MEDICINES AND RELATED PRODUCTS ACT, 2014

ARRANGEMENT OF SECTIONS

SECTION

PART VI–REGISTRATION OF MEDICINES AND RELATED PRODUCTS

PART VII – CLINICAL TRIALS AND SAFETY MONITORING

PART VIII – MISCELLANEOUS

MEDICINES AND RELATED PRODUCTS ACT, 2014

AN ACT to regulate the quality and safety of medicines and related products and for connected matters.

ENACTED by the President and the National Assembly.

PART I – PRELIMINARY

1. Short title

This Act may be cited as the Medicines and Related Products Act, 2014.

2. Interpretation

In this Act, unless the context otherwise requires-

“accident” means something unpleasant or damaging that happens unexpectedly or by chance;

“advertisement” includes any form of advertisement whether publication, or by display of any notice or by means of a catalogue, price list, letter, whether circular or addressed to a particular person, or by the exhibition of a photograph or a cinematograph film, or by way of sound recording, sound broadcasting, or television or any other means of communication;

“advertisement” includes a representation by any means for the purpose of promoting, directly or indirectly, the sale or disposal of a product regulated under this Act;

“Agency” means the Medicines Control Agency;

“Analyst” means a person appointed by the Minister to act as an Analyst for the purposes of this Act;

“approved prescriber” means a person authorised by law or by the Minister and required by [relevant bodies] to supply medicine;

“article” includes products regulated under this Act;

“authorized officer” means a medical officer of health, a health inspector or a person authorized in writing by the Agency, the Minister, or any other person authorized by the Agency to perform under this Act;

“certificate” means a certificate issued by the Agency under this Act;

“household chemical substance” means a substance or mixture of substances packaged for use in domestic or office setting as -

a) a germicide,

b) an antiseptic,

c) a disinfectant,

d) a pesticide,

e) an insecticide,

f) vermicide,

g) a detergent, or

h) any other substance or mixture of substances declared by the Minister after consultation with the Agency, to be a chemical substance;

“clinical trials” means an investigation or series of investigations consisting of a particular description by, or under the direction of, a medical practitioner, dentist or veterinary surgeon to the patient or animal where there is evidence that a medicine or related product of that description has effects which may be beneficial to and safe to the patient or animal, and the administration of the drug, medical device or herbal drug is for the purpose of ascertaining beneficial or harmful effects;

“Codex” means the standards, codes of practice, guidelines and recommendations issued by the Codex Alimentarius Commission;

“container” in relation to products regulated under this Act" includes a bottle, jar box, packet, sachet or any other receptacle which contains or is to contain in it a product regulated under this Act which is not a capsule or any other article in which the product is or is to be administered or eaten, and where the receptacle is or is to be contained in another receptacle, the former but not the later receptacle;

“cosmetic” includes a substance or mixture of substances manufactured, sold or represented for use in cleansing, improving or

altering the complexion, skin, hair, eye or teeth and deodorants and perfumes;

“court” means a court of competent jurisdiction;

“exigency” means a situation of depiction or inaccessibility to pharmaceutical service;

“export” means export out of The Gambia;

“health practitioner” includes a nurse, midwife, physician assistant and any other person approved by the Agency;

“herbal medicinal product” includes plant–derived materials preparations with therapeutic or any other human or animal health benefits which contain raw or processed ingredients from one or more plants and materials of organic or animal origin;

“homeopathic medicine” includes a substance that be attenuated to render it stronger as the potency increases and at some time that the original substance is diluted, and a substance that can cause certain symptoms in a healthy person and can be used to relieve those symptoms any other person suffering from those symptoms;

“homeopathy” means an alternative system of medicine based on the concept that diseases can be cured when a patient is treated with minute quantities of a substance that produces symptoms of the disease on a healthy person;

“import” means import into The Gambia;

“industrial purposes” means the use otherwise than for human or animal consumption;

“insanitary conditions” means the conditions or circumstances which might contaminate a product regulated under this Act with dirt or filth or might render the article injurious or dangerous to health;

“Inspector” means a person authorised to carry out inspections under this Act;

“itinerant medicines supplier” means a person who hawks restricted Medicines, other than from the approved premises;

“label” includes a legend, tag, brand, work or mark, pictorial or any

other descriptive matter written printed, stenciled, marked embossed or impressed on or attached to a product regulated under this Act;

“manufacture” includes the operations involved in the production, preparation, processing, compounding, formulating, filling, refining transformation, packing, packaging, re-packaging and labeling of products regulated under this Act;

“medical device” means an instrument, apparatus, implement, a medical equipment, machine, contrivance, implant, *in vitro* reagent or any other similar or related article, including a component, part or an accessory which is recognized in the official natural formulary or pharmacopoeia or a supplement to them, or intended for use in the diagnosis of a disease or any other condition, or in the cure, mitigation, treatment or prevention of disease in humans and animals, or intended to affect the structure or a function of the body of the human being or other animal and which does not achieve any of its principal intended purposes through chemical action within the body of the human being or any other animal and which is not dependent on being metabolized for the achievement of any of its principal intended purposes;

“medical treatment centre” means a health institution for the treatment of out-patients and which is under the immediate supervision of an attendant recognised by the Agency;

“medicines” includes a substances or mixture of substances prepared, sold or represented for use-

(a) in the diagnosis, treatment, mitigation or prevention of disease, disorder of abnormal physical state or the symptoms of it, in man or animal,

(b) restoring, correcting or modifying organic functions in man or animal,

(c) nutritional supplements, or

(d) herbal medicines;

“Minister” means the Minister responsible for Health and “Ministry” shall be construed accordingly;

“over the counter medicine” means drugs that can be bought or supplied without a prescription or without the supervision of a Pharmacist;

“package” means in relation to a product regulated under this Act, a box, packet or any other article in which one or more primary containers of products regulated under this Act is or are to be enclosed in one or more other boxes, packets or articles in question, the collective number of them;

“Pharmacy Support Personnel” includes Pharmacy Technicians, Dispensing or Pharmacy Assistants;

