External User Guide

Issuance of Marketing Authorization for a Medical Device

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1. Brief Overview

This manual is prepared to navigate applicants through the Drug Registration process in Emirates Drug Establishment (EDE) Portal.

This manual is designed to help applicants:

- Apply for Medical Pharmaceutical Product or Medical Device services
- Manage Medical Pharmaceutical Product or Medical Device applications

After completing this manual, the applicant should be able to perform all activities related to medical product registration on EDE Portal.

Please note: The services are only available to the Applicants listed below.

Applicant Type	Rules
Agents	Should have un-expired license Can only renew drugs registered under his name as agentCan register new products Can only initiate minor variation for drugs registered under his name as agent
Scientific Offices	Should have un-expired license Can only renew drugs registered under his name as Applicant or MAH Can register new products Can only initiate minor variation for drugs registered under his name as Applicant or MAH
Local Manufacturers	Should have un-expired license Can only Renew drugs where he is part of its manufacturing cycleCan register new products Can only initiate minor variation for drugs where he is part of its manufacturing cycle

Table 1: Applicant Types

2. Apply for Service

Portal users who have logged in successfully to EDE portal will be directed to Dashboard screen where they can apply to EDE's e-services. This user manual will focus on the following e-services:

1. New Medical Pharmaceutical Product or Medical Device Registration
2. Renewal of Registration to a registered pharmaceutical product or medical devices

3. Minor variation to Registered Pharmaceutical Products or Medical Devices

For applicants to apply to their available services, they must go through the followingprocess:

1. Create a new application
2. Complete application
3. Review application
4. Proceed to checkout

The sections below will help user through the step-by-step process of applying to an application.

Please note: Business Account users that are licensed by EDE will NOT be able to submitnew applications if their license has expired but will be able to still view and apply actions for existing applications.

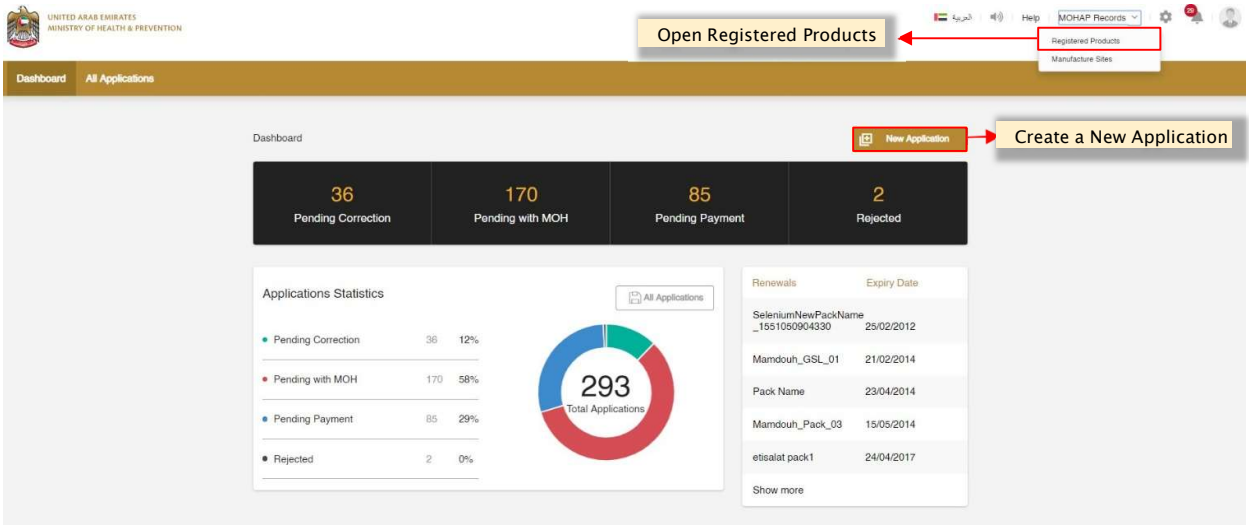


Figure A: Dashboard screen

2.1 Create a New Application

The Applicant can request the registration, renewal or minor modification of a medical product by either:

1. Selecting any of the following services from the Service Catalogue in EDE's website:
   - Medical Product Analysis for Pharmaceutical Establishment
   - Registration of A Pharmaceutical Product Derived from Natural Sources
   - Registration of Pharmaceutical Product with General Sale

- Registration of Medical Equipment
- Renewal of Registration to a registered pharmaceutical product or medical devices
- Minor variation to Registered Pharmaceutical Products or Medical Devices

2. Requesting to create a New Application form from the Applicant Portal and selecting any of the following services under the Drug ⇨ Registration services:

- Drug Registration
- Drug Renewal
- Minor Variation

To create a new application form from the Applicant Portal, the user must do the following:

a. Click on one of the New Application buttons found on the Dashboard Screen (or All Applications Screen) – which opens New Application Screen.
b. Pick one of the services found on New Application screen.
c. Click Create Application button

Once the user selects a service and creates an application, the user will be redirected to Product Details screen.

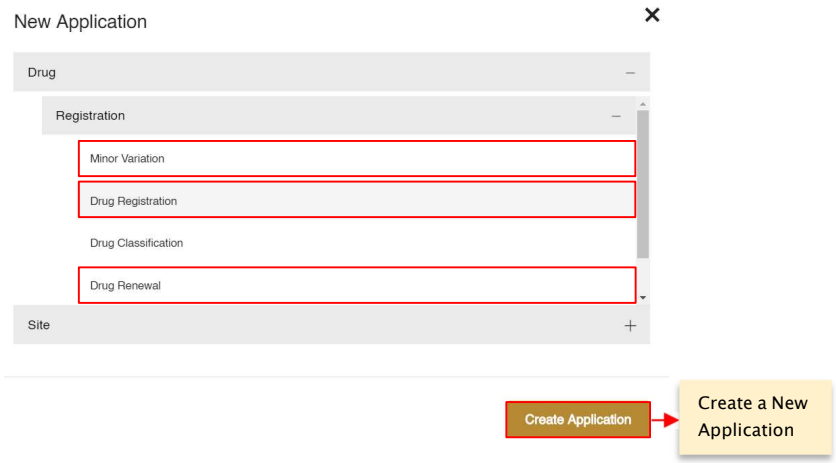


Figure B: New Application Screen

2.2 Complete Application

To complete an application, the applicant must fill the following three sections:

1. Product Details
2. Pack Details
3. Attachments

For an applicant to move from one section to another, they are required to fill the section's mandatory fields and tables.

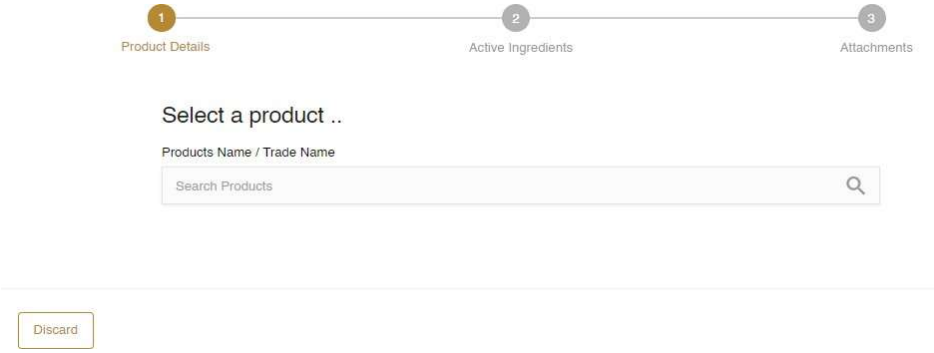


Figure C: Product Details Screen

At any application stage, the applicant can perform the following actions:

- ❖ Save application
- ❖ Discard application
- ❖ Proceed to next section
- ❖ Go back to previous sectionWarnings:
  - In case the applicant did not complete a mandatory filed, a warning message marked in red will be displayed under the field text box highlighting the note: This Field is Required.
  - In case the applicant did not fill a table, a warning message marked in red will be displayed under the table box highlighting the note: Table Cannot be empty.
  - In case the applicant inputs a non-numeric character in a field that only accepts numbers, a warning message marked in red will be displayed under the field text boxhighlighting the note: This field accepts numbers only.

Display icons:

- allows user to Delete table (usually found under Actions)
- allows user to Edit table (usually found under Actions)
- allows user to Add table
- allows the user to save application
- allows user to Insert attachment
- allows user to Insert photo

Tips: Each application section will contain a progress bar that shows the input progress of the application data

2.2.1 Drug Registration

This service allows the applicant to register a new medical product pack.

Once the applicant selects Drug Registration as a service, they will be redirected to Drug Registration – Product Details screen.

2.2.1.1 Product Details

In the Drug Registration – Product Details screen, the applicant must first search the Product Name / Trade Name in the search bar and check if the product was previously registered.

If the searched medical product was not recognized as a registered product, the applicant is asked to perform the following actions:

1. Fill the following information:
    a. Product Name
    b. Product Class
    c. Product Subclass
    d. Product Remark
    e. List of Active Ingredients
        - Active Ingredient Name
        - Description
    f. List of Body Systems
        - Body System
        - Body Subsystem

2. Click New Pack button – which redirects user to Pack Details screen

If the searched medical product was recognized as a registered product, the applicant must click New Pack button to request to add a new pack – which redirects user to Pack Details screen.

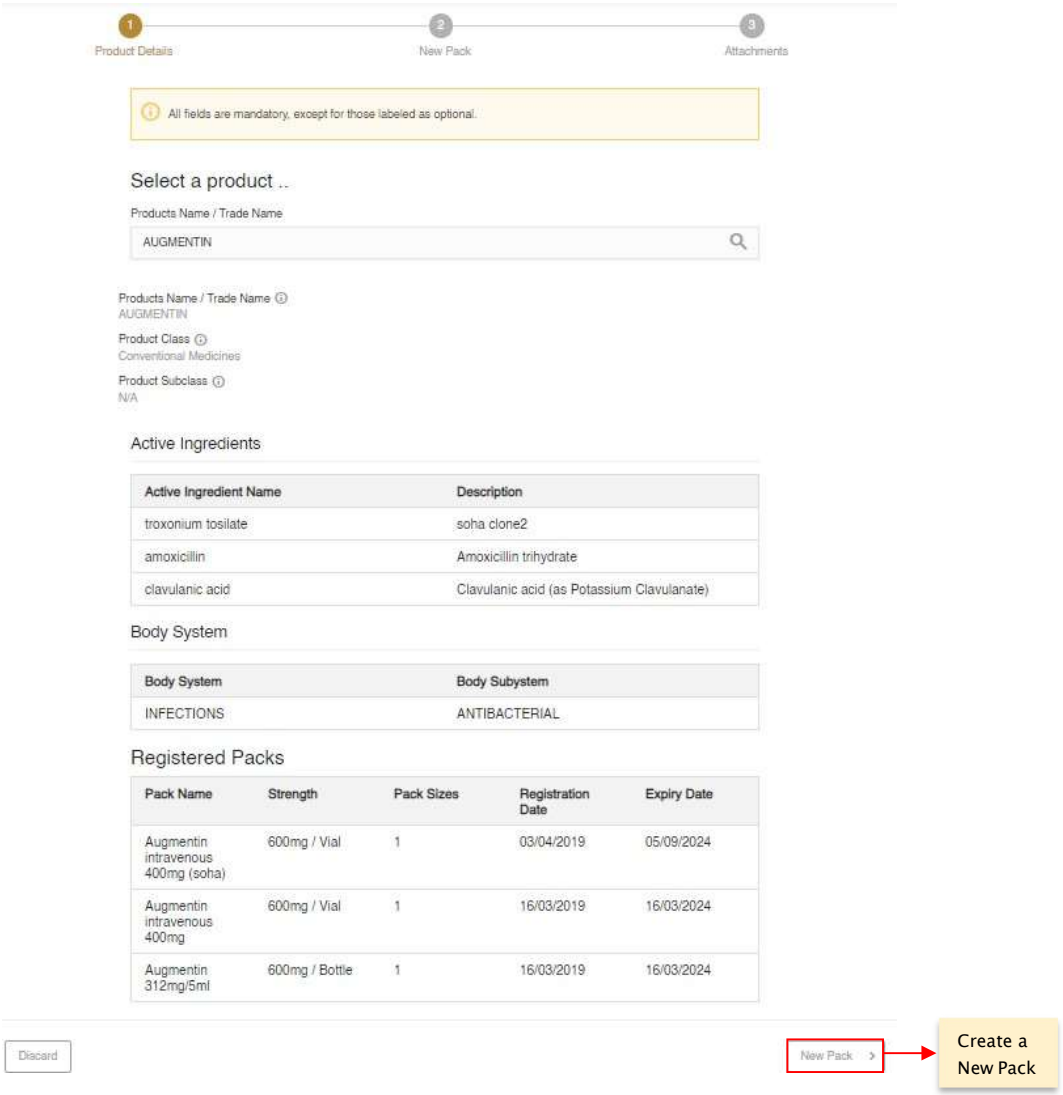


Figure D: Drug Registration – Product Details Screen

2.2.1.2 Pack Details

In Pack Details screen, the applicant is required to fill the following sections:

a. General Information
b. Package Insert Details
c. Product Form
d. Active Ingredients*
e. Inactive Ingredients*
f. Routes List

g. Market Authorization Holder
h. PV Officer*
i. Target Animals**
j. GCC Registration
k. Registration Status Country of Origin
l. Registration Status Other Countries
m. Patent Status
n. Pack Sizes
o. Additional Information (Optional)

Rule ID	Rules
R1	*Mandatory only if the Product Class is either: Conventional, Veterinary Narcotic, or Biological
R2	**Mandatory only if the Product Class is Veterinary Narcotic

Table 2: Pack Details Rules

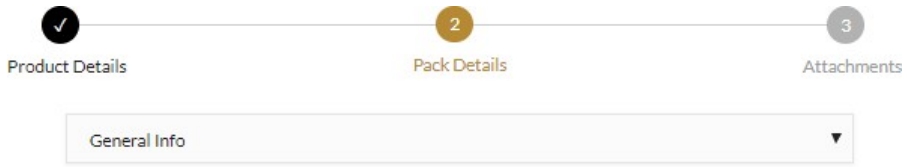


Figure E: Application Progress Bar & Dropdown Section List

Tip: Each section will contain a dropdown list of application section that will help users navigate between different sections

2.2.1.2.1 General Information

In this section, the applicant is required to fill the following information about the product pack:

a. Pack Name
b. Agent*
c. Strength
d. Shelf Life
e. Shelf Life Description
f. Storage Condition
g. Storage Condition Description
h. Manufacturer (Batch Releaser)

i. Indication

Rule: *Read-Only if the Applicant Type is Local Agent/Medical Store

Once the applicant provides the section's required information, they can move to the next section by clicking Next button.

