THE TANZANIA FOOD, DRUGS AND COSMETICS ACT

(CAP. 219)

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REGULATIONS

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(Made under Section 122 (1) (dd))

THE TANZANIA FOOD, DRUGS AND COSMETICS (PHARMACOVIGILANCE) REGULATIONS, 2018

ARRANGEMENT OF REGULATIONS

PART I
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PART I
PRELIMINARY PROVISIONS

Citation

1. These Regulations may be cited as the Tanzania Food, Drugs and Cosmetics (Pharmacovigilance) Regulations, 2018 and shall be deemed to have come into operation on the 22nd day of April, 2018.

2. These Regulations shall apply in Mainland Tanzania.

3. In these Regulations, unless the context otherwise requires-

Cap. 219

"Act" means the Tanzania Food, Drugs and Cosmetics Act;

"Authority" shall have the meaning ascribed to it under the Tanzania Food, Drugs and Cosmetics Act

"active surveillance" means active measures taken to monitor adverse events;

"Adverse Drug Reactions (ADRs)" means a response to a medicine which is noxious and unintended, and which occurs at a dose normally used in human for prophylaxis, diagnosis or therapy of disease or for the modification of physiological function;

"Adverse Event (AE)" means any untoward medical occurrence that may present during treatment with a pharmaceutical product but which does not necessarily have a causal relationship with the treatment. An adverse event can therefore be any unfavorable and unintended sign (including an abnormal laboratory finding), symptom, or disease temporarily associated with the use of the product whether or not related to the product;

"Audit" means action taken to establish findings and compliance with these Regulations;

"cosmetic product safety report" means all available data on the undesirable effects and serious undesirable effects to the cosmetic product or, where relevant, other cosmetic products including statistical data;

"Development Safety Update Report (DSUR)" means a periodic report on a

drug under development (including marketed products that are under further studies) deemed to be recognized by the Authority;
"health care providers" means medically qualified persons including physicians, dentists, pharmacists, nurses, assistant medical officers and clinical officers, pharmaceutical technicians, pharmaceutical assistants, laboratory technicians, laboratory technologists and traditional medicine practitioners;
"herbal medicines" includes crude plant materials such as leaves, flowers, fruit, and seed, herbal materials such as fresh juices, gums, fixed oils, essential oils, and dry powders, herbal preparations such as comminuted or powdered herbal materials, or extracts, tinctures and fatty oils of herbal materials and finished herbal products such as dosage forms preparations made from one or more herbs that may contain excipients used for therapeutic purposes;
"Individual Case Safety Report" which is also known by its acronym "ICSR" means a document providing the most complete information related to an individual case at a certain point in time. An individual case is the information provided by a primary source to describe suspected adverse reaction(s) related to the administration of one or more medicinal products to an individual patient at a particular point in time;
"lack of efficacy" means unexpected failure of a drug to produce the intended effect as determined by previous scientific investigation;
"Marketing Authorization Holder" which is also known by its acronym "MAH" means an individual or a corporate entity responsible for placing a pharmaceutical product in the market;
"medication error" means any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer. Such events may be related to professional practice, health care products, procedures and systems, including prescribing; order communication; product labeling, packaging and nomenclature; compounding; dispensing; distribution; administration; education; monitoring; and use;
"National Pharmacovigilance Centre" which is also known by its acronym "NPC" means a single, governmentally recognized Centre established under regulation 4 of these Regulations;
"over dosage" means accidental or intentional use of a drug or medicine in an amount that is higher than normally used;
"pharmacovigilance" which is also known by its acronym PV" means science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other possible medicine-related problems;
"pharmacovigilance site master file" means a file ascribed to it under regulation 18;
"Public Health Programs" means programs under the Ministry of Health responsible for health including National AIDS Control Program (NACP), National Malaria Control Programme (NMCP), National Tuberculosis and

Leprosy Programme (NTLP) and Expanded Programme for Immunization (EPI);
"Periodic Benefit-Risk Evaluation Report" which is also known by its acronym "PBER" means is a comprehensive safety evaluation report produced by the Marketing Authorization Holders (individuals or business that is granted authorization to market the medicine) at defined time points after a medicine has been given;
"products regulated" means medicines and complementary products;
"Periodic Safety Update Report" which is also known by its acronym "PSUR" means an update of the world-wide safety experience of a product obtained at defined times post marketing authorization
"risk-benefit balance" means an evaluation of the positive therapeutic effects of the medicinal product in relation to the risks (any risk relating to the quality, safety or efficacy of the medicinal product as regards patients' health or public health
"Risk Management System" means a risk management system comprise a set of pharmacovigilance activities and interventions designed to identify, characterize, prevent or minimize risks relating to medicinal products, including the assessment of the effectiveness of those interventions;
"risks related to use of a medicinal product" means any risk relating to the quality, safety or efficacy of the medicinal product as regards patients' health or public health and any risk of undesirable effects on the environment;
"Serious Adverse Event" which is also known by its acronym "SAE" means adverse event means an adverse event which results in death, is life threatening, requires in-patient hospitalization or prolongation of existing hospitalization, results in persistent or significant disability or incapacity, or is a congenital anomaly/birth defect;
"Serious Adverse Drug Reactions" means serious adverse reaction means an adverse reaction which results in death, is life threatening, requires in-patient hospitalization or prolongation of existing hospitalization, results in persistent or significant disability or incapacity, or is a congenital anomaly/birth defect;
"serious undesirable effects" means an undesirable effects which result in temporary or permanent functional incapacity, disability, hospitalization, congenital anomalies or an immediate vital risk or death;
"life threatening" means a reaction in which the patient was at risk of death at the time of the reaction but not including a reaction that hypothetically might have caused death if more severe;
"Signal" means reported information on a possible causal relationship between an adverse event and a medicine the relationship being unknown or incompletely documented previously;
"Summary Product Characteristics" which is also known by its acronym "SmPC" means Product information as approved by the Authority;
"unexpected adverse drug reaction" means an adverse reaction, the nature, severity or outcome of which is not consistent with domestic labeling, marketing authorization or the SmPC.

PART II
PHARMACOVIGILANCE SYSTEM

Establishment of National Pharmacovigilance Centre

4.-(1) The Authority shall establish and maintain, a National Pharmacovigilance Centre , which is also known by its acronym "NPC".

(2) Subject to sub-section (1), the Authority may establish pharmacovigilance zone centers for the appropriate coordination of pharmacovigilance activities in the zones.

Functions of National Pharmacovigilance Centre

5. The functions of the Centre shall be to collect, manage, assess, analyze, identify signals and communicate safety information related to the regulated products to all stakeholders.

Establishment of Pharmacovigilance Technical Committee

6.-(1) There shall be established a Committee to be known as a Pharmacovigilance Technical Committee to provide recommendations to the Director General on pharmacovigilance related safety issues.

(2). The Director General shall, upon such recommendations from the Committee, cause the action on any technical matter to be taken or implemented as the case may be.

Roles of Pharmacovigilance Technical Committee

7. The committee shall be responsible for providing recommendations to the Director General on pharmacovigilance activities including causality assessment of Adverse Drug Reaction and Adverse Events.

Establishment of pharmacovigilance system for manufacturers and marketing authorization holders

8.-(1) All manufacturers and Marketing Authorization holders shall establish a pharmacovigilance system for receiving, handling, evaluation and reporting of ADRs to sustain ADR reporting to the Authority.

