

**Ministry of Health and Prevention** 

**E-Services Application User Manual – Registration Services** 



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### 1 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.



#### 2 Introduction

This document explains all the steps which are required for Site Administrator and agent user to create and view registration applications.

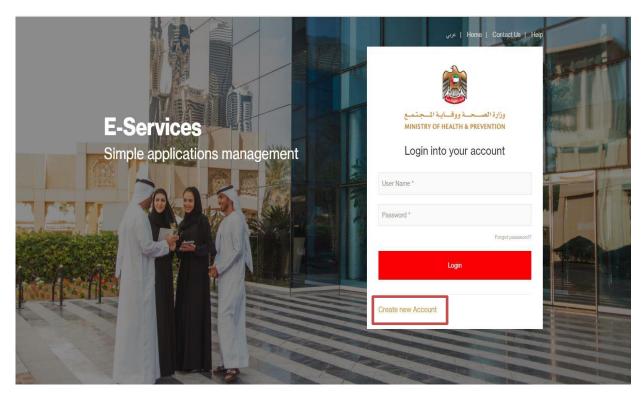
This document will provide ease to the business users in understanding all the screens of the application.



### 3 User Creation and Login

#### 3.1 User Creation

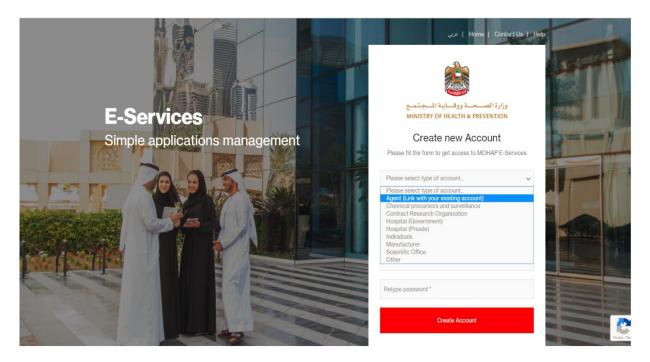
Navigate to the application login screen and click over "Create New Account"



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

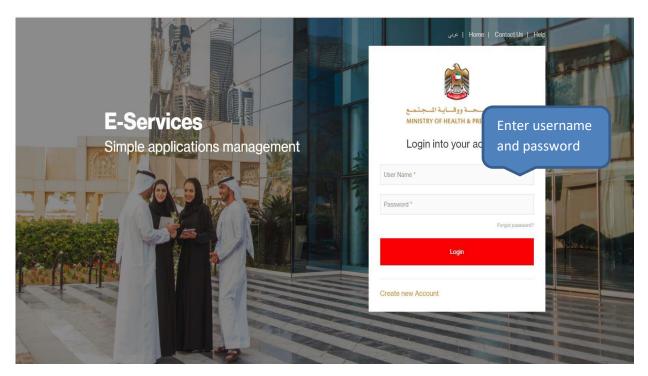
- B. For other user types, then the screen fields will be as follow:
  - Username
  - Email Address
  - New Password
  - Retype Password
  - "Create Account" button

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



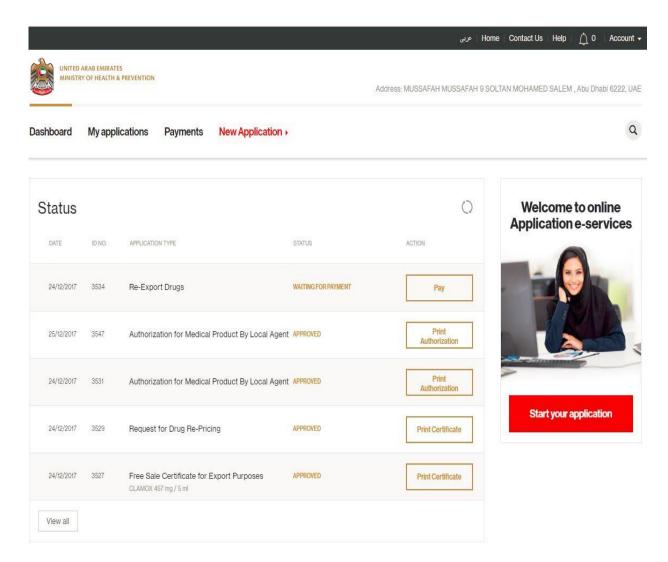
### 3.2 Login and dashboard

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.





### 4 Registration

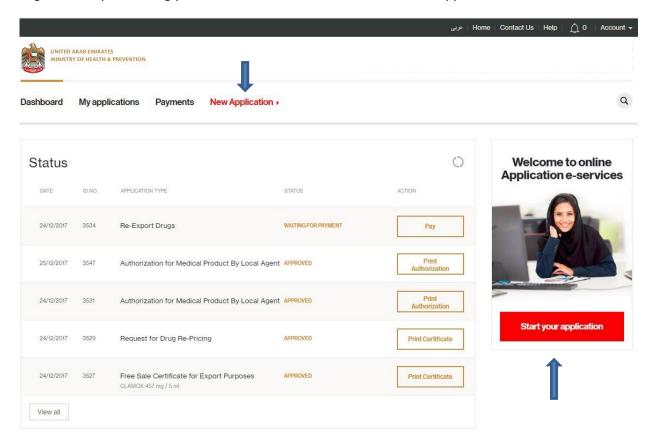
Under the registration tile, you will find the following services:

- 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.

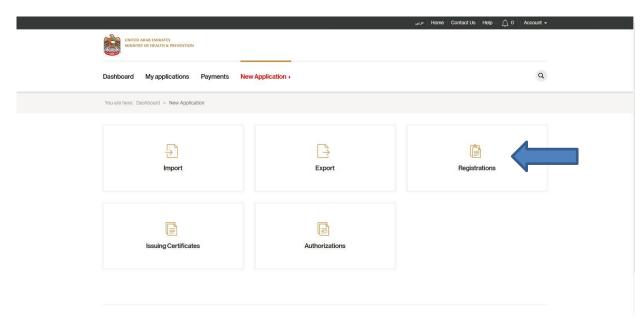
#### 4.1 Manufacturing site registration

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

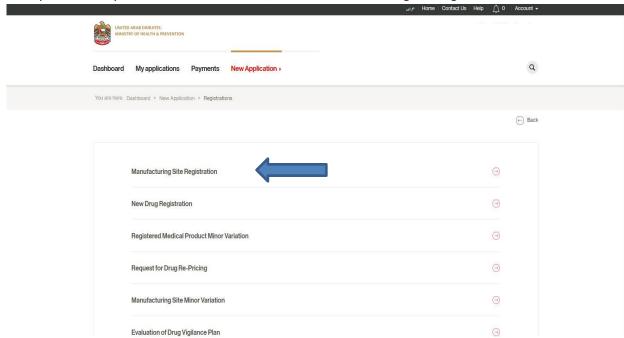




#### Click on registration tile

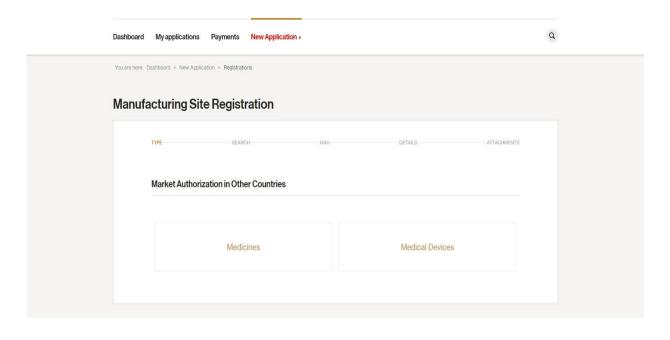


#### The system takes you to the services screen, click on manufacturing site registration

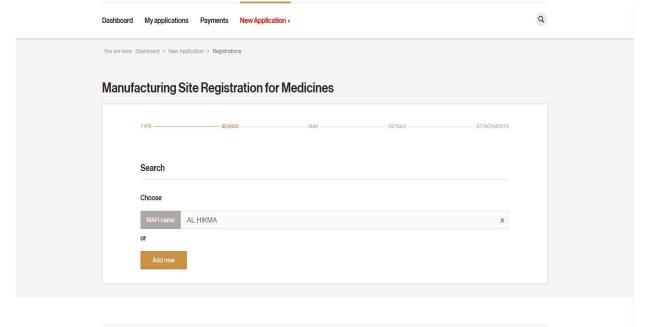


And then select whether you want to register a medicine or medical devices



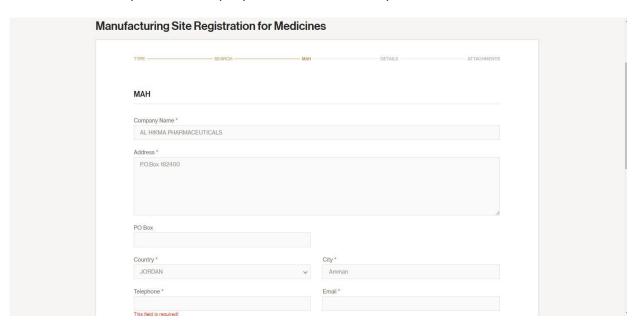


### Enter MAH Name or add new MAH by clicking on "Add new" button

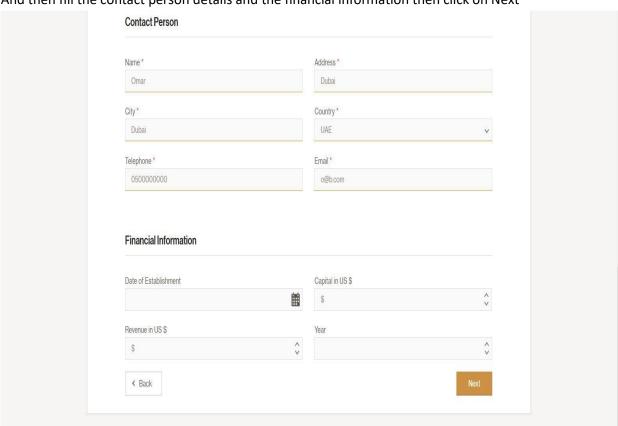




Fill all the mandatory data like company name, address, country, ...etc

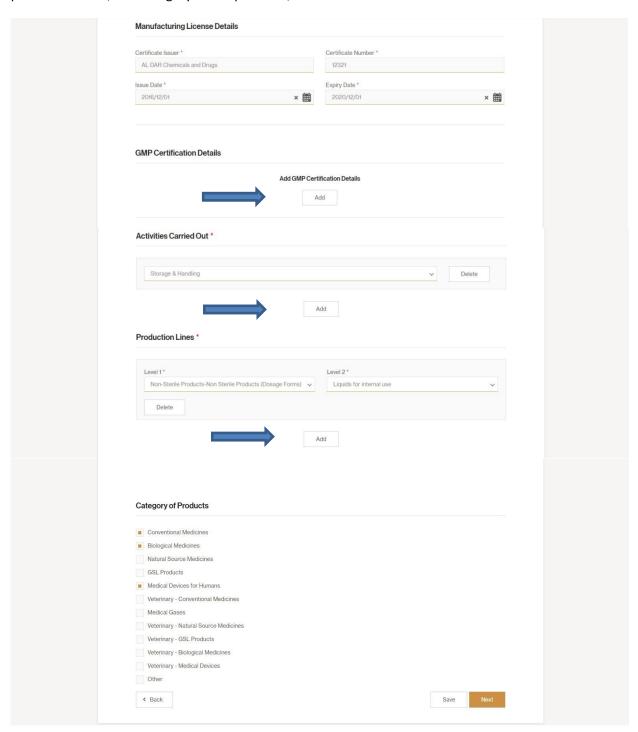


And then fill the contact person details and the financial information then click on Next



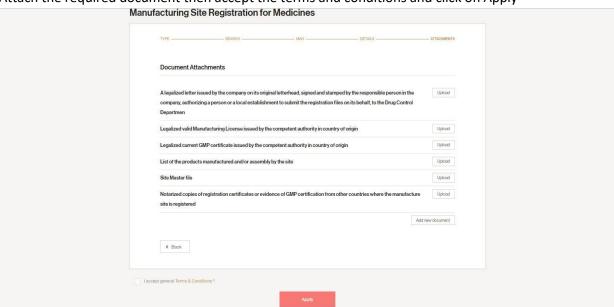


Enter the site name details, manufacturing license details. GMP Certification, Activities carried out, production lines, and category of the products, and then click on Next.

