



**ZAMRA**

**Self- Service Portal**

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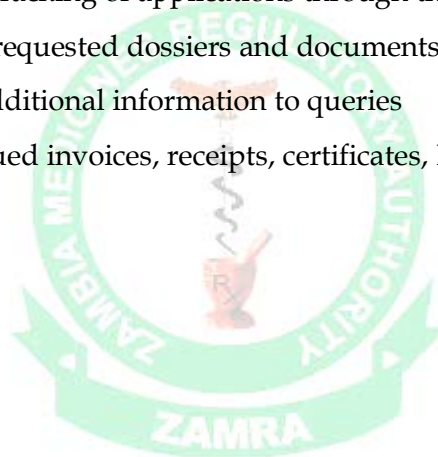
# 1 Introduction

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.

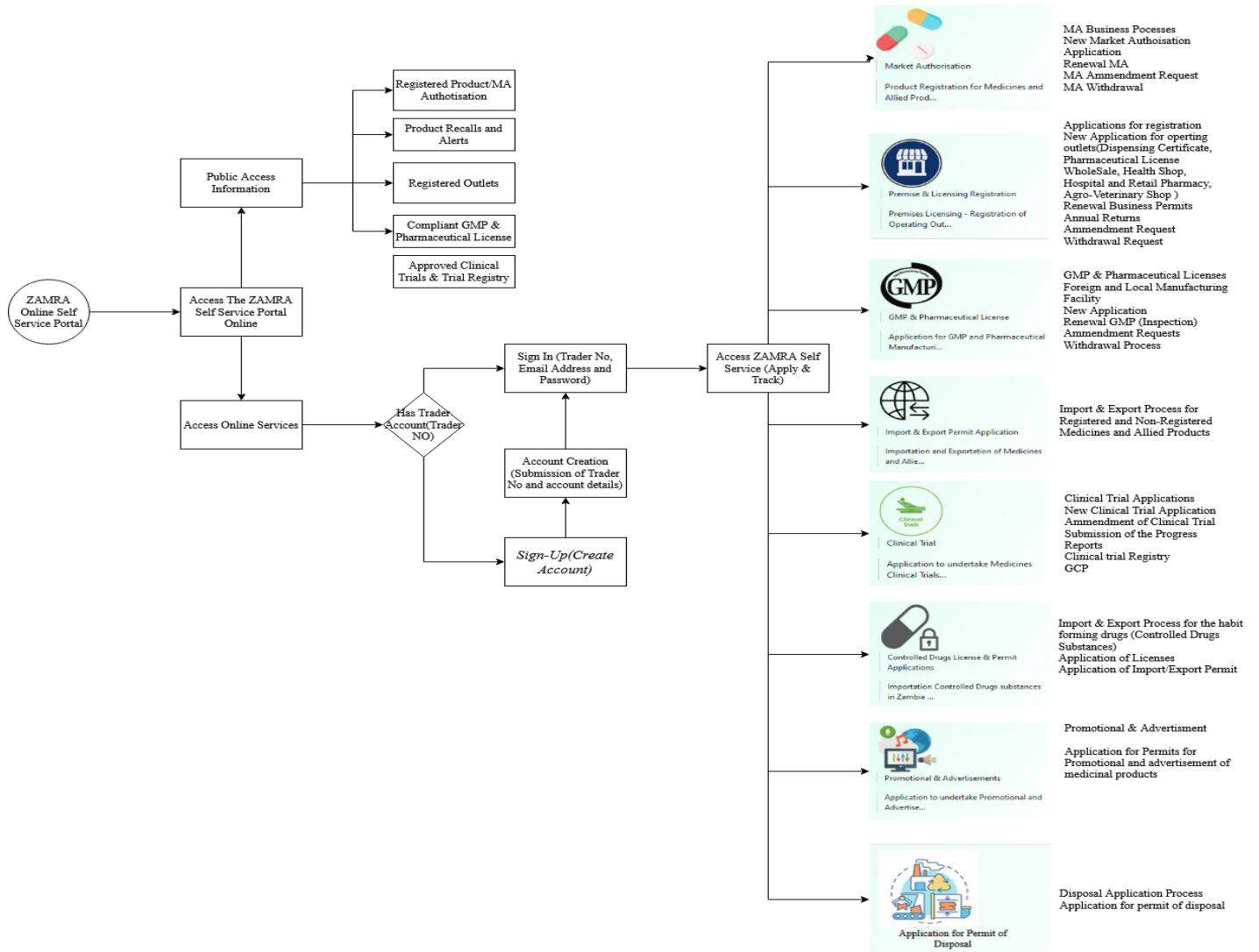
The Self-Service Portal incorporates a self-service portal where customers (traders) can submit a request for applications on various modules about the set workflow eliminating the physical submission of applications.

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

**ZAMRA Regulatory Information Management System**  
RIMS Customer Self Service Portal  
To protect and enhance public and animal health through the regulation of medicines and allied substances.

Online Services | Registered Products | Product Recalls & Alerts | Registered Premises | GMP Compliant Facilities | Clinical Trials | System User Manual | Complaint Submission

**Registered Medicines**

Registration/Certificate No: Registration No. [Enter Brand Name] Brand Name/Device Name: Enter Brand Name Product Category: Select Product Category Classification: Select Classification

Generic/Common Name: Select Common name Dosage/Product Form: Select Dosage/Product Form Marketing Authorization Holder: Marketing Authorization Holder Marketing Authorization Country: Select Authorization Country

Manufacturer: Manufacturer Name Manufacturing Country: Manufacturing Country Local Technical Representative: Local Representative

Search Products Clear Export Details

Drag a column header here to group by that column

| <input type="checkbox"/> | Product Category/Section | Certificate no | Brand name                    | Classification name     | Generic name                        | Active pharmaceutical Ingredients | Product Strength |     |
|--------------------------|--------------------------|----------------|-------------------------------|-------------------------|-------------------------------------|-----------------------------------|------------------|-----|
| <input type="checkbox"/> | Medicines                | ZAMRA21/0002   | Moxivone 125 Syrup            | Human Medicinal Product | Amoxicillin Trihydrate BP 125mg/5ml |                                   |                  | ... |
| <input type="checkbox"/> | Medicines                | 506/001VL      | Astra PHV 10 000TP12 Granules | Human Medicinal Product | 6-phytase EC 3.1.3.26 FTU/g         |                                   |                  | ... |
| <input type="checkbox"/> | Medicines                | 126/007        | Kanamycin injection           | Human Medicinal Product | Kanamycin                           |                                   |                  | ... |
| <input type="checkbox"/> | Medicines                | 113/080        | Cadillac Eye drops            | Human Medicinal Product | Ketorolac Tromethamol               |                                   |                  | ... |

- Register for the Approved Business dealing with medicinal products

**ZAMRA Regulatory Information Management System**  
RIMS Customer Self Service Portal  
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Online Services | Registered Products | Product Recalls & Alerts | Registered Premises | GMP Compliant Facilities | Clinical Trials | System User Manual | Complaint Submission

**Registered Premises**

Premises Registration/Certificate No: Registration No. Premises Name: Premises Name Premises Type: Select Premises Type Business Type: Select Business Type

Registrant Holder: Registrant

Search Premises Clear Print Export Details

Drag a column header here to group by that column

| <input type="checkbox"/> | Premise reg no | Premises name | Permit no | Region name | District name | Postal address | Email | Physical address | Registrant name | Date of registration | Premises type | Business type |
|--------------------------|----------------|---------------|-----------|-------------|---------------|----------------|-------|------------------|-----------------|----------------------|---------------|---------------|
|--------------------------|----------------|---------------|-----------|-------------|---------------|----------------|-------|------------------|-----------------|----------------------|---------------|---------------|

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



## ZAMRA Regulatory Information Management System

### RIMS Customer Self Service Portal

To protect and enhance public and animal health through the regulation of medicines and allied substances.

[Online Services](#)
[Registered Products](#)
[Product Recalls & Alerts](#)
[Registered Premises](#)
[GMP Compliant Facilities](#)
[Clinical Trials](#)
[System User Manual](#)
[Complaint Submission](#)

#### GMP Compliant Facilities

| Manufacturing Facility Registration/Certificate No  | Manufacturing Facility Name                    | Registrant/Manufacturer Name Holder     | Manufacturing Facility Location        |             |               |                |       |                  |                 |                      |
|---|--|---|--|-------------|---------------|----------------|-------|------------------|-----------------|----------------------|
| <input type="text" value="Registration No"/>  | <input type="text" value="GMP Facility Name"/> | <input type="text" value="Registrant"/> | <input type="text" value="Select..."/> |             |               |                |       |                  |                 |                      |
| <input type="button" value="Clear"/> <input type="button" value="Search Manufacturing Site Details"/> |  |   |  |             |               |                |       |                  |                 |                      |
| Drag a column header here to group by that column   |  |   |  |             |               |                |       |                  |                 |                      |
| <input type="checkbox"/>  | Gmp facility name                              | GMP Approval/Certificate No             | Country name                           | Region name | District name | Postal address | Email | Physical address | Registrant name | Date of registration |

- Register for submission of the Clinical Trial information



## ZAMRA Regulatory Information Management System

### RIMS Customer Self Service Portal

To protect and enhance public and animal health through the regulation of medicines and allied substances.

[Online Services](#)
[Registered Products](#)
[Product Recalls & Alerts](#)
[Registered Premises](#)
[GMP Compliant Facilities](#)
[Clinical Trials](#)
[System User Manual](#)
[Complaint Submission](#)

#### Clinical Trial Register

| Clinical Trial No  | Principal Investigator                  | Country  | Study Title                              |                       |              |         |             |            |                  |                 |                 |               |
|--|---|--|--|-----------------------|--------------|---------|-------------|------------|------------------|-----------------|-----------------|---------------|
| <input type="text" value="Certificate No"/>                  | <input type="text" value="Registrant"/> | <input type="text" value="Select Registrant Country"/> | <input type="text" value="Study Title"/> |                       |              |         |             |            |                  |                 |                 |               |
| <input type="checkbox"/> Advanced Search                     |   |  |  |                       |              |         |             |            |                  |                 |                 |               |
| <input type="button" value="Search Clinical Trial Details"/> |   |  |  |                       |              |         |             |            |                  |                 |                 |               |
| Clinical study phase ↑                                       |   |  |  |                       |              |         |             |            |                  |                 |                 |               |
| Principal Investigator                                       | Country                                 | Clinical Identification No                             | Scientific Study Title                   | Title – short version | Trial design | Acronym | Protocol no | Version no | Purpose of trial | Completion date | Publication url | Other Actions |



## 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.

**RIMS Customer Self Service Portal**  
To protect and enhance public and animal health through the regulation of medicines and allied substances.

The screenshot displays the RIMS Customer Self Service Portal interface. At the top, there is a navigation bar with tabs for: Online Services, Registered Medicines, Registered Medical Devices, Prohibited Products, Registered Premises, GMP Compliant Facilities, Clinical Trials, System User Manual, and External Evaluators/Inspectors Login. Below the navigation bar, there are several service tiles, each with an icon and a 'View Services Guidelines' link. The tiles include: Market Authorisation (Product Registration for Medicines and Allied Prod...), Premise & Licensing Registration (Premises Licensing - Registration of Operating Out...), GMP & Pharmaceutical License (Application for GMP and Pharmaceutical Manufactur...), Import & Export Permit Application (Importation and Exportation of Medicines and Allie...), Clinical Trial (Application to undertake Medicines Clinical Trials...), Controlled Drugs License & Permit Applications (Importation Controlled Drugs substances in Zambia ...), and Promotional & Advertisements (Application to undertake Promotional and Advertise...). On the right side of the page, there is a 'Please Sign In' section with input fields for Trader No, Email Address, and Password, a 'Lost Password' link, and a 'Sign-Up(Create Account)' button. At the bottom of the page, there is a footer with copyright information: Copyright © Zambia Medicines Regulatory Authority, 2021. All Rights Reserved. Website Maintained by Zambia Medicines Regulatory Authority. Location: Off Kenneth Kaunda International Airport Road, Lusaka Zambia. P. O Box 31890 Lusaka. Email Address: pharmacy@rims.zm.

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.



## RIMS Customer Self Service Portal

To protect and enhance public and animal health through the regulation of medicines and allied substances.

Online Services Registered Medicines Registered Medical Devices Prohibited Products Registered Premises GMP Compliant Facilities Clinical Trials System User Manual External Evaluators/Inspectors Login

### Account Guidelines

- All the information must be field for account Registration and issuance of Trader Number.

