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Bill No. of 2021

MEDICINES AND RELATED SUBSTANCES BILL, 2021

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MEMORANDUM

1. A draft of the above Bill, which it is intended to be presented to the National Assembly, is set out below.

2. The object of this to Bill is repeal and re-enact, with amendments, the Medicines and Related Substances Act (Cap. 63:04) to adequately address shortfalls identified in the existing Act. The said shortfalls reduced the Botswana Medicine Regulatory Authority's (Authority) ability to effectively regulate medicines and related substances. Notably, the re-enactment will align the Medicines and Related Substances Act with the model law that the African Union developed for harmonisation of African medical regulation. The African Union model law strengthens regulation across the continent, eases market access and encourages direct foreign investment. Further, the re-enactment introduces enhanced controls to meet the high standards of veterinary medicine regulation, which impacts Botswana's ability to access the export market for products such as beef and other meat products. The re-enactment will also allow for the incorporation of the 2018 enactment (Act No. 39 of 2018), which deleted Part IX on controlled substances.

3. Part I of Bill amends some of the definitions in clause 2 and also introduces new definitions for terms that have been introduced in the Bill. For instance, the definition of "medicated feed" has been modified to broaden its application while new definitions that include "pharmacovigilance" have been inserted to *inter alia* aid in the prevention and detection of drug related problems. Clause 3 excludes, from the application of the Act, a person who compound, supplies and administers indigenous medicine in crude form to a patient following a one-to-one consultation in the practice of his or her profession at his or her premises.

4. Part II of the Bill sets out the continuation of the Authority as the entity responsible for regulation of sale, distribution, importation, exportation, manufacture and dispensing of medicines and related substances in Botswana. Clause 5 expands the functions and powers of the Authority by *inter alia* empowering it to perform sampling for testing and analysis of medicines, for the determination of their compliance with standards of quality approved by the Minister (clause 5 (1) *(b)*) and also collaborate with other national, regional and international institutions on medicines and related substances regulation (clause 5 (1) *(n)*). Clause 6 empowers the Minister to prescribe related substances to ensure compliance with set standards.

5. Part III of the Bill provides for the constitution of the Board of the Authority, the powers and the functions of the Board and the tenure of office of members of the Board. Clause 8 of the Bill substitutes for section 8 of the Act to improve readability and match it with similar improved provisions in the Statute Book.

6. Part IV of the Bill provides for the meetings and proceedings of the Board of the Authority and the election of the Vice-Chairperson of the Board. In terms of clause 8(4), the Chairperson of the Board shall be appointed by the Minister.

7. Part V of the Bill makes provision for the appointment of the Chief Executive Officer who shall be charged with the day to day management of the affairs of the Authority. Clause 23 of the Bill substitutes for section 5 of the Act to give more detail to the duties of the Chief Executive Officer and match it with similar improved provisions in the statute book.

8. Part VI of the Bill contains the financial provisions, such as the financial year of the Authority and the submission of an annual report.

9. Part VII of the Bill makes provision for the establishment of the National Quality Control Laboratory which shall be responsible for performing functions relating to the quality of products regulated in terms of the Act. Such functions include analysing medical products and any other regulated products that may be considered to constitute a medical product.

10. Part VIII of the Bill provides for the control over registration, importation, exportation, manufacture, distribution sale and dispensing of medical products. Clause 34 prohibits the import, export, manufacture, *etc.* of medical products that have not been registered by the Authority. Clause 35 requires that an application for registration be made to the Authority and gives further details on when the Authority may reject an application for registration, suspend or revoke registration. Clause 37 provides for the licensing of pharmaceutical operations. Clause 41 provides for pharmarcovigilance to enable the Authority to monitor and report on the safety of medical products as part of national pharmarcovigilance programme. Any medical product that does not conform to the set standards shall be recalled or withdrawn by the Authority (clause 42).

11. Part IX of the Bill contains provisions dealing with classification of medicines and control of certain classes of medical products.

12. Part X of the Bill provides for the control of certain classes of medicine through the use of prescriptions issued by a medical practitioner, dentist or veterinary surgeon. (clause 55). Clause 57 provides that in order to control labelling and traceability, medical products imported, manufactured or dispensed in Botswana are to be labelled in a manner that shall be prescribed. Clause 58 provides how certain classes of medicines are to stored and kept for safety.

13. Part XI of the Bill gives the Authority to power to inspect premises and gives the inspectors powers to carry out the inspections.

14. Part XII of the Bill provides for controls over veterinary medicinal products. Clause 64 provides for the preparation of medicated feeds with the requirement that the Director of Veterinary Services shall approve feed addictive for use in animal nutrition. Feed mills are to be licenced by the Department of Veterinary Services (clause 65). Clauses 66 provides for control of residue feed.

15. Part XIII of the Bill makes provision for medicines in clinical trials. Clause 67 prohibits clinical trials of medical products on humans without clearance from the ethics committee or institutional review board and authorisation granted by the Authority. The sale, dispensing, supply, assembly or manufacture of medical products for clinical trial or research is prohibited without authorisation or exemption by the Authority (clause 67 (6)).

16. Part XIV of the Bill controls the sale, manufacture, labelling, *etc.* of cosmetics. The Part remains as it was in the repealed Act.

17. Part XV of the Bill provides for the establishment of the National Medicines and Therapeutics Board. Section 64 of the Act is amended in clause 77 of the Bill by adding paragraphs *(n)* to *(q)* to the list of people who compose the board.

18. Part XVI provides for the procedure for appeals made against the decisions of the Authority. Such appeals are to be made to an Appeals Committee established in terms of clause 78 (1).

18. Part XVII of the Bill contain miscellaneous provisions. Clause 80 makes provision for international cooperation and regulatory harmonisation in line with the African Union Model law on harmonisation of African medical regulation.

