



MINISTRY OF HEALTH

Pharmacovigilance Requirements in Kuwait

A Comprehensive Guide to the Kuwait Good Pharmacovigilance Practice (KuGVP) Guidelines

The Guardians of Patient Safety

Ministry of Health

Drug and Food Control (KDFC)

Kuwait Pharmacovigilance Center (KPVC)

- Operates with autonomy to detect, assess, and prevent adverse effects.



NEWKUWAIT

Vision & Mission:

To support patient safety by ensuring high-quality, safe, and effective medicinal products through the New Kuwait healthcare vision.



International Alignment:

Kuwait is full member #145 of the WHO Programme for International Drug Monitoring (WHO PIDM).

Governance: Global Oversight vs. Local Responsibility



The Global QPPV

Qualified Person for PV

Location: Resides at MAH Headquarters

Scope: ONE QPPV per Pharmacovigilance System

Role: Responsible for overall system and risk-benefit balance. Ensures LSR has access to PSMF.



The Local LSR



Local Safety Responsible

Location: MUST reside in Kuwait

Appointment: Designated by the local agent

Scope: Max 7 PV systems per LSR

Role: 24-hour contact point for KPVC. Ensures local submission compliance.

Qualification Standards for PV Officers



QPPV Requirements

- **Education:** Bachelor's in Pharmacy/PharmD or Medical Degree.
- **Experience:** Minimum 2 years in PV.
- **Skills:** Knowledge of epidemiology, biostatistics, and risk management.



LSR Requirements

- **Education:** Bachelor's in Pharmacy or Medicine.
- **Availability:** Resident in Kuwait. Available 24/7 for urgent KPVC requests.

Transitional Provision: Due to the novelty of PV in Kuwait, training certifications may substitute for practical experience during the transitional development stage of the local industry.

The Documentation Framework: PSMF & PSSMF



PSMF (Global)

Pharmacovigilance System Master File

Describes the global system. Maintained by QPPV. Must be accessible to LSR.

PSSMF (Local)

Pharmacovigilance Sub-System Master File

Specific to Kuwait. Contains local SOPs, reporting channels, local safety data sources, and LSR contact details.

Objective: Ensures detailed operational control over the local PV system.

Digital Infrastructure: The VigiFlow Ecosystem



Requirement: MAHs must ensure data compatibility and reporting through these established channels.

Operational Workflow: Spontaneous Reporting

The 4 Pillars of a Valid Report

-  **1 Identifiable Patient**
(Initials, age, sex)
-  **2 Identifiable Reporter**
(Contact details)
-  **3 Suspected Drug**
(Name, batch number)
-  **4 Adverse Event**
(Description of reaction)

