External User Guide

Issue of a Certificate of a Pharmaceutical Product for Export

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1. Brief Overview

This manual is prepared to navigate applicants through the process of issuing the Certificate of Pharmaceutical Products (CPP) for product packs in Emirates Drud Establishment (EDE) Portal.

This manual is designed to help applicants:

- Apply for a Certificate of Pharmaceutical Products (CPP) for their medical products
- Manage Certificate of Pharmaceutical Products (CPP) applications

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

Please note: This service is only available to the Applicants listed below.

Applicant Type	Rules
Agents	Should have un-expired license Can only issue CPP for drugs registered under his name as agent
Scientific Offices	Should have un-expired license Can only issue CPP for drugs registered under his name as Applicant or MAH
Local Manufacturers	Should have un-expired license Can only issue CPP for drugs they (Manufacturer) are a part of in the manufacturing cycle

TABLE 1: TYPES OF APPLICANTS

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 CPP service.

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

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.

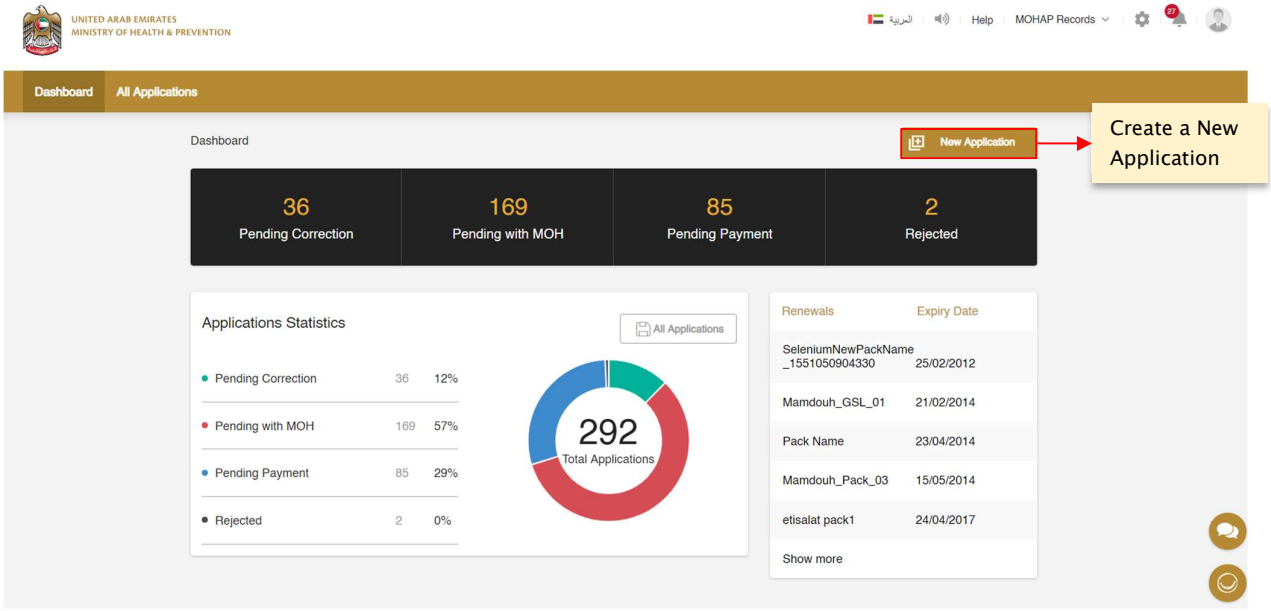

FIGURE A: DASHBOARD SCREEN

2.1 Create a New Application

The Applicant can request to classify their products based on EDE standards by:

Requesting to create a New Application form from the Applicant Portal and selecting the following service which falls under the **Drug Certificates** ⇨ services:

- Certificate of Pharmaceutical Products (CPP)

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. Select **Certificate of Pharmaceutical Products (CPP)**
c. Click **Create Application** button

Once the user selects **Certificate of Pharmaceutical Products (CPP)** as a service and creates an application, the user will be redirected to Product Details screen.