“pharmacy only medicine” means a restricted medicine classified as such Agency other than prescription only or over the counter medicines which may be sold or supplied by or under the supervision of a registered pharmacist;

“pharmaceutical care” means the situation where the practitioner takes responsibility and is accountable for the medicine related needs of a patient or client;

“practitioner” means a registered Pharmacist or a Pharmacy Support Personnel;

“precursor chemicals” means all substances used in the manufacture of narcotic drugs or Psychotropic substances as provided for under the International Drug Control Conventions;

“premises” includes land, buildings, structures, basements, and vessels, and in relation to a building, includes a part of a building and the cartilage, forecourt, yard or place of storage used in connection with the building or part of the building, and in relation to a vessel, includes a ship, boat, an aircraft, a carriage or receptacle of any kind whether open or closed;

“products regulated under this Act” includes medicines and related products, chemical substances, precursor chemicals;

“prescription only medicine” means a restricted medicine classified as such by the Agency which shall only be sold or supplied in accordance with a valid prescription given by a medical practitioner, dentist, veterinary practitioner or any person authorised by the Agency;

“professional” means the responsible for supervising the dispensing, preparation, sale or supply of medicines and related products in approved pharmacy premises;

“promotional or marketing office” means a place where medical

samples and publications related to medicines are kept for public information;

“public sector ” means health sector funded from the Consolidated Fund or directly out of moneys provided by National Assembly;

“regulations” means regulations made under this Act;

“related product” means an article other than medicine which includes cosmetics, homeopathic medicines, medical device, instrument or apparatus including, components, parts and accessories of it, manufactured, sold or represented for use in the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state, or the symptom of it in man or animal;

“restricted medicines” means scheduled medicines pre-scribed by regulations; “restricted medicine” includes medicines classified as “prescription only medicines”, “pharmacy only medicines”, and any other classification approved by the Minister;

“retail” means professional services that include the supply or sale of medicines or related products to a patient or final consumer for personal non-business use from premises by the holder of a retail license issued under this Part;

“sell or sale” includes sell or sale by wholesale or retail, import, offer advertise, keep, expose, display, transmit, consign, convey or deliver for sale or authorize, direct or allow a sale, or prepare or possess for sale and barter or exchange supply or dispose of to a person whether for a consideration or otherwise;

“selling” includes offering for sale, exposing for sale and having in possession for sale or distribution;

“substance” means a natural or artificial substance whether in solid or liquid form or in the form of a gas, vapour or radiation;

“supply outlet” means premises licensed under this Act where medicines are supplied; and

“unfit product” means a product regulated under this Act which violates a provision of this Act.

PART II- MEDICINES CONTROL AGENCY

3. Establishment of the Medicines Control Agency

(1) There is established by this Act, the Medicines Control Agency.

(2) The Agency shall be a body corporate with perpetual succession and may sue and be sued in its corporate name.

(3) The common seal and the seal of the Agency shall be authenticated by the signature of the Executive Director who shall be a registered Pharmacist or in his absence any person acting on his behalf authorized by him in writing

(4) The Agency may, for the performance of its functions, acquire and hold movable or immovable property and enter with a contract or any other transaction.

4. Functions of the Agency

The Agency shall be the regulatory body for the products regulated under this Act, and shall in particular-

(a) regulate all matters relating to efficacy, quality and safety of medicines and related products;

(b) regulate in accordance with this Act, the importation, manufacture, labeling, marking or identification, storage, promotion, sale and distribution of medicines and or any related product, materials or substances used in the manufacture of products regulated under this act;

(c) ensure that evidence of existing and new adverse events, interactions and information about pharmacovigilance of products being monitored globally, are analyzed and acted upon;

(d) ensure that, clinical trials on medicines and related products, and herbal medicines are being conducted in accordance with prescribed standards;

(e) foster co-operation between the Agency and other institutions or organizations and other stakeholders;

(f) approve and register medicines and related products regulated under this Act, manufactured within or imported

into, and intended for use in The Gambia as mentioned in Schedules I, II, and III;

(g) examine, grant, issue, suspend, cancel and revoke certificates and licenses or permits issued under this Act;

(h) appoint inspectors and order inspection of any premises;

(i) promote the rational use of medicines and herbal medicines;

(j) establish and maintain the Gambia National Formulary and Pharmacopoeia;

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

(l) Control of advertisements of medicines and related products

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

(n) maintain registers pertaining to regulation of medicines and related products prescribed under Schedule I, II and III under the regulations;

(o) be responsible for its human resource management and development;

(p) promote, monitor and ensure successful implementation of the provisions of this Act relating to medicines and related products;

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

(r) carry out such other functions as may be conferred upon the Agency by any written law or as are incidental to the performance of its functions under this Act;

(s) do such acts or take such measures as are, in the opinion of the Agency, necessary or expedient for the

prevention of health hazards to consumers which may result from the consumption or use of low or bad quality medicines and related products regulated under this Act;

5. Governing Board of the Agency

(1) The Agency shall be governed by a Board consisting of-

(a) a Chairperson;

(b) the Permanent Secretary of the Ministry;

(c) a representative of the Medical and Dental Association;

(d) the Director General of the National Drug Enforcement Agency;

(e) the President of the Pharmaceutical Society of Gambia;

(f) the Registrar of the Pharmacists Council;

(g) the Director of National Pharmaceutical Services;

(h) a representative of the Veterinary Practitioners Association;

(i) a representative of the Consumer association;

(j) a representative of the Herbal Practitioners Association;

(k) a legal practitioner from the Attorney General Chambers not below the rank of a Senior State Counsel; and

(l) the Executive Director of the Agency, who shall be the secretary to the Board.

(2) The members of the Board other than the ex officio members shall be appointed by the President after consultation with the Public Service Commission.

(3) The members of the Board other than an ex-officio member shall hold office for a period of three years renewable once.

(4) A member of the Board may at any time resign from office in writing addressed to the Minister.

