

# **MOHAP** e-Transformation

Drug Registration - External User Guide

Date: 11th April 2019

# Table of Contents

1.	Brie	ef Ov	erview	5
2.	Арр	oly fo	or Service	5
2	.1	Crea	ate a New Application	6
2	.2	Con	nplete Application	7
	2.2	.1	Drug Registration	9
	2.2	.2	Drug Renewal2	8
	2.2	.3	Minor Variation2	9
2	.3	Revi	iew Application3	3
2	.4	Che	ckout3	4
	2.4	.1	Drug Registration	5
	2.4	.2	Drug Renewal3	6
	2.4	.3	Minor Variation3	7
3.	Tak	ke Re	quired Actions3	8
3	.1	Арр	lication Correction3	9
3	.2	Sam	ple Request4	0
3	.3	Арр	ointment Request4	2
3	.4	Ana	lysis Request4	4
3	.5	Pha	rmacovigilance (PV) Request4	6
3	.6	Pric	ing Request4	7

Ministry of Health & Prevention - UAE, all rights reserved

	3.6.	1	Correction47
	3.6.	2	Rejection48
3	.7	Re	lease to Market Request49
3	.8	Sta	ability Request
	3.8.	1	Correction50
	3.8.	2	Rejection51
3	.9	Bic	52 Equivalence (BE) Request
	3.9.	1	Correction52
	3.9.	2	Rejection52
4.	Reje	ecte	ed Applications54
5.	Prin	tοι	ıts55
5	.1	Dr	ug Registration/Renewal Certificate55
5	.2	Mi	nor Variation Certificate56
5	.3	An	alysis Certificate57
5	.4	PV	Certificate57
	5.4.	1	Approval Letter
	5.4.	2	Rejection Letter58
5	.5	Re	lease to Market Certificate58
5	.6	Pri	cing Certificate
6.	Арр	en	dix60
3	of		Ministry of Health & Prevention – UAE, all rights reserved

67

6.1	Appendix I	60
6.2	Appendix II	62
6.3	Appendix III	66

# **1. Brief Overview**

This manual is prepared to navigate applicants through the Drug Registration process in Ministry of Health and Prevention (MOHAP) 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 MOHAP 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 agent Can 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 cycle Can 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 MOHAP portal will be directed to Dashboard screen where they can apply to MOHAP's e-services. This user manual will focus on the following e-services:

67

- 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 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.

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

UNITED ARAB EMIRATES MINISTRY OF HEALTH & PREVENTION			Open Registere	ed Products	■③   Help   MOHAP Records >   ✿ ጫ
Dashboard All Applications					manufacture Gries
	Dashboard			New Application	Create a New Application
	36 Pending Correction	170 Pending with MOH	85 Pending Payment	2 Rejected	
	Applications Statistics		All Applications Seleniu	als Expiry Date	
	Pending Correction	36 12%	_15510	050904330 25/02/2012	
	<ul> <li>Pending with MOH</li> </ul>	170 58% 29	3 Pack N	lame 23/04/2014	
	Pending Payment	B5 29%	cations	puh_Pack_03 15/05/2014	
	Rejected	2 0%	etisalat	t pack1 24/04/2017	
			Show n	nore	

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 MOHAP'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**  $\implies$  **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.

New Ap	pplication	×	
Drug		-	
Re	gistration	-	
	Minor Variation		
	Drug Registration		
	Drug Classification		
	Drug Renewal	•	
Site		+	
		Create Application	Create a New Application

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.

Prod	1 uct Details	2 Active Ingredients	3 Attachments
	Select a product Products Name / Trade Name		
	Search Products		Q
Discard			

#### Figure C: Product Details Screen

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

8 ofMinistry of Health & Prevention - UAE, all rights reserved67

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

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 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.

