REPUBLIC OF KENYA

PARLIAMENT

NATIONAL ASSEMBLY BILLS
(Bill No. 54 of 2022)

THE KENYA HEALTH PRODUCTS AND TECHNOLOGIES REGULATORY AUTHORITY BILL, 2022

(A Bill published in the Kenya Gazette Supplement No. 184 of 2022 and passed by the National Assembly, with amendments, on November 7th, 2024)

N.A. /B/No. 54/2022

THE KENYA HEALTH PRODUCTS AND TECHNOLOGIES REGULATORY AUTHORITY BILL, 2022

ARRANGEMENT OF CLAUSES

PART I—PRELIMINARY

Clause

PART II—THE KENYA HEALTH PRODUCTS AND TECHNOLOGIES REGULATORY AUTHORITY

PART III— HEALTH PRODUCTS AND TECHNOLOGIES

THE KENYA HEALTH PRODUCTS AND TECHNOLOGIES REGULATORY AUTHORITY BILL, 2022

A Bill for

AN ACT of Parliament to establish a comprehensive legal framework for the regulation of health products and technologies; to safeguard public health through development of a regulatory system to ensure safety, quality, efficacy, effectiveness and performance of health products; to establish the Kenya Health Products and Technologies Regulatory Authority and for connected purposes

ENACTED by the Parliament of Kenya, as follows—

PART I—PRELIMINARY

Short title.

1. This Act may be cited as the Kenya Health Products and Technologies Regulatory Authority Act, 2022.

Interpretation.

2. (1) In this Act, unless the context otherwise requires—

"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 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;

"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;

"advertisement" includes any statement, communication, representation or reference to the public designed to promote or publicize either directly or

indirectly the sale, use or disposal of any health product and technologies including blood and blood products, chemical substances, therapeutic cosmetics, herbal medicines and products, medical devices, medicines or scheduled substances;

"alternative medicine" means complementary medicine and includes a broad set of health care practices that are not part of Kenya's tradition and are not integrated into the dominant health care system;

"approved name" in relation to a medicine, means the international non-proprietary name of such medicine or where no such name exists, such other name as the Authority may determine, not being a brand name or trade mark registered in terms of the Trade Marks Act; Cap. 506.

"article" includes—

(a) any drug, therapeutic cosmetic, dietary supplement, herbal medicine, medical device or scheduled substance and any labelling or advertising materials in respect thereof; or

(b) anything used for the preparation, preservation, packing or storing of any drug, herbal medicine, therapeutic cosmetic, dietary supplement medical device or scheduled substance;

"Authority" means the Kenya Health Products and Technologies Regulatory Authority established under section 4 of this Act;

"authorized seller of scheduled substances" means a person designated as such under this Act;

"biologicals" means a diverse group of medicines which includes vaccines, growth factors, immune modulators, monoclonal antibodies and includes products derived from human blood and plasma;

"Board" means the Board of the Authority established under section 8;

"Cabinet Secretary" means the cabinet secretary for the time being responsible for matters relating to health;

"Centre" means the National Pharmacovigilance Centre established under section 66;

"chemical substance" means any substance or mixture of substances prepared, sold or represented for use as a germicide, antiseptic, disinfectant, pesticide, insecticide, rodenticide, vermicide or any other substance or mixture of substances which the Authority may declare to be a chemical substance;

"clinical trial" means any systematic study on pharmaceutical products in human subjects, whether in patients or other volunteers, in order to discover or verify the effects of, identify any adverse reaction to investigational products, study the absorption, distribution, metabolism and excretion of the products with the object of ascertaining their efficacy and safety;

"dentist" or "dental practitioner" means a person registered as such under the Medical Practitioners and Dentists Act; Cap. 253.

"dietary supplement" means a product taken by mouth that is added to the diet to help meet the daily requirements of essential nutrients, and which usually contains one or more dietary ingredient and includes vitamins, minerals and herbs;

"Director-General" means the Director-General appointed under section 6;

"drug" includes—

(a) any medicine, medicinal preparation, medicinal substance, therapeutic substance or vaccine; or

(b) any substance or mixture of substances including any medicine, medicinal preparation or therapeutic substance prepared, sold or represented for use in—

(i) the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state, or the symptoms thereof, in humans or animals; or

(ii) restoring, correcting or modifying functioning of organs in humans or animals;

"enrolled pharmaceutical technologist" means a person enrolled as such by the body for the time being

responsible for the enrolment of pharmaceutical technologists;

"falsified medical product" means a product that is deliberately or fraudulently misrepresented in relation to its identity, composition or source;

"falsified medicines" means medicines which do not contain the correct type or concentration of active or other ingredients or falsely labelled medicines;

"field safety corrective action" means any action taken by a product owner to reduce a risk of death or serious deterioration in the state of health associated with the use of a medical device, and includes—

(a) the return of a medical device to the product owner or its representative;

(b) device modification which may include—

(i) retrofit in accordance with the product owner's modification or design change;

(ii) permanent or temporary changes to the labelling or instructions for use;

(iii) software upgrades including those carried out by remote access;

(iv) modification to the clinical management of patients to address a risk of serious injury or death related specifically to the characteristics of the device;

(v) device exchange;

(vi) device destruction; or

(vii) advice given by a product owner regarding the use of the device;

"health product" includes a medicine, medical product, medicinal substance, vaccine, diagnostic, medical device, blood or blood product, herbal medicine, therapeutic feed and nutritional formulation, cosmetic and related products;

"health products and technologies" means chemical substances, therapeutic cosmetics, dietary supplements, herbal medicines and products, medical devices including radiation-emitting devices, medicines, scheduled

substances, and related products and substances;

"health technology" means the application of organized knowledge and skills in the form of medicines, devices, vaccines, procedures, and systems developed to solve a health problem and improve the quality of lives, and includes radiation-emitting devices and related products;

"herbal medicine or product" means a plant derived material or preparations with claimed therapeutic or other health benefits, which contain either raw or processed ingredients from one or more plants or material of inorganic or animal origin and includes herbs, herbal materials, herbal preparations, finished herbal products that contain active ingredients, parts of plants or other plant materials or combinations;

"insanitary conditions" means such conditions or circumstances that may contaminate a drug or a therapeutic cosmetic with dirt or filth or may render the drug or therapeutic cosmetic injurious or dangerous to health;

"Inspector of Drugs" means a person who is competitively recruited by the Authority as a drug inspector under this Act;

"interchangeable multi-source medicine" means a medicine that contains the same active substances which are identical in strength or concentration, dosage form and route of administration and meets the same or comparable standards, which comply with the requirements for therapeutic equivalence as prescribed;

"label" includes any legend, work or mark attached to, included in, belonging to or accompanying any drug, therapeutic cosmetic, medical device or scheduled substances;

"lot" or "sub-lot" means a defined quantity of starting material, packaging material or product, processed in a single process or series of processes so that the quantity is expected to be homogeneous; and in the case of continuous manufacture, the lot corresponds to a defined fraction of the production characterized by its intended homogeneity;

"lot release" means the process of the evaluation of an individual lot of a licensed biological product by the

Authority before giving approval for its release onto the market;

"manufacture" means any process carried out in the course of making a product or medicinal substance and includes packaging, blending, mixing, assembling, distillation, processing, changing of form or application of any chemical or physical process in the preparation of a medicinal substance or product; but does not include dissolving or dispensing the product by diluting or mixing it with some other substances used as vehicles for administration;

"marketing authorization" means the certificate of registration issued by the competent health product regulatory authority in the country of origin for the purpose of marketing or free distribution of a health product after evaluation for safety, efficacy and quality;

"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 human beings, for one or more of the specific medical purpose of—

(a) diagnosis, prevention, monitoring, treatment or alleviation of disease;

(b) diagnosis, monitoring, treatment, alleviation of or compensation for an injury;

(c) investigation, replacement, modification or support of the anatomy or of a physiological process;

(d) supporting or sustaining life;

(e) control of conception;

(f) disinfection of medical devices;

(g) providing information by means of in vitro examination of specimens derived from the human body;

(h) disinfection substances;

(i) aids for persons with disabilities;

(j) devices incorporating animal or human tissues;

and

(k) devices for in-vitro fertilization or assisted reproduction technologies,

and does not achieve its primary intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its intended function by such means;

"medical practitioner" means a person registered as such under the Medical Practitioners and Dentists Act; Cap. 253.

"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;

"medicine" means any substance or mixture of substances used or purporting to be suitable for use or manufactured or sold for use in—

(a) the diagnosis, treatment, mitigation, modification or prevention of disease, abnormal physical or mental state or the symptoms thereof in humans or animals; or

(b) restoring, correcting or modifying any somatic or psychic or organic function in humans or animals;

"package" includes anything in which any drug, therapeutic cosmetic, dietary supplement, medical device or scheduled substance is wholly or partly placed or packed;

"parallel importation" means importation into Kenya, by a licensed importer of a health product other than the marketing authorization holder or his or her technical representative, of the following health products which require marketing authorization in Kenya—

(a) patented health products under the applicable law;

(b) non-patented health products; or

(c) branded generic health products;

"parallel imported medicinal substance" means a medicinal substance imported into Kenya under this Act;

"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;

"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;

"premise" includes any land, building, dwelling-place or any other place whatsoever; and includes stand-alone community retail pharmacy, private hospital pharmacy, public health facility pharmacy, wholesale pharmacy or distribution outlet, where health products and technologies are stored, handled or distributed;

"radiopharmaceutical" means a medicinal substance which, when ready for use, contains one or more radionuclides included for a medicinal purpose;

"registered pharmacist" means a person registered as such by the body for the time being responsible for the registration of pharmacists;

"register" means a register established under this Act;

"Registrar" means the Director-General of the Authority appointed under section 6;

"regulatory officer" means a person appointed as such by the Authority under this Act;

"scheduled substance" means any substance or mixture of substances declared as such in the list published by the Cabinet Secretary under section 41;

"scheduling" in relation to a substance, means the determination of the schedule or schedules to the current Poisons Standard in which the name or a description of the substance is to be included;

"substance recommended as a medicine", in relation to the sale of an article consisting of or comprising a substance so recommended, means a substance which is

referred to—

(a) on the article or any wrapper or container in which the article is sold, or on any label affixed to, or in any document enclosed in the article, wrapper or container; or

(b) in any placard or other document exhibited at the place where the article is sold; or

(c) in any advertisement published by or on behalf of the manufacturer of the article, or the person carrying on the business in the course of which the article was sold, or, in a case where the article was sold under a proprietary designation, the proprietor of the designation, in terms which are calculated to lead to the use of the substance for the prevention or treatment of any ailment, infirmity or injury affecting human beings or animals, not being terms which give a definite indication that the substance is intended to be used as, or as part of, a food or drink, and not as, or as part of, a medicine.

"substance" includes a preparation or a liquid;

"substandard medicines" means medicines which do not meet defined specifications and includes products that have been contaminated;

"therapeutic cosmetic" means a product with the ability to trigger biological actions on the dermis, skin, eyes or teeth, to prevent future damage and contains ingredients that are usually not found in regular cosmetics or at higher strengths than could be sold safely over the counter;

"traditional medicine" includes the knowledge, skills and practices based on the theories, beliefs and experiences indigenous to different cultures, whether explicable or not, used in the maintenance of health as well as in the prevention, diagnosis, improvement or treatment of physical and mental illness;

"unregistered health product" means a product that has not undergone evaluation and approval by the Authority subject to permitted conditions under the Act and the rules therein;

"vessel" means a truck, van, bus, minibus, car, trailer,

aircraft, railway carriage, boat and other means that are used for purposes of conveying health products and technologies;

"veterinary surgeon" or "veterinary practitioner" means a person registered as such under the Veterinary Surgeons and Veterinary Para-Professionals Act; Cap 366

"veterinary medicine" means any curative or preventive substance, formulated medicament, or mixture of substances, whether proprietary or in the form of a preparation effective in animals, which is used, or is manufactured, sold or represented as suitable for use, in—

(a) the diagnosis, treatment, mitigation or prevention of disease or abnormal physical or mental state or the symptoms thereof in an animal;

(b) restoring, correcting or modifying any physical, mental or organic function in an animal; or

(c) controlling internal or external pests and parasites, and includes insecticides, vaccines, hormones, alternative medicines, antiseptics, disinfectants, surgical, nutrients and biological products; and

"wholesale dealer" means a person who is licensed to carry out a business where health products and technologies are stored, distributed or sold in bulk to persons other than individual consumers and includes registration, importation, warehousing, good distribution practices and pharmacovigilance.

(2) In this Act, reference to the sale of a health product or technology includes reference to the supply of a health product or technology as a sample for the purpose of inducing persons to buy by retail the substance of which the health product or technology consists or which it comprises.

Application.

3. (1) This Act applies to the regulation of —

(a) medicines, medical products and technologies;

(b) medical devices including radiation emitting devices;

(c) radiopharmaceuticals;

(d) complementary, alternative or herbal medicines;

(e) cosmetics and borderline products;

(f) in-vitro diagnostics medical devices;

(g) therapeutic feeds;

(h) clinical trials;

(i) nutraceuticals and dietary supplements;

(j) digital health and technologies;

(k) scheduled substances;

(l) chemical substances; and

(m) biological products for use in humans and the starting materials used in their manufacture.

(2) Unless provided otherwise in this Act or the Constitution, no other authority or law may regulate the items regulated under this law.

PART II – THE KENYA HEALTH PRODUCTS AND TECHNOLOGIES REGULATORY AUTHORITY

Establishment of the Authority.

4. (1) There is established an Authority to be known as the Kenya Health Products and Technologies Regulatory Authority.

