LEGAL NOTICE NO. 95

THE PHARMACY AND POISONS ACT

(Cap. 244)

THE PHARMACY AND POISONS (CONDUCT OF CLINICAL TRIALS) RULES, 2022

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THE PHARMACY AND POISONS ACT

(Cap. 244)

IN EXERCISE of the powers conferred by section 44 (1) (n) of the Pharmacy and Poisons Act, the Cabinet Secretary, in consultation with the Board, makes the following Rules—

THE PHARMACY AND POISONS (CONDUCT OF CLINICAL TRIALS) RULES, 2022

PART I—PRELIMINARY

Citation.

1. These Rules may be cited as the Pharmacy and Poisons (Conduct of Clinical Trials) Rules, 2022.

Interpretation.

2. In these Rules, unless the context otherwise requires—

"adverse drug reaction" means a noxious or unintended response to a clinical trial study or interventional product related to a dose or to a registered health product which occurs at doses normally used in humans for prophylaxis, diagnosis or therapy of diseases or for modification of physiological function;

"adverse event" means an untoward medical occurrence in a patient or a participant in a clinical investigation study or intervention product, and which does not necessarily have a causal relationship with the treatment;

"applicant" means a person applying to conduct a clinical trial in accordance with rule 4;

"audit" means a systematic examination that is carried out independently of the persons who are directly involved in a clinical trial to determine whether the conduct of that clinical trial complies with the approved study protocol and whether data reported are consistent with the data on record at the site of the trial;

"blinding" means a procedure in which a participant in a study, investigator or data analyst is unaware of the treatment assignment;

"clinical trial report" means a written description of a clinical trial;

"comparator" means a health product or marketed product, active or placebo, used as a reference in a clinical trial;

"contract research organisation" means an organisation that is contracted by the sponsor to perform one or more of the duties and functions of the sponsor in the conduct of the clinical trial;

"data and safety monitoring board" means an independent board that is appointed in accordance with rule 12;

"double blinding" means blinding which applies to a participant in a study, the investigator and data analyst;

"ethical clearance" means the authorisation issued by an ethics committee to conduct a clinical trial;

"ethics committee" means a scientific and ethical review committee of an institution which is accredited by the National Commission for Science, Technology and Innovation in accordance with the Science, Technology and Innovation (Registration and Accreditation of Research Institutions) Rules, 2014; L.N. 106/2014.

"expert advisory committee" means an expert advisory committee responsible for clinical trials that is appointed by the Board in accordance with rule 6;

"generic product" means a multisource health product which is intended to be interchangeable with the comparator product which is usually manufactured without a licence from the innovator company and marketed after the expiry of patent or other exclusivity rights;

"good clinical practice" means a standard for the design, conduct, performance and monitoring, auditing, recording, analysis and reporting of clinical trials that provides assurance that the data and reported results are credible and accurate and that the rights, integrity and confidentiality of participants in a clinical trial study are protected;

"good manufacturing practice" means that part of quality assurance which ensures that investigational health products are consistently produced and controlled to the quality standards appropriate to their intended use and as may be required by the marketing authorization;

"informed written consent" means authority voluntarily given by a participant to confirm the participant's willingness to participate in a particular clinical trial after having been informed of all aspects of the clinical trial that are relevant to the participant's decision to participate;

"interchangeable health product" means a health product which is therapeutically equivalent to a comparator product and can be interchanged in clinical practice;

"investigational health product" means a medical device, health technology or pharmaceutical form of an active ingredient or placebo being tested or used as a reference in a clinical trial, including a registered health product or technology, when used or assembled (formulated or packaged) in a way that is different from the registered form, or when used for an unregistered indication, or when used to gain further information about a registered use;

"investigator" means an appropriately qualified person responsible for the conduct of a clinical trial;

"investigator's brochure" means a compilation of the clinical and non-clinical data on the investigational health product that is relevant to the clinical trial;

"legal representative" means a person authorised to give informed written consent on behalf of a prospective participant in a clinical trial for that participant's participation in the clinical trial;

"material transfer agreement" means a written agreement between a provider and recipient of research material that is aimed at

protecting the intellectual and other property rights of the provider while permitting research with the material by the recipient to proceed;

"minimum anticipated biological effect level" means an anticipated dose needed to result in a biological effect in a participant of a clinical trial which is recommended as a useful approach to calculate the safe starting dose as the lowest dose that is active;

"monitor" means a person appointed by, and responsible to, the sponsor or contract research organization for the monitoring and reporting of progress of a clinical trial and verification of data therefrom;

"no observed adverse effect level" means the greatest concentration or amount of a substance found by experiment or observation that does not cause any alteration of morphology, functional capacity, growth, development or lifespan of the target organism distinguishable from those observed in normal (control) organisms of the same species and strain under the same defined conditions of exposure;

"participant" means an individual who participates in a clinical trial as a recipient of the investigational product or as part of the control group;

"periodic safety update report" means a report containing update safety data pertaining to a registered health product and a scientific evaluation report regarding the benefits and risks of the health product;

"protocol" means a document that states the background, rationale and objectives of a clinical trial and describes the clinical trial's design, methodology and organisation, including statistical considerations, and the conditions under which the trial is to be performed and managed;

"quality assurance" means planned and systematic actions that are established to ensure that the trial is performed and the data are generated, recorded and reported in compliance with good clinical practice requirements;

"quality control" means the operational techniques and activities undertaken within the quality assurance system to verify that the requirements for quality of the activities related to the clinical trial have been fulfilled;

"randomisation" means the process of assigning a participant or control group treatment using an element of chance to determine the assignments in order to reduce bias;

"recognition" means the acceptance of the regulatory decision of another regulator or trusted institution that is based on evidence that the regulatory requirements of that other regulator or trusted institution are sufficient to meet the regulatory requirements of the Board;

"reliance" means taking into account and giving significant weight to the assessments performed by another regulatory authority or trusted institution, or to any other authoritative information, by the

Board in reaching its own decision and involves remaining independent, responsible and accountable for the decisions taken by the Board;

"serious adverse event" means an untoward medical occurrence that, at any dose, results in death, is life threatening, requires hospitalization or prolongs hospitalization, results in persistent or significant disability, or is a congenital anomaly or birth defect;

"single blinding" means blinding which applies to a study participant;

"source data" means information in original records and certified copies of original records of clinical findings, observations or other activities in a clinical trial that is necessary for the reconstruction and evaluation of the trial;

"sponsor" means a person who takes legal responsibility for the initiation, management and financing of a clinical trial;

"suspected unexpected serious adverse reaction" means serious adverse reaction that is not identified in practice, severity or frequency by the reference safety information;

"vulnerable participant" means an individual whose decision to participate in a clinical trial may be unduly influenced by the expectation of benefits associated with participation or by coercion; and

"work sharing" means the sharing of activities to accomplish a particular regulatory task.

Scope of application.

3. (1) These Rules shall apply to the conduct of a clinical trial—

(a) to test an unregistered health product;

(b) to test a registered health product where the proposed clinical trial is on the changes relating to the health product including—

(i) the indications and clinical use;

(ii) the target patient population;

(iii) the administration of the health product; or

(iv) the dosage regimen;

(c) to undertake a comparative bioavailability trial;

(d) to generate data on a health product that is registered in Kenya based on recognition, reliance or a work sharing arrangement;

(e) to establish bioequivalence for registration of a generic health product;

(f) to identify adverse reactions;

(g) to generate data on the absorption, distribution, metabolism and excretion of a health product; and

(h) to conduct a post-marketing study of a registered health product including the efficacy studies monitoring resistance.

(2) These Rules shall not apply to a clinical trial—

(a) that covers randomised controlled clinical trials relating to behavioural intervention;

(b) that involves an adult participant in the use of an educational test, survey, interview or observation of public behaviour unless—

(i) the information obtained is recorded in such a manner that the participant can be identified, directly or through identifiers linked to the participant; and

(ii) a disclosure of the responses of the participant outside the clinical trial could reasonably place the participant at risk of criminal or civil liability or be damaging to the financial standing, employability or reputation of the participant; or

(c) that involves the collection or evaluation of existing data, documents, or pathological or diagnostic specimens which are publicly available or if the information is recorded by the investigator in such a manner that the participants thereof cannot be identified, directly or through identifiers linked to the participant.

PART II—APPROVAL TO CONDUCT CLINICAL TRIAL

Application for approval to conduct clinical trial.

4. (1) A person shall not conduct a clinical trial of any health product without the written authorisation of the Board.

(2) An application to conduct a clinical trial shall be made by a sponsor or the sponsor's legal representative.

(3) An application under sub-rule (2) shall—

(a) be made in a duly filled and signed application form as set out in the First Schedule;

(b) be accompanied by the documents specified in sub-rule (4); and

(c) be accompanied by the fee specified in the Second Schedule.

(4) An application made under sub-rule (2) shall be accompanied by the following documents—

(a) a cover letter addressed to the Board;

(b) the study protocol duly signed and dated by the sponsor and principal investigator;

(c) the proposed participant information leaflet;

(d) the proposed informed written consent form;

(e) the investigator's brochure;

(f) a good manufacturing practice certificate of the investigational health product from the manufacturer issued by a competent health authority in the manufacturer's jurisdiction of origin;

(g) a certificate of analysis of the investigational health product;

(h) a pictorial sample of the investigational health product;

(i) the *curriculum vitae* of the investigator and study pharmacist;

(j) proof of recent training in good clinical practice for core study staff;

(k) the charter, composition and meeting schedule of the data and safety monitoring board;

(l) a statistical analysis plan;

(m) a detailed budget of the study;

(n) a recommendation from the relevant ethics committee;

(o) a valid indemnity cover for the investigator issued by a regulated insurance agency in Kenya;

(p) a valid insurance certificate for the participants issued by a regulated insurance agency in Kenya;

(q) copies of current practice licences or certificates from the relevant professional body that regulates the conduct of the investigators or study pharmacists;

(r) a copy of the approval letter from a collaborating institution or other regulatory authority, if applicable;

(s) a material transfer agreement, if applicable; and

(t) declarations by the principal investigator and sponsor on—

(i) financial disclosure;

(ii) conflict of interest;

(iii) compliance with good clinical practice;

(iv) compliance with legal requirements; and

(v) submission of correct information.

(5) In this rule, "core study staff" means the persons actively involved in the conduct of the clinical trial.

Processing of applications to conduct clinical trials.

5. (1) The Board shall, through the expert advisory committee evaluate an application submitted in accordance with rule 4.

(2) When conducting an evaluation under sub-rule (1), the Board shall consider—

(a) the reliability and robustness of the data generated in the clinical trial;

(b) whether the applicant has complied with the requirements concerning the manufacturing or importation of the investigational health product and any auxiliary health product connected therewith the investigational health medicinal product;

(c) whether the applicant has complied with the labelling requirements set out in the Third Schedule; and

(d) whether the investigator's brochure is adequate.

(3) The Board may approve or reject the application submitted under rule 4 and shall specify the reasons for the rejection in writing.

(4) The reasons for the rejection of an application by the Board under sub-rule (3) may include—

(a) insufficient information provided in the application;

(b) submission of false or falsified information;

(c) lack of a favourable opinion from an ethics committee;

(d) that the investigational health product endangers a participant;

(e) the safety of a participant has not been guaranteed; or

(f) any other reason as may be determined by the Board

(5) The Board shall communicate the decision made under sub-rule (3) in writing to the applicant within thirty working days after the receipt of the application.

(6) The Board shall publish on its website a list of the approved or rejected applications under sub-rule (3) and update the list at least once in every six months.

Expert advisory committees.

6. (1) The Board shall appoint an expert advisory committee for clinical trials which shall assist the Board to efficiently process each application for approval to conduct a clinical trial and study oversight.

(2) The Board shall designate members of the staff of the Board to assist the expert advisory committee in the performance of its functions.

PART III—INVESTIGATORS AND SPONSORS

Principal investigators.

7. (1) A person is qualified to be appointed as a principal investigator if that person—

(a) has a degree in medicine, pharmacy, pharmacology, toxicology, biochemistry, dentistry or a related discipline from a university recognised in Kenya;

(b) has a valid practice licence from the relevant regulatory authority;

(c) has a valid professional indemnity cover;

(d) has had formal training in good clinical practice that was

undertaken at least two years before the date of an application under rule 4;

(e) has previous experience in at least two clinical trials; and

(f) is a citizen of Kenya or is permanently resident in Kenya.

(2) The responsibilities of the principal investigator shall be—

(a) to thoroughly familiarise himself or herself with the characteristics and appropriate use of the investigational health product;

(b) to comply with ethical, good clinical practice and legal requirements in the conduct of the clinical trial;

(c) to facilitate access by the Board to the clinical trial for the purpose of monitoring and auditing the clinical trial or for inspection;

(d) to ensure that the data from the clinical trial is accurately recorded and submitted to the Board;

(e) to maintain records of the delivery processes and health products used in the clinical trial;

(f) to maintain a record of the persons to whom the investigator has delegated duties;

(g) to be responsible for the investigational medical product at the study site; and

(h) to maintain a list of staff who conduct the clinical trial.

(3) The principal investigator shall be liable for all aspects of the conduct of the clinical trial at a study site.

(4) A principal investigator shall not deviate significantly from, or make major changes to, the protocol of the clinical trial or to the information specified in the participant information booklet without the prior review and approval of the Board.

(5) Sub-rule (4) shall not apply where the deviation or change involves a logistical or administrative aspect of the clinical trial, or is based on issues relating to the immediate safety of a participant.

Responsibilities of sponsors.

8. (1) A sponsor shall be responsible for—

(a) implementing and maintaining quality assurance to ensure that a clinical trial is conducted following good clinical practice requirements;

(b) ensuring that the investigational health product provided for the trial has been manufactured following good manufacturing practice; and

(c) ensuring that data is generated, recorded and reported in compliance with good clinical practice requirements and applicable Rules.

(2) A sponsor shall ensure that the clinical trial institution,

contract research organisation, investigator, monitor, study pharmacist and participant have sufficient insurance cover for the clinical trial.

(3) A sponsor shall ensure that adequate treatment of a participant in case of injury or disease occurs during the course of the clinical trial.

(4) A sponsor shall provide an up-to-date investigator's brochure and drug safety update report whenever available, and in any case, at least once in year to the Board, unless there are substantial changes to the previous version to the brochure or report.

(5) A sponsor shall appoint qualified and suitable trained individuals to monitor a clinical trial.

(6) A sponsor shall report to the Board any serious adverse events and suspected unexpected serious adverse reactions that occur during the course of the clinical trial.

(7) An immediate notification of the event referred to in sub-rule (6) shall be made in writing and a detailed written report be submitted within fifteen days after the occurrence of the event.

(8) Despite sub-rule (7), the Board may direct the sponsor to provide additional information in any case where the adverse event causes death or threatens the life of a participant.

(9) A sponsor shall inform the Board in writing of a voluntary suspension or termination of the clinical trial within fifteen days after the suspension or termination and the reasons thereof.

(10) At the conclusion of a clinical trial, the sponsor shall submit—

(a) an executive summary of the report of the clinical trial;

(b) an annual study progress report; and

(c) a copy of the clinical trial report.

PART IV—CONDUCT OF CLINICAL TRIALS

Adherence to protocols.

9. (1) Each clinical trial shall be conducted in compliance with the protocol approved by the Board.

(2) The sponsor of a clinical trial shall submit the protocol of the trial to the Board, which shall contain—

(a) the general information of the clinical trial;

(b) the background information of the clinical trial including non-clinical data;

(c) the objectives of the clinical trial;

(d) the design of the clinical trial;

(e) the selection, treatment and withdrawal of a participant;

(f) the ethical considerations of the clinical trial;

(g) a post-trial access program;

(h) the mode of the assessment of the efficacy of the investigational health product;

(i) the mode of assessment of the safety of the investigational health product;

(j) the mode for collecting, analysing and reporting the statistics of the clinical trial;

(k) the source data documents of the clinical trial; and

(l) the quality control measures of the clinical trial.

Child participants.

10. (1) A sponsor who intends to conduct a clinical trial where the intended participant is a child shall ensure that the information in an approved participant information booklet referred to in rule 4(4)(c) specifies—

(a) the pathophysiology of the disease or subject of the clinical trial;

(b) the methods of diagnosis;

(c) the currently available treatment or prevention strategy in the paediatric population;

(d) the incidence and prevalence of the disease or subject of the clinical trial in the overall population and in the paediatric population; and

(e) the evidence and assumptions on key differences between the disease or subject of the clinical trial in the overall population and the paediatric population.

(2) Where the intended participant is a child, before making an application under rule 4, a sponsor shall ensure that—

(a) the clinical trial has been conducted with a participant who was an adult;

(b) the objective of the clinical trial is to obtain knowledge relevant to the health needs of children;

(c) the legal representative of each participant has been issued with the approved participant information booklet; and

(d) no financial inducement has been offered to the participant or the legal representative of the participant.

(3) When conducting a clinical trial where the participant is a child, an investigator shall ensure that the informed written consent of each legal representative of the participant has been obtained.

(4) The conduct of a clinical trial where a participant is a child shall ensure that the well-being of the participant is not compromised by participating in the clinical trial.

(5) The Board shall consider the following when evaluating an application under rule 4 where a participant is a child —

(a) the prevalence of the condition to be treated among children in the population;

(b) the seriousness of the condition to be treated by the outcome of the clinical trial;

(c) the availability and suitability of an alternative treatment for the condition, including the efficacy and the adverse event profile of that treatment;

(d) whether the investigational health product is novel or one of a class of compounds with known properties;

(e) whether there are unique paediatric indications for the investigational health product;

(f) the need for the development of a paediatric-specific endpoint;

(g) the age ranges of the proposed paediatric patients likely to be treated with the investigative health product;

(h) the unique paediatric or developmental safety concerns of the investigational health product, including any nonclinical safety issues; and

(i) the potential for paediatric formulation development.

(6) An application made under rule 4 where a participant is a child shall specify the following information of the investigational health product—

(a) the genotoxicity;

(b) the reprotoxicity;

(c) the carcinogenicity, if applicable;

(d) the juvenile animal studies, if applicable;

(e) the pharmacokinetics;

(f) the absorption;

(g) the distribution;

(h) the metabolism;

(i) the excretion; and

(j) the pharmacodynamics.

Informed written consent.

11. (1) Before the making an application under rule 4, a sponsor shall obtain a recommendation to conduct the clinical trial from the relevant ethics committee.

(2) An investigator shall submit, in writing, an approved participant information booklet to each participant or the participant's legal representative, in English, Kiswahili or the local spoken language of the participant.

(3) If a participant or the participant's legal representative is unable to read the approved participant information booklet submitted under sub-rule (2), the investigator shall explain to the participant or legal representative, and in the presence of impartial witness, the information in the booklet.

(4) A participant information booklet shall contain the following information—

(a) a declaration that a clinical trial involves research activities;

(b) the objective of the clinical trial;

(c) the treatment that will be employed in the clinical trial;

(d) the procedure to be followed in the clinical trial;

(e) the responsibilities of the participant;

(f) the aspects of the clinical trial that are experimental;

(g) the reasonably foreseeable risks to a participant;

(h) the reasonably expected benefits of the clinical trial, if any;

(i) an alternative procedure or treatment available to participants and the important potential benefit and risk of the alternative;

(j) the compensation or treatment available to the participant in the event of injury or adverse event related to the clinical trial;

(k) that the participation in the clinical trial is voluntary and that the participant may decline to participate or withdraw from the trial at any time without penalty or loss of benefits to which the participant is otherwise entitled;

(l) the anticipated payment, if any, to the participant;

(m) the anticipated expenses, if any, of the participant;

(n) the foreseeable circumstances or reasons under which the participation of the participant may be terminated;

(o) the expected duration of a participant's role in the clinical trial; and

(p) the approximate number of participants involved in the clinical trial.

(5) On receipt the approved participant information booklet under sub-rule (2), the participant or participant's legal representative may submit an informed written consent to an investigator.

(6) If the participant or participant's legal representative agrees with the information submitted under sub-rule (3), the investigator shall prepare an informed written consent and the participant or legal representative, and the impartial witnesses, shall sign and date the informed written consent.

(7) A sponsor, investigator, study pharmacist, monitor and any other person connected with the conduct of the clinical trial shall not coerce or unduly influence a participant or participant's legal representative to participate or to continue to participate in the clinical trial if the participant or legal representative has withdrawn his or her informed written consent.

(8) Where new information is available that would require the informed written consent of a participant, an investigator shall prepare a revised participant information booklet, submit the revised booklet for approval in accordance with rule 4 and thereafter submit the revised booklet in accordance with sub-rule (2) or inform the participant of the revised booklet in accordance with sub-rule (3).

(9) The Board may gain access to a participant's original medical records for verification of data, or the conduct of a procedure or treatment used in the clinical trial without violating the confidentiality of the participant to the extent permitted by the participant or participant's legal representative as specified in the informed written consent authorizing such access.

(10) The information of a participant or participant's legal representative shall be kept confidential and not made publicly available or to any other person without the express written consent of the participant or participant's legal representative.

