24 April 2025
MCA-GL-308, version 2 - 2025
MCA Technical Working Group

Guideline for the National Pharmacovigilance System

Draft reviewed by MCA Technical Working Group	03 March 2025
Start of public consultation	18 March 2025
End of consultation (deadline for comments)	18 April 2025
Agreed by MCA Technical Working Group	22 April 2025
Approved by MCA Executive Director	24 April 2025
Date of coming into effect	02 May 2025

This guideline replaces version 1 dated 10 December 2021 of the 'MCA Guideline for the National Pharmacovigilance System'.

Version #	**Effective Date**	**Reasons for Change:**
1	10 December 2021	New document
2	02 May 2025	Format changed to the current template; editorial changes; Head of department replaced by Director; signal management moved to a separate section and more details added

Comments should be provided by using the template (MCA-F-021/03) for Submission of Comments and sent to info@mca.gm

Keywords	pharmacovigilance system, national pharmacovigilance centre, medicines safety experts committee, MSEC, regional focal person, signal management

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Guideline for the National Pharmacovigilance System

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Acknowledgements

We duly thank the World Health Organization (WHO) and the European Medicines Agency (EMA) for publishing their guidelines that contributed in several aspects relevantly to the development of this guideline.

1 Introduction (background)

1.1. Due to increased availability and use of medicines (medicinal products, drugs) by the population for the management and control of diseases in The Gambia, there is the need to monitor quality and safety of medicines. Monitoring the adverse reactions (ARs) of medicines, also known as Adverse Drug Reactions (ADRs) and Adverse Events Following Immunisation (AEFIs) are important measures for the safe use of medicines.

1.2. As a result of increased use of over-the-counter medicines, self-medication is on the rise and thus posing higher risk for drug-drug interaction, over dosage and other medicines-related problems.

1.3. Management of ARs and AEFIs require substantial amounts of resources which can be a burden on healthcare delivery systems. There is a need for vigilance starting at Ports of Entry from medicine importation, storage, distribution and use of medicines by the public until the disposal of unused medicines.

1.4. It is thus, essential to set up a National Pharmacovigilance System by the Medicines Control Agency (MCA) to monitor the safety of medicines at all times and at all levels of the healthcare system, supported by all stakeholders.

1.5. Marketing authorisation holders (MAHs), manufacturers and healthcare professionals are key stakeholders in the continuous safety monitoring of medicines marketed in The Gambia.

2 Legal basis

2.1. In pursuance to the Medicines and Related Products Act, 2014 ("Act"), Part VII, Section 48 the Agency shall continually monitor the safety of medicines and related products by analysis of the adverse effect or event reports and by any other means and take appropriate regulatory action when necessary.

2.2. According to the Medicines and Related Products Regulations, 2020 ("Regulations") Part VII Section 53 the Agency shall establish and operate a National Pharmacovigilance System.

2.3. In accordance with the Regulations and MCA Reliance Policy, the Agency recognises regulatory decisions, reports including inspections and recommendations from other Medicines Regulatory Agencies and international bodies like the WHO including the Global Advisory Committee on Vaccine Safety (GACVS). MCA may rely on methods, tools, common processes, standards and templates developed for the safety monitoring by other national and international organisations and implement changes to the existing processes accordingly, if necessary.

3 Purpose and Scope

3.1. This guideline sets out the principles for the performance of the National Pharmacovigilance System as laid down in the Regulations.

3.2. It applies to medicines as defined in the Act and the Regulations including biologicals (e.g. vaccines, blood and blood components), herbal medicines and radiopharmaceutical products.

3.3. This document applies to healthcare professionals in public, private and NGO health facilities, research institutions, marketing authorisation holders (MAH), representatives of MAHs including the Qualified Person for Pharmacovigilance (QPPV), manufacturers, importers, other pharmacovigilance (PV) stakeholders like wholesalers, Director of National Pharmaceutical Services, other persons or entities authorised to distribute medicines and the general public as well as the Medicines Control Agency (MCA).

3.4. The MCA *Guideline for Reporting of Adverse Reactions to Medicines including Vaccines* provides guidance on what, how, and where medicines' safety problems should be reported expedited and the MCA *Guideline for Safety Monitoring of Medicines (Pharmacovigilance) including Vaccines* provides guidance on the monitoring of safety of medicines by all relevant stakeholders.