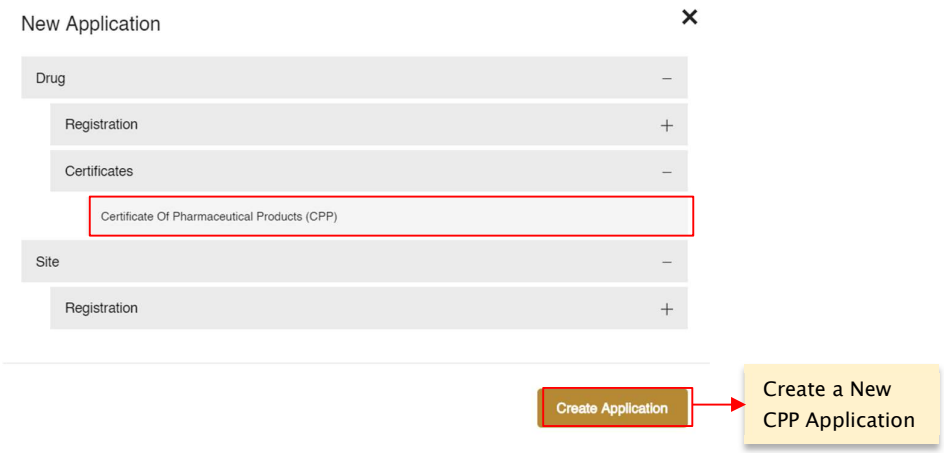

FIGURE B: NEW APPLICATION SCREEN

2.2 CPP Application

To complete a Drug Classification application, the applicant must fill the following three sections:

1. Product Details
2. Pack Details
3. CPP Details
4. Attachments

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

- Save application
- Discard application
- Proceed to next section
- Go back to previous section

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

FIGURE C: PROGRESS BAR

Warnings:

- 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 box highlighting the note: This field accepts numbers only.

Display icons:

- allows user to Delete data (usually found under Actions)
- allows user to Edit data (usually found under Actions)

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

2.2.1 Product Details

In the Product Details screen, the applicant is required to search and select the Medical Product's Name / Trade Name. Consequently, the screen will display the product details along with the pack list for the product selected.

To proceed with CPP request, the applicant must click on icon under Registered Packs to proceed to the Pack Details screen.