(11) Where the results of a clinical trial are published, the identity of a participant shall not be disclosed.

(12) The participation of a participant in a clinical trial is voluntary and a participant may decline to participate or withdraw the informed written consent issued by the participant at any time without penalty or loss of benefits to which the participant is otherwise entitled.

Safety reports.

12. (1) A sponsor shall submit to the Board a report of any suspected unexpected serious adverse reaction or serious adverse event that occurs in a clinical trial.

(2) Where a sponsor conducts a clinical trial on the same health product or active pharmaceutical substance in another country, the sponsor shall submit a report of any suspected unexpected serious adverse reaction or serious adverse event that occurs in that other clinical trial to the Board.

(3) A sponsor shall submit a report of an initially fatal or life threatening suspected unexpected serious adverse reaction or serious adverse event as soon as it occurs but, in any case, not later than seven days after the occurrence of the event.

(4) Subject to sub-rule (3), a sponsor shall submit a report on a suspected unexpected serious adverse reaction which is not fatal or life-threatening within fifteen days after the occurrence of the event.

(5) A report of the occurrence of a suspected unexpected serious adverse reaction or serious adverse event shall specify—

(a) the suspected unexpected serious adverse reaction or serious adverse event which is related to the clinical trial; and

(b) the suspected unexpected serious adverse reaction or serious adverse event which is not related to the clinical trial.

(6) A sponsor shall submit to the Board, at least once in each year from the date of authorisation of the clinical trial, and throughout the

conduct of the clinical trial, or on request by the Board, a safety report on the safety information received during the reporting period.

(7) The safety report submitted under sub-rule (6) shall contain a log of serious adverse events and suspected unexpected serious adverse reactions that occur during the clinical trial and indicate -–

(a) the age, date of the informed written consent and identity of the participant who was affected by the serious adverse event or suspected unexpected serious adverse reaction;

(b) the type, date of commencement and end date of the serious adverse event or suspected unexpected serious adverse reaction;

(c) the reason for reporting the occurrence as a serious adverse event or suspected unexpected serious adverse reaction;

(d) how the serious adverse event or suspected unexpected serious adverse reaction relates to the investigational health product; and

(e) the outcome of the serious adverse event or suspected unexpected serious adverse reaction.

(8) A sponsor shall notify the investigators involved in the clinical trial of any serious adverse event or suspected unexpected serious adverse reaction related to the clinical trial within fifteen days after the occurrence of the event.

(9) A sponsor shall submit to the Board a report of any new information or change in nature, severity or frequency of risk factors in respect of the investigational health product or conduct of the clinical trial within fifteen days after the sponsor becomes aware of the information or change.

Data and safety monitoring board.

13. (1) The sponsor shall establish a data and safety monitoring board in respect of a clinical trial which shall be responsible for the following—

(a) assessing the progress of the clinical trial;

(b) assessing the safety data of the clinical trial;

(c) assessing the critical efficacy endpoints of the clinical trial; and

(d) recommending to the sponsor whether to continue, modify, or stop the clinical trial.

(2) A sponsor shall appoint a data safety and monitoring board where—

(a) the endpoint of a clinical trial is such that a highly favourable or unfavourable result, or even a finding of futility, at an interim analysis might ethically require termination of the clinical trial before its planned completion;

(b) there are *a priori* justifications for a particular safety concern;

(c) there is prior information suggesting the possibility of toxicity with the treatment offered during the clinical trial;

(d) the clinical trial is being performed in a potentially vulnerable population;

(e) the clinical trial is being performed in a population at an elevated risk of death or other serious outcomes; or

(f) the clinical trial is being conducted for a period exceeding three years and at multiple centres.

(3) The data and safety board shall include the following persons—

(a) a clinician with expertise in the relevant clinical speciality that is the focus of the clinical trial;

(b) a biostatistician who is knowledgeable about statistical methods for a clinical trial and sequential analysis of data generated from a clinical trial;

(c) a toxicologist;

(d) an epidemiologist;

(e) a clinical pharmacologist; and

(f) where a clinical trial involves an unusually high risk or broad public health implication, a medical ethicist who is knowledgeable about the design, conduct and interpretation of clinical trials; and

(g) any other scientist who the sponsor considers to be necessary.

(4) In this paragraph, "medical ethicist" means a medical practitioner or medical professional who specialises in research, moral, legal and ethical issues that arise in health care settings.

Investigational health product.

14. (1) An investigational health product shall be manufactured in accordance with the requirements of good manufacturing practices.

(2) The import, export, storage and destruction of the investigational health product shall comply with the applicable regulatory requirements to ensure integrity and accountability of the products.

(3) An application for import or export of the investigational health product shall be made to the Board and a respective permit obtained.

(4) The Board may revoke or suspend a permit issued under sub-rule (3) for the following reasons—

(a) the investigational health product was manufactured in conditions that were or are not consistent with good manufacturing practices;

(b) the discontinuation of the clinical trial; or

(c) false information provided by the sponsor.

(5) The Board may authorise the disposal of an investigational health product upon written request by the sponsor or the sponsor's legal representative in accordance with the Board's procedures on safe management of pharmaceutical waste.

(6) A sponsor shall submit a certificate of analysis for an investigational health product and for a comparator product when making an application under rule 4.

(7) A sponsor shall specify the following information when making an application under rule 4—

(a) the name and source of the investigational health product;

(b) the method of manufacturing the investigational health product;

(c) the physicochemical properties and structure elucidation of the investigational health product;

(d) the impurities of the investigational health product;

(e) the specifications, test methods and batch analyses of the investigational health product;

(f) the stability and packaging of the investigational health product; and

(g) the proposed dosage form of the investigational health product.

(8) Where the pharmaceutical or chemical properties of an investigational health product have been altered compared to those in use during animal testing or a previous clinical trial, the sponsor shall describe and justify the alteration.

(9) A sponsor shall immediately notify the Board in writing where a pharmaceutical or chemical alteration that may affect the quality, safety or efficacy of the investigational health product occurs in an investigational health product that is used in an ongoing clinical trial.

(10) In this paragraph, "comparator product" means a product of established quality, safety and efficacy that may be used as a reference in a clinical trial or bioequivalence study.

Pharmacy at site for clinical trial.

15. (1) A sponsor shall ensure that a site at which a clinical trial is being undertaken has a designated pharmacy.

(2) The pharmacy designated under sub-rule (1) shall, at a minimum, have—

(a) facilities and equipment that reflect the types of procedures and treatments of the clinical trial that shall be undertaken by the investigator;

(b) a biosafety level cabinet, if necessary;

(c) a controlled environment that prevents microbiological contamination and regulates the temperature; and

(d) a designated storage area, with a quarantine area;

(e) documented procedures that comply with good pharmacy practice; and

(f) a rigorous quality management system.

(3) The designated storage area referred to in sub-rule (2)(d) shall—

(a) have adequate space for the separate storage of different health products;

(b) be temperature-controlled and, if appropriate, humidity monitored, with alarm controls;

(c) be shielded from direct sunlight; and

(d) be mapped to identify and avoid using hot and cold spots, if necessary.

Clinical trial laboratories.

16. A sponsor shall ensure that any laboratory that is used in support of a clinical trial is of a suitable size, construction and location to meet the requirements of the clinical trial and that—

(a) the design of the laboratory provides an adequate degree of separation of different activities of the laboratory;

(b) the equipment used in the laboratory has valid maintenance and calibration certificates;

(c) that the analysis conducted in the laboratory is organised and conducted in such a manner that the findings therefrom are transparent and stand up to retrospective verification;

(d) the roles and responsibilities of the staff of the laboratory are well established and documented before the commencement of the clinical trial;

(e) the laboratory possesses the protocol and any amendments thereto that was approved by the Board for the clinical trial;

(f) the impact of any deviations from the standard operating procedures or documented policies of the laboratory are assessed and documented; and

(g) the laboratory does not perform any analysis on a sample from a clinical trial that is not specified in the protocol that was approved by the Board for the clinical trial.

Quality assurance.

17. (1) A sponsor shall develop a quality assurance process that ensures—

(a) that a research centre, researcher, sponsor, clinical research organisation and any other person involved in a clinical trial

complies with good clinical practice including ensuring—

(i) that the study benefit outweighs risks;

(ii) that the rights and wellbeing of a participant are protected and preserved;

(iii) that the clinical trial is scientifically sound and performed in accordance with the approved protocol;

(iv) that the core study staff are adequately qualified and trained to perform their duties;

(v) that the confidentiality of the information of a participant is maintained; and

(vi) that informed written consent is obtained from a participant before participation in the clinical trial;

(b) that there is regular and continuous monitoring of the clinical trial and the recommendations of the report thereof are implemented;

(c) that the site where the clinical trial is undertaken has valid registration and approval;

(d) that the safety and confidentiality of the information of a participant are not compromised;

(e) that the analysis or evaluation of a sample from the clinical trial is conducted in accordance with the principles of good clinical practice;

(f) that the analysis or evaluation of samples is performed in accordance with the protocol approved by the Board;

(g) that data from the conduct of the clinical trial is recorded and reported accurately, legibly, completely and in a timely manner;

(h) that the equipment used in the conduct of the clinical trial is regularly maintained; and

(i) that the records, including source documents and final reports, are well kept.

(2) A sponsor shall establish an internal audit program for the conduct of the clinical trial once approval is obtained in accordance with rule 5.

Termination of clinical trials.

18. (1) A sponsor shall ensure that the protocol approved by the Board specifies the procedure for the termination of the clinical trial.

(2) If a clinical trial is terminated voluntarily by an investigator or a sponsor, the sponsor shall notify the Board of the termination within fifteen days after the termination.

(3) If a clinical trial is terminated under sub-rule (2), a sponsor shall—

(a) immediately inform, in writing, the investigators of the termination, the reasons for the termination and advise them

on the potential risks to the health of a participant or other person;

(b) if the termination is due to an adverse event, ensure that the affected participant receives medical care where the participant develops or experiences an adverse drug reaction to the investigational health product; and

(c) inform the Board, in writing, of—

(i) the reason for the termination;

(ii) the impact of the termination on the proposed or ongoing conduct of the clinical trial on the investigational health product;

(iii) the accountability and disposal of the investigational health product; and

(iv) the maintenance of records of the clinical trial that has been terminated

(4) The Board may revoke the approval to conduct a clinical trial if the Board determines—

(a) that the safety of a participant has been compromised;

(b) that the scientific reasons for conducting the clinical trial have changed;

(c) that the investigational health product has expired; or

(d) that the investigational health product is not usable.

(5) Where a clinical trial has been terminated, a sponsor shall—

(a) submit an executive summary report of the clinical trial to the Board within thirty days after the termination;

(b) submit a clinical trial report within one hundred and eighty days after the termination; and

(c) dispose of the investigational health products in accordance with the Board's procedures on the safe management of pharmaceutical waste.

PART V—MISCELLANEOUS

Amendments to protocol.

19. (1) A sponsor shall promptly apply to the Board for the amendment to the protocol where new information which affects the conduct of the clinical trial, safety of a participant or manufacture of the investigational health product, that necessitates a change to the protocol, becomes available.

(2) A sponsor shall take appropriate urgent safety measures to protect a participant against any hazard where an occurrence referred to in sub-rule (1) is likely to affect the safety of the participant.

(3) An application under sub-rule (1) shall be accompanied by a copy a recommendation from the relevant ethics committee.

(4) A sponsor shall make an application under sub-rule (1) where the proposed amendment includes—

(a) a change that may affect—

(i) the safety, or physical or mental integrity of a participant;

(ii) the scientific value of the clinical trial;

(iii) the conduct or management of the clinical trial;

(iv) the quality or safety of the investigational health product;

(v) an objective of the clinical trial;

(vi) a primary or secondary endpoint of the clinical trial;

(vii) the addition of a trial arm or placebo group to the clinical trial;

(viii) the inclusion or exclusion of a criterion of the clinical trial;

(ix) the monitoring of the clinical trial;

(x) the data and safety monitoring board;

(xi) an alternative to an investigational health product;

(xii) the dosage of an investigational health product;

(xiii) the mode of administration of an investigational health product;

(xiv) the design of the clinical trial which has an impact on statistical analysis or the risk-benefit assessment of the clinical trial;

(xv) an alternative to the sponsor;

(xvi) the revocation or suspension of the registration of the investigational health product;

(xvii) the manufacturing process or specifications of an active substance or the investigational health product;

(xviii) the reference safety information during the conduct of the clinical trial;

(xix) the site for the conduct of the clinical trial; or

(xx) an alternative to an investigator;

(b) a change that may affect the selection or discontinuation of a participant;

(c) a change that may affect the effectiveness of the investigational health product and safety of a participant; or

(d) a change that may affect the duration of the clinical trial.

(5) An application under sub-rule (1) shall specify—

(a) the proposed amendment;

(b) the justification for the proposed amendment;

(c) the impact of the proposed amendment on the objectives of the clinical trial;

(d) the impact of the proposed amendment on the endpoints and data generated from the conduct of the clinical trial; and

(e) the impact of the proposed amendment on the safety and wellbeing of a participant.

(6) An application under sub-rule (1) shall be accompanied by a favourable opinion by an Ethics Committee and applicable fees as may be prescribed by the Board.

Inspection of clinical trial sites.

20. (1) The Board shall conduct an inspection of the site at which a clinical trial is conducted.

(2) The objectives of an inspection under sub-rule (1) shall be—

(a) to ensure that a participant is not subjected to undue risks;

(b) to ensure that the rights, safety and wellbeing of the participants are protected;

(c) to validate the quality of the data generated;

(d) to investigate a complaint; and

(e) to assess the compliance of a sponsor with the Act and these Rules.

(3) An investigator shall, on the request of the Board, at reasonable times, give the Board access to, and copy and verify any records or reports made by the investigator when conducting the clinical trial.

(4) An inspection may be conducted before the commencement of a clinical trial, or at routine intervals as may be determined by the Board.

(5) The Board may carry out a routine inspection referred to in sub-rule (4) to assess—

(a) the adequacy of the clinical trial;

(b) the protection measures for a participant;

(c) the integrity of the data; or

(d) the historical background of the clinical trial site, a sponsor or an investigator.

(6) Any non-compliance by the sponsor, investigator or any person connected to the clinical trial during an inspection may form the basis of the revocation or suspension of the authorisation to conduct the clinical trial.

Clinical trials involving traditional or alternative medicines.

21. (1) A sponsor shall ensure that good clinical practice is applied when conducting a clinical trial involving traditional or alternative medicines.

(2) A sponsor shall ensure that a traditional medicine practitioner who is familiar with the traditional or alternative medicine proposed for investigation develops the protocol for the conduct of the clinical trial.

(3) The protocol developed under sub-rule (3) shall be submitted to the Board for approval before the commencement of the clinical trial.

(4) The protocol developed under sub-rule (3) shall not be amended without the approval of the Board.

Online registry for clinical trials.

22. Applications for the conduct of clinical trials shall be registered on the Board's online registry.

Clinical trials in special circumstances.

23. (1) The Board may, in special circumstances, through written guidelines, authorise the conduct of a clinical trials under fast-track procedures or non-routine procedures.

(2) The special circumstances referred to in sub-rule (1) may include—

(a) a public health emergency;

(b) the rapid spread of an epidemic disease; or

(c) any other circumstance as may be determined by the Board.

Reliance and recognition.

24. The Board may recognise and use of clinical trial decisions, reports or information from other competent authorities in rule of clinical trials.

Offences and penalties.

25. Any person who contravenes the provisions of these Rules commits an offence and shall be liable to the penalty prescribed under section 51 of the Act.

FIRST SCHEDULE (r. 4 (3) (a))
FORM

Application for Approval to Conduct Clinical Trial
Study Title: Protocol No: Version No: Date of Protocol: Study Drug: ECCT Ref number (if applicable): Sponsor: Contact Person: Address: Telephone Number: Fax Number: Cell Number: E-mail address:
TICK AND PROVIDE NECESSARY DETAILS AS APPROPRIATE
2. NUMBER OF SITES
Single site in Kenya: If yes, name of site……
Multiple sites in Kenya: Number of sites anticipated in Kenya ( ) If yes list the sites…… Multiple countries: Number of states anticipated in the trial ( ) If yes above list the countries……
Does this trial have a data monitoring committee? yes □ no □
3. PARTICIPANTS (SUBJECTS)

3.1 Number of participants in Kenya: 3.2 Total enrolment in each Kenyan site: (if competitive enrolment, state minimum and maximum number per site.) 3.3 Total participants worldwide:
4.0 AGE SPAN
Less than 18 years yes □ no □ If yes specify: In Utero yes □ no □ Preterm Newborn Infants (up to gestational age < 37 weeks) yes □ no □ Newborn (0-28 days) yes □ no □ Infant and toddler (29 days - 23 months) yes □ no □ Children (2-12 years) yes □ no □ Adolescent (13-17 years) yes □ no □ 18 years and overyes □ no □ Adult (18-65 years)yes □ no □ Elderly (> 65 years) yes □ no □
5.0 GROUP OF TRIAL SUBJECTS
Healthy volunteers yes □ no □ Patients yes □ no □ Specific vulnerable populations yes □ no □ Women of child bearing potential yes □ no □ Women of child bearing potential using contraception yes □ no □ Pregnant women yes □ no□

Nursing women yes □ no□ Emergency situation yes □ no□ Subjects incapable of giving consent personally yes □ no□ If yes, specify: Others: yes □ no□ If yes, specify:
6.0 GENDER
Female □ Male □
7.0 CO-ORDINATING INVESTIGATOR (*for multicentre trials in Kenya*)
Given name Middle name, if applicable Family name Qualification Professional address:
8.0 PRINCIPAL INVESTIGATOR *(for multicentre trial; where necessary, use additional forms)*
Given name Middle name, if applicable Family name Qualification Professional address
9.0 ORGANISATIONS TO WHOM THE SPONSOR HAS TRANSFERRED TRIAL RELATED DUTIES AND FUNCTIONS (repeat as needed for multiple organisations)
Has the sponsor transferred any major or all the sponsor's trial related duties and functions to another organisation or third party? yes □ no □ Repeat as necessary for multiple organisations: Organisation:

Name of contact person: Address: Telephone number:
All tasks of the sponsor yes □ no □ Monitoring yes □ no □ Regulatory (e.g. preparation of applications to CA and ethics committee) yes □ no □ Investigator recruitment yes □ no □ IVRS – treatment randomization yes □ no □ Data management yes □ no □ E-data capture yes □ no □ SUSAR reporting yes □ no □ Quality assurance auditing yes □ no □ Statistical analysis yes □ no □ Medical writing yes □ no □ Other duties subcontracted yes □ no □ If yes to other please specify:
10.0 PRINCIPAL INCLUSION CRITERIA
List them here;
11.0 PRINCIPAL EXCLUSION CRITERIA
List them here;
12.0 PRIMARY END POINT(S):

List them here;
13.0 SCOPE OF THE TRIAL – Tick all boxes where applicable
Diagnosis □ Prophylaxis □ Therapy □ Safety □ Efficacy □ Pharmacokinetic □
Pharmacodynamic □ Bioequivalence □ Dose Response □ Pharmacogenetic □ Pharmacogenomic □ Pharmacoeconomic □ Others □ If others, specify:
14.0 TRIAL TYPE AND PHASE
Human pharmacology (Phase I) □ Is it: First administration to humans □ Bioequivalence study □ Other: □ If other, please specify Therapeutic exploratory (Phase II) □

Therapeutic confirmatory (Phase III) □ Therapeutic use (Phase IV) □
15.0 DESIGN OF THE TRIAL
Controlled yes □ no □ If yes, specify: Randomised yes □ no □ Open: yes □ no □ Single blind: yes □ no □ Double blind: yes □ no □ Parallel group: yes □ no □ Cross over: yes □ no □ Other: yes □ no □ If yes to other specify: If controlled, specify the comparator: Other medicinal product(s) yes □ no □ Placebo yes □ no □

Other yes □ no □ If yes to other, specify:
16.0 INFORMATION ON PLACEBO (if relevant; repeat as necessary)
Is a there a placebo: yes □ no □ Pharmaceutical form: Route of administration: Composition, apart from the active substance(s): Is it otherwise identical to the INDP? yes □ no □ If not, specify major ingredients:
17.0 Details of Site(s)
Name of site Physical address Contact details Contact person:
18.0 Capacity of Site(s):
Number of staff (including study co-ordinators, site facilities, emergency facilities, other relevant infrastructure): Names: Qualifications: Experience:
19.0 OTHER DETAILS
19.1 If the trial is to be conducted in Kenya and not in the host country of the applicant / sponsor, provide an explanation:

19.2 Estimated duration of trial:

19.3 Name other Regulatory Authorities to which applications to do this trial have been submitted, but approval has not yet been granted. Include date(s) of application:

19.4 Name other Regulatory Authorities which have approved this trial, date(s) of approval and number of sites per country:

19.5 If applicable, name other Regulatory Authorities or Ethics Committees which have rejected this trial and give reasons for rejection:

19.6 If applicable, details of and reasons for this trial having been halted at any stage by other Regulatory Authorities:

SECOND SCHEDULE r. 4 (3) (c)

FEES		
	Purpose of Fees	Amount (Kshs.)
1.	Application for Approval to Conduct Clinical Trial	110,000

THIRD SCHEDULE r. 5 (2) (c)

LABELLING REQUIREMENTS

The final copy of the label of an investigational health product shall contain the following minimum information—

(a) a statement indicating that the product is for "clinical trial purpose only";

(b) the recommended storage conditions;

(c) the protocol code or identification;

(d) the name, address and telephone number of the sponsor, contract research organisation or investigator;

(e) the pharmaceutical dosage form, route of administration, quantity of dosage units, and in the case of open trials, the identifier and the potency;

(f) the batch and code number;

(g) a clinical trial reference code allowing identification of the clinical trial, site, investigator and sponsor, if not given elsewhere;

(h) the identification number or treatment number and, where relevant, the visit number of a participant;

(i) the directions for use;

(j) the period of use in month and year format and in a manner that avoids any ambiguity; and

(k) the complete physical address of the manufacturing site.