(2) The system shall be comprised of structures, processes, outcomes which shall be adaptable to public health emergencies or develop plans.

Pharmacovigilance quality system

9.-(1) For the purposes of Good Vigilance Practice every system shall have a quality system as part of the pharmacovigilance.

(2) The Pharmacovigilance quality system shall involve quality planning, adherence, control, assurance and improvements.

(3)The objectives of the quality system shall be to comply with legal requirements, prevention from adverse reactions, promotion of safe and effective use and protection of patients and public health.

Good Pharmacovigilance Practice

10.-(1) Any manufacturer or marketing authorization holder shall comply with the following Good Pharmacovigilance Practice requirements-

(a) needs of patients, healthcare professionals and the public in relation to the safety of medicines;

(b) commitment of the Management to implement the quality system in relation to the quality objectives;

(c) assign tasks and responsibilities to persons involved in implementation of the pharmacovigilance system;
(d) conduct and maintain continuous quality improvement by all parties implementing the pharmacovigilance system;
(e) allocate resources and tasks to support proactive, risk-proportionate, continuous and integrated conduct of pharmacovigilance;
(f) seek evidence on the risk-benefit balance of products and all relevant aspects, which could impact on the risk-benefit balance and the use of a product, to be considered for decision-making; and
(g) fostering good cooperation between marketing authorization holders, the Authority, public health programs, patients, healthcare professionals and other relevant bodies

(2) The Authority may at any time require a manufacturer or market authorisation holder to comply with any additional requirements of good pharmacovigilance practice as need arise.

Requirements for the quality system

11.-(1) The manufacturer and marketing authorization holder shall maintain the quality system with the following-
(a) designated focal person responsible for pharmacovigilance;
(b) record management system to afford handling and storage of documentation for accurate reporting, interpretation and verification;
(c) document control in relation to their creation, revision, approval and implementation;
(d) continuous training relevant to the system, premises, facilities and equipment to support pharmacovigilance processes which are located, designed, constructed, adapted and maintained to suit their intended purpose;
(e) procedures and processes in place to ensure continuous monitoring of pharmacovigilance data and scientific evaluation of all information on the risks of products;
(f) procedures and processes to ensure effective communication;

(2) Any additional requirement as need may deem appropriate to maintain the quality system.

Training of personnel for pharmacovigilance

12-(1) Every Market Authorization Holder or manufacturer shall provide initial and continued training to personnel involved in implementation of pharmacovigilance activities.

(2)The Training plans shall be based on the roles and responsibilities of the personnel and respective records shall be maintained.

(3) The training shall also apply to external vendors and partners and shall be clearly stipulated in the contractual agreements and audited regularly.

Facilities and equipment for

13. The market authorization holder and manufacturer shall maintain

pharmacovigilance

facilities and equipment for pharmacovigilance in relation to regulation 9(1)(e) of these Regulations.

Quality system procedures and processes

14. Every manufacturer and marketing authorization holder shall have a quality system procedures and processes in place in order to ensure continuous monitoring of pharmacovigilance data, scientific evaluation of products risks, submission of accurate and verifiable data on serious and non-serious adverse reactions to the Authority, update of product information and communication of relevant safety information to healthcare professionals and patients.

Record management and documentation

15.-(1) Every manufacturer and marketing authorization holder shall keep and maintain a record management system on pharmacovigilance information.

(2) The information in the record management system shall be handled and stored so as to allow for accurate reporting, interpretation and verification of that information and shall ensure that the confidentiality of the records of the study subjects remains protected.

(3) The Marketing Authorization Holder shall ensure that the analytical dataset and statistical programs used for generating the data included in the final study report are kept in electronic format and are available for auditing and inspection by the Authority.

(4) The system shall include mechanisms for timely retrieval, traceability, follow-up and communication of safety information.

(5) In case of outsourcing pharmacovigilance activities to a third-party person or external organization, a detailed pharmacovigilance contract or agreement shall be in place.

(6) Keep appropriate structures and processes in place to ensure that pharmacovigilance data and records are protected from destruction throughout the period in which the product will be in the Tanzanian market.

(7) All elements, requirements and provisions adopted for the quality system shall be documented in a systematic and orderly manner in written policies and procedures.

(8) Manufacturers, Market Authorization Holders and all parties involved in pharmacovigilance activities who use an electronic system shall ensure the following-

(a) data of the validation of system(s) used for recording, evaluating and tracking complaints and adverse reactions shall be available;

(b) computerized systems shall be validated and systems are periodically and suitably backed up at predefined intervals; and

(c) any changes done to the system shall be subjected to a revalidation.

Requirements for Pharmacovigilance Master plan

16.-(1) Every manufacturer and marketing authorization holder shall have Pharmacovigilance master plan that includes safety specifications and pharmacovigilance Plan.

(2) The Plan shall be developed by the sponsor and can be discussed

with the Authority during product development where practicable, prior to approval of a new product, or when a safety concern arises post-marketing.

(3) The safety specifications shall include the following-

(a) elements of the specification;
(b) non-clinical;
(c) clinical;
(d) limitations of the human safety database;
(e) populations not studied in the pre-approval phase;
(f) adverse events or adverse drug reactions;
(g) identified risks that require further evaluation potential risks that require further evaluation;
(h) identified and potential interactions, including food-drug and drug-drug interactions;
(i) epidemiology;
(j) pharmacological class effects;
(k) summary.

(4) The Pharmacovigilance plan shall be based on safety specifications and shall include the following-

(a) structure of the pharmacovigilance plan;
(b) summary of ongoing safety issues;
(c) routine pharmacovigilance practices;
(d) action plan for safety issues;
(e) summary of actions to be completed, including milestones;
(f) pharmacovigilance methods;
(g) design and conduct of observational studies;
(h) references.

Requirements for Pharmacovigilance System Master file

17.-(1) Every manufacturer and Marketing authorization holder shall maintain and make available upon request by the Authority a copy of Pharmacovigilance System Master file.

(2) The file shall be located and available at the manufacturer's site and the marketing authorization holder's designated focal person responsible for pharmacovigilance.

(3) During application for marketing authorization, the manufacturers and marketing authorization holders shall submit summary information about their pharmacovigilance system including the location of the Pharmacovigilance System Master file.

(4) The marketing authorization holder may subcontract certain activities of the pharmacovigilance system to third parties. It shall nevertheless retain full responsibility for the completeness and accuracy of the Pharmacovigilance System master file.

Accuracy reflection of information of the pharmacovigilance system

18.-(1) The information in the pharmacovigilance system master file shall be accurate and reflect the pharmacovigilance system in place.

(2) The marketing authorization holder may, where appropriate, use

separate pharmacovigilance systems for different categories of medicinal products and such system shall be described in a separate pharmacovigilance system master file.

(3) The pharmacovigilance system Master file shall cover all products for which the marketing authorization holder obtained a marketing authorization according to the act.

(4) The pharmacovigilance system master file may be stored in electronic form provided that the media used for storage remain readable over time and a clearly arranged copy can be made available for audits and inspections.

