



External User Guide

Approval of the Pharmacovigilance Officer for Pharmaceutical Establishments

Table of Contents

1. Brief Overview	3
2. Apply for Service	3
2.1 Create a New Application.....	4
2.1.1 PV Officer	5
2.1.2 Market Authorization Holder(s).....	6
2.1.3 Attachments	6
2.1.4 Review Application	7

1. Brief Overview

This manual is prepared to help applicants Apply for Approval of Pharmacovigilance Officer.

After completing this manual, the applicant should be able to perform all activities related to Approval of Pharmacovigilance Officer on EDE Portal.

Please note: This service is available to the **Local Manufacturers/ Medical Store /Scientific Office** 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.

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

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

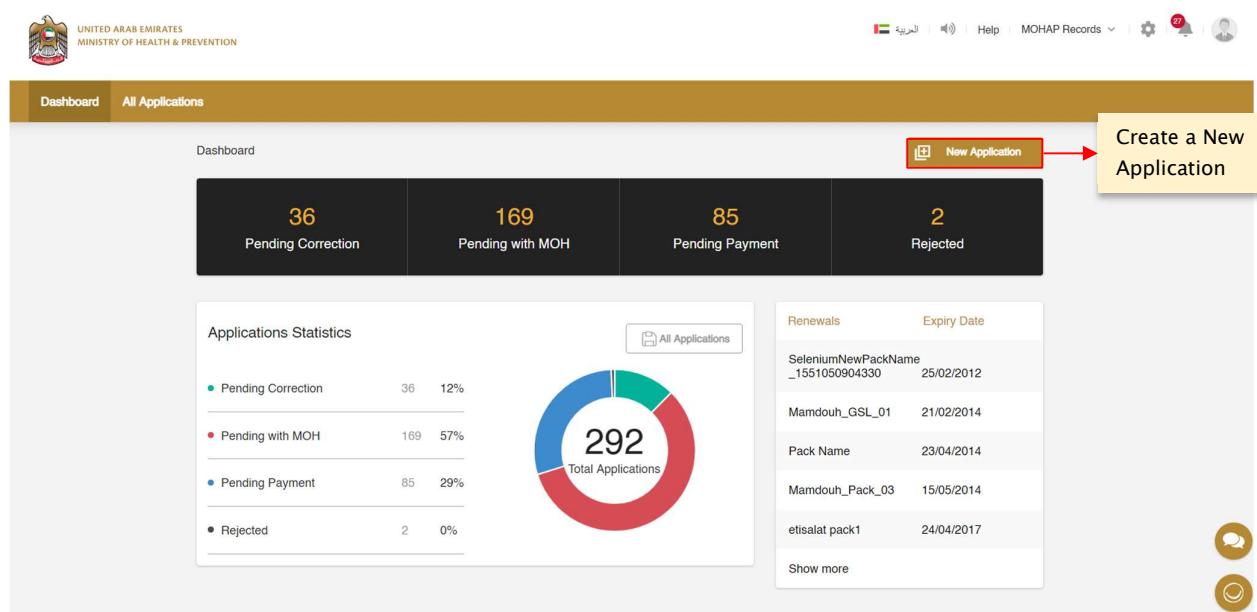


FIGURE A: DASHBOARD SCREEN

2.1 Create a New Application

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

- a. Click on the **New Application**
- b. Select **Pharmaceutical Vigilance** ➔ **Registration** ➔ **Approval**
- c. Click Create Application button