### Account Information

|  |  |  |
|--|--|--|
| <b>Account Type</b><br><input type="text" value="Select Account Type"/>                  | <b>Email Address</b><br><input type="text" value="Email Address"/>   | <b>Trader Name</b><br><input type="text" value="Trader Name"/>                   |
| <b>Country</b><br><input type="text" value="Select Country"/>                            | <b>Region/City</b><br><input type="text" value="Select..."/> <span style="color: green; font-weight: bold;">+ Add</span> |  |
| <b>District(Optional)</b><br><input type="text" value="Select District"/>                | <b>Postal Address</b><br><input type="text" value="Postal Address"/>   | <b>Telephone No</b><br><input type="text" value="Telephone No"/>                 |
| <b>Mobile No</b><br><input type="text" value="+ ( )"/>                                   | <b>Contact Person</b><br><input type="text" value="Contact Person"/>   | <b>Contact Person Email</b><br><input type="text" value="Contact Person Email"/> |
| <b>Contact Person Telephone</b><br><input type="text" value="Contact Person Telephone"/> |  |  |
| <b>Physical Address</b><br><input type="text" value="Physical Address"/>                 |  |  |

← Back to Login
Register Account

## 4.2 Forgot Password

### RIMS Customer Self Service Portal

To protect and enhance public and animal health through the regulation of medicines and allied substances.

Online Services Registered Medicines Registered Medical Devices Prohibited Products Registered Premises GMP Compliant Facilities Clinical Trials System User Manual External Evaluators/Inspectors Login

### Services available on the self service Portal.

| Organisation Services   | Description |
|---|-------------|
| <ul style="list-style-type: none"> <li>Clinical Trial</li> <li>Controlled Drugs License &amp; Permit Application</li> <li>GMP &amp; Pharmaceutical License</li> <li>Import &amp; Export Permit Application</li> <li>Market Authorisation</li> <li>Product &amp; Licensing Registration</li> <li>Promotional &amp; Advertisements</li> </ul> |             |

### Forgot Password

**Trader Account No**

**Email Address**

← Back to Login
Forgot Password Request

Copyright © Zambia Medicines Regulatory Authority, 2021. All Rights Reserved

Website Maintained by Zambia Medicines Regulatory Authority Location: Off Kenneth Kaunda International Airport Road, Lusaka Zambia

P. O Box 31890 Lusaka.

Email Address: pharmacy@rims.co.zm.

## 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

**ZAMRA Regulatory Information Management System**

**RIMS Customer Self Service Portal**  
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Online Services | Registered Products | Product Recalls & Alerts | Registered Premises | GMP Compliant Facilities | Clinical Trials | System User Manual | Complaint Submission

**Please Sign In** (1) Login Provision

Trader No

Email Address

Password

[Lost Password](#) | [Sign-Up\(Create Account\)](#)

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 P. O. Box 31690 Lusaka.  
 Email Address: pharmacy@zamra.co.zm.

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.

**ZAMRA Portal** 9126 - ZMR

**Dashboard** Home 4 Application Due for Renewal

**PENDING SUBMISSION** 19 **INVOICED PENDING PAYMENT** 0 **REQUEST FOR ADDITIONAL INFO.** 0 **APPROVED APPLICATIONS** 1 **REJECTED APPLICATIONS** 0

**Application processing**  
Application processing pending approval.

Select Application Type: [v] Select Application Sub-Ty...: [v] Select Application Categ...: [v] [Clear Filter](#)

Module name: [↑] [Search...]

| Tracking no | Reference no | Application type | Previous process | Current process |
|-------------|--------------|------------------|------------------|-----------------|
| No data     |              |                  |                  |                 |

**Latest Notifications**  
Latest notifications on application(s) processing

| Subject  | Sent on  |
|--|--|
| <a href="#">Preview</a> TRC-WEB21/PER/DON/0003         | Your application with tracking no: 2021-12-09 15:34:03 |
| <a href="#">Preview</a> TRC-WEB21/HM-NA/0048 Before... | <div>Your application with track: 2021-12-09 13:19:51  |
| <a href="#">Preview</a> TRC-WEB21/HM-NA/0048           | Your application with tracking no: 2021-12-09 13:16:24 |

**Pending Retention Invoices**  
Product Retentions Bills

Retention Year From: [v] Retention Year From: [v] Product category/section: [v] [Clear](#) [Print](#)

Retention year: [↑] [Search...]

## 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.

The screenshot shows the ZAMRA Portal Dashboard. At the top right, the user's name 'ZMR' is displayed. A dropdown menu is open, showing options: 'Change Password', 'Profile', and 'Logout'. The dashboard includes several status cards: 'PENDING SUBMISSION' (19), 'INVOICED PENDING PAYMENT' (0), 'REQUEST FOR ADDITIONAL INFO.' (0), 'APPROVED APPLICATIONS' (1), and 'REJECTED APPLICATIONS' (0). Below these cards is the 'Application processing' section with filters and a table. The table is currently empty, showing 'No data'. To the right, there is a 'Latest Notifications' section with a table of notifications.

| Subject                         | Sent on             |
|---------------------------------|---------------------|
| TRC-WEB2/1/PER/DON/0003         | 2021-12-09 15:34:03 |
| TRC-WEB2/1/HM-NA/0040 Refere... | 2021-12-09 13:19:51 |
| TRC-WEB2/1/HM-NA/0043           | 2021-12-09 13:16:24 |

## 5.2 Profile

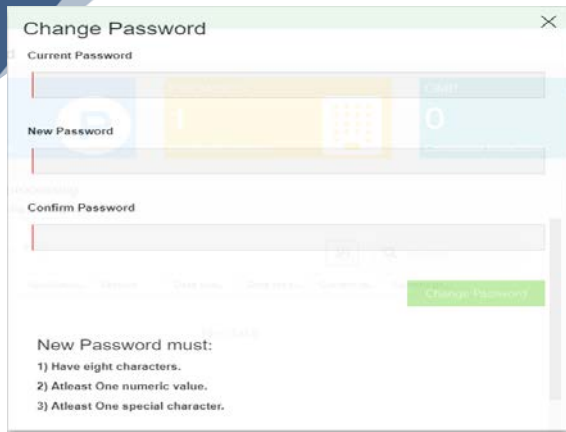
The screenshot shows the 'Trader Profile' page in the ZAMRA Portal. The page is divided into several sections for profile information:

- Account Type:** Select Account Type (dropdown)
- Country:** Zambia
- Postal Address:** P.O Box 356 Arusha
- TPIN No:** TPIN NO
- Physical Address:** Dar ES Salaam
- Contact Person:** Test Account
- Trader Name:** ZMR
- Region/City:** Select...
- Telephone No:** 12
- Contact Person Email:** Contact Person Email
- Email Address:** hiramwachira@gmail.com
- District(Optional):** Select District
- Mobile No:** 78
- Contact Person Telephone:** Contact Person Telephone

At the bottom right, there is a green button labeled 'Save Profile Information'.

## 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.



**Change Password**

Current Password

New Password

Confirm Password

Change Password

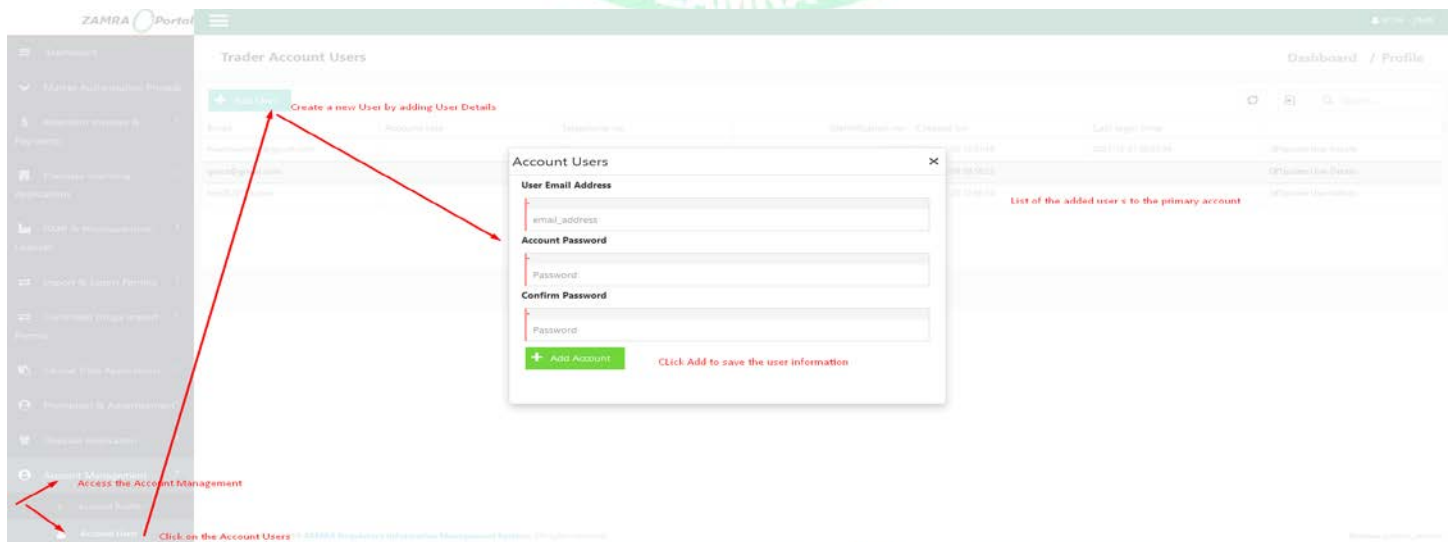
New Password must:

- 1) Have eight characters.
- 2) Atleast One numeric value.
- 3) Atleast One special character.

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](mailto:info@organ_name.com) then the other accounts to the [test1@organ\\_name.com](mailto:test1@organ_name.com) [test2@organ\\_name.com](mailto: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.



ZAMRA Portal

Trader Account Users

Create a new User by adding User Details

Account Users

User Email Address

Account Password

Confirm Password

Add Account

List of the added user's to the primary account

Access the Account Management

Click on the Account Users

## 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 | <ul style="list-style-type: none"> <li>Human Medicines</li> <li>Veterinary</li> <li>Biocidal Products</li> </ul>   |
| 2  | Allied Substances  | <ul style="list-style-type: none"> <li>Antiseptics, Disinfectants and Medicated Soap</li> <li>Medical Devices(In Vitro Diagnostic and Non-In Vitro Diagnostic) for Class A,B, C, D</li> <li>Cosmetics Products</li> <li>Condoms</li> </ul> |
|    |                    | <ul style="list-style-type: none"> <li>Acaricides are pesticides used to kill ticks and mites.</li> <li>Feed Additive's</li> <li>Nutritional Supplements</li> </ul>  |

### Marketing Authorization Dashboard

**ZAMRA Portal** 9126 - Aurebindo Pharma Limited - India

**Market Authorisation Application** 4 Application Due for Renewal Home / Dashboard / Market Authorisation Application

**PENDING SUBMISSION REQUEST(S)** 2 **REQUEST FOR ADDITIONAL INFORMATION** 0 **SAMPLE SUBMISSION REQUEST(S)** 0 **APPROVED APPLICATION** 0 **INTENTS OF REJECTION(S)** 0

View Pending Request Application View Queried Application View Sample Submission Request Application View Approved Applications View Rejected Application

Help & Guidelines New Marketing Authorisation Renewal of Marketing Authorisation Amendment of Marketing Authorisation Withdrawal of Marketing Authorisation

