Maldives Food and Drug Authority

Ministry of Health

Male', Maldives

Guideline on Pharmacovigilance and ADR Reporting

Version Number	2	
Issued Date	04.03.2026	
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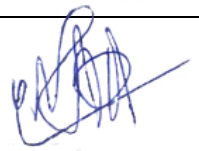
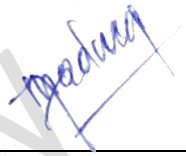
Approved By	Aishath Mohamed, Deputy Director General, Pharmaceutical	
Authorized by	Thooma Adam, Deputy Director General, Laboratory Services (Acting Head of MFDA)	

SUMMARY OF CHANGES

Version No.	Issued Date	Section / Clause	Summary of Change	Changes Made by
1	13.02.2020	-	Creation of the document	Aishath Jaleela, Director, Pharmaceutical
2	04.03.2026	Overall Document	Major revision of guidelines incorporating international standards	Mariyam Leena, Pharmaceutical Officer

CONTENTS

ABBREVIATIONS

ADR	Adverse Drug Reaction
AE	Adverse Event
AEFI	Adverse Event Following Immunization
HCP	Healthcare professionals
MFDA	Maldives Food and Drugs Authority
MTG	Medicines and Therapeutic Goods Division
MOH	Ministry of Health
NPB	National Pharmaceutical Board
NPSC	National Patient Safety Committee
MAH	Marketing Authorization Holder
PIDM	Programme for International Drug Monitoring
PV	Pharmacovigilance
GVP	Good Pharmacovigilance Practices
RMP	Risk Minimization Plan
RMM	Risk Minimization Measure
UMC	Uppsala Monitoring Centre
WHO	World Health Organization
QPPV	Qualified Person for Pharmacovigilance
ICSR	Individual Case Safety Report
SUSAR	Suspected Unexpected Serious Adverse Reaction
API	Active Pharmaceutical Ingredient
ICH	International Council for Harmonization

DEFINITIONS

Term	Definition
Pharmacovigilance (PV)	The science and activities related to the detection, assessment, understanding, and prevention of adverse effects or any other medicine-related problems.
Adverse Drug Reaction (ADR)	A harmful or unintended response to a medicine that occurs at normal doses used for prophylaxis, diagnosis, or therapy.
Adverse Event (AE)	An unintended medical event occurring after the use of a medicine, not necessarily caused by the treatment
Adverse Events Following Immunization (AEFI)	Any inappropriate medical event after immunization, which may or may not be related to the vaccine.
Medication Error (ME)	Any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of a healthcare professional, patient, or consumer.
Marketing Authorization Holder (MAH)	The local representative holds the license to market a pharmaceutical product in the Maldives and is responsible for ensuring its quality, safety, and efficacy.
National Pharmaceutical Board (NPB)	An advisory body under the MFDA that provides expert advice on medicine safety, efficacy, and quality.
National Patient Safety Committee (NPSC)	Committee managed by MOH Quality Assurance Division that provides expert advice on medicine safety, efficacy, and quality.
Nation Immunization Program (NIP)	Overseeing all program-based vaccination activities in the Maldives, ensuring access to safe, effective, and quality vaccines for the prevention of vaccine-preventable diseases.
Pharmacovigilance Focal Point	A designated person in a healthcare facility responsible for coordinating ADR reporting and communication with the MFDA.
Stakeholder	An individual or group responsible in pharmacovigilance, either through involvement in decision-making or being affected by related actions.
Spontaneous Reporting	A spontaneous report made by a healthcare professional or consumer to a regulatory authority or manufacturer concerning one or more suspected adverse drug reactions.
WHO-UMC (Uppsala Monitoring Centre)	The WHO Collaborating Centre in Uppsala, Sweden, that manages the global drug safety database (VigiBase) and supports countries in monitoring medicine safety through tools, training, and international coordination.
VigiFlow	A web-based Individual Case Safety Report (ICSR) management system developed by the Uppsala Monitoring Centre (UMC) for use by national pharmacovigilance centers.
VigiBase	The WHO global database of Individual Case Safety Reports, maintained by UMC, containing data submitted by member countries.
VigiLyze / VigiMine / VigiSearch / VigiMed	WHO-UMC tools used for signal detection, data visualization, case review, and pharmacovigilance training to support regulatory decision-making.

WHO Programme for International Drug Monitoring (PIDM)	A global network coordinated by WHO and UMC, where member countries share and analyze safety data to improve global medicine safety.
Signal Detection	The process of identifying new or rare adverse effects based on accumulated safety data.
Causality Assessment	The process of determining the probability that a specific medicinal product is responsible for an observed adverse event, based on factors such as timing, clinical evidence, and exclusion of alternative causes.
Naranjo Scale	A Standardized questionnaire used to assess the likelihood that an ADR is caused by specific drug.
Risk Management Plan (RMP)	A structured document that describes a system of pharmacovigilance and risk-minimization activities designed to identify, characterize, prevent, or minimize risks related to a medicinal product, including the assessment of the effectiveness of those risk-minimization measures and plans to generate further safety and efficacy data.
Risk minimisation measure (Risk minimization activity)	Interventions intended to prevent or reduce the occurrence of adverse reactions associated with the exposure to a medicine, or to reduce their severity or impact on the patient should adverse reactions occur.
Safety Signal	Information suggesting a new potentially casual association or a new aspect of known association between a medicine and an adverse event.