		New Pack		Attac	chments
i All fields are m	andatory, except for those	e labeled as optional.			
Select a proc	luct				
Products Name / Trad	le Name				
AUGMENTIN				Q	
Products Name / Trade AUGMENTIN	Name (i)				
Product Class (j) Conventional Medicines					
Product Subclass (i)					
N/A					
Active Ingredie	nts				
Active Ingredient	Name	Desc	ription		
troxonium tosilat	e	soha	clone2		
amoxicillin		Amo	cicillin trihydrate		
clavulanic acid		Clave	ulanic acid (as Potassi	um Clavulanate)	
Body System					
Body System		Body	Subvstem		
Body System Body System		Body			
Body System Body System INFECTIONS Begistered P	Packs	Body	Subystem BACTERIAL		
Body System INFECTIONS Registered P Pack Name	Packs Strength	Body ANTI Pack Sizes	Subystem BACTERIAL Registration Date	Expiry Date	
Body System Body System INFECTIONS Registered P Pack Name Augmentin intravenous 400mg (soha)	Packs Strength 600mg / Vial	Body ANTI Pack Sizes 1	Subystem BACTERIAL Registration Date 03/04/2019	Expiry Date 05/09/2024	
Body System Body System INFECTIONS Registered P Pack Name Augmentin intravenous 400mg (soha) Augmentin intravenous 400mg	Packs Strength 600mg / Vial 600mg / Vial	Body ANTI Pack Sizes 1	Subystem BACTERIAL Registration Date 03/04/2019 16/03/2019	Expiry Date 05/09/2024 16/03/2024	
Body System Body System INFECTIONS Registered P Pack Name Augmentin intravenous 400mg (soha) Augmentin intravenous 400mg Augmentin 312mg/5ml	Constraints of the second seco	Body ANTI Pack Sizes 1 1 1	Subject         Subject <t< td=""><td>Expiry Date 05/09/2024 16/03/2024 16/03/2024</td><td></td></t<>	Expiry Date 05/09/2024 16/03/2024 16/03/2024	

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
- I. 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				

	2	3
Product Details	Pack Details	Attachments
General Info		•

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

Ministry of Health & Prevention – UAE, all rights reserved

- 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.

Product Details	New Pack	Attachments
(i) All fields are mandatory, exce	pt for those labeled as optional.	
General Info -		
1/15		
Pack Name (j)		
Pack Name		
Agent (i)	Strength ④	
GULF DRUG L.L.C.	Strength	
Shelf Life 🛈		
Shelf Life		
Shelf Life Description (Optional) ()		
Storage Condition (i)	Storage Condition Desc	ription ③
	▼ Storage Condition De	scription
Manufacturer (Batch Releaser) ③	Indication ③	
Manufacturer (Batch Releaser)	Indication	

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.

		38% Completed		
Pro	oduct Details	2 New Pack	Attachments	
	(i) All fields are mandatory, exc	ept for those labeled as optional.		
	Insert Details -			
	2/15 Package Insert Description ()			
	Package Insert Description			
	Product Pack Details Document 1 Please add new file Product Pack Details	Document 1		
			Add	
Discard			< Back Next >	Proceed to Next Section

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.

	38% Completed		
Product Details	2 New Pack	Attachments	
(i) All fields are mandatory, ex	cept for those labeled as optional.		
Product Form -			
3/15			
Form (j)	Ŧ		
Discard		< Back Next > Procee	ed t

#### 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

67

- 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.

	40% Completed	
Product Details	2 New Pack	Attachments
() All fields are mandatory,	except for those labeled as optional.	
Active Ingredients	¥	
Build your Active Ingredients	Liet	I Add Active Ingredient
Discard		< Back Next > Proceed to Next Section

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.

		42% Completed			
	0	2		3	
Prod	uct Details	New Pack	Attac	chments	
	(i) All fields are mandatory, except for	those labeled as optional.			
	InActive Ingredients -				
	5/15				
	Inactive Ingredient				
	Build your Inactive Ingredient List		Add Inactive Ingredient		
Discard				Back Next >	Proceed to Next Section

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).

