11 Feb 2017

The Portal
User Manual

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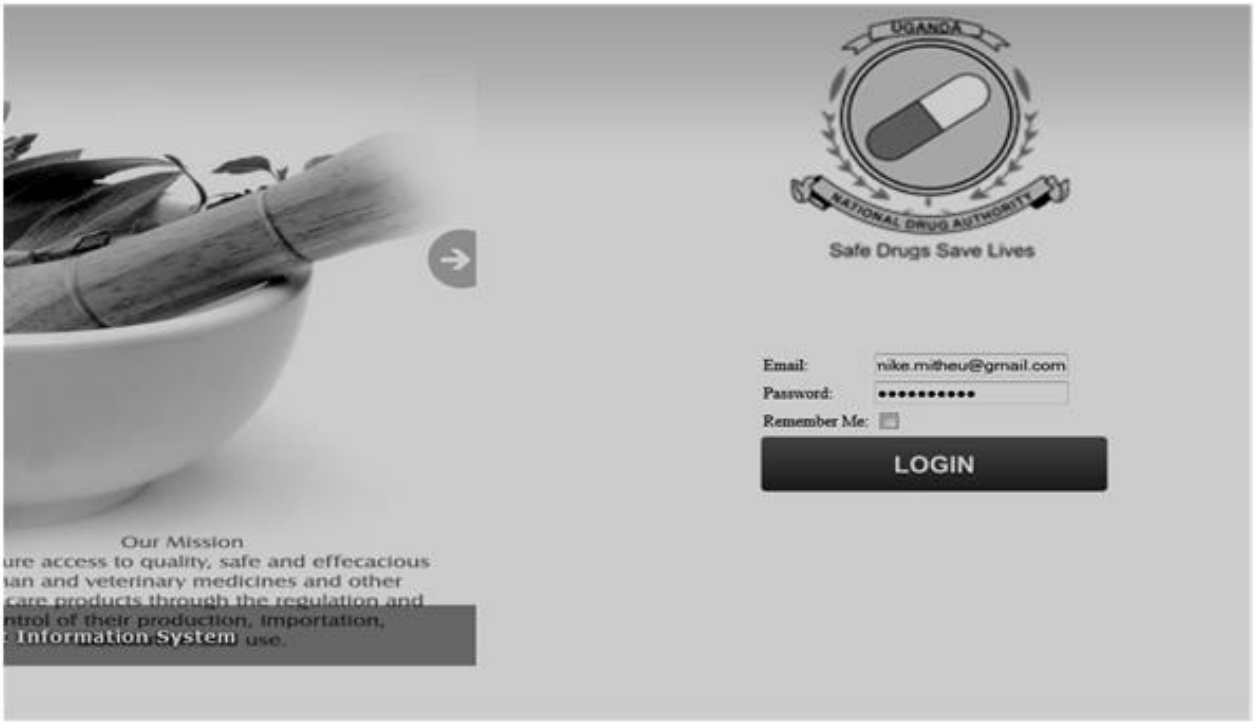
Authentication

Procedure:

To login to the system follow this steps:

1. Enter the **Email** in the email textbox,
2. Enter the **password** in the password textbox,



3. Click **Login** to gain access to the system,

Login Failure

4. If the **email or Password** is missing ,a message is prompted as below **or**
5. If the **username and password** entered don't match the window below will be displayed,

Home Page

It is the **key point of reference** when beginning any section on the System . The **Navigation bar** located on the left side of the window will facilitate navigation of the system to the desired destination.

After success authentication, the window below will show on your **screen:**

Logging Out

Always click the **Logout button** to securely log out of the System.

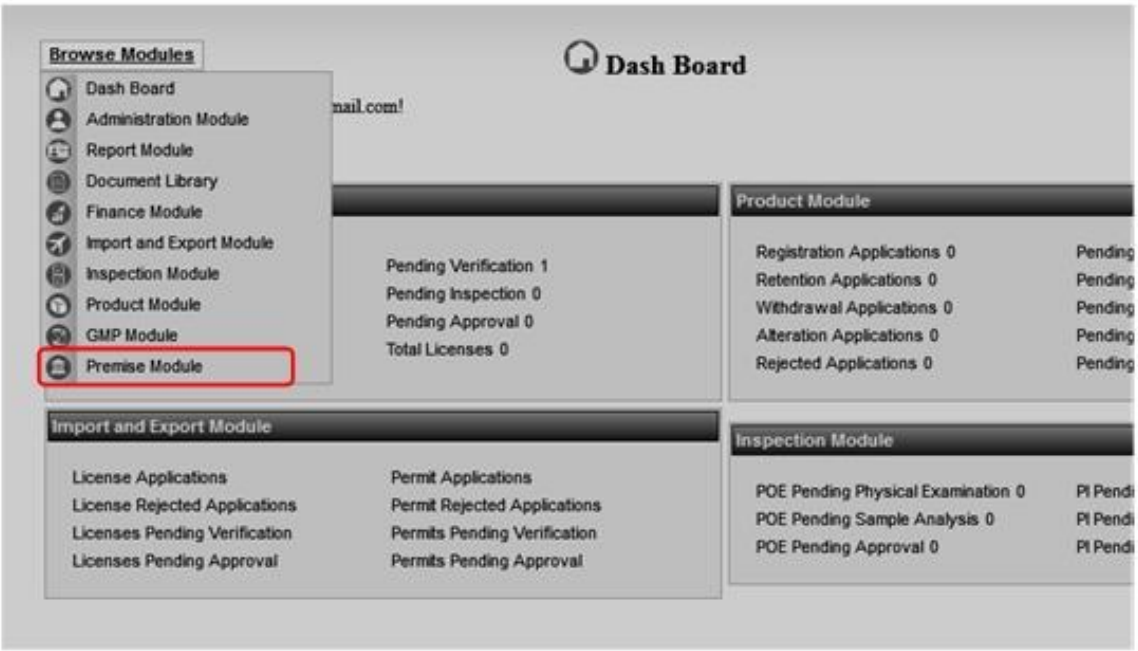
System will display the login screen as displayed below:

Premise Module

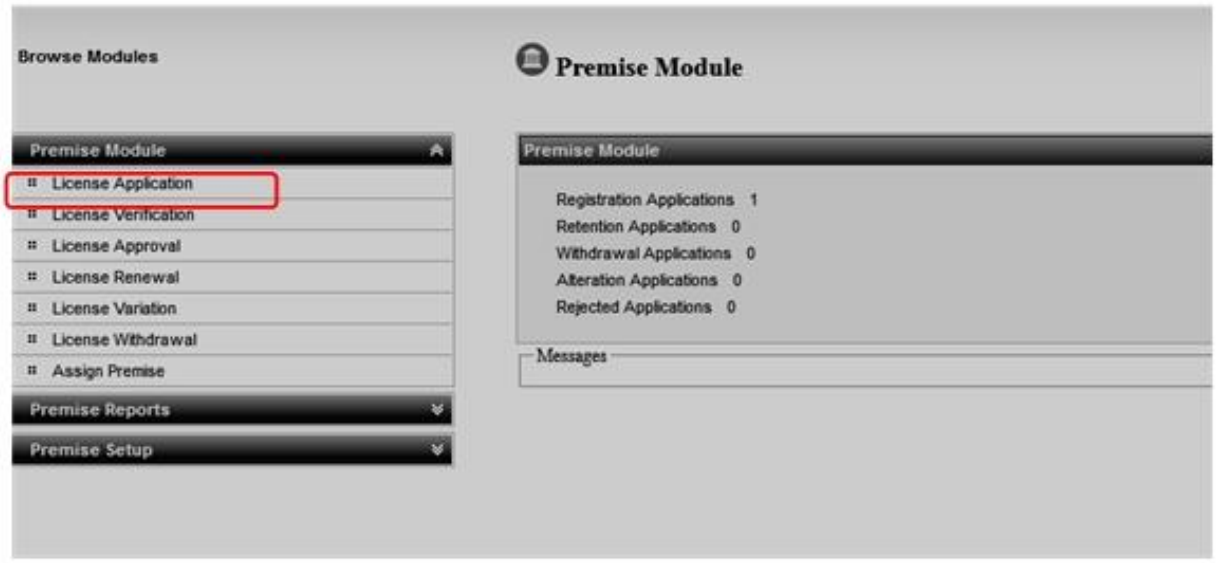
The Module has the Premise License Registration, License Verification, License Approval, License Renewal, License Variation and License withdrawal processes

Premise License registration Procedure

1. Click the **Browse modules** link and select the **Premise Module**

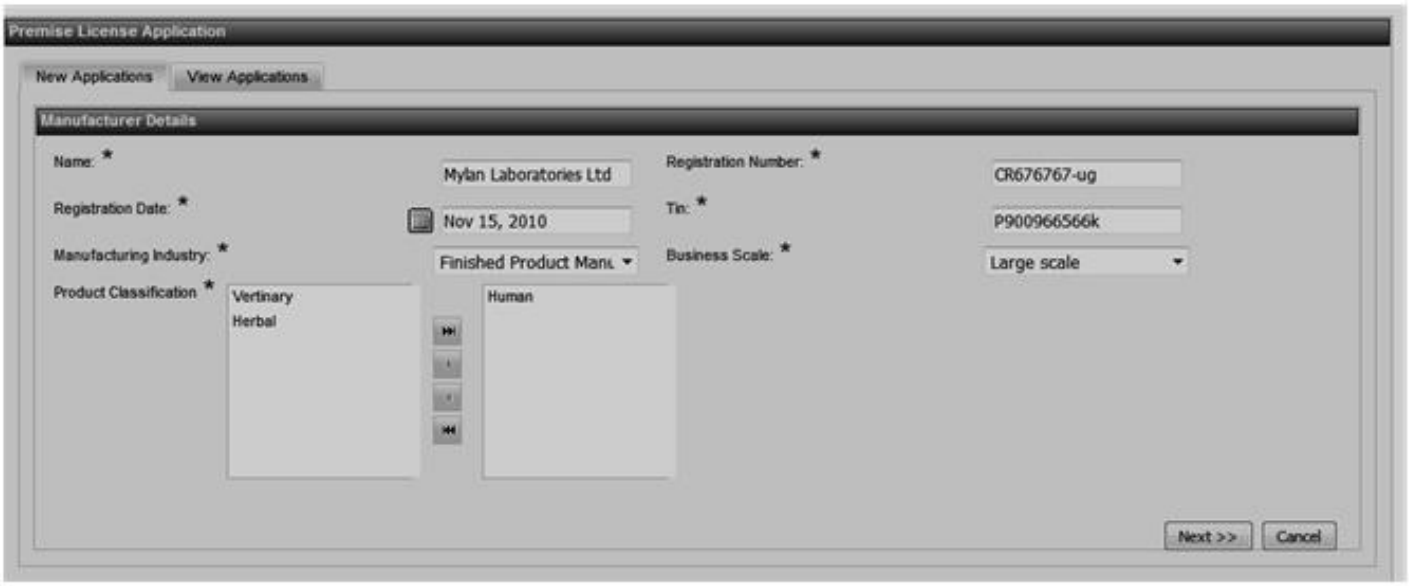


2. On the Premise module page, select **License Application,**



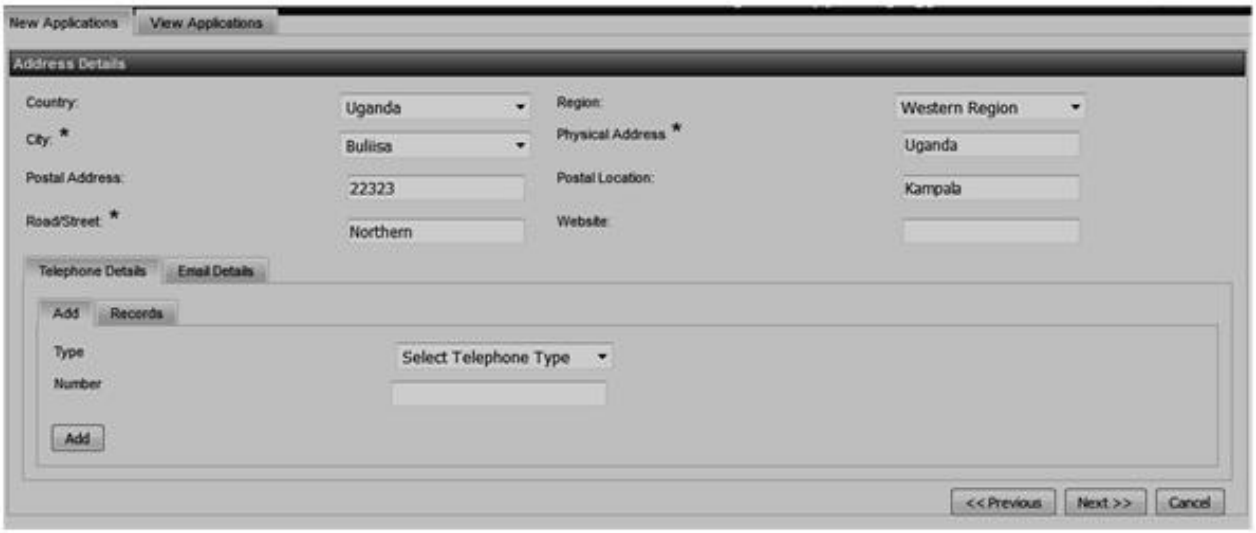
3. On the license application 1st page, select the **premise category** and click **next,**

4. On the 2nd page enter the **manufacturer details** and click **next**,



The mandatory fields are marked in red asterisks.

5. On the 3rd page of license application, enter the premise address location.



*The **cancel** button, cancels the application process and displays the Premise Category page.*

Add Telephone/Email contacts.

