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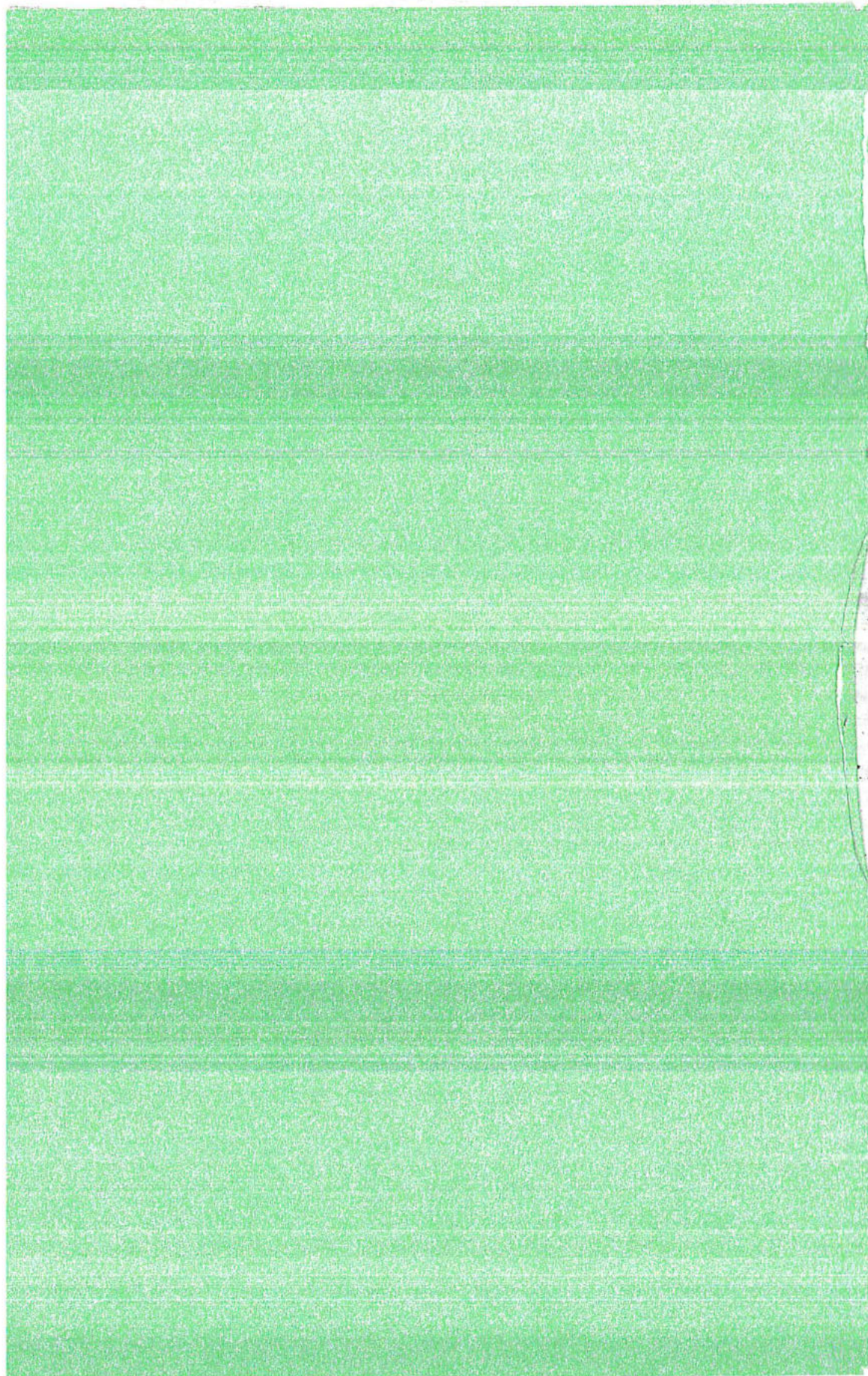
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THE KENYA DRUGS AUTHORITY BILL, 2022**A Bill for**

AN ACT of Parliament to establish the Kenya Drugs Authority; to provide for the regulation and management of drugs and chemical substances; to provide for the regulation of medical devices and other health technologies; to give effect to the principles and objects of devolved government in drug safety regulation and for connected purposes

ENACTED by the Parliament of Kenya, as follows—

PART I—PRELIMINARY

1. This Act may be cited as the Kenya Drugs Authority Act, 2022.

Short title and commencement.

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

Interpretation.

“advertisement” includes any statement, communication, representation or reference to the public and 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;

“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;

“article” includes —

- (a) any drug, therapeutic cosmetic, 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, medical device or scheduled substance;

“Authority” means the Kenya Drugs Authority established under section 4 of this Act;

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

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

“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 detergent, or any other substance or mixture of substances which the Authority may, declare to be a chemical substance;

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

“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 if organs in humans or animals;

“enrolled pharmaceutical technologist” has the meaning assigned to it in the Pharmacy and Poisons Act; Cap. 244.

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

“health products and technologies” means chemical substances, therapeutic cosmetics, herbal medicines and products, medical devices including radiation-emitting

devices, medicines, scheduled substances, and related products and substances;

“herbal medicine or product” means a plant derived material or preparations with claimed therapeutic or other human or veterinary health benefits, which contain either raw or processed ingredients from one or more plants, or material of inorganic or animal origin;

“insanitary conditions” means such conditions or circumstances as might contaminate a drug or a therapeutic cosmetic with dirt or filth or might render the same injurious or dangerous to health;

“interchangeable multi-source medicine” means medicines that contain the same active substances which are identical in strength or concentration, dosage form and route of administration and meet 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;

“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 vehicle for administration;

“medical device” means any material, instrument, apparatus or contrivance, whether radiation-emitting or not, including components, parts and accessories thereof, manufactured, sold or represented for use in the diagnosis, treatment, monitoring, mitigation or prevention of any disease, disorder or abnormal physical state or disability, or the symptoms thereof, in humans or animals but does not include medicines;

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

“medicinal substance” means any drug, medicine, product, article, or substance which is claimed to be useful for any of the following purposes—

- (a) treating, preventing or alleviating disease or symptoms of disease;
- (b) diagnosing disease or ascertaining the existence, degree or extent of a physiological condition; or
- (c) preventing or interfering with the normal operation of a physiological function whether permanently or temporarily and whether by way of terminating, reducing, postponing or increasing or accelerating the operation of the function in human beings or animals;

“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, medical device or scheduled substances is wholly or partly placed or packed;

“pharmaceutical technologist” has the meaning assigned to it in the Pharmacy and Poisons Act;

“pharmacy” means either—

Cap.244.

- (a) the profession of pharmacy as carried out by registered pharmacists; or
- (b) the duly licensed premises from which pharmacy services are provided by a registered pharmacist;

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

“registered midwife” means a person permitted by law to practice the profession of midwife in Kenya;

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

“register” means a register established under this Act;

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

“scheduled substance” means any substance or mixture of substances declared as such in the relevant schedule under this Act;

“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—

No. 29 of 2011.

- (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” includes any substance or mixture of substances manufactured, sold or represented for use in cleansing, improving or altering the complexion,

skin, hair, eyes or teeth, and includes deodorants and perfumes;

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

“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.

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

3. (1) This Act applies to regulation of health products and technologies including— Application.

- (a) chemical substances;
- (b) therapeutic cosmetics;
- (c) herbal medicines and products;
- (d) medical devices including radiation-emitting devices;
- (e) medicines; and
- (f) Scheduled substances.

(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 DRUGS AUTHORITY

4. (1) There is established an Authority to be known as the Kenya Drugs Authority.

Establishment of
the 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.

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

Headquarters.

6. (1) There shall be a Director-General of the Authority.

Director-General.

(2) The Director-General shall be appointed by the Public Service Commission through a transparent and competitive process, with the approval of Parliament.