(5) The Board shall ensure the proper and effective performance of the functions of the Agency

6. Meetings of the Board

(1) The Board shall meet at least once in every two months at the place and times determined by the Chairperson.

(2) The Chairperson shall preside at the meetings of the Board and in the absence of the chairperson one of the members elected by the members present shall preside.

(3) Decisions of the Board shall be by majority of votes and in the event of an equality of votes, the Chairperson or the person presiding at the meeting shall have a casting vote.

(4) The quorum for a meeting of the Board is seven.

(5) The validity of any of the proceedings of the Board shall not be affected by a vacancy among its members or by a defect in the appointment of any of them or by the absence of any one of them.

(6) The Board may co-opt a person to act as an adviser at a meeting of the Board, but a co-opted person is not entitled to vote on a matter for decision by the Council.

(7) A member of the Board who has an interest in a matter for consideration by the Board shall disclose in writing the nature of that interest, and is disqualified from participating in the deliberations of the Board in respect of that matter.

(8) A member who contravenes sub-section (7) may be removed from the Board on the recommendation of the Minister.

(9) Subject to this section, the Board shall regulate the procedure for its meetings.

7. Committees of the Agency

(1) The Board may appoint such committees of the Agency as it considers necessary, consisting of members of the Agency and non–members.

(2) A committee of the Agency may be chaired by a member of the Board except that the Disciplinary Committee shall be chaired by the legal practitioner on the Board.

(3) Members of a committee appointed by the Board shall be paid

the remuneration or allowances determined by the Minister in consultation with the Minister responsible for Finance.

8. Executive Director

(1) The Agency shall be headed by an Executive Director who shall be appointed by the President after consultation with the Board and the Public Service Commission.

(2) The Executive Director shall hold office on the terms and conditions specified in his letter of appointment.

9. Functions of the Executive Director

(1) The Executive Director is responsible for –

(a) the day-to-day administration of the affairs of the Agency;

(b) the proper management of its funds, property and business and for the personnel management;

(c) the development, organization, control and discipline of the employees of the Agency; and

(d) performing any other functions determined by the Board.

(2) The Executive Director shall be the Agency's Accounting officer with such financial responsibilities as may be provided for under the relevant Act.

10. Appointment of other staff

(1) There shall be appointed for the Agency, other officers and staff that are necessary for the proper and effective performance of its functions.

(2) Other public officers may be transferred or seconded to the Agency or may otherwise give assistance to it.

(3) The Agency may engage the services of advisers on the recommendations of the Board.

11. Departments of the Agency

The Board may create such departments within the Agency as it deems necessary.

PART III – FINANCIAL PROVISIONS

12. Funds of the Agency

(1) The operations of the Agency shall be financed from-

(a) appropriations by National Assembly;

(b) internally generated revenue;

(c) donations, grants and gifts; and

(d) any other moneys that are approved by the Minister responsible for Finance.

(2) The Agency may retain a percentage of internally generated revenue realized in the performance of its functions, as specified in writing by the Minister responsible for Finance in consultation with the Minister responsible for Health and Social welfare.

13. Exemption from taxation

Notwithstanding any other written law, no stamp duty or any tax shall be chargeable on receipts, contract instruments or other documents given or executed by the Agency or on behalf of the Agency or by any person in respect of any function done or performed under this Act.

14. Accounts and audit

(1) The Agency shall keep books of account and proper records in relation to its operations in the form approved by the Auditor-General.

(2) The Agency shall submit the accounts of the Agency to the Auditor-General for audit within one month after the end of the financial year.

(3) The Auditor- General shall after the receipt of the accounts, audit the accounts and forward a copy of the audit report to the Minister.

15. Annual report and other reports

(1) The Agency shall within one month after the receipt of the audit report, submit an annual report to the Minister covering the activities and the operations of the Agency for the year to which the report relates.

(2) The annual report shall include the report of the Auditor-General.

(3) The Minister shall within three months after the financial year, submit the report to the National Assembly.

(4) The Agency shall also submit to the Minister any other reports which the Minister may require in writing.

PART IV – LICENSING

16. Licenses and permits

(1) The Agency may, on an application made in the prescribed form, issue a license for-

(a) manufacturing premises;

(b) storage facilities;

(c) importers, or exporters;

(d) any other license or permit determined by the Agency for the purposes of this Act.

(2) An application for a license or permit under this Act shall be made to the Agency and shall be accompanied by the prescribed fees.

17. Licensing of medicines and related products

(1) An application for license or permit under this Part shall be made to the Agency in the prescribed form and shall be accompanied by such fees as may be prescribed in the regulations.

(2) Where an application is made for a license or permit under this Part in relation to medicines and related products, the Agency shall, before issuing the license or permit to which the application relates, consider in case of application for manufacturing products regulated under this Act, whether-

(a) the premises in which the applicant proposes to manufacture the respective products have been inspected and registered by the Agency for the purpose;

(b) the substances he or she intends to use are of a quality satisfactory of the standards prescribed by the Agency in respect of the product he or she proposes to manufacture;

(c) he or she has sufficient financial and human resources such as would enable him or her, in relation to the manufacture of products regulated under this Act, to maintain the standards of quality prescribed by or under this Act;

(d) he or she has not, within twelve months immediately preceding his or her present application, been convicted of an offence under this Act or any other written law relating to quality standards of products under this Act;

(e) he or she is not disqualified in any way from holding a license or a person whose license is suspended;

(f) he or she has adequate expertise or skill or has personnel qualified to execute the business for which he or she is seeking to be licensed;

(g) he or she meets in all respects such other requirements which may be prescribed in respect of manufacturers of products regulated under this Act;

(h) the equipment are available for storing the products regulated under this Act on those premises;

(i) the arrangements made or to be made for securing the safe-keeping of, and the maintenance of adequate records in respect of products regulated under this Act.

