MEDICINES AND RELATED SUBSTANCES ACT, 2025

No. 29 **of 2025**

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An Act to provide for the continuation of the Botswana Medicines Regulatory Authority whose main objective is to regulate the sale, distribution, importation, exportation, manufacture and dispensing of medical products and related substances; and matters incidental thereto.

Date of Assent: 24.12.2025
Date of commencement: ON NOTICE
ENACTED by the Parliament of Botswana.

PART I — *Preliminary*

Short title and commencement

1. This Act may be cited as the Medicines and Related Substances Act, 2025, and shall come into operation on such date as the Minister may, by Order published in the *Gazette*, appoint.

Interpretation

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

"adverse event" means any untoward medical occurrence in a patient or clinical trial subject administered a medical product, which does not necessarily have a causal relationship with the treatment;

"adverse reaction" means a response to a medical product which is noxious and unintended, and which occurs at doses normally used in humans or animals for the prophylaxis, diagnosis, or therapy of disease or for the restoration, correction, or modification of physiological function;

"advertisement", in relation to a medicinal product, includes any pictorial, visual or otherwise descriptive matter or verbal statement or reference communicated, distributed, or made available to the public or any section thereof through any medium or method to the public or any section thereof, including those —

(*a*) appearing in a print or electronic publication;
(*b*) broadcast on television or radio; or
(*c*) brought to the notice of members of the public in any manner whatsoever, which is intended to directly or indirectly advise of the existence and benefits of a medical product;

"applicant" means a company or entity registered in terms of the Companies Act and operating in Botswana; Cap. 42:01

"authorised premises" means premises other than a pharmaceutical wholesaler, pharmacy or veterinary clinic, authorised by the Authority under this Act;

"Authority" means the Botswana Medicines Regulatory Authority continued under section 5;

"Board" means the Board of the Authority, under section 9;

"cannabis control authority" means the National Cannabis Control Commission established under the Cannabis Act; Act No. 20 of 2025

"clinical trial" or "medical research" on a medicine means —

(*a*) any interventional or observational investigation in humans or animals intended to —
(i) discover or verify the clinical, pharmacological or pharmacodynamics effects of an investigational medicinal product or medical device;
(ii) identify any adverse reaction to an investigational medicinal product or medical device; or
(iii) study the absorption, distribution, metabolism and excretion of an investigational medicinal product or medical device, with the object of ascertaining the safety and efficacy of the investigational medicinal product or medical device; or
(*b*) any non-interventional investigation where the medical product is prescribed independent to inclusion of the participant in the study and as part of a therapeutic strategy, including diagnostic and monitoring procedures, which is not decided in advance by a study protocol but is applied according to the current clinical practice;

"complementary medicine" means a labelled substance or a mixture of substances manufactured, sold or represented for use solely, or as adjuvants, to conventional therapy in —

(*a*) the mitigation or prevention of an abnormal physical state; and
(*b*) restoring, correcting or modifying physical, mental or organic functions in humans and animals as determined by the Authority, and

which originates from plant, mineral, animal, including micro-organisms, unani, siddha, ayurveda, homeopathic preparation, traditional Chinese medicine or nutritional substances in accepted pharmaceutical dosage forms, or —
(i) a combination of (*a*) and (*b*), or
(ii) any other such preparations as may be approved by the Authority;

"controlled substances" means a prohibited substance or medicine listed in Schedules 1A, 1B, 1C, 1D, or a precursor chemical;

"coordinated assessment" means the technical evaluation process whereby cannabis product applications are received by the cannabis control authority, referred to the Authority for technical assessment and returned to the cannabis control authority for final licensing decision;

"cosmetic" means —

(*a*) any substance or mixture of substances manufactured, sold or represented for use by rubbing, pouring, spraying, or applying by any other means to the external parts of the human body, including —

(i) epidermis,

(ii) hair system,

(iii) nails,

(iv) lips,

(v) external genital organs,

(vi) teeth, or

(vii) the mucous membranes of the oral cavity, for the purpose of —

(*aa*) cleansing,

(*bb*) beautifying or alteration of appearance,

(*cc*) protecting, or

(*dd*) correcting body odours; or

(*b*) any article intended for use as a component of a cosmetic;

"dentist" means a person registered as a dentist in terms of the Botswana Health Professions Act; Cap. 61:02

"dispensary" means premises in which a dispenser stores, handles, and dispenses medicine listed under Schedule —

(*a*) 1, 2 or 3, in the case of human medicines; and

(*b*) 1, 2, 3, 4, POMS-VP and VPS;

"dispenser" means a pharmacist, veterinary surgen or person authorised to dispense medical products by his or her professional body;

"distribution" means the division and movement of regulated products —

(*a*) from the premises of the manufacturer of such products;

(*b*) from another central point to the end user; or

(*c*) to an intermediate point,

by means of various transport methods, via various storage or health establishments;

"ethics committee or institutional review board" means a disciplinary body, established by the Authority responsible for reviewing biomedical research for safeguarding the dignity, rights, safety and well-being of all actual or potential research participants;

"export" includes delivery or supply within Botswana for dispatch to a destination outside Botswana;

"falsified medical product" means any regulated product with a false representation of —

(*a*) its identity, including its packaging and labelling, its name or its composition as regards any of the ingredients including excipients and the strength of those ingredients;

(*b*) its source, including its manufacturer, its country of manufacturing, its country of origin or its marketing authorisation holder; or

(*c*) its history, including the records and documents relating to the distribution channels used;

"immediate member of the family" means the spouse, son, daughter, sibling or parent of a member of the Board;

"inspector" means a person appointed in terms of section 78;

"investigational medical product" means a medicine in pharmaceutical form of an active ingredient or placebo; or a medical device being tested or used as a reference in a clinical trial or medical research, including a product with marketing authorisation when used or assembled —

(*a*) in a way different from the approved form;

(*b*) for an unapproved indication; or

(*c*) used to gain further information about approved use;

"*in-vitro* diagnostics" means a medical device, whether used alone or in combination, intended by the manufacturer for the *in-vitro* examination of specimen derived from the human or animal solely or principally to provide information for diagnostic, monitoring or compatibility purposes which includes but not limited to re-agents used for *in-vitro* diagnostics purposes, calibrators, control chemicals, specimen receptacles, software and related instruments or apparatus or other articles and are used for diagnosis, aid to diagnosis, screening, monitoring, predisposition, prognosis, prediction or determination of physiological status;

"market authorisation" means a registration certificate issued by the Authority for the purpose of marketing or distribution of a product which has been approved by the Authority after evaluation for safety, quality and efficacy;

"maximum residue limit" means the maximum concentration of residue expressed in milligram or kilogram in a food product resulting from the use of a veterinary medicine, and that is recommended by the Codex Alimentarius to be legally permitted or recognised as acceptable concentration;

"medical device" means any instrument, apparatus, implement, machine, appliance, implant, *in-vitro* re-agent or calibrator, software, material or other similar or related article —

(*a*) intended by the manufacturer to be used, alone or in combination, for humans or animals for —

(i) diagnosis, prevention, monitoring, treatment or alleviation of diseases,

(ii) diagnosis, monitoring, treatment, alleviation of or compensation for an injury,
(iii) investigation, replacement, modification or support of the anatomy or of a physiological process,
(iv) supporting or sustaining life,
(v) control of conception,
(vi) cleaning, disinfection or sterilisation of medical devices, or
(vii) providing information for medical or diagnostic purpose by means of *in-vitro* examination of specimens derived from the human body; and

(*b*) which does not achieve its primary intended action in human or animal body by pharmacological, immunological or metabolic means but which may be assisted in its intended function by such means;

"medical practitioner" means a person registered as a medical practitioner in terms of the Botswana Health Professions Act;

"medical product" means medicine, complementary medicine, vaccines, *in-vitro* diagnostics and medical devices;

"medicine" means —

(*a*) any substance, mixture or combination of substances manufactured, sold or presented for use in —
(i) the diagnosis, treatment, alleviation, modification or prevention of disease, illness, abnormal physical or mental condition or the symptoms thereof, or
(ii) restoring, correcting or modifying any somatic or psychic or organic condition; or

(*b*) any controlled substance, to the extent that it complies with paragraph (*a*);

(*c*) a substance or mixture of substances that is used to manufacture medicine or is sold as a raw material, a pre-cursor chemical or intermediate;

(*d*) any labelled preparation in pharmaceutical dosage form that contains as active ingredients, one or more substances of natural origin that are derived from plants or animals;

(*e*) homeopathic, ayurvedic, or other, medicine that contains, as active ingredients, substances of natural origin, and may be derived from any part of plants or animals in a pharmaceutical dosage form;

(*f*) vitamins and minerals prepared in a pharmaceutical dosage form; or

(*g*) any premix;

"member" means a member of the Board appointed in terms of section 9 (2);

"mutual recognition" means the acceptance by the Authority of a certification of standards and procedures for medical product regulation by another medical products regulatory authority;

"pharmacist" means a person registered as a pharmacist under the Botswana Health Professions Act;

"pharmacy" means premises, labelled as such, licensed by the Authority for storing, dispensing, and selling of medical products, and which is under the continuous control and supervision of a pharmacist;

"precursor chemical" has the same meaning assigned to it under the Illicit Traffic in Narcotic Drugs and Psychotropic Substances Act. Cap. 08:12

"premix" means a mixture of one or more active pharmaceutical substances, solely intended for mixing into animal feed;

"prescription" means a formal written instruction from an authorised health professional to dispense a medical product or a combination of medicines for the treatment of a person or animal specified in the direction;

"principal investigator" means the individual responsible for the overall conduct of a clinical trial at a trial site who leads the research team, ensures compliance with the approved protocols, and safeguards the rights, safety, and well-being of trial "promotion" means all informational and persuasive activities by manufacturers and distributors, the effect of which is to induce prescription, supply, purchase or use of medicinal products, and includes advertising;

"promotion" means all informational and persuasive activities by manufacturers and distributors, the effect which is to induce prescription, supply, purchase or use of medicinal products, and includes advertising;

"recognition" means the routine acceptance by the Authority of regulatory decision of another regulatory authority or other credible institution, whereby evidence of conformity with the regulatory requirements of another regulatory authority or credible institution is sufficient to meet the regulatory requirements of the Authority;

"related substance" means any substance prescribed under section 116;

"reliance" means the practice whereby the Authority considers the regulatory work products of another competent regulatory authority to inform its own regulatory decisions while retaining full decision-making authority;

"regulated product" means medical products, blood and blood products, traditional medicines, food and related substances;

"repealed Act" means the Medicines and Related Substances Act;

"sell" includes —

(*a*) to sell by wholesale or retail, and includes to do the following for sale —

(i) import,
(ii) offer,
(iii) advertise,
(iv) keep,
(v) expose,
(vi) transmit,
(vii) export
(viii) consign,
(ix) convey, or
(x) deliver;

(*b*) to authorise, direct or allow a sale;
(*c*) to prepare or possess for purposes of sale;
(*d*) to barter, exchange, supply or dispose of to a person, whether for a consideration or otherwise;
(*e*) offering or attempting to sell;
(*f*) receiving for sale;
(*g*) having in possession for sale;
(*h*) exposing for sale; or
(*i*) sending or delivering for sale.