Structure of the pharmacovigilance system master file

19.-(1)The pharmacovigilance system master file shall contain the following elements-

(a) information relating to focal person responsible for pharmacovigilance;
(b) a description of the organizational structure, list of the site and pharmacovigilance activities undertaken;
(c) a description of the location, functionality and operational a responsibility for computerized systems and databases used in pharmacovigilance system;
(d) a description of data handling and recording and of the process used for each of the pharmacovigilance activities including the monitoring of the risk-benefit balance of the product(s), operation of the risk management system(s), collection, assessment and reporting of individual case safety reports, collection, assessment and preparation and reporting of individual case safety reports and procedures for communicating safety concerns;
(e) a description of the quality system for the performance of pharmacovigilance activities;
(f) a description of the activities or services subcontracted by the marketing authorization holder where applicable;

(2) Any other additional documents where the Authority deemed to be necessary.

Transfer or delegation of responsibilities

20.-In case of transfer or delegation of responsibilities and activities concerning the Pharmacovigilance System Master File shall be documented.

System master file

21.-Any changes to the Pharmacovigilance System Master File shall be notified to the designated focal person responsible for pharmacovigilance.

Contents of pharmacovigilance system master file

22. In case a pharmacovigilance system is shared there shall be written agreements between parties on how to maintain the relevant sections within their own Pharmacovigilance System Master File and accessibility of the file to all the applicable marketing authorisation holder(s).

PART III
PHARMACOVIGILANCE RESPONSIBILITIES

Requirements for pharmacovigilance inspection

23.-(1) The holders of marketing authorizations and manufacturers shall be proactively responsible for on-going safety monitoring of the products they place on the market.

(2) The Marketing authorization holder shall be responsible for the following tasks and responsibilities-

(a) establishment and operation of a pharmacovigilance system and quality system as prescribed under these regulations;
(b) ensuring that structures and processes for pharmacovigilance are in place;
(c) preparation and maintenance of a pharmacovigilance site master file;
(d) ppointment of a permanent designated focal person responsible for the establishment and maintenance of the pharmacovigilance system, who has university qualifications, knowledge and experience in pharmacovigilance;
(e) ensuring that there is an access to a registered medically qualified person for clinical assessments;
(f) ensuring that the focal person has sufficient Authority to influence the performance of the quality system and the pharmacovigilance activities of the Marketing Authorization Holder including access to the Pharmacovigilance Master File;
(g) submission to the Authority the name and contact details of the focal person responsible for pharmacovigilance, summary of the pharmacovigilance system, Risk Management Plans, Periodic Safety Update Reports, Risk-benefit assessment reports and reports on adverse reactions and events occurring within and outside Tanzania;
(h) development and maintenance of product-specific risk management systems and take any additional pharmacovigilance and risk minimization actions required;
(i) notification to the Authority of any change in details regarding the designated focal person responsible for pharmacovigilance the site master file location;
(j) submission of a six monthly report for the first two years and annually for the next three years;
(k) inform the Authority on any significant safety and product quality issues or actions taken by foreign agency, including the basis for such actions;
(l) submit to the Authority responses to additional information requests within the 14 working days from the date of the request;
(m) take any action necessary to mitigate and identified safety issue;
(n) conduct post-approval safety studies on their products as a condition of approval or long term safety follow up.

Role of the designated focal person responsible for pharmacovigilance

24.-(1)The designated focal person responsible for pharmacovigilance shall have the following responsibilities-

(a) establishment and maintenance the pharmacovigilance system;
(b) to provide oversight over the functioning of the system in all relevant aspects, including its quality system;
(c) to promote, maintain and improve compliance with the legal requirements;
(d) to ensure and to verify that the information contained in the PSMF is an accurate and up-to-date reflection of the pharmacovigilance system;
(e) to be aware of product safety profiles, emerging safety concerns, risk management plans and minimization measures;
(f) ensuring conduct of pharmacovigilance and submission of all pharmacovigilance-related documents in accordance with the legal requirements and Good Vigilance Practice;
(g) ensuring the necessary quality, including the correctness and completeness, of pharmacovigilance data submitted to the Authority;
(h) ensuring validation of the adverse reaction database and implementation of corrective actions to address any failures and be informed of significant changes that are made to the database;
(i) providing relevant information on benefit-risk evaluation to the Authority;
(j) providing responses to regulatory actions in emerging safety concerns including variations, urgent safety restrictions, and communication to patients and healthcare professionals;
(k) acting as a pharmacovigilance contact point for the Authority and for pharmacovigilance inspections.

(2) The focal person may delegate specific tasks, under supervision, to appropriately qualified and trained individuals. Such delegation shall be documented.

Responsibilities of health facilities and pharmaceutical outlets

25.-(1)The health facilities and pharmaceutical outlets shall establish a system for collecting, managing and reporting adverse reactions to the Authority.

(2) The Health facilities and pharmaceutical outlets shall appoint a focal person for coordination of pharmacovigilance activities within their facilities.

(3) The facilities shall perform the following functions-
(a) receive and distribute adverse events reporting forms to health care providers;
(b) detect, investigate, manage and report adverse events and take appropriate action to prevent their occurrence;
(c) maintain a register of suspected Adverse reactions, therapeutic

failures, overdose, quality defective products, medication errors and drug interactions;

(d) communicate appropriate safety information to health management teams and the community including patients;

(e) conduct preliminary identification of signals and other risk factors;

(f) organize and conduct staff training and sensitization on pharmacovigilance;

(g) integrate pharmacovigilance concept into relevant committees including hospital therapeutic committees and other health committees.

Requirements for Council and regional health management teams

26. Regional and Council Health Management Teams shall plan, budget and supervise the implementation of pharmacovigilance activities within their regions and councils and ensure reports are submitted to Authority on quarterly basis.

Requirements of public health programs

27.-(1) The public health programs shall have responsibility of following the safety of the products distributed within their programs.

(2).The public health programs shall have the following responsibilities with regards to pharmacovigilance system-

(a) identify focal persons to coordinate pharmacovigilance activities;

(b) plan and budget for pharmacovigilance activities;

(c) distribute reporting forms, collect and analyse safety data for products used in their programs;

(d) risk management and follow-up of patients;

(e) reporting of adverse event to the Authority for the products used within their programs;

(f) collaborate with Authority in implementing pharmacovigilance activities including training of health care providers on pharmacovigilance;

(g) promote rational and safe use of products by health care providers;

(h) educate and inform patients on their programs on importance of reporting adverse reactions; and

(i) assess and communicate risks and effectiveness of the products.

Requirements for zonal pharmacovigilance centres

28. The pharmacovigilance zonal centres shall work in collaboration with the Authority in coordinating the following pharmacovigilance activities in the respective zones-

(a) receiving safety information, respond to queries and provide information related to pharmacovigilance within the respective zones;

(b) receive and distribute reporting forms and collect data from health facilities;

(c) analyze adverse reaction reports and feed information into the data management tool where accessible and send them to Authority for

further action;

(d) receive safety alerts from the Authority and share them with health care providers and patients in the respective zones.

PART IV
PHARMACOVIGILANCE INSPECTIONS AND AUDITING

Requirements for Patients or consumers for reporting adverse drug reactions and events

29.-(1) The Authority shall inspect any manufacturer, marketing authorization holders and pharmaceutical facilities at all reasonable times for the purposes of ensuring compliance with Good Pharmacovigilance Practice and these Regulations.

(2) The inspection shall include the premises, records, documents and pharmacovigilance system master file (PSMF) of the Marketing Authorization Holder or any firms employed by the marketing authorisation holder to perform the activities.