(2) The Authority shall be a body corporate with perpetual succession and a common seal and shall be capable, in its corporate name, of—

(a) suing and being sued;

(b) taking, purchasing or otherwise acquiring, holding or disposing of movable or immovable property;

(c) entering into contracts;

(d) borrowing and lending money; and

(e) performing such other things or acts necessary for the proper performance of its functions under this Act which may lawfully be done by a body corporate.

Headquarters.

5. The headquarters of the Authority shall be in Nairobi, but the Authority may establish branches anywhere in Kenya.

Director-General.

6. (1) There shall be a Director-General of the Authority who shall be the chief executive officer of the Authority.

(2) The Director-General shall be appointed by the Board, through a transparent and competitive process, on such terms as may be specified in the instrument of appointment.

(3) The Director-General shall hold office for a term of three years and shall be eligible for reappointment for one further term of three years.

(4) A person shall be qualified for appointment as a Director-General if such person—

(a) holds a bachelor's degree in pharmacy from a university recognized in Kenya;

(b) holds a masters' degree in pharmacy, medicine or any relevant field from a university recognized in Kenya;

(c) has at least ten years' experience in pharmacy or its equivalent;

(d) has served in a senior management position for at least five years;

(e) is a member of a professional body; and

(f) meets the requirements of Chapter six of the Constitution.

(5) The Director-General shall be responsible for the management of the Authority.

(6) The Director-General shall be the accounting officer of the Authority.

(7) The Director-General shall be the principal representative of the Authority and shall, in that capacity have authority to—

(a) represent the Authority in its relations with other public entities, persons or bodies; and

(b) sign individually or jointly with other persons contracts concluded by the Authority, notes and securities issued by the Authority, reports, balance sheets and other financial statements,

correspondence and other documents of the Authority.

(8) The Director-General may delegate any of the powers provided for in this section to other officers of the Authority.

Disqualification from the position of Director-General.

7. A person shall not qualify for the position of Director-General if the person—

(a) is an undischarged bankrupt;

(b) has been convicted of an offence and sentenced to imprisonment for a term exceeding six months;

(c) is a salaried employee of any public entity except on a secondment basis; or

(d) is a director, officer, employee, partner in or shareholder of any specified pharmaceutical or other institution whose principal business is subject to regulation under this Act.

Management of the Authority.

8. (1) The Authority shall be managed by a Board to be known as the Kenya Health Products and Technologies Regulatory Board.

(2) The Board shall comprise—

(a) a non-executive Chairperson appointed by the President and who shall—

(i) be a registered pharmacist of good standing with a degree in pharmacy; and

(ii) have at least ten years' experience in the pharmaceutical sector, five of which shall be at senior management level;

(b) the Principal Secretary in the Ministry for the time being responsible for health or a representative designated in writing;

(c) the Principal Secretary in the Ministry for the time being responsible for finance or a representative designated in writing;

(d) the Director-General for Health or a representative designated in writing;

(e) one person nominated by the Pharmaceutical

Society of Kenya;

(f) one person nominated by the Kenya Pharmaceutical Association;

(g) one person nominated by the Kenya Medical Association;

(h) one person, not being a Governor, with knowledge and experience in health products and technologies nominated by the Council of County Governors to represent the interests of counties;

(i) one person, not being a public officer, representing consumer protection nominated by the Consumer Federation of Kenya; and

(j) the Director-General of the Authority who shall be the secretary and an *ex officio* member of the Board.

(3) The Cabinet Secretary shall appoint the members of the Board under subsection (2) (e), (f), (g), (h) and (i) by notice in the *Gazette*.

(4) A person shall be qualified for appointment to the Board if the person—

(a) is a citizen of Kenya; and

(b) meets the requirements of Chapter six of the Constitution.

(5) A person shall not be qualified for appointment as a member of the Board if such a person—

(a) is a member of Parliament;

(b) is a member of a county assembly or a county executive committee member;

(c) is a member of a governing body of a political party;

(d) is an undischarged bankrupt; or

(e) is convicted of an offence and sentenced to imprisonment for a term exceeding six months.

(6) In appointing members of the Board, regard shall be given to the need for regional balance, fair representation of persons with disabilities and the

realization of the principle that at least one third of the members must be from either gender.

(7) The members shall, at their first meeting, elect a vice-chairperson from amongst the members appointed under subsection (2) (e), (f), (g), (h) and (i).

(8) The chairperson and the vice-chairperson of the Board shall not be of the same gender.

(9) The members of the Board shall hold office for a term of three years and shall be eligible for reappointment for one further term of three years.

Vacation of office.

9. (1) The office of the chairperson or member of the Board shall become vacant if the holder—

(a) dies;

(b) resigns from office by writing under his hand addressed to the appointing authority;

(c) is removed from office in accordance with the provisions of section 10;

(d) is convicted of an offence and sentenced to imprisonment for a term exceeding six months without the option of a fine;

(e) is unable to discharge the functions of the office by reason of physical or mental infirmity;

(f) is absent, in the case of a member, without permission of the chairperson from three consecutive meetings of the Board without good cause; or

(g) is declared bankrupt.

(2) A Board member may resign from the position of vice-chairperson without losing his or her position as a Board member.

Removal from office.

10. (1) The Chairperson or a member of the Board may be removed from office for—

(a) gross violation of the Constitution or any other law;

(b) gross misconduct, whether in the performance of the member's functions or otherwise;

(c) physical or mental incapacity to perform the functions of the office; or

(d) incompetence or neglect of duty.

(2) The Cabinet Secretary may, upon the recommendation of the Board, revoke the appointment of a member of the Board on any of the grounds specified under subsection (1).

Functions of the Authority.

11. The primary object of the Authority is to provide for the regulation, investigation, inspection and approval of health products and technologies and related matters in public interest, and for that purpose the Authority shall—

(a) ensure adequate and effective standards and guidelines for regulation of health products and technologies;

(b) ensure that compliance with existing legislation is being promoted and controlled through a process of active inspection and investigation;

(c) ensure the efficient, effective and ethical evaluation and registration of health products and technologies that meet defined standards of quality, safety and efficacy;

(d) ensure that the process of evaluating and registering health products and technologies is, subject to this Act, transparent, fair, objective and concluded in a timely manner;

(e) ensure the periodic re-assessment and monitoring of health products and technologies;

(f) regulate the disposal of health products and technologies;

(g) monitor the market for the presence of unregistered and illegal health products and

technologies;

(h) conduct analytical tests of health products and technologies;

(i) ensure continuous monitoring of the safety of health products and technologies regulated under this Act through analysis of reports on adverse reactions and events, including any other health product and technology use related issues and take appropriate regulatory actions when necessary;

(j) regulate clinical trials and ensure that clinical trial protocols of health products and technologies are assessed according to the prescribed ethical and professional criteria and defined standards including mandatory bioequivalence studies;

(k) approve the use of any unregistered medicinal substance for purposes of clinical trials, emergency use and compassionate use;

(l) carry out pharmacovigilance audits and inspections in order to ensure compliance with good pharmacovigilance practices and the prescribed requirements;

(m) monitor compliance with this Act through its agencies and any other state agencies authorized under this Act;

(n) advise the Cabinet Secretary and the county governments on measures for the protection of the health of consumers;

(o) advise the Cabinet Secretary and the county governments on the implementation of this Act;

(p) foster co-operation between the Authority and other institutions or organizations and other stakeholders including the harmonization of guidelines and standards, information sharing and regulatory reliance on decisions made by other agencies;

(q) approve and register health products and technologies regulated under this Act, manufactured within or imported into, and intended for use in Kenya;

(r) examine, grant, issue, suspend, cancel or revoke licences or permits issued under this Act;

(s) appoint inspectors who hold a minimum qualification of a diploma in pharmacy and conduct inspection, either by itself or through its agents, of manufacturing premises, medical devices establishments, importing and exporting agents, wholesalers, distributors, pharmacies, including those in health facilities and clinics, retail outlets and any other premises and vessels subject to regulation under this Act;

(t) promote rational use of drugs, medical devices and herbal drugs;

(u) conduct national regulatory authority lot release, official authority batch release of specified biologicals to ensure the quality, safety and efficacy of biological products through a regulatory release system in compliance with established approaches, policies, guidelines, procedures and in line with World Health Organization and internationally recognized guidelines;

(v) carry out and promote research related to medicines and health products;

(w) provide the public with unbiased information on products regulated under this Act;

(x) prescribe standards of quality in respect of products regulated under this Act, manufactured or intended to be manufactured or imported into or exported from Kenya;

(y) ensure that all health products and technologies manufactured in, imported into or exported from the country including through parallel importation conform to prescribed standards of quality, safety and efficacy;

(z) enforce the prescribed standards of quality, safety and efficacy of health products and technologies manufactured, imported into or exported out of the country;

(aa) grant or revoke licenses and permits for the

manufacture, importation, exportation, distribution and sale of health products and technologies;

(bb) maintain a register of all authorized health products and technologies manually or electronically;

(cc) regulate licit use of narcotic, psychotropic substances and precursor chemical substances in accordance with the Single Convention on Narcotic Drugs, 1961, the Convention on Psychotropic substances,1971 or the United Nations Convention against Illicit Traffic of Precursor Chemical Substances, 1988;

(dd) inspect and license all manufacturing premises, importing and exporting agents, wholesalers, distributors, pharmacies including those in hospitals and clinics and other retail outlets;"

(ee) maintain the registers prescribed under this Act;

(ff) attend to and, where possible, take legal measures on complaints made by consumers against manufacturers of products regulated under this Act; and

(gg) perform any other functions assigned to it under this Act.

Powers of the Authority.

12. The Authority shall have powers necessary or expedient for the proper performance of its functions under this Act including to—

(a) collaborate with such other bodies or organizations within or outside Kenya as it may consider desirable or appropriate for the furtherance of the purpose of the Act;

(b) adopt and implement any such internationally recognized good regulatory practices;

(c) determine and implement effective and efficient reliance mechanisms;

(d) issue, suspend, withdraw or revoke any license or compliance certificate granted under this Act;

(e) levy, collect and utilize fees for services rendered;

(f) grant or withdraw licenses and permits to

manufacturers, wholesalers, retailers, importers, exporters and distributors;

(g) develop guidelines on the manufacture, import and export, distribution, sale and use of medical products".

(h) control, supervise and administer the assets of the Authority in such manner and for such purposes as best promotes the purpose for which the Authority is established;

(i) receive any grants, gifts, donations or endowments and make legitimate disbursements therefrom;

(j) open bank accounts for the funds of the Authority;

(k) establish such committees as it may consider necessary for the performance of its functions and the exercise of its powers under this Act; and

(l) co-opt in such committees persons whose knowledge and experience is necessary to enable the committee to effectively discharge its functions.

Affairs of the Board.

13. The conduct and regulation of the business and affairs of the Board of the Authority is provided in the First Schedule.

Delegation by the Board.

14. The Board may, by resolution either generally or in any particular case, delegate to any committee of the Authority or to any member, officer, employee or agent of the Authority, the exercise of any of the functions or duties of the Authority under this Act.

Allowances of the Board.

15. The Cabinet Secretary shall, on the advice of the Salaries and Remuneration Commission, determine the allowances of the members of the Board.

Staff of the Authority.

16. (1) The Authority may appoint such officers or staff including regulatory officers as may be necessary for the proper discharge of the functions of the Authority under this Act, upon such terms and conditions of service as the Authority may determine.

(2) The principles of ethnic, regional and gender balance shall guide all staff appointments.

(3) The Cabinet Secretary may, upon request by the

Authority, second to the Authority such number of public officers as may be necessary for the purposes of the Authority.

(4) A public officer seconded to the Authority shall, during the period of secondment, be deemed to be an officer of the Authority and shall be subject only to the direction and control of the Authority.

Common Seal of the Authority.

17. (1) The common seal of the Authority shall be kept in such custody as the Authority may direct and shall not be used except on the order of the Board.

(2) The common seal of the Authority when affixed to a document and authenticated shall be judicially and officially noticed and unless and until the contrary is proved, any necessary order or authorization of the Board under this section shall be presumed to have been given.

Liability of the Board and Staff.

18. Nothing done by a member of the Board or any officer, employee or agent of the Authority shall, if the matter or thing is done in good faith for executing the functions, powers and duties of the Authority render the member, officer, employee or agent personally liable to any action, claim or demand whatsoever.

The Registrar.

19. (1) The Director-General shall be the Registrar of the Authority.

(2) The Registrar shall perform such duties and exercise such powers, in addition to those required under the provisions of this Act to be performed and exercised, as the Board may from time to time direct.

Scientific Advisory Committees.

20. (1) The Board may establish such scientific advisory committees of the Authority, as may be necessary for the effective performance of the functions of the Authority.

(2) The scientific advisory committees established under subsection (1) shall be in addition to those established in the Second Schedule to this Act.

(3) The primary role of the advisory committees shall be to provide the Board of the Authority with expert, independent advice on complex scientific issues presented to the Authority.

(4) The Board of the Authority may co-opt into the membership of committees established under subsections (1) and (2), other persons whose knowledge and skills are found necessary for the functions of the Authority.

(5) A committee may be established for any purpose, or combination of purposes, connected with the execution of this Act or the exercise of any power conferred by it, either generally or in relation to any particular class of substances or articles to which any provision of this Act is applicable.

(6) Without prejudice to the generality of subsection (3), in relation to any such class of substances or articles, a committee may be established under this section for either or both of the following purposes—

(a) giving advice with respect to safety, quality or efficacy of health products and technologies; or

(b) promoting the collection and investigation of information relating to adverse reactions, for the purpose of enabling such advice to be given.

(7) The Authority shall provide adequate staff to enable the advisory committees to perform their functions effectively.

(8) The chairperson of an advisory committee shall convene a meeting of the committee at least once every two months and shall convene an additional meeting if requested by at least four members in writing.