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

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

- (a) holds a masters' degree from a university recognized in Kenya in either pharmacy, medicine, engineering or equivalent fields;
- (b) has demonstrable experience in the regulation of health products and technologies;
- (c) has at least ten years' experience in any field relating to the subject matter of this Act;

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

(e) Meets the requirements of Chapter Six of the Constitution.

(5) The Director-General shall be the chief executive officer of the Authority.

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

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

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

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

(b) to 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.

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

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

(a) is a Member of Parliament;

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

(c) is an undischarged bankrupt;

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

(e) a salaried employee of any public entity except on a secondment basis;

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

Disqualification
from the position
of Director-
General.

8. (1) The Authority shall be managed by a Board to be known as the Kenya Drugs Board.

Management of
the Authority.

(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 managerial level;
- (b) the Principal Secretary in the Ministry for the time being responsible for health or a designated representative;
- (c) the Principal Secretary the Ministry for the time being responsible for finance or a designated representative;
- (d) one person with knowledge and expertise in law, health products and technologies nominated by the Law Society of Kenya;
- (e) the Director-General for health or a designated representative;
- (f) the Director of Veterinary Services or a designated representative;
- (g) the Managing Director of the Kenya Bureau of Standards or a designated representative;
- (h) one person nominated by a pharmaceutical association;
- (i) one person nominated by the Kenya Association of Manufacturers;
- (j) one person, not being a Governor, with special knowledge of drugs and health technologies nominated by the Council of County Governors to represent the interests of counties;
- (k) a person, not being a public officer, representing consumer protection nominated by the Consumer Federation of Kenya; and

(1) The Director-General who shall be the secretary.

(3) The members of the Board appointed under paragraph (d), (h), (e), (i), (j) and (k) of subsection (2) shall be appointed by the Cabinet Secretary with the approval of Parliament.

(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 6 of the Constitution.

(5) In addition to the qualifications in subsection (4), the Chairperson to the Board shall possess the following minimum qualifications—

- (a) a masters' degree in science from a recognized university; and
- (b) at least fifteen years' experience in any field relating to the subject matter of this Act.

(6) A person shall not be qualified for appointment as member of the Board if such 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.

(7) In appointing members of the Board, regard shall be had of the need for regional balance and the realisation of the principle that at least one third of the members must be from either gender.

(8) The members shall, at their first meeting, elect a vice-chairperson from amongst the members appointed under paragraphs (d), (h), (i), (j) and (k) of subsection (2).

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

(10) 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.

(11) The members of the Board shall be appointed in accordance with the Third Schedule.

9. The Chairperson, Board members and the Director-General shall subscribe before the Chief Justice the oath or affirmation set out in the Second Schedule.

Oath of office.

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

Vacation of office.

- (a) dies;
- (b) resigns from office by writing under his hand addressed to the president;
- (c) is removed from office in accordance with the provisions of section 12;
- (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 his office by reason of physical or mental infirmity;
- (f) is absent 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.

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

Removal from office.

- (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 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).

12. 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—

Functions of the Authority.

- (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 timeously;
- (e) ensure the periodic re-assessment and monitoring of health products and technologies;
- (f) ensure that evidence of existing and new adverse events, interactions, information about health products and technologies is being monitored globally, analysed and acted upon;

- (g) ensure that clinical trial protocols where required for registration of health products and technologies are being assessed according to prescribed ethical and professional criteria and defined standards;
- (h) monitor compliance with this Act through its agencies and any other agencies of State authorised under this Act;
- (i) advise the cabinet secretary and county governments on measures for the protection of the health of consumers;
- (j) advise the cabinet secretary and county governments on the implementation of this Act;
- (k) 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;
- (l) approve and register health products and technologies regulated under this Act, manufactured within or imported into, and intended for use in Kenya;
- (m) examine, grant, issue, suspend, cancel and revoke licences or permits issued under this Act;
- (n) appoint inspectors and order inspection of any premises;
- (o) promote rational use of drugs, medical devices and herbal drugs;
- (p) provide the public with unbiased information on products regulated under this Act;
- (q) 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;
- (r) maintain registers prescribed under this Act;
- (s) attend to and, where possible, take legal measures on complaints made by consumers against manufacturers of products regulated under this Act;

- (t) be responsible for its human resource management and development; and
- (u) perform any other functions assigned to it under this Act.

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

Powers of the Authority.

- (a) enter into association with such other bodies or organizations within or outside Kenya as it may consider desirable or appropriate and in furtherance of the purpose for which the Authority is established;
- (b) 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;
- (c) receive any grants, gifts, donations or endowments and make legitimate disbursements there from;
- (d) open banking accounts for the funds of the Authority;
- (e) establish such committees as it may consider necessary for the performance of its functions and the exercise of its powers under this Act; and
- (f) co-opt in such committees persons whose knowledge and experience is necessary to enable the committee to effectively discharge its functions.

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

Affairs of the Board.

15. 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.

Committees of the Board.

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

Allowances of the Board.

17. (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.

Staff of the
Authority.

(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.

18. (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.

Common Seal of
the Authority.

(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.

19. 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.

Liability of the
Board and Staff.

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

Registrar.

(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.

21. (1) The Cabinet Secretary may establish scientific advisory committees, as may be necessary for the performance of the functions and powers of the Cabinet Secretary under this Act.

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

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

(4) The Cabinet Secretary 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; 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) An advisory committee shall submit, at least once every six months, a report to the Cabinet Secretary, with

respect to its activities and the Cabinet Secretary shall lay a copy of each report before Parliament.

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

PART IV—MEDICINES

22. (1) A person shall not sell any medicine that—

Prohibited sale of medicines.

- (a) is not registered by the Authority;
- (b) is adulterated;
- (c) is substandard; or
- (d) fails to comply with any specifications made under this Act or any other written law.

(2) A person who contravenes the provisions of sub-section (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) sub-section (1) shall not apply to the sale of a medicine 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 pharmaceutical product 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.

23. (1) A person shall not—

Deception and
falsification.

- (a) falsify medicines;
- (b) label, package, treat, process, sell or advertise any medicine 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 medicine 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 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.

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

Standards of
medicines.

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

(3) A person who manufactures, labels, packages, sells or advertises any medicine for which no standard has been prescribed, or for which no standard is contained in any of the publications specified in the Fifth Schedule, commits an offence unless the medicine—

- (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 drug for which a standard has been prescribed or which is contained in any of the publications specified in the Fifth 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 hundred thousand 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 hundred thousand shillings or to imprisonment for a term not exceeding five years, or to both.

25. A person who sells any medicine which is not of the nature, substance, or of the quality or article demanded by the purchaser commits an offence and shall on conviction, be liable—

Prohibition against sale of medicines not of nature, substance or quality demanded.

- (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.

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

Preparation of medicine under conditions not meeting prescribed standards.

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

Factors relevant to determination of application for a product licence.

- (a) the safety of the medicinal products to which the application relates;
- (b) the efficacy of the medicinal products to the purpose for which they are proposed to be administered;

- (c) the quality of the medicinal products of each such description, according to the specification and the method or proposed method of manufacture of the products, and the provisions proposed for securing that the products as sold or supplied will be of that quality; and
- (d) any other factor that the Authority considers necessary.

28. (1) There is established a medicines register.

Medicines
Register.

(2) The Authority shall prescribe the format and the content of the medicines register.

29. (1) Every application for the registration of a medicine or medical device shall be submitted to the Registrar in the prescribed form and shall be accompanied by the prescribed particulars and samples of the relevant medicine and by the prescribed registration fee.

Registration of
medicines and
medical devices.

(2) The Registrar shall ensure that such an application in respect of medicine which appears on the latest Essential Medicines List or Essential Veterinary Medicines 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 enquiry which it may consider necessary, the Authority shall approve of the registration if the authority is satisfied that—

- (a) the medicine in question is suitable for the purpose for which it is intended;
- (b) the medicine in question complies with the prescribed requirements; and
- (c) that registration of that medicine is in the public interest.

