



RISK COMMUNICATION AND AWARENESS PLAN OF PHARMACOVIGILANCE ACTIVITIES

Document Number: PHSR/PL/AR/002
Document History: 1st Edition
Effective Date: 17-06-2025

National Pharmacovigilance Centre
Drug Regulatory Authority of Pakistan
Islamabad- Pakistan



Table of Contents

1	<i>HISTORY</i>	3
2	<i>APPLICATION</i>	3
3	<i>PURPOSE</i>	3
4	<i>SAFETY COMMUNICATION</i>	4
5	<i>DEFINITION AND ACRONYMS:</i>	4
6	<i>Strategic Action Points for Communication</i>	6
7	<i>Regulatory and Compliance requirements</i>	6
8	<i>Role and Responsibilities</i>	7
9	<i>Risk Identification and Assessment Process</i>	7
10	<i>Awareness and Education</i>	8
11	<i>Risk Communication & Awareness Tools</i>	9
12	<i>Implementation Plan</i>	10
13	<i>Types of Communications</i>	10
14	<i>Crisis Communication Plan</i>	12
15	<i>Appendices</i>	13



1 HISTORY

This is the first edition of this document.

2 APPLICATION

- i. Risk communication and awareness are linked activities and each complements the other with the common objective of educating the stakeholders, while providing true and accurate information.
- ii. Applies to all registered therapeutic goods (pharmaceutical products and vaccines).
- iii. Covers coordination and communication of information to healthcare professionals, patients, Regional Pharmacovigilance Centres (Provincial Pharmacovigilance Centres/ Provincial health departments, Public Health Programmes), healthcare facilities and media.

3 PURPOSE

Enhancing stakeholder engagement and systematically communicating therapeutic goods safety risks to healthcare professionals (HCPs), patients, public and other relevant stakeholders is important to increase AE reporting, ensure timely, accurate, actionable information, minimize harm and promote safe use.

This document outlines the steps in communication and awareness of safety information as a routine procedure and addresses preparedness during crisis. Certain elements of this document will also be useful in harmonising and evaluating the communication and awareness process and enhancement or improvement of these with time.





4 SAFETY COMMUNICATION

Communication involves keeping the public informed about the investigation, results, and actions already taken or to be taken regarding the ADR/AEFI. At the same time, it is crucial to highlight the benefits of the treatment/immunisation even while communicating about an investigation.

Risk communication is an important part of pharmacovigilance when a safety investigation is underway as a result of a report of an ADR/AEFI.

4.1 Objectives

- i. Ensure compliance with *Pharmacovigilance Rules, 2022* and international standards (ICH, WHO).
- ii. Ensure timely, transparent, and accessible communication of pharmacovigilance data to healthcare professionals (HCPs), patients, and stakeholders.
- iii. Facilitate rapid dissemination of critical safety information (e.g., new adverse drug reactions, contraindications).
- iv. Promote active reporting of adverse drug reactions (ADRs) and foster collaboration with regional/international partners.
- v. Strengthen integrity of regulatory oversight through transparency, addressing public concerns and contextualizing risks within Pakistan's healthcare landscape.
- vi. Empower stakeholders to make informed decisions about therapeutic goods.

4.2 Principles of Communication

These principles are applicable to most if not all audiences. These include the need to:

- i. listen empathetically to concerns;
- ii. reassure and support but do not make false promises;
- iii. communicate frequently;
- iv. build-up and maintain the relationship among the stakeholders;
- v. inform audiences about possible common adverse events and how to handle them;
- vi. prepare fact sheets on adverse events and other key information for all audiences;

5 DEFINITION AND ACRONYMS:

ADRs	Adverse Drug Reactions
AEFIs	Adverse Events Following Immunisation
DRAP	Drug Regulatory Authority of Pakistan
GBT	Global Benchmarking Tool
HCPs	Healthcare Professionals
ICH	International Council of Harmonization