"sponsor" means an individual, company, institution or organisation that takes responsibility for the initiation, management or financing of a clinical trial;

"substandard medical product" means a medical product which fails to meet either its quality standards or its specifications, or both, as approved by the Authority in the marketing authorisation;

"unfit regulated product" means regulated products that do not meet the quality standards, specifications, or safety requirements established under this Act, or that pose an unacceptable risk to health due to contamination, adulteration, deterioration, incorrect composition, improper storage, non-compliant manufacturing, or other factors that render them unsuitable for their intended use and includes, substandard and falsified regulated products;

"variation" means —

(*a*) major variations which are changes that could have major effects on the overall safety, efficacy and quality of the medical product; and

(*b*) minor variations which are changes that may have minor effects on the overall safety, efficacy and quality of the medical product;

"veterinary medical product" means any substance or combination of substances presented for treating or preventing of disease in animals; and

"veterinary surgeon" means a person registered as a veterinary surgeon under the Veterinary Surgeons Act. Cap. 61:04

Act binds State

3. This Act binds the State.

Conflict with other laws

4. In the event of any conflict or inconsistency between the provisions of this legislation and other legislation on comprehensive regulation, sale, distribution, importation, exportation, storage, manufacture and dispensing of medicines and related substances, the provisions of this Act shall take precedence.

PART II — *Botswana Medicines Regulatory Authority*

Continuation of Authority

5. (1) The Medicines Regulatory Authority established under section 3 of the repealed Act shall continue to exist as if established under this Act.

(2) The Authority shall continue to be a body corporate with perpetual succession and a common seal, capable of suing and being sued in its own name and, subject to the provisions of this Act, performing such acts as bodies corporate may by law perform.

Powers of Authority

6. The Authority shall have the power to —

(*a*) formulate guidelines for regulating, manufacturing, importing and exporting, storing, distributing, selling and using regulated products;

(*b*) grant or withdraw authorisation for conducting clinical trial of regulated products;

(*c*) grant or withdraw authorisation for regulated products subject to appropriate conditions and revise such conditions as necessary;

(*d*) grant or withdraw licence or authorisation to manufacturer, wholesaler, retailer, importer, exporter and distributor of regulated products under this Act;

(*e*) examine, grant, issue, suspend, cancel and review authorisation or licences issued under this Act;

(*f*) investigate conduct related to the manufacture, import, export, distribution, storage, sale and use of a regulated product;

(*g*) order or recall an unfit product from the supply chain;

(*h*) levy, collect and utilise fees for services rendered;

(*i*) impose and collect administrative fines;

(*j*) condemn and order destruction or disposal of a regulated product under this Act;

(*k*) by Notice published in the *Gazette*, appoint, authorise or designate inspectors and order the inspections of any premises;

(*l*) designate laboratories for the investigation of regulated products;

(*m*) inspect regulated products quality control laboratories; and

(*n*) exercise such other powers as necessary for the performance of its functions.

Functions of Authority

7. (1) The functions of the Authority shall be to —

(*a*) ensure that —

(i) all regulated products manufactured in, imported into, or exported from, Botswana are registered and conform to established criteria of quality, safety and efficacy,

(ii) the personnel, premises and practices employed to manufacture, promote, procure, store, distribute and sell regulated products comply with defined codes of practice and other requirements,

(iii) cosmetics manufactured in, imported into, or exported from Botswana are safe to use, there is continuous regulatory presence at designated ports of entry, and

(iv) implementation of risk-based approaches in prioritising regulatory activities or decisions and develop and publish risk assessment tools and matrices;

(*b*) perform sampling for testing and analysis of regulated products, for the determination of their compliance with standards of quality;

(*c*) grant, renew, reject, suspend or cancel, after due assessment, marketing authorisations for regulated products;
(*d*) ensure that regulated products are imported, manufactured, exported, stored, sold, distributed or otherwise dealt with by duly authorised persons;
(*e*) inspect or cause to be inspected, all manufacturing premises, exporters, importers, wholesalers, distributors, clinics and hospital pharmacies, retail pharmacies, dispensaries and other outlets where medical products are dispensed or stored, for compliance with good practices;
(*f*) inspect or cause to be inspected, premises where medicated feeds are used, handled or stored;
(*g*) ensure the monitoring and reporting of adverse reactions to medical products;
(*h*) ensure that the promotion and advertising of medical products is one in accordance with this Act;
(*i*) issue guidelines necessary for the carrying out of the objectives of this Act;
(*j*) inspect foreign manufacturing premises, clinical research organisations, and testing premises seeking marketing authorisation for their products, for compliance with good manufacturing practices;
(*k*) undertake educational work in connection with the quality, safety and efficacy of regulated products;
(*l*) conduct post marketing surveillance of regulated products and control chemical precursors;
(*m*) collaborate with other national, regional and international institutions on regulated products;
(*n*) grant, reject, suspend or revoke approval of the use of regulated products for clinical trials or medical research;
(*o*) inspect and license quality control laboratories;
(*p*) disseminate information on the quality and safety of regulated products to health professionals and the public;
(*q*) specify the standards for granting marketing authorisation;
(*r*) specify standards and procedures for referencing, relying upon or otherwise weighing, the marketing assessments and approvals of other regulated products regulatory authorities;
(*s*) regulate the use of unregistered regulated products for trial purposes or compassionate use;
(*t*) all regulated products manufactured in, imported into, or exported from, Botswana are authorised, subjected to appropriate lot release procedures based on risk classification, and conform to established criteria of quality, safety and efficacy including batch-specific requirements; and
(*u*) do all such things and perform all such functions as may be necessary for, or incidental to, the attainment of the objectives of the Authority.

(2) For the purpose of performing monitoring and evaluation of national regulatory system functions, the Authority shall —

(*a*) create a monitoring and evaluation system charged with reviewing and assessing the performance of the Authority;

(*b*) prepare periodic reports and present to the supervising authority through the Board; and

(*c*) report on the performance of the Authority to relevant governing bodies at regional and international levels.

Seal of Authority

8. (1) The seal of the Authority shall be such device as may be determined by the Authority and shall be kept by the Chief Executive Officer.

(2) The seal of the Authority shall be authenticated by the signature of the Chief Executive Officer.

(3) In the absence of the Chief Executive Officer, the person performing the functions of the Chief Executive Officer may authenticate the seal in his or her place.

(4) The Chief Executive Officer may, in writing, delegate to another employee the power to authenticate the seal.

(5) A document issued by the Chief Executive Officer and sealed with the seal of the Authority, which seal is authenticated in the manner provided by this section shall be received and taken to be a true instrument without further proof unless the contrary is shown.

PART III — *Board of Authority*

Board of Authority

9. (1) There shall be a Board of the Authority which shall be the governing body of the Authority.

(2) The Board shall consist of not more than 10 members as may be appointed by the Minister, in writing, and after consultation with the Minister responsible for agriculture and the members shall be appointed from amongst persons with expertise in —

(*a*) law;

(*b*) finance;

(*c*) medicine;

(*d*) pharmacy;

(*e*) veterinary medicine;

(*f*) human resources;

(*g*) information technology;

(*h*) medical device;

(*i*) food science, food technology, nutrition or food safety and quality control; and

(*j*) ethnopharmacology, herbalism, anthropology or pharmacology.

(3) The Chief Executive Officer, Director responsible for Health Services and Director responsible for Veterinary Services shall be *ex-officio* members of the Board.

(4) The Minister shall appoint a Chairperson of the Board from among the members and the Chairperson shall serve for a period of not more than three years at a time.

(5) Members shall elect a Vice-Chairperson from amongst themselves.

(6) The Minister shall cause appointments to the Board to be published by Notice in the *Gazette*, within 30 days of the appointments, specifying the dates of their appointment and the period for which they are appointed to the Board.

Tenure of office

10. A member shall hold office for a period not exceeding three years and shall be eligible for re-appointment for a further term not exceeding three years.

Powers and functions of Board

11. (1) The Board shall be responsible for the direction of the affairs and operations of the Authority.

(2) Notwithstanding the generality of subsection (1), the Board shall —

(*a*) supervise and control the administration and financial management of the Authority; and

(*b*) formulate matters of policy for the purpose of providing general or specific guidance to the Authority in respect of the performance of its functions under this Act.

(3) The Board may, at the written request of any person and on the grounds of quality, safety or efficacy, carry out or cause to be carried out —

(*a*) investigations in respect of any particular regulated product; and

(*b*) comparative studies, examinations or tests in respect of regulated products whether produced in Botswana or elsewhere.

Directions by Minister

12. The Minister may give the Board directions of a general or specific nature regarding the exercise of its powers and the performance of its functions, which directions shall be consistent with this Act or with the contractual or other obligations of the Authority in terms of this Act, and the Board shall give effect to any such directions.

Disqualification, suspension and removal from office

13. (1) A person shall not be appointed as a member or be qualified to continue to hold office as a member where the person —

(*a*) has in terms of any law in force in any country —

(i) been adjudged or otherwise declared bankrupt or insolvent, and has not been rehabilitated discharged, or

(ii) made an assignment to, or arrangement or composition with his or her creditors, which has not been rescinded or set aside;

(*b*) has within a period of ten years immediately preceding the date of his or her appointment, been convicted –

(i) in Botswana, of a criminal offence, or

(ii) outside Botswana, of an offence which, if committed in Botswana would have been a criminal offence,

and sentenced by a court of competent jurisdiction to imprisonment for six months or more without an option of a fine, whether that sentence has been suspended or not, and for which he or she has not received a free pardon; or

(*c*) at the time of appointment, is a member of the National Assembly, a local authority or a member of *Ntlo ya Dikgosi*.

(2) The Minister may, in writing, suspend from office, a member against whom criminal proceedings are instituted for an offence in respect of which a sentence of imprisonment without an option of a fine may be imposed, and whilst that member is suspended, he or she shall not carry out any duties or be entitled to any remuneration or allowances as a member.

(3)The Minister shall revoke any suspension imposed under subsection (2) immediately in writing in the event that the Director of Public Prosecutions discontinues the proceedings against the member, or the proceedings against the member are dismissed by the court or the member is acquitted.

(4) The Minister shall remove a member from office, if the member —

(*a*) is absent without reasonable cause from three consecutive meetings of the Board of which he or she has had notice;

(*b*) has been found to be physically or mentally incapable of performing his or her duties efficiently, and a medical practitioner has issued a certificate to that effect;

(*c*) contravenes the provisions of this Act or otherwise misconducts himself or herself to the detriment of the objectives of the Board;

(*d*) has failed to comply with the provisions of sections 22 and 23; or

(*e*) has been convicted of an offence under this Act, or under any other Act for which he or she is sentenced to imprisonment for a term of six months or more without an option of a fine.

Vacation of office by member

14. A person shall vacate his or her office and his or her office shall become vacant —

(*a*) if he or she becomes disqualified in terms of section 13 to hold office as a member of the Board;

(*b*) if he or she is adjudged bankrupt or insolvent;

(*c*) if the member is absent without reasonable cause from three consecutive meetings of the Board without a reasonable excuse;

(*d*) upon his or her death;

(*e*) upon expiry of one months' notice, in writing, to the Minister of his or her intention to resign from office;

(*f*) if he or she becomes physically or mentally incapable of performing his or her duties efficiently and a medical practitioner has issued a certificate to that effect; or

(*g*) if he or she is convicted of an offence under this Act or any other law for which he or she is sentenced to imprisonment for a term of six months or more without an option of a fine.

Filling of vacancy

15. (1) Where the office of a member becomes vacant before the expiry of the member's term of office, the Minister shall appoint another person in the place of the member who vacates office, until the expiry of the period during which such member would have otherwise continued in office.

(2) The provisions of subsection (1) shall not apply where the remainder of the period for which the member whose office has been vacated is less than six months.

Remuneration and allowances

16. A member shall be paid such remuneration, travelling expenses and other expenses and allowances incurred in connection with his or her services on the Board, if any, as the Minister may from time to time determine.

PART IV — *Meetings and Proceedings of Board*

Election of Vice-Chairperson

17. (1) At the first meeting of the Board, the members shall elect from among their number, a Vice-Chairperson, who shall hold office for a period of not more than three years, unless he or she ceases to be a member of the Board.

(2) On the expiry of the term of office of the Chairperson or the Vice-Chairperson, or where the Chairperson or the Vice-Chairperson vacates office, a new Chairperson shall be appointed by the Minister and a new Vice-Chairperson, shall be elected by the members from among their number at the next meeting of the Board, or soon thereafter as may be convenient.

