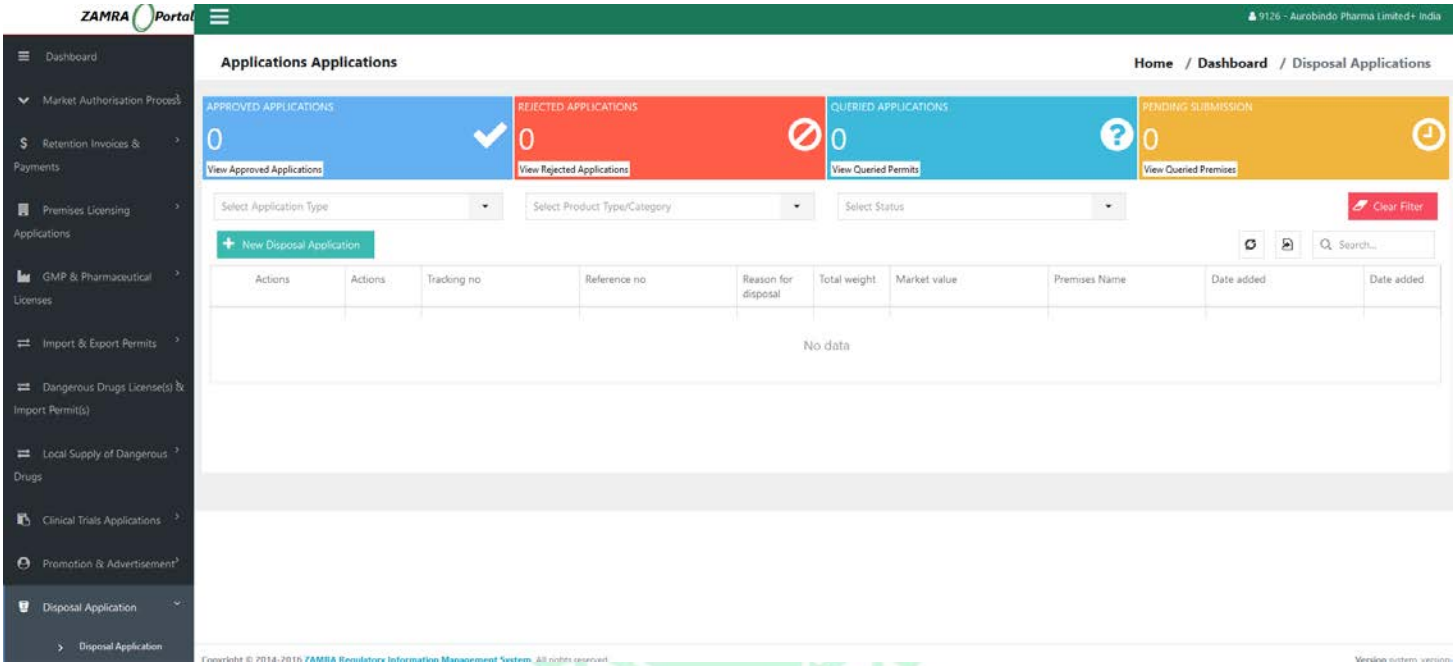
5: Submission

# 13 Disposal Application

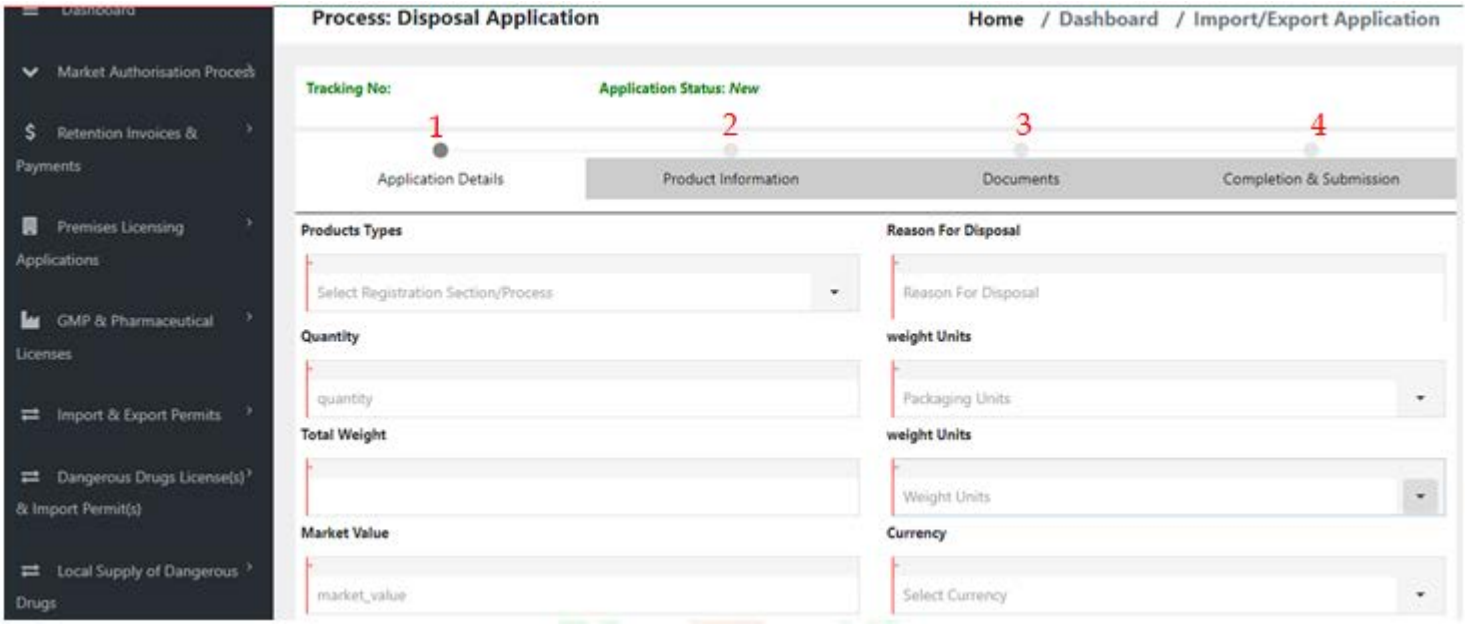
This allows for the submission of applications for disposal on medical products

The Disposal Dashboard provides for:

- List of already initiated applications
- Statistics on summary of keys statuses of the applications
- Provision to initiate various application to undertake promotional and advertisement




## 13.1 Initiating Application for Disposal



To complete the Disposal Application process one is required to follow several steps.

These steps include:

1: Providing Application Details

2: Providing Product Information

3: Documents upload

4: Completion & Submission

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