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MCA Technical Working Group

Guideline for Reporting of Adverse Reactions to Medicines including Vaccines

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This guideline replaces version 2 dated 10 December 2021 of the 'MCA Guideline for Reporting of Adverse Reactions to Medicines including Vaccines'.

Version #	**Effective Date**	**Reasons for Change:**
1	30 March 2017	New document
2	10 December 2021	Format changed to the current template; title changed; contents split into three different guidelines; adverse events following immunisation (AEFI) included; editorial changes
3	02 May 2025	Format changed to the current template; editorial changes; AEFIs more detailed; reporting timelines for healthcare professionals changed; Diagram included.

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

Keywords	adverse reaction, AR, ADR, adverse event, AE, adverse events following immunisation, AEFI, individual case safety report, ICSR, pharmacovigilance

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Guideline for Reporting of Adverse Reactions to Medicines including Vaccines

Table of contents

Acknowledgements

We duly thank the World Health Organization (WHO) and the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) 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 including vaccines by the population for the management and control of diseases in The Gambia, there is the need to monitor quality and safety of these products. 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. The effectiveness of safety monitoring of medicines including vaccines in The Gambia by the MCA is directly dependent on the active participation of healthcare professionals as they are in the best position to detect suspected adverse reactions observed in their everyday patient care.

1.3. All healthcare providers (physicians, pharmacists, dentists and others) should report adverse reactions to medicines to the Agency as part of their professional responsibility, even if they are doubtful about the precise relationship with the given medication.

1.4. Healthcare professionals, marketing authorisation holders (MAHs) and manufacturers are key stakeholders in the detection and reporting of safety issues of medicines marketed in The Gambia.

2 Legal basis

2.1. The regulation of medicines in The Gambia is governed by the provisions and requirements of the Medicines and Related Products Act, 2014 ("Act"), by which the Medicines Control Agency (MCA) was established as the regulatory body for medicines and related products.

2.2. Part II Sections 4 (c) requires the Agency to ensure that evidence of existing and new adverse events, interactions and information about pharmacovigilance of medicines being monitored globally, are analysed and acted upon.

2.3. The Medicines and Related Products Regulations, 2020 ("Regulations") details the legal requirements.

2.4. In accordance with the Regulations MCA functions as the National Pharmacovigilance Centre. Safety monitoring of medicines by the Agency ensures that they continue to be safe for patients and the general public.

2.5. 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. In pursuance of the law this document provides guidance on the detection of adverse reactions to medicines including vaccines in humans and reporting requirements to the Agency.

3.2. This guideline 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. It applies to healthcare professionals, MAHs, representatives of MAHs, manufacturers and other stakeholders who suspect an adverse reaction resulting

from the use of a marketed medicine including vaccine, its abuse, misuse, overdose, interactions, medication error, lack of efficacy or suspected counterfeit medicine.

3.4. This guideline applies also to clinical research including clinical trials using medicines including vaccines within the scope of their marketing authorisation (registration) (e.g. Phase IV clinical trials, auxiliary medicines or non-investigational medicinal products, etc) and non-interventional post-marketing safety or efficacy studies.

3.5. For reporting of adverse events occurring in clinical trials in relation to an investigational medicinal product a separate guideline is available (see MCA *Guideline for Clinical Trials in Humans* (MCA-GL-501).

4 Detection of Adverse Reactions (ARs and AEFIs)

4.1 Recognition of an Adverse Reaction (AR)

4.1.1. The risk of ARs is one probable consequence of the use of medicines which includes vaccines. Since ARs may act through the same physiological and pathological pathways as different diseases, they can be difficult and sometimes impossible to distinguish. However, the rational use of medicines and the following step-wise approach may be helpful in assessing possible ARs to a medicine:

- Use few medicines, whenever possible;
- Use medicines that you know well;
- Do not change therapy from known medicines to unfamiliar ones without good reasons;
- Use the product information provided by the marketing authorisation holder/manufacturer of the medicine, textbooks and other reference material providing information on medicine's indications, contraindications, precautions, adverse reactions and interactions;
- Examine the packaging for its condition, spelling mistakes, grammatical errors, registration number and expiry dates to avoid using a falsified or wrong product;
- Review the storage conditions to ensure the product was kept e.g. at the required temperature;
- Take extra care when you prescribe medicines known to exhibit a large variety of interactions and adverse reactions (anticoagulants, hypoglycaemics, and centrally acting medicines) with careful monitoring of patients for such reactions;
- Beware of the interaction of medicines with certain foods, alcohol or herbal medicines;
- Review all medicines used by patients regularly, taking special notice of those bought without prescription, (over the counter, herbal medicines, cosmetics, etc);

- Be particularly careful when prescribing for children, the elderly, pregnant and nursing women, the seriously ill patients with hepatic and renal diseases. Careful continuous monitoring is essential in these patients;
- If patients show signs or symptoms not clearly explained by the course of their illness, think of an adverse reaction to a medicine;
- If you suspect an adverse reaction, consider stopping the medicine or reduce the dosage as soon as possible and report the adverse reaction to the Agency.
- When reporting (see Section 3), describe the reaction as clearly as possible and provide an accurate diagnosis, where possible.

4.2 Assessment of the Reaction

4.2.1. It is essential that the patient is thoroughly investigated to decide what the actual cause of any new medical problem is.

4.2.2. To know whether a patient's condition is an AR the following steps may be helpful in the assessment:

- Take a full medical history and consider whether this reaction can be explained by other causes e.g. patient's underlying disease, other medicines, herbal medicines, toxins or foods.
- A medicine-related cause should be considered, especially when other causes do not explain the patient's condition.
- Establish the time relationship as some reactions occur immediately after being given a medicine while other reactions take time to develop. The time from the start of therapy to the time of onset of the suspected reaction must be logical.
- Do a thorough physical examination with appropriate laboratory investigations. Few medicines produce distinctive physical signs (e.g. steroid-induced dermal atrophy, acute extrapyramidal reactions).
- Lab tests are especially important if the medicine is considered essential in improving patient care or if the lab test results will improve management of the patient.
- Determine the effect of dechallenge and rechallenge, when necessary.
  - If you withdraw the medicine and the reaction resolves, the suspicion of a medicine-induced cause is a strong, although not conclusive.
  - If the medicine is reintroduced after its previous withdrawal (dechallenge) and the reaction reoccurs, the causal relationship with the suspected medicine is almost certain. A re-challenge happens often unintended by the healthcare professional or patient, where an event had occurred when the product was used before, but that a causal relationship was not assumed. An intended rechallenge is only justifiable when the benefit of re-introducing the medicine to the patient outweighs the risk of recurrence of the reaction, which is rare, and in some cases the reaction may be more severe on repeat exposure.
- Check the known pharmacology of the medicine and whether the reaction is known to occur as stated in product information or other reference. If

the reaction is not documented, it does not mean that the reaction cannot occur with that particular medicine.

4.2.3. In order to assess the likelihood that the suspected adverse reaction is actually due to the medicine, Appendix 1 provides a list of causality assessment criteria for deciding on the contribution of the medicine towards the adverse event.

4.2.4. For regulatory reporting purposes, if a reaction is spontaneously reported by the healthcare professional as primary source, even if the relationship is unknown or unstated, it meets the definition of an adverse reaction to the medicine, unless the primary source specifically states that they believe the event to be unrelated or that a causal relationship can be excluded.

4.3 Adverse Events Following Immunisation (AEFI)

4.3.1. Although the use of vaccines is very different from the use of medicines, some of the same safety principles apply.

4.3.2. One important difference is that most medicines are generally used to treat or control diseases among those who have health problems, while vaccines are usually administered to large numbers of healthy people in order to prevent diseases.

4.3.3. Vaccination induces immunity by causing the recipient's immune system to react to antigens contained in the vaccine. Ideally vaccines will cause no, or only minor (non-severe) adverse reactions. A successful vaccine keeps even minor reactions to a minimum while producing the best possible immune response.