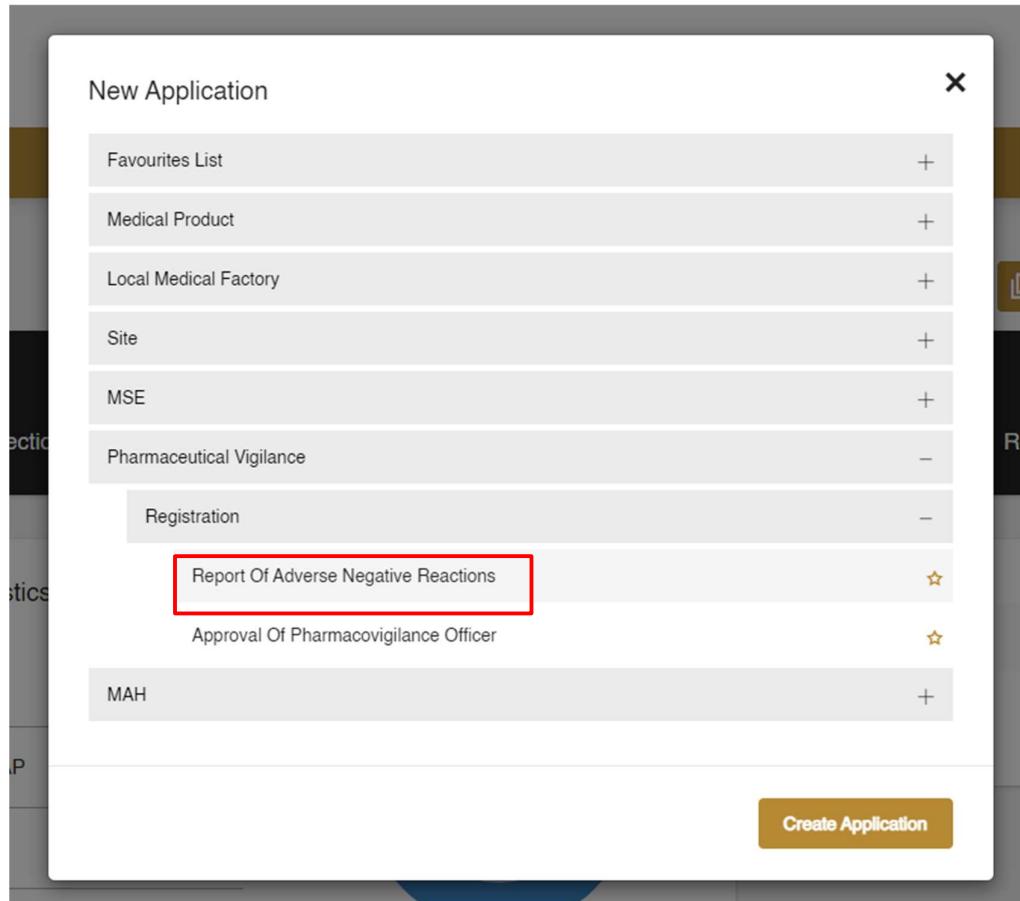


FIGURE B: NEW APPLICATION SCREEN

To complete the **Approval of Pharmacovigilance Officer**, the applicant must fill the following sections:

1. PV Officer
2. Market Authorization Holder(s)
3. Attachments

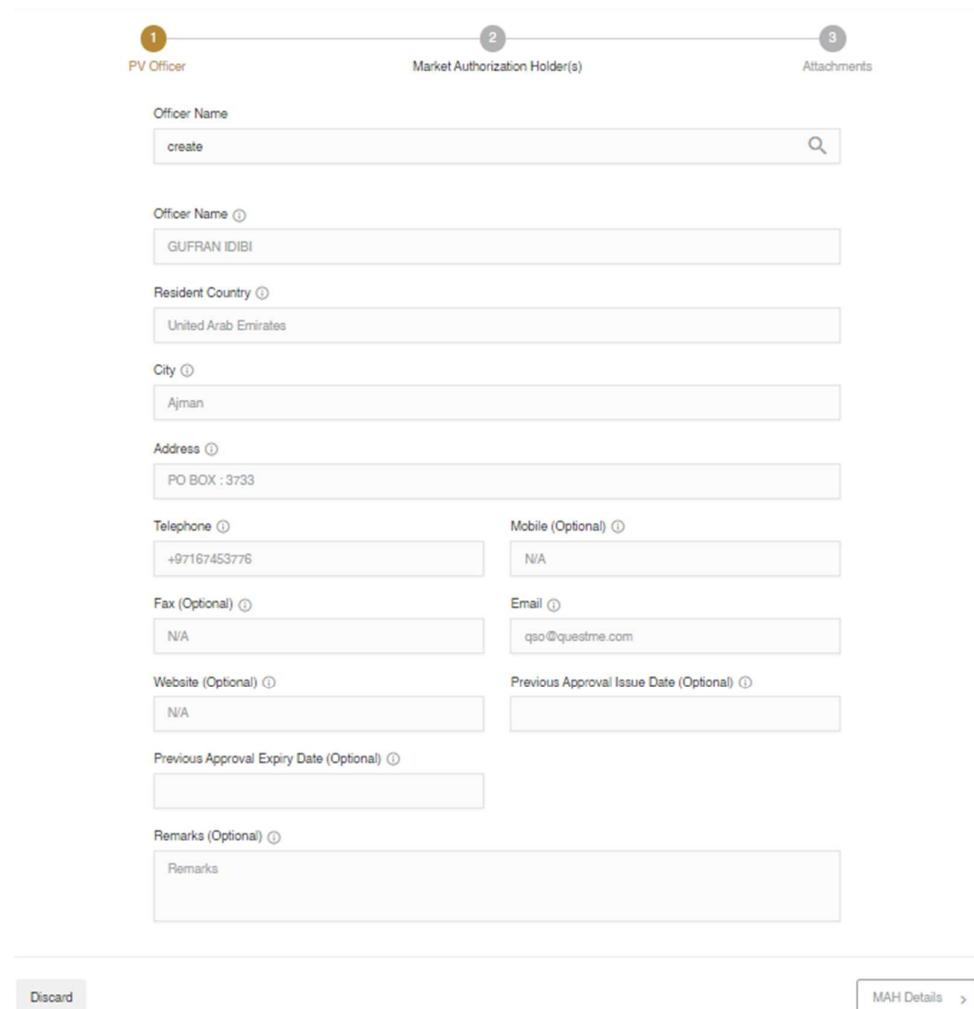


FIGURE C: PROGRESS BAR**2.1.1 PV Officer**

Applicant can search PV officer in the search bar and check if the PV officer was previously registered, the below data will be auto-populated.