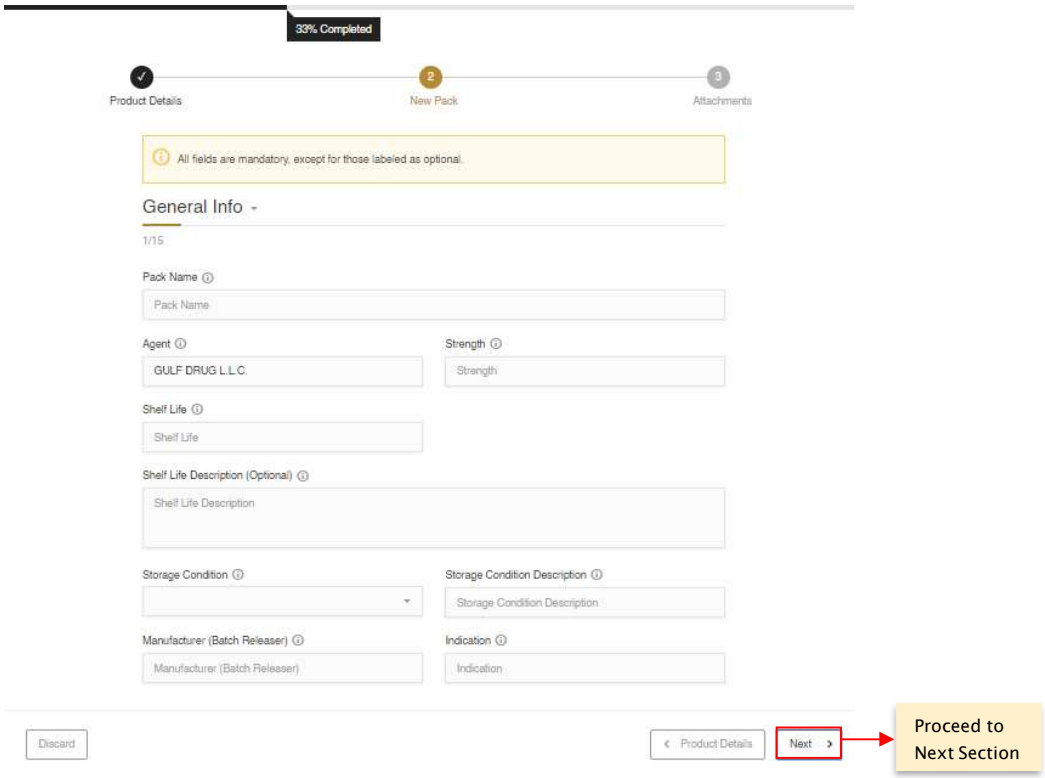


Figure F: General Information Screen

2.2.1.2.2 Package Insert Details

In this section, the applicant is required to fill the Package Insert Description along with a document that contains Product Pack Details Document

Once the applicant provides the section's required information, they can move to the next section by clicking Next button.

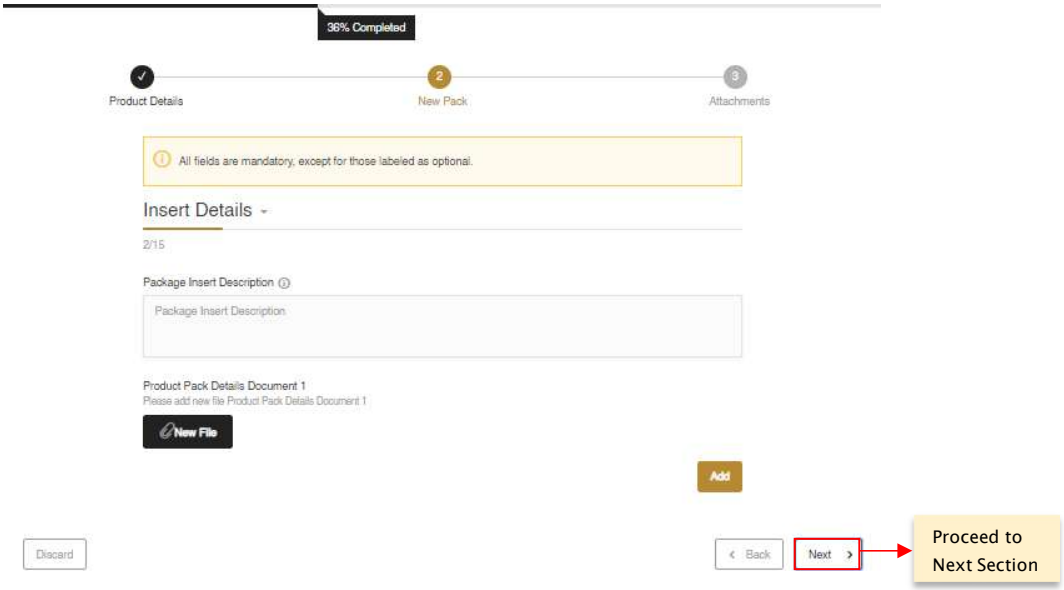


Figure G: Insert Details Screen

2.2.1.2.3 Product Form

In this section, the applicant is required to select the product's:

a. Form
b. Sub-form

Once the applicant provides the section's required information, they can move to the next section by clicking Next button.

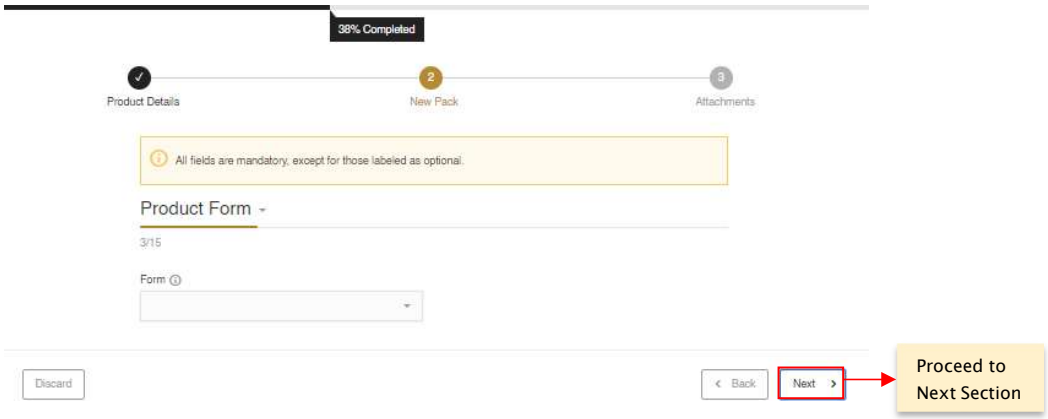


Figure H: Product Form Screen

2.2.1.2.4 Active Ingredients*

In this section, the applicant is required to add the product's list of active ingredients. The user must provide the following information about the product's active ingredients:

a. Active Ingredient Name
b. Quantity
c. Quantity Unit
d. In Quantity / Ref. Quantity
e. In Quantity / Ref. Quantity Unit
f. Description
g. Other Info/Salt
h. Content Factor
i. Attachment – Composition certificate (Optional)
j. List of API Sources
    - Holder City
    - Holder Address
    - Manufacturer Site Name
    - Manufacturer Site Country
    - Manufacturer Site City
    - Manufacturer Site Address
    - GMP Certificate Number
    - GMP Certificate Issuer
    - GMP Date of Issue
    - GMP Expiry Date
    - GMP Certificate

- EDQM certificate of Suitability Number
- EDQM certificate of Suitability Date
- EDQM Certificate
- US FDA DMF Approval Number
- US FDA DMF Approval Date
- US FDA DMF Approval

Rule: * This section is mandatory if the Product Class is either: Conventional, Veterinary Narcotic, or Biological.

Once the applicant provides the section's required information, they can move to the next section by clicking Next button.

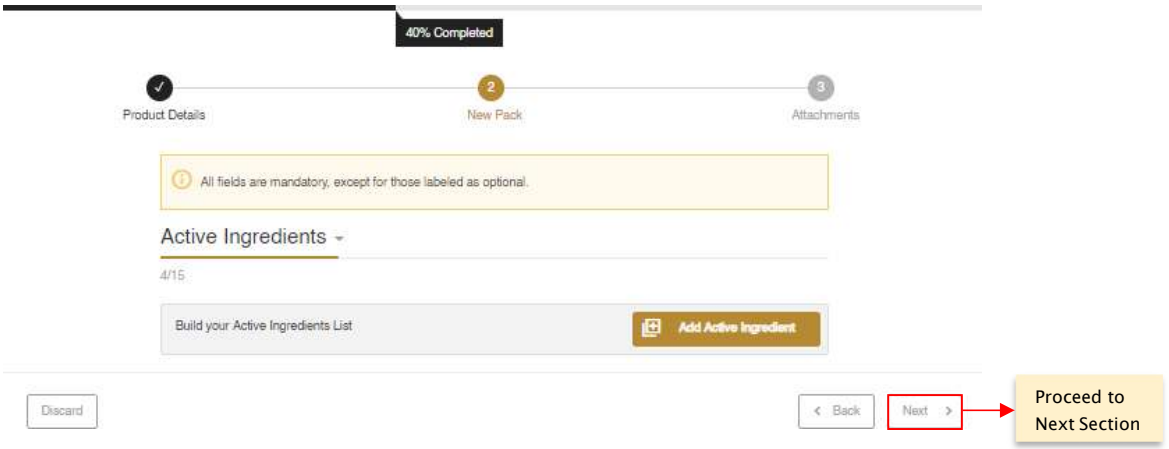


Figure I: Active Ingredients Screen

2.2.1.2.5 Inactive Ingredients*

In this section, the applicant is required to add the product's list of inactive ingredients. The user must provide the following information about the product's inactive ingredients:

a. Inactive Ingredient Name
b. Quantity
c. Quantity unit
d. In Quantity / Ref. Quantity
e. In Quantity / Ref. Quantity Unit
f. Function
g. Description (Optional)

Rule: *This section is mandatory if the Product Class is either: Conventional, Veterinary Narcotic, or Biological

Once the applicant provides the section's required information, they can move to the next section by clicking Next button.

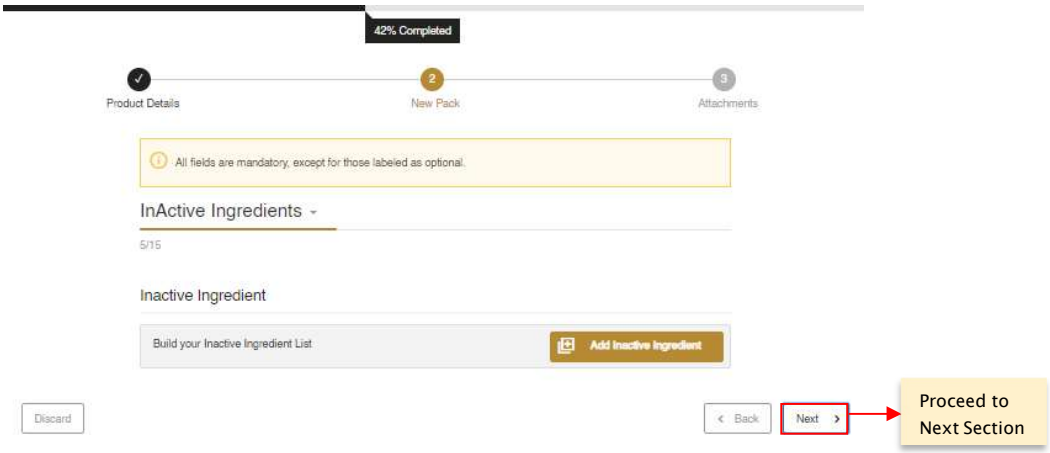


Figure J: Inactive Ingredients Screen

2.2.1.2.6 Route List

In this section, the applicant is required to provide the product's Route Name(s).

