UNITED ARAB EMIRATES
MINISTRY OF HEALTH & PREVENTION

E-SERVICES APPLICATION USER MANUAL

Registration Services

Table of content

COPYRIGHTS AND CONFIDENTIALITY **3**

INTRODUCTION **4**

1 USER CREATION AND LOGIN **5**

1.1 User Creation 5
1.2 Login and dashboard 7

2 REGISTRATION **9**

2.1 Drug Classification 10
2.2 Manufacturing site registration 15
2.3 Drug Registration 22
2.4 Registered medical product minor variation 32
2.5 Request for drug Re-Pricing 39
2.6 Manufacturing site minor variation 49
2.7 Evaluation of drug vigilance plan 56
2.8 Drug Classification 62

3 ISSUING CERTIFICATES **63**

3.1 Pricing Certificate 63
3.2 Certificate of Pharmaceutical Product (CPP) for Export Purposes 68
3.3 Free Sale Certificate for Export Purposes 74

COPYRIGHTS AND CONFIDENTIALITY

This document is submitted with understanding that the registration user manual information contained herein this document shall not be disclosed outside the recipient's used, shall not be duplicated, used or disclosed in whole or in part for any purpose.

The reader acknowledges that the information provided by MoHAP is confidential; therefore, reader agrees not to disclose it without the express written permission of MoHAP.

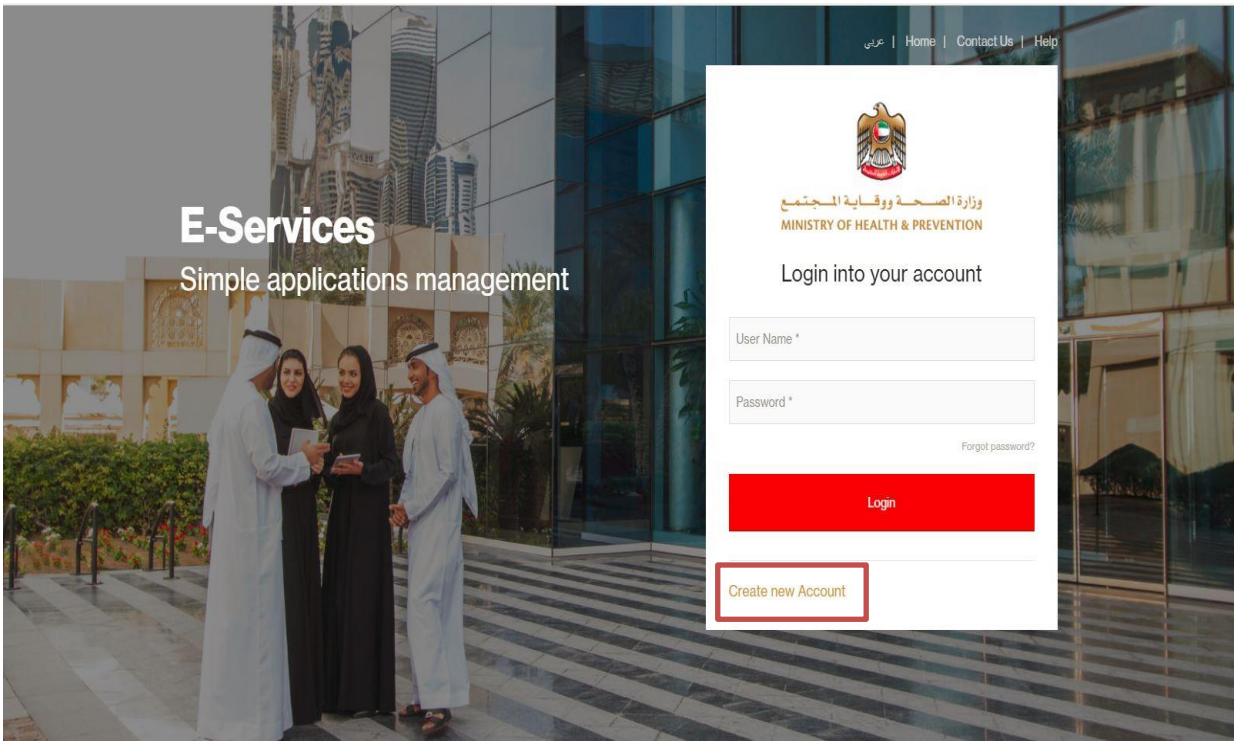
INTRODUCTION

This document explains all the steps which are required for Site Administrator and agent user to create and view registration applications.
This document will provide ease to the business users in understanding all the screens of the application.

1 User Creation and Login

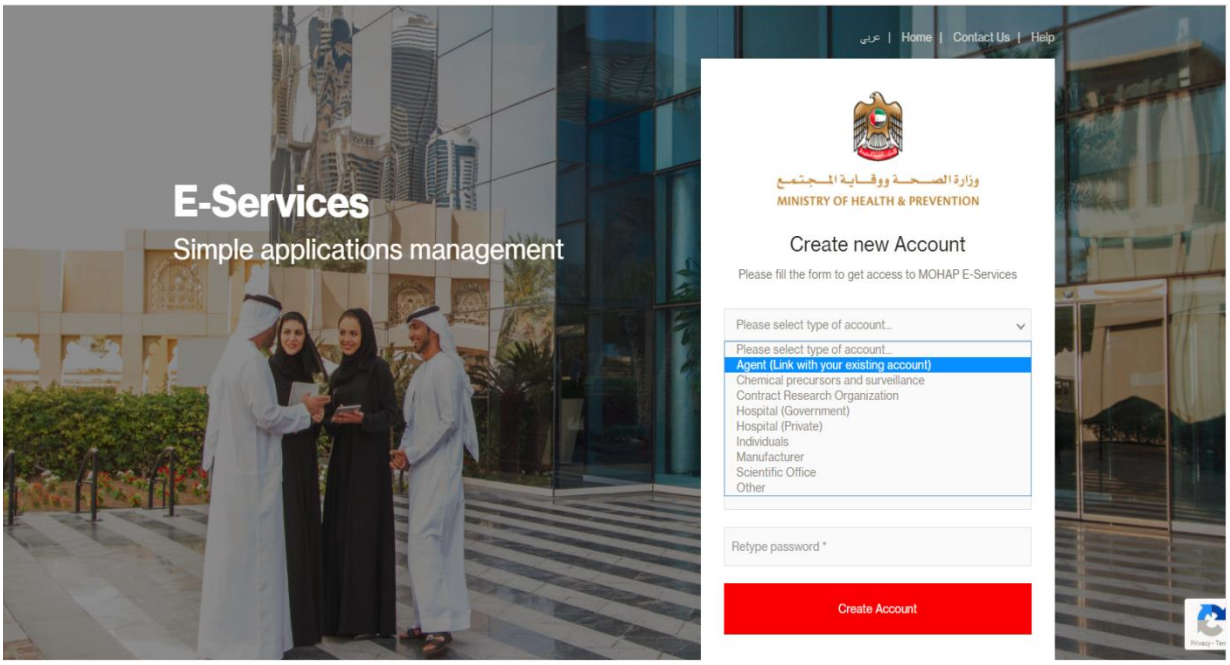
1.1 User Creation

Navigate to the application login screen and click over “Create New Account”



The application takes you to the “Create New Account” screen, select the account type:

A. If you select the account type as “Agent (Link with your existing account)”



Then the screen fields will be as follow:

- Your existing username
- Please set a new password
- Retype password
- “Link Account” button

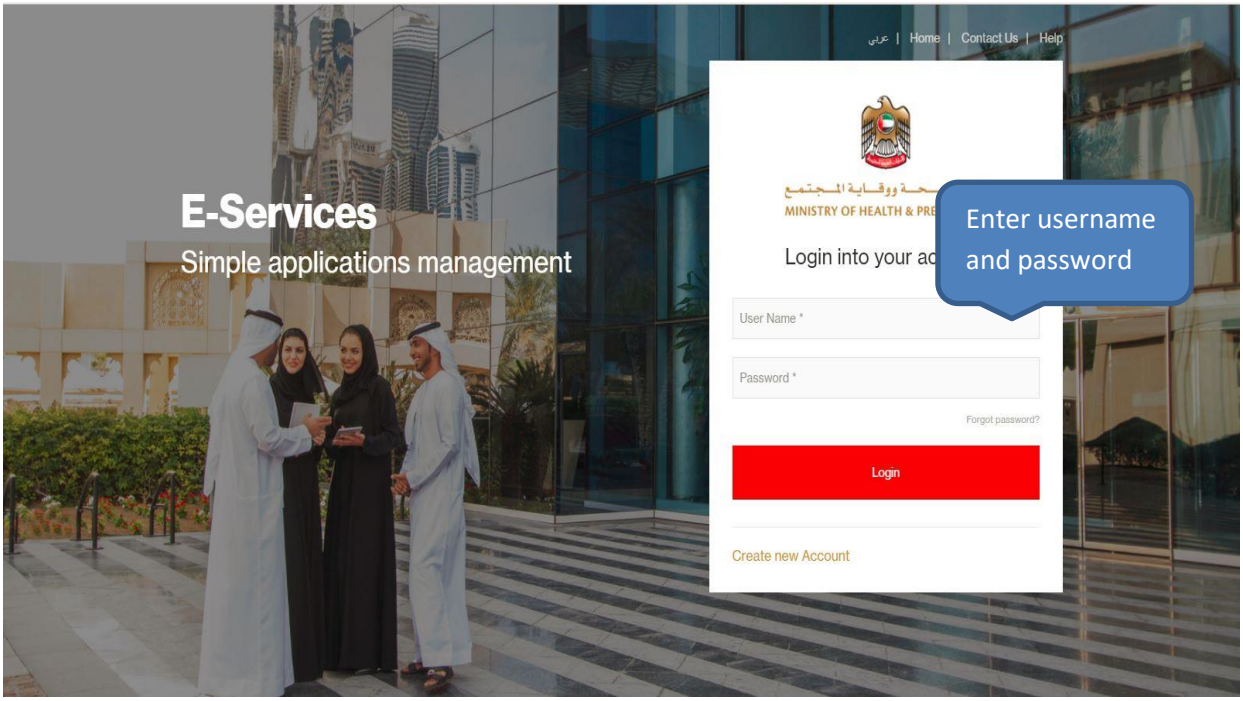
You should put the existing username for PH Licensing system and you should have a valid license

B. For other user types, then the screen fields will be as follow:
   - Username
   - Email Address
   - New Password
   - Retype Password
   - “Create Account” button

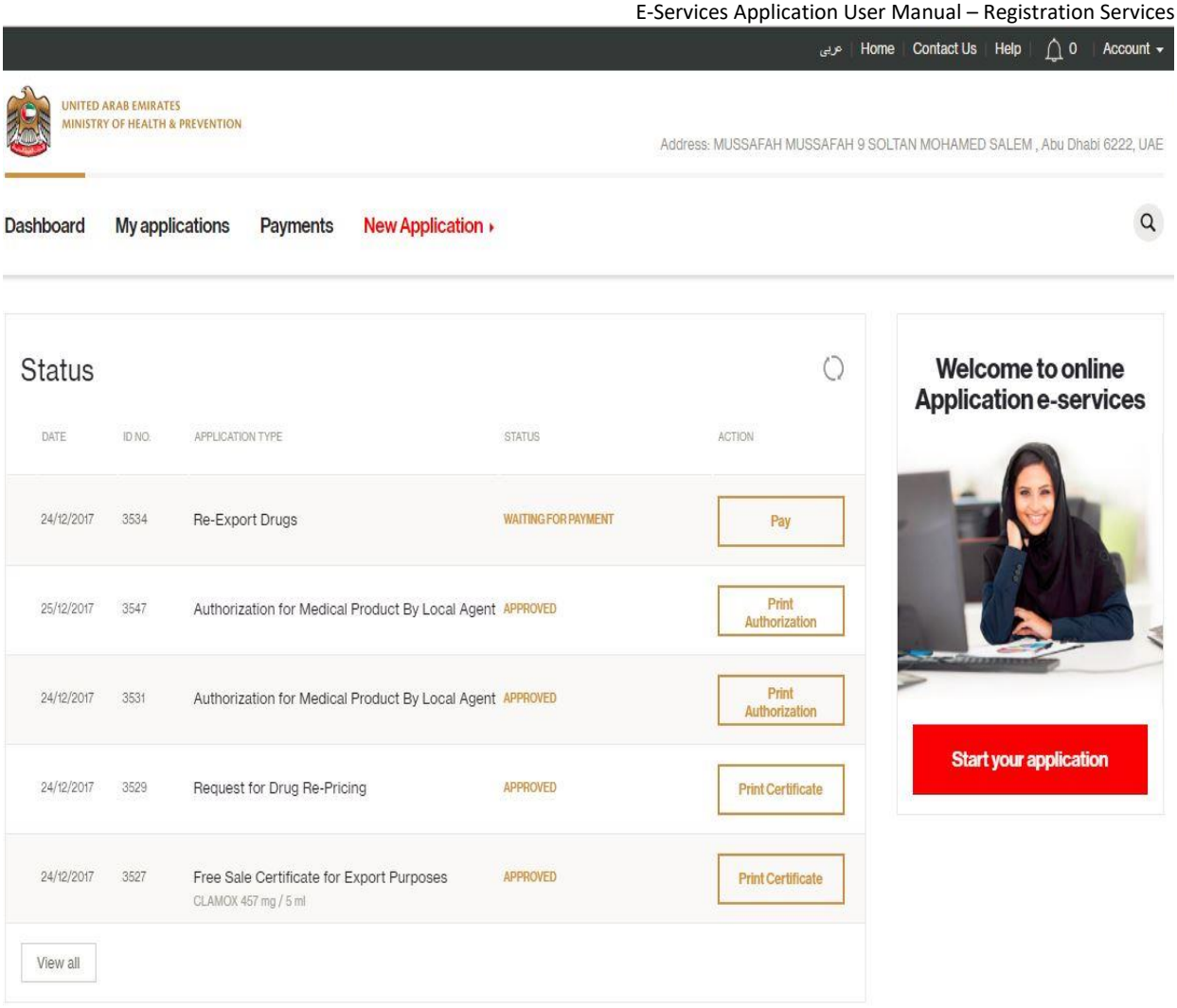
   The system sends an activation link to the provided email address; you can activate your account by clicking over the activation link.

1.2 LOGIN AND DASHBOARD

If you do not have a valid username and password go to the previous step and create a new account, otherwise, provide your user name and password and click over login.



After the user successfully logged onto the system, the dashboard page is displayed,



In the dashboard, you can know the status of the submitted applications, renew expired applications, print certificates/ letters, and create new applications.

2 REGISTRATION

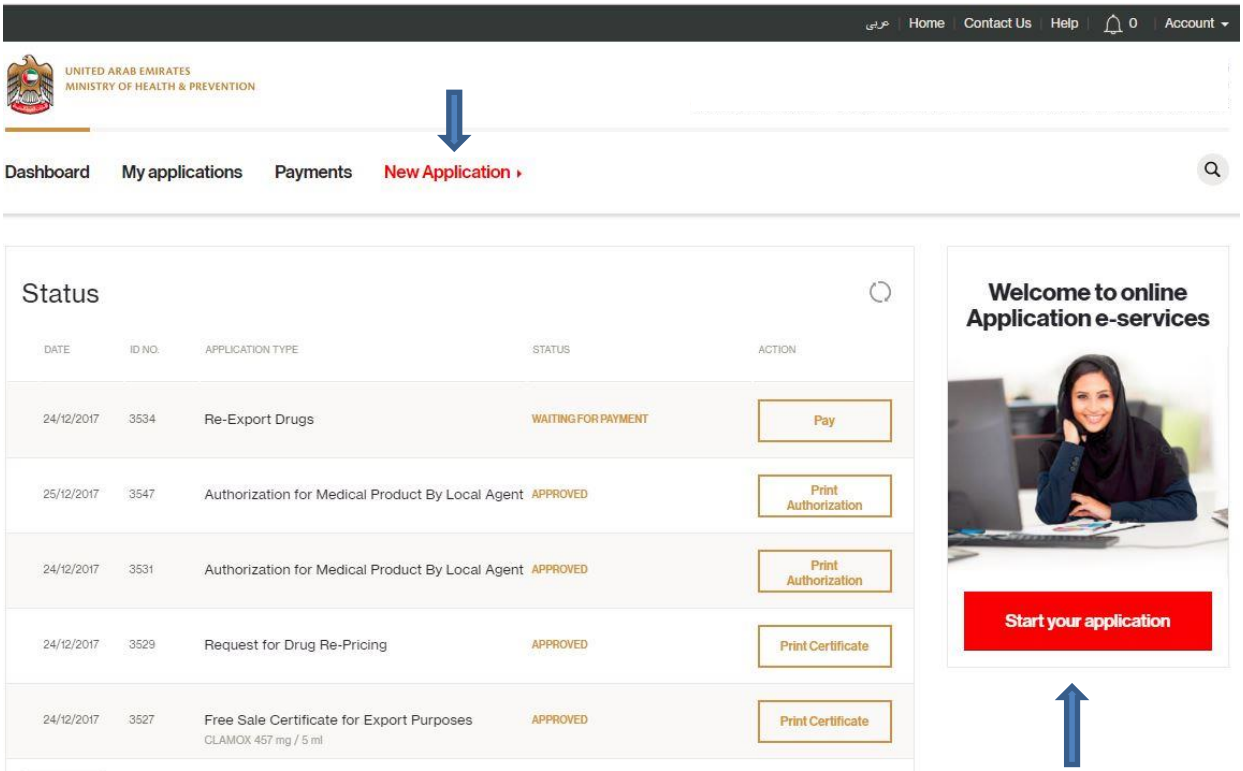
Under the registration tile, you will find the following services:

- Drug Classification
- Manufacturing site registration
- New drug registration
- Registered medical product minor variation
- Request for drug repricing
- Manufacturing site minor variation
- Evaluation of drug vigilance plan

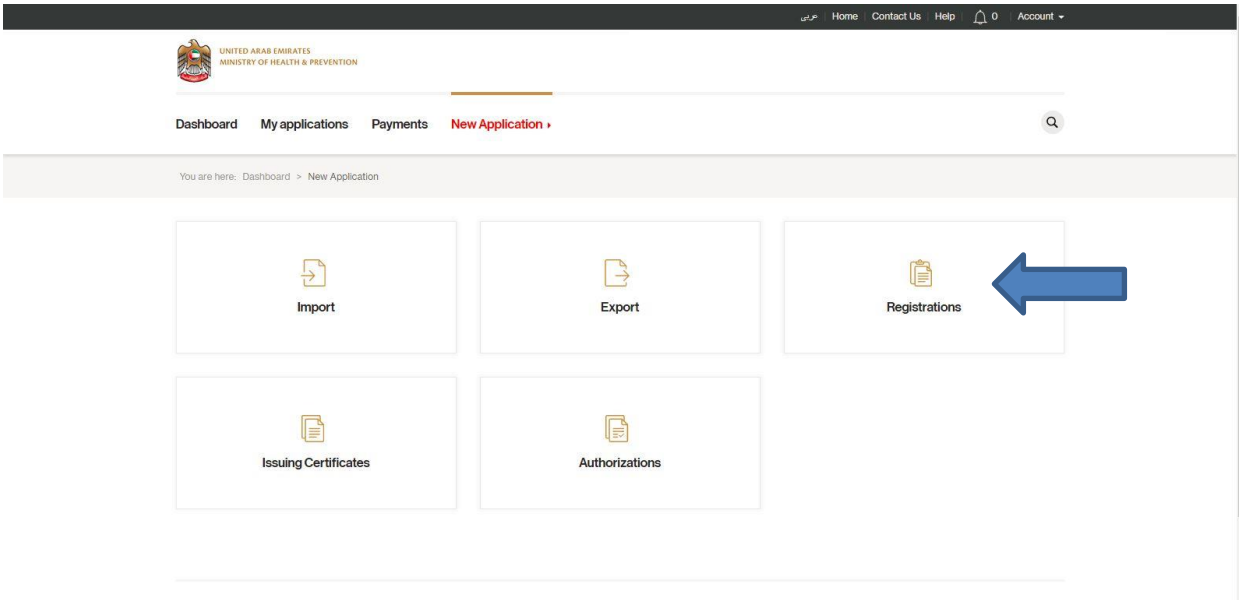
In order to use the listed services, you should be logged in to the system.

2.1 DRUG CLASSIFICATION

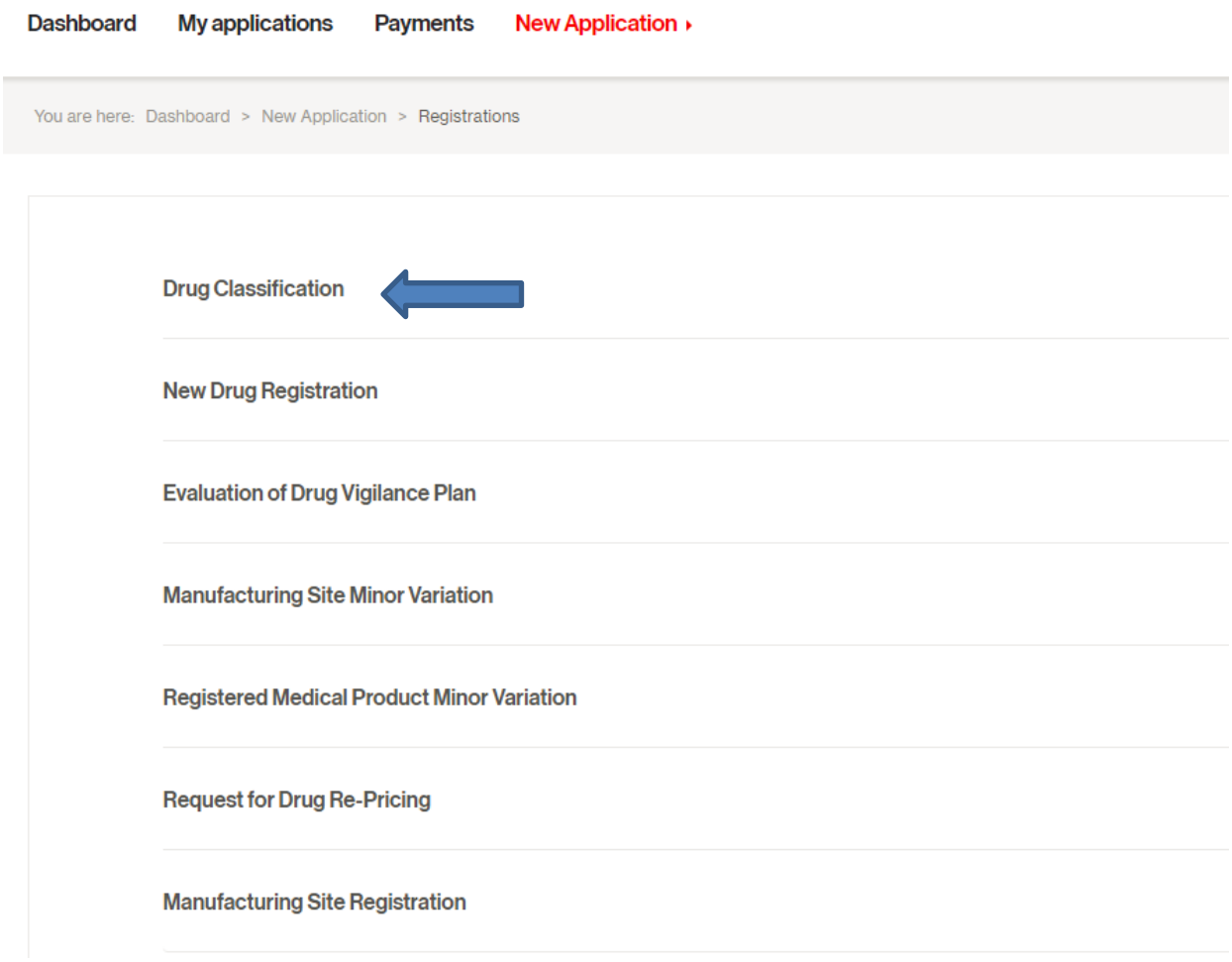
Log into the system using your credentials and then click on start new application link



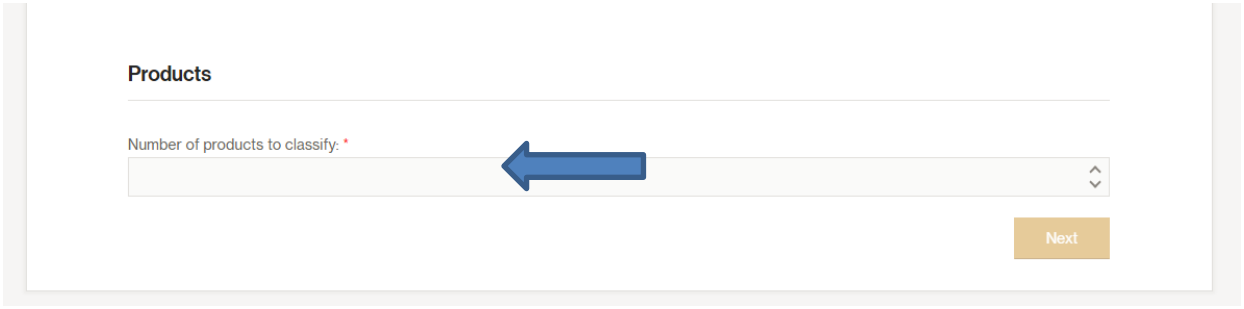
Click on registration tile



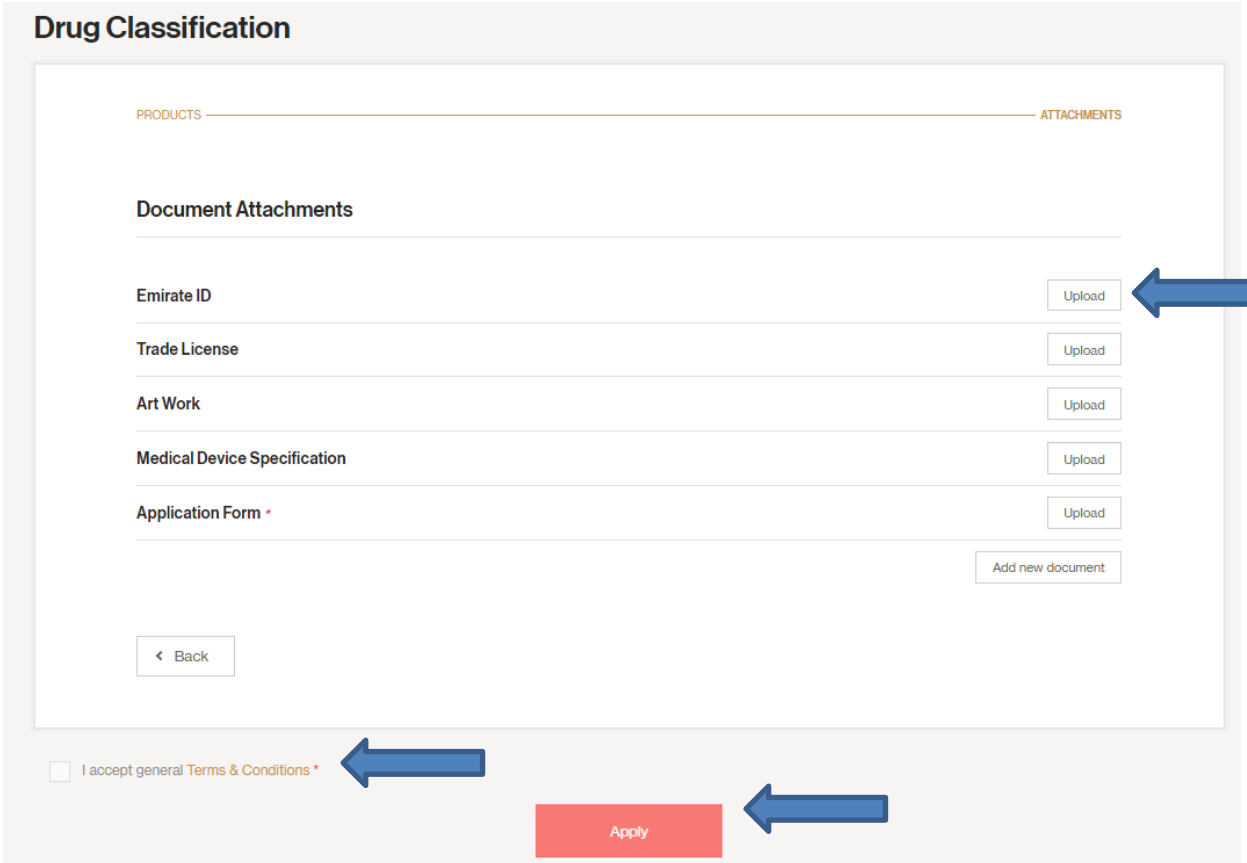
The system takes you to the services screen, click on Drug Classification



Provide the number of products and then click on Next

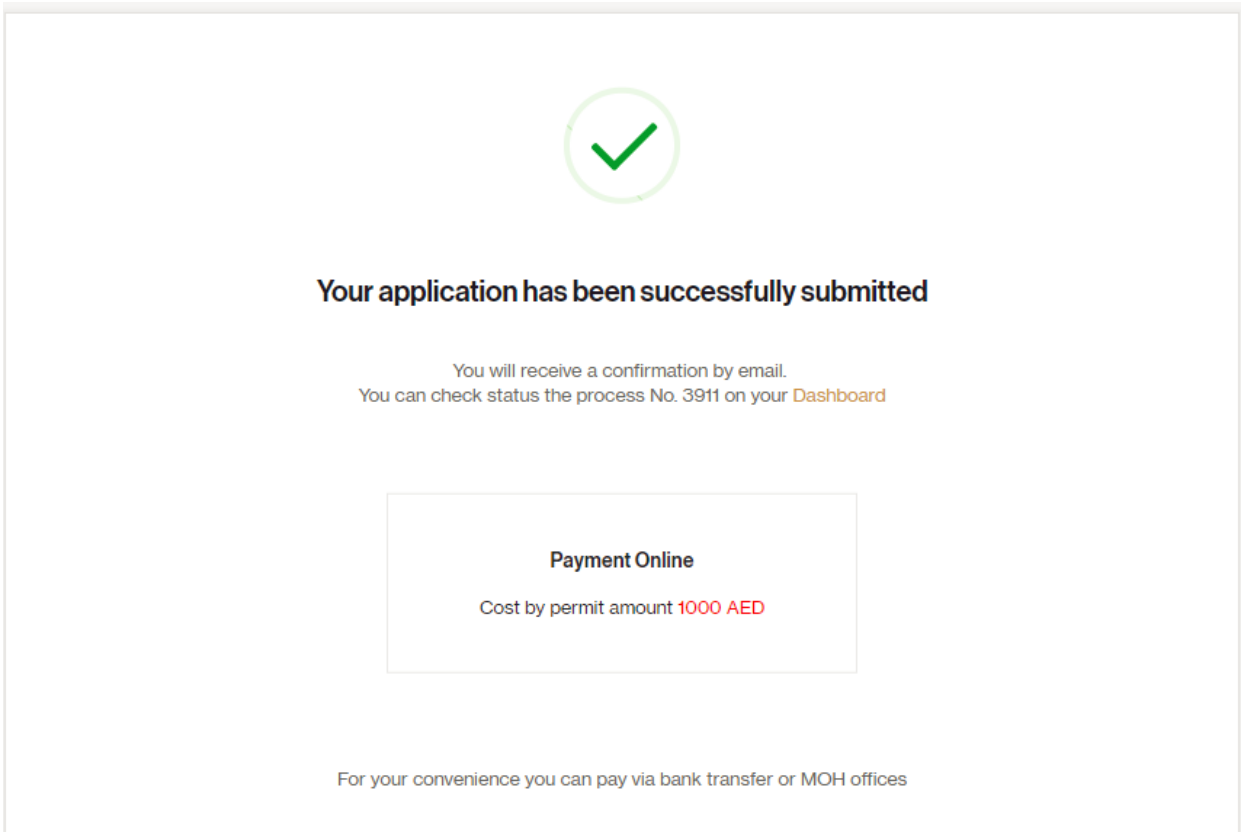


Uplaod the doscuments, accept the terms and conditions and then click on Applly



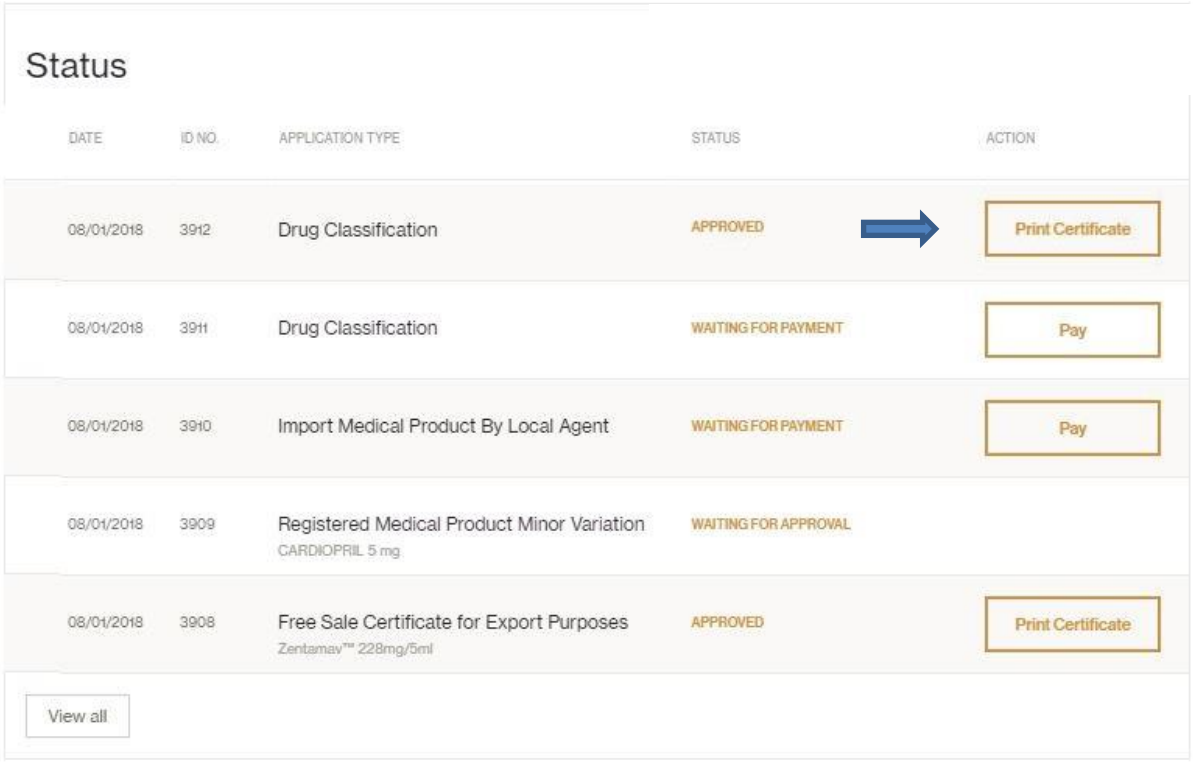
After submitting the application a successful message displayed to the user, and the permit fees is generated. The user can perform the payment from this screen by clicking over the amount, where the system directs you to the payment screen, the payment amount will be

calculated based on number of drugs to be classified multiplied by 500 AED.



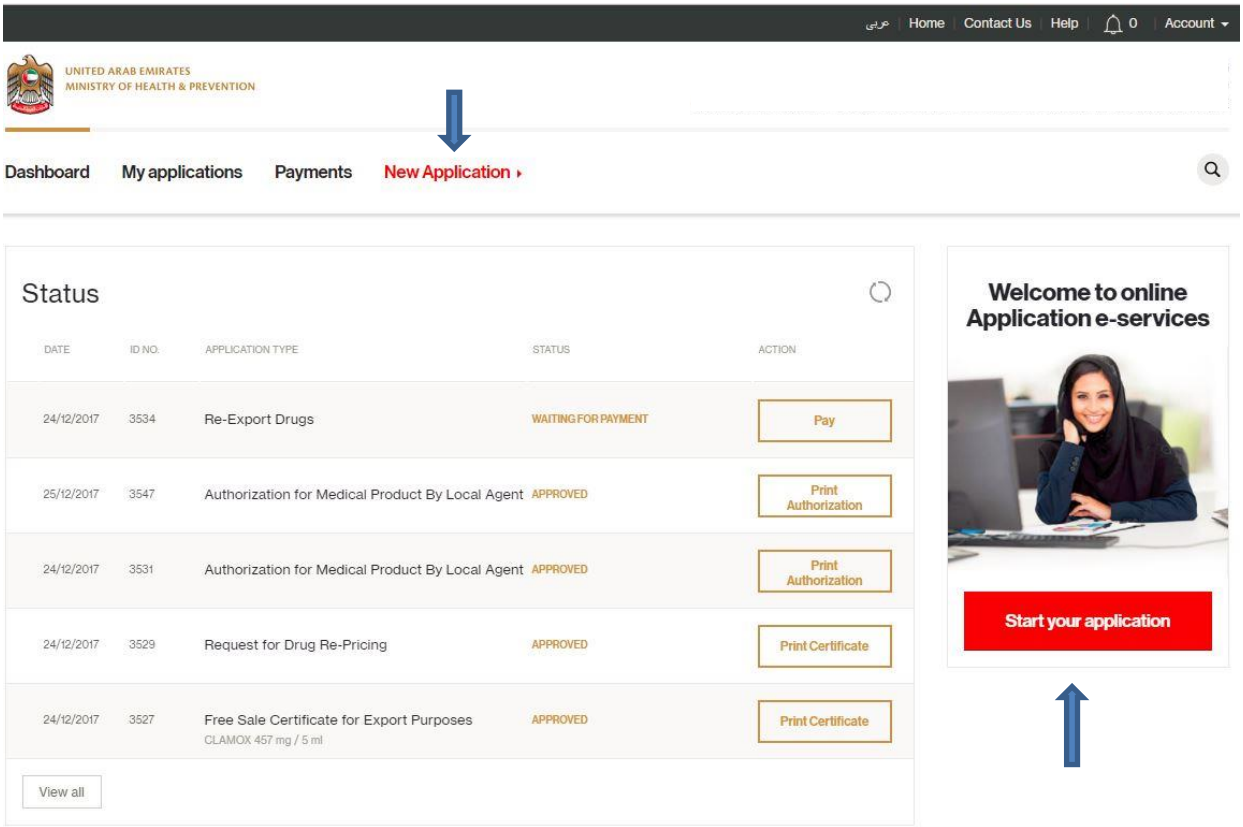
Alternatively, the user can go to the payment screen in the dashboard and click over the pay button and perform the payment.

To view the application status go to dashboard, and once the permit is approved click on "Print Permit" button on the dashboard to view and print the permit.

