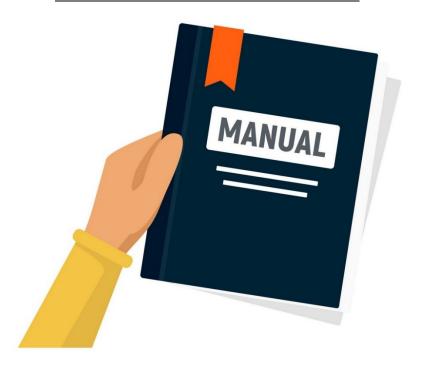


Tanzania Medicines and Medical Devices Authority

TMDA SELF SERVICE PORTAL MANUAL



(User Manual)

TABLE OF CONTENTS

Customer self-service Portal	3
Registered Products	3
Prohibited Products	4
Registered Premises	5
GMP Compliant Facilities	6
Clinical Facilities	7
Resources	8
Contact Information	9
Agencies Access	10
Creating a Trader Account	11
Dashboard	14
Change Password	
Product application	
Product applications	
Archived Applications	19
Premises Application	20
Premise application	20
Archived Applications	28
GMP Inspection	29
GMP application	29
Archived Applications	37
Import & Export Permits	38
Clinical Trails Applications	42
Products Notification	46
Account Management	46
GCP Applications	Error! Bookmark not defined.
Promotion & Advertisement	Error! Bookmark not defined.
Label & Artwork Application	Error! Bookmark not defined.
Retention Invoices	Frror! Bookmark not defined.

CUSTOMER SELF-SERVICE PORTAL/OFFLINE SERVICES

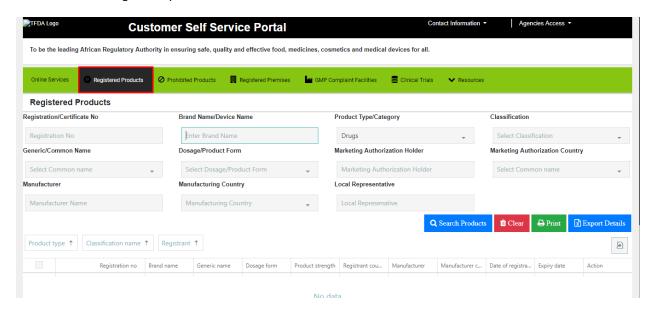
The customer self-service portal is a part of the portal system that be accessed by clients without having to log into the system. This section is used by the clients to request for product registration, product prohibition, premise registration and for registration of GMP product registration. The self-service portal also allows the user to request for clinical trials and offers the user other related resources.

The online services can only be used by registered traders/clients to access services that require a user account

REGISTERED PRODUCTS

This section of the sub-module is used to search for products registered by the TFDA. When accessed, the module illustrated below is displayed.

The window contains a list of records for all registered TFDA products. Each record containing an action button that shows the details of the registered product.



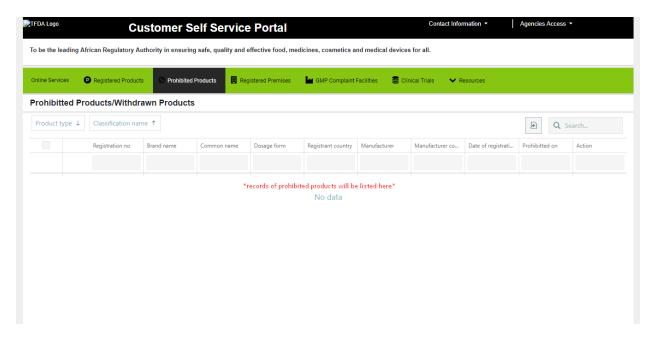
To find a registered product, the user may use the Brand/Device name or the registration/certificate number. The user can also enter other details into the provided fields to filter the search results. Once the user clicks on the "search products" button, records of products that fit the search criteria are displayed.

The sub module also allows the user to print and export the records of the search results.

To clear the filter filed, the user clicks on the **clear button** which will erase the data entered into the fields and the user is able to search for a new registered product.

PROHIBITED PRODUCTS

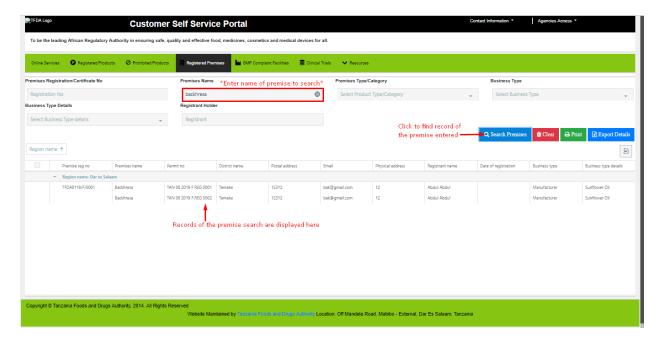
This section of the sub-module is used to display products prohibited by the TFDA. When accessed, the module illustrated below is displayed, containing a list of records of products that are prohibited.



To find a prohibited product, the user enters the product name into the search-box displayed on the right of the window. Once the user clicks on the "search" button, records of prohibited products that fit the search criteria are displayed.

REGISTERED PREMISES

This sub module is used to locate records of premises registered by TFDA. The main window of the module is illustrated below.

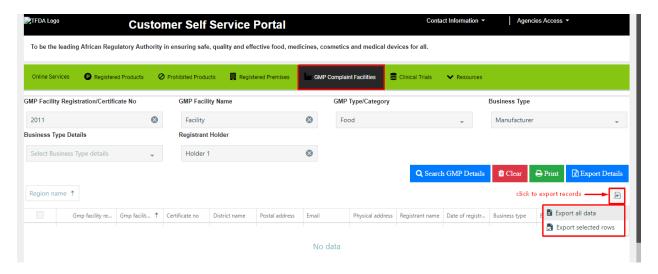


To find a registered premise, the user may use the premise name or the premise registration certificate number. The user can also enter other details into the provided fields to filter the search results. Once the user clicks on the "search premises" button, records of premises that fit the search criteria are displayed.

The sub module also allows the user to print and export the records of the search results or to export the records in a XLSX or Excel format. A single record or selected rows of records can both be exported.

GMP COMPLIANT FACILITIES

This sub module is used to locate records of GMP compliant facilities that have been registered by TFDA. The main window of the module is illustrated below.

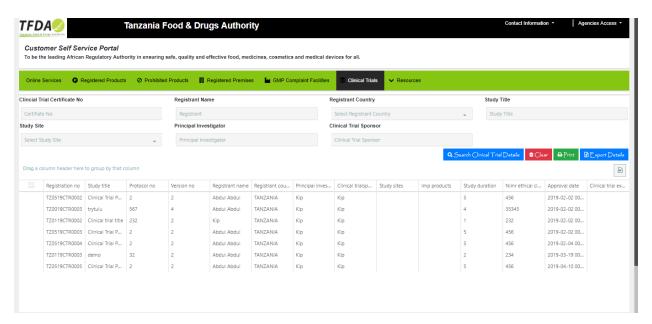


To find a GMP compliant facility, the user may use the GMP facility name or the GMP facility registration/certificate number. The user can also enter other details into the provided fields to filter the search results. Once the user clicks on the "search GMP details" button, records of GMP facilities that fit the search criteria are displayed.

The sub module also allows the user to print and export the records of the search results. The user can export certain records (by selecting the specific rows) or all the displayed records.

