UNITED ARAB EMIRATES
MINISTRY OF HEALTH & PREVENTION

الإمارات العربية المتحدة
وزارة الصحة ووقاية المجتمع

Evaluation of Pharmacovigilance Plan for Medical Products within UAE

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

Main service

Pharmaceutical vigilance

Service code

110-45-002-000

Service classification

- Government to business

Service type

Transactional

Service process

1. Login to the MoHAP website or smart app using the UAE PASS
2. Log in to the e-system to start the service
3. Apply for Evaluation of the Plan (within the Drug Registration File)
4. Application will be studied by the staff concerned, who will make the necessary recommendations

Service completion duration

3 working days

Payment channels

E-payment

Target audience

Marketing Offices
Medical drug stores
Local pharmaceutical factories

Service locations

MOHAP Website

Support

smartservicessupport@mohap.gov.ae

Service fees

Evaluation of PV Plan for pharmaceutical establishment and its subsidiaries: AED 1,000

SDGs Goals

3 GOOD HEALTH AND WELL-BEING

5 PV plan will be adopted

6 Approval will be issued and delivered to the applicant

Required documents

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

Conditions and requirements

- 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

1. MOHAP smart app

Resources

- User Manual - Registration Services-498.pdf
- Infographic - Evaluation of Pharmacovigilance Plan for Pharmaceutical Facility and its Subsidiaries - 358KB.pdf
- UAE MOHAP GVP Guidelines ver 13-581.pdf