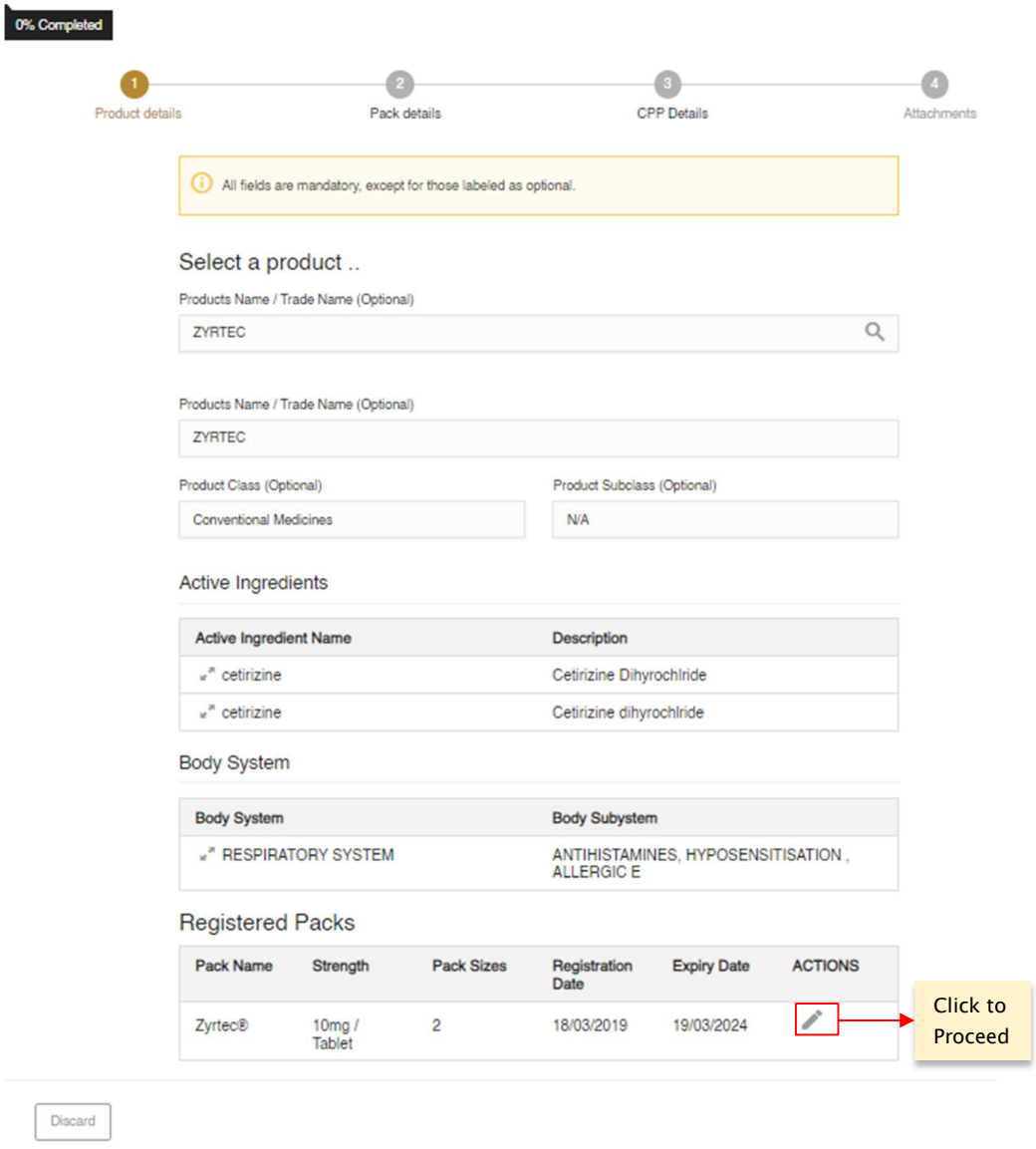

FIGURE D: PRODUCT DETAILS SCREEN

Rule ID	Rules
R1	The selected pack's MAH Country should be UAE.

Rule ID	Rules
R2	The selected pack should be partially/fully manufactured in UAE, i.e. if it's manufactured by one manufacturer, its country should be UAE, and if there are many manufacturers, at least one of them, its country should be UAE.
R3	The selected pack's Product Class should **not** be Medical Device.
R4	Pack registration should be non-expired.

FIGURE E: PRODUCT DETAILS RULES

2.2.2 Pack Details

The Pack Details section is broken down into many subsections, each containing essential details of the registered pack. Below are the following subsections:

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)

The landing page of the Pack Details section is the General Information sub-section. To proceed to the next screen, please proceed to click on the **Next** button.

Please note: This fields/attachments in this section are Read-Only.