(3) The Chairperson or the Vice-Chairperson may resign from the office of Chairperson or Vice-Chairperson without necessarily terminating his or her membership to the Board.

Meetings of Board

18. (1) Subject to the provisions of this Act, the Board shall regulate its own procedure.

(2) The Board shall meet at least four times a year for the transaction of its business.

(3) The Chairperson may, upon giving written notice of not less than 14 days, call a meeting of the Board but if the urgency of any particular matter does not permit the giving of such notice, a special meeting of the Board may be called upon the giving of a shorter notice.

(4) The Notice referred to in subsection (3) shall state —

(*a*) the place and time of the meeting; and

(*b*) the agenda for the meeting.

(5) There shall preside at any meeting of the Board –

(*a*) the Chairperson;

(*b*) in the absence of the Chairperson, the Vice-Chairperson; or

(*c*) in the absence of the Chairperson and the Vice-Chairperson, such member as the members present may elect from amongst themselves for the purpose of that meeting.

Quorum and procedure at meetings

19. (1) The quorum at all meetings shall be formed by a simple majority of the members.

(2) A decision of the Board on any question shall be decided by a majority of votes of the members present at the meeting at which the relevant question is being considered, and in the event of an equal number of votes being cast, the Chairperson, or the person presiding at that meeting, shall have a casting vote in addition to his or her deliberative vote.

(3) A decision of the Board shall not be rendered invalid by reason of a vacancy on the Board or the fact that a person who was not entitled to sit as a member did so sit.

(4) The Board may invite any person whose presence it deems necessary to attend and participate in the deliberations of a meeting of the Board, but such person shall have no vote.

Secretary of Board

20. (1) The Board shall, on the recommendation of the Chief Executive Officer, appoint a Secretary who shall be suitably qualified and experienced.

(2) The Secretary of the Board shall attend all meetings of the Board but shall have no right to vote, and shall be responsible for the recording of the Board's proceedings and decisions.

(3) The Secretary of the Board shall be accountable to the Board for his or her functions and responsibilities and shall report directly to the Chief Executive Officer.

(4) The conditions of service, including the remuneration package of the Secretary, shall be set by the Board on the recommendation of the Chief Executive Officer, with the concurrence of the Minister.

Committees of Board

21. (1) The Board may, for the purpose of performing its functions, establish such committees as it considers appropriate and may delegate to any such committee such of its functions as it considers necessary.

(2) The Board may appoint, to the Committee established in terms of subsection (1), such number of persons from the members and such number of persons with specialised skills, not being members of such committees as it considers appropriate and such persons shall hold office for such period as the Board may determine.

(3) The Board shall appoint a Chairperson and Vice-Chairperson for any of its committees from amongst its members.

(4) An officer of the Authority appointed, in writing, by the Chief Executive Officer shall be secretary to any committee and shall, on the instructions of the Chairperson of the Committee convene meetings of the committee.

(5) Subject to the specific or general directions of the Board, a committee may regulate its own procedure and the Board may attach any condition to the delegation of any of its powers to such committees.

(6) The Board may confirm, vary or revoke any decision taken in consequence of a delegation or assignment, but no variation or revocation of a decision may detract from any rights that may have accrued as a result of the decision.

(7) Meetings of a committee shall be held at such times and places as the committee may determine, or as the Board may direct.

Disclosure of interest

22. (1) Where a member is present at a meeting of the Board or any committee of the Board at which any matter in which the member or immediate member of the family of the member is directly or indirectly interested in a private capacity is the subject for consideration, the member shall as soon as practicable after the commencement of the meeting, disclose such interest and shall not, unless the Board otherwise directs, take part in any consideration or discussion of, or vote on, any question concerning that matter.

(2) A disclosure of interest made in terms of subsection (1) shall be recorded in the minutes of the meeting at which it is made.

(3) Where a member fails to disclose his or her interest in accordance with subsection (1) and a decision of the Board or committee is made benefitting such member or an immediate member of the family of the member, such decision shall be null and void to the extent that it benefits such member.

(4) A member who contravenes the provisions of subsection (1) commits an offence and is liable to a fine not exceeding P1 000 000, or to imprisonment for a term not exceeding three years, or to both.

Confidentiality

23. (1) A member and any other person assisting the Board shall observe and preserve the confidentiality of all matters coming before the Board or a committee, and such confidentiality shall subsist even after the termination of their terms of office or their mandates.

(2) Notwithstanding the provisions of subsection (1), a member may disclose information relating to the affairs of the Board or a committee acquired during the performance of his or her duties —

(*a*) within the scope of his or her duties; or

(*b*) when required to —

(i) by an order of court,

(ii) under any written law, or

(iii) in the investigation of an offence.

(3) A person who contravenes the provisions of this section commits an offence and is liable to a fine not exceeding P1 000 000 or to imprisonment for a term not exceeding three years, or to both.

PART V — *Chief Executive Officer and Other Staff of Authority*

Appointment of Chief Executive Officer

24. (1) The Minister shall on the recommendation of the Board, appoint a Chief Executive Officer on such terms and conditions as may be specified in the instrument of appointment.

(2) The Chief Executive Officer shall, subject to such directions on matters of policy, as may be given by the Board, be responsible for —

(*a*) the day-to-day management of the affairs of the Authority;

(*b*) the appointment, formation and development of an efficient administration of the Authority;

(*c*) the organisation, control and management of all staff of the Authority;

(*d*) establishing such scientific technical structures necessary for the execution of the mandate of the Authority;

(*e*) the maintenance of discipline in respect of the staff of the Authority;

(*f*) carrying out of the decisions of the Board;

(*g*) the management of the support structure of the Authority;

(*h*) all income and expenditure of the Authority; and

(*i*) the management of the Authority's assets and the discharge of the liabilities of the Authority.

(3) The Chief Executive Officer shall be assisted in his or her duties by such other senior officers as the Board may appoint on the recommendation of the Chief Executive Officer.

(4) The Chief Executive Officer may delegate, in writing, the exercise of any of his or her powers under this Act, to any senior officer of the Authority.

(5) The Chief Executive Officer may resign from office by giving three months' notice in writing, to the Minister and the Board.

(6) The Minister may, in consultation with the Board, remove the Chief Executive Officer from office by giving him or her three months' notice in writing, or by paying him or her three months' salary in lieu of notice, if the Chief Executive Officer —

(*a*) conducts himself or herself in a manner that is detrimental to the objectives of or the proper performance of the functions of the Authority;

(*b*) has been found to be physically or mentally incapable of performing his or her duties efficiently, and a medical practitioner has issued a certificate to that effect;

(*c*) becomes bankrupt or is declared insolvent by a court of law; or

(*d*) absents himself or herself from office without reasonable excuse.

(7) Where the Chief Executive Officer is incapacitated or away from office for an extended period of time as shall be determined by the Board, the Chairperson of the Board may designate another person to exercise his or her functions.

(8) The Chief Executive Officer shall receive such remuneration, allowances and other benefits as the Board, in consultation with the Minister, may determine.

Appointment of senior and other staff of Authority

25. (1) The Board shall, on the recommendation of the Chief Executive Officer, appoint the senior staff of the Authority.

(2) The senior staff shall under the direction of the Chief Executive Officer, assist the Chief Executive Officer in the proper administration and management of the functions and affairs of the Council, in accordance with the policies laid down by the Board.

(3) The Chief Executive Officer shall appoint such other officers and staff as may be necessary for the proper discharge of the functions of the Authority on such terms and conditions as the Board shall determine.

(4) The terms and conditions of employment of the members staff of the Authority shall be determined by the Chief Executive Officer, in consultation with the Board.

PART VI — *Financial Provisions*

Funds of Authority

26. (1) The revenue of the Authority shall consist of —

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

(*b*) such grants, contributions and donations that the Authority may receive from any source;

(*c*) any income that the Authority may receive from investments;
(*d*) fees and administrative fines as may be charged in terms of this Act;
(*e*) pre-authorisation deposits;
(*f*) cost recovery fees for regulatory services; and
(*g*) interest earned from monies deposited in the account of the Authority.

(2) The Authority may, subject to the provisions of any other written law and the approval of the Minister responsible for finance, raise by way of loans from any source in or outside Botswana, such monies as it may require for the discharge of its functions.

(3) The Authority may require pre-authorisation deposits or performance bonds to ensure compliance with regulatory requirements;

(4) The Authority may, with the approval of the Minister, invest in such manner as it considers appropriate, such funds as are not immediately required for the performance of its functions.

(5) The Authority shall use the revenue acquired under this section to meet the costs incurred in its operations and shall use any surplus accrued for such purposes as it may determine.

Financial year

27. The financial year of the Authority shall be a period of 12 months commencing on 1st April of each year and ending on 31st March of the following year.

Accounts and audit

28. (1) The Authority shall keep and maintain proper accounts and records in respect of each financial year relating to its assets, liabilities, income and expenditure and shall prepare, in each financial year, a statement of such accounts showing —

(*a*) an income and expenditure statement, showing all monies that were received by and had accrued to the Authority during the financial year, and all the expenditure incurred and payments made by the Authority during that year;
(*b*) a balance sheet, showing the Authority 's financial position and the state of its assets and liabilities as at the end of the previous financial year; and
(*c*) a cash flow statement for the previous year.

(2) The accounts of the Authority in respect of each financial year shall, within three months of the end of each financial year be audited by an auditor appointed by the Board.

(3) The auditor shall report in respect of the accounts of each financial year, in addition to any other matter on which the auditor considers it necessary to report on, whether or not —

(*a*) he or she has received all the information and explanation which, to the best of the auditor's knowledge and belief were necessary for the performance of the auditor's duties;
(*b*) the Authority has complied with all financial provisions of this Act with which it is the duty of the Authority to comply with; and
(*c*) the statement of accounts prepared by the Authority was prepared on a basis consistent with that of the preceding year and represents a true and fair view of the transactions and financial affairs of the Authority.

(4) The auditor shall within 14 days of completing the report, forward the auditor's report and a copy of the audited accounts to the Authority.

Annual report

29. (1) The Authority shall within a period of six months after the end of the financial year or such extended time after the end thereof as the Minister may approve, submit to the Minister, a comprehensive report of its operations during that year, together with the auditor's report and audited accounts as provided for in section 28 and the report shall be published in such manner as the Minister may require.

(2) The Minister shall lay the annual report of the Authority before the National Assembly within three months of its receipt.

Pensions and other funds

30. (1) The Authority may, out of its revenues, establish and maintain such pension, superannuation, provident or other funds as it may consider desirable or necessary for the payment of benefits or other allowances on the death, sickness, injury, superannuation, resignation, retirement or discharge of its staff and may make rules providing for the payment of the money out of its revenues to such funds and providing for contributions to such funds by its staff.

(2) The Authority may contract with insurance companies or such other bodies as may be appropriate for the maintenance and administration of the funds authorised under subsection (1).

PART VII — *National Quality Control Laboratory*

National Quality Control Laboratory

31. (1) There is hereby established the National Quality Control Laboratory (in this Part referred to as "the Laboratory") which shall be responsible for performing functions relating to the quality of products regulated in terms of this Act.

(2) Without prejudice to the generality of subsection (1), the Laboratory shall —

(*a*) analyse and test regulated products;

(*b*) conduct research and training;

(*c*) conduct quality control audits and inspect laboratories;

(*d*) assign such other laboratory as the Authority shall approve to carry out the functions; and

(*e*) undertake such other function as may be determined by the Authority.

(3) In performing its functions, the Laboratory may utilise the services of any accredited laboratory within or outside Botswana for the analysis of regulated products and related functions.