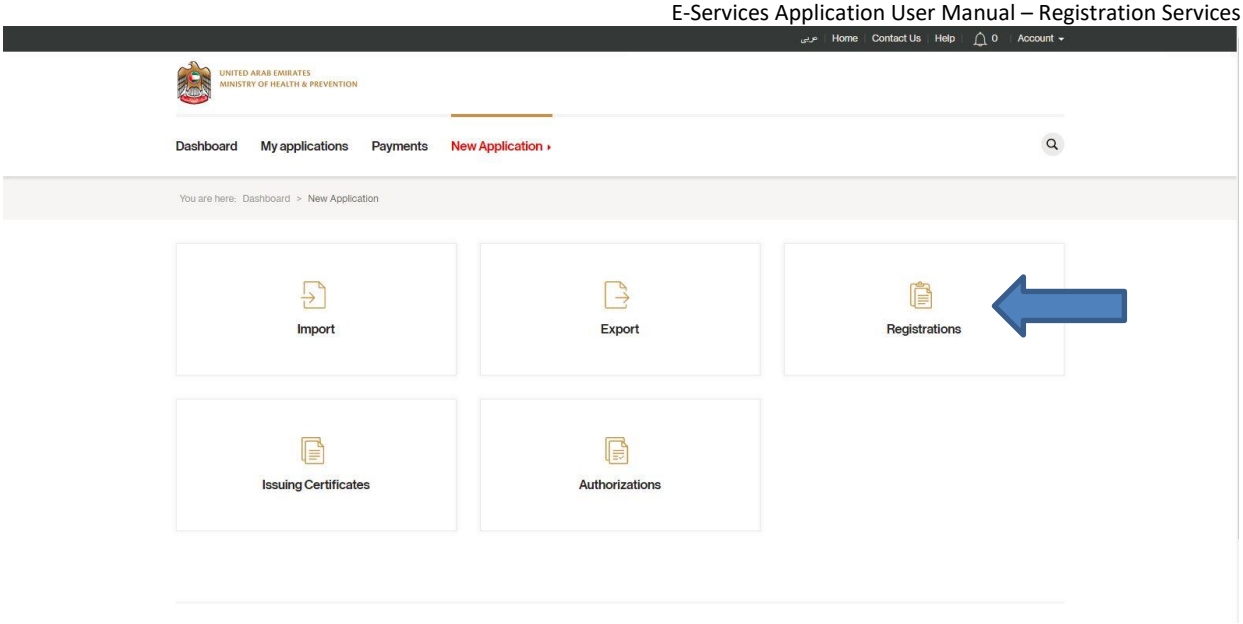


2.2 MANUFACTURING SITE REGISTRATION

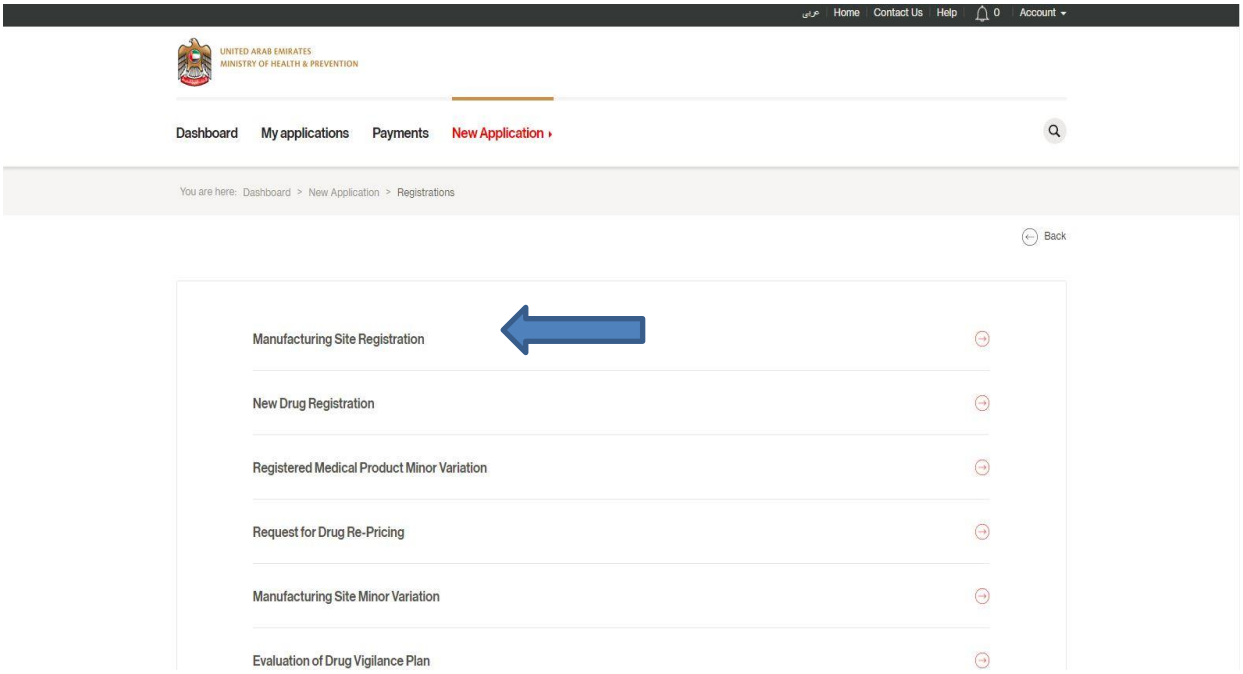
Log into the system using your credentials and then click on start new application link



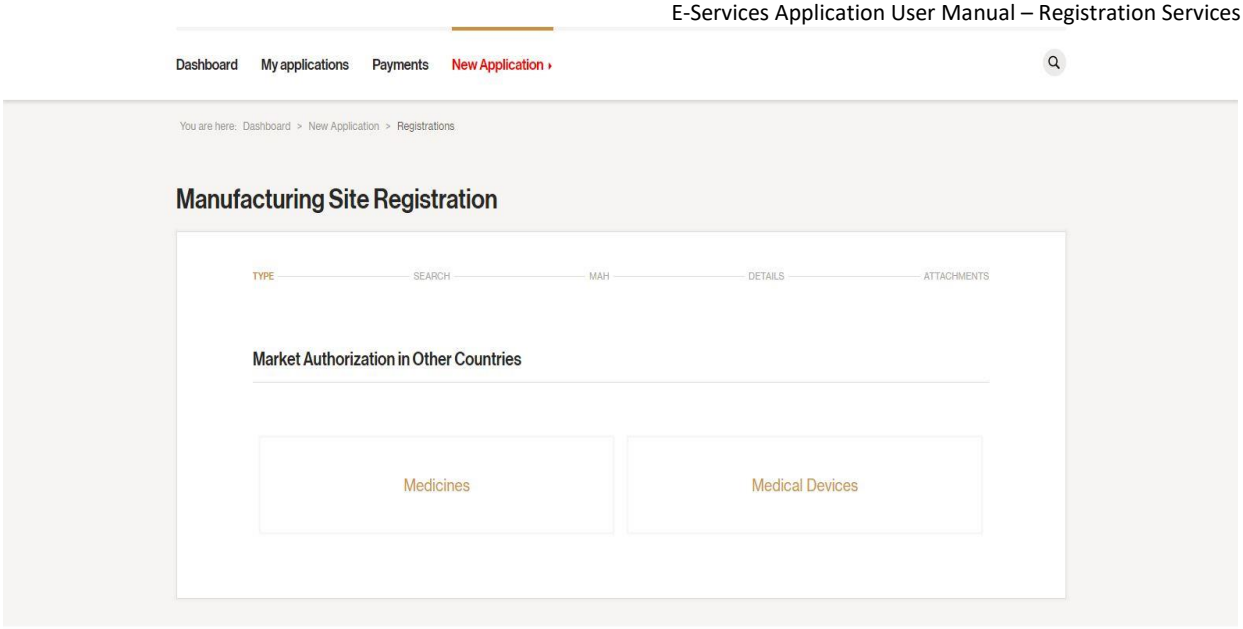
Click on registration tile



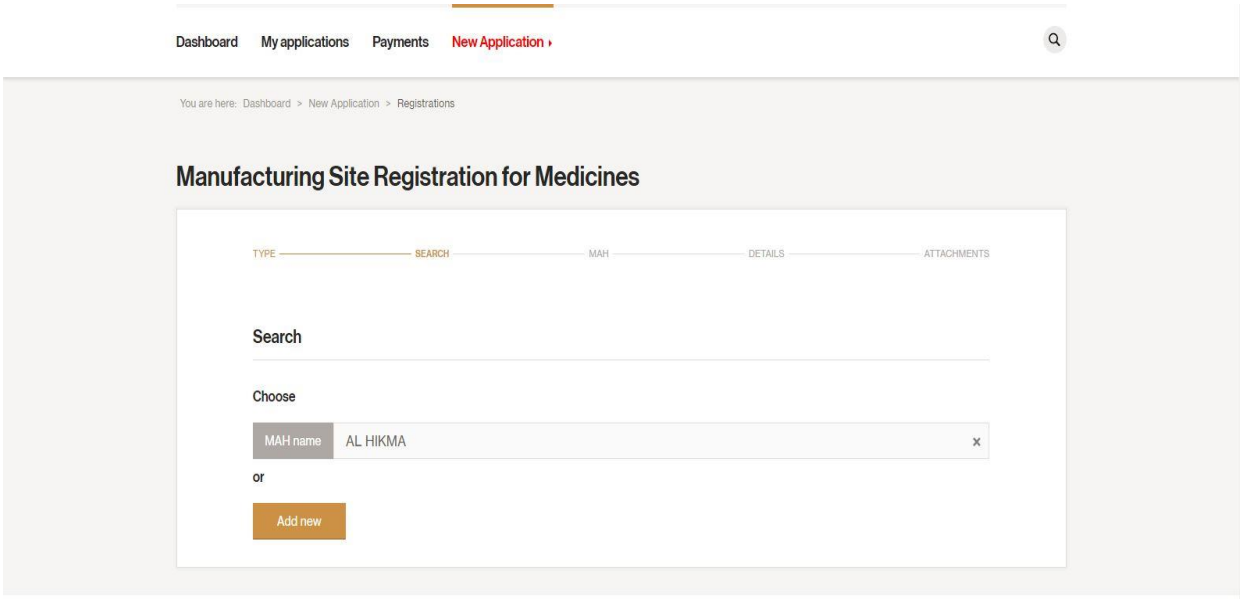
The system takes you to the services screen, click on manufacturing site registration



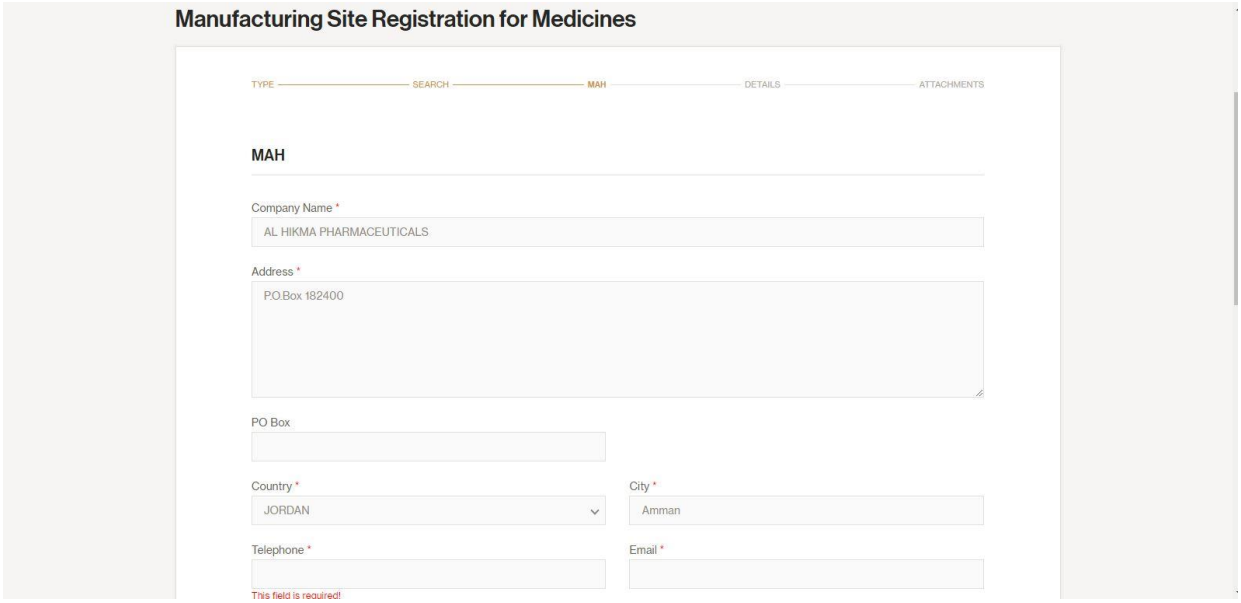
And then select whether you want to register a medicine or medical devices



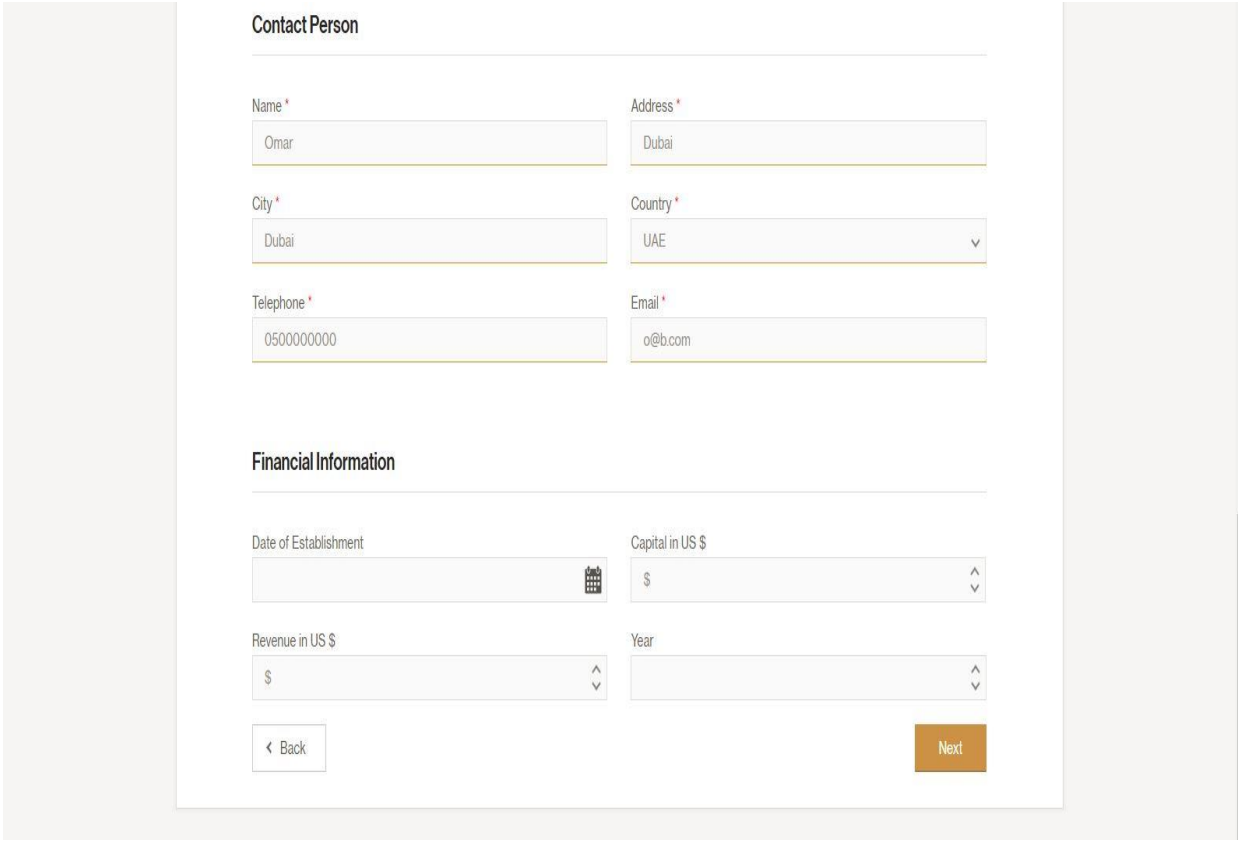
Enter MAH Name or add new MAH by clicking on “Add new” button



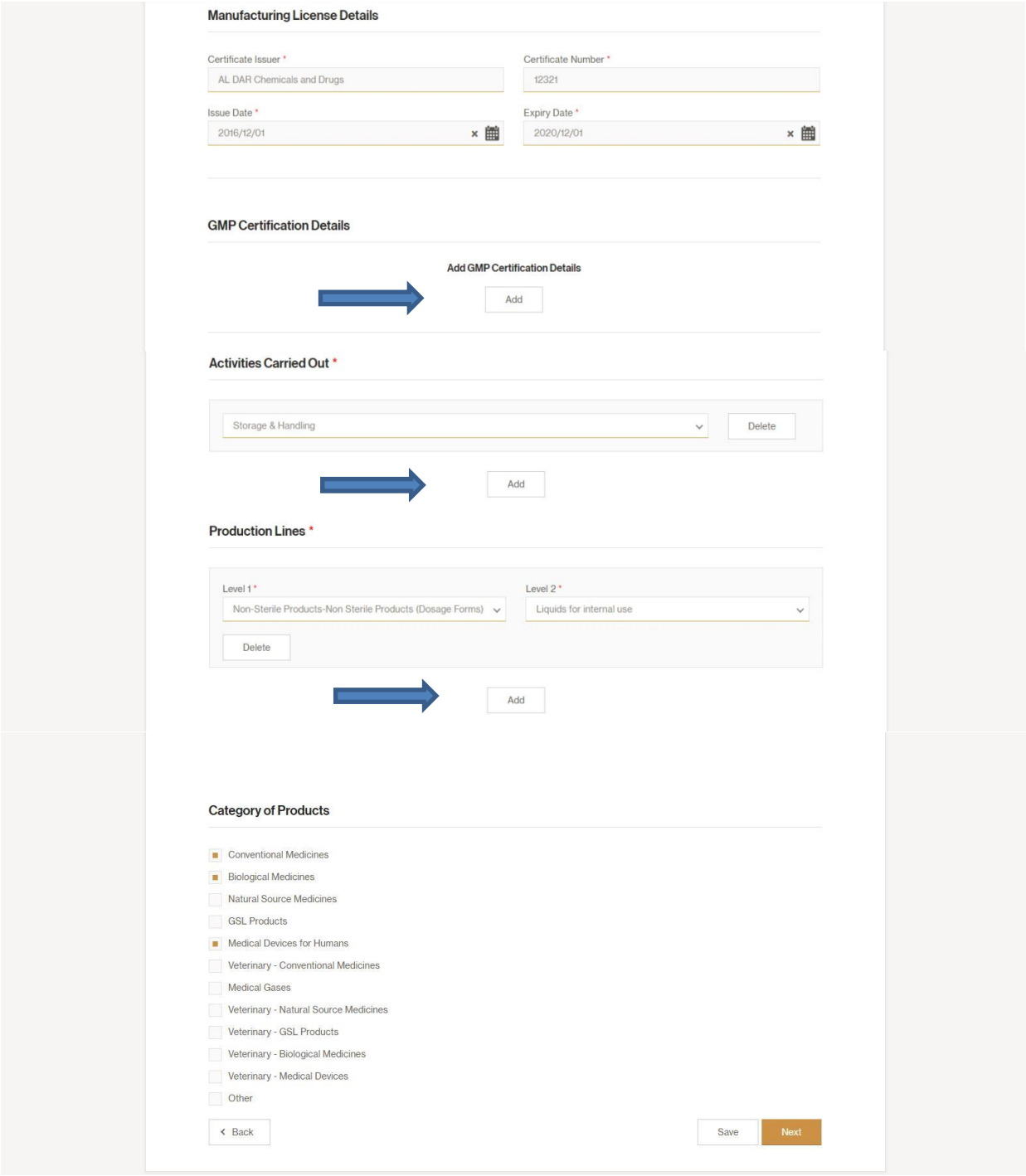
Fill all the mandatory data like company name, address, country, …etc



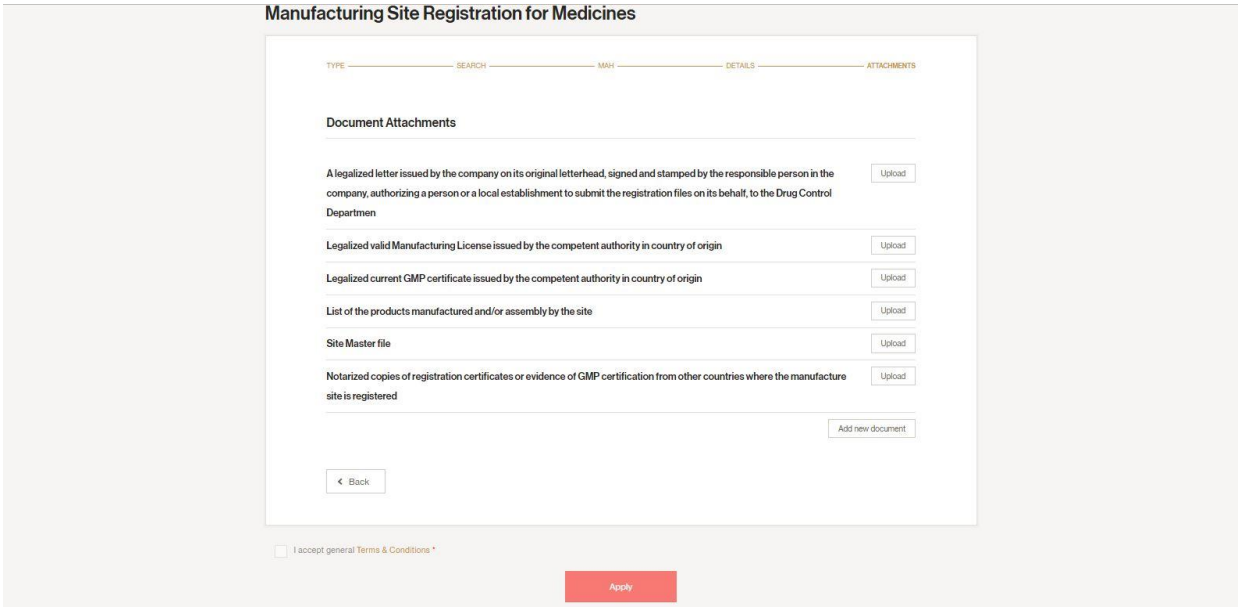
And then fill the contact person details and the financial information then click on Next



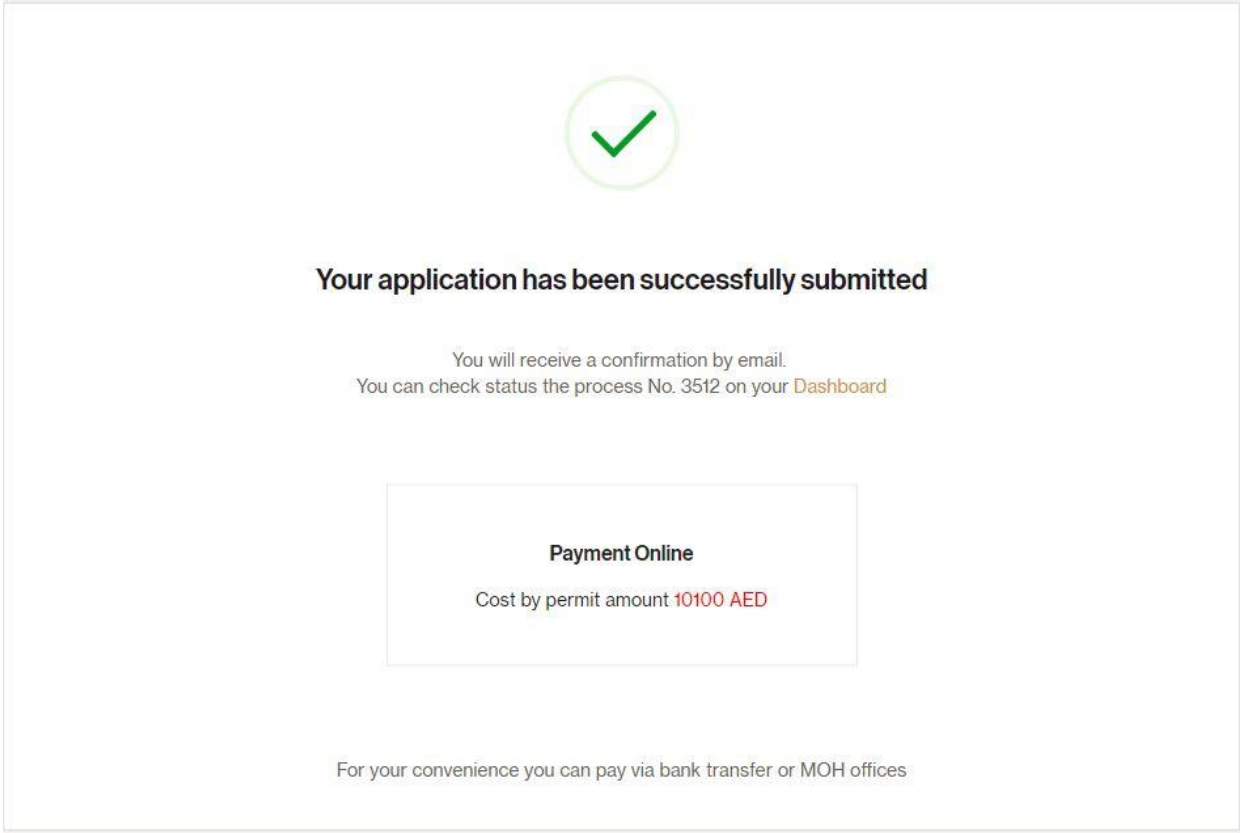
Enter the site name details, manufacturing license details. GMP Certification, Activities carried out, production lines, and category of the products, and then click on Next.



Attach the required document then accept the terms and conditions and click on Apply

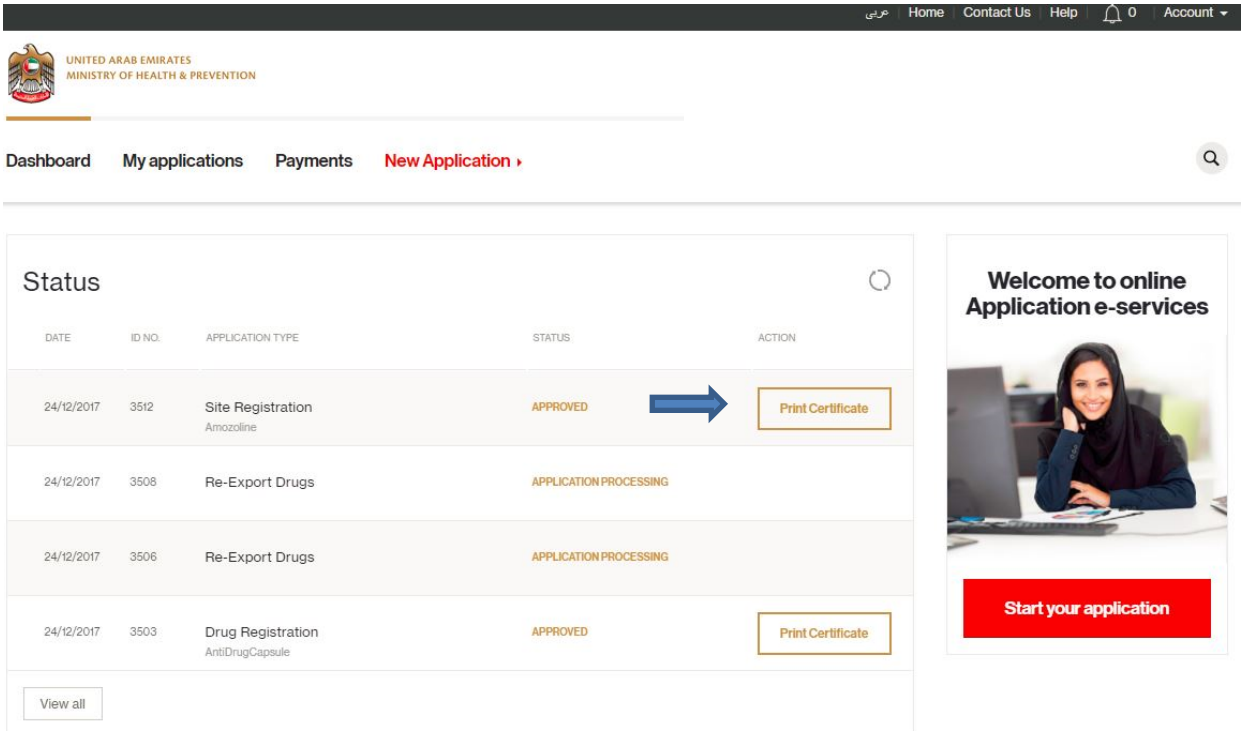


After submitting the application a successful message displayed to the user, and the permit fees is generated. The user can perform the payment from this screen by clicking over the amount, where the system directs you to the payment screen.



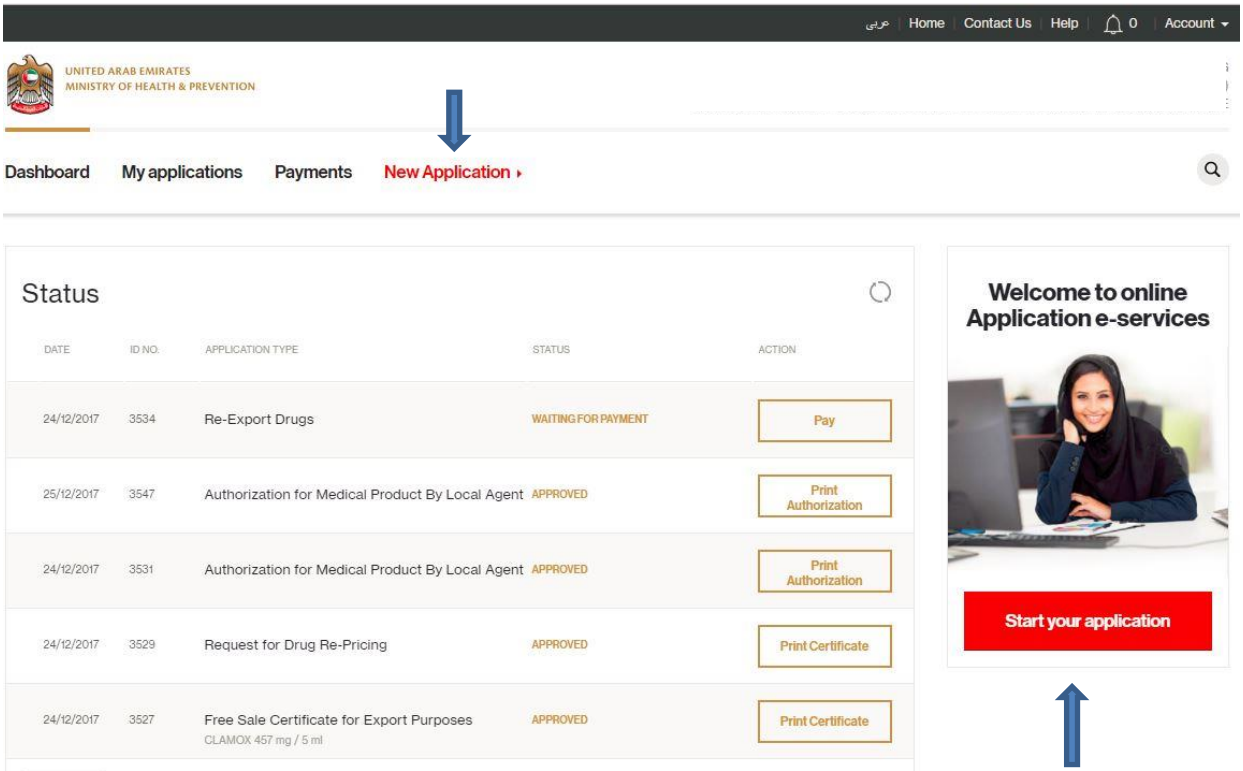
Alternatively, the user can go to the payment screen in the dashboard and click over the pay button and perform the payment.

To view the application status go to dashboard, and once the permit is approved click on "Print Permit" button on the dashboard to view and print the permit.

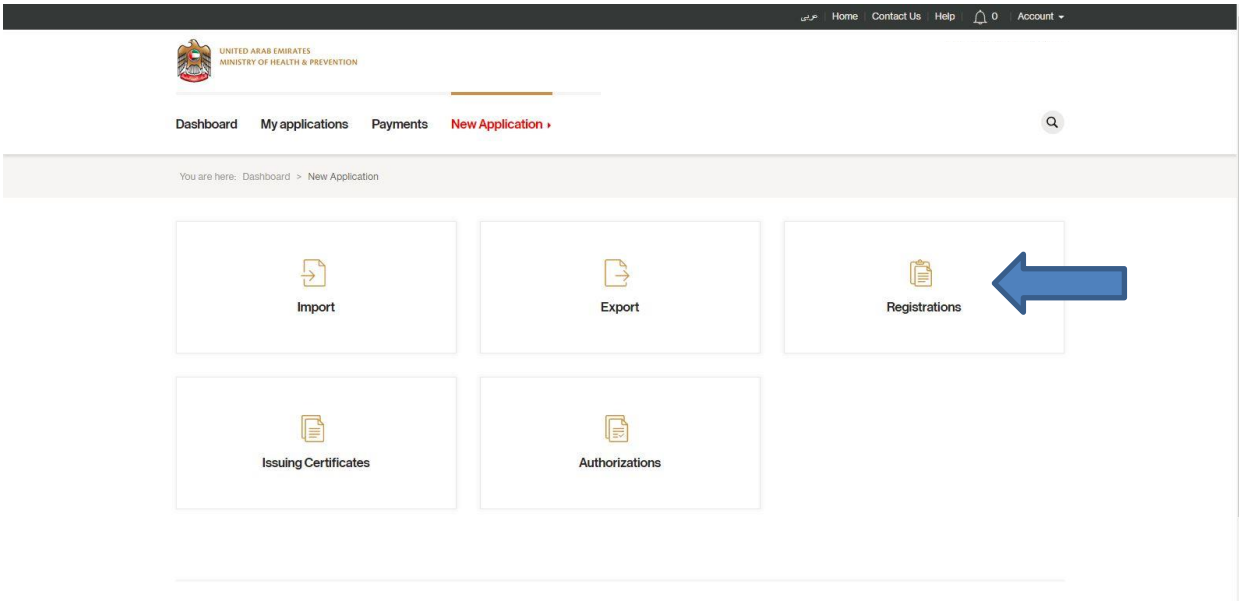


2.3 DRUG REGISTRATION

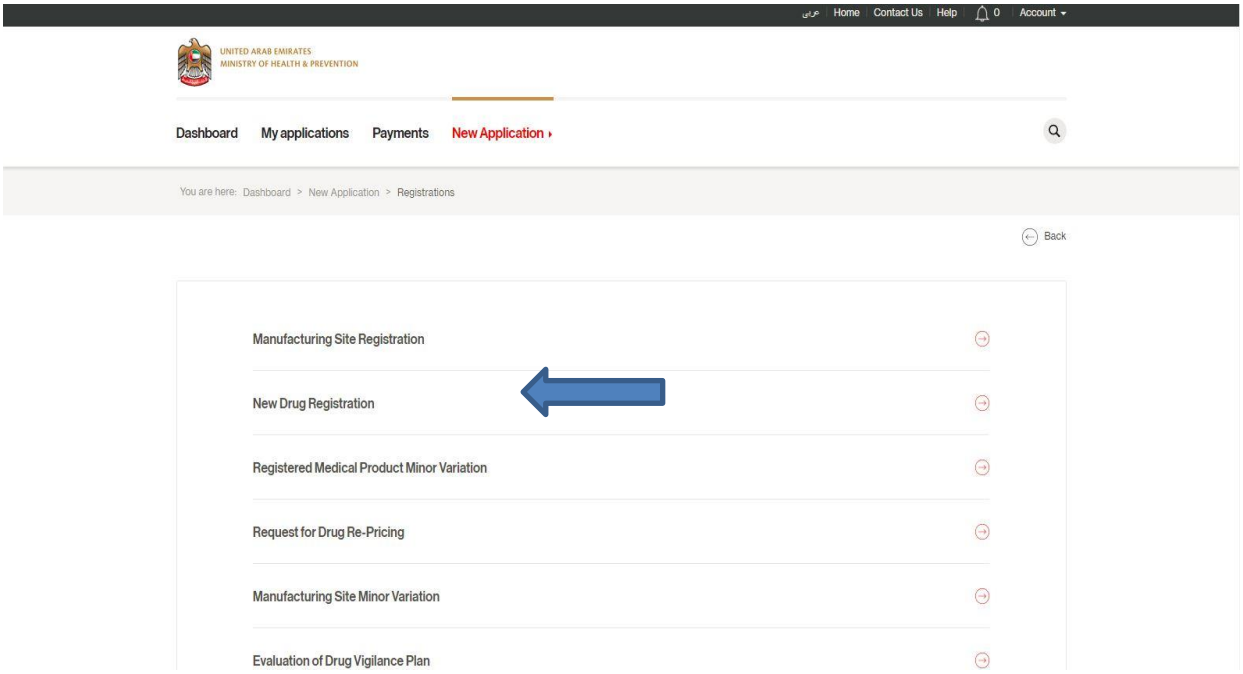
Log into the system using your credentials and then click on start new application link



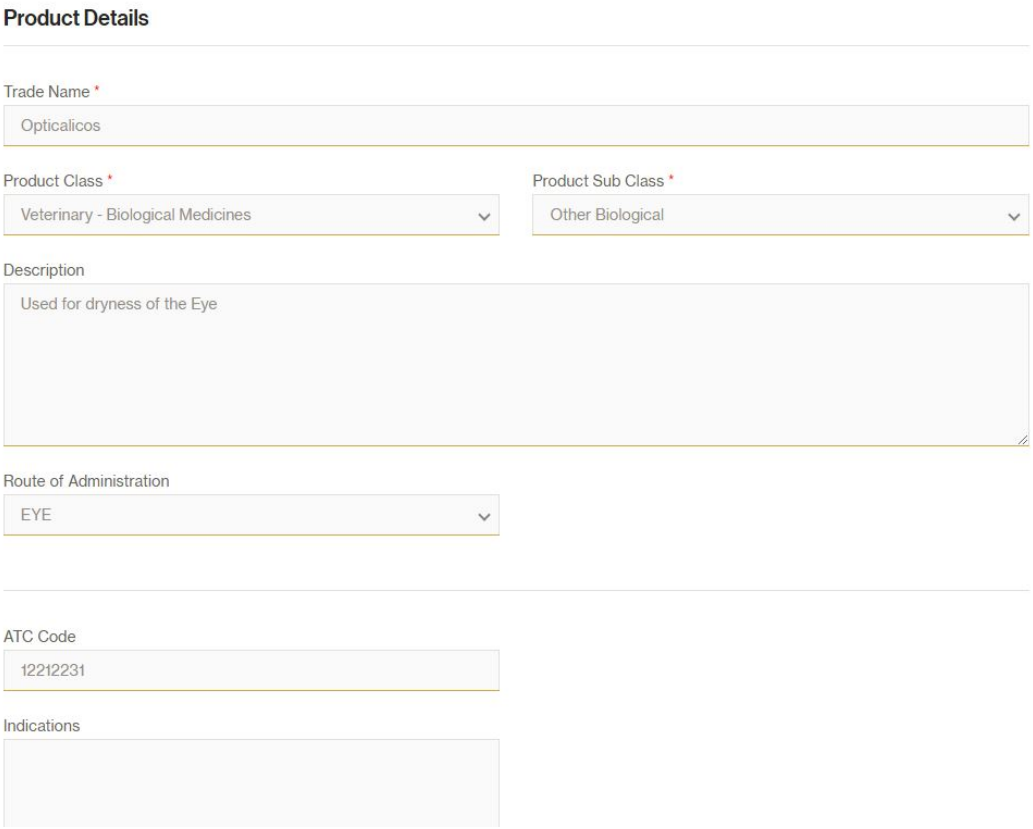
Click on registration tile



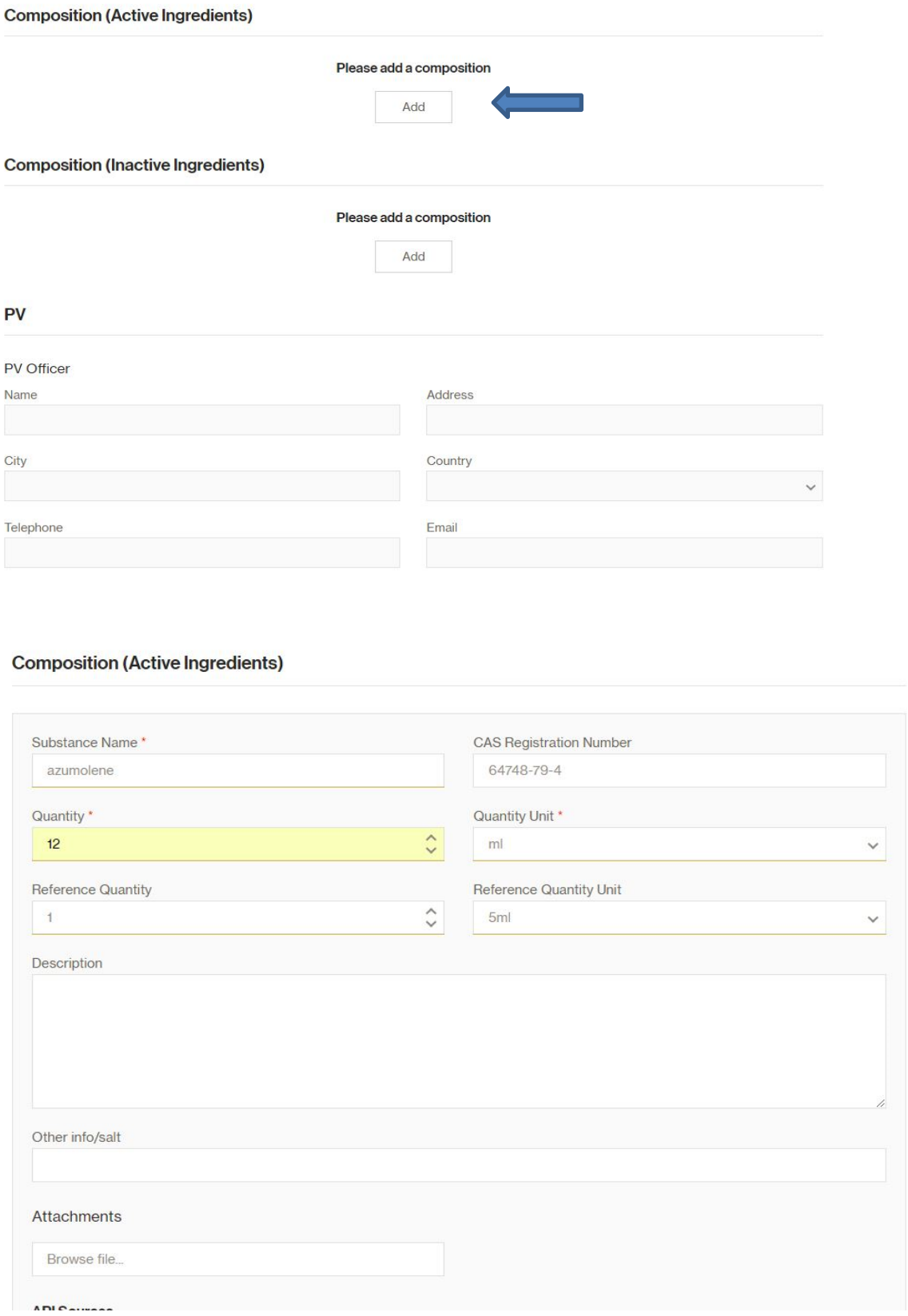
The system takes you to the services screen, click on drug registration