	44% Completed	
Product Details	2 New Pack	3 Attachments
(i) All fields are mandatory,	except for those labeled as optional.	
Routes List -		
6/15 Route Name 1 (j)		
	*	
		H Add New Poute
Discard		K Back Next > Proceed Next Sec

Ministry of Health & Prevention - UAE, all rights reserved

#### 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

67

oduct Details	New Pack	Attachments
All fields are mandatory, except	for those labeled as optional.	
Market Authorization H	lolder -	
7/15		
Market Authorization Holder (i)		
waymade Pic		Q
MAH Name ③	Address (Optional) (i)	
waymade Plc	sovereign house , miles gray road	l basildon , essex , un
City (Optional) ③	Country ③	
Basildon	United Kingdom	
Telephone (Optional) (;)	Mobile (Optional) (j)	
0044126853520		
FAX (Optional) ③	Email Address 🕄	
	info@waymade.co.uk	
Company Website (Optional) (i)	PO.BOX (Optional) ③	
www.waymade.co.uk		
MAH authorized contac	ct details	
MAH Authorized Contact Name (i)	Contact Address (i)	
sana awad	arabian home building near SKMC	C
Contact City (i)	Contact Country ③	
Abudhabi	United Arab Emirates	
Contact Telephone ③	Contact Email ③	
00971567820207	sana_awad@gulfdrug.com	

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

19 of

Ministry of Health & Prevention - UAE, all rights reserved

67

- g. Mobile
- h. Fax
- i. Email
- j. Website
- k. Remarks
- I. 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

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

	49% Completed		
Product Details	2 New Pack	3 Attachments	
(i) All fields are mandatory,	except for those labeled as optional.		
PV Officer -			
8/15			
Officer ID (i)			
Officer ID		Q	
Discard		K Back Next >	Proceed to Next Section
	Figure M: PV Officer Screen		

2.2.1.2.9 Target Animals\*\*

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

- a. Target Animals
- b. Product Type
- c. Withdrawal Period after last treatment

Ministry of Health & Prevention - UAE, all rights reserved

- 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.

	51% Completed		
Product Details	2 New Pack	3 Attachments	
() All fields are mandatory, exce	ept for those labeled as optional.		
Target Animals -			
9/15 Target Animals			
Build your Target Animals List		I Add Target Animal	
			Proc

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.

	nments
nal.	
GCC DR Committee Meeting Date ③	
dd/mm/yyyy × 🗎	
GCC Last Renewal Certificate Issue Date (Optional) 🛈	
dd/mm/yyyy 🗙 🗐	
	GCC DR Committee Meeting Date () ddimmiyyyy X 🗐 GCC Last Renewal Certificate Issue Date (Optional) () ddimmiyyyy X 🗐

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.

67

Ø		2	3		
Product Details	New	v Pack	Attachme	nts	
(i) All fields are mandatory, except	for those labeled as c	ptional.			
Registration Status Co	untry Origin	÷			
11/15					
Country (i)					
	-				
Name Of Regulatory Authority ③		MAH Name ③			
Name of Regulatory Authority		MAH Name			
Date Of Approval (i)		Date Of Marketing ③			
dd/mm/yyyy	× 🗎	dd/mm/yyyy	× 🗎		
Country Of Origin Cerificate	ment				

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.

	58% Comp	leted	
Product Details	2 New Pack	Attachments	
(i) All fields are mandatory, e	xcept for those labeled as optional.		
Registration Status	Other Countries -		
Registration status			
Build your Registration status I	list 🕑	Add Registration Status	
scard		< Back Next >	Proceed to

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
- I. 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.

			60% Completed		
Produ	Juct Details	2 New Pack			
	(i) All fields are mandatory, except fo	r those labeled as optional.			
	Patent Status -				
	Patents				
	Build your Patents List		Add Patent Status		
Discard				K Back Next >	Proceed to Next Section

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)
- I. 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.

Product Details	New Pack	Attachments
() All fields are mandatory, except for those lab	eled as optional.	
Additional Information -		
15/15		
Physical Capsule Shell Detail (Optional) ()	Physical Coating Detail (Optional)	
Physical Capsule Shell Detail	Physical Coating Detail	
Finished Product Details (Optional) (i)	Finished Product Specification/Test/Method (Optiona	1) ()
Finished Product Details	Finished Product Specification	
Manufacturing Process Details (Optional) (i)	Change Of Batch Size (Optional) (i)	
Manufacturing Process Details	Change of Batch Size	
Animal Forms (Optional) (i)		
Animal Forms		

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.

stered Products						0
500 ML						Q
Pack Name	Class	Strength	Dosage Form	Expiration Date	Action	
augmantin	GSL Products	500 ML	Capsule	2018-03-01	<b>چې</b>	Pack
Showing 1 to 1 of 1 entr	ies		< 1 > Last			