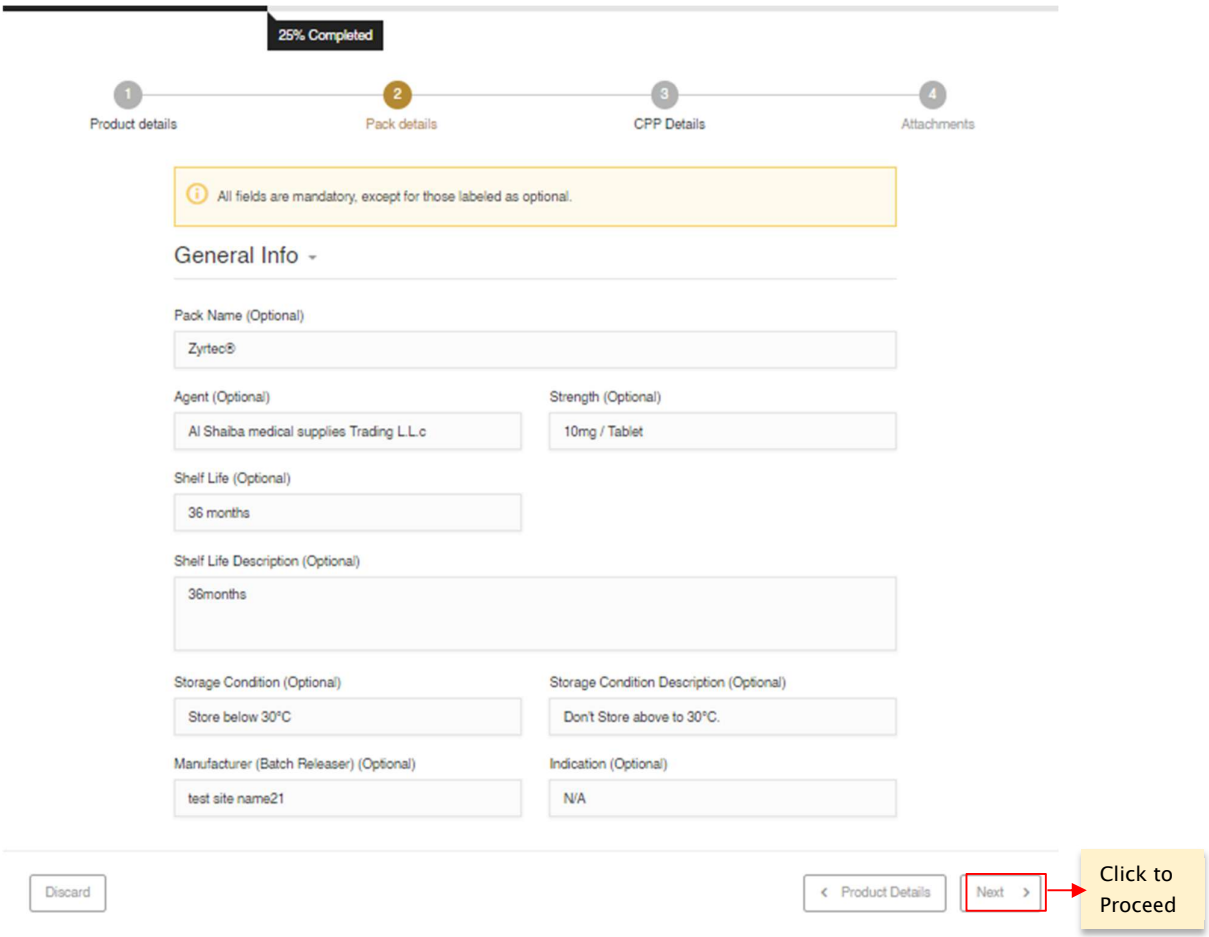

FIGURE F: PACK DETAILS SCREEN

2.2.3 CPP Details

For the applicant to proceed with the CPP request, they are required to provide the following information:

a. Exporting Name
b. Exporting Country
c. Importing Country

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

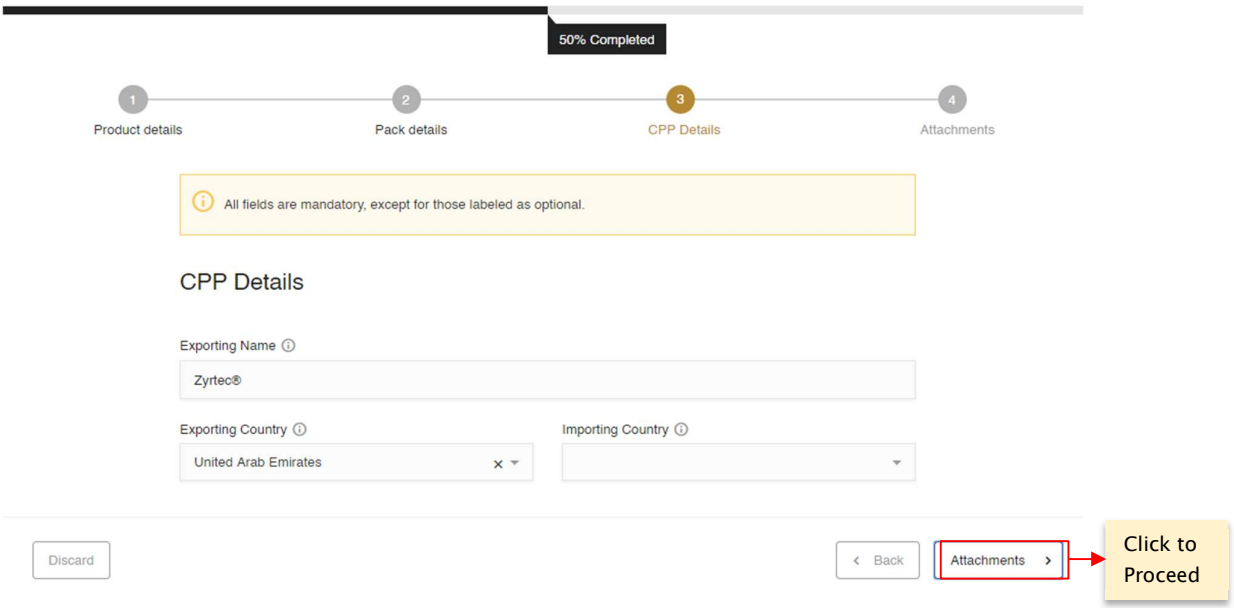

FIGURE G: CPP DETAILS SCREEN

2.2.4 Attachments

This section is where an applicant can upload General Attachments before proceeding to submit the application. Below are the attachments the applicant must submit before moving to the next section:

Documents
Insert which is last approved by EDE to be Signed by Authorized Person.
Original Composition Certificate signed by Authorized Person.

Table 2: List of Attachments

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

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

Once the applicant is done with this section, they can move to the Review section by clicking **Review** button.