Made on the 8th June, 2022.

MUTAHI KAGWE,
Cabinet Secretary for Health.

LEGAL NOTICE NO. 96

THE PHARMACY AND POISONS ACT

(Cap. 244)

THE PHARMACY AND POISONS (PHARMACOVIGILANCE AND POST MARKET SURVEILLANCE) RULES, 2022

ARRANGEMENT OF RULES

Rule

PART I – PRELIMINARY

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8 — Responsibility of patients and members of the public.

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24 — Role of health care providers.

25 — Role of market authorization holders.

26 — Role of manufacturers.

27 —The Quality Control Testing Laboratory.

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THE PHARMACY AND POISONS ACT

(*Cap.* 244)

IN EXERCISE of the powers conferred by section 44(1)(mme) of the Pharmacy and Poisons Act, the Cabinet Secretary for Health, in consultation with the Board, makes the following Rules—

THE PHARMACY AND POISONS (PHARMACOVIGILANCE AND POST MARKET SURVEILLANCE) RULES, 2022

PART I ─ PRELIMINARY

Citation.

1. These Rules may be cited as the Pharmacy and Poisons (Pharmacovigilance and Post Market Surveillance) Rules, 2022.

Application.

2. These Rules shall apply to health products and technologies manufactured, imported, distributed, marketed, licensed or used in healthcare practice in Kenya.

Interpretation.

3. In these Rules, unless the context otherwise requires─

"Act" means the Pharmacy and Poisons Act;

"active surveillance" means prospective measures taken to detect adverse drug reactions and adverse events and involves active follow-up during and after treatment of patients where the events may be detected by asking the patient directly or screening patient records;

"adverse event" 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;

"adverse drug reaction" means a response to a drug 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 and is characterized by the suspicion of a causal relationship between a medical product and an occurrence;

"Centre" means the National Pharmacovigilance Centre established under rule 5;

"falsified product" means health products and technologies that are deliberately or fraudulently misrepresented in identity, composition or source;

"healthcare provider" means a health care professional and any other person who provides health care services;

"health product" has the meaning assigned under the Act;

"marketing authorization holder" means an individual or a corporate entity responsible for placing a health product or technology in the market either through importation, donation, distribution or sale in Kenya;

"manufacturer" means a person who sells a product under their own name, or under a trademark, design, trade name or other name or mark owned or controlled by the person or the body, and who is responsible for designing, manufacturing, assembling, processing, labelling, packaging,

refurbishing or modifying the product, or for assigning to it a purpose, whether those tasks are performed by that person or on their behalf;

"medical device" means any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination for a medical purpose;

"passive surveillance" means that no active measures are taken to look for adverse effects other than the encouragement of health professionals and others to report safety concerns;

"parallel importer" means a person licensed to import medicinal substance other than the marketing authorization holder or his or her technical representative of the following medicinal substances which should have been granted marketing authorization in Kenya—

(a) patented medicinal substances under section 58(2) of the Industrial Property Act, 2001;

(b) non-patented medicinal substances;

(c) generic medicinal substances;

"pharmacovigilance" means the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other possible health product related problem;

"post-marketing surveillance" has the meaning assigned under the Act;

"pharmacovigilance electronic reporting system" means a suite of software applications implemented by the Pharmacy and Poisons Board for collection and processing of information on suspected Adverse drug reactions or adverse events and suspected poor-quality health products or technologies;

"product" means a health product and technology;

"qualified person for pharmacovigilance" means an individual appointed by a marketing authorization holder or a parallel importer as the main person responsible for ensuring that the company meets legal obligations for monitoring of the quality, safety and efficacy of the product marketed in Kenya;

"quality control testing laboratory" means the National Quality Control Laboratory, the Pharmacy and Poisons Board Quality Control Laboratory and other sub-contracted quality control laboratories as defined by the Board;

"quality defect" means attributes of a health product or health technology or component which may affect the quality, safety or efficacy of the product, or which are not in line with the approved market authorization requirements;

"quarantine" means the isolating, holding and restricting movement, physically or by other effective means a medical product and health technology. During quarantine period the product is not available for distribution or use;

"rapid alert system" refers to a system designed to ensure a timely, proportionate, accurate and consistent response to health events arising from sub-standard and falsified health products and technologies which represent a significant threat to health and safety of the public;

"recall" means the removal of a specific batch of a health product and technology from the market for products that do not meet marketing authorization requirements including reasons relating to deficiencies in the quality, safety, efficacy or effectiveness;

"withdrawal" refers to the total removal of health products and technologies from the market for reasons relating to deficiencies in the quality, safety, efficacy leading to cessation of its market authorization;

"wholesale dealer" means entity or individual licenced as such by the Board and as provided by section 27 of the Act.

Objects and purpose.

4. The purpose of these Rules shall be to—

(a) improve patient care and safety in relation to the use of health products and technologies;

(b) improve public health and safety in relation to the use of medicines;

(c) facilitate the detection of problems related to the use of health products and technologies and the communication of the findings in a timely manner;

(d) facilitate the assessment of benefit, harm, effectiveness and risk of a health product or technology, leading to the prevention of harm and maximization of benefits of the health product or technology;

(e) encourage the safe, rational and more effective, including cost effective, use of medicines;

(f) increase the trust of patients on medication and health care system;

(g) enhance distribution of information needed to improve drug prescribing and regulation;

(h) promote understanding, education and clinical training in pharmacovigilance and its effective communication to the public;

(i) strengthen the processes of monitoring quality, safety and efficacy of medical products and health technologies;

(j) enhance prevention, detection and response to substandard medical products and health technologies in Kenyan market;

(k) enhance monitoring of status of market authorization of medical products and health technologies in Kenya; and

(l) promote understanding, education training in post-marketing surveillance programs and activities and their effective communication to the public.

PART II — THE NATIONAL PHARMACOVIGILANCE SYSTEM

Establishment of the Centre.

5. (1) The Board shall establish a National Pharmacovigilance Centre which shall set up and manage the national pharmacovigilance and post marketing surveillance system to receive and maintain all relevant information about suspected adverse drug reactions and adverse events to health products or health technologies which have been authorised by the Board.

(2) The Centre shall be the single, government recognized integrated system with the clinical and scientific expertise to collect, collate, analyse and give advice on all information related to drug safety.

(3) The Centre shall, through the national system, collect, manage, assess, analyse, identify signals and communicate safety information related to health products and technologies authorised by the Board.

(4) The Centre shall consist of—

(a) the national pharmacovigilance and post marketing quality surveillance system with designated and qualified staff;

(b) the national spontaneous reporting system with reporting forms comparable to the international standards;

(c) the national database for collating and managing safety reports; and

(d) expert committees to provide technical assistance on causality assessment, risk management and case investigation of pharmacovigilance related issues.

(5) The system shall contain data and reports from—

(a) public, private and faith-based health facilities;

(b) other ministry departments, county health departments and public health programs;

(c) health practitioners, health organizations and institutions;

(d) marketing authorisation holders;

(e) regional economic communities;

(f) international agencies; and

(g) patients or members of the public.

Stakeholders under the system.

6. The system shall work with the support of the ministry responsible for matters related to health, County governments, healthcare providers, health regulatory bodies, the pharmaceutical industry, marketing authorisation holders, public health programs members of the public, development partners and other relevant stakeholders.

Roles and responsibilities of healthcare providers.

7. A health care provider shall—

(a) promote rational drug use;

(b) conduct patient education on adverse drug reactions and adverse events including counselling on medication use;

(c) detect and initiate appropriate clinical management and treatment of patients presenting with adverse reactions or events;

(d) report all suspected adverse drug reactions and adverse events and send the reports immediately to the County Vigilance focal persons or directly through the Pharmacovigilance Electronic Reporting System;

(e) utilize the collated data on adverse drug reactions and adverse events for decision making at the facility level; and

(f) participate in capacity building of other health care providers and public on pharmacovigilance.

Responsibility of patients and members of the public.

8. A patient or the general public shall report, to the Board, any suspected adverse effect or suspected poor-quality health product or technology dispensed to them.

Roles and responsibilities of public health programs.

9. The Ministry through its designated public health programs and in collaboration with the Board shall—

(a) provide public information during the launch of new drug regimens;

(b) ensure training of health facility staff in use of medicines or regimens and monitoring for any adverse events that may arise;

(c) conduct passive and active surveillance of medical products and health technologies in collaboration with the Board;

(d) when necessary, be called upon by the Board and to determine the risk-benefit assessment of health products and technologies, in order to update treatment guidelines and initiate new training and communications to health providers and the general public;

(e) provide technical support to the investigation teams on quality and safety issues at the County and Sub-County levels;

(f) conduct post-marketing quality surveys of health products and technologies;

(g) participate in activities of the National Pharmacovigilance and Post-marketing surveillance Technical Working Group;

(h) make programmatic decisions as concerns matters related to quality, safety and efficacy of health products and technologies;

(i) conduct education, training and advocacy to the relevant stakeholders;

(j) plan and budget for pharmacovigilance activities; and

(k) mobilize resources for pharmacovigilance and post marketing surveillance activities.

Role of county governments.

10. (1) The County governments shall, in collaboration with the Ministry responsible for matters related to health and the Board —

(a) plan and budget for pharmacovigilance activities at county level;

(b) implement pharmacovigilance and post market surveillance activities within the county;

(c) coordinate and participate in the investigations of serious adverse reactions, events, signals and quality defects of health products and technologies;

(d) conduct post market quality surveys of health products and technologies;

(e) submit safety reports and reports on suspected poor quality health products and technologies to the Board within the prescribed timelines;

(f) notify the Board in cases of quality defects that have high public health impact including quality defects that affect vaccines and other biological products within twenty-four hours;

(g) notify the Board on serious adverse events and serious adverse reactions within twenty-four hours;

(h) participate in training of healthcare professionals and the public on pharmacovigilance and post market surveillance in the county in collaboration with the other stakeholders;

(i) facilitate dissemination of feedback on pharmacovigilance and post marketing surveillance including information on product quarantine or recalls within 24 hours of receipt of communication, from the Board to the health care professionals where necessary; and

(j) collaborate with the National Pharmacovigilance and Post Marketing Surveillance Technical Working Group established under these Rules.

(2) The County Government shall designate a County Vigilance focal person to coordinate the implementation of the pharmacovigilance and post market surveillance activities within the County in collaboration with the Board.

(3) A person shall qualify for designation as the County vigilance focal person if that person has—

(a) at least Bachelor's degree in pharmacy; and

(b) valid practicing license issued by the Board.

Responsibilities of a marketing authorisation holders.

11. (1) A marketing authorization holder, parallel importer or local technical representative shall be responsible for the quality and compliance with the conditions of the marketing authorization and all other aspects of the health product or technology they have placed in the market.

(2) Every marketing authorization holder, local technical

representative and parallel importer shall establish and maintain a pharmacovigilance system for managing safety information of health products and technologies they have placed in the market.

(3) A marketing authorization holder or a parallel importer shall—

(a) appoint a qualified person to be responsible for pharmacovigilance;

(b) prepare reports to the Board in accordance with the requirements of the Act and these Rules;

(c) upon request by the Board, provide additional information necessary for the evaluation of the risks and benefits of a medicinal product;

(d) inform the Board of any prohibition or restriction imposed by the regulatory authorities of any country in which the medicinal substance or health technology is marketed and of any other new information which might influence the evaluation of the benefits and risks of the product in a timely manner;

(e) be responsible for the accuracy of the documents and of the data submitted;

(f) establish and maintain an updated pharmacovigilance system master file which shall be made available to the qualified person for pharmacovigilance;

(g) ensure that the pharmacovigilance system master file is readily available for inspection, at the site where it is kept;

(h) notify the Board on serious medical device (including in vitro diagnostics) incidents and any field safety corrective actions taken in a timely manner;

(i) submit to the Board, in electronic and hard copy, the pharmacovigilance system master file not later than seven days after receipt of the request from the Board; and

(j) submit to the Board a surveillance or data collection plan for review.

Qualified person for pharmacovigilance

12. (1) A person shall be qualified for appointment under rule 11(3)(a) if the person—

(a) is a resident of Kenya;

(b) has a Bachelor's Degree in Pharmacy;

(c) has a certificate, diploma, fellowship or post graduate training in good pharmacovigilance practices from an institution recognized by the Board; and

(d) has a valid practice license issued by the Board.

(2) A person appointed to be responsible for pharmacovigilance under rule 11(3)(a) shall—

(a) maintain the marketing authorization holder's pharmacovigilance system master file;

(b) have sufficient authority to influence the performance of the quality system and the good pharmacovigilance practices;

(c) have oversight over the functioning of the pharmacovigilance system in all relevant aspects including quality management system;

(d) act as a single point of contact for the Board on all matters relating to the product safety and quality of their marketed products including pharmacovigilance inspections;

(e) be aware of the validation status of the adverse reaction database if applicable, including any failures that occurred during validation and the corrective actions that have been taken to address the failures;

(f) prepare and submit safety reports that include the following to the Board through established channels and as stipulated by the Board—

(i) adverse events to health products and technologies;

(ii) periodic safety update reports and periodic benefit-risk evaluation reports;

(iii) company-sponsored pre- and post-registration study reports;

(iv) field safety corrective action reports and field safety notices;

(v) ongoing pharmacovigilance evaluation during the post-authorization period; and

(vi) field safety corrective action reports and field safety notices.

(g) ensure that any request from the Board for additional information deemed necessary for the evaluation of the risk-benefit ratio of a marketed product, is provided to the Board fully and promptly;

(h) oversee the safety profiles of the company's marketed products and any emerging safety concerns;

(i) ensure that all personnel involved in pharmacovigilance activities, which may include customer service and sales representatives etc. have their specific duties recorded in a written description and have adequate authority to carry out their responsibilities;

(j) ensure that all personnel involved in pharmacovigilance activities are aware of the principles of pharmacovigilance that affect them, and they receive relevant training;

(k) ensure that training is provided prior to implementation of new

or revised procedures and that the training records are maintained; and

(l) participate in post-authorization safety studies and provide results as requested by the Board.

Investigations for adverse drug event.

13. The Board shall conduct investigations, relating to a health product or technology where—

(a) a serious adverse reaction or event is reported;

(b) it is suspected or found that a product does not comply with the requirement of the Act;

(c) there is an international alert with regard to such a product;

(d) it is recalled in Kenya or in any other country;

(e) there is need for additional investigations into the product;

(f) there is need for educational initiatives to improve the safe use of the products;

(g) there is a change in the scheduling or manufacture of the product to make it safer;

(h) for regulatory and health promotion interventions, as the situation may warrant, including change in supply status or withdrawal; or

(i) the Board for any other reason considers it fit to conduct an investigation on the product.

Good pharmacovigilance practices.

14. Every marketing authorisation holder, health practitioner and other stakeholders in pharmacovigilance shall comply with good pharmacovigilance practice requirements issued by the Board.

PART III — POST-MARKETING SURVEILLANCE SYSTEM

Enforcement.

15. (1) The Board shall establish mechanisms to prevent, detect and respond to the risk of substandard and falsified medical products and health technologies.

(2) The Board shall implement and enforce regulatory actions to prevent and respond to risk of substandard and falsified medical products and health technologies. Such regulatory actions include but not limited to quarantine, recalls, withdrawals of medical products and health technologies, restriction of import or sale of products, suspension of registration, licences and marketing authorization or revocation of registration, licences and market authorizations.

Sampling of medical products and health technologies.

16. (1) An authorised officer who obtains a sample of any medical product for testing, examination or analysis shall notify the person or owner from whom the sample was obtained of his intention to submit a sample thereof to the Board for examination or analysis by an approved analyst.

(2) An authorized officer shall collect adequate quantities of the dosage unit of sample to allow for initial testing and repeat testing in cases of non-compliance and for any arising disputes.

(3) Every authorized officer or appointed officer shall follow the guidelines issued by the Pharmacy and Poisons Board regarding procedure of collecting samples for test, examination or analysis.

Recalls and withdrawals.

17. (1) The Board shall recall any medical product or health technology for which a notice has been issued by the Board to remove, ban or withdraw from use in accordance with section 3A(d), 3B(2)(l) and 3B(2)(m) of the Act, if the medical product does not meet the required standard or specification or its continued use would pose a risk to safety and health of the public.

(2) The Board shall undertake the following classes of recall—

(a) class I recall where there is a reasonable probability that the use of, or exposure to, a defective product will cause serious adverse health consequences or death;

(b) class II recall where the use of, or exposure to a defective product may cause temporary adverse health consequences, or where the probability of serious adverse health consequences is remote;

(c) class III recall where the use of, or exposure to a defective product is not likely to cause adverse health consequences.

(3) A person shall not sell, offer or expose for sale or supply medical product subjected to recall.

(4) The Board may recall any medical product or health technology based—

(a) on a certificate of analysis issued by the Pharmacy and Poisons Board Quality Control Laboratory;

(b) on the recommendation of Quality, Safety and Efficacy Committee;

(c) on safety alerts issued by the World Health Organization or any other competent National Regulatory Agency;

(d) on quality alerts issued by the World Health Organization or any other competent National Regulatory Agency; or

(e) on quality notification submitted to the Board by manufacturers or market authorization holders.

(5) The Board may recall such medical products or health technologies by—

(a) issuing a product recall notice on the Pharmacy and Poisons Board website;

(b) broadcasting or publishing to the general public through mass media; or

(c) issuing a product alert notice on receipt of reliable information of a falsified, smuggled, diverted, adulterated or prohibited medical product in circulation.

(6) A recall may be a permanent or temporary removal of medical product in order to correct a particular product quality defect or safety issue such as a labelling error.

(7) A recall shall be enforced on part of a consignment, one or more batches, or on the entire product, depending on the extent of the quality defect or safety (1) In the event of a recall, the Board shall—

(a) carry out investigations into the quality or safety issue;

(b) carry out an evaluation of the health risk posed by a product being recalled or considered for recall taking into account, among others, the following factors—

(i) whether any disease or injuries have already occurred from the use of the product;

(ii) whether any existing conditions could contribute to a clinical situation that could expose humans or animals to a health risk supported by scientific documentation or statements that the conclusion is the opinion of the individual making the health risk determination;

(iii) assessment of the degree of seriousness of the health risk to which the populations at risk would be exposed;

(iv) assessment of the likelihood of occurrence of the risk; and

(v) assessment of the consequences (immediate or long-range) of occurrence of the risk.

(c) assign the recall a classification in the form of Class I, Class II, or Class III, to indicate the relative degree of health risk of the product being recalled or considered for recall;

(d) ensure effective implementation of the recall;

(e) carry out special good manufacturing practices inspection of manufacturing site if deemed necessary by the Board;

(f) suspend or revoke certificate of registration and any related licenses for a period as shall be determined by the Board, if in the opinion of the Board—

(i) the quality defect or safety issue is persistently reported;

(ii) the quality defect or safety issue is resulting from negligence or deliberate omissions by the manufacturer; or

(iii) the findings of the Good Manufacturing Practice inspection are not satisfactory.

18. A market authorization holder shall— Responsibilities of Market authorization holders.

(a) recall every defective batch, consignment or entire product of the particular product under recall;

(b) ensure recalls are implemented in an effective manner and within given time frames and in levels specified in the recall guidelines issued by the Board;

(c) inform the Kenya Medical Supplies Authority and other central procurement agencies of the recall to ensure recalls of products circulating in the public sector;

(d) inform the ministry responsible for matters related to health and the county governments of the recall action to ensure recalls of products circulating in the public sector;

(e) collaborate with the Board on action taken to prevent or reduce risks posed to the health and safety of the public by the specific batch or entire product;

(f) liaise with manufacturer if the market authorization holder is not the manufacturer of the medical product, to investigate the reasons for the reported quality defect or safety issue and to implement corrective and preventive actions;

(g) correct the quality defect or safety issue and seek approval from the Board before re-supplying the product to the market;

(h) provide certificates of analysis for new batches as requested by the Board;

(i) release new batches to the market only after obtaining approval from the Board;

(j) voluntarily recall a medical product in part or whole if the Board approves such a recall after evaluation of the reasons and justification of the recall;

(k) inform the Board within twenty-four hours (24) of receiving information on the quality defect or safety issue that forms the basis of the recall;

(l) furnish the Board with all such information that is relevant to recalls as and when required by the Board;

(m) submit to the Board a weekly progress report of recall and the final report after completion of a recall which includes reconciliation between supplied and recovered quantities of the product; and

(n) carry out the recall within the time frame specified in the recall guidelines prescribed by the Board and as applicable to each class of defect.

