

MOHAP e-Transformation

Certificate of Pharmaceutical Products (CPP) - External User Guide

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Table of Contents

1.	Bri	ef Ov	erview3
2.	Ар	ply fo	or Service3
2	2.1	Cre	ate a New Application4
2	2.2	CPP	PApplication5
	2.2	2.1	Product Details6
	2.2	2.2	Pack Details
	2.2	2.3	CPP Details
	2.2	2.4	Attachments10
2	2.3	Rev	iew Application11
2	2.4	Che	eckout12
3.	Tal	ke Re	equired Actions
3	8.1	Арр	plication Correction14
4.	Pri	ntout	ts15
5.	Ар	pend	ix۱٤
5	5.1	Арр	endix ۱۱ ۵

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 Ministry of Health and Prevention (MOHAP) 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 MOHAP Portal.

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

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

TABLE 1: TYPES OF APPLICANTS

2. Apply for Service

Portal users who have logged in successfully to MOHAP portal will be directed to Dashboard screen where they can apply to MOHAP'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

- 3 of
- 21

- 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.

UNITED ARAB EMIRATES MINISTRY OF HEALTH & PREVENTION			العربية 🖿 🕪 Help MOHAP Re	ecords - 🔹 🚳 I 🕘
Dashboard All Applications				
Dashboard			H New Application	Create a New Application
36 Pending Correction	169 Pending with MC	85 DH Pending Payment	2 Rejected	
Applications Statistics		All Applications Seleni	vals Expiry Date	
Pending Correction	36 12%		050904330 25/02/2012	
Pending with MOH	169 57%	292 Pack N	Name 23/04/2014	
 Pending Payment 	85 29%	Total Applications Mamde	louh_Pack_03 15/05/2014	
Rejected	2 0%	etisala	at pack1 24/04/2017	
		Show	more	0

FIGURE A: DASHBOARD SCREEN

2.1 Create a New Application

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

Requesting to create a New Application form from the Applicant Portal and selecting the following service which falls under the **Drug** \implies **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.

New Application	×
Drug	-
Registration	+
Certificates	-
Certificate Of Pharmaceutical Products (CPP)	
Site	-
Registration	+
	Create Application Create a New CPP Application

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 \sim icon under Registered Packs to proceed to the Pack Details screen.

21

Product details		2 Pack of	letails	CP	3 P Details		Attachmer
(i) All fields are	mandatory, except	for those labeled as	optional.]
Se	elect a pro	duct					
Pro	Products Name / Trade Name (Optional)						
Z	ZYRTEC					Q	
Pro	oducts Name / Tra	de Name (Optiona)				
2	ZYRTEC						
Pro	oduct Class (Optic	nal)		Product Subclass	(Optional)		
C	Conventional Med	icines		N/A			
Ac	ctive Ingredie	ents					
	Active Ingredier	nt Name		Description			
	e" cetirizine			Cetirizine Dihyr	ochlride		
	e" cetirizine			Cetirizine dihyr	ochlride		
Bo	e" cetirizine			Cetirizine dihyr	ochlride		
Bo	⊭ [#] cetirizine ody System Body System			Cetirizine dihyre	ochlride		
Bo	e [#] cetirizine ody System Body System e [#] RESPIRATE	ORY SYSTEM		Cetirizine dihyra Body Subystem ANTIHISTAMIN ALLERGIC E	n IES, HYPOSENSI	TISATION ,	
Bo	e" cetirizine ody System Body System e" RESPIRATI egistered	DRY SYSTEM		Cetirizine dihyra Body Subystem ANTIHISTAMIN ALLERGIC E	n IES, HYPOSENSI	TISATION ,	
Bo	e" cetirizine ody System Body System e" RESPIRATI egistered I Pack Name	DRY SYSTEM Packs Strength	Pack Sizes	Cetirizine dihyra Body Subystem ANTIHISTAMIN ALLERGIC E Registration Date	IES, HYPOSENSI Expiry Date	TISATION , ACTIONS	

Discard

FIGURE D: PRODUCT DETAILS SCREEN

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

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7 of

Rule ID	Rules
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
- I. 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.

Product details	2 Pack details	3 CPP Details	4 Attachments
C	All fields are mandatory, except for those labeled as o	ptional.	
G	eneral Info –		
Pa	ok Name (Optional)		
2	Zyrtec®		
Ag	ent (Optional)	Strength (Optional)	
1	Al Shaiba medical supplies Trading L.L.c	10mg / Tablet	
Sh	elf Life (Optional)		
3	36 months		
She	elf Life Description (Optional)		
3	36months		
Sto	orage Condition (Optional)	Storage Condition Description (Optional)	
5	Store below 30°C	Don't Store above to 30°C.	
Ma	nufacturer (Batch Releaser) (Optional)	Indication (Optional)	
t	est site name21	N/A	

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.