1 INTRODUCTION

Maldives Food and Drug Authority (MFDA) is mandated to ensure that all medicines used in the country meet established standards of quality, safety, and efficacy. As the Maldives relies entirely on imported pharmaceuticals and has a rapidly expanding healthcare sector, monitoring medicine-related risks particularly Adverse Drug Reactions (ADRs) is essential. While modern medicines offer significant therapeutic benefits, ADRs may still occur and can sometimes result in serious or fatal outcomes. Importantly, many of these reactions are preventable.

Since becoming the 125th full member of the World Health Organization's Programme for International Drug Monitoring (WHO PIDM) in 2016, the Maldives has strengthened its collaboration with the WHO Collaborating Centre for International Drug Monitoring, the Uppsala Monitoring Centre (WHO-UMC). This partnership has facilitated access to advanced global pharmacovigilance tools and resources, enhancing the country's ability to ensure the safe use of medical products.

This guideline also outlines the operational framework of the national pharmacovigilance system, including stakeholder responsibilities and standardized procedures for detecting, classifying, and reporting ADRs to the National Pharmacovigilance Centre.

2 PURPOSE

The purpose of this guideline is to establish a comprehensive national framework for pharmacovigilance in the Maldives, with the ultimate goal of improving patient safety and reducing medicine-related risks. It provides clear guidance on:

- What to report (including ADRs and other safety concerns),
- The importance of reporting,
- When and how to report,
- Roles and responsibilities of various stakeholders in the pharmacovigilance system.
- Implement regulatory actions to ensure timely risk management and safeguard public health.

Recognizing that all medicines carry both benefits and risks, this guideline emphasizes the need for continuous safety monitoring to ensure that the benefits of medicines outweigh potential harms. Pharmacovigilance plays a vital role in protecting public health by identifying, evaluating, and minimizing safety issues related to medicines.

3 SCOPE

This guideline applies to all activities related to the detection, assessment, prevention, and management of Adverse Drug Reactions (ADRs), medication errors, and product quality issues that may affect the safety, efficacy, or quality of medical products in the Maldives.

It covers all therapeutic products, such as allopathic medicines as well as vaccines and biological products.

The scope of this guideline extends to all stakeholders involved in the regulation, use, distribution, and monitoring of medicines and medical products within the Maldives, specifically:

- Healthcare professionals, including physicians, nurses, pharmacists, and other allied health workers engaged in prescribing, dispensing, or administering medicines.
- The Health Protection Agency (HPA) — tasked with implementing and managing national vaccine safety monitoring and ensuring timely reporting of Adverse Events Following Immunization (AEFIs).
- Marketing Authorization Holders (MAHs), importers, distributors, and manufacturers responsible for the ongoing safety of their products.
- Public and government institutions involved in the use, management, or monitoring of medical products.
- The National Pharmacovigilance Unit and associated surveillance units responsible for data collection, analysis, and regulatory actions.

4 RESPONSIBILITY & ACCOUNTABILITY

Medicine Regulatory Officer of Pharmacovigilance Unit (MFDA)	MFDA is authority responsible for coordinating and overseeing all pharmacovigilance activities. Key responsibilities include: ✓ *Establish and maintain the national pharmacovigilance (PV) system.* ✓ *Collect, analyze, and evaluate ADR reports.* ✓ *Conduct signal detection and benefit–risk assessment.* ✓ *Coordinate with WHO-UMC and contribute to international databases (e.g. VigiBase).*

	✓ *Issue safety alerts, regulatory decisions, and public communication.* ✓ *Provide guidance and training to stakeholders.*
Director, Pharmaceuticals (Enforcement Section)	**Responsible for regulatory enforcement and compliance monitoring related to drug safety and quality, including:** ✓ *Overseeing enforcement of PV-related regulatory actions.* ✓ *Facilitate PV related awareness sessions* ✓ *Monitoring compliance of MAHs and other stakeholders with pharmacovigilance obligations.* ✓ *Coordinating inspections or investigations related to safety issues.*
Deputy Director General (MTG) Director General (MFDA)	Senior officials responsible for strategic leadership and oversight of the national pharmacovigilance system by: ✓ *Providing strategic directions.* ✓ *Ensuring compliance with national and international PV standards* ✓ *Overseeing implementation of safety monitoring systems and regulatory decisions.* ✓ *Coordinating with external partners and supporting inter-agency collaboration*
National Pharmaceutical Board / National Patient Safety Committee	An expert advisory body under MFDA responsible to provide regulatory and technical guidance on medicine safety, efficacy, and quality. ✓ *Advise on pharmacovigilance and regulatory matters.* ✓ *Review safety data and support benefit–risk evaluations.* ✓ *Endorse guidelines, safety communications, and policy decisions.*
Marketing Authorization Holders (MAHs)	Responsible for ensuring the safety of their products by implementing pharmacovigilance activities that include: ✓ *Maintain a pharmacovigilance system to monitor product safety when the product is in the market.* ✓ *Report ADRs and safety concerns received from the manufacturer to MFDA in a timely manner.* ✓ *Conduct risk management and post-marketing safety studies, where required.* ✓ *Appoint a Qualified Person for Pharmacovigilance (QPPV).* ✓ *Implement corrective actions based on safety updates.*