Dr. Edwin Dikoloti
Minister for Health and Wellness

ARRANGEMENT OF SECTIONS

SECTION

A Bill
– entitled –

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

Date of Assent:
Date of commencement:
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, 2020, 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 –

"advertisement", in relation to a medicinal product, includes any pictorial, visual or otherwise descriptive matter or verbal statements or references –

(a) appearing in a print or electronic publication or medium;

(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;

Cap. 42:01

"applicant" means a company or entity registered in terms of the Companies Act and operating in Botswana;

"authorised premises" means premises other than a pharmaceutical wholesaler, pharmacy or veterinary clinic, authorised by the Authority to supply Schedule 4 or general sales medicines;

"Authority" means the Botswana Medicines Regulatory Authority established in terms of section 4;

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

"Chief Executive officer" means the person appointed under section 23 (1);

"clinical trial or medical research on a medicine" means any interventional or observational investigation in humans or animals intended to –

(a) discover or verify the clinical, pharmacological or pharmacodynamics effects of an investigational medicinal product or medical device;

(b) identify any adverse reaction to an investigational medicinal product or medical device; or

(c) 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;

"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, homeopathic preparation 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 substance" means –

(a) a medicine listed in Schedule 1A to 1D;

(b) in the case of veterinary medicine, a medicine listed in Schedules 1 to 4; or

(c) a precursor chemical;

"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;

Cap. 61:02

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

"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 or any other health professional authorised in writing by the Director of Health Services, or a para-professional or veterinary surgeon authorised in writing by the Director of Veterinary Services, to dispense medicines within their scope of practice;

"distribution" means the division and movement of medical 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 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;

"feed additive" means micro-organism or preparations, other than feed materials and premixes, which are intentionally added to feed or water in order to perform one or more specific functions;

"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 62;

"investigational medicinal 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;

"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) disinfection 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;

"medicated feed" means a mixture of feed containing a veterinary medicinal product which is prepared for marketing and intended to be fed to animals without further processing, because of its curative or preventive properties or other properties as a medicinal product;

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

"medical product" means medicine, complementary medicine, cosmetic, vaccines, diagnostic 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

(h) any premix;

"member" means a member of the Board appointed in terms of section 8 (2);

"mutual recognition" means the acceptance of a National Medical Products Regulatory Authority certification of standards and procedures for medical product regulation by another National Medical Products Regulatory Authority;

"narcotic medicine" means any substance contained in Schedules I, II and IV of the United Nations Single Convention on Narcotic Drugs, 1961;

"para-professional" means a person, other than a veterinary surgeon, authorised by the Veterinary Surgeons Council, established under the Veterinary Surgeons Act, to carry out designated duties relating to veterinary medicine under the supervision of a veterinary surgeon;

Cap. 61:04

"pharmaceutical operation" means any premises or activities which deal in the research, manufacturing, marketing, advertising, dispensing, distribution, storage or handling of medical products or prohibited substances;

"pharmacovigilance" means the science and activities relating to the detection assessment and understanding the of prevention of adverse effects of drugs or any other drug-related problem;

"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;

"pharmacy technician" means a person registered as such under the Botswana Health Professions Act;

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

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

Act No. 15 of 2018

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

"prescriber" means a medical practitioner, veterinary surgeon, dentist, or any other health professional authorised in writing by the Director of Health Services or Director of Veterinary Services as the case may be, to prescribe within the scope of their practice, any medicine;

"prescription" means a direction in writing, in a prescribed format, by a prescriber, for the supply of medicine or a combination of medicines for the treatment of a person or animal specified in the direction;

"prohibited substance" means any prohibited plant, preparation, substance, or mixture of substances, as may be prescribed;

"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;

"psychotropic medicine" means any substance contained in Schedules I, II, III and IV of the United Nations Convention on Psychotropic Substances, 1971;

"related substance" means any substance prescribed under section 6;

"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) consign,

(viii) convey, or

(ix) 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; or

(e) offering or attempting to sell;

(f) receiving for sale;

(g) having in possession for sale;

(h) exposing for sale,

(i) sending or delivering for sale; and

(j) causing or allowing to be sold;

"substandard or falsified medical product" means –

(a) a medicine;

(b) a cosmetic;

(c) a related substance; or

(d) a product –

(i) with incorrect ingredients,

(ii) without active ingredients,

(iii) with insufficient ingredients, or

(iv) with fake packaging,

which is fraudulently mislabelled with respect to its identity or source;

"sterile complimentary medicine" means…..

"variation" means –

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

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

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

"veterinary surgeon" means a person registered as a veterinary surgeon under the Veterinary Surgeons Act.

3. (1) The provisions of this Act shall not apply to a person who compounds, supplies and administers indigenous medicine, in crude form, to a patient following a consultation in the practice of such person's profession and at such person's premises.

(2) For the purposes of this section –

(a) "indigenous medicine" means……; and

(b) "crude form" means…..

PART II – *Botswana Medicines Regulatory Authority*

Continuation of Authority

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

(2) The Authority shall 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.

Functions and powers of Authority

5. (1) The functions of the Authority shall be to –

(a) ensure that –

(i) all medicines and related substances 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 such medicines comply with defined codes of practice and other requirements;

(iii) cosmetics manufactured in, imported into, or exported from Botswana are safe to use, and

(iv) there is continuous regulatory presence at designated ports of entry;

(b) perform sampling for testing and analysis of medicines, for the determination of their compliance with standards of quality approved by the Minister, on the recommendations of the Board, and for the issue of certificates with regard thereto;

(c) grant, renew, reject, suspend or cancel, after due assessment, marketing authorisations for medical products, whether locally manufactured or imported and whether intended for local use or export;

(d) ensure that medicines are imported, manufactured, exported, stored, sold, distributed or otherwise dealt with by duly authorised persons;

(e) inspect or cause to be inspected, grant, review, revoke or cancel any licence of all domestic manufacturing premises, exporters, importers, wholesalers, distributors, clinics, pharmacies, dispensaries and other outlets where medicines are dispensed or stored;

(f) inspect or cause to be inspected, premises where medicated feed is used, handled or stored;

(g) ensure the monitoring and reporting of adverse reactions to medicines;

(h) ensure that promotion and advertising of medicines is in accordance with this Act;

(i) monitor and review the implementation of this Act;