MAH	Marketing Authorisation Holders
MSW	Med Safety Week
NPC	National Pharmacovigilance Centre
PBRERs	Pharmacovigilance Benefit Risk Evaluation Reports
PPCs	Provincial Pharmacovigilance Centre
PHPs	Public Health Programmes
PSUR	Periodic Safety Update Reports
PV	Pharmacovigilance
QMS	Quality Management System
RMPs	Risk Management Plans
WHO	World Health Organisation
UMC	Uppsala Monitoring Centre





6 Strategic Action Points for Communication

6.1 For communication to be effective and realistic, it may be done in two stages:

- i. sharing preliminary information at the initial stage and sharing
- ii. the final data/report after completion of the investigation/causality assessment.

6.2 It is required to establish strong communication channels and effective communication considering the following points:

- i. Communication with patients and the public, pharmacovigilance officers in regional/sub-regional centres and healthcare facilities, other government/ non-government organisations/stakeholders and the media.
- ii. Build confidence in the healthcare system, by avoiding false and misleading information. Being aware of the risks and benefits of the treatment/immunization and the progress and findings of the investigation will enhance accuracy of risk estimates which otherwise if shown to be incorrect can contribute to a breakdown of trust among the people involved.
- iii. Communication from DRAP can give assurance from a place of authority with knowledge and expertise in the subject.
- iv. If there is uncertainty about ADR/AEFI, it should be acknowledged. There should be a full investigation, and the community should be kept informed. Premature statements about the cause of the event before the investigation is complete should be avoided.
- v. If the cause is identified as medication/immunisation-related error, it is vital not to lay personal blame on anyone, but to focus on system-related problems that resulted in the error(s) and the steps being taken to correct them.
- vi. Having a communication plan in advance, will minimize the negative impact of AEFI-related matters.

6.3 Communication with healthcare professionals, pharmacovigilance officers, by pharmacovigilance centres (national/regional/sub-regional), regulatory bodies (DRAP, Provincial Governments, healthcare commissions/authorities etc.) and investigators should be sensitive to their needs. Therefore:

- i. Communication should include all levels of health authorities involved.
- ii. Reassure the healthcare professionals of their knowledge, ability, skills and performance.
- iii. Do not blame healthcare professionals and staff but focus on the correction and quality of the national immunization programme.
- iv. Keep healthcare professionals and staff updated on the investigation process, progress, and findings.

7 Regulatory and Compliance requirements

7.1 DRAP Act 2012 and Pharmacovigilance Rules 2022.

7.2 Drugs Act 1976.

7.3 WHO Global Benchmarking Tool (GBT) for pharmacovigilance.

7.4 ICH E2C(R2) guidelines on periodic benefit-risk evaluation.



7.5 Compliance Obligations for Marketing Authorisation Holders (MAH)

- i. Submit Risk Management Plans (RMPs) and Periodic Safety Update Reports (PSURs) to DRAP.
- ii. Notify critical risks within 72 hours to provincial health departments and HCPs.

8 Role and Responsibilities

NPC, DRAP	Validate clinical relevance of risks, Lead risk assessment, signal detection, and approval of communication materials, Develop/distribute alerts
CEO Office/QMS	Manage media inquiries, and update DRAP's official website for safety alerts.
PPCs/ PHPs	Disseminate alerts to healthcare facilities / provincial chapters of PHPs and circulate advisories to HCPs.
Pharmaceutical Companies	Provide updated product information and support risk minimization through active surveillance of registered therapeutic goods, patients safety programmes, submission of PBRERs and PSURs

9 Risk Identification and Assessment Process

9.1 Data Sources

- i. Adverse Drug Reaction (ADR) reports in National Database.
- ii. WHO VigiBase and international regulatory safety alerts.
- iii. RMPs, PSURs, PBRERs

9.2 Risk Evaluation Criteria

- i. **Severity:** Seriousness criteria (Life-threatening, hospitalization, disability etc.)
- ii. **Frequency:** Common (>1%), rare (<0.1%) / Cluster reports
- iii. **Causality Assessment:** WHO-UMC causality assessment criteria.
- iv. **Benefit-Risk Analysis:** Based on ICH E2C framework.