CLINICAL TRIAL

This sub module is used to locate records of clinical tials that have been registered by TFDA. The main window of the module is illustrated below.



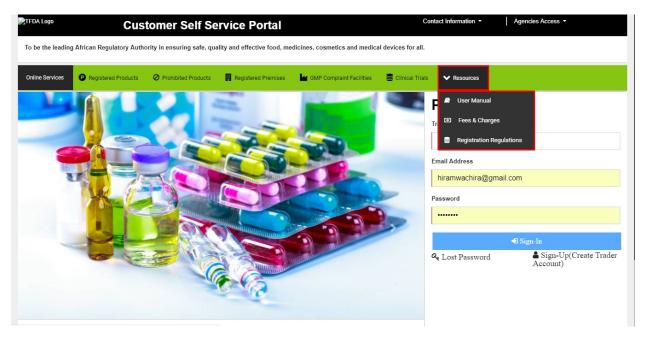
To find a clinical trial, the user may use the Brand/Device name or the registration/certificate number. The user can also enter other details into the provided fields to filter the search results. Once the user clicks on the "search products" button, records of products that fit the search criteria are displayed.

The sub module also allows the user to print and export the records of the search results.

To clear the filter filed, the user clicks on the **clear button** which will erase the data entered into the fields and the user is able to search for a new clinical trial.

RESOURCES

The resources sub-section provides the user with specific information. Clicking on this tab opens a drop down window illustrated below. From this menu, the user can access the system's user manual, information of the fees & charges and information on the Rules and regulations set by the Tanzania Food and Drugs Authority.



CONTACT INFORMATION

The contact information tab is accessible while using offline services. When clicked a dropdown is displayed containing the basic information of the user logged in to the online system. The details displayed can also be printed



A sample of the contact information is illustrated above.

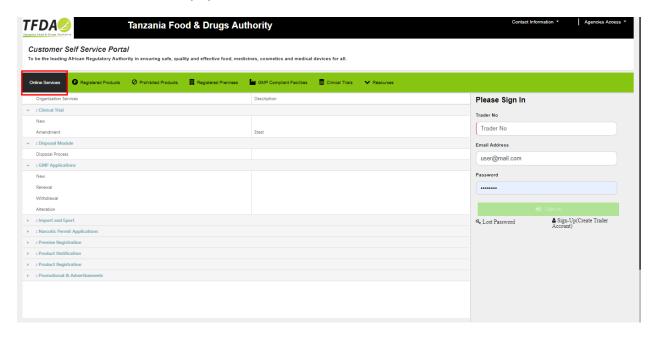
AGENCIES ACCESS

The Agencies access is used to log the user into the system for online services directly from the customer self-service section of the portal. Clicking it opens a small dropdown window that the user will use to sign into the system. The user will simply enter their login credentials and click "sign-in", this will redirect the user to the system's main dashboard. From this menu the user can also access the password recovery section by clicking the "lost password" button



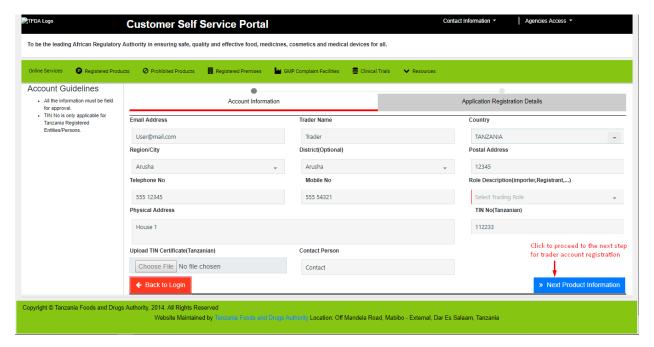
CREATING A TRADER ACCOUNT

To create a trader account, the user first navigates to the online services tab illustrated below. A list of records describing the online services offered is displayed on this tab.

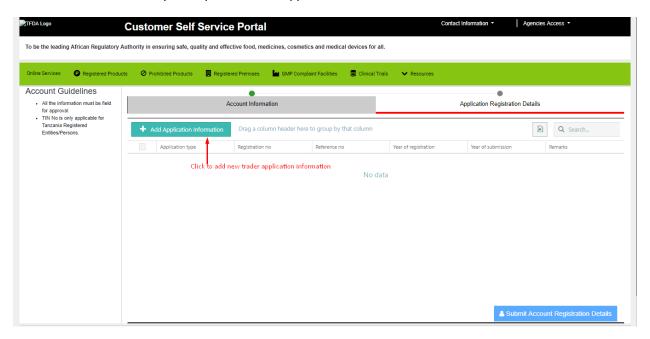


The user then clicks on the sign up(create trader account) button located under the sign in form.

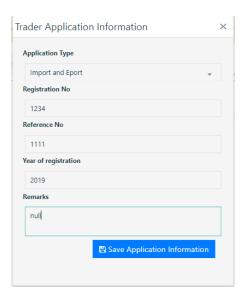
Once the button has been clicked, the window illustrated below is displayed. The user then enters all the required data into the fields provided.



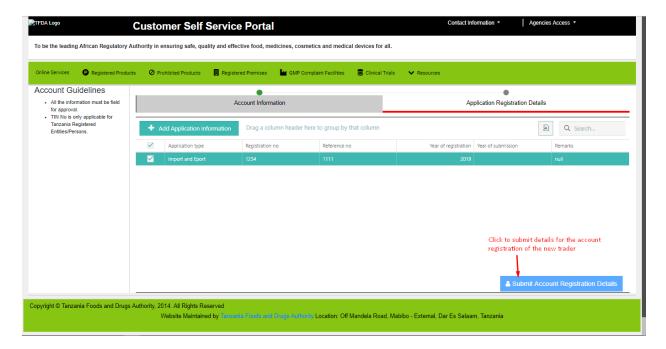
After the user has entered all the mandatory information and uploaded/attached a TIN certificate (for traders who are citizens of Tanzania), he/she proceeds to the next step by clicking the "product information" button. This opens the window illustrated below where they are expected to add application information.



Clicking this button opens a pop-up window illustrated below where the user enters additional trader information.



Once all the information has been entered, the "save application information" button becomes active. Clicking this will create a new trader application record that will be displayed under the **trader registration details** tab as illustrated below.



The user is also able to add multiple application information records just by clicking the "add application information" button and following the steps previously outlined.

Once complete the user can select the relevant application information records by placing a checkmark in the checkboxes displayed at the left hand side of each row/record. This are the application information records that will be linked to the new trader's account.

Once complete, the user selects the "submit account registration details" which will send the record to the manager for authorization.

If the trader's request is authorized, the new trader will receive an email containing the credentials the user will use to access the online services provided by the portal.

ONLINE SERVICES

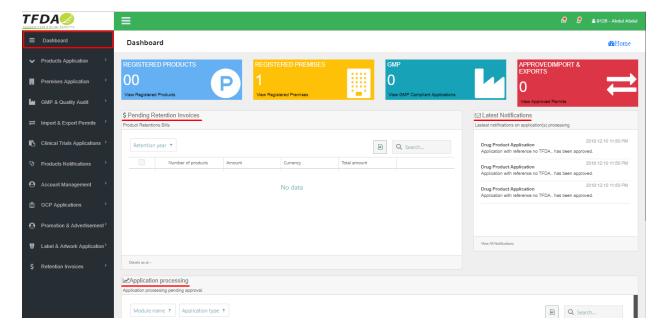
These are services that cannot be accessed by the general public as an information resource but only by authorized users (Trader Agents). To access this, the user has to have a valid account that can be registered by following the guidelines in the <u>creation of trader account</u> section illustrated in the previous section.