(j) issue any guidelines necessary for the carrying out of the objectives of this Act, and shall within reasonable time before the guidelines are issued, cause the text of the guidelines, together with a notice declaring the intention to issue guidelines, to be published in a newspaper with national circulation and such media as the Authority may consider appropriate, inviting stakeholders to furnish any comments thereon;

(k) inspect foreign manufacturing premises, clinical research organisations, and testing premises seeking marketing authorisation for their products, for good manufacturing

practice compliance and good laboratory practice compliance;

(l) undertake educational work in connection with the quality, safety and efficacy of medicines;

(m) conduct post marketing surveillance and control of precursor chemicals;

(n) collaborate with other national, regional and international institutions on medicines and related substances regulation;

(o) control and monitor the import, export, use, storage and dispensing of controlled substances;

(p) grant, reject, suspend or revoke approvals of the use of medicine for clinical trials or medical research;

(q) inspect and license privately owned medicine quality control laboratories;

(r) disseminate information on the quality and safety of medical products to health professionals and the public;

(s) develop a code of conduct for enforcement officers in accordance with the provisions of section 26 (4);

(t) specify the standards for granting marketing authorisation;

(u) specify standards and procedures for referencing, relying upon the marketing assessments and approvals of other medical products regulatory authorities; and

(v) 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.

Related substances

6. The Minister may prescribe related substances to ensure compliance with set standards, determined by the Authority.

Seal of Authority

7. (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 hisor 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 has been authenticated in the manner provided for in 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

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

(2) The Board shall consist of such persons and their alternates 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) the pharmaceutical industry;

(c) business management;

(d) medicine;

(e) pharmacy;

(f) veterinary medicine; and

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

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

(4) The Minister shall appoint a Chairperson of the Board.

(5) The Minister shall, by notice in the *Gazette*, publish the appointment of members and their alternates, within 30 days of the appointments, specifying the dates of their appointment and the period for which they are appointed to the Board.

Powers and functions of Board

9. (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 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 medicine; and

(b) comparative studies, examinations or tests in respect of medicines of different makes or brands, whether produced in Botswana or elsewhere.

Directions by Minister

10. The Minister may, after consultation with the Board, 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.

Tenure of office

11. A member shall hold office for a period not exceeding three years,

and shall be eligible for re-appointment for a term not exceeding two terms.

Disqualification, suspension and removal from office

12. (1) A person shall not be appointed as a member or be qualified to continue to hold office as a member where, he or she –

(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 medial 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 21 or 22; 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

13. 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 12 to hold office as a member;

(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 the expiry of such time as the Minister may specify, in writing, notifying the member of his or her removal from office;

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

(g) 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;

(h) 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; or

(i) if he or she is removed from office by the Minister in accordance with the provisions of section 12 (4).

Filling of vacancy

14.(1) Where the office of a member becomes vacant before the expiry of the member's term of office, the Minister shall appoint the alternate of that member in 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

15. A member, other than a member who is a public officer or who holds a public office, 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

16. (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.

(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

17.(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

18. (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) An alternate member shall attend and take part in the voting at meetings whenever the member whom he or she is alternate is absent from such meeting.

(5) 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

19. (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

20. (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 a 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

21. (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 P10 000, or to imprisonment for a term not exceeding one year, or to both.

Confidentiality

22.(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 P50 000 or to imprisonment

for a term not exceeding one year, or to both.

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

Appointment of Chief Executive Officer

23.(1) The Minister shall, in consultation with 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) the maintenance of discipline in respect of the staff of the Authority;

(e) carrying out of the decisions of the Board;

(f) the management of the support structure of the Authority;

(g) all income and expenditure of the Authority; and

(h) 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 Inspectorate;

(b) has been found to be physically or mentally incapable of performing his or her duties efficiently by an independent medical practitioner or psychiatrist registered as such under the Botswana Health Professions Act;

(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

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

(2) 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.

(3) 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.

Appointment of enforcement officers

25. (1) Subject to the provisions of section 24, the Authority shall appoint enforcement officers who shall perform such functions as may be specified in this Act or in the instrument of appointment.

(2) An enforcement officer shall be furnished with an identity card and shall, when performing any of his or her duties, if so required by any person to whom this Act applies, produce the identity card.

Powers of enforcement officers

26. (1) An enforcement officer appointed in accordance with the provisions of section 25 (1) shall have the powers to –

(a) seize and detain any medical product, substance or article consisting of, or containing any prohibited substances, which he or she have reasonable cause to suspect is liable to forfeiture in terms of this Act;

(b) seize and detain any medical product, articles, or records which appear to him or her to constitute or contain evidence of a contravention of any provision of this Act; and

(c) investigate and institute administrative or civil proceedings against any person who is found to have contravened the provisions of this Act.

(2) Notwithstanding anything to the contrary contained in any other written law, an enforcement officer shall at all reasonable times enter any premises at which there are reasonable grounds to believe that any person is in unlawful possession of any medical product, articles, or records.

(3) Upon entering the premises in terms of subsection (2), the enforcement officer may search such premises or any person and carry out such activities as may be prescribed.

(4) An enforcement officer appointed in terms of this section shall be bound by a code of conduct developed by the Authority.

PART VI - *Financial Provisions*

Funds of Authority

27.(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, levies and administrative fines as may be charged in terms of this Act; and

(e) 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 invest in such manner as it considers appropriate, such funds as are not immediately required for the performance of its functions.

(4) The Authority shall use the revenue acquired under subsections (1) and (2) to meet the costs incurred in its operations and shall use any surplus accrued for such purposes as it may determine.

Financial year

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

Accounts and audit

29.(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, detailing 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;

(c) the Authority has complied with all financial provisions of this Act with which it is the duty of the Authority to comply with; and

(d) 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

30. (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 29, 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.

Pension and other funds

31. (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

32. (1) There is hereby established the National 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 medical products and any other regulated products that may be considered to constitute a medical product for the purpose of this Act;

(b) conduct research and training; and

(c) 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 the country for analysis of medical products and related functions.

Appointment of Director and other staff of Laboratory Cap. 26:01

33. (1) There shall be a Director of the Laboratory, who shall be appointed by the Minister in accordance with the provisions of the Public Service Act.