9.3 Stakeholder Analysis and Engagement Plan

Stakeholder	Communication Needs
HCPs	Technical alerts: up to date information on safety and risks, any update in medicine prescribing or use / patient management information, warnings and precautions etc.
Patients	Information in Plain-language through leaflets or social media or safety alerts.

Stakeholder	Communication Needs
Media	Press releases, FAQs to prevent misinformation.

9.4 Engagement Strategies

- PPCs/PHPs:** Trainings, workshops, meetings, official correspondence
- MAH:** Trainings, meetings, official correspondence
- HCPs:** webinars, workshops on ADR reporting and risk mitigation, recorded training or information material, WhatsApp alerts for urgent risks.
- Patients:** DRAP website, social media pages, alerts through mobile application.

10 Awareness and Education

Alongside regulatory functioning it is important to strengthen regulatory communication capabilities, promote safe medicine use, and foster a transparent safety culture across all stakeholders involved in the lifecycle of therapeutic goods in Pakistan.

10.1 Objectives

- Enhance adverse event (AE) reporting from healthcare professionals (HCPs) and patients through available tools of DRAP
- Enhance adverse event (AE) reporting from pharmacovigilance stakeholders
- Increase stakeholder awareness and understanding of pharmacovigilance principles and systems
- Establish effective, timely, and transparent communication during safety events
- Reinforce public confidence in the regulatory authority through open engagement

Stakeholder Group	Communication Method/Strategy	Key Messages (examples)
Healthcare Professionals	Awareness workshops, orientation sessions, social media content, printed guides	“Your reports make a difference in drug safety.”
Patients and Public	TV/radio PSAs, social media campaigns, public seminars, posters in healthcare facilities	“Report side effects your experience ensures safer medicines.”
Provincial Health Authorities, PHPs, PPCs	Policy briefings, inter-provincial coordination, official correspondence, webinars	“Partnerships ensure timely safety communication.”
Pharmaceutical Industry	Safety communication letters, annual updates on pharmacovigilance obligations	“Transparent reporting ensures accountability and trust.”



Media	Press releases, fact sheets, briefings during safety signals or crises	“Accurate reporting promotes public health.”
-------	------------------------------------------------------------------------	----------------------------------------------

10.2 Internal Training

- i. **Annual** according to the Training Need Assessment and Annual Training Plan for NPC, DRAP.
- ii. **Orientation** for new hires on ADR reporting systems and pharmacovigilance.

10.3 External Training

Collaboration with Regional Pharmacovigilance Centres, Public Health Programmes, Academia or other stakeholders on pharmacovigilance for training of healthcare professionals, pharmacovigilance officers, marketing authorisation holders and other stakeholders.

- i. **Workshops and Webinars:** Conducted periodically for HCPs, public health officials, and pharmacovigilance officers across provinces to explain ADR reporting systems, importance of pharmacovigilance, and roles of stakeholders.
- ii. **Awareness Materials:** Infographics, safety posters, multilingual leaflets explaining how to identify and report side effects.
- iii. **Community Engagements:** academia-based awareness sessions and community forums to spread safe medicine use practices.
- iv. **Social Media Campaigns:** National digital initiatives such as MedSafetyWeek to reinforce key PV messages.

11 Risk Communication & Awareness Tools

Safety Alerts and Advisories: Issued by NPC via DRAP’s website, official correspondence, and regional coordination with PPCs/PHPs.

Infographics and FAQs: To ensure consistent messaging during public queries or emerging safety concerns.

Press Conferences and Briefings: In collaboration with provincial health departments and media during high-risk scenarios.