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  $\clubsuit$  icon in Registered Packs table under the Actions column
- c. Proceed to renew product
- d. Review application
- e. Proceed to checkout

Select a pro	duct							
Products Name / Tra	de Name							
AUGMENTIN							Q	
Products Name / Tra	de Name 🛈							
AUGMENTIN								
Product Class			P	roduct Subclass				
Conventional Med	icines			N/A				
Active Ingredie	ents							
Active Ingredier	nt Name		D	escription				
* <sup>a</sup> amoxicillin Amoxicillin trihvdrate								
⊯ <sup>#</sup> amoxicillin			a	moxicillin				
⊮ <sup>#</sup> clavulanic ac	id		С	lavulanic acid (	as Potassium Cl	avulanate)		
Body System								
Body System			B	ody Subystem				
⊮ <sup>#</sup> INFECTIONS	3		A	NTIBACTERIA	L			
Registered I	Packs							
Pack Name	Strength	Pack Sizes	R	egistration ate	Expiry Date	ACTIONS	5	
Marwa - Pack for CPP	1	1			20/12/2018	\$	•	Renew Pack
02/03/2001	1	1						

Figure U: Drug Renewal - Product Details screen

Rule: For a medical product pack to be renewed, the pack should be expired or will be expired in 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.

legistered Products						
ZYRTEC						Q
Pack Name	Class	Strength	Dosage Form	Expiration Date	Action	
						Madif.
ZYRTEC	Conventional Medicines	500	Capsule	2024-03-19		Modify Pack

#### 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:

Iodification Types		
egend for the user that explains the co	lor for each minor variation	
Modification Type	Fees	
1A	1000 AED	
1B	1000 AED	
2A	4500 AED	
2В	1000 AED	

#### Figure W: Modification Type Fees

0 Modifications						
Modification Type						
1A	1B	2A	2B			

Figure X: Modification Legend

Rule ID	Rules
R1	For a medical product's details to be modified, the product must not be expired.

Ministry of Health & Prevention - UAE, all rights reserved

67

Rule ID	Rules
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

Select a pro	oduct				0 Modific	ations		
Products Name / Tr	ade Name				Modificati	on Type	100	
AUGMENTIN					14	1B	24	28
Products Name / Tr AUGMENTIN Product Class Conventional Medic Product Subclass N/A Active Ingredi	ade Name ① ines ents						<u>L</u> A	20
Active Ingredie	nt Name		Description					
amoxicillin			Amoxicillin trihy	ydrate				
amoxicillin			amoxicillin					
clavulanic acid			Clavulanic acid	l (as Potassium Cl	lavulanate)			
Body System	List							
Body System			Body Subysten	n				
INFECTIONS			ANTIBACTERI	AL				
Registered	Packs							
Pack Name	Strength	Pack Sizes	Registration Date	Expiry Date	ACTIONS			
Marwa - Pack	1	1	02/02/2019		/	•	Modify	
augmentinhg u	180 mggjhgu	1	06/01/2019	15/01/2020	/	•	Pack	

Figure Y: Minor Modification – Product Details Screen

## 2.2.3.2 Pack Details

To modify the pack details, the applicant must:

- a. Click on con 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 II

Display icon:  ${}^{\mathfrak{O}}$  allows the user to undo change

t Details	Pack Details		Attachments		
General Info			•		
General Information					
1/15			2 Modifications		
Pack Name			2 Modifications		
Augmentin			Modification Type	(j	
Was: Marwa Pack D			1A 1B	2A 2B	
Agent					
strength					
1 Shelf Life					
1					
Shelf Life Description					
1					
Storage Condition	st	orage Condition Description			
Do not store above 8°C	x = 1				
Manufacturer (Batch Beleaser)	In	dication			
Eva Pharma	10	0			
Liuma					
	Was	: 11- 9			

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

< Back Review		
Please take a moment to check that everything is correct. You can edit anything that's not right		
> Product Details	1	
> New Pack Details	1	
> Attachments	ľ	
✓ I Accept The General Terms And Conditions		
Discard	Submit	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
- ど 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 MOHAP's Payment Gateway (e-dirham).