(3) Without prejudice to regulation (2) above, the inspection shall also involve review of procedures, systems, personnel, product-related pharmacovigilance issues and facilities to determine their compliance with regulatory pharmacovigilance obligations.

(4) The manufacturers and marketing authorisation holders shall be required to provide, on request, the pharmacovigilance system master file, which will be used to inform inspection conduct.

(5) The pharmacovigilance system master file shall be permanently and immediately available for inspection at the site where it is kept.

(6) Where the pharmacovigilance system master file is kept in electronic form, the data stored in electronic form shall be directly available at the site where the pharmacovigilance system master file is kept.

(7) The inspections shall include system and product-related inspections, routine inspections, "for cause" inspections, Pre-and Post-authorisation inspections, announced and unannounced inspections, re-inspections and remote inspections.

(8)The scope of inspections shall include the following elements, as appropriate-

(a) collection, assessment, follow-up, documentation, record keeping and archiving of Individual case safety reports (ICSRs);

(b) completeness, accuracy, analyses, submission timelines,

(c) safety evaluation of the Periodic Safety Update Reports (PSURs); and

(d) performance of the Pharmacovigilance system.

(9) The results of an inspection shall be provided to the inspected entity who will be given the opportunity to comment on any non-compliance identified within timelines prescribed by the Authority. Any non-compliance shall be rectified in a timely manner through the implementation of a corrective and preventive action plan.

(10) Inspection findings shall be graded as critical, major and minor in

order to indicate their relative criticality to risks impacting the pharmacovigilance system, processes and parts of processes.

Pharmacovigilance Self-audits

30.-(1) The manufacturers and marketing authorization holders shall establish processes to monitor the performance and effectiveness of a pharmacovigilance system and including risk based audits of their quality systems.

(2) The risk-based audits of the pharmacovigilance system shall cover all areas stipulated under these Regulations.

(3) The risk-based audits of the quality system shall be performed at regular intervals to ensure that the quality system complies with the quality system requirements set out in these regulations to determine its effectiveness.

(4) Risk assessment shall be documented appropriately for the strategic, tactical and operational planning of pharmacovigilance audit activity in the organization.

(5) Audits shall be conducted by individuals who have no direct involvement in or responsibility for the matters or processes being audited.

(6) The corrective actions, including a follow-up audit of deficiencies, shall be taken where necessary.

(7) A report on the results of the audit shall be drawn up for each audit and follow-up audit. The results of the audits and follow-up audits shall be documented.

(8)The issues that need to be urgently addressed shall be communicated in an expedited manner to the auditee's management and the upper management.

(9) The management of the organization shall be responsible for ensuring there is a mechanism in place to adequately address the issues arising from pharmacovigilance audits. Actions shall include root cause analysis and impact analysis of identified audit findings and preparation of a corrective and preventive action plan, where appropriate.

(10) The audit shall involve evaluating the effectiveness of actions taken with the products for the purpose of minimizing risks and supporting their safe and effective use in patients;

(11) The organization shall use performance indicators to continuously monitor the good performance of pharmacovigilance activities

PART V
RISK MANAGEMENT SYSTEMS

Establishment of risk management system

31.-(1) The manufacturers and marketing authorization holders shall be required to establish a risk management system as a condition to the Marketing authorization.

(2) The manufacturers and marketing authorization holders shall be responsible for having an appropriate risk management system in place.

(3) The risk management system shall be proportionate to the

identified risks and the potential risks of the medicinal product, and the need for post-authorisation safety data.

(4) The system shall include risk minimization activities.

(4) The marketing authorization holders shall plan risk management system very early on in a product's life cycle including characterization and minimization of the risks associated with the product in the post-authorization phase.

(5) The marketing authorization holders may be requested by Authority to submit a RMP focused on the safety concern(s).

(6) The risk management plans shall contain the following information-

(a) products overview;
(b) safety specification;
(c) epidemiology of the indication(s) and target population;
(d) non-clinical part of the safety specification;
(e) clinical trial exposure;
(f) populations not studied in clinical trials;
(g) post-authorization experience;
(h) additional requirements for the safety specification;
(i) identified and potential risks;
(j) summary of the safety concerns;
(k) pharmacovigilance plan (including post-authorisation safety studies);
(l) plans for post-authorisation efficacy studies;
(m) risk minimization measures (including evaluation of the effectiveness of risk minimization activities); and
(n) summary of the risk management plan.

(6) Ensuring that the knowledge and understanding on the product's safety profile, following its use in clinical practice, are critically reviewed.

(7) The marketing authorization holder shall monitor pharmacovigilance data to determine whether there are new risks or whether risks have changed or whether there are changes to the risk-benefit balance of the products.

(8) The marketing authorization holder shall update the risk management system and the RMP accordingly.

(9) Provide critical review of the safety profile of the product continuously and shall be reflected in data submitted with periodic safety update reports.

(10) The guidance on templates and submission of RMPs shall be kept up-to-date on the Authority website.

PART VI
COLLECTION, MANAGEMENT AND REPORTING REQUIREMENTS FOR ADVERSE EVENTS

Duty to report adverse reactions and events

32. The health facilities, public health programs, manufacturers and

Marketing Authorization Holders or any other designated person shall have a duty to report any of the following to the Authority-

(a) all suspected Adverse Drug Reactions as a result of prescription and non-prescription;
(b) unexpected reactions, regardless of their nature or severity, whether or not consistent with product information or labeling;
(c) all adverse drug reactions regardless of whether or not the product was used in accordance with the product information provided by the company marketing the product;
(d) all adverse events following immunization or use of biological;
(e) all adverse events, incidences, malfunctions associated use of medical devices or vitro diagnostic medical devices;
(f) an observed increase in frequency of a given reaction;
(g) a serious reaction, whether expected or not;
(h) all suspected Adverse Drug Reactions associated with drug-drug, drug-food or drug-food supplement interactions;
(i) adverse Drug Reactions in special field of interest including drug abuse and drug use in pregnancy and during lactation;
(j) adverse Drug Reactions occurring from overdose or medication errors;
(k) unusual lack of efficacy or when suspected quality defects are observed; and
(l) product quality problems.

Reporting of unusual failure in efficacy

33. All reports of unusual failure in efficacy shall be reported to the Authority by Marketing Authorization Holder, healthcare providers, public health programs using the Adverse Drug Reaction yellow form prescribed in the First Schedule to these Regulations

Reporting of medication Errors

34. Medication errors that arise during routine clinical practice shall be reported to the Authority using the Adverse Drug Reaction form mentioned under regulation 33 of these Regulations.

Requirements for Patients or consumers for reporting adverse drug reactions and events

35. Patients or consumers may report any suspected adverse reaction or event associated with the use of a product immediately to the nearest health facility, health care provider or directly to the Authority by using the Adverse Drug Reaction green form prescribed in the Second Schedule to these Regulations.

Reporting requirements for healthcare providers

36.-(1) Health care providers shall be obliged to report to the Authority all suspected adverse reactions, events or incidences reported by patients and any quality defect issues that may arise as follows-

(a) in case of suspected adverse reactions, events or incidences shall be as provided in the First Schedule;
(b) in case of filled in suspected adverse reactions, events or incidences from patients in shall be as provided in the Second

Schedule;

(c) in case of any quality defect issues that may arise shall be as provided in the blue form of the Third Schedule to these Regulations; and

(2) All healthcare providers shall be required to record Patients' Serious Adverse Reaction that are caused by allergic reactions to a product in the pink Alert Card as prescribed in the Fourth Schedule of these Regulations.