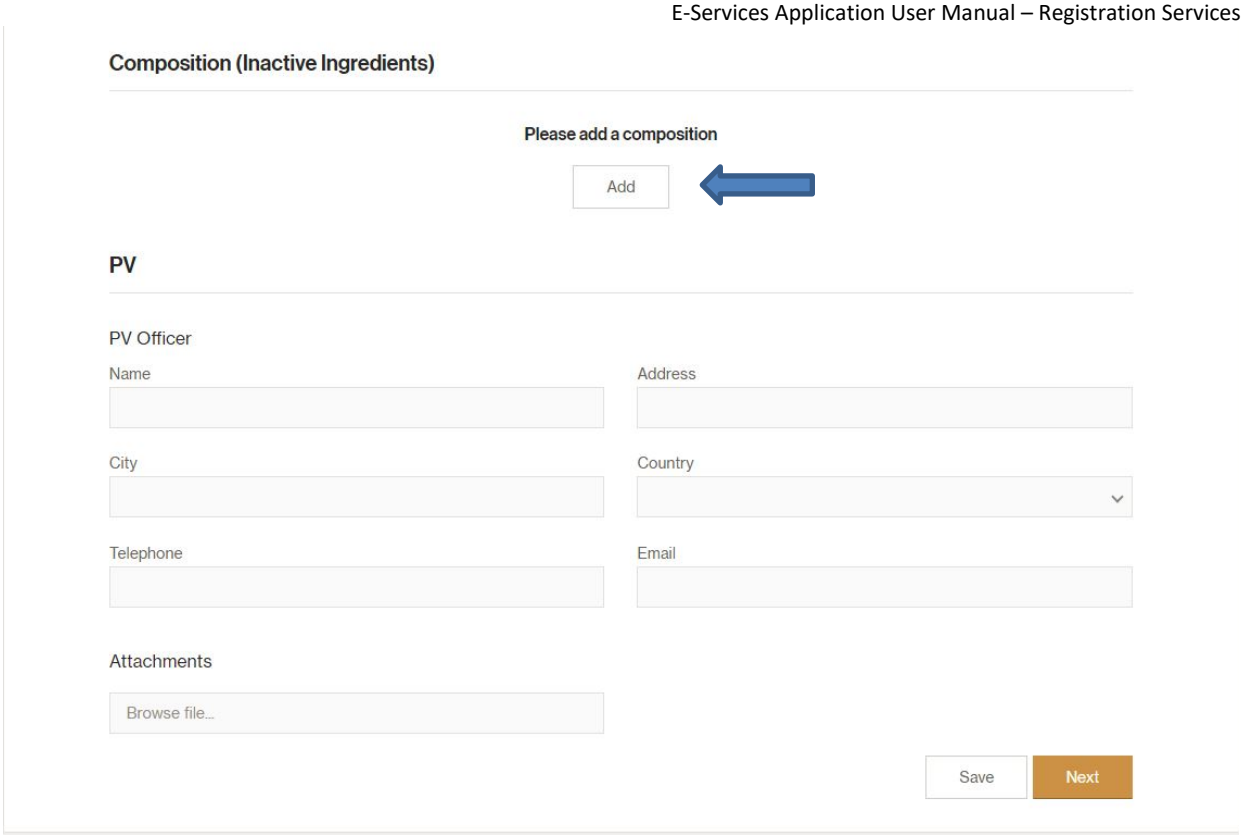
Enter product details

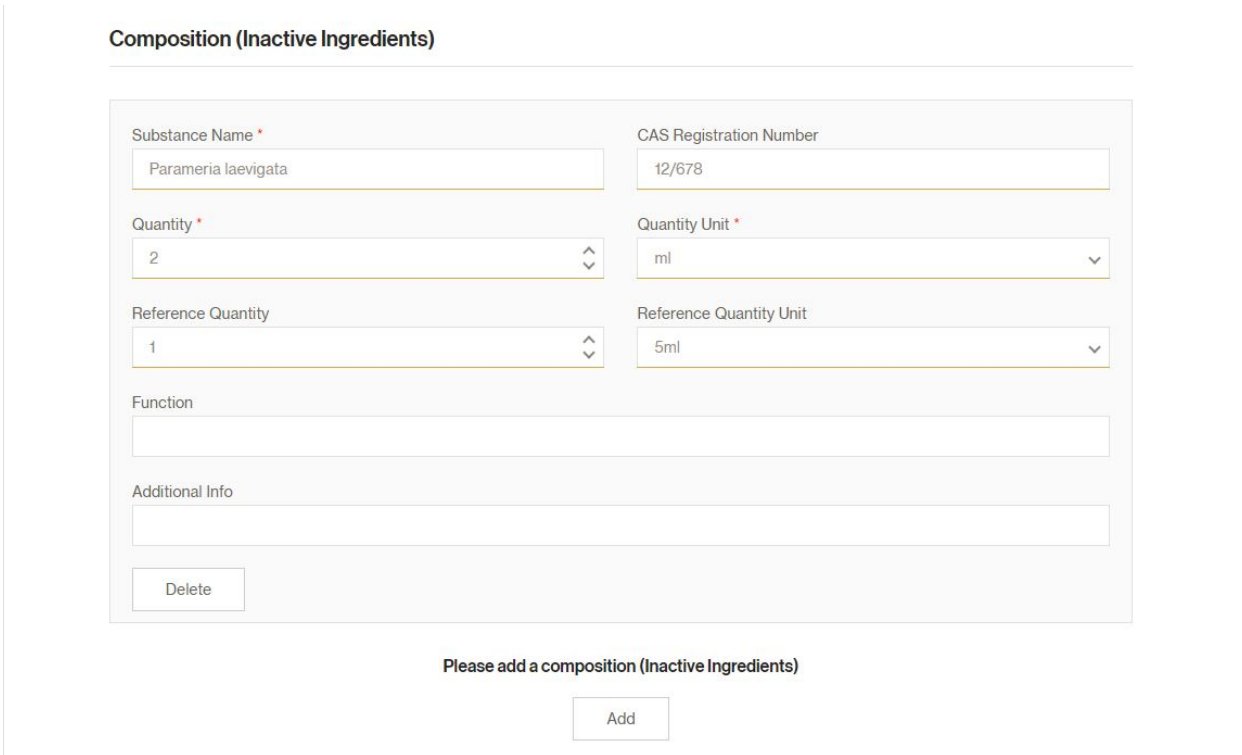


Add the active ingredient by clicking over add

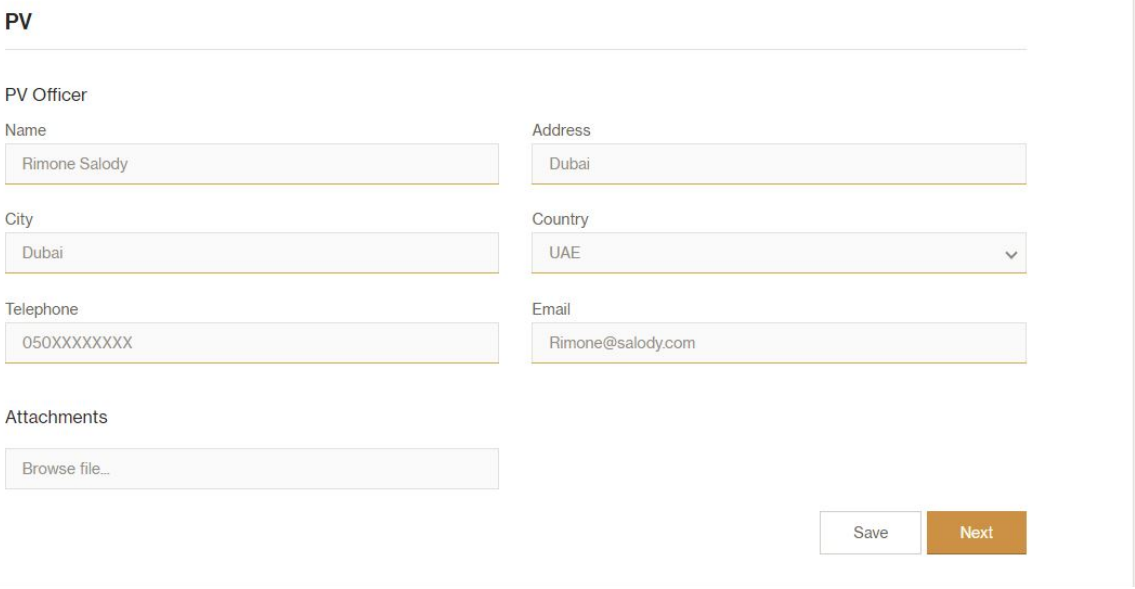


Add the inactive ingredient by clicking over add

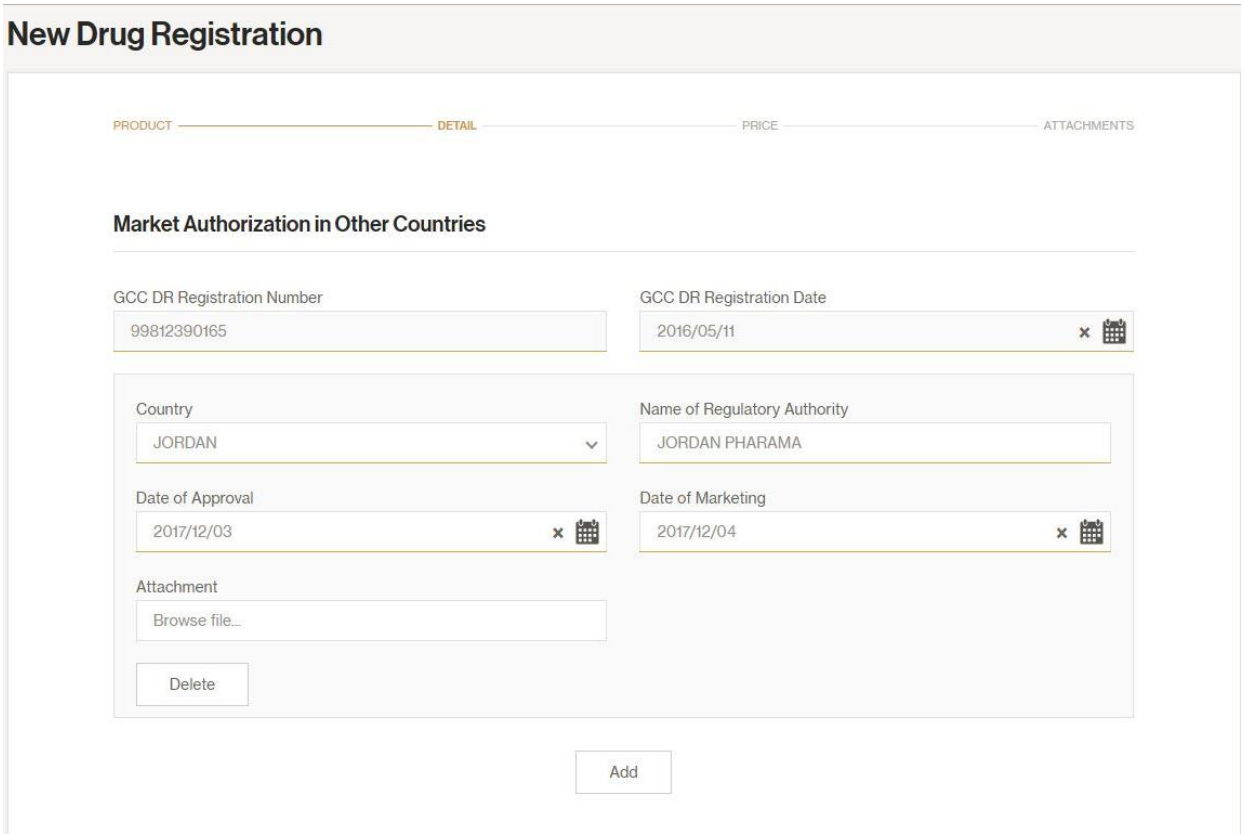




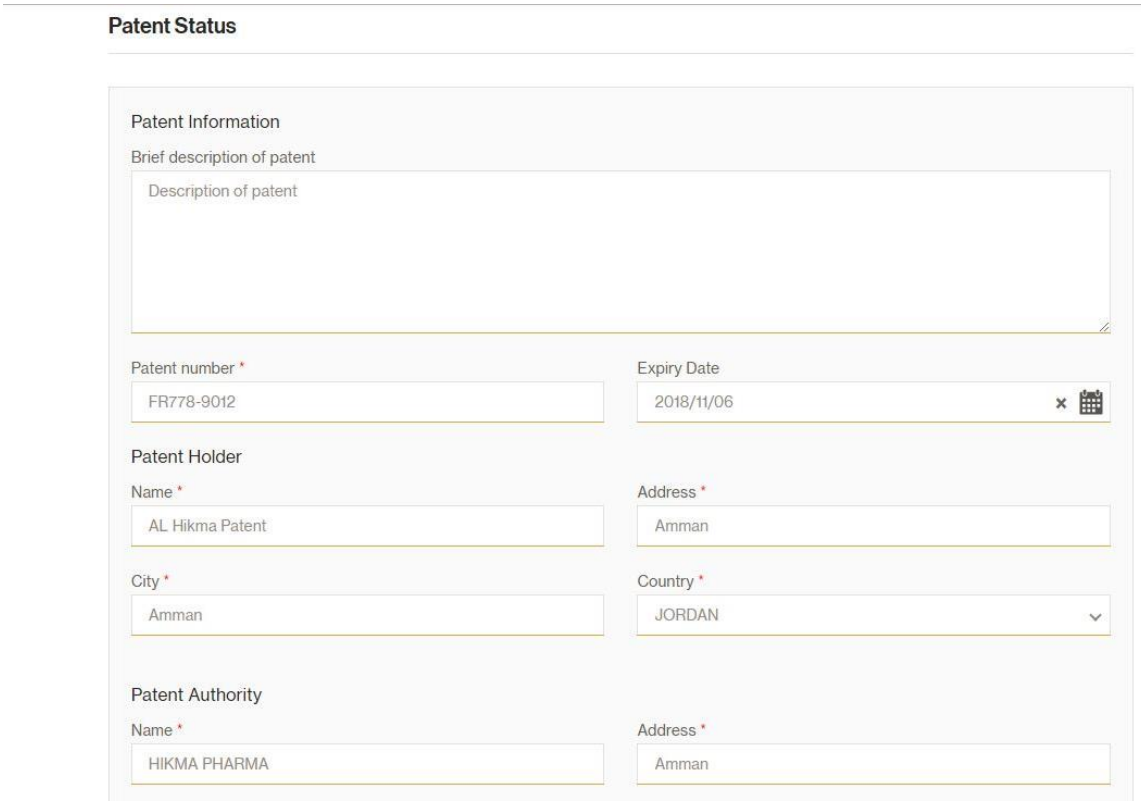
And then fill the PV details and click over Next



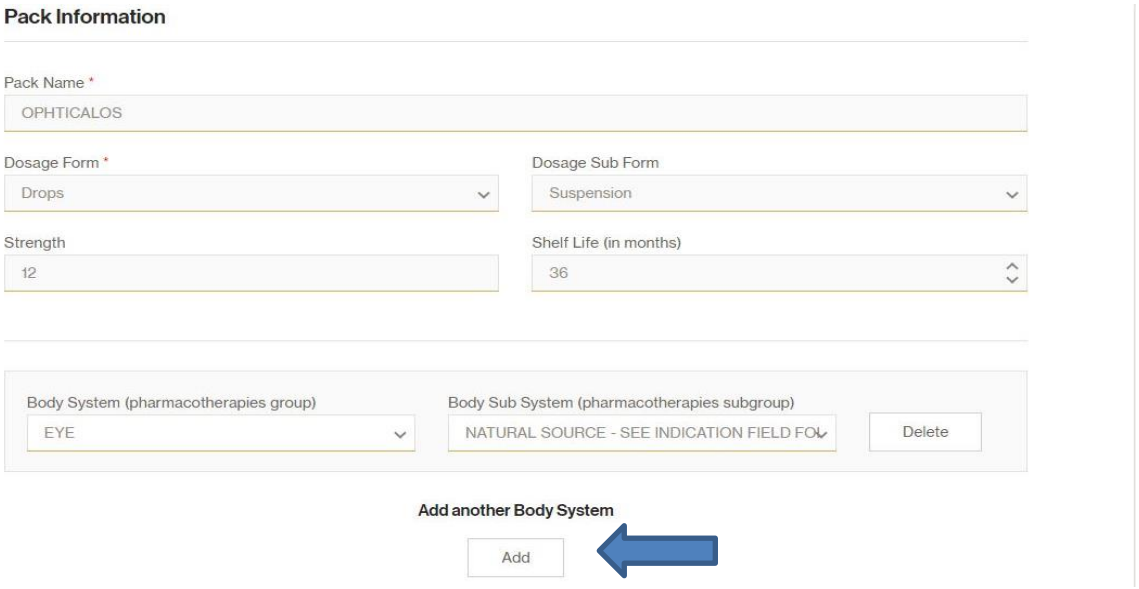
Add the Marketing Authorization holder in other countries details



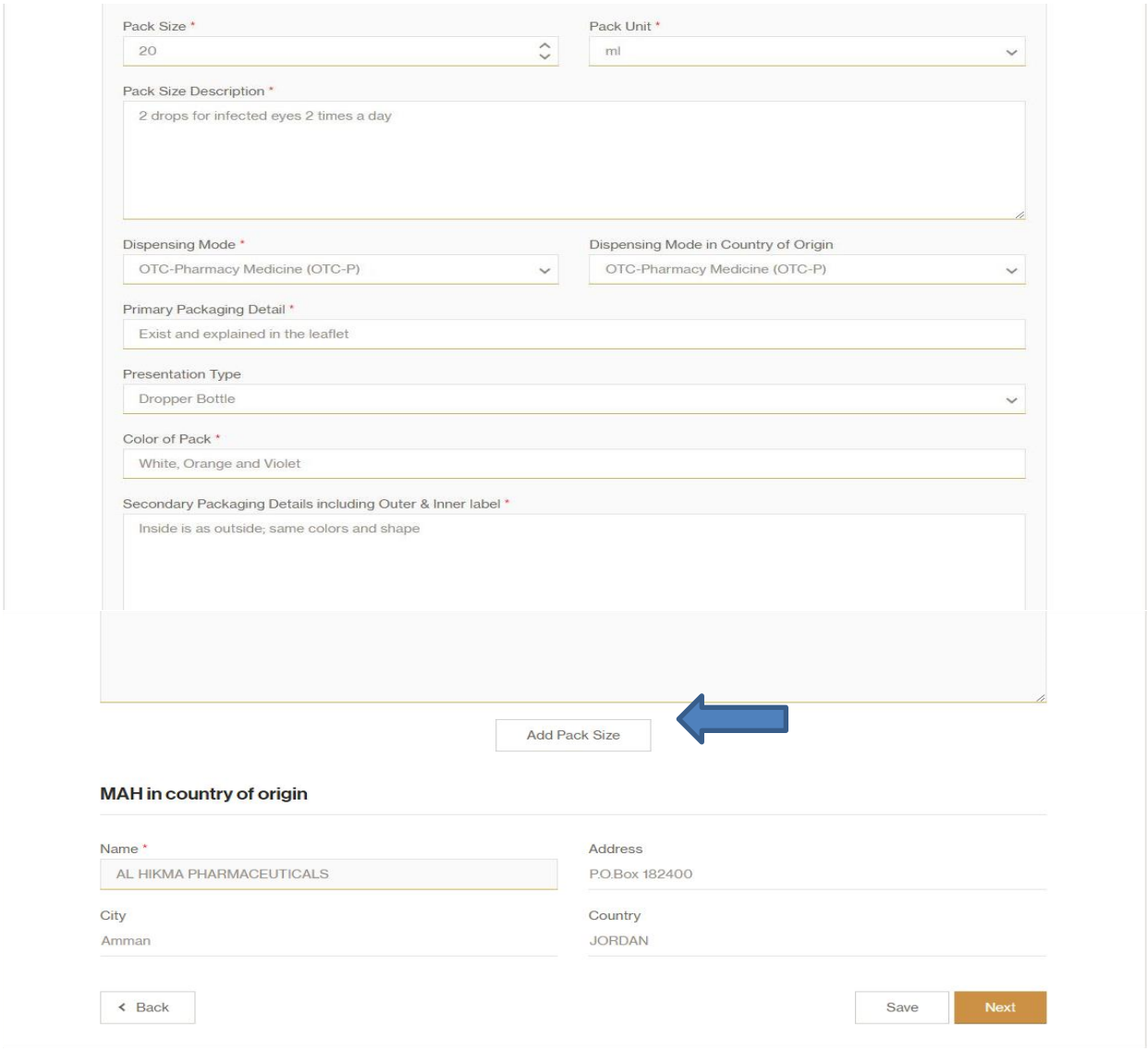
Fill the patent status and the pack information



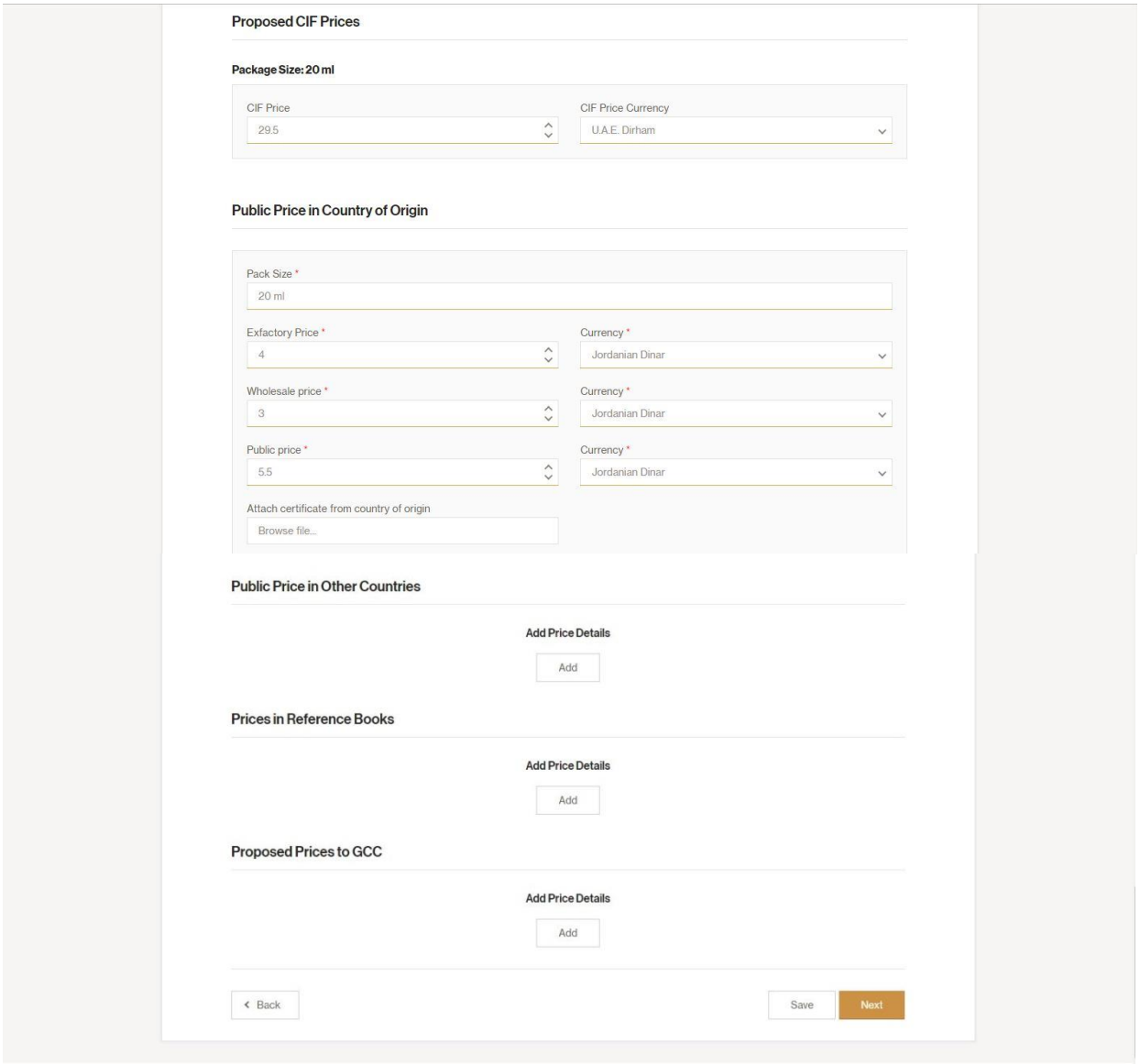
Click on “Add” button to Add Body System



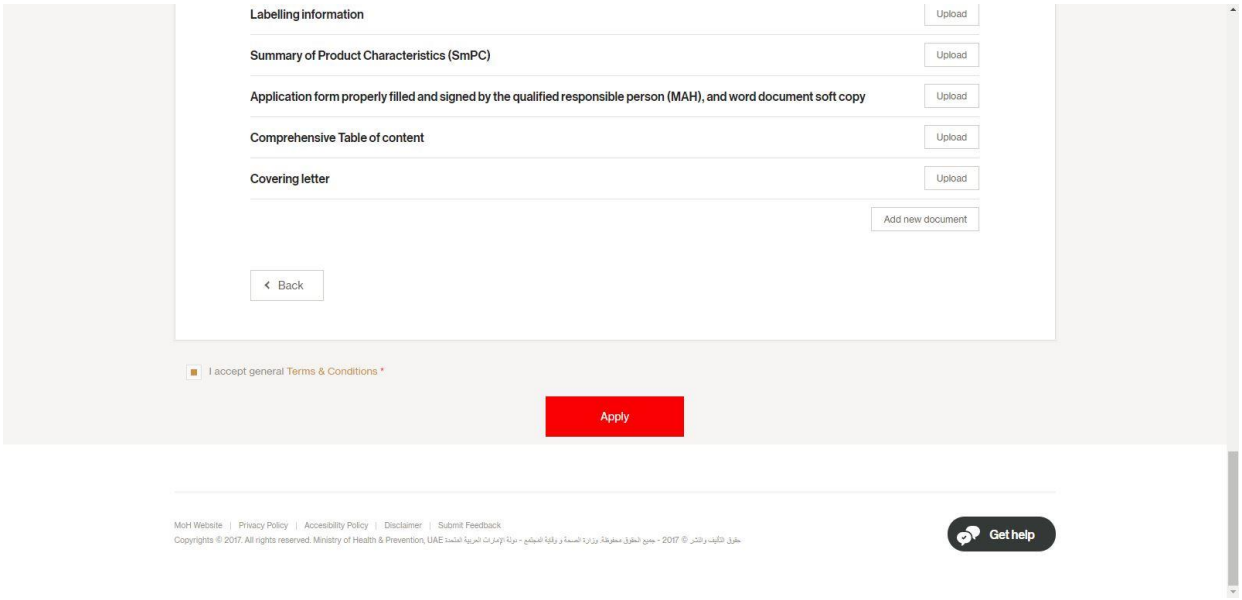
Enter the Pack Size information and the MAH country of origin then click on Next



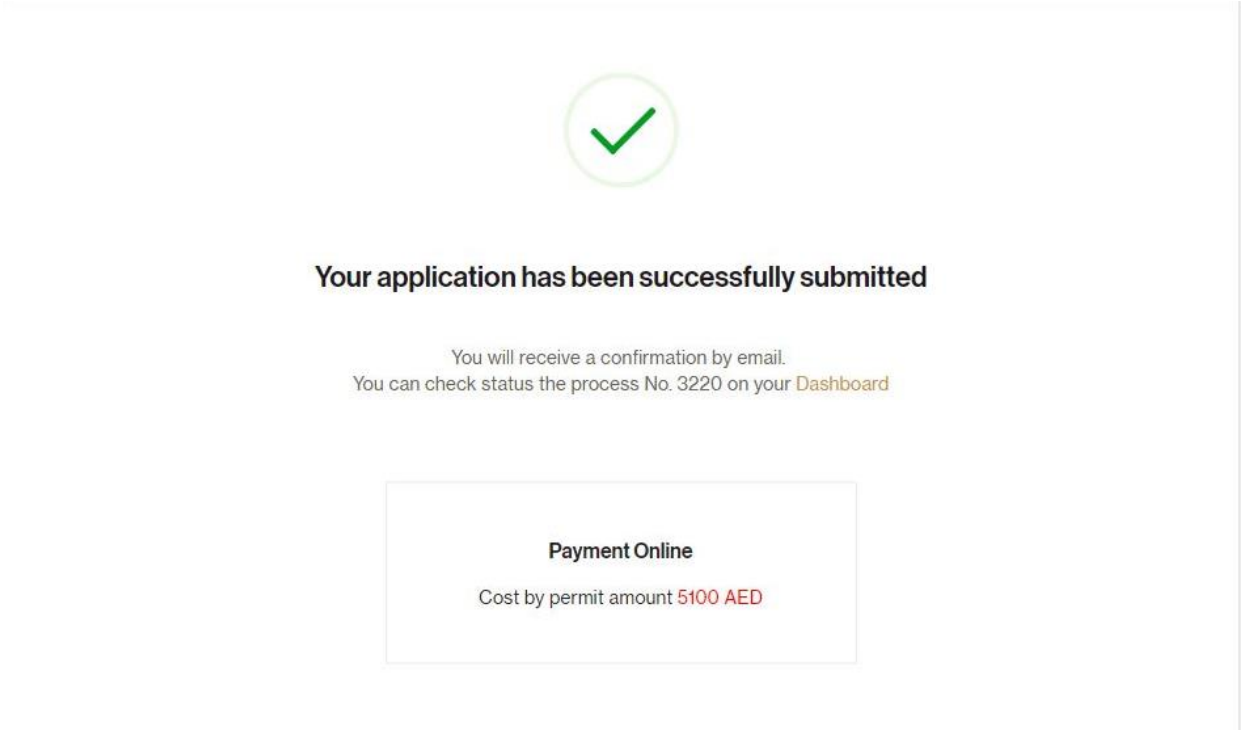
Add the proposed CIF price, Public price in the country of origin, public price in other countries, prices in reference book, and proposed price in GCC, by clicking over "Add price details" button and then click on Next



Then attach the required documents and accept the terms and conditions and click on Apply.

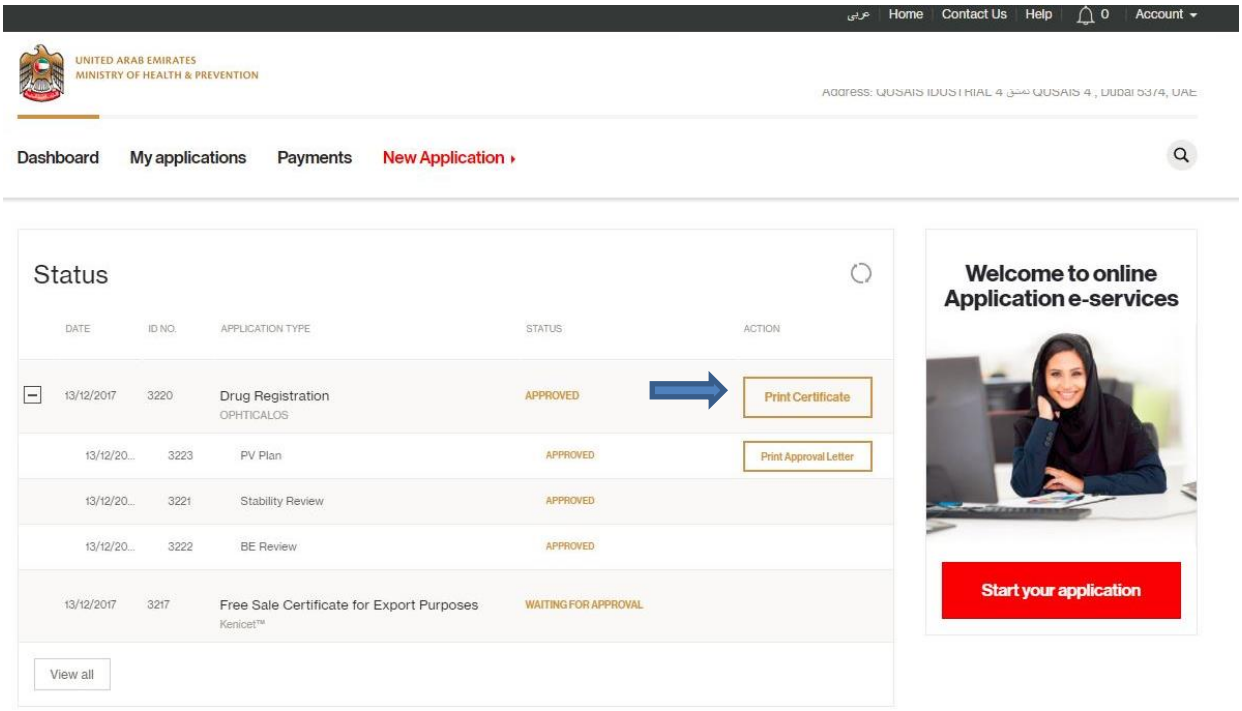


After submitting the application a successful message displayed to the user, and the permit fees is generated. The user can perform the payment from this screen by clicking over the amount, where the system directs you to the payment screen.



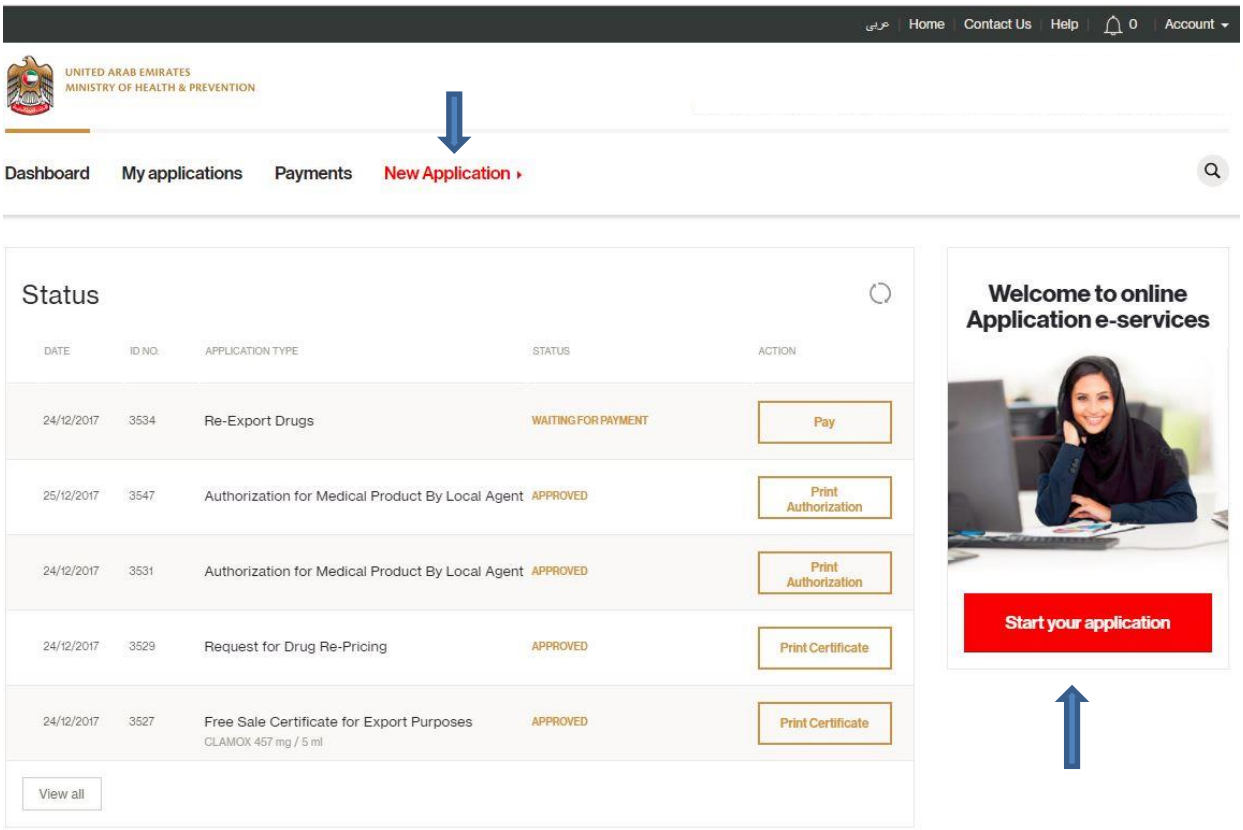
Alternatively, the user can go to the payment screen in the dashboard and click over the pay button and perform the payment.

To view the application status go to dashboard, and once the permit is approved click on "Print Permit" button on the dashboard to view and print the permit.