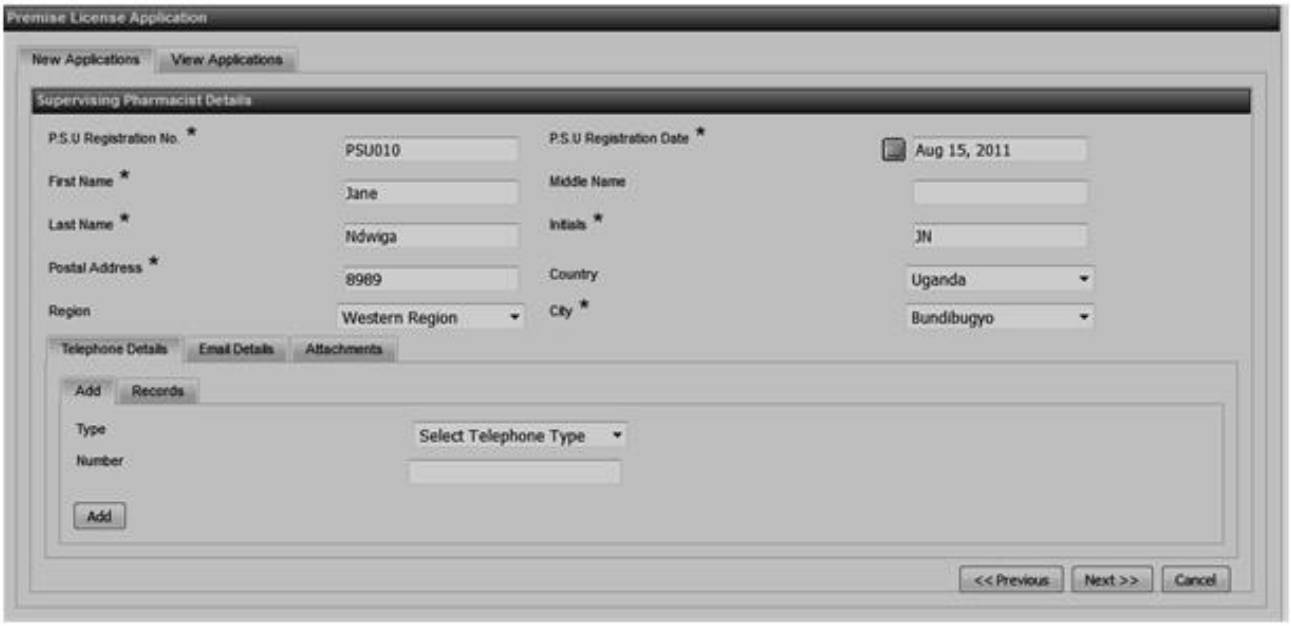
6. To add Telephone/Email contacts :
    a. Click the Telephone/Email Details tab,
    b. Select the type and enter the email address,
    c. Click the add button.

*Clicking the **Previous** button opens the preceding page.*

7. Click on the **Records** tab to view the list of Telephone/Email contacts added, user can delete the added record by clicking the **delete** button.

System displays a message to user after successful addition of a record.

8. Click **next** to enter the **Supervising Pharmacist Details,**



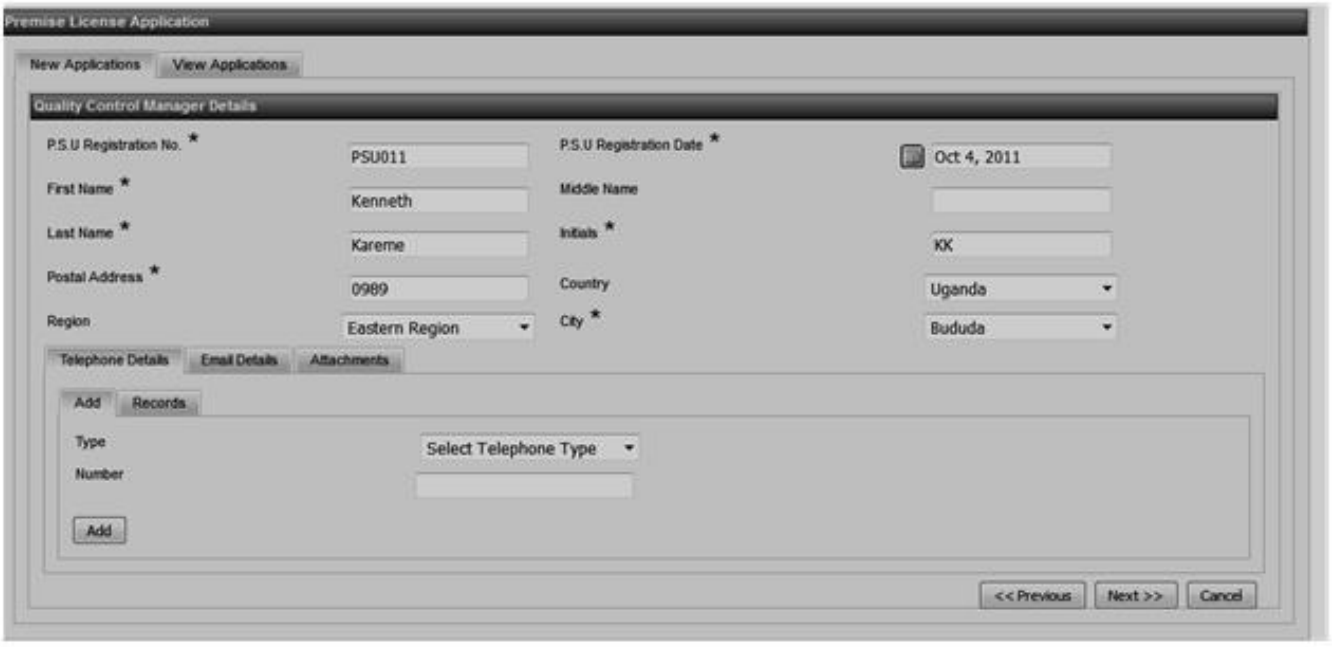
Upload Attachment.

9. To upload an attachment:
    a. Click the attachment tab,
    b. Click the add button and select the file to upload,
    c. Select attachment type,
    d. Click the submit button to upload the attachment.

10. To view the uploaded attachment, click the View Attachment tab.User can also delete the uploaded attachment using the Delete button

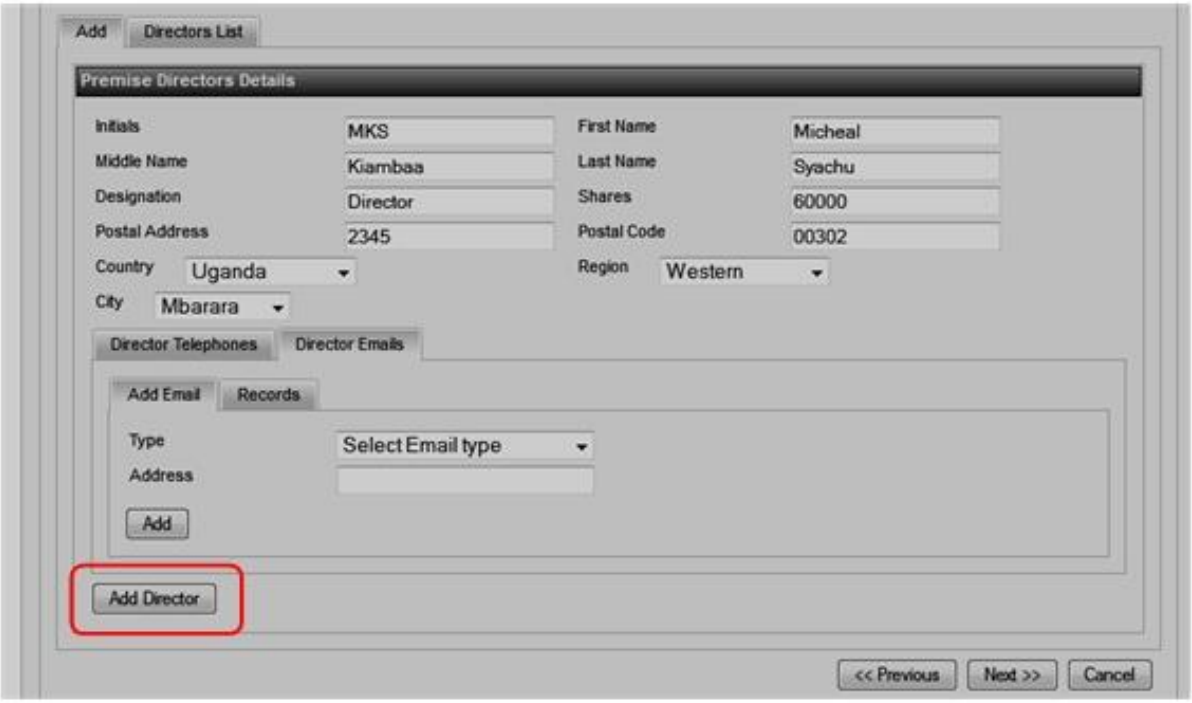
11. Click **next** to enter the **Quality Control Pharmacist Details.**

System automatically populates the Quality control and Supervising pharmacist details if the PSU registration number exists in the database.

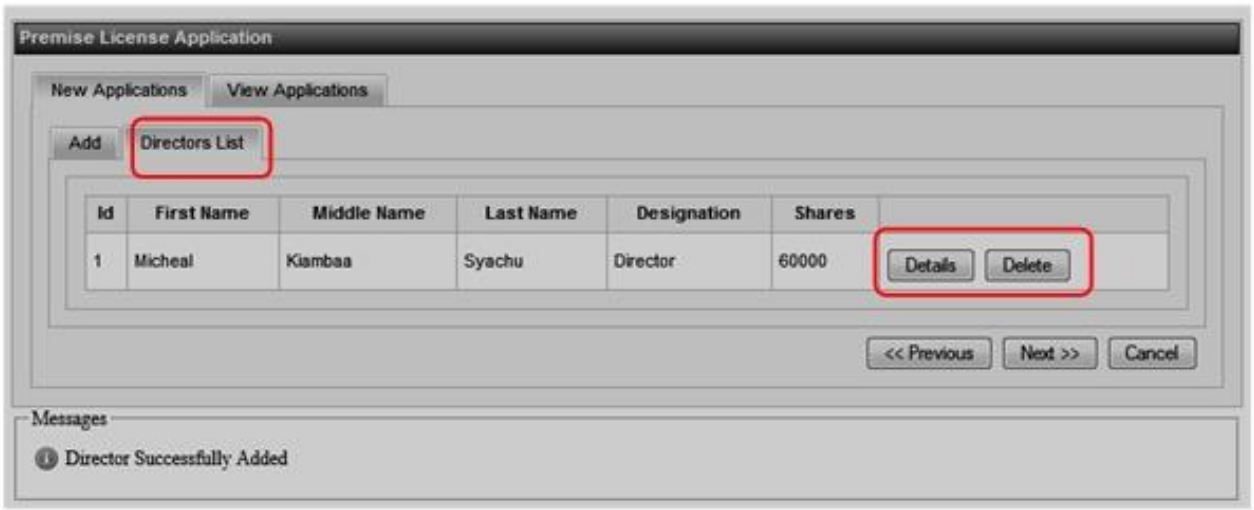


Click **Next** to continue with the registration:

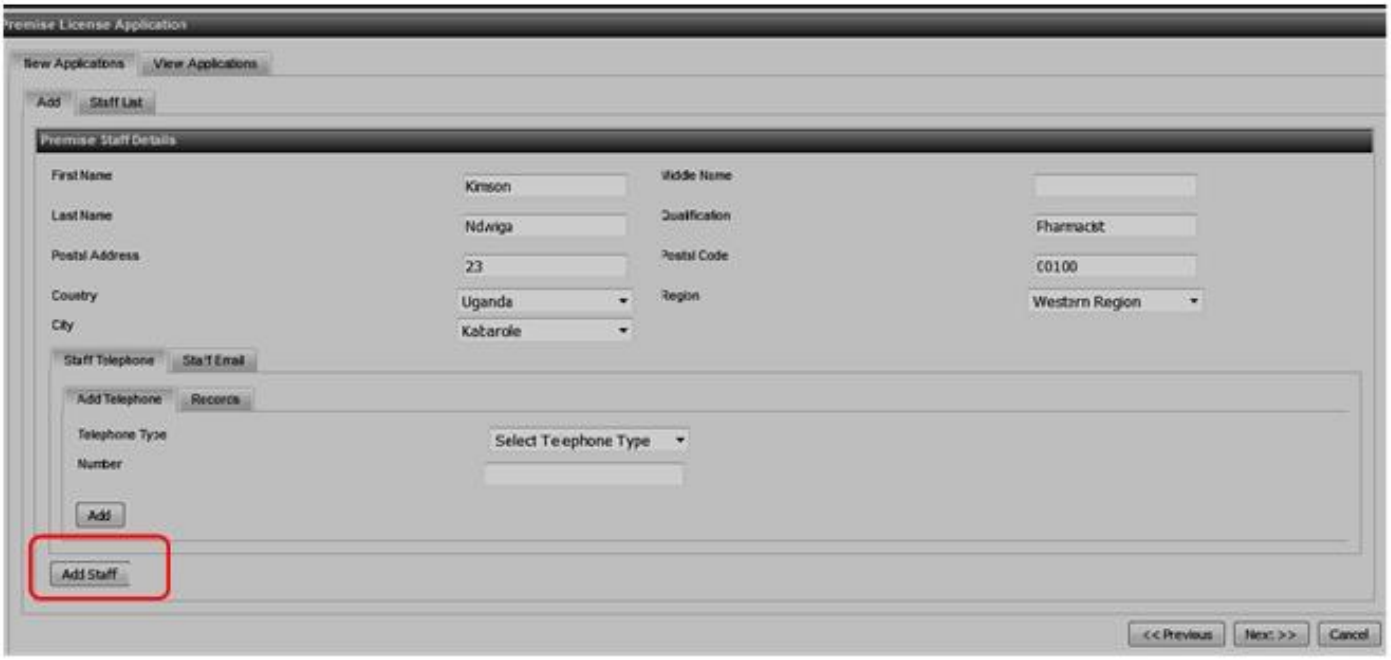
12. Enter the **Premise director details** then click the **Add Director** to add the record.