(4) If the Authority does not approve the registration of a medicine, 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 one month after the date of the notification furnish the registrar with the applicant's reasons for not being so satisfied.

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

(6) When the Authority has approved of the registration of any medicine, the registrar shall register that medicine and shall enter in the register such particulars in regard to the medicine 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 medicine.

(7) Every medicine shall be registered under such name as the Authority may approve.

(8) The Registrar shall allocate to every medicine registered under this Act a registration number which shall be recorded in the register opposite the name of such medicine and which shall be stated in the certificate of registration issued in respect of such medicine.

(9) Any registration under this section, including the registration of medicines already registered, shall be valid for a period of five 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 sub-section (9) whereby the sale of the medicine 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 sub-section (10) above are lodged with the Registrar by the applicant concerned within a period of one month after the receipt of the notification referred to in sub-section (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 medicine concerned subject to the said condition.

(12) Notice of the rejection of an application under this section in respect of a medicine 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 Registrar shall as soon as possible after the date of expiry of the appropriate period referred to in sixty days publish in the *Gazette* the prescribed particulars in respect of all applications for registration received by him or her prior to such date.

(14) For the purposes of this section —

- (a) ‘Essential 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 Health; and
- (b) ‘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.

30. (1) The Registrar, on application by the holder of a certificate of registration issued in respect of a medicine and with the approval of the Authority, may amend the entry in a register with respect to that medicine.

Amendment of
entries in register.

(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) 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 medicine, after receiving the existing certificate of registration in respect of that medicine for cancellation.

31. (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 medicine.

Transfer of
certificate of
registration.

(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) above, 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 on the prescribed form to the person making the application in respect of the relevant medicine.

32. (1) The Authority shall cancel the registration of a medicine or medical device if—

Cancellation of
registration.

- (a) a licensee has failed to comply with a condition subject to which a particular medicine or medical device has been registered;
- (b) a particular medicine or medical device does not comply with a prescribed requirement; or

- (c) it is not in the public interest to make a particular medicine or medical device available to the public.

(2) Before cancellation of the registration of any medicine or medical device, 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 medicine or medical device.

(3) The notice referred to in subsection (2) above 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 after the date of that 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 medicine or medical device, if—

- (a) no objection as contemplated in subsection (3)(b) are received; or
- (b) after consideration of any comments received, the Authority is of the opinion that the registration of the medicine or medical device in question should be cancelled.

(5) If the holder of the certificate of registration issued in respect of a medicine or medical device fails to pay the prescribed fee in respect of the retention of the registration of that medicine or medical device 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.

33. (1) The registrar shall give notice in the *gazette* of the registration, or cancellation of registration, of a medicine or medical device in terms of this Act.

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

(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.

34. The Cabinet Secretary in consultation with the authority, may prescribe conditions for the supply of more affordable medicines in certain circumstances so as to protect the health of the public, and in particular may—

- (a) prescribe the conditions under which any medicine which is identical in composition, meets the same quality standard and is intended to have the same proprietary name as that of another medicine 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 medicine 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, as well as the use of, the medicine referred to in paragraph (a).

Measures to ensure supply of more affordable medicines.

35. (1) A pharmacist shall dispense an interchangeable multi-source medicine instead of the medicine prescribed by a medical or dental practitioner, nurse or other person registered under the relevant statutes regulating health professionals.

Generic substitution.

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

(3) When an interchangeable multi-source medicine is dispensed by a pharmacist 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 medicine in the prescription book.

(4) A pharmacist shall not substitute for a prescribed medicine an interchangeable multi-source medicine—

- (a) if the person prescribing the medicine 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 medicine is higher than that of the prescribed medicine; or
- (c) where the product has been declared not substitutable by the Authority.

36. (1) A person who, on a commercial scale, manufactures, prepares, supplies, sells, distributes, exports or imports herbal medicine which is represented to the public to have therapeutic effect when it is consumed, applied or inhaled must be licensed.

Herbal medicines.

(2) Regulations may prescribe particulars to be provided for in the registration of items under sub-section (1).

(3) A person who contravenes sub-section (1) or any other law commits an offence.

PART V— SCHEDULED SUBSTANCES

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

Preparation of
Lists of scheduled
substances.

(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 and dealers in mining, agricultural or horticultural accessories;
- (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 may, by order, 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.

(4) The authority shall review the lists under subsection (2) at least once every year.

38. (1) The following persons may be in possession of Scheduled Substances, but to the extent only and subject to the Limitations prescribed by this sub-section—

Possession of
Scheduled
Substances.

- (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 licensed by the Authority to sell Schedules Substances for mining, agricultural or horticultural purposes, for the purposes of the licence and on premises so licensed;
- (d) 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;

- (e) 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;
- (f) the personal representative of a deceased person, or the liquidator, receiver or other person appointed to deal with the property of a bankrupt 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 up 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 shall commits an offence and upon conviction, is liable to a fine not exceeding one hundred thousand shillings or to imprisonment for a term not exceeding three year or to both.

39. (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

Wholesale
Dealer's Licence.

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 either 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 in control of the distribution of the Scheduled Substances who is resident in Kenya.

(5) Every licence issued under this Section shall expire on the 31st day of December in the year of issue, subject to renewal.

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

40. (1) A person carrying on a regular business in mining, agricultural or horticultural accessories shall apply to the Authority in writing on the prescribed form for a licence to deal in Scheduled Substances and any such licence, if granted shall authorize the licensee to sell only the Scheduled Substances specified therein, to persons who require them for a trade or business of mining, agricultural or horticulture.

Licence to deal in Scheduled Substances for mining, agricultural or horticultural purposes.

(2) 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.

(3) If the Authority is satisfied that it is in the public interest that a licence under this Section should be issued or renewed it may, upon payment of the prescribed fee, issue to the applicant a licence in the prescribed form, or, as the case may be, renew the licence.

(4) The Authority may refuse to issue or renew, or may revoke, a licence for any good and sufficient reason

relating either to the applicant or to the 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, whose decision thereon shall be final.

(5) Every licence under this Section shall expire on the 31st December in the year of issue, subject to renewal.

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

(7) A person who sells Scheduled Substances for the purposes specified in sub-section (1) contrary to any of the provisions of this Section commits an offence and is liable upon conviction, to a fine not exceeding two hundred thousand Shillings, or to imprisonment for a term not exceeding two years, or to both

41. (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—

Power to sell
Scheduled
Substances.

- (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 person licenced under this Act as lawfully carrying on the business of a dealer in Scheduled Substances for mining, agricultural or horticultural purposes in Kenya;
- (d) a qualified medical practitioner, dentist or veterinary surgeon for purposes of medical, dental or veterinary treatment respectively;
- (e) the Government or a county authority or its institutions for public purposes;
- (f) 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 (d) and (f) 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 the Scheduled Substances to any of the persons, institutions and others referred to in sub-section (1), and in addition may sell those Scheduled Substances to a person who is—

- (a) in possession of the prescription of a qualified medical practitioner, dentist, or veterinary surgeon, in accordance with the prescription; or
- (b) in possession of a written certificate to the effect that he may properly be supplied with the Scheduled Substances, the certificate having been issued by a person authorized by the Authority in that behalf, a list of which persons shall be published by the Authority in the Gazette from time to time; or
- (c) a person known by the seller to be a person to whom the Scheduled Substances may be properly sold.

(3) Subject to this Act, a person licenced under this Act to sell Scheduled Substances for mining, agricultural and horticultural purposes may sell Scheduled Substances in accordance with his licence.

(4) 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 after the time of revocation or expiry or such longer time as the Authority may allow.

(5) A person who sells a Scheduled Substances 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.

42. (1) Where a Scheduled Substance is sold in the presence of the person by whom it is to be used, the Authority may require that the seller shall not deliver it until—

Scheduled
Substances Book.