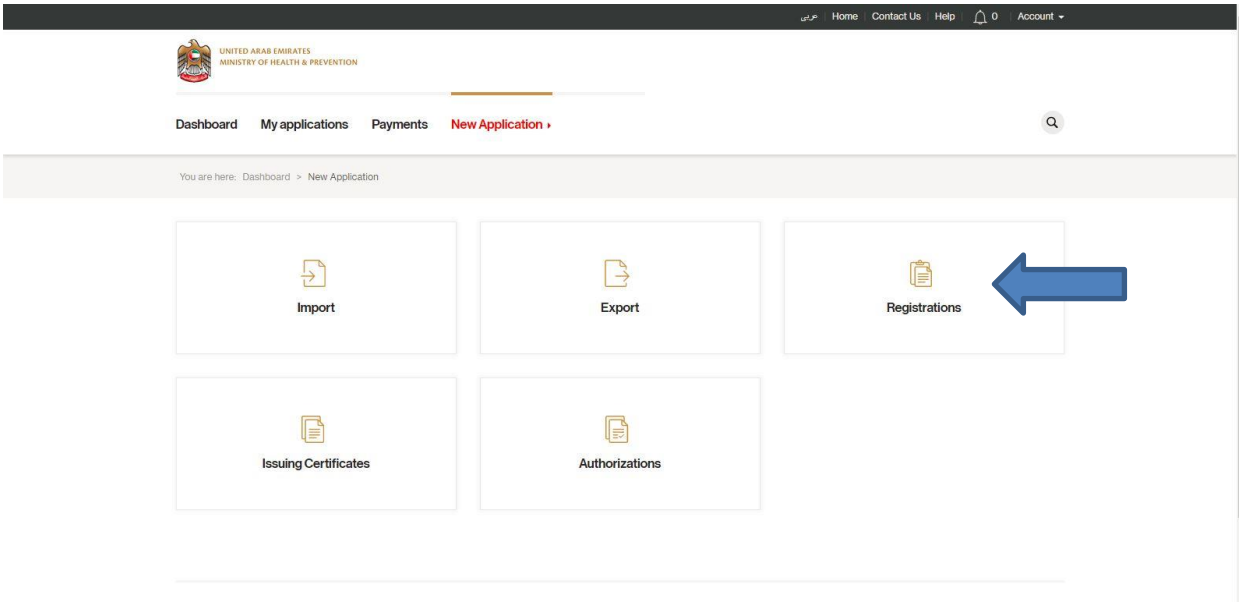


2.4 REGISTERED MEDICAL PRODUCT MINOR VARIATION

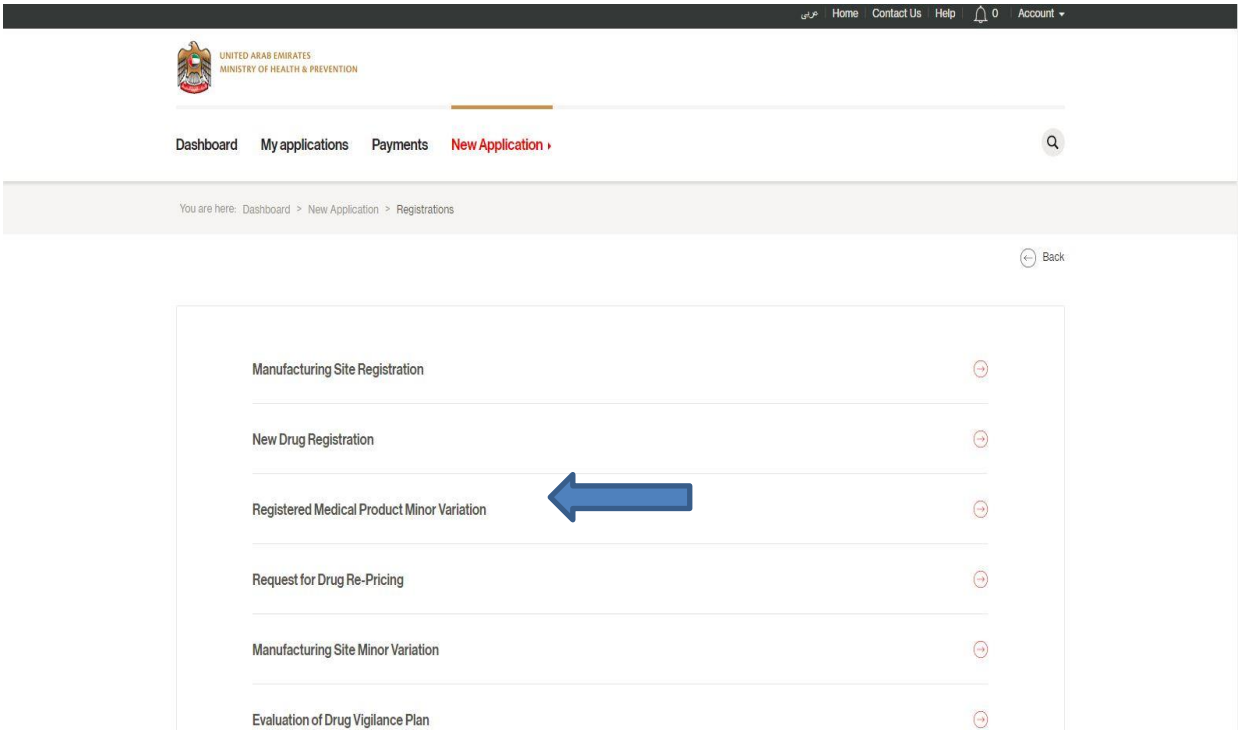
Log into the system using your credentials and then click on start new application link



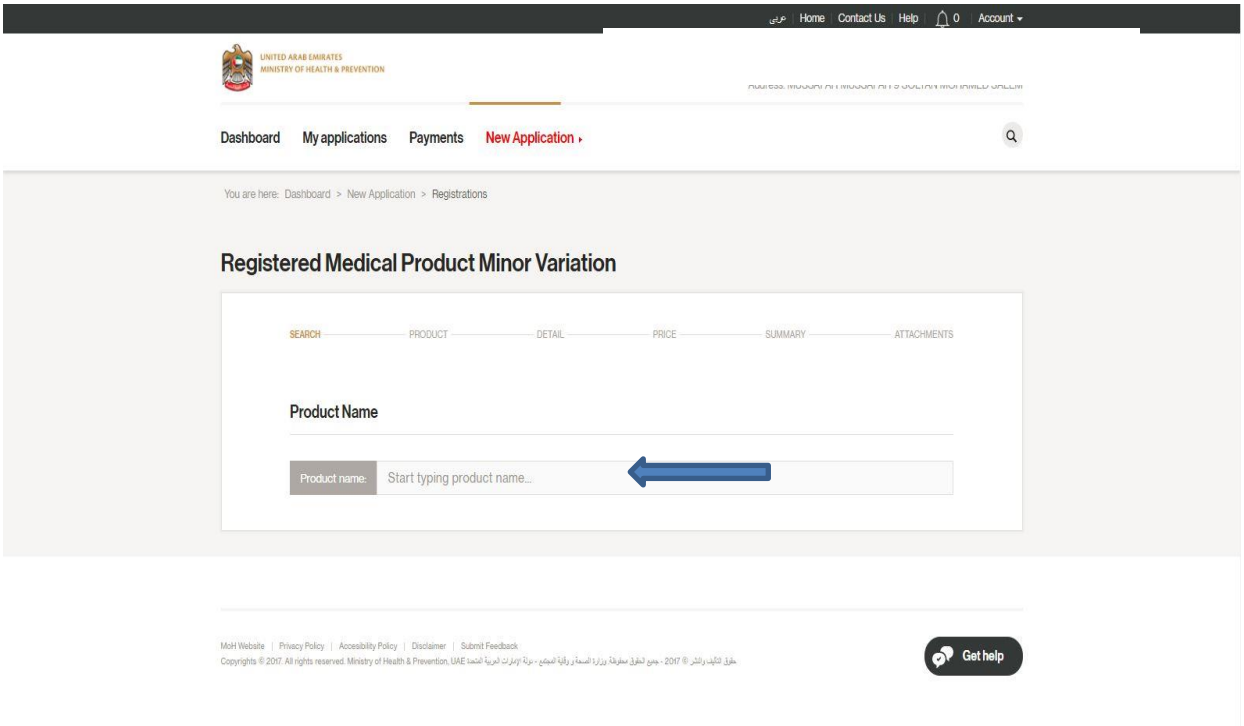
Click on registration tile



The system takes you to the services screen, click on drug registration

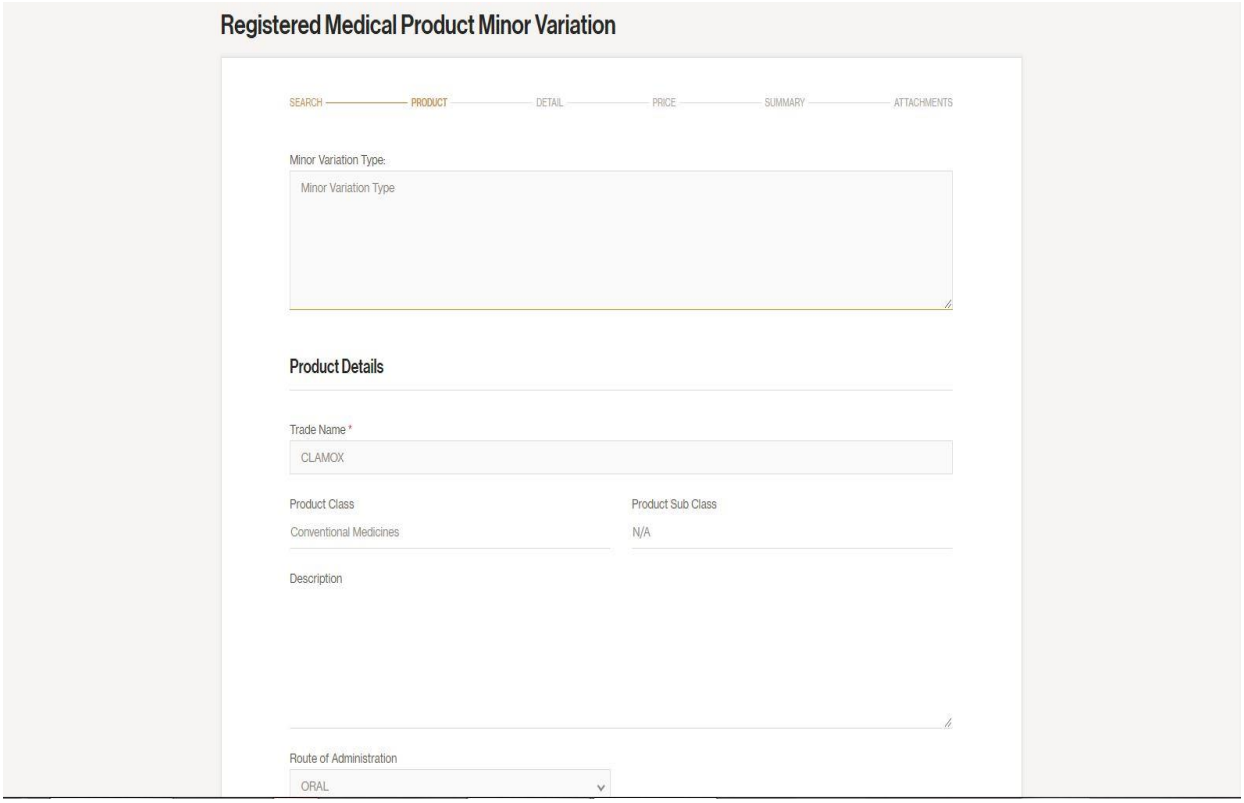


Start type the product name, the system will filter the results based on the entered characters

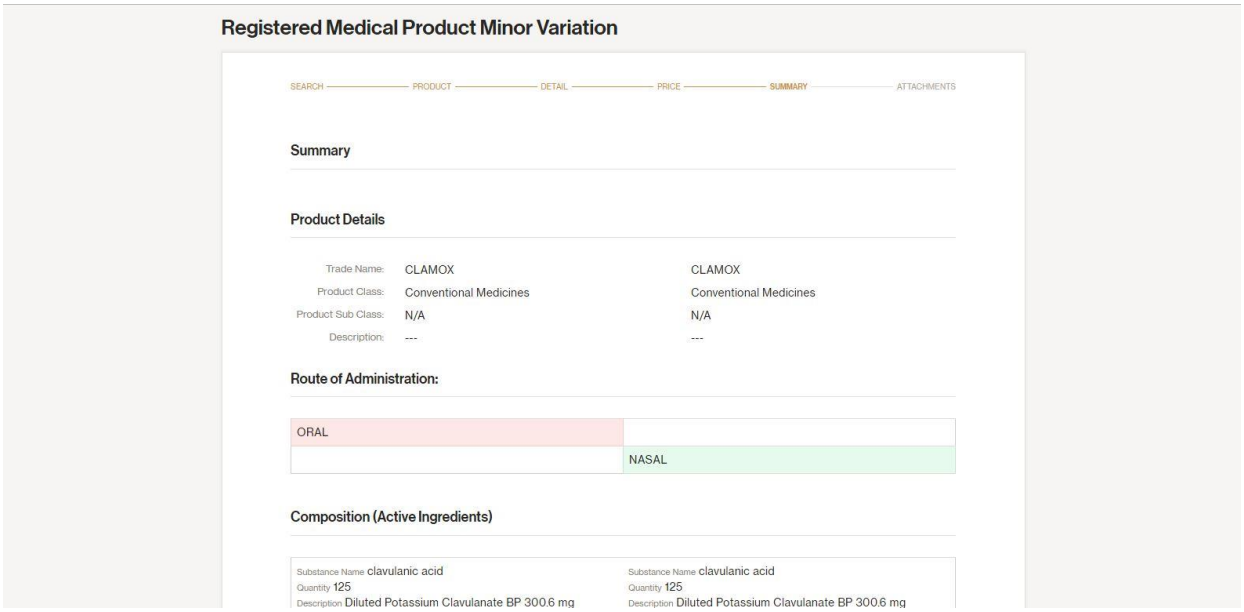


Modify the data of the drug to the desired change; you can reach to more information on the product by navigating over the product tabs. Or by clicking on next button at the bottom of

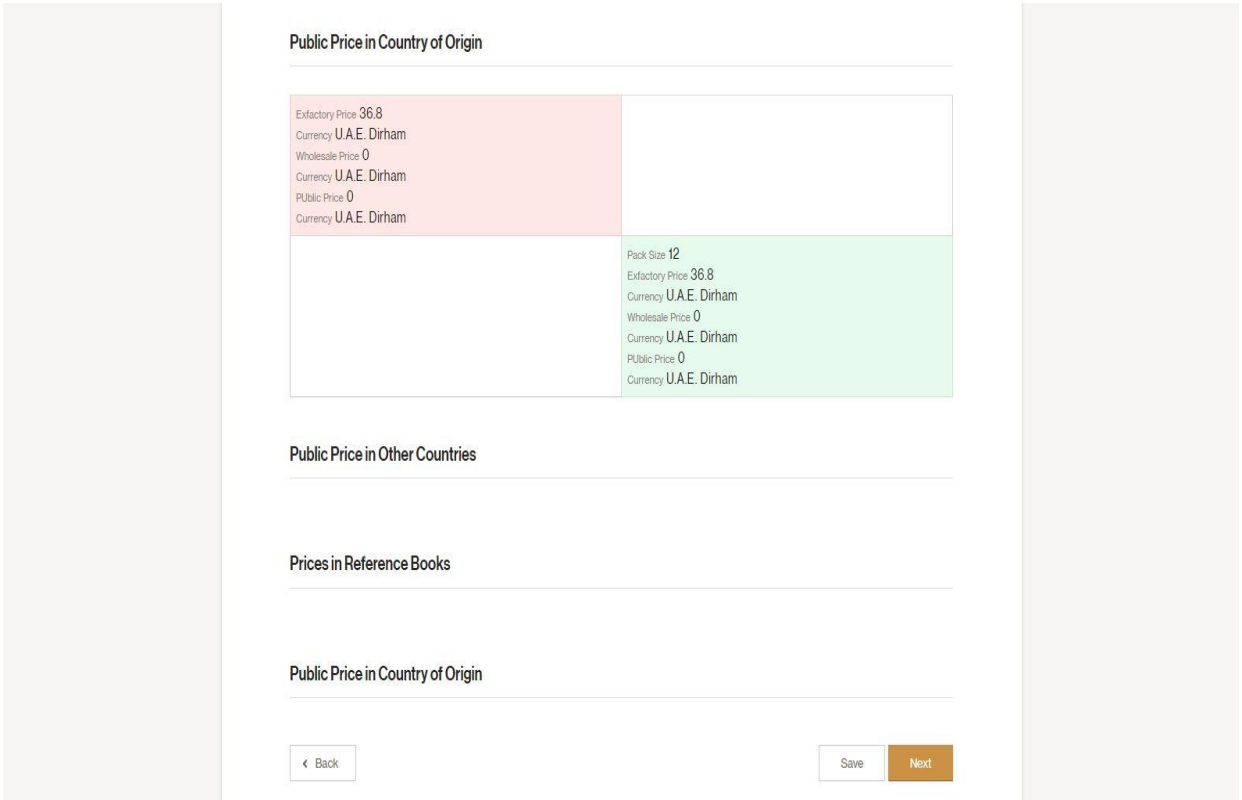
the page, please note that if there is any mandatory field empty, then you need to enter the correct values.



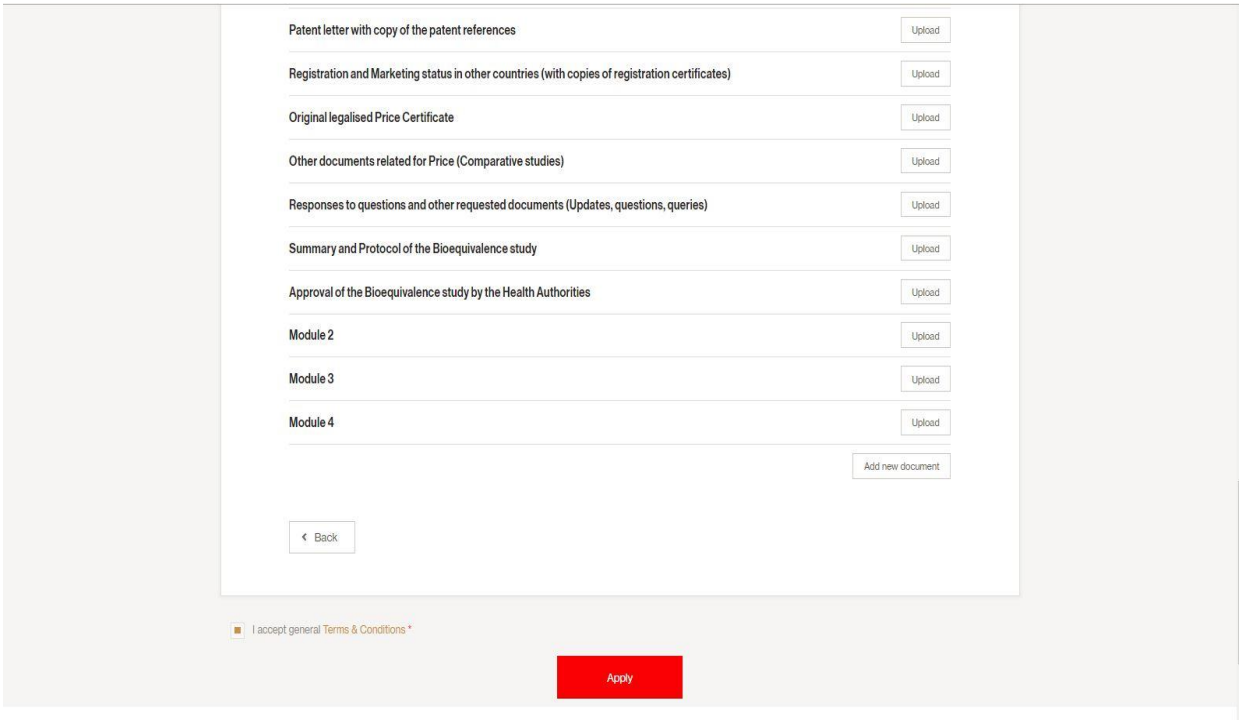
The summary page shows the changes or modifications done on the application, where it shows the application and the new value so you can review the changes one more time before submitting it to MOHAP for review. The old data highlighted in pink and the new data is highlighted in blue



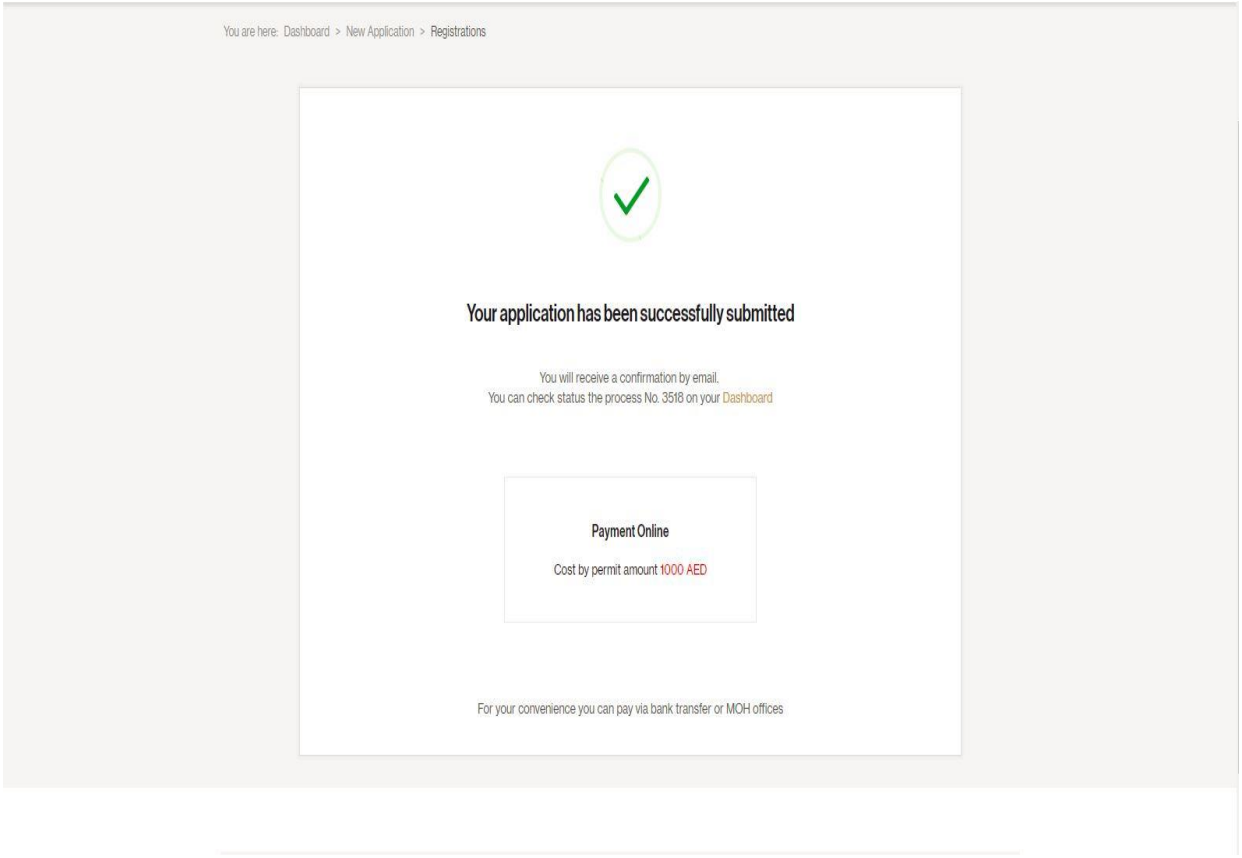
After you review the changes, click on next to attach the supportive documents and to perform the payment.



Attach the support documents and accept the terms and conditions, the click over apply

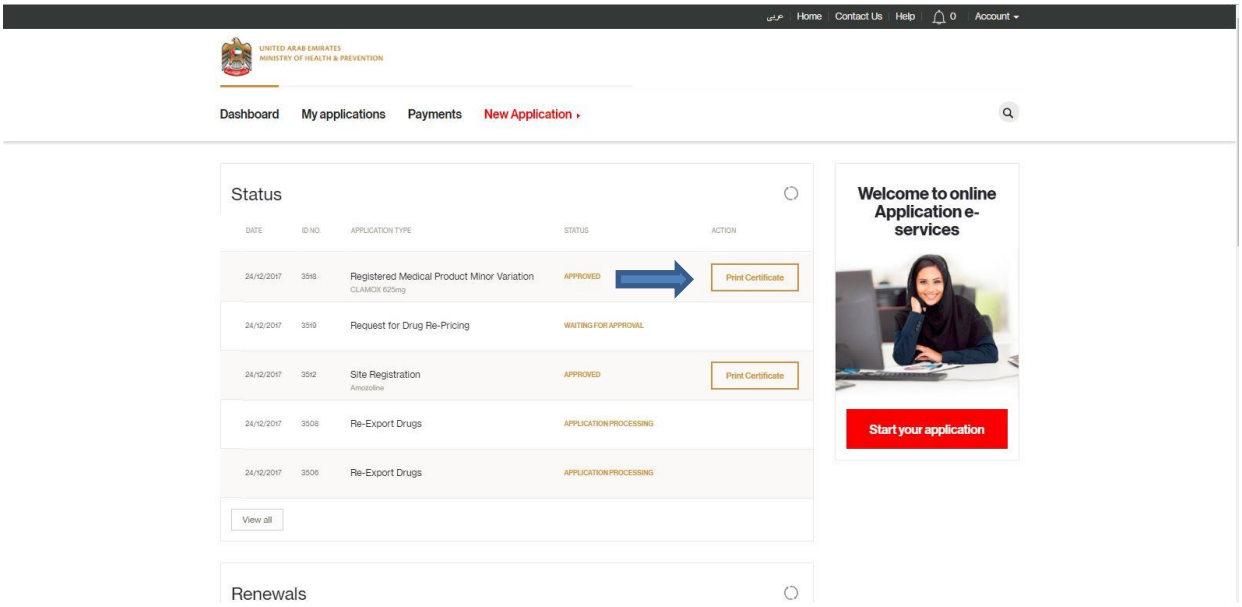


After submitting the application a successful message displayed to the user, and the permit fees is generated. The user can perform the payment from this screen by clicking over the amount, where the system directs you to the payment screen.



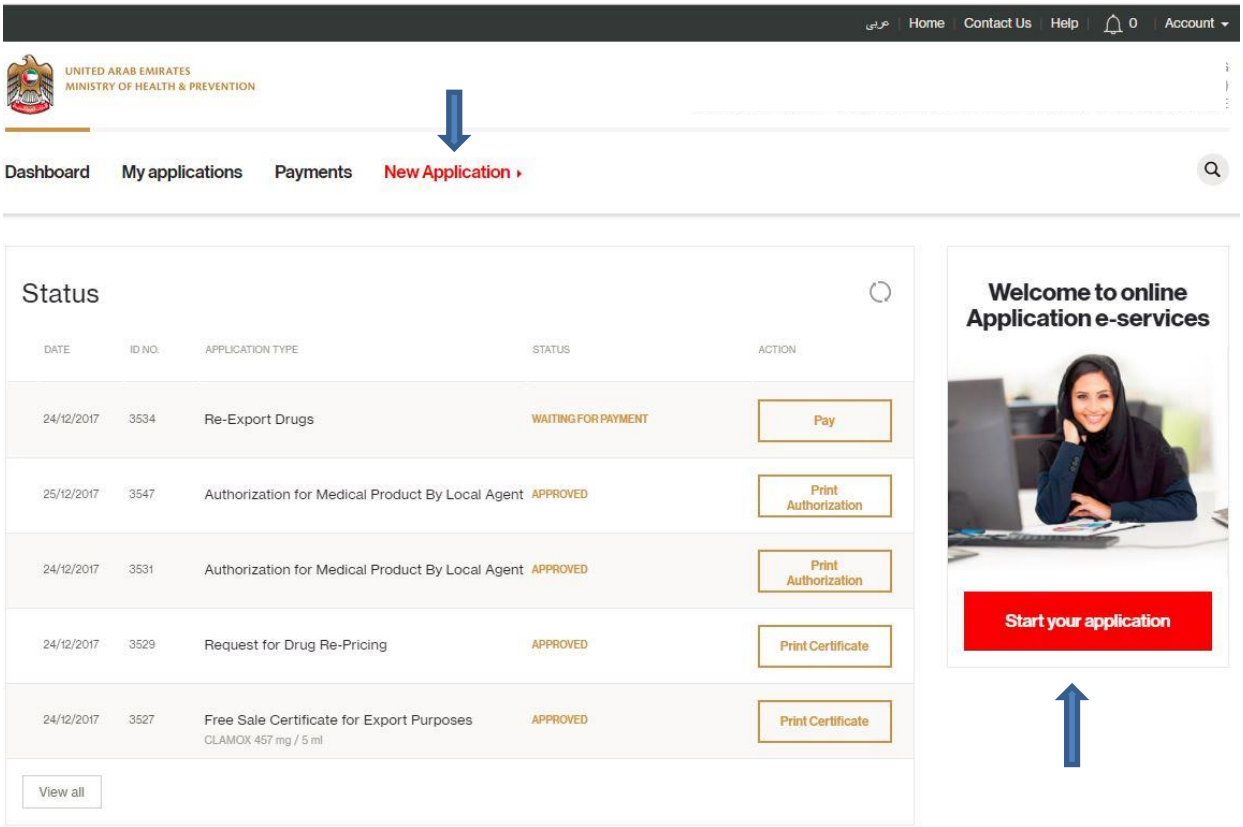
Alternatively, the user can go to the payment screen in the dashboard and click over the pay button and perform the payment.

To view the application status go to dashboard, and once the permit is approved click on "Print Permit" button on the dashboard to view and print the permit.

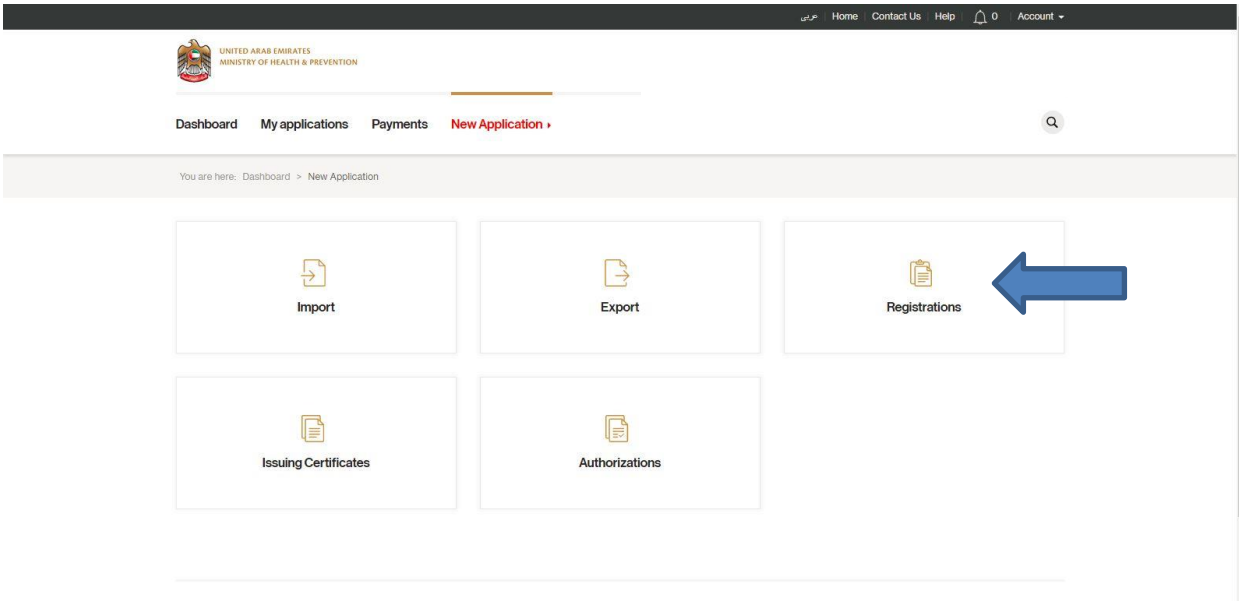


2.5 REQUEST FOR DRUG RE-PRICING

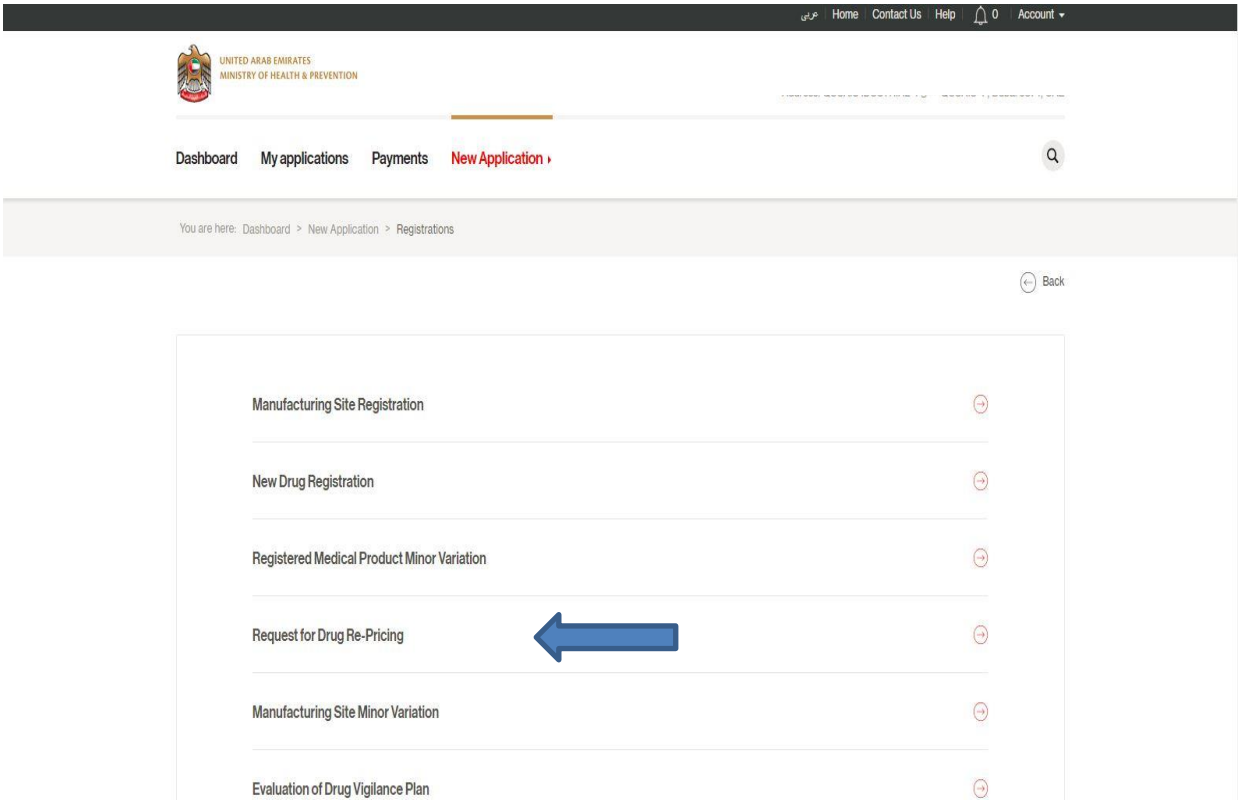
Log into the system using your credentials and then click on start new application link



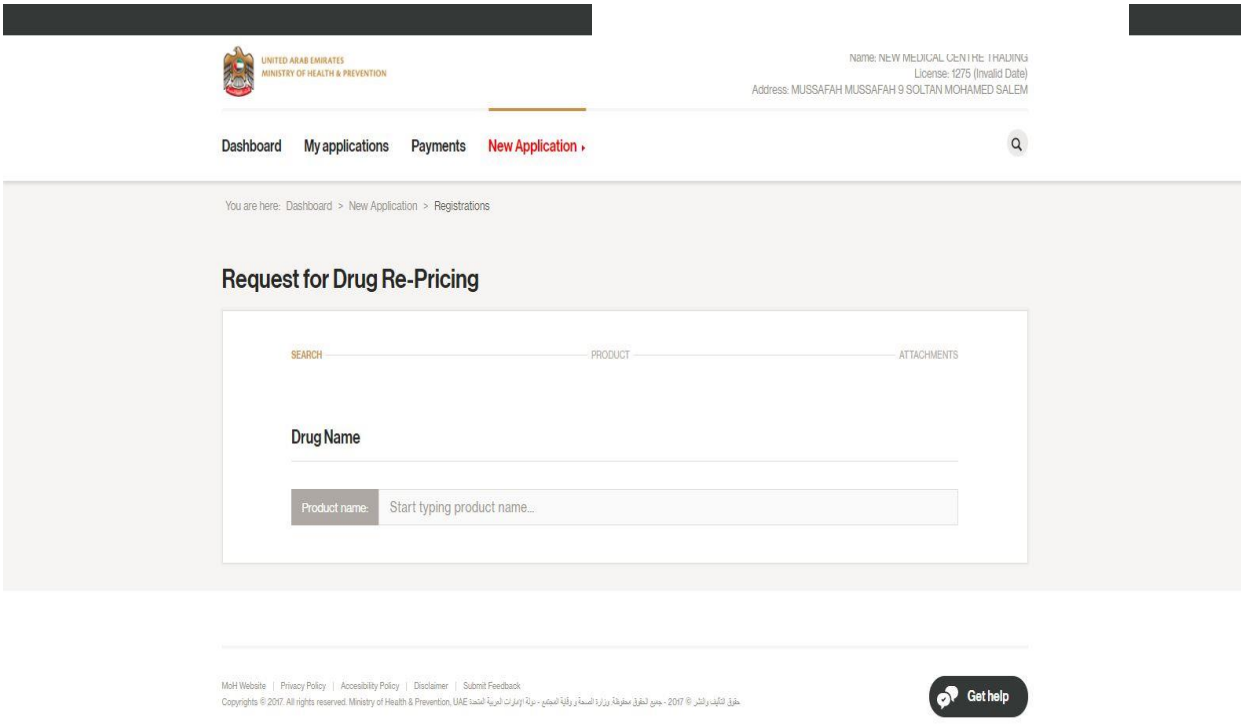
Click on registration tile



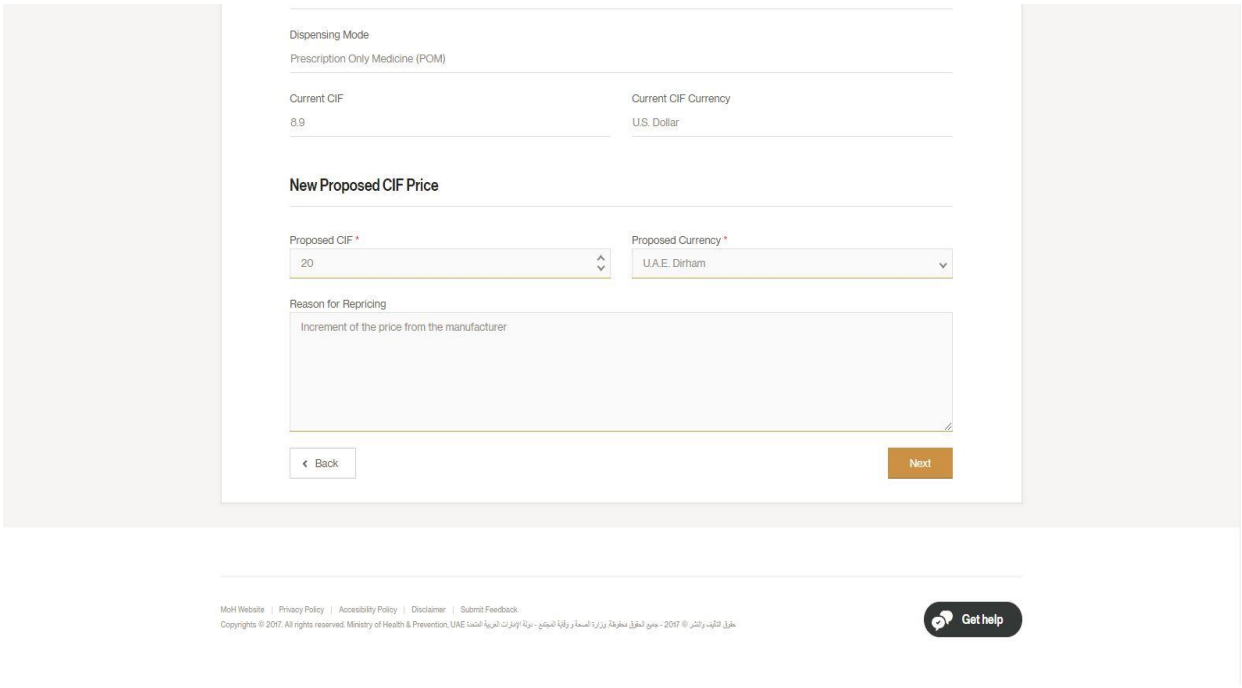
The system takes you to the services screen, click on drug registration