Reporting Channels



Primary: Online via VigiFlow



Mobile: Via the Sahel App



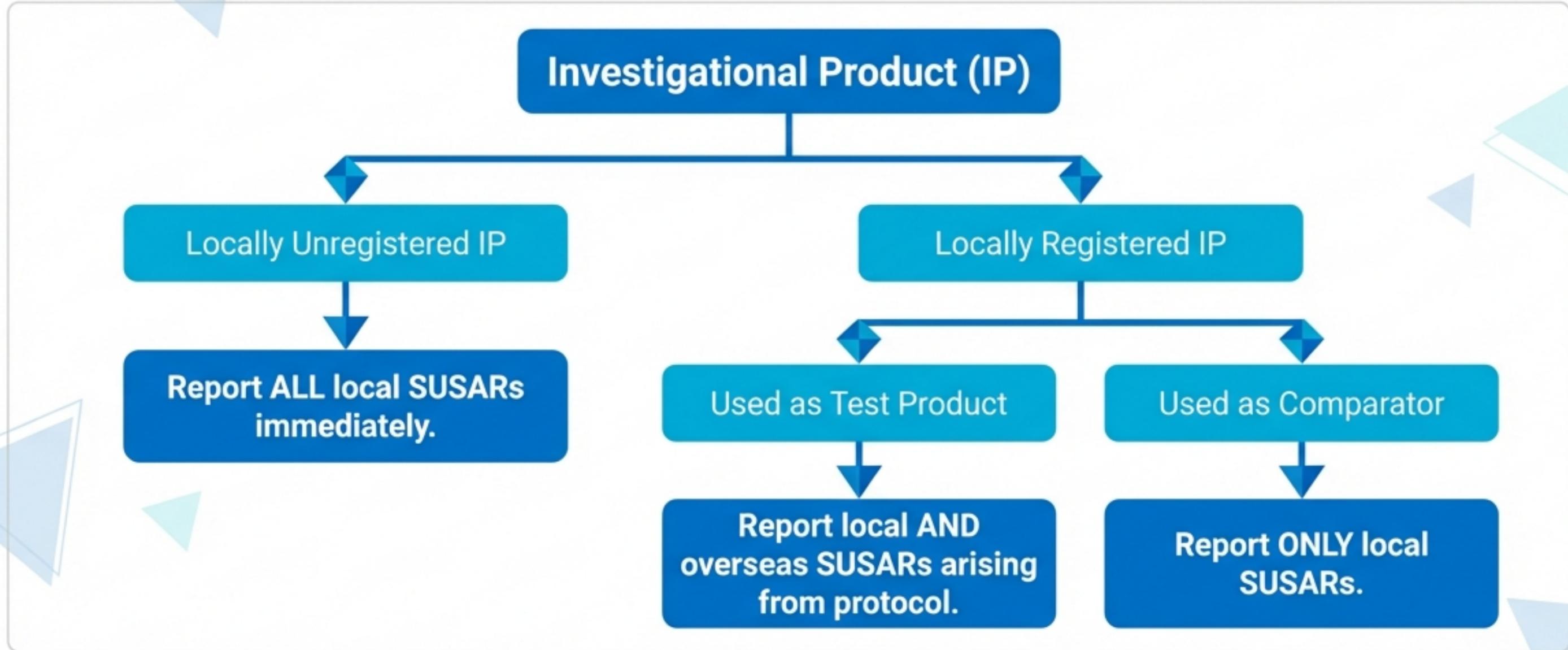
Direct Email

adr_reporting@moh.gov.kw

What to Report: ADRs, Lack of Efficacy, Medication Errors, Overdoses.