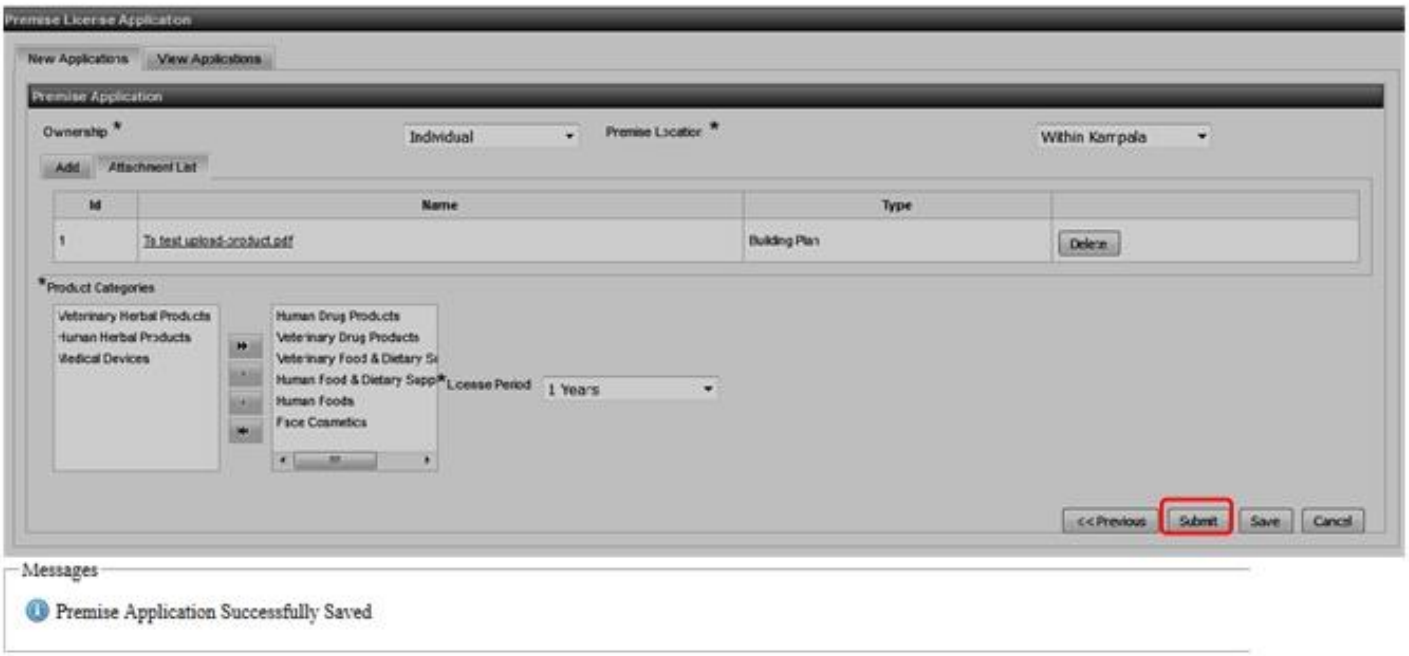
System adds the director record and user can view the details by clicking the **Directors List** tab. Use the **Details** button to view the director details and the **Delete** button to delete the record.



13. Click **Next** to enter the **Premise Staff Details** and add the record.



14. On the last page of application, pick the product category/s, select the ownership and License Period. Upload all attachments requirement required using the **Add Attachment** tab then click **Submit** to complete the application.



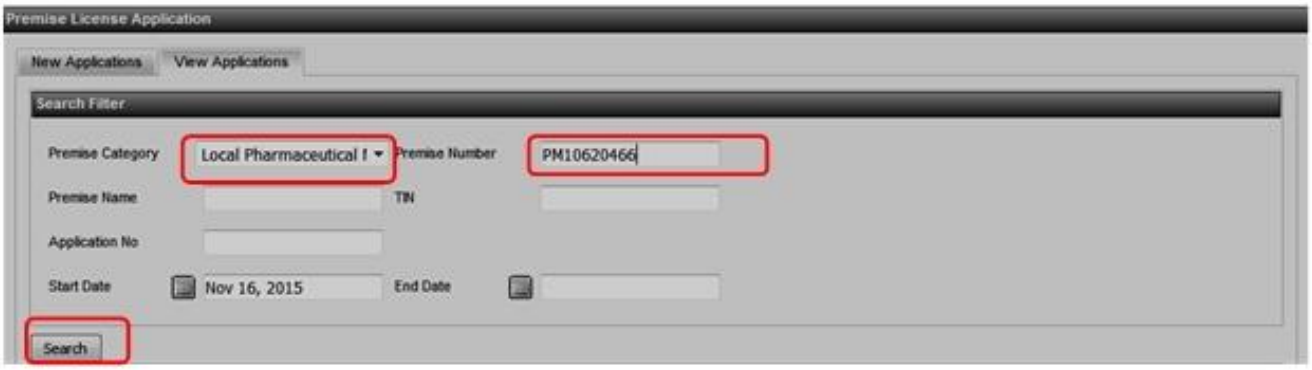
When the application is submitted, it's automatically assigned the status **New Application** and is ready for the Verification process.

Save button is used to partially save the application but the application has not been submitted for processing. The application is assigned the status ***Partially Submitted.***

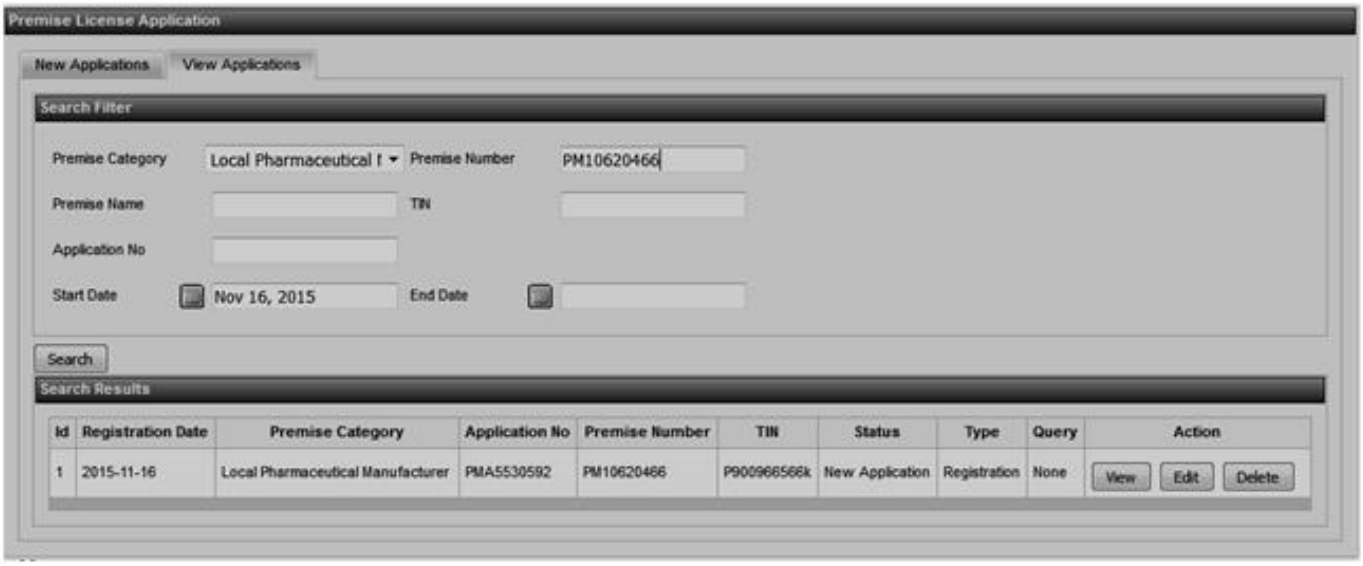
View Applications

Once a user has saved/submitted an application, one can view it using the **view application** feature.

1. Click on **View Application** tab on the Premise License Application page, enter at least one search parameter and click the search button.



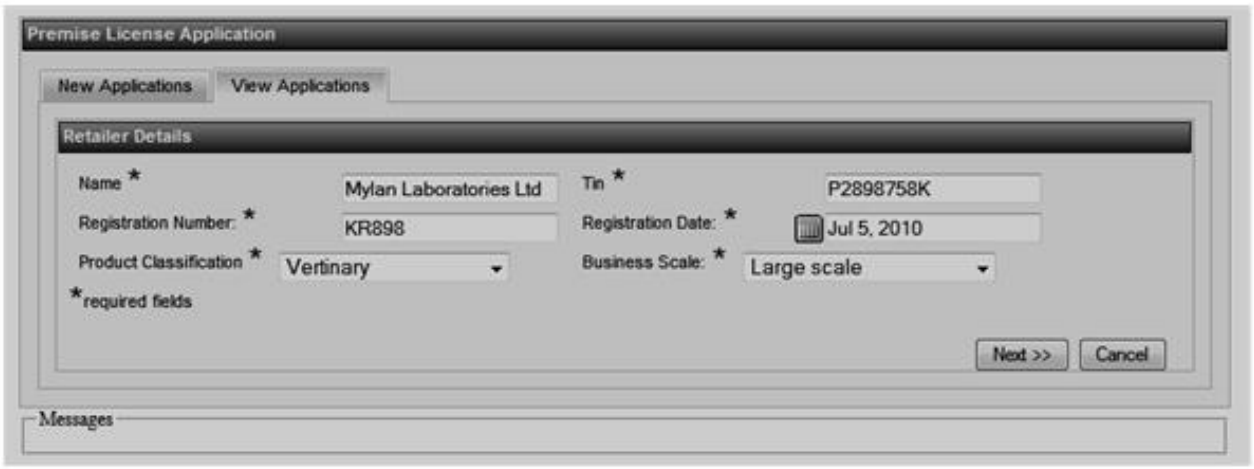
2. System displays the search results as shown below:



The ***status*** *of each application is displayed on the view applications page.*

3. Click the **View** button to review the details of the application, click on each header to expand and view the details.

4. Click **Edit** for the **partially submitted** applications to edit the details of the application. Save/submit on completion.



5. **Delete** button deletes the **partially submitted** application from the system.

GMP Module

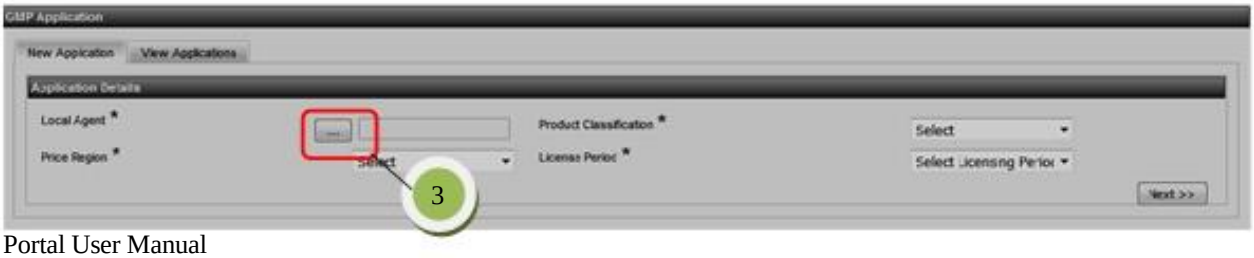
The Module has GMP License registration, License Verification, Invoicing, Technical Screening, License Approval and License Renewal Processes

GMP License registration

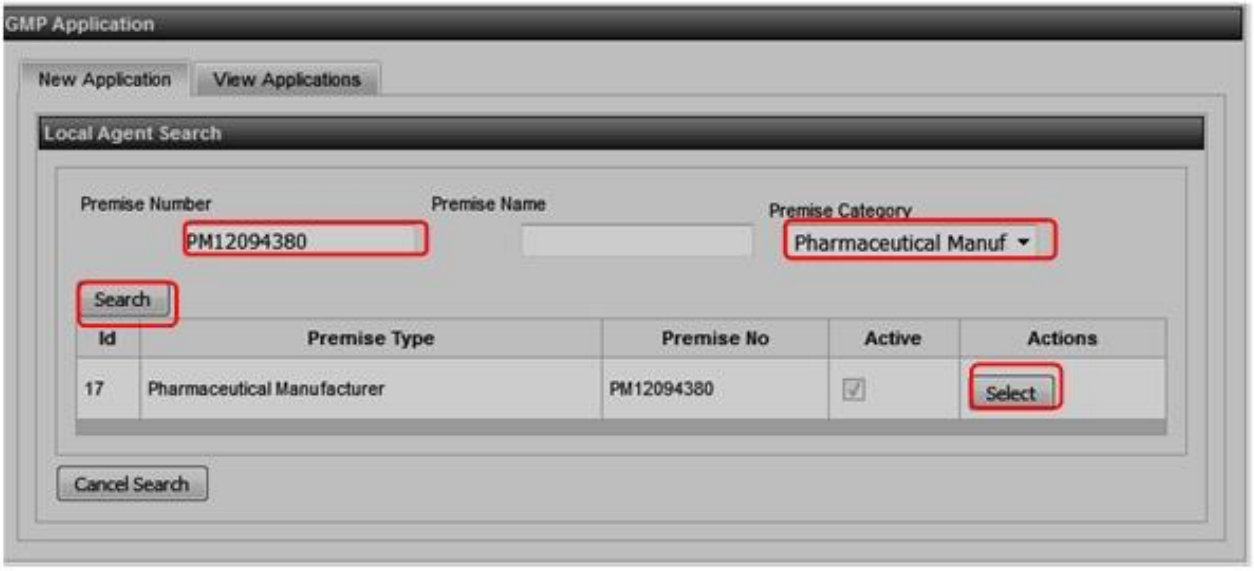
1. Click the **Browse modules** link and select the **GMP Module**

2. On the GMP module page, select **License Application,**

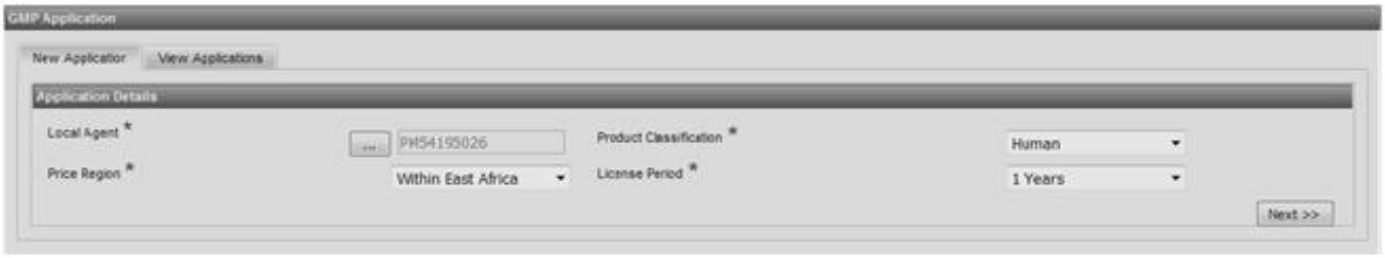
3. On the Application details page, click on the Local Agent tab to select details of the local agent**,**



System displays the page below. Enter the Premise number/Premise name and Premise category then click search. Select the premise displayed.