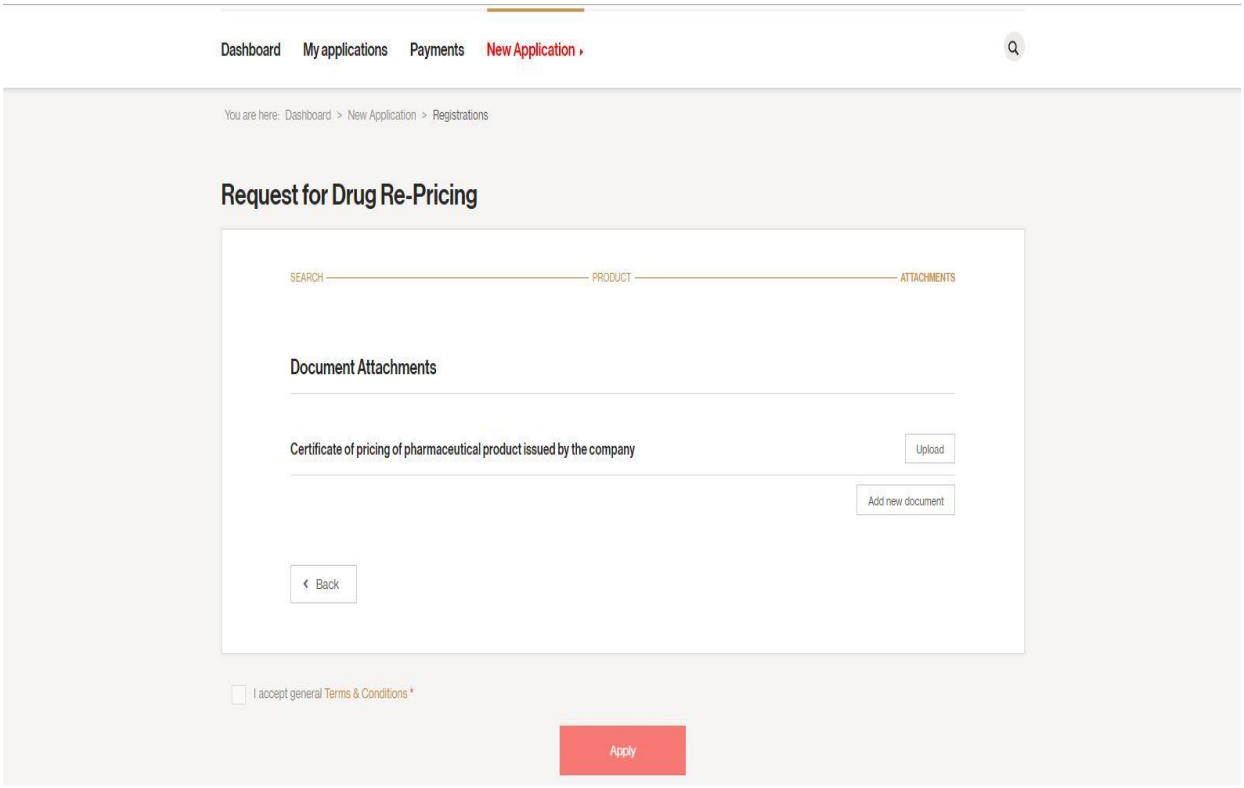
Start type the product name, the system filters the products based on the entered characters



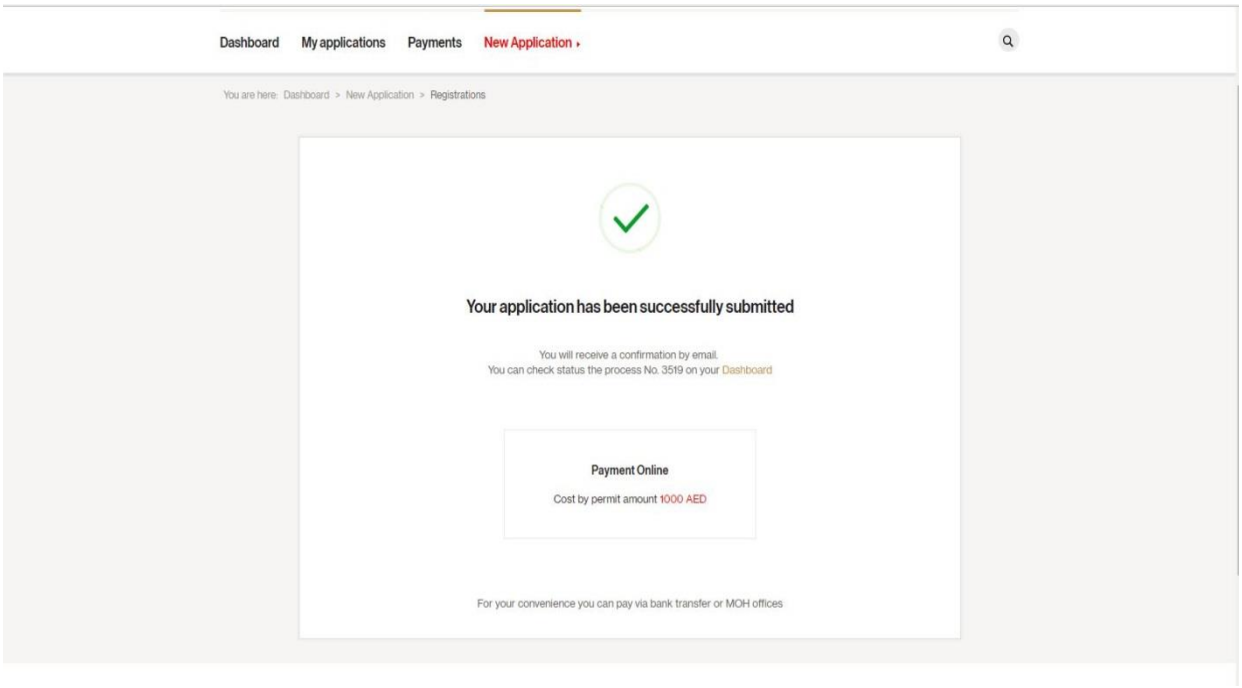
Enter the new proposed CIF price, select the currency, and provide the reason of repricing and then click on Next



Upload the support documents; accept the terms and conditions and then click on Apply button

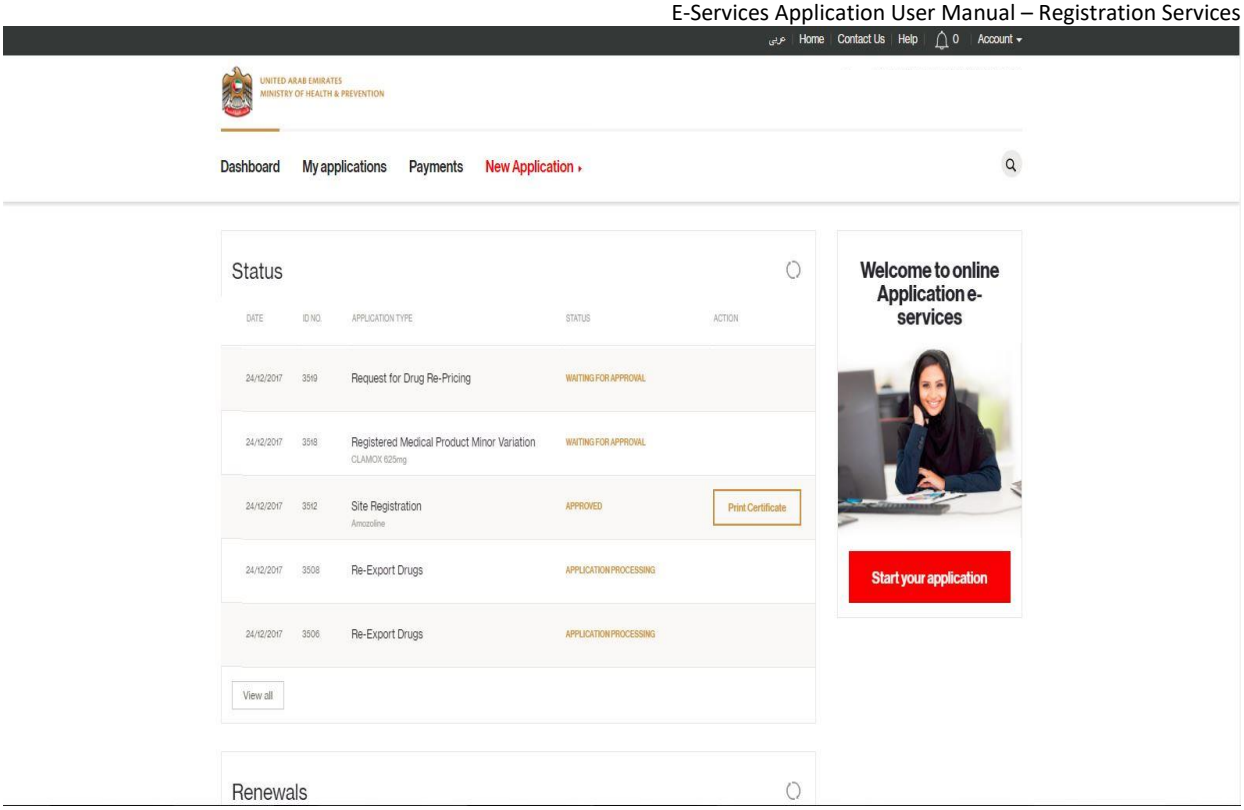


After submitting the application a successful message displayed to the user, and the permit fees is generated. The user can perform the payment from this screen by clicking over the amount, where the system directs you to the payment screen.



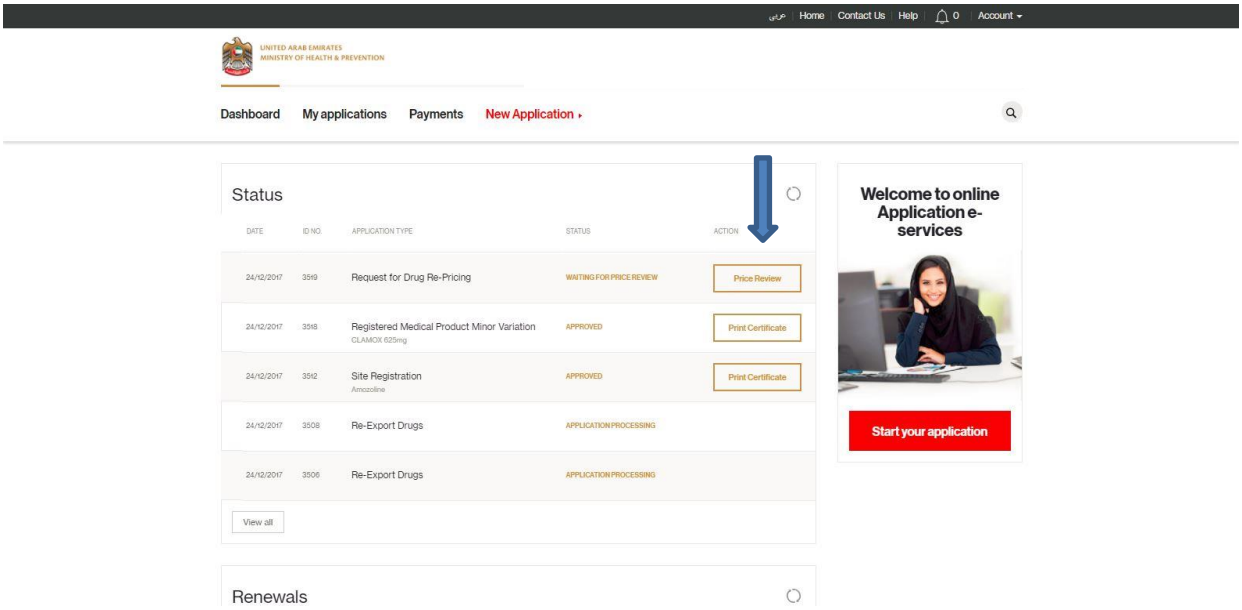
Alternatively, the user can go to the payment screen in the dashboard and click over the pay button and perform the payment.

Navigate to the dashboard to view the status of the application; the initial status will be "Waiting for approval"

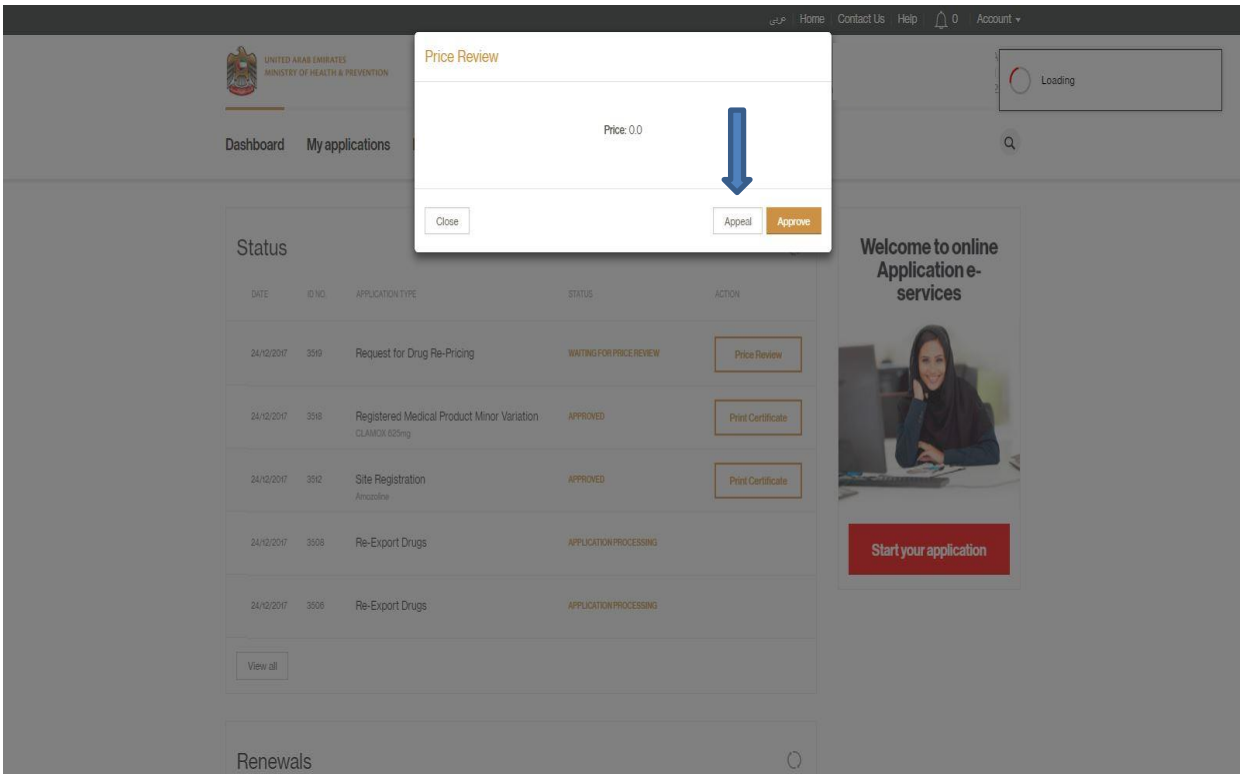

عربي | Home | Contact Us | Help | 0 | Account
UNITED ARAB EMIRATES
MINISTRY OF HEALTH & PREVENTION
Dashboard
My applications
Payments
New Application
Status
DATE
ID NO.
APPLICATION TYPE
STATUS
ACTION
24/12/2017 3519 Request for Drug Re-Pricing WAITING FOR APPROVAL
24/12/2017 3518 Registered Medical Product Minor Variation CLAMOX 625mg WAITING FOR APPROVAL
24/12/2017 3512 Site Registration Amozoline APPROVED Print Certificate
24/12/2017 3508 Re-Export Drugs APPLICATION PROCESSING
24/12/2017 3506 Re-Export Drugs APPLICATION PROCESSING
View all
Renewals
Welcome to online Application e-services
Start your application

After MOH approve the permit, the application status will be changed to waiting for price review, and a new button is displayed next to the application to review the approved price by MOH, You can do the following,

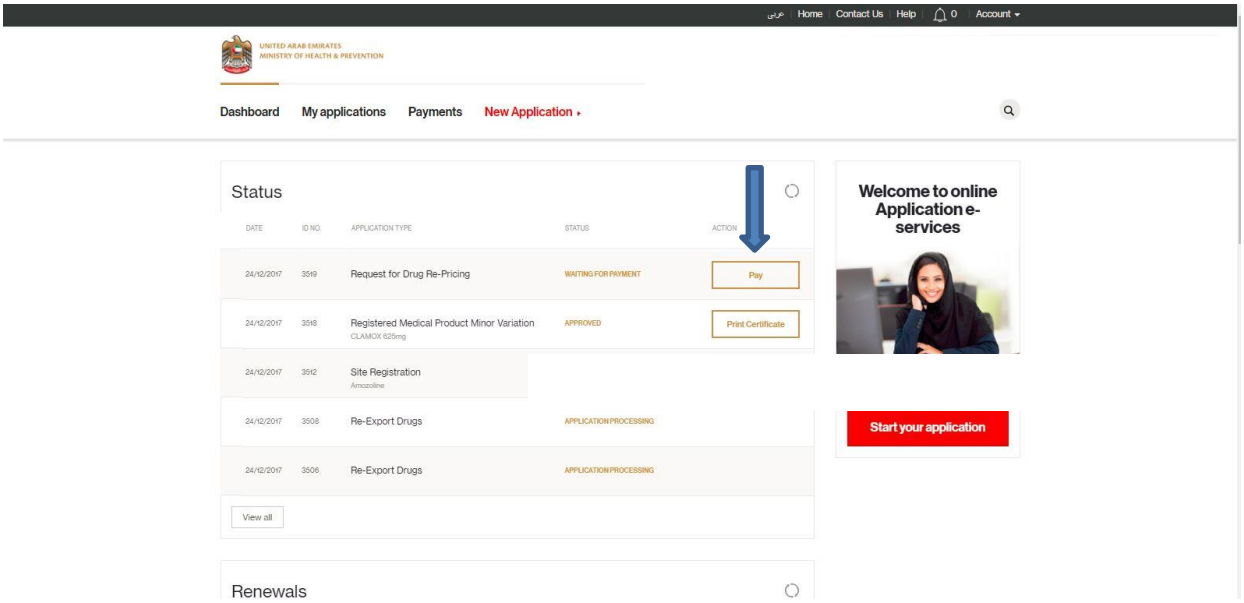
- Accept MOH approved price → click over "Approve" button.
- Do not accept the price and request for appeal → click over "Appeal" button.



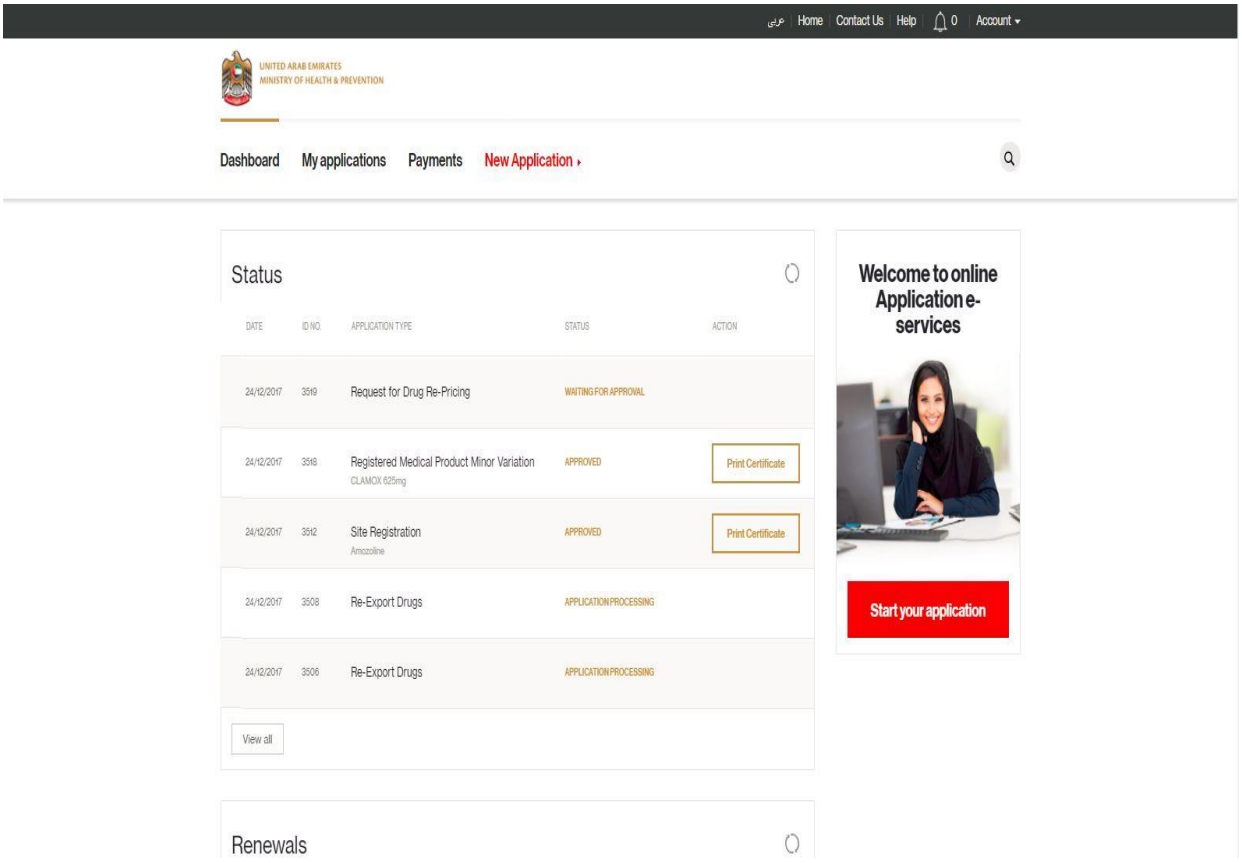
Click over "Appeal" button



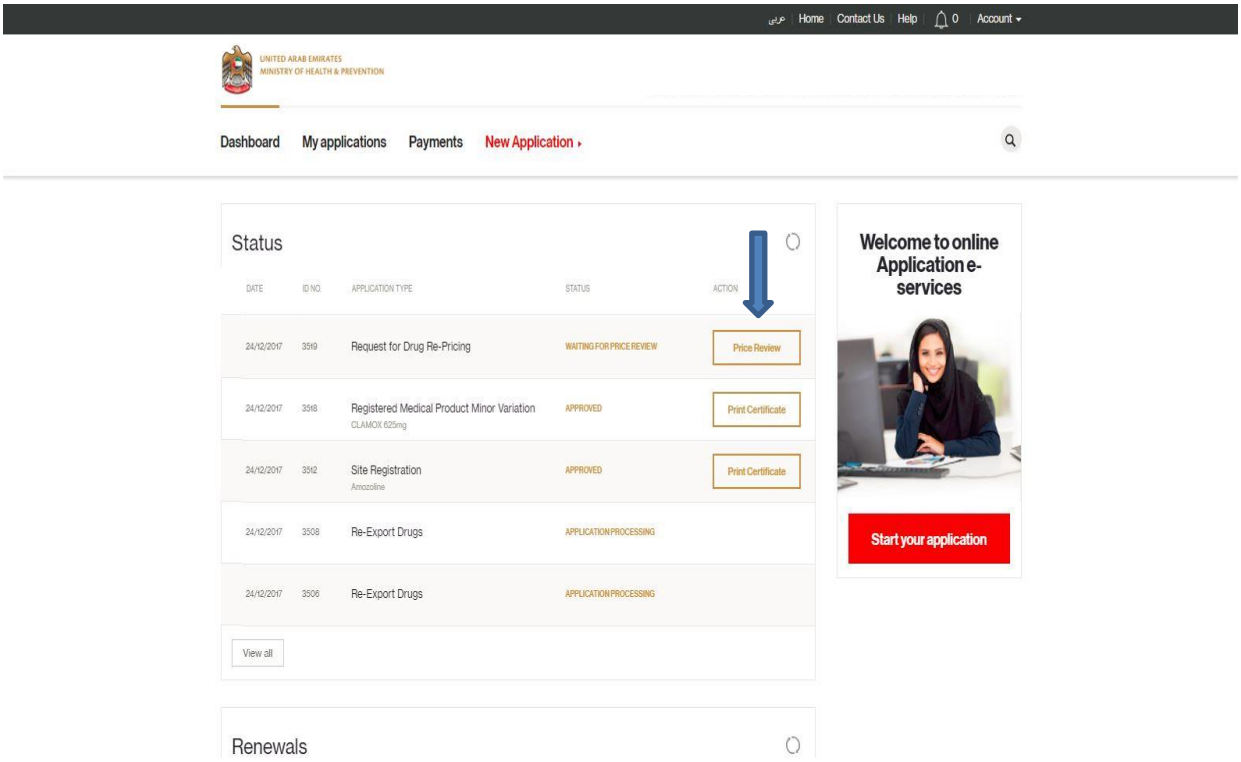
Click over “Pay” button, the system takes you to the payment screen, do the payment and wait till MOH review the application again.



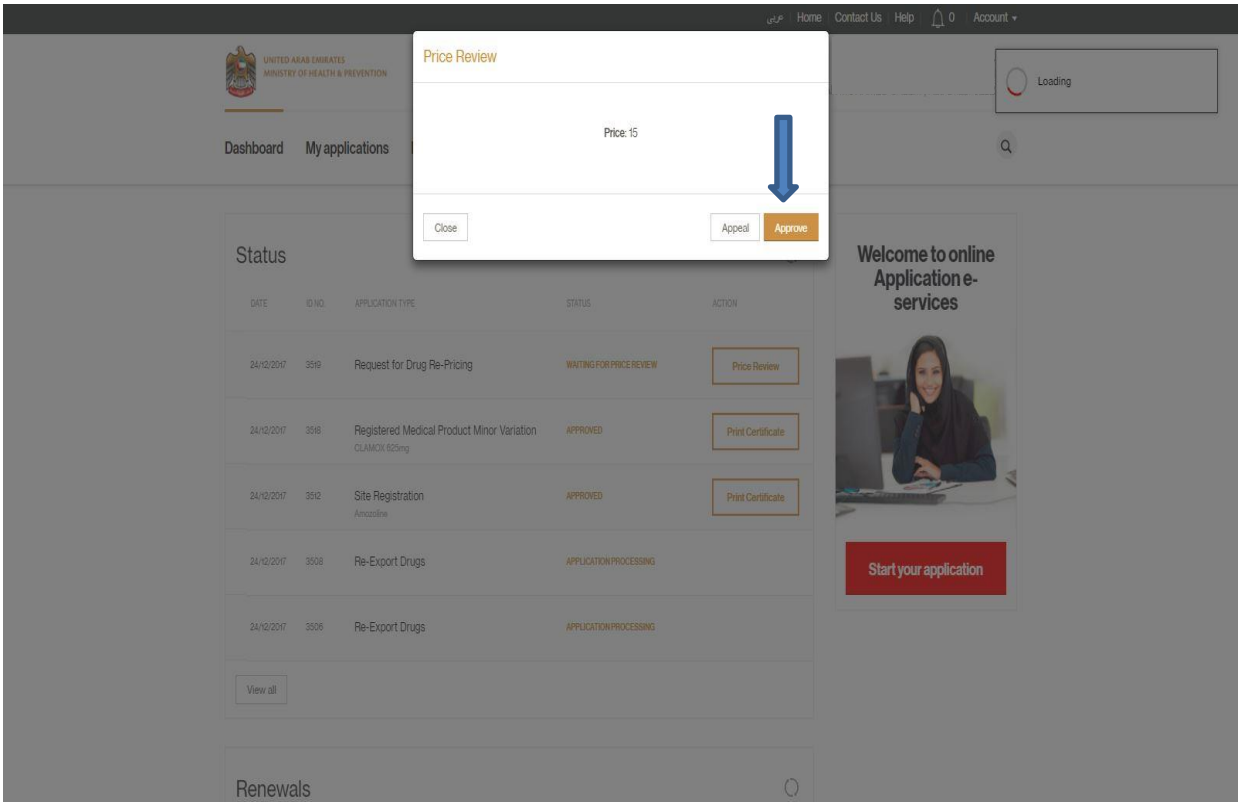
The status of the request will be “Waiting for approval”



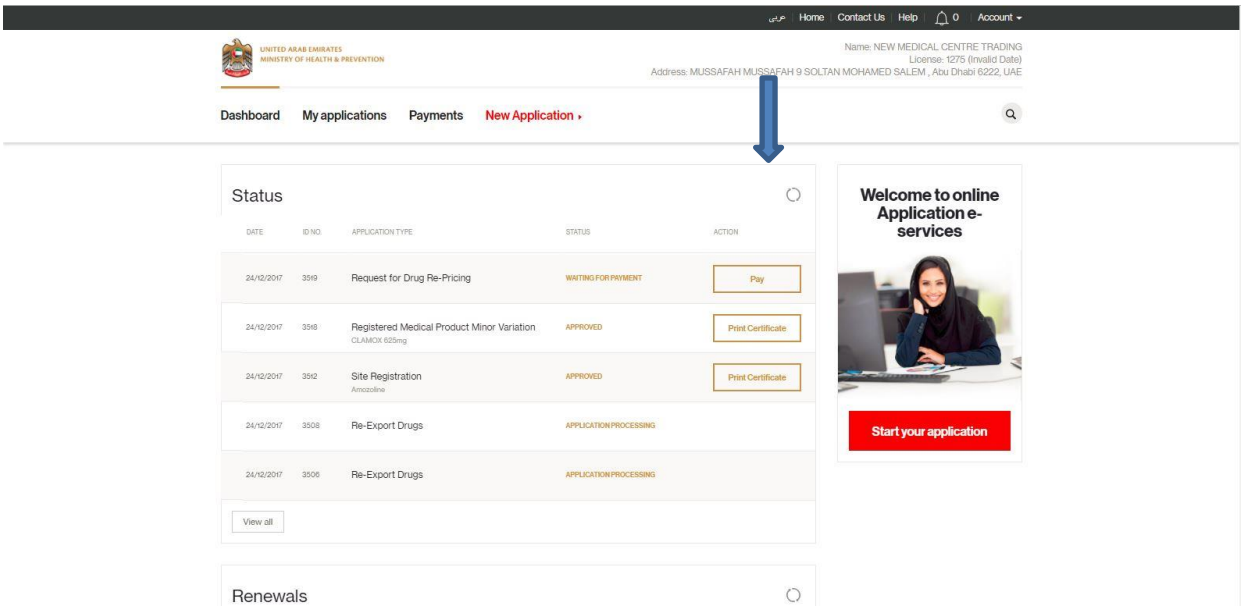
After MOH review, the application status will change to "Waiting for Price Review" and the "Price Review" button is enabled again.



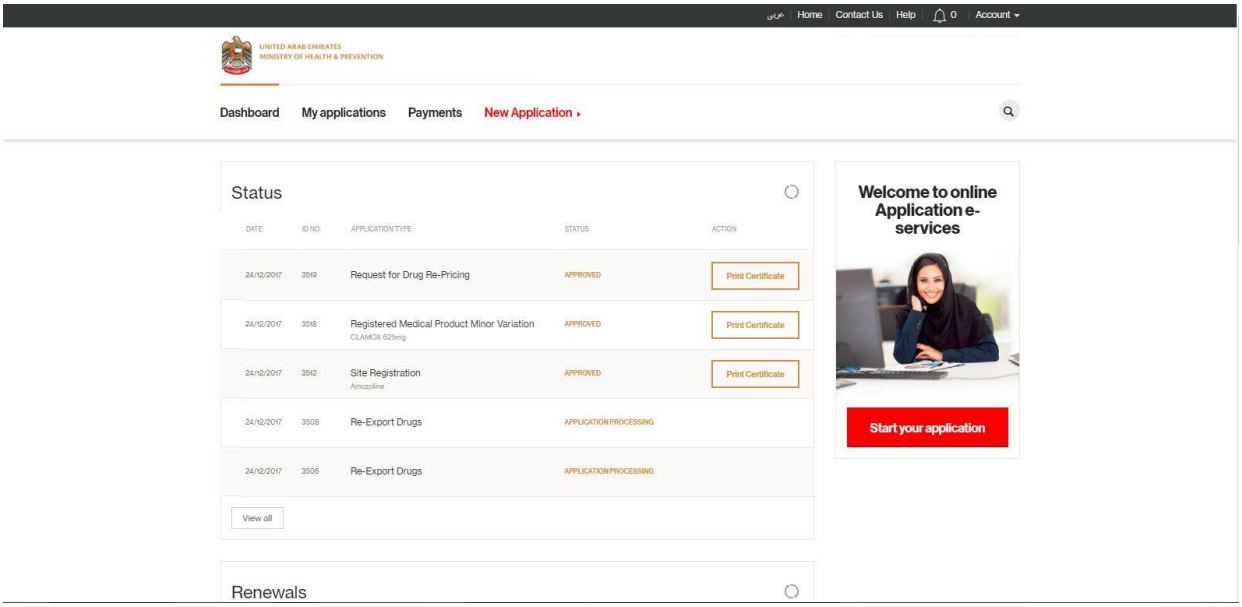
Click on the Price review button and the click on approve



After approving the permit, you need to pay the permit fees and then you will be able to print the permit

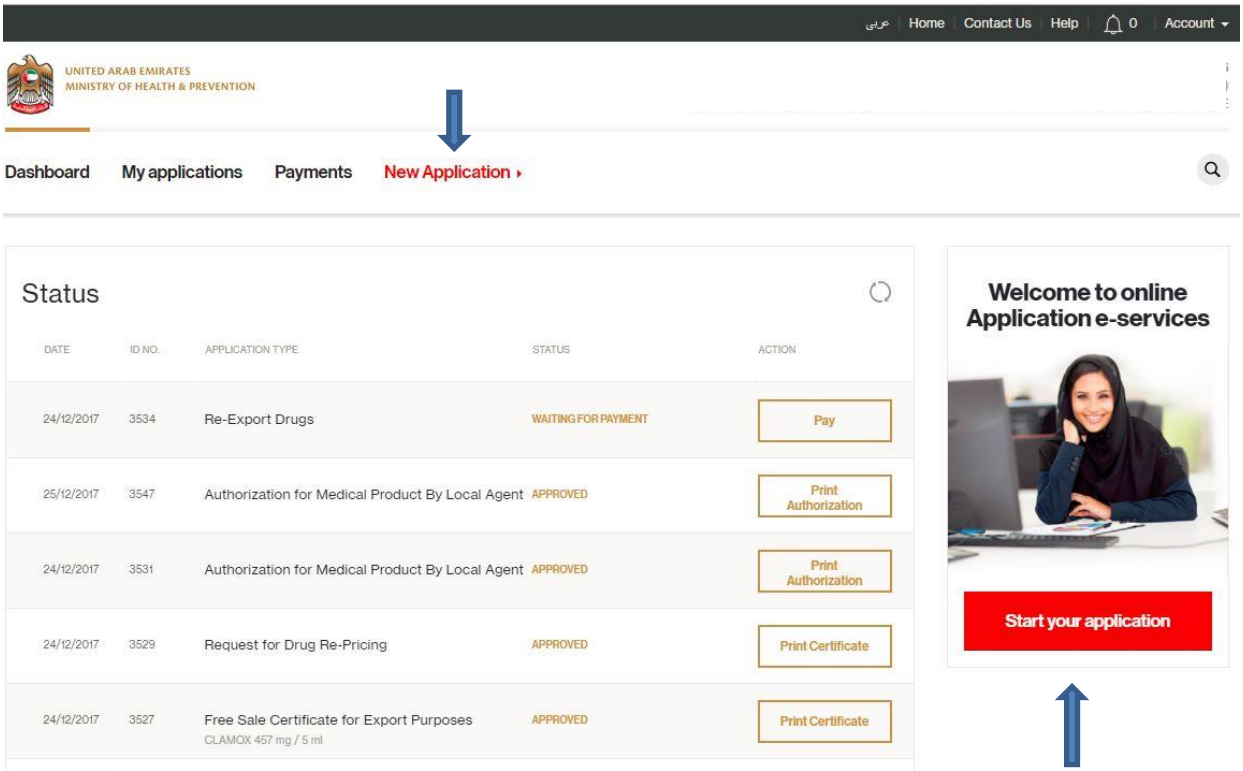


Print the permit by clicking on Print Certificate button

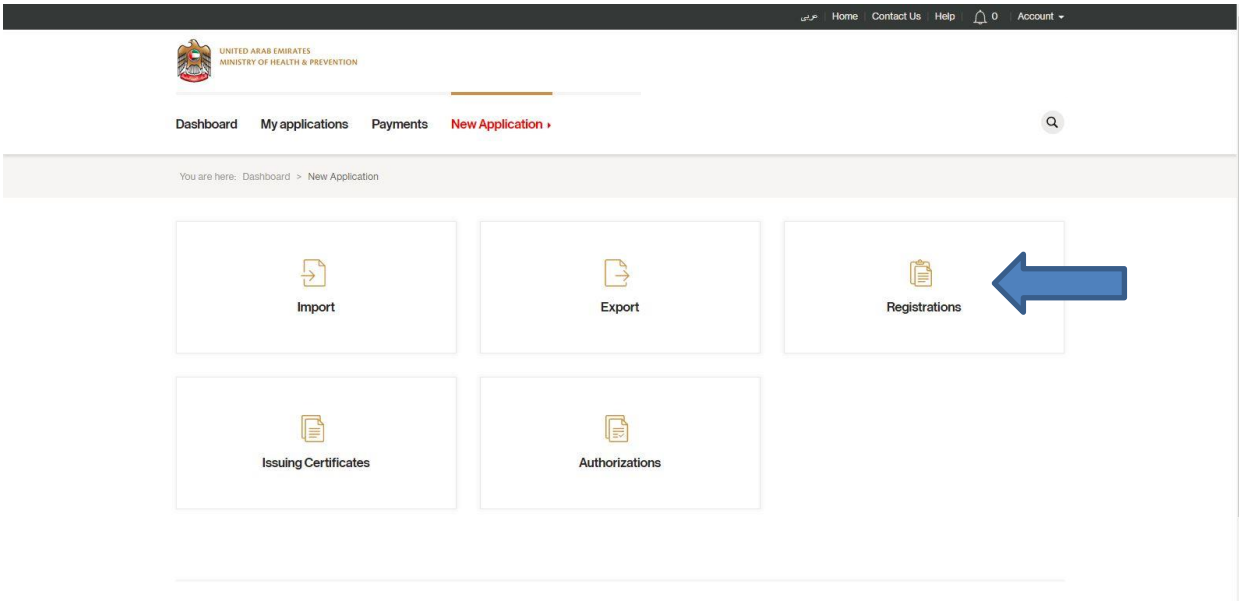


2.6 MANUFACTURING SITE MINOR VARIATION

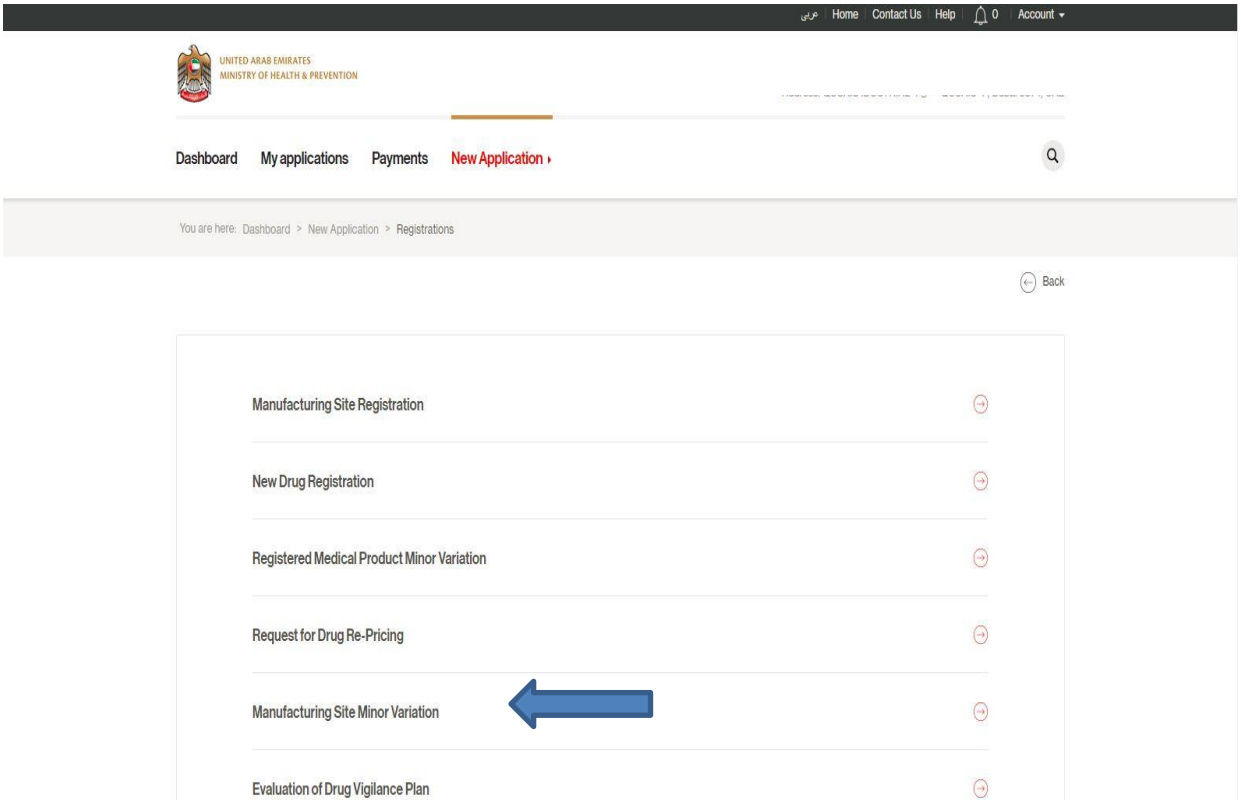
Log into the system using your credentials and then click on start new application link