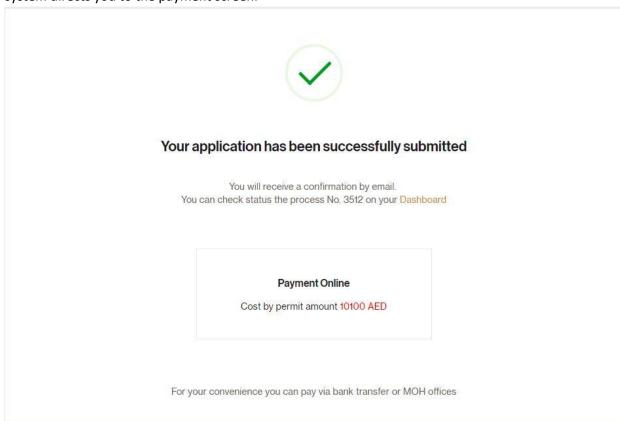




Attach the required document then accept the terms and conditions and click on Apply



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.



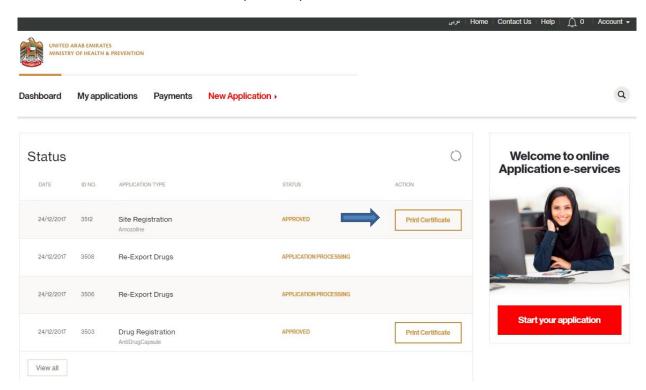


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Alternatively, the user can go to the payment screen in the dashboard and click over the pay button and perform the payment.

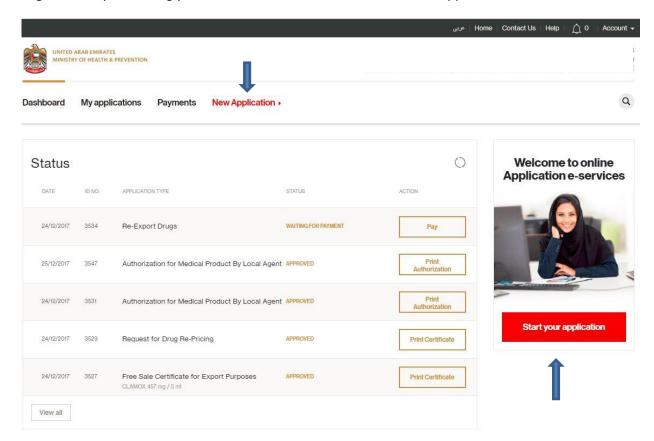
To view the application status go to dashboard, and once the permit is approved click on "Print Permit" button on the dashboard to view and print the permit.





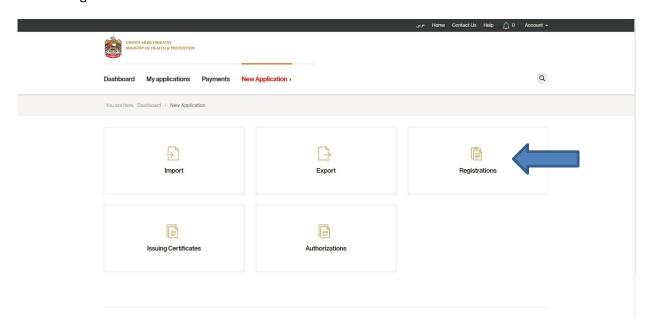
### 4.2 Drug Registration

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



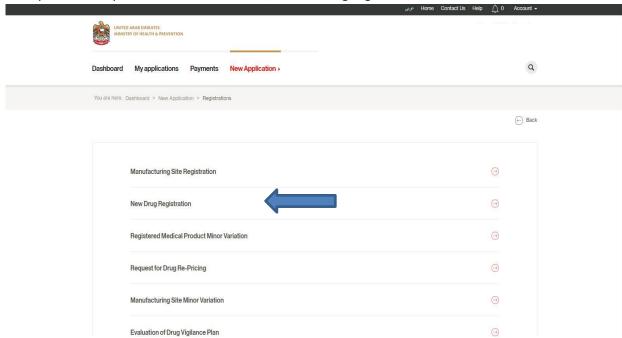
#### Click on registration tile

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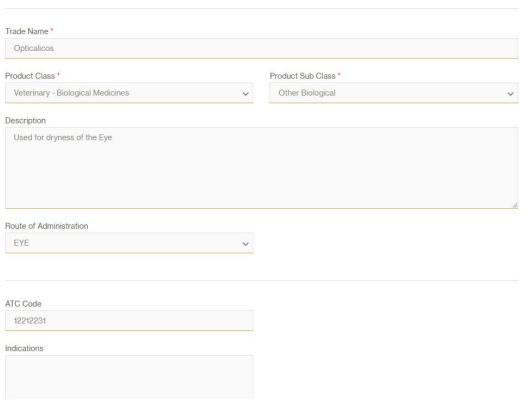


The system takes you to the services screen, click on drug registration



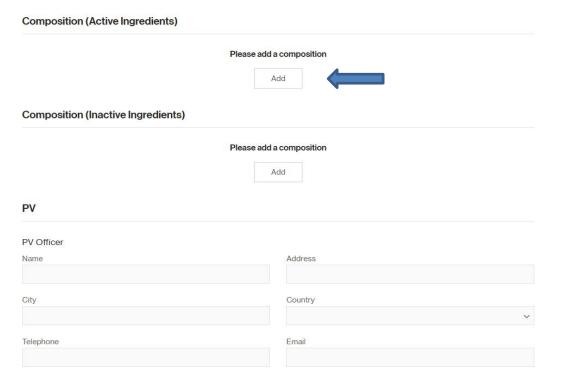
#### Enter product details

#### **Product Details**

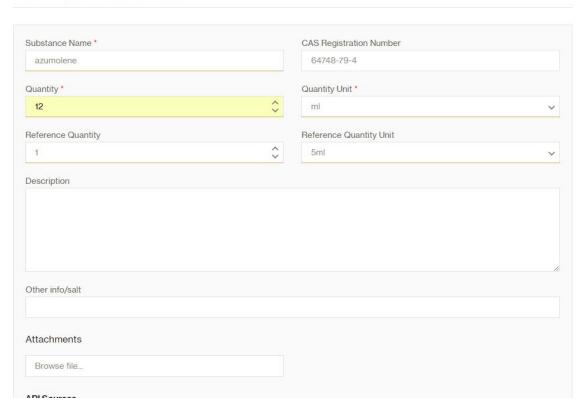




#### Add the active ingredient by clicking over add

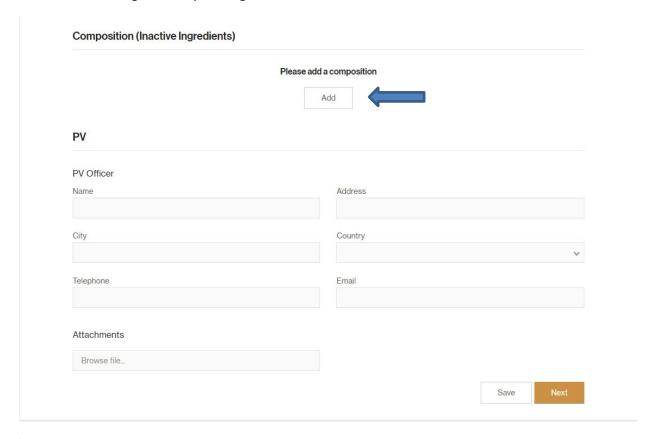


#### Composition (Active Ingredients)

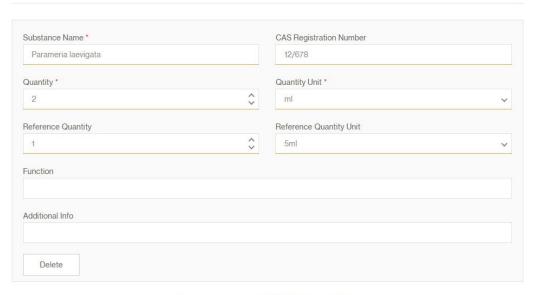




#### Add the inactive ingredient by clicking over add



#### Composition (Inactive Ingredients)

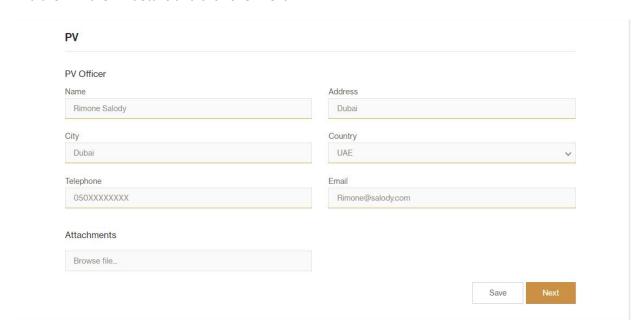


Please add a composition (Inactive Ingredients)