Quality control of Laboratory

32. The Minister shall by regulations prescribe forms, manner and procedures to regulate the Laboratory and such regulations shall include —

(*a*) forms and fees to be paid for laboratory services;

(*b*) procedures for the submission of samples for analysis or tests to the Laboratory and the forms of the Laboratory reports;

(*c*) the manner in which disputes regarding analytical or tests results shall be handled; and

(*d*) such other matter as may be necessary or expedient to enable the Laboratory to carry out its functions.

Application for Laboratory services

33. (1) A person who wishes to apply for Laboratory services shall apply to the Authority in the manner and upon payment of a fee as may be prescribed.

(2) Where an applicant under subsection (1) meets the prescribed conditions, the Authority shall issue a test report or certificate of analysis.

Certificate of analysis

34. (1) Where a sample for analysis is submitted to the Authority, the Laboratory shall cause it to be analysed as soon as is practicable and shall give to the person who requests the analysis to be made, a certificate of analysis or test report specifying the result of the analysis in the prescribed form.

(2) A certificate of analysis or test report of the result of an analysis given under subsection (1) shall be signed by —

(*a*) the head of the Laboratory;

(*b*) any other person acting on his or her behalf; or

(*c*) any person appointed, approved, or delegated by the Authority to do so.

PART VIII — *Marketing Authorisation*

Registration of regulated products

35. (1) A person shall not, in relation to any regulated product have in his or her possession or control any such regulated product for purposes of —

(*a*) importing;

(*b*) exporting;

(*c*) manufacturing;

(*d*) distributing;

(*e*) selling;

(f) promoting;

(g) advertising;

(*h*) storing; or

(*i*) dispensing,

unless the regulated product is registered by the Authority.

(2) A person who wishes apply for registration of a regulated product to undertake any activity referred to under subsection (1) shall apply to the Authority in the prescribed form and —

(*a*) pay a prescribed fee;

(*b*) provide particulars of a qualified technical person and samples of the relevant products as the Authority may require; and

(*c*) provide any further information that the Authority may require that is necessary for processing the application.

(3) The Authority shall, in considering the application consider whether —

(*a*) the availability of the regulated product is in the public interest;

(*b*) the regulated product is safe, of acceptable quality, efficacious or acceptable performance;

(*c*) the premises and manufacturing operation comply with prescribed good manufacturing practices or quality assurance requirements; and

(*d*) the product complies with any other prescribed requirements.

(4) The Authority may, in such special circumstances as it considers appropriate exempt, in writing, a regulated product from the requirements of this section.

(5) A regulated in relation to which an exemption is made in terms of subsection (4) may include —

(*a*) a regulated product which has not been registered but was prescribed outside Botswana for a patient's personal use;

(*b*) a regulated product which is required by a medical practitioner, dentist, or veterinary surgeon, for the treatment of the practitioner's or dentist's patient or animal under the care of the surgeon;

(*c*) a regulated product intended for re-export in the form and packaging that it was imported;

(*d*) extemporaneous preparations made —

(i) by a pharmacist for a particular patient in Botswana, or

(ii) or imported by a veterinary surgeon for an animal under his or her surgeon's care; or

(*e*) any donated regulated product.

(6) An application for a regulated product referred to under subsection (5) to be exempted from registration shall be made in such form as may be prescribed and shall be accompanied by such fee as may be prescribed.

(7) Where the Authority exempts a regulated product, the applicant shall be accountable for its quality, safety and efficacy on the supply chain.

(8) Where an application is for registration for a cannabis product, the Authority shall subject it to a coordinated assessment with the cannabis control authority in accordance to prescribed protocols that ensure compliance with this Act and the Cannabis Control Act.

(9) The Authority may by Notice published in the *Gazette*, declare any regulated product a prohibited product, in which case the product shall not be registered or if already registered, such registration shall be cancelled.

(10) The Authority shall publish and maintain a list of regulated products that are not required to be registered.

(11) A person who contravenes the provisions of subsection (1) commits an offence and is liable to a fine not exceeding P10 000 000, or to imprisonment for a term not exceeding 10 years, or to both.

Applicant to have local presence

36. (1) An application for a regulated product shall be made by a company registered, licensed or operating in Botswana.

(2) Where the applicant is not resident in Botswana, the applicant shall appoint a local technical representative or authorised representative who shall be resident or incorporated in Botswana.

(3) The appointment for a local technical representative shall be in such manner as may be prescribed.

(4) The local technical representative or authorised representative shall be qualified as may be prescribed.

Assessment of application

37. (1) The Authority shall assess the application in accordance with prescribed standards.

(2) The Authority shall, after assessing the application, if it determines that the application complies with the prescribed requirements, register the regulated product in Botswana.

(3) Where the Authority determines that an application does not comply with the prescribed requirements, it shall not register and shall, in writing, notify the applicant, stating the reasons for refusing the registration.

(4) The Authority may at any time suspend or revoke registration where there is a concern over the safety, efficacy, and quality of a registered regulated product.

(5) An applicant who is not satisfied with the decision of the Authority may submit representation with the Authority in such manner and within such time as may be prescribed.

(6) Where the Authority, upon considering the representation made in terms of subsection (5) determines that an applicant qualifies, it shall duly authorise the registration.

Registration during public health emergency

38. (1) Whenever there is a public health emergency, animal health emergency or in cases of public interest, the Authority may deviate from registration procedures or waive applicable fees as it considers necessary.

(2) The Authority shall make guidelines to be followed where a deviation or waiver is considered under subsection (1) and shall publish such information in the *Gazette* and in at least three newspapers with wide national coverage and on the Authority's website.

Validity, retention and renewal of registration

39. (1) A registration under this Part shall —

(*a*) be for a period as may be prescribed;

(*b*) be retained as may be prescribed; and

(*c*) be renewed as may be prescribed.

(2) Regulations under subsection (1) shall set out forms and such fees necessary to be paid.

Variation of registration

40. (1) A person who has been registered under this Part shall not vary any particulars of the registration without the prior approval of the Authority.

(2) A person who wishes to vary a registration shall apply for variation in such form and on such conditions as may be prescribed, which application shall be accompanied by a non-refundable application fee as may be prescribed.

(3) A person who contravenes the provisions of this section commits an offence and is liable to a fine not exceeding P1 000 000, or to imprisonment for a term not exceeding three years, or to both.

Cancellation, revocation, suspension or withdrawal of registration

41. (1) The Authority may cancel, revoke, suspend or withdraw a registration and shall duly remove the product from the register if it determines that the product is not compliant to any of the requirements prescribed.

(2) Without limiting subsection (1), the Authority may in taking any of the actions under subsection (1) consider whether —

(*a*) a person has failed to comply with the conditions of registration;

(*b*) the registered product is being treated in any manner that contravenes this Act;

(*c*) it is not in the public interest for the product to continue to be made available to the public; or

(*d*) there are other technical reasons as the Authority may determine to justify its action.

(3) The Authority shall by Notice in the *Gazette* and in at least three newspapers with wide national coverage and on the Authority's website, publish any action taken in relation to the registration of a regulated product.

Maintenance of register

42. (1) The Authority shall keep and maintain a register in which it shall record the particulars of every regulated product —

(*a*) registered in terms of this Act, including the conditions, if any, subject to which that regulated product has been registered; or

(*b*) cancelled, revoked, suspended or withdrawn in terms of this Act.

(2) The register shall be open for inspection by the public at such times and in such manner as may be determined by the Authority.

Prohibition of undesirable substance or products

43. (1) The Authority may by Notice published in the *Gazette* prohibit the use of a substance or product where it determines that —

(*a*) the use of the substance or product is likely to cause a risk to a human being;

(*b*) on the advice of the Director responsible for Veterinary Services, the use of the substance or product is likely to cause a risk to an animal;

(*c*) such substance or product does not have therapeutic value claimed for it;

(*d*) such substance or product contains ingredients and in such a quantity for which there is no therapeutic justification; or

(*e*) such substance or product is in the public interest to be used or it is not expedient to use.

(2) Any person who, whether in person or through another, manufactures, sells, possesses, stores, advertises or distributes or in any way trades in a product prohibited under this section commits an offence and is liable to a fine not exceeding P5 000 000, or to imprisonment for a term not exceeding seven years, or to both.

Orphan medical products

44. (1) The Authority may register an orphan medical product where —

(*a*) the medical product is intended to be used in threatening or chronically debilitating condition afflicting not more than five per cent of the population or as may be prescribed;

(*b*) the medical product is intended to be used in life threatening or chronically debilitating condition and that without incentive it is unlikely that the marketing of such product would generate sufficient returns to justify the necessary investment; or

(*c*) there exists no satisfactory method of diagnosis, prevention or treatment of the condition that has been authorised or if some method exists, the medical product shall be of significant benefit to those affected by the condition.

(2) The Minister shall prescribe requirements for qualifying for registration under this section.

(3) The Authority shall, where the conditions for the orphan medical product have not been met or no longer exist, refuse to grant, cancel, revoke or vary the authorisation.

Traditional medicines

45. (1) The Authority shall, in relation to registration of traditional medicines, make guidelines and shall publish such guidelines in the *Gazette* and in at least three newspapers with wide national coverage and on the Authority's website.

(2) Guidelines under subsection (1) shall include —

(*a*) quality and safety;

(*b*) commercialisation; and

(*c*) any other details as the Authority may determine.

PART IX — *Control of Clinical Trials*

Prohibition of clinical trials without authorisation

46. (1) A person shall not conduct a clinical trial of a regulated product in humans or animals without authorisation from the Authority.

(2) The Minister shall prescribe the procedure to be followed for ethical clearance before a clinical trial is authorised.

Application for clinical trial

47. (1) A person or principal investigator who wishes to conduct a clinical trial shall apply to the Authority in such form as may be prescribed, which application shall be accompanied by such particulars as may be prescribed.

(2) The Authority may, where it is satisfied that the applicant meets the requirements, grant authorisation in the manner as may be prescribed.

(3) Where the Authority is not satisfied with the information provided, it may request for further information or may refuse to grant authorisation, or revoke authorisation for the use of a medical product for a clinical trial.

(4) The Authority shall issue guidelines for conducting a clinical trial and shall publish such guidelines in the *Gazette* and in at least three newspapers with wide national coverage and on the Authority's website.

(5) A person or principal investigator shall not sell, dispense, supply, assemble, or manufacture a medical product for the purpose of a clinical trial or medical research on a regulated product without authorisation or exemption by the Authority.

(6) A person or principal investigator who conducts a clinical trial shall ensure that —

(*a*) the trial complies with good clinical practice guidelines issued by the Authority; and

(*b*) the investigational regulated product complies with good manufacturing practices or established standards as the Authority may determine for such investigational regulated product.

(7) The provisions of section 37 shall apply to clinical trials with necessary modifications.

(8) The Authority shall keep and maintain a register of —

(*a*) applications made in terms of this section;

(*b*) approved or rejected applications; and

(*c*) clinical trials conducted in Botswana.

(9)A person who contravenes the provisions this section commits an offence and is liable to a fine not exceeding P5 000 000 or to imprisonment for a term not exceeding seven years, or to both.

Clinical trial during public health emergency, etc.

48. (1) Whenever there is a public health emergency, animal health emergency or in cases of public health interest, the Authority may, during that period, deviate from clinical trial approved procedures or waive applicable fees as it considers necessary.

(2) The Authority shall make guidelines to be followed where a deviation or waiver is considered under subsection (1) and shall publish such guidelines in the *Gazette* and in at least three newspapers with wide national coverage and on the Authority's website.

Monitoring

49. (1) The Authority shall access and the licence holder shall allow the Authority to access the place where the clinical trial on a regulated product is being conducted at all reasonable times to carry out inspections and auditing of the clinical trial process and records.

(2) Where there is any adverse reaction to a medical product that is being used in a clinical trial or medical research, the licence holder shall report the adverse reaction to the Authority, in such manner as may be prescribed.