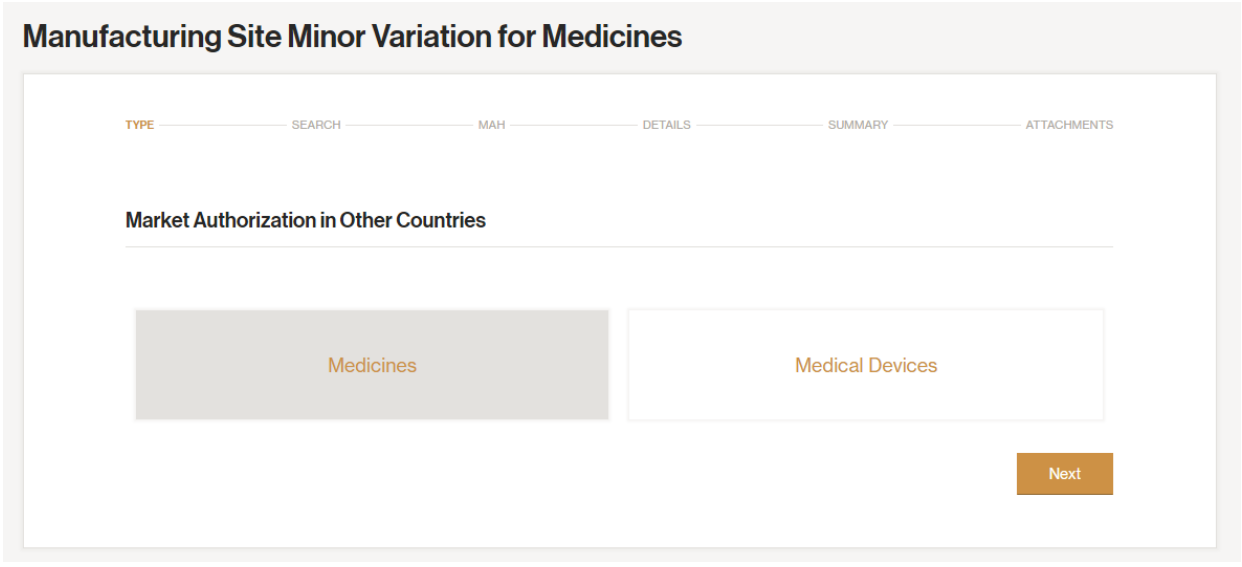
Click on registration tile



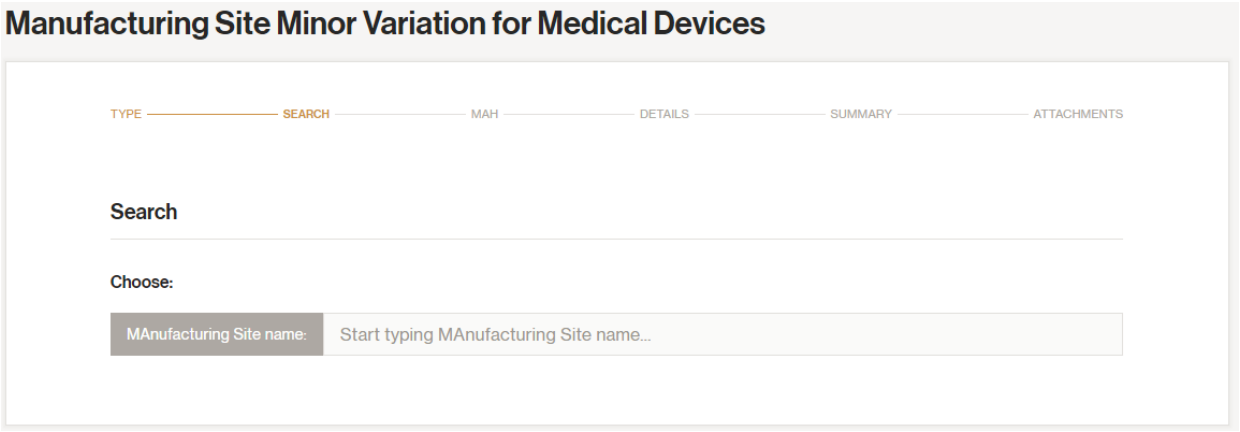
The system takes you to the services screen, click on drug registration



Select Medicines or Medical Devices and then click “Next”

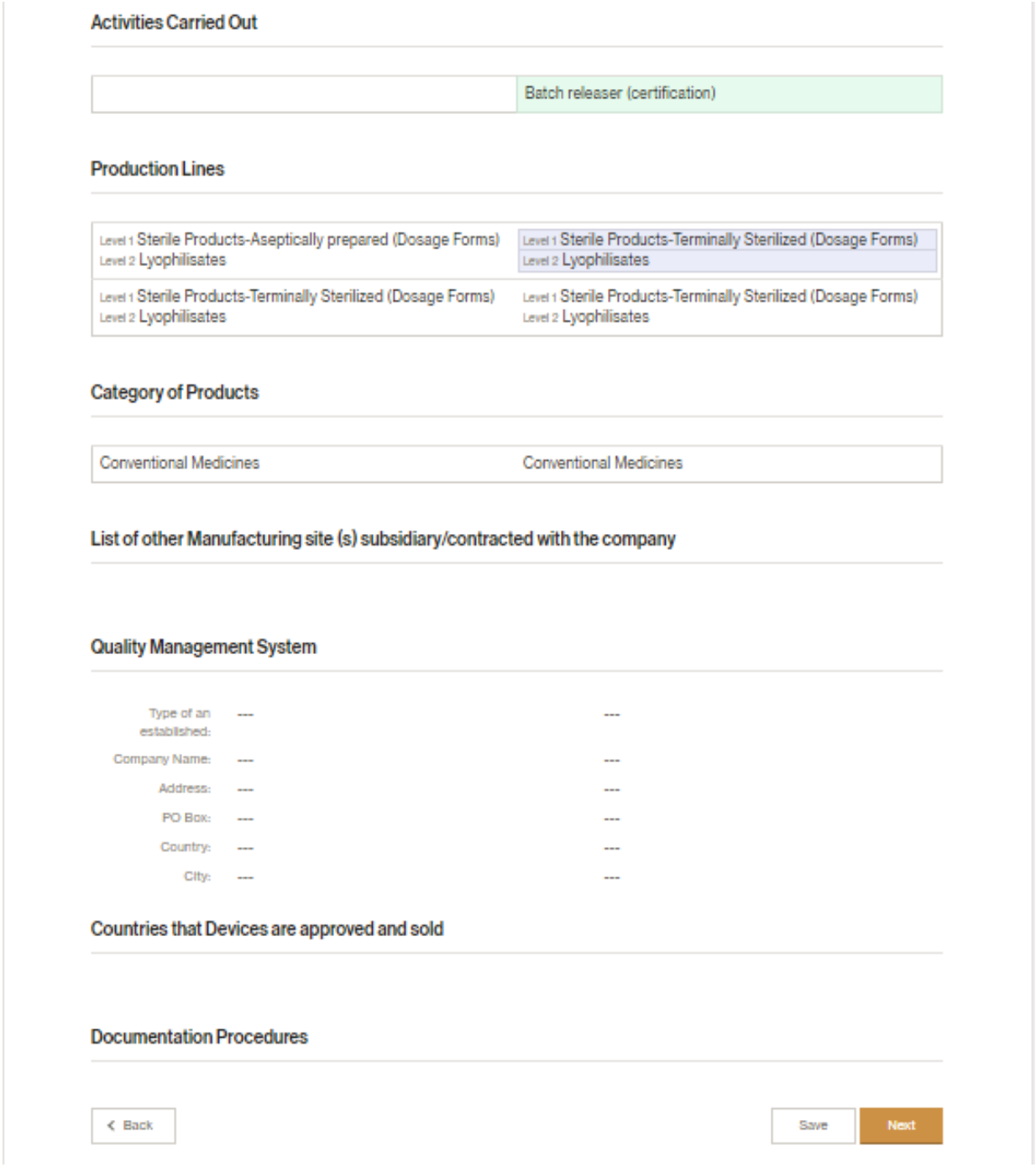


Start typing the site name, the system filters the sites based on the entered characters

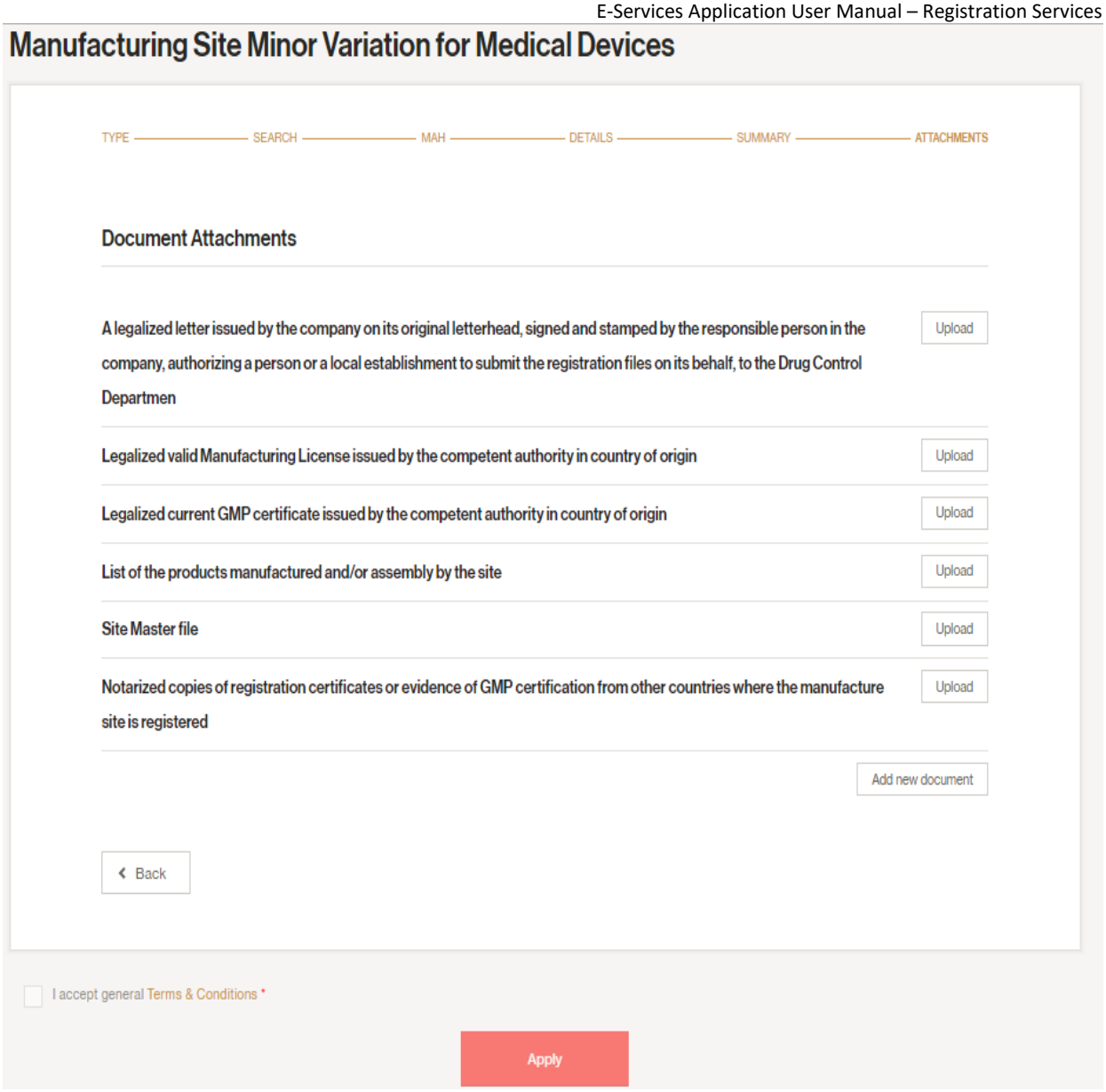


Modify the data of the drug to the desired change; you can reach to more information on the product by navigating over the product tabs. Or by clicking on next button at the bottom of the page, please note that if there is any mandatory field empty, then you need to enter the correct values.

Once you make sure that the changes are correct, click on next to attach the supportive documents and to perform the payment

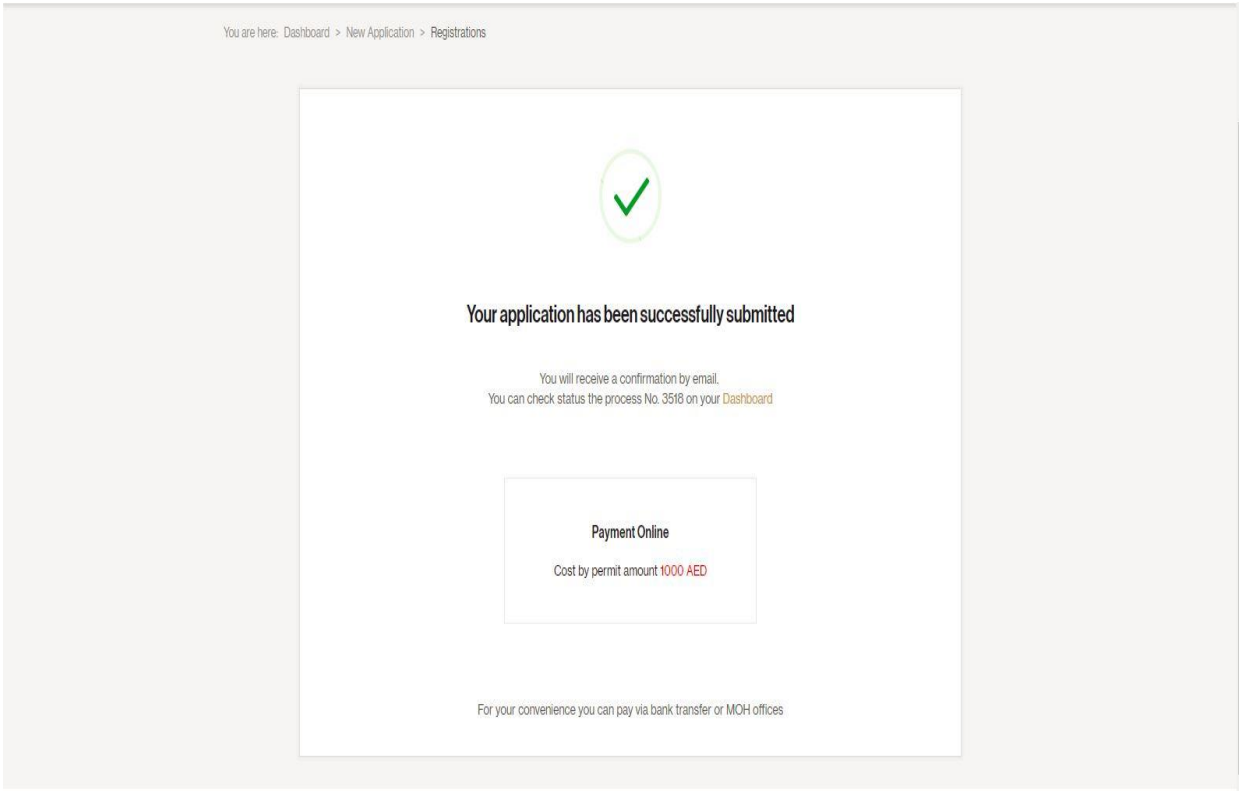


Attach the required document, accept the terms and conditions and then click on Apply



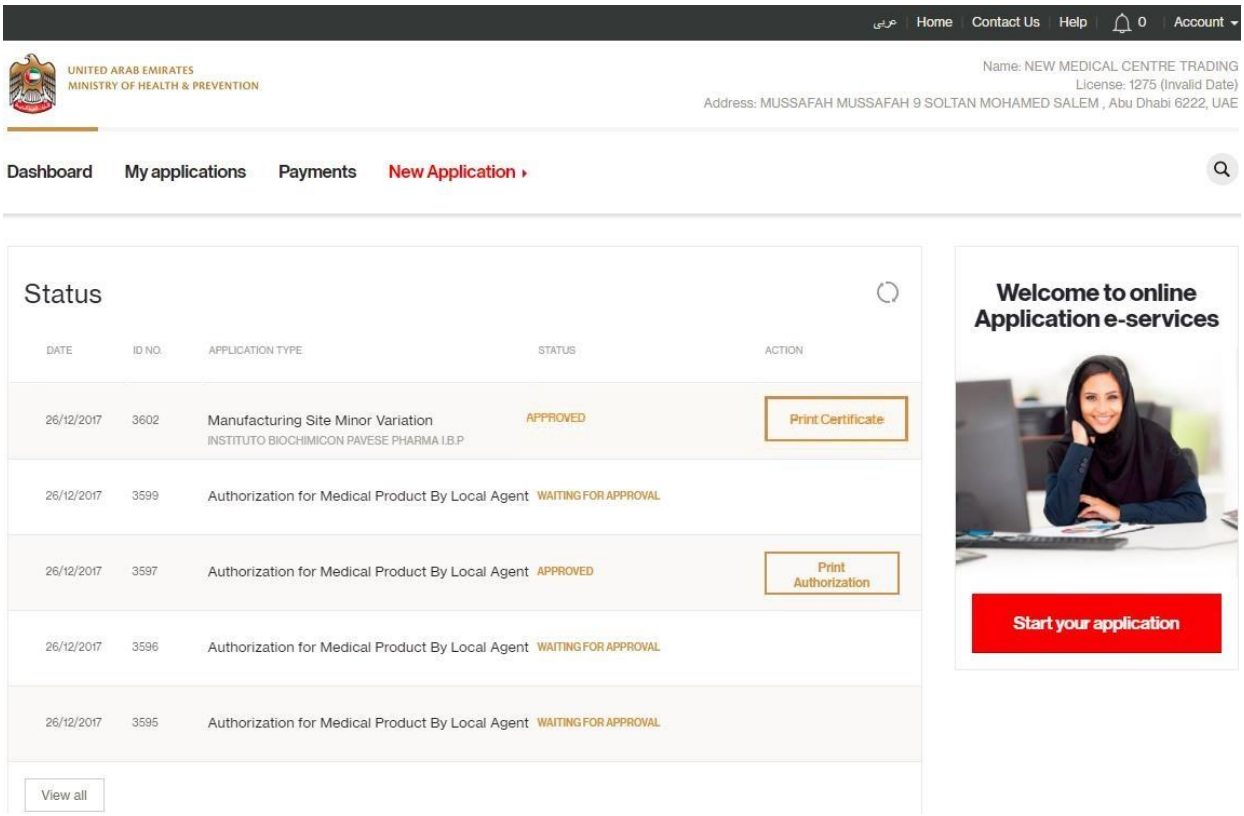
After submitting the application a successful message displayed to the user, and the permit fees is generated. The user can perform the payment from this screen by clicking over the

amount, where the system directs you to the payment screen.



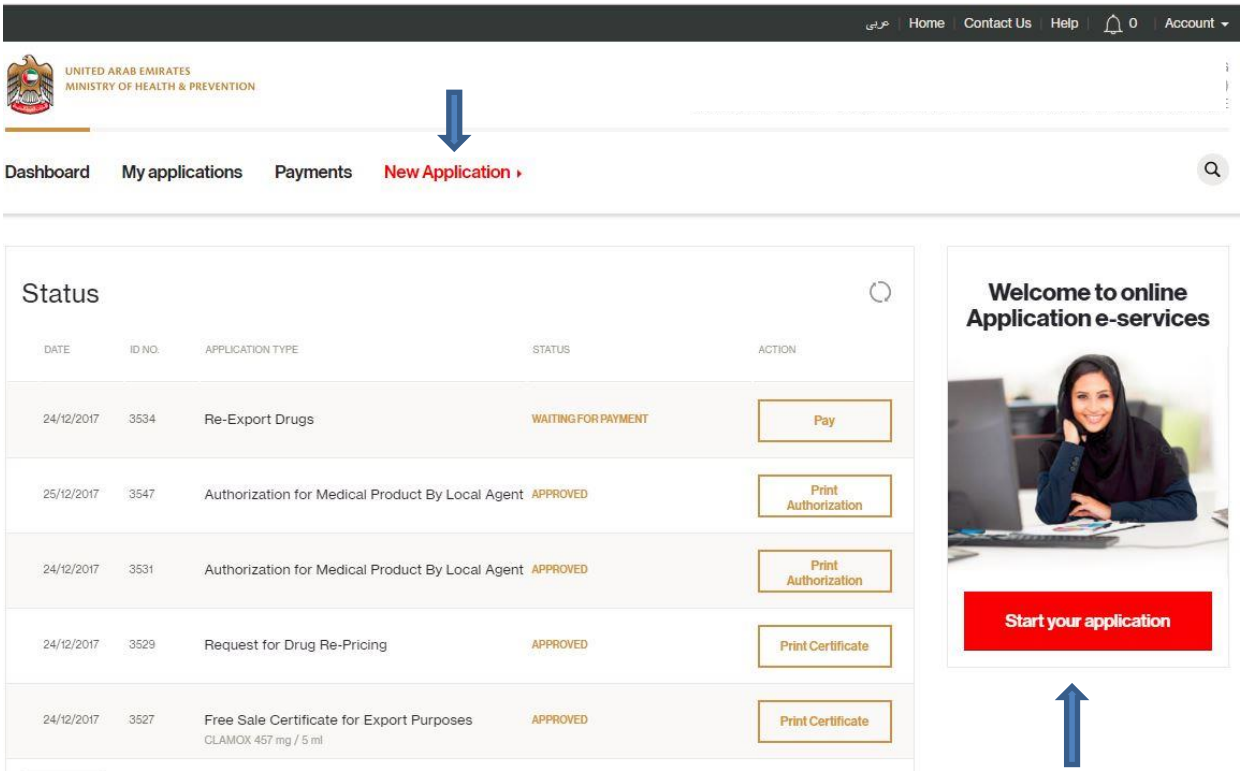
Alternatively, the user can go to the payment screen in the dashboard and click over the pay button and perform the payment.

To view the application status go to dashboard, and once the permit is approved click on "Print Permit" button on the dashboard to view and print the permit.

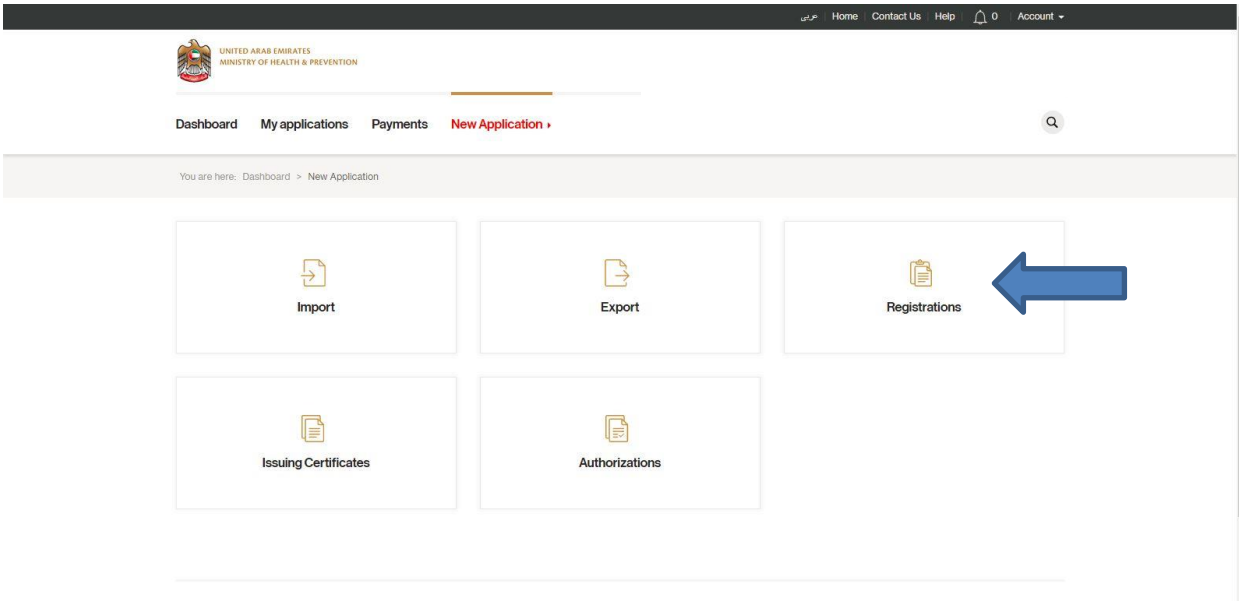


2.7 EVALUATION OF DRUG VIGILANCE PLAN

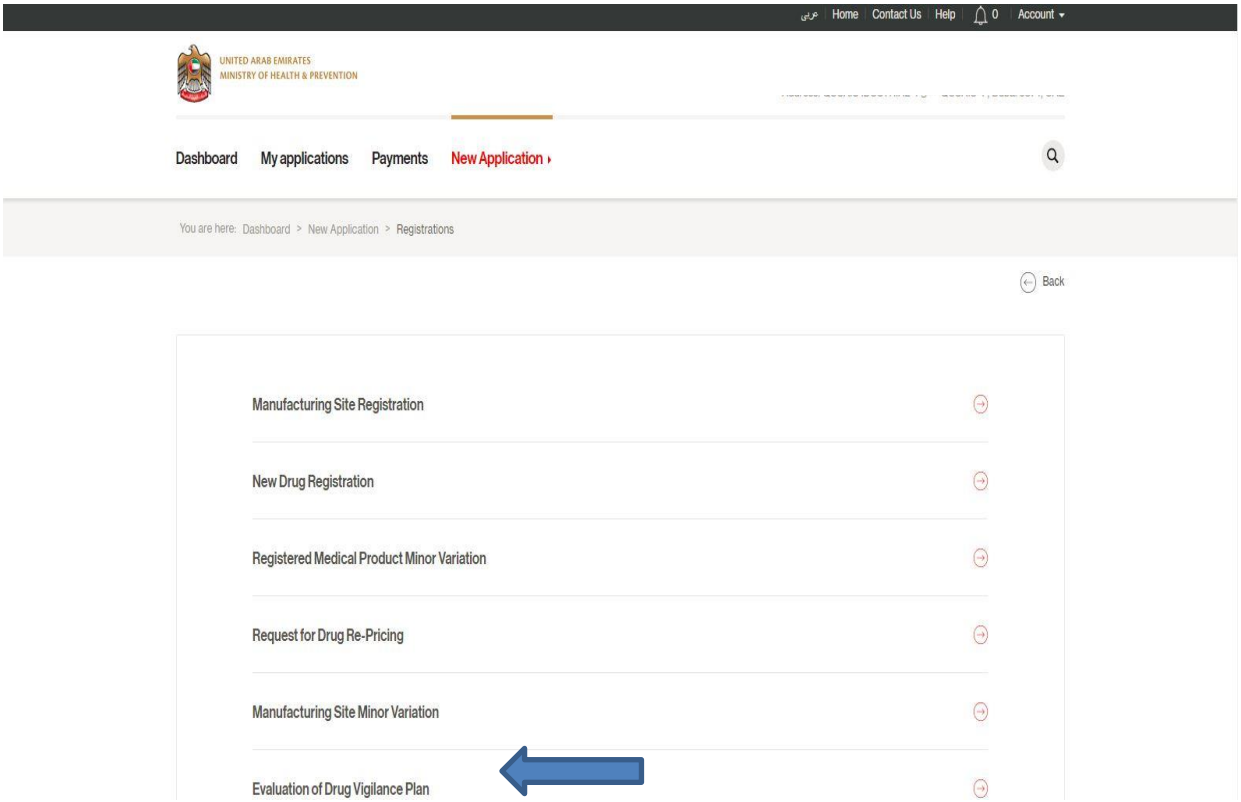
Log into the system using your credentials and then click on start new application link



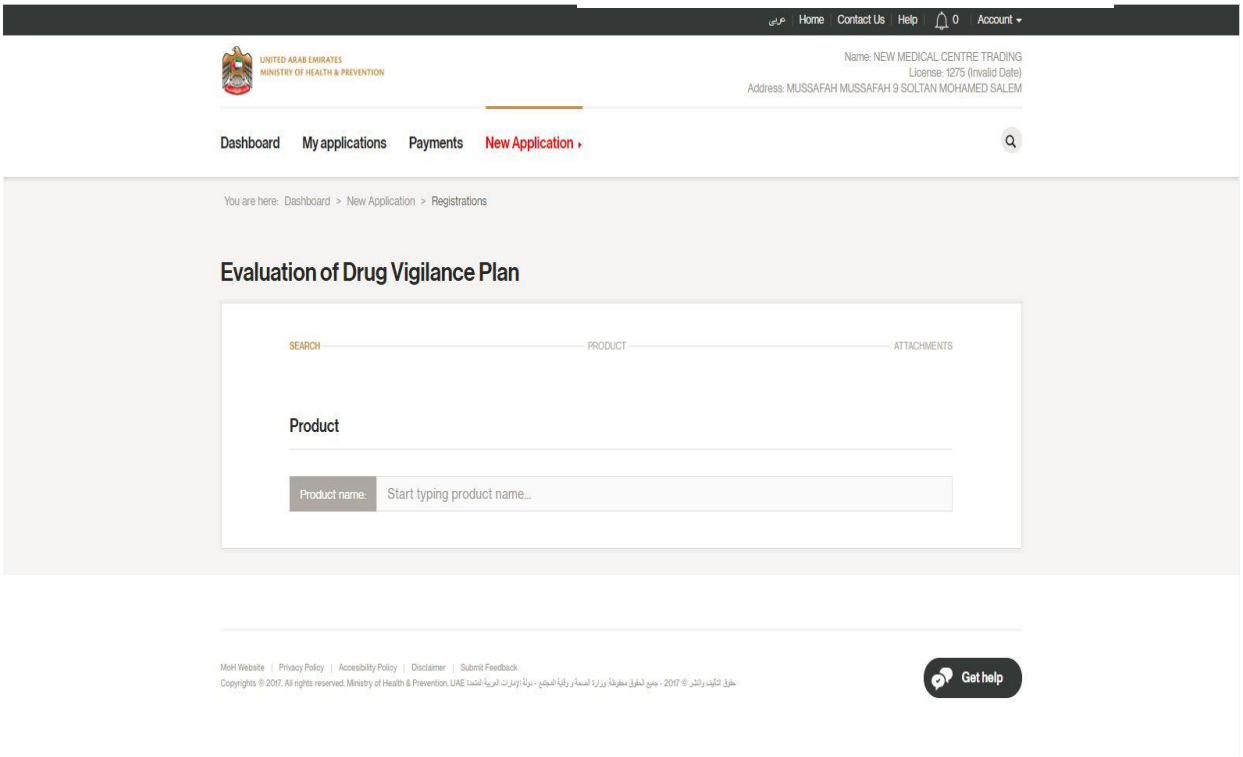
Click on registration tile



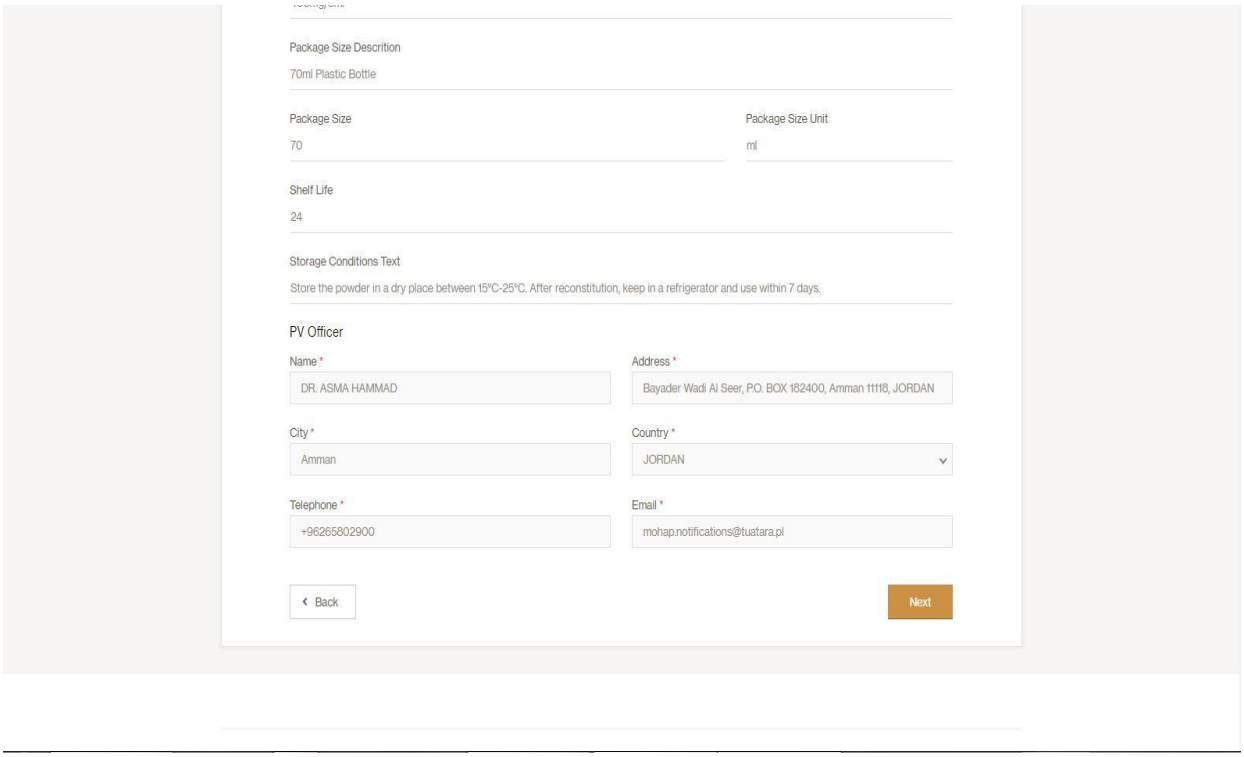
The system takes you to the services screen, click on drug registration



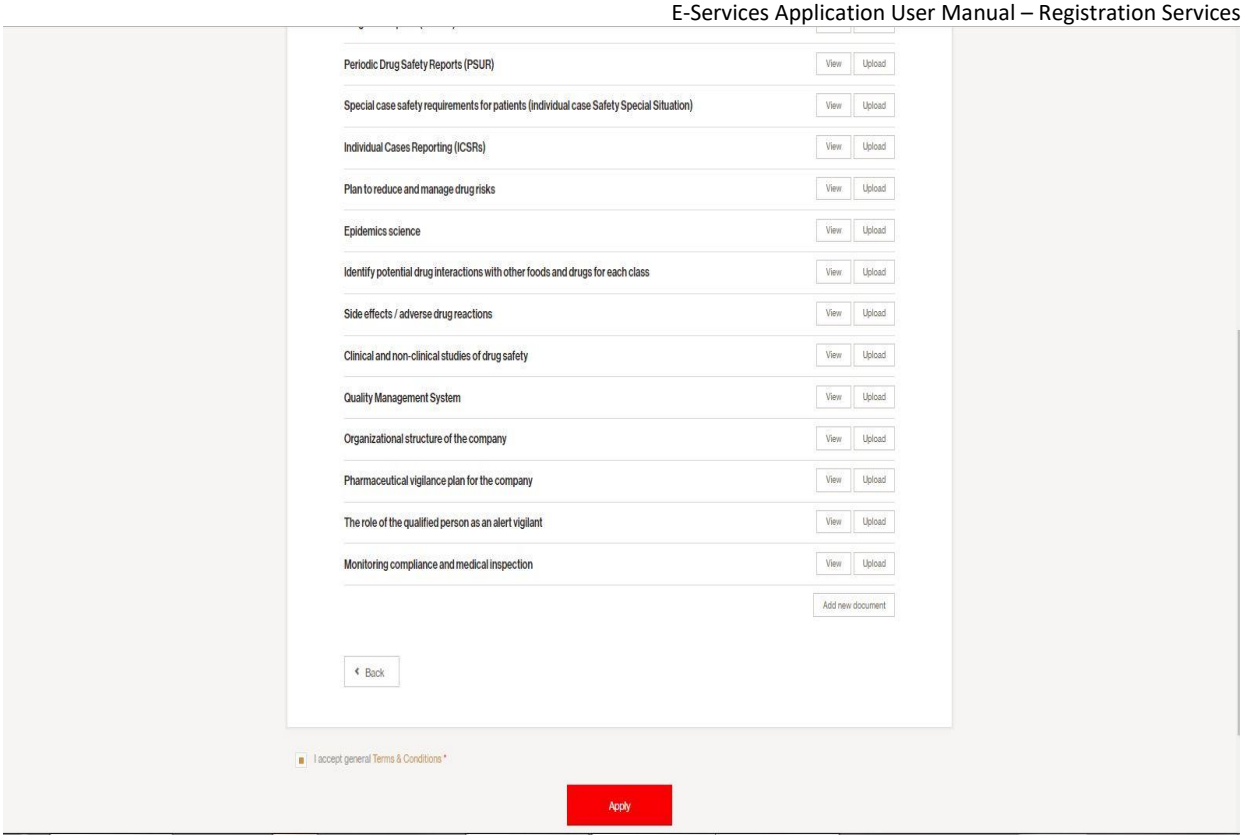
Start typing the product name, the system will filter the products based on the entered characters.



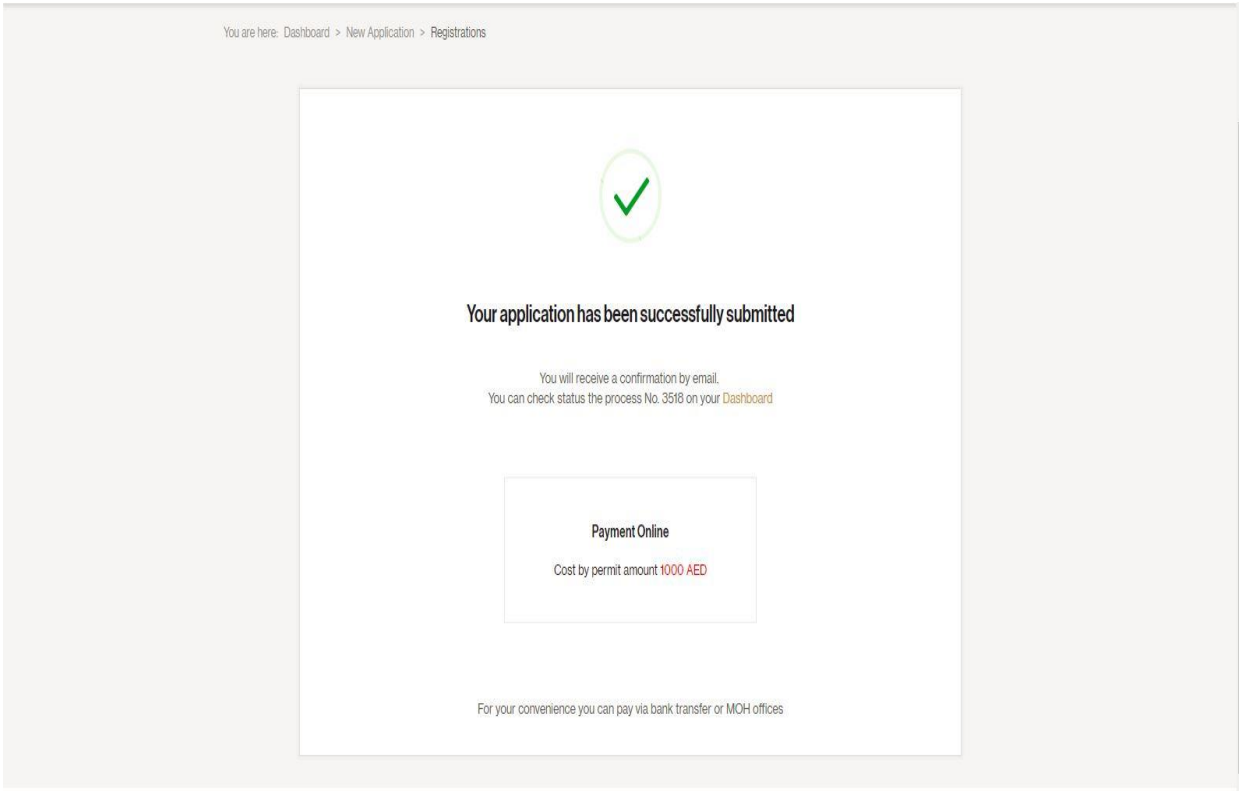
Fill the PV details and then click on Next.