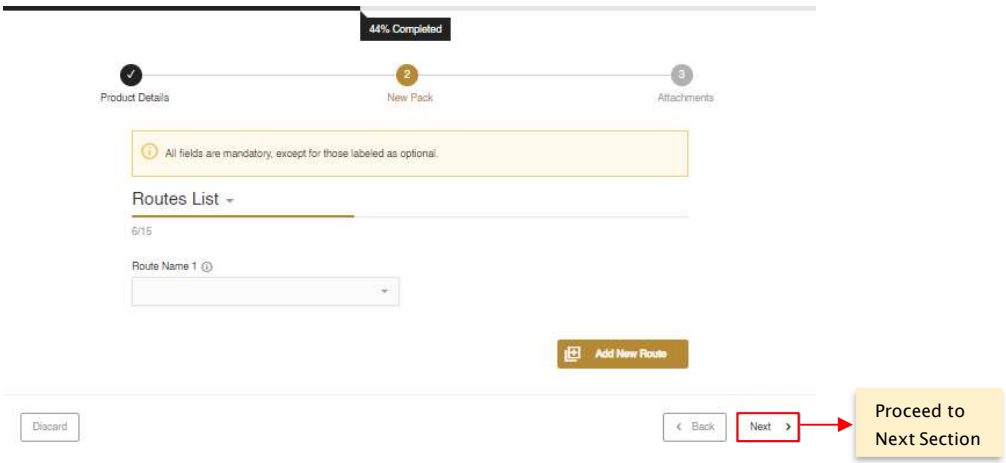


Figure K: Routes List Screen

2.2.1.2.7 Market Authorization Holder

In this section, the applicant is required to select the Market Authorization Holder (MAH).

Once the applicant selects the MAH, the applicant will be able to view the following information about MAH:

a. MAH Details
b. MAH Authorized Contact Name
c. Address
d. City
e. Country
f. Telephone
g. Mobile
h. Fax
i. Email
j. Company Website

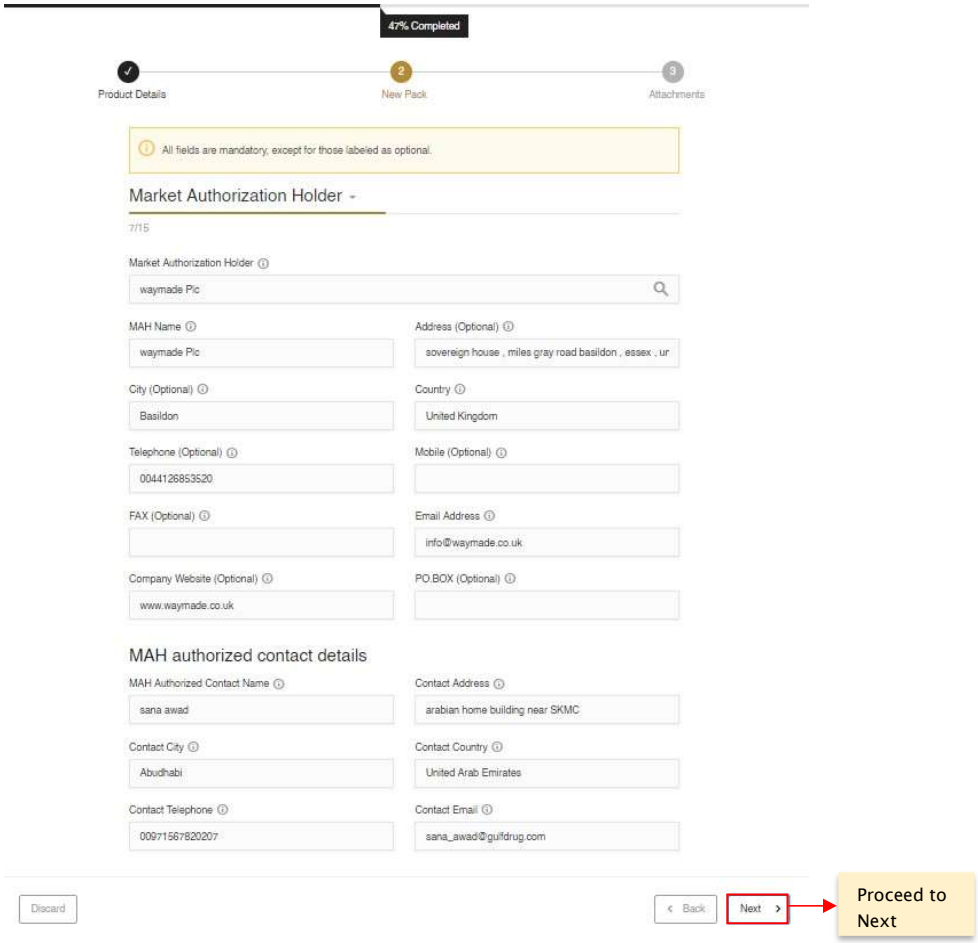


Figure L: MAH Screen

2.2.1.2.8 PV Officer*

In this section, the applicant is required to provide the following information about the PV officer:

a. PV Officer ID
b. Contact Name
c. Address
d. Country
e. City
f. Telephone
g. Mobile
h. Fax
i. Email
j. Website
k. Remarks

Attachment – PV Support Document

Rule ID	Rules
R1	* This section is mandatory if the Product Class is either: Conventional, Veterinary Narcotic, or Biological
R2	If PV Officer ID was found, all the other fields will be read-only

TABLE 3: PV OFFICER RULES

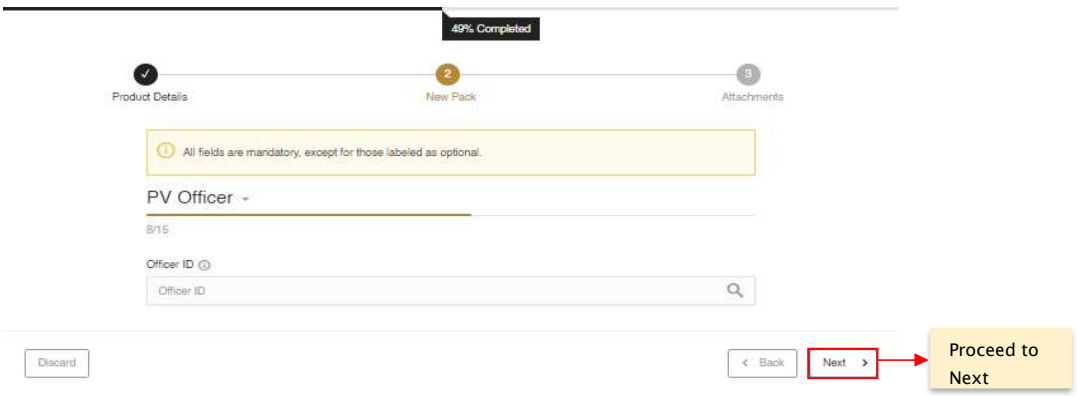


Figure M: PV Officer Screen

Once the applicant provides the section's required information, they can move to the next section by clicking Next button.

2.2.1.2.9 Target Animals**

In this section, the applicant is required to provide the following information about the Listof Target Animals:

a. Target Animals
b. Product Type
c. Withdrawal Period after last treatment
d. Period Unit
e. Remarks

Rule: ** This section is mandatory if the Product Class is Veterinary Narcotic

Once the applicant provides the section's required information, they can move to the next section by clicking Next button.

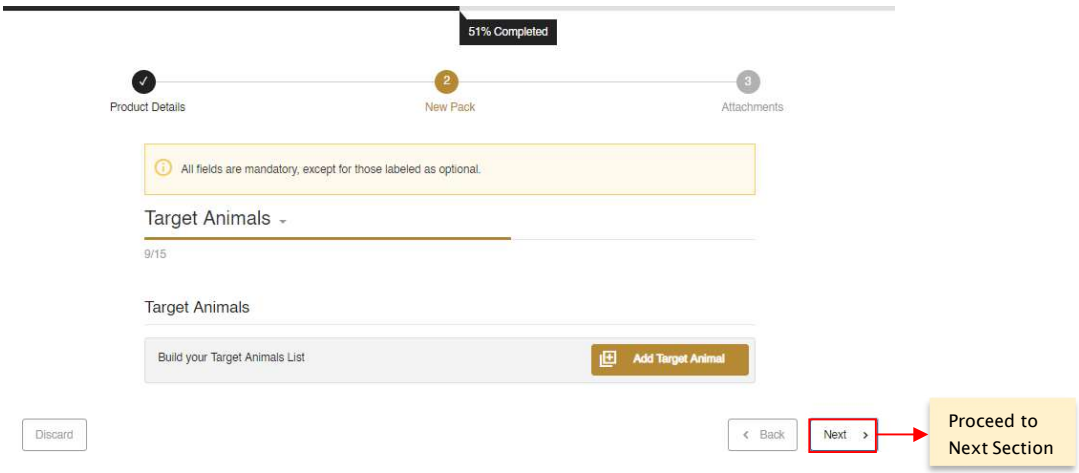


Figure N: Target Animals Screen

2.2.1.2.10 GCC Registration

In this section, the applicant is required to provide the following information about the product's GCC Registration:

a. Product Registered in GCC

b. GCC DR Registration Number
c. GCC DR Committee meeting Date
d. GCC DR First Certificate Issue Date
e. GCC Last Renewal Certificate Issue Date
f. Attachment – GCC Document

Rule: All fields will be optional if the product is not registered in GCC

Once the applicant provides the section's required information, they can move to the next section by clicking Next button.

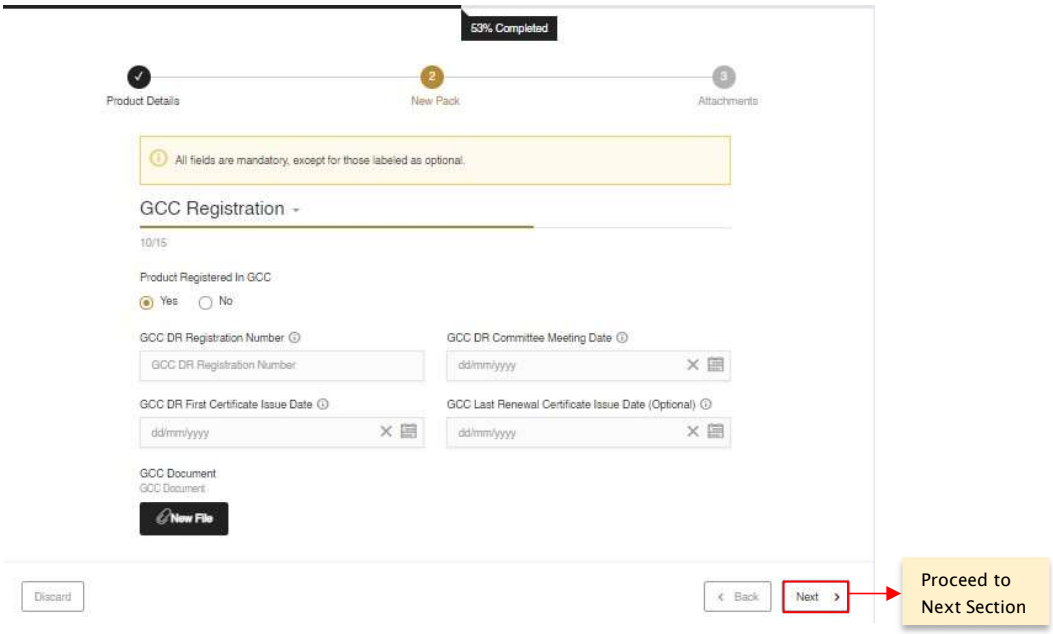


Figure O: GCC Registration Screen

2.2.1.2.11 Registration Status in Country of Origin

In this section, the applicant is required to provide the following information about the product's registration status in country of origin:

a. Country
b. Name of Regulatory Authority
c. MAH Name
d. Date of Approval
e. Date of Marketing
f. Attachment – Country of Origin Certificate

Rule: Mandatory if the product does not belong to MAH in UAE

Once the applicant provides the section's required information, they can move to the next section by clicking Next button.