Establishment of the Technical Working Group.

19. (1) The Board shall establish a working group to be known as the National Pharmacovigilance and Post-Marketing Surveillance Technical Working Group.

(2) The Technical Working Group shall comprise of the following members—

(a) one representative from the Directorate of Pharmaceutical Services, Ministry of Health who shall be the chair of the technical working group;

(b) two representatives from the Board's department responsible for Pharmacovigilance and Post Market Surveillance who shall be the secretariat;

(c) one representative from each of the Ministry of Health's Public Health Programs;

(d) one representative from Kenya Medical Supplies Authority;

(e) one representative from Mission for Essential drugs and supplies;

(f) two representatives from the National Quality Control Laboratory;

(g) one representative from teaching institutions offering programs in pharmacovigilance and post market surveillance;

(h) one representative from research institution relevant for pharmacovigilance and post market surveillance;

(i) one representative from Council of Governors;

(j) one representative from county governments with experience in pharmacovigilance and post market surveillance; and

(k) other members who shall be co-opted on ad hoc basis.

(3) The National Pharmacovigilance and Post-marketing surveillance Technical Working Group shall—

(a) provide technical guidance on the design, development and implementation of pharmacovigilance and post-marketing quality surveillance guidelines in Kenya including post-marketing quality surveillance forms and procedures;

(b) oversee the development and implementation of pharmacovigilance and post marketing surveillance strategies;

(c) provide technical guidance for the implementation of pharmacovigilance and post-marketing quality surveillance activities to ensure quality, safe and efficacious medical products and health technologies;

(d) provide technical assistance and guidance on the development of databases and information sharing system on quality profiles of medical products and health technologies;

(e) identify the logistical and resources needs for the implementation of pharmacovigilance and post-marketing quality surveillance activities;

(f) provide a forum for private and public sector groups to consider and recommend policy direction on pharmacovigilance and post marketing surveillance program in Kenya;

(g) participate in the review of training and sensitization materials for health care workers;

(h) provide a platform for the development, review and approval of pharmacovigilance and post-marketing quality surveillance messages for the health care workers and the general public;

(i) mobilize partners and advocate for funds for pharmacovigilance and post marketing surveillance research and surveys;

(j) provide a platform for the review and dissemination of reports on status of pharmacovigilance and post-marketing quality surveillance in Kenya ; and

(k) provide a platform for mutual information sharing on risk communication among the Hospital Medicines and Therapeutic Committees.

Manufacture of health product technologies.

20. (1) A person shall not manufacture, import, export, supply, possess or offer for sale falsified medical product or health technology.

(2) A falsified medical product shall include—

(a) a product which is deliberately or fraudulently mislabelled with respect to its identity;

(b) a product manufactured under a name which belongs to another product;

(c) the label or container bears the name of an individual or a company which is fictitious or does not exist and purports to be the manufacturer of the medical product;

(d) it has been substituted wholly or in part by any other medicinal substance;

(e) it purports to be a product of a manufacturer of whom it is not truly theirs;

(f) it is a medical product which or the container or labelling of which, without authorization, bears;

(g) the trademark, trade name or any other identifying mark, imprint, or device; or

(h) the likeness of manufacturer of medical product, processor, packer or distributor, other than the person who in fact manufactured, processed, packed, or distributed the medical product and which thereby falsely purports or is represented to be the product of or to have been packed or distributed by the other product manufacturer, processor, packer or distributor.

Surveillance system.

21. The National Post-marketing quality surveillance system established under 5 (1) shall comprise of the—

(a) the national reporting system for substandard and falsified products;

(b) the National Pharmacovigilance and Post-marketing Surveillance Technical Working Group; and

(c) the quality control testing laboratories.

Post-marketing surveillance approaches.

22. (1) The Board shall in order to ensure effective post-marketing surveillance of health products and technologies undertake—

(a) active Post-marketing quality surveillance; and

(b) proactive Post-marketing quality surveillance.

(2) In order to undertake effective active post-marketing quality surveillance, the Board shall—

(a) establish a national reporting system for suspected substandard and falsified medical products and health technologies;

(b) ensure the reporting system shall be both electronic and manual; and

(c) establish a system of investigating and review of reports on substandard and falsified medical products and health technologies and subsequent implementation of regulatory actions.

(3) The Board shall ensure that the system established under paragraph (2)(c) can support simplified reporting, search analysis, tracking and improved data quality.

(4) In order to undertake effective proactive post-marketing quality surveillance, the Board shall—

(a) carry out routine scientific, systematic, structured, risk based quality surveys to cover expanded scope of medical products and health technologies; and

(b) apply findings from post-marketing quality surveys to implement regulatory actions.

Roles of patients and the public.

23. Any patient or member of the public shall be required to—

(a) report any suspected substandard and falsified medical product dispensed to them to a healthcare provider or the nearest health facility or directly to the Board through email, telephone, walk in, or electronic reporting system;

(b) submit samples of suspected substandard and falsified products to a healthcare provider, or to the nearest healthcare facility or to the Board offices where applicable;

(c) report any deviations in handling and storage requirements to the Board;

(d) comply with regulatory actions in collaboration with the Board, including quarantine or recall of medical products; and

(e) support, detect and report suspected substandard and falsified medical products health technologies and submit the reports to the Board through the electronic reporting system or manual reports and copy to County Vigilance Focal Person.

Role of health care providers.

24. In order to facilitate post-marketing surveillance, every health care provider shall—

(a) report any suspected substandard and falsified health product and technologies they may be aware of to the County Vigilance focal person or directly to the Board through email, telephone, walk in, or electronic reporting system;

(b) submit samples of suspected substandard and falsified products to a healthcare provider or to the nearest healthcare facility or to the Board offices where applicable;

(c) report any deviations in handling and storage requirements to the Board;

(d) implement regulatory actions in collaboration with the Board, such regulatory actions include quarantine, recall and withdrawal of health products and technologies;

(e) detect and report suspected substandard and falsified health products and technologies and submit the reports to the Board through the electronic reporting system and copy to County Vigilance Focal Person; and

(f) submit reports on antimicrobial use and consumption to the Board.

Role of market authorization holders.

25. (1) A market authorization holder shall ensure that his or her products meet the quality, safety and efficacy at all times while the product is on the Kenyan market.

(2) A market authorization holder shall share data on quality surveillance detected and any local reports on quality of medical products which are brought to their attention, whether reported spontaneously by healthcare professionals, consumers or occurring in the context of market surveillance study, with the Board within seventy-two hours of receipt of the data or report.

(3) Where, in the event of reporting referred in subrule (1), and where cases of quality defect have high public health impact, a market authorization holder shall—

(a) implement directives of the Board on investigations of quality of the health products and technologies as well as implementation of regulatory actions;

(b) collaborate with the Board by providing any information or data on quality of their products when required to do so by the Board;

(c) inform the Board about product deterioration or detection of substandard and falsified products within twenty-four hours, from the time the information becomes available;

(d) establish an emergency plan to ensure effective implementation of recalls or withdrawals of products with voluntary or statutory recalls;

(e) ensure effective and efficient recall action or withdrawal of medical products where applicable;

(f) notify the Board, within seven days, of any quality defects or regulatory actions affecting their products in other markets, other than Kenya, by submitting a report on products similar to those circulating in Kenya including the impact of such quality defects and regulatory actions on the quality of products circulating in Kenya;

(g) submit data on antimicrobials supplied to the market on quarterly basis, or when required by the Board; and

(h) in cases of quality defects or problems with use of medical devices (including in-vitro diagnostics—

(i) follow corrective actions or preventive actions procedures under the manufacturer 's or distributor's quality management system;

(ii) inform the users about the problem of the medical device (including in-vitro diagnostic);

(iii) make corrections to the device or in-vitro diagnostics; and

(iv) removal i.e., recall the medical device (including in-vitro diagnostics) from the market where applicable;

(i) notify the Board where the following actions need to be taken as regards medical devices (including in-vitro diagnostics)—

(i) correcting product on the market;

(ii) removing product from the market; or

(iii) issuance of field safety corrective action;

(iv) issuance of field safety notice;

(v) advising users of an issue with a medical device.

(4) All the requirements applying to market authorization holders shall apply to parallel importers.

Role of manufacturers.

26. A manufacturer shall for the purposes of post-marketing surveillance—

(a) cooperate with the Board on matters of investigations on quality defects of medical products including among others—

(i) carrying out internal investigations and preparing root cause analysis reports, submitting the reports to the Board;

(ii) submitting data or information as required by Board and implementation of the proposed corrective and preventive actions; and

(iii) updating the board on implementation of and participating in special Good Manufacturing Practice inspections by the Board to investigate quality defects;

(b) submit a root cause investigation report to the Board within two weeks from the date of receipt of the request from the Board;

(c) inform the Board, following detection of non-compliance during manufacturing for a product that is already in the Kenya market, within seventy-two hours after the information becomes available;

(d) implement directives of the Board on investigations of quality of the products and implementation of regulatory actions;

(e) submit data on antimicrobials supplied to the market on quarterly basis, or when required by the Board;

(f) notify the Board where the following actions need to be taken as regards medical devices (including in-vitro diagnostics)—

(i) correcting product on the market;

(ii) removing product from the market;

(iii) issuance of field safety corrective action; or

(iv) issuance of field safety notice;

(g) in cases of quality defects or problems with use of medical devices (including in-vitro diagnostics);

(h) follow corrective actions or preventive actions procedures under the manufacturer's or distributor's quality management system;

(i) inform the users about the problem of the medical device (including in-vitro diagnostic); and

(j) make corrections to the device (including in-vitro diagnostic) and recall the medical device (including in-vitro diagnostic) from the market where applicable.

The Quality Control Testing Laboratory.

27. The Quality Control Testing Laboratory shall for the purposes of post-marketing surveillance—

(a) test health products and technologies on request of the Board or any other entity;

(b) prescribe testing methods, standards or specifications based on internationally acceptable standards including pharmacopeia standards;

(c) issue Certificates of Analysis on each sample tested to the clients in the format developed by the Board;

(d) participate in development and review of post-marketing surveillance protocols;

(e) train staff from the Board and other staff on MiniLab activities; and

(f) participate in the activities of the National Pharmacovigilance and Post-marketing Surveillance Technical Working Group.

Role of wholesale dealers.

28. The Wholesale dealers shall—

(a) participate in matters of investigations on quality defects of health products and technologies;

(b) submit data on antimicrobials supplied to the market on quarterly basis, or when required by the Board;

(c) notify the Board where the following actions need to be taken as regards medical devices, including in-vitro diagnostics—

(i) correcting product on the market;

(ii) removing product from the market; or

(iii) issuance of field safety corrective action;

(iv) issuance of field safety notice;

(v) advising users of an issue with a medical device;

(d) in cases of quality defects or problems with use of medical devices (including in-vitro diagnostics)—

(i) follow corrective actions or preventive actions procedures under the manufacturer's or distributor's quality management system;

(ii) inform the users about the problem of the medical device (including in-vitro diagnostic;

(iii) make corrections to the device or including in-vitro diagnostics; and

(iv) removal i.e., recall the medical device (including in-vitro diagnostics) from the market where applicable.

Role of the central procurement agencies.

29. The central procurement agencies shall in order to support post-marketing surveillance—

(a) participate in the activities of the National Pharmacovigilance and Post-marketing Surveillance Technical Working Group;

(b) participate in investigations on quality defects of medical products;

(c) share post-marketing quality surveillance data, and any local reports on quality of medical products which are brought to their attention, whether reported spontaneously by healthcare professionals or consumers or occurring in the context of market surveillance study, with the Board within seventy-two hours of receipt of the data or report and immediately in cases where the quality defect has high public health impact.

Role of the Board.

30. The Board shall for the purposes of post-marketing—

(a) receive and review reports on suspected poor quality medical products from healthcare providers, County vigilance focal persons, public, Central procurement agencies, market authorization holders and manufacturers;

(b) investigate suspected sub-standard and falsified medical products and health technologies;

(c) implement risk based expanded post-marketing quality surveys to cover broad category of products;

(d) implement, oversee and enforce regulatory actions including quarantine, recalls, suspension of marketing authorization and suspension of manufacturing licenses;

(e) provide feedback to reporters of poor-quality medical products on completion of the investigation report;

(f) disseminate findings from post-market surveillance activities to all relevant stakeholders;

(g) establish the Quality, Safety and Efficacy Committee which shall be responsible for the review of investigation reports and findings of post-market surveillance activities and make recommendations for appropriate regulatory actions;

(h) establish mechanisms for the coordination, communication and involvement of all relevant stakeholders and various departments or units within the Board in post-marketing surveillance programs;

(i) establish and provide secretariat to the National Pharmacovigilance and Post-Marketing Surveillance Technical Working Group;

(j) conduct advocacy, training, education and sensitization on post-marketing surveillance related activities;

(k) develop and disseminate information, education and communication materials;

(l) carry out communication to healthcare providers and the public on market surveillance related activities;

(m) maintain database on antimicrobial consumption in Kenya;

(n) maintain a rapid alert list;

(o) notify other National Regulatory Authorities and the World Health Organization on falsified products, where appropriate;

(p) participate in the World Health Organisation member state mechanism on substandard and falsified products;

(q) carry out routine analysis of quality data to inform regulatory actions and policy decisions;

(r) rely on and recognize regulatory decisions related to quality, safety and efficacy of medical products and health technologies that are made in other jurisdictions, where the Board considers it applicable to Kenya; and

(s) partner with stakeholders on post marketing surveillance activities as and when needed.

(t) receive and evaluate field safety corrective actions for medical devices (including in-vitro diagnostics);

(u) monitor implementation of field safety corrective actions for medical devices (including in-vitro diagnostics);

(v) collaborate with regional and international organizations on matters of quality, safety and efficacy of health products and technologies;

(w) collaborate with Ministry of Health to establish and implement a system for reporting on antimicrobial use and consumption by healthcare providers, importers, marketing authorization holders and local manufacturers of antimicrobial agents.

Rapid alert system.

31. (1) The Board shall establish a rapid alert system designed to ensure a timely, proportionate, accurate and consistent response to health events arising from sub-standard and falsified medical products which represent a significant threat to health and safety of the public.

(2) The Rapid alert system shall be applied to transmit alerts on quality, safety and efficacy of medical products and health technologies, alerts which cannot permit any delay.

(3) The Rapid alert system shall be triggered after new information on public health is received from any source, reviewed and validated and determined that the quality defect presents critical risk to public health.

(4) Pursuant to these Rules, the sources of information may include—

(a) market authorisation holder;

(b) patients or members of the public;

(c) media;

(d) healthcare providers;

(e) manufacturers;

(f) central procurement agencies; and

(g) other National Regulatory Authorities, Literature review or international organizations like the World Health Organization.

(5) A rapid alert notification shall include—

(a) quality defects and medical device deficiencies identified by the Board that requires urgent regulatory actions including Class I recalls, product withdrawal and product quarantine;

(b) quality defects for medical products of high public health impact including, among others, vaccines, parenteral formulations, male latex condoms, female condoms, surgical gloves, sutures;

(c) World Health Organisation alerts of finished products and Active Pharmaceutical Ingredients regarding safety issues;

(d) follow up actions on rapid alert notification;

(6) The Board may issue further guidance on the rapid alert system.

PART IV —GENERAL PROVISIONS

Offences.

32. A marketing authorisation holder, local technical representative or parallel importer or health care provider who—

(a) omits important safety warning;

(b) fails to report serious adverse reaction or event;

(c) delays or fails to submit safety reports to the Board; or

(d) fails to comply with the requirements of these Rules;

commits an offence and shall be liable, upon conviction to the penalty set out in section 51 of the Act.

Pharmacovigilanc Assessment and Inspections.

33. (1) The Board shall carry out pharmacovigilance audits and good pharmacovigilance practices inspections on manufacturers, marketing authorization holders, local technical representatives, parallel importers, distributors and any outsourced persons or companies in order to ensure compliance with good pharmacovigilance practice and these Rules.

(2) The Board shall conduct routine inspections every three years and may conduct frequent inspections on a case-to-case basis depending on other considerations such as risk-based inspections.

(3) Upon completion of the inspection under this regulation, the Board shall issue a certificate of good pharmacovigilance practices, in the Form set out in the Schedule, to manufacturers, marketing authorization holders, local technical representatives, parallel importers and outsourced persons or companies who have complied with the inspection.

(4) The Board shall periodically conduct pharmacovigilance assessments for the public health programs, health facilities, marketing authorization holders and central procurement agencies using such tools as the Board may determine from time to time.

Safety studies.

34. For a period of three years or such other period as may be determined by the Board, after the initial placing of a product in the Kenyan market, the Board may request that the marketing authorization holder to arrange for specific pharmacovigilance data to be collected from targeted groups of population or under specific conditions.

International collaboration for pharmacovigilanc activities.

35. The Board shall work closely with other regulatory authorities at regional and international level, development partners and the World Health Organisation for purposes of sharing information on safety issues and anticipated regulatory action.

Reliance.

36. The Board shall consider and rely on pharmacovigilance decisions from other competent national, regional and international regulatory authorities, where necessary.

SCHEDULE: (r.33(3)

CERTIFICATE OF GOOD PHARMACOVIGILANCE PRACTICES

Pharmacy and Poisons Board	CERTIFICATE OF COMPLIANCE WITH GVP	FOM023/VMS/SOP/021
		Rev No: 0

Certificate of Compliance Form: FOM023/VMS/SOP/021

On the basis of the inspection carried out on [date] _____ we certify that the company/entity indicated on this certificate:

Name of company/entity: ……

Postal address: ……

Physical address (building, road/street, City/town): ……..……..……...

……

complies with Good Pharmacovigilance Practices in Kenya.

This certificate remains valid until [date] _____. It becomes invalid if areas certified herewith are changed or if the company/entity is no longer considered to be in compliance with GVP.

Date:

Note:

1. This certificate certifies the status of the company/entity listed in the certificate
2. This certificate shall remain valid for a period of 3 years from the date of issue, but can be revoked at any time if there is evidence that the company/entity no longer complies with the current PPB Pharmacovigilance regulations.

Pharmacy and Poisons Board	NOTICE OF CONCERN LETTER	FOM024/VMS/SOP/021
		Rev No

Notice of concern Letter Form: FOM024/VMS/SOP/021

Ref No……

RE: NON- COMPLIANCE WITH GOOD PHARMACOVIGILANCE PRACTICES

On basis of the inspection carried out on (Dates of inspection) ……. we certify that at the time of inspection (Name of the company/entity inspected) ……, located at (Physical address of the company/entity) ……., DID NOT Comply with current Good Pharmacovigilance Practices for all the activities undertaken at the site.

You may however apply for re-inspection of the facility once corrective actions contained in the report attached to this letter have been addressed. The inspection however will not be undertaken earlier than six months from the date of this letter.

Thank you for your cooperation in this matter.

Made on the 8th June, 2022.

MUTAHI KAGWE,
Cabinet Secretary for Health.

LEGAL NOTICE NO. 97

THE PHARMACY AND POISONS ACT

(*Cap*. 244)

THE PHARMACY AND POISONS (TRANSPORTATION OF PHARMACEUTICALS) RULES, 2022

ARRANGEMENT OF RULES

Rule

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SCHEDULE

THE PHARMACY AND POISONS ACT

(*Cap*. 244)

IN EXERCISE of the powers conferred by section 44 of the Pharmacy and Poisons Act, the Cabinet Secretary for Health, in consultation with the Pharmacy and Poisons Board, makes the following Rules—

THE PHARMACY AND POISONS (TRANSPORTATION OF PHARMACEUTICALS) RULES, 2022

PART I—PRELIMINARY

Citation.

1. These Rules may be cited as the Pharmacy and Poisons (Transportation of Pharmaceuticals) Rules, 2022.

Interpretation.