DASHBOARD

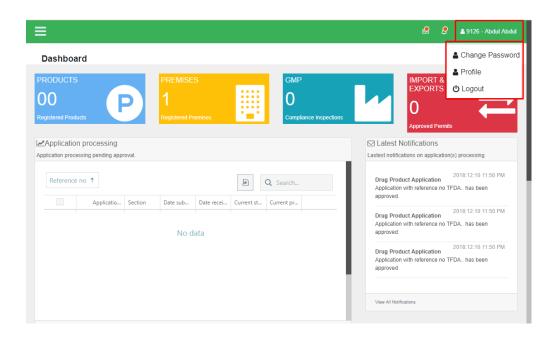
This is the main page/window displayed once the user has successfully logged into the system's online services. It displays all the system modules on a navigation pane located on the left side of the window/page.

The window also provides the user with statistics on the number of registered products, number of registered premises, number of GMP compliance inspections and the number of approved import and export permits

If there are any applications pending retention invoices, record of the applications will be displayed on the dashboard. To the right hand side of the dashboard is a list of all the latest notifications. All types of applications (food, drugs...etc) that have been approved will be listed here with the most recent located at the top most of the notification list.

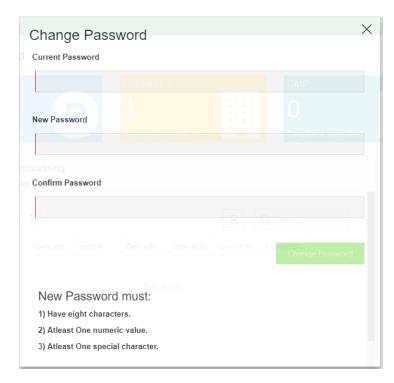


The user can also access the account information/configuration by clicking the **user's name** displayed at the top right of the window. Once clicked, a dropdown menu is displayed. It contains the change password button, the profile button and the logout button as illustrated below.



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 open the dropdown menu containing the "change password" button. Once clicked, the window illustrated below is displayed



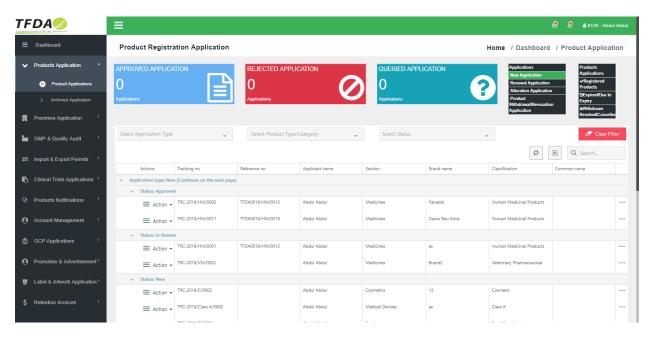
The user then enters his/her current password, then the new password and confirms it. The password must however have at least 8 characters, one special character and one numeric value. After all the requirements have been met and the all the password details entered, then the "change password" button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

PRODUCT APPLICATION

PRODUCT APPLICATIONS

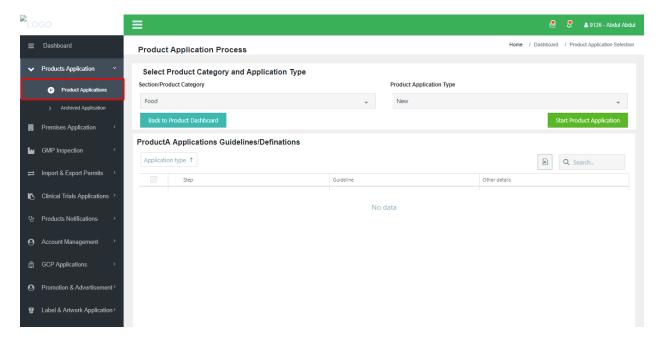
The products application module is used by traders to register new products to the TFDA system. When opened, the window illustrated below is displayed. On the top of the window, statistics about registered products are displayed. They offer information on the number of product applications that have been rejected, approved, queried and the number of product applications awaiting submission

The main window also contains a list of records for premises that have been applied for/registered

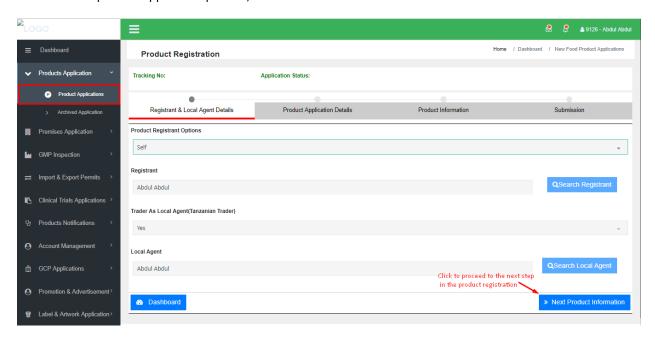


To create/register a new product, the user clicks on the "start product applications request" button. Doing this opens the window illustrated below.

The user begins the product application process by first selecting the product category then selecting the product application type. Doing this activates the "start product application" which when clicked allows the user to proceed to the next step.

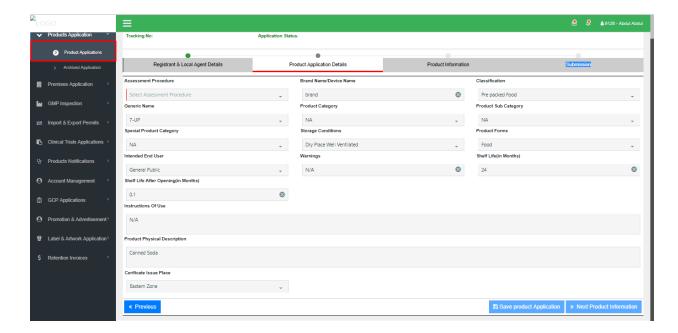


After start the product application process, the user is directed to the window illustrated below.



The new product application record will automatically be given a tracking number and the status will also change as the product moves through different approval processes.

The steps involved in the product registration are categorized into different tabs



ARCHIVED APPLICATIONS

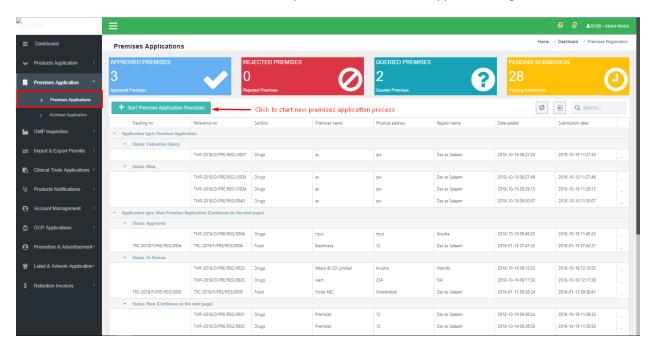
After a product has been either approved or rejected, the record of the product registration can be archived. After the user has decided to archive the record, it is sent to this section of the products application module.