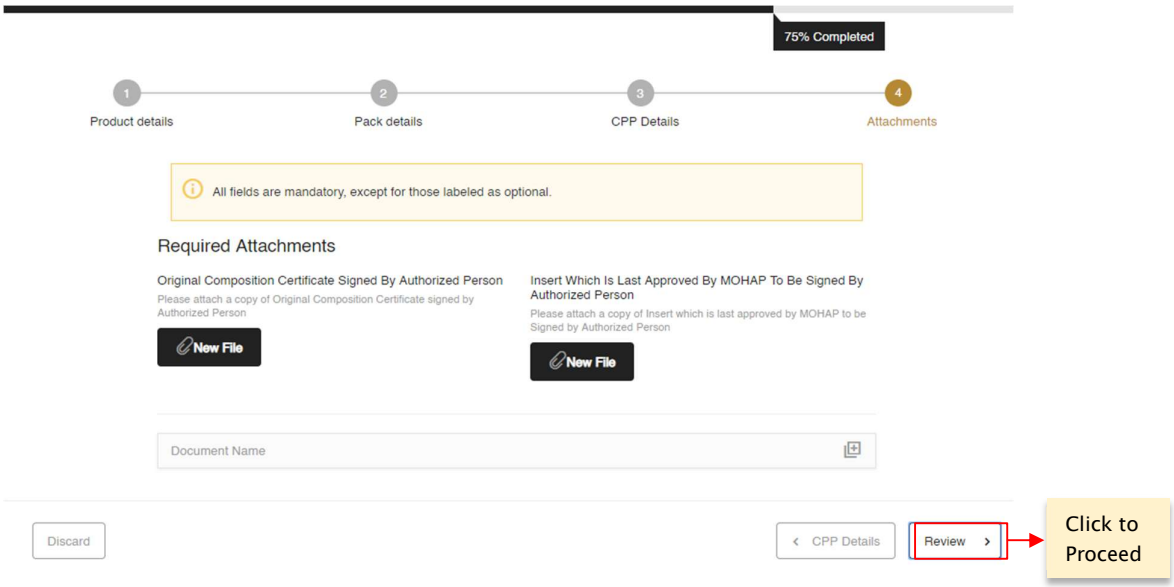

Figure H: Attachments Screen

2.3 Review Application

After the applicant completes filling all application details, they must click on the **Review** button to proceed with application submission. The Review section provides a full summary of the application and allows the user to perform the following actions:

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

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

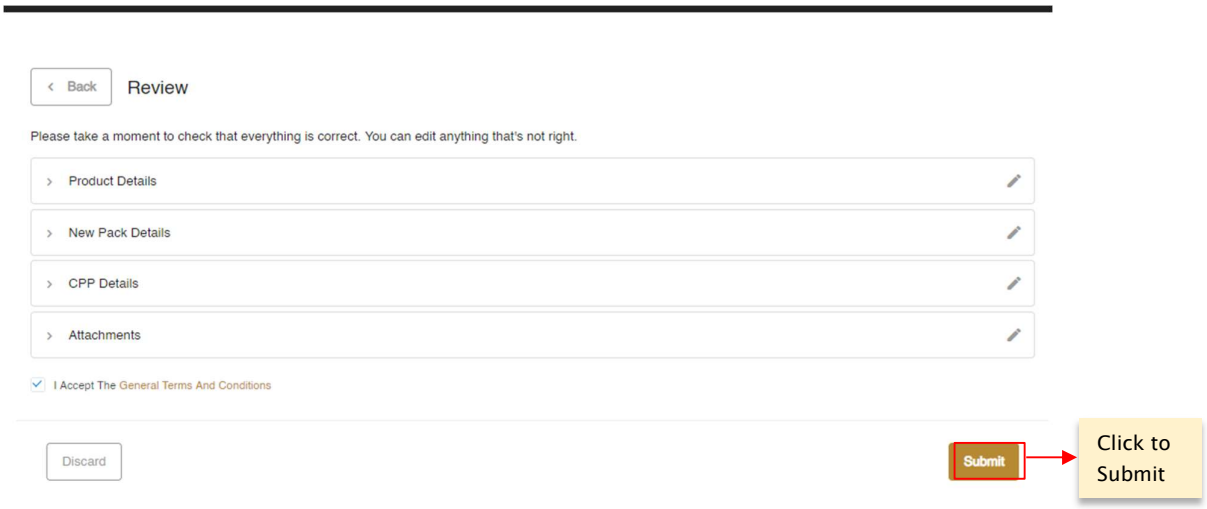

Figure I: Review Screen

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 1000 per Application

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).

