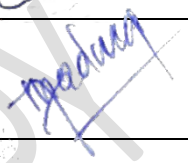
Maldives Food and Drug Authority

Ministry of Health

Male', Maldives

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Guideline on Pharmacovigilance and ADR Reporting

Version Number	3	
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Prepared By	Mariyam Leena, Regulatory Pharmacist	
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	25.01.2026	Overall Document	Major revision of guidelines incorporating international standards	Mariyam Leena, Pharmaceutical Officer
03	24.11.2026	Overall Document	Alignment of the pharmacovigilance and ADR reporting guideline with Medicine Regulation No. 2026/R-64, including ADR monitoring, importer obligations, safety-information sharing, complaints/incidents, rapid alerts, and recall-related PV requirements.	Mariyam Leena, Regulatory Pharmacist

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ABBREVIATIONS

ADR	Adverse Drug Reaction
AE	Adverse Event
AEFI	Adverse Event Following Immunization
API	Active Pharmaceutical Ingredient
CIOMS	Council for International Organizations of Medical Sciences
GVP	Good Pharmacovigilance Practices
HCP	Healthcare Professional
HPA	Health Protection Agency
ICH	International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use
ICSR	Individual Case Safety Report
MAH	Marketing Authorization Holder
MFDA	Maldives Food and Drug Authority
MOH	Ministry of Health
MTG	Medicines and Therapeutic Goods Division
NIP	National Immunization Programme
NPB	National Pharmaceutical Board
NPSC	National Patient Safety Committee
PIDM	Programmer for International Drug Monitoring
PV	Pharmacovigilance
QPPV	Qualified Person for Pharmacovigilance
RMM	Risk Minimization Measure
RMP	Risk Management Plan
SAE	Serious Adverse Event
SAR	Serious Adverse Reaction
SOP	Standard Operating Procedure
SUSAR	Suspected Unexpected Serious Adverse Reaction
UMC	Uppsala Monitoring Centre
WHO	World Health Organization

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DEFINITIONS

Term	Definition
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 Event Following Immunization (AEFI)	Any untoward medical event after immunization, which may or may not be related to the vaccine.
Causality Algorithm	A standardized series of questions used during causality assessment. Various causality algorithms are available; MFDA uses the Naranjo algorithm (see Naranjo Scale or Algorithm).
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.
Importer	A person or entity licensed by MTG to import medicines into the Maldives.
Marketing Authorization Holder (MAH)	The product registration holder (local representative) holding authorization to market a pharmaceutical product in the Maldives and responsible for ensuring the product's quality, safety, and efficacy.
Medication Error (ME)	An unintended failure in the medication process that leads to, or could lead to, harm to the patient. Intentional overdose, off-label use, misuse, and abuse are distinguished from medication errors.
Naranjo Scale (or Algorithm)	A structured questionnaire used to support assessment of the likelihood that a suspected adverse reaction is associated with a medicine. Its findings shall be interpreted alongside clinical judgement and other available evidence.
National Immunization Programme (NIP)	The national programme responsible for coordinating and implementing programme-based immunization activities in the Maldives.
National Patient Safety Committee (NPSC)	A committee managed by the MOH Quality Assurance Division that provides expert advice on medicine safety, efficacy, and quality.
National Pharmaceutical Board (NPB)	An advisory body under MFDA that provides expert advice on medicine safety, efficacy, and quality.
Pharmacovigilance (PV)	The science and activities related to the detection, assessment, understanding, and prevention of adverse effects or any other medicine-related problems.
Pharmacovigilance Focal Point	A person designated by an entity or healthcare facility to coordinate applicable pharmacovigilance activities, including documentation, ADR reporting, follow-up, and communication with MFDA.

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Registered Products	Any medicinal product registered in the Maldives by the MAH, including pre-authorization.
Risk Management Plan (RMP)	A product-specific document describing the medicine's safety profile, pharmacovigilance activities, and measures intended to identify, characterize, prevent, or minimize risks, including arrangements for evaluating the effectiveness of those measures.
Risk Minimization Measure (RMM)	Interventions intended to prevent or reduce the occurrence of adverse reactions associated with 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 causal association, or a new aspect of a known association, between a medicine and an adverse event that warrants further verification or assessment.
Serious Adverse Event / Serious Adverse Reaction (SAE / SAR)	A reaction that results in death, is life-threatening, requires or prolongs hospitalization, causes persistent or significant disability, or is a congenital anomaly. Medical judgement applies to other important medical events, and any suspected transmission of an infectious agent via a product is also serious.
Signal Detection	The process of identifying new or rare adverse effects based on accumulated safety data.
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.
Stakeholder	An individual or group involved in pharmacovigilance, either through participation in decision-making or being affected by related actions.
VigiBase	The WHO global database of Individual Case Safety Reports, maintained by UMC, containing data submitted by member countries.
VigiFlow	A web-based Individual Case Safety Report (ICSR) management system developed by the Uppsala Monitoring Centre (UMC) for use by national pharmacovigilance centres.
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.
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.

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1 INTRODUCTION

The Maldives Food and Drug Authority (MFDA) is responsible for ensuring that medicines used in the Maldives meet established standards of quality, safety, and efficacy. Given the country's reliance on imported medicines and the expanding healthcare sector, effective monitoring of medicine-related risks, including Adverse Drug Reactions (ADRs), medication errors, and pharmaceutical quality problems, is essential to safeguard public health.