9 of

1	2		3		
Product details	Pack deta	ils	CPP Details		Attachments
	ields are mandatory, except for	those labeled as option	ial.		
CPP D	etails				
Exporting N	lame ()				
Exporting N Zyrtec®	lame 🛈				
Exporting N Zyrtec® Exporting C	lame 🛈		mporting Country ③		
Exporting N Zyrtec® Exporting C United A	lame 🛈 Country 🛈 rab Emirates	× •	mporting Country ③	•	

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 MOHAP 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 $\stackrel{[\![t]]}{=}$
- 3. Upload Attachment

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

0-		75% Comple	ted4
Product details	Pack details All fields are mandatory, except for those labeled as opt	CPP Details ional.	Attachments
R Pi Au	equired Attachments iginal Composition Certificate Signed By Authorized Person asse attach a copy of Original Composition Certificate signed by thorized Person New File	Insert Which Is Last Approved By MOHAP To Be Signed E Authorized Person Please attach a copy of Insert which is last approved by MOHAP to Signed by Authorized Person	y be
	Document Name	E	9
iscard		< CPP De	tails Review > Click Proce

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

ease take a moment to check that everything is correct. You can edit anything that's not right.	
> Product Details	1
> New Pack Details	1
> CPP Details	/
> Attachments	/
I Accept The General Terms And Conditions	
Discard	Submit Click



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 MOHAP's Payment Gateway (e-dirham).

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

< back				
By submitting your application, you are	e obliged to pay the following fees:			
price Issuing Of Certificate CPP 1000				
Total 1000				
			Checkout	Click to



3. Take Required Actions

Once an application has been reviewed by a MOHAP 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

Take	Pending Correction	Application Type:Certificate of Pharmaceutical Products (CPP) Submitted On 27/03/2019
Required Actions	Application details Required actions Certificates	Application History
	> Product Details	
	> New Pack Details	
	> CPP Details	
	> Attachments	

Figure K: Submitted Application Screen

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

 13 of
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 21

1. Application Correction

This action will be explained in detail in the following sections.

3.1 Application Correction

In case a MOHAP 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

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14 of

Original Composition Certific	cate Signed By Authorized Person	Insert Which Is Last Approved By Me Authorized Person (Optional)	DHAP To Be Signed By
Attachment 2.txt	×	C Insert which is last approved by	MOHAP to be Signed by Authc
Figure N:	Modified Field	Figure O: Unm	odified Field
~ Attachments			2/2 Resolved Request(s)
Required Attachments			
Required Attachments Insert Which Is Last Approved B Authorized Person (Optional) authorized Person (Optional) authorized Attachment 1.txt Was Attachment C Comments:	By MOHAP To Be Signed By	Criginal Composition Certificate Sig (Optional) X Ø Attachment 2.txt Was Attachment 3	ned By Authorized Person
Required Attachments Insert Which is Last Approved B Authorized Person (Optional) authorized Person (Op	By MOHAP To Be Signed By	Original Composition Certificate Sig (Optional) @ Attachment 2.txt Was Attachment 3	ned By Authorized Person

Figure P: Correction Screen

Display icons: ⁵ 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 MOHAP 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 MOHAP Officer and the step at which the application got rejected, please click on the **Application History** button.

Date	Action	Comment
09-04-2019	Payment Received	Transaction was processed successfully.
09-04-2019	submit	
09-04-2019	Approve	Approved

×

Figure Q: Application History

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

- a. Click on ¹/₁ icon shown in the All Applications screen (or Submitted Application screen)
 which redirected to Patient Details screen
- b. Make changes based on MOHAP Officer's rejection comments
- c. Proceed to submit application

Resubmit Application	■ Rejected	Application Type:Emergency Drug Order Approval Submitted On:21/03/2019
	Application Details Required Actions Certificates	Application History
	> Pateint Details	
	> Medicine	
	> Attachments	



5. Printouts

Once an application has been reviewed and approved by a MOHAP 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:

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16 of

- 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

Open Certificates	D Issued		Ap	plication Type Certificate of Pharmaceutical Products (OPP) Submitted On 27/02/2019
Tab	Application details Required actions Certificate	s		Application History
	Certificate	Issue Date	Expiry Date	Print
	Certificate of Pharmaceutical Products (CPP)	2019-02-27T16:08:49		C Attachment

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 <u>Appendix I</u>.

21

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	In case of 'No' option of # 1.2; below			
fields are displayed	fields are displayed			
2.A.1 Number of product license and	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			
	b. Packages and/or labels a dosage			
Country	from manufactured by an independent			
	company			
2.A.3 Status of Product License Holder	c. Is involved in none of the above			

Fields		
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	
 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.	
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	
	rnalmaceutical Particulars	

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Fie	lds
	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

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Fields	
	Date of Issue
	Date of Expiry
	Address of Certifying Authority

Table 3: Certificate Fields