



**Islamic Republic of Afghanistan  
Ministry of Public Health**

**National Medicine and Healthcare Products  
Regulatory Authority**

**National Policy for  
Pharmacovigilance**

December 2016



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## ABBREVIATIONS AND ACRONYMS

ADR	adverse drug reaction
MOPH	Ministry of Public Health
MSC	Medicine Safety Committee
NMHRA	National Medicines and Healthcare Products Regulatory Authority
NMP	National Medicines Policy
PV	pharmacovigilance
SPS	Strengthening Pharmaceutical Systems Project
USAID	US Agency for International Development
WHO	World Health Organization

## FOREWORD


This is the overall policy document for the pharmacovigilance (PV) system for Afghanistan's pharmaceutical sector. This policy constitutes part of the continuous efforts by the Ministry of Public Health (MOPH) and stakeholders to ensure the safety of patients and to completely protect the health of the people. It aims to create and provide a comprehensive system to recognize or discover, evaluate, know, prevent, and report adverse drug reactions (ADRs) to ensure availability, accessibility, affordability, and rational use of safe, efficacious, and quality medicines.

The national PV policy was developed through a systematic, accepted process through a Medicine Safety Committee (MSC) under the direct supervision and leadership of the National Medicine and Healthcare Products Regulatory Authority (NMHRA) of MOPH. The MSC reviewed the current PV situation in Afghanistan; an initial draft of the policy was developed, and the final draft document compiled and presented to the MOPH, which took the final decision on all aspects of the policy and duly approved it for implementation.

This policy document will be followed by an implementation plan, which will set out objectives, strategies, activities, and expected outcomes/outputs to implement all agreed components of the policy.

I am very optimistic that all stakeholders involved in developing this policy will remain committed to it, and support government efforts to fully implement it. It is also my hope that our development partners will find the policy a useful guide in providing technical and financial assistance to the pharmaceutical sector. Hopefully, in the next few years when we have implemented this policy, we can together rejoice over positive results of our combined efforts.

I wish to sincerely commend the Strengthening Pharmaceutical Systems (SPS) Project funded by the US Agency for International Development (USAID) and implemented by Management Sciences for Health for the tremendous technical support. I also thank the MSC members and all those who contributed to developing this policy document.



**Dr. Ferozudin Feroz**  
**Minister of Public Health**

## ACKNOWLEDGMENT

This policy was developed on the basis of the outline provided in the National Medicines Policy (NMP) and World Health Organization (WHO) recommendations. This policy closely follows all the WHO's recommendations for PV, has been completely observed, and is in accordance with the criteria and needs the pharmaceutical sector in Afghanistan. It has been drafted through a systematic process that provided consultative access to all concerned and involved stakeholders.

The NMHRA in the MOPH wishes to acknowledge the contributions of the MSC for the development of this policy. Acknowledgment is given to the following people in particular:

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**Dr. Noor Shah Kamawal**  
**Executive Director**  
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## INTRODUCTION

The Afghanistan National Medicines Policy (NMP) 2014-2019 is the overall policy document for the Afghanistan pharmaceutical sector. Within the NMP is a section on PV, Section 5.7. Adverse Reaction Monitoring (Pharmacovigilance).

PV is also recognized in key documents of the MOPH, including the National Health Strategy 2016–2020 that indicates the MOPH’s intention to enhance its capacity to regulate the pharmaceutical sector through different mechanisms including pre- and post-marketing surveillance of medicines. Another MOPH document of relevance is the NMHRA Concept Note (January 2016).

PV is the science and activities relating to the detection, assessment, understanding, and prevention of adverse effects (side effects) or any other possible medicine-related problems. The Afghanistan NMP calls for the implementation of improved medicine surveillance, including PV activities. The MOPH established the National PV Program as the framework for an organized, systematic, structured system for collection, analysis, risk/benefit management, establishment of a database, and report-alerting of suspected ADRs, product inefficacy, product defects, counterfeit drugs, and other safety-related issues. The program includes the MSC and, collectively, is an integral part of ensuring safety and quality of medicines.

## GOAL AND OBJECTIVES

### Goal

To ensure the safety and safe use of high-quality drugs, vaccines, medical equipment, and complementary medicines for all people in Afghanistan.

### Objectives

- Promote PV in the country, collect and manage ADRs and adverse events following immunization reports as well as reports of medication errors and suspected counterfeit/substandard drugs
- Collaborate and harmonize with other ADR collection activities within the country (e.g., public health programs) and international ADR monitoring programs
- Identify signals of drug and vaccine safety
- Undertake assessments of risk and options for risk management
- Identify any quality problems in medicines that result in ADRs and, more generally, support the identification of medicine quality issues
- Provide effective communication on aspects related to drug safety, including dispelling unfounded rumors of toxicity attributed to medicines and/or vaccines
- Apply information from PV for the benefit of public health programs, individual patients, the NMP, and treatment guidelines
- Ensure that public health programs routinely monitor the safety of the drugs and vaccines used in their programs and coordinate these activities with the PV program
- Encourage conduct of drug utilization studies
- Be an active participating member of the WHO Programme for International Drug Monitoring (WHO Collaborating Centre for International Drug Monitoring [also known as the Uppsala Monitoring Centre (UMC) in Uppsala, Sweden])
- Report ADRs to the WHO drug safety databases and share safety data for analysis and signal detection



## STRATEGIES

- Establish the PV Center in the NMHRA-ADR Section.
- Encourage practicing physicians, pharmacists, and nurses as well as patients to submit data to the PV Center on suspected ADRs associated with licensed or traditional medicines. Activities should include orientation and training of practicing physicians, pharmacists, and nurses regarding the detection, assessment, understanding, and prevention of adverse effects (side effects) and adding ADR reporting to their duties.
- Require local manufacturers, exporters, importers and distributors of medicines and their authorized representatives in Afghanistan to keep records of all adverse reactions and interactions of medicines reported to them and submit such reports to the PV Center.
- Ensure that the PV Center establishes and maintains close relations, coordination, and cooperation with the relevant international medicines and therapeutics information centers and the WHO Collaborating Centre for International Medicines Monitoring in the monitoring and reporting of ADRs.
- Maintain effective linkages between the PV Center and various departments and sections of the MOPH and also other stakeholders, such as the pharmaceutical industry, universities, nongovernmental organizations, and professional associations having responsibility for education on rational use of medicines and pharmacotherapy monitoring.
- Work in a coordinated manner with public health programs to ensure that PV and safety monitoring is conducted on the drugs and vaccines used in their programs.
- As needed, establish regional PV centers to work in collaboration with the National PV Center in coordinating PV activities in the respective regions.
- Provide evidence-based information on ADRs to professionals and consumers.
- Ensure sufficient, sustainable funding for the PV Center.
- Ensure political support for the PV system.
- Monitor the performance of the PV Center.

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