4.3.4. Unfavourable or unintended signs, abnormal laboratory findings, symptoms or diseases that might be linked to the vaccine can be as follows:

- Local reactions (e.g. pain, swelling, redness) and systemic reactions (e.g. fever, irritability, malaise, systemic symptoms) can occur as part of the immune response. Other vaccine components (e.g. adjuvants, stabilisers, preservatives) can trigger reactions.

  These reactions typically occur within a day or two of immunisation (except for rash reactions after measles vaccine) and persist from one to a few days.

- Severe vaccine reactions include, among others, seizures, thrombocytopenia, hypotonic hyporesponsive episodes (HHE) and prolonged crying. Most severe vaccine reactions do not lead to long-term problems. Anaphylaxis, while potentially fatal, is treatable without leaving any long-term effects.

4.3.5. The valid diagnosis should meet a standard case definition (or it could also be a syndromic case definition) like the Brighton Collaboration case definition which can be accessed online (https://www.brightoncollaboration.org/). Some case definitions for AEFI and corresponding vaccines are listed in Annex 3.

4.3.6. Other AEFIs may be due to a vaccine quality defect, immunisation error or immunisation anxiety or it may be a coincidental event.

4.3.7. Events that should be reported after immunisation to the Agency as ICSR are listed in Appendix 2.

4.3.8. Prior to vaccination, the responsible healthcare professional should

- read the product information provided by the marketing authorisation holder/manufacturer of the vaccine;
- examine the packaging for its condition, spelling mistakes, grammatical errors, registration number and expiry dates to avoid using a falsified or wrong product;
- inspect the product to ensure it looks correct, is not discoloured, degraded, etc. to identify quality problems;
- review the storage conditions to ensure the vaccine was kept e.g. at the required temperature.

5 Requirements for Reporting of Adverse Reactions (ARs and AEFIs)

5.1 Some Basic Principles of Efficient Reporting

Timelines of Reporting (see also table below)

- The AR should be reported soon after it occurs. A recent AR is easier to report upon as the report is likely to be more accurate. The completed report should be sent through the appropriate channel to the MCA immediately, but not later than stipulated in this guideline.
- If possible, the decision to report whilst the patient is still with the healthcare professional should be taken, so that s/he can easily be questioned about the AR and all the details can be filled on the reporting form at once.
- Healthcare professionals are requested to report all suspected serious adverse reactions (SARs) and serious Adverse Events Following Immunisation (AEFIs), whether expected or unexpected, associated with the use of any medicine or vaccine in The Gambia to the MCA within **7 calendar days** of becomibg aware of the SAR or AEFI.
- MAHs and representatives of MAHs shall report suspected serious adverse reactions (SARs) and serious AEFIs, whether expected or unexpected, associated with the use of any medicine or vaccine in The Gambia to the Agency immediately but not later than **15 calendar days** of becoming aware of the SAR or AEFI.
- Events which may affect the benefit-risk balance of a medicine (emerging safety issue) shall be reported in writing to the Agency immediately but not later than **3 calendar days (72 hours)** when becoming aware of them. For details refer to the MCA *Guideline for Safety Monitoring of Medicines (Pharmacovigilance) including Vaccines*.
- In case all the information needed is not available at the time of reporting, the reporter should submit an initial report containing at least the minimum data required (patient details, suspected product details, reaction details and the reporter details). A follow-up report containing more detailed information should be submitted not later than 15 calendar days.

- Non-serious adverse reactions should be reported to the Agency within **90 days**.

Integrity/Reliability

- If any supplementary data is obtained later, e.g. if the same patient develops the reaction again, or if something happens which increases or verifies the suspicion or seems to exclude the reaction caused by the medicine, a follow-up report should be sent immediately.