Select Application Type Select Product Type/Category Select Status Clear Filter

| Actions                              | Other Actions | Tracking no          | Reference no           | Applicant name                  | Section   | Brand name          | Application type            | Classification          |
|--------------------------------------|---------------|----------------------|------------------------|---------------------------------|-----------|---------------------|-----------------------------|-------------------------|
| Status: New                          |               |                      |                        |                                 |           |                     |                             |                         |
| Q/Preview                            | Action        | TRC-WEB21/VV-NA/0049 |                        | Aurebindo Pharma Limited- In... | Medicines | Amis                | New Marketing Authorisation | Human Medicinal Product |
| Q/Preview                            | Action        | TRC-WEB21/HM-NA/0047 |                        | Aurebindo Pharma Limited- In... | Medicines | Amoxil              | New Marketing Authorisation | Human Medicinal Product |
| Status: Screening Query Response     |               |                      |                        |                                 |           |                     |                             |                         |
| Q/View Application                   | Action        | TRC-WEB21/HM-NA/0048 | ZAMRA-WEB21/HM-NA/0019 | Aurebindo Pharma Limited- In... | Medicines | Amoxil              | New Marketing Authorisation | Human Medicinal Product |
| Status: Submitted- Pending Receiving |               |                      |                        |                                 |           |                     |                             |                         |
| Q/Preview                            | Action        | TRC-WEB21/HM-NA/0046 |                        | Aurebindo Pharma Limited- In... | Medicines | Panadol Extra 20155 | New Marketing Authorisation | Human Medicinal Product |
| Q/Preview                            | Action        | TRC-WEB21/HM-NA/0045 |                        | Aurebindo Pharma Limited- In... | Medicines | Panadol Extra       | New Marketing Authorisation | Human Medicinal Product |
| Q/Preview                            | Action        | TRC-WEB21/HM-NA/0044 |                        | Aurebindo Pharma Limited- In... | Medicines | Panadol Extra 125   | New Marketing Authorisation | Human Medicinal Product |

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

The screenshot displays the 'Marketing Authorisation Application Selection' page on the ZAMRA Portal. The page is divided into several sections:

- Navigation:** A sidebar on the left contains menu items such as 'Dashboard', 'Market Authorisation Process', 'Retention Invoices & Payments', 'Premises Licensing Applications', 'GMP & Pharmaceutical Licenses', 'Import & Export Permits', 'Dangerous Drugs License(s) & Import Permits', 'Local Supply of Dangerous Drugs', 'Clinical Trials Applications', 'Promotion & Advertisement', 'Disposal Application', and 'Account Management'.
- Header:** The top header shows 'ZAMRA Portal' on the left and '9126 - Aurobindo Pharma Limited - India' on the right.
- Main Content:**
  - Select Product Category/Type Application:** This section offers two radio button options:
    - New Allied Substances Product Application** (selected): on Allied Substances
    - New Medicines Product Application**: on Medical drugs (Human and veterinary), antiseptics, herbal
  - Select Product Classification Category:** This section lists several categories with radio buttons:
    - Nutritional Supplements
    - Feed Additives/EF™s
    - Acaricides are pesticides
    - Condoms
    - Cosmetics Products
    - Medical Devices(In Vitro and Non In Vitro Diagnostic products)
    - Antiseptics, Disinfectants and Medicated Soap
  - Marketing Authorisation Applications Guidelines/Definitions:** This section includes a search bar for 'Application type', a 'Download Guidelines' button, and a search icon. Below the search bar, there is a dropdown menu for 'Application type: New Marketing Authorisation' and a 'Guidelines' section with a 'Note' and 'The 1st Step' instructions.

- Step 2: Fill in MA Application details

## Step 1: Preview MA Holder's/ Applicant Information

**ZAMRA Portal** 9126 - Aurobindo Pharma Limited+ India

**Product Registration** New Drugs Product Applications ::

Tracking No: Application Status: New

Applicant Information/Market Authorisation Holder

Product Application Details

Product Information

Dossier Documents Submission

Product Mockups

Submission

Trader Name  
Trader Name

Email Address  
Email Address

Country  
Select Country

Region/City  
Select...

District(Optional)  
Select District

Postal Address  
Postal Address

Telephone No  
Telephone No

Mobile No  
Mobile No

Physical Address  
Physical Address

Dashboard

Next Product Information

## Step 2: Fill in Product General Product Information

**ZAMRA Portal** 9126 - Aurobindo Pharma Limited+ India

**Product Registration** New Drugs Product Applications ::

Tracking No: Application Status: New

Applicant Information/Market Authorisation Holder

Product Application Details

Product Information

Dossier Documents Submission

Product Mockups

Submission

Assessment Type  
Select Assessment Types

Brand Name/Trade Name  
Enter Brand Name

Classification  
Select Classification

Product Sub-Category  
Product Sub-Category

Generic Name(Optional)  
Select Common name + Add Generic/INN Name

ATC Code(Optional)  
Select ATC Code

ATC Description(Optional)

Product Strength  
Product Strength

Proposed Distribution Category  
Distribution Category

Other Distribution Category(Remarks)  
Other Distribution Category(Remarks)

Storage Conditions  
Storage Condition

Dosage Forms  
Dosage Form

Route Of Administration  
Route Of Administration

Proposed Shelf Life After Opening(Months)  
shelf\_lifeafter\_opening

Product Origin  
Product Origin

Stability Studies Data  
Stability Studies Data

Product Physical Description(Description of Finished Product Specification)

## 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



**Tracking No:** TRC-WEB21/VV-NA/0049 **Application Status:** New

Product Information Details(Fill all the information on the Tabs)

- Product Ingredients(expand to fill in the product ingredients)
- Packaging Information(expand to fill in the product packaging)
- Finished Product Manufacturers(expand to fill in the finished manufacturers)
- API Manufacturers(expand to fill in the API manufacturers)
- GMP Inspection Details(expand to fill in the Gmp Inspection)
- GMP Inspections In other States/Countries(Optional)

| Action                        | Ingredient   | Specification        | Strength | SI units   | Reason of inclusion |
|-------------------------------|--------------|----------------------|----------|------------|---------------------|
| <span>✔</span> <span>✖</span> | Disintegrant | Orthophosphoric acid | 3213     | g/canister | Adsorbent           |

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

**Tracking No:** TRC-WEB21/VV-NA/0049 **Application Status:** New

Document requirement

| Action | File name | Initial file name | Uploaded on | Allowed File Types         |
|--------|-----------|-------------------|-------------|----------------------------|
| Upload |           |                   |             | DOC.doc,WORD DOCUMENT.docx |
| Upload |           |                   |             | DOC.doc,WORD DOCUMENT.docx |
| Upload |           |                   |             | DOC.doc,WORD DOCUMENT.docx |

Step 5: Upload of the Products Mock-ups

**Tracking No:** TRC-WEB21/VV-NA/0049 **Application Status:** New

Product Label Requirement

| Label Type     | File name            | Initial file name                 | Uploaded on         | Action |
|----------------|----------------------|-----------------------------------|---------------------|--------|
| Product Images | svdN:1639040000.jpeg | 0005720_coming-soon-page_550.jpeg | 2021-12-09 08:53:20 | Upload |
| Product Images | DWA:51639089352.jpeg | 0005720_coming-soon-page_350.jpeg | 2021-12-09 08:42:32 | Upload |

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

**Product Registration** New Drugs Product Applications ::

Tracking No: **TRC-WEB21/VV-NA/0049** Application Status: **New**

Progress: Applicant Information/Market Authorisation Holder | Product Application Details | Product Information | Dossier Documents Submission | Product Mockups | Submission

**Declaration**

**Track Option Process** Selection of the Fast Track and Normal track option

Select Fast Track

**Submission Comments(Optional)**

Enter Comments(optional)

Agree to the Declaration

[Previous Step](#)
[Proforma Invoice \(Generation\) & Payment Details](#)
[Preview Products Details Application](#)
[Submit Product Application](#)

Provision to generate Proforma Invoice and Proceed with Payment Upload of the Online Payment options

### Generation of the Proforma Invoice

**Invoice Generation**

| Invoice description | Tracking no | Date of invoicing   | Element costs                     | Total invoice amount | Currency |
|---------------------|-------------|---------------------|-----------------------------------|----------------------|----------|
| Quotation           |             | 2022-01-03 16:51:04 | FEES FOR MARKETING AUTHORISATI... | 2000                 | USD      |

[Generate Invoice](#)
[Upload Payments Details\(Payment Remittance Bank Slip\)](#)
[Proceed with Payment \(Online Payment\)](#)

### Submission: Submission of MA application for Processing

Do you want to submit the application with tracking no TRC-WEB21/VV-NA/0049 for processing?

[Yes](#) [no](#)

## 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

**ZAMRA Portal** Product Application Selection Process Home /

Product Category/Type ↑ Application Type ↓

| Actions   | Brand name               | Common name       | Classification name     | Marketing Authorisation No | Reference no | Expiry date         | Registrant | Local Agent |
|---|--------------------------|-------------------|-------------------------|----------------------------|--------------|---------------------|------------|-------------|
| Product Category/Type: Allied Substances              |                          |                   |                         |                            |              |                     |            |             |
| <input checked="" type="checkbox"/> Renewal of Market | Cefogen 750 injection    | Cefuroxime        | Human Medicinal Prod... | 113/062                    | 0098/98      | 2015-08-05 00:00:00 | TEST       | TEST        |
| <input checked="" type="checkbox"/> Renewal of Market | Encardil 20 tablets      | Enalapril Maleate | Human Medicinal Prod... | 106/009                    |              | 2015-08-05 00:00:00 | TEST       | TEST        |
| Product Category/Type: Medicines                      |                          |                   |                         |                            |              |                     |            |             |
| <input checked="" type="checkbox"/> Renewal of Market | pyrantel pamoate susp... | Pyrantel Pamoate  | Human Medicinal Prod... | 106/005                    |              | 2015-08-05 00:00:00 | TEST       | TEST        |

Step 2: Preview the registered product information

**ZAMRA Portal** 9126 - Aurobindo Pharma Limited - India

**Product Registration** Renew Drugs Product Applications

Tracking No: ZMR-WEB21/class\_code-NA/0001 Application Status: New

Product Renewal Details Dossier Documents Submission Submission

|  |  |   |
|--|--|---|
| <b>Brand Name/Trade Name</b><br>Cefogen 750 injection  | <b>Classification</b><br>Human Medicinal Product               | <b>Product Sub-Category</b><br>Product Sub-Category                         |
| <b>Generic Name(Optional)</b><br>Select Common name <span style="float: right;">+ Add New Common Name</span> | <b>ATC Code(Optional)</b><br>Select ATC Code                   | <b>ATC Description(Optional)</b>  |
| <b>Product Strength</b><br>750mg   | <b>Proposed Distribution Category</b><br>Distribution Category | <b>Dosage Forms</b><br>Dosage Form  |
| <b>Other Distribution Category(Remarks)</b><br>Other Distribution Category(Remarks)                          | <b>Storage Conditions</b><br>Storage Condition                 | <b>Proposed Shelf Life After Opening(Months)</b><br>shelf_lifeafter_opening |
| <b>Route Of Administration</b><br>Route Of Administration  | <b>Proposed Shelf Life(Months)</b><br>0                        |   |
| <b>Product Origin</b><br>Product Origin  | <b>Stability Studies Data</b><br>Stability Studies Data        |   |
| <b>Product Physical Description(Description of Finished Product Specification)</b><br>Vial                   |  |   |
| <b>Contraindication</b>  |  |   |

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

**ZAMRA Portal** | Product Registration | Application Status: New

Tracking No: 0090/90/R1

Product Renewal Details | Dossier Documents Submission | Submission

«Previous Application Details» **Next »**

**Note:** Maximum File Size per upload is 250 MB. Multiple Documents can be uploaded under the specified group(s).

| Action  | File name | Initial file name 1 | Uploaded on | Allowed File Types |
|---------|-----------|---------------------|-------------|--------------------|
| No data |           |                     |             |                    |

«Previous Application Details» **Next »**

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

- Step 1 : Submission Stage

**ZAMRA Portal** | Product Registration | Application Status: New

Tracking No: 0090/90/R1

Product Renewal Details | Dossier Documents Submission | Submission

**Declaration**

Track Option Process: Select Fast Track

Submission Comments(Optional): Enter Comments(optional)

Agree to the Declaration

**Previous Step** | Proforma Invoice (Generation) & Payment Details | **Preview Products Details Application** | **Submit Product Application**

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

Tracking No: 0098/98/R1 Application Status: New

Product Renewal Details Document Submission Submission

### Invoice Generation

| Print   | Invoice description | Tracking no | Date of invoicing | Element costs | Total invoice amount | Currency |
|---------|---------------------|-------------|-------------------|---------------|----------------------|----------|
| No data |                     |             |                   |               |                      |          |

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

Product Registration Renew Drugs Product Application

Tracking No: 0098/98/R1 Application Status: New

Product Renewal Details Document Submission Submission

### Declaration

Track Option Process

Select Fast Track

Submission Comments(Optional)

Enter Comments(Optional)

Agree to the Declaration

Do you want to submit the application with tracking no ZMR-WEB21/class\_code-NA/0001 for processing?