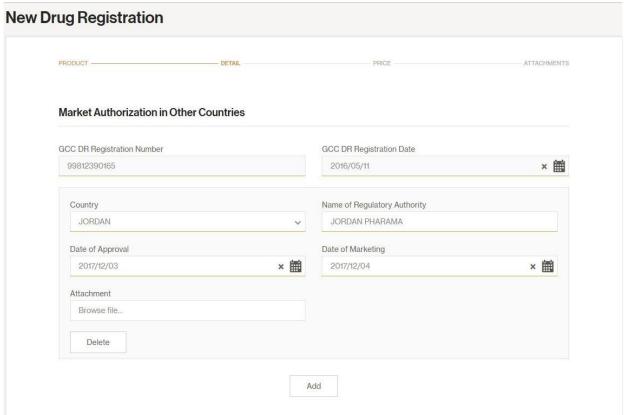
Add



#### And then fill the PV details and click over Next

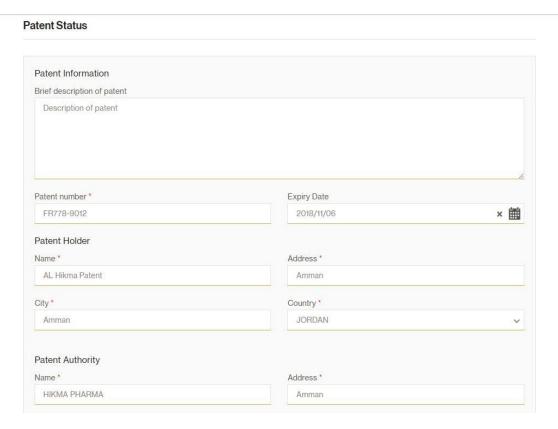


#### Add the Marketing Authorization holder in other countries details

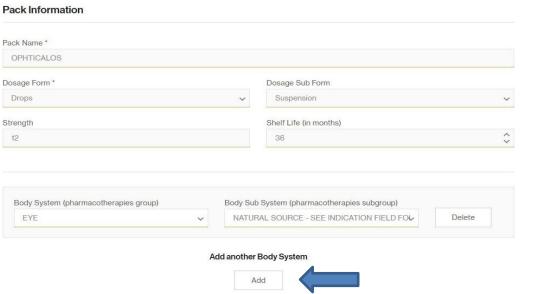




#### Fill the patent status and the pack information

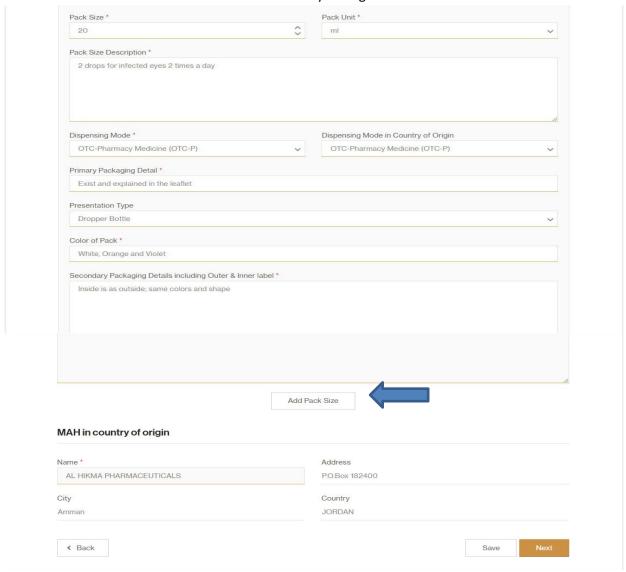


#### Click on "Add" button to Add Body System





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

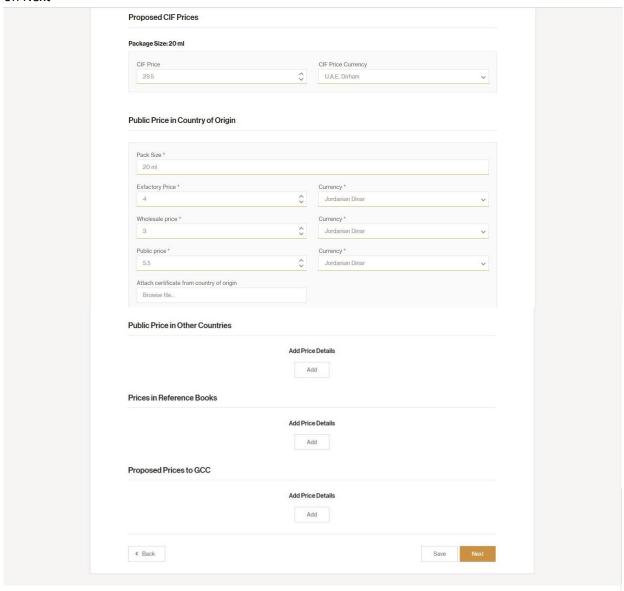




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Add the proposed CIF price, Public price in the country of origin, public price in other countries, prices in reference book, and proposed price in GCC, by clicking over "Add price details" button and then click on Next





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

Labelling information

Summary of Product Characteristics (SmPC)

Application form properly filled and signed by the qualified responsible person (MAH), and word document soft copy

Comprehensive Table of content

Covering letter

Upload

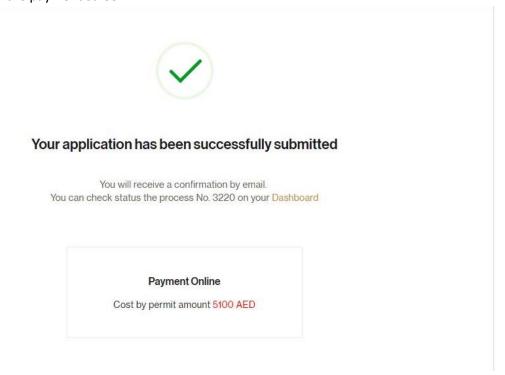
Add new document

Add new document

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Copyright & 2017. All rights merved Minitry of Health & Preventor, Use Land July Pilley - gold Holy, Sind You, Salan Jala gar- 2018 (July July - 2018 (July - 2018

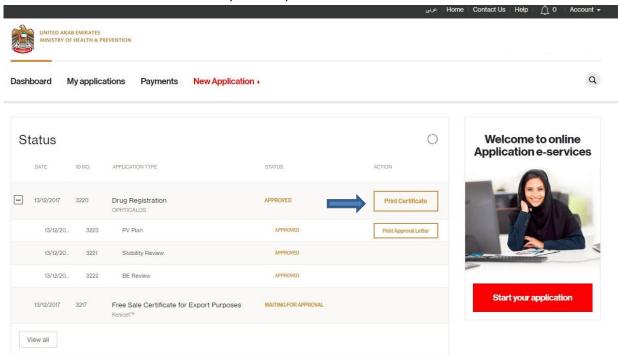
After submitting the application a successful message displayed to the user, and the permit fees is generated. The user can perform the payment from this screen by clicking over the amount, where the system directs you to the payment screen.



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



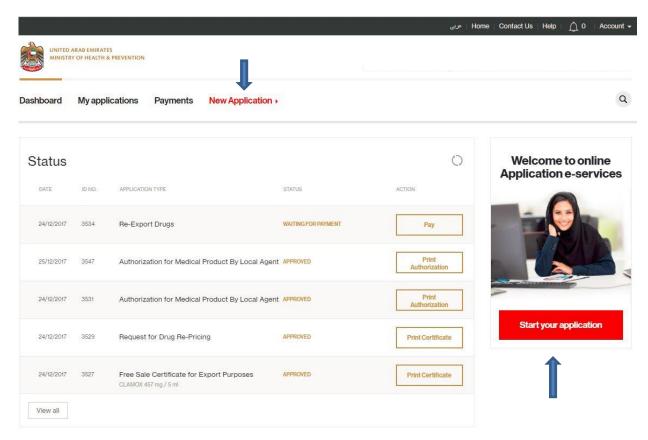
To view the application status go to dashboard, and once the permit is approved click on "Print Permit" button on the dashboard to view and print the permit.



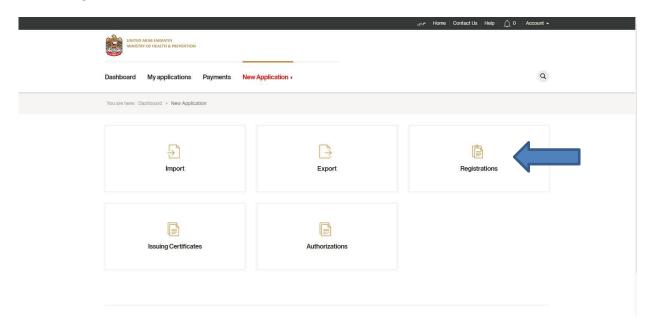


### 4.3 Registered medical product minor variation

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

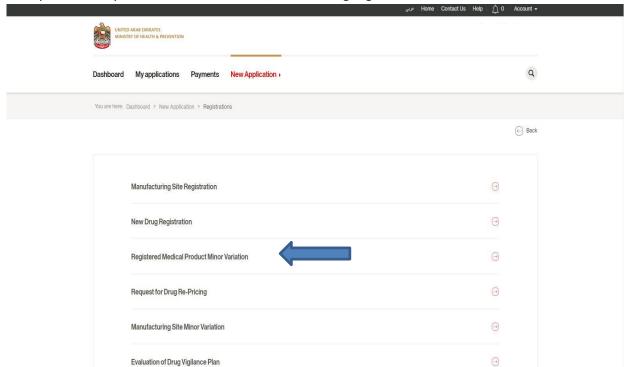


#### Click on registration tile

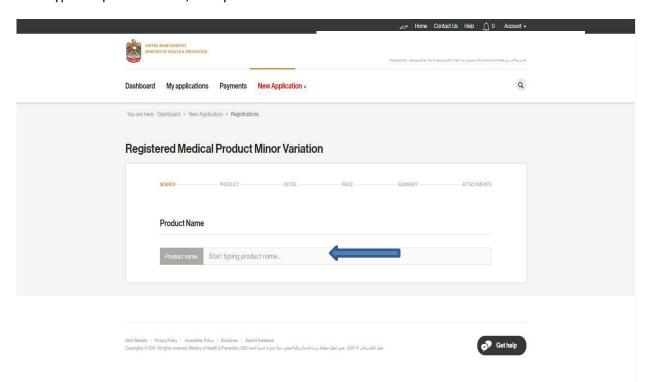




The system takes you to the services screen, click on drug registration

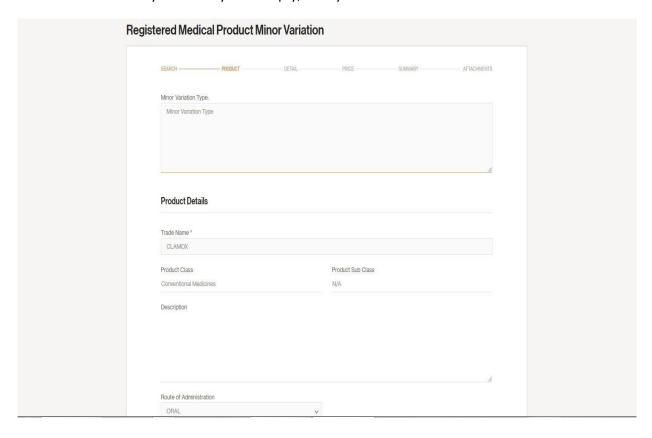


Start type the product name, the system will filter the results based on the entered characters



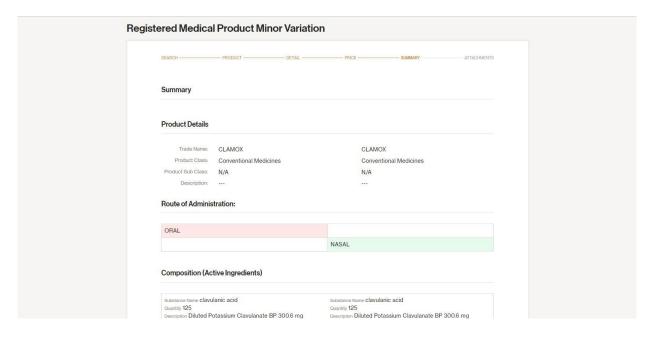


Modify the data of the drug to the desired change; you can reach to more information on the product by navigating over the product tabs. Or by clicking on next button at the bottom of the page, please note that if there is any mandatory field empty, then you need to enter the correct values.