Ministry of Health	The Ministry of Health plays a key role in supporting and strengthening the national pharmacovigilance (PV) system by: ✓ *Providing policy oversight and strategic direction.* ✓ *Facilitating public health responses based on medicine safety data and regulatory decisions.* ✓ *Coordinate with hospitals and health facilities nationwide to support PV activities.* ✓ *Ensuring financial support for sustaining the PV program and maintaining WHO-PIDM membership.*
Health Protection Agency (HPA)	Responsible for monitoring Adverse Events Following Immunization (AEFI) and ensuring integration with the national pharmacovigilance system by: ✓ *Establish and maintain the national pharmacovigilance (PV) system in relate to vaccines.* ✓ *Collect, analyze, and evaluate AEFI reports* ✓ *Conduct signal detection and risk–benefit assessment.* ✓ *Coordinate with WHO-UMC and contribute to international databases (e.g. VigiBase).* ✓ *Maintain AEFI cases in alignment with national PV requirements.* ✓ *Collaborating with MFDA to ensure consistent data sharing and coordinated safety monitoring.* ✓ *Integrating MFDA into AEFI reporting workflows to enable joint evaluation of vaccine-related safety signals.*
Hospitals	All Hospitals are required to implement & maintain pharmacovigilance systems. Key responsibilities include: ✓ *Designating a focal point for pharmacovigilance and ADR reporting* ✓ *Ensuring regular submission of ADR reports to MFDA* ✓ *Training staff appropriately for their roles in PV activities* ✓ *Supporting MFDA in safety monitoring and audits*
Clinics	Clinics shall support pharmacovigilance systems. Key responsibilities include: ✓ *Designating a focal point for pharmacovigilance and ADR reporting* ✓ *Ensuring regular submission of ADR reports to MFDA* ✓ *Training staff appropriately for their roles in PV activities* ✓ *Supporting MFDA in safety monitoring and audits*
PV Focal Point	Doctors, pharmacists, nurses, and other licensed healthcare providers are critical to the early detection of ADRs. Their responsibilities include: ✓ *Identifying and reporting suspected ADRs and medication errors promptly.* ✓ *Ensuring accuracy and completeness in submitted reports.* ✓ *Promoting a culture of safety in clinical practice.* ✓ *Responding to safety communications and implementing updated safety measures.*

Individual Reporting (Doctors, Nurses, Pharmacists, Patients etc.,)	Report any suspicious ADR.

5 PHARMACOVIGILANCE OVERVIEW

This section provides an overview of pharmacovigilance (PV) as a key component of medicine safety and public health protection in the Maldives. While the general introduction outlines the purpose and scope of this guideline, the following provides essential context on the principles, importance, and objectives of Pharmacovigilance within the national healthcare system.

5.1 What is Pharmacovigilance?

Pharmacovigilance is defined by the World Health Organization (WHO) as the science and activities related to the detection, assessment, understanding, and prevention of adverse effects or any other medicine-related problems.

5.2 Importance of Pharmacovigilance

Pharmacovigilance is essential for ensuring the safe and effective use of medicines throughout their lifecycle. While pre-marketing clinical trials provide safety data under controlled conditions, they often involve limited populations and may not detect all adverse drug reactions (ADRs). Post-marketing surveillance allows for the detection of rare, delayed, or population specific ADRs.

Key benefits include:

- Maintains a favorable benefit–risk balance through continuous monitoring of medicines in real-world use, supporting timely regulatory action, better prescribing practices, and improved patient outcomes.
- Supports safer clinical practice by enabling early detection of new adverse reactions, changes in known reactions, and identification of risk factors.
- Informs evidence-based decision-making by providing healthcare professionals with up-to-date safety information, raising public awareness, and promoting transparency and trust.
- Ensures continued medicine safety by detecting rare or serious ADRs and maintaining the safe and effective use of medical products.

5.3 Aims of Pharmacovigilance

The aims of pharmacovigilance are to:

- Ensure the safe and rational use of medicines and medical products.
- Identify, assess, and communicate risks and benefits associated with medicines.
- Improve patient care and safety in the use of medicines and medical interventions.
- Enhance public health by detecting and preventing medicine-related problems.
- Support regulatory decisions by evaluating the safety, effectiveness, and quality of medicines.
- Promote awareness among healthcare professionals and the public on medicine safety.
- Encourage the safe, rational, and cost-effective use of medicines.

5.4 Key Focus Areas of the Pharmacovigilance System

The National Pharmacovigilance System is designed to operate across the entire country and will include all healthcare sectors—public, private, and NGO/mission-based services. Its key focus areas include:

- **All levels of healthcare**, including community-based healthcare providers.
- **All medicines** which are used within the country, regardless of source or type.
- **All disease conditions** encountered in the healthcare system.
- **All categories of healthcare professionals**, across various disciplines and levels of practice.
- **All individuals residing in the Maldives** who may experience or suspect an adverse reaction to a medicine.