PREMISES APPLICATION

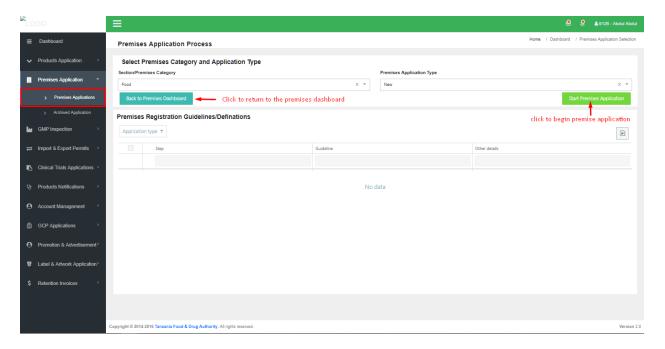
PREMISE APPLICATION

The premises application module is used to register new business premises. When opened, the window illustrated below is displayed. On the top of the window, statistics about registered premises are displayed. They offer information on the number of premises that have been rejected, approve, queried and the number of premises awaiting submission

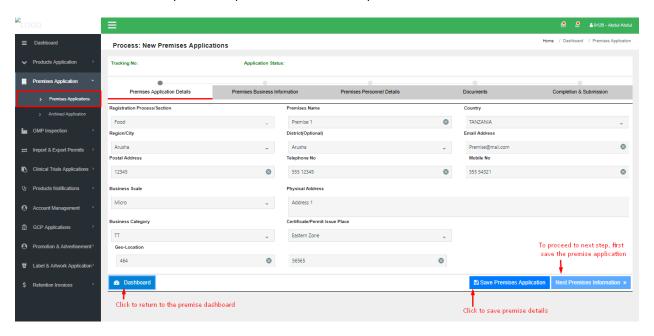
The main window also contains a list of records for premises that have been applied for/registered



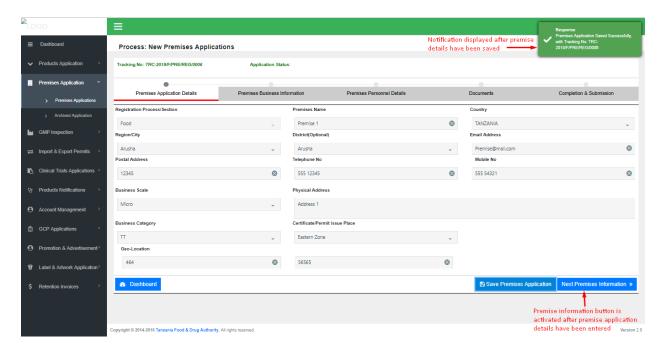
To create/register a new premise, the user clicks on the "start premises application process" button. Doing this opens the window illustrated below.



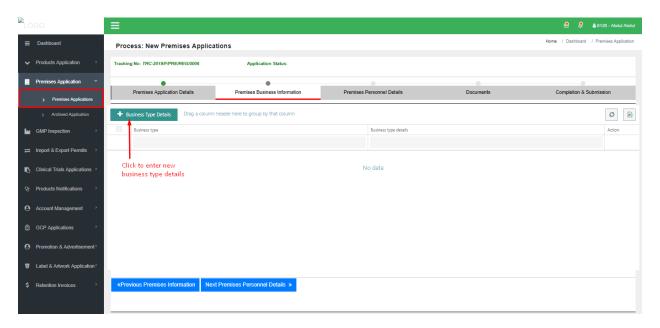
The user then proceeds to select a premise category and then selecting a premise application type. After selecting this, the user then clicks on the "start premise inspection" button which opens the window illustrated below.



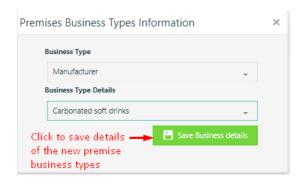
Sections of this registration process are categorized into tabs as illustrated above. The first step is the **premise application details** tab, where the user enters details of the premise. After all the required details have been entered, the user clicks on the "save premise application" button. This saves the data entered and activates the "next premise information" button and displays a success notification as shown below.



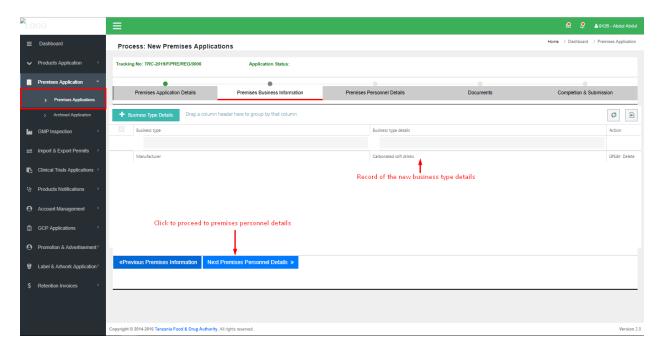
Clicking the "next premise information" button opens the window illustrated below which is the **premise business information.**



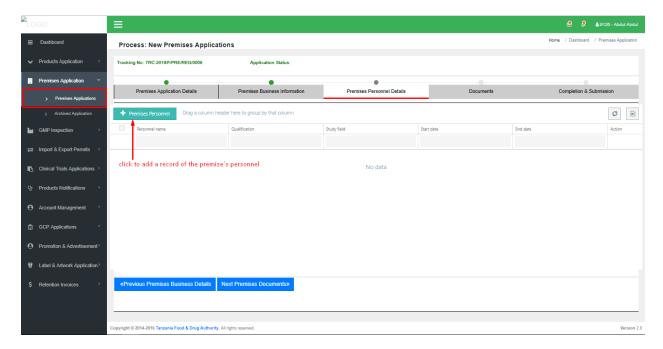
The user enters the premise business information by creating a record of the business type details by clicking the "business type details" button. This opens the window illustrated below



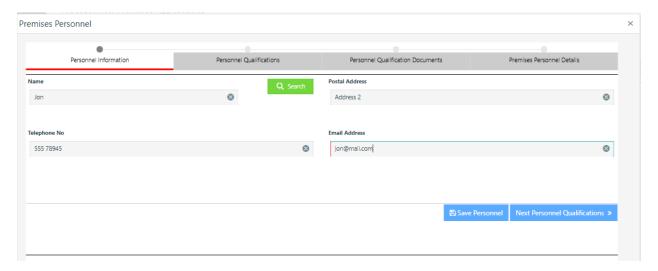
Creating a premises business type information record involves selecting a business type and selecting a business type details. After selecting this, the user clicks on the "save business details" button which closes the window, saves the record, returns the user to the **premise business information** tab and activates the "next premise personal details" button.



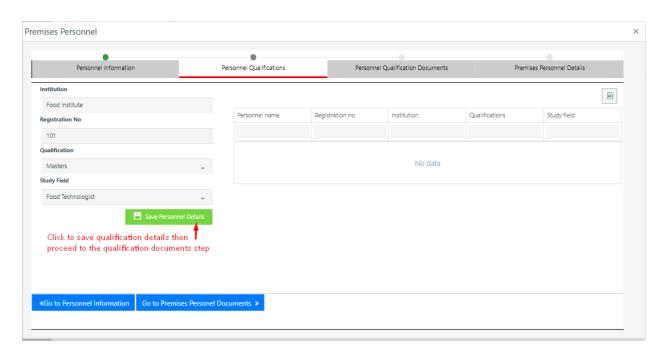
The next stage of the new premises application process is the premises personnel details Tab, illustrated below.