2. In these Rules, unless the context otherwise requires—

"cold chain" means any material, equipment, process or procedure used to maintain a product within the required temperature range of 2 °C to 8 °C or according to the manufacturer's recommended storage conditions from the time of manufacture until the product is administered to an individual;

"consignment" means the quantity of pharmaceuticals supplied at one time in response to a particular request or order and may comprise one or more packages or containers which may include pharmaceuticals belonging to more than one batch;

"consignor" means a person engaged in the activity of distributing pharmaceuticals;

"consignee" means a person to whom goods or documents are officially sent or delivered ;

"container" means the material employed in the packaging of a pharmaceutical and may include a primary or secondary transportation container;

"importation" means the act of bringing or causing any pharmaceuticals to be brought into Kenya;

"primary container" means a container that is intended to be in direct contact with a product;

"product recall" means the removal of specific batches of a pharmaceutical from the market due to deficiency in quality, safety or efficacy of a pharmaceutical;

"secondary container" means a container that is not intended to be in direct contact with a product;

"storage" means the storing of pharmaceuticals up to the point of use;

"transit" means the period during which pharmaceuticals are in the process of being carried, conveyed or transported across, over or through a passage or route to reach the destination; and

"vehicle" means a carrier which can be used to convey pharmaceuticals from one point to another and includes a motorcycle, bicycle, truck, van, bus, minibus, car, trailer, aircraft, railway carriage, boat or other means which are used to convey pharmaceuticals.

Objectives of the Rules.

3. The objectives of these Rules are to—

(a) provide for the licensing transporters of pharmaceuticals;

(b) provide for the enforcement transportation requirements;

(c) ensure the security of pharmaceuticals while on transit;

(d) ensure that any pharmaceuticals within the possession of transporters are accounted for; and

(e) ensure that any transported pharmaceuticals conform to the prescribed standards of quality, safety and efficacy.

Application.

4. These Rules shall apply to any person who is authorized to store, distribute or transport pharmaceuticals.

PART II—REQUIREMENTS FOR TRANSPORTATION OF PHARMACEUTICALS

Transportation licence.

5. (1) A person who intends to engage in the business of transporting pharmaceuticals shall make an application for a licence to the Board in Form 1 set out in the Schedule.

(2) An application under subrule (1) shall be accompanied by the following documents—

(a) a certificate of incorporation for a company, a registration certificate for a business name or partnership deed for a partnership;

(b) a certificate of registration of a registered pharmacist or an enrolment certificate of an enrolled pharmaceutical technologist appointed by the applicant;

(c) registration and inspection documents for any vehicles or vessel to be used in transporting pharmaceuticals issued by the relevant regulatory agencies;

(d) a licence for every operator of a vehicle;

(e) inspection reports on the suitability of any vehicle for transportation of pharmaceuticals from a competent authority;

(f) a declaration on the type of pharmaceuticals that the applicant intends to transport;

(g) for any vehicle that is to be used in the transportation of cold-chain products, a copy of a job card showing the installation and validation of the cold-chain control, monitoring and recording system with in-built alarm and alert capabilities from a duly registered and authorized firm; and

(h) any other information as shall be required by the Board.

(3) The Board shall review the application made under paragraph (1) and may approve or reject the application.

(4) Where the Board approves the application, the Board shall issue a licence in the Form 2 set out in the Schedule.

(5) Where the Board rejects the application, the Board shall, within fifteen days from the date of receipt of the application, communicate to the applicant the decision specifying reasons for the rejection, in writing.

(6) A person who is aggrieved by the decision of the Board may appeal to the High Court.

Enforcement.

6. (1) A licence issued under rule 5 may be revoked, suspended or modified for any of the reasons specified in subrule (3).

(2) The Board may prohibit the possession of a pharmaceutical product for any of the reasons specified in subrule (3).

(3) A person is liable to a decision of the Board under paragraph (1) or (2) if the person—

(a) contravenes these Rules; or

(b) an agent of the person provides misleading information.

(4) A person who is aggrieved by the decision of the Board under subrule (1) or (2) may appeal to the High Court.

Verification.

7. (1) A consignor shall, before commencing transportation, verify—

(a) the type of the pharmaceuticals that are to be transported and identify the appropriate protection arrangements for the consignment; and

(b) that the consignee is authorized to possess the pharmaceuticals.

(2) A person shall not transport any radioactive material without authorization from the Board.

(3) The Board may, before authorizing a person to transport radioactive material, consult the Nuclear Regulatory Authority and any relevant body established by any written law to regulate the transportation of radioactive materials.

(4) A person shall not use a motorcycle to transport narcotic, psychotropic substances or precursor chemical substances in accordance with the Single Convention on Narcotic Drugs of 1961, the Convention on Psychotropic Substances 1971, and the UN Convention against Illicit Traffic Drug and Psychotropic Substances, 1988.

(5) A person who contravenes subrules (1), (2) or (4) commits an offence and shall, on conviction, be liable to the penalty prescribed in section 51 of the Act.

Security during transportation.

8. A person who is engaged in the transportation of pharmaceuticals shall—

(a) ensure that each vehicle is equipped with lockable doors or where possible an intruder alarm;

(b) document and track all deliveries; and

(c) keep signed dispatch and arrival records.

PART III—CATEGORIES OF TRANSPORT

Obligations of air transporters.

9. A person who is engaged in the transportation of pharmaceuticals by air shall ensure that—

(a) the pharmaceuticals meet the handling requirements stipulated by the manufacturer;

(b) that a time and temperature sensitive label is affixed on any shipment booked as time and temperature sensitive cargo;

(c) that an acceptance checklist for any time and temperature sensitive shipment is executed; and

(d) that an authorized officer of the Board is notified on the arrival of the shipment at the port of entry for pre-clearance inspection.

Obligations of sea transporters.

10. (1) A person who is engaged in the transportation of pharmaceuticals by sea shall ensure that—

(a) the pharmaceuticals are packaged in a refrigerated container for transporting temperature sensitive cargo in accordance with the storage specifications of the manufacturer;

(b) the importation of pharmaceuticals shall be through a *Gazetted* ports of entry that are equipped to handle the products;

(c) upon arrival at the port of entry, the pharmaceuticals are removed from the transporting vessel as soon as possible and moved to a safe and suitable temperature-controlled storage location to minimize the risk of temperature related damage and theft;

(d) he receives and forwards records of storage conditions during transportation to the authorized officer of the Board at the port of entry to confirm that storage is compliant while on transit;

(e) any excursion is reported to the owner of the consignment and the authorized officer of the Board at the port of entry so that it can be adequately addressed; and

(f) an authorized officer of the Board is notified on the arrival of the shipment at the port of entry for pre-clearance inspection.

(2) The conditions under subrule (1) shall also apply to the exportation of pharmaceuticals.

(3) A consignor shall ensure that a shipping container—

(a) protects the personnel and the general public from any hazard arising from spillage or leakage;

(b) protects the product being transported against mechanical damage and the temperature changes encountered during transit;

(c) is closed in a manner that allows the recipient of the consignment to establish that the product has not been tampered with during transportation; and

(d) is insulated.

(4) A consignor shall ensure that chemical or electric freeze indicators, electronic loggers or any other suitable indicators are used to monitor temperature or humidity exposure during transportation.

Obligations of road transporters.

11. A person who is engaged in transportation of pharmaceuticals by road shall ensure—

(a) that any vehicle or equipment used to distribute pharmaceuticals is suitable for its purpose and is appropriately equipped;

(b) that the design and use of any vehicle aims to minimize the risk of errors on the product being distributed;

(c) that tracking devices and engine kill buttons are installed on every vehicle; and

(d) the use of dedicated vehicles and equipment.

PART IV—SPECIFICATIONS

Loading and receiving bays.

12. (1) A person who is licensed to transport pharmaceuticals under these Rules shall ensure that—

(a) every loading, receiving or dispatch bay has sufficient facilities and space allowance to ensure pharmaceuticals are protected from adverse environmental conditions;

(b) any area where pharmaceuticals are temporarily held during arrival or dispatch is—

(i) maintained within the temperature and humidity range specified for the goods being handled;

(ii) protected from direct sunlight, dust or rain; and

(iii) adequately ventilated and lit;

(c) temperature and humidity are monitored at all times and documented in temperature logs or humidity logs which shall be maintained and readily available;

(d) any equipment, appliance or gadget used in temperature control is connected to uninterruptible power supply system and power back up; and

(e) temperature control equipment is calibrated as recommended by the manufacturer and the records are maintained.

Transport and delivery.

13. An authorized person shall ensure that any vessel used for transportation of pharmaceutical products is—

(a) equipped with calibrated temperature and humidity monitoring devices with sensors located at points representing temperature extremes;

(b) equipped with alarms to alert the operator in the event of temperature or humidity excursions or refrigeration unit failure; and

(c) fitted with doors with security seals or security locks that protect against unauthorized access during transit.

Monitoring of storage conditions during transit.

14. A person who is engaged in the transportation of pharmaceuticals shall ensure any vessel used in transportation is fitted with—

(a) temperature control systems that are able to continuously maintain air temperature within the set points and the accuracy shall be within 0.5 °C; and

(b) humidity control systems with an accuracy of + or -5% relative humidity.

Temperature controlled vehicles.

15. A consignor shall ensure that a temperature-controlled vessel demonstrates—

(a) that the air temperature and humidity is uniformly distributed in the temperature controlled compartment of the vessel by installing temperature probes; and

(b) the time taken for temperatures to exceed the designated maximum in the event that the temperature controlling unit fails.

Calibration of vessels.

16. (1) Any vessel used for transportation of pharmaceuticals shall undergo routine inspection.

(2) Any vessel used for transportation of temperature sensitive pharmaceuticals shall undergo calibration of devices for temperature and humidity control in accordance with recommendations of the manufacturer or at least once every year by the Kenya Bureau of Standards or any other certified standards accreditation body to ensure compliance.

Insulated containers.

17. (1) A consignor shall ensure that—

(a) for short terms periods of transportation of pharmaceuticals, insulated containers with icepacks are used; and

(b) for long periods of transportation of pharmaceuticals, insulated containers of up to ninety six hours are used.

(2) The sender shall ensure that the packaging system is capable of maintaining the pharmaceuticals within the temperature range.

(3) A consignee shall ensure that non-conforming pharmaceuticals are quarantined and shall, as soon as possible, report to the Board.

Contingency planning.

18. A consignor shall put in place contingency plans for the safe storage of pharmaceuticals in cases of extended power outages, equipment failure or vehicle breakdown in transit.

Record keeping.

19. (1) A transporter shall maintain records in paper and electronic formats.

(2) The paper records shall be—

(a) stored and maintained so that they are easily accessible;

(b) labeled, dated and filed for easy identification;

(c) protected against deterioration and loss due to fire, flood or other hazards;

(d) kept secure and protected against unauthorized access; and

(e) signed and dated by the authorized persons and not changed without due authorization;

(3) Electronic or computer records shall be—

(a) logically filed for easy identification and retrieval;

(b) kept secure and protected against unauthorized access;

(c) where feasible, manually signed, dated and scanned; and

(d) regularly backed-up and archived.

(4) The records referred to in paragraph (1) shall be kept for a period of at least two years and made available for inspection by authorized officers of the Board.

Standard operating procedures.

20. Every transporter, authorized persons, consignors and consignees shall comply with good distribution, transportation and storage practices requirements issued by the Board.

Compliance.

21. A person who intends to store, distribute or transport pharmaceuticals shall, within six months from the date of publication of these Rules, comply with the requirements under these Rules.

Offences and penalties.

22. A person who contravenes any of the provisions of these Rules commits an offence and shall be liable to the penalty prescribed under section 51 of the Act.

SCHEDULE

Form 1 r. 5(1)

MINISTRY OF HEALTH

PHARMACY AND POISONS BOARD

APPLICATION FOR LICENSE TO TRANSPORT PHARMACEUTICALS FOR DISTRIBUTION

I /We, ...of .....here by apply for a license to transport pharmaceuticals

Part 1. Details of the applicant:

1.1 (a) Name of applicant: .....

(b) Designation: ..... Registration/Enrolment no……

(c) National Identity Card/Passport No.....

(d) Mailing address: .....

(e) E-mail address .....

(f) Telephone No. .....

Part 2. Details of business

2.1 (a) Transportation of pharmaceuticals ☐ ☐

Where Part 2(a) is requested, attach copy of Premises Registration Certificate and Wholesale Dealer's license

Part 3. Type(s) of pharmaceuticals intended to be transported.

(a) Biological Products

(b) Vaccines

(c) Medical devices

(d) Finished Pharmaceutical products

(e) Active Pharmaceutical Ingredients

Part 4. Details of vehicle(s) /vessel(s)to be used in transport

Type of Vehicle	*Car*	*Van*	*Freezer truck*	*Others*
Vehicle Registration number				

(Add more lines if necessary)

Declaration

I, the undersigned, certify that all information in this application for license to transport pharmaceuticals for distribution is true and correct.

I understand that I have the responsibility to inform the Authority with immediate effect of any change to the information provided in this application.

Signature: .....

Applicant: .....

Name: .....

Designation: .....

Date: .....

Form 2 r.5(4)

REPUBLIC OF KENYA

MINISTRY OF HEALTH

PHARMACY AND POISONS BOARD

LICENSE TO TRANSPORT PHARMACEUTICALS

Messrs……

Address……is registered to carry on the business of transportation of pharmaceuticals in the listed vessels and approved warehouse(s) as per the type(s) indicated.

i. Type(s) of pharmaceuticals transported……..……

ii. Source and destination……

iii. Registration number of the vessel……..

iv. Name and ID. No of the operator……..

Note: a) This registration expires on 31st December……

b) No change of the transport vessel without the authority of the Board.

c) Any new vessel must be inspected by the Board before certification.

d) This registration shall become void upon expiration of 30 days from any change of the nature of the business.

Chief Executive Officer……..……

Signature……

Date……

Made on the 8th June, 2022.

MUTAHI KAGWE,
Cabinet Secretary for Health.

LEGAL NOTICE NO. 98

THE PHARMACY AND POISONS ACT

(Cap. 244)

IN EXERCISE of the power conferred by section 44(1) of the Pharmacy and Poison Act, the Cabinet Secretary for Health, in consultation with the Pharmacy and Poisons Board, makes the following Rules—

THE PHARMACY AND POISONS (AMENDMENT) RULES, 2022

1. These Rules may be cited as the Pharmacy and Poisons (Amendment) Rules, 2022. Citation.

2. The Pharmacy and Poisons Rules, hereinafter referred to as "the principal Rules" are amended in Rule 2 by inserting the following new definitions in their proper alphabetical sequence— Cap. 244.

"Act" means the Pharmacy and Poisons Board Act;

"applicant" means a person, organization, company or entity seeking approval to advertise or promote a medicine or medical device;

"batch" also referred to as "lot" means a defined quantity of starting material, packaging material or product processed in a single series of processes so that it is expected to be homogeneous;

"batch release", also referred to as "lot release" means the process of evaluation of an individual lot of a licensed vaccine by a national regulatory authority before giving approval for its release onto the market;

"biological therapeutic" means a class of medicines which are grown and then purified from large-scale cell cultures of bacteria, yeast, plant or animal cells and includes vaccines, growth factors, immune modulators, monoclonal antibodies and products derived from human blood and plasma;

"Board" means the Pharmacy and Poisons Board established under section 3 of the Act;

"claim" means any presentation which states, suggests or implies that a product has particular qualities relating to its origin, nutritional properties, nature, processing, composition or any other quality, and is capable of objective substantiation;

"general public" means a person other than a healthcare professional;

"general sale drug'' means any drug whose use does not need the direction or prescription by a medical practitioner, pharmacist, dentist or veterinary surgeon;

"health care professional" means any person who has obtained health professional qualifications and is licensed by the relevant regulatory body;

''herbal drug'' means a finished medicinal product containing

plant which has its preparation presented with a therapeutic or prophylactic claim and includes any preparation which, partly or wholly, contains a plant material;

"human and veterinary use" means any medicament or curative or preventive substance, whether proprietary or in the form of a preparation, used in both humans and animals;

"label" means a display of written, printed or graphic matter on a product, the immediate container or wrapper accompanying the product;

"marketing authorization" means an official authorization or registration of a product by the Board for the purpose of marketing it in Kenya after evaluation for safety, efficacy and quality;

"marketing authorization holder" means an entity that holds the marketing approval for a product;

"media enterprise" means an organization whose business involves the collection, processing and dissemination of news or news articles, or in entertainment and education through the media;

"medical claim" includes any statement that conveys information about the state or attributes of a product in respect of its therapeutic use in connection with the—

(a) diagnosis, treatment, mitigation or prevention of a disease, disorder, abnormal physical or mental state, or the symptoms thereof, in a human being or an animal;

(b) restoration, correction or beneficial modification of organic or mental functions in a human being or an animal; or

(c) disinfection in premises in which food and drugs are manufactured, prepared or kept, hospitals, equipment and farm houses;

"medium" means a newspaper, magazine, medical journal, television, radio, the internet, vehicle branding, poster, handbill, cinema, point of sale material, digital and social media, any form of projected light or sound recordings or any other means of communication;

"misleading information" means information that gives a wrong idea or impression;

"new chemical entity" means an active ingredient, including its salts or esters, that has not been approved by the Board for marketing in Kenya;

''prescription only health product '' means any product required to be dispensed only upon a prescription given by a medical practitioner, dentist or veterinary surgeon or any other person approved by the Cabinet Secretary;

"publication" means the act of making information, stories or pictures available to people in any medium including books, newspapers, magazines or electronic media;

"product" means a medicine, medical device or herbal drug;

"promotion" means any informal and persuasive activity by a manufacturing pharmaceutical company, distributor of medicines or a body appointed by any of them, which induces the prescription, supply, purchase or sale of any medicine; and

"promotional material" means any representation concerning the attributes of a product conveyed by any means for the purpose of encouraging the prescription, supply, purchase, sale or usage of a product.

3. The principal Rules are amended by inserting the following new rule immediately after rule 3A—

Importation of biological therapeutics.

3B. (1) A person shall not import any biological therapeutic without a valid import licence issued under rule 3.

(2) A consignment of imported biological therapeutics shall not be released into the market from the port of entry or any approved premises until it is evaluated and approved in accordance with this rule.

(3) Every batch of a licensed biological therapeutic imported into Kenya shall be evaluated by a person authorized by the Board before approving its release into the market.

(4) In undertaking the evaluation of a batch under subrule (3), the person authorized by the Board—

(a) shall evaluate whether the biological therapeutic meets the approved specifications and related provisions; and

(b) may review and test the sampled biological therapeutics and conduct an independent review of the summary protocol for each biological therapeutic.

(5) Upon evaluation of a batch of the imported biological therapeutic under this rule, the Board shall, on being satisfied of compliance, approve and issue a certificate of batch release into the market for the evaluated batch of imported biological therapeutic.

(6) A person who contravenes paragraph (2) commits an offence.

4. The principal Rules are amended by inserting the following new rule immediately after rule 4—

Exportation of biological therapeutics.

4A. (1) A person shall not export a biological therapeutic to a destination outside Kenya without a valid export licence issued under rule 4.

(2) A consignment of any biological therapeutic shall not be released for exportation to a destination outside Kenya until it is evaluated and approved in accordance with this rule.

(3) A person authorized by the Board shall evaluate every batch of a biological therapeutic to be exported before approving its release for export to a destination outside Kenya.

(4) In undertaking the evaluation of a batch under subrule (3), the person authorized by the Board—

(a) shall evaluate whether the biological therapeutic meets the approved specifications and related provisions;

(b) may review and test the sampled biological therapeutic including—

(i) conducting an independent review of the summary protocol for each biological therapeutic;

(ii) collecting and testing samples from each batch to be evaluated;

(iii) reviewing the literature regarding the manufacturing process, testing method, specifications and standards of the biological therapeutic; or

(iv) reviewing the standard operating procedures of source management on animal raw materials and proof of source of raw materials.

(6) Upon evaluation of a batch of any biological therapeutic to be exported under this rule, the Board may, on being satisfied of compliance, approve and issue a certificate of

batch release for exportation to a destination outside Kenya.

(7) A person who contravenes paragraph (2) commits an offence.

5. The principal Rules are amended by inserting the following new rule immediately after rule 16—

Manufacture of biological therapeutics.

16A. (1) A person shall not manufacture for distribution any biological therapeutic which is or may be used for the treatment of any human ailment without a valid licence issued under rule 16.

(2) A consignment of biological therapeutics manufactured pursuant to a licence issued under these Rules shall not be released for distribution unless the consignment has been evaluated and approved in accordance with this rule.

(3) A person authorised by the Board shall evaluate every batch of any biological therapeutic before it is released onto the market for distribution.

(4) In evaluating a batch under paragraph (3), the person authorized by the Board—

(a) shall evaluate whether it meets the approved specifications and related provisions; and

(b) may review and test the sampled biological therapeutic including—

(i) conducting an independent review of the summary protocol for each biological therapeutic;

(ii) collecting and testing samples from each batch which is to be evaluated;

(iii) reviewing literature regarding the manufacturing process, testing method, specifications and standards of the biological therapeutic; or

(iv) reviewing the standard operating procedures for source management on animal raw materials and proof of source of raw materials.

(5) Upon evaluation of a batch under this rule, the Board may, on being satisfied of compliance, approve and issue a certificate of batch release for distribution of the evaluated batch of manufactured biological therapeutic.

(6) A person who contravenes paragraph (2) commits an offence.

Insertion of new rules.

6. The principal Rules are amended by inserting the following new rules immediately after Rule 21—

Requirements for advertisement.

22. (1) A person shall not advertise any health product except with the written approval of the Board.