The Pharmacovigilance System will collaborate closely with other departments and programs under the Ministry of Health, as well as with national and international organizations, to establish an efficient feedback and communication mechanism. This will ensure that medicine safety information is effectively shared and acted upon across the health system.

The MFDA will also work to strengthen regional collaboration and harmonization with other pharmacovigilance systems to promote consistent practices and improve overall patient safety.

5.5 What is Adverse Drug Reaction (ADR)?

An Adverse Drug Reaction (ADR) is a harmful or unintended response to a medicine that occurs at normal doses used for treatment, prevention, or diagnosis of diseases.

ADRs may range from mild effects, such as a rash or stomach upset, to serious outcomes like allergic reactions, liver damage, or even death. They can happen even when the medicine is used correctly.

ADRs may result from:

- Known or unexpected effects of a medicine,
- Interactions with other medicines, foods, or substances,
- Medication errors, such as taking the wrong dose,
- Off-label use, misuse, or overdose,
- Poor product quality, such as contamination or incorrect labeling.

Monitoring and reporting ADRs is essential to improve the safety of medicines, support informed regulatory actions, and protect patients and public health.

5.6 Classification of Adverse Drug Reactions (ADR)

Adverse Drug Reactions (ADRs) are primarily classified into two main types: Type A (Augmented), which are predictable and dose-related, and Type B (Bizarre), which are unpredictable and unrelated to the drug's usual pharmacological action. However, additional categories—Types C, D, E, and F—also exist to capture reactions related to long-term use, delayed onset, withdrawal effects, and therapy failure.

This classification helps healthcare professionals understand and manage ADRs based on their characteristics and mechanisms.

Type	Description	Examples
Type A (Augmented)	These reactions happen when a medicine causes an exaggerated version of its usual effect, often depending on the dose. Type A reactions can also include side effects that aren't directly related to the main purpose of the medicine.	Opioids can cause too much breathing suppression, warfarin can lead to excessive bleeding, and tricyclic antidepressants may cause dry mouth.

Type B (Bizarre)	These are unusual reactions that can't be predicted from how the medicine normally works. They are rare and often only found after the medicine has been used by many people (post-marketing).	Allergic reactions like anaphylaxis to penicillin Malignant hyperthermia triggered by certain anesthesia drugs. Severe skin reactions such as Stevens-Johnson syndrome caused by some anticonvulsants.
Type C (Continuous)	Reactions resulting from long-term use of a medicine.	Adrenal suppression with corticosteroids
Type D (Delayed)	Reactions appearing sometime after drug use; often difficult to detect.	Tardive dyskinesia with neuroleptics, teratogenic effects
Type E (End of Use)	Reactions occurring after withdrawal of the medicine.	Withdrawal symptoms
Type F (Failure of Therapy)	Lack or failure of expected therapeutic effect.	Treatment failure

5.7 Identification of suspected Adverse Drug Reactions

Distinguishing ADRs from the symptoms of the underlying disease may be difficult, as both can involve similar physiological and pathological mechanisms. However, the following approach shall be used to assess possible drug related ADRs:

5.8 Comprehensive History and Examination

5.8.1 A full drug and medical history shall be obtained, including all prescribed, over the counter, and traditional medicines.

5.8.2 ADRs shall always be considered as a potential diagnosis.

5.8.3 Alternative causes such as underlying diseases, other medications, toxins, or dietary factors shall be evaluated.

5.8.4 A thorough investigation of the patient shall be conducted to identify the true cause of any new medical issues.

5.8.5 A drug-related cause shall be considered especially if no other explanation suffices.

5.9 Assess the time sequence of events

5.9.1 The timing of symptom onset in relation to drug administration shall be determined.

5.9.2 ADRs may occur immediately or develop after some time; the interval between drug exposure and onset shall be consistent with the suspected reaction.

5.10 Physical examination and laboratory investigations

5.10.1 A detailed physical examination shall be performed to detect any distinctive signs of ADRs.

5.10.2 Laboratory investigations shall be carried out if essential for patient management or when the suspected drug is critical to therapy.

5.10.3 The reaction shall be clearly described and, where possible, an accurate diagnosis shall be provided.

5.11 Assessment of Drug Withdrawal and Re-administration

5.11.1 The resolution or improvement of symptoms upon withdrawal of the suspected drug shall be recorded as a key, though not definitive, indicator of a potential adverse drug reaction.

5.11.2 Re-administration of the suspected drug shall only be considered if the expected therapeutic benefits clearly outweigh the risks and must be conducted with careful ethical evaluation due to the possibility of recurrence or exacerbation of the reaction.

6 Establishment of the National Pharmacovigilance System in Maldives

6.1 The National Pharmacovigilance System in the Maldives is coordinated and managed by the Maldives Food and Drug Authority (MFDA) through its Pharmacovigilance Unit. This unit oversees the implementation of pharmacovigilance (PV) activities nationwide, including data collection, signal detection, risk assessment, and communication of safety information.