Medicines may cause adverse reactions despite appropriate prescribing, dispensing, and use. Certain safety risks may only become apparent following widespread or prolonged use, including among diverse patient populations. Pharmacovigilance (PV) plays a vital role in identifying previously unrecognized adverse reactions, monitoring known safety risks, assessing factors contributing to medicine-related harm, and supporting the continuous evaluation of the benefits and risks of medicines. These activities contribute to safer medicine use, prevention of avoidable harm, and timely regulatory interventions.

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 Uppsala Monitoring Centre (UMC), the WHO Collaborating Centre for International Drug Monitoring. This collaboration supports national pharmacovigilance activities through access to international safety information, reporting systems, technical resources, and expertise.

This Guideline establishes the national pharmacovigilance framework, including the responsibilities of relevant stakeholders and standardized procedures for the identification, documentation, reporting, assessment, investigation, and monitoring of suspected ADRs and other medicine-related safety concerns. It also provides guidance on the management of safety information, signal detection, and communication of identified risks to support appropriate regulatory decisions and the safe use of medicines in the Maldives.

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2 PURPOSE

The main purpose of these Guidelines is to establish a comprehensive national pharmacovigilance framework 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 all medicinal and related products used in the Maldives, including allopathic (conventional) medicines, vaccines and other biological products, blood products, radiological contrast media, and traditional and herbal medicinal products. Suspected ADRs arising from interactions between conventional medicines and traditional or herbal preparations are within scope and shall be reported. Medical devices and *in-vitro* diagnostics are within scope to the extent provided for in the applicable regulations; where a separate reporting route exists for such products, this Guideline records the interface rather than a duplicate procedure.

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.

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- 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 LEGAL BASIS

This Guideline is established in accordance with Medicine Regulation No. 2026/R-64, made under the Health Service Act (Law No. 29/2015), and provides the operational framework for implementing applicable pharmacovigilance and medicine safety requirements.

The relevant provisions of Medicine Regulation No. 2026/R-64 include:

a) ***Clause 11:*** *Pharmacovigilance obligations of medicine registrants, including establishment of pharmacovigilance systems, appointment of designated focal points, post-marketing safety monitoring, reporting, assessment and management of medicine-related risks.*

b) ***Clause 41:*** *Pharmacovigilance and periodic reporting requirements applicable to medicines imported under special healthcare-facility import arrangements.*

c) ***Clause 42:*** *Consideration of relevant international and regional regulatory decisions, recommendations and guidance.*

d) ***Clause 43:*** *Exchange of medicine-related regulatory and safety information with relevant international authorities and organizations.*

e) ***Clause 44:*** *Laboratory analysis and investigation of medicines in accordance with applicable regulatory requirements.*

f) ***Clause 45:*** *Reporting and sharing of suspected adverse drug reactions (ADRs), medicine-related safety concerns and Adverse Events Following Immunization (AEFI), including coordination with the Health Protection Agency (HPA).*

g) ***Clause 47:*** *Reporting, assessment and management of medicine-related complaints and incidents.*

This Guideline shall be read in conjunction with applicable MFDA guidelines governing medicine registration, importation, inspection, quality defects, product recalls, complaints and incident management, and regulatory enforcement.

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5 RESPONSIBILITY & ACCOUNTABILITY

Pharmacovigilance Unit (MFDA) Medicine Regulatory Officer	Responsible for coordinating and implementing the national pharmacovigilance system to ensure continuous monitoring and assessment of medicine safety. Key responsibilities include: ✓ *Establishing and maintaining the national pharmacovigilance system, including mechanisms for ADR reporting, safety monitoring, assessment and regulatory follow-up.* ✓ *Receiving, documenting, assessing and investigating suspected ADR reports and other medicine-related safety concerns, including obtaining additional information where required.* ✓ *Submitting eligible Individual Case Safety Reports (ICSRs) to the WHO global pharmacovigilance database (VigiBase) through approved reporting systems.* ✓ *Conducting signal detection, evaluating emerging safety concerns and performing benefit–risk assessments to recommend appropriate regulatory and risk-minimization measures.* ✓ *Preparing and disseminating approved medicine safety alerts, advisories and other safety communications, and coordinating relevant regulatory follow-up in accordance with applicable MFDA procedures.* ✓ *Coordinating pharmacovigilance activities with relevant regulatory functions, including medicine quality-defect investigations, complaints and incident management, product recalls, inspections and enforcement actions.* ✓ *Collaborating with WHO-PIDM, the Uppsala Monitoring Centre (UMC), HPA and other relevant national and international organizations to support medicine safety surveillance and information sharing.* ✓ *Providing technical guidance, training and awareness programmes on pharmacovigilance and ADR reporting to healthcare professionals, PV focal points and other relevant stakeholders.* ✓ *Maintaining accurate and confidential pharmacovigilance records, monitoring reporting activities and evaluating the effectiveness of the national pharmacovigilance system.*
Director, Pharmaceuticals (Enforcement Section)	Responsible for overseeing regulatory compliance and enforcement activities relating to pharmacovigilance and medicine safety. Key responsibilities include: ✓ *Monitoring compliance of MAHs, importers and other regulated entities with applicable pharmacovigilance requirements.* ✓ *Coordinating regulatory inspections and investigations concerning suspected medicine safety violations and non-compliance.* ✓ *Reviewing and overseeing enforcement actions arising from pharmacovigilance findings, in accordance with applicable legislation, MFDA enforcement guidelines and delegated authority.*