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

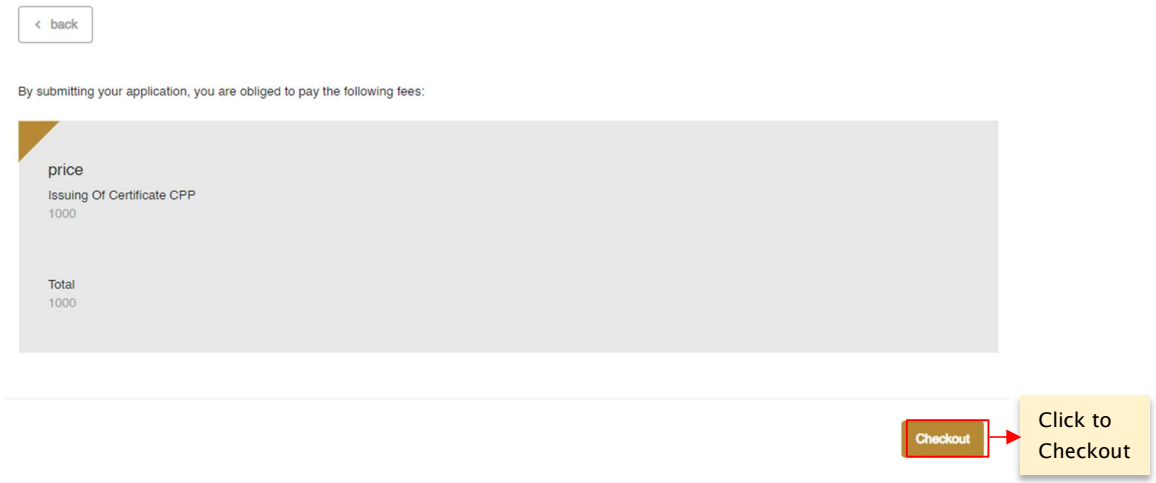

Figure J: Checkout Screen

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

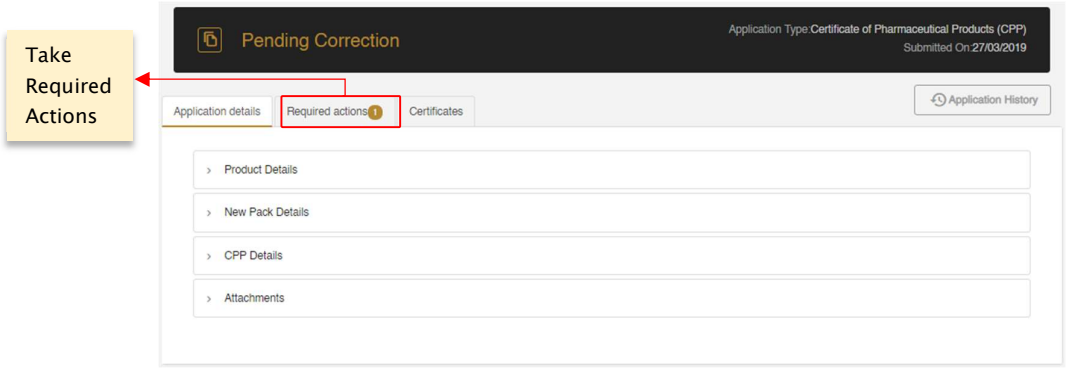

Figure K: Submitted Application Screen

The request the officer can ask an applicant is the following:

1. Application Correction

This action 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 Drug Classification 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 applicant to 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: *Only fields/attachments needed for correction are displayed for change