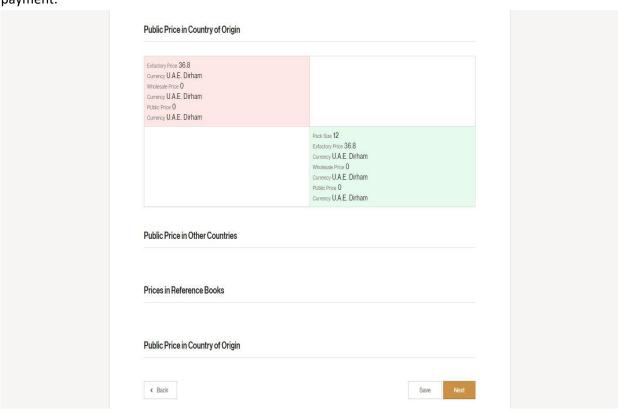




The summary page shows the changes or modifications done on the application, where it shows the application and the new value so you can review the changes one more time before submitting it to MOHAP for review. The old data highlighted in pink and the new data is highlighted in blue

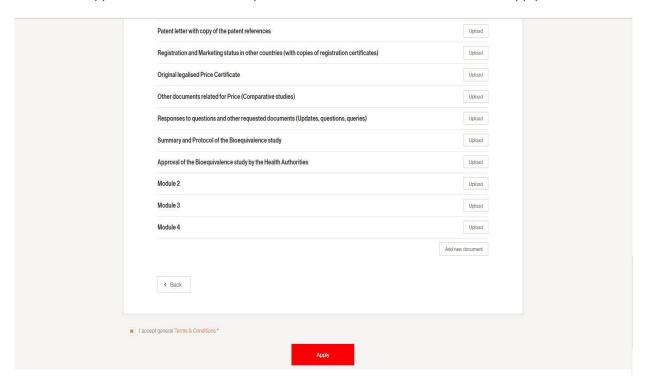


After you review the changes, click on next to attach the supportive documents and to perform the payment.



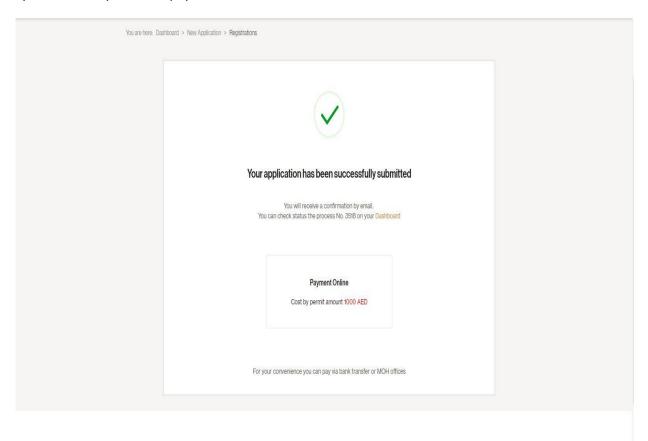


Attach the support documents and accept the terms and conditions, the click over apply





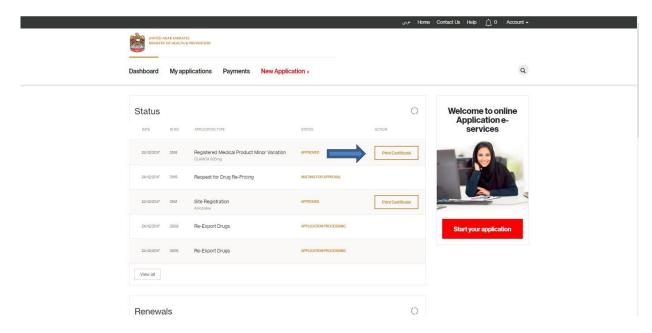
After submitting the application a successful message displayed to the user, and the permit fees is generated. The user can perform the payment from this screen by clicking over the amount, where the system directs you to the payment screen.



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



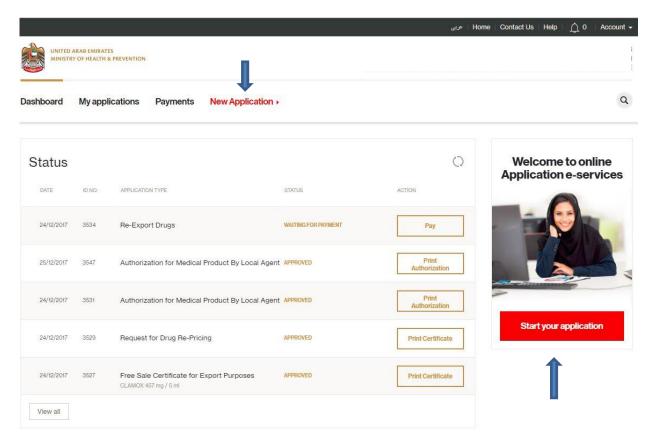
To view the application status go to dashboard, and once the permit is approved click on "Print Permit" button on the dashboard to view and print the permit.



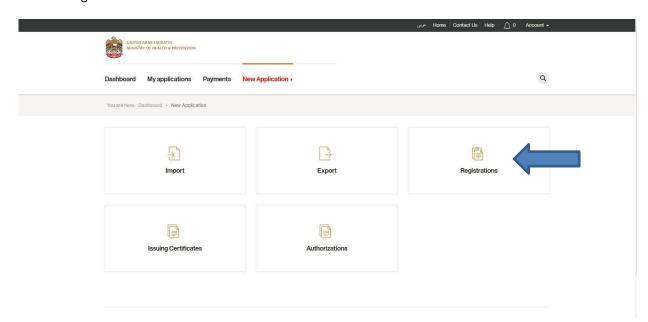


### 4.4 Request for drug Re-Pricing

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

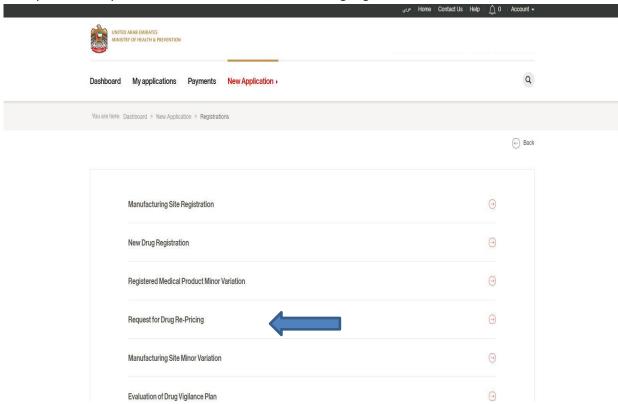


#### Click on registration tile

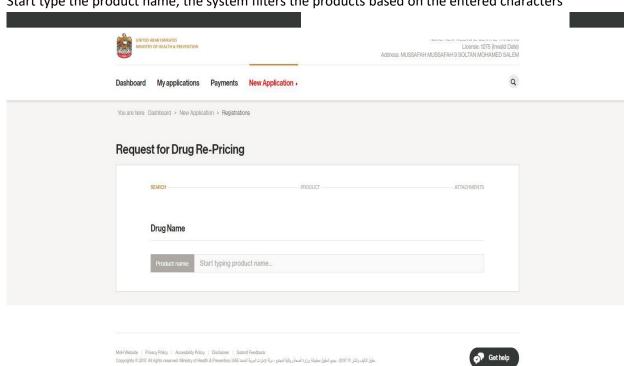




The system takes you to the services screen, click on drug registration

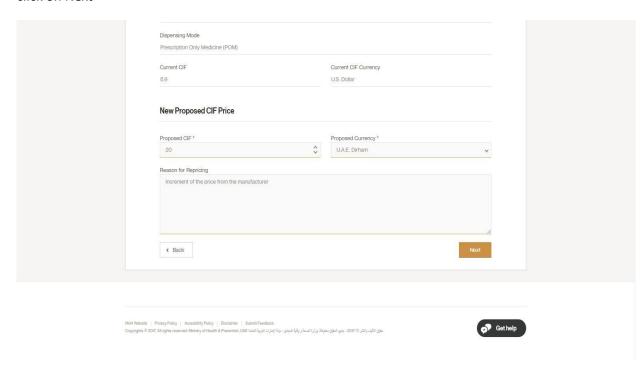


Start type the product name, the system filters the products based on the entered characters



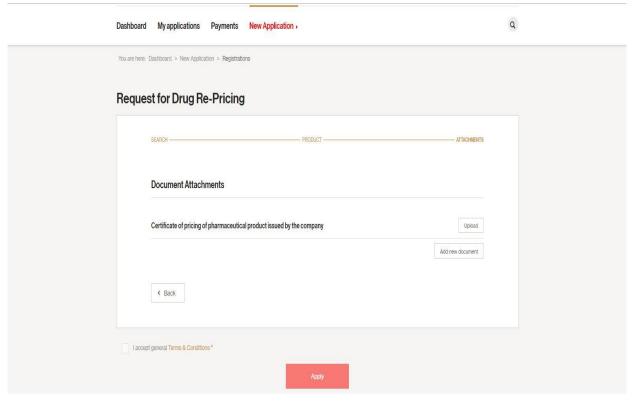


Enter the new proposed CIF price, select the currency, and provide the reason of repricing and then click on Next

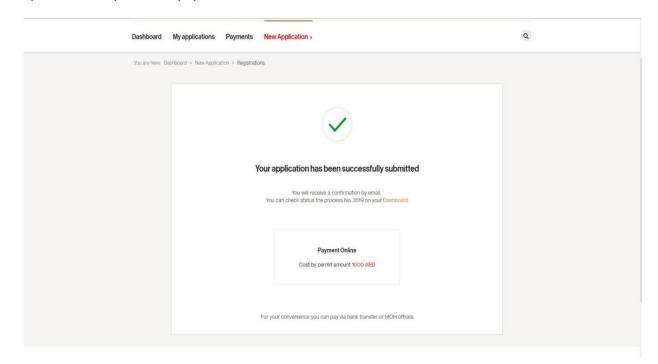




Upload the support documents; accept the terms and conditions and then click on Apply button



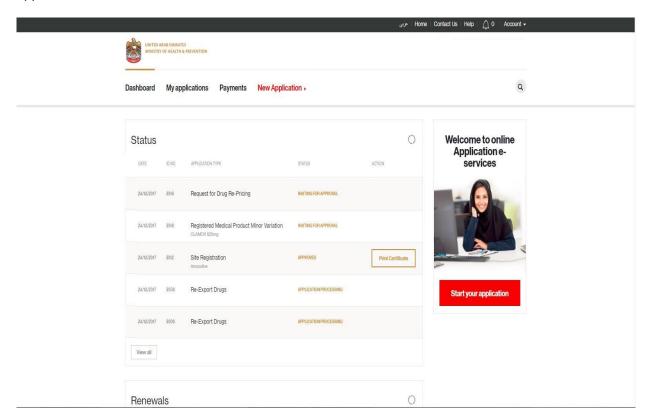
After submitting the application a successful message displayed to the user, and the permit fees is generated. The user can perform the payment from this screen by clicking over the amount, where the system directs you to the payment screen.