## 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.

**Market Authorisation Application**

4 Application Due for Renewal Home / Dashboard / Market Authorisation Application

PENDING SUBMISSION REQUEST(S) 3 REQUEST FOR ADDITIONAL INFORMATION 0 SAMPLE SUBMISSION REQUEST(S) 0 APPROVED APPLICATION 0 INTENTS OF REJECTION(S) 0

View Pending Request Application View Queried Application View Sample Submissions Request Application View Approved Applications View Rejected Application

Help & Guidelines New Marketing Authorisation Renewal of Marketing Authorisation **Amendment of Marketing Authorisation** Withdrawal of Marketing Authorisation

Select Application Type Select Product Type/Category Click to initiate the Marketing Authorisation Select Status Clear Filter

| Actions                             | Other Actions | Tracking no          | Reference no           | Applicant name                  | Section   | Brand name            | Application type                  | Classification          |
|-------------------------------------|---------------|----------------------|------------------------|---------------------------------|-----------|-----------------------|-----------------------------------|-------------------------|
| Status: New                         |               |                      |                        |                                 |           |                       |                                   |                         |
| <a href="#">Edit/Preview</a>        | Action        | 0050/96/91           |                        | Aurobindo Pharma Limited+ In... | Medicines | Cefogen 750 injection | Renewal of Marketing Authorisa... | Human Medicinal Product |
| <a href="#">Edit/Preview</a>        | Action        | TRC-WEB21/VV-NA/0049 |                        | Aurobindo Pharma Limited+ In... | Medicines | Amo                   | New Marketing Authorisation       | Human Medicinal Product |
| <a href="#">Edit/Preview</a>        | Action        | TRC-WEB21/HM-NA/0047 |                        | Aurobindo Pharma Limited+ In... | Medicines | Amoxiclin             | New Marketing Authorisation       | Human Medicinal Product |
| Status: Screening Query Response    |               |                      |                        |                                 |           |                       |                                   |                         |
| <a href="#">View Application</a>    | Action        | TRC-WEB21/HM-NA/0048 | ZAMBA-WEB21/HM-NA/0019 | Aurobindo Pharma Limited+ In... | Medicines | Amoxiclin             | New Marketing Authorisation       | Human Medicinal Product |
| Status: Submitted-Pending Receiving |               |                      |                        |                                 |           |                       |                                   |                         |
| <a href="#">Preview</a>             | Action        | TRC-WEB21/HM-NA/0046 |                        | Aurobindo Pharma Limited+ In... | Medicines | Panadol Extra 20155   | New Marketing Authorisation       | Human Medicinal Product |
| <a href="#">Preview</a>             | Action        | TRC-WEB21/HM-NA/0045 |                        | Aurobindo Pharma Limited+ In... | Medicines | Panadol Extra         | New Marketing Authorisation       | Human Medicinal Product |
| <a href="#">Preview</a>             | Action        | TRC-WEB21/HM-NA/0044 |                        | Aurobindo Pharma Limited+ In... | Medicines | Panadol Extra 323     | New Marketing Authorisation       | Human Medicinal Product |

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

**Product Application Selection Process**

Home / Da

Product Category/Type Application Type

| Actions                                  | Brand name               | Common name       | Classification name     | Marketing Authorisation No | Reference no | Expiry date         | Registrant | Local Agent |
|--|--------------------------|-------------------|-------------------------|----------------------------|--------------|---------------------|------------|-------------|
| Product Category/Type: Allied Substances |                          |                   |                         |                            |              |                     |            |             |
| <a href="#">Amendment of</a>             | Encardil 20 tablets      | Enalapril Maleate | Human Medicinal Prod... | 106/009                    |              | 2015-08-05 00:00:00 | TEST       | TEST        |
| Product Category/Type: Medicines         |                          |                   |                         |                            |              |                     |            |             |
| <a href="#">Amendment of</a>             | pyrantel pamoate susp... | Pyrantel Pamoate  | Human Medicinal Prod... | 106/005                    |              | 2015-08-05 00:00:00 | TEST       | TEST        |
| <a href="#">Amendment of</a>             | Cefogen 750 injection    | Cefuroxime        | Human Medicinal Prod... | 113/062                    | 0098/98      | 2015-08-05 00:00:00 | TEST       | TEST        |

Provision to Initiate a Request for Amendment of MA

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

| Type of variation | Present details | Proposed variation | Variation background information | Action |
|-------------------|-----------------|--------------------|----------------------------------|--------|
|                   |                 | No data            |                                  |        |

Option 2: Provision to enter the amendment Requests

## Step 5: Enter the Amendment supporting Documents

Dashboard Home / Dashboard / Alteration Medical Device Applications

**Product Registration**

Tracking No: 000224H/R1/A1 Application Status: New

Product Application Details | **Amendments/Variation Request** | Documents Submission | Submission

«Previous Application Details Next Application Submission»

+ Note: Maximum File Size per upload is 250 MB. Multiple Documents can be uploaded under the specified groups) Document requirement ↑

| Action  | File name | Initial file name 1 | Uploaded on | Allowed File Types |
|---------|-----------|---------------------|-------------|--------------------|
| No data |           |                     |             |                    |

«Previous: Application Details Next Application Submission(S)»

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

### - Step 1 : Submission Stage



Retention Invoices & Payments | Premises Licensing Applications | GMP & Pharmaceutical Licenses | Import & Export Permits | Dangerous Drugs License(s) & Import Permit(s) | Local Supply of Dangerous Drugs | Clinical Trials Applications | Promotion & Advertisement

Product Renewal Details | **Dossier Documents Submission** | Submission

**Declaration**

**Track Option Process**  
Select Fast Track: -

**Submission Comments(Optional)**

Agree to the Declaration

Previous Step Proforma Invoice (Generation) & Payment Details Preview Products Details Application Submit Product Application



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

Tracking No: 0002/90/R1 Application Status: New authority for active

Product Removal Details Dossier Documents Submission Submission

### Invoice Generation

| Print   | Invoice description | Tracking no | Date of invoicing | Element costs | Total invoice amount | Currency |
|---------|---------------------|-------------|-------------------|---------------|----------------------|----------|
| No data |                     |             |                   |               |                      |          |

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

Product Removal Details Dossier Documents Submission Submission

Declaration

Track Option Process

Select Past Track

Submission Comments(Optional)

Enter Comments(Optional)

Agree to the Declaration

Previous Step

Do you want to submit the application with tracking no ZMR-WEB21/class\_code-NA/0001 for processing?

## 7 Premises Licensing Applications

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

The screenshot displays the ZAMRA Self Service Portal dashboard. On the left, there is a navigation menu with categories like 'Retention Invoices & Payments', 'Premises Licensing Applications', 'GMP & Pharmaceutical Licenses', 'Import & Export Permits', 'Dangerous Drugs License(s) & Import Permit(s)', and 'Local Supply of Dangerous Drugs'. The main area features several status indicators (0 View Approved Premises, 0 View Rejected Premises, 0 View Queried Premises, 0 View Premises Inspection) and a central navigation bar with buttons for 'New Premises Registration Application', 'Renewal Business Permits Application', 'Alteration Application', 'Withdrawal Application', and 'Premises Annual Returns Application'. Below this, there are filters for 'Select Application Type' and 'Select Status', along with a 'Clear Filter' button. A prominent red text overlay says 'Click here to start New Application' with an arrow pointing to the 'New Premises Registration Application' button. At the bottom, a table lists application details:

| Actions   | Actions | Tracking no             | Reference no | License type           | Premises name | Physical address |
|---|---------|-------------------------|--------------|------------------------|---------------|------------------|
| Application types: New Premises Registration Premises Application |         |                         |              |                        |               |                  |
| Status: New   |         |                         |              |                        |               |                  |
| <a href="#">Edit/Preview</a>                                      | Action  | TRC-2021/AM/PRE/REG/... |              | Health Shop            | K Pharm       | 34               |
| Status: Submitted-Pending Receiving                               |         |                         |              |                        |               |                  |
| <a href="#">Q/Preview</a>   | Action  | TRC-2021/AM/PRE/REG/... |              | Dispensing Certificate | Tes 12        | 12               |

### 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.

The screenshot shows the 'Process: New Premises Registration' workflow. At the top, there are navigation links for 'Home / Dashboard / Premises Application'. The main content area displays the application status as 'New' and the tracking number. Below this, a progress bar indicates the current step: 'Particulars of Premises Proprietor(S)/Directors(S) & Personnel Details'. This step is highlighted with a red box and an arrow pointing to it. Below the progress bar, there are input fields for various details:

| Trader Name                     | Email Address      | Country  |
|---------------------------------|--------------------|--|
| Aurobindo Pharma Limited+ India | Email Address      | India  |
| Region/City                     | District(Optional) | Postal Address                                 |
| Select...                       | Fort Pierce North  | Plot No. 2+ Maitrivihar Complex Ameerpet Hyder |
| Telephone No                    | Mobile No          |  |
| Telephone No                    | 78                 |  |
| Physical Address                |                    |  |
| Physical Address                |                    |  |

A red text overlay at the bottom right says 'Different Sections to be filled in order to complete the application' with an arrow pointing to the 'Particulars of Premises Proprietor(S)/Directors(S) & Personnel Details' step.

## 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.

**Renewal Business Permits Premises Application Selection Process** Home / Dashboard / Premises Application

Premises Category/Type ↑

| Actions | Name | Premise reg no | Permit no | Physical address | Postal address | Region name | Registration Status | Validity Status |
|---------|------|----------------|-----------|------------------|----------------|-------------|---------------------|-----------------|
| No data |      |                |           |                  |                |             |                     |                 |

**All Business Permit Applications that need to be renewed will appear here**

## 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.

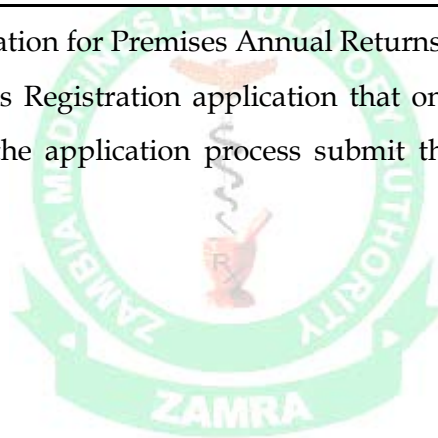
The screenshot shows the ZAMRA Self Service Portal interface. The left sidebar contains a navigation menu with 'Premises Licensing' expanded to show 'Applications'. Under 'Applications', 'Withdrawal Application' is highlighted with a red circle and a red arrow. A red text annotation 'Navigate to withdrawal application page from here' points to the arrow. The main content area shows a dashboard with tabs for 'New Premises Registration Application', 'Renewal Business Permits Application', 'Alteration Application', and 'Premises Annual Returns Application'. Below the tabs are filters for 'Select Application Type' and 'Select Status', a 'Clear Filter' button, and a search bar. A table displays application data with columns for 'Actions', 'Tracking no', 'Reference no', 'License type', 'Premises name', and 'Physical address'. The table is filtered by 'Application type: New Premises Registration Premises Application' and shows two rows of data.

| Actions  | Actions | Tracking no             | Reference no | License type           | Premises name | Physical address |
|--|---------|-------------------------|--------------|------------------------|---------------|------------------|
| Application type: New Premises Registration Premises Application |         |                         |              |                        |               |                  |
| Status: New  |         |                         |              |                        |               |                  |
| <a href="#">Edit/Preview</a>                                     | Action  | TRC-2021/AM/PRE/REG/... |              | Health Shop            | K Pham        | 34               |
| Status: Submitted-Pending Receiving                              |         |                         |              |                        |               |                  |
| <a href="#">Preview</a>  | Action  | TRC-2021/AM/PRE/REG/... |              | Dispensing Certificate | Tes 12        | 12               |

## 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.

**GMP Inspection (Foreign-Based Facility)** Home / Dashboard / GMP Inspection (Foreign-Based Facility)

0 Application Due for Renewal

| APPROVED INSPECTIONS              | REJECTED APPLICATION                      | QUERIED APPLICATION                      | PENDING SUBMISSION(S)                    |
|-----------------------------------|---|--|--|
| 0                                 | 0   | 0  | 1  |
| <a href="#">View Approved GMP</a> | <a href="#">View Rejected Application</a> | <a href="#">View Queried Inspections</a> | <a href="#">View Pending Submissions</a> |

[Help & Guidelines](#)
[New Gmp Inspection](#)
[Renewal Gmp Inspection](#)
[Withdrawal Application Request](#)
[Variation Request](#)