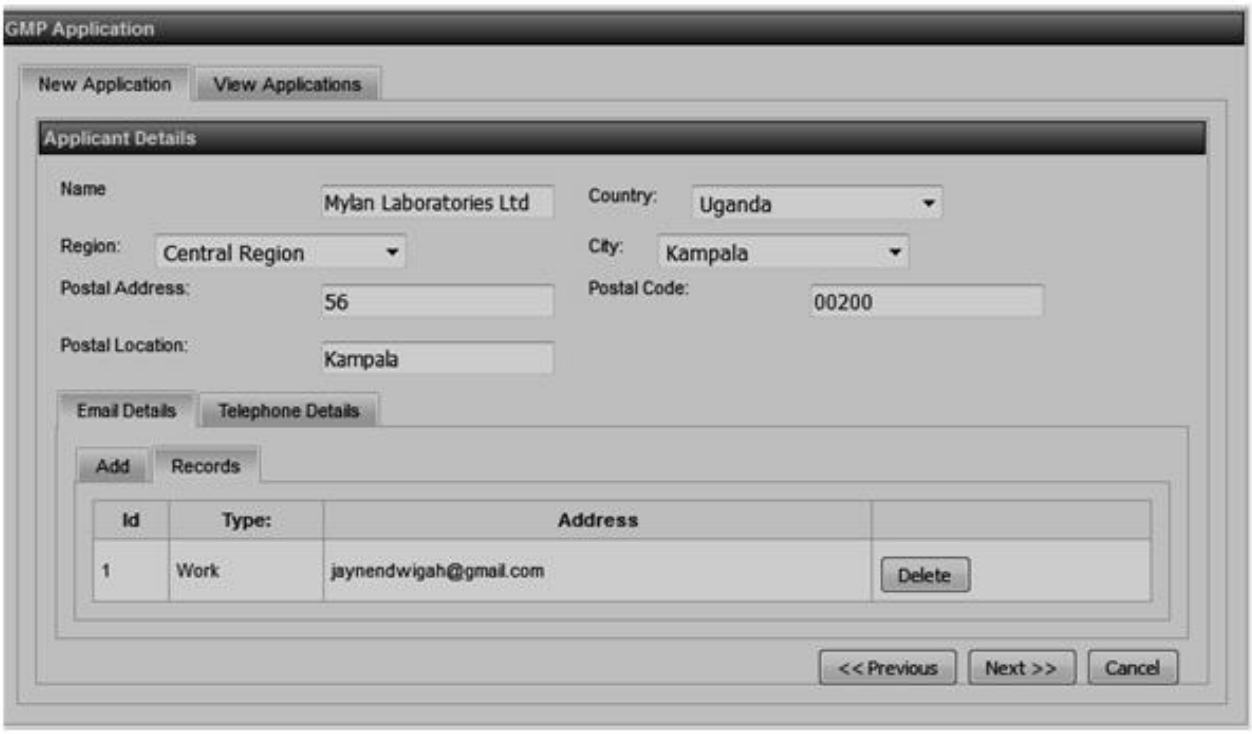


Enter the rest of the details on the Application details page and click the **Next** button,



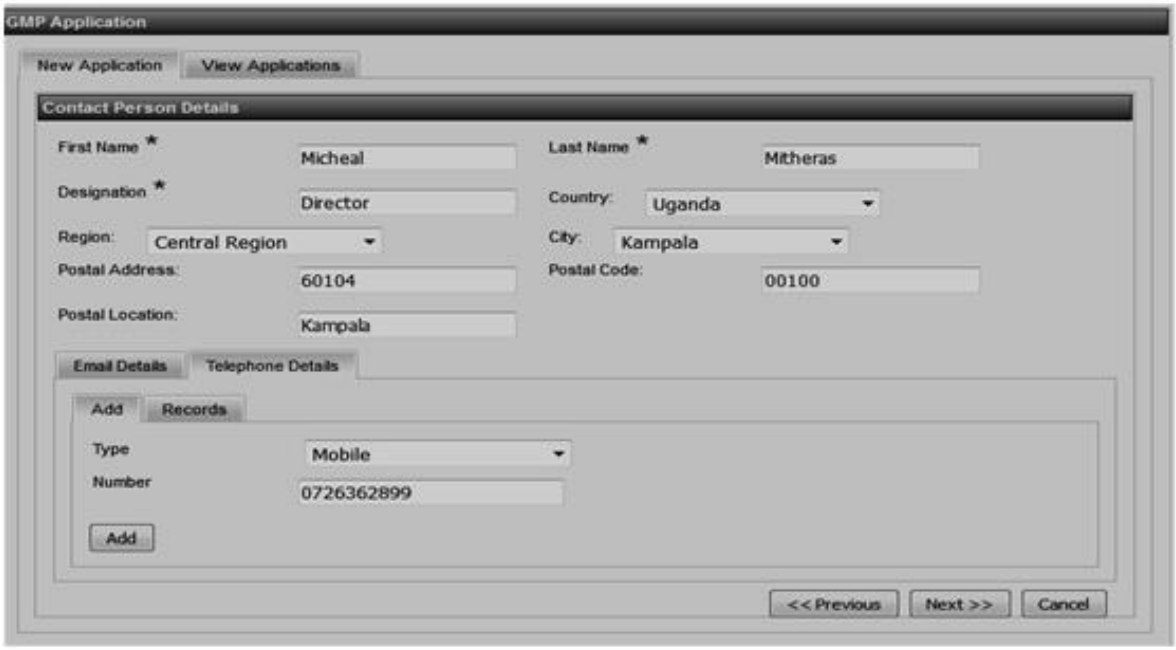
The mandatory fields are marked in red asterisks.

4. Enter the Applicant details and click next:



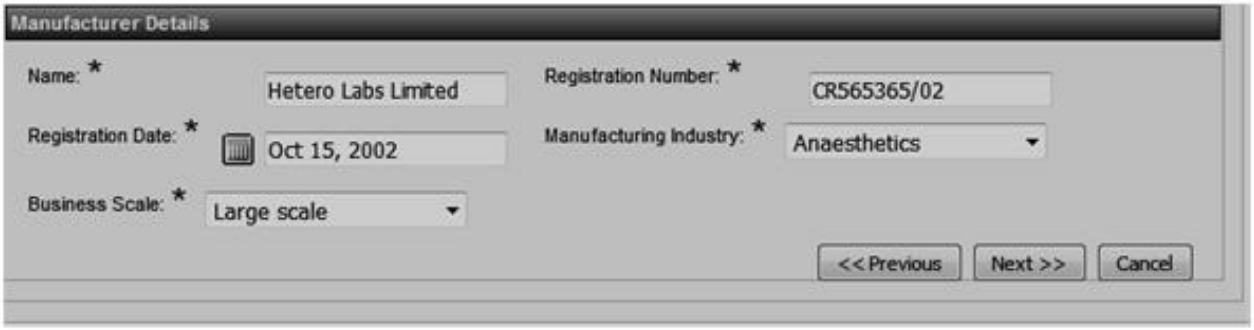
See how to add Email/Telephone details on Premise License Registration section.

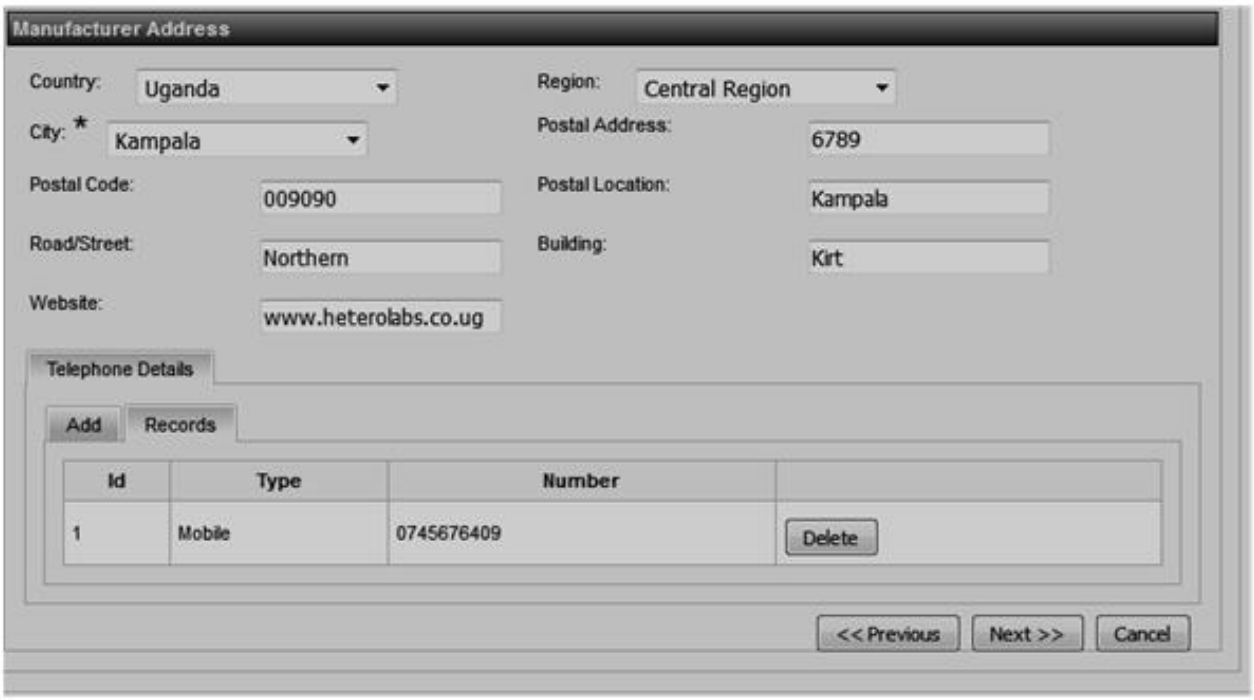
5. Enter the Contact Person Details and click next:



*The **cancel** button, cancels the application process and displays the first page.*

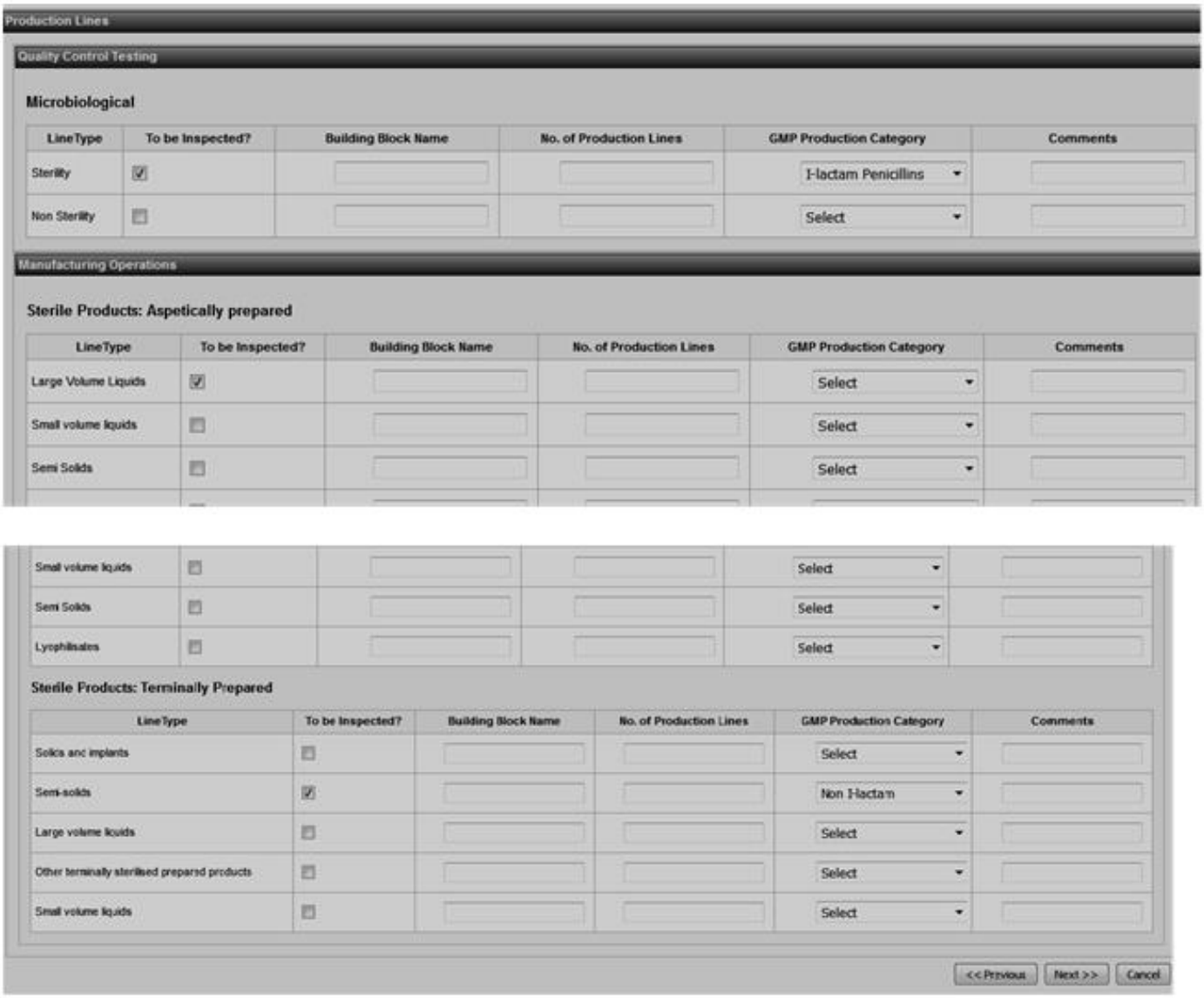
6. Enter the Manufacturers Details/Address and click next,



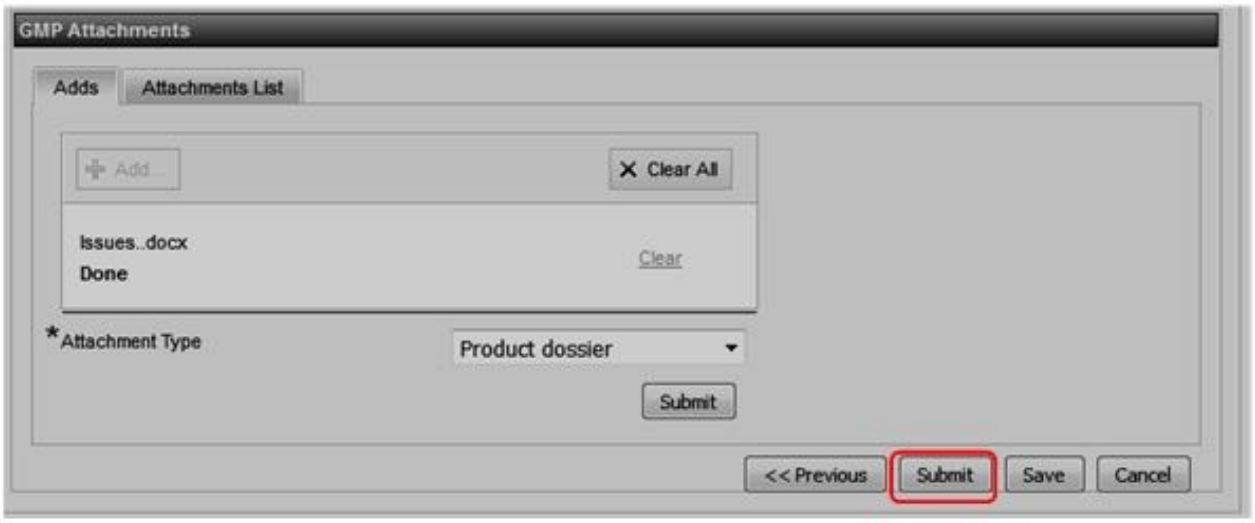


*Clicking the **Previous** button opens the preceding page.*

7. Enter details for the Production Lines:



8. Upload attachments (Help) for the application and click the Submit button to complete the application.



System displays a message to user after successful addition of a record.