Pre-developed Communication Templates: For routine and urgent safety messages with contextual adaptation for different audiences.

refer to Chapter 8 of the Guidelines on National Pharmacovigilance System for Communication Channels, tools and risk minimisation measures

11.1 Pharmacovigilance Newsletter



The National Pharmacovigilance Centres publishes a newsletter biannually with safety information, informative articles and other important information. The mechanism of publication is as follows:

- i. Preparation of articles by pharmacovigilance officers
- ii. Review of submitted articles by the Editors (PV Officers) at the NPC
- iii. Coordination of editor with developer for designing the newsletter
- iv. Editor calls a meeting for review of the document by the review committee notified by the Authority
- v. Final document submitted by the editor for approval of the CEO, DRAP
- vi. Approval of newsletter by the CEO DRAP for official publication
- vii. Division of Admin then takes over the process for printing as per Procurement Rules
- viii. One printed copy is also shared with the Regional Pharmacovigilance Centres and hospitals from public and private sectors actively involved in Pharmacovigilance.

11.2 Core Elements of Safety Alerts

- i. **Risk Description:** Clear summary of the issue (e.g., “Increased risk of hepatic failure with Drug X”).
- ii. **Evidence:** data sources (e.g., “Vigibase/confirmed cases through investigation”).
- iii. **Recommendations:** dosage adjustments, monitoring protocols.
- iv. **Contacts:** DRAP NPC (npc@drap.gov.pk).
- v. Safety Alert Template [See Appendix 1].

12 Implementation Plan

Phase	Activities	Timeline
Phase I	Situation Analysis / Assessment	Months 4
Phase II	Launch workshops, media outreach, dissemination of printed/online content	Months 12
Phase III	Continual engagement, annual public campaigns, regular policy updates	Month 12 onward

13 Types of Communications

13.1 Routine Communications

Safety information and routine updates on risks and adverse events through established channels.

- i. Periodic pharmacovigilance newsletters/reports, publicly accessible information (official website and social media channels of DRAP), social media messages to encourage reporting, talk about medicine safety issues,



- educate about pharmacovigilance, safety alerts for healthcare professionals and stakeholders including (PPCs, PHPs, registration holders and patients).
- ii. Annual social media campaign (#MedSafetyWeek) Public awareness campaigns
- iii. Communication with Focal Persons & Heads of PPCs and PHPs and with Qualified Persons for Pharmacovigilance (QPPV) / Local Safety Officer (LSO) of the registration holders.
- iv. Regular communication with WHO and WHO-UMC on matters of pharmacovigilance.
- v. The pertinent information on any urgent matter, is communicated to the relevant pharmacovigilance stakeholder at the earliest in the form of therapeutic goods safety alerts, communication letters and emails within the shortest possible period to ensure patient safety.
- vi. Feedback to healthcare professionals and patients or consumers and acknowledgement of the reports and issuing newsletters which include Global and National new safety risks for the awareness.
- vii. Educational outreach by arranging training sessions or preparing educational material based on lessons learned from incidents.

13.2 Crisis Management and Communication:

Aside from risk communication it is vital to be prepared for any future emergency situations. A crisis is a situation in which a real or potential loss of confidence in the therapeutic good or the public health programme is triggered by information about an ADR/AEFI.

Crises can often be avoided through foresight, care and training. If managed properly, the investigation and management of a therapeutic good safety situation will boost public confidence and acceptance and ultimately strengthen the healthcare system/immunization programme.

It is essential to prepare for the unavoidable and maintain good relationship with the media. Public awareness and understanding of the situation (treatment and risk) is necessary.

- i. Train staff at all levels to respond adequately. Develop confidence in responding to the public and the media (particularly the local media) properly and correctly.
- ii. Confirm all facts and prepare (for a press conference or press release) before making any public comments.
- iii. Prepare a plan to react to a crisis when it occurs. This has to be done in advance, identifying responsible persons to handle the crisis and preparing all supporting documents and information.

Crisis communication plan is activated promptly during the instances when:

- i. high-severity adverse events occur, or
- ii. any public concern arises or
- iii. the impact on public health is significant due to the frequency of the hazard, the number of users and seriousness or



- iv. new evidence emerges suggesting that the risks of medicine may outweigh the benefits either for all users or in specific circumstances (e.g particular indication).