PART V – MEDICINES AND RELATED PRODUCTS

18. Prohibited sale of medicines and related products

A person who sells a medicine or related product that -

(a) has in or on it a substance that may cause injury to the health of the user when the article is used-

(i) according to the directions on the label accompanying the article, or

(ii) for a purpose and by a method of use that is customary or usual,

(b) consists in whole or in part of a filthy, rotten, decomposed or diseased substance or of a foreign matter likely to cause injury;

(c) is adulterated; and

(d) is prepared, preserved, packed or stored under insanitary conditions.

commits an offence.

19. Standards

(1) Where a standard is prescribed for a medicine or related product, a person who manufactures labels, packages, sells or advertises any other substance in a manner that it is likely to be mistaken for that drug, product, cosmetic, medical device or household chemical substance commits an offence unless the substance is the medicine or related product in question and complies with the prescribed standard.

(2) Where a standard has not been prescribed for a medicine or a related product but a standard for the medicine or a related product is contained in a publication specified in the Regulations, a person who labels packages, sells or advertises any other substance or article in a manner that it is likely to be mistaken for the medicine or the related product commits an offence.

(3) A person who manufactures, labels, packages, sells or advertises a medicine or a related product for which a standard has not been prescribed, or for which a standard is not contained in a publication specified in the Regulations commits an offence unless the medicine or the related product -

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

(b) does not resemble, in a manner likely to deceive, the medicine or the related product for which a standard has been prescribed or which is contained in a publication specified in the Regulations.

20. Deception of consumers

A person who labels, packages, sells or advertises a medicines or a related product-

(a) in contravention of a regulation made under this Act;

(b) in a manner that is false, misleading or deceptive as regards its character, constitution, value, potency, quality, composition, merits or safety;

(c) if it is so coloured, coated powdered or polished that damage is concealed or if it is made to appear of a better or greater therapeutic value than it really is;

(d) if it is not labelled in the prescribed manner; and

(e) if its label or container or anything accompanying the drug or herbal medicinal product bears a statement, design or device which makes a false claim for the medicine or herbal medicinal product, or which is false or misleading in a material particular,

commits an offence.

21. Advertisement and promotion

(1) The Minister on advice of the Agency, may make regulations to regulate any promotional activities connected to medicines and related products under this Act.

(2) Without prejudice to provisions of this Act, no person shall publish, distribute or in any other manner bring to the notice of the public or cause or permit to be published or distributed or to be so brought to the notice of the public any false or misleading advertisement of products regulated under this Act, except in accordance with the code of conduct for promotion of such products as provided in the regulations.

(3) If any medicine or related product, medical device, herbal drug has been registered subject to the condition that it shall be available to a medical practitioner, a dentist or veterinary surgeon, no person shall advertize any medicine or related product, medical device, herbal medicine other than-

(a) in a medical, dental, veterinary or pharmaceutical journal; and

(b) to members of the medical, dental, veterinary or pharmacy profession.

(4) A person shall not advertise or carry out promotional activities of a medicine or related products regulated under this Act, to the

general public as a treatment, preventive or cure for a disease, disorder or an abnormal physical state unless the advertisement has been approved by the Agency.

(5) Regulations made under section 52 may provide for the penalties for a contravention of a provision of sub-section (1).

22. Control of manufacturing

(1) A person shall not manufacture a medicine or related product for sale unless-

(a) the process of manufacture is carried on, or is supervised by a pharmacist or a qualified person approved by the Agency as having specialist knowledge in the product to be manufactured; and

(b) the conditions under which the manufacture is to be carried on are in the opinion of the Agency suitable to ensure that the product will be safe for use.

(2) An application for approval under sub-section (1) shall be made to the Agency and may be granted by the Agency subject to the conditions determined by the Agency.

23. Restriction on importation, manufacture etc.

The Minister may, by notice published in the gazette, prohibit the importation, manufacture, exportation, advertisement or sale of a medicine or related product specified in the Regulations.

PART VI – REGISTRATION OF MEDICINES AND RELATED PRODUCTS

24. Registers

The Agency shall keep separate registers for the registration of human and animal Medicines, homeopathic medicines and related products.

25. Application for registration

(1) An application for the registration of a medicine or related product shall be made to the Agency in the prescribed manner together with the prescribed application fees.

(2) The Agency shall register the medicine or related product if it is satisfied that the medicine or related product complies with the prescribed standards and that the manufacturing operations for the product comply with the prescribed current code of good

manufacturing practice.

(3) The Agency may charge an applicant fees for the purposes of carrying out good manufacturing practice inspection or for laboratory investigations prior to registration of the medicine or related product.

(4) An application under sub-section (1) may at any time be withdrawn by the applicant but the withdrawal does not entitle the applicant to the refund of the application fee.

(5) Where the application for renewable is made after the expiration of the certificate of registration of a medicine or related product, the application shall be considered as a fresh application and the provisions of section 36 shall apply accordingly.

26. Registration of the medicines and related products

(1) A person shall not manufacture, prepare, import, export, distribute, sell, supply or exhibit for sale a medicine or related product unless the article has been registered by the Agency.

(2) Sub-section (1) does not apply to an import permit issued by the Agency for the importation of any of the products mentioned in that sub-section which is imported for personal use.

(3) Sub-section (1) does not prevent the importation of a sample for purposes of registration of the medicine or the related product

(4) The Agency may on an application made to it, approve the registration of a medicine or related product subject to such conditions as it may impose after conducting the necessary investigation and it is satisfied that –

(a) the medicine or related product is suitable for the purpose for which it is intended; and

(b) it complies with the prescribed requirements.

27. Registration of homeopathic medicines

(1) A person shall not manufacture, prepare, supply, sell, distribute, export or import a homeopathic medicine unless the homeopathic medicine has been registered with the Agency.

(2) The Agency may by regulations, prescribe particulars to be provided for the registration of homeopathic medicines under sub-section (1).

28. Applicant to be informed of decision

Where the Agency -

(a) refuses to approve the registration of the medicine or related product; or

(b) approves registration of the products referred to in paragraph (a) subject to the conditions fixed in terms of sub-section 36 (4),

the Executive Director shall inform the applicant in writing of the decision and the reasons for the decision.