Completeness/Eligibility of Report

- The minimum required information for a report is the following:
  - An identifiable source of information;
  - An identifiable patient;
  - An identifiable suspect medicine; and
  - An identifiable event, reaction or outcome that can be identified as serious.
- If any of these essential elements is missing, then such a report is incomplete and not useful as it cannot be evaluated by MCA.

Type of Report	**Time frame for reporting**	**Format**
Occurred in The Gambia		
SARs and serious AEFIs (expected and unexpected) by healthcare professionals as ICSR	7 calendar days	AR Form
SARs and serious AEFIs (expected and unexpected) by MAHs as ICSR	15 calendar days	AR Form
Non serious ARs and AEFIs by all as ICSR	90 days	AR Form
Follow-up reports	15 calendar days	AR Form
Foreign reports including literature		
Foreign serious and unexpected ARs and AEFIs by MAHs as ICSR	15 calendar days	AR Form
All other ARs and AEFIs	Periodically	PSUR/PBRER
Emerging Safety Issues		
New information that impacts the benefit-risk profile of product including international regulatory decisions	72 hours (3 calendar days)	Detailed report
Action relating to product safety taken by a NMRA outside the country	3 working days	Detailed report

5.2 General Principles

What to report

5.2.1. For all medicines including vaccines the following should be reported to the Agency:

- Adverse reactions (AR) resulting from non-prescription and prescription medicines;
- Adverse reactions following immunisation;
- Adverse reactions occurring in a recipient of blood or blood components;
- Adverse reactions resulting from medicines used within the scope of their marketing authorisation during clinical research studies;
- Overdose, misuse, abuse or medication errors resulting in an adverse reaction;
- Quality defects of a medicine resulting in an adverse reaction;
- Lack of therapeutic efficacy of certain medicines or vaccination failure following immunisation;
- Serious adverse reactions should be reported expedited as individual case safety reports (ICSR). The outcomes that constitute a serious adverse event or reaction are listed under definitions.

How to report

5.2.2. For an ICSR of a serious adverse reaction to a medicine or 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-305/02), respectively, which are available from the MCA website: www.mca.gm or an equivalent complying with the CIOMS 1 format (e.g. in-house reporting forms, FDA-3500 form, CIOMS form).

5.2.3. 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, mobile no.3363068 and office line no. 4380632.

5.2.4. Although consumers are encouraged to report all adverse events to their healthcare providers, consumer reports will however be documented by the Agency as any other type of report and will be taken into account when overall safety assessments are made. Consumer may report adverse reactions by email (info@mca.gm) or by phone using the short code number (Qcell), 1233, mobile no. 3363068 and office line no. 4380632.

5.2.5. 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.

5.3 Information to be provided on the Reporting Form

5.3.1. The following information about the **patient** should be provided:

- Patient initials or patient number (the patient's data protection shall be observed)
- Date of Birth and/or Age;

- Sex;
- Weight (for AR reports);
- Name of the health facility or vaccination centre (for AEFI reports);

5.3.2. The following information about the **reaction** should be provided:

- A detailed description of the reaction;
- The date~~s~~ of onset of the reaction;
- Outcome of the reaction;
- The treatment provided for the reaction (if any).

5.3.3. The following information about the **suspected medicine** should be provided:

- Brand and generic name of the medicine, expiry date, batch/lot number (if known), name of the manufacturer, route of administration and daily dose. If there is more than one suspected medicine, a separate sheet should be attached;
- The dates the therapy was initiated and stopped;
- Dechallenge and rechallenge information, where available;
- Indication or reason(s) for use of the medicine;
- Concomitant medicines including herbal medicines and self-medication taken within the last three months with dates of administration (if known).
- Laboratory tests and results, if any;
- Suspected or confirmed medication error, where available;
- Suspected or confirmed poor quality/defect of the medicine or vaccine, where available.

5.3.4. The following information about the **reporter** should be provided:

- Name and address;
- Institution & Department (for AEFI reports);
- Profession/Designation;
- Region (for AEFI reports)
- Contact details (phone number, e-mail).