Select Application Type:  Select Status:  [Clear Filter](#)

| Actions  | Actions | Tracking no                              | Reference no | License Type                                  |
|--|---------|--|--------------|---|
| Application type: New Gmp Inspection Application |         |  |              |   |
| Status: New                                      |         |  |              |   |
| <a href="#">Edit/Preview</a>                     | Action  | TRC-WEB-21/GMP/NA/O/0018                 |              | Good Manufacturing Practices (Foreign-Base... |
| Status: Submitted-Pending Receiving              |         |  |              |   |
| <a href="#">Preview</a>                          | Action  | TRC-WEB-21/GMP/assessment_types_code/... |              | Good Manufacturing Practices (Foreign-Base... |

ZAMRA

### 8.1 GMP Inspection (Foreign-Based Facility)

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

**GMP Inspection (Foreign-Based Facility)** Home / Dashboard / GMP Inspection (Foreign-Based Facility)

0 Application Due for Renewal

| APPROVED INSPECTIONS              | REJECTED APPLICATION                      | QUERIED APPLICATION                      | PENDING SUBMISSION(S)                    |
|-----------------------------------|---|--|--|
| 0                                 | 0   | 0  | 1  |
| <a href="#">View Approved GMP</a> | <a href="#">View Rejected Application</a> | <a href="#">View Queried Inspections</a> | <a href="#">View Pending Submissions</a> |

[Help & Guidelines](#)
[New Gmp Inspection](#)
[Renewal Gmp Inspection](#)
[Withdrawal Application Request](#)
[Variation Request](#)

## 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.

License Type: New Pharmaceutical Licence & Inspection (Foreign Facility) Home / Dashboard

Tracking No: Application Status: New

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

Trader Name: Aurobindo Pharma Limited+ India Email Address: Email Address Country: India

Region/City: Select... District(Optional): Fort Pierce North Postal Address: Plot No. 2+ Mairivihar Complex Ameerpet Hyder

Telephone No: Telephone No Mobile No: 78

Physical Address: Physical Address

Different Sections to be filled to complete GMP Inspection Application

## 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.

**Renewal Gmp Inspection New Pharmaceutical Licence & Inspection (Foreign Facility) GMP/Quality Audit Application Selection Process**

Home / Dashboard / GMP/Quality Audit Application

Category/Type ↑

| Actions | Manufacture site name | Premise reg no | Permit no | Country | Region | Physical address | Postal address | Region | Registration Status | Validity Status |
|---------|-----------------------|----------------|-----------|---------|--------|------------------|----------------|--------|---------------------|-----------------|
| No data |                       |                |           |         |        |                  |                |        |                     |                 |

## 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.

The screenshot shows the 'Pharmaceutical Licence & Inspection (Domestic Facility)' dashboard. At the top right, a notification indicates '0 Application Due for Renewal'. The dashboard is divided into four colored boxes representing application statuses: APPROVED APPLICATIONS (0), REJECTED APPLICATION (0), QUERIED APPLICATION (0), and PENDING SUBMISSIONS (1). Below these boxes, there are four buttons: 'New Gmp Inspection', 'Renewal Gmp Inspection', 'Withdrawal Application Request', and 'Variation Request'. A table below these buttons is currently empty, showing 'No data'.

## 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.

License Type: New Pharmaceutical Licence & Inspection (Domestic Facility) Home / Dashboard

Tracking No: Application Status: New

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

Trader Name: Aurobindo Pharma Limited + India Email Address: Email Address Country: India

Region/City: Select... District(Optional): Fort Pierce North Postal Address: Plot No. 2+ Matrivihar Complex Ameerpet Hyder

Telephone No: Telephone No Mobile No: 78

Physical Address: Physical Address

Several sections to be filled in order to complete the application process

## 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.

Renewal Gmp Inspection New Pharmaceutical Licence & Inspection (Domestic Facility) GMP/Quality Audit Application Selection Process Home / Dashboard / GMP/Quality Audit Application

Category/Type ↑ Search...

| Actions | Manufactu... site name | Premise reg no | Permit no | Country | Region | Physical address | Postal address | Region | Registration Status | Validity Status |
|---------|------------------------|----------------|-----------|---------|--------|------------------|----------------|--------|---------------------|-----------------|
| No data |                        |                |           |         |        |                  |                |        |                     |                 |

## 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.

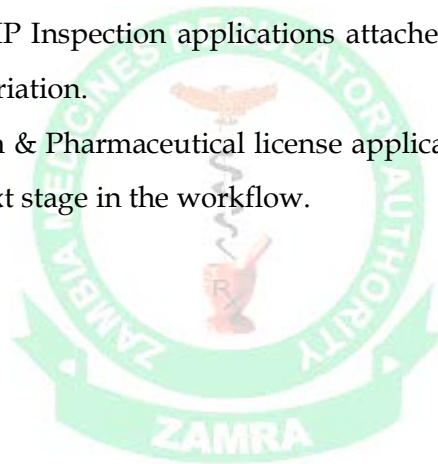
The screenshot displays the ZAMRA Self Service Portal dashboard. On the left is a navigation menu with categories like 'Market Authorisation Process', 'Retention Invoices & Payments', 'Premises Licensing', 'Applications', and 'Licenses'. The main area features four status cards: 'APPROVED APPLICATIONS' (0), 'REJECTED APPLICATION' (0), 'QUERIED APPLICATION' (0), and 'PENDING SUBMISSIONS' (1). Below these are navigation buttons: 'Help & Guidelines', 'New Gmp Inspection', 'Renewal Gmp Inspection', 'Withdrawal Application Request' (highlighted with a red box and arrow), and 'Variation Request'. A table below shows columns for 'Actions', 'Tracking no', 'Reference no', 'Gmp type', 'Inspection Type', 'Manufacturing site name', and 'Physical address'. A red text overlay reads: 'Click here to navigate to Withdrawal Application Request page'.

## 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.

The screenshot displays the 'Applications' dashboard in the ZAMRA Self Service Portal. The dashboard is divided into four colored boxes representing application statuses: APPROVED APPLICATIONS (0), REJECTED APPLICATIONS (0), QUERIED APPLICATIONS (0), and PENDING SUBMISSION (1). Below these boxes is a 'Filter Applications' section with a '+ New Import/Export Application' button circled in red and labeled 'Click to start New Application'. The sidebar menu on the left shows 'Import & Export Permits' highlighted.

### 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).

**Import Export Application Process** Dashboard / Import Export Application Selection

**Import/Export Permits**

Import Permit Application  
 Export Permit Application

**Import/Export Permit Type**

Permits Active Pharmaceutical Ingredients (API), Bulk finished products and intermediates (1% of FOB Value)  
 Import Permits for Personal Use  
 Permits for Donations (1% FOB Charge)  
 Permits for Non-Registered commercial consignments (5 % of FOB invoice value)  
 Permits for Registered commercial consignments (1.5 % of FOB invoice value)

[View Registered/Authorised Products](#) [Start Permit Application Process](#)

**Import Export Registration Guidelines/Definations**

Application type ↑ **After Selecting permit type click here to start application process**

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.

**Import/Export Permits**

Import Permit Application  
 Export Permit Application

**Import/Export Permit Type**

Export Permits for Registered & Non-Registered Products

[View Registered/Authorised Products](#) [Start Permit Application Process](#)

**Import Export Registration Guidelines/Definations**

Application type ↑

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.

**Process: Permits for Donations (1% FOB Charge)** Home / Dashboard / Import/Export Application

Tracking No: Application Status: New

Permit Applicant Information | Application Details | Permit Product Information | Documents | Completion & Submission

**Trader Name:** Aurobindo Pharma Limited+ India

**Email Address:** Email Address

**Country:** India

**Region/City:** Select...

**District(Optional):** Select District

**Postal Address:** Plot No. 2+ Maitrivihar Complex Ameerpet Hyder

**Telephone No:** Telephone No

**Mobile No:** 78

**Physical Address:** Physical Address

Several Sections to be filled in order to complete  
Import/Export Permit Application

## 9.2 Steps for the Import/Export Permit Application

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

**ZAMRA Portal** 9126 - Aurobindo Pharma Limited+ India

**Process: Permits Active Pharmaceutical Ingredients (API), Bulk finished products and intermediates (1% of FOB Value)** Home / Dashboard / Import/Export Application

Tracking No: TRC-WEB21/IPER/RW/0010 Application Status: New

Permit Applicant Information | Application Details | Permit Product Information | Documents | Completion & Submission

**Trader Name:** Aurobindo Pharma Limited+ India

**Email Address:** Email Address

**Country:** India

**Region/City:** Select...

**District(Optional):** Select District

**Postal Address:** Plot No. 2+ Maitrivihar Complex Ameerpet Hyderabad India

**Telephone No:** Telephone No

**Mobile No:** 78

**Physical Address:** Physical Address

Dashboard Application Details

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

**ZAMRA Portal** 9126 - Aurobindo Pharma Limited - India

Process: Permits Active Pharmaceutical Ingredients (API), Bulk finished products and Intermediates (1% of FOB Value) Home / Dashboard / Import/Export Application

Tracking No: TRC-WEB21/IPER/RW/0010 Application Status: New

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

**Application Type**  
 Import Permit Application

**Import/Export Permit Type**  
 Permits Active Pharmaceutical Ingredients (API), Bulk finished products and int ...

**Permit Reason**  
 Other Reasons

**Other Reasons for Permit Application**  
 1

**Port of Entry/Exit**  
 Simon Mwansa Kapwepwe International Airport

**Mode of Transport**  
 Rail

**Proforma Invoice No**  
 12

**Proforma Invoice Date**  
 12/14/2021

**Proforma Invoice Currency**  
 USD-United States dollar

**Consignee Options**  
 Self

**Consignee**  
 Consignee

**Consignor Details**  
 Consignor Details

**Registered Premises(Registered Outlet(s)) (Optional)**  
 Premises Name

«Previous Applicant Details Save Application Next Permit Product(s)»

## 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

**ZAMRA Portal** 9126 - Aurobindo Pharma Limited - India

Process: Permits Active Pharmaceutical Ingredients (API), Bulk finished products and Intermediates (1% of FOB Value) Home / Dashboard / Import/Export Application

Tracking No: TRC-WEB21/IPER/RW/0010 Application Status: New

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

«Previous Application Details Next Documents Upload»

+ Add Permit Products

| Action | Brand Name/Product Name | Product type      | Product subcategory         | Quantity | Packaging units | Currency name | Unit price | FOB Value |
|--------|-------------------------|-------------------|-----------------------------|----------|-----------------|---------------|------------|-----------|
| Action | Sanbeta Eye drops       | Medicines         | New Medicines(Human Medi... | 12       | Suppository     | USD           | 12         | 144       |
| Action |                         | Allied Substances | Nutritional Supplements     | 12       | Suppository     | USD           | 12         | 144       |
|        |                         |                   |                             |          |                 |               |            | Sum: 288  |

«Previous Application Details Next Documents Upload»

## 4) Step 4: Select Existing or registered products

Process: Permits Active Pharmaceutical Ingredients (API), Bulk finished products and intermediates (1% of FOB Value) Home / Dashboard / Import/Export A

Tracking No: TAC-WEB21/PER/RW/0010 Application Status: New

### Permits Products

+ Add New Products (Search before adding new)

| Action         | Brand Name/Device Name                | Market Authorisation No. | Common Name/INN Name/API          | Product Strength | Product Registration Status | Registration Validity Status | Product Retention Fees Status |
|----------------|---------------------------------------|--------------------------|-----------------------------------|------------------|-----------------------------|------------------------------|-------------------------------|
| Select Product | Sambeta Eye drops                     | ZAMRA21/0002             | Betamethasone                     | 1mg/ml           | Registered/Compliance       | Registered/Compliance        | ..                            |
| Select Product | Sanvic ophthalmic solutions eye dr... |                          | Hydroxypropylmethylcellulose      | 2%w/v            |                             |                              | ..                            |
| Select Product | Timide Plus Eye drops                 |                          | Benzalkonium Hcl - Phenylephri... |                  |                             |                              | ..                            |
| Select Product | Zmos capsules                         |                          | Amoxicillin Trihydrate            | 250mg            |                             |                              | ..                            |
| Select Product | Renor 400 tablets                     |                          | Norfloxacin                       | 400mg            |                             |                              | ..                            |
| Select Product | Recipro 250 tablets                   |                          | Ciprofloxacin                     | 250 mg           |                             |                              | ..                            |
| Select Product | Recipro 250 tablets                   |                          | Ciprofloxacin                     | 250 mg           |                             |                              | ..                            |

Page #1, Total: 4 (100 items) 1 2 3 4

Previous Application Details Next Documents Upload

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.