Requirements for reporting adverse events reporting by manufacturers and marketing authorization holders

37.-(1)Without prejudice to establishment of pharmacovigilance system and quality system provided under these Regulations, all manufacturers and marketing Authorization holders shall be required to report to the Authority any adverse reactions or events suspected to be associated with the use of their products notified to them by healthcare professionals, patients or consumers.

(2) The adverse events reports shall include reports that arise from post-marketing experience, unsolicited and solicited sources, clinical trials, non-interventional post-registration studies and other post marketing studies and programs.

(3) The reports shall meet requirements for reporting and record-keeping stipulated in under these Regulations.

(4) Every manufacturers and marketing Authorization holders shall regularly screen internet including websites, webpages, blogs, vlogs, social networks, internet forums, chat rooms and health portals or digital media for potential reports of suspected adverse reactions.

(5) Every manufacturers and Marketing Authorization Holders shall reports all suspected adverse reactions from medical and non-medical sources within the time specified in these Regulations.

(6) All manufacturers and marketing authorization holders shall systematically assess the reports to establish relationship to the product.

(7) All manufacturers and marketing authorization holders shall regularly monitor international and domestic literature, ongoing safety and efficacy studies for any identification of adverse reaction reports or relevant safety findings regarding their products.

Reporting and field investigation of Adverse Events Following Immunization

38.-(1) Every healthcare workers or any person responsible for immunization or vaccination at the district or regional level shall be required to report to the Authority all Adverse Events Following Immunization (AEFI) of a vaccine or biological product using the reporting form described the First Schedule of these Regulations.

(2) The Adverse Events Following Immunization or its acronym AEFI shall include vaccine reactions, immunization error-related reactions, anxiety related immunization reactions and incidental events.

(3) The Authority in collaboration with Program responsible for Immunization and Vaccine Development or as the case may be, shall conduct field investigation of the AEFIs for the following purpose-

(a) to confirm the reported diagnosis or propose other possible diagnoses as well as clarify the outcome of the medical incident comprising the AEFI;
(b) to ascertain the particulars, circumstances and procedures around the vaccine used to immunize the affected recipient, identify any potential vaccine related link to the given AEFI;
(c) to examine the operational aspects of the programme. Even if an event seems to be vaccine product induced or coincidental;
(d) to determine whether a reported event was a single incident or one of a cluster and if it is a cluster, confirm that the suspected immunizations were indeed given and the individual vaccines that were used; or
(e) to determine whether unimmunized people are experiencing the same medical incidents.

(4) Field investigation for different stakeholders and causality assessment of the events shall be conducted as described in the guidelines for surveillance of adverse events following immunization.

(5) In case of vaccine related reactions the following actions shall be taken by the Authority-
(a) withdrawal the lot with higher reaction rate than expected;
(b) conduct Investigation in collaboration with the manufacturer to identify the root cause;
(c) suspension, de-registration or cancellation of registration if the benefit-risk balance is not favourable.

(6) In case of Immunization error related events the following error correction measures shall be taken by the Immunization programme-
(a) changing logistics for supplying the vaccine;
(b) changing procedures at the health facility;
(c) training of health workers; and
(d) intensifying supervision.

(7) Notwithstanding the provisions of regulation 37, the Authority may designate or authorize officers responsible for immunization and vaccine development assigned by the Ministry for the time being responsible for health to report all AEFIs to the Authority.

(8)The Authority shall be required to communicate with parents, other members of the community, health staff and media regarding AEFI to keep them informed about the investigation, results and action taken already or going to be taken regarding the AEFI.

Requirements for Expedited Reporting and reporting timelines

39.-(1) All serious adverse reactions associated with the use of a product shall be reported on an expedited basis.

(2) The expedited reporting of serious reactions shall be as soon as possible, but in no case later than 15 calendar days of initial receipt of the minimum information.

(3)Every serious suspected adverse reaction occurring in all post-

marketing studies of which the manufacturer is aware shall be reported to the Authority on an expedited basis.

(4) A case initially classified as a non-expedited report, would qualify for expedited reporting upon receipt of follow-up information that indicates the case should be re-classified.

(5)The reporting time shall be considered to begin again for submission of the follow-up report if any medically relevant information is received for a previously reported case.

(6) The management of the adverse reactions shall follow good case management practice to ensure are authentic, accurate, as complete as possible, and non-duplicative.

PART VII
PERIODIC SAFETY UPDATE REPORTS, PERIODIC BENEFIT-RISK EVALUATION REPORTS AND DEVELOPMENT OF SAFETY UPDATE REPORTS

Requirements for Periodic safety update reports and periodic benefit-risk evaluation reports

40.-(1) Every marketing authorization holder shall submit to the Authority periodic safety update and Benefit-Risk Evaluation Reports for their products in the following cases-

(a) where such obligation has been prescribed by the Authority as a condition during marketing authorization of a product;

(b) when requested by the Authority on the basis of concerns relating to pharmacovigilance data or due to the lack of periodic safety update reports relating to an active substance after the marketing authorization has been granted;

(2) The reports shall be submitted to the Authority immediately upon request or in accordance with the following-

(a) where a product has not yet been placed on the market, at least every 6 months following authorization and until the placing on the market;

(b) where a product has been placed on the market, at least every six months during the first two years following the initial placing on the market, once a year for the following two years and at three-yearly intervals thereafter;

(c) the dates of submission according to the specified frequency shall be calculated from the date of the authorization of the product;

(4) The periodic safety update reports shall contain at a minimum the following-

(a) summaries of data relevant to the benefits and risks of the medicinal product, including results of all studies with a consideration of their potential impact on the marketing authorization;

(b) a scientific evaluation of the risk-benefit balance of the medicinal product;

(c) all data relating to the volume of sales of the medicinal product and any data in possession of the marketing authorization holder

relating to the volume of prescriptions, including an estimate of the population exposed to the medicinal product;

(d) collection of adverse drug reaction (ADR) information (i.e. local serious ADRs, local non-serious ADRs, foreign serious ADRs, foreign non-serious ADRs, case reports published on international or local literatures including academic conferences);

(5)The Periodic Benefit Risk Evaluation Report shall contain a comprehensive, concise, and critical analysis of product's known or emerging important risks and to evidence of emerging important benefits including the following-

(a) summary of relevant new safety information that could have an impact on the benefit-risk profile of the product;

(b) summary of any important new efficacy or effectiveness information that has become available during the reporting interval;

(c) assessment of whether the information obtained by the MAH during the reporting interval is in accord with previous knowledge of the product's benefit and risk profile;

(d) conducting an integrated benefit-risk evaluation for approved; indications in case a new safety information that has emerged;

(e) recommend action to optimize the benefit-risk profile.

(6)The PSUR and PBER reports shall be submitted both in hard copy and soft copy in electronically.

Development Safety Update Reports(DSURs)

41.-(1) Every Sponsor and Marketing Authorization Holder shall be required to submit to the Authority the periodic Development Safety Update Report (DSUR) on drugs under development including marketed drugs that are under further study.

(2) The DSUR shall provide safety information from all ongoing clinical trials and other studies that the sponsor is conducting or has completed during the review period including-

(a) clinical trials using an investigational drug such as human pharmacology, therapeutic exploratory and therapeutic confirmatory trials (Phase I to III);

(b) clinical trials conducted using marketed drugs in approved indications such as therapeutic use trials (Phase IV);

(c) therapeutic use of an investigational drug;

(d) clinical trials conducted to support changes in the manufacturing process of medicinal products;

(e) any significant other findings pertinent to the safety of the investigational drug.