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	✓ *Coordinating with the Pharmacovigilance Unit and other relevant regulatory sections to ensure appropriate follow-up of identified safety concerns and regulatory violations.*
Deputy Director General (MTG) Director General (MFDA)	Responsible for providing strategic leadership, institutional oversight and regulatory direction for the national pharmacovigilance system, within their respective delegated authorities. Key responsibilities include: ✓ *Providing strategic direction and oversight for the implementation and continuous improvement of national pharmacovigilance activities.* ✓ *Ensuring that pharmacovigilance systems and regulatory activities are implemented in accordance with applicable legislation, national policies and relevant international standards.* ✓ *Reviewing and approving significant regulatory decisions, safety communications and risk-management measures, where required under applicable approval procedures.* ✓ *Supporting inter-agency coordination, international collaboration and the allocation of appropriate resources for effective pharmacovigilance activities.*
National Pharmaceutical Board / National Patient Safety Committee	The National Pharmaceutical Board (NPB) and National Patient Safety Committee (NPSC) shall provide technical and expert advice on medicine safety and pharmacovigilance matters within their respective mandates. Their responsibilities, where applicable, include: ✓ *Reviewing significant medicine safety concerns and providing expert recommendations on appropriate regulatory or patient safety measures.* ✓ *Providing technical advice on pharmacovigilance policies, guidelines, risk-management measures and safety communications referred for consultation.* ✓ *Supporting the evaluation of emerging safety risks and recommending appropriate actions within their respective advisory functions.*

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Marketing Authorization Holders (MAHs)	MAHs shall ensure continuous safety monitoring of their registered medicinal products and compliance with applicable pharmacovigilance requirements under Clause 11 of Medicine Regulation No. 2026/R-64. Key responsibilities include: ✓ *Establishing and maintaining a documented pharmacovigilance system supported by approved Standard Operating Procedures (SOPs) for receiving, assessing, documenting, reporting and following up suspected ADRs and other medicine-related safety concerns.* ✓ *Appointing a designated PV focal point and communicating the focal point's name, designation, contact number, email address and subsequent changes to MFDA through mtg.vigilance@mfda.gov.mv.* ✓ *Continuously collecting, reviewing and evaluating post-marketing information on product quality and safety, including information received from manufacturers, healthcare professionals and other relevant sources.* ✓ *Reporting suspected ADRs, emerging safety concerns and significant new safety information to MFDA in accordance with Section 8 of this Guideline and applicable regulatory requirements.* ✓ *Notifying MFDA within the prescribed reporting timeline of any safety-related withdrawal, suspension or significant regulatory restriction affecting their registered products in other countries, together with relevant supporting information.* ✓ *Implementing applicable risk management and risk-minimization measures, including post-marketing safety studies where required, and providing relevant safety information to MFDA upon request.* ✓ *Implementing corrective and preventive measures arising from identified safety risks, including product recalls where applicable, and cooperating with MFDA in regulatory investigations, inspections and enforcement actions.* ✓ *Maintaining accurate and traceable records of suspected ADRs, safety assessments, regulatory communications and risk-management activities in accordance with applicable MFDA requirements.*

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Importers, Distributors, Wholesalers, Retailers and Other Regulated Entities	Medicine importers, distributors, wholesalers, retailers, suppliers and other relevant regulated entities shall comply with applicable medicine safety monitoring and reporting requirements under Medicine Regulation No. 2026/R-64. Key responsibilities include: ✓ *Establishing and maintaining appropriate procedures for identifying, documenting and reporting suspected ADRs, medicine quality defects and other safety concerns, where applicable to their regulated activities.* ✓ *Reporting suspected ADRs and relevant medicine-related safety information to MFDA in accordance with Clause 45 and applicable reporting procedures and timelines.* ✓ *Communicating significant product safety information received from manufacturers, MAHs, regulatory authorities or other relevant sources to MFDA, where required.* ✓ *Cooperating with MFDA in medicine safety investigations, product recalls, inspections and implementation of applicable regulatory measures.* ✓ *Maintaining relevant safety-related records and submitting information to MFDA upon request, in accordance with applicable regulatory requirements.*
Ministry of Health	The Ministry of Health shall provide policy-level support and oversight for the national pharmacovigilance system. Key responsibilities include: ✓ *Providing national policy direction and supporting the integration of pharmacovigilance into healthcare services and patient safety programmes.* ✓ *Facilitating coordination among healthcare institutions and relevant national authorities to strengthen medicine safety monitoring and reporting.* ✓ *Supporting public health responses arising from significant medicine safety concerns and regulatory decisions.* ✓ *Facilitating appropriate institutional and financial support for the sustainability of national pharmacovigilance activities and participation in WHO-PIDM.*
Health Protection Agency (HPA)	HPA shall be responsible for coordinating national vaccine safety monitoring and Adverse Events Following Immunization (AEFI) surveillance in accordance with applicable national requirements. Key responsibilities include: ✓ *Establishing and maintaining appropriate systems for receiving, documenting, assessing and monitoring AEFI reports.* ✓ *Conducting or coordinating AEFI investigations, causality assessments, signal detection and vaccine safety risk assessments, as applicable.* ✓ *Sharing relevant AEFI reports, assessment findings and emerging vaccine safety concerns with the MFDA Pharmacovigilance Unit through approved information-sharing mechanisms.*