5.3.5. Additional information, not available at the time of the initial report, should be provided in the form of follow-up reports.

5.4 Responsibilities of Marketing Authorisation Holders (MAHs)

5.4.1. The MAH is responsible for the quality, safety and efficacy of the products in the market which includes to monitor the products to detect any adverse reaction.

5.4.2. MAHs shall permanently and continuously have at their disposal a person who is responsible for Pharmacovigilance, referred to as Qualified Person for Pharmacovigilance (QPPV). For details on the QPPV refer to the MCA *Guideline for Safety Monitoring of Medicines (Pharmacovigilance) including Vaccines* (MCA-GL-307).

5.4.3. 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* (MCA-GL-102).

5.4.4. MAHs or their representatives shall immediately inform the Agency of any suspected serious adverse reaction that occurred in The Gambia and suspected unexpected serious adverse reactions (SUSARs) that occurred in any other country as described above in sections 5.1 - 5.3.

5.4.5. All other safety information shall be reported to the Agency periodically as described in the MCA *Guideline for Safety Monitoring of Medicines (Pharmacovigilance) including Vaccines* (MCA-GL-307).

5.5 Roles of Healthcare Professionals

5.5.1. Healthcare professionals are encouraged to assess all adverse events received from consumers or patients guided by the following general approach:

- Consumers and patients should be encouraged to report any adverse event to their healthcare providers and seek medical attention from them; and
- During all contacts, attempts should be made to obtain information sufficient to ascertain the nature, severity and course of the event.

5.5.2. Additional follow-up or medical confirmation may not be necessary for an apparently non-serious and expected adverse reaction to a medicine.

5.5.3. If the event is serious or unexpected, additional efforts should be made to receive the relevant medical documentation to allow for assessment of causality. A guide for the assessment of causality is provided in Appendix 1.

5.5.4. Adverse reactions shall be considered reportable according to the requirements outlined in this guideline regardless of whether or not the medicine was used in accordance with the product information provided by the marketing authorisation holder or manufacturer.

5.5.5. Healthcare professionals shall report all serious adverse reactions to the Agency. Refer above to the section on "How to report".

5.5.6. **In summary, the purpose of AR reporting is to reduce the risks associated with prescribing and administration of medicines and to ultimately improve patient care, safety and treatment outcomes.**

5.6 Roles of Consumers and General Public

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

What are the benefits of reporting?

5.6.2. 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.

5.7 Reporting in Special Situations

Overdose, abuse, misuse and medication error

5.7.1. Healthcare professionals, MAHs, representatives of MAHs and other stakeholders should notify the MCA when they are aware of overdose, abuse, misuse or medication error (accidental or intentional).

5.7.2. If overdose, abuse, misuse or medication error is associated with a suspected serious adverse reaction, the adverse reaction should be submitted to MCA as ICSR.

5.7.3. The reports of overdose, abuse, misuse or medication error should be routinely followed-up by the MCA to ensure that the information is as complete as possible with regard to the symptoms, suspected medicines, outcomes and context of occurrence (e.g. error in prescription, administration, dispensing, dosage, unauthorised indication or population, etc.).

Lack of Efficacy

5.7.4. Healthcare professionals, MAHs, representatives of MAHs and other stakeholders should notify the MCA when they are aware of lack of efficacy or vaccination failure.

5.7.5. If the medicines used in critical conditions or for the treatment of life-threatening diseases or contraceptives, lack of therapeutic efficacy should be reported as ICSRs, unless the reporter has specifically stated that the outcome was due to disease progression and was not related to the medicine.

5.7.6. Clinical judgement should be used when considering if cases of lack of therapeutic efficacy is qualified for submission or not. For example, a report of lack of therapeutic efficacy with an antibiotic used in a life-threatening situation where the use of the medicine was not in fact appropriate for the infective agent should not be submitted.

5.7.7. For vaccines, cases of lack of prophylactic efficacy should always be submitted as ICSRs, in particular with the view to highlight potential signals of reduced immunogenicity in a sub-group of vaccines, waning immunity, or strain replacement.