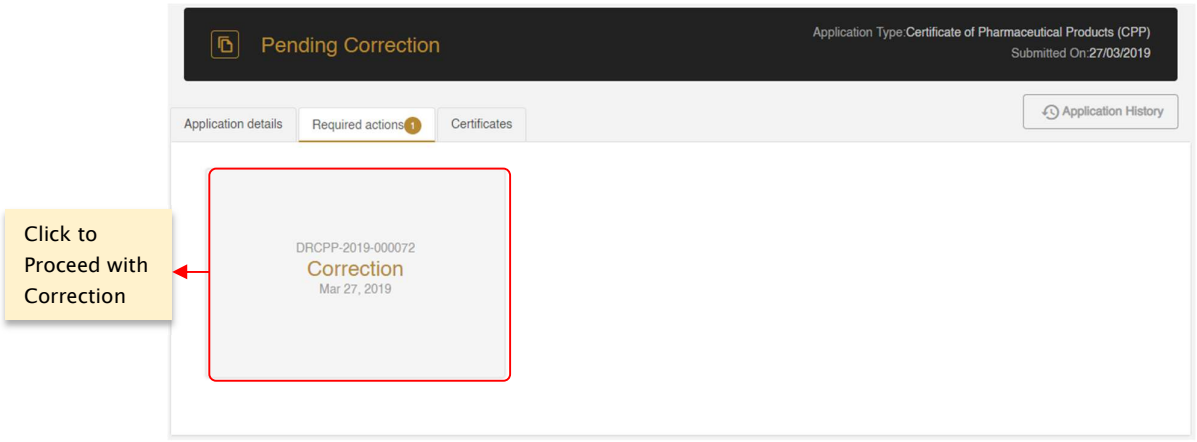

Figure L: Submitted Application Screen – Required Actions

Figure M: Field Correction Cursor

Figure N: Modified Field

Figure O: Unmodified Field

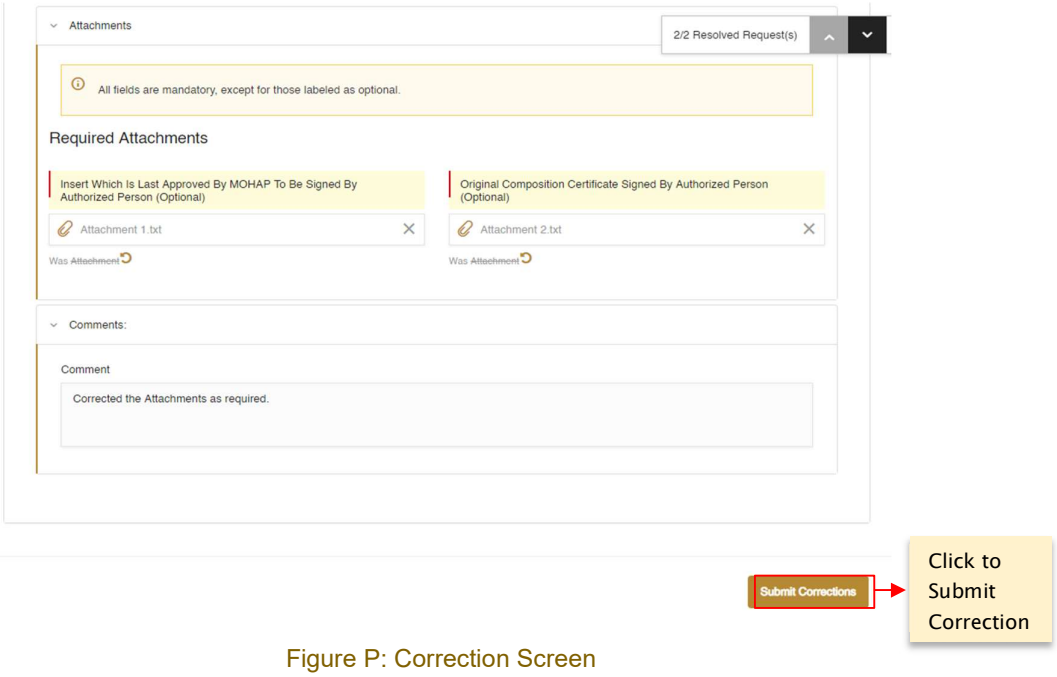

Figure P: Correction Screen

Display icons: allows the user to undo change

Tips:

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.

4. Rejected Applications

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

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

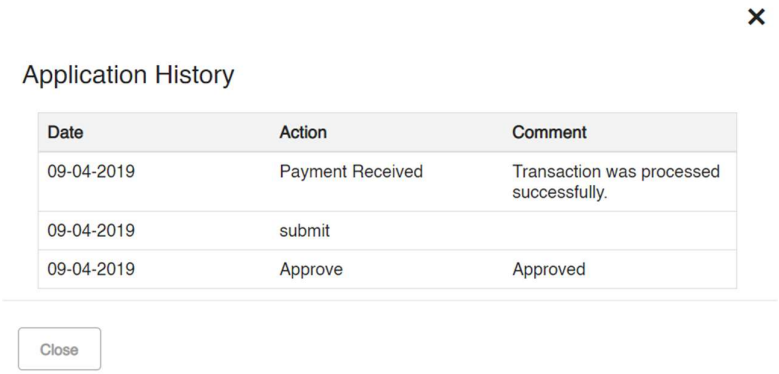

Figure Q: Application History

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 R: Submitted Application Screen – Application Details

5. Printouts

Once an application has been reviewed and approved by a EDE officer, the officer will issue the applicant a Certificate associated with the service type. The applicant will get notified via SMS 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
b. Click on the **Certificate** tab
c. Click on the Attachment – which opens the certificate as a PDF
d. Print PDF