Price	
Request For Issuance / Renewal Of GSL Product 100	
Registration Of New GSL Product 5000	
Total 5100	
Checkout	Proceed with Payment
Figure RR: Checkout Screen	

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 MOHAP'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		
<b>Conventional Veterinary</b>	5000 AED		
Biological	7000 AED		
GSL Product			
Natural Source Medicines	5000 AED		
GSL Product	5000 AED		

Ministry of Health & Prevention - UAE, all rights reserved

Product Class	Fees	
Medical Device	5000 AED	
Table 5: Drug Registration – Product Class Fees		

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

- Issue Certificate
- Reject Application
- Require Action from Applicant

Tips:

- 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 MOHAP officer for review where they could perform the following:

- Issue Certificate
- Reject Application
- ✤ Require Action from Applicant

Tips:

- 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
Туре1А	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 MOHAP officer for review where they could perform the following:

- Accept Variation
- Reject Application
- Require Action from Applicant

## Tips:

- Actions required by applicant is discussed in further detail in <u>Section 3</u>
- 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 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 Review         Application Type D           Submitted	rug Registration
Required		Application History
Actions	Application Details Required Actions 1 Certificates	
	> Product Details	
	> New Pack Details	
	> Attachments	

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 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 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 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 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





#### Figure DD: Submitted Application - Correction

39 of

Ministry of Health & Prevention - UAE, all rights reserved

	4/5 Unresolv Request(s)	red	^	*	
	Figure EE	: Field Cor	rection Tool		
Country			Product Form/ Dosage	Form	
Albania	\$	K -	Capsule		× *
F	Figure FF: Modified F	ield Figu	ıre GG: Unmo	dified Field	
Correction r 2801.2019 Remarks: test	equest			1/2 Unresolved Request(s)	~
<ul> <li>Product Detail</li> </ul>	ls				
Product					
Product Name/ 1	Trade Name 🕢				
Product Fo	orm/ Dosage Form				
Capsule		× *			
Product Descrip 1	ption/ Indication				
Multiple Sizes/	Accessories				
Ves (	No				
1					
Country					
Albania	_	X *			
Was: Aland Iola City	C <sub>obre</sub>				
1					
> Active Ingredi	ients				
> Attachments					
> Comments:					
				Submit Corrections	

#### Figure HH: Correction Screen

Display icons: <sup>O</sup> allows the user to undo change

Tips:

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

#### 3.2 **Sample Request**

In case a MOHAP officer requires an applicant to submit a sample to MOHAP 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

< Back Analysis	
Sample Request	
Officer Comment	
Sample Specification	
Sample Details	
Courier Company Name	
This field is required Tracking Number	
This field is required Send Date	
dd/mm/yyyy	
This field is required	
Ask For Clarification	Submit

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

Ask For Clarification

Figure JJ: Clarification Window

## Case B

For the applicant to provide sample details to MOHAP, 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 MOHAP 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

Appointment request 28-01-2019	
Remarks remarks of appointment	
Appointment Date 09-02-2019 Time 11.23 AM GMT+04:00 Location Ministry of Health – Drug Registration Department	
Suggest New Appointment	Accept

#### 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.

Appointment Date	×
09/02/2019	
Time (Optional)	
HH : MM AM	
Leave A Comment (Optional)	
Cancel	Submit

Figure LL: New Appointment Window

## 3.4 Analysis Request

As part of the New Drug Registration, Drug Renewal or Minor Variation\* reviewing process, a MOHAP 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 <u>Section 3.1</u>
- 2. Sample <u>Section 3.2</u>
- 3. Appointment <u>Section 3.3</u>

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

Review Results	
Remarks	
Analysis Result Analysis after first Consignment but file completion required before Pricing	
Re-Analysis	Accept

#### 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 <u>section 5.3</u>.

## 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 analysis will 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 MOHAP officer might request an applicant to submit a Pharmacovigilance (PV) plan. This PV plan requires an 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 applicant to PV screen
- b. Attach PV plan
- c. Click on Submit button
- d. Confirm submission



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 <u>Section 5.4.1</u> to learn about the PV Approval Letter.
- Please refer to <u>Section 5.4.2</u> 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 MOHAP 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 MOHAP 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 MOHAP 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 Price

## Case 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 1000

## Case 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

Remarks		
Sed ut perspiciatis unde omnis iste natus error sit voluptatem accusantium doloremque laudantium, totam rem aperiam, eaque ipsa quae ab illo inventore veritatis et quasi architecto beatae vitae dicta sunt explicabo.		
Pack Size Pack Size (Numbers) Pack Size Unit Pricing Pack Size (Optional) Pricing Pack Unit (Optional)		
Proposed Price Proposed CIF (Optional) Currency (Optional)	Approved Price Approved CIF Currency (Optional)	
Appeal	Accept	

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 will be 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 MOHAP officer might request an applicant to resubmit an application to get approval for a product's Release to Market Certificate.