### Permits Products

#### Permit Products Details

Brand Name/Devices Name:

Product Type:

Product Category:

Product Unit Pack Size:  Units:

Product Physical Description:

Item Quantity:  Packaging Unit:  Unit Price:  Currency:

Save Products Details

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

The screenshot shows the ZAMRA Portal interface for a permit application. The process is titled "Process: Permits Active Pharmaceutical Ingredients (API), Bulk finished products and intermediates (1% of FOB Value)". The application status is "New". The tracking number is TRC-WEB21/IPER/RW/0010. A progress bar shows the current step is "Permit Product Information".

Below the progress bar, there are buttons for "Permit Products Details" and "Next Application Submission". A note states: "Note: Maximum File Size per upload is 250 MB. Multiple Documents can be uploaded under the specified group(s)".

| Action   | File name   | Initial file name 1 | Uploaded on         | Allowed File Types                            |
|--|---|---------------------|---------------------|---|
| Document requirement: Copy of practitioners licence(if applicable)     | Copy of practitioners licence(if applicable)010.jpg |                     | 2021-12-31 04:40:12 | DOC.doc, WORD DOCUMENT.docx, pdf.pdf          |
| Document requirement: Extra Supporting Documents                       |   |                     |                     | DOC.doc, WORD DOCUMENT.docx, pdf.pdf, RAR.rar |
| Document requirement: Operating License                                |   |                     |                     | DOC.doc, WORD DOCUMENT.docx, pdf.pdf          |
| Document requirement: Permits under other relevant laws(if applicable) |   |                     |                     | DOC.doc, WORD DOCUMENT.docx, pdf.pdf          |
| Document requirement: Proforma Invoice                                 |   |                     |                     | DOC.doc, WORD DOCUMENT.docx, pdf.pdf          |

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

The screenshot shows the ZAMRA Portal interface for the submission stage of a permit application. The process is titled "Process: Permits Active Pharmaceutical Ingredients (API), Bulk finished products and intermediates (1% of FOB Value)". The application status is "New". The tracking number is TRC-WEB21/IPER/RW/0010. The progress bar shows the current step is "Documents".

Below the progress bar, there is a "Submission Comments(Optional)" section with a text input field. A "Declaration" section contains the text "I confirm that the Import Details have been filled Correctly" and a checkbox labeled "Agree to the Declaration".

At the bottom, there are three buttons: "Previous Step", "Proforma Invoice (Generation) & Payment Details" (highlighted with a red box and an arrow), and "Submit Permit Application".



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

Tracking No: TRC-WEB21/IPER/RW/0010 Application Status: New

| Print                                  | Invoice description | Tracking no            | Date of invoicing   | Element costs                          | Total invoice amount | Currency |
|--|---------------------|------------------------|---------------------|--|----------------------|----------|
| <a href="#">Print Proforma Invoice</a> | Proforma Invoice    | TRC-WEB21/IPER/RW/0010 | 2021-12-31 05:21:09 | FEEES FOR PERMITS-Preclearance Fees... | 50.1696              | ZMW      |
| <a href="#">Print Proforma Invoice</a> | Proforma Invoice    | TRC-WEB21/IPER/RW/0010 | 2021-12-31 05:21:09 | FEEES FOR PERMITS-Application for P... | 100                  | ZMW      |

[Generate Invoice](#)
[Upload Payments Details/Payment Remittance Bank Slip](#)
[Proceed with Payment \(Online Payment\)](#)

## 9) Step 9: Submit Permit Application for Processing

Process: Permits Active Pharmaceutical Ingredients (API), Bulk finished products and intermediates (1% of FOB Value) Home / Dashboard / Import/Export

Tracking No: TRC-WEB21/IPER/RW/0010 Application Status: New

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

Submission Comments(Optional)  
Enter Comments(optional)

Declaration  
I confirm that the Import Details have been filled Correctly

Agree to the Declaration

Do you want to submit the application with tracking no TRC-WEB21/IPER/RW/0010 for processing?

[Yes](#) [no](#)

[Previous Step](#)
[Proforma Invoice Generation & Payment Details](#)
[Submit Permit Application](#)



## 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.

**Process: Control Drugs License Application(s)**

Tracking No: Application Status:

Permit Applicant Information Application Details License Controlled Drugs Particulars Information Documents Completion & Submission

**Trader Name**  
Aurobindo Pharma Limited+ India

**Email Address**  
Email Address

**Country**  
India

**Region/City**  
Select...

**District(Optional)**  
Select District

**Postal Address**  
Plot No. 2+ Maitrivihar Complex Ameerpet Hyderabad India

**Telephone No**  
Telephone No

**Mobile No**  
78

**Physical Address**  
Physical Address

[Dashboard](#) [Application Details](#)

## 10.2 Steps for the Import/Export Permit Application

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

**ZAMRA Portal** 9126 - Aurobindo Pharma Limited+ India

**Process: Permits Active Pharmaceutical Ingredients (API), Bulk finished products and Intermediates (1% of FOB Value)** Home / Dashboard / Import/Export Application

Tracking No: TRC-WEB21/IPER/RW/0010 Application Status: New

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

**Trader Name**  
Aurobindo Pharma Limited+ India

**Email Address**  
Email Address

**Country**  
India

**Region/City**  
Select...

**District(Optional)**  
Select District

**Postal Address**  
Plot No. 2+ Maitrivihar Complex Ameerpet Hyderabad India

**Telephone No**  
Telephone No

**Mobile No**  
78

**Physical Address**  
Physical Address

[Dashboard](#) [Application Details](#)

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

**Process: Control Drugs License Application(s)**

Tracking No: Application Status:

Permit Applicant Information Application Details License Controlled Drugs Particulars Information Documents Completion & Submission

Application Type: Control Drugs License Application(s) Permit Reason: Select permit Reason Port of Entry/Exit: Select Port

Mode of Transport: Select Mode of Transport Proforma Invoice No: Invoice No Proforma Invoice Date: Invoice Date

Approximate Date of Arrival: Approximate Date of Arrival Consignor Details: Consignor Search

«Previous Applicant Details» Save Application Next Controlled Drugs Particulars »

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

This provides for

**Process: Control Drugs License Application(s)** Saved Successfully

Tracking No: ZMR-WEB22/CD-LIC/0007 Application Status:

Permit Applicant Information Application Details License Controlled Drugs Particulars Information Documents Completion & Submission

«Previous Application Details» Next Documents Upload »

+ Add Control Drugs Particulars

| Action | Drug Name | Controlled Drugs Type | Controlled Drugs Substance | Ether/Salt | Drugs Contents | Dosage form            | Product strength | Strength asgrams | Pack Unit Details | Quantity | Base (g) |
|--------|-----------|-----------------------|----------------------------|------------|----------------|------------------------|------------------|------------------|-------------------|----------|----------|
| Action | 12        | Precursor Drugs       | pethidine Hydrochloride    | HCL        | 87             | Pressurized inhalation | 12               | 144              | 12 ml             | 12       | 1503     |

«Previous Application Details» Next Documents Upload »

4) Step 4: Enter the Controlled Drugs Substance

Note: There is provision to select already issued MA or registered drugs by the authority based on the MA number.

Process: Control Drugs License Application(s)

### Permit Products Details

**Controlled Drug Type**  
 Precursor Drugs

**Market Authorisation No**  
 Market Authorisation...

**Controlled Drugs Substance**  
 Select Controlled Drugs Substance

**Drug Contents(%)**  
 Drug Contents(%)

**Purpose of Drug Use**  
 Purpose of Drug Use

**Packaging Unit(in ml)**  
 Pack Unit

**Packaging Type**  
 Select Packaging Type

**Quantity**  
 Item Quantity

**Is a Registered Drug**  
 Yes

**Drug Name**  
 Drug Name

**Ether/Salt**  
 Select Ether /Salt

**Dosage Form**  
 Select Product Dosage Form

**Product Strength**  
 Product Strength

**Units**  
 Select Units

**Strength(g)**  
 Strength(g)

**Base(g)**  
 Base(g)

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

Process: Control Drugs License Application(s)

Tracking No: ZMR-1WEB22/CD-LIC/0001      Application Status:

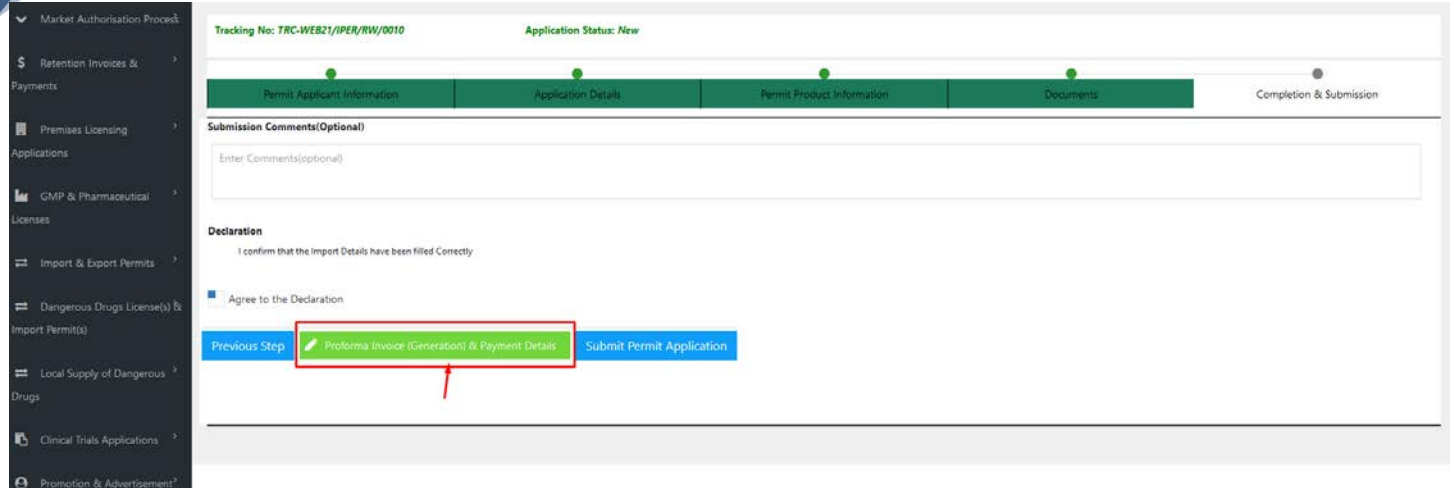
Permit Applicant Information   
  Application Details   
  License Controlled Drugs Particulars Information   
  Documents   
  Completion & Submission

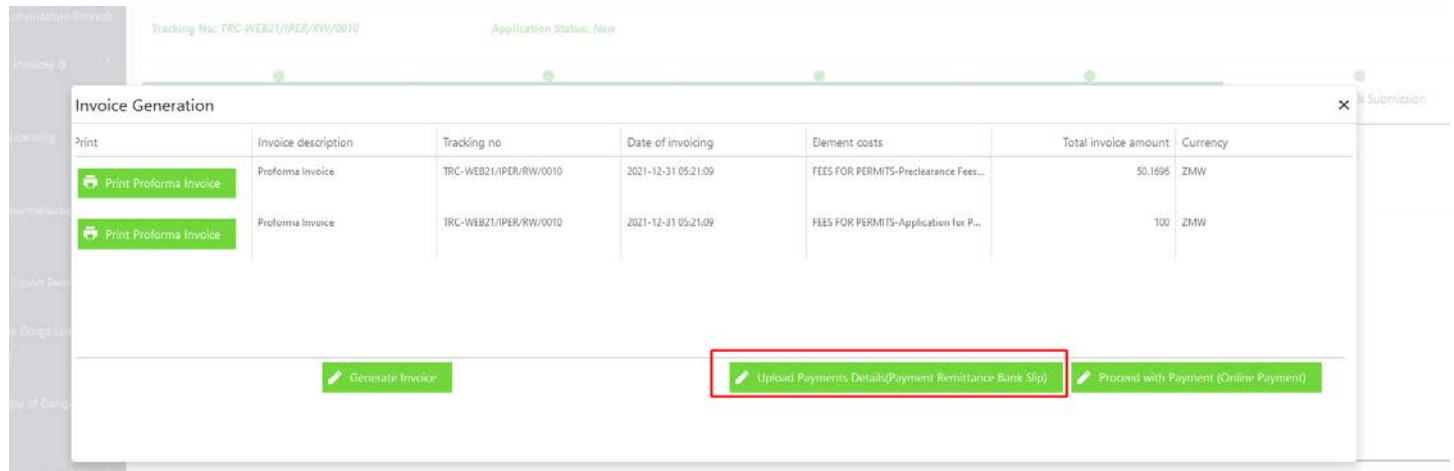
**Note:** Maximum File Size per upload is 250 MB. Multiple Documents can be uploaded under the specified group(s)    Document requirement: ↑

| Action  | File name | Initial file name ↑ | Uploaded on | Allowed File Types |
|---------|-----------|---------------------|-------------|--------------------|
| No data |           |                     |             |                    |

