
# Islamic Republic of Afghanistan
# Ministry of Public Health

## National Medicine and Healthcare Products Regulatory Authority

# National Pharmacovigilance Policy

December 2016

# Contents

## Abbreviations and Acronyms

| | |
|---|---|
| ADR | Adverse Drug Reaction |
| AEFI | Adverse Events Following Immunization |
| MoPH | Ministry of Public Health |
| NGO | Non-governmental Organizations |
| NMHRA | National Medicines and Healthcare Products Regulatory Authority |
| NMP | National Medicines Policy |
| PV | Pharmacovigilance |
| UMC | Uppsala Monitoring Centre |
| WHO | World Health Organization |

## Foreword

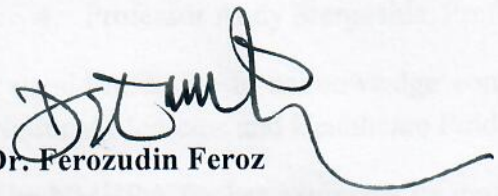
This is the overall policy document for Pharmacovigilance system for Afghanistan's pharmaceutical sector. This policy constitutes part of continuous efforts by the Ministry of Public Health (MoPH) and the stakeholders to ensure safety of the patients and to completely protect health of the people. It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

The national pharmacovigilance policy was developed through a systematic accepted process by using a Medicine Safety Committee (MSC) under the direct supervision and leadership of the National Medicine and Healthcare Products Regulatory (NMHRA) of MoPH. The MSC reviewed the current pharmacovigilance situation in Afghanistan, and an initial draft of the policy was developed and the final draft document was 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 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 (MSH) 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 developed based on the outline provided in the National Medicine Policy, and World Health Organization (WHO) recommendations. This policy closely follows all the World Health Organization's recommendation for pharmacovigilance 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 Medicine Safety Committee for the development of this policy. Acknowledgment is given to the following people in particular:

1. Professor Mohammad Nasim Sediqqui,- Faculty of Pharmacy, Kabul University
2. Pharmacist Azizullah Bahrami, NMHRA-MoPH
3. Professor Hafiza Hamid - Faculty of Pharmacy, Kabul University
4. Dr. Mohammad Azim Samim, Ibn-e-Sina Emergency Hospital
5. Pharmacist Fauzia Maihanyar, NHMRA-MoPH
6. Professor Qand Agha Nazari, , Faculty of Pharmacy, Kabul University
7. Professor Mohammad Ibrahim Kamal, Kabul Medical Universty
8. Pharmacist Mohammad Saber Hotak, Antani Hospital
9. Dr. Abdul Ghafar Hamdard, Maiwand Teaching Hospital
10. Dr. Safiullah Nadeeb, WHO

The NMHRA would also like to thank the following technical advisors of the Strengthening Pharmaceutical Systems (SPS) project who provided technical support to the development and formulation of the policy:

1. Pharmacist Mohamed Basir, Pharmaceutical Regulatory System Program Manager
2. Dr. Mohammadullah Alishungi, Pharmacovigilance Technical Adviser
3. Pharmacist Mohammad Zafar Omari, SPS/Afghanistan Chief of Party,
4. Professor Andy Stergachis, Professor of Pharmacy & Global Health, University of Washington

I would also like to acknowledge comments received from the NMHRA Executive Board and the National Medicine and Healthcare Products Board members.

The NMHRA further expresses its gratitude to the SPS project for providing technical support in the development of this policy, with the financial assistance of USAID.

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

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

Pharmacovigilance is also recognized in key documents of the Ministry of Public Health (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-market surveillance of medicines. Other MoPH documents of relevance are the MoPH's National Medicines & Healthcare Products Regulatory Authority (NMHRA) Concept Note in January 2016.

Pharmacovigilance 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 National Medicines policy calls for the implementation of improved medicine surveillance, including pharmacovigilance activities. The MoPH established the National Pharmacovigilance Program as the framework for an organized systematic, structured system for collection, analysis, risk/benefit management, data-base, report alerting of suspected adverse reactions, product inefficacy, product defect, counterfeit drugs, and other safety related issues. The Program includes the Medicine Safety Committee and, collectively is an integral part of ensuring safety and quality of medicines.

## Goal

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

## Objectives

1. Promote pharmacovigilance in the country, collect and manage adverse drug reaction (ADR) and adverse events following immunization (AEFI) reports as well as reports of medication errors and suspected counterfeit/substandard drugs
2. Collaborate and harmonize with other ADR collection activities within the country (e.g. public health programs) and international ADR monitoring programs.
3. Identify signals of drug and vaccine safety.
4. Undertake assessments of risk and options for risk management.
5. Identify if there are quality problems in medicines resulting in ADRs and more generally, support the identification of medicine quality issues.
6. Provide effective communication on aspects related to drug safety, including dispelling unfounded rumors of toxicity attributed to medicines and/or vaccines.
7. Apply information from pharmacovigilance for the benefit of public health programs, individual patients and national medicines policies and treatment guidelines.
8. Ensure that public health programs routinely monitor the safety of the drugs and vaccines used in their programs and coordinate these activities with the Pharmacovigilance Program.
9. Encourage conduct of drug utilization studies.

10. Be an active participating member of the WHO International Drug Monitoring Program WHO Collaborating Centers for Pharmacovigilance, the Uppsala Monitoring Centre (UMC) in Uppsala, Sweden.
11. Report ADRs to the WHO drug safety databases and share safety data for analysis and signal detection.

## Strategies

1. Establish the Pharmacovigilance Center at the NMHRA-ADR Section.
2. Encourage practicing physicians, pharmacists, and nurses as well as patients to submit data to the Pharmacovigilance Center on suspected adverse 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.
3. 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 Pharmacovigilance Center.
4. Ensure that the Pharmacovigilance Center establish and maintain 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 adverse medicines reactions.
5. Maintain effective linkages between the Pharmacovigilance Center and various departments and sections of the MoPH and also with other stakeholders, such as the pharmaceutical industry, universities, nongovernmental organizations (NGOs) and those professional associations having responsibility for education on rational use of medicines and pharmacotherapy monitoring.
6. Work in a coordinated manner with public health programs to ensure pharmacovigilance and safety monitoring is conducted with the drugs and vaccines used in their programs.
7. As needed, establish regional pharmacovigilance centers to work in collaboration with the National Pharmacovigilance Center in coordinating PV activities in the respective regions.
8. Provide evidence-based information on adverse reactions to professionals and consumers.
9. Ensure sufficient, sustainable funding for the Pharmacovigilance Center.
10. Ensure political support for the pharmacovigilance system.
11. Monitor the performance of the Pharmacovigilance Center.

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