6.2 The MFDA reviews product safety data during market authorization, assesses the benefit–risk profile of new medicines at registration and continuously post-marketing, and monitors ongoing safety to implement timely regulatory actions as needed.

6.3 The Health Protection Agency (HPA) supports the national PV system by monitoring vaccine safety, coordinating immunization programs, and ensuring the timely reporting of Adverse Events Following Immunization (AEFIs). HPA plays a key role in collecting, analyzing, and responding to vaccine-related safety data to protect public health.

6.4 The Pharmaceutical Board under the MFDA serves as the expert committee, providing technical guidance and making evidence-based recommendations to strengthen the national pharmacovigilance (PV) system and ensure the safe use of therapeutic goods across the country.

6.5 Since joining the WHO Programme for International Drug Monitoring (WHO PIDM) in 2016, the Maldives has partnered with the Uppsala Monitoring Centre (WHO-UMC). Through this collaboration, the MFDA uses global PV tools such as VigiFlow, VigiBase, VigiLyze, VigiMine, and VigiSearch to efficiently manage data and detect safety signals.

6.6 To establish a robust National Pharmacovigilance System in the Maldives, the Pharmacovigilance Unit of the MFDA has developed reporting systems, tools, and national guidelines to support medicine safety monitoring. This Guideline has been prepared to educate healthcare professionals, Marketing Authorization Holders (MAHs), and other relevant stakeholders on their roles and responsibilities within the pharmacovigilance system.

7 ADVERSE DRUG REACTION (ADR) REPORTING GUIDE

7.1 HOW TO REPORT?

7.1.1 The ADR Reporting Form is the standardized tool designed for the systematic collection of information related to ADRs and adverse events (AEs).

7.1.2 Each ADR report shall be recorded using ADR Reporting Form No. [MTG/QA-SA/FO 0055], containing required fields that must be filled in completely and accurately.

7.1.3 The form is accessible on the MFDA website (mfda.gov.mv). Submission to the MTG must be completed by mail, adhering fully to the instructions provided.

7.1.4 ADR form shall be completed accurately and clearly, using legible handwriting or typed text, to prevent misinterpretation.

7.2 WHO CAN REPORT?

7.2.1 The effectiveness of a national pharmacovigilance system relies heavily on the active participation of healthcare professionals, who are best placed to detect, and report suspected ADRs through their direct role in diagnosing, prescribing, dispensing, and monitoring patient outcomes.

7.2.2 The following parties shall report suspected ADRs to the Pharmacovigilance (PV) Division of MFDA/MTG:

a. All healthcare professionals — including physicians, dentists, pharmacists, nurses, and other qualified personnel involved in patient care — shall report suspected Adverse Drug Reactions (ADRs) as part of their professional and ethical responsibility.

b. Patients, relatives, and caregivers who observe suspected adverse reactions or therapeutic failures, and their reports shall be actively encouraged as part of patient-centered pharmacovigilance.

c. Marketing Authorization Holders (MAHs), who shall report all ADRs associated with their registered products in accordance with the product registration guideline.

d. Public Health Programs (PHPs) involved in large-scale medication or vaccination campaigns.

e. Spontaneous reports may be submitted directly to the MTG Pharmacovigilance Section by healthcare professionals (including physicians, dentists, pharmacists, and nurses), patients, consumers or their relatives, Marketing Authorization Holders (MAHs), Registration Holders, and Public Health Programs

f. All reporters must fulfill their ethical obligation to report suspected ADRs, even if causality is uncertain. Timely and accurate reporting enables early detection of risks, supports regulatory decisions, and improves patient safety and outcomes.

7.3 WHAT TO REPORT?

Reporters shall submit information on the following situations:

7.3.1 Serious or non-serious suspected adverse drug reactions (ADRs) or adverse events (AEs), whether known or unknown, associated with the use of therapeutic goods.

7.3.2 Lack of therapeutic efficacy, particularly in the case of vaccines, contraceptives, antibiotics, or medicines used in critical or life-threatening conditions.

7.3.3 Adverse outcomes arising from overdose, misuse, abuse, off-label use, occupational exposure, or medication errors involving therapeutic goods

7.3.4 Drug interactions, including both drug–drug and drug–food interactions, that result in adverse effects or treatment failure, shall be reported as adverse reactions in the prescribed manner.

7.3.5 Suspected pharmaceutical defects (quality issues) resulting in adverse events. Such events shall be reported as suspected ADRs, including the batch or lot number of the product if available.

Note: Product quality issues without associated adverse events shall be reported according to the Guideline for Quality Defects and Product Recall (MTG/QA-DR/GLN-TE 004).

7.4 WHEN TO REPORT?

7.4.1 Healthcare professionals and patients shall report suspected adverse events promptly, according to the following timelines:

7.4.1.1 Serious ADRs/AEs – Events such as death, life-threatening reactions, hospitalization, disability, congenital anomalies, or therapy modification shall be reported immediately (within 24–48 hours) to the MTG hotline or the facility's Pharmacovigilance (PV) focal point.