PART VIII
SIGNAL MANAGEMENT

Signal detection, identification and

42.-(1) The Authority shall perform the initial analysis and

management

prioritization of signals of new risks or risks that have changed or changes to the risk-benefit balance.

(2) Subject to subsection (1), where the Authority considers that follow-up action may be necessary, the assessment of the signals and agreement on any subsequent action concerning the marketing authorisation shall be conducted in a timescale commensurate with the extent and seriousness of the issue.

(2) Every manufacturer and marketing authorization holder shall be required to have mechanisms in place for signal detection and investigation including the following-

(a) have a system in place for detecting and investigating safety issues (or signals) that may arise at any stage in the life cycle of a product, including the clinical development, manufacturing or in the post-market setting in a timely manner;
(b) have written procedures in place that adequately describes the way in which the MAH shall perform signal detection;
(c) roles and responsibilities of each person involved in the signal detection process shall be clearly identified and documented;
(d) the source of the information to include in the analysis and the method used for signal detection shall be documented;
(e) actions taken based on the outcome generated from the signal detection activities shall be documented adequately;
(f) data regarding changes of what is known about the risks and benefits of the drug shall be sent to the Authority and shall be documented; and
(g) safety monitoring activities shall include a review of cumulative cases, in order to allow for a comprehensive review of potential safety issues.

PART IX
POST-AUTHORIZATION STUDIES

Requirements Post-authorization safety studies GN NO 53 of 2013

43.-(1) The Authority may impose on the marketing authorization holder the obligation to conduct post-authorization studies on safety and on efficacy as a condition at the time of the granting of the marketing authorization or later.

(2) The post-authorisation study shall be registered in accordance with the regulations for Control of Clinical Trials in force.

(3) The marketing authorization holder shall monitor the data generated while the study is being conducted and consider their implications for the risk-benefit balance of the product concerned.

(4) Every new information that may affect the risk-benefit balance of the product shall be communicated immediately within 14 days in writing as an emerging safety issue to the Authority.

(5) The communication under this section shall, without prejudice to the information on the findings of studies, be provided by means of Periodic

Safety Update Reports (PSURs).

(6) Individual cases of suspected adverse reactions and Serious Adverse Events that arise from the studies shall be reported to the Authority according to the requirements set out in the regulations for Control of Clinical Trials in force.

(7) A six months progress reports on the studies shall be submitted to the Authority;

(8) Final study report shall be submitted to the Authority within twelve months of the end of data collection.

(9) The marketing authorization holder shall ensure the fulfilment of its pharmacovigilance obligations in relation to the study may be audited, inspected and verified.

(10) Information on studies conducted pursuant to an obligation imposed by the Authority shall be included in the risk management plan.

(11)The Authority shall from time to time conduct its own post marketing surveillance studies if deemed relevant to determine safety, quality and effectiveness of the products placed on the market.

PART X
VIGILANCE OF OTHER PRODUCTS

Reporting of medical devices adverse events, incidences and malfunctions

44.-(1) All operators, users, distributors, healthcare workers, manufacturers and marketing authorization holders shall be required to report to the Authority all adverse events or incidences associated with use of the medical devices.

(2) All Marketing Authorization Holders shall be required to ensure that there is collection, analysis and evaluation of risks arising from the use of their medical devices, in particular, adverse effects, interactions with other substances or products, contra-indications, falsifications, operational defects, malfunctions and technical defects and the necessary measures to be taken.

(3) The collection, analysis, report management, timelines and reporting requirements shall be as provided in the medical devices control regulation in force and the guidelines for medical devices vigilance applicable.

Reporting of adverse events following cosmetics use

45.-(1) All manufacturers, Marketing Authorization Holders and distributors of cosmetics shall be required to report to the Authority the following-

(a) all serious undesirable effects which are known to him or which may reasonably be expected to be known to him;

(b) the name of the cosmetic product concerned, enabling its specific identification; and

(c) the corrective measures taken by him, if any.

(2) The reports shall be submitted to the Authority within fourteen days from the date they become aware of the serious undesirable effects.

(3) Where end users report serious undesirable effects to health

professionals they shall immediately transmit the information to the Authority.

(4) In the event of serious doubt regarding the safety of any substance contained in cosmetic products, in which a product containing such a substance is made available on the market, the Marketing Authorization Holder and manufacturers shall submit a list of all cosmetic products for which he is responsible and which contain such substance.

(5) The list referred to under sub-regulation (4) shall indicate the concentration of the substance in the cosmetic products.

(6) The manufacturers and marketing Authorization Holders shall be required to take all appropriate measures, including corrective actions bringing the cosmetic product into conformity, the withdrawal of the product from the market or its recall, within an expressly mentioned time limit, commensurate with the nature of the risk.

(6) The manufacturers and marketing Authorization Holders shall be required to conduct investigations as requested by the Authority.

(7) The manufacturers and marketing Authorization Holders shall be required to establish a cosmecovigilance system and to a management and communication system on serious undesirable effects to monitor the safety of their products in the market.

(8) The manufacturers and marketing Authorization Holders shall submit to the Authority annual Cosmetics Product Safety Report (CPSR) of their new products.

(9) The report shall be accompanied with a causality assessment report to determine whether a notified serious undesirable event is considered to be attributable to the use of a cosmetic product.

(10) The manufacturers and marketing Authorization Holders shall undertake corrective actions following assessment of the post marketing surveillance data, together with other sources of safety data.

(11) The Authority shall conduct market surveillance, market analysis, evaluation, and end user information and evaluation of trend and signal analysis.

(12)The Authority shall take all appropriate measures to prohibit or restrict the making available on the market of the cosmetic product or to withdraw the product from the market or to recall it in the following cases-

(a) where an immediate action is necessary in the event of serious risk to human health; or

(b) where the responsible person does not take all appropriate measures within the time limit.

Reporting of adverse events on use of antiseptics and disinfectants

46.-(1) Every manufacturers and Marketing Authorization Holders shall be required to report adverse reactions associated with the use antiseptics and disinfectants using the First Schedule prescribed in these regulations in their conventional paper forms or electronically.

(2) The reporting requirements and timelines shall be as stipulated these Regulations.

Reporting of adverse events in clinical trials

GN No. 53 of 2013

47.-Reporting of serious adverse events and Serious Unexpected Adverse Drug Reactions occurring in clinical trials shall comply with the requirements stipulated under the Clinical Trials Control Regulations in force.

Reporting of falsified and or substandard products

48.-(1) Where a medicines, biological, medical devices, herbal medicines, antiseptics and disinfectants is suspected to be a falsified or substandard, the marketing authorization holder, distributor, healthcare professional or any other person shall be required to report to the Authority using a form specified in the Third Schedule of these Regulations.

(2)A person shall not deal in any medicine or vaccine that is confirmed to be a substandard or falsified.

(3)The Authority shall investigate and confiscate if a product is suspected to be a substandard or falsified.

(4) The Authority may require the manufacturer and marketing authorization holder to conduct extra monitoring of their products and submit reports if it determines that a medicine or vaccine suspected to be a substandard or falsified.