(2) The Director of the Laboratory shall be responsible for the day to day administration of the Laboratory, subject to the general or specific directions of the Minister, which directions shall be consistent with the provisions of this Act.

(3) Other officers of the Laboratory shall be appointed by the Minister in accordance with the Public Service Act as necessary for purposes of implementing the provisions of this Part.

Part VIII - *Control over Registration, Import, Export, Manufacture, Distribution, Sale and Dispensing of Medical Products*

Registration of medical products

34.(1) A person shall not –

(a) import;

(b) export;

(c) manufacture;

(d) distribute;

(e) sell;

(f) promote;

(g) advertise;

(h) store; or

(i) dispense,

any medical product that has not been registered by the Authority.

(2) The Authority may, under such special circumstances as it considers appropriate –

(a) exempt, in writing, any medical product from the requirements of subsection (1); or

(b) by an order published in the *Gazette*, declare any medical product to be a prohibited medical product, in which case the medical product shall not be registered or if already registered, such registration shall be cancelled.

(3) A medical product in relation to which an exemption is made in terms of subsection (2) *(a)* may include –

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

(b) a medical 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 medical product intended for re-export in the form and packaging that it was imported;

(d) extemporaneous preparations made by a pharmacist for a particular patient or made by a veterinary surgeon for an animal under the surgeon's care; or

(e) any medical product donated to the Government.

(4) An application for exemption of a medical product shall be made in such form as may be prescribed, and shall be accompanied by such fee as may be prescribed.

(5) A person who contravenes the provisions of subsection (1) commits an offence and is liable to a fine not exceeding P100 000, or to

imprisonment for a term not exceeding 10 years or to both.

(6) A person who manufactures, imports, exports, distributes, sells, promotes, advertises, stores, prescribes or dispenses any medicine or cosmetic prohibited in terms of subsection (2) *(b)*, commits an offence and is liable to a fine not exceeding P100 000, or to imprisonment for a term not exceeding 15 years, or to both.

Application for registration of medical products

35. (1) An application for the registration of a medical product shall be submitted to the Authority in such form as may be prescribed which application shall be accompanied by –

(a) such particulars as may be prescribed; and

(b) a prescribed non-refundable application fee.

(2) An application made in terms of subsection (1) shall be made by a company registered, licensed or operating in Botswana.

(3) When considering an application for registration of a medical product under this Act, the Authority shall consider the safety, efficacy, and quality of the medical product.

(4) Where the Authority is satisfied –

(a) with the safety, efficacy, and quality of a medical product or cosmetic; and

(b) that the applicant meets all the requirements for registration in terms of this Act,

it shall register the applicant in such form as may be prescribed.

(5) In the case of a medical device, a device manufacturer shall demonstrate to the Authority that its medical device –

(a) complies with the essential principles for safety and performance of medical devices;

(b) has been approved by a recognised conformity assessment body; and

(c) has been designated and manufactured to be safe and perform as intended during its lifetime when used according to the manufacturer's stated intended purpose.

(6) For the purposes of subsection (5) *(b)* "conformity assessment body" means a body corporate or other legal entity locally or internationally, approved by the Authority as competent to carry out assessment, verification and certification of medical devices before they are placed on the market by manufacturers.

(7) any registration made by the Authority in terms of this section may be granted subject to such terms and conditions as the Authority may consider necessary.

(8) The Authority shall not register an applicant where –

(a) the applicant has not met any requirement for registration in terms of this Act; or

(b) the Authority is not satisfied with the safety, efficacy, and quality of a medicine, complementary medicine, medical product or cosmetic.

(9) Where an application for registration is refused, the Authority shall notify the applicant, in writing, stating the reasons for refusing the registration.

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

(11) Where the Authority registers a medical product, the applicant who applied for the registration shall submit such information as may be prescribed to the Authority, which information shall be accompanied by a prescribed fee.

(12) Where the holder of market authorisation is aware of a safety, efficacy or quality concern which could have detrimental effects on public health, such holder of market authorisation shall, in consultation with the Authority, recall the medical product.

(13) Notwithstanding the provisions of subsection (1), an application for registration of a medical product shall not be made to the Authority for –

(a) a cosmetic that has therapeutic claims on its labelling or advertisement thereof; or

(b) sterile complementary medicine.

(14) The Authority may, during a public health emergency or where special circumstances exist, as may be determined by the Minister, deviate from registration procedures or waive applicable fees as it considers necessary.

(15) The Authority may, without prior consultation from the holder of market authorisation, recall a medical product.

(16) The Authority shall consider the safety, quality, conformity and risk level of a medical product according to its potential harm to the patient or user, when considering an application for registration of a medical product.

(17) any registration granted in terms of this section shall be valid for a period of 12 months from the date of registration.

(18) A person who contravenes subsection (12) commits an offence and is liable to a fine not exceeding P100 000 or to imprisonment not exceeding 10 years, or to both.

Maintenance of register

36. (1) The Authority shall keep and maintain a register in which it shall record –

(a) the particulars of every medicine, complementary medicine, medical product or cosmetic registered in terms of this Act, including the conditions, if any, subject to which that medicine, complementary medicine, medical product or cosmetic has been registered; or

(b) the cancellation of the registration or variation of the conditions of registration of any medical product registered in terms of this Act.

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

Licensing of pharmaceutical operations

37. (1) A person shall not manufacture, import, export, wholesale, distribute, supply, store, sell medicine, complementary medicine, medical products or cosmetics without a licence issued by the Authority.

(2) The Authority shall issue, renew, exempt, suspend, cancel or revoke a licence referred to in subsection (1) in such manner as may be prescribed.

(3) A licence issued under this section may be granted subject to such

terms and conditions as the Authority may consider necessary.

(4) A manufacturer, importer, exporter, wholesaler or distributor shall comply with such standards of good manufacturing practice, standards of good distribution practice and any other standard of good practice 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 P50 000, or to imprisonment for a term not exceeding three years, or to both.