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	✓ *Integrating MFDA into AEFI reporting workflows to enable joint evaluation of vaccine-related safety signals.* ✓ *Coordinating with MFDA on vaccine-related safety signals, regulatory assessments, safety communications and necessary risk-management measures.* ✓ *Maintaining accurate and confidential AEFI records and supporting coordinated national vaccine safety surveillance.*
Hospitals	All Hospitals are required to implement & maintain pharmacovigilance systems. Key responsibilities include: ✓ *Designating a focal point for pharmacovigilance and ADR reporting.* ✓ *Notify the MFDA of the designated pharmacovigilance focal point's details, including name, designation, number, and email address. Any changes to the designated focal point's details shall also be communicated to the MFDA via mtg.vigilance@mfda.gov.mv.* ✓ *Ensuring regular submission of ADR reports to MFDA.* ✓ *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* ✓ *Notify the MFDA of the designated pharmacovigilance focal point's details, including name, designation, number, and email address. Any changes to the designated focal point's details shall also be communicated to the MFDA via mtg.vigilance@mfda.gov.mv.* ✓ *Ensuring regular submission of ADR reports to MFDA* ✓ *Supporting MFDA in safety monitoring and audits*
Pharmacovigilance (PV) Focal Point	The designated PV Focal Point shall coordinate pharmacovigilance activities within the respective entity and serve as the primary contact for communication with MFDA. Key responsibilities include: ✓ *Coordinating the identification, collection, documentation and timely reporting of suspected ADRs and other medicine-related safety concerns in accordance with applicable MFDA requirements.* ✓ *Facilitating follow-up of reported cases and providing additional clinical or safety information requested by MFDA.* ✓ *Maintaining accurate and traceable records of ADR reports, follow-up activities and relevant safety communications.* ✓ *Promoting awareness of pharmacovigilance requirements and communicating relevant medicine safety information to concerned personnel.* ✓ *Coordinating the implementation of applicable safety communications, risk-minimization measures and regulatory recommendations issued by MFDA.*

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	✓ *Ensuring that internal review or approval procedures do not delay reporting within prescribed timelines.*
Healthcare Professionals (HCPs)	Doctors, pharmacists, nurses and other relevant healthcare professionals shall contribute to the identification, reporting and prevention of medicine-related safety risks. Key responsibilities include: ✓ *Identifying, documenting and promptly reporting suspected ADRs, medication errors, suspected lack of efficacy and medicine quality concerns in accordance with applicable MFDA requirements.* ✓ *Providing accurate and relevant clinical information in ADR reports, including details of the suspected medicine, adverse reaction and available supporting evidence, while maintaining patient confidentiality.* ✓ *Providing additional clinical information or clarification requested by MFDA or the designated PV focal point to support case assessment and investigation.* ✓ *Promoting safe medicine use and encouraging patients and healthcare personnel to report suspected medicine-related safety concerns.* ✓ *Implementing applicable medicine safety communications and risk-minimization recommendations issued by MFDA or other competent authorities.*
Individual Reporting (Doctors, Nurses, Pharmacists, Community workers, Patients, etc.,)	*Patients, caregivers, community health workers and other individuals are encouraged to report suspected ADRs and medicine-related safety concerns directly to MFDA through designated hotlines, email or other approved reporting channels, or through healthcare professionals.* *Reporting does not require confirmation of a causal relationship between the suspected medicine and the adverse event. The absence of a designated PV focal point or access to a healthcare professional shall not prevent direct reporting.*

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6 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.

6.1 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.

This Guideline addresses spontaneous reporting, active pharmacovigilance, case assessment, signal management, risk management, safety communication and coordination of regulatory responses.

Pharmacovigilance activities shall support the identification and assessment of medicine-related risks to patients and populations and the implementation of measures to prevent or minimize harm.

6.2 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:

- Monitors those medicines and vaccines continue to show a favorable benefit–risk balance through continuous vigilance of patients using medicinal products in real-world conditions, supporting: (1) better prescribing practices based on the newly acquired knowledge, thus improving patient outcomes, and (2) timely regulatory actions if required.
- Supports safer clinical practice by promoting better and more accurate use of medicines based on safety knowledge. This objective is attained through the early detection of new adverse reactions, the observation of changes in known reactions, and the 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.
- Informs the Academia with independent safety information that includes local data.
- Through continued medicine safety monitoring, helps detect rare or serious ADRs and maintain the safe and effective use of medical products.

Therefore, a mature PV system helps improve public health by enabling early identification of new risks and preventing well-known risks, thereby reducing hospitalizations due to medication-related harm and the personal, familial, and economic impact of ADRs.

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6.3 Aims of Pharmacovigilance

The aims of pharmacovigilance are to:

- Promote the safe and rational use of medicines and medical products and medical interventions.
- Detect ADRs promptly.
- Identify, assess, and communicate risks and benefits associated with medicines.
- 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

6.4 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 National 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.

Internally, the National PV System will collaborate with academia to either include PV knowledge in health sciences curricula or design and conduct specific PV research studies that complement PV-based spontaneous reporting.

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6.5 What is Adverse Drug Reaction (ADR)?

An Adverse Drug Reaction (ADR) is a harmful or unintended response to a medicine or any other medicinal product 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. ADRs can happen even when the medicine is used correctly.

Harm associated with the use of a medicine, which is reported in the same way as an ADR, 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 our knowledge and understanding of medicine safety, protect patients and public health, and support informed regulatory action.

6.6 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 were described as: Types C (Continuous), D (Delayed), E (End of use, withdrawal), and F (Failure of therapy). The idea was to try 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
Type A (Augmented)	These reactions happen when a medicine causes an exaggerated version of its usual effect, often depending on the dose. which are predictable and dose-related

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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). which are reactions unpredictable and unrelated to the drug's usual pharmacological action (i.e. most hypersensitivity ADRs.

6.7 Identification, Comprehensive History and Examination of suspected Adverse Drug Reactions

Distinguishing ADRs from the symptoms of an underlying disease may be difficult, as both may involve similar physiological and pathological mechanisms. ADRs may present as a wide range of clinical signs, symptoms, or conditions.