PART XI
REGULATORY ACTIONS

Suspension of Registration

49. The Authority may cancel or suspend registration of the product which fails to comply with the conditions of these Regulations.

Notice of suspension

50.-(1) Any suspension shall be effected upon a written notice thereof.

GN No 314 of 2015

(2) The notice for suspension of registration of a medicinal product as set out in the Regulations for Registrations of Medicinal Products in force.

(3) In additional to the reasons for suspension, the notice shall state any corrective action required to be taken and the time within which it must be taken.

(4) Before suspension, the Authority shall require the marketing authorization holder to show cause as to why the suspension should not be effected.

Suspension or cancelation of registration without Notice

51.-(1) The Authority may cancel or suspend the registration of a medicinal product without prior notice if it is necessary to do so in order to prevent injury to the health or safety of patients, users or other persons.

(2) The marketing authorization holder may apply to the Authority, in writing, that the cancelation or suspension be uplifted.

(3) The Authority may, within forty five days after the date of receiving the application, review its decision.

Restoration of registration

52.-Pursuant to the provision regulations 50 and 51 the Authority may, upon satisfaction that the reason giving rise to the suspension or

cancellation of registration has been corrected or if such reason for suspension or cancelation was unfounded, reinstate the registration of a medicinal product.

Cancellation or revocation of marketing Authorization

53.-(1) The Authority may cancel or revoke the marketing authorization of a registered medicinal product if-

(a) the medicinal product no longer meets the quality, safety and effectiveness requirements; and

(b) the marketing authorization has been suspended for a period of more than twelve months.

(2) Pursuant to the provision of sub regulation (1), a written notice of cancellation shall be issued to the marketing authorization holder stating the reasons for cancellation.

PART XII
GENERAL PROVISIONS

Offence

54.-(1) Any person who contravenes any provision of these Regulations or directly or indirectly aids any other person to do what is prohibited under these Regulations commits an offence and shall be punished in accordance with the provisions under the Act.

(2) Any person who fails to notify the Authority of adverse reactions and adverse events commits an offence under the Act and upon conviction shall be liable to the fine or imprisonment or any legal action under the Act.

Penalty

55. Any person found guilty of an offence under these Regulations shall be liable to the sanctions prescribed in the Act.

Review and Appeals

56.-(1) Any person aggrieved by a decision of the Authority may, within sixty days from the date of notice, apply for review or re-consideration of the decision to the Authority showing grounds for dissatisfaction.

(2) The Authority shall, within thirty days from the date of receiving the application, review, re-considering, reject or vary the decision.

(3) Notwithstanding the provision of sub regulation (1), the applicant shall not be barred from appealing to the Minister without applying for review or re-consideration to the Authority.

Procedure of appeal

57.-(1) Notwithstanding the provisions of regulation 56(4) any person aggrieved by a decision of the Authority may, within sixty days appeal in writing to the Minister

(2) The appellant shall copy a notice of the appeal to the Authority who shall within fourteen days submit a written response to the Minister and copy the appellant.

(3) Where the Minister is of the opinion that a case has been made, he may summon parties for additional information or make a decision to allow

or dismiss the appeal.

(4) The decision of the Minister made under sub regulation (3) shall be final.

Recognition

58.- The Authority may, upon proof of scientific information received relating to safety of medicinal products from other regulatory authorities or relevant international bodies, make decision or take any corrective action to protect the public from any eminent safety concerns that may likely arise.

FIRST SCHEDULE

ADVERSE DRUG REACTION REPORTING FORM FOR HCWS

TANZANIA FOOD AND DRUGS AUTHORITY

REPORT OF SUSPECTED ADVERSE REACTION TO MEDICINES OR VACCINES

(Made under regulations 33, 36(1)(a), 38(1), and 46(1)))

Note: Identities of reporter, patient and institution will remain confidential Follow up report; Yes/No

I. PARTICULARS OF PATIENT

Patient Initials or Record No.: - _____

Date of Birth (dd-mm-yyyy) or age:-_____

Sex: - Male ❑ Female ❑

Weight in kg:-_____

II. DETAILS OF ADVERSE REACTION

Description of reaction: .....

.....

.....

.....

Date Reaction Started →__/__/__

Date Reaction Stopped (if known) →__/__/__

Onset latency.....

Duration (min/hours) .....

Health related information/ Other additional information: Medical history (e.g. hepatic, renal, HIV), allergies, pregnancy, smoking, alcohol use, etc. ***Please write any relevant medical and laboratory results including dates (if done)***

.....

.....

.....

.....

.....

III. DETAILS OF SUSPECTED MEDICINE/VACCINE USED

Name of suspected medicine(s)/ vaccine(s) (Specify brand name or manufacturer if known) include dosage form and strength	**Dosage**	**Frequency**	**Route**	**Therapy Date**		**Batch. No & Expiry date (If known)**	**Reason for use**
				Start	**Stop**		
1.							
2.							
3.							
4.							
5.							
Other medicines used at the same time and or one month before (including herbal medicines)							

1.							
2.							
3.							

IV. MANAGEMENT OF ADVERSE REACTION

Reaction subsided after stopping the suspected drug/reducing the dose: ❑ Yes ❑ No ❑Unknown

Reaction reappeared after reintroducing drug: ❑ Yes ❑ No ❑ Not applicable

Seriousness of the Reaction **(please tick all that apply):**

❑ Discomfort but able to work	❑ Caused persistent disability or incapacity
❑ Discomfort could not work	❑ Caused a congenital anomaly
❑ Required or prolonged hospitalization	❑ Patient Died
❑ Life threatening	❑ Others, please give details……

Treatment of adverse reaction ❑ No ❑ Yes **(if yes please specify)**:……

……

Outcome of the reaction Not yet recovered ❑ Recovered (Date):___/___/___ ❑ Died (Date):___/___/___ Unknown ❑

Cause of death……

V. THERAPEUTIC FAILURE

PLEASE WRITE IF THE MEDICINE(S)/VACCINE(S) SHOWED LACK OF EFFICACY BELOW : (Continue at the back)

VI. MEDICATION ERRORS AND OVERDOSAGE

PLEASE WRITE DETAILS OF MEDICATION ERRORS AND OVERDOSAGE BELOW:

VII. PARTICULARS OF REPORTER /HEALTH CARE PROVIDER

Name: _____ Profession: _____

Contact phone No: _____ E-mail: _____

Signature: _____ Date of this report: ___ ___/___/___

Name and Address of the health facility:

_____

_____

_____

❑ *Please tick if you wish to receive information about other local reports associated with the suspected drug(s)*

Thank you for your cooperation	***Submission of an ADR case report does not discredit the competence of the reporter.***	***Ref No. (for official use)***

First Fold

Guide to filling the form

How to report?

- Dully fill in the form as required
- Use a separate form for each patient
- Report direct to AUTHORITY through the following addres ses:-

Mail : Tanzania Food and Drugs Authority,

P. O. Box 77150, Dar es Salaam

An Adverse Drug Reaction (ADR) is defined as a reaction which is noxious and unintended, and which occurs at doses normally used in human for prophylaxis, diagnosis, or therapy of a disease, or for the modification of physiological function.

What to report?

