MEDICINES CONTROL AGENCY

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GUIDELINE FOR REPORTING OF ADVERSE REACTIONS TO MEDICINES INCLUDING VACCINES

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1 INTRODUCTION

1.1 LEGAL BASIS

1.1.1. 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.

1.1.2. 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.

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

1.1.4. 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. Healthcare professionals, marketing authorisation holders (MAHs) or their national representatives and manufacturers are key stakeholders in the continuous safety monitoring of medicines marketed in The Gambia.

1.1.5. Where the MAH is not resident in The Gambia, it shall identify a local or regional agent to represent the MAH (national representative). In case of imported medicines in to the Gambia, where no national representative is identified, the importer fulfills this obligation.

1.1.6. The effectiveness of safety monitoring of medicines including vaccines by the Agency 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.

1.1.7. 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

1.1.8. The Agency based on principles of Reliance, recognises regulatory decisions, reports and recommendations and relies on tools and methods developed for the safety monitoring, common processes and standards, templates of organisations such as, WHO, EMA, US-FDA, MHRA, WHO listed countries, etc. and will implement the update changes to the existing processes accordingly, if necessary.

1.2 INTERPRETATION AND ABBREVIATIONS

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

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-authorization 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.

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.

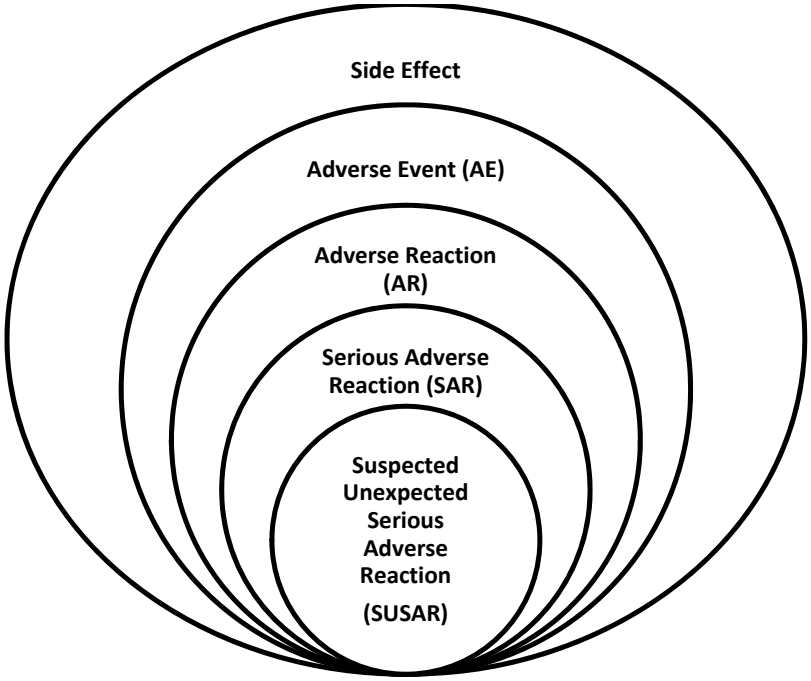
Signal
Refers to “Reported information on a possible causal relationship between an adverse event and a medicine; the relationship being known or incompletely documented previously” Usually more than a single report is required to generate a signal depending upon the seriousness of the event and the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

Spontaneous Report or Spontaneous Notification
Unsolicited voluntary communication by a patient, consumer, healthcare professional, marketing authorisation holder or national representative or an organisation to the Agency 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.

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

Relationship of effects



1.3 PURPOSE AND SCOPE

1.3.1. 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.

1.3.2. This guideline applies to medicines as defined in the Act and the Regulations including biologicals (e.g. vaccines, blood and blood components), herbal medicines, radiopharmaceutical products and nutritional supplements.

1.3.3. It applies to healthcare professionals, MAHs or their national representatives, manufacturers and other stakeholders who suspect an adverse reaction resulting from the use of a marketed medicine, its abuse, misuse, overdose, medication error or interactions, or suspected counterfeit medicine including vaccines or lack of efficacy.

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

1.3.5. 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).

2 DETECTION OF ADVERSE REACTIONS (ADRs AND AEFIs)

2.1 RECOGNITION OF AN ADVERSE REACTION (AR)

2.1.1. 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.

2.2 ASSESSMENT OF THE REACTION

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

2.2.2. 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.

2.2.3. 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.

2.2.4. 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.

2.3 ADVERSE EVENTS FOLLOWING IMMUNISATION (AEFI)

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

2.3.2. 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.

2.3.3. 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.

2.3.4. 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.

2.3.5. 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.

2.3.6. 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.

2.3.7. Severe vaccine reactions and reactions that fulfill the definition of serious need to be reported to the Agency.

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

2.3.9. 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.