(2) An application for the advertisement of any health product shall be made to the Board in form 34 set out in the Schedule VIII and shall be accompanied by the fee stipulated in rule 19.

(3) A health product shall not be promoted or advertised through any media, including social media, unless it is registered by the Board.

(4) A person shall not take part in the publication of any advertisement or promotion referring to a drug, medicine, medical appliance or similar article in terms which in the opinion of the Board are considered to be exaggerated or to bear little or no relation to the pharmacological properties and action of the ingredients or components thereof.

(5) Any printed material shall be clearly labelled with the advertisement approval reference number of the Board as a footer or header; or at any other place that is easily identifiable by the Board and the general public.

(6) The name and contact details of the marketing authorization holder or manufacturing company shall be displayed on every print media.

(7) A person who contravenes subrule (1), (3), (4), (5) or (6) commits an offence.

Advertisement and promotion.

23. An advertisement or promotion includes any written, pictorial, visual or other descriptive matter or verbal statement with a medical claim designed to promote the prescription, supply, sale or consumption of a health product—

(a) appearing in any paper, newspaper, diary, calendar, business card or other print publication;

(b) appearing on any television, cinema, radio or social media;

(c) circulated through electronic mail, short message service or multimedia message;

(d) offering trials of the health product to members of the public;

(e) distributed to the members of the public as a branded item;

(f) undertaken through a telephone help line or point of sale material;

(g) effected through branding on a vehicle, building, bench or other similar medium;

(h) undertaken through a road show or other similar means; or

(i) through any other means that may introduce, publicize or raise the profile or public awareness or visibility;

(j) through the activities of a medical representative including detail aids and other printed material used by the medical representative to update members of the general public to promote purchase;

(k) through the provision of branded materials to promote the prescription, dispensing, supply, administration and use of products materials to be used in sponsored meetings;

(l) through the provision of medical information with product claims to the general public; or

(m) through all other sales promotion of a medical product and technology in whatever form, such as participation in exhibitions, the use of audio-cassettes, films, records, tapes, video recordings, radio, television, internet, electronic media or interactive data systems.

Threshold for advertisement or promotion.

24. (1) An activity shall not be construed as a health product advertisement or promotion if it is not designed to promote the sale or consumption of the product.

(2) Without prejudice to the generality of subrule (1), the following activities shall not be construed as health product advertisement or promotion—

(a) any factual, accurate or informative announcement or reference material concerning any licensed medicine relating to pack changes, adverse reaction warnings, trade catalogues or price lists which do not contain any product claim;

(b) any reply made in response to an individual enquiry from a healthcare professional in response to specific communication which is accurate, not misleading and is not promotional in nature;

(c) non-promotional information to the general public through a press conference, press announcement, television, any radio report or public relations activity;

(d) any summary of product characteristics, a patient information leaflet, public assessment report or direct response to a question;

(e) the mandated and registered packaging and pack information including the patient or prescriber information leaflet;

(f) a statement relating to human health or disease which does not make reference to a specific product; or

(g) matters relating to pricing, bonuses or incentives stipulated in any written law.

Prohibited advertisements.

25. (1) A health product or technology shall not be advertised or promoted unless it is registered by the Board.

(2) A person shall not promote—

(a) any off-label or unregistered indication;

(b) any health product or technology that bears a different packaging from that approved by the Board;

(c) any material sent under the guise of personal communication;

(d) any herbal or complimentary medicine that is not listed by the Board; or

(e) any medical cosmetics not listed or registered by the Board.

(3) A person shall not advertise or promote a health product by providing a private prescription form that is pre-printed with the name of the health product in the main body of the prescription.

(4) A health product shall be advertised on the header section of the prescription perforated from the main body.

(5) A clinical trial or safety study shall not be undertaken for the purpose of promotion or advertisement.

(6) Where companies jointly or individually promote a health product, each company shall certify and bear the responsibility of the promotional material or activity.

(7) An advertisement or promotion shall not contain a statement or visual presentation which may lead to or support any act of violence, criminal or illegal activity or appear to condone such act or activity.

(8) A person who contravenes subrule (1), (2),(3),(4), (5) or (7) commits an offence.

Advertisement to the general public.

26. (1) An advertisement to the general public shall meet the following conditions—

(a) general sales health products shall be advertised only to the general public.;

(b) pharmacy only health products shall be advertised to the general public only within the pharmacy or hospital premise;

(c) any prescription only medicine, medical cosmetic, medical device or herbal or complementary product shall not be advertised to the public unless at the point-of-sale and the advertising materials such as dummy boxes should be used within the confines of the pharmacy; and

(d) controlled, narcotic and psychotropic substances shall not be advertised to the general public in any format.

(2) Subrule (1) shall not apply to—

(a) the advertisement or promotion of a licensed vaccine granted emergency use authorization by the Board as part of a national government-controlled vaccination campaign; or

(b) any other licensed medicine or health technology used in a public health emergency in response to the suspected or confirmed spread of a pathogenic agent, toxin, chemical agent or nuclear radiation.

Advertisements to health care practitioners.

27. A promotional advertisement of any general sales or prescription only health product shall be directed towards healthcare professionals who are qualified to prescribe, dispense, handle or supply medicines.

Promotion and advertisement of medical devices.

28. (1) The promotion of a medical device may be conducted if—

(a) the medical device being advertised to the general public does not require prescription or professional intervention;

(b) a prescription only medical device and in-vitro diagnostics is being promoted to healthcare professionals; or

(c) the medical device has supply restrictions and the restrictions feature on the advertisement

(2) A medical device that is used only for research shall not be advertised to the general public.

(3) The promotion of a medical device shall not indicate that the medical device can prevent or reverse the physiological changes or

degenerative conditions brought about or associated with ageing.

(4) A person who contravenes any provision of this rule commits an offence.

Advertisement of herbal and complementary medicine.

29. (1) A person shall not promote or advertise a herbal or complementary medicine without the approval of the Board.

(2) A person shall not promote or advertise any herbal or complementary medicine unless the herbal or complementary medicine is listed or registered by the Board.

(3) A promotion or advertisement of any herbal or complementary medicine shall—

(a) be based on evidence of traditional use of a substance or product, or on scientific evidence categorized depending on the level of claim being made;

(b) contain indications that are true, valid and not misleading, and do not lead to unsafe or inappropriate use of the product;

(c) be based on evidence which relates to the whole product or the same active ingredients with similar dosage regimen, dose form and route of administration to the product and the ingredient for which the claim is being made;

(d) not imitate the general layout, text, slogan or visual presentation of another herbal medicine or conventional product in a manner likely to mislead;

(e) have cautionary labels or disclaimer statements displayed on the label of the advertisement material of the herbal medicine or complementary medicine;

(f) not contain words such as “magic” or “miracle’’ or an exotic description such as “upper potency” or such other words as to induce the daily or continuous use of the product; and

(g) not contain words like “most effective” “least toxic, “best tolerated” or other special status such as “herbal medicine

or related products of choice".

(4) A person who contravenes any provision of this rule commits an offence.

Vitamin supplements.

30. (1) An advertisement for vitamin supplements shall not state or imply that—

(a) good health is likely to be jeopardized solely because there is lack of dietary supplementation with vitamins; or

(b) the vitamin supplements are a substitute for a balanced diet.

(2) A person who contravenes paragraph (1) commits an offence.

Weight management claims.

31. (1) A claim for weight management, body slimming, fat burning or fat or starch blocking product shall —

(a) be made in conjunction with reference to sensible lifestyle factors including diet and exercise; and

(b) have a mark with a clear disclaimer stating that "this product has not been proven to burn fat or block starch".

(2) A person who contravenes subrule (1) commits an offence.

Advertisements targeting pregnant or lactating women.

32. (1) An advertisement targeted towards pregnant or lactating women shall not—

(a) suggest or recommend any medicinal product, with the exception of some vitamin or mineral supplements, for use by pregnant or lactating women; or

(b) convey a message that—

(i) the advertised medicine or medicinal product does not cause harm or risk;

(ii) it is routine practice for pregnant women to take the medicine or medicinal product; or

(iii) the development of the unborn baby would be affected if the product is not taken.

(2) A person who contravenes paragraph (1) commits an offence.

Advertisements for children.

33. (1) An advertisement that is targeted towards children shall not —

(a) be aimed principally or exclusively at children under the age of twelve years;

(b) show a child using, or within reach of a health product without adult supervision; and

(c) display the image of a child unless accompanied by the image of an adult.

(2) A person who contravenes paragraph (1) commits an offence.

Advertisements for the general public.

34. An advertisement intended for the general public shall—

(a) indicate the generic name of the drug, the brand name or trade name of the drug which shall be succeeded by the names of the active ingredients using international non-proprietary names in brackets or below the trade name;

(b) display approved indications for use and major precautions, contra-indications and warnings;

(c) provide the dosage regimen and maximum allowed daily dosage in cases of herbal and complementary medicines; and

(d) display the phrase "*Maumivu yakizidi pata ushauri wa daktari"* or "If symptoms persist seek medical advice" or a phrase with a similar meaning.

Advertisements for health care professionals.

35. A promotion or advertisement for health care professionals shall prominently display—

(a) the brand or trade name which shall be succeeded by the name of the active pharmaceutical ingredient using either the international non-proprietary name or the approved generic name of the drug;

(b) the content of any active ingredient per dosage form or regimen;

(c) the name of other excipients known to have an effect;

(d) the approved therapeutic uses, dosage form or regimen;

(e) summarised information regarding safety of the product;

(f) references to the current scientific literature, as appropriate; and

(g) the contact details of the marketing authorization holder, name and address of manufacturer or distributor on every print media.

Publication of advertisement standards.

36. The Board shall, from time to time, publish and enforce the advertisement standards.

Organizational websites and portals.

37. (1) A company or an organization that intends to conduct an online pharmacy and health product advertisement or promotion shall—

(a) be licensed by the Board;

(b) have two windows, one for healthcare professionals whose access shall be restricted and another one for the general public; and

(c) ensure that the website or portal is operated, maintained and regulated by an authorized market authorization holder, manufacturer, distributor or their appointed representatives.

(2) A person who contravenes subrule (1) commits an offence.

Websites and portals for the general public.

38. (1) Any advertisement conducted on a website or portal that is aimed at the general public shall —

(a) be approved by the Board prior to being uploaded on the portal or website;

(b) be used to advertise general sales health products, medical devices and the services that the website or platform provides;

(c) not include any reference to named prescription only medicines, including price information;

(d) ensure that casual browsers are not presented with advertising for specific prescription only medicines through text or small prints at the bottom of the home page;

(e) ensure that any page other than the landing page which the consumer chooses to access contains non-promotional information which is accurate, factual and scientific;

(f) provide the indicative price for a general sales product on the homepage only;

(g) not mention any prescription only medicine on the home page;

(h) provide a factual list of prices of prescription only medicines on pages other than the home page and the price list shall not include product claims or actively encourage viewers to choose a product based on the price;

(i) not highlight any special offer on the price of a health product on the website as they are likely to promote irrational use; or

(j) not give free offers of health products during advertisements competitions or bonanzas.

(2) A person who contravenes subrule (1) commits an offence.

Websites and portals for health care professionals.

39. Any advertisement conducted on a website or portal that is aimed at healthcare professionals shall—

(a) be approved by the Board;

(b) have restricted access and shall be conspicuously labelled ‘for healthcare professionals only”;

(c) not contravene any of the provisions of the Act;

(d) ensure that the content meant for information, education and awareness is technical, factual, current and consistent with the latest scientific literature;

(e) ensure that a journal which is published or posted on the internet and which is expressly stated to be for healthcare professionals is directed at persons who are qualified to prescribe or supply medicines and the promotions contained in the journal are restricted and comply with the law; and

(f) ensure that each section of the journal promoting medical products and technologies is clearly labelled "intended for healthcare practitioners only".

(2) A person who contravenes subrule (1) commits an offence.

Press releases and product launches.

40. (1) Any product advertisement conducted through a press release or a product launch shall—

(a) ensure that the press release for a new chemical entity or health technology innovation is allowed only once; and

(b) ensure that the use of a brand name is succeeded by the generic name.

(2) A person who contravenes subrule (1) commits an offence.

Promotional meetings.

41. (1) Any product promotion or advertisement conducted through a promotional meeting, scientific conference or a webinar shall—

(a) be submitted to the Board one month prior for approval;

(b) not be circulated as a promotional material whether at a national or international meeting before approval; and

(c) be preprinted with the approval reference number of the Board.

(2) A person who contravenes subrule (1) commits an offence

Obligations of marketing authorization holders.

42. A marketing authorization holder shall—

(a) ensure that the product conforms to quality, safety and efficacy standards and is registered or retained by the Board before subjecting it to any promotion and advertisement;

(b) provide product education and training to healthcare professionals to ensure the appropriate, safe and effective utilization of a particular type of medical technology;

(c) ensure that its medical representatives and marketing team track the validity of

approved samples and refrain from illegal and unauthorized practices in relation to product promotional activities;

(d) ensure that the information provided about a product is correct and in accordance with the Act, these Rules and any guidelines issued under the Act;

(e) ensure compliance with the following requirements if the marketing authorization holder is involved in any patient support program—

(i) no incentive, other than material that will enhance positive health outcomes and compliance, is provided to a patient who is involved in the support program;

(ii) the data collected from the support program shall not be used for any purpose other than to increase positive health outcomes and not for any promotional activity; and

(iii) the duration of the support program is appropriate for the disease state treated by the product; and

(iv) report any contravention of the law and collaborate and cooperate in sharing information.

Obligations of media enterprises.

43. (1) A media enterprise shall—

(a) only advertise a product that is registered, retained and granted approval by the Board for advertisement;

(b) reject advertising and promotional materials that are not approved by the Board; and

(c) comply with the requirements of Act, other regulations and Rules for advertisements and promotions and report and contraventions on the said laws.

(2) A person who contravenes subrule (1) commits an offence.

Advertising offences.

44. A person who contravenes any of the provisions of these Rules in relation to advertising or promotion of a health product commits an offence and is liable on conviction to the penalties prescribed in section 40 of the Act.

General penalties.

45. A person who commits an offence under these Rules for which no penalty is provided shall, on conviction, be liable to the penalties prescribed in section 51 of the Act.

7. The principal Rules are amended in Schedule VIII by inserting the following new form immediately after form 33—

Form 34

PHARMACY AND POISONS BOARD
Application for approval of promotion materials

Pharmacy and Poisons Board		Application form	FOM017/MIR/SOP/006
			Rev No
1.0	Company Details		
		Name of company	
		Registration No	
		Physical address	
		Building	
		Street/Road	
2.0	Applicant Information		
	Name of applicant		
	Registration number		
	Cadre		
	Telephone		
3.0	Responsible Person Information		
	Name of the officer		
	Registration No		
	Cadre		

Telephone			
4.0 Product Particulars			
legal category	Product	Reg No	Type of Media
5.0 Application check list			
A copy of the proposed advert			
Proof of payment			
Copy of reference materials			
Copy of previous approval			
6.0 Applicant Declaration			
…… ……declare that the information contained within this application is true and correct.		Date ……	
		Sign…….	
7.0 FOR OFFICIAL USE ONLY			
Product	Approval granted	Rejection granted	
Reason for Rejection			
Name of officer		Date	

Made on the 8th June, 2022.

MUTAHI KAGWE,
Cabinet Secretary for Health.

LEGAL NOTICE NO. 99

THE PHARMACY AND POISONS ACT

(*Cap*. 244)

THE PHARMACY AND POISONS (PHARMACEUTICAL WASTE MANAGEMENT) RULES, 2022

ARRANGMENT OF RULES

Rule

1—Citation
2—Interpretation
3—Application of the Rules
4—Pharmaceutical waste minimization
5—Management of pharmaceutical waste
6—Responsibility of waste generator
7—Segregation of pharmaceutical waste
8—Packaging of pharmaceutical waste
9—Labeling of pharmaceutical waste
10—Recording of pharmaceutical waste
11—Handling and collection of pharmaceutical waste
12—Storage of pharmaceutical waste
13—Transportation of pharmaceutical waste
14—Importation of pharmaceutical waste
15—Export of pharmaceutical waste
16—Pharmaceutical waste treatment and disposal methods
17—Supervision of disposal of pharmaceutical waste
18—Disposal under section 46

THE PHARMACY AND POISONS ACT

(*Cap*. 244)

IN EXERCISE of the powers conferred by section 44 (1) (n) of the Pharmacy and Poisons Act, the Cabinet Secretary for Health, in consultation with the Pharmacy and Poisons Board, makes the following Rules—

THE PHARMACY AND POISONS (PHARMACEUTICAL WASTE MANAGEMENT) RULES, 2022

Citation.

1. These Rules may be cited as the Pharmacy and Poisons (Pharmaceutical Waste Management) Rules, 2022.

Interpretation.

2. In these Rules, unless the context otherwise requires—

"cleaner production measures" means preventive measures applied to processes, products and services to minimise waste production and limit environmental pollution;

"cytotoxic pharmaceutical waste" means waste associated with cytotoxic drugs which contain chemicals that are toxic to the cells including materials, equipment and residue that are contaminated by cytotoxic drugs;

"falsified medical products" means products that deliberately or fraudulently misrepresent their identity, source, composition or both;

"incineration" means the use of temperatures in excess of 800 °C dry oxidation process that reduces organic and combustible waste to inorganic, incombustible matter and results in a significant reduction of waste volume and weight;

"segregation" means the separation of waste materials for processing;

"waste generator" means any person whose activities or activities under his or her direction produces pharmaceutical waste or, if that person is not known, the person who is in possession or control of that pharmaceutical waste;

"waste management" means any activities either administrative or operational used in handling, packaging, treatment, condition, storage and disposal of waste; and

"substandard medical products" means products that are authorised but fail to meet their quality standards or specifications.

Application of the Rules.

3. (1) These Rules shall apply to the management of pharmaceutical waste including—

(a) waste containing pharmaceuticals that are expired, damaged or no longer needed;

(b) items contaminated by or containing pharmaceutical waste including bottles and boxes;

(c) applicable medical devices;

(d) substandard and falsified medical products;

(e) obsolete investigational medicinal products; and

(f) cytotoxic pharmaceutical waste.

(2) These Rules shall not apply to —

(a) sharps waste;

(b) infectious waste;

(c) pathological waste;

(d) radioactive waste;

(e) chemical waste; or

(f) non-hazardous or general healthcare waste.

Pharmaceutical waste minimization.

4. For the purposes of these Rules, a waste generator shall be encouraged to employ pharmaceutical waste minimization through the adoption of the following practices—

(a) checking of the expiry date of all pharmaceuticals at the time of delivery to ensure they have acceptable shelf life;

(b) refusal to accept short-dated pharmaceuticals (less than a third of shelf life remaining) from a supplier except when the consumption rate of the pharmaceuticals is high;

(c) ordering pharmaceuticals from suppliers who accept the return of short-dated pharmaceutical supplies;

(d) implementing a First Expiry First Out stock control system;

(e) dispensing of all the medicines in a given container; and

(f) replacing pre-packaged unit dose liquids with patient-specific oral doses.

Management of pharmaceutical waste.

5. (1) A person shall not collect, record, segregate, store, transport or dispose any pharmaceutical waste except in the manner provided in these Rules.

(2) A person who contravenes the provisions of sub-rule (1) commits an offence and shall be liable, on conviction, to the penalty prescribed by section 51 of the Act.

Responsibility of waste generator.

6. (1) A waste generator shall collect, record, segregate, store, transport and dispose of pharmaceutical waste in the manner provided for in these Rules.

(2) A waste generator shall adopt cleaner production measures in the management of pharmaceutical waste including—

(a) incorporating environmental considerations in the design and disposal of pharmaceutical waste; and

(b) improvement of the production process through—

(i) the elimination of use of toxic raw materials;

(ii) the minimising of the emission of toxic waste; and

(iii) the conservation of raw materials and energy.

Segregation of pharmaceutical waste.

7. (1) A waste generator shall segregate pharmaceutical waste from other forms of medical waste at the point of generation and at all stages thereafter.

(2) The segregation of waste under sub-rule (1) shall be as follows—

(a) cytotoxic pharmaceutical waste shall be segregated from other forms of pharmaceutical waste; and

(b) compressed-container medications (including aerosols and inhalers) shall be segregated from other forms of pharmaceutical waste.

Packaging of pharmaceutical waste.

8. (1) A waste generator shall take reasonable steps to ensure that pharmaceutical waste is in a package that is easily identifiable, including being in its original primary packaging, to aid in identification and preventing reaction between incompatible molecules.

(2) The measures envisaged under sub-rule (1) shall include the following—

(a) in as far as may be practicable, ensuring that pharmaceutical wastes are in their original primary packaging; and

(b) securely packaging any pharmaceutical waste in a suitable bag, container or other appropriate packaging; and

(c) appropriately labelling any package containing pharmaceutical waste.

(3) Where a package contains different types of pharmaceutical waste, a waste generator shall include an inventory of all the pharmaceutical waste contained in the package indicating the following—

(a) a description of each pharmaceutical waste and the quantity contained therein;

(b) the total weight of the pharmaceutical waste; and

(c) a label prepared in accordance with these Rules.