Due to this lack of specificity and the fact that there is no clinical label "ADR", it is difficult to identify any condition as an ADR.

Therefore, the following approach shall be used to assess suspected ADRs:

a) ADRs shall be considered as a potential diagnosis in any patient presenting with new or worsening signs, symptoms, or medical conditions.
b) **A possible medicine-related cause shall be included in the differential diagnosis**, with consideration given to the question: "Could this be caused by a medicine or vaccine?"
c) **A comprehensive medical and medication history shall be obtained**, including all prescribed, over-the-counter, traditional and herbal medicines, vaccines, supplements, and other relevant exposures.
d) **A thorough clinical assessment and examination shall be conducted** to evaluate the patient's condition and the possible relationship between medicine exposure and the reported event.
e) **Alternative causes shall be evaluated**, including underlying diseases, other medicines, toxins, and dietary factors.
f) A medicine-related cause shall be considered particularly when no alternative explanation adequately accounts for the patient's condition.
g) A thorough investigation of the patient shall be conducted to identify the true cause of any new medical issues.
h) **The assessment findings and suspected ADR shall be documented** in the patient's medical records to support appropriate management and reporting.

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6.8 Assess the time sequence of events.

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

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

6.9 Physical examination and laboratory investigations

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

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

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

6.10 Assessment of Drug Withdrawal and Re-administration

6.10.1 Available information on improvement following withdrawal or dose reduction of the suspected medicine shall be documented and considered during causality assessment.

6.10.2 Re-administration shall not be undertaken solely to establish causality. Where re-administration is clinically necessary, the treating healthcare professional shall assess the expected benefits and risks and ensure appropriate patient information, monitoring and documentation.

6.10.3 Absence of withdrawal or re-administration information shall not prevent submission of a suspected ADR report.

6.11 Discarding alternative causes

6.11.1 Assessment shall consider other possible explanations, including underlying disease, concomitant medicines, infections, and other relevant exposures.

6.11.2 Available findings shall be documented and provided with the report or as follow-up information. Reporting shall not be delayed while investigations or causality assessment remain incomplete.

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7 ESTABLISHMENT OF THE NATIONAL PHARMACOVIGILANCE SYSTEM IN MALDIVES

7.1.1 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.

7.1.2 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.

7.1.3 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 and shares AEFI reports with the MFDA via Google Sheets.

7.1.4 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.

7.1.5 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.

7.1.6 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.

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8 COORDINATION OF THE NATIONAL PHARMACOVIGILANCE SYSTEM

8.1.1 The national pharmacovigilance system shall include mechanisms to receive, document, and evaluate information from Marketing Authorization Holders (MAHs), importers, distributors, wholesalers, retailers, healthcare professionals, patients, and other relevant persons regarding suspected adverse drug reactions (ADRs) and other medicine-related safety concerns.

8.1.2 Pharmacovigilance activities shall be coordinated with relevant regulatory functions, including medicine quality-defect investigations, laboratory testing, product complaints, incidents, inspections, safety alerts, and product recalls, where necessary to support comprehensive safety assessment and appropriate regulatory intervention.

8.1.3 MFDA shall coordinate with the Health Protection Agency (HPA) on vaccine safety surveillance, including the reporting, assessment, and follow-up of Adverse Events Following Immunization (AEFI), in accordance with applicable national procedures. Relevant information shall be exchanged through approved secure reporting mechanisms, with arrangements for urgent notification and prevention of duplicate reporting.

8.1.4 MFDA shall facilitate the exchange of medicine safety information with relevant national and international regulatory authorities in accordance with Clauses 42 and 43 of Medicine Regulation No. 2026/R-64, subject to applicable confidentiality and an approved secure information-sharing mechanism. Laboratory investigations shall be conducted in accordance with Clause 44 and relevant approved procedures.

8.1.5 Information obtained through pharmacovigilance activities shall support evidence-based regulatory decisions, including safety communications, risk-minimization measures, further investigations, restrictions, suspension, product recalls, or withdrawal of medicines, where warranted by identified risks and applicable regulatory requirements.

8.2 Risk Management Plans

8.2.1 Where a product-specific Risk Management Plan (RMP) is required, its submission shall be carried out in accordance with the Guideline for Product Registration Including Emergency Use Authorization (MTG/RE-RP/GLN-TE 001) and applicable MFDA procedures.

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8.2.2 Marketing Authorization Holders (MAHs) and other relevant regulated entities shall establish, document, and maintain internal Standard Operating Procedures (SOPs) for applicable pharmacovigilance activities, including safety monitoring, risk assessment, reporting, follow-up, and implementation of risk-minimization measures, in accordance with applicable MFDA regulatory requirements.

8.2.3 MAHs shall implement applicable risk-minimization measures, monitor their effectiveness where required and communicate significant new safety information to MFDA in accordance with this Guideline and applicable authorization conditions.

8.2.4 Submission of an RMP shall not replace individual ADR reporting, periodic submissions or urgent safety notifications required under applicable regulatory provisions.

9 METHODS OF SAFETY DATA COLLECTION: PASSIVE AND ACTIVE PV, AND SENTINEL NETWORKS

9.1.1 The national pharmacovigilance (PV) system shall use two complementary methods: Passive (spontaneous) reporting of suspected ADRs by healthcare professionals, patients, and other reporters; and active PV, which systematically collects adverse-event data for selected medicines, patient groups, or settings.

9.1.2 Spontaneous reporting is the foundation of the PV system and helps detect rare or previously unrecognized ADRs. However, underreporting limits its ability to estimate ADR frequency and identify expected, delayed, or clinically silent reactions. MFDA Shall use active PV and a sentinel hospital network to improve detection and reporting.