(9) A scientific advisory committee shall submit, at least once every six months, a report to the Board of the Authority, with respect to its activities and the Board shall submit a copy of each report to the Cabinet Secretary.

(10) The quorum of an advisory committee shall be five members including the chairperson.

PART III- HEALTH PRODUCTS AND TECHNOLOGIES

Prohibited sale of health products and technologies.

21. (1) A person shall not sell, manufacture, supply, distribute or dispense any health product or technology that—

(a) is not registered by the Authority;

(b) is adulterated;

(c) is substandard; or

(d) is falsified.

(2) A person who contravenes the provisions of subsection (1) commits an offence and shall on conviction be liable—

(a) in the case of a first offence, to a fine not exceeding one million shillings or to imprisonment for a term not exceeding three months, or to both; or

(b) in the case of a subsequent offence, to a fine not exceeding two million shillings or to imprisonment for a term not exceeding five years, or to both.

(3) Subsection (1)(a) shall not apply to the sale of a health product or technology compounded by a pharmacist or pharmaceutical technologist—

(a) in a quantity not greater than that prescribed under this Act for sale in the retail trade, subject to prescribed conditions; or

(b) in a quantity for a particular person or animal as prescribed by an approved medical practitioner as the case may be, if that health product or technology does not contain any component the sale of which is prohibited by this Act, or any component in respect of which an application has been rejected, and if that pharmaceutical product has not been advertised.

Deception and falsification.

22. (1) A person shall not—

(a) falsify health products or technologies;

(b) label, package, treat, process, sell or advertise any health product or technology in contravention of any regulations made under this Act; or

(c) make statements regarding the character, constitution, value, potency, quality, composition, merit or safety of a health product or technology in a manner that is false, misleading or deceptive.

(2) A person who contravenes subsection (1) commits an offence and shall on conviction, be liable—

(a) in the case of a first offence, to a fine not exceeding two million shillings or to imprisonment for a term not exceeding three years, or to both; or

(b) in the case of a subsequent offence, to a fine not exceeding five million shillings or to imprisonment for a term not exceeding five years, or to both.

Standards of health products and technologies.

23. (1) If a standard has been prescribed for a health product or technology, a person who manufactures, labels, packages, sells or advertises any substance in such a manner that it is likely to be mistaken for that health product or technology having met the prescribed standard, commits an offence unless the substance is the medicine in question and complies with the prescribed standard.

(2) If a standard has not been prescribed for a health product or technology but a standard for the health product or technology is contained in any of the publications specified in the Third Schedule, any person who manufactures, labels, packages, sells or advertises any other substance or article in such a manner that is likely to be mistaken for the health product or technology having met any of the standards contained in any of the publications specified in the Third Schedule, commits an offence.

(3) A person who manufactures, labels, packages, sells or advertises any health product or technology for which no standard has been prescribed, or for which no standard is contained in any of the publications specified in the Third

Schedule, commits an offence unless the health product or technology —

(a) is in accordance with the professed standard under which it is labelled, packaged, sold or advertised; and

(b) does not resemble, in a manner likely to deceive, any health product or technology for which a standard has been prescribed or which is contained in any of the publications specified in the Third Schedule.

(4) A person convicted of an offence under this section is liable—

(a) in the case of a first offence, to a fine not exceeding one million shillings or to imprisonment for a term not exceeding three years , or to both; or

(b) in the case of a subsequent offence, to a fine not exceeding two million shillings or to imprisonment for a term not exceeding five years, or to both.

Preparation of a health product or technology under conditions not meeting prescribed standards.

24. A person who manufactures, sells, prepares, preserves, packages, stores or conveys for sale any health product or technology under conditions not meeting prescribed standards commits an offence.

Factors relevant to determination of an application for a product licence.

25. In considering an application for a product licence, the Authority shall in particular take into consideration—

(a) the safety of the health products or technologies to which the application relates;

(b) the efficacy of the health products or technologies to the purpose for which they are proposed to be administered;

(c) the quality of the health products or technologies of such description, according to the specification and the method or proposed method of manufacture of the health products or technologies, and the provisions proposed for securing that the health products or technologies as sold or supplied shall be of that quality; and

(d) any other factor that the Authority considers

necessary.

Application for product licence.

26. (1) A person who intends to import, manufacture or sell a health product or technology shall apply to the Authority for the registration of the health product or health technology, in the prescribed form.

(2) An applicant under subsection (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 Authority 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 or has permanent residence or a company incorporated in Kenya.

(3) The application made under subsection (1) shall be accompanied by—

(a) a proposed label for use on the health product or technology;

(b) a copy of the manufacturing licence of the health product or technology, where applicable;

(c) a copy of the good manufacturing practice certificate from the Authority and the regulatory authority of the country where the health product or technology is manufactured;

(d) a copy of a certificate of analysis from a quality control laboratory recognized by the Authority, where applicable;

(e) a copy of the marketing authorization 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 or technology;

(h) proof of ownership of the site for the manufacture of the health product or technology, where 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;

(iii) the conditions of the registration of the health product or technology; and

(k) proof that the applicant holds—

(i) a valid practising licence issued by the body responsible for the profession of pharmacy;

(ii) a valid wholesale dealer's licence issued in accordance with this Act;

(iii) a valid licence to sell poisons issued in accordance with this Act; or

(iv) a valid manufacturing licence issued in accordance with this Act; and

(v) proof of payment of the application fees as prescribed by the Authority.

(4) An applicant shall notify the Authority of any variation to the agreement appointing the local representative within seven days of the variation.

Processing of an application for registration of a health product or technology.

27. (1) The Authority shall consider the application made under section 26, 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 the prescribed form.

(2) The Authority may, while considering the

application, 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 or technology; and

(c) the statement of the representations to be made for the promotion of the health product or technology regarding—

(i) the claim to be made for the health product or technology;

(ii) the route of administering the health product or technology;

(iii) the dosage of the health product or technology;

(iv) the storage conditions of the health product or technology;

(v) the contra-indications, the side effects and precautions, if any of the health product or technology; and

(vi) the package size of the health product or technology.

(3) When evaluating an application, the Authority may—

(a) subject a sample of the health product or technology to an evaluation by an analyst; and

(b) consider the evaluation report of the analyst that has evaluated the health product or technology.

(4) Where the Authority is not satisfied as to the quality, safety efficacy, performance or economic value of the health product or technology, it may, after providing an opportunity to the applicant to be heard, reject the application and inform the applicant the reasons for rejection in writing.

Registration during emergency.

28. (1) The Authority may, where it considers it necessary to protect public health or in the event of a threat to life or health, 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 subsection (1) shall apply to the Authority in the prescribed form.

(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 or has permanent residence or a company incorporated in Kenya.

(4) An application under subsection (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 practising licence issued by the body responsible for the profession of pharmacy;

(ii) a valid wholesale dealer's licence issued in accordance with this Act;

(iii) a valid licence to sell health products or technologies issued in accordance with this Act; or

(iv) a valid manufacturing licence issued in accordance with this Act; and

(d) proof of payment of the application fees as prescribed by the Authority.

(5) When determining an application under this section, the Authority shall consider the facts established from the valid marketing authorization for the health product or technology and the report on the assessment of the health product or technology obtained from the authority competent for health products and technologies, if available.

(6) The person to whom the certificate of registration is issued under this section, shall be responsible

for the labelling, packaging, advertising and pharmacovigilance system of the health product or technology.

(7) A provisional certificate of registration issued under subsection (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.

(8) Any variation to the agreement appointing the local representative to the application made under subsection (2) shall be notified to the Authority within seven days of the variation.

Authorization of unregistered health product or technology.

29. (1) The Authority may, in writing, authorize a person to import or distribute for a specified period to a specified person or institution a specified quantity of a particular health product or technology that is not registered.

(2) A health product or technology distributed pursuant to authorization granted under subsection (1) may be used for such purposes and in such manner and during such period as the Authority may in writing determine.

(3) A person who intends to obtain the authorization under subsection (1), for purposes other than a clinical trial, shall apply to the Authority in the prescribed form.

(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 or has permanent residence or a company incorporated in Kenya.

(5) The application made under subsection (3) shall be accompanied by—

(a) a product brochure containing relevant chemical, pharmaceutical, pre-clinical pharmacological and toxicological data and where applicable, human pharmacological and clinical data related to the health product or technology for which authority is sought;

(b) written consent of the applicant, where applicable;

(c) details of registration or pending registration of the health product or technology with any other

regulatory authority, where applicable;

(d) evidence of compliance by the manufacturer of the health product or technology with good manufacturing practice standards as determined by the Authority;

(e) reasons why a registered health product or technology 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; and

(g) proof that the applicant holds—

(i) a valid practising licence issued by the body responsible for the profession of pharmacy;

(ii) a valid wholesale dealer's licence issued in accordance with this Act;

(iii) a valid licence to sell health products or technologies issued in accordance with this Act; or

(iv) a valid manufacturing licence issued in accordance with this Act; and

(v) proof of payment of the application fees as prescribed by the Authority.

(6) Where the Authority issues an authorization under subsection (1), the person to whom the authorization is issued shall submit to the Authority—

(a) progress reports after every six months from the date of issuance of the authorization;

(b) any adverse event report, where an adverse event occurred; and

(c) a progress report within thirty days after the completion or termination of the use of the health product or technology.

(7) The Authority may, where it is of the opinion that the safety of any patient is compromised or where the scientific reasons for administering the unregistered health product or technology have changed—

(a) impose any additional conditions;

(b) request additional information;

(c) inspect the site where the unregistered health product or technology is manufactured, stored or administered; or

(d) withdraw the authorization to treat the patient.

(8) The Authority may, by notice in writing withdraw the authorization issued under subsection (1) if any of the purposes or the manner specified in subsection (2) is contravened.

(9) A health product or technology authorized under this section shall be labelled in accordance with this Act.

(10) An applicant shall notify the Authority of any variation to the agreement appointing the local representative within seven days of the variation.

(11) The requirements in this section shall apply to applications for donations of health products and technologies.

Health Products and Technologies Register.

30. (1) There is established a Health Products and Technologies Register.

(2) The Authority shall prescribe the format and the content of the Health Products and Technologies Register .

Registration of health products and technologies.

31. (1) Every application for registration of a health product or technology shall be submitted to the Registrar in the prescribed form and shall be accompanied by the prescribed particulars and samples of the relevant health product or technology and by the prescribed registration fee.

(2) The Registrar shall ensure that an application in respect of medicine which appears on the latest Kenya Essential Medicines List, Kenya Essential Diagnostics List, Kenya Essential Medical Supplies List and Kenya Essential Veterinary Medicine List or a medicine which does not appear thereon but which, in the opinion of the relevant Cabinet Secretary, is essential for national human or veterinary health is subject to such procedures as may be prescribed in order to expedite the registration.

(3) After consideration of an application and after any

investigation or inquiry which it may consider necessary, the Authority shall approve the registration if the Authority is satisfied that—

(a) the health product or technology in question is suitable for the purpose for which it is intended;

(b) the health product or technology in question complies with the prescribed requirements; and

(c) the registration of that health product or technology is in public interest.

(4) If the Authority does not approve the registration of a health product or technology, it shall cause the applicant to be notified—

(a) in writing of the reasons why it is not so satisfied; and

(b) that the applicant may, within a period of three months after the date of the notification, furnish the Registrar with the comments on the Authority's reasons for not being so satisfied.

(5) If no comments under subsection (4) are submitted by the applicant within the prescribed period, or if after consideration of any comments so submitted the Authority is still not satisfied, the Authority shall reject the application.

(6) Where the Authority has approved the registration of any health product or technology if it is satisfied of the safety, efficacy, quality, performance and economic value of the health product or technology, the Registrar shall register that health product or technology and shall enter in the register such particulars in regard to the health product or technology as are required by this Act to be so entered and shall issue to the applicant a certificate of registration in the prescribed form in respect of that health product or technology.

(7) Every health product or technology shall be registered under such name as the Authority may approve.

(8) The Registrar shall allocate to every health product or technology registered under this Act a registration number which shall be recorded in the register opposite the

name of such health product or technology and which shall be stated in the certificate of registration issued in respect of such health product or technology.

(9) Any registration under this section, including the registration of health products and technologies already registered, shall be valid for a period of ten years and may be made subject to such conditions as may with regard to the succeeding provisions of this section be determined by the Authority.

(10) No condition shall be imposed under subsection (9) where the sale of the health product or technology in question by any person other than a pharmacist is prohibited or until after the applicant has been notified in writing by the Registrar that the imposition of such condition is contemplated and invited to submit written representations to the Authority in regard to the matter.

(11) If no representations under subsection (10) are lodged with the Registrar by the applicant concerned within a period of one month after the receipt of the notification referred to in subsection (10), or if after consideration of any such representations the Authority is still of the opinion that the condition in question should be imposed, the Authority shall direct the Registrar to register the health product or technology concerned subject to the said condition.

(12) Notice of the rejection of an application under this section in respect of a health product or technology referred to in subsection (4) shall be given in the *Gazette* by the Registrar—

(a) if no appeal is lodged against the rejection within sixty days, as soon as possible after the expiration of that period; or

(b) if any appeal so lodged is dismissed, as soon as possible after the decision dismissing the appeal has been given.

(13) The Authority may reject any application if the applicant fails to meet the standards as required by this Act or any other written law.

(14) A person dissatisfied with the decision of the

Registrar may appeal to the Board within sixty days.

(15) Where a person is dissatisfied with the decision of the Board, the applicant may appeal to the High Court within thirty days from the date of the decision being communicated to him or her.

(16) The Registrar shall as soon as possible after the date of expiry of the appropriate period of appeal publish in the *Gazette* the prescribed particulars in respect of all applications for registration received by him or her prior to such date.