(3) A person who contravenes this section commits an offence and is liable to a fine not exceeding P1 000 000, or to imprisonment for a term not exceeding three years, or to both.

Suspension or termination of clinical trial

50. (1) The Authority may suspend a clinical trial without giving notice where it determines on reasonable grounds that it is necessary to do so to prevent or mitigate damage to public health and order the principal investigator to suspend or terminate the clinical trial.

(2) The Authority shall issue guidelines to be followed where a clinical trial is suspended or terminated under subsection (1).

Cancellation, refusal or rejection of clinical trial authorisation

51. (1) The Authority may refuse or reject an approval for a clinical trial or cancel an authorisation for a clinical trial where it determines that —

(*a*) the principal investigator has failed to comply with conditions to which a trial was authorised;

(*b*) the trial has failed to comply with good clinical practices, good laboratory practices, good manufacturing practices inspections or quality audit in the case of medical devices or other established standards;

(*c*) the investigational product has been assessed and concluded to be associated with serious adverse events;

(*d*) the trial does not follow the ethical principles as prescribed;

(*e*) the trial has proven to be futile after all the assessments have been done;

(*f*) there is evidence of data manipulation in the design, conduct and analysis of the trial; or

(*g*) any other such evidence as may be determined by the Authority to be a violation of authorisation of the trial exists.

(2) Where the Authority takes any action under subsection (1), it shall, in writing, notify the principal investigator and sponsor of its decision and the reason for its decision.

(3) A person who is aggrieved by a decision of the Authority under this section may make his or her representations to the Authority against the reasons for such decision within such period as may be prescribed.

Variation of clinical trial

52. (1) A person who has been granted an approval to conduct a clinical trial shall not amend any particulars of the protocol without prior approval from the Authority.

(2) A person who wishes to amend an approved protocol shall apply for amendment in the prescribed form and pay such fee as may be prescribed.

(3) Any person who contravenes this section commits an offence and is liable to a fine not exceeding P500 000, or to imprisonment for a term not exceeding two years, or to both.

Protection of study participants

53. (1) The principal investigator shall ensure that a study participant is protected, safeguarded and consents, in writing, to participate in a clinical trial.

(2) Where a study participant is unable to provide informed consent either due to age, permanent disability or temporary incapacity resulting from illness or medical condition, consent shall be obtained from a legally authorised representative or guardian, in accordance with ethical and regulatory requirements.

(3) Where a clinical a trial involves an animal, voluntary written consent of the owner shall be obtained.

(4) A study participant or owner of an animal may withdraw a consent to a clinical trial at any time without any penalty or loss of benefits.

(5) Where applicable, the principal investigator shall ensure each clinical trial participant has an adequate and valid insurance cover to protect him or her against any clinical trial related injuries or harm.

Inspection of clinical trials

54. (1) The Authority may at any time inspect a clinical trial in order to ensure adequate protection of the participants against any risks or adverse events and to satisfy itself that all specific and general conditions subject to which the trial was authorised for are being strictly observed by the principal investigator and that for all intents and purposes the trial achieves its aims and objectives.

(2) Any inspections under this section shall be conducted according to risk-based principles, considering trial complexity, participant vulnerability, investigational product risk profile, and compliance history.

(3) The Authority may suspend, cancel, stop or take any other legal action for any non-compliance observed after inspection in accordance with this Act, ensuring proportionate responses and due process.

Manufacture and importation of investigational products

55. (1) A person issued with a clinical trial authorisation under this Part may manufacture, assemble, import or export any investigation product in compliance with the good manufacturing practices and international quality standards.

(2) The Authority shall ensure that a clinical trial for investigational regulated product is conducted in accordance with the guidelines it may issue.

Reports on clinical trials

56. (1) The Authority may require the person issued with authorisation to conduct a clinical trial to submit such reports as it may direct.

(2) The person issued with authorisation shall report to the Authority any adverse events observed during a trial in accordance with the guidelines issued by the Authority.

(3) The person issued with authorisation for a clinical trial shall be responsible for —

(*a*) providing information and reports as may be prescribed;

(*b*) applying to the Authority for any amendments to the clinical trial; and

(*c*) notifying the Authority of the termination of the clinical trial.

Offence and penalty

57. Any person who contravenes any provisions of this Part commits an offence and is liable to a fine not exceeding P5 000 000 or to imprisonment for a term not exceeding seven years, or to both.

PART X — *Authorisation and Licensing of Premises*

Licensing of operators

58. (1) A person shall not manufacture, sell, supply, export, import, distribute, dispense or store a regulated product unless he or she is authorised or licensed by the Authority in accordance with good manufacturing practices and international quality standards.

(2) A person who wishes to apply for an authorisation or licence under subsection (1) shall apply to the Authority in such form and manner and upon payment of such a fee as prescribed.

(3) Where the Authority is satisfied that an application meets the prescribed requirements, the Authority shall issue an authorisation or licence in the form and manner prescribed.

(4) The Authority may cancel, suspend, withdraw, revoke, vary or renew an authorisation or licence and the provisions of sections 40 and 41 shall apply with necessary modifications.

(5) Whenever there is a public health emergency, animal health emergency or in cases of public health interest, the Authority may deviate from authorisation or licensing requirements or waive a fee under this section.

(6) The Authority shall make guidelines to be followed where a deviation or waiver is considered under subsection (1), and shall publish such guidelines in the *Gazette* and in at least three newspapers with wide national coverage and on the Authority's website.

(7) The Authority shall —

(*a*) carry out necessary inspections to verify compliance with prescribed requirements and standards of good practice;

(*b*) keep and maintain a register of all authorised, licensed, suspended, withdrawn, revoked, varied, cancelled and other change of the premises; if satisfied that the prescribed requirement standards of good practice have not been met;

(*c*) prescribe a form of the register and make it accessible to the public; and

(*d*) for good and sufficient reasons refuse to licence or cancel a licence for premises which have become unsuitable for purposes for which it is licensed.

(8) A person who contravenes this section commits an offence and is liable to a fine not exceeding P1 000 000 or to imprisonment for a term not exceeding three years, or to both.

Change of business ownership or any other change

59. Where a licensee under this Part wishes to change the ownership of his or her licence, he or she shall apply for authorisation by the Authority.

(2) The Authority shall, where it authorises the change under subsection (1), it shall vary the licence in the manner as the Authority may provide in the guidelines which shall be published in the *Gazette* and in at least three newspapers with wide national coverage and on the Authority's website.

Validity, renewal of licence

60. (1) A licence issued under this Part shall be valid for such period as may be prescribed.

(2) A person who wishes to apply for a renewal of a licence shall apply to the Authority in such form and manner and pay such fee as prescribed.

Sale of medical products online

61. A person shall not sell any regulated products online without authorisation issued under this Act.

(2) The requirements and procedure for an online licence shall be as may be prescribed.

PART XI — *Import and Export Control*

Application and authorisation for importation and exportation of regulated products

62. (1) A person shall not import or export any regulated product unless such person has applied for and is issued with authorisation from the Authority.

(2) An application for importation of regulated products into or exportation outside Botswana shall be made in a prescribed form and accompanied by applicable fees as may be prescribed.

(3) The Authority shall, upon being satisfied that the prescribed requirements for import and export under this Act have been complied with, approve importation or exportation of regulated products which have obtained prior marketing authorisation in Botswana.

(4) A person shall not import, export, manufacture for sale, sell, store, distribute or supply any regulated product which is substandard or falsified.

(5) A person shall not import any regulated product with a shelf-life which does not comply with the requirements of the Authority as may be prescribed.

Authorised ports of entry

63. (1) The Authority shall liaise with the Botswana Unified Revenue Service in the designation of ports of entry for regulated products to be imported into and exported outside Botswana.

(2) The ports of entry under subsection (1) may be varied from time to time as circumstances may determine.

(3) The Authority shall maintain a register of designated ports.

Importation of products for personal use

64. (1) Notwithstanding the provisions of section 62, a person or animal that enters into, or a person or animal normally resident, who re-enters Botswana, may bring with them such quantity of any medical product as may be required for the medical treatment of himself or herself, or any member of family, or partner travelling with him or her or animals in compliance with prescribed requirements.

(2) Subsection (1) shall not apply where the medical product is prohibited in Botswana.

(3) Notwithstanding subsection (1), a person shall not import into Botswana any narcotics, psychotropics, precursor chemicals or class D medical devices or *in-vitro* diagnostics.

Revocation or suspension of import or export authorisation

65. The Authority may revoke, cancel, or suspend any import or export authorisation issued if it determines that the importer, exporter, or consignment contravenes any provision of this Act.

Importation of donated products

66. (1) A person shall not import donated regulated products without obtaining authorisation from the Authority.

(2) An application for authorisation for importation of donated regulated products shall be made in the prescribed form and shall be accompanied by a prescribed fee.

(3) The Authority shall issue an import or export authorisation or permit after being satisfied that the donated regulated products meet prescribed requirements.

(4) Where the Authority upon inspection at port of entry, is satisfied that any imported donated regulated products are unfit for intended use, it shall seize, quarantine, confiscate, and order destruction or re-exportation to the country of origin, and the cost shall be borne by the importer.

Import and export of narcotics, psychotropics and precursor chemicals

67. (1) A person who wishes to import or export narcotics, psychotropics or precursor chemicals, shall —

(*a*) apply to the Authority in the prescribed form accompanied by a prescribed fee;

(*b*) for every import and export, as the case may be, whether such import or export consists of one or more substances, obtain a separate permit from the Authority for such importation or exportation as prescribed; and

(*c*) provide such information, in such form and manner as may be prescribed, to the Authority.

(2) A person who contravenes the provisions of —

(*a*) subsection (1) (*a*) or (*b*) commits an offence and is liable to a fine not exceeding P5 000 000, or to imprisonment for a term not exceeding seven years, or to both; or

(*b*) subsection (1) (*c*) commits an offence and is liable to a fine not exceeding P500 000, or to imprisonment for a term not exceeding two years, or to both.

Records of narcotics, psychotropic and precursor chemicals

68. (1) A person who —

(*a*) imports;

(*b*) exports;

(*c*) manufactures;

(*d*) distributes;

(*e*) sells,

(*f*) stores; or

(*g*) supplies

narcotics, psychotropic or a precursor or chemicals shall, keep a separate register for each of the categories of narcotics, psychotropic, precursor or chemical.

(2) Each register referred to in subsection (1) shall —

(*a*) be written, in indelible ink or recorded in any other manner including electronic format as may be prescribed; and

(*b*) be kept for five years on the premises from which the importation, exportation, manufacture, distribution, sale, storage or supply of the medicine takes place.

(3) Any entry into a register referred to in subsection (1) shall be made within 24 hours of the importation, exportation, manufacture, distribution, sale, storage or supply of the medicine or precursor chemical.

(4) Any correction to the register shall be made in such manner as may be prescribed.

(5) A person who contravenes the provisions of this section commits an offence and is liable to a fine not exceeding P5 000 000 or to imprisonment for a term not exceeding seven years, or to both.

Inspection of imported consignment at ports of entry

69. (1) A person shall not remove any regulated product from a port of entry before it is inspected and released by the Authority.

(2) Where the inspector suspects any regulated product in the consignment contravenes any of the provisions of this Act, he or she shall seize or quarantine, the consignment and take samples for further investigation.

(3) Any consignment that is taken for investigation that fails inspection may be re-exported, condemned, seized, detained, or confiscated and disposed at the cost of the person responsible for the consignment.

Regulated products in transit

70. (1) A person who wishes to transit a regulated product through Botswana shall apply to the Authority in such form as may be prescribed for authorisation, and shall comply with such other requirements as may be prescribed.

(2) The application for authorisation referred to in subsection (1) shall be accompanied by —

(*a*) such particulars as may be prescribed;

(*b*) a prescribed non-refundable application fee; and

(*c*) proof that authority to transit such regulated product has been granted by —

(i) the Botswana Unified Revenue Service, and

(ii) where applicable, the authority responsible for regulating registration of a product in the final destination country.