If the PV Officer is not recognized, then applicant can create new PV Officer and fill the mandatory fields.

- Officer Name
- Resident Country
- City
- Address
- Telephone
- Mobile (optional)
- Fax (Optional)
- Email
- Website (Optional)
- Previous Approval Issue Date (Optional)
- Previous Approval Expiry Date (Optional)
- Remarks (Optional)



The screenshot shows a registration form for a PV Officer. At the top, there is a horizontal progress bar with three numbered circles: 1 (PV Officer), 2 (Market Authorization Holder(s)), and 3 (Attachments). Below the progress bar, the form fields are arranged in a grid. The fields are as follows:

Officer Name	GUFRAN IDIBI
Resident Country	United Arab Emirates
City	Ajman
Address	PO BOX :3733
Telephone	+97167453776
Fax (Optional)	N/A
Mobile (Optional)	N/A
Email	qso@questme.com
Website (Optional)	N/A
Previous Approval Issue Date (Optional)	
Previous Approval Expiry Date (Optional)	
Remarks (Optional)	Remarks

At the bottom of the form, there are two buttons: "Discard" on the left and "MAH Details >" on the right.

FIGURE D: PV OFFICER

Applicants can move to the next section by clicking MAH Details button.

2.1.2 Market Authorization Holder(s)

In This Section the Applicant is required to search and select the Market Authorization Holder(s).

The Applicant can Select and Add Multiple Market Authorization Holders by clicking on Select MAH

The screenshot shows a progress bar at the top indicating '50% Completed'. Below it is a navigation bar with three steps: 'PV Officer' (step 1), 'Market Authorization Holder(s)' (step 2, highlighted in orange), and 'Attachments' (step 3). The 'Market Authorization Holder(s)' section contains a table with two rows of data. The columns are 'MAH Name', 'Country', 'City', 'Address', and 'ACTIONS'. The first row is for 'waymade Plcs' (United Kingdom, Basildon, address: sovereign house , miles gray road basildon , essex , united kingdom). The second row is for 'i.com medical GmbH' (Germany, Munich, address: Kaflerstr. 15, Postal Code 81241, Munich). A red box highlights the 'Select MAH' button at the bottom right of the table. Below the table are buttons for 'Discard', 'PV Officer', 'Attachments', and 'Next'.

MAH Name	Country	City	Address	ACTIONS
waymade Plcs	United Kingdom	Basildon	sovereign house , miles gray road basildon , essex , united kingdom	
i.com medical GmbH	Germany	Munich	Kaflerstr. 15, Postal Code 81241, Munich	
2				Select MAH

FIGURE E: MARKET AUTHORIZATION HOLDER(S)

Applicants can move to the next section by clicking Attachments button.

2.1.3 Attachments

Below are the attachments the applicant must upload before moving to the next section.

- Appointment Letter
- Educational Certificate
- Training Certificates (PV Related)
- Experience Letter
- List Of Products
- PV Standard Operations Procedures
- CV
- Domestic ADR Reports
- Previous PV Officer Approval Letter (If Available) (Optional)

1 PV Officer 2 Market Authorization Holder(s) 3 Attachments

Required Attachments

Appointment Letter
Please attach a copy of Appointment letter
New File

Educational Certificate
Please attach a copy of Educational certificate
New File

Training Certificates (PV Related)
Please attach a copy of Training certificates (PV Related)
New File

Experience Letter
Please attach a copy of Experience letter
New File

List Of Products
Please attach a copy of List of Products
New File

PV Standard Operations Procedures
Please attach a copy of PV Standard Operations Procedures
New File

CV
Please attach a copy of CV
New File

Domestic ADR Reports
Please attach a copy of Domestic ADR reports
New File

Previous PV Officer Approval Letter (If Available) (Optional)
Please attach a copy of Previous PV officer approval letter (if available)
New File

Document Name

Discard MAH Details Review >

FIGURE H: ATTACHMENTS

2.1.4 Review Application

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:

- a. Edit Application
- b. Discard Application
- c. Read & Accept General Terms & Conditions
- d. Submit Application

[Back](#) **Review**

Please take a moment to check that everything is correct. You can edit anything that's not right.

> PV Officer	
> Market Authorization Holder(s)	
> Attachments	

I Accept The General Terms And Conditions

[Discard](#) **Submit**

FIGURE I: REVIEW APPLICATION SCREEN

NOTE: THIS SERVICE IS FREE OF COST.