Record-keeping

38.(1) An importer, exporter, manufacturer, distributer, dispenser or user of veterinary medicinal products shall keep, in such form as may be prescribed, records of all transactions or activities relating to the medical product they import, export, manufacture, distribute, dispense or use.

(2) A person who contravenes subsection (1) commits an offence and is liable to a fine not exceeding P100 000, or to imprisonment for a term not exceeding two years, or to both.

Variation of authorisation

39. (1) A person to whom a licence to manufacture, import, export, wholesale, distribute, supply, store or sell medicine, complementary medicine, medical products or cosmetics has already been granted in terms of this Act shall not effect any minor or major variation to the manufacturing process, labelling or packaging of a medical product without the prior authorisation of the Authority.

(2) A person shall apply for authorisation referred to under subsection (1) in such form as may be prescribed, which application shall be accompanied by a prescribed non-refundable application fee.

(3) A person who contravenes the provisions of this section commits an offence and is liable to a fine not exceeding P50 000, or to imprisonment for a term not exceeding three years, or to both.

Importation of generic products Cap. 68:03

40. Where the Minister responsible for trade has, in terms of the Industrial Property Act, authorised the exploitation of a patent medicine, complementary medicine, medical products or cosmetics, the Authority may grant an applicant who satisfies all other requirements for the registration and importation of a medicine, complementary medicine, medical products or cosmetics under this Act, a licence to import such medicine, complementary medicine, medical products or cosmetics.

Pharmarcovigilance

41. (1) The Authority shall monitor and report on the safety of medical products as part of the national pharmarcovigilance programme.

(2) A person whose medicine or medical product is registered in terms of this Act shall have a vigilance system of their medical products and shall provide periodical vigilance data to the Authority, at such intervals as the Authority may consider appropriate.

(3) A manufacturer, distributor and health care professional shall report and submit periodic safety updates to the Authority in such manner as may be prescribed.

(4) Where the product is exempted from registration for wholesale in terms of this Act, the person exempted in terms of this Act shall submit a risk management plan the Authority.

(5) Where a specific safety study is required by the Authority, the marketing authorisation holder or manufacturer shall be required to perform a Post Authorisation Safety Study and submit the findings to the Authority, in writing.

(6) A person whose medicine or medical product is registered in terms of this Act shall designate a qualified person who shall be responsible for pharmacovigilance.

Recall and withdrawal of medical products

42. (1) The Authority shall instruct a person to discontinue the sale of any medical product that does not conform to the standards of identity, strength, quality and purity, safety or any other requirement specified in the registration documents, and as far as is practicable, recall any portion of the batch already sold.

(2) The Authority shall withdraw or remove any medical product from the register which on the latest available scientific evidence is shown to be hazardous to public health and welfare, or is unsafe, inefficacious or of unacceptable quality.

(3) The Authority shall cause a notice of the withdrawal or removal made in terms of subsection (2) to be published in the *Gazette* and a newspaper with national circulation and in such media as the Authority may consider appropriate.

Quality monitoring

43. The Authority may develop and implement a risk-based testing scheme consisting of sampling of medical products throughout the supply chain to identify quality and purity or any other requirement specified in the registration documents.

Substandard or falsified medical products

44. (1) A person shall not manufacture, supply, possess or offer for sale, promote, advertise, store or dispense any substandard or falsified medical product or cosmetic.

(2) A person who contravenes the provisions of subsection (1) commits an offence and is liable to fine P1 000 000 or to imprisonment for term of two years, or to both.

(3) A medical product or cosmetic shall be considered to be substandard or falsified medical product or cosmetic where –

(a) it is manufactured under a name which belongs to another medical product or cosmetic;

(b) it is an imitation of or is a substitute for another medical product or cosmetic;

(c) it resembles another medical product or cosmetic likely to deceive;

(d) it bears upon its label or container the name of another medical product or cosmetic;

(e) the label or container bears the name of an individual or company purporting to be a manufacturer of the medical product or cosmetic, which individual or company is fictitious or has never existed;

(f) it has been substituted wholly or in part by another medical product or cosmetic; and

(g) it is passed off as a product of a manufacturer of whom it is not.

(4) The Authority shall issue guidelines specifying procedures for handling substandard or falsified medical products or cosmetics.

Prohibition of importation of substandard or falsified medical products or cosmetics

45. (1) A person shall not import or export, a substandard or falsified medical product or cosmetic.

(2) A person who contravenes subsection (1), commits an offence and is liable to a fine not exceeding P100 000, or to imprisonment for a term not exceeding 10 years, or to both.

Medical products or

46. (1) A person who wishes to transit a medical product or cosmetic

cosmetics in transit

through Botswana shall make an application to the Authority in such form as may be prescribed, requesting authorisation.

(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 medical product or cosmetic has been granted by –

(i) the Botswana Unified Revenue Service, and

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

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

(4) A person in control of a medical product or veterinary medicine stored in a bonded warehouse or whilst in transit shall –

(a) not subject such a medical product or veterinary medicine to any process which would change the nature of that medical product or veterinary medicine; and

(b) alter the packaging of such medical product or veterinary medicine.

(5) A 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 10 years, or to both.

Designation of ports

47. The Minister, in consultation with the Authority, may designate ports through which medical products may be imported or exported.

Disposal of unwanted medical

48. (1) A person in possession of an unwanted medical product shall dispose of such medical product in such manner as may be prescribed.

products

(2) In this section, "unwanted medical product" means a medical product which has expired, is substandard or falsified or prohibited.