9.1.3 MFDA shall initiate active PV, where necessary, for:

9.1.3.1 Newly registered products with limited local safety data;

9.1.3.2 Products used in public health programmes or mass campaigns;

9.1.3.3 Products whose safety is affected by conditions prevalent in the Maldivian population, such as haemoglobinopathies or glucose-6-phosphate dehydrogenase deficiency;

9.1.3.4 Validated safety signals requiring quantification; or Specific ADRs associated with medicines or herbal remedies requiring further characterisation or quantification.

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9.1.4 MFDA Shall initiate a sentinel hospital network to stimulate PV in the facilities where most serious ADRs are expected to converge hospitals. The sentinel network begins with two or three hospitals and is gradually expanded to other hospitals that are smaller or more remote.

9.1.5 Hospital shall designate a PV focal point, preferably a hospital pharmacist or medical doctor, who is responsible for disseminating PV within the facility and for collecting, documenting, Reporting and filing reports of suspected ADRs.

9.1.6 The PV focal point shall collect any type of ADR identified in the emergency room and inpatient and outpatient services and report to MFDA PV Unit.

10 ADVERSE DRUG REACTION (ADR) REPORTING GUIDE

10.1.1 Reports form the basis of safety monitoring of medicines and vaccines; therefore, the MFDA encourages accurate, detailed, and prompt reporting of any suspected adverse reaction associated with medicines and vaccines.

10.1.2 Spontaneous reporting systems are based on recollection of suspected adverse reactions, not certainty. The PV Unit analyses many suspicions and generates hypotheses about new safety issues related to medicinal products. Therefore, do not refrain from reporting because some information is uncertain or missing.

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10.2 HOW TO REPORT?

Reporting Channels and Submission Procedures

10.2.1 Suspected adverse drug reactions (ADRs) and other reportable medicine-related safety concerns shall be documented using the approved MFDA ADR Reporting Form (No. MTG/QA-SA/FO 0055). Reports shall be completed accurately, clearly, and legibly, with all required information provided to the extent available.

10.2.2 The approved ADR Reporting Form shall be accessible through the Ministry website, MFDA website and Dhirithi Portal. Completed reports shall be submitted to the MFDA Pharmacovigilance Unit through the designated email address (mtg.vigilance@mfda.gov.mv) or other approved reporting channels.

10.2.3 Urgent ADR reports and significant medicine-related safety concerns may initially be communicated to MFDA through the official hotline (7200321) or designated email address. Available supporting information and the completed reporting form shall be submitted subsequently in accordance with applicable reporting requirements.

10.2.4 Patients, caregivers, and other individuals may report suspected adverse drug reactions (ADRs) and other medicine-related safety concerns directly to MFDA through designated hotlines, email, or other reporting channels, or through healthcare professionals or community health workers. Direct reporting shall not be restricted by the absence of a designated pharmacovigilance (PV) focal point or access to a healthcare professional.

10.2.5 Healthcare professionals shall assess suspected ADRs based on available clinical information, including patient history, suspected medicines, concomitant treatments, and other possible causes. Relevant medicine quality concerns shall also be documented. Appropriate clinical measures shall be taken to ensure patient safety, and suspected ADRs shall be reported without requiring confirmation of causality.

10.2.6 Designated PV focal points shall facilitate the collection, review, documentation, and timely submission of suspected ADR reports from their respective facilities to MFDA. Internal review, endorsement, or administrative procedures shall not delay reporting within the prescribed timelines.

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10.2.7 For suspected ADRs occurring outside the Maldives involving their registered products, Marketing Authorization Holders (MAHs) shall submit reports using the approved MFDA ADR Reporting Form or another format accepted by MFDA, including the Council for International Organizations of Medical Sciences (CIOMS) reporting form, where applicable.

10.2.8 Suspected medicine quality defects associated with an adverse event shall be reported through the ADR reporting system and referred for appropriate quality investigation. Quality defects without an associated adverse event shall be managed in accordance with the *Guideline for Quality Defects and Product Recall (MTG/QA-DR/GLN-TE 004)*.

10.3 HOW TO FILL THE ADR REPORTING FORM

Minimum Information and Completion of Reports

10.3.1 The minimum information required for a valid Individual Case Safety Report (ICSR) shall include:

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 (i.e. the onset dates of the suspected drug and the ADR, as precise as possible).*

10.3.2 Reporters shall complete the approved ADR Reporting Form accurately, clearly, and as comprehensively as possible, providing all available relevant information, including medicine exposure dates, reaction onset, dose, route of administration, indication, concomitant medicines, relevant medical history, clinical investigations, management, and patient outcome.

10.3.3 Batch or lot numbers and other relevant product-traceability information shall be documented where available, particularly for vaccines, biological products, and suspected medicine quality defects.

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10.3.4 Suspected ADRs shall be reported promptly in accordance with applicable reporting timelines, without awaiting complete information, confirmation of causality, or establishment of a plausible temporal relationship between medicine exposure and reaction onset. Missing or additional information shall be obtained through appropriate follow-up.

10.3.5 Reports that do not initially meet the minimum validity criteria shall be documented and followed up, where appropriate, to obtain the information necessary for further assessment.

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10.4 WHO CAN REPORT?

Persons and Entities Responsible for ADR Reporting

10.4.1 Suspected ADRs and other medicine-related safety concerns may be reported by healthcare professionals, patients, caregivers, Marketing Authorization Holders (MAHs), medicine importers, distributors, wholesalers, retailers, suppliers, public health programmes, and other relevant persons or entities.