4 Principles of Pharmacovigilance

4.1 Objectives of Pharmacovigilance

The objectives of Pharmacovigilance are to:

- Improve patient care and safety in relation to the use of medicines;
- Detect problems related to the use of medicines and communicate the findings in a timely manner;
- Contribute to the assessment of benefit, harm, effectiveness and risk of medicines, leading to the prevention of harm and maximisation of benefit;
- Encourage the safe, rational and more effective use of medicines;
- Promote understanding, education and clinical training in the detection of problems related to the use of medicines and its effective communication to the public;
- Monitoring of vaccine safety and efficacy of vaccination programmes;
- Collection, evaluation and reporting of the Adverse Events Following Immunisation (AEFI);
- Timely signal detection; and
- Implementation of appropriate actions to improve access to safe and efficacious medicines and to ensure public health.

4.2 Scope of Pharmacovigilance

4.2.1. The scope of Pharmacovigilance includes:

- Adverse events (AEs) and adverse reactions (ARs) to medicines;

- Adverse events following immunisation (AEFI) and Adverse events of special interest (AESI) with vaccines;
- Medication errors;
- Counterfeit and substandard & falsified medicines;
- Lack of efficacy of medicines or therapeutic failure;
- Interactions;
- Overdose;
- Misuse and abuse of medicines;
- Ongoing benefit-risk evaluation of medicines including post-marketing safety and efficacy studies; and
- Risk management plans (RMP) at time of marketing authorisation of medicines;
- Safety signal detection, analysis and management (see section 8);
- Regulatory actions.

4.3 Pharmacovigilance Process

4.3.1. Pharmacovigilance process comprises:

- Monitoring medicines to identify previously unrecognised adverse effects or indeed any changes in the patterns of known adverse effects;
- Assessing the risks and benefits of medicines in order to determine what action if any (e.g. change in product information, change in category of distribution and/or product recall) is necessary to improve their safe use;
- Monitor the impact of any action taken and give feedback to reporters; and
- Establish back-up system for urgent exchange of information.

5 The National Pharmacovigilance System

5.1 Organisation of the National Pharmacovigilance System

5.1.1. The National Pharmacovigilance System shall comprise

- the Medicines Control Agency (MCA) serving as the National Pharmacovigilance Centre;
- the Medicines Safety Experts Committee (MSEC);
- regional and hospital investigation teams;
- focal persons at the Regional Health Directorates, public health facilities and other health institutions; and
- Public Health Programmes (PHP).

5.1.2. Key stakeholders who will contribute to the National Pharmacovigilance System may include:

- MAHs, representatives of MAHs including the QPPVs, manufacturers and suppliers of medicines;
- representatives from the Ministry of Health, Ministry of Trade and Ministry of Agriculture;
- Director of National Pharmaceutical Services

- the Gambia Chamber of Commerce;
- AEFI Committee, MOH;
- health training institutions;
- health research institutions;
- consumer associations;
- representatives of the media; and
- the public.

5.2 Goals of the National Pharmacovigilance System

5.2.1. The goals of the National Pharmacovigilance System are

- Detection and reporting of medicine safety issues;
- Evaluation of reported medicine safety issues;
- Assessment of the risks and benefits of medicines on the Gambian market;
- Reliable and timely exchange of information on medicine safety issues;
- Educating and informing healthcare professionals, stakeholders and the general public about the safety of medicines;
- Advocate for the rational and safe use of medicines in The Gambia.

5.3 What the Pharmacovigilance system covers

5.3.1. The National Pharmacovigilance System covers all parts of the country:

- All levels of health facilities (public, private and non-governmental);
- All medicines distributed and used in the country;
- All diseases and conditions encountered in the country where medicines are involved;
- All cadres and disciplines of healthcare professionals; and
- Any individual in the country, suspecting a safety or efficacy issue of a medicine including biologicals (e.g. vaccines, blood and blood components), herbal medicines and radiopharmaceutical products.