PART IX - *Classification of Medicines and Control of Certain Classes of Medical Products*

Classification and description of human medicines

49. (1) A human medicine shall be classified according to the following classifications and descriptions, which shall be prescribed –

(a) Schedule 1 medicine – a medicine which is, or contains, a prescribed psychotropic or narcotic medicine, and shall be kept under the control of a registered pharmacist; which medicines shall be further classified as follows –

(i) Schedule 1A medicine – a medicine which is highly liable to abuse and which may be dispensed only on written prescription, which prescription shall be kept by the dispensing pharmacist for a minimum of five years;

(ii) Schedule 1B medicine – a medicine which is also liable to abuse though not as highly liable as a Schedule 1A medicine, and which may be dispensed only on written prescription;

(i) Schedule 1C medicine – a medicine which, though widely used therapeutically, is liable to some but relatively minor, abuse in comparison with a Schedule 1A or a Schedule 1B medicine, and may be dispensed only on written prescription;

(ii) Schedule 1D medicine – a medicine which is unlikely to produce dependence or cause harm if misused, and may be dispensed without prescription;

(iii) precursor chemical – a medicine which contains chemicals which are unlikely to cause harm or dependence, but are likely to be used in the manufacture of narcotic or psychotropic medicine;

(b) Schedule 2 medicine – a medicine, not being or containing a psychotropic medicine, or narcotic medicine which may be dispensed only on written prescription, and which must otherwise be kept in a pharmacy under the control of a registered pharmacist;

(c) Schedule 3 medicine – a medicine which may be sold from a pharmacy without prescription; and

(d) Schedule 4 medicine – a medicine which may be sold by any licensed trader.

(2) The dispensing of Schedule 1A, 1B, 1C, 1D, Schedule 2 and Schedule 3 medicines, shall be by a pharmacist through a pharmacy or dispensary.

(3) The Minister, in consultation with the Director of Veterinary Services, may provide for medical practitioners, dentists, pharmacy technicians or other health personnel to dispense human medicines to the extent or in the circumstances as may be prescribed.

(4) A person who sells, imports, distributes, exports or dispenses human medicine shall keep separate registers indicating the medicines that the person has sold or dispensed.

(5) A person who contravenes the provisions of subsection (4) commits an offence and is liable to a fine not exceeding P100 000, or to imprisonment for a term not exceeding two years, or to both.

Classification and description of veterinary medicines

50. Veterinary medicine shall be classified according to the following classification and description, which shall be prescribed –

(a) Controlled veterinary medicines - medicines which contain psychotropic or narcotic substances, and shall be kept by a registered veterinary surgeon or a registered pharmaceutical wholesaler and shall only be administered by a registered veterinary surgeon, which medicines shall be further classified as follows–

(i) Schedule 1 medicine, which is –

(aa) highly addictive and liable to abuse,

(bb) subject to strict storage, dispensing and destruction, and

(cc) may be dispensed only on written prescription, which prescription shall be kept by the dispensing pharmacist or veterinary surgeon for a minimum of five years,

(ii) Schedule 2 medicine, which is less liable to abuse than schedule 1, and shall be kept in locked storage,

(iii) Schedule 3 medicine, which is –

(aa) less liable to abuse and does not have strict storage requirements, but is subject to normal storage requirements, and

(bb) exempted from control when used in normal practice,

(iv) Schedule 4 medicine, which is a very low preparation of codeine-containing products that are exempt from all controlled drug requirements,

(v) Precursor chemicals which contain chemicals unlikely to cause dependence, but are likely to be used to produce narcotic or psychotropic substances;

(b) Prescription Only Medicine - Veterinary Pharmacy, which is a medicine which does not contain narcotic or psychotropic substance and which may be dispensed only on written prescription by a veterinary surgeon or pharmacist, or by a veterinary surgeon from his or her own stock to treat animals under his or her care;

(c) Veterinary, para-professional, which is a medicine which –

(i) does not contain narcotic or psychotropic substances,

(ii) shall be dispensed with prescription by veterinary surgeon, pharmacist or para-professional in authorised premises, and

(iii) shall be supplied by registered pharmaceutical wholesaler; and

(d) general sales medicine which is a medicine which –

(i) does not contain narcotic or psychotropic substances, and

(ii) shall be sold without prescription in authorised premises.

Classification and description of medical devices

51. The Authority shall classify medical devices according to the following classifications and descriptions, which shall be prescribed –

(a) Class A – Low Risk;

(b) Class B – Low-moderate Risk;

(c) Class C – Moderate-high Risk; and

(d) Class D – High Risk.

Classification of in-vitro diagnostic devices

52. The Authority shall classify in-vitro diagnostic devices according to the following classification, which shall be prescribed –

(a) Class A – Low individual risk;

(b) Class B – Low public health risk or moderate individual risk;

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

(d) Class D – Highest Risk.

Classification of complementary medicine

53. For purposes of registration, the Authority shall classify complementary medicine into –

(a) Schedule C1 – Complementary Medicines Pharmacy only, where consultation with a healthcare professional is required; and

(b) Schedule C2 – Complementary Medicine General Sale, where consultation with a healthcare professional is not required.

Classification of cosmetics

54. 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 a risk to 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.

PART X – *Control of Certain Classes of Medicines*

Prescriptions

55. (1) A registered medical practitioner, dentist or veterinary surgeon may prescribe all medicines in the exercise of their professions.

(2) The Minister, in consultation with the Director of Health Services and the Director of Veterinary Services, may prescribe limited powers of prescription of medicines to pharmacists, nurses, para-professionals and other health personnel.

(3) A person authorised to issue a prescription in terms of this Act shall do so in such manner as may be the prescribed.

(4) A prescription issued outside Botswana shall not be honoured unless it is endorsed by a registered medical practitioner, dentist or veterinary surgeon registered to practise in Botswana.

(5) For the purposes of subsection (4), "endorsed" means the appending of a signature and a stamp on a prescription issued outside Botswana by a registered medical practitioner, dentist or veterinary surgeon registered to practise in Botswana.

(6) A person who imports a prescription medicine, other than a veterinary medicine, issued outside Botswana, for personal use, shall not bring in a quantity of that medicine which is in excess of the prescribed limit, and shall produce on demand by an inspector appointed in terms of this Act, a certified copy of the prescription under which it was issued.

(7) A person who contravenes the provisions of –

(a) subsections (1), (2), (3) or (4) commits an offence and is liable to a fine not exceeding P5 000 or to imprisonment for a term not exceeding one year, or to both; or

(b) subsection (6) commits an offence and is liable to a fine not exceeding P10 000, or to imprisonment for a term not exceeding one year, or to both.

(8) A person who issues a prescription in terms of this Act shall keep a copy of each prescription issued by him or her, for a prescribed period.