10.4.2 Healthcare professionals, including doctors, dentists, pharmacists, nurses, and other qualified personnel involved in patient care, shall identify, document, and report suspected ADRs encountered during clinical practice in accordance with applicable MFDA reporting requirements.

10.4.3 MAHs, medicine importers, distributors, wholesalers, retailers, suppliers, and other regulated persons shall report suspected ADRs and relevant medicine-related safety concerns in accordance with Medicine Regulation No. 2026/R-64 and applicable MFDA requirements.

10.4.4 Public health programmes, including immunization and other medicine-related public health initiatives, shall facilitate the identification, documentation, and reporting of suspected ADRs and relevant safety concerns through the applicable national reporting mechanisms.

10.4.5 Patients, relatives, caregivers, and other members of the public are encouraged to report suspected ADRs, unexpected medicine-related effects, and suspected lack of efficacy directly to MFDA or through healthcare professionals using the approved reporting channels specified in Section 8.2.

10.4.6 Suspected ADRs shall be reported even where the causal relationship with the medicine has not been confirmed. Reporters shall provide available relevant information to support timely safety assessment and appropriate follow-up.

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10.5 CONFIDENTIALITY AND PROTECTION OF REPORTERS

10.5.1 Patient and reporter information shall be handled confidentially and used for authorized pharmacovigilance and regulatory purposes.

10.5.2 Access shall be restricted to authorized persons. Information disclosed for assessment, follow-up, regulatory coordination, or international reporting shall be limited to what is necessary and handled in accordance with applicable law and approved safeguards.

10.5.3 MFDA shall promote a non-punitive reporting culture and protect the confidentiality of persons reporting in good faith, subject to applicable law.

10.5.4 Submission of a suspected ADR report does not, by itself, establish causation, negligence or professional fault.

10.5.5 Medication-error assessments shall identify contributing system factors and opportunities to prevent recurrence. This approach shall not displace legal obligations concerning investigation, disclosure, or accountability.

10.6 WHAT TO REPORT?

Any suspicion of an ADR should be reported in an accurate and timely manner.

Reporters shall submit information on the following situations:

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10.6.1 All serious or fatal suspected ADRs to any medicinal product.

10.6.2 All ADRs or AEs, whether known or unknown, associated with the use of newly marketed therapeutic goods (less than 3 years on the market).

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

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

10.6.5 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.

10.6.6 All suspected pharmaceutical defects (quality issues) associated with an adverse event. 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).

10.7 WHEN TO REPORT?



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

10.7.1.1 Serious ADRs/AEs – Events such as death, life-threatening reactions, hospitalization, disability, congenital anomalies, or therapy modification shall be reported immediately to the MTG hotline (7200321) or via email (mtg.vigilance@mfda.gov.mv)

10.7.1.2 Non-serious ADRs/AEs – These shall be reported within 48-72 hours of identification.

10.7.2 Prompt reporting ensures timely safety interventions, helps protect other patients, and supports regulatory action. It is always better to submit an incomplete report than to wait for more accurate information while other patients are exposed to potential risk.

a.

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10.8 Documenting and record-keeping at the facility

10.8.1 All suspected reactions, including event details, patient information, and actions taken, shall be documented in the patient's records.

10.8.2 Suspected lack of efficacy shall be treated as an ADR for reporting purposes and reported through the same channels.

10.8.3 Medication errors shall be reported regardless of whether they caused harm. The report shall describe the circumstances and contributing factors, be completed in accordance with facility policy, and be submitted to the Pharmacovigilance Unit.

10.8.4 Where similar reactions occur in several patients within the same facility or involve the same product or batch, each case shall be reported, and the facility PV Focal Point shall be informed of the suspected cluster.

10.8.5 Pharmacovigilance records shall be maintained securely and shall permit reconstruction of the original report, follow-up information, assessments, communications, and actions taken.

10.8.6 Related ADR, complaint, incident, quality-defect, laboratory and recall records shall be cross-referenced using appropriate case or product identifiers.

10.8.7 Record-retention periods, access controls, backup arrangements and disposal procedures shall be specified in the applicable approved records-management procedure.

10.9 WHAT HAPPENS ONCE ADR IS REPORTED?

10.9.1 Upon receipt, the Pharmacovigilance Unit shall record the report, assign a unique identifier, and conduct initial triage according to seriousness, urgency and potential public-health impact.

10.9.2 Unit shall review minimum case information, identify possible duplicate reports, seek follow-up information, and acknowledge receipt through the applicable procedure.

10.9.3 The reporter will receive an acknowledgement mail including the official identification number of the report and, if necessary, information about the drug or the ADR.

10.9.4 All ADR reports are assessed for seriousness and causality using standardized algorithms.

- ✓ The assessment includes the detection of potential safety signals or clusters of unexpected reports, which are fully analyzed to raise a safety signal alert, if necessary.

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- ✓ After the identification and characterization of a new safety signal, if required, risk management measures are defined according to the potential impact on public health. These measures can include changes in the product label and/or SPC, communication letters to healthcare professionals and patients.

10.9.5 Depending on the type of safety signal detected, an evaluation of the benefit–risk balance of the implicated medicinal product(s) considering the newly identified risk is conducted. As a result, some recommendations in the clinical guidelines may need to be modified. If the risk exceeds the benefit, or if the ADR has a potential impact on public health, other regulatory measures (including marketing discontinuation) can be considered.