- (a) he has made or caused to be made an entry into the book kept for the purpose, to be called a Scheduled Substances Book, indicating in the form prescribed the date of the sale, the name and address of the purchaser and of the person, if any, by whom the certificate required under paragraph (b) of Section 53 (2) was given, the name and quantity of the Scheduled Substances sold, and the purpose for which it is stated by the purchaser to be required; and

- (b) the purchaser has affixed his signature to the entry.

(2) Where a Scheduled Substances 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 Substances for the purpose of his trade, business or profession and satisfies the seller that by reason of some emergency he is unable before delivery to furnish the order in writing, the seller may forthwith deliver the Scheduled Substances 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 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 Substances to be purchased is properly required;

- (c) the requirements of the sub-section (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 whereby 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
- (e) if the Scheduled substance is sent by post it shall be sent by registered post or courier.

(3) 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 three years, or both.

43.(1) A qualified medical practitioner, dentist or veterinary surgeon, or a member of the staff of a hospital, dispensary or similar institution who has been authorized so to do by general or special order of the Cabinet Secretary, 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—

Supply and
dispensing of
Scheduled
Substances with
therapeutic value
by doctors,
hospitals, etc.

- (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;
- (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;
 - (iv) the name and address of the person by whom the prescription was given; and
- (c) a registered midwife practicing domiciliary midwifery may supply or dispense a Scheduled Substance with therapeutic value in accordance with the regulations made under the Nurses Act, if he or she complies with paragraph (b) of this sub-section in relation to the supplying or dispensing of the Scheduled Substances with therapeutic value.

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(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 Substances 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 sub-section (1) applies who, supplies or dispenses a Scheduled Substance with therapeutic value otherwise than in compliance with these provisions commits an offence and is upon conviction, liable to a fine not exceeding one hundred thousand shillings or to imprisonment for a term not exceeding one year or both.

44. (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—

Labelling of
containers.

- (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 paragraphs (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 two hundred thousand shillings, or to imprisonment for a term not exceeding one year, or to both.

45. A person exposing or causing to be exposed for sale any Scheduled Substance in or by means of an automatic machine commits an offence and shall be liable to a fine not exceeding five hundred thousand shillings, or to imprisonment for a term not exceeding three year, or to both.

Automatic machines.

46. (1) This shall be permitted as long as the supply of the medicine conforms with all requirements for the particular medicine in terms of its scheduling status and any other requirements as may be specified in Regulations pertaining to this type of supply. 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.

Electronic sale of medicines.

(2) Any online pharmacy or other electronic source of supply of medicines which does not comply with these

provisions shall be guilty of an offence and shall be liable to a fine not exceeding two hundred thousand shillings, or to imprisonment for a term not exceeding one year, or to both.

PART VI—MANUFACTURE OF MEDICINAL SUBSTANCES

47. (1) A person shall not manufacture any medicinal substance unless the person has been granted a manufacturing licence by the Authority.

Licence to manufacture medicinal substances.

(2) Each manufacturing licence shall expire on the 31st December of every year and the renewal shall be subject to the compliance with conditions prescribed by the Authority.

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

(4) Any person who intends to manufacture a medicinal substance 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 licencing conditions that it considers necessary.

48. A person who is granted a manufacturing licence under Section 47 shall comply with the good manufacturing practices prescribed by the Authority.

Compliance with good manufacturing practice.

PART VII—THERAPEUTIC COSMETICS

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

Prohibited sale of therapeutic cosmetics.

(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.

50. 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.

Standards of therapeutic cosmetics.

51. Any person who sells, prepares, preserves, packages, conveys, stores or displays for sale any therapeutic cosmetic under insanitary conditions commits an offence.

Preparation of therapeutic cosmetic under insanitary conditions.

52. Any therapeutic cosmetic which either contains a Scheduled Substance or claims to have a therapeutic effect or value shall be treated as a medicine.

Restriction on supply of therapeutic cosmetics.

53. The Registrar shall keep a register of all therapeutic cosmetics which shall be called a Therapeutic Cosmetics Register.

Therapeutic cosmetics register.

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

Prohibited Ingredients.

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

(3) Any person who manufactures or knowingly sells a therapeutic cosmetic which contains a prohibited ingredient commits an offence

PART VIII—MEDICAL DEVICES

55. (1) The Registrar shall keep in the prescribed form a human medical devices register and a veterinary medical devices register, to be known as the medical devices registers in which the registrar shall register all medical devices, the registration of which has been approved by the Authority.

Medical Devices Registers.

(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.

56. (1) A person shall not sell any medical device—

Prohibited sale of medical devices.

(a) that is not registered by the Authority

(b) that is adulterated;

(c) substandard;

(d) defective; or

(e) which fails to comply in any way with 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 the purchaser or its user commits an offence.

57. 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.

Deception.

58. (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.

Standards of medical devices.

(2) The Authority 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 minimised, having regard to the levels of radiation required to enable the device to perform its therapeutic and diagnostic functions and the intended purpose of the device.

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

Offences relating to medical devices.

(2) A person who knowingly sells a medical device that has a measuring function that does not provides 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 sells or supplies unapproved medical devices commits an offence.

PART XI—NATIONAL QUALITY CONTROL LABORATORY

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

Establishment of the National Quality Control Laboratory.

- (a) the examination and testing of the drugs 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, biochemical, physiological and pharmacological analysis and other pharmaceutical evaluation;
- (c) conduct research and training; and testing the quality of locally manufactured and imported medicines or medicinal substances, medical devices or therapeutic cosmetics on behalf of the Authority, with a view to determining whether such drugs or medicinal substances comply with this Act or rules made hereunder.; and
- (d) do such other function as shall be determined by the Authority.

61. (1) A certificate of analysis shall be issued and signed by the Director-General 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.

Certificate of analysis.

PART XII—ADVERTISEMENTS AND LABELLING

62. (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.

Advertisement of health products and technologies.

(2) Applications 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.

63. (1) Subject to this Act, a person shall not take part in the preparation or publication of an advertisement referring to a medicine, drug, appliance or article of any description in terms which are calculated to imply that the medicine, drug, appliance or article may be effective for any of the purposes specified in the Sixth Schedule under this Act.

Prohibition of advertisements as to certain diseases etc.

(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, 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.

(3) The Cabinet Secretary may from time to time, by notice in the Gazette, amend or vary the Schedule.

64. Subject to this Act, a person shall not take part in the publication of an advertisement referring to a medicine, drug, appliance or article of any description, in terms which are calculated to lead to the use of the drug, appliance or article for procuring the miscarriage of women.

Prohibition of advertisement as to abortion.

65. Subject to this Act—

Prohibition of misleading or false advertisements.

- (a) A person shall not take part in the publication of an advertisement referring to a health product or technology or similar article in terms which in the opinion of the Authority are considered to be extravagant, 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 article;
- (b) A person shall not in an advertisement claim that the therapeutic efficacy of a health product or technology or use of an article 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.

66. (1) In proceedings for contravention of any of the provisions of Sections 64 and 65—

Defences for offences related to advertisements.

- (a) that an advertisement was published referring to a drug, appliance or article 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 63, 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 64, for procuring the miscarriage of women; and
- (b) that the advertisement also referred to the medicine, drug, appliance or article 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.

(3) In proceedings for contravention of any of the provisions of Sections 62, 63, 64 and 65, 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 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.

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

Labelling of
articles containing
medicine.

- (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; provided that this subsection shall not apply to an article made up and supplied for the use of a particular person, being an article prescribed by reference to the needs of that person.

(2) In sub-section (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 Pharmacopœia* or the *British Pharmaceutical Codex* or the *International Pharmacopœia* or the *British Veterinary Codex* which was last published before the date on which the article 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

article sold or supplied or contained in a defined quantity of the article; or

- (b) in the case where the article 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.