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

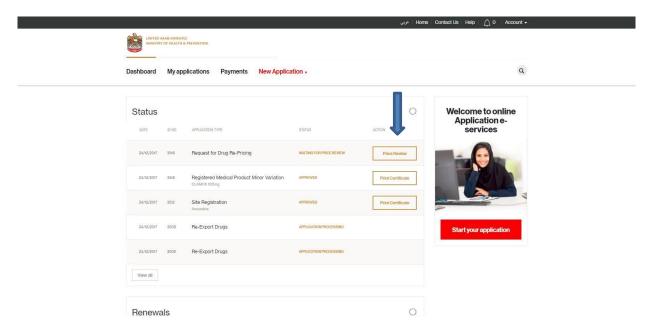
Navigate to the dashboard to view the status of the application; the initial status will be "Waiting for approval"



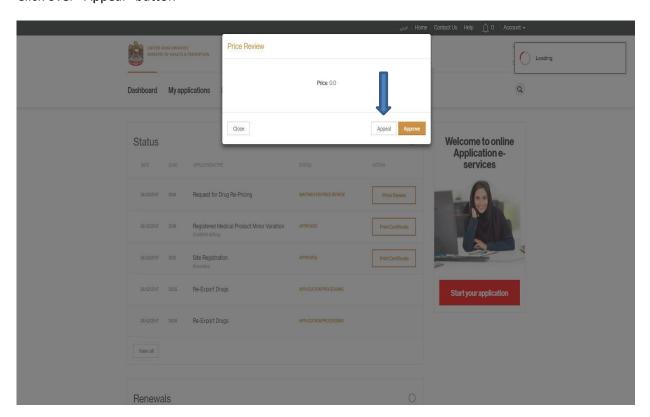


After MOH approve the permit, the application status will be changed to waiting for price review, and a new button is displayed next to the application to review the approved price by MOH, You can do the following,

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

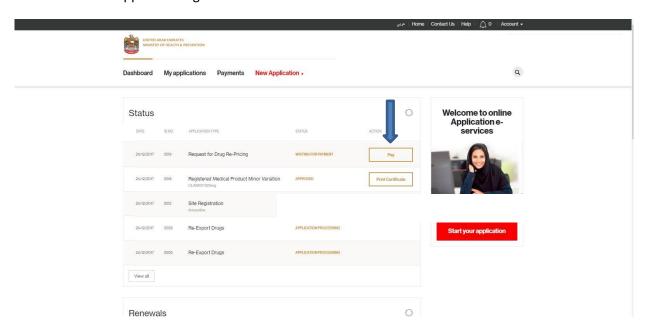


#### Click over "Appeal" button

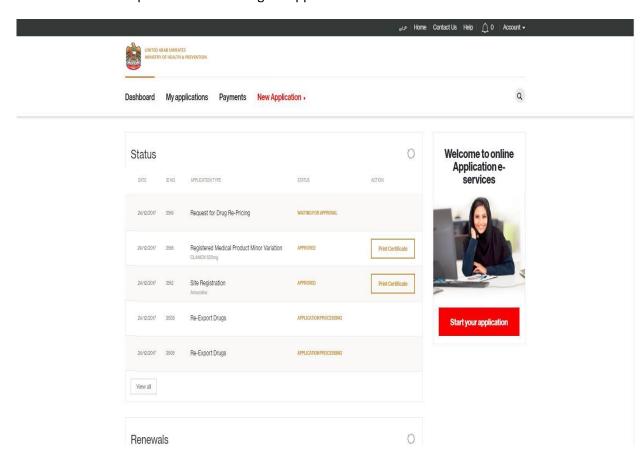




Click over "Pay" button, the system takes you to the payment screen, do the payment and wait till MOH review the application again.

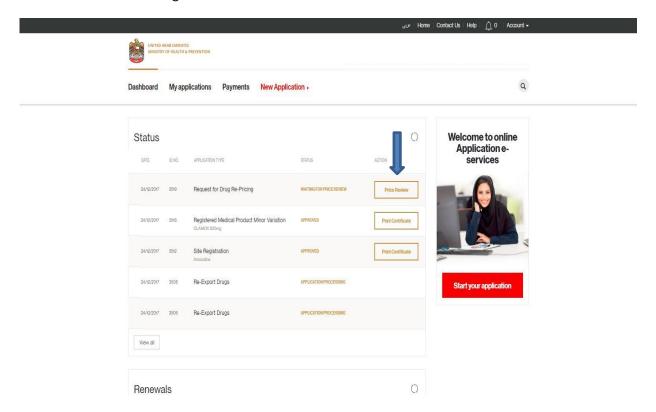


The status of the request will be "Waiting for approval"



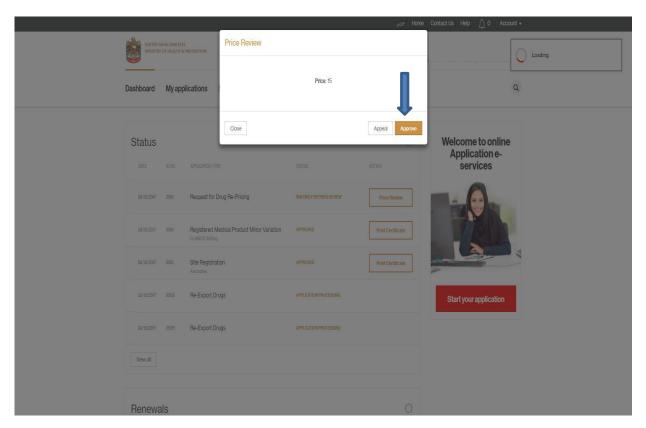


After MOH review, the application status will change to "Waiting for Price Review" and the "Price Review" button is enabled again.

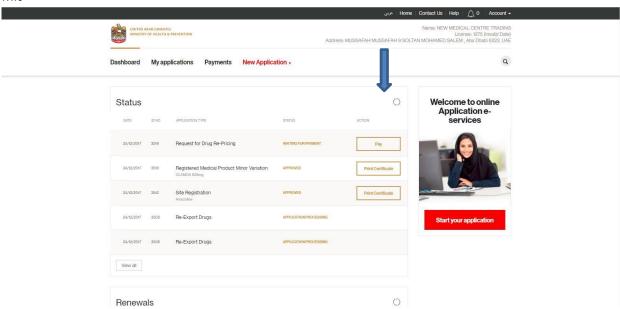




Click on the Price review button and the click on approve

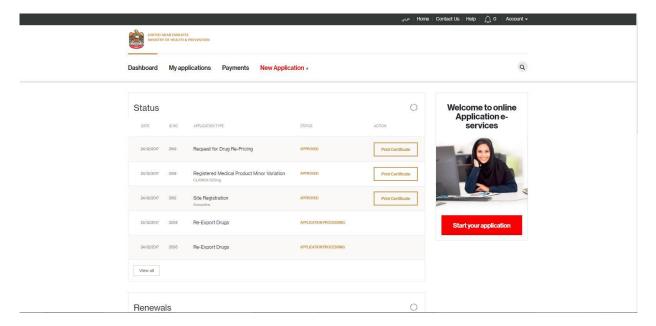


After approving the permit, you need to pay the permit fees and then you will be able to print the permit





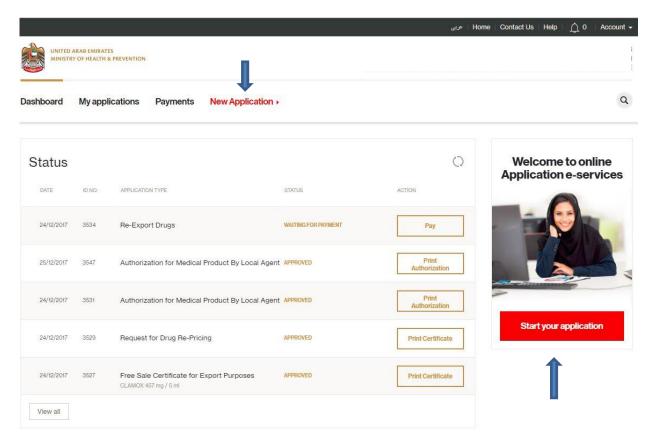
#### Print the permit by clicking on Print Certificate button



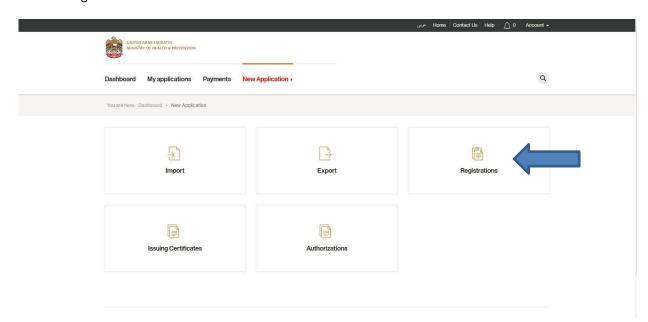


#### 4.5 Manufacturing site minor variation

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

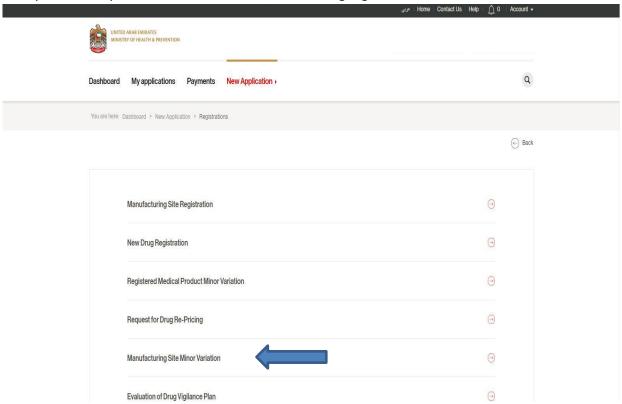


#### Click on registration tile

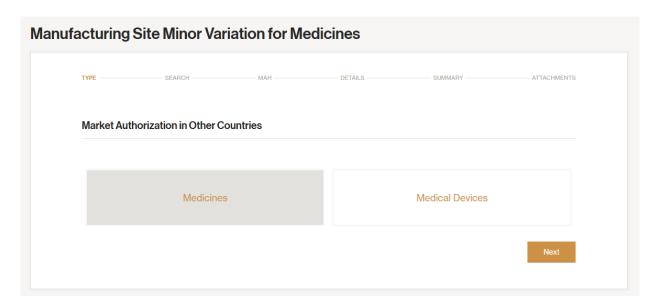




The system takes you to the services screen, click on drug registration



Select Medicines or Medical Devices and then click "Next"