5.4 The Success of the Pharmacovigilance System

5.4.1. The functionality of the National Pharmacovigilance System is directly dependent on the active participation of all healthcare professionals, MAHs, representatives of MAHs including QPPVs, the general public and other stakeholders.

5.4.2. Healthcare professionals are in the best position to report suspected problems with medicines like ARs and AEFIs observed in their day-to-day patient and consumer care as they diagnose, prescribe and dispense the medicines and monitor the patients' and consumers' response to the medicines.

5.4.3. **All healthcare professionals shall report ARs and AEFIs as part of their professional responsibility, even if they are doubtful about the relationship with the given medicine.**

5.4.4. Healthcare professionals may reduce suffering and save patients' lives by reporting suspected ARs and AEFIs including therapeutic failures.

5.5 Monitoring of the National Pharmacovigilance System

5.5.1. The monitoring of the performance and effectiveness of the National Pharmacovigilance System includes:

- Reviews of the systems by staff involved in pharmacovigilance activities;
- Internal and external audits;
- Pharmacovigilance inspections;
- Regular monitoring and evaluation of the performance of the MCA in accordance with the MCA quality management system requirements;
- Evaluation of the effectiveness of actions taken with respect to minimising risks and increasing the safe use of medicines.

6 Roles and Responsibilities

6.1 National Pharmacovigilance Centre at the Medicines Control Agency (MCA)

6.1.1. The Agency is the core of the National Pharmacovigilance System and will be led by the Director responsible for clinical trials and pharmacovigilance.

6.1.2. The Director and his/her team:

- Shall have the necessary facilities for carrying out his or her duties. She/he shall ensure all safety reports are processed appropriately and timely for review by the MSEC, and in accordance with the applicable standard operating procedure(s).
- Implements appropriate regulatory framework for pharmacovigilance and coordinates and provides technical and managerial support for pharmacovigilance activities.
- Establishes the MSEC, provides the Secretariat for the Committee and supports its work.
- Receives, reviews and processes safety reports such as individual case safety reports (ICSR), periodic safety update reports or periodic benefit-risks evaluation reports, risk management plans, etc and any other information on safety issues of medicines.
- Makes preliminary assessments of the reports and request the reporter for further information in case of missing or unclear data, and supports reporters to investigate ARs and AEFIs reports, if necessary.
- Prepares PV summary reports on all relevant information on a medicine safety issue and submits them together with the ICSRs and PSURs or PBRERs quarterly to the MSEC or as required.
- Develops and maintains the national safety reports database and enters ICSRs into the WHO database "VigiFlow" at the WHO Uppsala Monitoring Centre (UMC).

- Reviews the databases regularly to detect possible safety signals associated with medicines. The evaluation of safety signals is essential to ensuring that MCA has the most up-to-date information on a medicine's benefits and risks.
- Communicates regulatory actions to MAHs, representatives of MAHs including QPPV, manufacturers and suppliers of medicines as well as to other stakeholders and international organisations, as applicable.
- Provides a forum for meetings of pharmacovigilance stakeholders as appropriate, but at least one meeting annually, and provides training to healthcare professionals and other stakeholders on pharmacovigilance, as appropriate. MCA maintains the agenda and minutes and all other documentation of the meetings.
- Communicates with healthcare professionals and professional organisations on evidence-based safety information, provides the general public with information on safety of medicines, and communicates with the media on safety information of medicines.
- Provides feedback to stakeholders on safety issues of medicines.

6.1.3. The Executive Director (ED) of MCA is responsible

- for any regulatory action based on the recommendations from the MSEC with respect to the implicated medicines;
- to ensure that risk assessments are performed, the risk-benefit balance of suspected medicines is determined and options for regulatory actions in respect to implicated medicines are considered;
- to use the rapid alert system for exchange of information on quality issues, batch recalls and substandard and falsified medicines;
- for the public information about any safety issues;
- for the public information during the launch of new medicines regimens and with the update of respective treatment guidelines;
- to ensure the conduct of pharmacovigilance inspections of MAHs, representatives of MAHs including QPPV, and manufacturers of medicines to ensure that they comply with pharmacovigilance regulatory obligations and to facilitate compliance; and
- to ensure the conduct regular audits of its Pharmacovigilance System and its monitoring.