3 REQUIREMENTS FOR REPORTING OF ADVERSE REACTIONS (ARs and AEFIs)

3.1 SOME BASIC PRINCIPLES OF EFFICIENT REPORTING

Timelines of Reporting

- 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.
- Reporting by healthcare professionals: All serious adverse reactions (suspected, expected and unexpected) associated with the use of any medicine in The Gambia should be reported to the Agency urgently but not later than within 15 calendar days. All other adverse reactions will be reported to the Agency within a period of 28 calendar days.
- Reporting by the MAHs or their national representatives: Serious adverse reaction reports received by MAHs shall be submitted to the Agency within 15 calendar days. In case all the information needed is not available within 15 calendar days, the MAH should submit an initial report containing at least the minimum data required (patient details, suspected product details, reaction details and the reporter details) in order to meet the expedited reporting time frames. A follow-up report containing more detailed information should be submitted later as soon as it becomes available.
- 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.

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.

3.2 GENERAL PRINCIPLES

What to report

3.2.1. 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

3.2.2. 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-305/01), 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).

3.2.3. Should a report form not be available 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, 4380632.

3.2.4. 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 4380632.

3.2.5. 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, 54 Kairaba Avenue, K.S.M.D, P.O. BOX 3162, The Gambia.

When to report

3.2.6. All suspected serious adverse reactions associated with the use of a medicine (including vaccine) in The Gambia should be reported as an ICSR immediately but not later than within 15 calendar days to the Agency.

3.3 INFORMATION TO BE PROVIDED ON THE REPORTING FORM

3.3.1. 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);

3.3.2. 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).

3.3.3. 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.

3.3.4. 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).

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

3.4 RESPONSIBILITIES OF MARKETING AUTHORISATION HOLDERS OR THEIR NATIONAL REPRESENTATIVES

3.4.1. MAHs or their national representatives shall immediately inform the Agency of any suspected serious adverse reaction that occurred in The Gambia as described above in section 3.1.

3.4.2. Any suspected serious adverse drug reaction that occurred in any other country shall be reported to the Agency periodically as described in the MCA *Guideline for Safety Monitoring of Medicines (Pharmacovigilance) including Vaccines* (MCA-GL-307).

3.5 ROLES OF HEALTHCARE PROFESSIONALS

3.5.1. 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.

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

3.5.3. 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.

3.5.4. 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.

3.5.5. Healthcare professionals shall report all serious adverse reactions to the

Agency. Refer above to the section on “How to report”.

3.5.6. **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.**

3.6 ROLES OF CONSUMERS AND GENERAL PUBLIC

3.6.1. 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?

3.6.2. 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.

3.7 REPORTING IN SPECIAL SITUATIONS

Overdose, abuse, misuse and medication error

3.7.1. Healthcare professionals, MAHs or their national representatives and other stakeholders should notify the MCA when becoming aware of overdose, abuse, misuse or medication error (accidental or intentional).

3.7.2. 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 within 15 calendar days as described above.

3.7.3. 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

3.7.4. Healthcare professionals, MAHs or their national representatives and other stakeholders should notify the MCA when becoming aware of lack of efficacy or vaccination failure.

3.7.5. 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 within 15 calendar days as described above, unless the reporter has specifically stated that the outcome was due to disease progression and was not related to the medicine.

3.7.6. 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.

3.7.7. 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 of Medicines (including Vaccines)

3.7.8. 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.

3.7.9. If a product quality problem is associated with a suspected serious adverse reaction, the adverse reaction should be submitted to MCA as ICSR within 15 calendar days as described above.

4 MANAGEMENT OF ADVERSE REACTION REPORTS BY THE AGENCY

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

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

4.3. 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)

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

4.5. The Agency should acknowledge receipt of ICSRs within 10 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.

4.6. The Agency provides feedback of evaluation of an ICSR to the reporter after the causality assessment of the submitted report.

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

5 FINAL PROVISIONS

5.1. This guideline is the second version published by the MCA and will become effective on 10 December 2021.

5.2. This guideline will be reviewed within 5 years of becoming effective.

6 DOCUMENTS NEEDED FOR THIS GUIDELINE

Document No	**Title** (as referenced on the document)
MCA-F-305/01	Suspected Adverse Reaction Reporting Form
MCA-F-305/02	Adverse Event Following Immunisation Reporting Form

7 REFERENCES

- Medicines and Related Products Act, 2014
- Medicines and Related Products Regulations, 2020
- WHO Safety of Medicines, A guide to detecting and reporting adverse drug reactions, 2002
- WHO, Causality assessment of an adverse event following immunization (AEFI), user manual for the revised WHO classification, 2019
- The Council for International Organizations of Medical Sciences (CIOMS) reporting form: https://cioms.ch/wp-content/uploads/2017/05/cioms-form1.pdf
- ICH Harmonised Tripartite Guideline, Clinical Safety Data Management: Definitions and Standards for Expedited Reporting (E2A), 27 October 1994
- ICH Harmonised Tripartite Guideline, Post-approval Safety Data Management: Definitions and Standards for Expedited Reporting (E2D), 12 November 2003

8 DOCUMENT HISTORY

Version #	**Implementation 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

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.