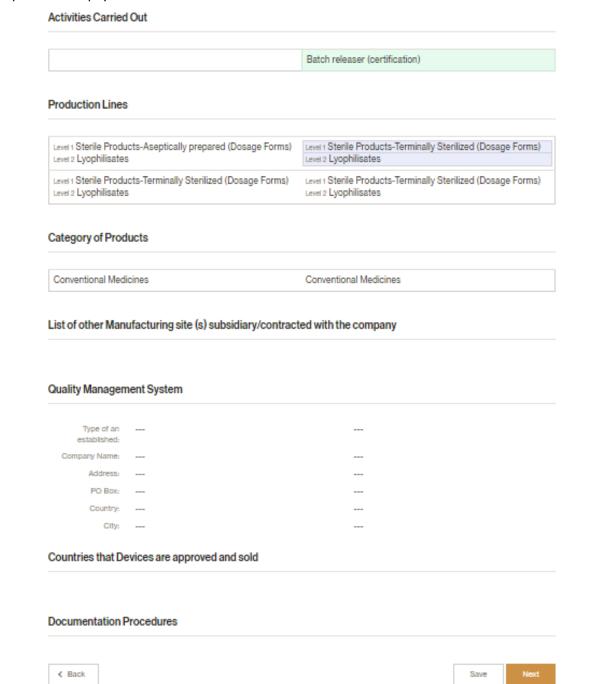
Start typing the site name, the system filters the sites based on the entered characters

# Manufacturing Site Minor Variation for Medical Devices TYPE \_\_\_\_\_\_\_ SEARCH \_\_\_\_\_\_\_ MAH \_\_\_\_\_\_\_ DETAILS \_\_\_\_\_\_\_ SUMMARY \_\_\_\_\_\_\_ ATTACHMENTS Search Choose: MAnufacturing Site name: Start typing MAnufacturing Site name...

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.

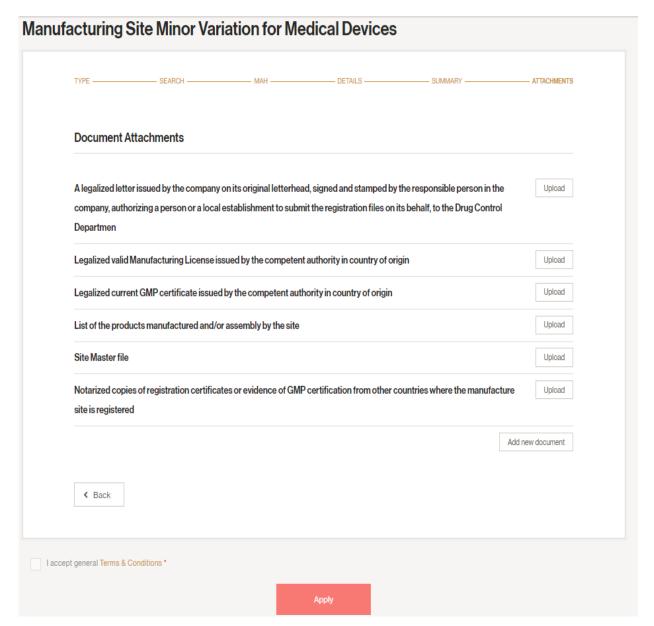


Once you make sure that the changes are correct, click on next to attach the supportive documents and to perform the payment



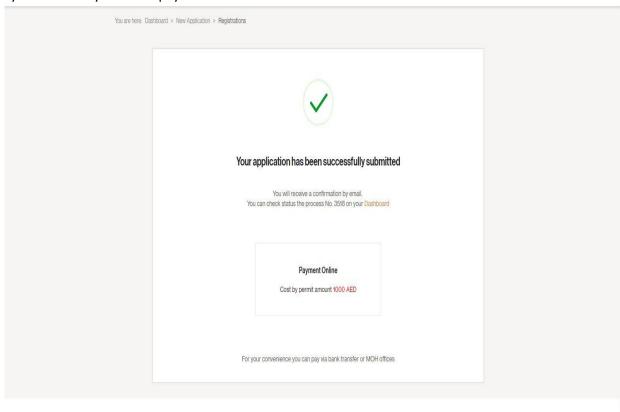


Attach the required document, accept the terms and conditions and then click on Apply





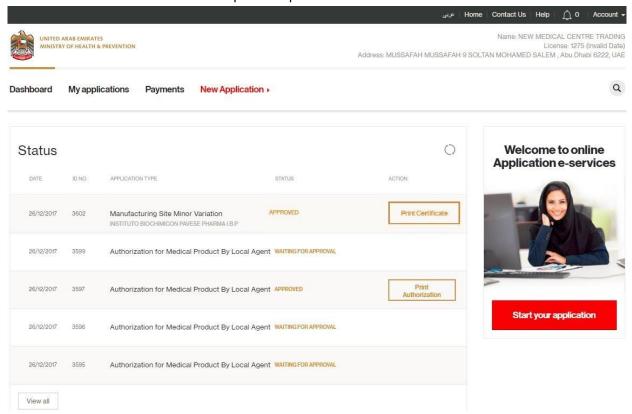
After submitting the application a successful message displayed to the user, and the permit fees is generated. The user can perform the payment from this screen by clicking over the amount, where the system directs you to the payment screen.



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



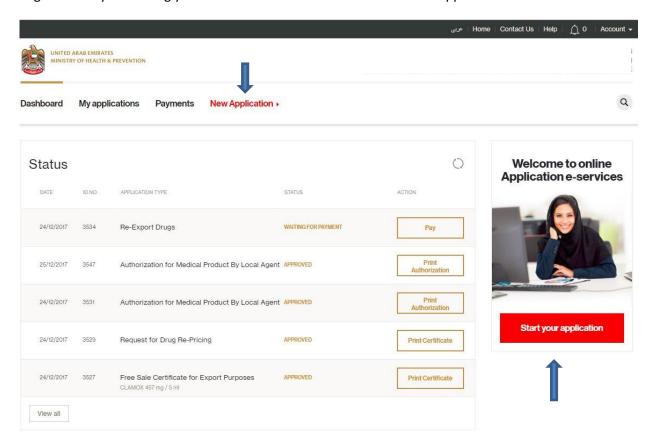
To view the application status go to dashboard, and once the permit is approved click on "Print Permit" button on the dashboard to view and print the permit.



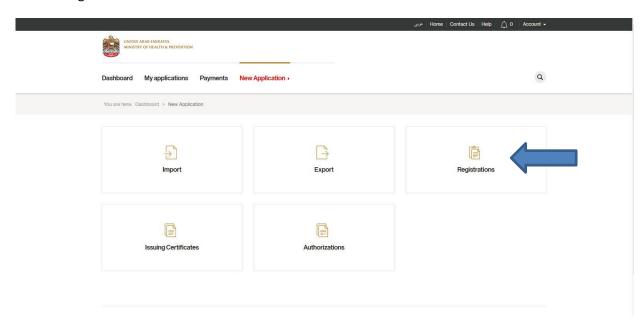


#### 4.6 Evaluation of drug vigilance plan

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

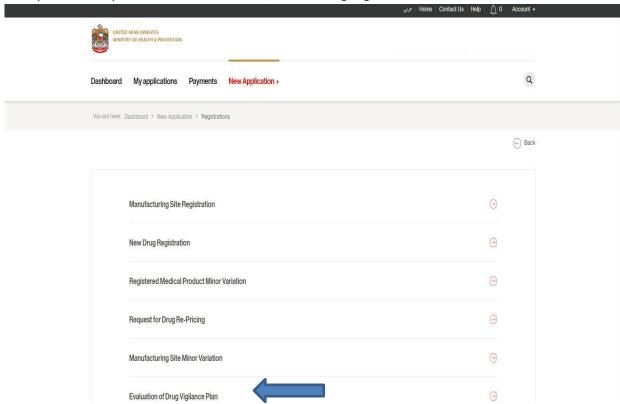


#### Click on registration tile



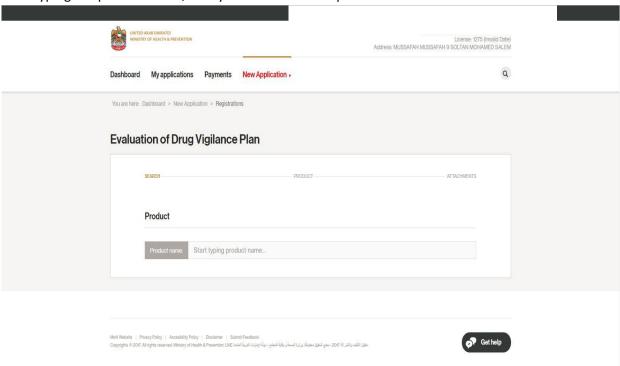


The system takes you to the services screen, click on drug registration

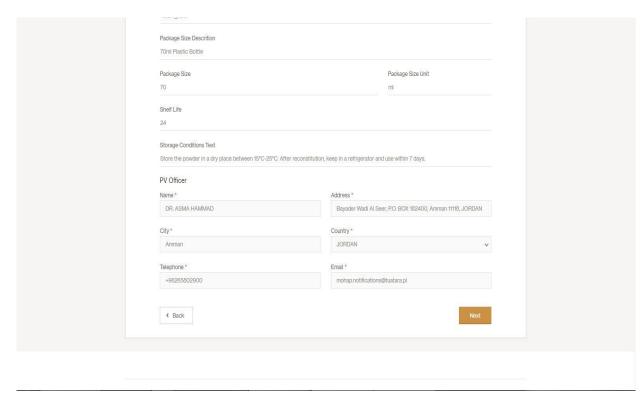




Start typing the product name, the system will filter the products based on the entered characters.

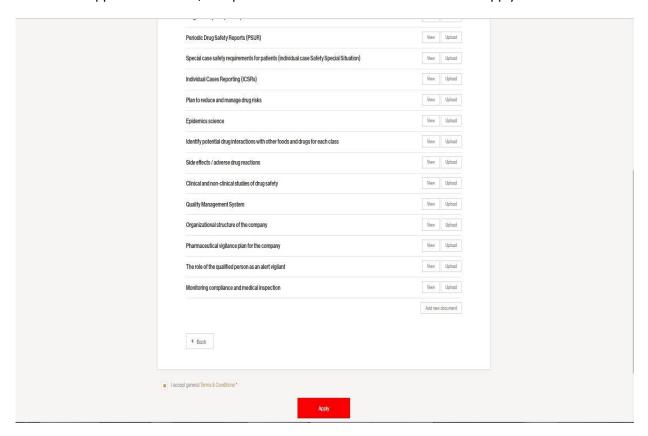


#### Fill the PV details and then click on Next.



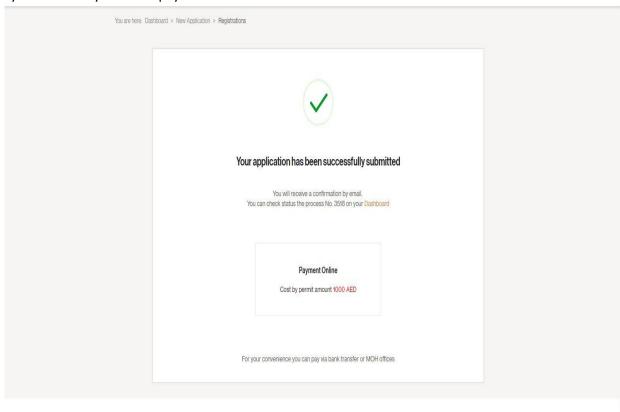


Attach the support documents, accept terms and conditions and then click on Apply.