Please report all undesirable patient effect suspected to be associated with drugs, cosmetics or medical devices use

Second Fold

POSTAGE WILL BE PAID BY LICENCEE

No postage stamp required
If posted in Tanzania

BUSINESS REPLY SERVICE
LICENCE No. BRS 01

TO: THE DIRECTOR GENERAL
TANZANIA FOOD AND DRUGS AUTHORITY
P. O. BOX 77150
DAR ES SALAAM

SECOND SCHEDULE

PATIENT ADR REPORTING FORM

TANZANIA FOOD AND DRUGS AUTHORITY

ADVERSE REACTION PATIENTS' REPORTING FORM

(Made under regulations 35 and 36(1)(b))

(For reporting adverse reactions and product problems by non-health care providers)

Note: Identities of patient will remain confidential

I. PERSON REPORTING

Patient ❑ Community health worker ❑ Parent ❑
Relative ❑
Other ❑ Specify: _____
Name and location of the health facility the medicine was obtained from:
_____

Sex: - Male ❑
Female ❑

Age of the patient_____

II. BRIEF DESCRIPTION OF THE REACTION/EVENT

.....
.....
.....

Date Reaction Started →___ /___ /____

Date Reaction Stopped (if known) → ___/ ____ / ____
Date reported.....

. DETAILS OF SUSPECTED MEDICINE USED

Name of suspected medicine(s)	Dosage	Frequency	Route	Therapy Date		Batch No. and expiry date(if known)	Reason for use
				Start	Stop		
1							
2.							
3.							
4.							
5.							

IV. DESCRIPTION OF ANY HERBAL MEDICINE THE PATIENT WAS TAKING

V. SERIOUSNESS OF THE ADVERSE REACTION

❑ Discomfort but able to work	❑ Caused persistent disability or incapacity
❑ Discomfort could not work	❑ Caused a congenital anomaly
❑ Required or prolonged hospitalization	❑ Patient Died: Date of death _____
❑ Life threatening	❑ Others, please give details.....

VI. SOURCE OF THE MEDICINE	
❑ Hospital Pharmacy	❑ Traditional Healer
❑ Retail Pharmacy	❑ Supermarket/Open Market
❑ Wholesale Pharmacy	❑ Family/Neighbour
❑ ADDO Shop	❑ Others, please specify.....

VII. REPORTER NAME AND CONTACT ADDRESS

Name: (Optional):

Contact Address:

Contact Phone No: _____

E-mail: (if available) _____

Date of this report: _____

Thank you for your cooperation

Ref No. (for official use)

First Fold

Guide to filling the form

How to report?

- Dully fill in the form as required
- Report direct to AUTHORITY through the following addres ses:-

Mail : Tanzania Food and Drugs Authority,

P. O. Box 77150, Dar es Salaam

Fax:: 22- 2450793

Phone: 22-2450512 / 2450751/0658 445222

Moisten gum a

POST
WILL
PAID

An Adverse Drug Reaction (ADR) is defined as a reaction which is noxious and unintended, and which occurs at doses normally used in human for prophylaxis, diagnosis, or therapy of a disease, or for the modification of physiological function.

What to report?

Please report all undesirable effects suspected to be associated with drugs, cosmetics or medical devices use.

LICENCEE

No postage stamp required

If posted in Tanzania

BUSINESS REPLY SERVICE LICENCE No. BRS 01

TO: THE DIRECTOR GENERAL

TANZANIA FOOD AND DRUGS AUTHORITY

P. O. BOX 77150

DAR ES SALAAM

THIRD SCHEDULE

QUALITY DEFECTS REPORTING FORM

TANZANIA FOOD AND DRUGS AUTHORITY

FORM FOR REPORTING POOR QUALITY PRODUCTS

(Made under regulations 36(1)(c), and 48(1)))

Note: Identities of reporter(s) will remain confidential

PRODUCT IDENTITY	
Brand Name:..... Generic Name:..... Batch/Lot Number:..... Date of Manufacture:..... Expiry Date:..... Country of Origin:.....	Name and Address of Distributor/Supplier: ....
PRODUCT FORMULATION **(Tick appropriate box)**	**COMPLAINT** **(Tick appropriate box(es))**
❑ Tablets/Capsules	❑ Colour change
❑ Oral Suspension/Syrup	❑ Turbid Solution
❑ Injection	❑ Change of Odour
❑ Cream/Ointment/Liniment/Paste	❑ Caking
❑ Powder for reconstitution of suspension	❑ Moulding
❑ Powder for reconstitution of injection	❑ Separating
❑ Eye drops	❑ Powdering/Crumbling
❑ Ear drops	❑ Incomplete Pack
❑ Nebulizer solution	❑ Mislabeling
❑ Diluent	❑ Other, please specify:
❑ Other, please specify:	
Describe the complaint in detail:	

STORAGE CONDITIONS			
Does the product require refrigeration?	❑ Yes	❑ No	Other details (if necessary)
Was the product available at the facility?	❑ Yes	❑ No	
Was the product dispensed and returned by client?	❑ Yes	❑ No	
Was the product stored according to manufacturer's recommendations?	❑ Yes	❑ No	
Comments (if any)			

REPORTER NAME AND CONTACT ADDRESS	
Name of Reporter: Contact Phone No: _____ E-mail: (if available) _____ Date of this report: _____	Contact Address:
Thank you for your cooperation	***Ref No. (for official use)***

First Fold

Guide to filling the form

How to report?

- Dully fill in the form as required
- Report direct to AUTHORITY through the following addresses:-

Mail : Tanzania Food and Drugs Authority,

P. O. Box 77150, Dar es Salaam

Fax:: 22- 2450793

Phone: 22-2450512 / 2450751/0658 445222

What to report?

Please report all product defects suspected to be associated with drugs, vaccines, cosmetics or medical devices use.

When to report?

As soon as possible

Moisten gum and fold. For maximum adhesion, press down for few seconds

Second Fold

POSTAGE WILL BE PAID BY LICENCEE

No postage stamp required

If posted in Tanzania

BUSINESS REPLY SERVICE LICENCE No. BRS 01

TO: THE DIRECTOR GENERAL

TANZANIA FOOD AND DRUGS AUTHORITY

P. O. BOX 77150

DAR ES SALAAM

FOURTH SCHEDULE

PATIENT ADR ALERT CARD

(Made under regulation 36(2))

TANZANIA FOOD AND DRUGS AUTHORITY *Front side* PATIENT ADVERSE DRUG REACTION ALERT CARD	
PATIENT NAME: ..... AGE: ..... GENDER: ..... DATE ISSUED: .....ADDRESS: ..... SUSPECTED DRUG(S): ..... DESCRIPTION OF REACTION: ..... Other comments (if any):	
Please carry this card with you at all	*Tafadhali hakikisha umebeba kadi hii*

times and remember to show it to your health care provider at each time of consultation	*kila wakati na kumbuka kumwonyesha mhudumu wa afya unapo pata matibabu*
CRITERIA FOR ISSUE OF A PATIENT ALERT CARD *Rear side*	
The alert card is to be given to: • Patients who are hypersensitive/allergic/intolerant to a particular drug, • Patients who developed a 'near-fatal' reaction to any particular drug, • Patients who had a drug-induced morbidity to any drug, • Patients who had hospital admission due to an AR to any drug. In-case of emergency contact, Tel: +255-22-2450512/2450751/ 2452108, Fax: +255-22-2450793, Website: **www.Authority.go.tz**, Email: info@Authority.go.tz	

Dodoma
……., 2018

UMMY A, MWALIMU
Minister for Health, Community Development,
Gender, Elderly and Children