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.

PRINTED AND PUBLISHED BY THE GOVERNMENT PRINTER, NAIROBI