# Evaluation of Pharmacovigilance Plan for Pharmaceutical Facility and its Subsidiaries

This service enables pharmaceutical companies and their subsidiaries to apply for their pharmacovigilance plan to be evaluated for registering and marketing medicines within the UAE.

**Department name**
Drug

**Sector**
Health Regulation

**Main Service**
Pharmaceutical vigilance

**Service Code**
110-45-002-000

**Service Classification**
Transactional

**Variation / Auxiliary**
Variation

**Service Type**
Government to Business

## Service Process

01 To apply for e-services, create an account on MOHAP website or smart app with a username and password.

02 Log in to the e-system to start the service.

03 Apply for Evaluation of the Plan (within the Drug Registration File).

04 Application will be studied by the staff concerned, who will make the necessary recommendations.

05 PV plan will be adopted.

06 Approval will be issued and delivered to the applicant.

## Required Documents

- The role and responsibilities of the manufacturer regarding PV
- Compliance monitoring and pharmacovigilance inspections
- Role of the Qualified Person Responsible for Pharmacovigilance (QPPV)
- Pharmacovigilance Plan of the company
- Organizational chart of the company
- Quality Management System
- Risk Management Systems requirement: Clinical & non-clinical studies of the drug's safety specifications
- Drugs' adverse events/adverse reactions
- Clarification and identification of potential interactions, including food-drug and drug-drug interactions
- Epidemiology
- Risk Minimization Plan
- Requirements for expedited reporting of the side effects of patients (Individual Safety reports)
- Requirements for reporting for patients in special situations (Individual Case Safety Special Situation)
- Requirements for Periodic Safety Update reports or Periodic Benefit Risk reports
- QPPV training plan
- Documentation of PV system

## Requirements & Conditions

- Clarification of the roles and responsibilities of the manufacturer regarding pharmacovigilance.
- Clarification of plan for monitoring compliance and inspection of pharmaceutical products.
- Appointment of a qualified person to be the responsible pharmacovigilance officer.

## Service Channels

MOHAP Website: www.mohap.gov.ae

## Resources

- User Manual - Registration Services

**Average Service Time**
10 working days

**Payment channels**
E-Payment

**Target Audience**
Marketing offices, medical drug stores, and local pharmaceutical factories

**Service Locations**
- MOHAP website
  www.mohap.gov.ae

**Related Services**
This service is not linked to any other services

**Service Bundle**
This service is not linked to any bundles

**Contact Details**
**Email:**
smartservicessupport@mohap.gov.ae

## Service Fees

AED 1,000

## Sustainable Development Goals


## Notes

None

## FAQs

**None.**