(17) For the purposes of this section —

(a) "Kenya Essential Medicines List, Kenya Essential Diagnostics List and Kenya Essential Medical Supplies List" means the list of essential medicines, diagnostics and medical supplies included in the latest editions of the official publications relating to guidelines for standard treatment which is compiled by the state department responsible for Health; and

(b) "Kenya Essential Veterinary Medicines List" means the list of essential medicines included in the latest edition of the official publication relating to guidelines for standard treatment which is compiled by the state department responsible for veterinary medicines.

Authorization of health products and technologies.

32. (1) A person shall not import any health product or technology unless—

(a) the imported health product or technology has been authorized through issuance of an import permit or a written authorization by the Authority; and

(b) the imported health product or technology is inspected and verified by an inspector of the Authority at the port of entry prior to its release.

(2) A batch or lot of any registered product shall not be released by the manufacturer prior to the completion of tests for conformity with standards applicable to such product and official batch or lot release by the Authority in

cases of biological therapeutics.

(3) Each applicable test conducted by the manufacturer under subsection (2) shall be made on each batch or lot after completion of all processes of manufacture and such test may affect compliance with the standard applicable to the product.

(4) The manufacturer or marketing authorization holder of any registered biological therapeutic shall submit lot summary protocol for each lot that contains registered tests and results of tests performed and, such manufacturer or marketing authorization holder may be required to submit samples of product from the specified lot to the Authority for official batch or lot release in accordance with the prescribed regulations.

(5) Every batch or lot of a registered biological therapeutic imported into Kenya or manufactured in Kenya shall be evaluated and, on being satisfied of conformity with prescribed standards and payment of prescribed fees, the Director-General shall approve its release into the market and issue a certificate of official batch or lot release in the prescribed format.

(6) The Authority may recognize and accept official lot release certificates issued by other national regulatory authorities of other countries for a specific batch or lots of biological therapeutic manufactured within the territories of those national regulatory authorities, in issuance of a certificate under this section.

(7) A person who contravenes this section commits an offence and shall on conviction be liable—

(a) in the case of a first offence, to a fine not exceeding one million shillings or to imprisonment for a term not exceeding two years, or to both; or

(b) in the case of a subsequent offence, to a fine not exceeding two million shillings or to imprisonment for a term not exceeding five years, or to both.

Parallel importation of health products

33. (1) A person shall not engage in the parallel importation of a health product or technology into Kenya

unless— and technologies.

(a) the person is incorporated as a limited liability company under the Companies Act; Cap. 486.

(b) the person has been granted a certificate of parallel importation;

(c) the person is licensed to parallel import the health product or technology;

(d) the health product or technology has a valid registration in Kenya under this Act; and

(e) the health product or technology has a valid market authorization in the country of origin.

(2) A person who wishes to undertake parallel importation of a health product or technology shall apply to the Board for a certificate of parallel importation in the prescribed manner.

(3) The Board shall establish and maintain a system that ensures that a registered parallel imported health product or technology can be traced from its sourcing, manufacturing, packaging, storage, transport to its delivery to the health facility, institution or private practice where the health product or technology is intended to be used.

(4) A person who—

(a) is the holder of a certificate of parallel importation or licensee and fails to comply with any requirement or obligation in this Act;

(b) contravenes any prohibition prescribed by the Authority; or

(c) fails to comply with any requirement imposed on that person by the Board pursuant to this Act,

commits an offence and is liable, upon conviction, to a fine not exceeding one million shillings or to imprisonment for a term not exceeding two years, or to both.

Amendment of entries in the register.

34. (1) The Registrar, on application by the holder of a certificate of registration issued in respect of a health product or technology and with the approval of the

Authority, may amend the entry in a register with respect to that health product or technology.

(2) An application for the amendment of an entry in a register shall be made to the Registrar in the prescribed form and shall be accompanied by the prescribed application fee.

(3) A person who makes an application under this section shall provide reasons for the proposed amendments to the register.

(4) If the Authority grants its approval in respect of an application submitted to it in terms of subsection (2), the Registrar shall—

(a) make the required amendments in the relevant register; and

(b) if the name of the applicant changes, issue a new certificate of registration on the prescribed form to the applicant in respect of the health product or technology, after receiving the existing certificate of registration in respect of that health product or technology for cancellation.

Transfer of certificate of registration.

35. (1) The holder of a certificate of registration may transfer, with the approval of the Authority, the certificate of registration to another person, who is duly licensed to practice the profession of pharmacy and holds a valid practising certificate to apply for the registration of a health product or technology.

(2) An application for approval of the transfer of a certificate of registration shall be made to the Registrar in the prescribed form and shall be accompanied by the certificate of registration in question and the prescribed application fee.

(3) If the Authority allows the application submitted to it in terms of subsection (2) , the Registrar shall—

(a) make the necessary entries in the register relating to the person to whom the certificate of registration is transferred;

(b) cancel the existing certificate of registration; and

(c) issue a new certificate of registration in the prescribed form to the person making the application in respect of the relevant health product or technology.

Cancellation of registration.

36. (1) The Authority shall cancel the registration of a health product or technology if—

(a) a licensee has failed to comply with a condition subject to which a particular health product or technology has been registered;

(b) a particular health product or technology does not comply with a prescribed requirement; or

(c) it is not in the public interest to make a particular health product or technology available to the public.

(2) Before cancellation of the registration of any health product or technology, the Authority shall issue a notice of cancellation of registration in writing to the holder of the certificate of registration issued in respect of that health product or technology.

(3) The notice referred to in subsection (2) shall—

(a) specify the grounds on which the decision of the Authority is based; and

(b) indicate that the person to whom the notice is directed may within one month from the date of the notice submit to the Registrar any objection, which he or she may wish to make in connection with the matter.

(4) The Authority shall direct the Registrar to cancel the registration of that health product or technology, if—

(a) no objection as contemplated in subsection (3)(b) is received; or

(b) after consideration of any comments received, the Authority is of the opinion that the registration of the health product or technology in question should be cancelled.

(5) If the holder of the certificate of registration issued

in respect of a health product or technology fails to pay the prescribed fee in respect of the retention of the registration of that health product or technology before or on the prescribed date or such later date as the Registrar, with the approval of the Authority, may determine on application by that person, the Registrar shall cancel the registration of that medicine or medical device.

Notification of registration, or cancellation of registration, in the Gazette.

37. (1) The Registrar shall give notice in the *Gazette* of the registration, or cancellation of the registration of a health product or technology in terms of this Act.

(2) The Registrar shall in such notice specify, in the case of a registration of a medicine, —

(a) the name under which that medicine is registered;

(b) the active components of that medicine;

(c) the name of the applicant;

(d) the name of the manufacturer;

(e) the registration number allocated to that medicine; and

(f) the conditions, if any, subject to which that medicine is registered;

(3) In the case of a cancellation of registration of a medical device, the Registrar shall in such notice specify—

(a) the name under which that medical device was registered;

(b) the name of the holder of the certificate of registration issued in respect of that medical device; and

(c) the number which was allocated to that medical device in terms of this Act.

Measures to ensure supply of more affordable health products and technologies.

38. The Cabinet Secretary, in consultation with the Authority, may prescribe conditions for the supply of more affordable health products or technologies in certain circumstances so as to protect the health of the public, and in particular may—

(a) prescribe the conditions under which any health product or technology which is identical in composition, meets the same quality standard and

is intended to have the same proprietary name as that of another health product or technology already registered in the Republic, but which is imported by a person other than the person who is the holder of the registration certificate of the health product or technology already registered and which originates from any site of manufacture of the original manufacturer as approved by the Authority in the prescribed manner, may be imported; or

(b) prescribe the registration procedure for, and of the use of, the health product or technology referred to in paragraph (a).

Generic substitution.

39. (1) A pharmacist or an enrolled pharmaceutical technologist may, in consultation with the person prescribing the health product or technology and the patient, dispense an interchangeable multi-source health product or technology instead of the health product or technology prescribed by a medical or dental practitioner, nurse or other person registered under the relevant statutes regulating health professionals.

(2) A medical or dental practitioner, nurse or other person registered under the relevant statutes regulating health professionals may prohibit a pharmacist or an enrolled pharmaceutical technologist from interchanging a health product or technology contemplated in subsection (1) and that fact shall be noted on the prescription.

(3) When an interchangeable multi-source health product or technology is dispensed by a pharmacist or an enrolled pharmaceutical technologist, he or she shall note the brand name or where no such brand name exists, the name of the manufacturer of that interchangeable multi-source health product or technology in the prescription book.

(4) A pharmacist or an enrolled pharmaceutical technologist shall not substitute for a prescribed health product or technology an interchangeable multi-source medicine—

(a) if the person prescribing the health product or technology has written in his or her own hand on

the prescription the words 'no substitution' next to the item prescribed;

(b) if the retail price of the interchangeable multi-source health product or technology is higher than that of the prescribed health product or technology;

(c) where the product has been declared not substitutable by the Authority; and

(d) unless the purchaser or patient is first informed of the same and agrees to the change.

Clinical trials.

40. (1) A health product or technology shall not be used for clinical trial unless an approval is granted by the Authority.

(2) An approval under subsection (1) shall only be granted by the Authority after approval by the relevant ethics body has been granted.

(3) A person who intends to commence a clinical trial on a health product or technology shall make an application to the Authority in the prescribed form and the application shall be accompanied by the study protocol in the prescribed format and the prescribed fee.

(4) The study protocol submitted under subsection (2) shall include a post-trial access programme to ensure access of investigational medicinal substances by participants in the trial before grant of marketing authorization by the Authority.

(5) The Authority shall prescribe guidelines for evaluation of applications made under subsection (2) to be implemented for accelerated evaluations during emergency situations, epidemics and outbreaks.

(6) A person granted an approval under this section shall put in place a robust quality assurance system to ensure that the clinical trial is carried out in a manner that ensures the integrity of data generated and the safety and well-being of the participants of the study.

(7) The Authority shall carry out inspection of the clinical trials and monitor compliance of the clinical trials

with the prescribed requirements.

(8) Any amendments to clinical trials protocols shall be submitted to the Authority for approval before implementation.

PART IV — SCHEDULED SUBSTANCES

Preparation of lists of scheduled substances.

41. (1) The Authority shall prepare and submit to the Cabinet Secretary lists of substances which are to be treated as scheduled substances for the purposes of this Act.

(2) The lists to be prepared under this section shall include—

(a) substances which, subject to this Act, are not to be sold except by authorized sellers of scheduled substances and by licenced wholesale dealers;

(b) substances which, subject to this Act, are not to be sold except by persons specially licensed to do so; and

(c) any other substance declared to be a scheduled substance by the Authority.

(3) The Cabinet Secretary shall publish in the *Gazette* the list of scheduled substances prepared under subsection (1).

(4) The Cabinet Secretary may confirm the list with or without modification, and may, after consultation with or on the recommendation of the Authority, by order amend or vary the list.

(5) The Authority shall at least once every two years, review the lists under subsection (3), or whenever necessary in the interest of public health and safety.

(6) Any modification of the list of scheduled substances prepared under this section shall be subject to the procedure provided in subsections (1), (2) and (3).

Possession of scheduled substances.

42. (1) The following persons may be in possession of scheduled substances, but to the extent only and subject to the following limitations —

(a) a wholesale dealer licensed under this Act, for the purposes of the licence and on the premises so

licensed;

(b) an authorized seller of scheduled substances, on premises registered by the Authority;

(c) a person, institution or department, to which a scheduled substance has been lawfully sold under this Act, for the purpose for which the sale was made;

(d) a person for whom the scheduled substance has been lawfully supplied or dispensed by a qualified medical practitioner, dentist or veterinary surgeon, or by a hospital, dispensary or similar institution; subject to any conditions which may be prescribed, a representative of the person engaged in the business of selling and supplying pharmaceutical goods, for the purpose of giving free samples of those goods, in the course of the business, to persons who may lawfully be in possession of scheduled substances;

(e) the personal representative of a deceased person, or the liquidator, receiver or other person appointed to deal with the property of a bankrupt person or of a company which is being wound up compulsorily, or the manager of the estate of a person of unsound mind, in respect of poisons in the possession of the deceased person, bankrupt person, company or person of unsound mind at the time of death or bankruptcy or the beginning of the winding up of the order appointing the manager, for the purpose of disposing of the scheduled substances, with the written permission of the Authority and in accordance with its directions, to a wholesale dealer in scheduled substances licensed under this Act or to an authorized seller of scheduled substances.

(2) A person who is in possession of a scheduled substance otherwise than in accordance with the provisions of this section commits an offence and shall on conviction, be liable to a fine not exceeding two million shillings or to

imprisonment for a term not exceeding three years; or to both.

Wholesale Dealer's Licence.

43. (1) If the Authority is satisfied that it is in the public interest that a licence to deal as a wholesale dealer in scheduled substances should be issued or renewed it may, on application being made to the Authority in writing on such form as may be prescribed, and on payment of the prescribed fee, issue to the applicant a licence in the form prescribed, or, as the case may be, renew the licence.

(2) The Authority may refuse to issue or renew, or may revoke, a licence under this section, for any good and sufficient reason relating to the applicant or licensee, or to the premises in which the business is, or is proposed to be, carried on, and in case of refusal or revocation an appeal shall lie to the Cabinet Secretary.

(3) A separate licence under this section shall be required in respect of each set of premises in which the business of the licensee is carried on.

(4) No licence shall be issued or renewed under this section relating to scheduled substances unless the person applying for or holding the licence is or has a registered pharmacist or enrolled pharmaceutical technologist in control of the distribution of the scheduled substances and who is resident in Kenya.

(5) A licence issued under this section shall be valid for a period of one year, renewable annually.

(6) The Registrar shall keep a register of all licences issued by the Authority under this section.

Power to sell scheduled substances.