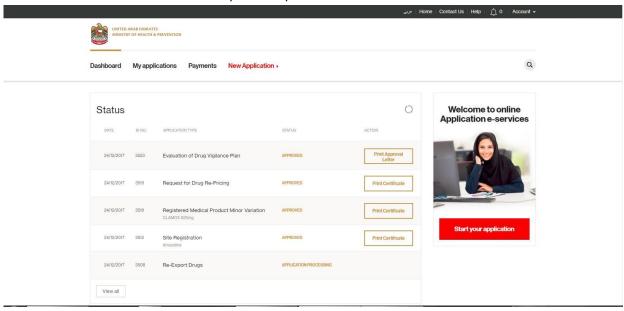
After submitting the application a successful message displayed to the user, and the permit fees is generated. The user can perform the payment from this screen by clicking over the amount, where the system directs you to the payment screen.



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.





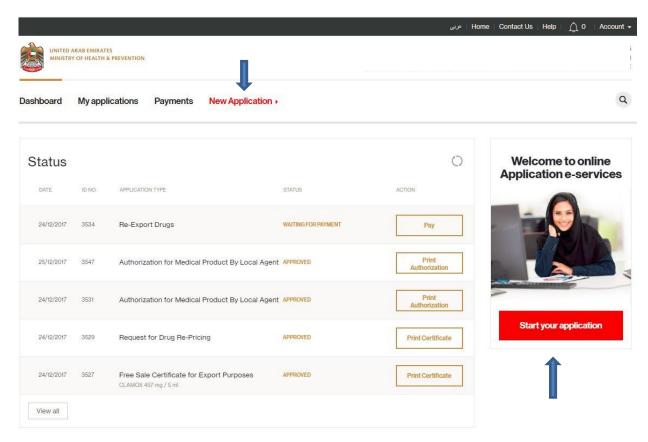
#### 5 Issuing Certificates

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

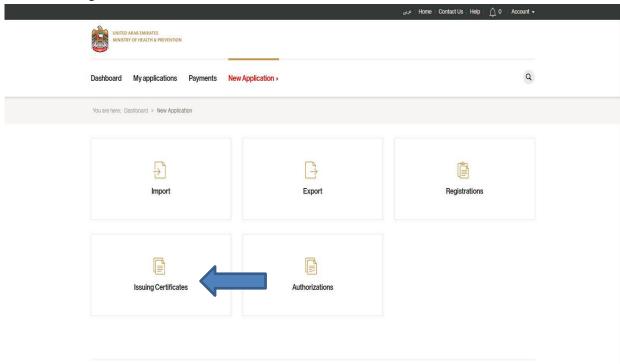
#### **5.1 Pricing Certificate**

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

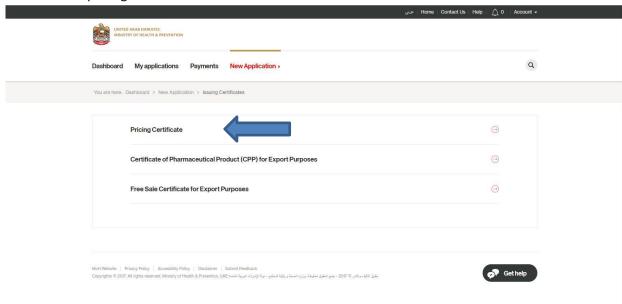




#### Click on Issuing Certificates tile

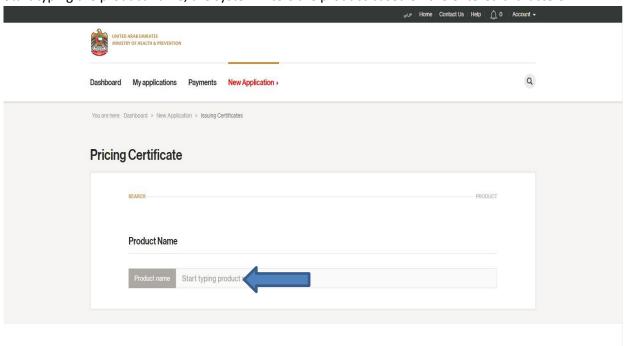


#### Then click on pricing certificate

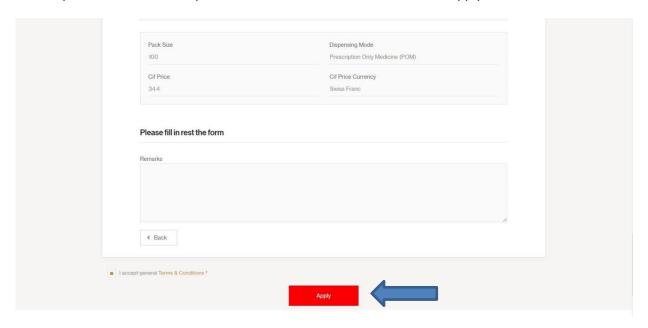




Start typing the product name, the system filters the product based on the entered characters

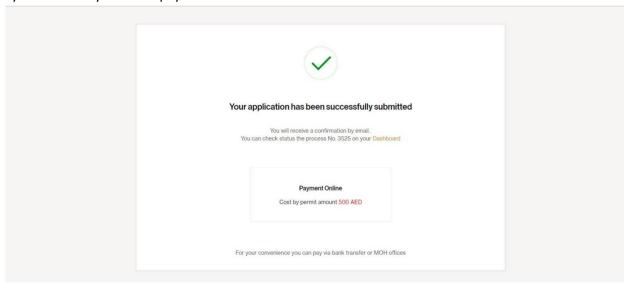


Review product data and accept terms and conditions, and then click on Apply button

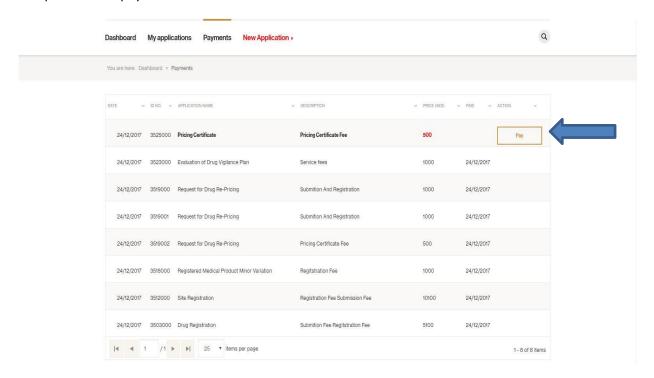




After submitting the application a successful message displayed to the user, and the permit fees is generated. The user can perform the payment from this screen by clicking over the amount, where the system directs you to the payment screen.

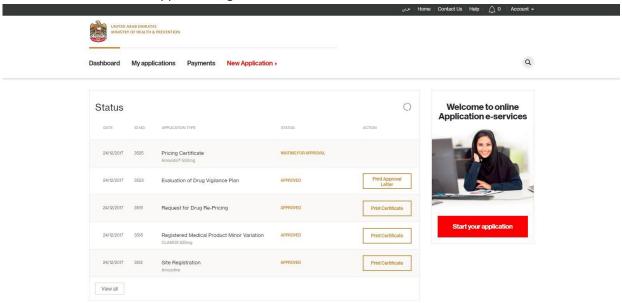


Alternatively, the user can go to the payment screen in the dashboard and click over the pay button and perform the payment.

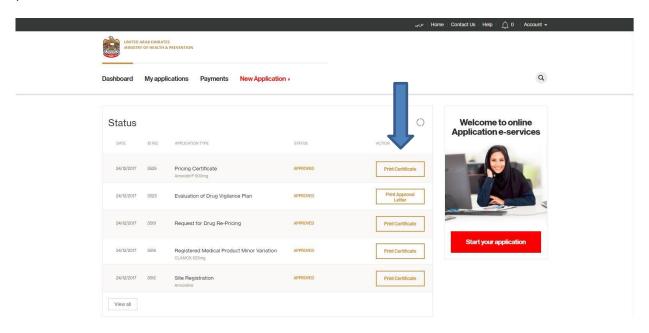




To view the status of the application, go to dashboard



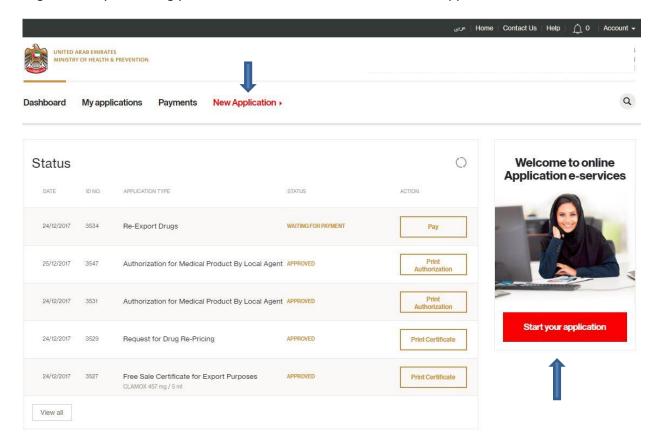
Once the permit is approved click on "Print Permit" button on the dashboard to view and print the permit.