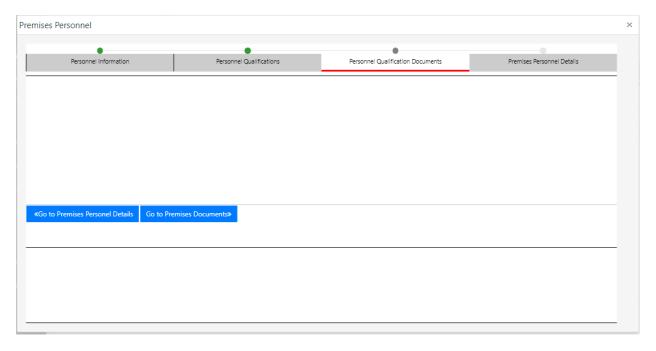
The next step of the process involves the user creating a record of the premises personnel. The user does this by clicking the "premises personnel" button located on the **premises personnel details** tab which opens a pop up window containing a number of tabs where the premises personnel details will be entered.



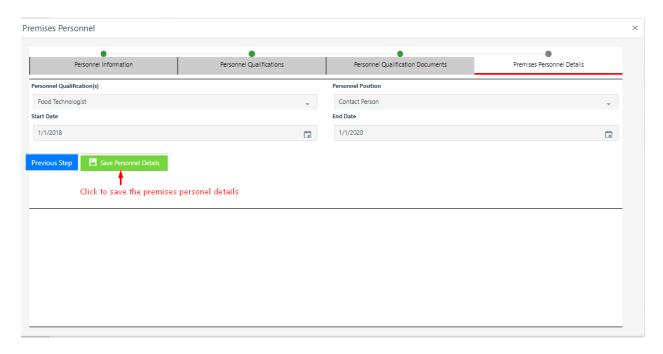
After the user has entered all the required personnel information, he/she has to save the details before proceeding to the next step. Saving the details activates the "next personnel qualifications" button which enables the user to move to the next step. Clicking the next button open the window illustrated below.



The user is then to enter the personnel's qualification details then save the data. After saving, a success notification is displayed and a record of the personnel's qualifications is displayed on the right hand side of the window. The user then proceeds to the next stage by clicking the "go to premises personnel documents" button which opens the window illustrated below.

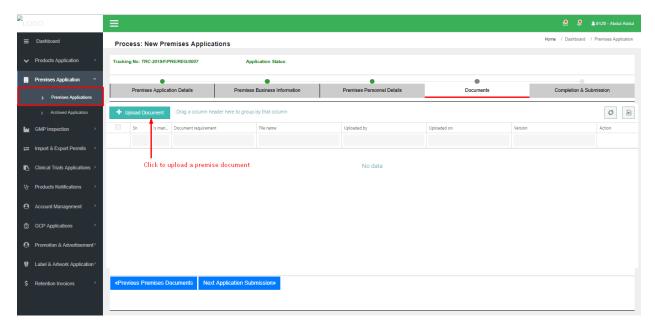


From this window, the user can upload digital (softcopy) documents that the provide information of the personnel's qualification. After uploading, the user moves to the next step by clicking on the "premises personnel details" button which opens the window illustrated below.



From the window illustrated above, the user will enter the personnel position and qualification then enter the length of days in which the personnel will be active at the new premise. The user will then save the details and a success notification will be displayed as well as a record of the new premise personnel.

Once complete, the user will continue with the process of premise application by clicking the next button located under the personnel's record. This will open the premise documents window illustrated below which will allow the user to upload documents of the new premise being registered.

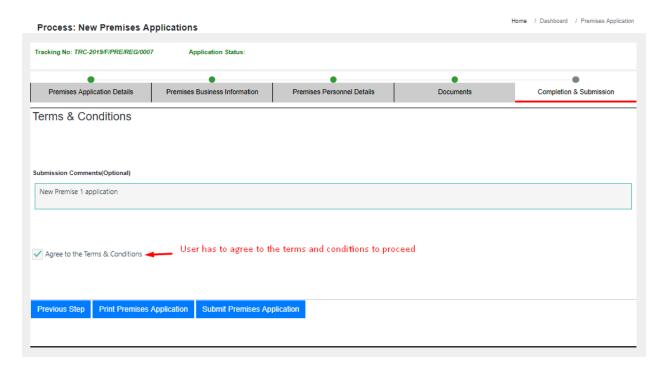


Selecting the "upload documents" button opens the window below.

opens the personnel document

After uploading the related premise documents, the user proceeds to the next step. It is worth noting that the user can still proceed to the next level without uploading any premises documents.

The next process in the premises application is the "completion and submission" step. This is used to submit the new premise record for authorization

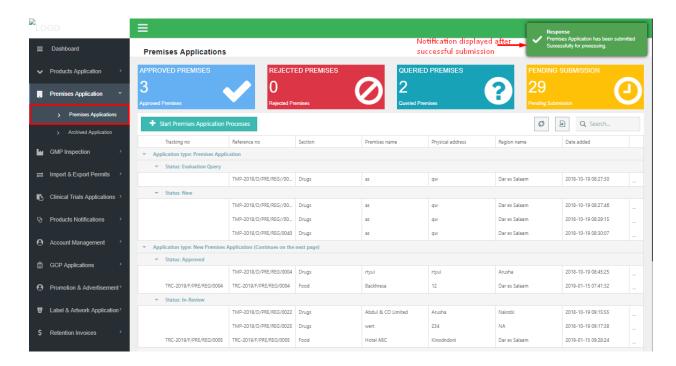


The user can enter a comment optionally to provide any added information relevant to the new premise. The user also has to agree to the term and conditions, if the user does not place a checkmark into the checkbox, the "submit premises application" button remains inactive and the user is unable to submit the application.

The window illustrated below is displayed once the user submits the application



After selection of the "yes" button, a success notification is displayed and the user is returned to the premises application dashboard illustrated below



ARCHIVED APPLICATIONS

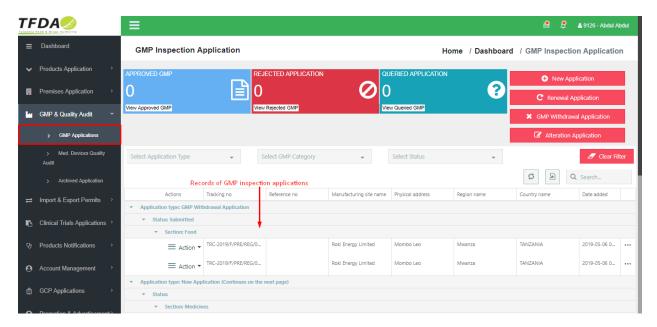
After a premise application has been either approved or rejected, the record of the premise application can be archived. After the user has decided to archive the record, it is sent to this section of the premise application module.

GMP AND QUALITY AUDIT

GMP APPLICATION

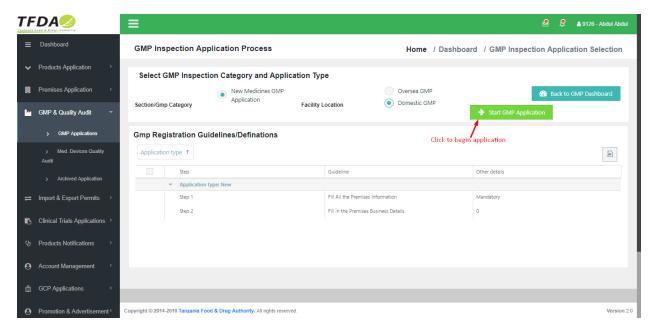
Good manufacturing practices are the practices required in order to conform to the guidelines recommended by agencies that control the authorization and licensing of the manufacture and sale of food and beverages, cosmetics, pharmaceutical products, dietary supplements, and medical devices.

