

## External User Guide

### Approval of the Pharmacovigilance Officer for Pharmaceutical Establishments

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## 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.

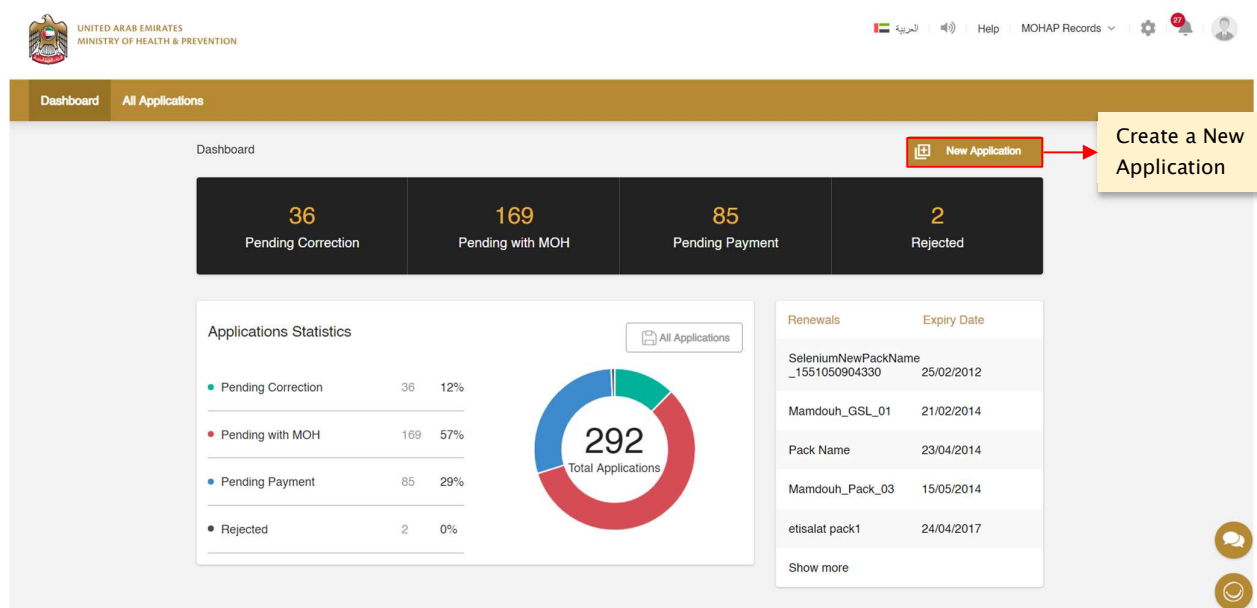


FIGURE A: DASHBOARD SCREEN

## 2.1 Create a New Application

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

- Click on the **New Application**
- Select **Pharmaceutical Vigilance** ➡ **Registration** ➡ **Approval Of Pharmacovigilance Officer**.
- Click Create Application button

The screenshot shows a 'New Application' modal window. It contains a list of application types, each with a '+' or '-' icon to expand or collapse it. The expanded 'Pharmaceutical Vigilance' section shows 'Registration' (with a '-' icon) and 'Report Of Adverse Negative Reactions' (with a star icon and highlighted by a red box). Below it, 'Approval Of Pharmacovigilance Officer' is also visible with a star icon. At the bottom right, there is a 'Create Application' button.

FIGURE B: NEW APPLICATION SCREEN

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

- PV Officer
- Market Authorization Holder(s)
- 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 web form for registering a PV Officer. At the top, there is a progress bar with three steps: 1. PV Officer, 2. Market Authorization Holder(s), and 3. Attachments. The first step is active. Below the progress bar, there is a search bar for 'Officer Name' with the text 'create' and a magnifying glass icon. Below the search bar, there are several text input fields for the officer's details: Officer Name (with a help icon), Resident Country (with a help icon), City (with a help icon), Address (with a help icon), Telephone (with a help icon), Mobile (Optional) (with a help icon), Fax (Optional) (with a help icon), Email (with a help icon), Website (Optional) (with a help icon), Previous Approval Issue Date (Optional) (with a help icon), Previous Approval Expiry Date (Optional) (with a help icon), and Remarks (Optional) (with a help icon). At the bottom of the form, there are two buttons: 'Discard' and 'MAH Details >'.

**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

50% Completed

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

Market Authorization Holder(s)

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

Discard < PV Officer Attachments >

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

**i** - Supported files MS office, Images and PDF files

- Maximum file size is 10 MB
- Please note that all attachments are mandatory except the ones have the word (Optional) at the end of the document name
- Please note that some attachments have a specific requirement that will be mentioned in front of each attachment

### Required Attachments

<p><b>Appointment Letter</b> Please attach a copy of Appointment letter</p> <p> New File</p>	<p><b>Educational Certificate</b> Please attach a copy of Educational certificate</p> <p> New File</p>
<p><b>Training Certificates (PV Related)</b> Please attach a copy of Training certificates (PV Related)</p> <p> New File</p>	<p><b>Experience Letter</b> Please attach a copy of Experience letter</p> <p> New File</p>
<p><b>List Of Products</b> Please attach a copy of List of Products</p> <p> New File</p>	<p><b>PV Standard Operations Procedures</b> Please attach a copy of PV Standard Operations Procedures</p> <p> New File</p>
<p><b>CV</b> Please attach a copy of CV</p> <p> New File</p>	<p><b>Domestic ADR Reports</b> Please attach a copy of Domestic ADR reports</p> <p> New File</p>
<p><b>Previous PV Officer Approval Letter (If Available) (Optional)</b> Please attach a copy of Previous PV officer approval letter (if available)</p> <p> New File</p>	

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.