(3) A person who is granted authority to transit a regulated product through Botswana shall, within 48 hours of the regulated product leaving Botswana, notify the Authority, in writing, of the departure of the regulated product, stating the date, time of the arrival and the time of exit.

(4) A person in control of human or veterinary medical products stored in a bonded warehouse or whilst in transit shall not subject such human or veterinary medical product to any process which would change the nature of that human or veterinary medical product or alter the packaging of such human or veterinary medical product.

(5) A person who contravenes the provisions of this section commits an offence and is liable to a fine not exceeding P1 000 000, or to imprisonment for a term not exceeding three years, or to both.

PART XII — *Vigilance and Post-Market Surveillance*

National vigilance program

71. (1) The Authority shall establish a National Vigilance Program function to monitor and report on the safety of regulated products.

(2) Notwithstanding the provisions of subsection (1), a marketing authorisation holder or importer shall establish a vigilance system safety monitoring of regulated products marked in Botswana and reporting to the Authority.

(3) A marketing authorisation holder or importer under subsection (2), shall appoint a person qualified in vigilance who shall be responsible for vigilance of regulated products or authorised person in the care of regulated products.

(4) The Authority shall inspect any authorised person at all reasonable times for the purpose of ensuring compliance to established standards as may be provided in the regulations or guidelines made under this Act.

(5) A person managing a health facility, veterinary facility or running a health program in authorised premises shall establish a system for collecting, managing and reporting to the Authority adverse events from regulated products and shall appoint a focal person suitably qualified by education and training for that purpose.

Reports on vigilance

72. (1) Any person authorised who deals in a regulated product, person running a health program, or any institution, shall report any of the following to the Authority —

(*a*) all suspected, unexpected, adverse, observed increase in frequency, serious reaction whether expected or not;

(*b*) adverse reactions occurring from overdose of regulated product error;

(*c*) adverse reactions in special fields of interest including abuse and use in pregnancy and lactation;

(*d*) unusual lack of efficacy or safety alerts in case of medical devices;

(*e*) field safety corrective actions taken;

(*f*) any safety signal or any quality defects which could impact patient or animal safety of a regulated product; and

(*g*) any safety or quality regulatory decisions taken in country of origin or other countries where the products are marketed.

(2) Where the adverse event involves a cannabis product, a person who makes a report shall avail the report to both the Authority and the cannabis control authority according to coordinated reporting protocols as the authorities may determine.

(3) A patient or a consumer may report any suspected adverse reaction or event associated with the use of a regulated product immediately to the nearest health facility, health care provider or directly to Authority in accordance with the forms and manner prescribed.

(4) The procedure for reporting of adverse reactions, events of adverse events following immunisation, shall be as prescribed.

(5) Where a specific safety study is required by the Authority, market authorisation holder shall be required to perform a post authorisation safety study and submit the findings to the Authority writing.

(6) The marketing authorisation holder shall submit periodic safety update report to the Authority in such a manner as prescribed.

Hemovigilance system

73. (1) A blood establishment shall set up a hemovigilance system receiving, handling, evaluating, and reporting adverse events and reactions to the Authority.

(2) A blood establishment shall ensure that activities related to blood and blood products comply with good hemovigilance practice requirements as prescribed.

(3) A blood establishment or health care provider shall report to the Authority suspected adverse reactions, events or incidences related to blood and blood products reported by patients and any quality defects issues that will arise.

(4) A marketing authorisation holder shall report to the Authority any adverse reaction or event suspected to be associated with the use of blood and blood products notified to them by health care professionals, patients, or consumers.

(5) The collection, analysis, timelines, and reporting including expedited reporting requirements shall be as provided for in the blood and blood products regulations and guidelines.

(6) For purposes of this section, "blood establishment" means any structure, facility, premises or body that is performing any aspect of the collection, testing, processing, storage, release or distribution of human blood or blood component when intended for transfusion or industrial manufacturing.

Post-marketing surveillance

74. (1) The Authority shall establish a system for sampling and testing of the quality of regulated products in the supply chain of Botswana.

(2) Notwithstanding the provision of subsection (1), a marketing authorisation holder or an authorised importer shall establish a post market surveillance system of its products that in the supply chain of Botswana.

(3) A person shall not import, export, manufacture for sale, sell, store, distribute or supply any regulated product which is a substandard medical product or which is a falsified medical product.

(4) A marketing authorisation holder shall prepare and submit to the Authority post-marketing surveillance reports on an annual basis or at a frequency determined by the Authority in the guidelines.

PART XIII — *Recall and Disposal of Unfit Products*

Recall of unfit products

75. (1) A marketing authorisation holder of a regulated product shall voluntarily initiate a recall of any regulated product upon proof that such product —

(*a*) does not conform to quality specifications, safety or other requirement specified in the marketing authorisation;

(*b*) has caused or is about to cause injury to the health and safety of patients, animals, users, consumers or other persons; or

(*c*) is defective or mislabelled.

(2) Notwithstanding the provisions of subsection (1), the Authority may order recall of any regulated product after receiving complaints from patients or users and upon investigation that such product —

(*a*) does not conform to quality specifications, safety or other requirement specified in the marketing authorisation documents; and

(*b*) has caused or is about to cause injury to the health or safety of patients, animals, users, or other persons; or

(*c*) deliberately or fraudulently misrepresents its identity, composition or source.

(3) Subject to subsections (1) and (2), recall procedures shall be as the Authority shall determine in the guidelines.

(4) A person shall not sell, offer, or expose for sale or supply a regulated product which has been subjected to recall.

(5) All costs associated with the recall shall be borne by the authorisation holder or any other person responsible for the product.

Disposal of unfit products

76. (1) A person shall not sell or supply or offer or expose for sale or supply or have in his possession for the purpose of sale or supply of any unfit regulated products.

(2) Where the Authority finds any unfit regulated product, it shall order such a person to dispose such unfit regulated products in such manner as may be prescribed.

(3) Where the Authority is of the opinion that the person responsible for disposal is unlikely to dispose of the unfit product or may use unfit products to be destroyed or disposed of, the Authority shall dispose such unfit regulated products and any costs borne by the Authority in causing such disposal shall be due and payable to the Authority by the person responsible.

PART XIV — *Regulatory Inspection and Enforcement*

Appointment of inspectors

77. (1) The Chief Executive Officer may —

(*a*) appoint inspectors with relevant qualifications;

(*b*) authorise such inspectors to perform such functions as stipulated under this Act; or

(*c*) designate any other authorised person to enforce any requirements of this Act.

(2) An inspector appointed under this section shall be furnished with —

(*a*) a signed certificate of appointment specifying his or her scope of authority and limitations; and

(*b*) an official identity card.

(3) An inspector appointed under this Act shall be bound by a code of conduct specified in the instrument of appointment.

(4) Where an inspection involves a cannabis product, an inspector shall coordinate with the cannabis control authority and notify both the authorities of inspection findings related to the cannabis product.

(5) An inspector or person who contravenes the provisions of this section commits an offence and is liable to a fine not exceeding P100 000, or to imprisonment for a term not exceeding one year, or to both.

Powers of inspectors

78. (1) An inspector may, at any reasonable time and, where necessary, without prior notice —

(*a*) enter, inspect, examine, and search —

(i) any premises, vehicle, vessel, aircraft, or receptacle for which an authorisation has been issued under this Act, or

(ii) any premises, vehicle, vessel, aircraft, or receptacle that the inspector has reasonable grounds to believe is being used in the manufacture, import, export, storage, distribution, marketing, or sale of a regulated product;

(*b*) stop and board any vehicle, vessel, or aircraft reasonably suspected of being used in connection with a regulated product;

(*c*) examine any activity conducted on the premises and question any person present regarding such activity;

(*d*) examine, make copies of, take extracts from, or seize any record, document, or data, including data stored electronically, and may request from any person in charge of such record an explanation of any entry;

(*e*) take or obtain samples, without compensation, of any regulated product, substance, or article for analysis, testing, or examination, in accordance with prescribed methodology;

(*f*) seize, detain, or condemn for destruction any regulated product, substance, or article which the inspector has reasonable cause to believe —

(i) consists of or contains a prohibited substance,

(ii) is falsified, substandard, unregistered, or unapproved; or

(iii) is otherwise in contravention of this Act and is liable to forfeiture;

(*g*) seize and detain any product, article, equipment, or record which may constitute evidence of a contravention of any provision of this Act;

(*h*) affix seals or take other measures necessary to secure premises, vehicles, or products for the period necessary for the inspection;

(*i*) close, or issue an order to cease operations for, any premises found to be in contravention of this Act, posing an immediate risk to public health; and

(*j*) investigate and institute administrative fines against any person who is found to have contravened the provisions of the Act.

(2) Where admission to premises has been refused, or where there are reasonable grounds to believe that admission would be refused, or that evidence may be removed or destroyed, an inspector may apply to a Magistrate for a warrant to enter, if necessary, by reasonable force.

(3) An inspector shall —

(*a*) investigate any suspected contravention of this Act; and

(*b*) institute or recommend administrative proceedings, including the imposition of fines or the suspension or revocation of authorisations.

PART XV — *Scheduling and Classification of Products*

Classification of medicines

79. (1) The Minister shall make regulations prescribing for medicines and complementary medicines for humans and animals.

(2) Subject to subsection (1), human and animal medicines and complementary medicines shall be categorised into groups of —

(*a*) controlled medicines;

(*b*) prescription only medicines or its acronym "POM" "POM-VS";

(*c*) pharmacy only medicines or its acronym "P" or "POM – VPS";

(*d*) over the counter medicines or its acronyms or its acronym "OTC";

(*e*) general sale medicines or its acronym "GSM";

(*f*) cannabis products which shall be classified according to their tetrahydrocannabinol "THC" content and subject to coordination with the cannabis control authority; and

(*g*) any other category as the Authority may determine.

(3) The Authority shall issue guidelines for the use, storage, distribution, sale, dispensing or any other manner of dealing with such medicine or complementary medicine.

Classification of medical devices

80. (1) The Minister may prescribe description of medical devices which fall under —

(*a*) Class A – low risk;

(*b*) Class B – low-moderate risk;

(*c*) Class C – moderate-high risk; and

(*d*) Class D – high risk; and

(2) The Minister may, whenever it becomes necessary to do so, declare any other classification and description of medical devices.

(3) The Authority may issue guidelines for use, storage, distribution, sale or any other manner of dealing with such medical device.

Classification of *in-vitro* diagnostics

81. (1) The Minister may prescribe description of *in-vitro* diagnostics which fall under the following classifications —

(*a*) Class A – low individual risk;

(*b*) Class B – low public health risk and/or moderate individual risk;

(*c*) Class C – moderate public health risk, but high individual risk; and

(*d*) Class D – highest risk.

(2) The Minister may, whenever it becomes necessary, prescribe further classifications for *in-vitro* diagnostics.

(3) The Authority shall determine the classification rules for medical devices and *in-vitro* diagnostics from time to time.

Borderline products

82. (1) Notwithstanding any provisions of this Act, the Authority may, where it is not possible to identify any borderline product within any prescribed classifications, allocate a classification of that product in accordance with the guidelines as it may issue.

(2) For purposes of this section, a "borderline product" is a product that does not contain all the properties that lend it to an outright identification as one or the other of the prescribed regulated products.

PART XVI — *Control of Advertisements and Promotions*

Advertising and promotion restricted

83. (1) A person shall not advertise or promote any regulated product unless he or she is authorised by the Authority.

(2) A person who wishes to advertise or promote any regulated product shall apply in writing, for an approval from the Authority.

(3) An application under subsection (2), shall be accompanied by prescribed fee.