Validity of prescriptions

56. (1) A prescription for a Schedule 1A, 1B or 1C human medicine and schedule 1, 2 or 3 shall be valid for 30 days.

(2) A prescription for a Schedule 2 medicine and Schedule 1A for palliative care may be repeated a maximum of six times and shall be valid, for initial dispensing, for a period of one month from the date of prescription.

(3) A dispenser shall endorse every prescription presented to the dispenser with the quantity dispensed, signature of that dispenser, and the date of dispensing, and shall keep the prescription in the pharmaceutical operation for five years.

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

Labelling and traceability

57. (1) Any medical product imported, manufactured or dispensed within Botswana shall be labelled in such manner as may be prescribed.

(2) A market authorisation holder or a person authorised to supply medicinal products shall –

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

(b) use such form as may be prescribed for labelling medicinal product to make it possible to ascertain the identification and authenticity of such medical product.

Storage and safe custody

58. (1) A person shall not possess a Schedule 1A, 1B, 1C, Schedule 2 or Schedule 3 human medicine and Schedule 1, 2, 3, POM-VP or VPS veterinary medicine unless –

(a) the medicine, complementary medicine, medical product or cosmetic has been prescribed to –

(i) such a person, or

(ii) an animal under the care of such person; or

(b) the person is authorised in terms of this Act to store, administer, dispense or obtain such medicine, complementary medicine, medical product or cosmetic.

(2) A person who is authorised in terms of this Act to be in possession of Schedule 1A, 1B, 1C, Schedule 2 or Schedule 3 human medicine or, Schedule 1, 2, 3, POM-VP or VPS, in the case of veterinary medicine, shall store such medical product in a licensed premises to which members of the public do not have access and in such manner as may be prescribed.

(3) A person who is in possession of any human or veterinary medicine shall keep such medical product in a place where children do not normally have access.

(4) A person who possesses Schedule 4 medicine shall ensure that such medicine is kept in a designated area within facilities and stored under such conditions as may be prescribed.

Import and export of narcotics, psychotropic and precursors

59. (1) A person who wishes to import or export a Schedule 1A, 1B or 1C human medicine, Schedule 1, 2, or 3 veterinary medicine or a precursor chemical, 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 licence from the Authority for such importation or exportation; and

(c) within seven days of such import or export, provide such information, in such form as may be, to the Authority as the Authority may require.

(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 P100 000, or to imprisonment for a term not exceeding 10 years, or to both; or

(b) subsection 1 *(c)* commits an offence and is liable to a fine not exceeding P20 000, or to imprisonment for a term not exceeding three years, or to both.

Records of narcotics, psychotropic and precursors

60. (1) A person who –

(a) imports;

(b) exports;

(c) manufactures;

(d) distributes; or

(e) sells,

Schedule 1A, 1B or 1C human medicine, Schedule 1, 2, or 3 veterinary medicine or a precursor chemical shall keep a separate register for each of the categories of medicine, and a separate register for the precursor chemicals.

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

(a) be hand written, in indelible ink or in any other manner as may be specified by the Authority; and

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

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

(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 P100 000 or to imprisonment for a term not exceeding two years, or to both.

Advertising and promotion of medical products

61. (1) The Authority shall issue guidelines relating to advertising and promotion of medical products in terms of this Act.

(2) The advertising or promotion of any medical product shall not, by word, illustration or by any other way give any false, misleading, or deceptive information concerning the properties of the medical product, or information which is likely to encourage wrong or excessive use of the medicine.

(3) The advertising or promotion of a medical product which may be dispensed on prescription only shall be disseminated solely through professional journals and magazines, or only to a person authorised to dispense, prescribe or administer such medical product.

(4) The advertising or promotion of a medical product which may be dispensed without prescription may be addressed to the public but shall not include promises of unfailing results or expressions or illustrations of a nature likely to offend or intimidate members of the public, or make reference to symptoms in a manner likely to induce members of the public to make wrong diagnosis.

(5) A 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 10 years, or to both.

PART XI – *Authority to Inspect Premises*

Inspection of premises

62. (1) The Authority shall –

(a) recommend to the appointing authority the appointment of inspectors; and

(b) authorise such inspectors to perform such functions as are set out in this Act.

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

(3) An inspector shall be furnished with an identity card and shall, when performing his or her duties, if so required by any person to whom this Act applies, produce the identity card.

Powers of Inspectors

63. (1) An inspector may, at any reasonable time, without prior notice –

(a) enter, inspect or search any premises –

(i) which is on the register of premises,

(ii) registered under this Act,

(iii) used in the manufacture, marketing, or distribution of a medicines, complementary medicine, medical product or cosmetic that is the subject of a marketing authorisation or licensing request, or

(iv) suspected of or dealing in products regulated in terms of this Act;

(b) examine or make copies of or take extracts from any document found in or upon such premises, including documents stored in electronic information storage system and request from any person in whose capacity or charge that document is, an explanation of any entry in that document;

(c) take samples, for analysis other examination, of any medicine, complementary medicine, medical product, cosmetic or any other substance capable of being used in the manufacture of medical products;

(d) seize, upon the issue of a receipt, any medicine, complementary medicine, medical product, cosmetic or any such article, document or object, it appears to provide proof of a contravention of a provision of this Act, or if he or she wishes to retain it for further examination or for safe custody; and

(e) close the premises found to be in contravention of this Act; and

(2) Where an inspector is satisfied on reasonable grounds that a person has contravened the provisions of this Act, he or she may –

(a) issue a written warning;

(b) direct the person to do or refrain from a specified act; or

(c) recommend the institution of administrative, civil or criminal proceedings against the offender.

PART XII – *Control over Veterinary Medicinal Products*

Preparation of medicated feed

64. (1) The preparation of medicated feed shall only be done at a feed mill authorised in a manner specified by the Authority acting in consultation with the Department of Veterinary Services, to manufacture medicated feed.

(2) Medicated feed shall be prepared from a registered veterinary medical product in such manner as may be specified by the Authority acting in consultation with the Department of Veterinary Services.