6.2 Medicines Safety Experts Committee (MSEC)

6.2.1. The MSEC reviews and evaluates all safety reports and provides technical expertise.

6.2.2. The committee makes recommendations to the MCA on regulatory actions in response to findings supported by good evidence.

6.2.3. The MSEC shall meet quarterly and in addition when necessary.

6.2.4. The MSEC works in accordance with regulatory requirements, guidelines, standard operating procedures (SOPs) and their Terms of References.

6.3 Health Facilities and Regional Focal Persons

6.3.1. The health facilities are in the frontline of patient care and provide data on ARs and AEFIs based on consumer and patient reports, observations of patients and/or laboratory investigations.

6.3.2. Healthcare professionals shall inform the Agency of any new or existing quality, safety or effectiveness concerns related to any medicine, and shall report ARs or AEFIs in accordance with the MCA *Guideline for Reporting of Adverse Reactions to Medicines including Vaccines* to the Agency.

6.3.3. The Regional Focal Persons provide administrative support to the health facilities and may collect AR and AEFI reports from health facilities and forward them to the MCA.

6.3.4. Healthcare professionals shall encourage patients and consumers to report suspected adverse reactions to medicines to the nearest health facilities.

6.4 Marketing Authorisation Holders

6.4.1. The Marketing Authorisation Holders (MAHs) are responsible for all aspects of their medicines.

6.4.2. MAHs shall permanently and continuously have at their disposal a person who is responsible for Pharmacovigilance, referred to as Qualified Person for Pharmacovigilance (QPPV) as described in the MCA *Guideline for Safety Monitoring of Medicines (Pharmacovigilance) including Vaccines*.

6.4.3. MAHs not resident in The Gambia must have a local representative residing in The Gambia at their disposal. The Agency may accept a regional representative residing a West African country. Where no local representative is identified, the importer fulfills this obligation. For details on representatives of MAHs refer to the MCA *Guideline for Marketing Authorisation (Registration) of Medicines*.

6.4.4. MAHs and representatives of MAHs are required to report safety issues to the Agency in accordance with MCA *Guideline for Reporting of Adverse Reactions to Medicines including Vaccines* and MCA *Guideline for Medicines Safety Monitoring (Pharmacovigilance) including Vaccines.*

6.5 Consumers and General Public

6.5.1. Consumers and General Public should be encouraged to report any adverse event to their healthcare providers and seek medical attention from them.

What are the benefits of reporting?

6.5.2. The healthcare professional and patient stand to benefit as follows:

- Improvement on the quality of care offered to patients;
- Reduction of medicines-related problems leading to better treatment outcome;
- Improved patient confidence in the professional's practice and consequently professional growth;
- Improved knowledge, access to feedback information on medicine related problems reported within the country and internationally;

- Satisfaction for the fulfillment of moral and professional obligation.

7 Reporting of Safety Issues to MCA

7.1 Sources and Types of Safety Issue Reporting

7.1.1. Safety monitoring of medicines by MCA starts before their marketing authorisation and continues while the medicine is marketed in The Gambia until their safe disposal.

Clinical Trials

7.1.2. Adverse Events and Adverse Reactions to medicines occurring in clinical trials are usually reported to the MCA by the sponsor or investigator of the clinical trial. The requirements for safety reporting in clinical trials including Development Safety Updated Reports (DSURs) are described in the MCA *Guideline for Clinical Trials in Humans*.

Spontaneous Reporting

7.1.3. Spontaneous reporting is a process whereby an individual case safety report (ICSR) of an adverse reaction is voluntarily submitted by healthcare professionals from both, the public and private sector including NGOs and research institutions as well as pharmaceutical outlets or other stakeholders, to the MCA.

Literature

7.1.4. The source for a safety report could also be the literature. A list of literature references or a reference to where more detailed information can be found should be provided with the report.

Reporting from Systematic Surveillance

7.1.5. Active surveillance seeks to ascertain information on the safety of medicines via a continuous pre-organised process. Examples are post-marketing surveillance activities including Post Authorisation Safety or Efficacy Studies, Public Health Programs (PHP) such as e.g. 'Expanded Program on Immunization' (EPI) or Drug Event Monitoring and Registries.