When the application is submitted, it's automatically assigned the status **New Application** and is ready for the Verification process.

Save button is used to partially save the application but the application has not been submitted for processing. The application is assigned the status ***Partially Submitted.***

a)

View Applications

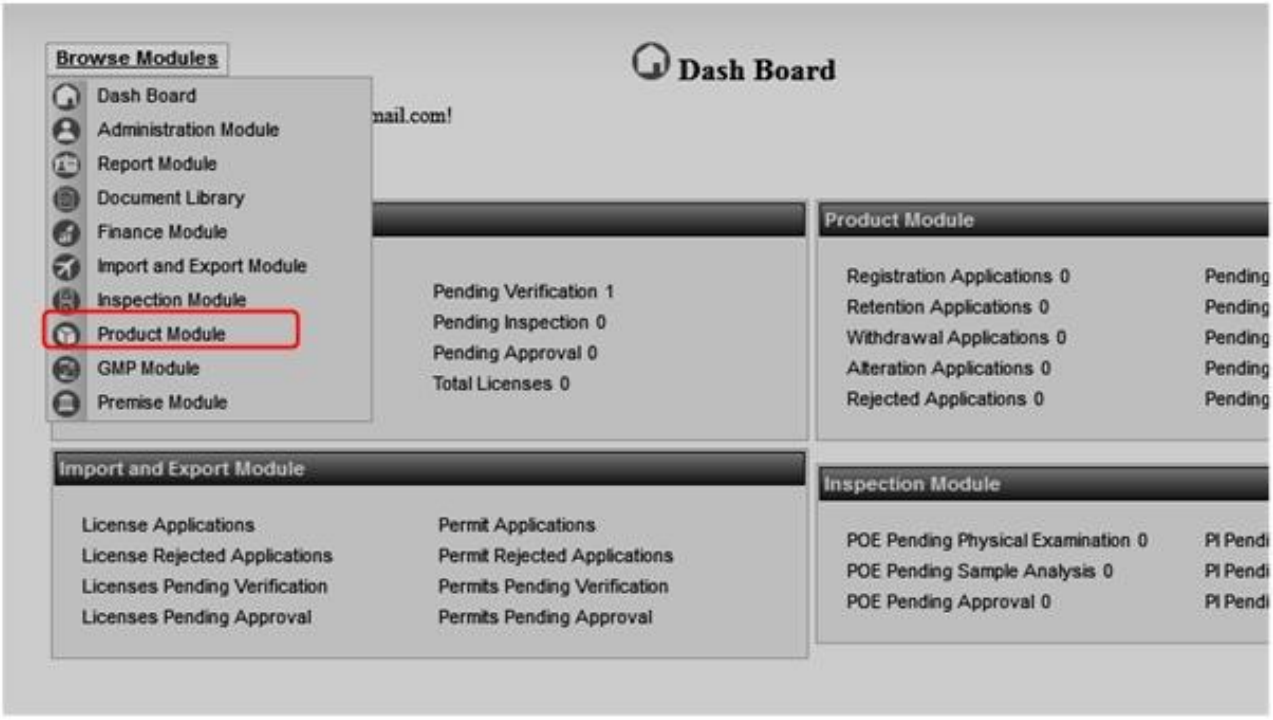
How to view the GMP application submitted/saved.

Product Module

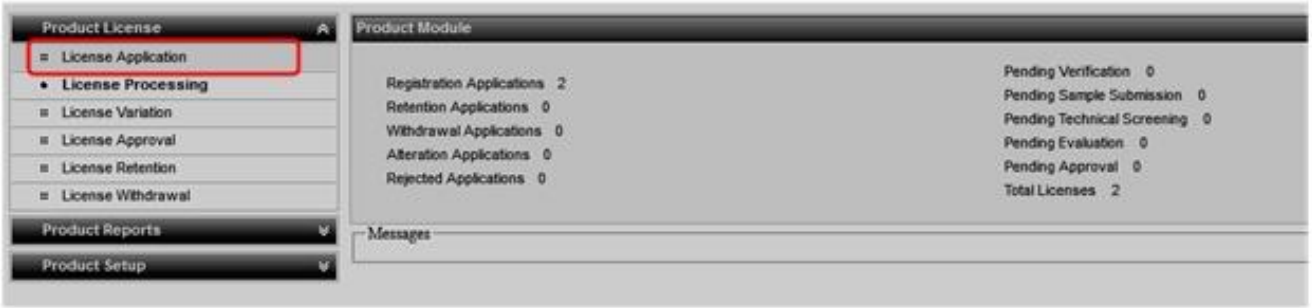
The Module consists of product License application, License Processing, License Approval, License Variation, License Retention and License Withdrawal Processes.

Product License Application

1. Click the **Browse modules** link and select the **Product Module**

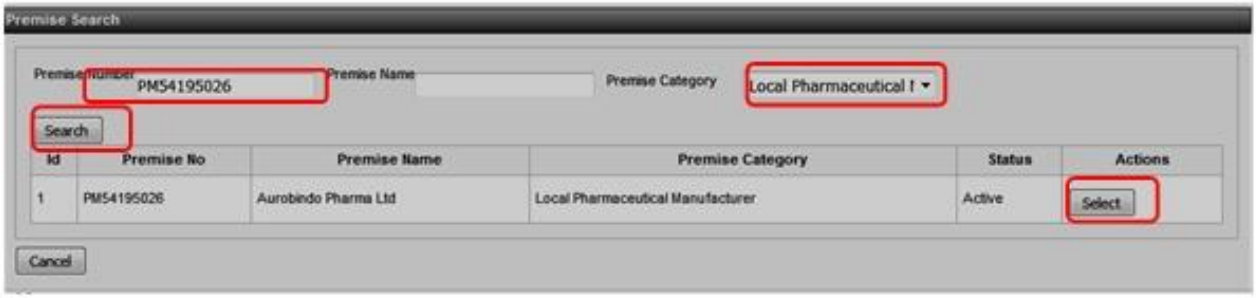


2. On the Product module page, select **License Application,**



3. On the New Applications page, click on the **Local Agent** button to select the local agent**,**

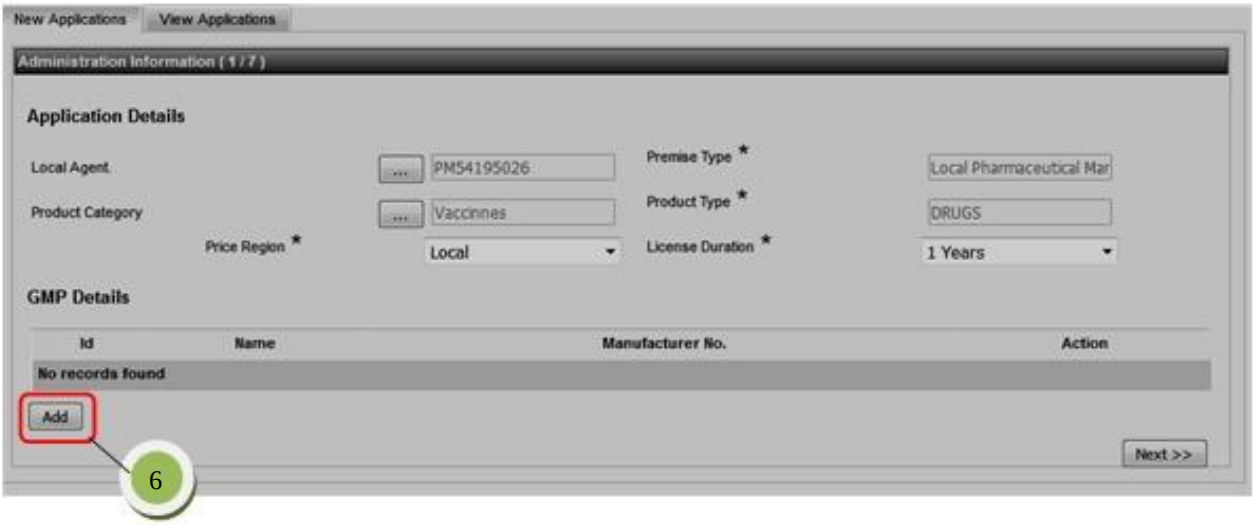
System displays the page below. Enter the Premise number/Premise name and Premise category then click the **Search** button. Select one premise displayed to proceed.



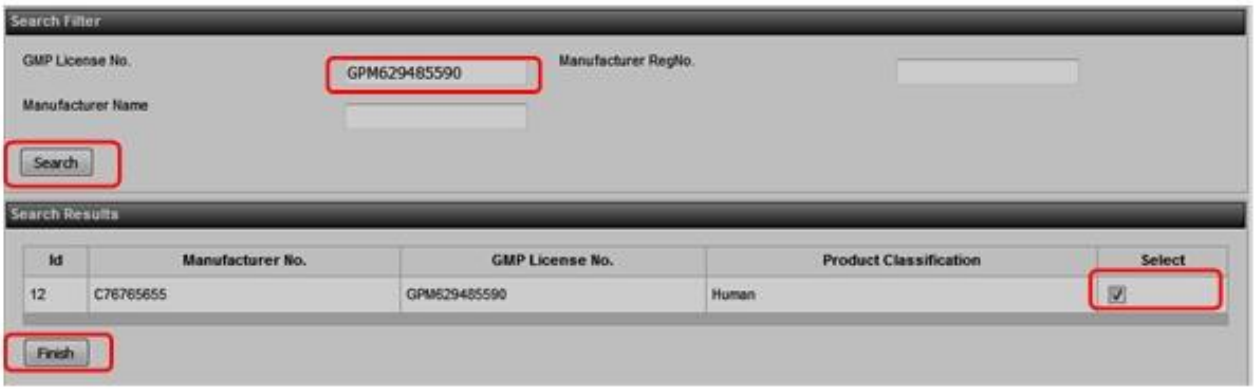
4. Repeat step 3 to select the Product Category and Product type:

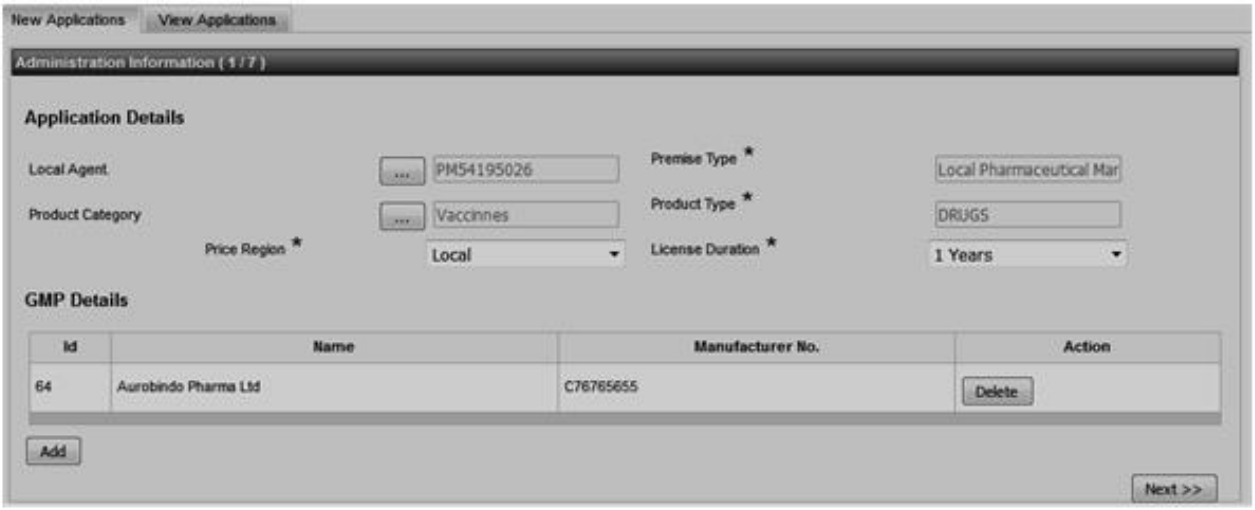
The mandatory fields are marked in red asterisks.