44. (1) Subject to this Act, a person licenced under this Act to deal as a wholesaler dealer in scheduled substances may sell scheduled substances to—

(a) a person licenced under this Act as lawfully carrying on the business of a wholesale dealer in scheduled substances in Kenya;

(b) a person registered as lawfully carrying on the business of a pharmacist in Kenya;

(c) a qualified medical practitioner, dentist or

veterinary surgeon for purposes of medical, dental or veterinary treatment ;

(d) a hospital, dispensary or similar institution or a person or institution concerned with scientific education or research whether within or outside Kenya, where such hospital, dispensary, institution or person has been approved in that behalf by an order whether general or special, of the Cabinet Secretary, but it shall be an offence to sell scheduled substances to any of the persons or institutions specified in paragraphs (c) and (d) unless a registered pharmacist is in direct control of the scheduled substances at the premises from which they are sold.

(2) Subject to this Act, an authorised seller of scheduled substances may sell scheduled substances to any of the persons or institutions referred to in subsection (1), and in addition may sell such scheduled substances to a person who is in possession of the prescription of a qualified medical practitioner, dentist, or veterinary surgeon, in accordance with the prescription.

(3) Nothing in this section shall make it illegal for a person to sell or resell to a wholesale dealer licenced under this Act, or to an authorized seller of scheduled substances, stocks of scheduled substances which are found to be surplus to requirements, or for a person whose licence has been revoked or has expired to sell the scheduled substances in his possession at the time of revocation or expiry, if the sale takes place within three months from the time of revocation or expiry or such longer time as the Authority may allow.

(4) A person who sells a scheduled substance except in accordance with the provisions of this section commits an offence and is liable, upon conviction, to a fine not exceeding one hundred million shillings or to imprisonment for a term not exceeding ten years or to both.

Scheduled Substances Book.

45. (1) An authorized seller shall enter a record of such particulars of the scheduled substance before delivery of the scheduled substance under this Act.

(2) A record under subsection (1) shall be in the

format prescribed by the Authority and shall indicate —

(a) the date of the sale;

(b) the name and address of the purchaser;

(c) the quantity of the scheduled substances sold; and

(d) the purpose for which it is stated by the purchaser to be required.

(3) Where a scheduled substance is sold in the presence of an agent or servant of the person by whom it is to be used, or where any such sale is effected by post, the following provisions apply—

(a) before the sale is completed the seller shall obtain an order in writing signed by the purchaser showing the purchaser's name, address and occupation, the name and quantity of the scheduled substances to be purchased and the purpose for which it is required:

provided that where a person represents that he urgently requires a scheduled substance for the purpose of his or her trade, business or profession and satisfies the seller that by reason of some emergency he or she is unable before delivery to furnish the order in writing, the seller may forthwith deliver the scheduled substance to the purchaser who shall within twenty four hours of the sale furnish the seller with the written order;

(b) before the sale is completed the seller shall satisfy himself or herself that the signature on the order is that of the person by whom it purports to be signed, and that that person carries on the occupation stated in the order, being an occupation in which the scheduled substance to be purchased is properly required;

(c) the requirements of subsection (1) as to the making of entries in the Scheduled Substances Book shall be complied with, except that in place of the purchaser's signature in the Scheduled Substances Book it shall be sufficient to enter in the space provided for signature the words "signed order", together with a reference such that the

particular order may be readily identified;

(d) all signed orders and prescribed records of transactions to which this section applies shall be retained on the premises where the sales were made, for such period as shall be prescribed; and

(e) if the scheduled substance is sent by post it shall be sent by registered post or courier.

(4) A person who fails to comply with this section commits an offence and is liable, upon conviction, to a fine not exceeding one hundred thousand shillings or to imprisonment for a term not exceeding one year , or both.

Supply and dispensing of scheduled substances with therapeutic value by doctors, hospitals, etc.

46. (1) A qualified healthcare professional may supply or dispense a scheduled substance with therapeutic value for the purpose of medical, dental or veterinary treatment, as the case may be, subject to the following provisions——

(a) the scheduled substance with therapeutic value shall be distinctly labelled with the name and address of the person by whom it is supplied or dispensed; and

(b) the following particulars shall within twenty-four hours after the scheduled substance with therapeutic value has been supplied or dispensed be entered in a book used regularly for the purpose, but which need not be used exclusively for that purpose, and which shall be called the Prescription Book—

(i) the date on which the scheduled substance with therapeutic value was supplied or dispensed;

(ii) the ingredients and the quantity supplied;

(iii) the name and address of the person to whom the scheduled substance with therapeutic value was supplied; and

(iv) the name and address of the person by whom the prescription was given.

(2) An authorized seller of scheduled substances with therapeutic value may supply a scheduled substance with therapeutic value prescribed and dispensed by himself, and

in every case in which he supplies a scheduled substance with therapeutic value on prescription, whether the prescription has been drawn up by himself or not, shall enter the particulars in a prescription book in accordance with this section, but shall not in respect of the supply be required to make an entry in the Scheduled Substances in the prescription book.

(3) A person to whom subsection (1) applies who, supplies or dispenses a scheduled substance with therapeutic value otherwise than in compliance with these provisions commits an offence and is on conviction, liable to a fine not exceeding one million shillings or to imprisonment for a term not exceeding one year or both.

Labelling of containers.

47. (1) It is an offence for any person to supply any scheduled substance unless the container of the scheduled substance is labelled in the prescribed manner—

(a) with the name of the scheduled substance;

(b) in the case of a preparation which contains a scheduled substance as one of the ingredients, with the prescribed particulars as to the proportion which the scheduled substance contained in the preparation bears to the total ingredients;

(c) with the word "Scheduled Substance" or other prescribed indication of the character of the article;

(d) if supplied on sale other than wholesale, with the name of the seller and the address of the premises on which it is sold; and

(e) if supplied otherwise than on sale, with the name and address of the supplier.

(2) The provisions of the subsection 1 (a), (b) and (c) shall not apply in respect of a scheduled substance made up and supplied for the use of a particular person being a scheduled substance prescribed by reference to the needs of that person.

(3) Any person who commits an offence under this section is upon conviction, liable to a fine not exceeding one million shillings, or to imprisonment for a term not

exceeding one year, or to both.

Automatic machines.

48. (1) An authorized seller may use an automatic machine to dispense over-the-counter scheduled substances.

(2) The Authority shall develop regulations on the—

(a) classes of substances permitted;

(b) quantities of substances to be dispensed;

(c) records of substances dispensed;

(d) location of automatic machines; and

(e) registration of automatic machines.

Electronic sale of health products and technologies.

49. (1)The Authority shall prescribe regulations to provide for the electronic supply and dispensing of scheduled substances including through e-pharmacy, telemedicine, medication therapy management and online pharmacy.

(2) The regulations made under subsection (1) shall provide for—

(a) licensure of e-pharmacies;

(b) safety of patients;

(c) verification of the identity and traceability of patients;

(d) verification of the identity and traceability of prescribers; and

(e) integrity, legitimacy and authenticity of prescriptions including avoidance of multiple use of the same prescription.

(3) The electronic supply and dispensing of scheduled substances shall be permitted provided that the supply of such health products and technologies conforms with all requirements for the particular health product or technology in terms of its scheduling status and any other requirements as may be specified in regulations in relation

to such supply or dispensing.

(4) In the case of a prescription-only medicine, the required prescription shall have been obtained as a result of at least one physical interaction between an authorised practitioner and the patient within a period of at least six months.

(5) A person who contravenes this section shall be guilty of an offence, and shall on conviction, be liable to a fine not exceeding one million shillings, or to imprisonment for a term not exceeding one year, or to both.

Dietary supplements.

50. (1) A dietary supplement shall—

(a) have a stated or implied therapeutic purpose; and

(b) not contain a scheduled substance.

(2) Where a supplement contains a dietary ingredient, the maximum daily dose for the dietary ingredient shall be as per the guidelines prescribed by the Authority.

PART V—MANUFACTURE OF HEALTH PRODUCTS

Licence to manufacture health products.

51. (1) A person shall not manufacture any health product unless the person has been granted a manufacturing licence by the Authority.

(2) A manufacturing licence issued under this section shall be valid for a period of one year, renewable annually.

(3) A person shall not manufacture any health product for sale unless the person has applied for and obtained a licence from the Authority in respect of each health product intended to be manufactured.

(4) Any person who intends to manufacture a health product shall make an application in the prescribed form for the licensing of the premises and the application shall be accompanied by the prescribed fee.

(5) In issuing a licence, the Authority may prescribe any licensing conditions that it considers necessary.

(6) The Authority shall prescribe regulations setting out conditions for the qualifications of personnel involved in the production processes of a health product regulated

under this Act.

(7) The personnel qualified to conduct lot release of vaccines and batch release of health products shall submit their qualifications to the Authority.

(8) A person who commits an offence under this section shall on conviction, be liable to a fine not exceeding ten million shillings, or to imprisonment for a term not exceeding ten years, or to both.

Compliance with good manufacturing practice.

52. (1) A person who is granted a manufacturing licence under section 51 shall comply with the good manufacturing practices prescribed by the Authority.

(2) The Authority shall have power to enter and inspect manufacturing premises to confirm compliance with prescribed good manufacturing practices and issue a certificate of compliance in the prescribed format upon payment of prescribed fees.

(3) The Cabinet Secretary shall make regulations for the better carrying out of the provisions of this section.

(4) Without prejudice to the generality of subsection (3), the Cabinet Secretary shall make regulations on—

(a) revocation and suspension of manufacturing licences;

(b) withdrawal of revocation of manufacturing licences upon request; and

(c) transfer of manufacturing licences.

PART VI—THERAPEUTIC COSMETICS

Prohibited sale of therapeutic cosmetics.

53. (1) A person shall not sell any therapeutic cosmetic that—

(a) contains any substance that may cause injury to the health of the user when the therapeutic cosmetic is used—

(i) according to the directions on the label of or accompanying such therapeutic cosmetic; or

(ii) for such purposes and by such methods of use as are customary or usual thereof; or

(b) consists in whole or in part of, any filthy, disgusting, rotten, decomposed or diseased substance or of any injurious foreign matter; or

(c) was prepared, preserved, packed or stored under insanitary conditions.

(2) A person who contravenes subsection (1) commits an offence.

Standards of therapeutic cosmetics.

54. If a standard has been prescribed for a therapeutic cosmetic, any person who labels, packages, sells or advertises any article in such a manner that it is likely to be mistaken for a therapeutic cosmetic of the prescribed standard commits an offence.

Information that is required to be displayed on the pack.

55. (1) A person dealing in a therapeutic cosmetic shall indicate—

(a) the common name of the therapeutic cosmetic;

(b) the net weight of the theraupetic cosmetic;

(c) all the cosmetic ingredients in the order of prominence but not including flavours or fragrances;

(d) the name and address of the manufacturer of the therapeutic cosmetic;

(e) a warning statement; and

(f) a statement that the therapeutic cosmetic is capable of curing or treating any disease or medical condition.

(2) The Cabinet Secretary shall make regulations for the effective implementation of this section.

(3) The regulations made under subsection (2) may—

(a) require manufacturers of cosmetics to register with the Authority; and

(b) impose restrictions, requirements or other conditions on manufacturers of cosmetics, if such restrictions, requirements or conditions are necessary to protect public health.

Preparation of therapeutic cosmetic under insanitary conditions.

56. Any person who sells, prepares, preserves, packages, conveys, stores or displays for sale any therapeutic cosmetic under insanitary conditions commits an offence and shall on conviction be liable to a fine not exceeding one million shillings, or to imprisonment for a term not exceeding two years, or to both.

Restriction on supply of therapeutic cosmetics.

57. Any therapeutic cosmetic which contains a scheduled substance or claims to treat, diagnose or prevent disease, or affect the structure or functions of the body shall be treated as a health product or technology.

Therapeutic cosmetics register.

58. The Registrar shall keep a register of all therapeutic cosmetics which shall be known as a Therapeutic Cosmetics Register.

Prohibited Ingredients.

59. (1) The Authority, in public interest, may prohibit any ingredient contained in therapeutic cosmetics by notice in the *Gazette.*

(2) Except as otherwise provided in regulations, a cosmetic shall not contain any prohibited ingredient.

(3) A person who manufactures, sells, supplies, imports or exports a therapeutic cosmetic which contains a prohibited ingredient commits an offence and, shall on conviction, be liable to a fine not exceeding one million shillings, or to imprisonment for a term not exceeding two years, or to both.

PART VII—MEDICAL DEVICES

Medical Devices Register.

60. (1)The Registrar shall keep in the prescribed form a register of all medical devices approved by the Authority.

(2) The Register under subsection (1) shall contain all such particulars in regard to such medical devices and the holder of the certificate of registration in respect of such medical devices as are required by this Act or any other law to be entered therein.

Prohibited sale of medical devices.

61. (1)A person shall not sell any medical device that is —

(a) not registered by the Authority;

(b) adulterated;

(c) substandard, falsified, falsely labelled or

counterfeited; or

(d) which fails to comply in any way with the specifications of this Act or any other law.

(2) Any person who sells any medical device that, when used according to directions on the label or contained in a separate document delivered with the medical device or under such conditions as are customary or usual, may cause injury to the health of a purchaser or its user commits an offence.

Deception.

62. Any person who labels, packages, treats, processes, sells or advertises any medical device in contravention of this Act or any other law, or in a manner that is false, misleading or deceptive as regards its character, value, composition, merit or safety, commits an offence and shall, on conviction be liable to a fine not exceeding two million shillings, or imprisonment for a term not exceeding three years, or to both.

Standards of medical devices.

63. (1) Where a standard has been prescribed for a medical device, any person who labels, packages, sells or advertises any article in such a manner that it is likely to be mistaken for that medical device commits an offence unless the article complies with the prescribed standard.