(3) If a person sells or supplies an article 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 two hundred thousand 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 three hundred thousand shillings or to imprisonment to a term not exceeding three year or to both.

68. (1) It shall be a defence for a person charged with selling or supplying, in contravention of Section 67, an article consisting of or comprising a substance recommended as a medicine to prove—

Defences on charge concerning labelling.

- (a) that the person did not know and had no reason to believe, that the article consisted of or comprised such a substance; or
- (b) that, in relation to the matter in respect of which the person is charged, the person acted in the course of the person’s employment as a servant or agent of another person on the instruction of the person’s employer or of some other specified person.

(2) In proceedings for contravention of section 67 a document purporting to be a certificate signed by a public analyst or by an officer authorized in writing by the Cabinet Secretary to perform such analysis, and stating the result of an analysis made by the person, shall be admissible as evidence of the matters stated therein, but a party to the

proceedings may require the person by whom the analysis was made to be called as a witness.

69. 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 as containing a article, 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 articles of the description specified on the label, until the contrary is proved.

Proceedings on charge concerning labelling.

70. An appeal under any Section shall be in writing and shall be lodged within 30 days after the date of the act appealed against.

Appeal from Proceedings on charge concerning labelling.

PART XIII—ADMINISTRATION AND ENFORCEMENT

71. (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 or homoeopathic medicine, preparation or medical device.

Power to prohibit or control certain medicines or medical devices.

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

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

Authorised sale or supply of unregistered medicine or medical device.

(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 medicine or medical device product in terms of this section, outweigh the potential benefits, the Authority may at any time, in writing, withdraw any such authority granted.

73. (1) A drug, article 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 drug, article or document, until the final determination of those proceedings.

Retention and disposal of goods seized.

(2) Where a magistrate is satisfied that any such drug or article 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 drug or article would unduly prejudice the owner, the magistrate may authorize the sale or other disposal of the drug or article.

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

(4) In this section references to a drug or article shall be construed as including the proceeds of a sale effected in accordance with the provisions of subsection (2).

74. The Authority may —

Authority to be supplied with information.

(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.

75. (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.

Inspection of licences and books.

(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 there under, shall be open for inspection by a regulatory officer at all reasonable times.

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

Obstruction of
Regulatory
Officers.

77. (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 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.

Vicarious criminal
responsibility.

(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.

78. (1) If—

Penal sanctions
with regard to
body corporates.

- (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.

79. A regulatory officer may, for the purposes of this Act, inspect any animal intended for slaughter and may seize and examine any meat which the regulatory officer considers to be unfit for consumption.

Inspection of
animals by
Regulatory
Officers.

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

Powers of
Regulatory
Officers.

- (a) enter any premises where the regulatory officer believes any article to which this Act or any regulations made thereunder apply is prepared, preserved, packaged, stored or conveyed, examine any such article 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 in which the regulatory officer believes

that any article subject to the provisions of this Act is being conveyed and to examine any such article and take samples for the purposes of this Act;

- (c) open and examine any receptacle or package which the regulatory officer believes contains any article 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 sub-Section (1) that the regulatory officer believes contain any information relevant to the enforcement of this Act with respect to any article 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 article 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 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 article 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 an article under this Act and the owner thereof or the person in whose possession the article was at the time of seizure consents to the destruction thereof, the article 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 article 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 article, be forfeited, and upon such order being made such articles and things may be disposed of as the court may direct.

(9) Where any article 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 article may be destroyed or otherwise disposed of as the regulatory officer may direct.

(10) Any article 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 articles 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 article 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 article.

(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 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.

81. The Director of Medical Services, in relation to any matter appearing to affect the general interests of the consumer or the Director of Veterinary Services, in relation to any matter appearing to affect the general interests of animal husbandry in Kenya, and the Director of Agriculture in relation to any matter appearing to affect the general interests of agriculture in Kenya, and any other person authorized in writing by the Cabinet Secretary so to do, may direct a public officer to procure for analysis samples of any health product or technology, and thereupon that officer shall have all the powers of a regulatory officer under this Act and this Act shall apply as if the officer were a regulatory officer.

Power of Directors of Medical Services, Veterinary Services and Agriculture to have articles analysed.

82. It shall be the duty of every county authority to exercise such powers with which it is vested as may be, in its special circumstances, reasonably practicable so as to provide proper safeguards for the sale of scheduled substance and health products and technologies in a pure and genuine condition, and in particular to direct its officers to procure samples for analysis.

Duty of county authority.

83. (1) The Cabinet Secretary may direct any person who at the date of the direction or at any subsequent time carries on a business which includes the production, importation or use of substances or articles of any class to which this Act applies to furnish to the cabinet secretary, within such time as may be specified in such direction, such particulars as may be so specified of the composition and use of any such substance or article sold or for sale in the course of that business or used in the preparation of any article.

Power of Cabinet Secretary to obtain particulars substances.

(2) Without prejudice to the generality of subsection (1), a direction made thereunder may require the following particulars to be furnished in respect of any substance—

- (a) particulars of the composition and chemical formula of a substance;
- (b) particulars of any investigations carried out by or to the knowledge of the person carrying on the business in question, for the purpose of determining whether and to what extent the substance, or any product formed when the substance is used as aforesaid, is injurious to, or in any other way affects health;
- (c) particulars of any investigations or inquiries carried out by or to the knowledge of the person carrying on the business in question for the purpose of determining the cumulative effect on the health of a person consuming the substance in ordinary quantities.

(3) No particulars furnished in accordance with a direction under this section, and no information relating to any individual business obtained by means of such particulars shall, without the previous consent in writing of the person carrying on the business in question, be disclosed except—

- (a) in accordance with regulations made by the Authority, so far as may be necessary for the purposes of this Act; and
- (b) for the purposes of any proceedings for an offence against the order or any report of those proceedings, and any person who discloses any such particulars or information in contravention of this subsection shall be guilty of an offence.

84. 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.

Power of court to order licence to be cancelled.

85. (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 article sold was actually delivered to the purchaser or where the sample was taken.

Prosecution.

(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 an article of the description specified on the label.

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

Penalties.

(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;

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

(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.

87. In any proceedings under this Act—

Certificates of analysis and presumptions.

(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 (a) above—

(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 article 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 article 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 XIV—FINANCIAL PROVISIONS

88. The funds of the Authority shall consist of—

Funds for the
Authority.

- (a) Appropriations and budgetary allocations from the Consolidated Funds;
- (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

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

Financial year.

90. (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.

Annual Estimates.

(2) The annual estimates shall make provisions for all 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;
- (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 think fit.

(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 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.

91. (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.

Accounts and
Audit.

(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 Kenya National Audit Office 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 Kenya National Audit Office.

92. (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.

Investment of
Funds.

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

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

Annual Reports.

(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;
- (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.

94. 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.

Special Reports.

PART XV—MISCELLANEOUS PROVISIONS

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

Regulations.

(2) Without prejudice to the generality of sub-section (1), the authority may make regulations—

- (a) with respect to—
 - (i) the labelling and packing and the offering, exposing and advertising for sale of drugs, health products and technologies;
 - (ii) the sale or the conditions of sale of any drug, 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 product 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 drugs or scheduled substances to submit test portions of any batch of such drugs 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 article 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 articles regulated by this Act from the ports;
 - (n) prescribing forms and particulars to be provided in forms;

- (o) governing donation and disposal of drugs, medical devices, 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 medicines;
- (w) providing for the categorization and classification of medical devices;
- (x) governing administration of clinical trials of drugs and any other health product and technology;
- (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 medicine, medical device 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 or a person otherwise authorized under this Act may dispense medicines or medical devices;
- (cc) provide the manner and procedure in which clinical trials may be conducted in Kenya;
- (dd) the compounding of medicines and the dispensing of medicines and medical devices;
- (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;
- (ii) generally, for giving effect to this Act.