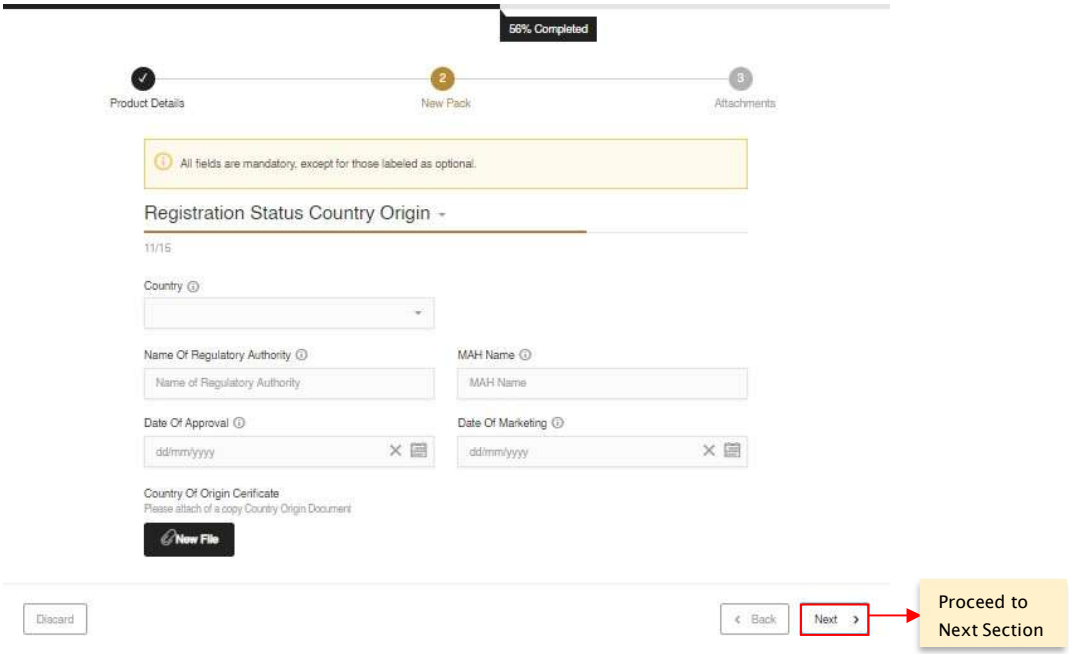


Figure P: Registration Status Country Origin Screen

2.2.1.2.12 Registration Status in Other Countries

In this section, the applicant is required to provide the following information about the product's registration status in other countries:

a. Country
b. Name of Regulatory Authority
c. MAH Name
d. Date of Approval
e. Date of Marketing
f. Attachment

Once the applicant provides the section's required information, they can move to the next section by clicking Next button.

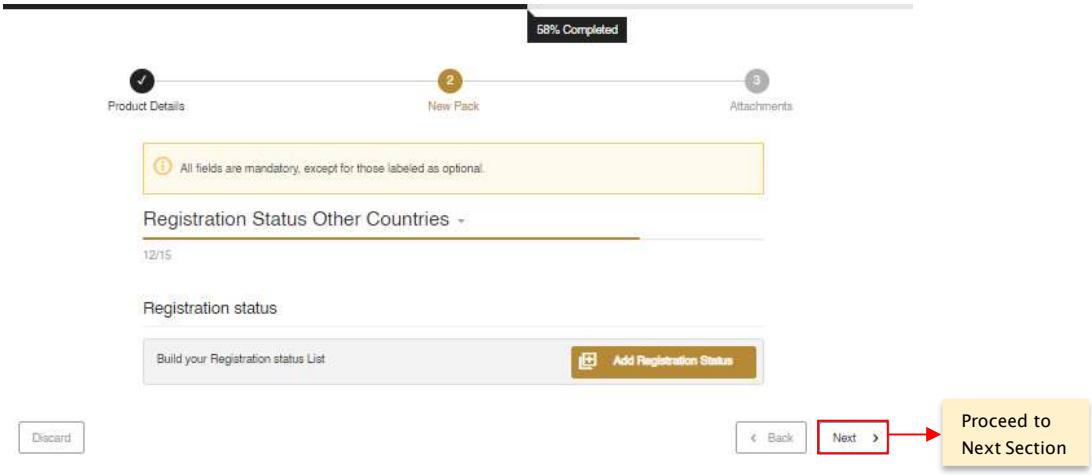


Figure Q: Registration Status Other Countries Screen

2.2.1.2.13 Patent Status

In this section, the applicant is required to provide the following information about the product's patent status:

a. Brief description of patent
b. Patent number
c. Expiry Date
d. Patent Holder Name
e. Country
f. City
g. Address
h. Patent Authority Name
i. Country
j. City
k. Address
l. Attachment – Patent Document
m. Status Remarks

Once the applicant provides the section's required information, they can move to the next section by clicking Next button.

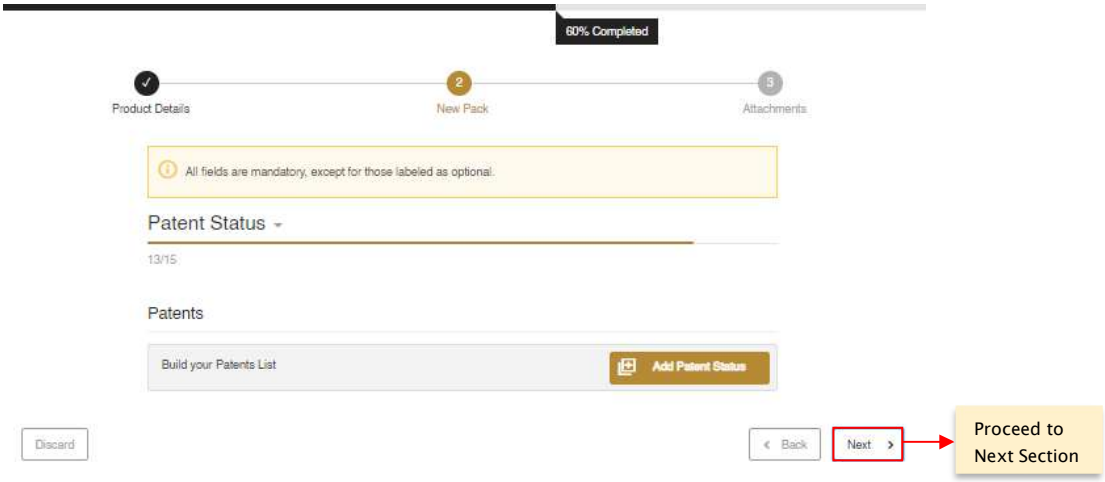


Figure R: Patent Status Screen

2.2.1.2.14 Pack Sizes

In this section, the applicant is required to provide the following information about the product's pack size:

a. Pack Size (Numbers)
b. Pack Size Unit
c. Pricing Pack Size (Numbers) – (Optional)
d. Pricing Pack Size Unit – (Optional)
e. Pack Size Description
f. GTIN (Global Trade Item Number) – (Optional)
g. Dispensing Mode
h. Dispensing Mode in Country of Origin – (Optional)
i. Container Type (Presentation Type)
j. Container Details (Primary Packaging Details)
k. Label Details (Secondary Packaging Details – Outer label details) – (Optional)
l. Label Details (Secondary Packaging Details – Inner label details) – (Optional)
m. Other label details (Solvent or Pouch or any other inner package details) – (Optional)
n. List of Manufacturing Stages
    - Manufacturing Site
    - Manufacturing Stage
o. Attachments – Photos
    - Outer carton artwork
    - Inner label artwork
p. Proposed Pack Size Price – (Optional)
    - CIF
    - Currency
q. List of Reference Prices for Each Pack Size
    - Price Type
    - Country
    - Ex-factory Price
    - Currency
    - Wholesale price
    - Currency
    - Public price

- Currency
- Reference Book
- Support Document

Once the applicant provides the section's required information, they can move to the next section by clicking Next button.

2.2.1.2.15 Additional Information (Optional)

This section is where an applicant can add notes on product regarding the following:

a. Physical Capsule Shell Detail
b. Physical Coating Detail
c. Finished Product Details
d. Finished Product Specification/Test/Method
e. Manufacturing Process Details
f. Change of Batch Size
g. Animal Forms

Rule: This section is optional

Once the applicant provides the section's required information, they can move to the next section by clicking Attachment button.

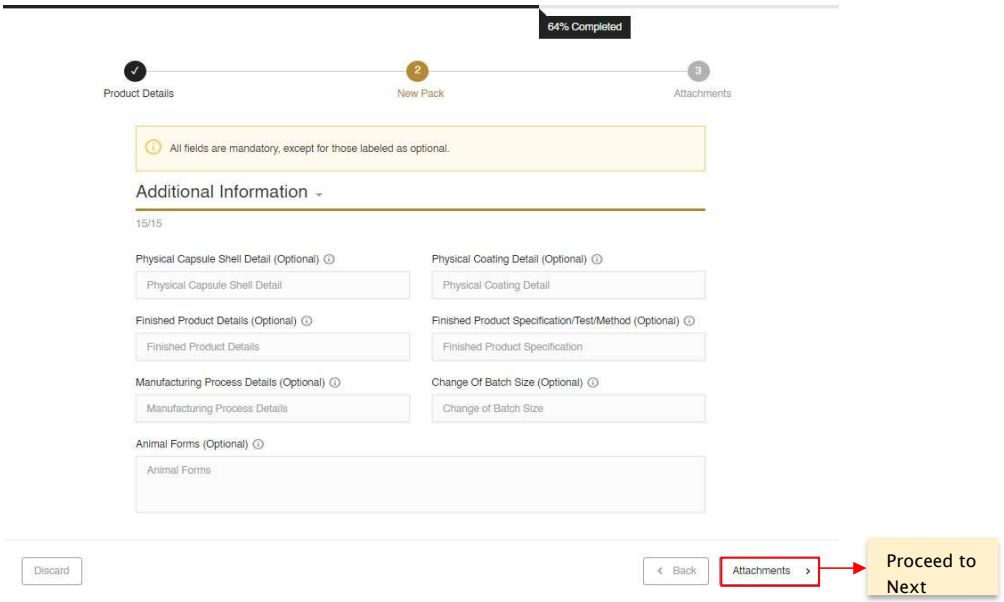


Figure S: Additional Information Screen

2.2.1.3 Attachments

This section is where an applicant can upload General Attachments before proceeding to submit the application. Once the applicant is done with this section, they can move to the Review section by clicking Review button.

The user can add more attachments to their Drug Registration application by performing the following:

1. Enter the Document Name
2. Click the Add Attachment icon
3. Upload Attachment

Tip: To view the list of attachments, please refer to Appendix I

2.2.2 Drug Renewal

This service allows the user to renew an expired or soon to be expired medical product.

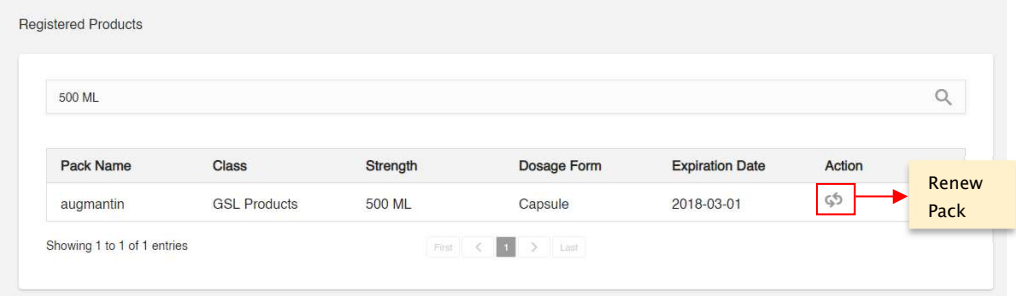


Figure T: Registered Products – Renewal Screen

Once the applicant selects Drug Renewal as a service, they will be redirected to Drug Renewal – Product Details screen where they are required to complete a renewal application.In the Drug Renewal – Product Details screen, the applicant is required to:

a. Search the Product Name in the search bar
b. Click on icon in Registered Packs table under the Actions column
c. Proceed to renew product
d. Review application
e. Proceed to checkout

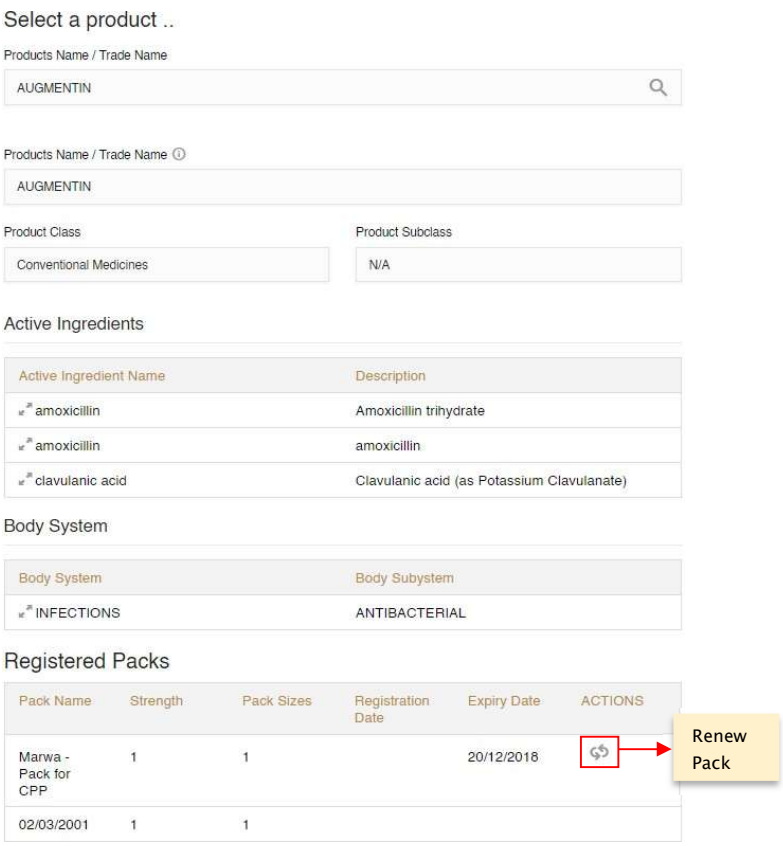


Figure U: Drug Renewal – Product Details screen

Rule: For a medical product pack to be renewed, the pack should be expired or will be expiredin the following 3 months.