(2) The Authority in accordance with the most recent World Health Organization prescribed guidelines on good manufacturing practice may issue standards to ensure that medical devices are designed and produced in a way that ensures that the exposure of a patient, the user, or any other person, to radiation is minimized, having regard to the levels of radiation required to enable the medical device to perform its therapeutic and diagnostic functions and the intended purpose of the medical device.

(3) The Authority shall receive from the Kenya Nuclear Regulatory Authority established under the Nuclear Regulatory Act documented evidence of radiation required to enable a medical device perform its therapeutic and diagnostic functions and the intended purpose of the device, for issuance of a registration certificate for a medical device.

Cap, 243.

(4) An importer, distributor or dealer shall establish and implement documented procedures for the maintenance

of importation or distribution records and shall maintain an importation or distribution record of each medical device to be submitted to the Authority.

Offences relating to medical devices.

64. (1) A person who sells, manufactures, packages, stores or conveys for sale any medical device under unregistered establishments for medical devices and insanitary conditions commits an offence.

(2) A person who knowingly sells a medical device that has a measuring function that does not provide accurate, precise and stable measurements within the limits indicated by the manufacturer and having regard to the intended purpose of the device commits an offence.

(3) A person who sells or supplies unapproved medical devices commits an offence and shall, on conviction be liable to a fine not exceeding one million shillings or to imprisonment for a term not exceeding two years, or to both.

Registration of medical devices establishment.

65. (1) An application for registration of a medical devices establishment shall be submitted to the Authority in the prescribed format and shall be accompanied by the prescribed fees.

(2) An importer, distributor or dealer will establish a system of notification of field safety corrective action and shall notify the Authority of such system.

(3) Where the Authority is satisfied that the application under subsection (1) meets the prescribed requirements, the Director-General shall issue a registration certificate for the medical devices establishment in the prescribed format.

(4) A medical devices establishment registration certificate issued under this section shall be valid for a period of one year, renewable annually upon application in accordance with the prescribed conditions.

(5) The registration certificate for manufacturers shall be valid for five years following a successful reinspection.

(6) The Authority may refuse to issue a medical devices establishment registration certificate where—

(a) an applicant has made a false or misleading statement in the application;

(b) the Authority has reasonable grounds to believe that issuing the medical devices establishment registration certificate will constitute a risk to the health or safety of patients, users or other persons; or

(c) an applicant has failed to meet the prescribed conditions for medical devices establishment registration.

(7) Where the Authority does not issue a medical devices establishment registration certificate under subsection (6), the Authority shall—

(a) notify the applicant in writing of the reasons for refusing the registration of the establishment; and

(b) cause the applicant to be notified that the applicant may, within a period of three months from the date of notification, furnish the Authority with additional relevant documentation or evidence in support of the application.

(8) After the issuance of a medical devices establishment registration certificate, where there is a change to any of the information submitted at the time of application, the holder of the registration certificate shall submit the new information to the Authority within ten working days of the change.

PART VIII-THE NATIONAL PHARMACOVIGILANCE SYSTEM

Pharmacovigilance.

66. (1) The Authority shall establish a National Pharmacovigilance Centre which shall set up and manage the national pharmacovigilance and post marketing surveillance system.

(2) The Centre established under subsection (1) shall receive and maintain all relevant information about suspected adverse drug reactions and adverse events to health products or technologies which have been authorized by the Authority.

(3) The Authority shall conduct both passive surveillance and active surveillance of health products and technologies.

(4) The Authority shall carry out pharmacovigilance audits and inspections in order to ensure compliance with good pharmacovigilance practices and the prescribed requirements.

(5) All entities responsible for placing a health product or technology in the market shall establish and maintain a pharmacovigilance system for managing safety information of health products and technologies.

(6) The entities referred to in subsection (5) shall submit safety information to the Authority in the prescribed manner.

(7) The consumers, general public and health care professionals shall report adverse reactions and adverse events to the Authority in the prescribed manner.

PART IX—NATIONAL QUALITY CONTROL LABORATORY

Establishment of the National Quality Control Laboratory.

67. (1) There is established a National Quality Control Laboratory of the Authority which shall be used as a facility for—

(a) the examination and testing of health products and technologies including vaccines and biopharmaceuticals and any material or substance from or with which and the manner in which drugs may be manufactured, processed or treated and ensuring the quality control of drugs and medicinal substances;

(b) performing chemical, biological, bio-chemical, physiological and pharmacological analysis and other pharmaceutical evaluation;

(c) testing, on behalf of the Government, of locally manufactured and imported health products and technologies in the Kenyan market prior to marketing authorization, redistribution and post-distribution;

(d) providing technical support to local manufacturers

and building their capacity in matters pertaining to quality control of regulated products through on site and off-site training and laboratory assessments;

(e) conducting investigations into the quality and safety status of regulated products developing and administering a data bank on quality assurance of all health products and technologies and generating scientific evidence and reports on the quality and safety status of the registered products;

(f) conducting research and training and providing high quality analytics and expert knowledge in the areas of health products and technologies and active pharmaceutical ingredients; and

(g) developing and administering a data bank on quality assurance on behalf of the Authority.

(2) The National Quality Control Laboratory shall be the quality control laboratory of health products and technologies for the Authority.

(3) The Board shall appoint a Director of the National Quality Control Laboratory who shall be responsible to the Authority for the day-to-day management of the National Quality Control Laboratory.

(4) The Director of the National Quality Control Laboratory shall hold office on such terms and conditions of service as may be specified in the instrument of appointment by the Board.

(5) The Director of the National Quality Control Laboratory shall be a registered pharmacist and shall possess a Master's degree in a science related field from a recognized university.

(6) The Director of the National Quality Control Laboratory shall—

(a) oversee and coordinate all operations and administration of the National Quality Control Laboratory and provide technical guidance on quality control;

(b) ensure timely quality control testing of all samples

in conformity with national and international standards;

(c) co-ordinate and supervise the activities of the National Quality Control Laboratory including staff;

(d) collaborate with other laboratories, regulatory and law enforcement agencies to ensure quality in health products and technologies;

(e) handle appeals on test results;

(f) where the laboratory lacks capacity, subcontract laboratory testing services;

(g) advice the Authority on matters of testing and quality control over health products and technologies; and

(h) perform any other duties assigned by the Authority from time to time.

(7) The funds to be used for the management of the National Quality Control Laboratory shall consist of all moneys received or recovered under this Part and a portion of the monies appropriated by the National Assembly to the Authority.

(8) Subject to subsection (7), the monies generated by the National Quality Control Laboratory in the course of the performance of its functions under this section shall be solely expended on the Laboratory.

Certificate of analysis.

68. (1) A certificate of analysis shall be issued and signed by the Director of the National Quality Control Laboratory for every analysis done by the National Quality Control Laboratory.

(2) The certificate of analysis issued under subsection (1) shall be in the prescribed form.

PART X—ADVERTISEMENTS AND LABELLING

Advertisement of health products and technologies.

69. (1) Subject to the provisions of this Act, no person shall advertise any health product and technology except with the written permission of the Authority.

(2) An application for the advertisement of any health

product and technology shall be made to the Authority in the prescribed form and shall be accompanied by the prescribed fee.

Prohibition of advertisements as to certain diseases etc.

70. (1) Subject to this Act, a person shall not take part in the preparation or publication of an advertisement referring to a health product or technology of any description in terms which are calculated to imply that the health product or technology may be effective for any of the purposes specified in the Fourth Schedule under this Act.

(2) In proceedings for the contravention of subsection (1), it shall be a defence for the person charged to prove that the advertisement to which the proceedings relate was published only so far as was reasonably necessary to bring it to the notice of one or more persons of the following classes—

(a) members of Parliament;

(b) members of the board of a hospital;

(c) duly qualified medical practitioners, dentists and veterinary surgeons;

(d) registered pharmacists or enrolled pharmaceutical technologists, authorized sellers of scheduled substances and licenced wholesale dealers; or

(e) persons carrying on business which includes the sale or supply of surgical appliances, or that the advertisement was so published in connection with an application for a patent submitted to the appropriate authority so far only as was requisite for the purpose of the application.

Prohibition of advertisement as to abortion.

71. Subject to this Act, a person shall not take part in the publication of an advertisement referring to a health product or technology of any description, in terms which are calculated to lead to the use of the health product or technology for procuring the miscarriage of women.

Prohibition of misleading or false advertisements.

72. Subject to this Act—

(a) a person shall not take part in the publication of an advertisement referring to a health product or technology in terms which in the opinion of the

Authority are considered to be false or misleading and to bear little or no relation to the pharmacological properties and action of the ingredients or the component or correct use of the health product or technology;

(b) a person shall not in an advertisement claim that the therapeutic efficacy of a health product or technology or use of a health product or technology is other than that for which the drug has been registered by the Board in terms of this Act or state or suggest that such health product or technology should be used for a purpose, under a circumstance, or in a manner, other than that for which it is registered by the Authority.

Defences for offences related to advertisements.

73. (1) In proceedings for contravention of any of the provisions of sections 71 and 72—

(a) that an advertisement was published referring to a health product or technology of any description, in terms calculated to lead to the use of the drug, appliance or article—

(i) in the case of contravention of section 70, for the treatment of any of the human ailments referred to in subsection (1) of that section; or

(ii) in the case of a contravention of section 71, for procuring the miscarriage of women; and

(b) that the advertisement also referred to the health product or technology in terms calculated to indicate that it was manufactured, produced, imported, sold or offered for sale by the person charged,

unless the contrary is proved, it shall be presumed for the purpose of those proceedings that that person took part in the publication of the advertisement, but without prejudice to the liability of any other person.

(2) In proceedings for contravention of any of the provisions of sections 69, 70, 71 and 72, it shall be a defence for the person charged to prove—

(a) that the advertisements to which the proceedings relate was published in such circumstances that he

did not know and had no reason to believe that he was taking part in the publication; or

(b) that the advertisement was published only in a publication of a technical character intended for circulation only amongst persons of the following classes, or of one or some of them—

(i) qualified medical practitioners, dentists and veterinary surgeons;

(ii) registered pharmacists, enrolled pharmaceutical technologists and authorized sellers of Scheduled Substances;

(iii) persons undergoing training with a view to becoming qualified medical practitioners, dentists or veterinary surgeons, or registered pharmacists; or

(iv) persons carrying on business which includes the sale or supply of surgical appliances.

Labelling of health products and technologies containing medicine.

74. (1) Subject to this Act, a person shall not sell by retail a health product or technology consisting of or comprising a substance recommended as a medicine unless there is written so as to be clearly legible on the health product or technology or on a label affixed thereto, or if the health product or technology is sold or supplied in more than one container, on the inner container or on a label affixed thereto—

(a) the appropriate designation of the substance so recommended or of each of the active constituents, or of each of the ingredients from which it has been compounded; and

(b) in a case where the appropriate designation of each of the active constituents or ingredients is written, the appropriate quantitative particulars of the constituents or ingredients.

(2) Subsection (1) shall not apply to a health product or technology made up and supplied for the use of a particular person, being a health product or technology prescribed by reference to the needs of that person.

(3) In subsection (1)—

"appropriate designation", in relation to a substance, constituent or ingredient, means—

(a) in a case where the substance, constituent or ingredient is a scheduled substance included in the schedules under this Act, the name with which the container of the scheduled substance is for the time being required to be labelled in accordance with this Act or regulations made under this Act; or

(b) in a case where the substance, constituent or ingredient is not such a scheduled substance and is described in any of the monographs contained in the edition of the *British Pharmatocopœia* or the *British Pharmaceutical Codex* or the *International Pharmacopœia* or the *British Veterinary Codex* which was last published before the date on which the health product or technology was sold or supplied, the description set out at the head of that monograph;

(c) in a case where the substance, constituent or ingredient is not such a scheduled substance and is not so described, the accepted scientific name, or other name descriptive of the true nature of the substance, constituent or ingredient, and in all cases the appropriate name of the substance shall be written in English;

"appropriate quantitative particulars", in relation to the active constituents or the ingredients of a substance, means—

(a) the approximate percentage of each of those constituents or ingredients contained in the substance or the approximate quantity of each of those constituents or ingredients contained in the health product or technology sold or supplied or contained in a defined quantity of the health product or technology ; or

(b) in the case where the health product or technology consists of or comprises a number of separate portions of the substance, either the approximate

percentage or quantity or the approximate quantity of each of the constituents or ingredients contained in each portion;

"container" includes a wrapper.

(4) If a person sells or supplies a health product or technology in contravention of this section, subject to this Act, the person commits an offence and upon conviction, is liable—

(a) in the case of a first conviction, to a fine not exceeding one million shillings or to an imprisonment term not exceeding two years or to both;

(b) in the case of a subsequent conviction, to a fine of at least two million shillings or to imprisonment to a term not exceeding three year or to both.

Proceedings on charge concerning labelling.

75. Where a person is charged with an offence under this Act by a reason of the person having sold or been in possession of a container containing a health product or technology, and the container seems to have been packed by the manufacturer of the contents and to be intact, the container shall be presumed to contain health products and technologies of the description specified on the label, until the contrary is proved.

Appeal from proceedings on charge concerning labelling.

76. An appeal under any section shall be in writing and shall be lodged within thirty days after the date of the act appealed against.

PART XI—ADMINISTRATION AND ENFORCEMENT

Power to prohibit or control certain health products and technologies.

77. (1) The Cabinet Secretary, on the recommendation of the Authority may, by order, prohibit or control the manufacture, sale, advertisement or possession of any secret, patent, proprietary. health products and technologies.

(2) A person who contravenes an order made by the Cabinet Secretary under subsection (1) commits an offence.

Authorized sale or supply of unregistered health products and technologies.

78. (1) The Authority may authorise a registered pharmacist, in writing, to supply a specified quantity of a particular health product or technology including a health product and technology for emergency use, which is subject to registration under this Act, but is not registered, during a specified period and to a specified person or institution.