The GMP application module is used to apply for GMP inspections. When opened, the window illustrated below is displayed. On the top of the window, statistics about registered premises are displayed. They offer information on the number of GMP inspection applications that have been rejected, approve, queried and the number of premises awaiting submission

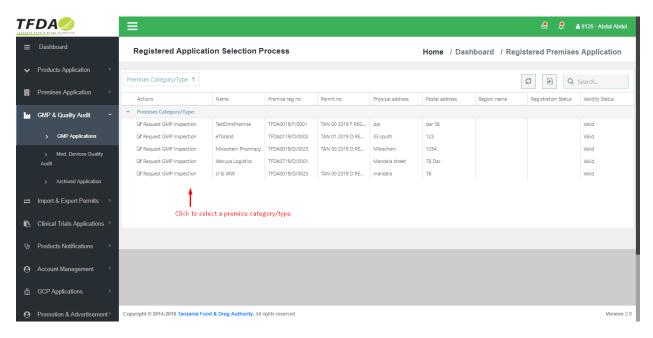


The main window also displays records of GMP inspections that have been applied for. The user can open and view a GMP inspection by double clicking the record.

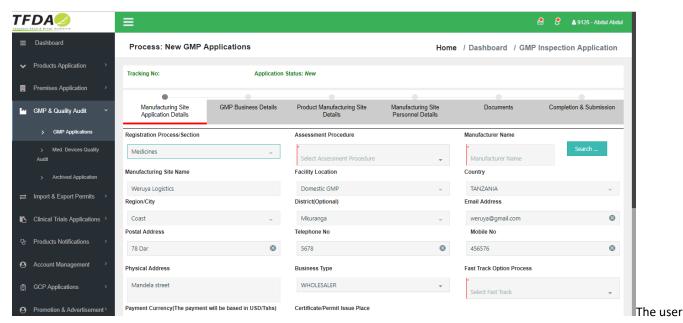
To apply for a new GMP inspection, the user clicks on the **new application** button which opens the window illustrated below.



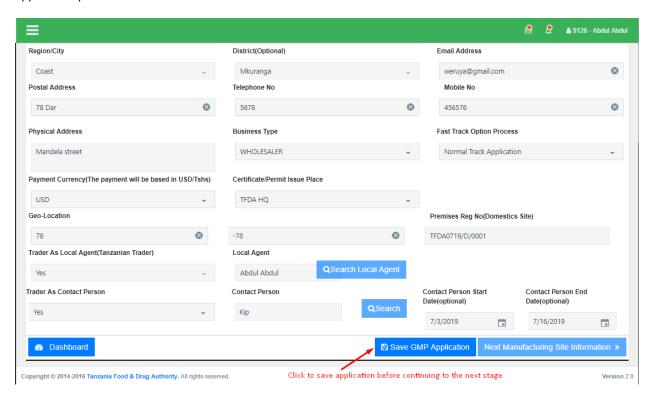
The user will first select the GMP category and the Facility location before proceeding with the application. After this has been selected, the user then clicks the **start GMP application** button which opens the window illustrated below.



The user will then select a premise category/type in order to continue with the application.



begins the application from the **manufacturing site application details** tab. The user selects the registration process section, the assessment procedure and the manufacture's name. The user is also given the option to fast track the application process

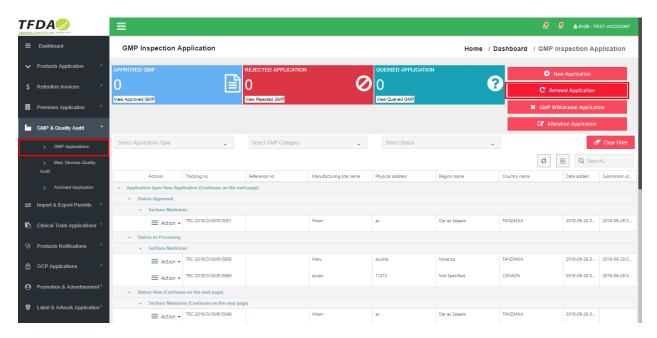


Scrolling down the window will display the fields illustrated above. The user will then select the payment currency type and the certificate permit issue place. The user also has an optional choice to enter the contact person start and end date.

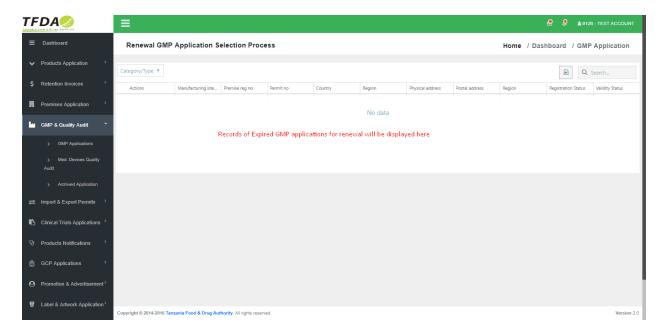
Before proceeding to the next step the user will have to save the application by clicking the save GMP application button.

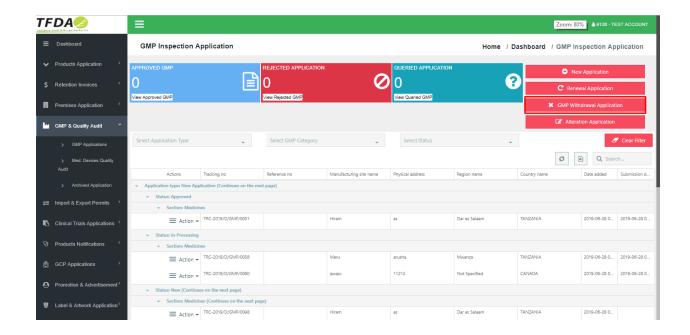
RENEWAL

To renew a GMP application, the user clicks on the **renewal application** button on the GMP application module main window as illustrated below.



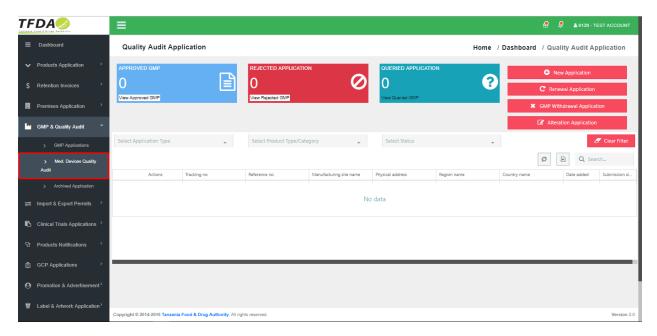
Clicking this button will open the window below which contains a list of records of expired GMP applications. To renew an application, the user will click on the desired record to open it.