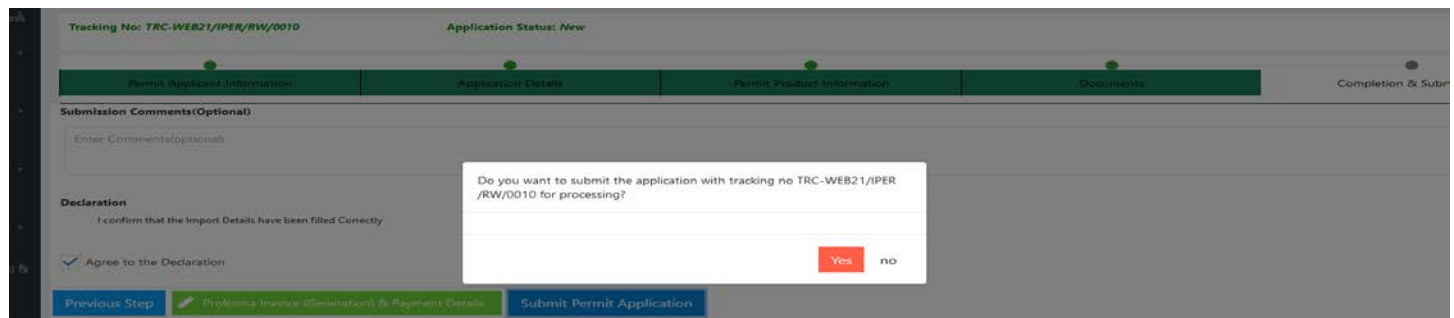
7) Step 6: Provision to generate and submit the permit application for processing



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

**ZAMRA Portal** 9126 - ZMR

**Clinical Trial Applications** Home / Dashboard / Clinical Trial Application

APPROVED APPLICATIONS 0 REJECTED APPLICATION 0 QUERIED APPLICATION 0 GOOD CLINICAL PRACTISE INSPECTIONS 0

View Approved Applications View Rejected Applications View Queried Applications View GCP Inspection Requests

Help & Guidelines New Clinical Trial Application Clinical Trial Amendments Application 6 Months Progress Report Application SAE Reports Application

New Clinical Trial Select Status Clear Filter

| Actions   | Actions | Tracking no          | Reference no | Study Title      | Protocol no | Clinical trial sponsor    | Principal investigator    | Date of protocol    | Date added          |
|---|---------|----------------------|--------------|------------------|-------------|---------------------------|---------------------------|---------------------|---------------------|
| Application type: New Clinical Trial Clinical Trial Application |         |                      |              |                  |             |                           |                           |                     |                     |
| Status name: Approved   |         |                      |              |                  |             |                           |                           |                     |                     |
| Preview Certificate   | Action  | ZMR-WEB0021/CTR/0011 |              | Malanian Vaccine | 15          | ClinWin Research Services | ClinWin Research Services | 2021-08-02 00:00:00 | 2021-08-15 10:26:23 |
| Status name: New  |         |                      |              |                  |             |                           |                           |                     |                     |
| Edit/Preview  | Action  | ZMR-WEB0021/CTR/0001 |              | Malanian Vaccine | 15          | ClinWin Research Services | ClinWin Research Services | 2021-08-02 00:00:00 | 2021-08-15 10:30:20 |

## 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.

**ZAMRA Portal** Home / Dashboard / Clinical Trial Application

**Clinical Trial Applications**

APPROVED APPLICATIONS: 0  
REJECTED APPLICATION: 0  
QUERIED APPLICATION: 0  
GOOD CLINICAL PRACTISE INSPECTIONS: 0

Click to Initiate Application for Clinical Trials

Help & Guidelines | New Clinical Trial Application | Clinical Trial Amendments Application | 6 Months Progress Report Application | SAE Reports Application

Select Application Type: [Dropdown] | Select Status: [Dropdown] | Clear Filter

| Actions   | Actions | Tracking no.         | Reference no. | Study Title    | Protocol no. | Clinical trial sponsor    | Principal investigator    | Date of protocol    | Date added          |
|---|---------|----------------------|---------------|----------------|--------------|---------------------------|---------------------------|---------------------|---------------------|
| Application type: New Clinical Trial Clinical Trial Application |         |                      |               |                |              |                           |                           |                     |                     |
| Status name: Approved   |         |                      |               |                |              |                           |                           |                     |                     |
| Preview Certificate   | Action  | ZMR-WEB0021/CTR/0011 |               | Malian Vaccine | 15           | ClinWin Research Services | ClinWin Research Services | 2021-08-02 00:00:00 | 2021-08-15 10:36:23 |
| Status name: New  |         |                      |               |                |              |                           |                           |                     |                     |
| Preview/Preview   | Action  | ZMR-WEB0021/CTR/0001 |               | Malian Vaccine | 13           | ClinWin Research Services | ClinWin Research Services | 2021-08-02 00:00:00 | 2021-08-15 10:30:20 |

Step 2: Preview the application applicant details

**New Clinical Trial Application** Home / Dashboard / New Clinical Trial Applications

Tracking No: ZMR-WEB0021/CTR/0001 | Application Status: New

Progress: Name and address of Applicant | Particulars of the Clinical Trial | Details of Local Trial Site(S) | Details of Investigator(S)/Co-/Sub Investigators & Monitors | Particulars of Investigational/Comparator Medical Product(S) | Participants | Regulatory Status | Supporting Documentation And Conditions | Completion & Submission

**Trader Name**  
Trader Name

**Region/City**  
Select...

**Telephone No**  
Telephone No

**Physical Address**  
Physical Address

**Email Address**  
Email Address

**District (Optional)**  
Select District

**Mobile No**  
Mobile No

**Country**  
Select Country

**Postal Address**  
Postal Address

Dashboard | Application Details



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

**ZAMRA Portal** Home / Dashboard / New Clinical Trial Applications

Tracking No: ZMR-WE0021/CTR/0001 Application Status: New

**Name and address of Applicant** | **Particulars of the Clinical Trial** | **Details of Local Trial Site(S)** | **Details of Investigator(S)/Co-Sub Investigators & Monitors** | **Particulars of Investigational/Comparator Medicinal Product(S)** | **Participants** | **Regulatory Status** | **Supporting Documentation And Conditions** | **Completion & Submission**

**Study Title**  
Malarian Vaccine  
Title - short version: 12

**Clinical Study Phase**: Phase IV  
**Protocol No**: 15  
**Date of Protocol**: 8/2/2021

**Version No**: 150  
**Purpose of the Trial**: Purpose of the Trial

**Brief summary describing the background and objectives of trial**  
Brief summary describing the background and objectives of trial

**Clinical Trial Identification Number**: 10  
**Trial Registry**: ClinicalTrials.gov Trial  
**Clinical Trial Registry Publication Url**: Publication Url  
**Study Design**: 10

**Number of sites in Zambia**: 12  
**Investigational Product Type**: Medicines  
**Proposed date of commencement of clinical trial**: 8/15/2021

**Estimated duration of trial** | **Duration Description** | **Is Clinical Trial conducted in Host country**

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

List of Entered Trial Sites

**ZAMRA Portal** Home / Dashboard / New Clinical Trial Applications

Tracking No: ZMR-WE0021/CTR/0001 Application Status: New

**Name and address of Applicant** | **Particulars of the Clinical Trial** | **Details of Local Trial Site(S)** | **Details of Investigator(S)/Co-Sub Investigators & Monitors** | **Particulars of Investigational/Comparator Medicinal Product(S)** | **Participants** | **Regulatory Status** | **Supporting Documentation And Conditions** | **Completion & Submission**

◀ Previous Clinical Trial Information ▶ Next Investigators Details ▶

+ Add Study Site Drag a column header here to group by that column

| Action                 | Site name                        | Approving Institution | Responsible ethics committee | Application reference no | Country    | Region      | Physical address                 | Postal address                   |
|------------------------|----------------------------------|-----------------------|------------------------------|--------------------------|------------|-------------|----------------------------------|----------------------------------|
| <a href="#">Delete</a> | Kenya Medical Research Instit... | 12                    | 12                           | 12                       | Bangladesh | Pest County | Kenya Medical Research Instit... | Kenya Medical Research Instit... |

◀ Previous Clinical Trial Information ▶ Next Investigators Details ▶

## Provision to add clinical trial Sites

### Clinical Trial Study Site Details ✕

●  
Details Of Local Trial Site(S)

---

**Study Site**

🔍

**Approving Institution**

**Responsible Ethics Committee**

**Application Ref: No**

**Date of Approval**

📅

💾 Save Clinical Study Site

## Provision to select A list of Clinical Trial Sites

### Study Sites ✕

+
Drag a column header her...
🔍 Search...

| Action                              | Name  | Country | Region       | District | Physical address                                   |
|-------------------------------------|---|---------|--------------|----------|--|
| <input checked="" type="checkbox"/> | University Teaching Hospital, Road                  | Zambia  | Lusaka       |          | University Teaching Hospital, Nationalist Road     |
| <input checked="" type="checkbox"/> | UTH – Adult Hospital, Nationalist Road              | Zambia  | Lusaka       |          | UTH – Adult Hospital, Nationalist Road             |
| <input checked="" type="checkbox"/> | University Teaching Hospital, Department of Ob...   | Zambia  | Lusaka       |          | University Teaching Hospital, Department of Ob...  |
| <input checked="" type="checkbox"/> | Choma, Kalomo                                       | Zambia  | Choma/Kalomo |          | Choma, Kalomo                                      |
| <input checked="" type="checkbox"/> | Centre for Infectious Disease Research Zambia ...   | Zambia  | Lusaka       |          | Centre for Infectious Disease Research Zambia P... |
| <input checked="" type="checkbox"/> | 1. CIDRZ Clinical Research Centre, Matero Level ... | Zambia  | Lusaka       |          | 1.CIDRZ Clinical Research Centre, Matero Level ... |
| <input checked="" type="checkbox"/> | 1. University Teaching Hospital 2. Kamwala Heal...  | Zambia  | Lusaka       |          | 1. University Teaching Hospital 2. Kamwala Heal... |
| <input checked="" type="checkbox"/> | CIDRZ Clinical Research Centre Matero Level 1 ...   | Zambia  | Lusaka       |          | CIDRZ Clinical Research Centre Matero Level 1 ...  |
| <input checked="" type="checkbox"/> | 1. Center for Family Health Research in Zambia ...  | Zambia  | Lusaka/Ndola |          | 1. Center for Family Health Research in Zambia ... |
| <input checked="" type="checkbox"/> | University Teaching Hospital (UTH)adult and Ch...   | Zambia  | Lusaka       |          | University Teaching Hospital (UTH)adult and Ch...  |

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

Provision to Preview the already submitted investigators details

**New Clinical Trial Application** Home / Dashboard / New Clinical Trial Applications

Tracking No: ZMR-WE80021/CTR/0001 Application Status: New

Progress Bar: Name and address of Applicant, Particulars of the Clinical Trial, Details of Local Trial Site(S), **Details of Investigator(S)/Co-/Sub Investigators & Monitors**, Particulars of Investigational/Comparator Medicinal Product(S), Participants, Regulatory Status, Supporting Documentation And Conditions, Completion & Submission

Buttons: <Previous Clinical trial Study Site, Next IMP Details>

**Clinical Trial Investigators Co-/Sub Investigators**

+ Investigators Details Drag a column header here to group by that column

| Action                 | Study site                        | Investigator category                 | Investigator              | Country    | Region      | District     | Physical address           | Postal address                    |
|------------------------|-----------------------------------|---------------------------------------|---------------------------|------------|-------------|--------------|----------------------------|-----------------------------------|
| <a href="#">Delete</a> | Kenya Medical Research Institu... | Site Principle Investigator (Site ... | ClinWin Research Services | Bangladesh | Constantine | Castle Pines | Landmark Plaza, 13th Floor | P O. Box 3289 Nairobi 00200 Ke... |