(2) A health product or technology supplied under the authority granted in terms of this section may be used for such purposes, in such manner and during such period, as the Authority may determine in writing.

(3) Subsequently, if effect is not given to a determination made in terms of this section, or if the Authority is of the opinion that the risks of supplying a specified quantity of a particular health product or technology in terms of this section, outweigh the potential benefits, the Authority may at any time, in writing, withdraw any such authority granted.

Retention and disposal of health products and technologies seized.

79. (1) A health product or technology or document seized under the provisions of this Act may be retained for a period not exceeding one month or if within that period proceedings are commenced for an offence under this Act in respect of that health product or technology or document, until the final determination of those proceedings.

(2) Where a magistrate is satisfied that any such health product or technology is of a perishable nature or that by reason of the fact that the market for the drug or article is seasonal, or for any other reason, delay in disposing the health product or technology would unduly prejudice the owner, the magistrate may authorize the sale or other disposal of the health product or technology.

(3) Where proceedings are taken for an offence under this Act or any rules thereunder the court by or before which the alleged offender is tried may make such order as to the forfeiture or other disposal of any health product or technology in respect of which such offence was committed as the court shall see fit.

(4) In this section, references to a health product or technology shall be construed as including the proceeds of a sale effected in accordance with the provisions of

subsection (2).

Authority to be supplied with information.

80. The Authority may—

(a) by notice in writing, require a person, who manufactures, supplies, administers or prescribes a health product or technology, or on whose direction a health product or technology is manufactured, supplied or administered, to furnish the Authority, within a period specified in that notice, with information, which is in that person's possession or which that person is in a position to obtain with respect to that health product or technology.

(b) if requested by a person to whom a notice under this section is addressed, extend the period specified in that notice.

Inspection of licences and books.

81. (1) An authorized or licenced seller of any scheduled substance health product or technology shall, on the demand of a regulatory officer, produce for inspection his certificate of registration or his licence as the case may be.

(2) All books kept by any seller of scheduled substances, health product or technology, medical practitioner, dentist or veterinary surgeon, or by a hospital, dispensary or similar institution, in accordance with the provisions of this Act or any rules thereunder, shall be open for inspection by a regulatory officer at all reasonable times.

Obstruction of Regulatory Officers.

82. A person who obstructs or hinders a regulatory officer in the lawful exercise of the powers conferred by this Act commits an offence.

Vicarious criminal responsibility.

83. (1) An act which if done by an individual would be an offence under this Act or by any rules thereunder shall, if done by a body corporate, be an offence by every director, secretary and manager unless it is proved that the offence was committed without the individual's consent or connivance and that the individual exercised all such diligence to prevent the commission of the offence as the individual ought to have exercised having regard to the nature of the individual's functions in that capacity and to

all the circumstances.

(2) If an offence against this Act or any rules thereunder has been committed by a partner in a firm, every person who at the time of the commission of the offence was a partner in that firm, or was purporting to act in that capacity, shall be deemed to be guilty of that offence unless the person proves that the offence was done without the person's consent or connivance and that the person exercised all such diligence to prevent the commission of the offence as the person ought to have exercised having regard to the nature of the person's functions in that capacity and to all the circumstances.

Penal sanctions with regard to body corporates.

84. (1) If—

(a) a body corporate has been convicted of an offence under this Act or any other rules thereunder; or

(b) a member of the Authority or an officer of a body corporate, or a person employed by a body corporate in carrying on a business has been convicted of any such criminal offence, or been guilty of misconduct which in the opinion of the Authority renders the person, or would if the person were a registered pharmacist render the person, unfit to be on the register, then, whether the body corporate was or was not an Authorized Seller of scheduled substance, health product or technology at the time when the offence or the misconduct was committed, the Authority may inquire into the case and may, subject to this Act direct—

(i) that the body corporate shall, in a case where it is an Authorized Seller of scheduled substance health product or technology, cease to be a seller and, in any case, be disqualified for such period as may be specified in the direction from being an authorized seller of scheduled substance health product technology; or

(ii) that all or any other of the premises of the body corporate shall, in a case where they are registered in the register of premises kept in pursuance under this Act, be removed from

that register and in any case be disqualified for such period as may be specified in the directions from being registered therein.

(2) A body corporate may appeal to the Cabinet Secretary against a direction given under this section.

Inspection and verification of health products and technologies at the ports of entry.

85. (1) A person who imports a health product or technology shall notify the inspectors of the Authority at the port of entry to conduct pre-clearance inspection and verification.

(2) A person who imports a health product or technology and causes it to be released to the market without inspection and verification under subsection (1) commits an offence.

(3) A person who commits an offence under this section shall on conviction, be liable to a fine not exceeding three million shillings, or to imprisonment for a term not exceeding two years, or to both.

Powers of Regulatory Officers.

86. (1) A regulatory officer may, at any hour reasonable for the proper performance of duty—

(a) enter any premises where the regulatory officer believes any health product or technology to which this Act or any regulations made thereunder apply is prepared, preserved, packaged, stored or conveyed, examine any such health product or technology and take samples, and examine anything that the regulatory officer believes is used or capable of being used for such preparation, preservation, packaging or storing or conveying;

(b) stop or search or detain any aircraft, ship or vehicle or any other vessel in which the regulatory officer believes that any health product or technology subject to the provisions of this Act is being conveyed and to examine any such health product or technology and take samples for the purposes of this Act;

(c) open and examine any receptacle or package which the regulatory officer believes contains any health product or technology to which this Act or any regulations made thereunder apply;

(d) examine any books, documents, or other records found in any place mentioned in paragraph (a) of subsection (1) that the regulatory officer believes contain any information relevant to the enforcement of this Act with respect to any health product or technology to which this Act or any regulations made apply and make copies or take extracts;

(e) seize and detain for such time as may be necessary any health product or technology by means of or in relation to which he believes any provision of this Act or any regulations made thereunder has been contravened.

(2) A regulatory officer acting under this section shall, produce his authority.

(3) Any owner, occupier or person in charge of any premises entered by a regulatory officer pursuant to paragraph (a) of subsection (1), or any person found therein, who does not give to the regulatory office all reasonable assistance the person's power and furnish the regulatory officer with such information as the regulatory officer may reasonably require, shall be guilty of an offence.

(4) Any person who obstructs or impedes any regulatory officer in the course of the regulatory officer's duties or by any gratuity, bribe, promise, or other inducement prevents, or attempts to prevent the due execution by the regulatory officer of the regulatory officer's duty under this Act or any regulations made thereunder commits of an offence.

(5) Any person who knowingly makes any false or misleading statement either verbally or in writing to any regulatory officer commits an offence.

(6) A regulatory officer shall release any health product or technology seized by the regulatory officer under this Act when the regulatory officer is satisfied that all the provisions of this Act and any regulations made thereunder with respect thereto have been complied with.

(7) Where a regulatory officer has seized a health product or technology under this Act and the owner thereof

or the person in whose possession the health product or technology was at the time of seizure consents to the destruction thereof, the health product or technology may be destroyed or otherwise disposed of as the regulatory officer may direct.

(8) Where a person has been convicted of an offence under this Act or any regulations made thereunder, the court may order that any health product or technology by means of or in relation to which the offence was committed or anything of a similar nature belonging to or in the possession of the convicted person or found with such health product or technology, be forfeited, and upon such order being made such health product or technology and things may be disposed of as the court may direct.

(9) Where any health product or technology has been seized under the provisions of paragraph (e) of subsection (1) and the owner thereof has been convicted of an offence under this Act, the health product or technology may be destroyed or otherwise disposed of as the regulatory officer may direct.

(10) Any health product or technology seized under this Act may at the option of a regulatory officer be kept or stored in the premises where it was seized or may at the direction of a regulatory officer be removed to any other proper place; and any person who removes, alters or interferes in any way with the health product or technology seized under this Act without the authority of a regulatory officer shall be guilty of an offence.

(11) A regulatory officer may submit any seized health product or technology or any sample therefrom to the National Quality Control Laboratory for analysis or examination and a public analyst shall as soon as practicable analyse or examine any sample sent to the public analyst in pursuance of this Act and shall give the regulatory officer a certificate specifying the result of the analysis or examination, and such certificate shall be in such form as may be prescribed by the Authority.

(12) In this section, "premises" includes a street, open space, place of public resort, or bicycle or other vehicle utilized for the preparation, preservation, packaging,

storage or conveyance of any health product or technology .

(13) In performing any of the functions under this Act, the regulatory officer, as the situation may require, may be accompanied and assisted by a Police Officer.

(14) The procedure to be followed by a regulatory officer in obtaining, transmitting for analysis or examination or otherwise dealing with any sample, shall be prescribed by this Act or any other law.

Power of court to order licence to be cancelled.

87. On the conviction of any person for any offence under this Act or any regulations made under the Act, the court may, in addition to or in lieu of any other penalty which it may lawfully impose, cancel any licence issued under this Act, or any regulations made under the Act, to such person.

Prosecution.

88. (1) A regulatory officer may take out proceedings for an offence under this Act or the regulations before any magistrate having jurisdiction in the place where any health product or technology sold was actually delivered to the purchaser or where the sample was taken.

(2) In any proceedings under this Act, the contents of any container appearing to be intact and in the original state of packing by the manufacturer thereof shall be deemed, unless the contrary is proved, to be a health product or technology of the description specified on the label.

Penalties.

89. (1) A person who is guilty of an offence under this Act for which no special penalty is provided shall be liable—

(a) in the case of a first offence, to a fine not exceeding five hundred thousand shillings or to imprisonment for a term not exceeding one year, or to both such fine and imprisonment; and

(b) in the case of a subsequent offence, to a fine not exceeding one million shillings, or to imprisonment for a term not exceeding two years, or to both.

(2) In any prosecution under this Act the summons shall state the particulars of the offence or offences alleged and also the name of the prosecutor and shall not be made returnable in less than fourteen days from the date on which

it is served.

Certificates of analysis and presumptions.

90. In any proceedings under this Act—

(a) a certificate of analysis purporting to be signed by a National Quality Control Laboratory shall be accepted as prima facie evidence of the facts stated;

(b) despite paragraph (a) —

(i) the party against whom it is produced may require the attendance of the public analyst for the purposes of cross-examination; and

(ii) no such certificate of a public analyst shall be received in evidence unless the party intending to produce it has, before the trial given to the party against whom it is intended to be produced, reasonable notice of such intention together with a copy of the certificate;

(c) evidence that a package containing any health product or technology to which this Act or any regulations made thereunder apply bore a name, address or registered mark of the person by whom it was manufactured or packed shall be prima facie evidence that such health product or technology was manufactured or packed, as the case may be, by that person;

(d) any substance commonly used for human consumption shall, if sold or offered, exposed or kept for sale, be presumed, until the contrary is proved, to have been sold or, as the case may be, to have been or to be intended for sale for human consumption;

(e) any substance commonly used for human consumption which is found on premises used for the preparation, storage, or sale of that substance and any substance commonly used in the manufacture of products for human consumption which is found on premises used for the preparation, storage or sale of those products, shall be presumed, until the contrary is proved, to be

intended for sale, or for manufacturing products for sale, for human consumption; or

(f) any substance capable of being used in the composition or preparation of any substance commonly used for human consumption which is found on premises on which that substance is prepared shall, until the contrary is proved, be presumed to be intended for such use.

PART XII—FINANCIAL PROVISIONS

Funds for the Authority.

91. The funds of the Authority shall consist of—

(a) such monies as may be appropriated by the National Assembly for the purposes of the Authority;

(b) such monies or assets as may accrue to the Authority in the course of the exercise of its powers or the performance of its functions under this Act;

(c) gifts, grants or donations as may be given to the Authority;

(d) monies that may be borrowed by the Board for the discharge of the functions of the Authority; and

(e) monies from any other source.

Financial year.

92. The financial year of the Authority shall be the period of twelve months ending on the thirtieth day of June in each year.

Annual Estimates.

93. (1) At least three months before the commencement of each financial year, the Board shall cause to be prepared estimates of the revenue and expenditure of the Authority of that year.

(2) The annual estimates shall make provisions for the estimated expenditure of the Authority for the financial year concerned and in particular, shall provide for—

(a) the payment of the salaries, allowances and other charges in respect of the staff of the Authority;

(b) the payment of pensions, gratuities and other charges in respect of benefits which are payable out of the funds of the Authority;

(c) the acquisition and maintenance of the buildings

and grounds of the Authority;

(d) the funding of training, research and development activities of the Authority;

(e) the proper maintenance, repair and replacement of any installation and of the equipment and other movable property of the Authority; and

(f) the creation of such funds to meet future or contingent liabilities in respect of benefits, insurance or replacement of buildings or installation or equipment and in respect of such other matters as the Authority may consider appropriate.

(3) The annual estimates shall be approved by the Authority before the commencement of the financial year to which they relate, and shall be submitted to the Cabinet Secretary for approval and after the Cabinet Secretary has given approval, the Authority shall not increase any sum provided in the estimates without the written consent of the Cabinet Secretary.

(4) No expenditure shall be incurred for the purposes of the Authority except in accordance with the annual estimates approved under subsection (3), or in pursuance of an authorization of the Authority given with the prior approval of the Cabinet Secretary.

Accounts and Audit.

94. (1) The Authority shall cause to be kept all proper books and records of account of the income, expenditure, assets and liabilities of the Authority.

(2) The Cabinet Secretary for the time being responsible for finance may prescribe the form of any book required to be kept under subsection (1) and unless a form has been prescribed, a form suitable for the purpose shall be used.

(3) Within a period of three months after the end of each financial year, the Authority shall submit to the Auditor-General the accounts of the Authority in respect of that year together with—

(a) a statement of the income and expenditure of the Authority during the financial year; and

(b) a statement of the assets and liabilities of the

Authority on the last day of that financial year.