Clinical Development: Managing SUSARs

Suspected Unexpected Serious Adverse Reaction

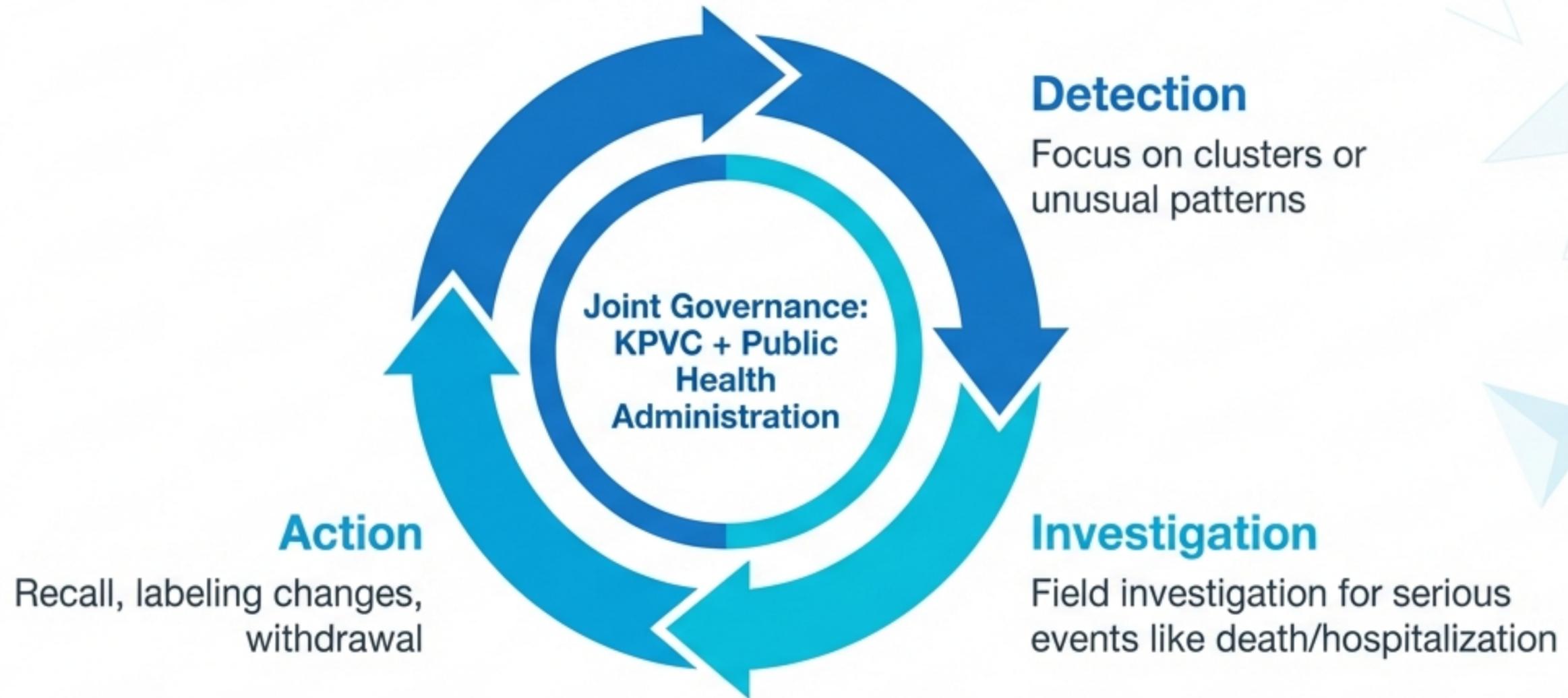


Scope: Applies to Therapeutic Products (TP) and Medicinal Products (MP) in clinical development. Sponsors must report to KPVC immediately.

Vaccine Safety: The AEFI Surveillance System

Adverse Events Following Immunization

VAER System (Vaccine Adverse Event Reporting)



“Minimize harm and risks while maximizing known benefits.”

Signal Management: From Data to Action

Bento Box

Detection

Reviewing VigiBase and local data for new risks.

Validation

Using the Pharmacovigilance Issues Tracking Tool (PITT).

Assessment

Conducted by KuPRAC (Kuwait Pharmacovigilance Risk Assessment Committee).

Escalation

Prioritizing signals based on public health impact.

Bento Box: KPVC maintains a mandatory audit trail of all signal detection activities.

Proactive Safety: RMPs and Periodic Reporting

Risk Management Plan (RMP)

- **Trigger:** New molecules, significant changes (dosage, route), or KPVC request.
- **Goal:** Identify risk factors and apply minimization measures.

PBRER

- Periodic Benefit-Risk Evaluation Report.
- Mandatory submission to evaluate benefit-risk balance over product lifecycle.

Generics Rule: Abridged PBRERs are accepted for generic medicinal products.

Safety Communication: The DHPC Protocol

Dear Healthcare Professional Communication

Triggers for DHPC

- ▶ New major warnings or precautions.
- ▶ Change in frequency/severity of known risks.
- ▶ Product withdrawal or lack of efficacy.

The Workflow

1. MAH notifies KPVC. **(MUST be before dissemination)**
2. KPVC Review.
3. Dissemination to Healthcare Professionals.
4. Publication on MOH Website.

Institutional Oversight: The Pharmacovigilance Focal Point

Contact:

Single point of contact for KPVC.



Culture:

Promote reporting among staff.

Coordination:

Manage ICSR submission.

Pharmacovigilance Focal Point (PVFP)

Eligibility: MUST be a licensed Pharmacist. (Cannot be a physician or nurse).

Records:

Maintain internal traceability.

Scope: Government Hospitals, Private Hospitals, and Medical Clinics.

Regulatory Oversight: Audits & Inspections

Audit	Inspection
Purpose: Assess QUALITY and EFFICIENCY of the system.	Purpose: Assess COMPLIANCE with laws.
Type: Internal or by KPVC.	Triggers: Risk-based (High volume, non-compliance, failure to report).

Outcome

1. Findings require CAPA (Corrective Action Preventive Action) plans.
2. Note: Inspectors must be Pharmacists with PV experience.

Vital Connections Blue Helvetica Now Display

Partnering for a Safer Kuwait

Reporting Email:

adr_reporting@moh.gov.kw

General Enquiries:

pv-info@moh.gov.kw

Location: Al-Sabah Medical Town,
Kuwait Drug and Food Control.



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VigiServe Foundation