Poor Quality/Defect of Medicines (including Vaccines)

5.7.8. Poor medicine quality including suspected counterfeits not associated with a suspected adverse reaction should be reported using the form 'Product Complaint Form' which is available on the MCA website www.mca.gm.

5.7.9. If a product quality problem is associated with a suspected serious adverse reaction, the adverse reaction should be submitted to MCA as ICSR.

6 Management of Adverse Reaction Reports by the Agency

6.1. Any information related to the reporter and consumer or patient is kept strictly confidential.

6.2. The Agency analyses the adverse reaction reports and takes appropriate regulatory action when necessary.

6.3. The Agency shall establish a Medicines Safety Experts Committee (MSEC) for the review and causality assessment of the reports in line with WHO Causality assessment criteria (Appendix 1)

6.4. The Agency may perform additional investigations, if necessary.

6.5. The Agency should acknowledge receipt of ICSRs within 5 working days of receipt. The initial acknowledgement may be in the form of a telephone call or e-mail which may be followed by an official written acknowledgement letter.

6.6. The Agency may provide feedback of evaluation of an ICSR to the reporter after the causality assessment of the submitted report, if it has an implication for further treatment of the patient or leads to regulatory actions. The information obtained from the report will not be used for commercial or other purposes, but is only meant to improve the understanding of safety in relation to the use of medicines in The Gambia.

6.7. The Agency submits ICSRs received from healthcare professionals in The Gambia that are both serious and unexpected to the MAHs or representatives of MAHs within seven (7) calendar days.

6.8. The Agency enters ICSRs on marketed medicines into the WHO provided web-based individual case safety report (ICSR) management system, VigiFlow. Details of the reports are stored confidentially in the WHO global ICSRs database VigiBase.

6.9. The Agency maintains all ICSRs and related documentation in respective files for at least ten years.

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.

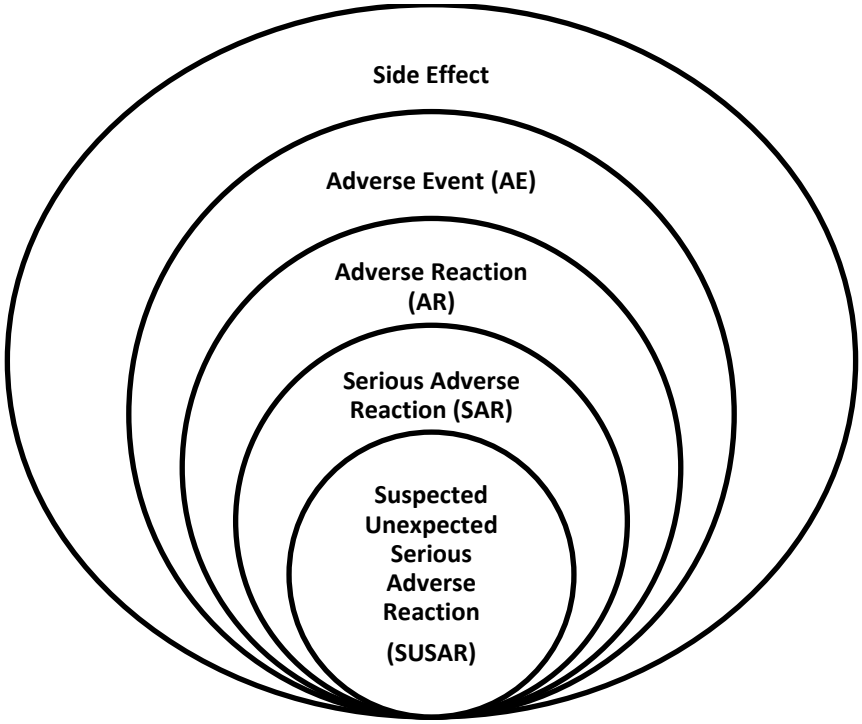
Side Effect
Any unintended effect of a pharmaceutical product occurring at doses normally used in human, which is related to the pharmaceutical properties of the medicine. Such effects may or may not be beneficial. Side effects are related to the known properties of the medicine and can often be predicted. 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.