Labeling of pharmaceutical waste.

9. (1) A waste generator shall ensure that every container or package for storing pharmaceutical waste is labelled in easily legible characters, written in both English and Kiswahili.

(2) The label envisaged under sub-rule (1) shall contain the following information—

(a) a description of the pharmaceutical waste;

(b) the name, physical address and telephone contact of the waste generator;

(c) any of the following warning or caution statements, as may be appropriate—

(i) the words "WARNING" or "CAUTION";

(ii) the word "POISON";

(iii) the words "DANGER - KEEP AWAY FROM UNAUTHORIZED PERSONS"; or

(iv) a pictogram of a skull and crossbones.

(3) Where a package contains different types of pharmaceutical waste, it shall be packed in the manner specified under rule 8.

Recording of pharmaceutical waste.

10. A waste generator shall maintain records of pharmaceutical waste with updated information on the following—

(a) date;

(b) product trade name;

(c) active pharmaceutical ingredient;

(d) dosage form;

(e) unit of issue;

(f) quantity; and

(g) justification.

Handling and collection of pharmaceutical waste.

11. (1) Waste collection and storage bags for pharmaceutical waste needing incineration shall not be made of chlorinated plastics.

(2) Any plastic bag or bin liner used in the storage or transportation of pharmaceutical waste shall be legibly and permanently labelled with the name of the waste generator and the end-user.

(3) A waste generator shall ensure that pharmaceutical waste is transferred to a person who is licensed to dispose such pharmaceutical waste in an approved pharmaceutical waste disposal facility.

Storage of pharmaceutical waste.

12. (1) Pharmaceutical waste shall be stored in designated quarantine stores marked with the words "PHARMACEUTICAL WASTE AREA" which shall be away from other usable pharmaceuticals.

(2) A storage facility used for the storage of pharmaceutical waste shall—

(a) be labeled on the outside with the hazard sign of a skull and two crossbones;

(b) have a sign with the words "NO ENTRY FOR UNAUTHORIZED PERSONS";

(c) be properly secured and locked; and

(d) have a register of persons entering and exiting the facility that shall be kept by the waste generator.

Transportation of pharmaceutical waste.

13. (1) A person transporting pharmaceutical waste shall use a means of conveyance so as to prevent scattering, escaping, flowing, spillage or leakage of the pharmaceutical waste.

(2) A person shall not transport pharmaceutical waste destined for another country through any part of the territory of Kenya without a valid Prior Informed Consent for such transportation issued by the National Environment Management Authority.

(3) On-site transportation of pharmaceutical waste should be separated from infectious waste.

(4) A driver engaged in the off-site transportation of pharmaceutical waste shall be medically fit to drive and have appropriate training on the risks and handling of pharmaceutical waste.

(5) A vehicle used in the transportation of pharmaceutical waste shall be licensed by the National Environment Management Authority and meet the following criteria—

(a) be road worthy;

(b) labelled with the words "PHARMACEUTICAL WASTE CARRIER";

(c) bear the name and address of the pharmaceutical waste carrier;

(d) bear a hazard sign for pharmaceutical waste (skull and two crossbones);

(e) have a suitable system for securing the load during transport;

(f) have empty plastic bags, suitable protective clothing, cleaning equipment, tools and disinfectant, and special kits for dealing with liquid spills;

(g) be designed so as to prevent spillage, leakage or scattering of such pharmaceutical waste.

(6) During off-site transportation of pharmaceutical waste, the driver shall carry a consignment indicating—

(a) the source of the pharmaceutical waste;

(b) the date of pick-up of the pharmaceutical waste;

(c) the details of the driver;

(d) the destination of the pharmaceutical waste;

(e) the number of containers being transported;

(f) the total weight of the pharmaceutical waste; and

(g) any other relevant information.

(7) On the delivery of a consignment of pharmaceutical waste, the consignee shall confirm receipt of the pharmaceutical waste and the driver shall return the consignment note to the waste generator.

Importation of pharmaceutical waste.

14. (1) A person shall not import pharmaceutical waste into the territory of Kenya.

(2) A person who contravenes sub-rule (1) commits an offence and shall be liable, on conviction to the penalty prescribed by section 51 of the Act.

Export of pharmaceutical waste.

15. (1) A person shall not export pharmaceutical waste without a valid permit issued by the National Environment Management Authority and a valid Prior Informed Consent document issued by the designated national authority of the receiving country.

(2) A person who contravenes sub-rule (1) commits an offence and shall be liable, on conviction to the penalty prescribed by section 51 of the Act.

Pharmaceutical waste treatment and disposal methods.

16. (1) Before treatment and disposal, pharmaceutical waste shall be sorted according to dosage, form or active pharmaceutical ingredient, depending on treatment options available.

(2) Pharmaceutical waste shall be disposed of within one year from the date of its generation.

(3) Pharmaceutical waste shall be disposed of based on dosage in the manner set out in the First Schedule.

Supervision of disposal of pharmaceutical waste.

17. (1) The disposal of pharmaceutical waste shall be done under the supervision of the Board at a pharmaceutical waste disposal site approved by the National Environmental Management Authority.

(2) The application for the disposal of pharmaceutical waste shall be made to the Board in the form set out in the Second Schedule and accompanied by the fee set out in the Second Schedule.

(3) The Certificate of Safe Disposal of Pharmaceutical Waste shall be in the form set out in the Second Schedule and shall be issued by the Board within thirty days after the receipt of the application for the disposal of pharmaceutical waste.

Disposal under section 46.

18. Where goods are to disposed under section 46 of the Act, the goods shall be destroyed or disposed of in the manner set out in these Rules and in an environmentally-sound manner.

FIRST SCHEDULE (r. 16(3))

MANNER OF DISPOSAL

A. Disposal of small quantities of pharmaceutical waste

The following are the options for disposal of small quantities of pharmaceutical waste:

1. Return of expired pharmaceuticals to the donor or manufacturer where possible

2. Encapsulation and burial in a sanitary landfill

3. Inertization with subsequent—

(a) production of cubes or pellets which are then transported to a suitable storage site

(b) pouring of the liquid homogenous mass onto the surface of previously landfilled municipal waste and then covering with fresh municipal waste

4. Chemical decomposition in accordance with the manufacturer' recommendations if expertise and materials are available

5. Discharge into a sewer with or without dilution for intravenous electrolyte solutions and water for injection

6. Dilution in large amounts of water and discharge into a sewer for solutions containing vitamins and aminoacids

B. Disposal of large quantities of waste

The following are the options for disposal of large quantities of pharmaceutical waste:

1. Encapsulation and burial in a sanitary landfill

2. Inertization with subsequent:

(a)Production of cubes or pellets which are then transported to a suitable storage site

(b)Pouring of the liquid homogenous mass onto the surface of previously landfilled municipal waste and then covering with fresh municipal waste

3. Incineration in kilns that operate at high temperatures (in excess of 800 °C).

4. Discharge into a sewer with or without dilution for intravenous electrolyte solutions and water for injection

5. Dilution in large amounts of water and discharge into a sewer for solutions containing vitamins and aminoacids

C. Disposal of Cytotoxic drugs

The following are the recommended disposal methods for pharmaceutical waste comprised of cytotoxic drugs such as antineoplastic agents—

1. Cytotoxic drugs should never be landfilled.

2. Return to original supplier

3. Chemical degradation in accordance with manufacturer's instructions

4. Incineration at high temperature. Full destruction of cytotoxic drugs may require incineration temperatures up to 1200 °C

SECOND SCHEDULE (r. 17(2), (3))

PART A: FORMS

APPLICATION FOR DISPOSAL OF PHARMACEUTICAL WASTE

PHARMACY AND POISONS BOARD.
P.O. BOX 27663 – 00506,
NAIROBI.

1. Name of applicant: _____

2. Applicant address:

   Physical: _____

   Postal: _____ Telephone: _____

   Email: _____

3. Description of pharmaceutical products to be disposed

S/N	Product trade name	Active Pharmaceutical Ingredient (s)	Dosage form	Unit of issue	Quantity	Proposed method of disposal

For public health facilities attach the Report of the Board of Survey on Stores (Unserviceable and Surplus to Requirements) – FO 58

4. Justification for disposal of pharmaceutical waste

   _____

5. Proposed disposal site

   Name: _____

   Location: _____

6. Applicant details

   Name: _____

   Designation: _____

   Signature: _____
   Date: _____

Certificate of safe disposal of pharmaceutical waste

PHARMACY AND POISONS BOARD

P.O. BOX 27663-00506

NAIROBI

Certificate of Safe Disposal of Pharmaceutical Waste

This is to certify that the pharmaceutical waste:

From (company) _____
Application reference number _____
Weighing _____

was safely disposed off

on _____

Through the following disposal method _____

and at the following pharmaceutical waste disposal site
_____
____

In compliance with the Pharmacy and Poisons (Pharmaceutical Waste Management) Rules, 2022 and the Pharmacy and Poisons Board Guidelines on Safe Management of Pharmaceutical Waste.

Signed:

_____

Chief Executive Officer,
Pharmacy and Poison Board, Kenya.

PART B: FEES

Particulars	*Amount (Kshs)*
Application for the disposal of pharmaceutical waste	2500

Made on the 8th June, 2022.

MUTAHI KAGWE,
Cabinet Secretary for Health.

LEGAL NOTICE NO. 100

THE PHARMACY AND POISONS ACT

(*Cap*. 244)

IN EXERCISE of the powers conferred by section 44(1)(d) of the Pharmacy and Poisons Act, the Cabinet Secretary for Health, after consultation with the Pharmacy and Poisons Board, makes the following rules—

THE PHARMACY AND POISONS (REGISTRATION OF HEALTH PRODUCTS AND TECHNOLOGIES) RULES, 2022

PART I—PRELIMINARIES

Citation.

1. These Rules may be cited as the Pharmacy and Poisons (Registration of Health Products and Technologies) Rules, 2022.

Interpretation.

2. In these Rules, unless the context otherwise requires—

Cap. 244.

"Act" means the Pharmacy and Poisons Act;

"blood product" means a medicinal product based on a blood constituent which is prepared industrially and includes albumin, immunoglobulin and a coagulating factor;

"cosmetics" includes any substance or mixture of substances manufactured, sold or represented for use in cleansing, improving or altering the complexion, skin, hair, eyes or teeth, and includes deodorants and perfumes;

"good manufacturing practice certificate" means a document issued by a competent regulatory authority that certifies compliance to good manufacturing practice;

"immunogenic substance" means an unformulated active substance which may be—

(a) subsequently formulated with excipients to produce a medicinal product;

(b) whole bacterial cells, viruses, or parasites whether live or killed, split bacterial cells, viruses, or parasites, crude or purified antigens isolated from killed or living cells;

(c) crude or purified antigens secreted from living cells, recombinant or synthetic carbohydrate, protein or peptide antigens, polynucleotides; or

(d) conjugates;

"import" includes importation in accordance with the Pharmacy and Poisons (Parallel Imported Medicinal Substances) Rules, 2019; No. 126 of 2019.

"in-vitro diagnostics medical device" means a medical device, whether used alone or in combination, intended by the manufacturer for the in vitro examination of specimens derived from the human body solely or principally to provide information for diagnostic, monitoring or compatibility purposes;

"medicinal product" means a natural or synthetic active substance or combination of substances administered to a human being with a view to treating or preventing a disease, making a diagnosis, correcting or modifying a physiological function;

"medicinal substance" means a substance, the origin of which may be human, animal, vegetable or chemical including human blood and human blood products, micro-organisms, whole animals, parts of organs, animal secretions, toxins, extracts, blood products, micro-organisms, plants, parts of plants, vegetable secretions, extracts, elements, naturally occurring chemical materials and chemical products obtained by chemical change or synthesis;

"parallel importation" means the importation of patented drugs under section 58(2) of the Industrial Property Act, 2001; No. 3 of 2001.

"permanent residence" means a status granted to a person under section 37 of the Kenya Citizenship and Immigration Act, 2011; No. 12 of 2011.

"registered health product or technology" means a health product or technology for human use, approved by the Board, and presented into the market in a ready form, in a special package and with a specific name;

"vaccine" means heterogeneous class of medicinal substance containing immunogenic substances capable of inducing specific, active and protective host immunity against infectious diseases.

PART II—REGISTRATION OF HEALTH PRODUCTS AND TECHNOLOGIES

Control of the manufacture, etc., of drugs

3. A person shall not import, manufacture or sell a health product or technology in Kenya unless that health product or technology has been registered under these Rules.

Application for registration of health product or technology.

4. (1) A person who intends to import, manufacture or sell a health product or technology shall apply to the Board for the registration of the health product or health technology in Form 1 set out in the First Schedule.

(2) An applicant subrule (1) shall—

(a) specify the particulars of the person with appropriate knowledge of all aspects of the health product or health technology who shall be responsible for all communication between the applicant and the Board in the declaration page of the application form; and

(b) where the applicant is not a citizen of Kenya or is a company incorporated outside Kenya, appoint a local representative who shall be a citizen of Kenya, a person who is has permanent residence or a company incorporated in Kenya.

(3) The application made under subrule (1) shall be accompanied by—

(a) a proposed label for use on the health product;

(b) a copy of the manufacturing licence of the health product, where applicable;

(c) a copy of the good manufacturing practice certificate from the Board and the regulatory authority of the country where the health product is manufactured;

(d) a copy of a certificate of analysis from a quality control laboratory recognised by the Board, where applicable;

(e) a copy of the marketing authorisation or certificate of registration of the health product or technology from the regulatory authority of the country where the health product or technology is sold;

(f) the available data on the quality, safety, efficacy and performance of the health product or technology submitted in a common technical dossier format;

(g) a sample of the health product;

(h) proof of ownership of the site for the manufacture of the health product, if applicable;

(i) where the applicant is not a citizen of Kenya or is a company incorporated outside Kenya, a copy of the agreement appointing the local representative;

(j) where the application relates to a health product or technology which is registered with a foreign regulatory body,—

(i) a copy of the certificate of registration;

(ii) the professional information relating to the health product or technology; and

(iii) the conditions of the registration of the health product or technology;

(k) proof that the applicant holds—

(i) a valid practicing licence issued in accordance with section 9A of the Act;

(ii) a valid wholesale dealer's licence issued in accordance with section 27 of the Act;

(iii) a valid licence to deal in poisons for mining or agricultural purposes issued in accordance with section 28 of the Act;

(iv) a valid licence to sell Part II poisons issued in accordance with section 32 of the Act; or

(v) a valid manufacturing licence issued in accordance with section 35A of the Act; and

(l) proof of payment of the application fees set out in the Second Schedule.

(4) An applicant shall notify the Board of any variation to the agreement appointing the local representative within seven days of the variation.

Processing of application for registration of health product or technology.

5. (1) The Board shall consider the application made under rule 4, and, shall, if it is satisfied of the safety, efficacy, quality, performance and economic value of the health product or technology, register the health product or technology and issue a certificate of registration in Form 2 set out in the First Schedule.

(2) The Board may, while considering the application made under rule 4, approve the details as supplied by the applicant or approve it with such amendments as it may consider appropriate in respect of the following particulars—

(a) the name under which the health product or technology may be sold;

(b) the labelling of the health product;

(c) the statement of the representations to be made for the promotion of the health product regarding—

(i) the claim to be made for the health product;

(ii) the route of administering the health product;

(iii) the dosage of the health product;

(iv) the storage conditions of the health product;

(vi) the contra-indications, the side effects and precautions, if any of the health product; and

(vii) the package size of the health product.

(3) When evaluating an application made under rule 4, the Board may—

(a) subject a sample of the health product to an evaluation by an analyst; and

(b) consider the evaluation report of an institution that has evaluated the health product.

(4) The Board shall issue a certificate of registration under subrule (1) if the applicant has—

(a) a valid practicing licence issued in accordance with section 9A of the Act;

(b) a valid wholesale dealer's licence issued in accordance with section 27 of the Act;

(c) a valid licence to deal in poisons for mining or agricultural purposes issued in accordance with section 28 of the Act;

(d) a valid licence to sell Part II poisons issued in accordance with section 32 of the Act; or

(e) a valid manufacturing licence issued I accordance with section 35A of the Act.

(5) If the Board is not satisfied as to the quality, safety efficacy and performance, or economic value of the health product, it may, after providing an opportunity to the applicant to be heard, reject the application made under rule 4 and inform the applicant the reasons for rejection in writing.

Register of health products and technologies.

6. The Registrar shall maintain a register of health products and technologies registered in under there Rules in Form 3 set out in the First Schedule.

Collaborative measures when processing application for registration.

7. When processing an application made under rule 4, the Board may liaise with any other regulatory authority or institution in respect of matters of common interest or a specification investigation.

Annual retention.

8. (1) A person who holds a certificate of registration under rule 5(1) who wishes to have the product retained in the register shall annually apply for the retention of the product in the register in the in Form 4 set out in the Schedule.

(3) An application made under subrule (1) shall specify information on—

(a) the product summary;

(b) the finished product manufacturing sites;

(c) the active ingredient manufacturing sites;

(d) the approved presentations of actual product and product appearance;

(e) the approved batch formula and batch sizes;

(f) the approved specifications and analytical procedures; and

(g) the steps taken post-registration including variations, if any

(3) An application made under subrule (1) shall be accompanied by—

(a) a copy of a valid good manufacturing certificate; and

(b) the annual retention fees specified in the Second Schedule.

Renewal of certificate of registration.

9. (1) A person who intends to renew their registration shall apply for renewal of registration in Form 4 set out in the First Schedule.

(2) A person who makes an application under sub-rule (1) shall—

(a) have paid the retention fees referred to in rule 8; and

(b) comply with the prescribed guideline for Re-registration and Renewal of health products and technologies.

(3) An application made under sub-rule (1) shall specify information on—

(a) the health product or technology;

(b) non clinical study reports;

(c) clinical study report;

(d) variations;

(e) quality review of the health product or technology; and

(f) vigilance and product safety reports, including product complaints and market surveillance.

(4) The Board shall consider the application made under subrule (1), and, shall, if it is satisfied of the safety, efficacy, quality, performance and economic value of the health product or technology, register the health product or technology and renew the registration and issue a Renewal of Registration Certificate in Form 3 set out in the First Schedule.

Validity of certificates.

10. (1) A certificate of registration issued under rule 5(1) or a renewal certificate under rule 9(3), shall be valid for five years from the date of issue.

(2) If an application made under rule 9 is submitted before the expiration of the period referred to in subrule (1), the certificate shall remain in force until the Board makes a decision on the application.

Withholding, Suspension, or revocation of certificate of registration.

11. (1) The Board may withhold, suspend, or cancel the registration of a health product or health technology if—

(a) the person issued with a certificate of registration requests the Board to cancel the registration of the health product or technology;

(b) the person who was issued with the certificate misrepresented the information contained in the application made under rule 4;

(c) the certificate was acquired fraudulently;

(d) the person who was issued with the certificate has failed to comply with—

(i) the Act;

(ii) these Rules; or

(iii) a condition of the certificate;

(e) the formulation, composition, design specification, quality, safety or presentation of the health product has changed to the extent that it renders the health product unsuitable to continue to be registered; or

(f) it is in the public interest to do so.

(3) The Board shall, before suspending or cancelling the registration of health product or technology under subrule (1), issue a notice of intention to suspend or cancel the registration of a health product or technology in Form 5 set out in the First Schedule to the person who was issued with the certificate of registration and give the person an opportunity to be heard.

Withdrawal of certificate of registration.

12. The person to whom a certificate of registration is issued is required to notify the Board, in Form 6 set out in the First Schedule, of his intention to withdraw the registration for a health product and technology.

PART III—MISCELLANEOUS

Variation of information on health product or technology.

13. (1) Where there is a change in a health product or technology or the Board is satisfied that a variation to a registered health product or technology is required, the Board may, by notice in writing given to the person to whom a certificate of registration was issued, make such variation as it considers appropriate and enter the variation in the Register.

(2) Where there is a change in the product details of a health product or technology, the person to whom a certificate of registration is issued shall report the Board—

(a) any quality and safety changes or any defect which could impact patient safety of a marketed product; or

(b) any marketing or regulatory decisions made in the country of origin or in another country where the product is marketed.

Registration during emergency.

14.(1) The Board may, where it considers it necessary to protect public or animal health or in the event of a threat to human or animal life or health, the Board, issue a provisional certificate of registration for a health product or technology.

(2) A person who intends to obtain the provisional certificate of registration for a health product or technology under subrule (1) shall apply to the Board, in Form 2 set out in the First Schedule.

(3) Where the applicant is not a citizen of Kenya or is a company incorporated outside Kenya, the applicant shall appoint a local representative who shall be a citizen of Kenya, a person who is has permanent residence or a company incorporated in Kenya.