7.4.1.2 Non-serious ADRs/AEs – These shall be reported within one week of identification.

7.4.2 Rationale: Prompt reporting ensures timely safety interventions, helping protect other patients and supporting regulatory action.

7.5 HOW TO REPORT?

7.5.1 All suspected Adverse Drug Reactions (ADRs), including those resulting from medication errors or product quality issues, shall be reported using the Adverse Drug Reaction Reporting Form, available on the MFDA website (mfda.gov.mv).

7.5.2 Patients or individuals who experience unexpected changes or suspect an adverse reaction to a medicine or other substance shall report these concerns to a healthcare professional at the nearest health facility.

7.5.3 Healthcare professionals shall:

a. Examine the product and collect relevant information.
b. Complete the ADR reporting form for any suspected adverse event or product quality issue.
c. Take appropriate action to ensure patient safety and well-being.

7.5.4 In facilities without a designated Pharmacovigilance (PV) focal point, or when patients cannot access a healthcare professional, reports shall be submitted directly to a community health worker or the MTG Pharmacovigilance Section via email (mtg.pharmacovigilance@mfda.gov.mv) or the official hotline.

7.5.5 PV focal points shall collect, review, and ensure timely submission of all ADR reporting forms from their facility to the MTG Pharmacovigilance Section.

7.5.6 All sections of the Suspected ADR Reporting Form shall be completed fully and clearly. Accurate and comprehensive information is essential for causality assessment, regulatory action, and patient safety. Suspected ADRs shall be reported immediately to ensure timely and effective response.

7.5.7 To ensure the report is valid and assessable, the following **five key elements** must be included:

a. *An **identifiable reporter*** (e.g., healthcare professional or facility),
b. *An **identifiable patient*** (name, age, sex, or unique identifier),
c. *A **suspected medicine**,*
d. *A **suspected adverse reaction**, and*
e. *A **plausible time relationship*** between drug administration and reaction onset.

7.6 WHAT HAPPENS ONCE ADR IS REPORTED?

7.6.1 Upon receipt of an identified Adverse Drug Reaction (ADR) or Adverse Event (AE) report, the Pharmacovigilance (PV) Unit staff shall assign a unique identification number and shall document it in the official register.

7.6.2 The report shall be reviewed to ensure all mandatory and required fields are completed. If any follow-up information is needed, the Pharmacovigilance Officer (PO) shall contact the reporting healthcare professional or patient to obtain the missing details.

7.6.3 All ADR reports shall be assessed to determine their severity, causality, and potential impact on public health.

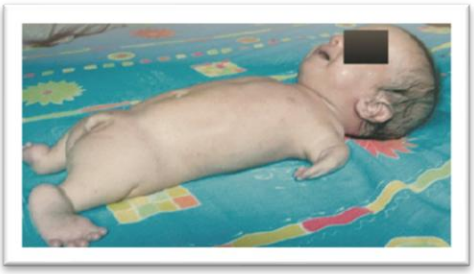
7.6.4 The assessment shall include signal detection, risk management, and evaluation of the benefit–risk balance of the implicated medicinal product(s).

7.6.5 Assessment Process:

a. The PV Officer from the MTG shall perform the initial causality assessment of the reported ADR.
b. The Naranjo Algorithm shall be used as a standardized tool during the causality assessment process to determine the likelihood that the drug caused the reported reaction. (Refer to Annex 2 for further details and the full Naranjo Scale)
c. The outcome of the Naranjo assessment shall categorize the causality as definite, probable, possible, or doubtful.
d. Following initial assessment, the report shall be presented to the Pharmacovigilance Committee for further review and regulatory decision-making.
e. Once causality has been reviewed and confirmed by the Committee, the PO shall enter the finalized report into VigiFlow for international sharing and analysis.
f. All findings and conclusions shall be documented and retained as part of the ADR record for reference, evaluation, and regulatory reporting.
g. A well-completed and duly submitted ADR report may lead to one or more of the following outcomes:

- Additional investigations into the use and safety of the medicine within the country.
- Reclassification or change in the scheduling of the medicine.
- Strengthening of educational initiatives to promote the safe use of medicines.
- Implementation of regulatory or public health interventions, including product recall or withdrawal, where necessary.

7.6.6 Consequently, the ultimate goal of ADR monitoring is to safeguard patients by reducing medication-related risks and improving overall treatment outcomes.



Thalidomide-induced birth defects – *a condition in which babies are born with missing limbs or severely deformed arms and legs, known as phocomelia.*

8 RISK MANAGEMENT PLAN AND SAFETY COMMUNICATION

8.1 Risk Management Plan

8.1.1 Risk management Plan is the structured process of identifying, characterizing, assessing, and prioritizing risks associated with medicinal products, followed by the coordination and efficient deployment of resources to minimize, monitor, control and prevent the probability and impact of adverse events.

8.1.2 The key components of risk management shall include:

- characterizing the safety profile of the medicinal product, including both known and unknown aspects.
- Planning pharmacovigilance (PV) activities to detect new risks, further characterize existing risks, and deepen knowledge of the product's safety profile.
- Implementing risk-minimization and mitigation activities and assessing their effectiveness.