Reports by MAHs

7.1.6. The MAHs are required to maintain a pharmacovigilance system, to record all adverse reactions to medicines they become aware of and to report them to the MCA for medicines marketed in The Gambia. Suspected serious adverse reactions that occur in The Gambia and other safety issues must be reported in line with the MCA *Guideline for Reporting of Adverse Reactions to Medicines including Vaccines* and the MCA *Guideline for Safety Monitoring of Medicines (Pharmacovigilance) including Vaccines*. Collated safety information about medicines is provided regularly with Periodic Safety Update Reports (PSURs) or Periodic Benefit-Risk Evaluation Reports (PBRERs).

Consumers

7.1.7. Although consumers are encouraged to report all adverse events to their healthcare providers and seek medical attention from them, consumer may also be the source to report a safety issue to the Agency. Consumer reports will be taken into account when overall safety assessments are made.

Other Sources

7.1.8. Other sources for reports of adverse reactions can be the media including social media and other online sources.

7.2 Forms for Safety Issue Reporting

7.2.1. For an ICSR of a serious adverse reaction to a medicine or a vaccine marketed in The Gambia, the reporter should complete the Adverse Reaction Reporting Form (MCA-F-305/01) or the Adverse Event Following Immunisation Reporting Form (MCA-F-305/01), respectively, which are available from the MCA web-site: www.mca.gm.

7.2.2. Should a report form not be available to a healthcare professional or cannot be completed for any reason within the required time frame for reporting, the initial report to MCA may be provided in writing or verbally by phone or voice message stating the minimum required information on short code number (Qcell), 1233, 3363068 and office line, 4380632.

7.2.3. The completed form may be sent by email at info@mca.gm, provided through an officer of the Agency (e.g. inspector) or delivered by post or hand to: Executive Director, Medicines Control Agency, Off Bertil Harding Highway, Kotu East, Kanifing Municipality, P.O. BOX 3162, Serekunda, The Gambia. For further details on reporting of ICSRs refer to the MCA *Guideline for Reporting of Adverse Reactions to Medicines including Vaccines*.

8 Signal Management

For more details on signal management refer to the MCA *Guideline for Signal Management* and the European Medicines Agency (EMA) guideline on good pharmacovigilance practices (GVP), Module IX – Signal management.

8.1 Sources of data and information

8.1.1. Signals can arise from a wide variety of data sources. This potentially includes all scientific information concerning the use of medicines and the outcome of the use such as quality, non-clinical and clinical data (including pharmacovigilance and pharmacoepidemiological data.

8.1.2. Common sources for signals include spontaneous reporting systems, active surveillance systems, studies and the scientific literature reporting such data.

8.1.3. Signal detection is often based on the periodic monitoring of databases of suspected adverse reactions, which can vary in size or remit (e.g. marketing authorisation holder databases, national databases, EudraVigilance, VigiBase) and other sources.

8.2 Signal detection

8.2.1. Signal detection should follow a methodology which takes into account the nature of data and the characteristics (e.g. time on market, patient exposure, target population) as well as the type of medicine concerned (e.g. vaccines and other biologicals may require specific methodological strategies). Clinical judgement should always be applied.

8.2.2. Signal detection may involve a review of ICSRs, statistical analyses, or a combination of both, depending on the size of the data set. When it is not relevant or feasible to assess each individual case (e.g. signals detected from published studies, healthcare record data), assessment of aggregated data should be considered.

8.2.3. The signal detection process should be adequately documented by each organisation.

8.3 Evaluation during signal validation and further assessment

8.3.1. The following elements should be considered when performing signal validation based on the review of ICSR data:

- Previous awareness;
- Strength of the evidence; and
- Clinical relevance and context.

8.3.2. Additional sources of information may provide further evidence for or against a causal association, or a new aspect of a known association, and may be considered during further assessment of the signal, depending on their relevance for the signal and availability to each organisation.

8.3.3. Within individual organisations, the signal management process may involve several rounds of expert discussions and different levels of decision-making. This may result in various decisions. Any such decision tree should be documented as part of the description of the signal management process.