(2) The authority shall adhere to the principle of public participation in making regulations.

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

Transition and savings.

- (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 officers of the former Boards shall become the officers 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 or elected as officers of the former Boards.

(2) In this section “the former Boards” means the Board of the National Quality Control Laboratory established under the Pharmacy and Poisons Act, and, the Public Health (Standards) Board established under the Food, Drugs and Chemical Substances Act.

(3) Within a period of twelve months from the date of coming into operation of this Act—

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

97. (1) The enactments specified in the second column of the Seventh Schedule are repealed to the extent specified in the third column of that Schedule.

Repeals.

(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.14)****PROVISIONS AS TO THE CONDUCT OF BUSINESS
AND AFFAIRS OF THE BOARD**

1. The Board shall meet at least four times in each year. Meetings of the Board.
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. Special meetings.
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. Chairperson to 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.
4. The quorum for the conduct of the business of the Board shall be nine members. Quorum.
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. Voting procedure.
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. Validity of proceedings.
7. 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. Minutes.
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. Committees of the Board.
9. Subject to the provisions of this Schedule, the Board shall regulate its own procedure. Power of the Board to regulate own procedure.

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.

Disclosure of interest.

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

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.

Declaration of commercial interest.

SECOND SCHEDULE**(s. 9)****OATH/AFFIRMATION OF THE OFFICE OF
CHAIRPERSON/MEMBER/DIRECTOR**

I,..... having been appointed (the chairperson/member/director of) the Kenya Drugs Authority under the Kenya Drugs Authority Act, 2022, do solemnly (swear/declare and affirm) that I will at all times obey, act and uphold the Constitution of Kenya and all other written laws of the Republic, that I faithfully and fully, and impartially and to the best of my ability, will discharge the trust and affirm the functions and exercise the powers devolving upon me by virtue of this appointment without favour, bias, affection, ill-will or prejudice. (SO HELP ME GOD).

Declared by the said
.....
.....

Before me this day of
.....

.....
Chief Justice

THIRD SCHEDULE (s.8)

PROVISIONS RELATING TO MEMBERS OF THE BOARD

1. (1) This paragraph provides for the appointment of a member of the Board nominated by a body under section 8(2) (d), (h), (i) (j) and (k) of this Act.

- (a) The nominating body shall submit the names of the nominees to the Cabinet Secretary.
- (b) Being satisfied that the nominating bodies have complied with the conditions under the Act, the Cabinet Secretary shall by notice in the gazette appoint the said members.

2. This paragraph provides for the appointment of a member of the Board under section 10(2)(a) of this Act—

- (a) A selection panel shall submit the names of the nominees to the Cabinet Secretary.
- (b) Being satisfied that the selection panel has complied with the conditions under the Act, shall submit the names of the nominees to the National Assembly for approval.
- (c) The National Assembly shall, within fourteen days after it first meets after receiving the names of the nominees—
 - (i) consider the nominees and either approve them or reject all or any one of them; and
 - (ii) Notify the Cabinet Secretary as to its approval or rejection under subparagraph (a).
- (d) If the National Assembly approves a nominee, the Cabinet Secretary shall, within fourteen days after receiving the notification of the National Assembly, forward the name of the nominees to the President and the President shall, within fourteen days after receiving the name, appoint the nominee as a member of the Board.
- (e) If the National Assembly rejects any of the nominees submitted by the nominating body, the Cabinet Secretary shall, within fourteen days after receiving the notification of the National Assembly, request the nominating body to submit a new nominee to the Cabinet Secretary and subparagraph (3), (4) and (5) and this subparagraph apply with necessary modifications with respect to that new nominee.

- (f) In nominating and approving persons to be members of the Board, the selection panel and the National Assembly shall have regard to—
 - (i) the honesty and integrity of the person and the person's knowledge and experience;
 - (ii) the importance of representing Kenya's gender, regional and other diversities on the Board;
 - (iii) absence of any commercial interest in the pharmaceutical, veterinary or healthcare industry;
 - (iv) any other provisions in this Act and in the Constitution;
- (g) Within seven days after any vacancy arises in the membership of the Board, the Cabinet Secretary shall request the nominating body or the Selection Panel as the case may be to submit nominees under subparagraph (2) and the nominating body or selection panel shall do so within twenty-one days after being requested to

3. The following shall apply with respect to the initial appointment to the Board following the commencement of this Act—

- (a) Each nominating body shall submit its initial nominees within twenty-one days after the commencement of this Act.
- (b) the Cabinet Secretary shall wait until sufficient nominees are approved to form a quorum before submitting the names of the approved nominees under subparagraph (5);
- (c) Within fifteen days after sufficient numbers of the members of the Board are appointed to form a quorum, the Cabinet Secretary shall call a meeting of the Board for the purposes of nominating the Chairman and the Vice-chairman.

4. (1) A person may not serve more than two terms as a member of the Board.

(2) A member of the Board shall, unless his office becomes vacant as provided for under this Act, continue to hold office until he is appointed or replaced by another member appointed under the Act.

4. The President, on the recommendation of the Board, may terminate a person's appointment as a chairperson of the Board only if the person—

- (a) is unable to perform the functions of his office by reason of mental, or physical infirmity;

- (b) is adjudged bankrupt;
- (c) is convicted of a crime carrying a jail term of not less than six months; or
- (d) Is absent from three consecutive meetings of the Board without reasonable excuse.

6. (a) A member of the Board who has direct or indirect personal interest in a matter being considered or to be considered by the Board shall, as soon as reasonably practicable after the relevant facts concerning the matter have come to his knowledge, disclose the nature of his interest to the Board .

(b) A disclosure of interest in a matter shall be recorded in the minutes of the meeting of the Board and the members shall not be present while that matter is being dealt with by the Board and shall not take part in any deliberations or vote relating to the matter.

7. The Authority shall pay the members of the Board such allowances and expenses as are determined by the Cabinet Secretary in charge of finance in consultation with a Committee of the National Assembly designated by the National Assembly for that purpose.

8. (a) No action or proceeding for compensation or damages shall be brought against a member of the Board or any other person authorized by the Board, in respect of anything done or omitted to be done in good faith under this Act.

(b) This paragraph shall not relieve the Board of any liability in law.

FOURTH SCHEDULE**(s.21(2))****SCIENTIFIC ADVISORY COMMITTEES**

1. (1) There shall be a committee of the Authority, to be known as the National Food Safety Committee, which shall have the responsibility within the Authority for advising the Cabinet Secretary on the formulation, implementation and monitoring of the food safety policy.

National Food
Safety Committee.

(2) The Committee shall consist of the following members—

- (a) a representative of the Kenya Bureau of Standards;
- (b) a representative of the Kenya Agricultural and Livestock Research Organization;
- (c) a representative of the Kenya Plant Health Inspectorate Services;
- (d) a representative of the Department of Public Health;
- (e) a representative of the Weights and Measures Department;
- (f) a representative of the Government Chemist's Department;
- (g) a representative of the Department of Veterinary Services;
- (h) a representative of the Kenya Dairy Board;
- (i) a representative of the Horticultural Crops Development Authority;
- (j) the Deputy Director-General for Foods of the Authority, who will act as Secretary to the Committee; and
- (k) Two members appointed by the Director-General from among the staff.

(3) Of the two members appointed under subparagraph (2) (k)—

- (a) one shall be a person with executive responsibility in the Authority for food inspections and
- (b) One shall be a person with responsibility within the Authority.

(4) The members of the National Food Safety Coordination Committee shall hold office for a term of three years and shall be eligible for re-appointment for one further term of three years.

2. (1) There shall be a Committee of the Authority, to be known as the Human Medicines Committee, which shall have the responsibility within the Authority for advising the Authority on regulatory policy relating to human medicinal products, giving advice in relation to the safety, quality and efficacy of these, and promoting the collection and investigation of information relating to adverse reactions involving these products.