5. Select the Price region and the License Duration,



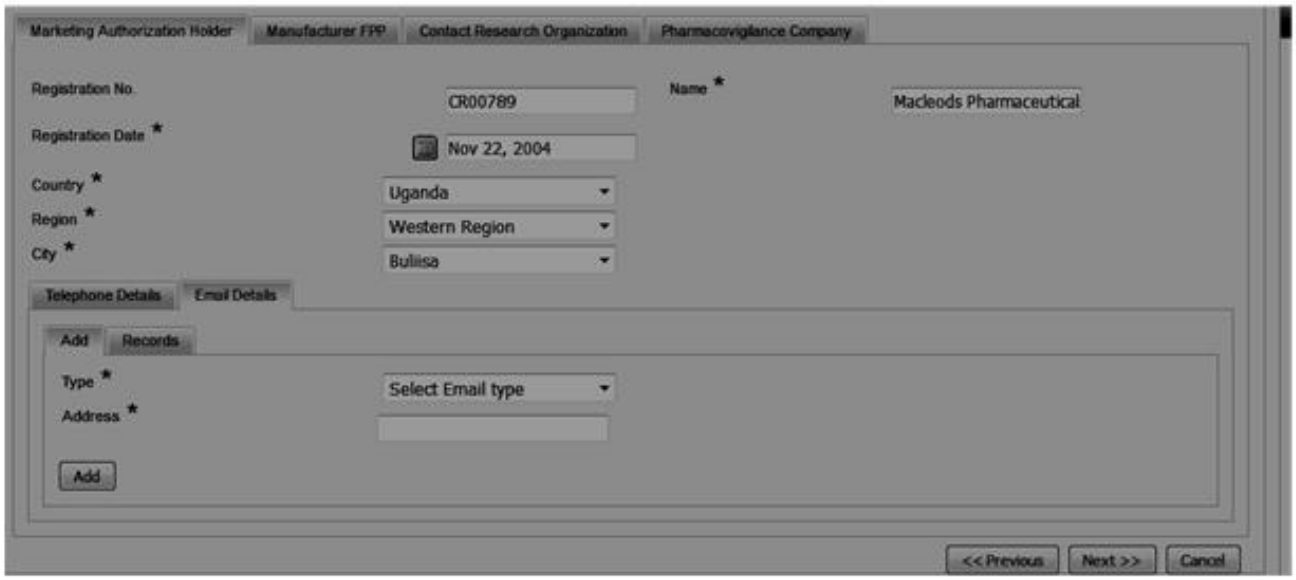
6. To add The GMP details, click the **Add** button. On the GMP Manufacturer Search page displayed, enter any of the Search parameters and click the **Search** button.
   Select the GMP License displayed in the search results and click the **Finish** button.





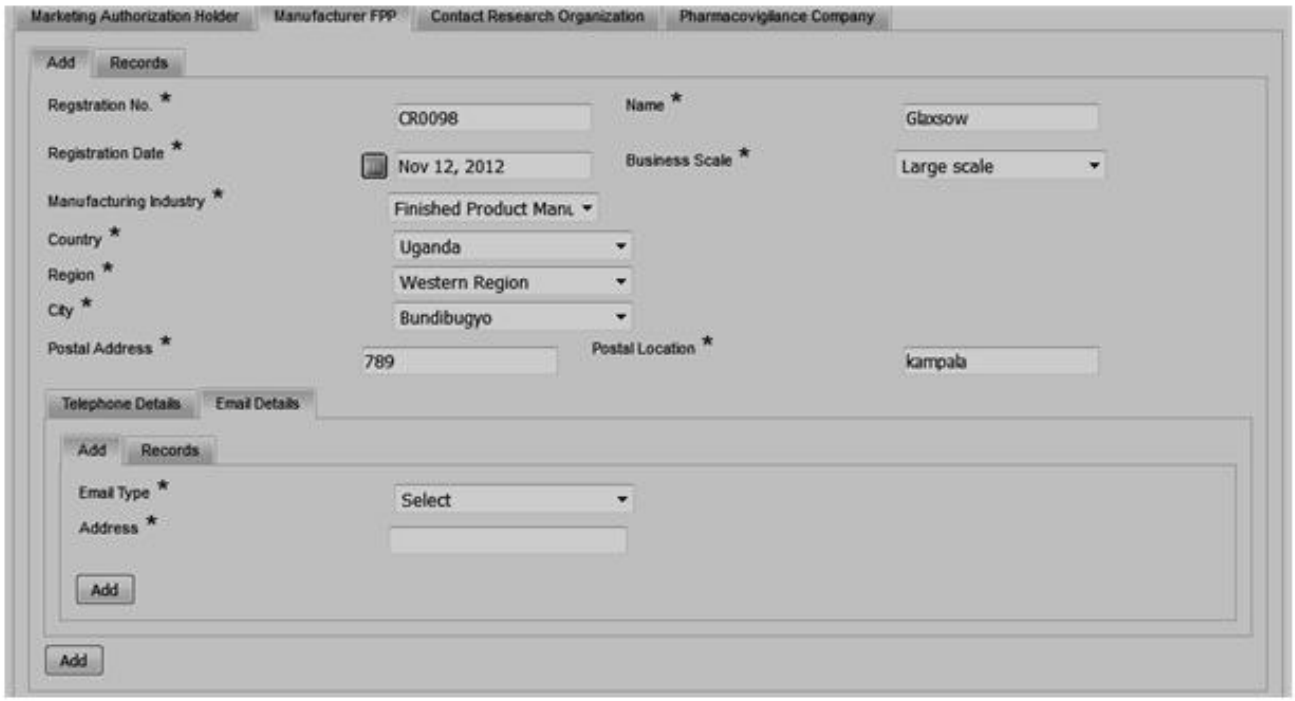
7. Click the Next button to proceed.

8. On the Administration Information page 2, enter the
    a. Marketing Authorization Holder details



*Clicking the **Previous** button opens the preceding page.*

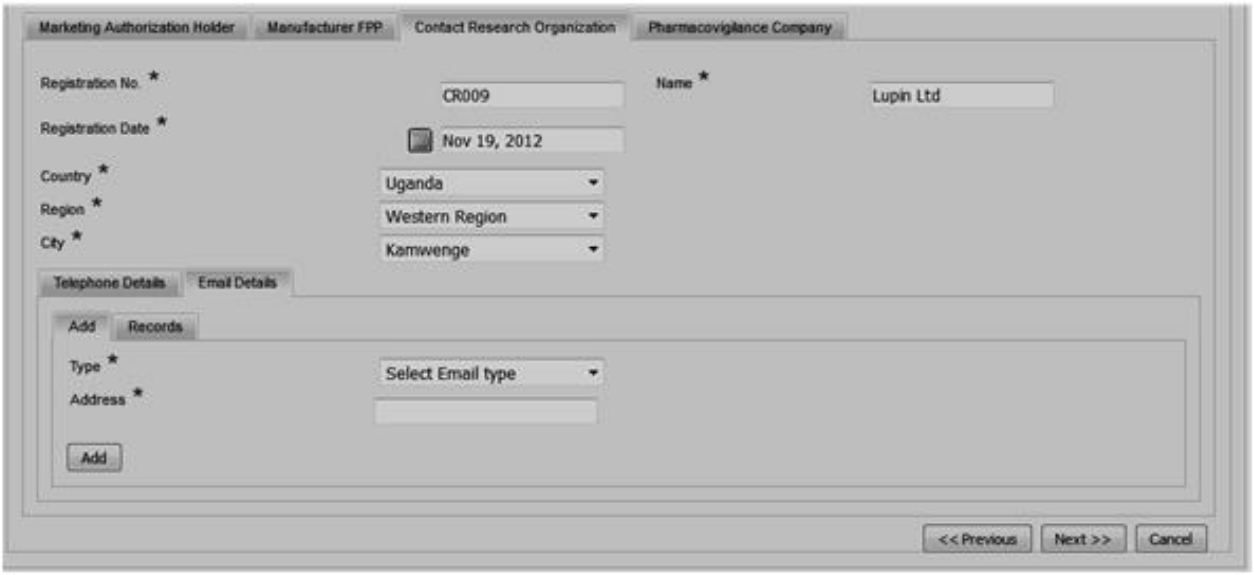
    b. Click the **Next** button to enter the Manufacturer FPP details :



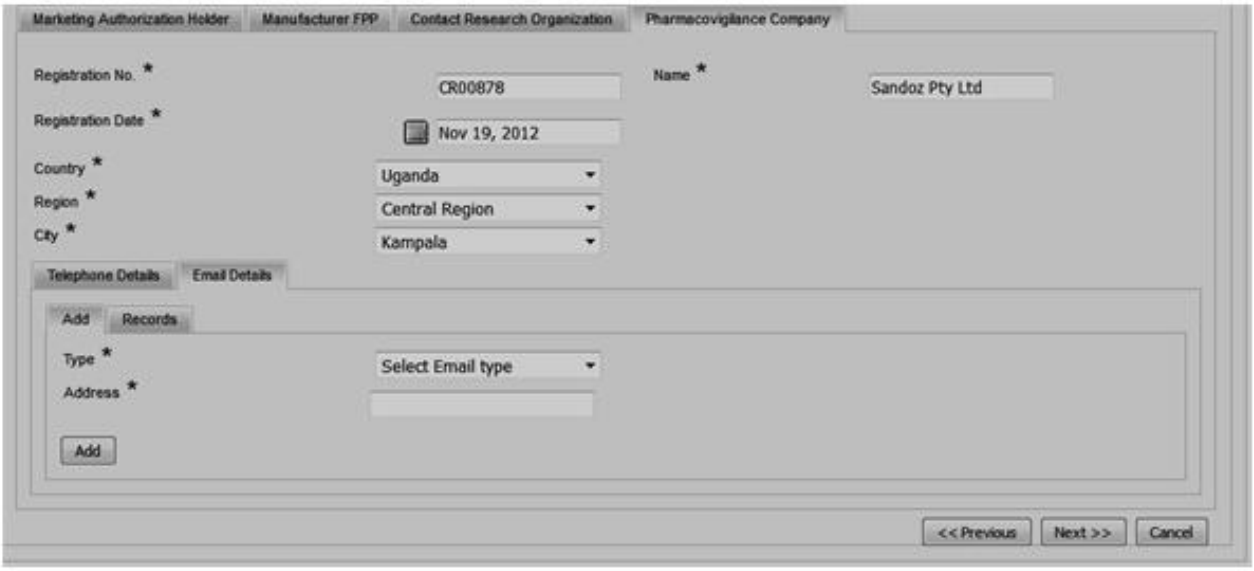
After entering the Manufacturer FPP details click the **ADD** button to add the record. Click the **Records** tab to view the added record:

See how to add Email/Telephone details on Premise License Registration section.

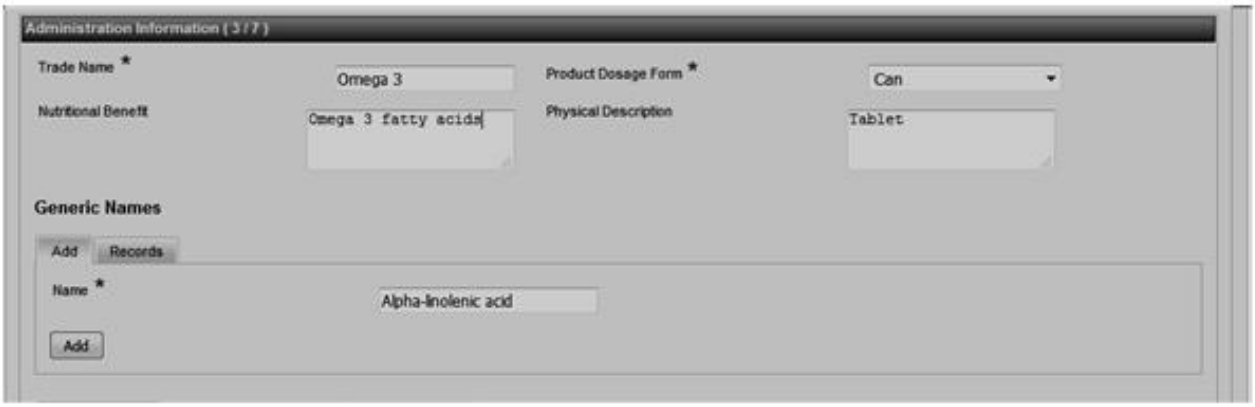
c. Click the **Next button** to enter the Contact Research Organization details



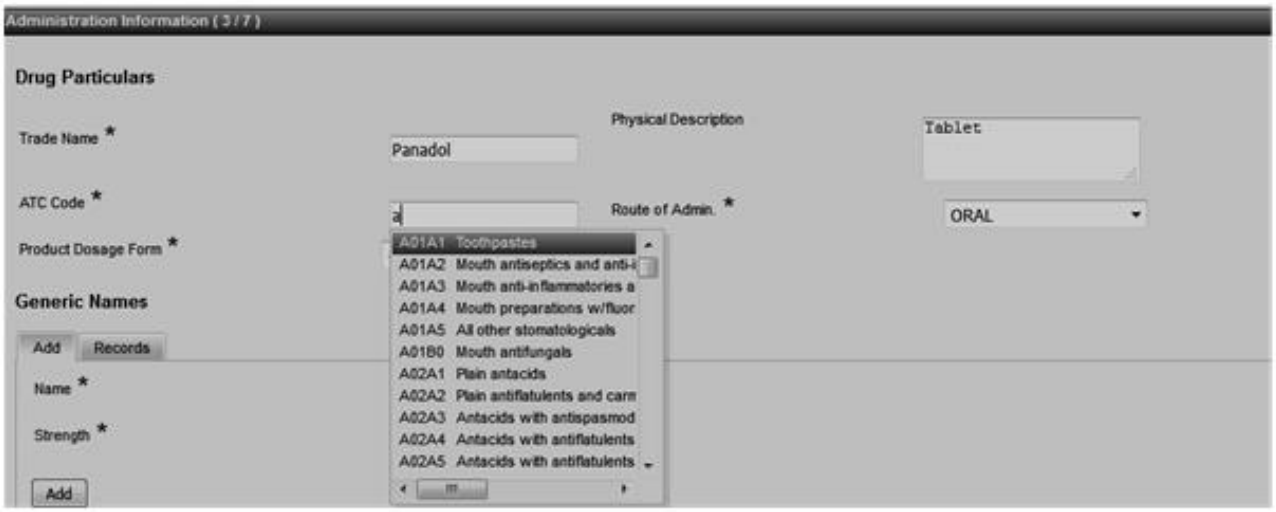
d. Click the **Next** button to enter the Pharmacovigilance Company details



9. Click the Next button to proceed to the next page.
10. On the Administration Information page 3: Add the product description details :

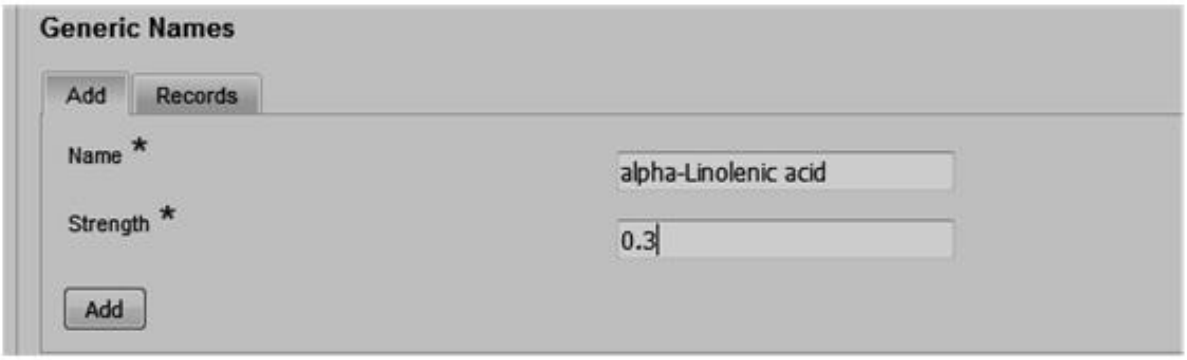


For Drug registartion, when adding drug particulars, System will auto-populate the list of the ATC codes when you enter the first letter on the **ATC code** text field.