Attach the support documents, accept terms and conditions and then click on Apply.

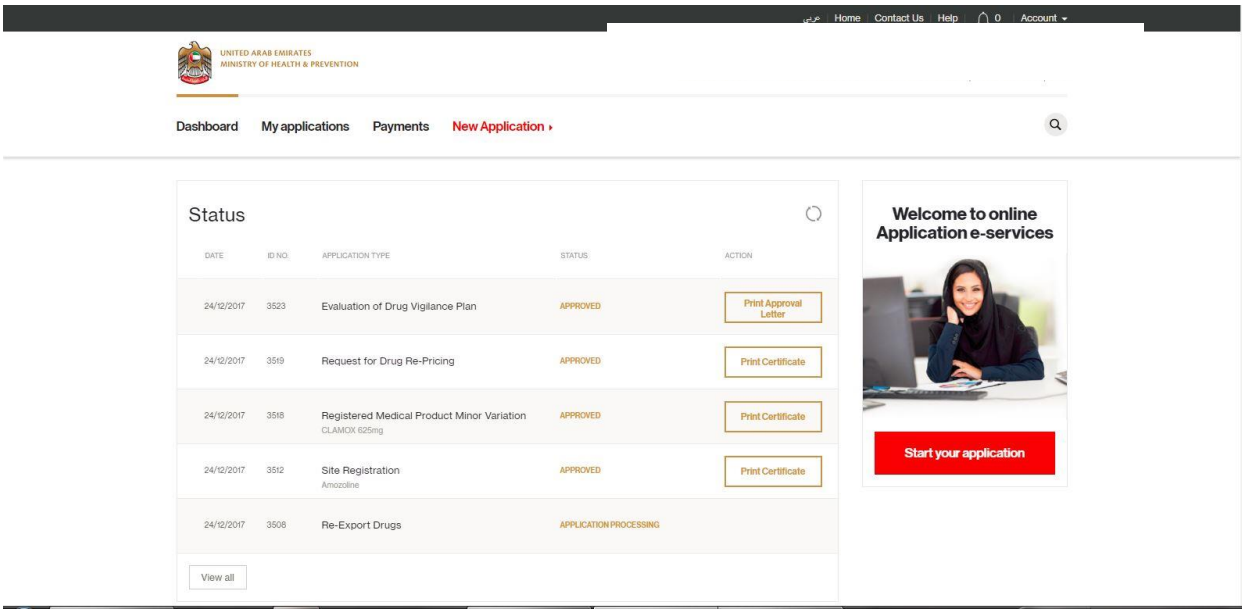

Periodic Drug Safety Reports (PSUR)
Special case safety requirements for patients (individual case Safety Special Situation)
Individual Cases Reporting (ICSRs)
Plan to reduce and manage drug risks
Epidemics science
Identify potential drug interactions with other foods and drugs for each class
Side effects / adverse drug reactions
Clinical and non-clinical studies of drug safety
Quality Management System
Organizational structure of the company
Pharmaceutical vigilance plan for the company
The role of the qualified person as an alert vigilant
Monitoring compliance and medical inspection
View
Upload
Add new document
Back
I accept general Terms & Conditions *
Apply

After submitting the application a successful message displayed to the user, and the permit fees is generated. The user can perform the payment from this screen by clicking over the amount, where the system directs you to the payment screen.



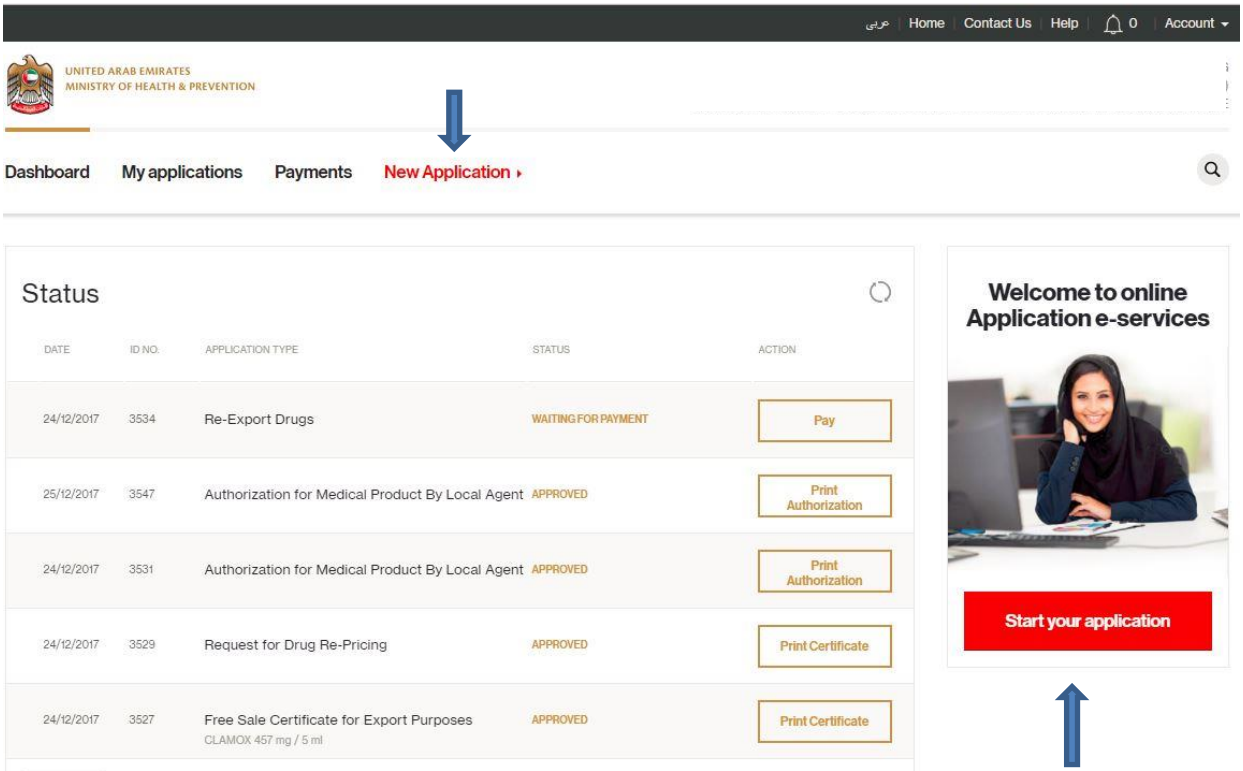
Alternatively, the user can go to the payment screen in the dashboard and click over the pay button and perform the payment.

To view the application status go to dashboard, and once the permit is approved click on “Print Permit” button on the dashboard to view and print the permit.

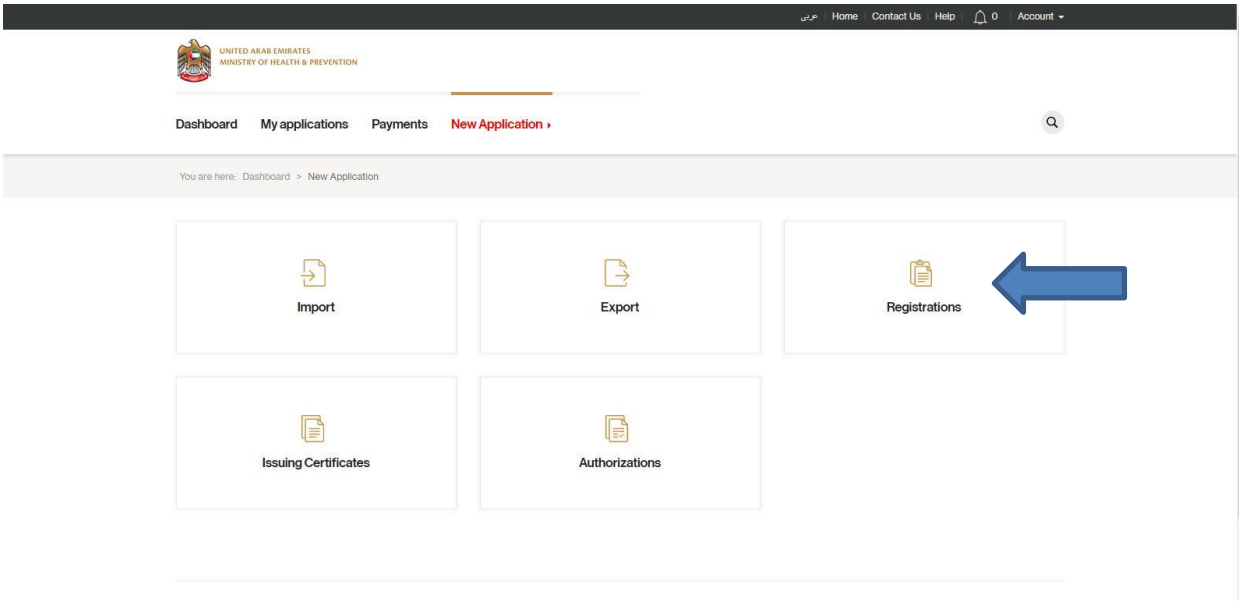


2.8 DRUG CLASSIFICATION

Log into the system using your credentials and then click on start new application link



Click on registration tile



Th , click on drug registration

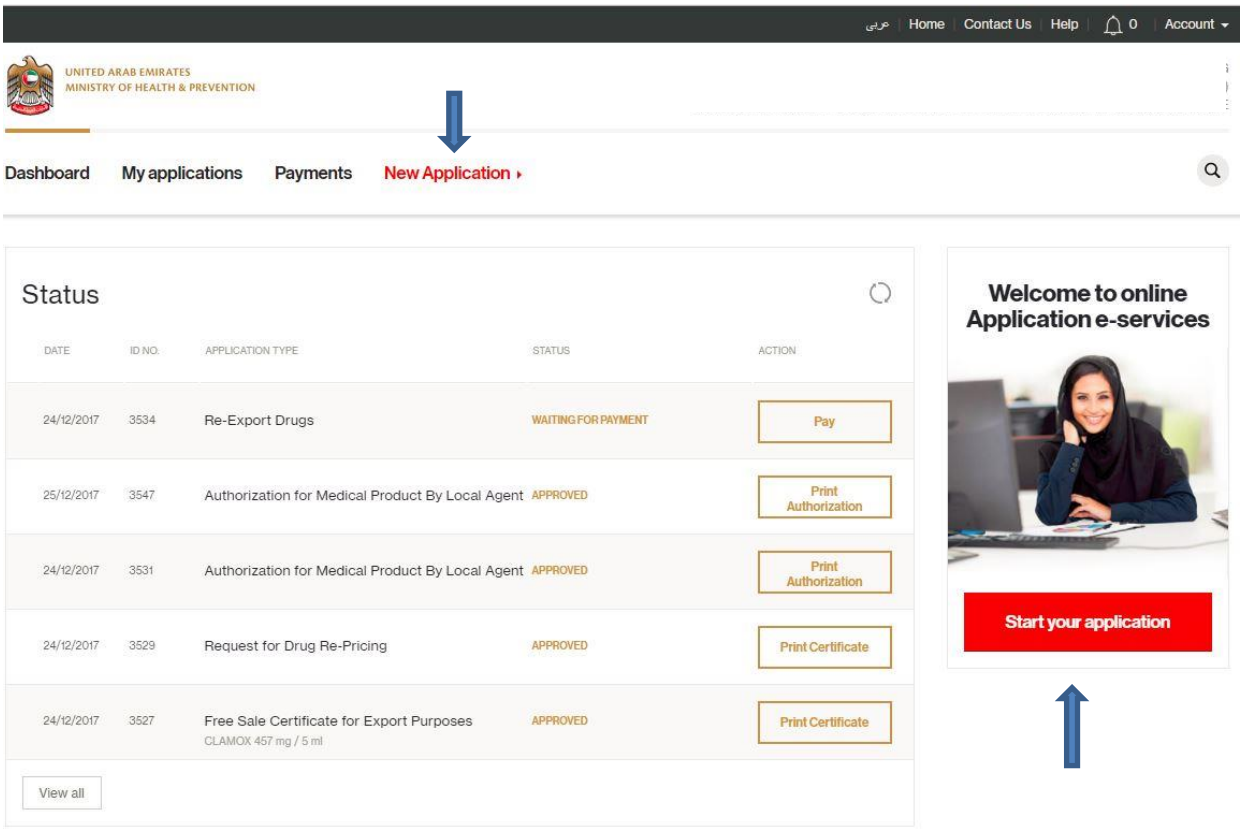
3 ISSUING CERTIFICATES

Under the Issuing Certificates tile, you will find the following services:

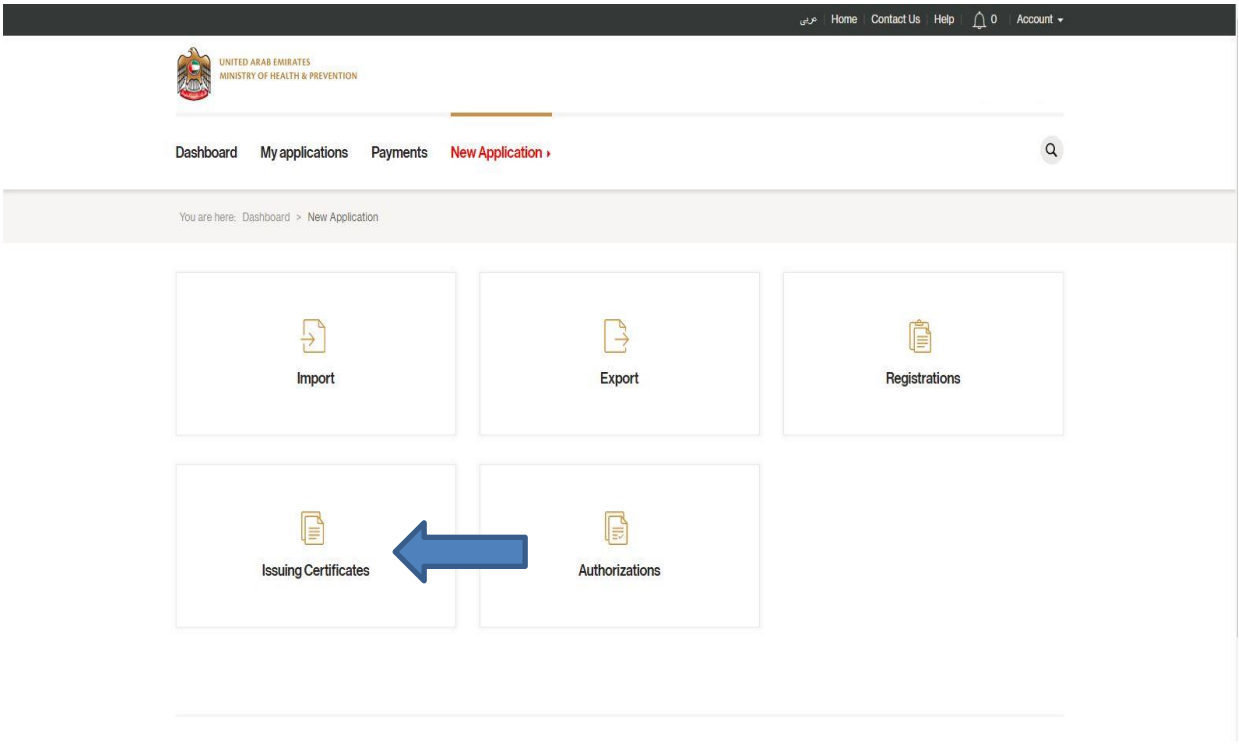
- Pricing Certificate
- Certificate of Pharmaceutical Product (CPP) for Export Purposes
- Free Sale Certificate for Export Purposes

3.1 PRICING CERTIFICATE

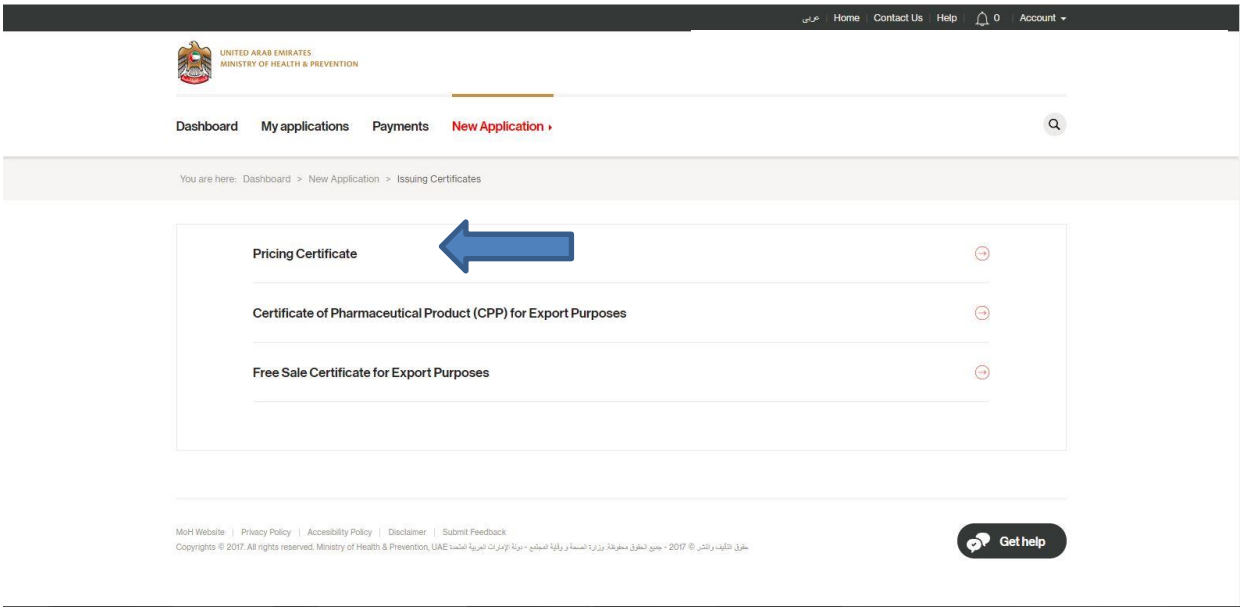
Log into the system using your credentials and then click on start new application link



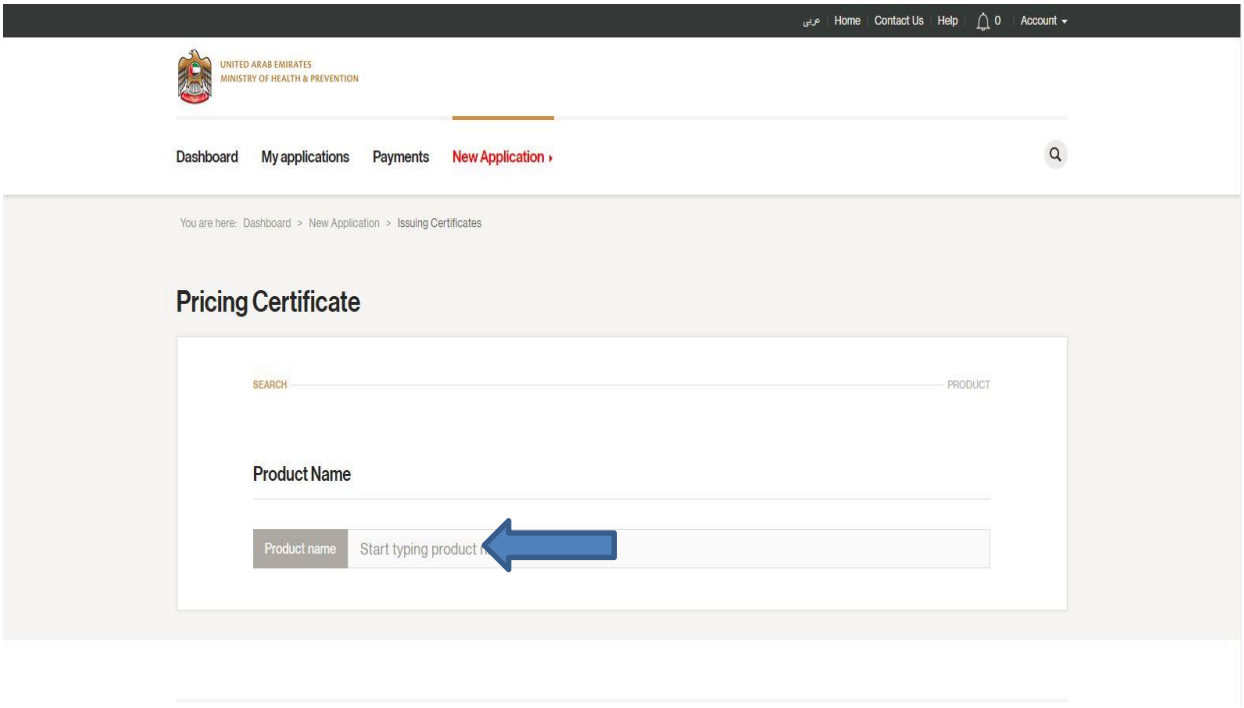
Click on Issuing Certificates tile



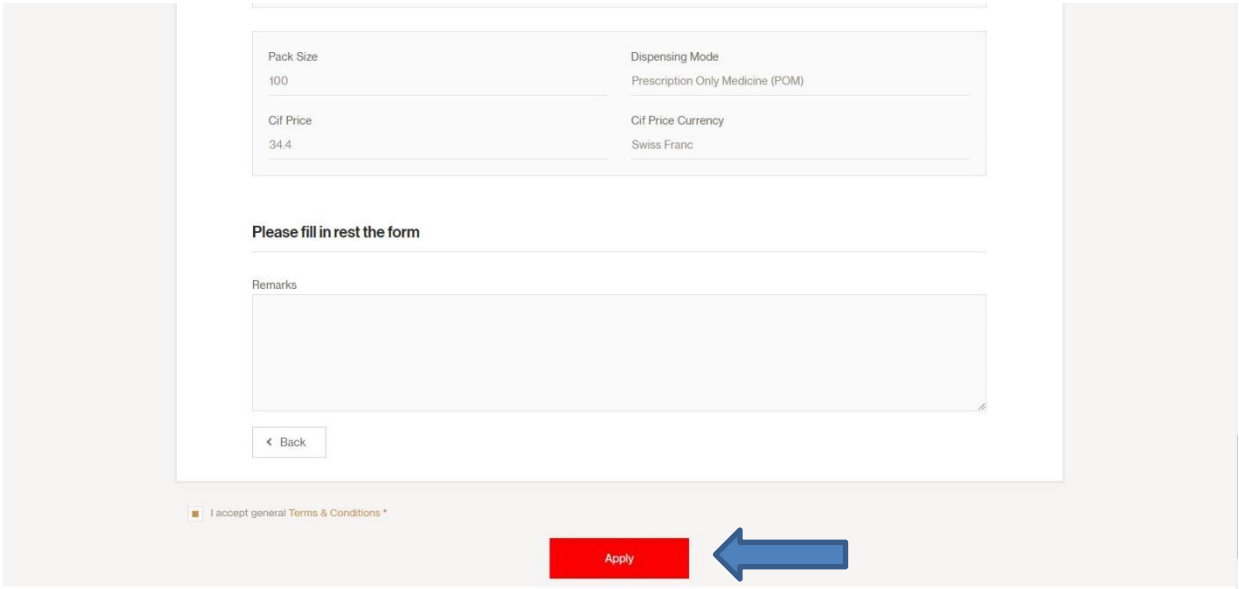
Then click on pricing certificate



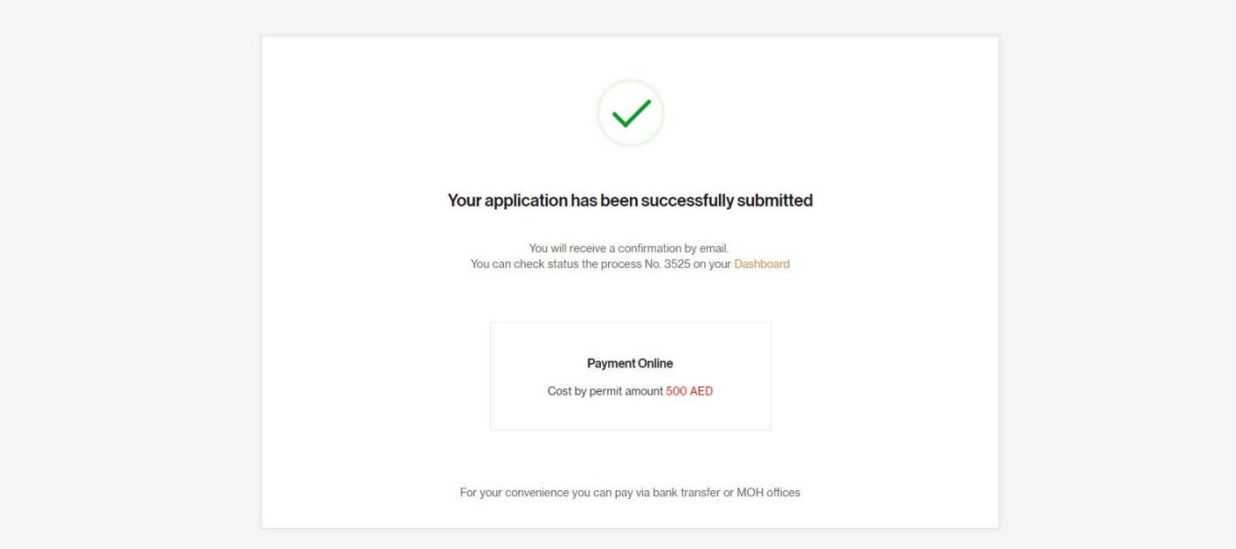
Start typing the product name, the system filters the product based on the entered characters



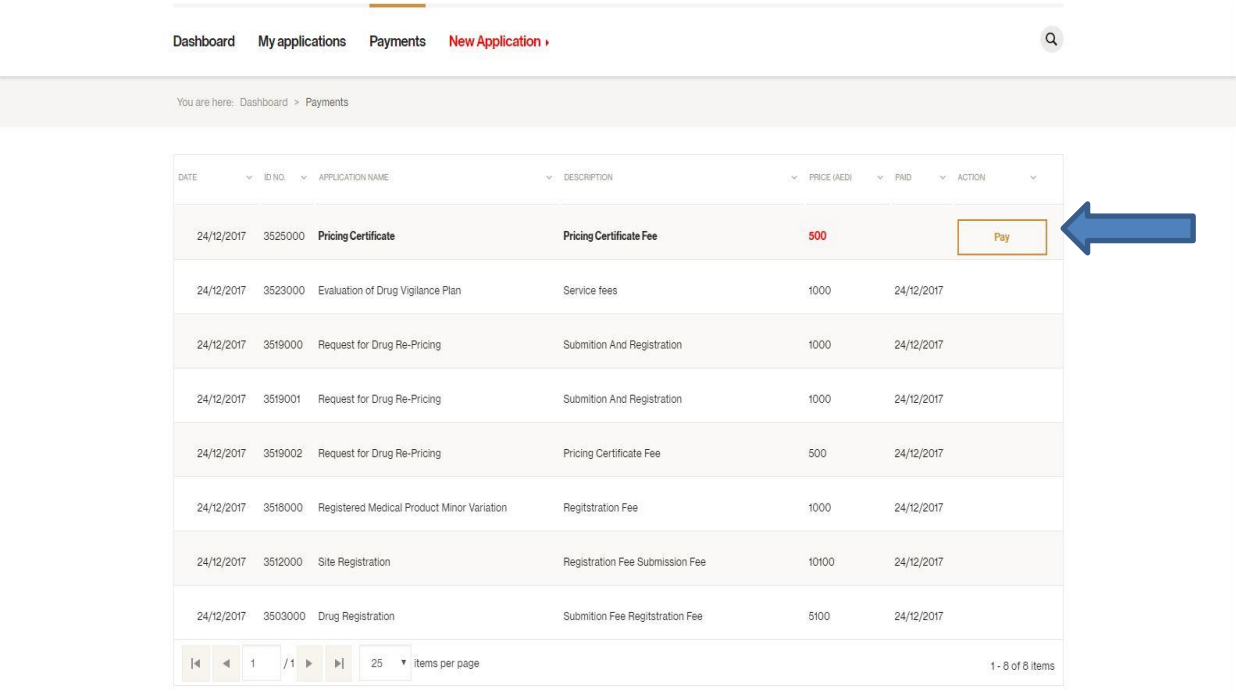
Review product data and accept terms and conditions, and then click on Apply button



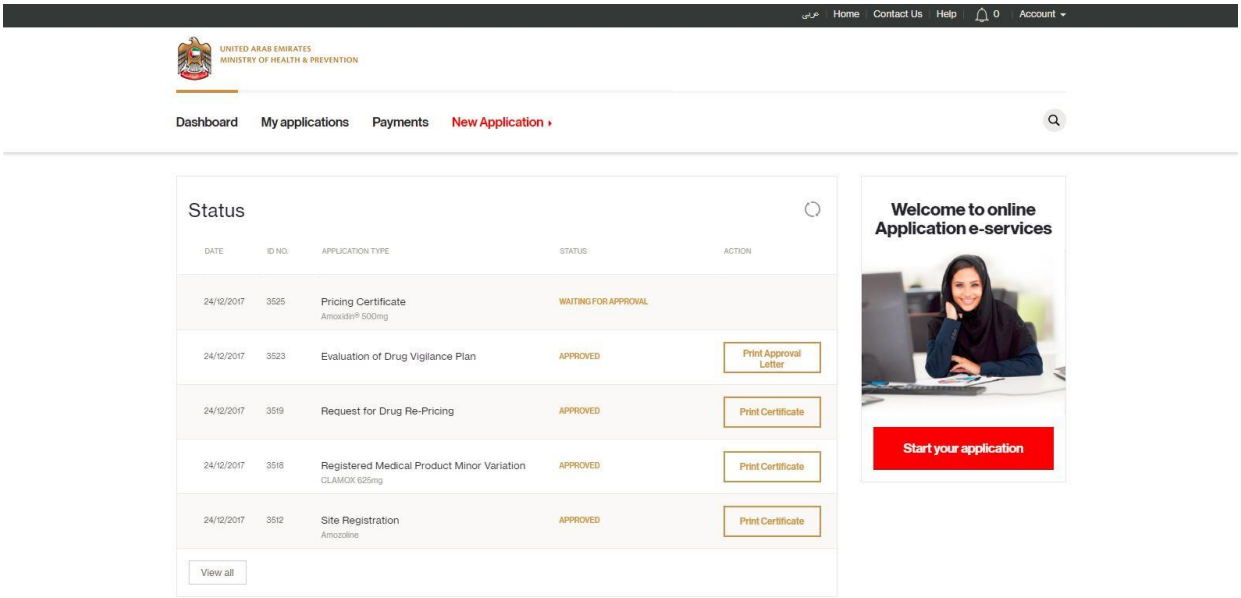
After submitting the application a successful message displayed to the user, and the permit fees is generated. The user can perform the payment from this screen by clicking over the amount, where the system directs you to the payment screen.



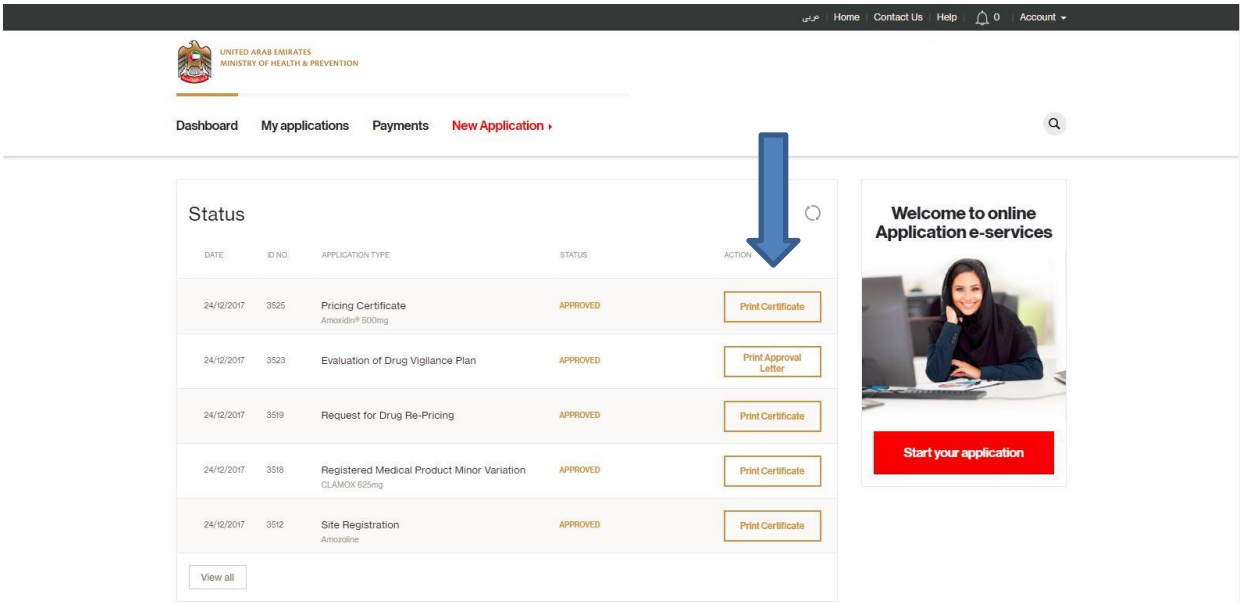
Alternatively, the user can go to the payment screen in the dashboard and click over the pay button and perform the payment.



To view the status of the application, go to dashboard

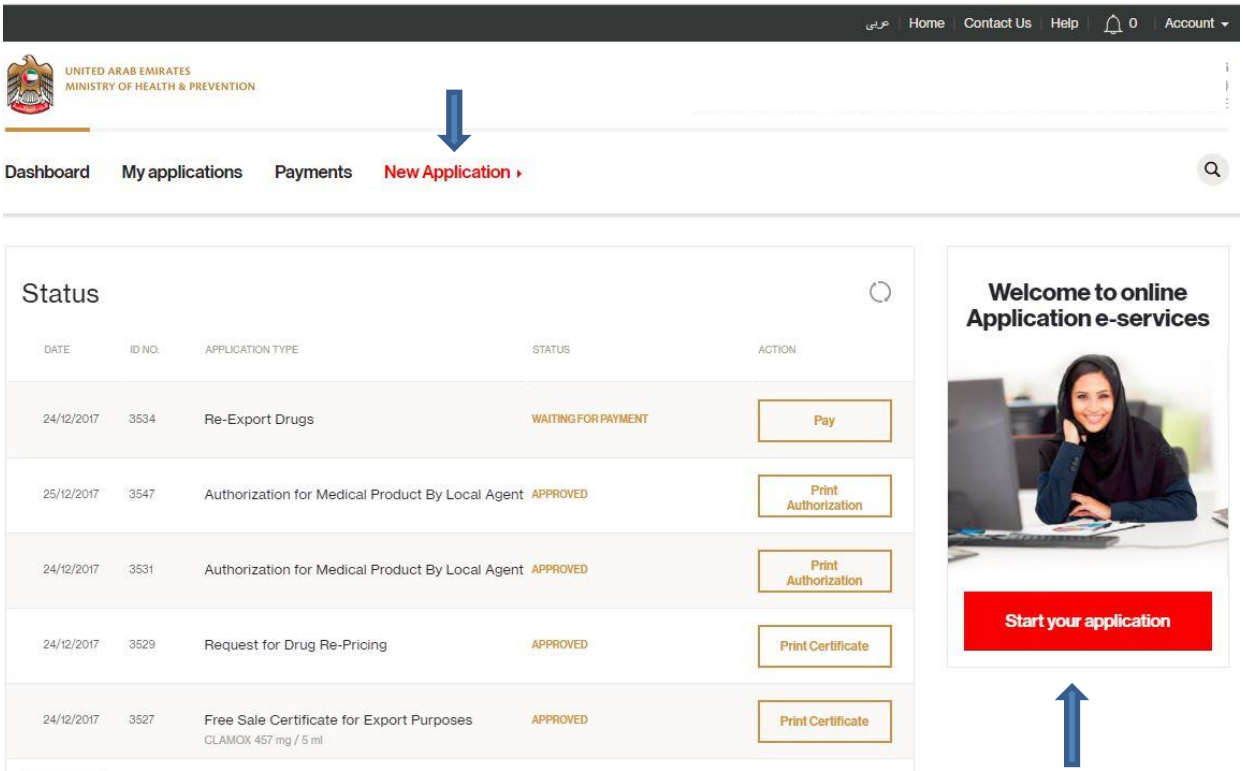


Once the permit is approved click on “Print Permit” button on the dashboard to view and print the permit.