29. Recourse against decision

(1) If the applicant is not satisfied with the decision of the Agency, he or she may, make representations through the Executive Director within sixty days after the date of the notification.

(2) After consideration of the representations submitted by an applicant, the Agency may approve the registration of the medicine or the related product or if it is still not satisfied, reject the application.

30. Approval of medicines and related products

(1) Where the Agency approves the registration of a medicine or related product, the Executive Director shall-

(a) enter in the register, the prescribed particulars of the medicine or related product and the relevant conditions or particulars;

(b) allocate a registration number to the medicine or related product for a period of not more than five years; and

(c) issue to the applicant a certificate of registration in the prescribed form, showing the registration number of the medicine or related product and the conditions subject to which it is registered.

(2) Where the Agency approves, refuses to approve or cancels the registration of a medicine or related product, the Executive Director shall cause to be published in the Gazette notification of such approval or refusal and shall in such notices specify, the name under which such notice specify, the name under which such drug is registered, the qualitative and quantitative content of its active components, the name of the registrant and the registration number.

31. Rejection of application in the public interest

The Agency may reject the name of a medicine or related product contained in an application on specified grounds if it is satisfied that it would be in the public interest.

32. Cancellation, suspension of registration

(1) The Agency may suspend or cancel a license issued under this Act for a medicine or related product if information submitted in respect of the registration changes or it is found to have been inaccurate.

(2) An applicant may at any time after suspension or cancellation of a registration re-submit new information on the medicine or related product

(3) A person responsible for the registration of a medicine or related product who fails to inform the Agency of a change in the information submitted for its registration commits an offence.

33. Renewal of medicine and related products registration and licenses

(1) A product registration made or issued under this Act may be renewed for a further period of not more than three years.

(2) A premise license issued under this Act shall be renewed annually.

34. Certificate on imported medicines

Where a medicine or related product is imported as a finished product, an application for the registration of that article shall be accompanied by a certificate of analysis or certificate of pharmaceutical product for medicines issued by the competent regulatory Agency of the exporting country.

35. Medicines and related products not to be distributed as samples

(1) A person shall not distribute a medicine or related product as a sample.

(2) A person who, without authority from the Agency, distributes a medicine or related product as sample commits an offence.

36. Importation

(1) A person who has not been issued with a license or permit under this Act, shall not import a medicine or related product.

(2) Subject to sub-section (1), the Agency may in the public interest, authorise parallel importation of medicines or related products.

(3) A person shall not import medicines or related products with a shelf life of less than sixty percent unless approved by the Agency.

(4) The Agency shall grant import licence or permit to only licensed pharmaceutical companies.

(5) The Agency may grant an import licence or permit to hospitals or similar health related institutions on special request only when such medicines or related products are not locally available

(6) In this section, parallel importation means importing a medicine without authorisation of the medicine registration holder from another country where it is legitimately placed.

37. Import, export, re-export, transportation and transit transportation of medicines and related products

(1) A person shall not import, export, re-export, transport or use of a port for transit transportation of medicines or related products unless that person is licensed or authorised by the Agency to carry on the business.

(2) The import, export, re-export, transportation or use of a port for transit transportation of medicines or related products shall be carried out in accordance with regulations determined by the Agency.

38. Counterfeit medicines and related products

(1) A person shall not manufacture, import, export, supply, possess or offer for sale a counterfeit medicine or related product

(2) For the purposes of this Act, a medicine or related product is counterfeit if -

(a) it is deliberately or fraudulently mislabeled with respect to its identity or source;

(b) it is manufactured under a name which belongs to another drug; or

(c) it is an imitation of, or is a substitute for another medicine or related product or resembles another medicine or related product or it is likely to deceive or bears on its label or container the name of another medicine or related product, unless it is plainly and conspicuously marked so as to reveal its true character and its lack of identity with any other medicine or related product;

(d) the label or container bears the name of an individual or a company purporting to be the manufacturer of the medicine or related product which individual or company is fictitious or does not exist;

(e) it has been substituted wholly or in part by any other medicine or substance;

(f) it purports to be a product of a manufacturer of whom it is not truly a product; or

(g) it is a medicine which or the container or labelling of which, without authorization, bears the trademark, trade name or any other identifying mark, imprint, or device or the likeness of a medicine manufacturer, processor, packer or distributor, other than the person who in fact manufactured, processed, packed, or distributed the medicine or article and which thereby falsely purports or is represented to be the product of or to have been packed or distributed by the other medicine manufacturer, processor, packer or distributor.

PART VII – CLINICAL TRIALS AND SAFETY MONITORING

39. Clinical trials

(1) A person shall not, in the course of a business carried on by him or her-

(a) sell or supply a medicine or related product for the purpose of a clinical trial; or

(b) procure, import, manufacture or assemble a medicine or related product for sale or supply for the purpose of clinical trial, unless-

(i) he or she is a holder of a product registration which authorises the clinical trial,

(ii) does it to the order of the proprietor of the license, and in either case does it in accordance with the product registration,

(iii) a clinical trial certificate, for the purposes of this section, has been issued in writing to him or her certifying that, subject to the conditions of the certificate, the Agency has authorized the clinical trial, or

(iv) that a clinical trial certificate is for the time being valid and the trial is to be carried out in accordance with that certificate or instruction issued in writing by the Agency.

(2) A person shall not conduct a clinical trial of a medicine, or related product without the written authorisation of the Agency.

(3) A person who intends to conduct a clinical trial of a medicine or related product shall submit to the Agency -

(a) an application in the prescribed form duly signed and accompanied with the prescribed fee;

(b) an ethical clearance certificate issued for medical research by an approved institution; and

(c) the relevant information as provided under the guidelines for registration of medicines and related products for clinical trials.

(4) Where a clinical trial is to be conducted in a hospital, veterinary institution or designated institution, the application referred to in sub-section (1) shall be countersigned by a medical superintendent or medical officer, or veterinary surgeon of the medical or veterinary institution.

(5) For the purposes of this section, a designated institution includes a medical or veterinary institution, or any other institution approved by the Agency.