8.4 Signal prioritisation

8.4.1. Every organisation should consider throughout the signal management process whether signals suggest risks with an important impact on patients' or public health and/or on the risk-benefit balance of the medicine.

8.4.2. In some circumstances, signals that could cause media attention and/or public concerns (e.g. adverse events following mass immunisation) may deserve special attention.

8.4.3. The timeframe for further management of the signal will depend on the prioritisation. Appropriate measures should be considered at any stage if the information available suggests that there could be a risk that requires prevention or minimisation in a timely manner. Such measures may be required before a formal assessment of the signal is concluded. Clinical judgement and flexibility should be applied throughout the process.

8.5 Quality requirements

8.5.1. Signal management is considered a critical process. Any signal management system should be clearly documented to ensure that the system functions properly and effectively, that the roles, responsibilities and required tasks are clear and standardised, that these tasks are conducted by staff with appropriate qualifications and expertise and that there are provisions for appropriate control and, when needed, improvement of the system.

8.5.2. A system of quality management should be applied to all signal management processes. Detailed procedures for this quality system should be developed, documented and implemented. This includes the rationale for the method and periodicity of signal detection activities.

Definitions

Interpretations and abbreviations contained in the MCA Glossary can be found on the MCA Website: **www.mca.gm.**

The definitions provided below apply to the terms used in this guideline. They may have different meanings in other contexts and documents.

The interpretation of terms provided in the Act and Regulations apply, unless further defined in this guideline.

Abuse
The persistent or sporadic, intentional excessive use of a medicine, which is accompanied by harmful physical or psychological effects

Adverse Drug Reaction (ADR) Case Report
A case report in pharmacovigilance is a notification related to a patient who has experienced an adverse medical event or laboratory test abnormality suspected to be induced by a medicine. It is important to stress that healthcare professionals should send reports of ADRs even if they do not have all the information required.

Adverse Event/Experience
Any unwanted medical occurrence that may present during treatment with a pharmaceutical product but which does not necessarily have a causal relationship with this treatment. The basic point here is that an unwanted event occurs during or after the use of a medicine; the time of occurrence may be related to the use of the medicine but the event is not necessarily caused by it.

Adverse Event Following Immunisation (AEFI)
Any untoward medical occurrence which follows immunisation and which does not necessarily have a causal relationship with the usage of the vaccine. The adverse event may be any unfavourable or unintended sign, abnormal laboratory finding, symptom or disease.

Adverse Reaction (AR)/Adverse Drug Reaction (ADR)
A response to a medicine which is noxious and unintended, and which occurs at doses normally used in humans for the prophylaxis, diagnosis, or therapy of disease, or for the modification of physiological function.

Consumer
A person who is not a healthcare professional such as a patient, friend or relative of the patient or any member of the public.

Expedited Reporting
Is the immediate reporting of a serious adverse reaction to the Agency in not more than the certain required time period.

Healthcare professional (Health professional, Health practitioner)
A person who is a medically qualified person such as a physician, dentist, pharmacist, or nurse.

Marketing Authorisation Holder
An organisation that has been issued a licence by the competent authority to market a medicine, medical equipment, or cosmetics within The Gambia or any other country and may or may not be the manufacturer of the particular product.

Individual Case Safety Report (ICSR); synonym: Adverse (Drug) Reaction Report
Format and content for the reporting of one or several suspected adverse reactions to a medicine that occur in a single patient at a specific point of time.

ICSRs shall be used for collection, processing, quality control, coding, classification, medical review and reporting suspected adverse reactions to a medicine that occur in a single patient at a specific point in time. The source for an ICSR could also be the literature, clinical study or post-authorisation safety study.

Medication Error
Any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the healthcare professional, patient or consumer.

Misuse
Situations where the medicine is intentionally and inappropriately used not in accordance with the terms of the marketing authorisation.

New Drug/Medicine
A chemical or biologically active pharmaceutical ingredient that has not previously been issued with a marketing authorisation as an ingredient in any pharmaceutical product in The Gambia.

Overdose
The administration of a quantity of a medicine given per administration or cumulatively, which is above the maximum recommended dose according to the authorised product information.

Periodic Benefit Risk Evaluation Report (PBRER)
An update of the world-wide marketing experience of a product at defined times with focus on formal evaluation of benefit in special population at defined times during post-registration period.