2.2.3 Minor Variation

This service allows the user to modify/update the allowed the product and pack details allowed by the user to modify.

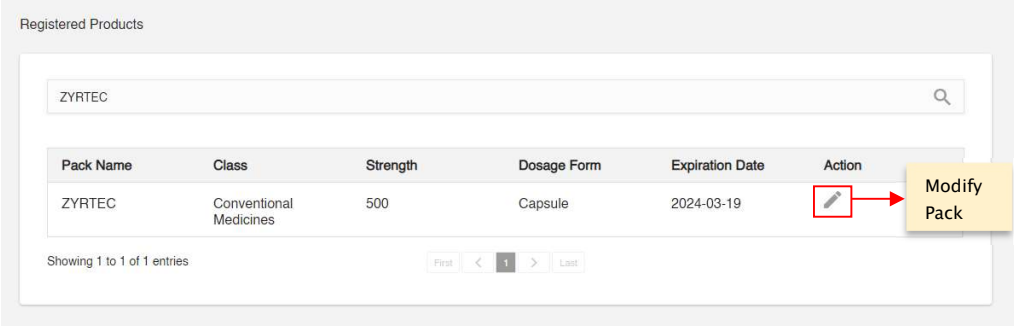


Figure V: Registered Products – MV Screen

Once the applicant selects Minor Variation as a service, they will be redirected to Minor Variation – Product Details screen where they can modify product and pack fields open for modification. Each of these product and pack fields will correspond to a type of modification.

The modification types and their corresponding fees are shown in the following figure:



Figure W: Modification Type Fees

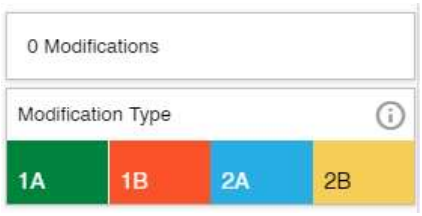


Figure X: Modification Legend

Rule ID	Rules
R1	For a medical product's details to be modified, the product must not be expired.
R2	Users will be allowed to modify only certain open fields – not all fields are necessarily open for modification

Table 4: Modification Rules

Tips:

- A legend that explains the color for each minor modification will be displayed on the screens
- List of fields that might be open for minor variation are shown in the Appendix II

2.2.3.1 Product Details

In the Minor Variation – Product Details screen, the applicant must first search for the Product Name / Trade Name of the product that requires modification.

To modify the product details, the applicant must:

a. Click on icon found next to field
b. Modify field(s)
c. Proceed to Pack Details screen

Tip: List of product details that are open for minor variation are shown in the Appendix II

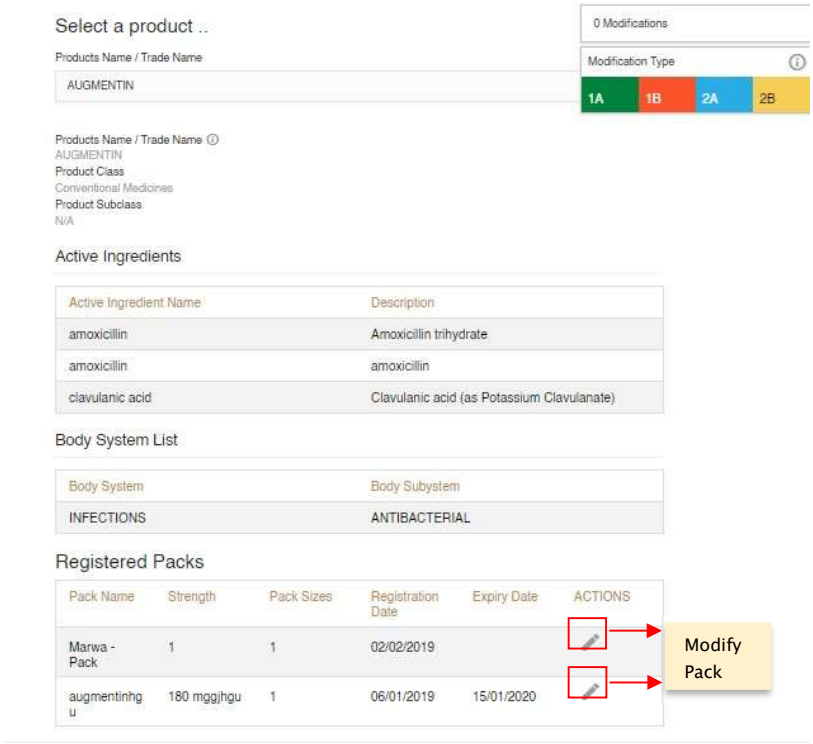


Figure Y: Minor Modification – Product Details Screen

2.2.3.2 Pack Details

To modify the pack details, the applicant must:

a. Click on icon under Registered Packs in Product Details screen – which redirects user to Pack Details screen
b. Modify field(s)
c. Proceed to Attachments screen

Tip: List of pack details that are open for minor variation are shown in the Appendix IIDisplay icon: allows the user to undo change

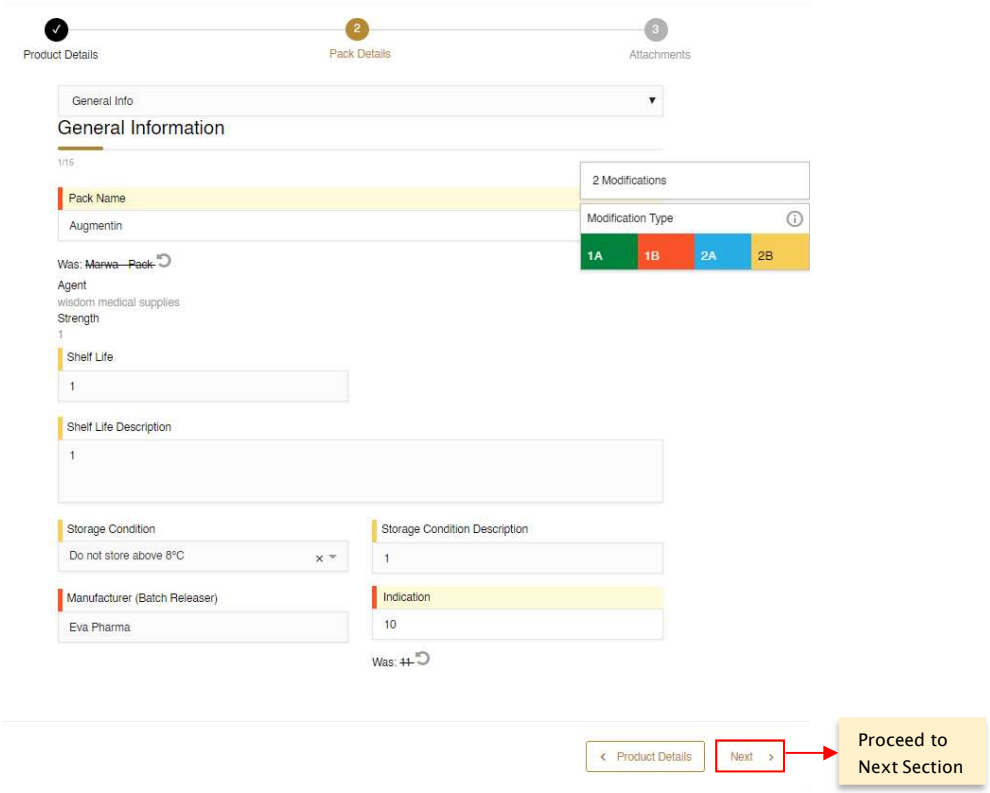


Figure Z: Minor Modification – Pack Details Screen

2.2.3.3 Attachments

The applicant will only be able to add 2 additional attachments to the Attachments section.

The user can add attachments to their Minor Variation application by performing the following:

a. Enter the Document Name
b. Click the Add Attachment icon
c. Upload Attachment
d. Proceed to Review screen

2.3 Review Application

After the applicant completes filling all application details, they must click on the Review button to proceed with application submission. Once the applicant clicks the Review button, they will be redirected to Review screen where they are able to perform the following actions:

- Edit Application
- Save Application
- Discard Application
- Go Back to Previous Section
- Read & Accept General Terms & Conditions
- Submit Application

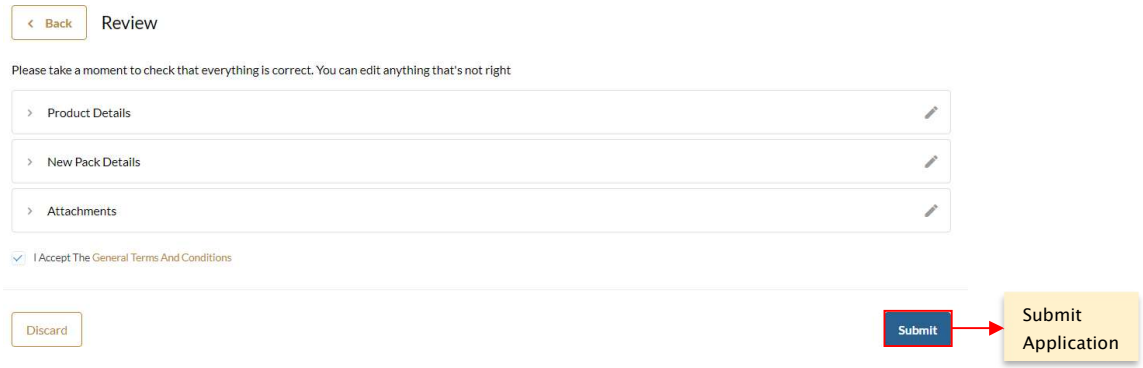


Figure AA: Review Screen

Once the applicant reviews application and accepts the General Terms and Conditions, they must click the Submit button to proceed to checkout.

Please note: to proceed with application submission, the applicant must read & accept the General Terms and Conditions.

Warning: In case the user did not fill all mandatory fields, a warning message will be displayed noting that applicant must fill all required fields before submitting the application.

Display icon:

- allows user to Edit application details
- allows user to view table

2.4 Checkout

After an application has been submitted, the applicant will be redirected to Checkout screen where they will be asked to pay the following:

- Application Fees: AED 100 per Application
- Processing Fee*

To proceed with payment, the applicant must click on the Checkout button shown at the bottom-right corner of the Checkout screen which will redirect the applicant to EDE's Payment Gateway (e-dirham).

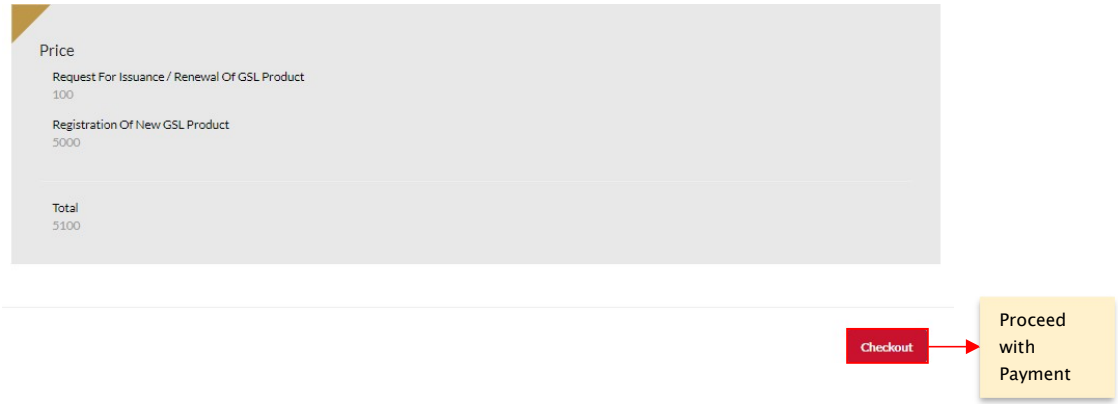


Figure BB: Checkout Screen

Rule: *The processing fee is based on the service the applicant applied for – which will be discussed in detail in the following sections.