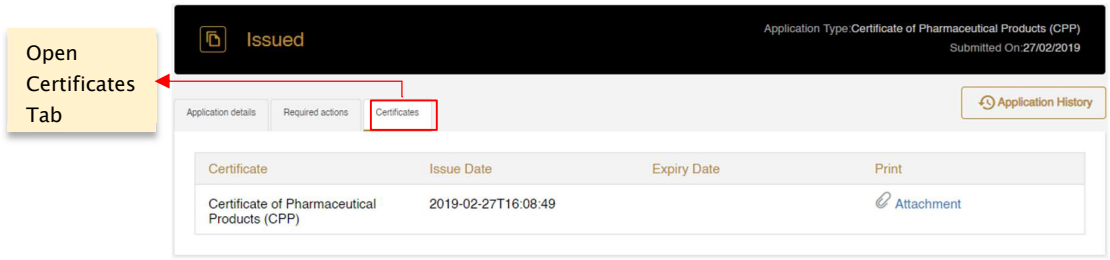

Figure S: Submitted Application Screen – Printout

The issued certificates will have a validity of 2 year or up to product registration expiry date in case product registration validity is less than 2 years.

The Certificate of Pharmaceutical Products (CPP) will contain the information shown in Appendix I.

6. Appendix

6.1 Appendix I

Fields	
Certificate No.	
1. Exporting (certifying) Country	
Importing (requesting) Country	
Exporting Name and Dosage Form	
Active Ingredient (Multiple Records) • Ingredient • Quantity	
Inactive Ingredient (Multiple Records) • Ingredient • Quantity	
1.2 Whether this licensed product is to be placed on the market for use in the exporting country?	
1.3 Whether this product actually on the market in the exporting country?	
In case of 'Yes' option of # 1.2, below fields are displayed	In case of 'No' option of # 1.2; below fields are displayed
2.A.1 Number of product license and date issue	2.B.1 Applicant for Certificate
License/ Registration Number	· Applicant Name
Date of Issue	· Address
2.A.2 Product-license holder Name	· City
Name	· Country
Address	2.B.2 Status of Applicant
City	a. Manufactures the dosage form
Country	b. Packages and/or labels a dosage from manufactured by an independent company
2.A.3 Status of Product License Holder	c. Is involved in none of the above
a. Manufactures the dosage form	2.B.2.1 For categories 'b' and 'c' the name and address of the manufacturer producing the dosage form are
b. Packages and/or labels a dosage from manufactured by an independent company	Name of Manufacturer
c. Is involved in none of the above	Address
2.A.3.1 For categories 'b' and 'c' the name and address of the manufacturer producing the dosage form are	City
Name of Manufacturer	Country
Address	2.B.3 Why is marketing authorization lacking?
City	2.B.4 Remarks
Country	3. Does the certified authority arrange for periodic inspection of the manufacturing plant in which the dosage form is produced.

Fields	
2.A.4 Is the summary basis of approval appended?	In Case of 'Yes' Option of 3, below fields are displayed
2.A.5 Is the attached officially approved product information, complete and consonant with the license?	3.1. Periodicity of routine inspection (Years)
2.A.6 Applicant for certificate, if different from license holder	3.2. Has the manufacture of this type of dosage form been inspected?
	3.3 Do the facilities and operations confirm to GMP as recommended by World Health.
	4. Does the information submitted by the applicant satisfy the certifying authority on all aspects of the manufacture of the product?
	4.1 If No Explain
	Pharmaceutical Particulars
	Product class
	Date of First Registration
	Shelf Life (Months)
	Storage Condition Description
	Pack Size (Multiple Records)
	Pack Size
	Dispensing Mode
	Name of Authorized Person
	Date of Issue
	Date of Expiry
	Address of Certifying Authority
	In Case of 'Yes' Option of 3, below fields are displayed
	3.1. Periodicity of routine inspection (Years)
	3.2. Has the manufacture of this type of dosage form been inspected?
	3.3 Do the facilities and operations confirm to GMP as recommended by World Health.
	4. Does the information submitted by the applicant satisfy the certifying authority on all aspects of the manufacture of the product?
	4.1 If No Explain
	Pharmaceutical Particulars
	Product class
	Date of First Registration
	Shelf Life (Months)
	Storage Condition Description
	Pack Size (Multiple Records)
	Pack Size
	Dispensing Mode
	Name of Authorized Person
	Date of Issue
	Date of Expiry
	Address of Certifying Authority

Table 3: Certificate Fields