(4) The accounts of the Authority shall be audited and reported upon by the Auditor-General.

Investment of Funds.

95. (1) The Authority may invest any of its funds in securities in which for the time being trustees may by law invest trust funds or in any other securities which the Treasury may, from time to time approve.

(2) The Authority may, with the approval of the Cabinet Secretary of the National Treasury, place on deposit with such bank or banks or financial institutions as it may determine, any monies not immediately required of the purposes of the Authority.

Annual Reports.

96. (1) The Authority shall cause an annual report to be prepared for each financial year.

(2) The Authority shall submit the annual report to the Cabinet Secretary within three months after the end of the year to which it relates.

(3) The annual report shall contain, in respect of the year to which it relates—

(a) the financial statements of the Authority;

(b) a description of the activities of the Authority;

(c) such other statistical information as the Authority considers appropriate relating to the work of the Authority; and

(d) any other information relating to the functions that the Authority considers necessary.

(4) The Cabinet Secretary shall, within thirty days, after receiving the annual report, transmit it to the National Assembly.

Special Reports.

97. The Authority may, at any time, submit a special report to the National Assembly with respect to any aspect of the functions of the Authority which the Authority considers should, in the national interest, be brought to the attention of the National Assembly because it affects a wide cross-section of the populace and there could be disastrous consequences if a report thereon is not brought to the attention of the National Assembly.

PART XIII—MISCELLANEOUS PROVISIONS

Regulations.

98. (1) The Authority shall make regulations for the better carrying out of the provisions of this Act.

(2) Without prejudice to the generality of subsection (1), the Authority may make regulations—

(a) with respect to—

(i) the labelling and packing and the offering, exposing and advertising for sale of health products and technologies;

(ii) the sale or the conditions of sale of health products and technologies; and

(iii) the use of any substance as an ingredient in any health products and technologies;

(b) to prevent the consumer or purchaser from being deceived or misled as to its quality, quantity, character, value, composition, effect, merit or safety of any health product and technology or to prevent injury to the health of the consumer or purchaser;

(c) prescribing standards of composition, strength, potency, purity, quality or other property of any health products and technologies;

(d) respecting the importation or exportation of health products and technologies in order to ensure compliance with this Act or any other law;

(e) respecting the method of preparation, preserving, packing, storing, conveying, distribution and testing of any health products or technologies;

(f) respecting the carriage of goods subject to the

provisions of this Act, including the licensing of vehicles used in such carriage;

(g) requiring persons who sell health products and technologies to maintain such books and records as the Authority considers necessary for the proper enforcement and administration of this Act and any other law;

(h) requiring the manufacturers of any health products or technologies or scheduled substances to submit test portions of any batch of such health products or technologies or scheduled substances;

(i) providing for the analysis of health products and technologies for the purposes of this Act or for any other purpose;

(j) prescribing a tariff of fees to be paid for such analysis and for prescribing methods of analysis;

(k) providing for the taking of samples of any health product or technology for the purposes of this Act or for any other purpose;

(l) exempting any health products and technologies from all or any of the provisions of this Act and prescribing the conditions of such exemption;

(m) for the method of clearance of the health products and technologies regulated by this Act from the ports of entry;

(n) prescribing forms and particulars to be provided in forms;

(o) governing donation and disposal of health products and technologies therapeutic cosmetics or scheduled substances;

(p) governing generic substitution;

(q) prohibiting, regulating or restricting the sale of specified health product or technology by any of the persons licenced under this Act or by any class of those persons;

(r) exempting from any of the provisions of this Act relating to the sale of any article;

(s) prohibiting, regulating or restricting the manufacture, sale or advertising of health products or technologies;

(t) the safe custody and storage of health products or technologies;

(u) prescribing the procedure for the declaration of commercial interest by members of the Board and Committees of the Authority;

(v) governing the electronic sale of health products and technologies;

(w) providing for the categorization and classification of medical devices;

(x) governing administration of clinical trials of health products and technologies;

(y) governing the compiling, processing, keeping, and submission of the information on donation, collection, testing, processing, distribution, transfusion and other use, exportation, importation and destruction of blood and blood products; the containers in which scheduled substance health products may be supplied;

(z) the addition to scheduled substances of specified ingredients for the purpose of rendering them readily distinguishable as scheduled substances;

(aa) prohibiting the sale by retail of a specified health product or technology or Scheduled Substance except on prescription given by a qualified medical practitioner, dentist or veterinary surgeon and for prescribing the form and regulating the use of those prescriptions;

(bb) providing for the manner in which a pharmacist, an enrolled pharmaceutical technologist or a person otherwise authorized under this Act may dispense health products or technologies ;

(cc) provide the manner and procedure in which clinical trials may be conducted in Kenya;

(dd) the compounding of health products and technologies and the dispensing of health

products and technologies ;

(ee) the period for which books or registers required to be kept for the purposes of this Act are to be preserved;

(ff) the fees to be paid for anything to be done under this Act;

(gg) a particular procedure to be observed by the Authority;

(hh) the conduct of inquiries by the Authority under this Act and the attendance of witnesses and the production of evidence thereat;

(ii) prescribing powers or duties to be performed or exercised by an analyst, methods of analysis or examination of samples for the purposes of this Act, the form of any certificate or report to be furnished in connection with such analysis or examination, or the nature or arrangement of particulars to be reflected in such a certificate or report;

(jj) on pharmacovigilance and post market surveillance;

(kk) official regulatory lot release of vaccines and other biological products imported and manufactured in Kenya;

(ll) pricing of health products and technologies;

(mm) good practices in the regulation of health products and technologies;

(nn) inspections, licensure and certification of the manufacture of health products and technologies by health facilities;

(oo) inspections, licensure and certification of manufacture of health products and technologies and other regulated products by facilities not directly regulated by the Authority including steel industries, sugar industries;

(pp) inspection and recognition of pharmaceutical quality control laboratories;

(qq) to regulate licit use of narcotic and psychotropic substances; and

(rr) to regulate parallel importation of health products and technologies.

(3) The Authority shall adhere to the principle of public participation in making regulations.

Transition and savings.

99. (1)Upon the date of coming into operation of this Act, the former Board shall be dissolved and—

(a) all assets and liabilities of the former Boards shall be transferred to and vest in the Authority without further assurance and the Authority shall have all powers necessary to take possession of, recover and deal with such assets and discharge such liabilities;

(b) every agreement, whether in writing or not, and every deed, bond or other instrument to which the former Boards was a party or which affected the former Boards, and whether or not of such a nature that the rights, liabilities and obligations thereunder could be assigned, shall have effect as if the Authority were a party thereto or affected thereby instead of the former Boards and as if for every reference (however worded and whether express or implied) therein to the former Boards there were substituted in respect of anything to be done on or after such date of coming into operation a reference to the Authority.

(c) any proceedings pending immediately before such date of coming into operation to which the former Boards was a party shall be continued as if the Authority was a party thereto in lieu of the former Boards;

(d) all members and staff of the former Board shall be deemed to be members and staff of the Authority, and subject to the provisions of any rules made under this Act, shall continue in office for the period for which they were appointed as members and staff of the former Board; and

(e) the staff of the Pharmacy and Poisons Board for

the time being working in the directorate responsible for the regulation of health products and technologies shall be deemed to be staff of the Authority, and subject to the provisions of any rules made under this Act, shall continue in office for the period for which they were appointed as staff of the Pharmacy and Poisons Board.

(2) In this section, "the former Board" means the Board of the National Quality Control Laboratory established under the Pharmacy and Poisons Act.

(3) Within a period of twenty four months from the date of coming into operation of this Act— Cap. 244.

(a) the Pharmacy and Poisons Board shall continue to exist for the purpose of the regulation of the profession of pharmacy, including the registration and licensing of pharmacists and pharmaceutical technologists;

(b) Parliament shall enact legislation providing for the regulation of the pharmacy practice; and

(c) after the expiry of the period of twenty-four months—

(i)the Pharmacy and Poisons Board shall be dissolved, and the provisions of subsection (1)(a), (b) and (c) shall, with the necessary modifications, apply; and

(ii) the remaining members and staff of the Pharmacy and Poisons Board shall be deemed to be members and staff of the Authority, and subject to the provisions of any rules made under this Act, shall continue in office for the period for which they were appointed as members and staff of the Pharmacy and Poisons Board.

Repeals.

100. (1) The enactments specified in the second column of the Fifth Schedule are repealed to the extent specified in the third column of that Schedule with reference to section 99(3).

Cap. 242.

(2) The provisions of this Act shall be in addition to and not in derogation of the provisions of the Public Health Act or its successor.

FIRST SCHEDULE (s.13)

PROVISIONS AS TO THE CONDUCT OF BUSINESS AND AFFAIRS OF THE BOARD

Meetings of the Board.

1. The Board shall meet at least four times in each year.

Special meetings.

2. The Chairperson may at any time convene a special meeting of the Board and shall do so within fifteen days of a written requisition for the meeting signed by at least three members.

Chairperson to preside.

3. (1) The Chairperson shall preside at all meetings of the Board, at which he is present and in the case of his absence, the Vice Chairperson shall preside.

(2) At a meeting of the Board at which neither the Chairperson nor the Vice-Chairperson is present, the members of the Board present shall elect one of their numbers to preside, and the person so elected shall have all the powers of the chairperson with respect to that meeting and the business transacted thereat.

Quorum.

4. The quorum for the conduct of the business of the Board shall be nine members.

Voting procedure.

5. The decisions of the Board shall be by a majority of votes, and the Chairperson of the meeting shall have an original and a casting vote.

Validity of proceedings.

6. The validity of any proceedings of the Board shall not be affected by any vacancy among the membership thereof, or by any defect in the appointment of a member thereof.

Minutes.

7. The minutes of the proceedings at meetings of the Board shall be kept in such a manner as the Council directs, and, on the written request of the Cabinet Secretary, shall be made available to him or any person nominated by him.

Committees of the Board.

8. The Board may establish such committees as may be necessary for the performance of the functions of the Board and may, subject to the provisions of this Act, delegate powers conferred on it to any such committee.

Power of the Board to regulate own procedure.

9. Subject to the provisions of this Schedule, the Board shall regulate its own procedure.

Disclosure of interest.

10. (1) If a member of the Board is directly or indirectly interested in any contract, proposed contract or other matter before the Board and is present at a meeting of the Board at which the contract, proposed contract or other matter is the subject of consideration, he shall, at the meeting and as soon as reasonably practicable after the commencement thereof, disclose the fact and shall not take part in the consideration or discussion of, or vote on, any questions with respect to the contract or other matter, or be counted in the quorum of the meeting during consideration of the matter.

(2) A disclosure of interest made under this paragraph shall be recorded in the minutes of the meeting at which it is made.

Declaration of commercial interest.

11. A member of the Board or of an Advisory Committee appointed under this Act shall declare in writing upon appointment and at any time thereafter as applicable his or her commercial interests related to the pharmaceutical or health care industry, which interests shall include, but shall not be limited to, any consultancy, paid or unpaid, any research grant from which the member directly or indirectly benefits, or any equity holding or any executive or non-executive directorship or any other payment or benefit in kind, and shall recuse himself or herself from any discussion or decision-making to which the said interests relate or may relate.

SECOND SCHEDULE (s.20(2))

SCIENTIFIC ADVISORY COMMITTEES

1. Human Health Products and Technologies Committee.
2. Pharmacovigilance Committee.
3. Cosmetics and Borderline Products Committee.
4. Clinical Trial Scientific Technical Advisory Committee.
5. Dietary Supplements Committee.
6. Digital Health and Technologies Committee.
7. Veterinary Health Products and Technologies Committee.

THIRD SCHEDULE (s. 23(2), 23(3), 23(3)(b))
PUBLICATIONS

The current editions of:

Name	*Abbreviation*
Pharmacopoeia Internationalis	(Ph.I.)
The British Pharmacopoeia	(B.P.)
The Pharmacopeia of the United States of America	(U.S.P.)
Codex Francais	(Codex)
The Canadian Formulary	(C.F.)
The British Pharmaceutical Codex	(B.P.C.)
The National Formulary	(N.F.)
The British Veterinary Codex	(B.Vet.C.)

FOURTH SCHEDULE (s. 70(1))

PURPOSES FOR WHICH DRUGS, MAY NOT BE ADVERTISED

1. The cure of syphilis, gonorrhea or soft chancre in any of their forms.

2. The prevention, relief or cure of Bright's disease, schistosomiasis, cancer, Human Immunodeficiency Virus infection/Acquired Immune Deficiency Syndrome, consumption or tuberculosis, leprosy, lupus, diabetes, epilepsy or fits, locomotor ataxia, paralysis, or infantile paralysis.

3. The cure of arteria-sclerosis, septicemia, diphtheria, dropsy, erysipelas, gallstones, kidney stones and bladder stones, goiter, heart disease, tetanus or lockjaw, pleurisy, pneumonia, scarlet-fever, smallpox, trachoma, amenorrhea, hernia or rupture, blindness or any structural or organic ailment of the auditory system.

4. The cure of any habit associated with sexual indulgence, or of any ailment associated with those habits, or the restoration or stimulation of the sexual functions.

FIFTH SCHEDULE (s.100(1))

Number	Short title	Extent of Repeal
Cap. 244	The Pharmacy and Poisons Act	The whole Act
Cap. 247	Narcotic Drugs and Psychotropic Substances (Control) Act	Sections 16, 17 and 18

I certify that this printed impression is a true copy of the Bill passed by the National Assembly on the 7th November, 2024.

Clerk of the National Assembly

Endorsed for presentation to the Senate in accordance with the provisions of Standing Order 142 of the National Assembly Standing Orders.

Speaker of the National Assembly