The Head of the NPC, DRAP with the approval of CEO, DRAP activates crisis communication protocol by:

- i. Notifying a crisis communication team/ rapid response team,
- ii. identifying communication channels,
- iii. approving template messages or alerts prepared by the team and
- iv. coordinating with spokespersons and media contact persons.

14 Crisis Communication Plan

14.1 Protocols

- i. **Rapid Response Team/Crisis Communication Team:** Composed of CEO DRAP, Officers of NPC, medical advisors or experts if required, and media contact person Representative.
- ii. **Pre-Approved Statements:** For media to ensure consistent messaging.

14.2 Escalation Pathways

- i. **Level 1 (Local Risk):** Notify provincial health departments.
- ii. **Level 2 (National Emergency):** Activate inter-ministerial/ inter-organisational coordination for collaborated action (e.g., pandemic and mass immunisation or mass use of a drug, quality related ADRs etc).

14.3 Urgent Communications

- i. **Within 24-48 hours:** For life-threatening risks (e.g., product recalls, fatal ADRs).
- ii. **Within 72 hours:** Updates to provincial health departments.

14.4 Monitoring, Evaluation, and Continuous Improvement

Indicator	Assessment Method
ADR reporting rate	VigiFlow data and trend analysis
Stakeholder awareness levels	Pre- and post-training surveys, quiz scores
Public reach and engagement	Social media analytics, event participation
Communication responsiveness	Timeliness of alert dissemination, stakeholder feedback logs
Internal self audits	Annual review of communication logs

14.5 Sustainability Plan

- i. Annual Campaigns: #MedSafety Week campaigns and other outreach events.



- ii. Periodic Review and Updates: Based on stakeholder input and regulatory priorities.
- iii. Collaborations with Academia and professional associations: To reach wider audiences and maintain program vitality.
- iv. Recognition Mechanisms: Acknowledgement in newsletters for consistent individual, regional or institutional reporting.

15 Appendices

◆ ◆
Template for Safety Alert HCPs and Patients

Appendix 1





SAFETY ALERT

DRAP SAFETY ALERT NO. XX

Title.

Date: xth of MM, YYYY.

Target Audience.

- Provincial Health Departments/Provincial PV Centres/Healthcare Commissions;
- Manufacturers and importers of Medroxyprogesterone Acetate; and
- Healthcare Professionals.

Background.

International and national evidence, findings, regulatory actions/ decisions by international medicine regulators etc.....

Action in Pakistan.

The case was discussed in the xth meeting of the Pharmacovigilance Risk Assessment Expert Committee (PRAEC) held on xnd of MM, yyyy which decided as per Rule xxxx of Pharmacovigilance Rules, 2022, that....

Therapeutic Good Affected.

Name:

Advice for Healthcare Professionals.

Advice for patients.

Guidelines for reporting Adverse Drug Reactions (ADRs).

Healthcare professionals and patients are requested to report any adverse drug reaction with _____ and/or any other medicine to the National Pharmacovigilance Centre (NPC), Drug Regulatory Authority of Pakistan (DRAP) through the [Med Vigilance E-Reporting System](#) (E-forms) available on the DRAP website. Similarly, adverse events and adverse drug reactions can also be reported through the VigiMobile App, which can be downloaded by scanning the barcode available on the DRAP website.

References.

-



NPC, DRAP, PM Health Complex, Chak Shahzad Islamabad

+92 51 9255981

npc@dra.gov.pk



Prepared by:

Abdul Mateen, Deputy Director PV-I, National Pharmacovigilance Centre, DRAP
Aqsa Hashmi, Deputy Director PV-II, National Pharmacovigilance Centre, DRAP
Reviewed by: Abdullah Diyo, Head of National Pharmacovigilance Centre, DRAP
Approved by: Dr. Obaidullah, Chief Executive Officer, DRAP

DRUG REGULATORY AUTHORITY OF PAKISTAN
Prime Minister's National Health Complex, Park Road, Islamabad.
Phone No. 051 9255981
Email: npc@dra.gov.pk
Website: www.dra.gov.pk