Assessment Process:

10.9.6 The Naranjo Algorithm is 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).

10.9.7 The outcome of the Naranjo assessment shall categorise the causality as definite, probable, possible, or doubtful. However, the main utility of the algorithms is to ensure a homogeneous analysis of all reports, including a search for literature evidence on the ADR and the medicine or vaccine, and to ensure that all available information for discarding causal alternatives has been considered.

10.9.8 Upon receipt of the Adverse Drug Reaction (ADR) or Adverse Event (AE) report, the Pharmacovigilance (PV) Unit staff from the MTG starts a starts a triage process to prioritise the report according to the seriousness of the ADR, the novelty of the drug or in case of a potential cluster of similar ADRs.

10.9.9 The PV Officer performs the initial causality assessment of the reported ADR.

10.9.10 Following initial assessment, the report is classified again. All reports of fatal reactions, new serious ADRs and all serious ADRs of newly marketed drugs are presented to the National Pharmaceutical Board for advice.

All reports are entered into VigiFlow for international sharing once the minimum information is complete, without waiting for the causality assessment or review by the NPB; the assessment is added when it is completed

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10.9.11 All findings and conclusions shall be documented and retained as part of the ADR record for reference, evaluation, and regulatory reporting.

10.9.12 Any complete and duly submitted ADR report may become part of a safety signal, which can lead to one or more of the following outcomes:

- *Additional investigations* into the use and safety of the involved medicine within the country.
- *Reclassification* or *change in the recommended dosing or schedule* of the medicine.
- *Educational initiatives* to promote the safe use of medicines.
- *Changes in the label*, SPC or recommendations in the treatment guidelines.

NOTE: *Not all reports are signals, and not all signals carry label modifications or end with market withdrawal. The final decision depends on the type of ADR, the drug, the causality assessment and the number of similar reports received*

10.10 Signal Management

10.10.1 In PV, a "signal" is information that suggests a new, potentially causal association between a medicine and an adverse event, or a new aspect of a known association, and that is of sufficient likelihood to justify verification. "Signal management" is the set of activities by which such information is detected, assessed, and acted upon.

Signal management proceeds through defined stages:

- detection — the identification of a candidate signal, whether from the accumulation of national reports, from analysis in the WHO global database and its associated tools, from clinician suspicion, or from information communicated by another authority.
- validation — the examination of the available evidence to determine whether the candidate signal is supported well enough to warrant further assessment, or should be closed;
- prioritization — the ranking of validated signals according to the seriousness of the reaction, the number of cases, the strength of the association, and the potential public-health impact;

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- assessment and recommendation — the detailed evaluation of a prioritised signal, leading to a recommendation to the expert advisory body; and
- action and communication — the regulatory or communication measures taken in response, and the recording of the outcome.

11 SAFETY COMMUNICATION

11.1.1 Safety communication is a fundamental public health responsibility and a core component of PV. Any communication describing a signal or a new risk shall promote the rational, safe and effective use of the involved medicine; prevent adverse reactions; minimise risks; and protect both patient and public health.

11.1.2 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. Additionally, it is good practice to use safety communications to actively invite others to identify and report similar cases immediately, to strengthen the signal and understand the real impact of the ADR.

Additional reporting and coordination requirements under Medicine Regulation No. 2026/R-64:

11.1.3 Reports shall not be limited to suspected ADRs alone. Relevant medicine-safety information shall include suspected adverse effects, quality-related safety concerns, clinically significant incidents, and other information that may affect the safety or appropriate use of a medicine.

11.1.4 Marketing Authorization Holders (MAHs), Importers, distributors, wholesalers, retailers, healthcare professionals, and other persons covered by the Regulation shall cooperate with MFDA/MTG in providing information necessary for assessment of a medicine-safety concern. Where a medicine-safety issue is identified, the information shall be escalated without undue delay according to its seriousness and potential public-health impact.

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11.1.5 When an ADR or safety report suggests a product-quality defect, the PV Unit shall coordinate with the responsible quality/inspection function so that the case can be investigated under the applicable quality-defect and product-recall procedures. The ADR record shall retain the available batch/lot and traceability information.

11.1.6 Where the safety concern requires urgent public-health action, the PV Unit shall support rapid communication and regulatory action, including safety alerts, restrictions on use, suspension, withdrawal, or recall, as applicable.

11.2 Target Audiences for Safety Communication

11.2.1 Safety communication issued by MTG shall primarily target healthcare professionals involved in prescribing, handling, dispensing or administering the involved drug. Additionally, MAH (or MAHs) shall also be informed.

11.2.2 Depending on the type of drug and ADR, communication addressed to users should be designed.

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

11.2.4 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 and MAHs shall disseminate relevant MFDA safety communications to their customers, including pharmacies, hospitals, and clinics, as applicable.

c. **Population.** Certain risks and new information about drug safety shall be communicated to the population through social media.

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11.3 Coordination of Regulatory Action

11.3.1 Where safety findings indicate the need for regulatory action, the Pharmacovigilance Unit shall submit its assessment and recommendations to the authorized MFDA decision-maker.

11.3.2 Inspections, investigations, restrictions, suspension, withdrawal, recall and enforcement action shall follow applicable legislation and the relevant approved MFDA guidelines and SOPs.

11.3.3 The Pharmacovigilance Unit shall provide relevant safety evidence and maintain links to the resulting regulatory decisions and follow-up records.

12 References

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

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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

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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 and Concomitant Drugs 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 and time 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):

Doc. No: MTG/QA-SA/FO 0055 **Doc. Name**: Adverse Drug Reactions Reporting Form **Ver. No:** 03 **Issued Date:** 19.10.2026

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

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 from any pharmaceutical product, vaccine, biological, herbal medicine/traditional medicines and any radiological contrast media.*
- *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.