Relationship of effects



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Annex

Annex 1: Suspected Adverse Reaction Reporting Form (MCA-F-305/01)

Annex 2: Adverse Event Following Immunisation Reporting Form (MCA-F-305/02)

Appendix 1: Causality Assessment

All points under 'assessment criteria' should be reasonably complied with.

Causality Term	Assessment Criteria
Certain	• Event or laboratory test abnormality, with plausible time relationship to medicine intake • Cannot be explained by disease or any other medicine • Response to withdrawal plausible (pharmacologically, pathologically) • Event definitive pharmacologically or phenomenologically (e.g. an objective and specific medical disorder or a recognised pharmacological phenomenon) • Re-challenge satisfactory, if necessary
Probable / Likely	• Event or laboratory test abnormality, with reasonable time relationship to medicine intake • Unlikely to be attributed to disease or other medicine • Response to withdrawal clinically reasonable • Re-challenge not required (e.g. not done)
Possible	• Event or laboratory test abnormality, with reasonable time relationship to medicine intake • Could also be explained by disease or other medicine • Information on medicine withdrawal may be lacking or unclear
Unlikely	• Event or laboratory test abnormality, with a time to medicine intake that makes a relationship improbable (but not impossible) • Disease or other medicine 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

To classify the relationship between an event and a medicine as 'Certain', re-challenge information with a satisfactory outcome is requested, which is not required to categorise a causal relationship as 'Probable'.

To qualify a relationship as 'Certain' the interval between the start of the medicine and the onset of the event must be 'plausible', while for 'Probable' the time relationship should be 'reasonable', which covers everything that is not unreasonable.

Also, for 'Certain' the occurrence of the event cannot be explained by any disease the patient is known to or any other medicine, while for 'Probable' the event is 'unlikely' to be attributable to another cause.

The essential distinctions between 'Probable' and 'Possible' are that in the latter case there may be another equally likely explanation for the event and/or there is no information or uncertainty with regard to what has happened after stopping.

Appendix 2: AEFIS to Report

Occurring within 24 hours of immunisation	• Anaphylactoid reaction (acute hypersensitivity reaction) • Anaphylaxis • Persistent (more than 3 hours) inconsolable screaming • Hypotonic hyporesponsive episode (HHE) • Toxic shock syndrome (TSS)
Occurring within 5 days of immunisation	• Severe local reaction • Sepsis • Injection site abscess (bacterial/sterile)
Occurring within 15 days of immunisation	• Seizures, including febrile seizures (6-12 days for measles/MMR; 0-2 days for DTP) • Encephalopathy (6-12 days for measles/MMR; 0-2 days for DTP)
Occurring within 3 months of immunisation	• Acute flaccid paralysis (4-30 days for OPV recipient; 4-75 days for contact) • Brachial neuritis (2-28 days after tetanus containing vaccine) • Thrombocytopaenia (15-35 days after measles/MMR)
Occurring between 1 and 12 months after BCG immunisation	• Lymphadenitis • Disseminated BCG infection • Osteitis/Osteomyelitis
No time limit	• Any death, hospitalisation, or other severe and unusual events that are thought by health workers or the public to be related to immunisation