40. Agency to investigate

(1) On the receipt of an application under section 47 (3), the Agency shall conduct investigations to authenticate the safety, efficacy, purity and quality of the medicine or related product and if it is satisfied that the medicine or related product is reasonably safe, efficacious and of acceptable quality, the Agency shall register the

medicine or related product for the purposes of the clinical trial.

(2) Subject to sub-section (1), the Agency may issue a clinical trial certificate for the approved products

(3) A person who is aggrieved by a decision of the Agency regarding the granting of an authorisation for the conduct of a clinical trial may make representations within sixty days to the Agency.

(4) Where a representation is not submitted by the applicant within sixty days or if after consideration of the representation the Agency is still not satisfied, the Agency shall reject the application.

41. Conditions to conduct clinical trials

A clinical trial of a medicine or related product authorised under section 48 –

(a) is subject to the specific and general conditions imposed by the Agency; and

(b) for the safety of the persons or animals taking part in the trial, shall strictly observe the conditions imposed subject to which the trial was authorised.

42. Consent for clinical trials

Where the Agency grants written authorisation under section 48 for the conduct of a clinical trial of a medicine or a related product, the trial shall not take place until, in the case of a medicine or related product-

(a) for the treatment of adult persons, the voluntary written consents of the persons taking part in the clinical trial have been freely obtained by the person conducting the trial;

(b) for the treatment of minors or persons under legal disability, the voluntary written consents of their parents or legal guardians have been freely obtained by the person conducting the trial; and

(c) for the treatment of animals, the voluntary written consent of the owners of the animals taking part in the clinical trial have been freely obtained by the person conducting the trial.

43. Supply of information prior to clinical trials

(1) Where a clinical trial of a medicine or related product is authorised under section 49, the person conducting the trial shall, before commencing the trial-

(a) inform the persons taking part in the trial or persons whose animals will take part in the trial about-

(i) the aims and objectives of the clinical trial and the way in which it will be conducted;

(ii) the possible risks, discomforts and any other adverse effects that may result;

(b) ensure that a person or an animal taking part in the trial does not sustain an injury during the trial; and

(c) sign an indemnity in the prescribed form indemnifying the Government and the Agency from liability in respect of an injury or an adverse effect which may be sustained by a person or an animal, directly or directly, as a result of the conduct of the trial and which occurs or reveals itself at the time of trial or subsequently.

44. Powers to stop or suspend clinical trials

(1) If at any stage during the clinical trial of a medicine or related product, the Agency is satisfied that considering the initial risks, discomforts or any other adverse effect caused to a person or an animal taking part in the trial, it is in the public interest to stop or suspend the trial, the Agency shall order the person conducting the clinical trial to stop or suspend the trial immediately.

(2) Without prejudice to sub-section (1), the Agency may for any other reasonable cause suspend, vary or stop a clinical trial.

(3) The Agency shall notify the person conducting the trial of its decision and the reasons for the decision.

45. Monitoring of clinical trials

The Agency shall monitor a clinical trial from the beginning to the end in order to ensure -

(a) adequate protection of the general public against the risks or adverse effects from the clinical trial of a medicine or related product;

(b) that the specific and general conditions subject to which the trial was authorized are being strictly observed by the person conducting the trial; and

(c) that the trial will achieve its aims and objectives.

46. Reports on clinical trials

(1) The Agency may require the person conducting the trial to submit to the Agency, such reports as it may direct.

(2) In addition to the report referred to in sub-section (1), the person who is conducting the trial shall immediately report to the Agency, any serious adverse effect or event observed during the trial.

47. Renewal and revocation of clinical trial certificate

(1) Subject to sub-section (2), a clinical trial certificate shall expire at the end of the authorized period of the trial unless earlier revoked.

(2) A certificate may be renewed on the application of the holder, by the Agency for such further period specified by the Agency.

48. Safety monitoring

(1) A local representative for a regulated product shall be appointed by the relevant body.

(2) The local representative-

(a) shall monitor the safety of the product granted marketing approval; and

(b) shall report an adverse affect or event to the Agency during the period under which the product is registered.

(3) The Agency shall continually monitor the safety of the products regulated under this Act by analysis of the adverse effect or event reports and by any other means and take appropriate regulatory action when necessary.

PART VIII - MISCELLANEOUS

49. Regulation of narcotic and psychotropic substances

(1) The Agency shall regulate the manufacture, import, export, or distribution of narcotic medicines, psychotropic substances for legal or medical use and precursor chemicals in accordance with-

(a) the Drug Control Act; and

[cap. 13.05]

(b) the international conventions and any other relevant guidelines and protocols to which The Gambia subscribes, including-

(i) the single convention on Narcotic Medicines of 1961 (1961 Convention) as amended by the 1972 Protocol,

(ii) the Convention on Psychotropic substances of 1971 adopted in 1988, or

(iii) the united Nations convention against illicit Traffic Drug and Psychotropic substances, 1988.

50. Quality control of medicines and related products

(1) There is established by this Act, the National Medicines Quality Control Laboratory.

(2) The Laboratory shall work independently of the Agency.

(3) The Laboratory shall perform functions relating to the quality of products regulated under this Act and shall in particular-

(a) analyse medicines and related products, raw materials, drug adjuvant, packaging material, drug delivery systems, systemic diagnostic agent and any other product that the Agency considers a medicinal product for the purposes of this Act;

(b) conduct research and training; and

(c) perform any other functions in relation to the Laboratory as determined by the Agency.

(4) The Minister may on the advice of the Agency, make regulations prescribing-

(a) the procedure for the submission to the Laboratory of samples of articles of medicines and related products and provisions for analysis or tests and the forms of the Laboratory‘s report; and

(b) any other matters that are necessary or expedient to enable the Laboratory to perform its functions.

(5) The Minister may, in case of a dispute regarding analytical results, appoint an independent laboratory or an independent qualified person to comment on the analytical results.