Human Medicines
Committee.

(2) The Committee shall consist of the following members: -

- (a) a Chairperson appointed by the Cabinet Secretary knowledgeable in matters of human medicines regulation;
- (b) the Deputy Director-General for medicines who shall be the secretary to the committee;
- (c) two members with relevant knowledge, experience and expertise appointed by the Director-General from among the Authority staff;
- (d) four other members who have knowledge, experience and expertise in matters relating to human medicines, healthcare and public health appointed by the Cabinet Secretary; and
- (e) The Ministry of Health Director of Health Products and Technologies (or equivalent), or his or her designate, who shall be a non-voting member.

(3) Of the two members appointed under subparagraph (2) (d) —

- (a) one shall be a person with executive responsibility in the Authority for medicines evaluation and assessment; and
- (b) One shall be a person with responsibility within the Authority for inspections related to human medicines.

(4) Each member appointed under subparagraph (2) (a), (b) and (d) shall hold office for a term of three years and shall be eligible to be appointed for one additional term.

(5) The Committee shall elect a Vice-chairperson from amongst its members of a different gender to the Chairperson who person shall hold this office for a term of three years and shall be eligible to be appointed for one additional term.

3. (1) There shall be a Committee of the Authority, to be known as the Veterinary Medicines Committee, which shall have the responsibility within the Authority for advising the Authority on regulatory policy relating to veterinary medicinal products, giving advice in relation to the safety, quality and efficacy of these, and promoting the collection and investigation of information relating to adverse reactions involving these medicines.

Veterinary
Medicines
Committee.

(2) The Committee shall consist of the following members—

- (a) a Chairperson appointed by the Cabinet Secretary, in consultation with the Cabinet Secretary responsible for veterinary services, and who is knowledgeable in matters of veterinary medicines regulation;
- (b) The Director of Veterinary Services or his or her designate;
- (c) the Deputy Director-General for Medicines who shall be the secretary;
- (d) two members with relevant knowledge, experience and expertise appointed by the Director-General from among the staff;
- (e) four other members who have knowledge, experience and expertise in matters relating to medicines regulation, veterinary services and veterinary public health appointed by the Cabinet Secretary; and
- (f) The Director of Health Products and Technologies, or his representative, who shall be a non-voting member.

(3) Of the two members appointed under subparagraph (2) (d)—

- (a) one shall be a person with executive responsibility in the Authority for veterinary medicines evaluation and assessment
- (b) One shall be a person with responsibility within the Authority for veterinary medicines related inspections.

(4) Each member appointed under subparagraph (2) (a), (b) and (e) shall hold office for a term of three years and shall be eligible to be appointed for one additional term.

4. (1) There shall be a Committee of the Authority, to be known as the Medical Devices Committee, which shall have the responsibility within the Authority for advising the Authority on regulatory policy relating to medical devices, giving advice in relation to the safety, quality and efficacy of these, and promoting the collection and investigation of information relating to any issues involving their use.

Medical Devices
Committee.

(2) The Committee shall consist of the following members—

- (a) a Chairperson appointed by the Cabinet Secretary, in consultation with the Cabinet Secretary responsible for health, and who is knowledgeable in matters of medical devices specifications and use;
- (b) The Director of Medical Engineering Services or ;
- (c) the Deputy Director-General for Medicines who shall be the secretary;
- (d) two members with relevant knowledge, experience and expertise appointed by the Director-General from among the staff;
- (e) four other members who have knowledge, experience and expertise in matters relating to medical devices regulation, nursing services and public health services appointed by the Cabinet Secretary; and

- (f) The Director of Health Products and Technologies, or his representative, who shall be a non-voting member.
- (3) Of the two members appointed under subparagraph (2) (d)—
 - (a) one shall be a person with executive responsibility in the Authority for medical devices evaluation and assessment; and
 - (b) One shall be a person with responsibility within the Authority for medical devices related inspections.

5. (1) There shall be a Scientific Committee of the Authority, to be known as the National Quality Control Committee, which shall have the responsibility for advising the Authority and Cabinet Secretary on quality control of health products and promoting the collection and investigation of information relating to quality of health products, maintaining relevant standards and certifications; and related matters necessary to ensure proper and efficient running of the National Quality Control Laboratory.

(2). The National Quality Control Committee shall consist of the following members—

- (a) a chairman appointed by the Cabinet Secretary, and who is knowledgeable in matters of quality control
- (b) the Deputy Director-General for medicines or his or her designate;
- (c) the Deputy Director-General for foods or his or her designate;
- (d) four other members who have knowledge, experience and expertise in matters relating to health products regulation, and quality control of medicines, therapeutic foods and therapeutic cosmetics, and medical devices; and
- (e) the Director of the National Quality Control Laboratory, who shall be the secretary.

FIFTH SCHEDULE (s. 24)

The current editions of:

<i>Name</i>	<i>Abbreviation</i>
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.)

SIXTH SCHEDULE (s. 63(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.

SEVENTH SCHEDULE (s.116)

Number	Short title	Extent of Repeal
Cap 244	The Pharmacy and Poisons Board Act	The whole Act
Cap. 254	Food, Drugs and scheduled substances Act	The whole Act
No. 14 of 1994	Narcotic Drugs and Psychotropic Substances Act	Sections 16, 17 and 18

MEMORANDUM OF OBJECTS AND REASONS

The regulation of medicines, pharmaceutical practice, drugs, scheduled substances, therapeutic cosmetics, medical devices and related substances has been in fragmented legislation. In keeping with international best practices and guidance from the World Health Organization, the aim of the proposed national health products regulatory system is to safeguard the health of the public by ensuring the quality, safety and efficacy/effectiveness of medicines and related health products; based on principles of sound science, evidence and transparency. This requires an institutional framework with a clear legal mandate; and with the requisite expertise and independence in decision-making. It is for these main reasons that the Kenya Drugs Authority Bill is proposed. The proposed Authority will be established within National Government, its functions being a critical and integral part of Health Policy, as set out in the Fourth Schedule to the Constitution.

Clause 2 of the Bill provides for the definition and interpretation of terms used in the Bill.

Clause 3 of the Bill further provides where the Act shall apply regarding the regulation of health products and technologies including;

- (a) Chemical substances
- (b) Therapeutic cosmetics
- (c) Herbal medicines and products
- (d) Medical devices including radiation-emitting devices;
- (e) Medicines; and
- (f) Scheduled substances.

Clause 4 of the Bill establishes the Kenya Drugs Authority as a corporate body capable of suing and being sued; taking, purchasing, acquiring, holding or disposing of movable or immovable property; and doing or performing all such other things or acts for the proper discharge of its functions under the Act, which may be lawfully done by a body corporate.

Clause 6-7 of the Bill establishes the office of the Director-General of the Authority. The Clause further establishes the qualifications for appointment as Director-General of the Authority as well as the function of the Director-General.

Clause 8 of the Bill establishes the management of the Authority. It stipulates who shall sit on the Board of the Authority. It further states who shall qualify to be on the Board of the management.

Clause 9 of the Bill provides for the oath of office.

Clause 10 of the Bill states when the office of the chairperson or member of the Board shall become vacant.

Clause 11 of the Bill states the procedure for removing a member of the Board and such application shall be copied to the Chairperson.

Clause 12-20 of the Bill provide for the functions and the powers and affairs of the Authority.

Clause 21 of the Bill provides for the establishment and functions of scientific advisory committees. These committees shall be established as necessary for the performance of the cabinet secretary's functions and powers under this Bill.

Clause 22 of the Bill stipulates that the Authority shall regulate and monitor the manufacture, processing, distribution, sale and importation of health products in Kenya.

Clause 23 of the Bill makes it an offence to falsify medicines, to label, package, treat, process, sell or advertise any medicine and make statements regarding the character of constitution, value, potency, quality, composition in a manner that is deceptive or false.