(4) An application under subrule (2) shall be accompanied by—

(a) such documents as may be necessary to support the application;

(b) where the applicant is not a citizen of Kenya or is a company incorporated outside Kenya, a copy of the agreement appointing the local representative;

(c) proof that the applicant holds—

(i) a valid practicing licence issued in accordance with section 9A of the Act;

(ii) a valid wholesale dealer's licence issued in accordance with section 27 of the Act;

(iii) a valid licence to deal in poisons for mining or agricultural purposes issued in accordance with section 28 of the Act;

(iv) a valid licence to sell Part II poisons issued in accordance with section 32 of the Act; or

(iv) a valid manufacturing licence issued in accordance with section 35A of the Act; and

(e) the fees specified in the Second Schedule.

(5) When determining an application under subrule (1), the Board shall consider the facts established from the valid marketing authorisation for the health product or technology and the report on the assessment of the health product or technology obtained from the authority competent for medicinal products, if available.

(6) The person to whom the certificate of registration is issued under subrule (1) shall be responsible for the labelling, packaging, advertising and pharmacovigilance system of the health product or technology.

(7) The Board shall issue a provisional certificate of registration under subrule (1) if the person has—

(a) a valid practicing licence issued in accordance with section 9A of the Act;

(b) a valid licence to deal in poisons for mining or agricultural purposes issued in accordance with section 28 of the Act;

(c) a valid licence to sell Part II poisons issued in accordance with section 32 of the Act; or

(d) a valid manufacturing licence issued I accordance with section 35A of the Act.

(8) A provisional certificate of registration issued under subrule (1) shall be valid for two years from the date of issue or until the declaration made under section 35 of the Public Health Act is revoked. Cap. 242

(9) Any variation to the agreement appointing the local

representative to the application made under subrule (2) shall be notified to the Board within seven days of the variation.

Registration for compassionate use.

15.(1) The Board may, where it considers it necessary register a health product or technology, for compassionate use by a person whose application under rule 4 is pending or a sponsor of a clinical trial in relation to an investigational health product.

(2) An application for the registration of a health product or technology for compassionate use of the health product or technology in Form 7 set out in the First Schedule.

(3) Where the applicant is not a citizen of Kenya or is a company incorporated outside Kenya, the applicant shall appoint a local representative who shall be a citizen of Kenya, a person who is has permanent residence or a company incorporated in Kenya.

(4) An application under subrule (1) shall be accompanied—

(a) by relevant documents indicating—

(i) that the health product or technology is authorised in a country with equivalent requirements as regards the quality, safety efficacy and performance of the health product or technology;

(ii) where the health product or technology does not have a marketing authorisation, the quality analysis of the health product or technology;

(iii) that the health product or technology constitutes a significant therapeutic, scientific and technical innovation;

(iv) that the health product or technology is intended for a group of patients with chronic or severely debilitating disease that cannot be satisfactorily treated with any health product or technology that has been registered by the Board;

(v) the related adverse effects, which shall be prepared or confirmed by the competent clinical department;

(vi) the protocol for treatment with the health product or technology; and

(vii) the warranties of the manufacturer of the health product or technology as specified in subrule (3);

(b) where the applicant is not a citizen of Kenya or is a company incorporated outside Kenya, a copy of the agreement appointing the local representative; and

(c) the fees specified in the Second Schedule.

(5) The manufacturer of a health product or technology which is the subject of the application made under subrule (1) shall—

(a) supply the health product or technology for at least one year

after the expiry of the period specified in the certificate of registration issued under this rule;

(b) avail the health product or technology free of charge during the period specified in the certificate of registration issued under this rule; and

(c) label the health product or technology in accordance with section 41 of the Act.

(6) If the health product or technology relates to a clinical trial in relation to an investigational health product, the applicant shall attach the recommendation of the National Clinical Trial Expert Committee.

(7) The Board shall consider the application made under subrule (2), and, if it is satisfied of the safety, efficacy, quality, performance and economic value of the health product or technology, register the health product or technology and issue a certificate of registration in Form 2 set out in the First Schedule.

(8) Any variation to the agreement appointing the local representative to the application made under subrule (3) shall be notified to the Board within seven days of the variation.

Authorisation of unregistered health product or technology.

16.(1) The Board may, in writing, authorise a person to import or distribute for a specified period to a specified person or institution a specified quantity of a particular health product that is not registered.

(2) A health product distributed pursuant to authorisation granted under subrule (1) may be used for such purposes and in such manner and during such period as the Board may in writing determine.

(3) A person who intends to obtain the authorisation under subrule (1), for purposes other than a clinical trial, shall apply to the Board, in Form 8 set out in the First Schedule.

(4) Where the applicant is not a citizen of Kenya or is a company incorporated outside Kenya, the applicant shall appoint a local representative who shall be a citizen of Kenya, a person who is has permanent residence or a company incorporated in Kenya.

(5) The application made under subrule (3) shall be accompanied by—

(a) a product brochure containing relevant chemical, pharmaceutical, pre-clinical pharmacological and toxicological data and where applicable, human or animal pharmacological and clinical data with the health product concerned;

(b) witnessed informed written consent document, where applicable;

(c) details of registration or pending registration of the health product with any other regulatory authority, if available;

(d) evidence of compliance of the manufacturer of the health product with Good Manufacturing Practice standards as determined by the Board;

(e) reasons why a registered health product cannot be used;

(f) where the applicant is not a citizen of Kenya or is a company incorporated outside Kenya, a copy of the agreement appointing the local representative;

(g) proof that the applicant holds—

(i) a valid practicing licence issued in accordance with section 9A of the Act;

(ii) a valid wholesale dealer's licence issued in accordance with section 27 of the Act;

(iii) a valid licence to deal in poisons for mining or agricultural purposes issued in accordance with section 28 of the Act;

(iv) a valid licence to sell Part II poisons issued in accordance with section 32 of the Act; or

(v) a valid manufacturing licence issued in accordance with section 35A of the Act; and

(h) the fees specified in the Second Schedule.

(6) The Board shall grant authorisation under subrule (1) if the applicant has—

(a) a valid practicing licence issued in accordance with section 9A of the Act;

(b) a valid wholesale dealer's licence issued in accordance with section 27 of the Act;

(c) a valid licence to deal in poisons for mining or agricultural purposes issued in accordance with section 28 of the Act;

(d) a valid licence to sell Part II poisons issued in accordance with section 32 of the Act; or

(e) a valid manufacturing licence issued I accordance with section 35A of the Act.

(7) Where the Board issues an authorisation under subrule (1), the person to whom the authorisation is issued shall submit to the Board—

(a) progress reports after every six months from the date when the authorisation was issued;

(b) any adverse event report, whenever an adverse event occurs; and

(c) a progress report within thirty days after the completion or termination of the use of the health product.

(8) The Board may, if the Board is of the opinion that the safety of any patient or animal is compromised or the scientific reasons for administering the unregistered health product have changed—

(a) impose any additional conditions;

(b) request additional information;

(c) inspect the site where the unregistered health product is manufactured, stored or administered; or

(d) withdraw the authorisation to treat the patient or animal.

(9) The Board may, by notice in writing withdraw the authorisation issued under subrule (1) if the any of purposes or the manner specified in subrule (2) is contravened.

(10) A health product authorised under this rule shall be labelled in accordance with section 41 of the Act.

(11) An applicant shall notify the Board of any variation to the agreement appointing the local representative within seven days of the variation.

(12) The requirements in this regulation shall apply to applications for donations of health products and technologies.

17. The Pharmacy and Poisons (Registration of Drugs) Rules are revoked. Revocation of LN 147 of 1981.

FIRST SCHEDULE

FORM 1 (r. 4(1), 14(2))

APPLICATION FOR REGISTRATION OF HEALTH PRODUCT OR HEALTH TECHNOLOGY

To:

The Registrar

Pharmacy and Poisons Board

Nairobi.

1. Name of Applicant ……..
2. Address of Applicant ……..
3. Contact of Applicant ……
4. Name of health product or health technology ……..
5. Type of health product or technology ……..
6. Presentation of health product or technology ……..
7. Physical appearance of health product ……
8. Therapeutic classification of health product or technology ……

   ……...
9. Name of manufacturer of health product ……
10. Address of manufacturer of health product ……..
11. Country of origin of health product or technology ……..
12. Registration numbers and countries of registration of the health product or technology ……
13. Pharmaceutical Formula of the health product ……
14. Name and structural formula of the active ingredient of the health product ……

    ……...
15. Specifications for all the active and inactive raw materials used in the manufacturing process ……

    ……...
16. Analytical control procedures which are performed on all active and inactive materials before the materials are used in the manufacturing process ……

    ……...
17. Analytical control procedures and the frequency with which they are performed in the manufacturing process ……..……

    ……...

18. Full specifications of the final manufactured health product ……..

……...

19. The analytical procedures performed on the final manufactured health product ……

20. The inferred shelf life of the final manufactured health product …….

……...

21. Method of packaging of the final manufactured health product ……..

……...

22. Summary of the experimental details of the tests performed on the health product or technology to confirm its pharmaceutical effects….

23. Proposed dosage of the health product ……

……...

……...

24. Summary of the experimental details of the tests performed on the health product or technology to confirm its physiological ability……..…

……...

……...

……...

25. Declaration by the applicant: ……...……

……...……
...……...……...….

Name of the responsible person ……..

Signature of applicant……Date of application ……

FORM 2 (r. 5(1), 9(3), 15(7))

CERTIFICATE OF REGISTRATION/RENEWAL OF REGISTRATION OF HEALTH PRODUCT OR HEALTH TECHNOLOGY

Serial Number……..

It is notified that the health product or health technology described in this certificate has been registered by the Pharmacy and Poisons Board subject to the conditions specified in this certificate.

1. International Non-proprietary name of health product or technology ……
2. Name under which the health product or technology is to be marketed (Trade Name) ……
3. Registration number of the health product or technology ……...
4. Quantities per unit (strength) of the health product ……
5. Dosage Form of preparations ……
6. Conditions under which the health product or technology is registered ……...
7. Name, address and contact information of the manufacturer of the health product ……
8. Date of registration ……..……..
9. Date of expiry of registration ……
10. Authorised signature of the Board …..…….. Date……

FORM 3 (r. 6)

REGISTER OF HEALTH PRODUCTS

No.	Brand Name	Generic	Strength	Dosage form	Pack Size	Certificate of Registration Holder	Local Technical Representative	Country of Origin	Registration Date

FORM 4 (r. 8(1), 9(1))

APPLICATION FOR RE-REGISTRATION/RENEWAL OF CERTIFICATE OF REGISTRATION

TYPE OF APPLICATION – HUMAN PRODUCT (Registration/Re-Registration)	
MODULE 1: ADMINISTRATIVE INFORMATION	
SECTION 1: PARTICULARS OF THE PRODUCT	
1.0 Name and address of Applicant	
1.1	Type of the Medicinal product licence application
	Type of the medicinal product application New/innovator Generic Conditional Authorization Emergency Use Authorization Extension application Duplicate license Renewal/Re-registration* * If variation has been made, information supporting the changes should be submitted. See variation guidelines for registered medicinal products.
1.2	Trade/Proprietary name (proprietary Product name):
1.3	Approved / generic name/Active Pharmaceutical Ingredient:
1.4	Strength of the Active Pharmaceutical Ingredient (API) per unit dosage of the product and specifications of the API:
1.5	Dosage form
1.5.1	Pharmaceutical Dosage form of the product:
1.5.2	Therapeutic Indication (s):
1.5.2	Route(s) of administration (use current list of standard terms - European Pharmacopoeia):
1.6	Packing/Pack size of the product:
1.6.1	Pack size:
1.6.2	Primary packing materials:
1.6.3	Secondary packing materials:

1.7	Visual Description of the product
1.8	Proposed/Approved Shelf life of the product (In months):
1.9	Pharmacotherapeutic group and ATC Code
1.10	Legal category
1.11	Country of origin or country of release:
1.12	Product Marketing Authorisation in the country of origin. (Attach certificate of pharmaceutical product from competent regulatory authority)
1.12.1	Registration status from countries with Stringent Regulatory Authorities where applicable
1.12.2	List of countries in which a similar application has been submitted
1.12.3	Statement on whether an application for the Marketing Authorisation has been previously rejected, withdrawn or repeatedly deferred in the East Africa Community Partner States
1.12.4	Certificates of approval of Drug Master File by Stringent Regulatory Authority
1.12.5	Manufacturing Licence and Product registration certificate/Licence
1.13	Name(s) and complete address (es) of the manufacturer(s)
1.13.1	Name and complete address(es)of the manufacturer(s) of the FPP, including the finished pharmaceutical product release if different from the manufacturer.
1.13.2	Name(s) and complete address (es) of the manufacturer(s) of the active pharmaceutical ingredient
1.14	Compliance to Good Manufacturing Practice and Good Clinical Practice
1.14.1	Good Manufacturing Practice from the Board
1.14.2	Good Clinical Practice or Good Laboratory Practice
1.15	Name and complete address of the Local Technical Representative of Manufacture (for finished pharmaceutical Product)
1.16	Product Information: Summary of Product Characteristics, Prescribers/Patient information leaflet, Mock-ups and Photo scan of the product:
1.17	State the reference/monograph standard used for Finished Medicinal Product.
1.18.1	Specification of active ingredient(s) from active pharmaceutical ingredient

	manufacturer (Specification number and Version):
1.18.2	Specification of active ingredient(s) from FPP manufacturer (Specification number and Version):
1.18.3	Specification of Finished Pharmaceutical Product (Specification number and Version):
1.19	Name and address (physical and postal) of the Contract Research Organisation(s) where the clinical studies of the product were conducted. *(If applicable)*
1.20	DECLARATION BY AN APPLICANT That information is true and correct Name, position and signature …… Official stamp:…….. * *Note: If fees have been paid, attach proof of payment*

FORM 5 (r. 11(3))

NOTICE OF INTENTION TO WITHHOLD, SUSPEND OR CANCEL THE REGISTRATION OF A HEALTH PRODUCT OR TECHNOLOGY

Date	Month	Year

TYPE OF MEDICAL PRODUCT OR HEALTH TECHNOLOGY				
☐	☐	☐	☐	☐
Human health product	Veterinary health product	Herbal product	Parallel product	Medical device

PRODUCT DETAILS	
Certificate of registration No.	
Name of product	
Strength	
Dosage/pharmaceutical form	
Certificate of registration holder	

DETAILS OF CONTACT PERSON	
Name	
Address	
Telephone No.	
E-Mail Address	

REASON FOR WITHHOLDING, SUSPENSION OR CANCELATION/REVOCATION

SIGNATURE		
Date	Name	Signature

FORM 6 (r. 12)

NOTICE OF INTENTION TO WITHDRAW THE REGISTRATION OF A HEALTH PRODUCT OR TECHNOLOGY

Date	Month	Year

TYPE OF MEDICAL PRODUCT OR HEALTH TECHNOLOGY				
☐	☐	☐	☐	☐
Human health product	Veterinary health product	Herbal product	Parallel product	Medical device

PRODUCT DETAILS	
Certificate of registration No.	
Name of product	
Strength	
Dosage/pharmaceutical form	
Certificate of registration holder	

DETAILS OF CONTACT PERSON	
Name	
Address	
Telephone No.	
E-Mail Address	

REASON FOR WITHDRAWAL

SIGNATURE		
Date	Name	Signature

FORM 7 (r. 15(2))

APPLICATION FOR COMPASSIONATE USE OF HEALTH PRODUCT AND TECHNOLOGIES

Date

Application No.	
Active substance[s]:	
Orphan indication	

1. Description of the condition under which the HPT is to be used

1.1. Details of the condition

1.1.1 Definition

1.1.2 Aetiology

1.1.3 Specific characteristics; pathophysiological, histopathological, clinical characteristics

1.1.4. Classification

1.1.5 Diagnosis and symptoms

1.2. Proposed indication

1.3. Medical plausibility

1.3.1. Active substance: description of the medicinal product, pharmacological class and mode of action

1.3.2. Plausibility of the condition; data with the specific product as applied for designation in specific models or in patients affected the condition

1.4. Justification of the life-threatening or debilitating nature of the condition

2. Prevalence of the condition

2.1. Prevalence of the disease or condition in the Kenya

2.2. Prevalence and incidence of the condition in the Kenya

3. Other methods for diagnosis, prevention or treatment of the condition

3.1. Details of any existing diagnosis, prevention or treatment methods

3.2. Justification as to why methods are not satisfactory (Applicable/Not applicable. (Delete as appropriate)

(Note that sections 3.2 and 3.3 are mutually exclusive.)

3.3. Justification of significant benefit

Applicable/Not applicable. (Delete as appropriate)

4. Description of the stage of development

4.1. Summary of the development of the product

4.1.1 Quality aspects

4.1.2 Non-clinical aspects

4.1.3 Proof-of concept in relevant model

4.1.4 Pharmacology

4.1.5 Pharmacokinetics

4.1.6 Toxicology

4.1.7 Clinical aspects

4.1.8 Pharmacokinetics

4.1.9 Pharmacodynamics

4.1.10 Clinical efficacy

4.1.11 Dose-response studies and main clinical studies

4.1.12 Clinical studies in applied condition

4.1.13 Planned clinical studies

4.1.14 Clinical safety

4.1.15 Adverse events

4.1.16 Serious adverse events and deaths

4.2. Details of current regulatory status and marketing history in the Kenya and other countries

5. Applicant's position:

(Please delete any paragraph above that does not apply.)

FORM 8 (r. 16(3))

Application Form for Unregistered Health Product and Technologies

<Date>

Application No.	
Active substance[s]:	
Orphan indication	

1. Description of the condition under which the HPT is to be used

1.1. Details of the condition

Definition

Aetiology
Specific characteristics; pathophysiological, histopathological, clinical characteristics
Classification
Diagnosis and symptoms
1.2. Proposed indication
1.3. Medical plausibility
1.3.1. Active substance: description of the medicinal product, pharmacological class and mode of action
1.3.2. Plausibility of the condition; data with the specific product as applied for designation in specific models or in patients affected the condition
1.4. Justification of the life-threatening or debilitating nature of the condition
2. Prevalence of the condition
2.1. Prevalence of the disease or condition in the Kenya
2.2. Prevalence and incidence of the condition in the Kenya
3. Other methods for diagnosis, prevention or treatment of the condition
3.1. Details of any existing diagnosis, prevention or treatment methods
3.2. Justification as to why methods are not satisfactory *or* Not applicable. *(delete as appropriate)*
Note that sections 3.2 and 3.3 are mutually exclusive.
3.3. Justification of significant benefit *or* Not applicable. *(delete as appropriate)*

4. Description of the stage of development
4.1. Summary of the development of the product
Quality aspects
Non-clinical aspects
Proof-of concept in relevant model
Pharmacology
Pharmacokinetics
Toxicology
Clinical aspects
Pharmacokinetics
Pharmacodynamics
Clinical efficacy
Dose-response studies and main clinical studies
Clinical studies in applied condition
Planned clinical studies
Clinical safety
Adverse events
Serious adverse events and deaths
4.2. Details of current regulatory status and marketing history in the Kenya and other countries
Applicant's position:
Please delete any paragraph above that does not apply.

SECOND SCHEDULE (r. 4(3)(l)), 8(3)(b), 14(4)(d), 15(4)(c), 16(5)(h))

FEES

	Purpose of Fees	Amount (USD.)
1.	Application for registration of health product not manufactured in Kenya.	1,000.00
2.	Application for registration of health product manufactured in Kenya.	500.00
3.	Application for renewal of registration of health product not manufactured in Kenya.	1,000.00
4.	Application for renewal of registration of health product manufactured in Kenya.	500.00
5.	Application for Fast tracking Evaluation of applications for Health product not manufactured in Kenya	2,000.00
6.	Application for donated health products	0
7.	Application for Issuance of Emergency Use Authorization for a Medical Devices and In-Vitro Diagnostic	2,500.00
8.	Application for registration of Class A Medical Device	100.00
9.	Application for registration of Class B Medical Device	200.00
10.	Application for registration of Class C Medical Device	1,000.00
11.	Application for registration Class D Medical Device	1,000.00
12.	Application for renewal of a Class A Medical Device	100.00
13.	Application for renewal of a Class B Medical Device	200.00
	Purpose of Fees	Amount (USD.)
14.	Application for renewal of a Class C Medical Device	1,000.00
15.	Application for renewal of a Class D Medical Device	1,000.00
16.	Application for registration of health product not manufactured in Kenya. (Food Supplement, Cosmetics and Borderline Products)	500.00
17.	Application for registration of health product manufactured in Kenya. (Food Supplement, Cosmetics and Borderline Products)	100.00
18.	Application for renewal of registration of health product not manufactured in Kenya. (Food Supplement, Cosmetics and Borderline Products)	500.00
19.	Application for renewal of registration of health product manufactured in Kenya. (Food Supplement, Cosmetics and Borderline Products)	100.00
20.	Application for registration of health product (Traditional Health Products – Locally Manufactured)	50.00
21.	Application for renewal of registration/listing of health products (Traditional Health Products – Locally Manufactured)	20.00

Made on the 8th June, 2022.

MUTAHI KAGWE,
Cabinet Secretary for Health.

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