8.1.3 Marketing Authorization Holders (MAHs) shall submit a Risk Management Plan (RMP) for the company. The RMP shall describe the risk management system implemented by the MAH for registered medicinal products and shall include:

- The objectives of the risk management system
- Details of routine risk minimization activities
- Risk Communication measures

8.1.4 At the commencement of each calendar year, the Risk Management Plan (RMP) shall be prepared and submitted to MFDA no later than January of that year.

8.1.5 Upon completion of each calendar year, the MAH shall compile a report detailing all activities undertaken in relate to the approved Risk Management Plan (RMP). The annual data shall be submitted electronically to the MTG Vigilance email address: mtg.vigilance@mfda.gov.mv

8.1.6 The overall objective of risk management shall be to ensure that the benefits of a medicinal product outweigh its risks by the widest achievable margin, both for individual patients and for the target population.

8.2 Safety Communication

8.2.1 Safety communication is a fundamental public health responsibility and a core component of pharmacovigilance. It shall promote the rational, safe and effective use of medicines; prevent adverse reactions; minimize risks; and protect both patient and public health.

8.2.2 Safety communication shall encompass the collection of safety-relevant information from reported Adverse Drug Reactions (ADRs) and global safety data, and the dissemination of this information to relevant audiences.

8.3 Target Audiences for Safety Communication

8.3.1 Safety communication issued by MTG shall primarily target patients and healthcare professionals involved in prescribing, handling, dispensing, administering, or using therapeutic goods and Marketing Authorization Holders (MAHs).

8.3.2 Effective communication shall enable them to implement risk minimization measures and provide clear, reliable information to patients, thereby enhancing patient safety and strengthening public trust in the regulatory system.

8.3.3 Safety communication channels include:

a. **Healthcare professionals (doctors, nurses):** A communication intervention by MTG (for example, a “Dear Healthcare Professional Letter”) shall deliver important safety information directly, instructing on specific actions or changes in clinical practice relating to a medicinal product.

b. **Marketing Authorization Holders (MAHs):** Safety communications to MAHs shall be disseminated via email or other appropriate electronic channels.

9 LEGAL BASIS

These guidelines shall be read in conjunction with the other applicable legislations on drug product (pharmaceutical and biological products) which include but not limited to:

c. Health Service Act (29/2015)

d. Medicine Regulation R-46 (2014)

e. Medicine Regulation Amendment R-49 (2016)

10 References

1. Good pharmacovigilance practices (GVP) | European Medicines Agency (EMA). (2026, February 16). European Medicines Agency (EMA). https://www.ema.europa.eu/en/human-regulatory-overview/post-authorisation/pharmacovigilance-post-authorisation/good-pharmacovigilance-practices-gvp
2. Strategies. (2021, December 1). https://www.who.int/teams/regulation-prequalification/regulation-and-safety/pharmacovigilance/guidance/strategies
3. Guidelines for Detecting & Reporting Adverse Drug Reactions Individual Case Safety, Reports For Healthcare Professionals, Rational Drug Use and Pharmacovigilance Department- JFDA (2014) https://who-umc.org/media/1079/jordan.pdf
4. Access to Medicines and Health Products (MHP). (2002, January 1). *Safety of medicines : a guide to detecting and reporting adverse drug reactions : why health professionals need to take action*. https://www.who.int/publications/i/item/WHO-EDM-QSM-2002-2

11 Annex

ANNEX 1 – ADVERSE DRUG REACTION FORM

ANNEX 2 - NARANJO ALGORITHM FOR CAUSALITY ASSESSMENT

ANNEX 3 - WHO-UMC CAUSALITY CATEGORIES

ANNEX 4 - ADR SEVERITY ASSESSMENT SCALE

ANNEX 1 – ADVERSE DRUG REACTION FORM

Adverse Drug Reaction Reporting Form

MALDIVES FOOD AND DRUG AUTHORITY
MEDICINE AND THERAPEUTIC GOODS DIVISION

For MFDA use only

Rec. No.: MTG/OA-SA/FO 0055/ /

A. PATIENT INFORMATION*

NAME:

DOB: ___/___/_____

NIC/PPN:

Age at Onset: ____Years ____ Months ___ Days

Sex: M/F

If female, pregnant or not: Y/N

Weight (Kg):

Other relevant history of the patient (Allergies, Smoking, Alcohol Use, Hepatic/Renal Problems, and Pre-Existing Medical Problems etc.:

B. SUSPECTED DRUG(S)/VACCINE(S)* *(use additional pages if necessary)*

Name of Drug (Brand Name & Generic Name)	Strength	Dosage Form	Manufacturer / Country of Origin	Batch No.	Route of Administration and Administered Dose	Date Started	Date Stopped
Reason for Use:							

C. ADVERSE REACTION EXPERIENCED/OBSERVED*

Date of onset of reaction:

Does reaction subside after suspect drug discontinuation? ☐ Yes ☐ No

Outcome of the event:

☐ Recovered ☐ Hospitalized ☐ Disability ☐ Unknown ☐ Death, If Died, date of death(D/M/Y):

Description of adverse event (specify if any laboratory test have done):