Clause 24-26 of the Bill provides for standards of medicines, prohibition against the sale of medicines not of nature, substance or quality demanded and preparation of medicine under conditions not meeting the prescribed standards respectively.

Clause 28 -29 of the Bill establishes the medicines register for purposes of registration of medicines and medical devices.

Clause 30 of the Bill provides for the procedure for amendment of entries in the medicines register.

Clause 31 of the Bill stipulates that 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 by the Authority.

Clause 32-33 of the Bill provides for the procedure for cancellation of registration of a medicine or medicinal device by the Authority.

Clause 34 of the Bill grants the Cabinet Secretary the power to prescribe measures to ensure supply of more affordable medicines so as to protect the health of the public.

Clause 35 of the Bill provides for the Generic substitution of medicines. It allows the substitutions of interchangeable multi source

medicine while at the same times prohibiting substitution of medicines in certain circumstances.

Clause 36 provides that manufactures, suppliers and sellers of herbal medicines must be licensed under the Act.

Clause 37 of the Bill provides for the preparation of lists of substances that are to be treated by as scheduled substances which shall be submitted to the Cabinet Secretary.

Clause 38 of the Bill provides a lists of persons who may have possession of Scheduled substances which is subject to the limitations prescribed in the Act.

Clause 39-41 of the Bill provides for licensing procedures for persons intending to deal with Scheduled substances.

Clause 42 of the Bill provides for the requirement for a seller to have a scheduled substances book to record purchases and sale of scheduled substances.

Clause 43 of the Bill provides for the supply and dispensing of scheduled substances with therapeutic value by doctors and hospitals.

Clause 44 of the Bill provides for the requirement for labelling of containers. It makes it an offence to supply scheduled substances without labelling its container in a manner prescribed by this Bill.

Clause 45 of the Bill makes it an offence to sell scheduled drugs in or by means of an automatic machines.

Clause 46 of the Bill permits the electronic sale of medicines so long as they conform to all the requirements stipulated in the section.

Clause 47-48 of the Bill provides for the requirement of applying for a manufacturing licensee to the authority before manufacturing medicinal substances and compliance with good manufacturing practices as prescribed by the Authority and the Bill.

Clause 50 of the Bill prohibits the sale of therapeutic substances in conditions stipulated by the Bill.

Clause 50 of the Bill provides for the standards of therapeutic cosmetics.

Clause 51 of the Bill makes it an offence to sell, prepare, preserve, package, convey, store or display any therapeutic cosmetic under unsanitary conditions.

Clause 52 of the Bill stipulates that therapeutic cosmetics that contain scheduled substances or claims to have therapeutic effect or value to be treated as a medicine.

Clause 53 of the Bill stipulates that the Registrar shall keep a register of all therapeutic cosmetics to be known as the Therapeutic cosmetics register.

Clause 54 of the Bill grants the Authority the power to prohibit certain any ingredient contained in therapeutic cosmetics by notice in the Gazette.

Clause 55 of the Bill mandates the Registrar to keep a human medical devices register that is to be known as the Medical devices register.

Clause 56 of the Bill prohibits the sale of a medical devices that is not registered by the Authority, adulterated, substandard, and defective and which fails to comply with the specifications of the Bill and any other legislations.

Clause 57 of the Bill prohibits the labeling, treating, packaging, selling, advertising of any medical device in a manner that is false, misleading or deceptive as regards the character, value, composition, merit or safety of the products.

Clause 58 and 59 of the Bill provides for standards of medical devices.

Clause 60 of the Bill establishes and provides for the functions of the National Quality Control Laboratory.

Clause 61 of the Bill provides for a Certificate of Analysis that will be issued and signed by the Director-General for every analysis conducted by the National Quality Control Laboratory.

Clause 62 of the Bill stipulates that health products and technologies shall be advertised by only with the written permission of the Authority.

Clause 63 of the Bill prohibits the advertisements as to certain diseases and thereafter provides circumstances under which advertisements as to certain diseases may be allowed.

Clause 64 of the Bill prohibits advertisements in terms which are calculated to lead to the use of the drug, appliance or article for procuring an abortion.

Clause 65 of the Bill makes it an offence to make misleading or false advertisements.

Clause 66 of the Bill establishes the Defences for offences related to advertisements prescribed in section 62, 63, 64 and 65 of the Bill.

Clause 67 -70 of the Bill provides for the conditions for labeling articles containing Medicines , Defences on the charges concerning labelling, proceedings concerning labelling and appeals from proceedings on charges concerning labelling respectively.

Clause 71 of the Bill grants the Cabinet Secretary on the recommendation of the Authority the power to prohibit or control certain medicines or medical devices.

Clause 72 of the Bill provides that the Authority may authorise in writing, for a person to supply a specified quantity of a particular health product or technology which is subject to registration but is not registered during a specified period.

Clause 73 of the Bill provides for the Retention and disposal of goods seized.

Clause 74 of the Bill provides grants the Authority the power to be supplied with information concerning a health product or technology.

Clause 75 of the Bill grants a regulatory officer the power to inspect licenses and books of authorized or licensed sellers.

Clause 76 of the Bill makes it an offence to hinder a regulatory officer from exercising their duties in accordance with the Act.

Clause 77 of the Bill provides for vicarious criminal responsibility. It stipulates that if an offence is committed under the Act by a body corporate. The offence shall be deemed to have been committed by the Directors. Secretary and manager of the body corporate.

Clause 78 of the Bill provides for penal sanctions with regards to body corporates.

Clause 79 of the Bill grants a regulatory officer the power to inspect any animals intended for slaughter. In addition, the regulatory officers may seize and examine any meat which they may consider unfit for consumption.

Clause 80 of the Bill provides for the powers of regulatory officers. These powers include —

- a) The power to enter into premises to perform their duties as prescribed under the Bill;
- b) The power to conduct searches;

- c) The power to open and examine any receptacle or package they believe contains any article to which the Bill or any regulations apply;
- d) The power to examine any books, documents or other records; and
- e) The power to seize and detain for such time as may be necessary.

Clause 81 of the Bill provides for the powers Directors of medical services, veterinary services and agriculture to have articles analysed.

Clause 82 of the Bill stipulates the duty of the county authority to exercise powers that is vested with to provide proper safeguards for the sale of scheduled substances, health products and technologies.

Clause 83 of the Bill grants the Cabinet Secretary power to obtain particulars of substances.

Clause 84 of the Bill grants the Court the power to order licence to be cancelled.

Clause 85 of the Bill grants a regulatory officer the power to take out proceedings for an offence under the Act or regulations.

Clause 86 of the Bill stipulates the penalties for offences committed under the Bill.

Clause 87 of the Bill stipulates that a certificate of Analysis signed by the National Quality Control Laboratory shall be accepted as evidence in a Court of law.

Clause 88-94 of the Bill provides for the financial provisions relating to the Authority including

- a) Funds of the Authority;
- b) Financial year of the Authority;
- c) Annual estimates of revenue and expenditure of the Authority of that year;
- d) Accounts and Audits of the income, expenditure, assets and liabilities of the Authority;
- e) Investment of funds of the Authority;
- f) Preparation of annual reports for each financial year; and
- g) Preparation of special reports to be submitted in parliament.

Clause 95-97 of the Bill provides for miscellaneous provisions relating to the functioning of the Authority including

- (a) Making of regulations for the effective enforcement of the Act;
- (b) Transitional provisions; and
- (c) The laws or sections thereof repealed by the enactment of this Act

The Bill does not contain any provisions limiting any fundamental rights or freedom.

The Bill affects the functions of County governments as set out in the Fourth Schedule to the Constitution and is therefore a Bill concerning counties.

The enactment of this Bill shall occasion additional expenditure of public funds.

Dated the 2nd November, 2022.

ROBERT PUKOSE,
Member of Parliament.