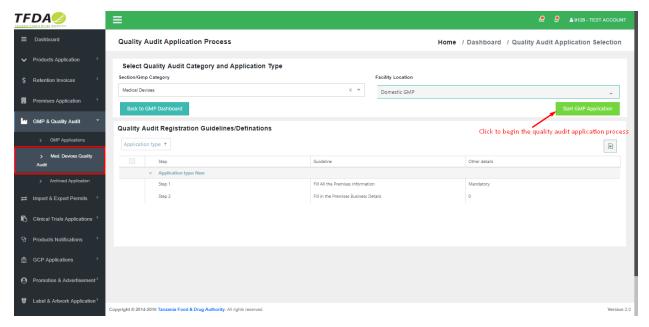


MEDICAL DEVICES QUALITY AUDIT

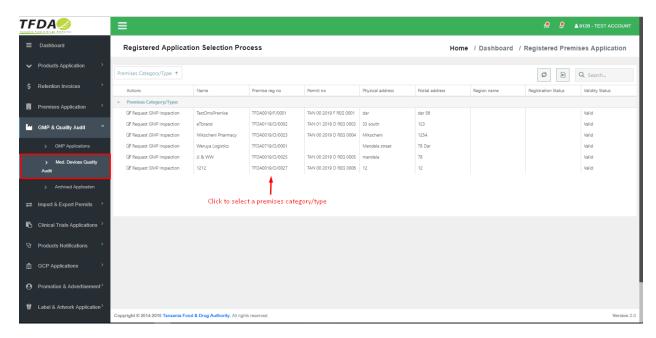
The medical devices quality audit module is used to apply for a quality audit for a medical devices. The buttons to the top right of the window also allow the user to renew an expired application. The user can also withdraw a GMP When opened, the window illustrated below is displayed. On the top of the window, statistics about Quality audit applications are displayed. They offer information on the number of GMP inspection applications that have been rejected, approved and gueried.



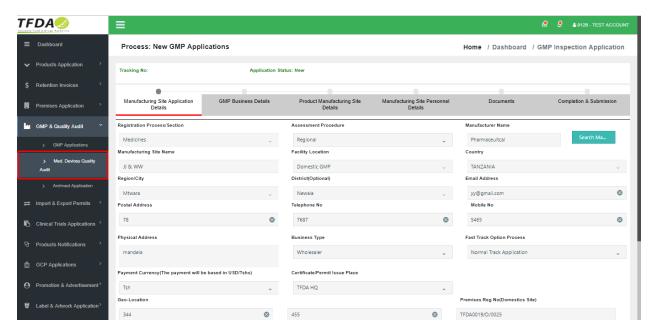
NEW APPLICATION



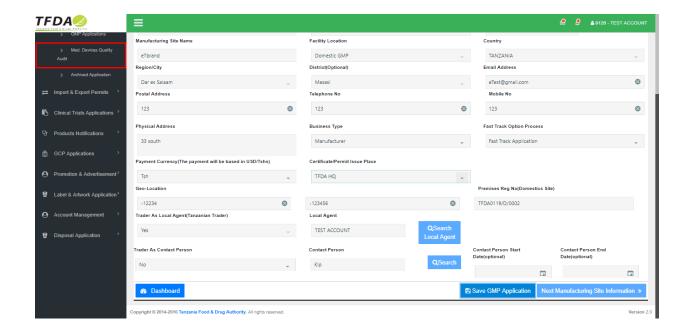
The user will first select the GMP category and the Facility location before proceeding with the application. After this has been selected, the user then clicks the **start GMP application** button which opens the window illustrated below.



The user will then select a premise category/type in order to continue with the application.



The user begins the application from the **manufacturing site application details** tab. The user selects the registration process section, the assessment procedure and the manufacture's name. The user is also given the option to fast track the application process.

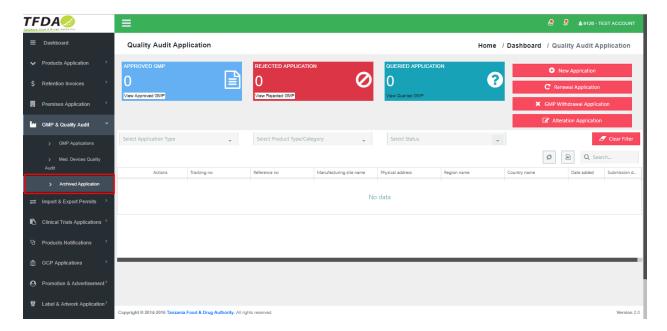


Scrolling down the window will display the fields illustrated above. The user will then select the payment currency type and the certificate permit issue place. The user also has an optional choice to enter the contact person start and end date.

Before proceeding to the next step the user will have to save the application by clicking the **save GMP application** button.

ARCHIVED APPLICATIONS

After a GMP application has been either approved or rejected, the record of the GMP application can be archived. After the user has decided to archive the record, it is sent to this section of the GMP application module.

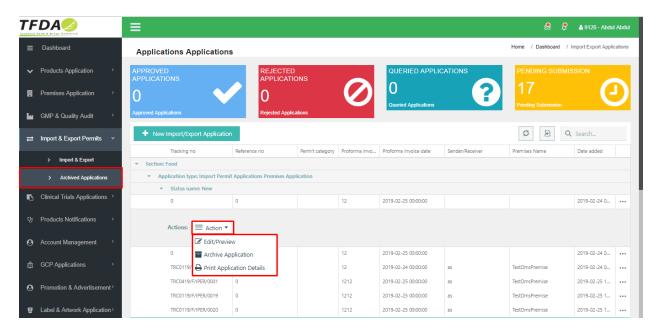


IMPORT & EXPORT PERMITS

Import and export permits are documents issued by a national government authorizing the importation of certain goods into its territory. Import licenses are considered to be non-tariff barriers to trade when used as a way to protect a domestic industry from foreign competition.

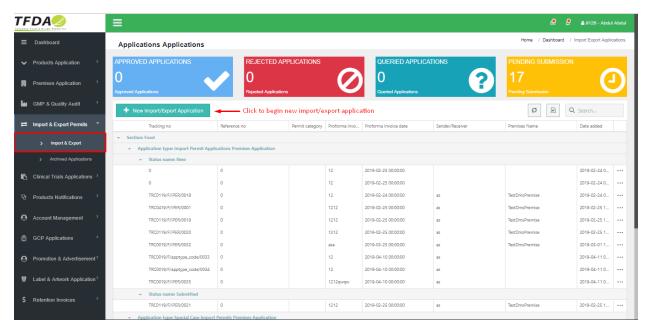
IMPORT & EXPORT

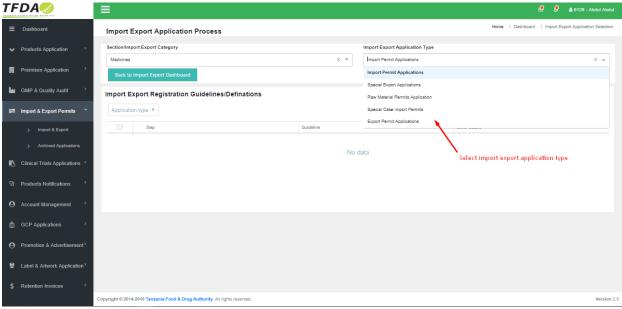
This section of the portal is used to receive application of permits relating to export and imports into Tanzania. When accessed, the window below is displayed, it contains a list of application records. When clicked, the record displays action sub-modules as illustrated below.