(4) Where the Authority approves, it shall write the applicant and state such conditions as may be required in the guidelines and shall where it rejects the application, notify the applicant in writing and provide the reasons for rejection.

(5) The Authority shall issue guidelines relating to the advertising and promotion of regulated products in terms of this Act.

(6) A person who contravenes the provisions of this section commits an offence and is liable to a fine not exceeding P1 000 000, or to imprisonment for a term not exceeding three years, or to both.

Packaging and labelling of regulated products

84. (1) Any regulated product authorised for use in Botswana shall be packaged and labelled in such manner as may be prescribed.

(2) A market authorisation holder of a regulated product shall —

(*a*) provide information that makes it possible to trace the distribution path of every regulated product; and

(*b*) use such form as may be prescribed for labelling the regulated product to make it possible to ascertain its identification and authenticity.

Offence and penalty

85. A person who contravenes the provisions of this Part commits an offence and is liable to a fine not exceeding P1 000 000 or to imprisonment to a term not exceeding three years, or to both.

PART XVII — *Lot Release for Vaccines and Biologics*

Lot release for vaccines and biologics

86. (1) An authorisation holder of any vaccine, biologic or *in-vitro* diagnostic shall ensure that every lot of such product has been evaluated, tested and certified by the Authority before its release into the market.

(2) Notwithstanding the provisions of subsection (1), a manufacturer shall be accountable on quality, safety and efficacy vaccines or *in-vitro* diagnostics supplied into Botswana.

(3) An authorisation holder shall comply with such requirements as the Authority shall determine in the guidelines.

(4) Notwithstanding the preceding provisions, lot release for *in-vitro* diagnostics shall apply only to high-risk products as may be prescribed.

(5) The Authority may authorise expedited lot release during public health emergencies or urgent health needs.

(6) The Minister may, on the recommendation of the Authority, prescribe regulations for lot release.

(7) Any person who contravenes the provisions of this section commits an offence and is liable for a fine not exceeding P10 000 000 or to imprisonment not exceeding ten years, or to both.

PART XVIII — *Control of Cosmetics*

Cosmetics authorisation

87. (1) A person shall not, in relation to any cosmetic product have in his or her possession or have in his or her control any such cosmetic product for purposes of —

(*a*) importing;
(*b*) exporting;
(*c*) manufacturing;
(*d*) distributing;
(*e*) sale;
(*f*) promoting;
(*g*) advertising;
(*h*) storing; or
(*i*) dispensing,

unless the person has notified the Authority of the cosmetic product in a manner prescribed by this Act.

(2) A person who wishes to notify the Authority in accordance with subsection (1), shall pay such a fee as may be prescribed.

(3) The Authority shall maintain a register of notified cosmetic products and such register shall be accessible online to the public.

(4) A cosmetic shall not be presented for sale as having properties of preventing, treating, or curing a human or animal disease.

Classification of cosmetics

88. For purposes of registration, the Authority shall classify cosmetics into —

(*a*) general use cosmetics which shall be simple in the method of application and do not pose much risk for the consumers' health; and
(*b*) special use cosmetics which shall have increasing complexity in their claims, properties and have a higher risk for human health under normal use.

Safety of cosmetics for use

89. (1) A person shall ensure that a cosmetic product placed in the market is safe for humans and animals when used under normal or reasonably foreseeable conditions of use, considering —

(*a*) the use of acceptable ingredients at acceptable levels;
(*b*) labelling requirements as prescribed; and
(*c*) instructions for use, storage and disposal.

(2) The Minister shall prescribe requirements for acceptable, restricted prohibited cosmetic ingredients for purposes of ensuring that every cosmetic product is safe for use.

(3) Where the Authority determines that a cosmetic product placed in the market is unsafe or does not conform to the prescribed requirements, the Authority shall order the responsible person —

(*a*) to immediately take any corrective measures necessary for conformity, withdraw or recall the product; or

(*b*) to cooperate with the Authority on any regulatory actions required to eliminate the risks posed by the cosmetic product.

(4) A person who contravenes the provisions of this section commits an offence is liable to a fine not exceeding P 1 000 000 or to a term not exceeding three years, or to both.

Cosmetic products notification portal

90. (1) The Authority shall establish a notification system on cosmetic products placed or made available on the supply chain in Botswana.

(2) A person who deals in cosmetic products shall submit information about the cosmetic to the Authority for notification in accordance with the notification system under subsection (1).

(3) A person who contravenes the provisions of this section commits an offence and is liable to a fine not exceeding P500 000 or to a term not exceeding two years, or to both.

Duty to report risky cosmetics

91. (1) Where a cosmetic product presents a safety risk to humans or animals, a person who deals in the cosmetic product shall immediately —

(*a*) inform the manufacturer or product owner and report to the Authority giving details, in particular of the non-compliance and of any corrective measures to be taken;

(*b*) inform the Authority about the premises where the cosmetic product is being availed to the market; and

(*c*) inform the Authority about all adverse effects related to the product, the name, nature of adverse effect and necessary corrective measures to manage the effects of the cosmetic products.

(2) Notwithstanding the provisions of subsection (1), the provisions of section 78 shall apply with necessary modification in relation to cosmetics.

Obligation of cosmetic manufacturer

92. A cosmetics manufacturer shall keep such information on the standards as may be prescribed.

Restriction on cosmetics

93. (1) The Authority may restrict or prohibit the use of a cosmetic substance used in the manufacture of cosmetics.

(2) Without limiting the generality of subsection (1), the Authority may restrict the use of cosmetic or substance on the basis of —

(*a*) safety and public's interest; or

(*b*) prior prohibition by the Authority.

(3) Cannabidiol "CBD" containing cosmetics with the tetrahydrocannabinol "THC" content may be regulated as cosmetics subject to compliance with cannabis control standards as may be prescribed.

Publication of list of prohibited cosmetics

94. The Authority shall publish and maintain a list of restricted and prohibited cosmetic ingredient used in the manufacture of cosmetics.

Cosmetic label, claims and promotional materials

95. (1) A person shall not sell a cosmetic product if any label or promotion of the cosmetic product contains a claim that is not commensurate with the functions or characteristics of the product and is not cosmetic in nature.

(2) A person who deals in a cosmetic product that shall not a label a cosmetic product making a claim about a property that such cosmetic product does not possess.

PART IX — *National Medicines and Therapeutics Board*

Therapeutics Board

96. There is hereby established a National Medicines and Therapeutics Board (in this Part referred to as "the board").

Functions of Therapeutics Board

97. The functions of the board shall be to —

(*a*) select medicines for the Botswana Essential Medicines List;
(*b*) produce the Botswana Medicines Formulary;
(*c*) develop and update the Botswana Treatment Guide;
(*d*) monitor the use of medicines and effect the necessary medicine treatment policy and protocol changes;
(*e*) oversee the development and implementation of national therapeutics guidelines;
(*f*) distribute and publish therapeutic bulletins relating to medical products;
(*g*) determine restrictions to be placed on prescribing by different cadres of clinical staff and pharmacists;
(*h*) determine the content of lists of medicines within the national formulary which may be availed in government health facilities;
(*i*) approve the medicines to be included in treatment protocols; and
(*j*) undertake training on the rational use of medicines.

Composition of Therapeutics Board

98. (1) The board shall consist of the following people, appointed, in writing by the Minister —

(*a*) two specialist physicians representing, the public sector and private sector respectively;
(*b*) a paediatrician;
(*c*) a clinical medical practitioner from either a mission hospital or a mine hospital;
(*d*) a clinical pharmacist;
(*e*) a clinical pharmacist representing the Botswana Essential Medicines Programme;
(*f*) the Head of the Department responsible for pharmaceutical services, in the Ministry responsible for Health;
(*g*) the Head of Central Medical Stores;
(*h*) a public health specialist representing District Health Management Teams;
(*i*) a representative of the Department responsible for health, in the Ministry responsible for Local Government;
(*j*) a pharmacist representing the Pharmaceutical Society of Botswana;

(*k*) a medical practitioner representing the private sector;
(*l*) a nurse representing the Botswana Nurses Association;
(*m*) a veterinary surgeon representing the veterinary pharmaceutical industry;
(*n*) a member of the public; and
(*o*) any other person as the Minister may appoint.

(2) The board may co-opt persons qualified or able to assist it in its functions under the Act, to attend any meeting of the board, but such persons may not vote on any matter before the board.

(3) The Minister shall appoint the Chairperson of the board from amongst its members.

(4) The Vice-Chairperson of the board shall be elected by members from amongst themselves.

(5) The Minister shall cause appointments to the board to be published by Notice published in the *Gazette*.

(6) The provisions of sections 12, 13, 14, 15, 18, 19, 21, 22 and 23 shall apply to this Part, with the necessary modifications.

(7) The Secretary of the Therapeutics Board shall be a clinical pharmacist from the Botswana Essential Medicines Program.

Co-option of member

99. The Therapeutics Board may co-opt any person or persons qualified or able to assist in its functions to attend any of its meetings but such person or persons may not vote on any matter before the Board.

Remuneration of members of Therapeutics Board

100. A member of the Therapeutics Board shall be paid such remuneration, travelling expenses and allowances incurred in connection with his or her services on the board, if any, as the Minister may determine.

PART XX — *National Health Research Ethics Committee*

Ethics Committee

101. There is hereby established for purposes of this Act, a body independent of the Authority, under the Ministry known as the National Health Research Ethics Committee, referred to as "the Ethics Committee".

Functions of Ethics Committee

102. The Ethics Committee shall —
(*a*) give its opinion on every application for a permit for research submitted to it by the Ministry;
(*b*) advise the Ministry on the health, welfare, safety and protection of human and animal subjects participating in research;
(*c*) advise the Ministry on the public assurance of the protection mentioned under paragraph (*b*);
(*d*) advise the Ministry on ethical values and international scientific standards to ensure compliance with those values and standards;
(*e*) advise the Ministry on local community values and customs so that the Ministry ensures that values and customs are respected;
(*f*) consider ethical issues with regard to the research protocols;
(*g*) prepare statements of general principles on which the Ministry shall base its evaluations of the research;

(*h*) keep records of all its proceedings in relation to a research for a period of at least 15 years following the completion of the research;

(*i*) seek advice from any person qualified in any scientific or medical field for purposes of forming an opinion on any research to be conducted;

(*j*) advise the Ministry on ethical issues relating to health;

(*k*) advise the Ministry on guidelines on research on human subjects and animal subjects;

(*l*) review high risk research studies and advise the Ministry accordingly; and

(*m*) advise the Ministry on any other matter related to research.

Members of Ethics Committee

103. (1) The Ethics Committee shall consist of the following members appointed by the Minister —

(*a*) an epidemiologist;

(*b*) an academic in human or animal science;

(*c*) a human health scientist or an animal scientist;

(*d*) a laboratory human scientist or a laboratory animal scientist;

(*e*) a biostatistician or demographer;

(*f*) a person with extensive experience and training in research ethics;

(*g*) a member of the public;

(*h*) a veterinary surgeon or medical doctor;

(*i*) a representative of a non-governmental human rights organisation or a representative of an animal welfare organisation; and

(*j*) a legal practitioner.

(2) The provisions of sections 12, 13, 14, 15, 18, 19, 21, 22 and 23 shall apply to this Part, with the necessary modifications.

Co-option of member

104. The Ethics Committee may co-opt persons qualified or able to assist it in its functions under the Act attend any meeting of the Ethics Committee, but such persons may not vote on any matter before the Ethics Committee.

Appointment of Chairperson

105. (1) The Minister shall appoint the Chairperson of the Ethics Committee from amongst its members.

(2) The Vice-Chairperson of the Ethics Committee shall be elected by members from amongst themselves.

(3) The Minister shall cause to be published by Notice in the *Gazette* appointments to the Ethics Committee.

(4) The Ethics Committee shall appoint a Secretary of the Ethics Committee who shall be a suitably qualified and experienced person.