Tip: Overrun Pop-up Blocker to open EDE's Payment Gaterway (e-dirham)

2.4.1 Drug Registration

The drug registration processing fee is based on the Product Class:

Product Class	Fees
Conventional Product	
Conventional	7000 AED
Conventional Veterinary	5000 AED
Biological	7000 AED
GSL Product	
Natural Source Medicines	5000 AED
GSL Product	5000 AED
Medical Device	5000 AED

Table 5: Drug Registration – Product Class Fees

Once the payment was done successfully, the application will be sent to a EDE officer for review where they could perform the following:

- ❖ Issue Certificate
- ❖ Reject Application
- ❖ Require Action from ApplicantTips:

- Actions required by applicant is discussed in further detail in Section 3
- To learn about the Drug Registration Certificate, please refer to Section 5.1

2.4.2 Drug Renewal

The drug renewal processing fee is based on the following:

1. Product Class:

Product Class	Fees
Conventional Product	
Conventional	3500 AED
Conventional Veterinary	3500 AED
Biological	3500 AED
GSL Product	
Natural Source Medicines	2500 AED
GSL Product	2500 AED
Medical Device	2500 AED

Table 6: Drug Renewal – Product Class Fees

2. Last Renewal Date:

The application fees will be multiplied by the cycles (of 5 years) from the last time the product has been renewed.

Once the payment was done successfully, the application will be sent to a EDE officer for review where they could perform the following:

- ❖ Issue Certificate
- ❖ Reject Application
- ❖ Require Action from ApplicantTips:

- Actions required by applicant is discussed in further detail in Section 3
- To learn about the Drug Renewal Certificate, please refer to Section 5.1

2.4.3 Minor Variation

The drug modification processing fee is the summation of all the Minor Variations fees in an application.

Minor Variation Type	Fees
Type1A	1000 AED
Type1B	1000 AED
Type 2A (Variation Fees)	1000 AED
Type 2A (Analysis Fees)	3000 AED
Type 2A Analysis certificate fees	500 AED
Type 2B	1000 AED

Table 7: Minor Variation Fees

Once the payment was done successfully, the application will be sent to a EDE officer for review where they could perform the following:

- ❖ Accept Variation
- ❖ Reject Application
- ❖ Require Action from ApplicantTips:

- Actions required by applicant is discussed in further detail in Section 3
- To learn about the Minor Variation Certificate, please refer to Section 5.2

3. Take Required Actions

Once an application has been reviewed by a EDE officer, the officer might request the applicant to take actions before proceeding with application. The applicant will get notified via SMS or email once the officer requires an action.

For a user to view and take these actions, they must:

a. Click on the Application Number in All Applications screen – which redirects user to Submitted Application screen
b. Click on Required Actions tab
c. Click on the Action – which opens an Action window



Figure CC: Submitted Application Screen

The requests the officer can ask an applicant are the following:

1. Application Correction
2. Sample Request
3. Appointment Request
4. Analysis Request
5. Pharmacovigilance (PV) Request
6. Pricing Request
7. Release to Market Request
8. Stability Request
9. Bio Equivalence (BE) Request

These actions will be explained in detail in the following sections.

3.1 Application Correction

In case a EDE officer identifies fields/attachments in application that require modification,the officer will send back the application to applicant for correction as part of the New Drug Registration, Drug Renewal or Minor Variation reviewing process.

For the applicant to view and change the fields/attachments that require correction, the applicant must:

a. Click on Correction button found in Required Actions tab – which redirects applicantto Correction screen
b. Make changes to fields/attachments*
c. Add comment in Comment box
d. Click on Submit Correction button
e. Confirm correction

Once the applicant confirms correction, the application will be sent back to officer for further review.

Rule ID	Rules
*R1	*Only fields/attachments needed for correction are displayed for change
R2	The application will be considered as rejected if the applicant did not send back corrected application within 60 days

Table 8: Correction Rules

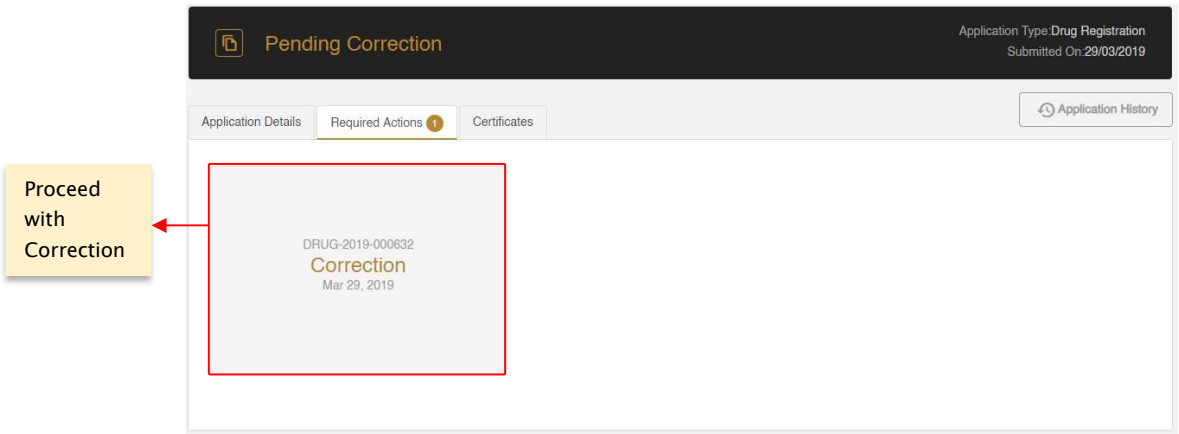


Figure DD: Submitted Application – Correction



Figure EE: Field Correction Tool



Figure FF: Modified Field Figure GG: Unmodified Field

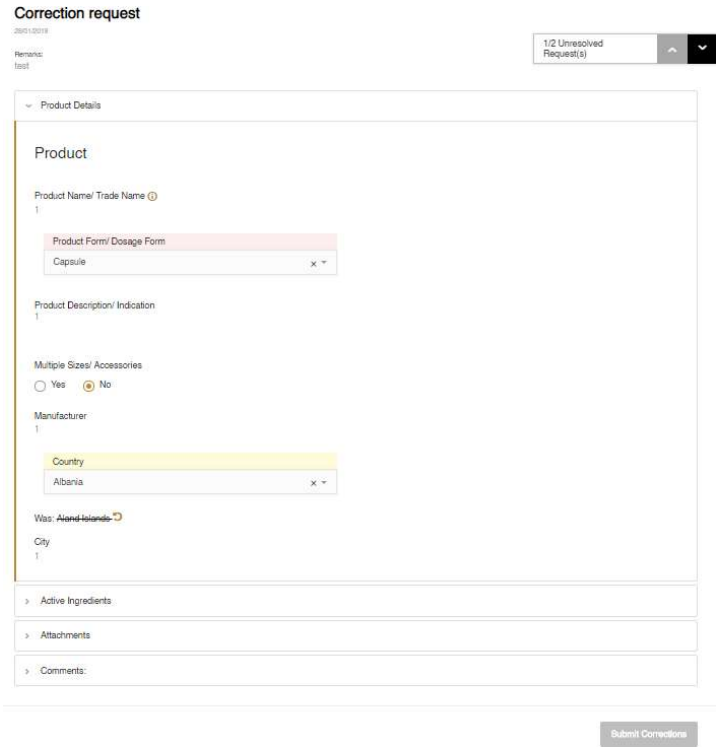


Figure HH: Correction Screen

Display icons: ↺ allows the user to undo changeTips:

i. Field Correction Tool helps user navigate from one unsolved request to another
ii. Fields required for change are highlighted in Red
iii. Modified fields are highlighted in Yellow.

3.2 Sample Request

In case a EDE officer requires an applicant to submit a sample to EDE as part of the New Drug Registration, Drug Renewal or Minor Variation reviewing process, the officer will send the applicant a sample request.

This sample request will have a Sample Specification section which explains what the officer requires a sample for.

The applicant is then given the option to either:

A. Ask for more clarification
B. Fill & submit sample details

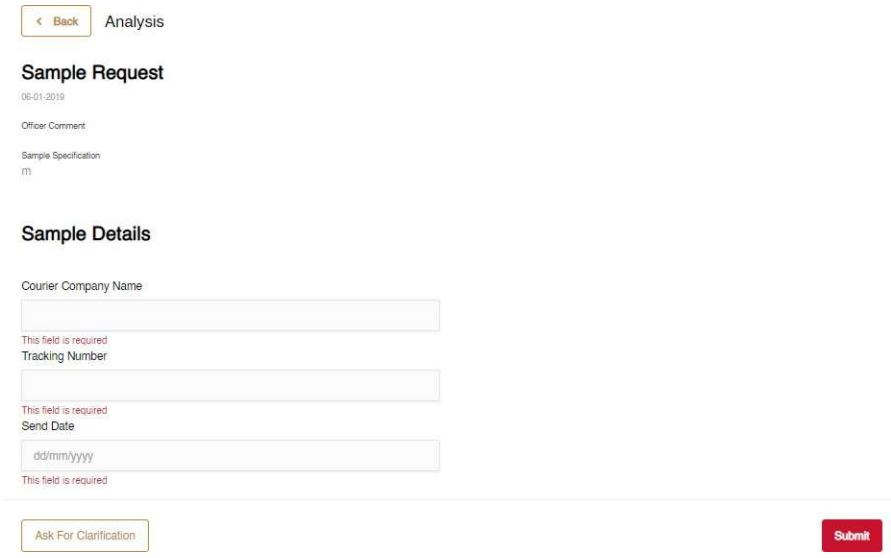


Figure II: Sample Request Screen

Case A

In case the applicant requires more clarification before proceeding to fulfill sample request, the user must do the following:

a. Click on Request Sample button found in Required Actions tab – which redirects applicant to Request Sample screen
b. Click Ask For Clarification button – open a Clarification window
c. Fill Clarification box
d. Click Ask For Clarification button

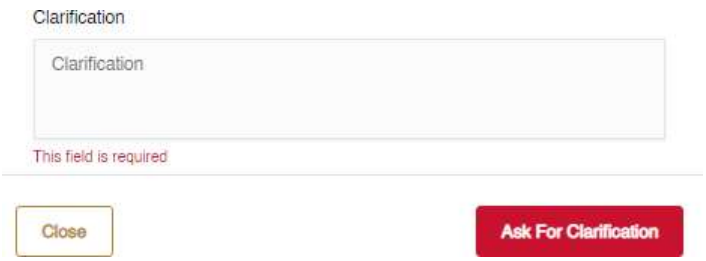


Figure JJ: Clarification Window

Case B

For the applicant to provide sample details to EDE, they must:

a. Click on Request Sample button found in Required Actions tab – which redirects applicant to Request Sample screen
b. Fill the following information in Sample Details section:
   - Courier Company Name
   - Tracking Number
   - Send Date
c. Click Submit button
d. Confirm Sample Receipt

Once the applicant confirms, the sample details will be sent back to officer for further review.

3.3 Appointment Request

In case a EDE officer requires to have an appointment with applicant as part of the New Drug Registration, Drug Renewal or Minor Variation reviewing process, the officer will send the applicant an appointment request.

This appointment request includes the following:

- Appointment Date
- Appointment Time
- Appointment Location

The applicant is given the option to either

A. Accept this appointment
B. Suggest a New Appointment.

Case A

For the applicant to accept an appointment, they must:

a. Click on Request Appointment button found in Required Actions tab – which redirects applicant to Appointment screen
b. Review appointment details
c. Click on Accept button
d. Confirm appointment

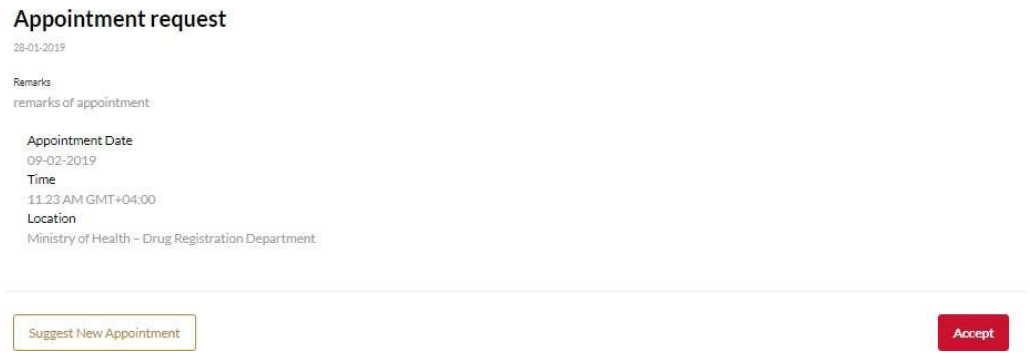


Figure KK: Appointment Screen

Case B

If an applicant wishes to suggest an appointment, they must:

a. Click on Request Appointment button found in Required Actions tab – which redirects applicant to Appointment screen
b. Click on Suggest New Appointment button – which opens New Appointment window
c. Fill the following in New Appointment window:
    - Appointment Date
    - Time (Optional)
    - Leave a Comment (Optional)
d. Click Submit button

Once the applicant submits suggested new appointment, the new appointment form will be sent back to officer for further review.