**Clinical Trial Monitors**

+ Clinical Trial Monitors Details Drag a column header here to group by that column

| Action                 | Monitors                  | Country    | Region      | District     | Physical address           | Postal address                    |
|------------------------|---------------------------|------------|-------------|--------------|----------------------------|-----------------------------------|
| <a href="#">Delete</a> | ClinWin Research Services | Bangladesh | Constantine | Castle Pines | Landmark Plaza, 13th Floor | P O. Box 3289 Nairobi 00200 Kenya |

## Provision to Add Investigator Details

**NEW CLINICAL TRIAL APPLICATION** Home / Dashboard / New Clin

Tracking No: ZMR-WE80021/CTR/0001 Application Status: New

**Clinical trial Investigator** [Close]

Investigator

such a list of Investigators in the database and provision to add new Investigator if the details are missing

Investigator Category

- Select...
- Site Principle Investigator (Site PI)
- International Principal Investigator
- Monitor
- Study Coordinator
- Co-Investigator

## 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)

The screenshot displays the 'New Clinical Trial Application' interface. The top navigation bar includes 'Home / Dashboard / New Clinical Trial Applications'. The main content area shows a progress bar with steps: 'Name and address of Applicant', 'Particulars of the Clinical Trial', 'Details of Local Trial Site(S)', 'Details of Investigator(S)/Co-Sub Investigator(s) & Monitor', 'Particulars of Investigational/Comparator Medicinal Product(S)', 'Participants', 'Regulatory Status', 'Supporting Documentation And Conditions', and 'Completion & Submission'. The 'Particulars of Investigational/Comparator Medicinal Product(S)' step is currently active. Below the progress bar, there are buttons for '<Previous Clinical Trial Investigators' and 'Next Application Participants>'. A table with columns for 'Action', 'Product category', 'Brand name', 'Generic name', 'Classification name', 'Registration no', 'Identification mark', 'Market location', and 'Market location' is visible. The first row contains the text 'Investigational immunogeni...' under 'Product category', '12' under 'Brand name', and '21' under 'Market location'. There are also 'Edit' and 'Delete' buttons for the first row.

Provision to enter details of the investigation/comparator product

The screenshot shows the 'Particulars of Investigational/Comparator Medicinal Product(S)' form. The form is divided into two main sections: 'Details of Investigational Medicinal Product(s)' and 'Composition of Investigational/Comparator Medicinal Product(s)'. The 'Details' section includes fields for 'Clinical Trial Product Category', 'Product Type Category', and 'Product Classification', each with a 'Select...' dropdown. Below these are 'Is Registered(Has Marketing Authorisation)' with a 'Select...' dropdown, 'Generic Name' with a 'Select...' dropdown and a '+ Add' button, and 'Finished Product Manufacturer' with a search field and 'Search Details' button. The 'Composition' section includes 'Brand Name(If its Registered Products Please search from Registered Products)' with a search field and 'Search' button, 'Identification Mark' with a search field, and 'Market Authorisation Number' with a search field. There are also fields for 'Investigation Product Source/Origin' with a 'Select...' dropdown, 'Product Description' with a text area, 'Estimated Quantity of Investigational Medicinal Product for which exemption will be required' with a text field, 'Has the Investigational Medicinal Product been previously authorised in a clinical trial conducted by the sponsor?' with a 'Select...' dropdown, and a final text field for 'If so provide details of the authorising institution(s), date(s) and approval number(s), trial title(s), clinical trial protocol number(s), principal investigator(s) and date(s) of the final report(s)'. The form has a close button (X) in the top right corner.

## Step 7: Participants

## Provision to enter information of the clinical trial participants

The screenshot displays the 'Participants' step of a clinical trial application. The tracking number is ZMR-WE0021/CTR/0001 and the application status is 'New'. The process flow includes: Name and address of Applicant, Particulars of the Clinical Trial, Details of Local Trial (S/N/S), Details of Investigator(S)/Co-/Sub-Investigators & Monitors, Particulars of Investigational/Comparator Medicinal Product(S), **Participants**, Regulatory Status, Supporting Documentation And Conditions, and Completion & Submission.

Fields for participant information include:

- Type of study participants (State target participants e.g. children, women, pregnant women, patients, differently abled, etc.): Select...
- Number of local participants: 12
- Total number of participants (in case of multicentre trial sites): 12
- Total enrolment in each local site/centre [If competitive enrolment, state minimum and maximum number per site.]: 12, 12
- Volunteer base from which local participants will be drawn: 12
- Retrospective data indicating potential of each site to recruit required number of participants within envisaged duration of trial [Attached as an documents uploads section if necessary]: 12

Navigation buttons: «Previous and Next Regulatory Status».

## Step 8: Regulatory Status

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

The screenshot shows the 'Regulatory Status in other Countries' modal form. The background displays the 'New Clinical Trial Application' page with tracking number ZMR-WE0021/CTR/0001. The modal form includes the following fields:

- Country:** Country (dropdown menu)
- Approving Authority:** Approving Authority (text field)
- Reference No.:** Registration Reference No. (text field)
- Date of Registration:** Date of Registration (calendar icon)
- Current Registration Status (Approved, Pending, Rejected, Suspended, Revoked):** Current Registration Status (dropdown menu)

A 'Save Details' button is located at the bottom right of the modal. A red arrow points from the 'Approving Authority' field in the modal to the 'Approving Authority' field in the background application form.

## Step 9: Supporting Documentation and Conditions

Provision to upload the required documents based on regulation

The screenshot displays the ZAMRA Portal interface for a clinical trial application. The top navigation bar shows the tracking number 'TRC-WEB-21/CTR/0053' and the application status 'New'. A progress bar at the top indicates the current step is 'Supporting Documentation And Conditions'. Below this, a table lists document requirements with columns for 'Action', 'File name', 'Initial file name 1', 'Uploaded on', and 'Allowed File Types'. Two document requirements are visible: 'Document requirement: General Investigational plan' and 'Document requirement: Overall Summary of the clinical trial Protocol in MS Word'. Each requirement has an 'Upload' button and a dropdown menu for 'Action(s)'. A note at the top states: 'Note: Maximum File Size per upload is 250 MB. Multiple Documents can be uploaded under the specified group(s)'. The interface also includes 'Previous Documents' and 'Next Application Submission' buttons.

## 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

The screenshot displays the ZAMRA Portal interface for the submission process of a clinical trial application. The top navigation bar shows the tracking number 'TRC-WEB-21/CTR/0053' and the application status 'New'. A progress bar at the top indicates the current step is 'Supporting Documentation And Conditions'. Below this, the 'Fast Track Option Process' section includes a 'Select Fast Track' dropdown menu. The 'Submission Comments(Optional)' section has a text area for 'Enter Comments(optional)'. A red box highlights the 'Declaration' section, which contains the following text: 'I the undersigned has/have submitted all requested and required documentation, and have disclosed all information which may influence the approval of this application. I hereby declare that all information contained in, or referenced by, this application is complete and accurate and is not false or misleading. I agree to ensure that if the above said clinical trial is approved, it will be conducted according to the submitted protocol and all applicable legal, ethical and regulatory requirements.  Agree to the Declaration'. Below the declaration, there are three buttons: 'Previous Step', 'Proforma Invoice (Generation) & Payment Details', and 'Submit Application'.

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

**Invoice Generation**

| Print                                  | Invoice description | Tracking no         | Date of invoicing   | Element costs                                 | Total invoice amount | Currency |
|--|---------------------|---------------------|---------------------|---|----------------------|----------|
| <a href="#">Print Proforma Invoice</a> | Quotation           | TRC-WEB-21/CTR/0053 | 2022-01-03 18:48:02 | Fee for clinical Trials-Clinical Trials In... | 18000                | USD      |

[Generate Invoice](#) [Upload Payments Details\(Payment Remittance Bank Slip\)](#) [Proceed with Payment \(Online Payment\)](#)

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

**Fast Track Option Process**

Select Fast Track:

**Submission Comments(Optional)**

Enter Comments(Optional)

**Declaration**

I the undersigned has/have submitted all requested and required documentation

I hereby declare that all information contained in, or referenced by, this application

I agree to ensure that if the above said clinical trial is approved, it will be conducted in accordance with the regulatory requirements.

Agree to the Declaration

[Previous Step](#) [Proforma Invoice Generation & Payment Details](#) [Submit Application](#)

## 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

**ZAMRA Portal** 9126 - Aurobindo Pharma Limited - India

**Promotion & Advertisement Applications** Home / Dashboard / Promotion & Advertisement Application

PENDING SUBMISSION 0 View Queried Applications

APPROVED APPLICATIONS 0 View Approved Applications

REJECTED APPLICATION 0 View Rejected Applications

REQUEST FOR ADDITIONAL INFORMATION 0 View Applications

Help & Guidelines Promotion & Advertisements Permits

Select Application Type: Select Status: Clear Filter

| Actions | Actions | Tracking no | Reference no | Exhibition start date | Exhibition end date | Venue of exhibition | Applicant name | Name of sponsor | Date added | Submission date |
|---------|---------|-------------|--------------|-----------------------|---------------------|---------------------|----------------|-----------------|------------|-----------------|
| No data |         |             |              |                       |                     |                     |                |                 |            |                 |

Search...

Promotion & Advertisement

Promotion & Advert

Archived Applications



## 12.1 Initiating Request to Undertake promotional and Advertisement

**Promotional & Advertisements Registration** Home / Dashboard / Promotional Materials Applications

Tracking No: Application Status: New

1 Promotional Materials Application Details 2 Product Particulars 3 Promotional Materials Details 4 Documents 5 Submission

**Promotional Materials Applications Details**

Registration Process/Section: Allied and Medicine Products

Application Type: Promotion & Advertisements Permits

Classification: Select Classification

Product Type: Select Product Type

Applicant As Sponsor: Applicant As Name of Sponsor

Sponsor Name: [Input Field]

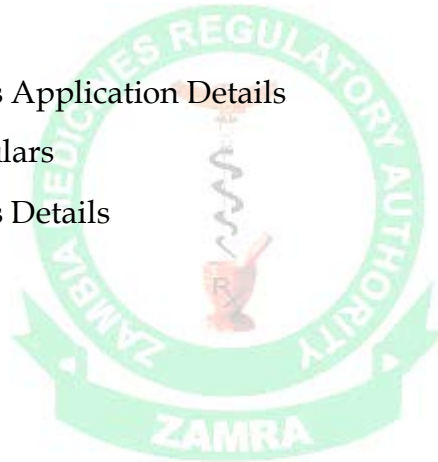
Certificate Issue Place: Select Certificate Issue Place

Search

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

**ZAMRA Portal** 9126 - Aurobindo Pharma Limited+ India

**Applications Applications** Home / Dashboard / Disposal Applications

APPROVED APPLICATIONS 0 ✓ View Approved Applications

REJECTED APPLICATIONS 0 ✗ View Rejected Applications

QUERIED APPLICATIONS 0 ? View Queried Permits

PENDING SUBMISSION 0 ⌚ View Queried Premises

Select Application Type Select Product Type/Category Select Status Clear Filter

+ New Disposal Application

| Actions | Actions | Tracking no | Reference no | Reason for disposal | Total weight | Market value | Premises Name | Date added | Date added |
|---------|---------|-------------|--------------|---------------------|--------------|--------------|---------------|------------|------------|
| No data |         |             |              |                     |              |              |               |            |            |

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## 13.1 Initiating Application for Disposal

**Process: Disposal Application** Home / Dashboard / Import/Export Application

Tracking No: Application Status: New

1 Application Details 2 Product Information 3 Documents 4 Completion & Submission

**Products Types**

Select Registration Section/Process

**Quantity**

quantity

**Total Weight**

Total Weight

**Market Value**

market\_value

**Reason For Disposal**

Reason For Disposal

**weight Units**

Packaging Units

**weight Units**

Weight Units

**Currency**

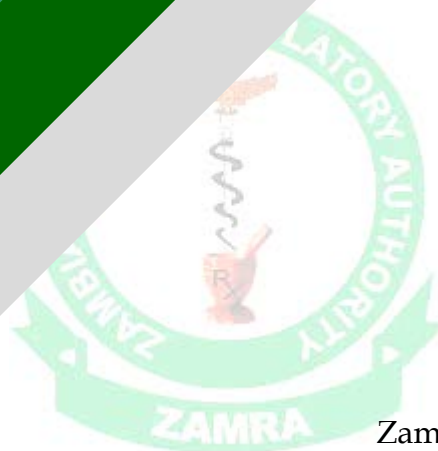
Select Currency

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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