In case the drug application needs correction, the MOHAP Pricing officer will send it to applicant after identifying fields/attachments in application that require modification. For this

49 of

67

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 **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 MOHAP officer might request for a Stability Study to be conducted before proceeding with application.

## 3.8.1 Correction

The MOHAP 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 attachments
- 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 MOHAP 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-Evaluation

## Case 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 Acceptance

## Case 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 MOHAP 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 MOHAP 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 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.

## 3.9.2 Rejection

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

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

Back Bio-equivalence Request		
Initial Rejection		
Remarks Wisi labore vel te, cibo docendi consectetuer usu in. An sea utroque facilis dissentiet, an cum erat sale deseruisse, has admodum albucius facilisi cu. Id vis justo utinam vocent, pri cu officiis senserit expetenda. Ius idque probatus ne, electram dignissim interesset mel no. Quis magna etiam ad sea, probo impedit ne sea, in eos meis ludus comprehensam. Vix principes posidonium ad, in sed vitae numquam. Ex qui audiam intellegebat, congue populo luptatum an vix, ea sed aperiri eleifend argumentum.		
Re-Evaluate Accept		
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 applicant to BE screen
- b. Select Accept Rejection
- c. Confirm Acceptance

## Case 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 applicant to 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.

53 of Ministry of Health & Prevention – UAE, all rights reserved

67

# 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
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!

Application History

## 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 MOHAP Officer's rejection comments
- c. Proceed to submit application

Resubmit Application	< ────────────────────────────────────	Application Type Drug Registration Submitted On:01/04/2019
	Application Details Required Actions () Certificates	Application History     Application History
> Product Details		
	> New Pack Details	
	> Attachments	

Figure RR: Submitted Application Screen – Application Details

## 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:

- 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

	Expired			Application Type:Drug Registration Submitted On:15/01/2019
Open Certificates	Application Details Required Actions 0	Certificates		Application History
	Certificate	Issue Date	Expiry Date	Print
	Drug Registration	2019-01-15T10:05:09	2024-01-15T10:05:09	C Attachment

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
  - o Pack Size
  - Pack Size Presentation
  - o Dispensing Mode
  - o 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 MOHAP will 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
  - o Quantity
- Inactive Ingredient (Multiple line)
  - o Inactive ingredient
  - o 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

Ministry of Health & Prevention – UAE, all rights reserved

67

- 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

#### **Appendix I** 6.1

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)		
60 of Ministry of Health & Prevention – UAE, all rights reserved		

Ministry of Health & Prevention - UAE, all rights reserved

Documents		
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)		
Relation-ship letter between two parties (if batch releaser & bulk manufacturer are		
different) (in PDF format)		
Copy of the manufacturing site registration certificate for batch releaser & hulk		
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 unit		
dose 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) (in		
PDF 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		
61 of Ministry of Health & Prevention – UAE, all rights reserved		

Ministry of Health & Prevention - UAE, all rights reserved

67

	Documents	
Module 3		
Module 4		
	TABLE 11: LIST OF ATTACHMENTS	

# 6.2 Appendix II

List of fields that are open for minor variation

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

Ministry of Health & Prevention - UAE, all rights reserved

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

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

Ministry of Health & Prevention - UAE, all rights reserved

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

Section Name	Field Name
	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
	Price Type
Reference Prices For each Pack Size (Multiple Record)	Country
	Exfactory Price
	Currency
	Wholesale price
	Currency
	Public price
	Currency
	Reference Book
	Support Document

TABLE 12: OPEN MV FIELDS

# 6.3 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	

Ministry of Health & Prevention - UAE, all rights reserved

Attachment Name	Mandatory
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 each class	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