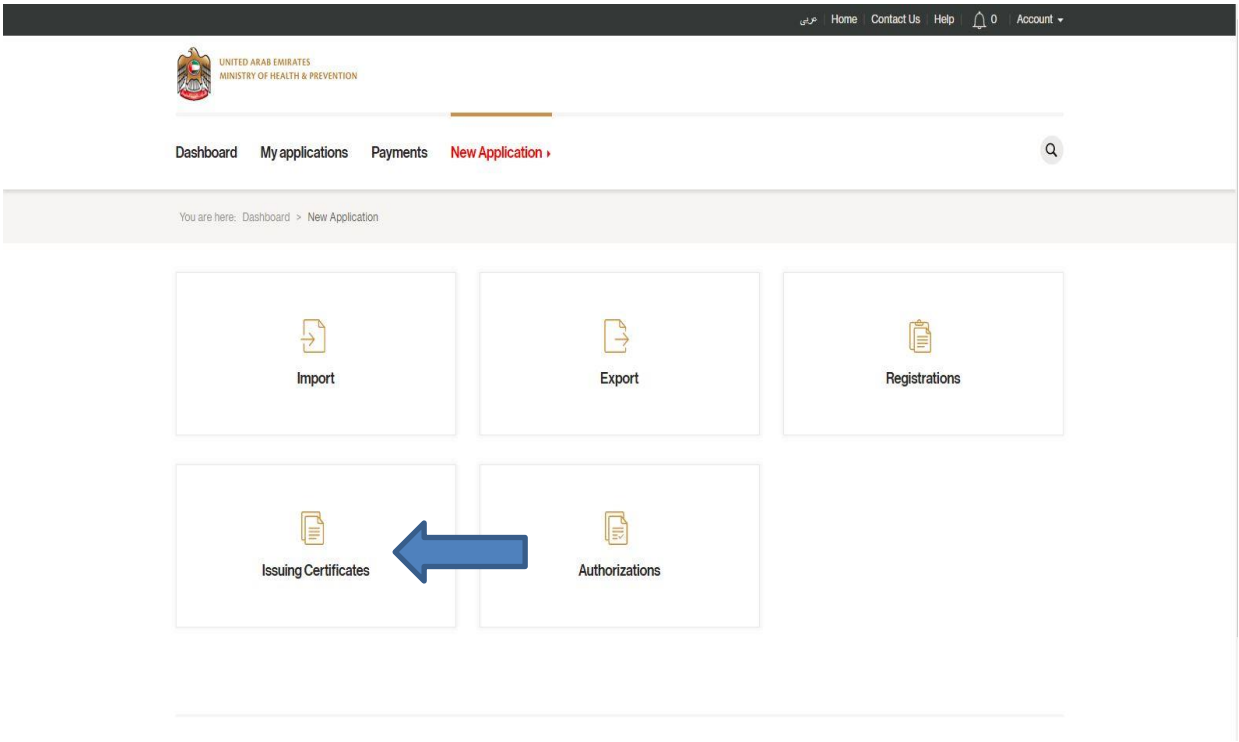


3.2 CERTIFICATE OF PHARMACEUTICAL PRODUCT (CPP) FOR EXPORT PURPOSES

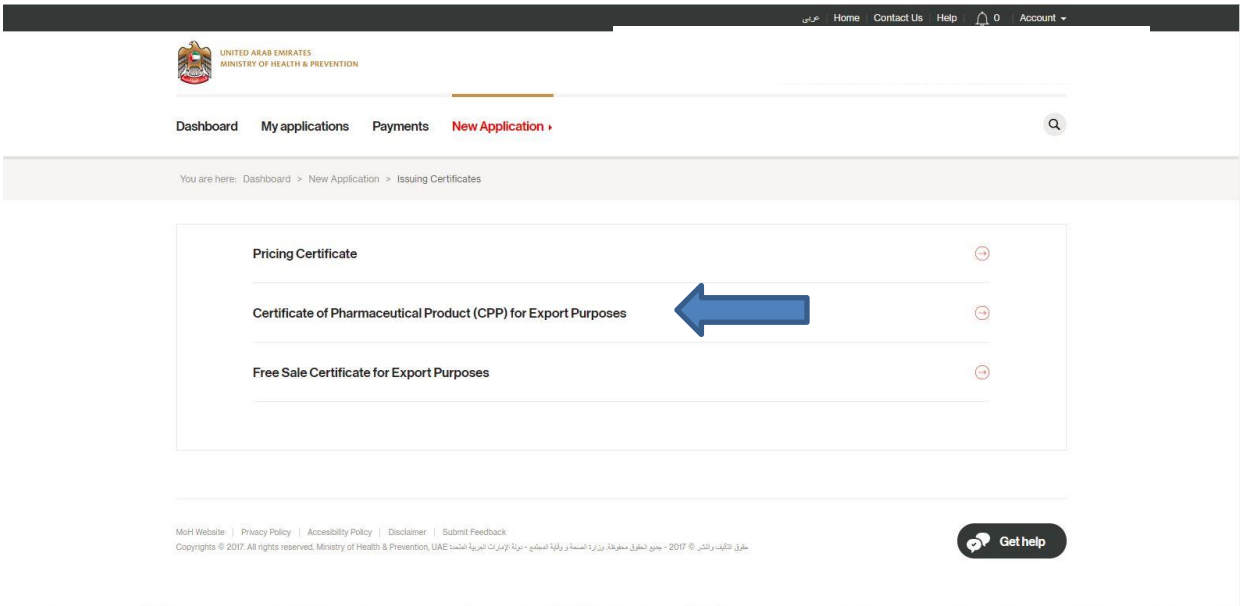
Log into the system using your credentials and then click on start new application link



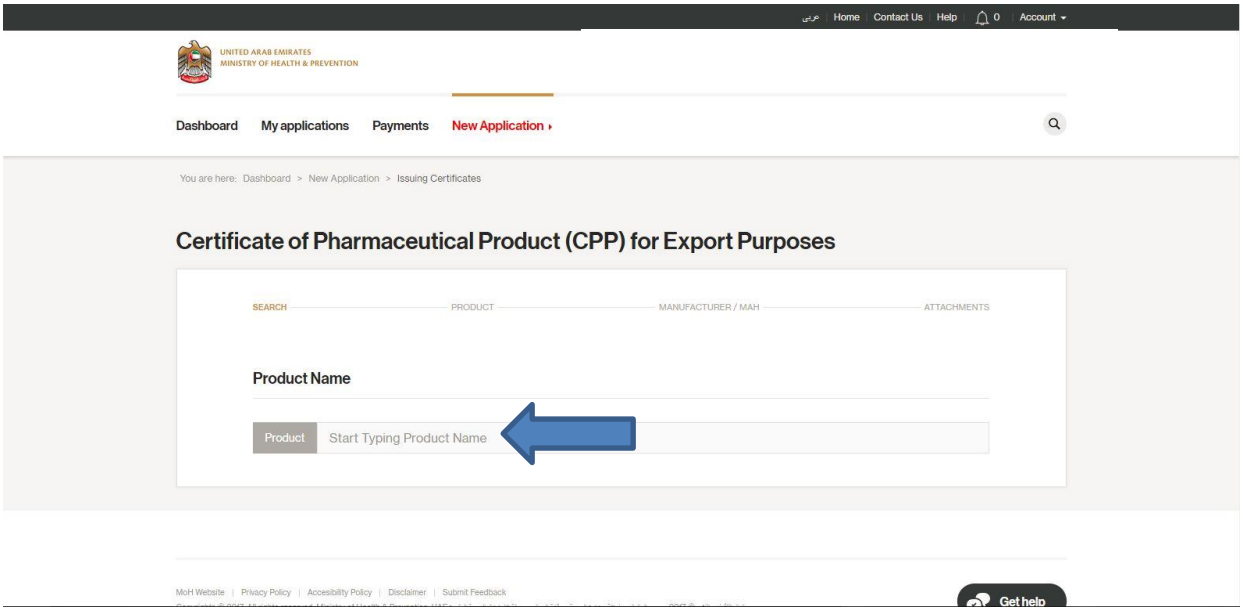
Click on Issuing Certificates tile



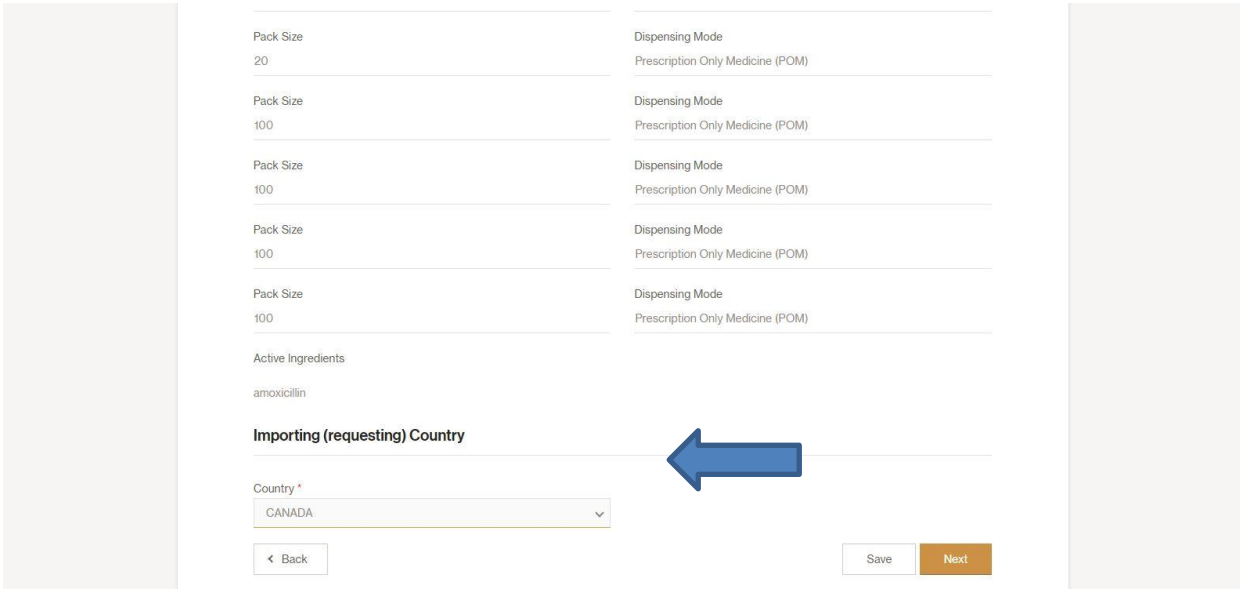
Then click on Certificate of Pharmaceutical Product (CPP) for Export Purposes



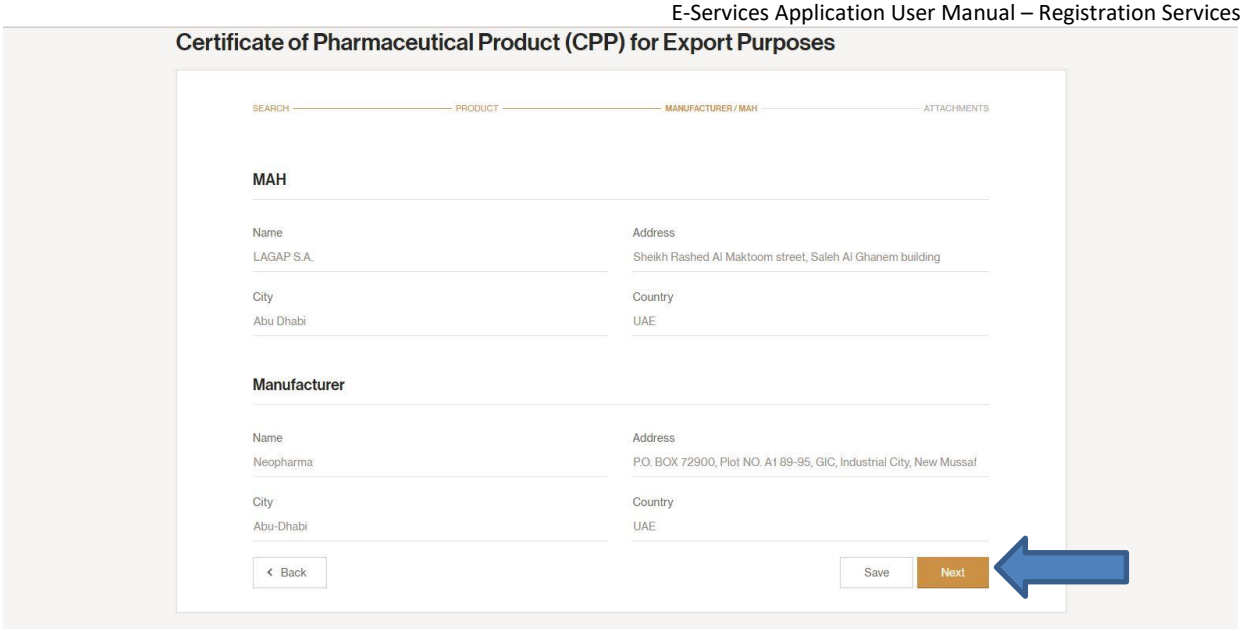
Start typing the product name, the system filters the product based on the entered characters



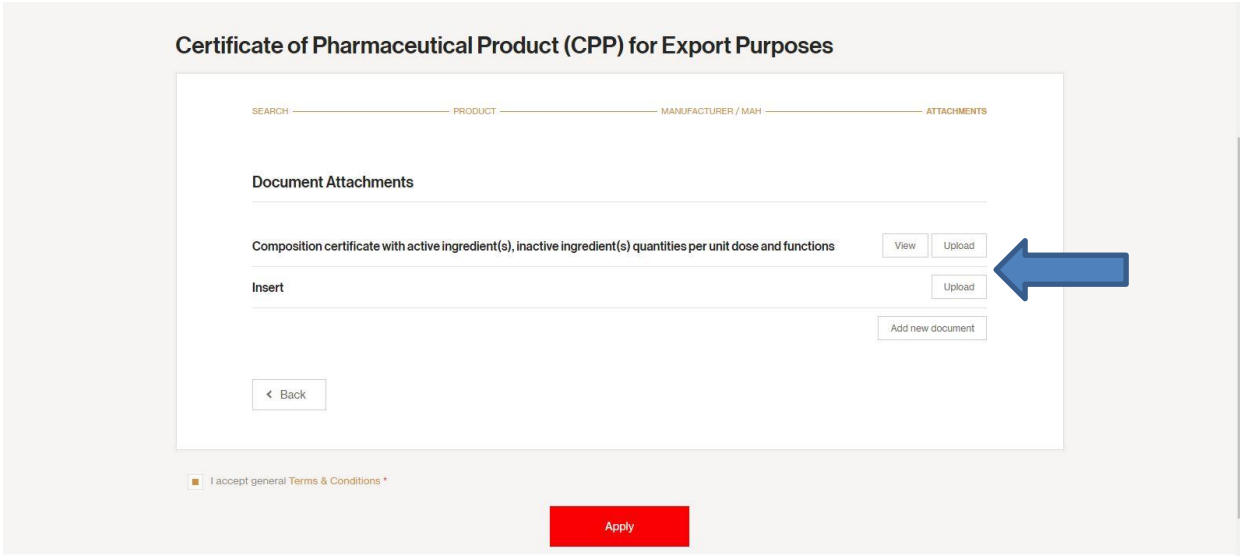
Review product data and accept terms and conditions, and fill the importing (requesting) country then click on Next



Review the MAH and the manufacturer and then click on Next

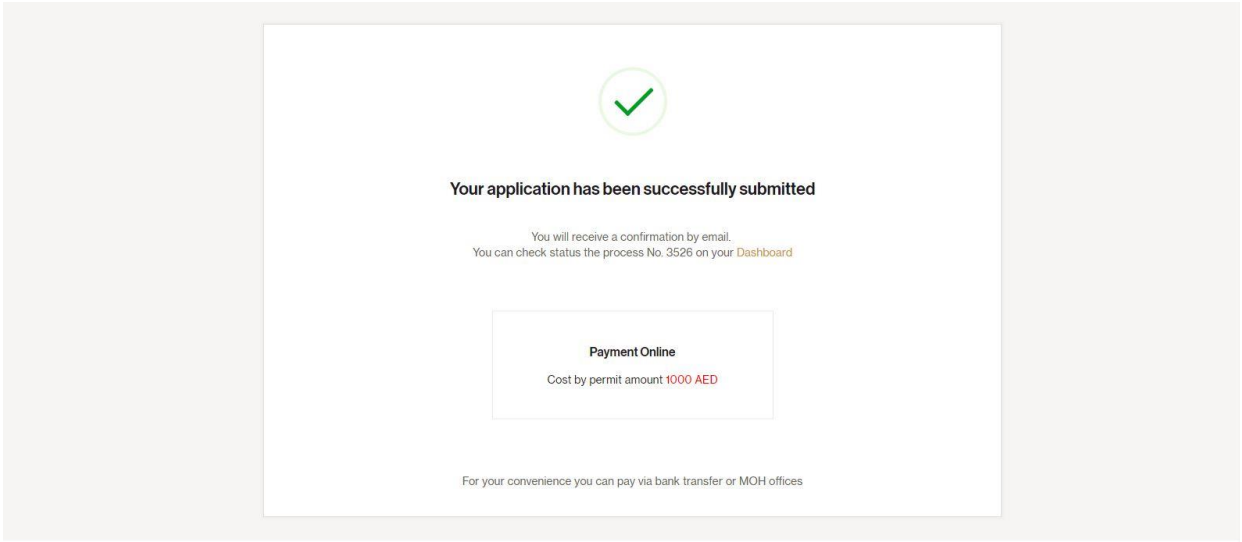


Upload the support document, accept the terms and conditions and then click on Apply

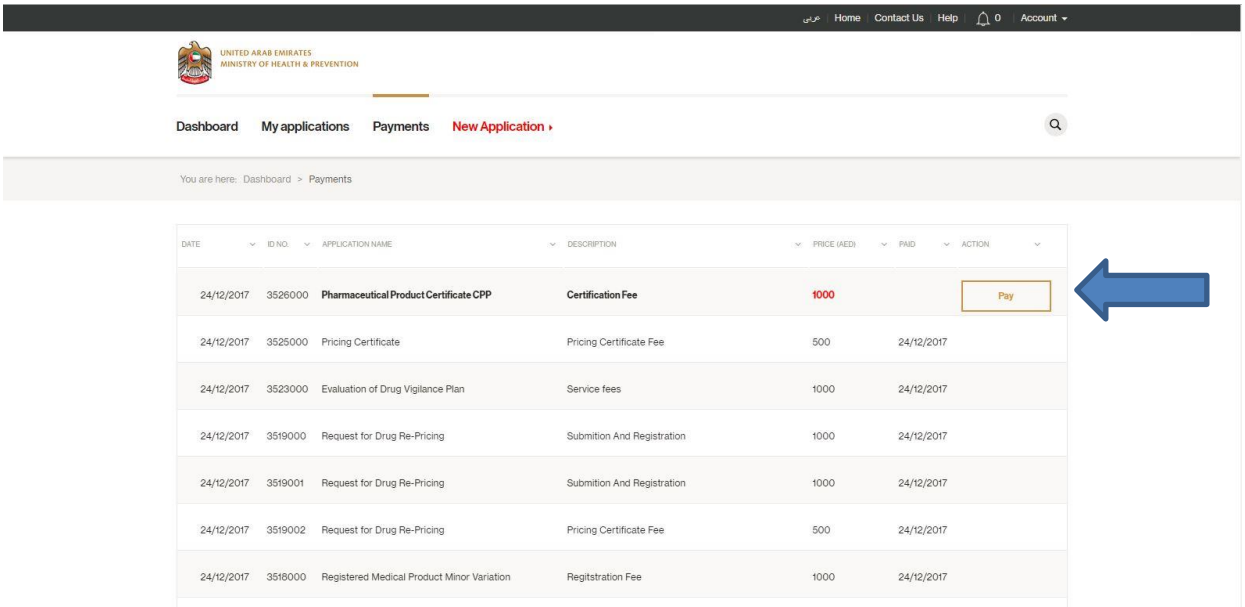


After submitting the application a successful message displayed to the user, and the permit fees is generated. The user can perform the payment from this screen by clicking over the

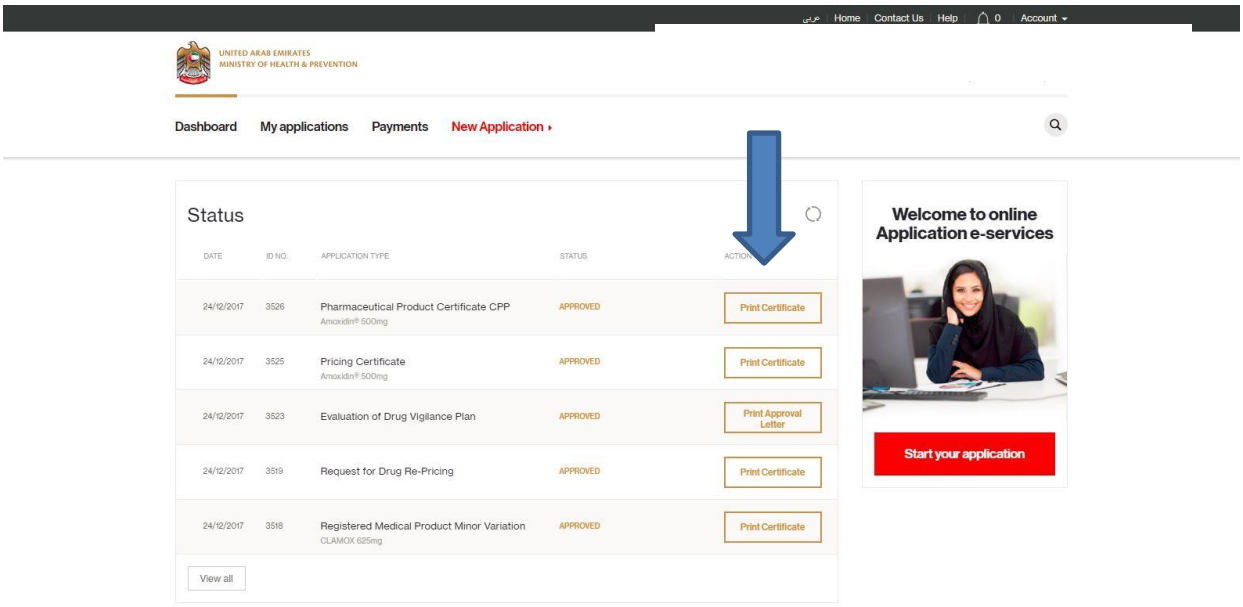
amount, where the system directs you to the payment screen



Alternatively, the user can go to the payment screen in the dashboard and click over the pay button and perform the payment.

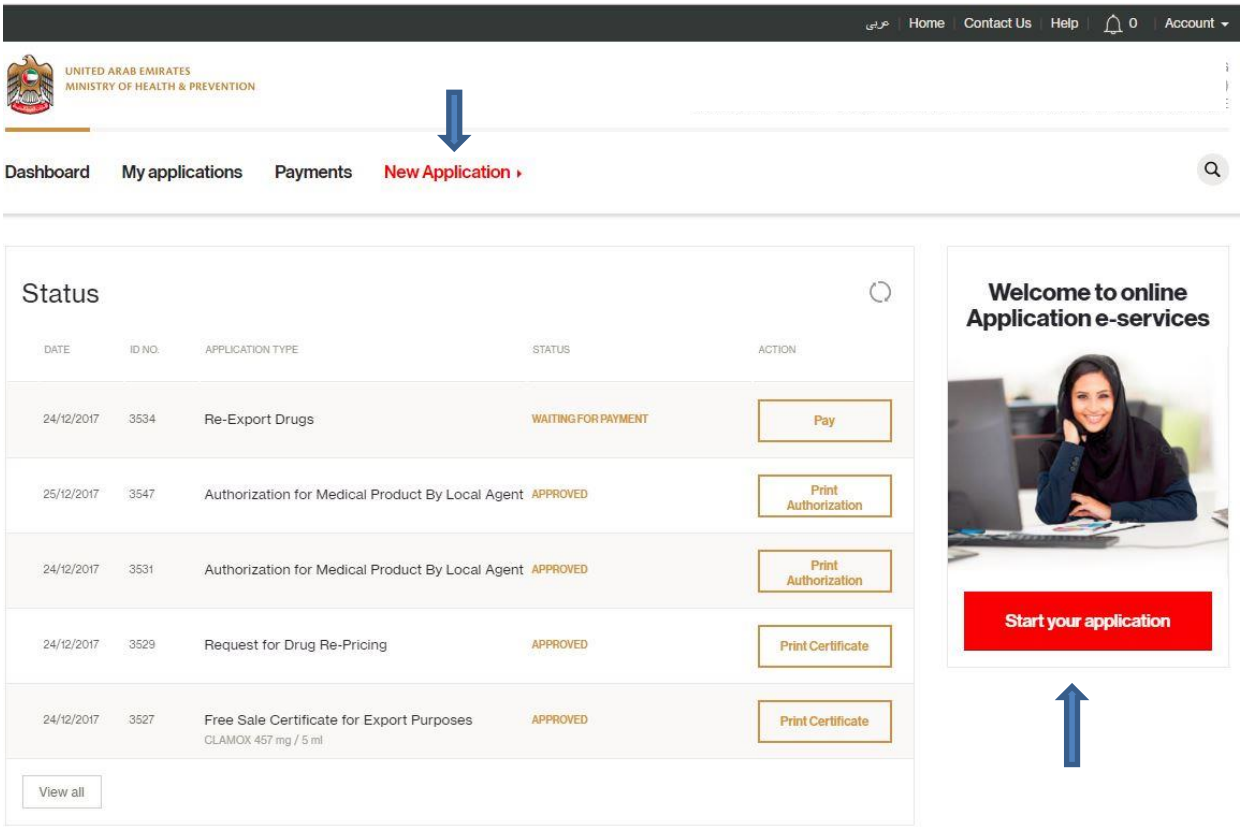


Once the permit is approved click on “Print Permit” button on the dashboard to view and print the permit.

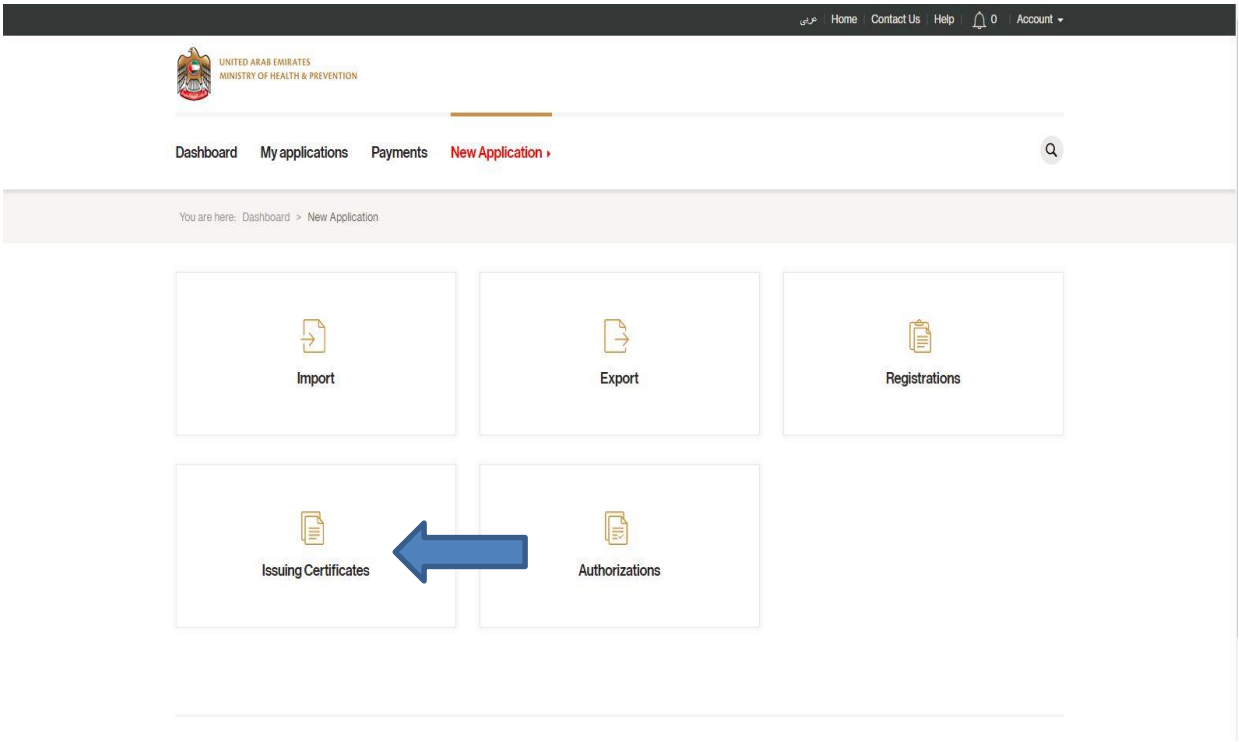


3.3 Free Sale Certificate for Export Purposes

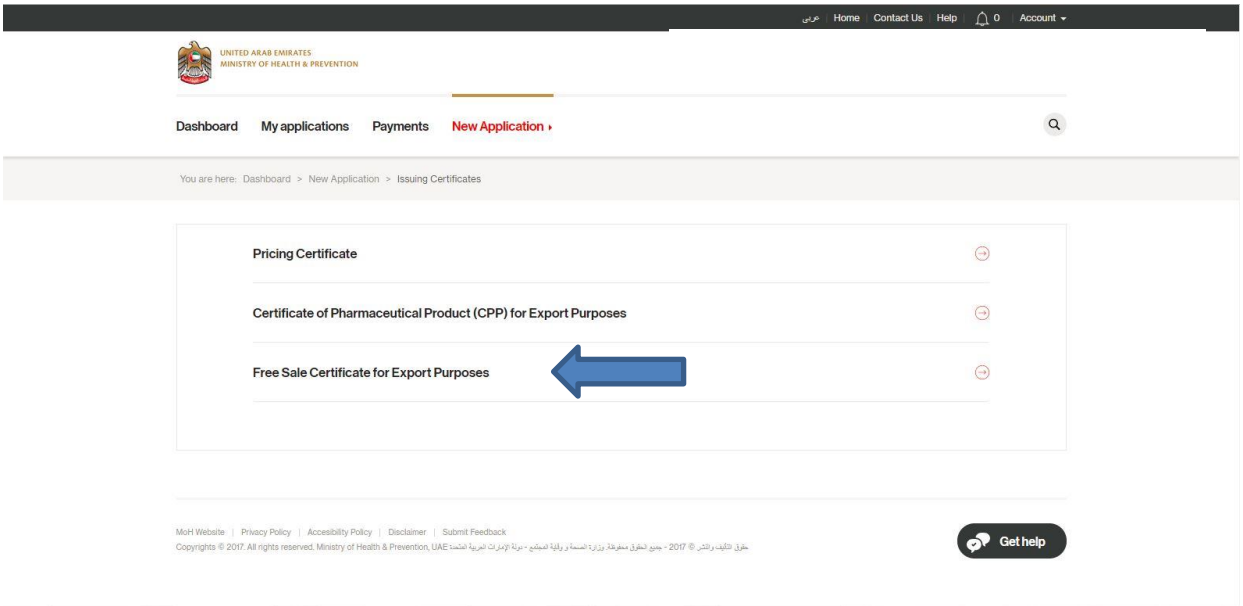
Log into the system using your credentials and then click on start new application link



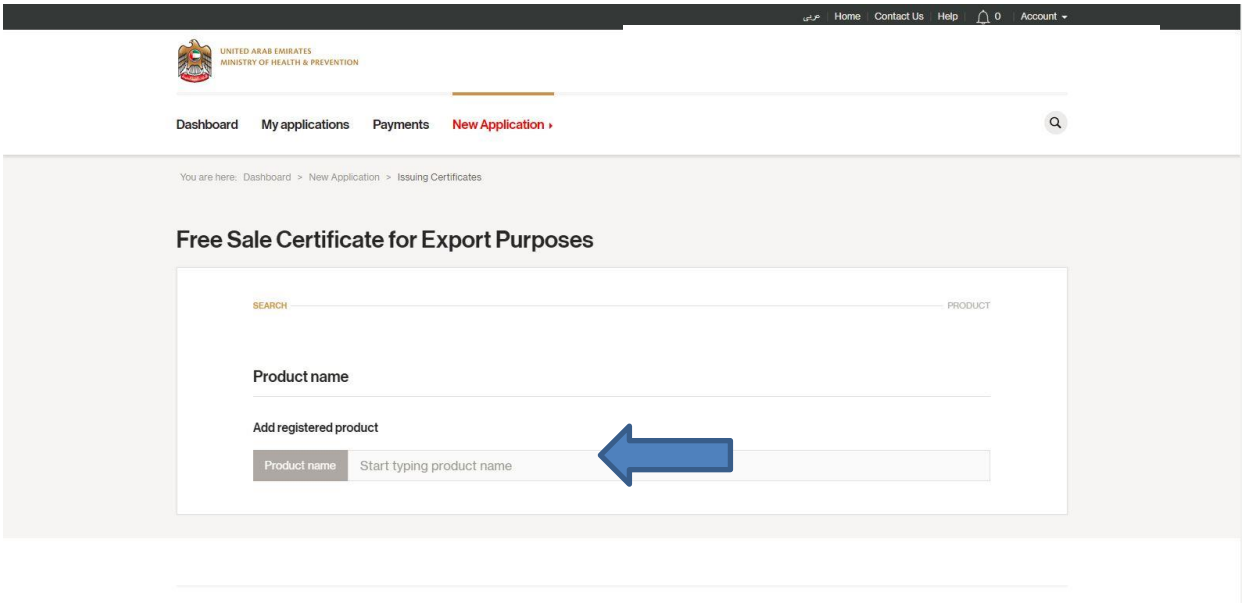
Click on Issuing Certificates tile



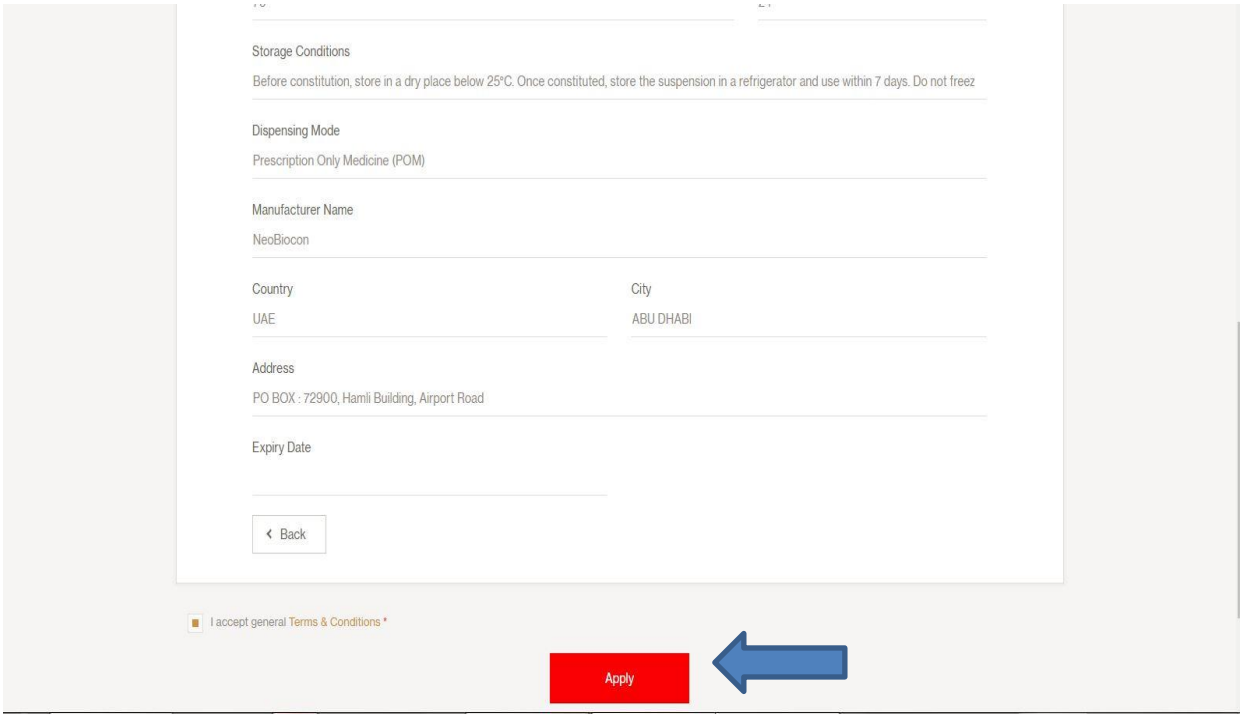
Then click on Free sale certificate for export purposes



Start typing the product name, the system filters the product based on the entered characters

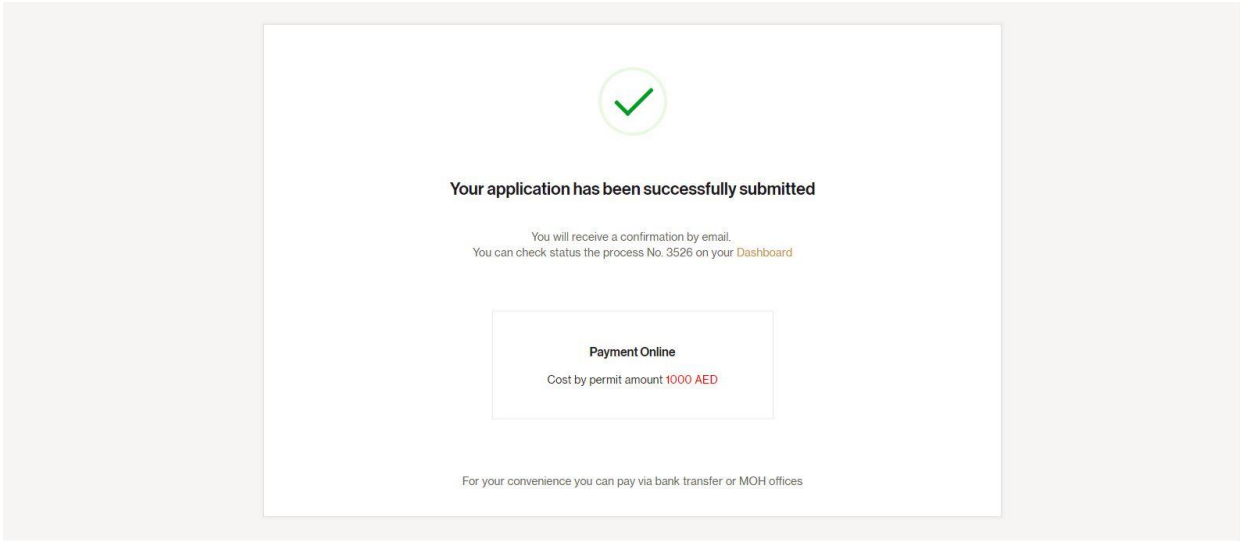


Review the data and click on “Apply”

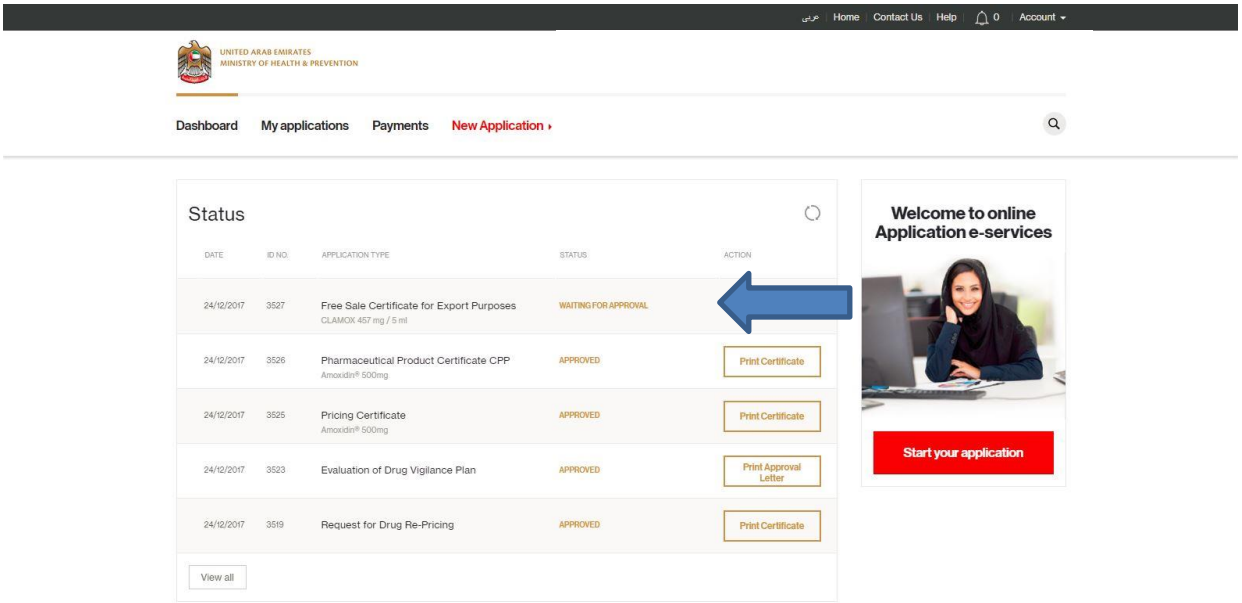
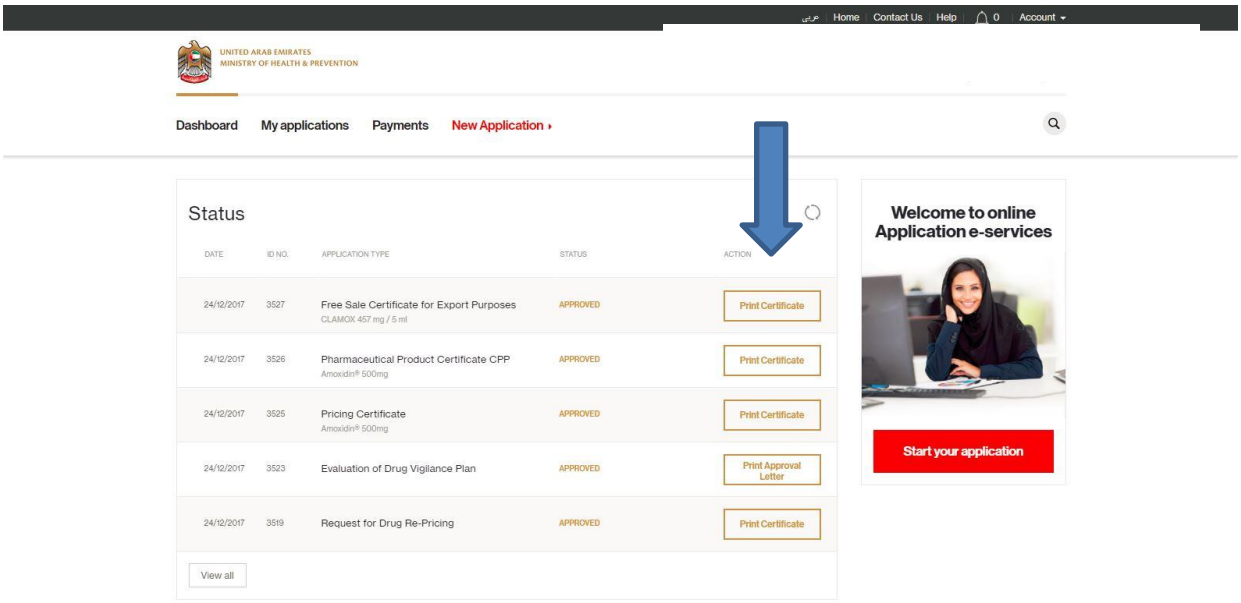


After submitting the application a successful message displayed to the user, and the permit fees is generated. The user can perform the payment from this screen by clicking over the

amount, where the system directs you to the payment screen



Alternatively, the user can go to the payment screen in the dashboard and click over the pay button and perform the payment.



Once the permit is approved click on “Print Permit” button on the dashboard to view and print the permit.