Appendix 3: Case definitions for AEFI and related vaccines

Adverse event	Case definition	Vaccines
Acute flaccid paralysis (Vaccine associated paralytic poliomyelitis)	Acute onset of flaccid paralysis within 4 to 30 days of receipt of oral poliovirus vaccine (OPV), or within 4 to 75 days after contact with a vaccine recipient and neurological deficits remaining 60 days after onset, or death.	OPV
Anaphylactoid reaction (acute hypersensitivity reaction)	Exaggerated acute allergic reaction, occurring within 2 hours after immunization, characterized by one or more of the following: • wheezing and shortness of breath due to bronchospasm, laryngospasm/laryngeal oedema • one or more skin manifestations, e.g. hives, facial oedema, or generalized oedema Less severe allergic reactions do not need to be reported.	All
Anaphylaxis	Severe immediate (within 1 hour) allergic reaction leading to circulatory failure with or without bronchospasm and/or laryngospasm/laryngeal oedema.	All
Arthralgia	Joint pain usually including the small peripheral joints. Persistent if lasting longer than 10 days, transient: if lasting up to 10 days.	Rubella, MMR
Brachial neuritis	Dysfunction of nerves supplying the arm/shoulder without other involvement of nervous system. A deep steady, often severe aching pain in the shoulder and upper arm followed in days or weakness by weakness and wasting in arm/shoulder muscles. Sensory loss may be present, but is less prominent. May present on the same or the opposite side to the injection and sometimes affects both arms.	Tetanus
Disseminated BCG infections	Widespread infection occurring within 1 to 12 months after BCG vaccination and confirmed by isolation of Mycobacterium bovis BCG strain. Usually in immunocompromised individuals.	BCG
Encephalopathy	Acute onset of major illness characterized by any two of the following three conditions: • seizures; • severe alteration in level of consciousness lasting for one day or more; • distinct change in behaviour lasting one day or more. Needs to occur within 48 hours of DTP vaccine or from 7 to 12 days after measles or MMR vaccine, to be related to immunization.	Measles, Pertussis
Fever	The fever can be classified (based on rectal temperature) as mild (38 to 38.9^{o}C), high (39 to 40.4^{o}C) and extreme (40.5^{o}C or higher). Fever on its own does not need to be reported.	All

Adverse event	Case definition	Vaccines
Hypotonic, hyporesponsive episode (HHE or shock-collapse)	Event of sudden onset occurring within 48 [usually less than 12] hours of vaccination and lasting from one minute to several hours, in children younger than 10 years of age. All of the following must be present: • limpness (hypotonic); • reduced responsiveness (hyporesponsive); • pallor or cyanosis – or failure to observe/recall.	Mainly DTP, rarely others
Injection site abscess	Fluctuant or draining fluid-filled lesion at the site of injection. Bacterial if evidence of infection (e.g. purulent, inflammatory signs, fever, culture), sterile abscess if not.	All
Lymphadenitis (includes suppurative lymphadenitis)	Either at least one lymph nodes enlarged to >1.5 cm in size (one adult finger width) or a draining sinus over a lymph node. Almost exclusively caused by BCG and then occurring within 2 to 6 months after receipt of BCG vaccine, on the same side as inoculation (mostly axillary).	BCG
Osteitis/ Osteomyelitis	Inflammation of the bone with isolation of Mycobacterium bovis BCG strain.	BCG
Persistent inconsolable screaming	Inconsolable continuous crying lasting 3 hours or longer accompanied by high-pitched screaming.	DTP, Pertussis
Seizures	Occurrence of generalized convulsions that are not accompanied by focal neurological signs or symptoms. Febrile seizures: if temperature elevated >38°C (rectal) Afebrile seizures: if temperature normal	All, especially Pertussis, Measles
Sepsis	Acute onset of severe generalized illness due to bacterial infection and confirmed (if possible) by positive blood culture. Needs to be reported as possible indicator of programme error.	All
Severe local reaction	Redness and/or swelling centred at the site of injection and one or more of the following: • swelling beyond the nearest joint, pain, redness and swelling of more than 3 days duration requires hospitalization. Local reactions of lesser intensity occur commonly and are trivial and do not need to be reported.	All
Thrombocytopaenia	Serum platelet count of less than 50,000/ml leading to bruising and/or bleeding	MMR
Toxic shock syndrome (TSS)	Abrupt onset of fever, vomiting and watery diarrhoea within a few hours of immunization. Often leading to death within 24 to 48 hours. Needs to be reported as possible indicator of programme error.	All

Flow Chart: Management of ICSRs