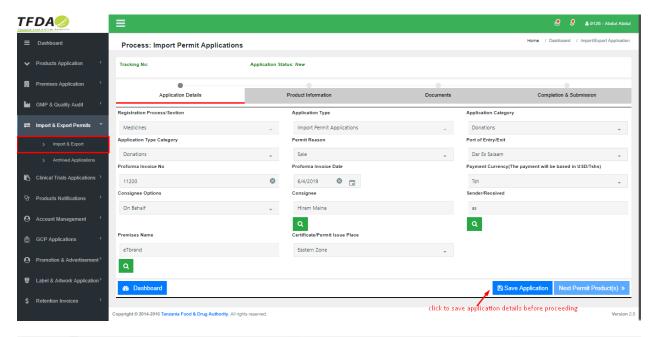


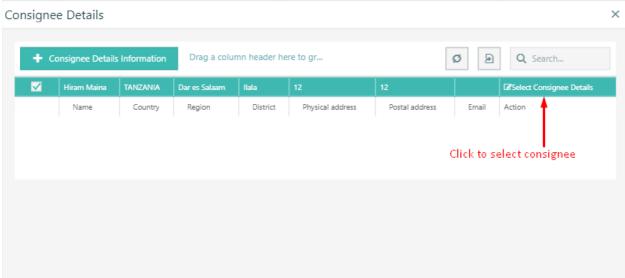
Clicking the edit/preview button allows the user to view the associated details of the permit and change details if the user has the appropriate user permissions.

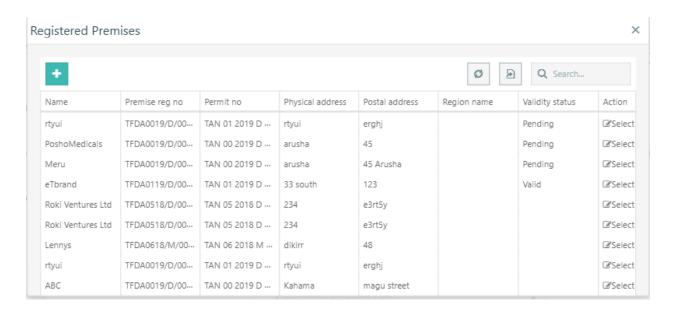
Clicking the Archive application button will send the record of the application to the Archive application sub-module. Clicking the print application details, will print the record as a document from a printer connected to the device.





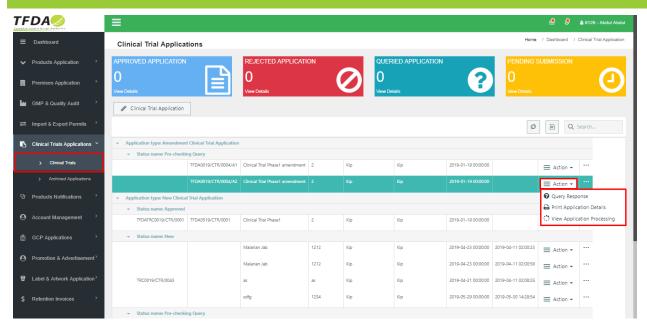


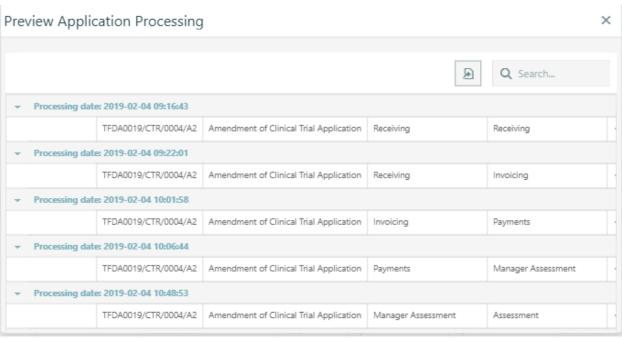


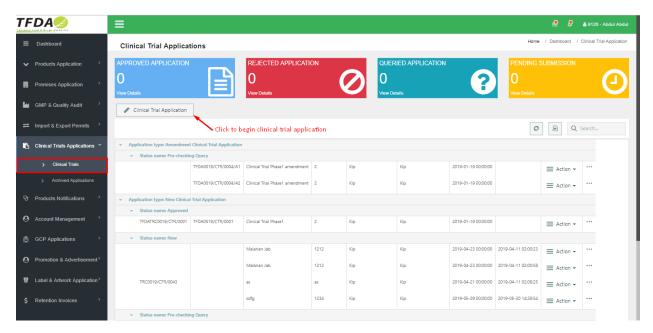


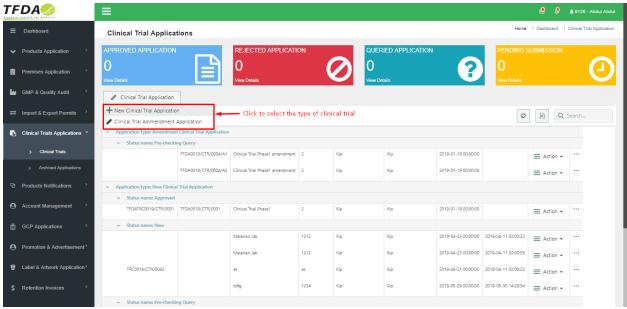
ARCHIVED APPLICATIONS

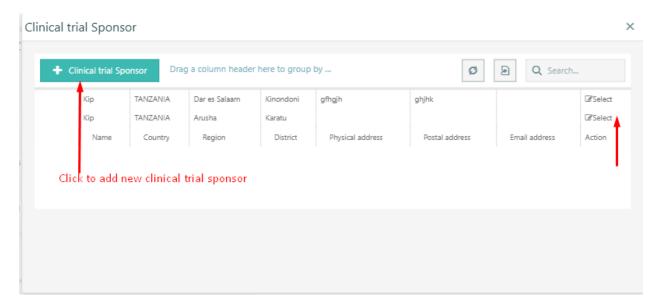
CLINICAL TRAILS APPLICATIONS

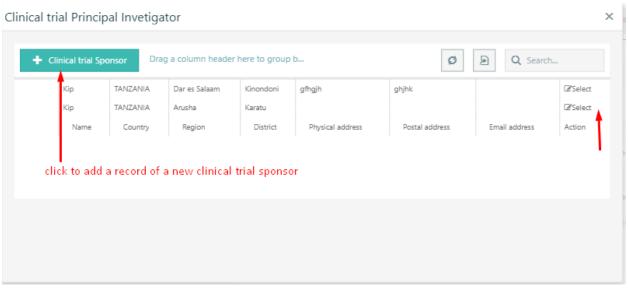


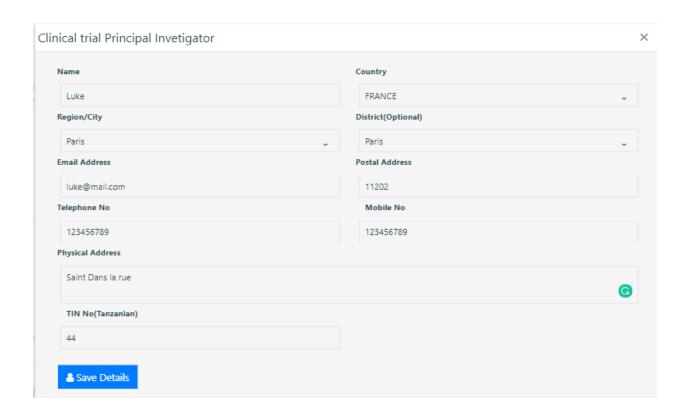












PRODUCTS NOTIFICATION

ACCOUNT MANAGEMENT

ACCOUNT PROFILE