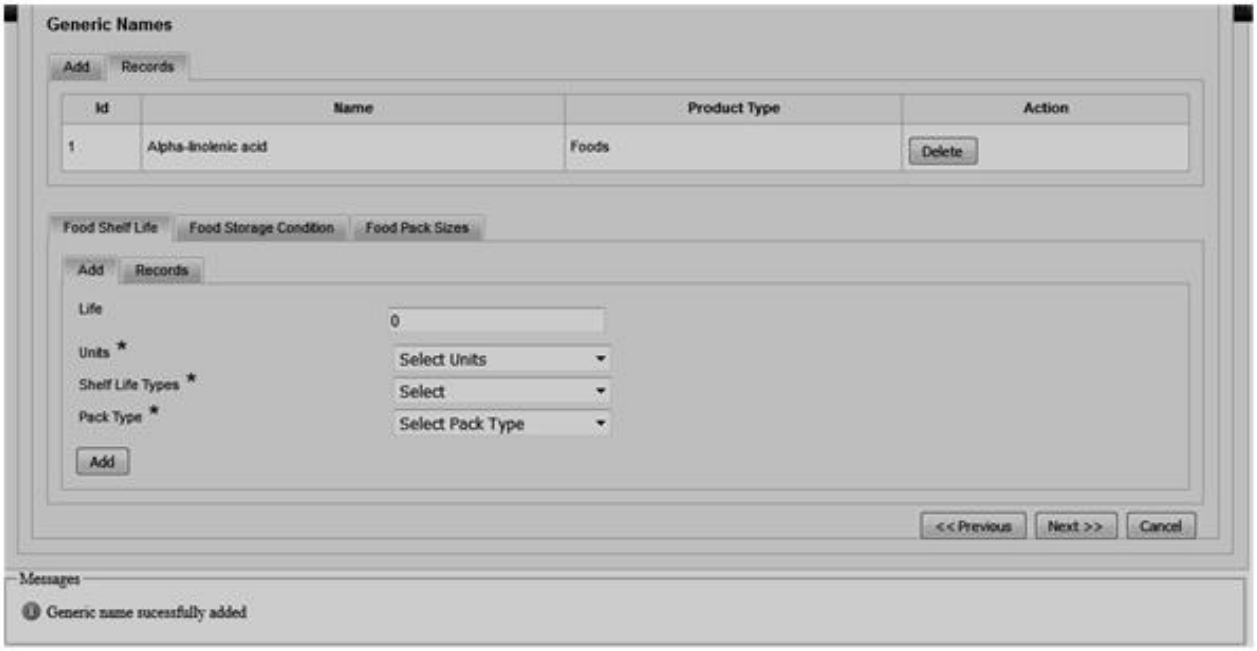


11. Proceed to add the Generic name records.

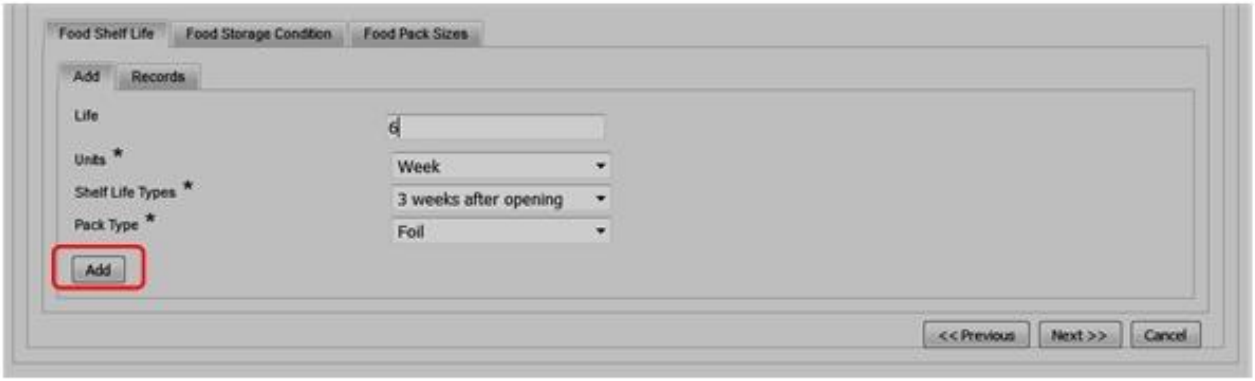
Click the **ADD** button to add the Generic name record



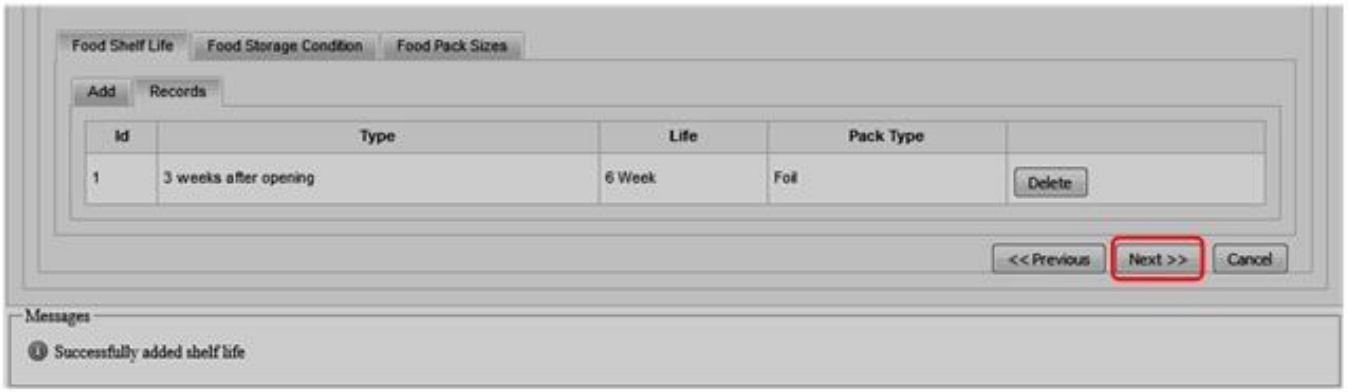
Click the **Records** tab to view the added record.



12. Enter details for the shelf-Life and click the **Add** button to add the record.



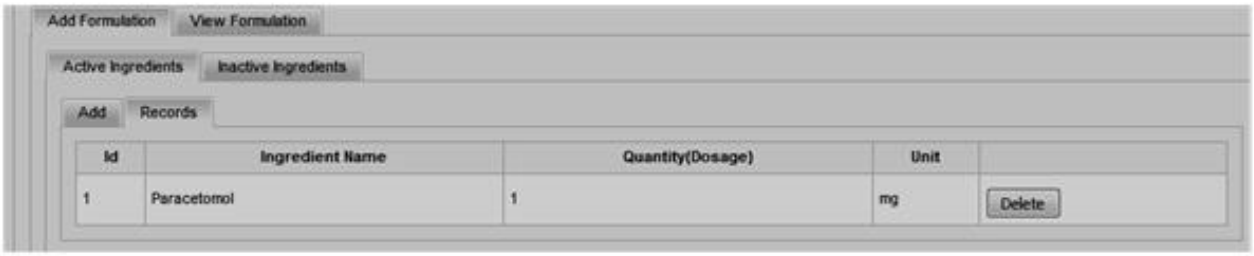
Click the **Records** tab to view the added record.



13. Repeat **step 11** to add the Storage Condition and Pack size records and click the **Next** button to proceed.

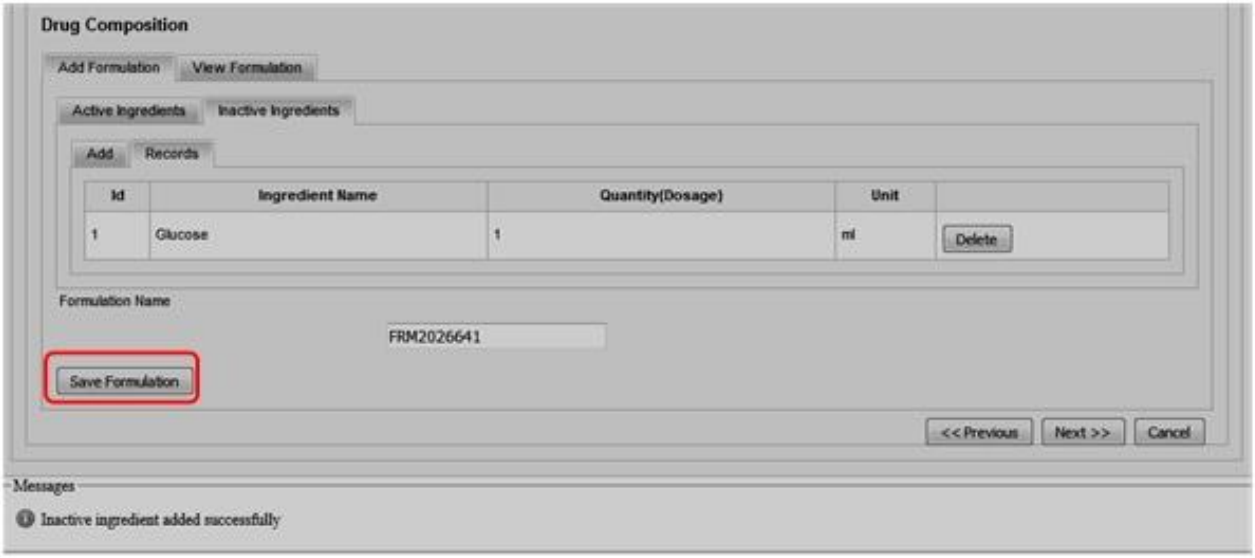
14. On the Administration Information page 4:
    To add the Active Ingredients of the Product formulation, enter the manufacturer and the rest of the details, then click the **ADD** button to save the record:

To view the saved record, click the **Records** tab:



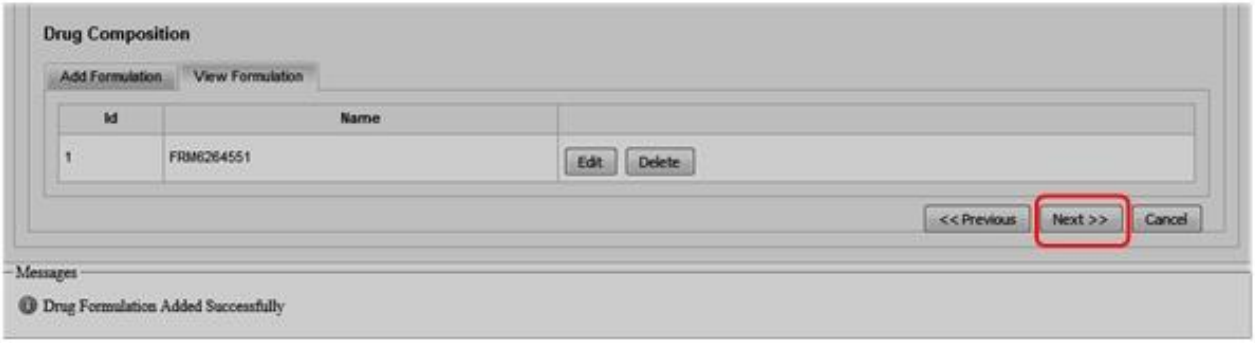
Repeat **Step 14** to add Inactive Ingredients of the formulation.

15. After adding the Active/Inactive Ingredients of the formulation, click the Save Formulation button to save the Formulation details:

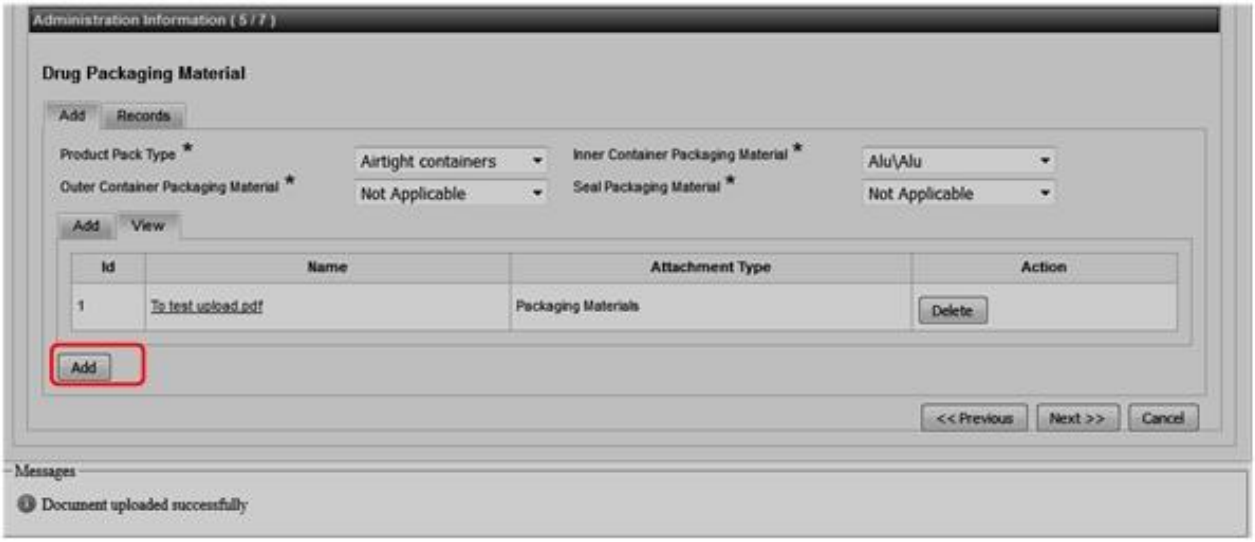


System displays a message to user after successful addition of a record.