51. Powers of authorised officers

(1) An authorised officer may, at reasonable hours of the day-

(a) enter any premises where the officer believes an article to which this Act applies is prepared, preserved, packed, stored or conveyed and examine the article and take samples and examine anything that the officer believes is used or is capable of being used for the preparation, preservation, packaging, storing or conveying of the article;

(b) open and examine a receptacle or package which the officer believes contains an article to which this Act applies;

(c) examine the books, documents, or any other records found in a place mentioned in paragraph (a) which the officer believes contains an information relevant to the enforcement of this Act and make copies of them or take extracts from them; and

(d) seize and detain for the period that the officer considers necessary an article by means of or in relation to which it is believed a provision of this Act has been contravened.

(2) An authorised officer acting under this section shall, if required, produce the authority to act.

(3) Where the owner or a responsible person in occupation of premises is present and refuses to open a container or door on being asked to do so, an authorised officer may by a warrant break open the container or door of the premises where medicines may be kept for storage or sale.

(4) A person who obstructs or impedes an authorised officer in the course of the officer‘s duties or by a gratuity, bribe, promise, or any other inducement prevents, or attempts to prevent, the due execution by the authorized officer of duties under this Act or of the Regulations commits of an offence.

52. Forfeiture and disposal of seized articles

(1) Where a person is convicted of an offence under this Act, the court may order that an article by means of or in relation to which the offence was committed or a thing of a similar nature belonging to or in the possession of the convicted person or found with the article, be forfeited, and on the order being made the article or thing may be disposed of as directed by the court.

(2) A person who removes, alters or interferes with an article or a thing seized under this Act without the authority of an authorised officer commits an offence.

53. Head of the National Medicines Quality Control Laboratory

(1) The Minister may on the advice of the Agency, appoint on the terms determined by the Minister, the Head of the National Medicines Quality Control Laboratory to undertake the analysis required under this Act.

(2) An authorised officer may submit an article seized by the officer or a sample of it to the Head of the National Medicines Quality Control Laboratory for analysis.

(3) The Head of the National Medicines Quality Control Laboratory An Analyst shall as soon as practicable, analyse or examine a sample sent to him or her in pursuance of this Act and shall give the authorised officer a certificate specifying the result of the analysis .

(4) The certificate shall be in the form prescribed by the Minister after consultation with the Agency.

(5) A person shall not be appointed the Head of the National Medicines Quality Control Laboratory a public Analyst where he or she is engaged directly or indirectly in a trade or business connected with the sale of medicines, related products or medical devices.

54. Quarterly reports of Analysts

The Head of the National Medicines Quality Control Laboratory shall submit a quarterly report to the Agency, on the number of products which have been analysed by his/her laboratory under this Act.

55. Power of Agency to obtain particulars of certain ingredients

(1) The Agency may direct a person who at the date of the directive or at a subsequent time carries on a business which includes the production, importation or use of articles to which this Act applies to furnish the Agency, within a period specified in the

directive, specified particulars on the composition and use of the substance sold or for sale in the course of that business or used in the preparation of medicines.

(2) In addition to sub-section (1), a directive may require the following particulars to be furnished in respect of the substance-

(a) particulars of the composition and chemical formula of the substance;

(b) particulars of the investigations carried out by or to the knowledge of the persons carrying on the business, to determine whether and to what extent the substance used, is injurious to, or in any other way affect, health; and

(c) particulars of the investigations or inquiries carried out by or to the knowledge of the person carrying on the business for the purpose of determining the cumulative effect on the health of a person consuming the substance in ordinary quantities.

(3) Particulars furnished in accordance with directives under this section and information on the particulars shall not, without the previous consent in writing of the persons carrying on the business, be disclosed except for the purposes of proceedings for an offence under this Act.

(4) A person who discloses any particulars or information in contravention of sub-section (3) commits an offence.

56. Classification of medicines

The Minister shall on the advice of the Agency, by notice published in the gazette classify medicines and conditions for the supply and dispensing of medicines for the purpose of this Act.

57. Investigation by Inspector

(1) An Inspector -

(a) may require a person on the premises to furnish information in the person‘s possession concerning the activities carried on the premises and the people who carry out the activities;

(b) may inspect the premises and articles found on the premises; and

(c) may take away medicines found on the premises.

(2) The Inspector shall tender reasonable payment for a medicine taken away under this section.

(3) Notwithstanding sub-section (2), payment shall not be tendered for medicine if the Inspector reasonably suspects that the medicine is unfit for its purpose due to deterioration, impurity, adulteration or other defect.

(4) If the medicine is found to be fit, reasonable payment shall be tendered by the Inspector for the portion of the medicine that is not returned to its owner in good condition.

(5) Payment shall not be tendered for a medicine if the Inspector anticipates that proceedings for an offence under this Act may be brought in respect of the medicine.

(6) The Inspector shall tender reasonable payment for the portion of the medicines that have not been returned to the owner in good condition where proceedings are not commenced within six months.

(7) Where medicines are taken under this section, an inventory of the medicines or articles shall be made and shall be signed by the by a responsible officer in the facility and the Inspector and a copy of the inventory shall be given to the pharmacist or the pharmacy support personnel.

(8) The Inspector shall seize the medicines and devices that constitute an imminent danger to public health or welfare.

(9) An Inspector exercising any power conferred by this Act shall produce on demand a duly authenticated document which shows that the inspector has the Agency to exercise the power.

58. Power of closure

(1) An Inspector may close premises that manufactures, sells or supplies medicines where there are grounds to believe that a health hazard may exist on the premises or where the premises are unlicensed.

(2) The closure of the premises shall be made with the assistance of the police but where this is not possible, the closure shall be reported to the police within twenty four hours after the closure.

(3) The order in respect of the health hazard may have conditions attached as determined by the Agency.