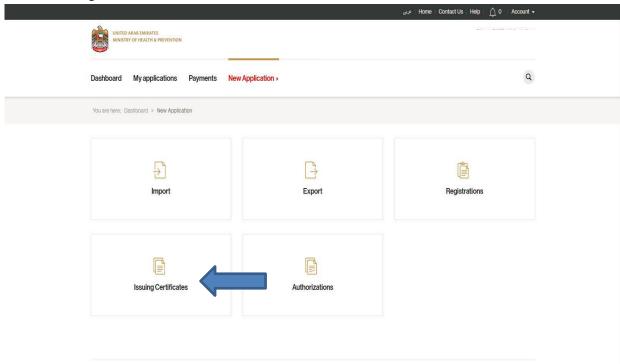
#### 5.2 Certificate of Pharmaceutical Product (CPP) for Export Purposes

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

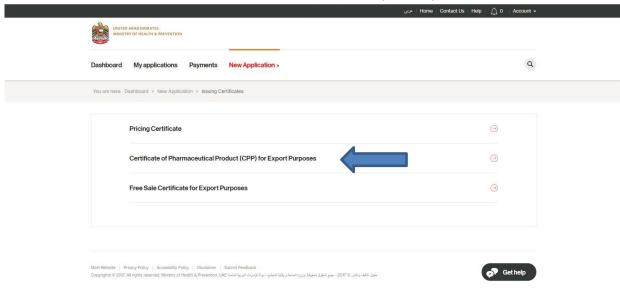




#### Click on Issuing Certificates tile

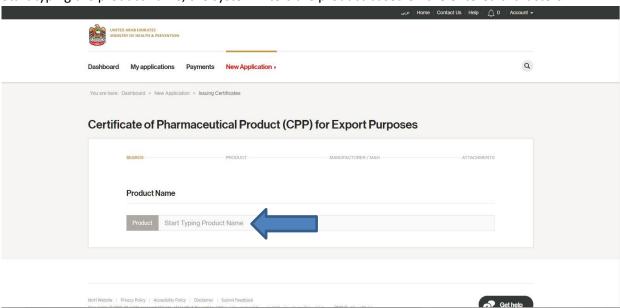


#### Then click on Certificate of Pharmaceutical Product (CPP) for Export Purposes

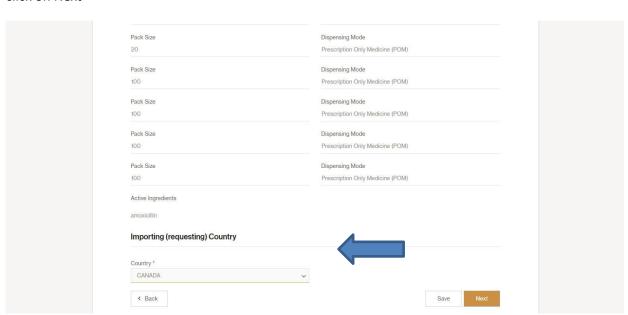




Start typing the product name, the system filters the product based on the entered characters

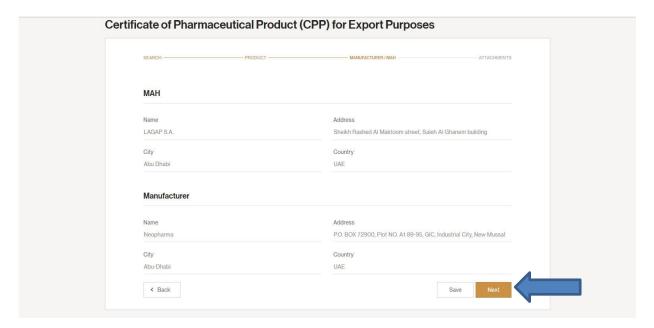


Review product data and accept terms and conditions, and fill the importing (requesting) country then click on Next

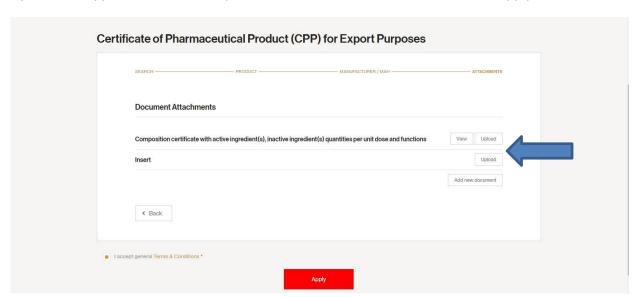




Review the MAH and the manufacturer and then click on Next

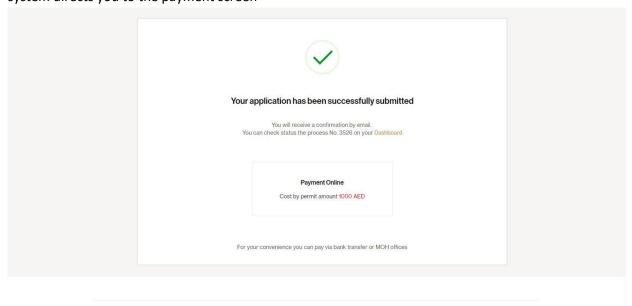


Upload the support document, accept the terms and conditions and then click on Apply

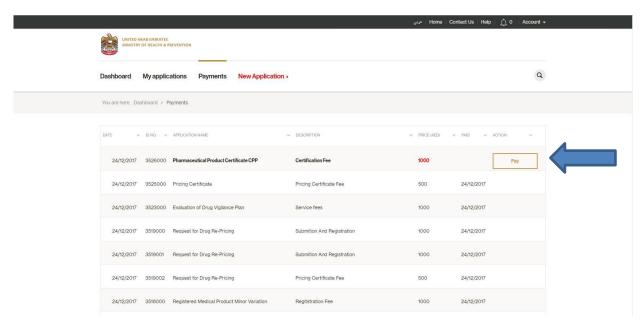




After submitting the application a successful message displayed to the user, and the permit fees is generated. The user can perform the payment from this screen by clicking over the amount, where the system directs you to the payment screen

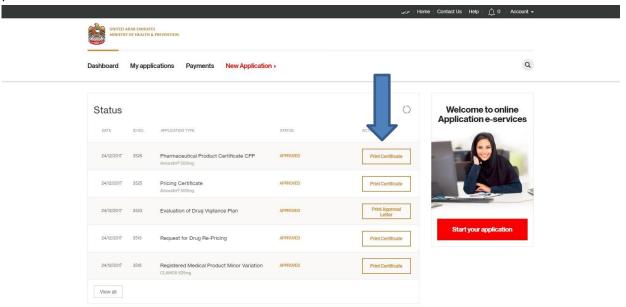


Alternatively, the user can go to the payment screen in the dashboard and click over the pay button and perform the payment.



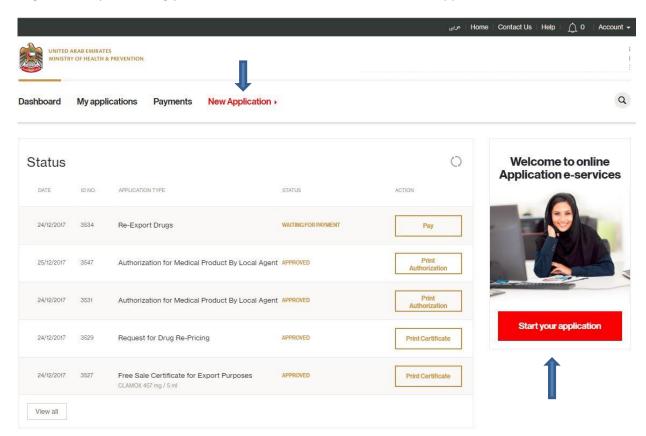


Once the permit is approved click on "Print Permit" button on the dashboard to view and print the permit.



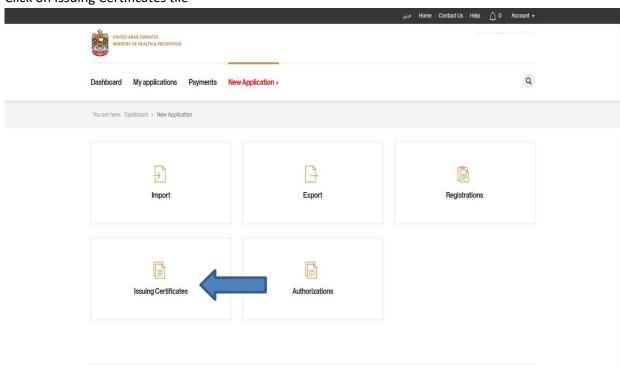
#### **5.3** Free Sale Certificate for Export Purposes

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

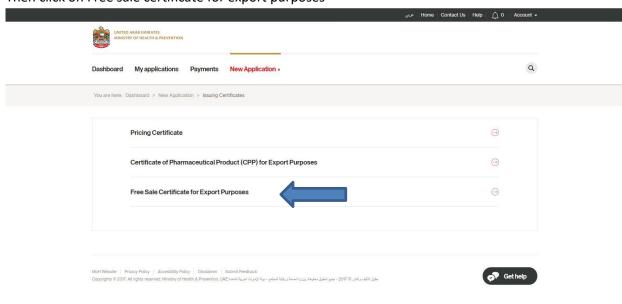




#### Click on Issuing Certificates tile

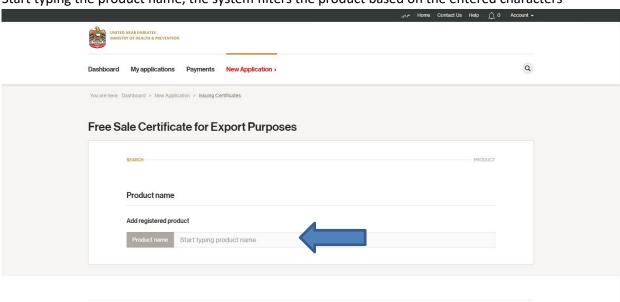


#### Then click on Free sale certificate for export purposes

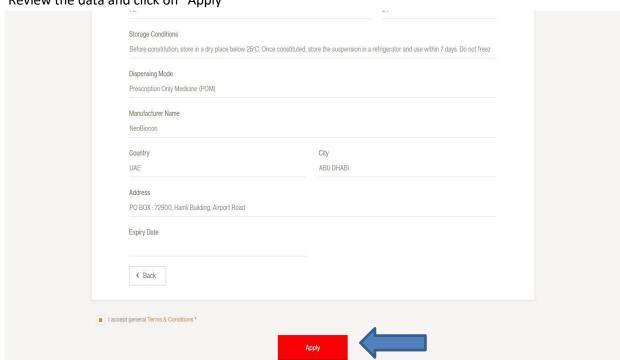




#### Start typing the product name, the system filters the product based on the entered characters

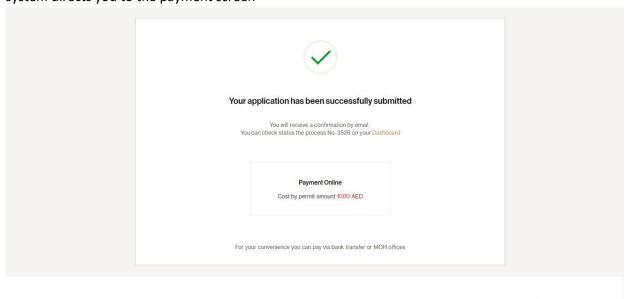


#### Review the data and click on "Apply"

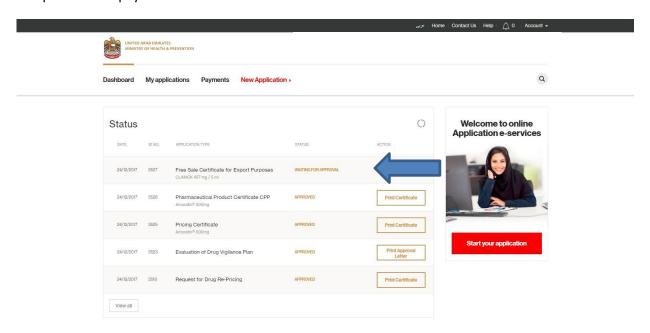




After submitting the application a successful message displayed to the user, and the permit fees is generated. The user can perform the payment from this screen by clicking over the amount, where the system directs you to the payment screen



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.