To view the saved record, click the **View Formulation** tab:

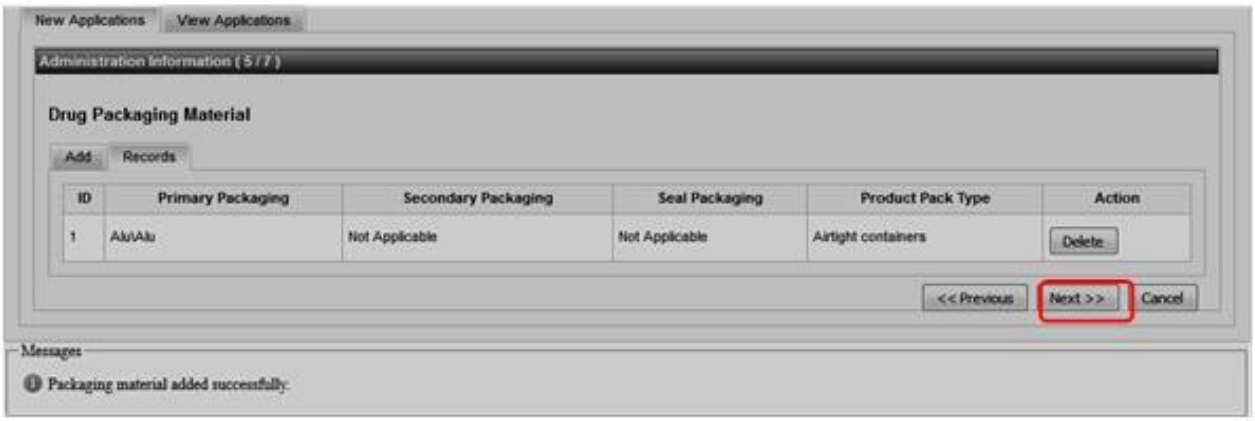


16. Click the Next button to proceed.
17. On the Administration Information page 5: Enter the product packaging material and upload the supporting documents (Help).



Click the **Add** button to save the packaging material records.

*The **cancel** button, cancels the application process and displays the first page.*



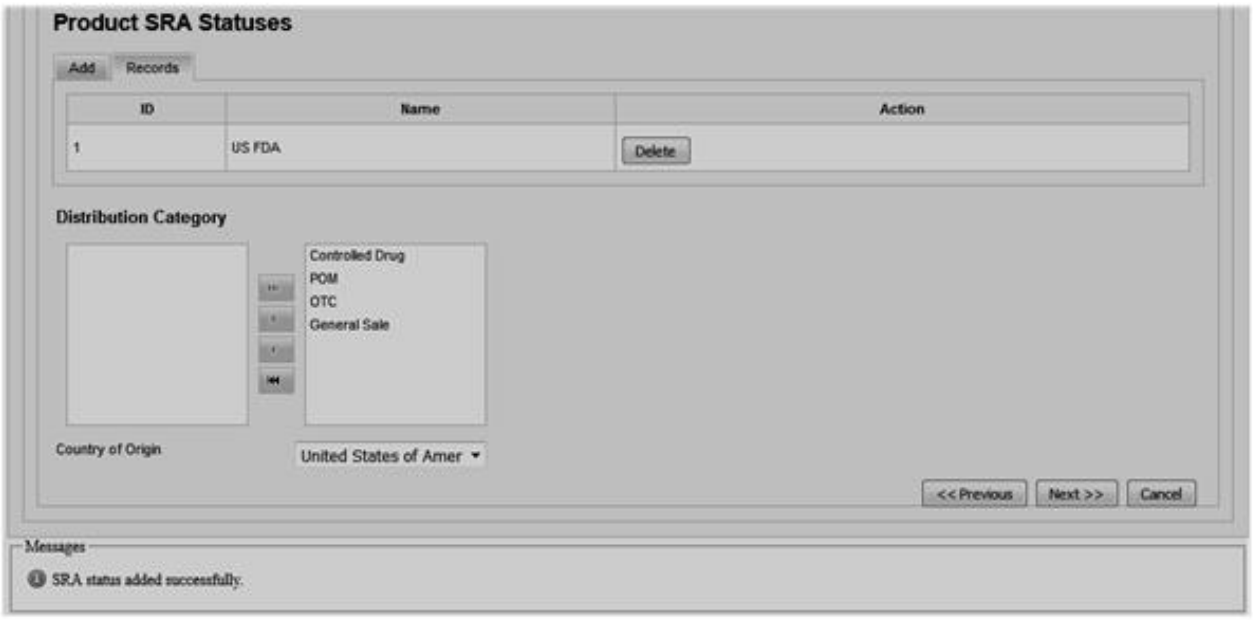
18. Click the Next button to proceed.
19. On the Administration Information page 6: Enter the authorized country details and upload supporting documents. Click the **ADD** button to save the record.

To view the saved record, click the **Records** tab:

Repeat **step 19 to** add records for Refused/Withdrawn/Suspended Countries

20. Proceed to enter the product SRA statuses records:

21. Select the distribution Categories and click **Next**:



22. On the Administration Information page 7: Upload all supporting documents for the product application.
    Click **Submit** button to submit the completed application

Save button *is used to partially save the application but the application has not been submitted for processing. The application is assigned the status* ***Partially Submitted.***

System displays the Pop-up message below after successful Submission of the application.

When the application is submitted, it's automatically assigned the status **New Application** and is ready for the **Verification process.**

Save button is used to partially save the application but the application has not been submitted for processing. The application is assigned the status ***Partially Submitted.***

View Applications

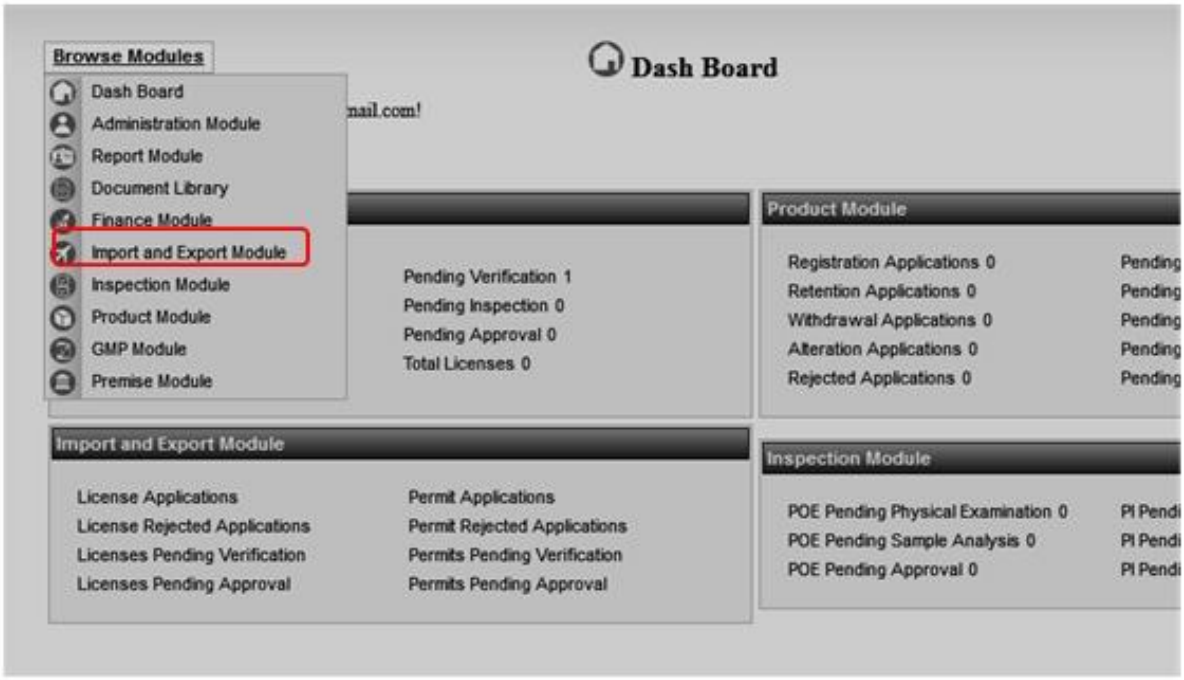
How to view the Product application submitted/saved.

Import and Export Module

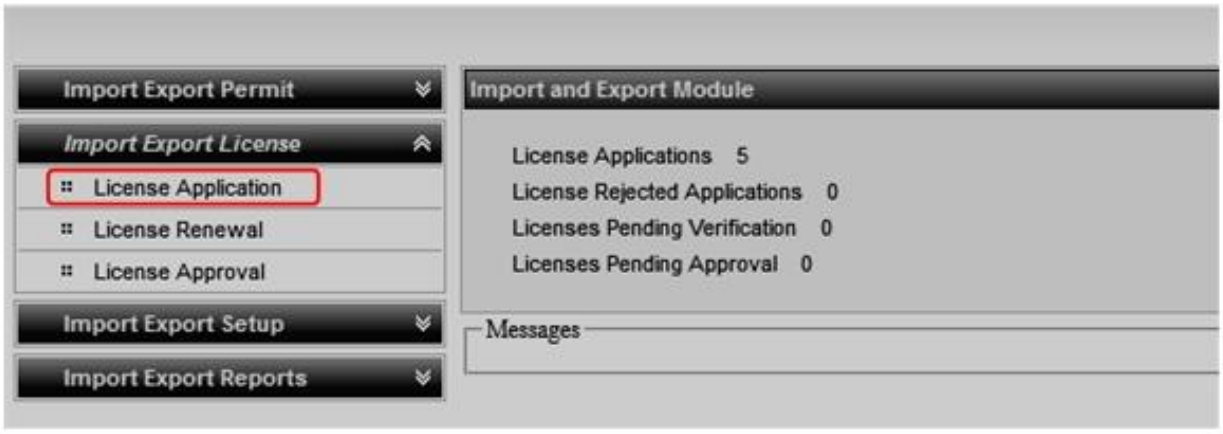
The Module has the Import Application, Permit Verification, Permit Approval, License Application, License Renewal, License Approval Import Export setups and Reports processes.

License Application Procedure

1. Click the **Browse modules** link and select the **Import and Export Module**

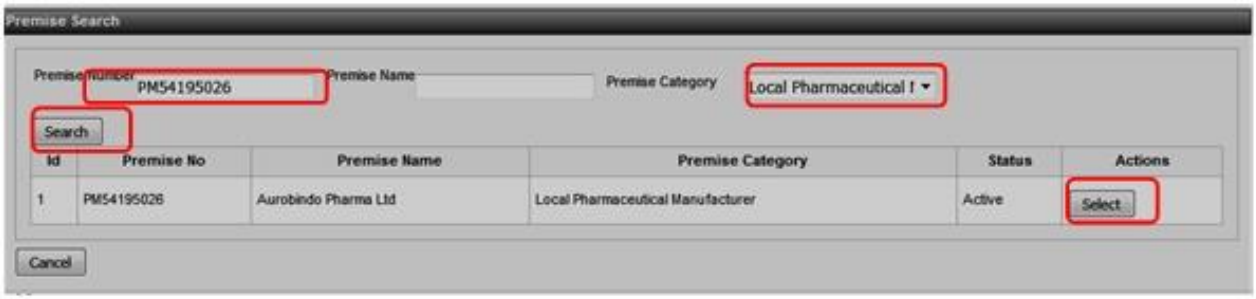


2. On the **Import Export license** sub module , select **License Application,**



3. On the license application page, click the **Local Agent** button:

System displays the page below. Enter the Premise number/Premise name and Premise category then click the **Search button**.
Click the **Select** button to select a premise.



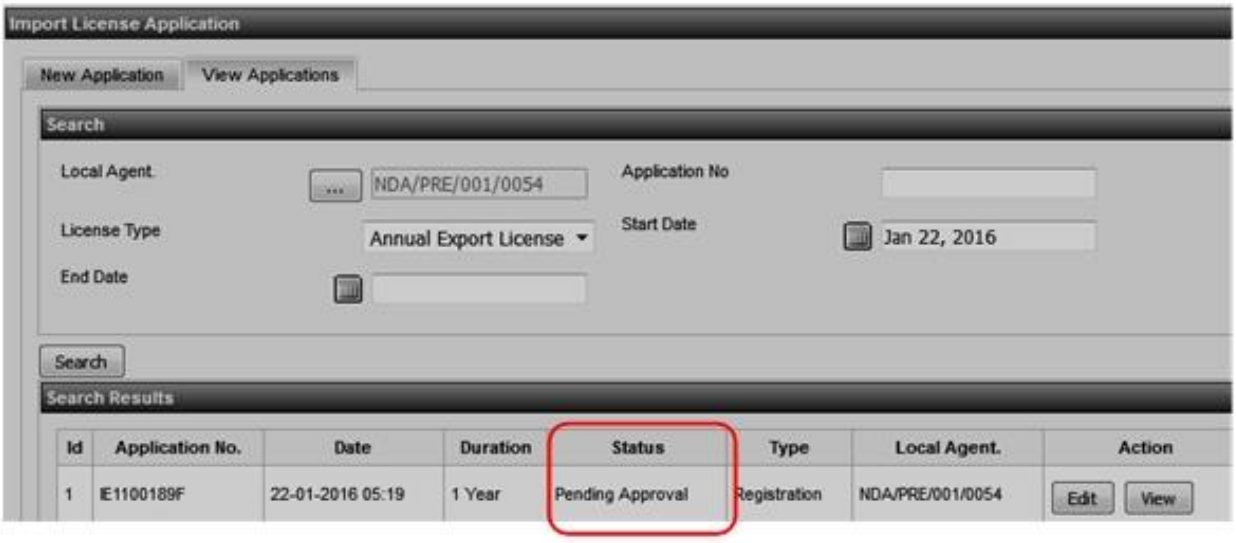
The mandatory fields are marked in red asterisks.

4. Back on the License Application page, select the **Product Classification** from the dropdown. System displays the **Product Categories** registered for the local agent**.**

5. Select the **Product Categories, License Type and License Duration** and click the **Submit** button:

   System displays the message below to show successful submission of an Import or Export License Application:

The License application is created in the system and assigned the status **Pending Approval.**



View Applications

How to view the License application submitted.