Remuneration of members of Ethics Committee

106. A member of the Ethics Committee shall be paid such remuneration, travelling expenses and allowances incurred in connection with his or her services on the board, if any, as the Minister may determine.

PART XXI — *National and International Cooperation and Harmonisation*

National cooperation

107. (1) The Authority shall in the performance of its functions, as far as practicable, maintain a system of consultation and cooperation with any government institution or department responsible for —

(*a*) atomic energy;
(*b*) cannabis control;
(*c*) control of illicit drugs and narcotics;
(*d*) standards setting;
(*e*) environmental management;
(*f*) telecommunication;
(*g*) veterinary services;
(*h*) chemicals management;
(*i*) research institutions;
(*j*) tax management;
(*k*) regulation of health and veterinary professionals;
(*l*) industry and trade;
(*m*) law enforcement;
(*n*) health institutions;
(*o*) non-governmental institutions;
(*p*) academia; or
(*q*) any other institution established by or under any other written law and having functions which relate to regulated products.

(2) The Authority shall establish and maintain operational coordination with the cannabis control authority for all matters involving cannabis products intended for regulation as medical products.

(3) The Authority shall, in coordinating with the cannabis control authority carry out —

(*a*) joint application assessment procedures;
(*b*) information sharing protocols;
(*c*) inspection activities;
(*d*) joint adverse event monitoring;
(*e*) enforcement actions; and
(*f*) international treaty compliance measures.

International cooperation

108. (1) The Authority may cooperate with regional and international bodies on matters related to regulation of products under this Act.

(2) The Authority may take appropriate measures to ensure effective bilateral, regional and international cooperation on regulated products.

Recognition and reliance on regulatory decisions

109. (1) The Authority may make or adopt regulatory decisions based on reports, information or decisions made by another regulatory authority or trusted institution in reaching its own decision.

(2) The Authority may enter into mutual agreements, mutual recognitions with other regulatory authorities for the purpose of facilitating performance and regulatory decision making.

Outsourcing, recognition and reliance on Laboratory

110. (1) The Authority may in performing its functions, subcontract or outsource some of its services to any approved independent laboratory within or outside the country for analysis of medical products and related substances.

(2) The Authority may rely, recognise and use laboratory tests related decisions, reports or information from other regulatory, national, regional and international institutions.

(3) The Authority may take cognisance of the Government Laboratories performing similar functions and wherever necessary may seek assistance from such laboratories.

Regulatory harmonisation initiatives

111. The Authority may participate in regional and international regulatory harmonisation initiatives that aim at —

(*a*) harmonising systems for product authorisation inspections, quality management, information management and any other regulatory activities as may be appropriate;

(*b*) providing for the use of competent quality control laboratories within the harmonisation framework;

(*c*) providing for the recognition, including mutual recognition of regional, continental and other international guidelines;

(*d*) providing for harmonisation of data requirements evidence of quality, safety and efficacy of regulated products and the grounds on which authorisation distribution shall be granted within the region;

(*e*) participating in post-marketing surveillance activities;

(*f*) providing for the use of conformity assessment bodies;

(*g*) establishing networks with other regulatory bodies;

(*h*) collaborating in protecting and promoting public health through enforcement activities; and

(*i*) improving any other harmonisation initiatives.

PART XXII — *Appeals*

Appeal

112. A person aggrieved by a decision of the Authority may appeal, in writing, to the Appeals Committee, within 30 days of receiving notice of such decision.

Appeals Committee

113. (1)There is hereby established a committee to be known as the Appeals Committee.

(2) The Appeals Committee shall consist of such number of persons as may be appointed by the Minister from amongst persons with expertise in —

(*a*) law;

(*b*) medical device;

(*c*) business management;

(*d*) medicine;

(*e*) pharmacy;

(*f*) veterinary medicine; and

(*g*) two other areas as may be determined by the Minister.

(3) The Minister shall appoint the Chairperson of the Committee and the Vice-Chairperson shall be elected by members from amongst their number.

(4) The Committee shall issue guidelines setting out the procedure to be followed in an appeal hearing, and shall publish such guidelines in the *Gazette* and in at least three newspapers with wide national coverage and on the Authority's website.

(5) The provisions of sections 12, 13, 14, 15, 18, 19, 21, 22 and 23 shall, with the necessary modifications, apply to a member of the Appeals Committee.

Hearing of appeal

114. (1) An appeal shall be heard on a date and at a time and place appointed by the Chairperson of the Appeals Committee, who shall notify the appellant and the Authority, in writing, of such date, time and place.

(2) The Chairperson of the Appeals Committee may, for the purpose of hearing an appeal before the Appeals Committee —

(*a*) summon any person who —

(i) in the Chairperson of the Appeals Committee's opinion, may give material information concerning the subject of the hearing, or

(ii) the Chairperson of the Appeals Committee believes has, in that person's possession, custody or control of any document which has a bearing on the subject of the hearing, to appear before the Appeals Committee at a date, time and place specified in the summons, and to produce, as the case may be, any document in that person's possession, custody or control, relevant to the hearing;

(*b*) administer an oath or affirmation from any person called as a witness at the hearing; and

(*c*) call any person present at the hearing as a witness and require that person to produce any document under that person's control.

Decision of Appeals Committee

115. (1) The Appeals Committee may, after hearing the appeal, confirm, set aside or vary the decision of the Authority.

(2) The decision of the Appeals Committee, including the reasons for the decision shall be in writing, and a copy thereof shall be availed to the appellant within 14 days of the decision.

PART XXIII — *Miscellaneous Provisions*

Related substances

116. The Minister may prescribe related substances to ensure compliance with set standards.

Tracking and tracing of regulated products

117. The Minister may, by regulation and in consultation with the Authority, provide for tracking and tracing for all regulated products throughout their lifecycle from manufacturing to patient administration or end-user consumption.

Indemnity

118. No matter or thing done or omitted to be done by a member or employee of the Authority shall, if the matter or thing is done or omitted to be done in good faith in the course of the performance of the functions of the Authority, render that member or employee personally liable to an action, claim or demand.

Offences and penalties

119. (1) A person who contravenes the provisions of this Act for which a penalty is not provided or who —

(*a*) exports, imports, distributes, manufactures or stores or sells —
  (i) any substandard or falsified products or unauthorised regulated products,
  (ii) any regulated products without authorisation, or
  (ii) by misrepresenting or purporting to misrepresent the true effect of the regulated product;

(*b*) sells an expired product;

(*c*) advertises or promotes a regulated product without authorisation;

(*d*) imports or exports a prohibited regulated product;

(*e*) obstructs any inspector from performing his or her functions under this Act;

(*f*) with fraudulent intent tampers with any sample taken in terms of this Act; or

(*g*) acts in any manner that contravenes this Act,

commits an offence and without prejudice to the person's liability in terms of subsection (2), is liable to a fine of P5 000 000, or to a term of imprisonment not exceeding seven years, or to both.

(2) Any person who imports, exports, manufactures, distributes, sells, dispenses, prescribes or advertises any medical product or other substance falsely purporting to be, or intended to or likely to induce anyone to a mistaken belief that it is a registered medical product, commits an offence and is liable to a fine not exceeding of P10 000 000, or to imprisonment for 10 years, or to both.

Recovery of expenses incidental to taking samples

120. Where a person is convicted of an offence under this Act, the court may order that all expenses incidental to the taking of any sample on making of analysis of any product regulated under this Act in respect of which the conviction is obtained shall be paid by the person convicted.

Compounding of offences

121. (1) Notwithstanding the provisions of this Act relating to penalty where a person admits in writing that he or she has committed an offence under this Act, the Authority may, at any time prior to the commencement of hearing by a court of competent jurisdiction, compound such offence, order such person to pay a sum of money to the Authority, not exceeding one half of the amount of the fine to which such person would have been liable to pay if he or she had been convicted of offence.

(2) Where an offence is compounded in accordance with subsection (1) and proceedings are brought against the offender for same offence, it shall be a good defence for the offender to prove to the satisfaction of the court that the offence with which the offender is charged has been compounded under subsection (1).

(3) Where a person is aggrieved by an order under subsection (2), he or she may within the prescribed period appeal against such order to the High Court.

(4) Where a person fails to comply with the order issued under this section, the Authority may enforce the order in the same manner as a decree of court for the payment of the amount stated in the order.

(5) The Minister may prescribe offences to be compounded and the procedure for compounding offences under this Act.

Power to notify the public

122. The Authority may publish on the Authority's website, *Gazette* and other media with wide population coverage, any information of interest to the public for the public notification.

Regulations

123. (1) The Minister may, in consultation with the Authority, make regulations prescribing anything under this Act which is to be prescribed or which is necessary or convenient to be prescribed for the better carrying out of the objects and purposes of this Act, or to give force and effect to its provisions.

(2) Without prejudice to the generality of subsection (1), regulations may provide for —

(*a*) the procedure for the registration of medical products, and the cancellation or suspension of such registration;

(*b*) the procedure for obtaining the approval of the Authority in any matter where approval is required under this Act, and for the withdrawal or suspension of such approval;

(*c*) the control and regulation of the manufacture, import, export, distribution sale and dispensing of medicines;

(*d*) the labelling and advertising of medicines;

(*e*) forms to be used and fees to be paid in respect of applications under this Act;

(*f*) the inspection of premises under this Act;

(*g*) the control, conduct and regulation of clinical trials;

(*h*) controlling of importation and exportation of narcotics, psychotropics and precursor chemicals;

(*i*) providing sampling procedures analysis and laboratory results;

(*j*) recalling and disposing of products which do not comply with this Act;

(*k*) scheduling and classification of regulated products;

(*l*) control of cosmetics;

(*m*) related substances;

(*n*) control of orphan medical products and regulated products needed for public health emergencies;

(*o*) offences to be compounded and the procedure for compounding offences;

(*p*) facilitation of traceability and prudent use of veterinary medical products;

(*q*) establishing coordinated assessment processes for cannabis products;

(*r*) prescribing information-sharing protocols with the cannabis control authority; and

(*s*) ensuring compliance with international cannabis control treaties through coordinated oversight.

Repeal of Cap. 63:04

124. The Medicines and Related Substances Act is hereby repealed.

Savings and transition

125. (1) Notwithstanding the repeal effected under section 124 all subsidiary legislation made under the repealed Act and in force immediately prior to the coming into operation of this Act shall, so far as they are not inconsistent with the provisions of this Act, continue in force as if made under this Act, until revoked or amended under this Act.

(2) A licence or other authorisation granted in terms of the repealed Act shall —

(*a*) not be invalidated by the said repeal but shall have effect as though granted in terms of this Act; and

(*b*) remain valid until its expiry date whereupon an application shall be made under this Act for the relevant licence or other authorisation.

(3) Any person who is an officer or employee of the Authority immediately before the coming into operation of this Act shall continue in office for the period for which, and subject to the conditions under which he or she was appointed.

(4) Any right of appeal which subsisted immediately before the commencement of this Act by virtue of the repealed Act shall be treated as subsisting by virtue of the corresponding provisions in this Act.

(5) Any enquiry or disciplinary proceedings which, before the coming into operation of this Act, were pending shall be continued or enforced by or against the Authority in the same manner as they would have been continued or enforced before the coming into operation of this Act.

(6) Any legal proceedings in respect of any offence committed or alleged to be committed under the repealed Act shall be carried out or prosecuted as if commenced under this Act.

(7) Any fines imposed by the Authority under the repealed Act shall continue as if imposed under this Act.

(8) Manufacturers, retailers and wholesalers of medical devices who are unlicensed or unregistered at the commencement of this Act shall apply for a licence or registration within such time as may be prescribed.

PASSED by the National Assembly on this 11th day of December, 2025.

DR. GABRIEL G. G. MALEBANG,
Clerk of the National Assembly.

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