59. Offences

(1) A person who-

(a) supplies medicines from a promotional or marketing office without the supervision of a registered Pharmacist;

(b) obstructs a person authorised by the Agency from exercising lawful authority;

(c) is found to be in possession of restricted medicines without lawful authority;

(d) peddles medicines as an itinerant medicine supplier; or

(k) manufactures, prepares, stores, medicines from unauthorised premises,

commits an offence and is liable on conviction to a fine of not exceeding five hundred thousand Dalasi or to imprisonment not exceeding five years or both; and in the case of a continuing offence to a further fine of one thousand Dalasi for each day during which the offence continues after written notice has been served on the offender by the Agency.

(2) Where an offence is committed by a body of persons-

(a) in the case of a body corporate other than a partnership, each director, secretary or other officers of that body shall be deemed to commit that offence; and

(b) in the case of partnership, each partner shall be deemed to commit the offence.

(3) A person shall not be convicted of an offence if it is proved that the offence was committed without personal knowledge or consent of that person or that steps were taken to prevent the commission of the offence.

60. General penalty

A person who commits an offence under this Act or the Regulations for which a special penalty is not provided is liable on conviction-

(a) in the case of a first offence, to a fine of not exceeding five hundred thousand Dalasi or to imprisonment not exceeding five years, or to both the fine and the imprisonment, or

(b) in the case of a subsequent offence, to a fine of not less than five hundred thousand Dalasi or to imprisonment of not less than .five years or to both the fine and the imprisonment.

61. Certificate of analysis and presumptions

In proceedings under this Act or the regulations-

(a) a certificate of analysis signed by a public Analyst shall be accepted as prima facie evidence of the facts stated in it;

(b) evidence that a package containing an article to which this Act or the regulations apply, bore a name, address or registered mark of the person by whom it was manufactured or packed in prima facie evidence that the article was manufactured or packed by that person;

(c) a substance commonly used for human or animal consumption shall, if sold, or offered or exposed for sale, be presumed until the contrary is proved, to have been sold or to be intended for sale for human or animal consumption;

(d) a substance commonly used for human or animal consumption in which is found on premises used for the preparation or sale of that substance and a substance commonly used in the manufacture of products for human or animal consumption which is found on premises used for the preparation or sale of those products, shall be presumed, until the contrary is proved, to be intended for sale, or for manufacturing the products for sale for human or animal consumption.

62. Power of Court to suspend or cancel license

(1) On conviction of a person for an offence under this Act or the Regulations, the court may in addition to, or in lieu of any other penalty which it may impose, suspend or cancel a license issued to that person under this Act or the Regulations.

(2) The Registrar of the Court shall, within seven days of the conviction, inform the Agency of the conviction, or the suspension or the cancellation of the license.

63. Compensation

(1) Where at the trial of a person for an offence under this Act or the Regulations, the court on the application of an interested person-

(a) determines that at the date of a closure order, the use of the premises did not involve imminent risk of danger to health; and

(b) is satisfied that loss has been occasioned by the closure order,

the Court may order the Agency to pay compensation to that person of such amount as specified by the court.

(2) For the purposes of sub-section (1), "interested person" includes-

(a) the person accused of an offence under this Act or the Regulations; and

(b) any other person who at the time when the closure order was made, was carrying on business at those premises.

64. Guidelines

The Agency may publish guidelines in connection with matters provided for under this Act for the purpose of giving guidance.

65. Regulations

The Minister may on the advice of the Agency, make Regulations -

(a) to prescribe the fees to be paid under this Act;

(b) to provide for the registration of an article to which this Act applies;

(c) to provide for the regulation of importation or exportation of medicines and related products, in order to ensure compliance with this Act;

(d) prescribing methods of manufacture, processing, sale, storage and transportation of medicines and related products;

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

(f) for the allocation and reporting of narcotics and psycho-tropic substances; and

(g) to provide for any other matters necessary for the effective implementation of the provisions of the Act.

66. Repeal and savings

(1) The Medicines Act 1984 is repealed.

[cap 40.01]

(2) Notwithstanding the repeal of the Medicines Act, any license, permit or certificate issued under that Act shall remain valid until revoked or expired.

OBJECTS AND REASONS

The provision of health care, which includes access to essential medicines and other medical supplies, is a fundamental human right of the citizenry. The National Medicines Policy (2007) aims to contribute to the attainment of quality health care for the population of The Gambia through ensuring availability and accessibility to essential medicines of appropriate quality, efficacy and safety and the promotion of the rational use of the medicines.

The legal framework regulating the importation, distribution and sale of medicines for human and veterinary use are embodied in the Medicines Act 1984 and the Medicines Regulations 1986. A review of this Act identified a number of inadequacies and thus resulting in a number of weaknesses in the regulation of the business of pharmaceuticals and the practice of pharmacy.

A major weakness of the 1984 Act was it combines the regulation of the practice of pharmacy and the regulation of the business of pharmaceuticals (products), to be managed by a Board grossly inadequate to regulate the practice of Pharmacy. Also, whilst the regulation of the pharmaceutical products could be termed as relatively adequate at that time, the regulation of the practice of Pharmacy was deficient in several areas. Another major weakness of the 1984 Medicines Act was the limited regulatory infrastructure for medicines safety monitoring (Pharmacovigilance) and above all, developments in the pharmaceutical sector over the years (since 1984) and newer technologies being used in medicines and other medical supplies manufacture requires upgrading of the legislations to adequately protect the population from consumption of substandard or unsafe medicines.

The new Medicines Control Act (2014) is envisaged to adequately address the weakness in the control of the importation, manufacture, storage and export of medicines and other medical supplies in The Gambia. The new Act shall also ensure the

provision of relevant and accurate information on all medicines authorized for use in the country. This Act will establish the Medicines Control Agency of the Ministry of Health. This Agency be governed by a Board, The Agency will be managed by an Executive Director who accounts to the Governing Board.

The new Medicines Control Act will also establish the National Medicines Control Laboratory as an autonomous institution charged with the quality control of all medicines and other medical supplies imported or manufactured in The Gambia. The National Medicines Control Laboratory shall support the work of the Medicines Control Agency, but shall act independent of the agency.

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HON. OMAR SEY
MINISTER OF HEALTH AND SOCIAL WELFARE