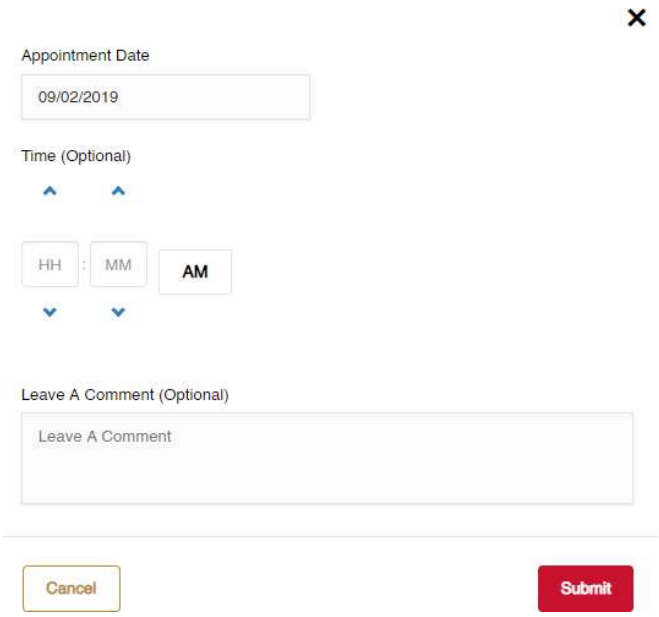


Figure LL: New Appointment Window

3.4 Analysis Request

As part of the New Drug Registration, Drug Renewal or Minor Variation* reviewing process, a EDE officer might request for an Analysis on a medical product.

For this request to be initiated, the applicant must first pay the following fees:

- Analysis fees: AED 3000
- Certificate fees: AED 500

During the Analysis evaluation, the Analysis officer can request the applicant the following:

1. Application Correction – Section 3.1
2. Sample – Section 3.2
3. Appointment – Section 3.3

Tip: To learn how to fulfill the requests above, please refer to there respective sections

After the Analysis evaluation has been completed, the applicant will be provided with the officer's analysis results. If the Analysis certificate was approved and generated by Analysis officer, the applicant will be asked to choose one of two of the following options:

A. Accept Analysis
B. Request Re-Analysis

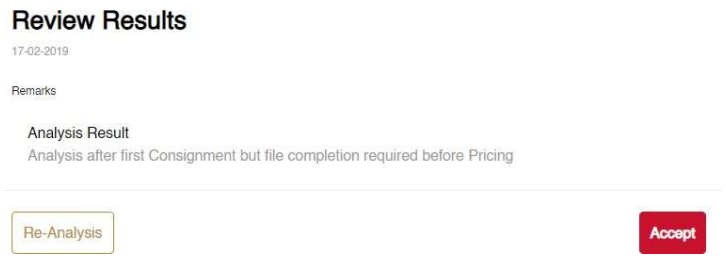


Figure MM: Analysis Screen

Case A

In case the applicant wishes to Accept Analysis, they must perform the following:

a. Click on Analysis Request button found in Required Actions tab – which redirects applicant to Analysis screen
b. Select Accept
c. Confirm Acceptance

If the applicant chooses to accept Analysis, then they will be able to print the certificate from the Certificate tab. To learn about the Analysis certificate, please refer to section 5.3.

Case B

In case the applicant wishes to Request a Re-Analysis, they must perform the following:

a. Click on Analysis Request button found in Required Actions tab – which redirects applicant to Analysis screen
b. Select Request for Re-Analysis
c. Add remarks in Comment box
d. Click on Submit button

If the applicant chooses to request for Re-Analysis, they must first repay the Analysis fees before the application is sent back to Analysis officer for re-analysis.

Rule ID	Rules
R1	*Only Minor Variation type 2A is qualified for Analysis
R2	If the applicant did not provide an action for 60 working days, the analysiswill be accepted automatically

Table 9: Analysis Rules

3.5 Pharmacovigilance (PV) Request

As part of the New Drug Registration or Drug Renewal reviewing process, a EDE officermight request an applicant to submit a Pharmacovigilance (PV) plan. This PV plan requiresan applicant to upload additional attachments in the Attachment section.

For the applicant to upload PV plan attachments*, the applicant must:

a. Click on PV Request button found in Required Actions tab – which redirects applicantto PV screen
b. Attach PV plan
c. Click on Submit button
d. Confirm submission



Figure NN: PV Request Screen

Once the applicant attaches the required attachments for the PV plan and submits it, they must proceed to pay the following fees:

- Application Fees: AED 1000

Once the applicant pays the application fees, the PV plan will be sent to PV officer for review.

After reviewing the PV plan, the PV officer could either:

1. Send back applicant for correction
2. Accept PV plan and issue certificate
3. Reject PV plan

The PV Evaluation letter will be generated when the officer approves or rejects the PV plan.The applicant will be able to print the certificate from the Certificate tab.

Tips:

- *PV attachments are presented in the Appendix III.
- Please refer to Section 5.4.1 to learn about the PV Approval Letter.
- Please refer to Section 5.4.2 to learn about the PV Rejection Letter.

3.6 Pricing Request

As part of the New Drug Registration, Drug Renewal or Minor Variation* reviewing process, a EDE officer might request to set a price for a medical product.

Rule: *Any Minor Variation could lead to product a pricing request

3.6.1 Correction

The EDE Pricing officer might send back the application to applicant for correction after identifying attachments in application that require modification. For this case, the applicant is required to modify/correct Drug details according to the Pricing officer's needs and remarks.

For the applicant to view and change the attachments that require correction, the applicant must:

a. Click on Pricing button found in Required Actions tab – which redirects applicant to Correction screen
b. Make changes to attachments
c. Add comment in Comment box
d. Click on Submit Correction button
e. Confirm correction

Once the applicant modifies the application and Submits correction, the application will be sent back to officer for review.

3.6.2 Rejection

The EDE Pricing officer might reject the pricing of the medical product suggested by the applicant and propose a new CIF price for the product. This leaves the applicant with one of two options:

A. Request for Appeal
B. Accept New CIF PriceCase A

In case the applicant requests for appeal, the applicant must perform the following:

a. Click on Pricing Request button found in Required Actions tab – which redirects applicant to Pricing screen
b. Click Appeal button
c. Add remarks in Comment box
d. Click Submit button

If the applicant chooses to request for appeal, the applicant will first be asked to pay the following fees:

- Pricing Fees: AED 1000Case B

In case the applicant Accepts New CIF Price, the applicant must perform the following:

a. Click on Pricing Request button found in Required Actions tab – which redirects applicant to Pricing screen
b. Click Accept button
c. Confirm Acceptance

If the applicant chooses to accept new CIF price, the applicant will first be asked to pay the following fees before printing the Pricing Certificate:

- Pricing Certificate fees: AED 500

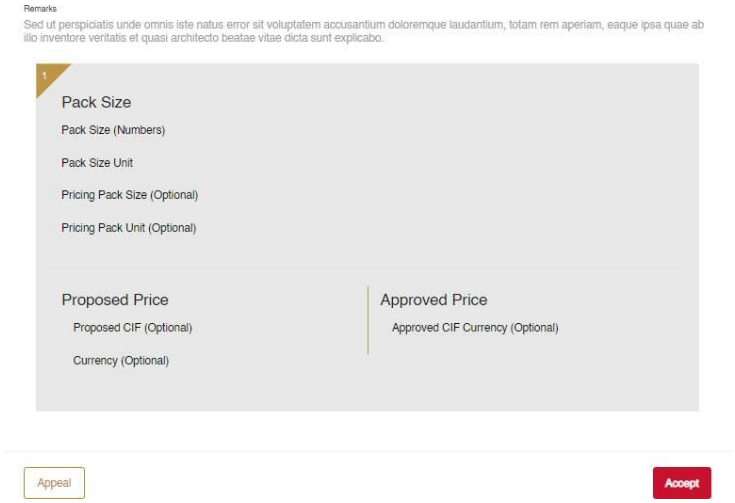


Figure OO: Repricing Screen

Once the applicant accepts new CIF Price and proceeds with the Certificate payment, the applicant will be able to print the certificate from the Certificate tab.

Please note: If applicant does not Accept or Appeal repricing in 60 days, the application willbe automatically rejected.

Tip: To learn more about the Pricing certificate, please refer to Section 5.6

3.7 Release to Market Request

As part of the New Drug Registration or Drug Renewal process, a EDE officer might requestan applicant to resubmit an application to get approval for a product's Release to Market Certificate.

In case the drug application needs correction, the EDE Pricing officer will send it to applicant after identifying fields/attachments in application that require modification. For thiscase, the applicant is required to modify/correct Drug details according to the Pricing officer'sneeds and remarks.

For the applicant to view and change the attachments that require correction, the applicant must:

a. Click on Release to Market button found in Required Actions tab – which redirects applicant to Correction screen
b. Make changes to attachments
c. Add comment in Comment box

d. Click on Submit Correction button
e. Confirm correction

Once the Release to Market certificate has been approved*, the applicant will be able to print the certificate from the Certificate tab.

Tip: To learn about the Release to Market certificate, please refer to Section 5.5

Rule ID	Rules
R1	*The product's price must be approved prior to approval of Release to Market certificate
R2	There is no release to market for GSL products

Table 10: Release to Market Rules

3.8 Stability Request

As part of the New Drug Registration or Drug Renewal reviewing process, a EDE officer might request for a Stability Study to be conducted before proceeding with application.

3.8.1 Correction

The EDE Stability officer might send back the application to applicant for correction after identifying attachments in application that require modification. For this case, the applicant is required to modify/correct Drug details according to the stability officer's needs and remarks.

For the applicant to view and change the attachments that require correction, the applicant must:

d. Click on Stability button found in Required Actions tab – which redirects applicant to Correction screen
e. Make changes to attachmentsP
f. Add comment in Comment box
g. Click on Submit Correction button
h. Confirm correction

Once the applicant modifies the application and Submits correction, the application will be sent back to officer for review.

3.8.2 Rejection

The EDE Stability officer might reject an application after reviewing and conducting a Stability Study on drug application. For this case, the applicant will have one of two options:

A. Accept Rejection
B. Request for Re-EvaluationCase A

In case the applicant accepts rejection, the applicant must:

a. Click on Stability Request button found in Required Actions tab – which redirects applicant to Stability screen
b. Select Accept
c. Confirm AcceptanceCase B

In case the applicant requests for re-evaluation, the applicant must:

a. Click on Stability Request button found in Required Actions tab – which redirects applicant to Stability screen
b. Select Request for Re-Evaluation
c. Add remarks in Comment box
d. Click on Submit button

If the applicant chooses to request a re-evaluation, the application will be sent back to Stability officer for re-evaluation.

Please note: Accepting rejection will lead to the rejection of drug application as whole.

3.9 Bio Equivalence (BE) Request

As part of the New Drug Registration or Drug Renewal reviewing process, a EDE officer might request for a Bio Equivalence (BE) Study to be conducted before proceeding with application. To an applicant, these BE Requests can come in one of two forms:

3.9.1 Correction

In this case, the EDE BE officer sends back the application to applicant for correction after identifying attachments in application that require modification. For this case, the applicant is required to modify/correct Drug details according to the BE officer's needs and remarks.

For the applicant to view and change the attachments that require correction, the applicant must:

a. Click on BE Request button found in Required Actions tab – which redirects applicantto Correction screen
b. Make changes to attachments
c. Add comment in Comment box
d. Click on Submit Correction button
e. Confirm correction

Once the applicant modifies the application and Submits correction, the application will be sent back to officer for review.

3.9.2 Rejection

In this case, the EDE BE officer rejects an application after reviewing and conducting a BEStudy on drug application. For this case, the applicant will have one of two options:

A. Accept Rejection
B. Request for Re-Evaluation



Figure PP: BE Screen

Case A

For the applicant to accept rejection, the applicant must:

a. Click on BE Request button found in Required Actions tab – which redirects applicantto BE screen
b. Select Accept Rejection
c. Confirm AcceptanceCase B

In case the applicant requests for re-evaluation, the applicant must:

a. Click on BE Request button found in Required Actions tab – which redirects applicantto BE screen
b. Select Request for Re-Evaluation
c. Add remarks in Comment box
d. Click on Submit button

If the applicant chooses to request a re-evaluation, the application will be sent back to BE officer for re-evaluation.

Please note: Accepting rejection will lead to the rejection of drug application as whole.

4. Rejected Applications

Once an application has been rejected by a EDE Officer, an email or an SMS will be sentto the applicant containing the application's latest updates and results.

To view the rejection comments given by EDE Officer and the step at which theapplication got rejected, please click on the Application History button.