Doc. No: MTG/QA-SA/FO 0055 **Doc. Name**: Adverse Drug Reaction Reporting Form **Ver. No:** 02 **Issued Date:** 05.12.2024

Treatment for reaction:
Results:

D. REPORTER INFORMATION*

Reporter Name:

Institution: Designation & Department:

Mobile Number: E-mail Address:

FOR OFFICE USE ONLY		
Received By:	Date:	Signature:
Action Taken:		

IMPORTANT NOTES:

- *Please ensure that all sections are filled especially the mandatory fields identified by *.*
- *Report any suspected reaction or event at the earliest (preferably within 24hours) from any pharmaceutical product, vaccine, biological, vitamins & minerals, supplements, herbal medicine/traditional medicines and any radiopharmaceutical.*
- *Provide as much details as possible, attached additional sheets/reports of investigations to ensure full assessment of the event.*

------ **Please send the form to: mtg.vigilance@mfda.gov.mv** ------

ANNEX 2 - NARANJO ALGORITHM FOR CAUSALITY ASSESSMENT

NARANJO ALGORITHM FOR CAUSALITY ASSESSMENT

Naranjo is one of the most widely used methods. It is a questionnaire designed by Naranjo et al, to determine the likelihood of whether an ADR is actually due to the drug rather than the result of other factors. It uses a series of 10 questions and these questions can be answered as Yes, No or Do Not Know. Answers are weighted with scores (-1 to +2) and the total score is ranked on four probability scales, the answer of the aggregate score is the result of causality assessment:

i. "Definite" (Certain): if the score is more than 9.
ii. ii. "Probable": if the score is between 5 -8.
iii. iii. "Possible": if the score is between 1-4.
iv. iv. "Doubtful" (Unlikely): if is less than 1.

S. No	Question	Yes	No	Don't Know	Score
01	Are there previous conclusive reports on this reaction?	(+1)	(0)	(0)	
02	Did the adverse event appear after the suspected drug was administered?	(+2)	(-1)	(0)	
03	Did the adverse event improve when the drug was discontinued or a specific antagonist was administered?	(+1)	(0)	(0)	
04	Did the adverse event reappear when the drug was readministered?	(+2)	(-1)	(0)	
05	Are there alternative causes that could on their own have caused the reaction?	(-1)	(+2)	(0)	
06	Did the reaction reappear when a placebo was given?	(-1)	(+1)	(0)	
07	Was the drug detected in blood or other fluids in concentrations known to be toxic?	(+1)	(0)	(0)	
08	Was the reaction more severe when the dose was increased or less severe when the dose was decreased?	(+1)	(0)	(0)	
09	Did the patient have a similar reaction to the same or similar drugs in any previous exposure?	(+1)	(0)	(0)	
10	Was the adverse event confirmed by any objective evidence?	(+1)	(0)	(0)	

ANNEX 3 - WHO-UMC CAUSALITY CATEGORIES

WHO-UMC Causality Categories

Causality term	*Assessment criteria**
Certain	• Event or laboratory test abnormality, with plausible time relationship to • drug intake • Cannot be explained by disease or other drugs • Response to withdrawal plausible (pharmacologically, pathologically) • Event definitive pharmacologically or phenomenologically (i.e. an objective and specific medical disorder or a recognized pharmacological phenomenon) • Rechallenge satisfactory, if necessary
Probable / Likely	• Event or laboratory test abnormality, with reasonable time relationship to drug intake • Unlikely to be attributed to disease or other drugs • Response to withdrawal clinically reasonable • Rechallenge not required
Possible	• Event or laboratory test abnormality, with reasonable time relationship to drug intake • Could also be explained by disease or other drugs • Information on drug withdrawal may be lacking or unclear
Unlikely	• Event or laboratory test abnormality, with a time to drug intake that • makes a relationship improbable (but not impossible) • Disease or other drugs provide plausible explanations
Conditional / Unclassified	• Event or laboratory test abnormality • More data for proper assessment needed, or • Additional data under examination
Unassessable / Unclassifiable	• Report suggesting an adverse reaction • Cannot be judged because information is insufficient or contradictory • Data cannot be supplemented or verified

ANNEX 4 - ADR SEVERITY ASSESSMENT SCALE

ADR SEVERITY ASSESSMENT SCALE

The severity of a reaction shall be judged according to the: "ADR Severity Assessment Scale". This scale categorizes each ADR broadly into 'Mild', 'Moderate' and 'Severe', and 'Fatal.'

Criteria for Assessment of Severity of an ADR

MILD

- The ADR requires no change in treatment with the suspected drug.
- The ADR requires that the suspected drug be withheld, discontinued, or otherwise changed. No antidote or other treatment is required.
- No increase in length of stay.

MODERATE

- The ADR requires that the suspected drug be withheld, discontinued, or otherwise changed, and/or an antidote or other treatment is required.
- Increases length of stay by at least one day.
- The ADR is the reason for admission.

SEVERE

- The ADR requires intensive medical care.
- The ADR causes permanent harm to the patient.

FATAL

- The ADR either directly or indirectly leads to the death of the patient.