Periodic Safety Update Report (PSUR)
A regular update of the world-wide safety experience of a product at defined times during post registration period.

Pharmacovigilance
The science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other medicine related problem.

Post Authorisation Efficacy Study (PAES)
Any study conducted within the authorised therapeutic indication to address well-reasoned scientific uncertainties on aspects of the evidence of benefits that should be, or can only be, addressed post-authorisation.

Post Authorisation Safety Study (PASS)
Any study relating to an authorised product conducted with the aim of identifying, characterising or quantifying a safety hazard, confirming the safety profile of the product, or of measuring the effectiveness of risk management measures.

Qualified Person for Pharmacovigilance (QPPV)
An individual named by a Marketing Authorisation Holder (MAH) and approved by the Agency as the person responsible for ensuring that the company (the MAH) meets its legal obligations for monitoring of the safety of the product marketed in The Gambia.

Risk Benefit Balance
An evaluation of the positive therapeutic effects of the medicine in relation to the risks (any risk relating to the quality, safety or efficacy of the medicine as regards patients' health or public health).

Risk Management Plan
A systematic approach and set of pharmacovigilance activities and interventions designed to identify, characterise, prevent or minimise risks relating to medicines, and the assessment of effectiveness of those interventions and how these risks will be communicated to the Agency and the general population.

Serious Adverse Event or Reaction (SAE/SAR)
Any untoward medical occurrence that at any dose:

- results in death, or
- is life-threatening, or
- requires inpatient hospitalisation or prolongation of existing hospitalisation, or
- results in persistent or significant disability/incapacity, or
- is a congenital anomaly (birth defect), or
- is otherwise medically important event or reaction (e.g. that it does not meet preceding criteria, but is considered serious because treatment/intervention would be required to prevent one of the preceding criteria).

  Note: The term "life-threatening" in the definition of "serious" refers to an event/reaction in which the patient was at risk of death at the time of the event/reaction; it does not refer to an event/reaction which hypothetically might have caused death if it were more severe.

Side Effect
Any unintended effect of a pharmaceutical product occurring at doses normally used in human, which is related to the pharmaceutical properties of the medicine. Such effects may or may not be beneficial. Side effects are related to the known properties of the medicine and can often be predicted. It must be stressed that in pharmacovigilance, interest lies in all medicine related reactions, this includes side effects and suspected adverse drug reactions. Healthcare professionals must therefore report all medicine related problems to the National Pharmacovigilance Centre (NPC) at the Agency.

Signal
Refers to "Reported information on a possible causal relationship between an adverse event and a medicine; the relationship being known or incompletely documented previously" Usually more than a single report is required to generate a signal depending upon the seriousness of the event and the quality of the information.

Spontaneous Report or Spontaneous Notification
Unsolicited voluntary communication to the Agency by a patient, consumer, healthcare professional, marketing authorisation holder, representative of a MAH or any other organisation that describes a suspected adverse reaction in a patient or consumer who is given one or more medicines and which is not derived from a study or any organised data collection systems where adverse event reporting is actively sought.

Unexpected adverse reaction
An adverse reaction, the nature or severity of which is not consistent with domestic labelling or market authorisation, or expected from the characteristic of the medicine.

References

- Medicines and Related Products Act, 2014
- Medicines and Related Products Regulations, 2020
- MCA Guideline for Marketing Authorisation (Registration) of Medicines (MCA-GL-102)
- MCA Guideline for Reporting of Adverse Reactions to Medicines including Vaccines (MCA-GL-305)
- MCA Guideline for Medicines Safety Monitoring (Pharmacovigilance) including Vaccines (MCA-GL-307)
- MCA Guideline for Signal Management (MCA-GL-309)
- MCA Guideline for Clinical Trials in Humans (MCA-GL-501)
- WAHO Good Pharmacovigilance Practice Guidelines, 2018
- WHO Collaborating Centre for International Drug Monitoring (UMC). Safety Monitoring of Medicinal products – Guidelines for Setting Up and Running a Pharmacovigilance Centre. 2000
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Diagram: Stakeholders in Pharmacovigilance