Application History

Date	Action	Comment
01-04-2019	submit	
01-04-2019	submit	
01-04-2019	Reject	stability study is required zone 4 climatic condition
01-04-2019	Resume	
01-04-2019	Accept	Accepted
01-04-2019	submit	
01-04-2019	Send Back for Correction	COMPLETE MODULE 5 IS REQUIRED FOR EVALUATION, Correction Required : Attachments : Summary and Protocol of the Bioequivalence study (in PDF format)
01-04-2019	Resume	
15-04-2019	Accept	
15-04-2019	Rejected by the Officer	This application does not meet MOHAP standards!

Figure QQ: Application History

To resubmit a rejected application, please perform the following actions:

a. Click on icon shown in the All Applications screen (or Submitted Application screen) – which redirected to Patient Details screen
b. Make changes based on EDE Officer's rejection comments
c. Proceed to submit application



Figure RR: Submitted Application Screen – Application Details

5. Printouts

Once an application has been reviewed and approved by a EDE officer, the officer will issuethe applicant a Certificate associated with the service type. The applicant will get notified viaSMS or email once the officer issues the certificate.

For a user to view and printout a certificate, they must:

a. Click on the Application Number in All Applications screen – which redirects user to Submitted Application screen
4. Click on the Certificate tab
5. Click on the Attachment – which opens the certificate as a PDF
6. Print PDF

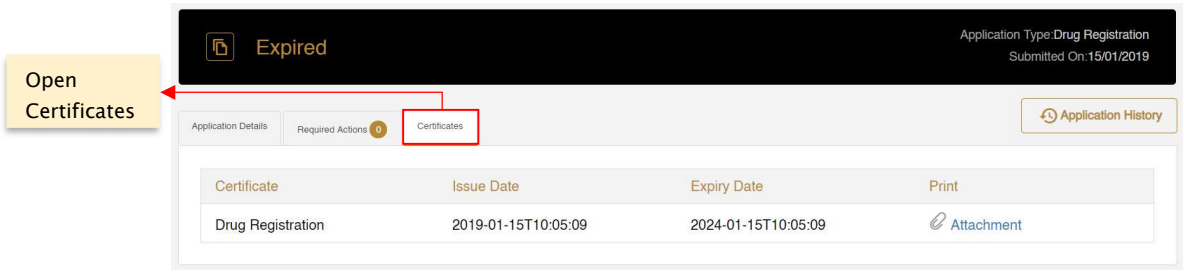


Figure SS: Submitted Application Screen – Printout

5.1 Drug Registration/Renewal Certificate

The Drug Registration/Renewal Certificate will contain the following information:

- Certificate Number
- Registration Number
- First Registration
- Expiry Date
- Product Name
- Pharmaceutical Form
- Shelf Life
- Storage Condition
- List of All Pack Sizes
    - Pack Size
    - Pack Size Presentation
    - Dispensing Mode

  - NDC
- Active Ingredient(s)
- Quantity
- Manufacturer
- Market Authorization Holder
- Agent
- Issue Date

The Drug Registration/Renewal expiration date = Date of Registration Committee + 5 Years -1 Day. In case product was already registered in GCC then the product expiry date in EDEwill be 5 years from the GCC DR First Certificate Issue Date.

5.2 Minor Variation Certificate

The Drug Minor Variation Certificate will contain the following information:

- Registration Number
- Product Name
- Pack Strength
- Pharmaceutical Form
- Pack Size(s)
- Market Authorization Holder
- Manufacturer
- Authorized Agent
- Minor Change Details (Multiple Sections)
  - Minor Change Type
  - Approved Details
- Issue Date

5.3 Analysis Certificate

The Analysis Certificate will contain the following information:

- Quality Control Number
- Purpose
- Reference Number
- Source

- Product Name
- Pharmaceutical Form:
- Manufacturer & Origin
- Package Description
- Sample Description
- Batch Number
- Manufacturing Date
- Expiry Date
- Pack Size
- Receiving Date
- Completion Date
- Composition
- Quantity
- Analysis Results

5.4 PV Certificate

5.4.1 Approval Letter

The PV Evaluation – Approval Letter will contain the following information:

- Date: [Approval Date]
- M/S: [Establishment Name form user profile]
- ATTN.: [MAH Name from Drug Registration Application]
- Receipt #: [Payment receipt number from Payment Gateway]
- Payment Date
- Pack Name from Drug Registration application
- [Approval Letter]
- [PV Remarks]

5.4.2 Rejection Letter

The PV Evaluation – Rejection Letter will contain the following information:

- Date: [Approval Date]
- M/S: [Establishment Name form user profile]
- ATTN.: [MAH Name from Drug Registration Application]

- Receipt #: [Payment receipt number from Payment Gateway]
- Payment Date
- Pack Name from Drug Registration application]
- [Rejection Letter]
- [PV Remarks]

5.5 Release to Market Certificate

The Release to Market Certificate will contain the following information:

- Quality Control No
- Reference Number
- Purpose (or Other Purpose)
- Source (or Other Source)
- Product Name
- Pharmaceutical Form
- Manufacturer & Origin
- Package Description
- Sample Description
- Batch Number
- Manufacture Date
- Exp. Date
- Pack Size
- Receiving Date
- Completion Date
- Active Ingredient (Multiple line)
    - Active ingredient
    - Quantity
- Inactive Ingredient (Multiple line)
    - Inactive ingredient
    - Quantity
- Analysis Remarks

5.6 Pricing Certificate

The Approved, Increased, Decreased Pricing Certificate will contain the following information:

- Date
- To:
- Attn:
- Ministerial Decree No
- Ministerial Decree Date
- Table Header
- Sr. No.
- Reg. No. & Date
- Product Name
- Form
- Pack Size(s)
- Ex-Factory Price
- Ex-Factory Currency
- Pharmacy Price (AED)
- Public Price (AED)
- CIF Price
- CIF Price Currency
- Price Status
- Under the table comes the officer provided comments
- Certificate Comments

6. Appendix

6.1 Appendix I

General attachments that the applicant will upload when submitting the application

Documents
Covering letter (in editable searchable PDF format)
Comprehensive Table of content (in editable searchable PDF format)
Application form properly filled and signed by the qualified responsible person (MAH) in scanned PDF format. (Size must be less than 2 MB)
Application form in MS-Word format
Summary of Product Characteristics (SmPC) (in editable searchable PDF format)
Arabic leaflet (in editable searchable PDF format) – size must be less than 2 MB
English leaflet (in editable searchable PDF format) – size must be less than 2 MB
Outer carton artworks (in editable searchable PDF format) – size must be less than 1 MB
Inner label artworks (in editable searchable PDF format) – size must be less than 1 MB
Other labels artworks inside the pack artworks (in editable searchable PDF format) – size must be less than 1 MB
Quality information of the Experts (in PDF format)
Non-clinical information of the Experts (in PDF format)
Clinical information of the Experts (in PDF format)
Non-Genetically Modified Organism (Non-GMO) (in PDF format)
Genetically Modified Organism (GMO) (in PDF format)
Pharmacovigilance System (in editable searchable PDF format)
Risk Management Plan (in editable searchable PDF format)
Original legalized valid Certificate of a Pharmaceutical Product (CPP) (in PDF format)
Copy of valid GMP certificates for the batch releaser & bulk manufacturer (in PDF format)
Certificate of Analysis – Drug Substance (At least three batches for non-local and one batch for local manufacturer) (in PDF format)
Certificate of Analysis – Finished Product (At least three batches for non-local and one batch for local manufacturer) (in PDF format)
Alcohol-content declaration (in PDF format)
Pork – free declaration (in PDF format)
TSE/BSE free declaration for the product from MAH (in PDF format)
TSE/BSE free declaration from source for ingredients present from animal source (in PDF format)
API EDQM certificate of suitability or US-FDA approval of the DMF (in PDF format)
Copy of valid GMP certificate for the API source from COO (in PDF format)
API Acknowledgment letter from API source (in PDF format)

Documents
Copy of the manufacturing site registration certificate for batch releaser & bulk manufacturer (in PDF format)
Composition certificate with active ingredient(s), inactive ingredient(s) quantities per unitdose and functions (in editable searchable PDF format)
The diluents and coloring agents in the product formula (in PDF format)
Patent letter with copy of the patent references (in PDF format)
Registration and Marketing status in other countries (with copies of registration certificates) (in PDF format)
Original legalized Price Certificate (in PDF format)
Other documents related for Price (Comparative studies) (in PDF format)
Responses to questions and other requested documents (Updates, questions, queries) (inPDF format)
Summary and Protocol of the Bioequivalence study (in PDF format)
Approval of the Bioequivalence study by the Health Authorities (in PDF format)
Module 2
Module 3
Module 4
Module 5
Relation-ship letter between two parties (if batch releaser & bulk manufacturer are different) (in PDF format)
Appointment letter for the local distributor from MAH (in PDF forma)

TABLE 11: LIST OF ATTACHMENTS

6.1 Appendix II

List of fields that are open for minor variation

Section Name	Field Name
Products Details	• Trade Name • Product Class • Product Sub-Class
Active Ingredient	• Active Ingredient Name • Description
Body System	• Body System • Body Sub-System
Dosage Form Details	• Form • Sub Form
Pack Details	• Pack name
	• Strength • Shelf Life • Shelf Life Description • Storage Condition • Storage Condition Description • Indication
MAH Details in country of Origin	• Market Authorization Holder • MAH Authorized Contact Name • Address • City • Country • Telephone • Mobile • Fax • Email • Company Website
Route	• Route of Administration

PV Officer	• Contact Name • Address • City • Country • Telephone • Mobile • Fax • Email • Website • Remarks • PV Support Document
Active Ingredients (Multi Records)	• Active Ingredient Name • Quantity • Quantity Unit • In Quantity / Ref. Quantity • In Quantity / Ref. Quantity Unit • Active Ingredient Description Details • Other Info/Salt • Attachment (Composition certificate)
API Source	• Holder name • Country • City • Address • Manufacturing Site Name • Country • City • Address • GMP Certificate Number • GMP Certificate Issuing Authority • GMP Date of Issue • GMP Expiry Date • GMP Certificate • EDQM COS Number • EDQM COS Number Issue Date • EDQM COS Certificate • US FDA DMF Approval Number • US FDA DMF Approval Date • US FDA DMF Approval Certificate

Inactive Ingredients (Multi Records)	• Inactive Ingredient Name • Quantity • Quantity unit • In Quantity / Ref. Quantity • In Quantity / Ref. Quantity Unit • Inactive Ingredient Description Details • Function • Manufacturer (Batch Releaser)
Additional Information	• Physical Capsule Shell Detail • Physical Coating Detail • Finished Product Details • Finished Product Specification/Test/Method • Manufacturing Process Details • Animal Forms
GCC Registration	• Product Registered in GCC
	• GCC DR Registration Number • GCC DR Registration Date • Attachment • Is product belongs to MAH in UAE?
Registration status in Country of Origin	• Country • Name of Regulatory Authority • MAH Name • Date of Approval • Date of Marketing • Attachment
Registration status in other Countries	• Country • Name of Regulatory Authority • MAH Name • Date of Approval • Date of Marketing • Attachment

Patent Status (Multi Records)	• Brief description of patent • Patent number • Expiry Date • Patent Holder Name • Country • City • Address • Patent Authority Name • Country • City • Address • Attachment • Status Remarks
Product Pack Size (Multiple Records)	• Pack Size (Numbers) • Pack Size Unit • Pricing Pack Size (Numbers) • Pricing Pack Size Unit • Pack Size Description • GTIN • Dispensing Mode

Section Name	Field Name
	• Dispensing Mode in Country of Origin • Container Type (Presentation Type) • Container Details (Primary Packaging Details) • Label Details (Secondary Packaging Details – Outer label details) • Label Details (Secondary Packaging Details – Inner label details) • Other label details (Solvent or Pouch or any other inner package details) • Manufacturing Staging (Multi) • Manufacture Site • Manufacture Stage • Photo • Outer carton artwork • Attachment • Inner label artwork • Attachment • Other labels (Multi) • Attachment
Proposed For each Pack Size Price	• CIF • Currency
Reference Prices For each Pack Size (Multiple Record)	• Price Type • Country • Ex-factory Price • Currency • Wholesale price • Currency • Public price • Currency • Reference Book • Support Document

TABLE 12: OPEN MV FIELDS

6.1 Appendix III

The applicant will upload the following additional attachments for the PV Plan

Attachment Name	Mandatory
The role and responsibilities of the manufacturer about drug vigilance	Y
Monitoring compliance and medical inspection	Y
The role of the qualified person as an alert vigilant	Y
Pharmaceutical vigilance plan for the company	Y
Organizational structure of the company	Y
Quality Management System	Y
Clinical and non-clinical studies of drug safety	Y
Side effects / adverse drug reactions	Y
Identify potential drug interactions with other foods and drugs for eachclass	Y
Epidemics science	Y
Plan to reduce and manage drug risks	Y
Individual Cases Reporting (ICSRs)	Y
Special case safety requirements for patients (individual case Safety Special Situation)	Y
Periodic Drug Safety Reports (PSUR)	Y
Drug Risk Reports (PBRER)	Y
Training plan for drug alert communication officers	Y
Pharmaceutical Vigilance System	Y

TABLE 13: PV PLAN ATTACHMENTS