(3) The Director of Veterinary Services shall approve feed additives for

use in animal nutrition, and cause a notice of the list of approved feed additives for animal use to be published in the *Gazette*.

(4) The Authority shall by notice in the *Gazette*, publish a list of approved feed additives for use in animal nutrition, which list shall be reviewed from time to time.

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

Feed mills

65. (1) A person shall not operate a feed mill except in accordance with a licence issued by the Department of Veterinary Services.

(2) A person who contravenes the provisions of subsection (1) commits an offence and is liable to a fine not exceeding P200 000, or to imprisonment for a term not exceeding three years, or to both.

Control over residue feed

66. (1) The Director of Veterinary Services may, by Order published in the *Gazette* –

(a) prescribe active pharmacological substances for use in animals and their maximum residue limits;

(b) prohibit substances for use in animals; or

(c) prescribe a withdrawal period for medicinal product used on an animal.

(2) A person who uses a veterinary medicinal product on an animal under his or her care or uses medicated feed to feed an animal that he or she keeps in a feed lot or other premises, shall ensure that –

(a) the animal is not slaughtered for consumption before the withdrawal period specified in the Order, referred to in subsection (1) has elapsed; and

(b) the prescribed maximum residue limit allowable in meat falls within the limit allowed.

(3) A person who contravenes the provisions of subsection (2) commits an offence and is liable to a fine not exceeding P100 000 or to imprisonment for a term not exceeding three years, or to both.

(4) A person who uses a substance prohibited in terms of subsection (1)

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

PART XIII – *Medicines in Clinical Trials and Medical Research*

Sale, etc. of medical products for clinical trial or medical research

67. (1) A person shall not conduct clinical trials of medical products on humans without clearance from the ethics committee or institutional review board and authorisation granted by the Authority.

(2) A person who wishes to conduct clinical trials referred to in subsection (1) shall make an application to the Authority in such form as may be prescribed, which application shall be accompanied by such particulars as may be prescribed.

(3) The Authority may, where it is satisfied that the information the applicant has provided is sufficient, grant authorisation.

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

(5) The Authority shall issue guidelines that shall be used by any person who conducts a clinical trial.

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

(7) Where applicable, the Authority may authorise amendments to the protocol.

(8) A person who conducts a clinical trial shall ensure that –

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

(b) the investigational medical product complies with good manufacturing practices specified by the Authority for investigational medical product.

(9) The Authority shall keep and maintain a register of –

(a) any application made in terms of this section;

(b) any rejected application; and

(c) any clinical trial conducted in Botswana.

(10) A person who contravenes the provisions this section commits an offence and is liable to a fine not exceeding P100 000 or to imprisonment for a term not exceeding five years, or to both.

Monitoring

68. (1) Notwithstanding that a person may hold a clinical research licence issued under a different Act, the licence holder shall allow the Authority access to the place where a clinical trial or medical research on a medicine 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 medicine that is being used in a clinical trial or medical research on a medicine, the licence holder shall report the adverse reaction to the Authority, in such manner as may be prescribed.

(3) A person who contravenes subsection (1) commits an offence and is liable to a fine not exceeding P100 000, or to imprisonment for a term not exceeding three years, or to both.

PART XIV – *Sale, Manufacture, Labelling, etc. of Cosmetics*

Sale of cosmetics

69.(1) A person shall not sell a cosmetic that –

(a) has in it, or on it, any substance that may cause injury to the health of the user when the cosmetic is used –

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

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

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

(c) the Authority has, in the public interest, declared as prohibited.

(2) The Authority may, where it has determined that a cosmetic is unsafe for the public to use, prohibit the manufacture, sale or storage of the cosmetic and such prohibition shall be published in a newspaper with

national circulation and such media as the Authority may consider appropriate.

(3) The Minister, acting on the advice of the Authority, may by Order published in the *Gazette*, prohibit the use of an ingredient in any cosmetic, where the Authority considers it to be in the public interest.

(4) A person who contravenes the provisions of this section commits an offence and is liable to a fine not exceeding P50 000, or to imprisonment for a term not exceeding three years, or to both.

Unsanitary conditions for cosmetics

70. (1) A person shall not manufacture, prepare, preserve, package or store for sale, any cosmetic, under unsanitary conditions.

(2) A person who contravenes subsection (1) commits an offence and is liable to a fine not exceeding P75 000, or to imprisonment for a term not exceeding five years, or to both.

Therapeutic claims in cosmetics

71. A person shall not sell a cosmetic if any label or advertisement of the cosmetic contains any symbol or statement that implies that the cosmetic has been compounded in accordance with a prescription.

Ingredients in cosmetics

72. A manufacturer or importer shall not manufacture or sell a cosmetic that contains any ingredient that has been declared by the Minister, by Order published in the *Gazette*, to be a prohibited ingredient.

Labelling of cosmetics

73. A person shall not sell a cosmetic unless it is labelled in such manner as may be prescribed.

Safety of cosmetics

74. (1) The Authority may request, in writing, that a manufacturer submit to the Authority, on or before a specified day, evidence to establish the safety of a cosmetic under the recommended or the normal conditions of use.

(2) A manufacturer who does not submit the evidence requested under subsection (1) shall cease to sell the cosmetic after the day specified in the instrument of request.

(3) Where the Authority determines that the evidence submitted by a manufacturer in terms subsection (1) is not sufficient, the Authority shall notify the manufacturer, in writing, to that effect, and the manufacturer shall cease to sell the cosmetic until the manufacturer –

(a) has submitted further evidence to the Authority; and

(b) has been notified, in writing, by the Authority that the further evidence is sufficient.

(4) A manufacturer or importer shall provide the Authority with such documentation and information as may be prescribed, within such period 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 P50 000, or to imprisonment for a term not exceeding two years, or to both.

PART XV – *National Medicines and Therapeutics Board*

National Medicines and Therapeutics Board

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

Functions of board

76. The functions of the board shall be to –

(a) select medicines and related substances 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; and

(e) oversee the development and implementation of national therapeutics guidelines;

(f) distribute and publish therapeutic bulletins relating to medicines and related substances use;

(g) determine restrictions to be placed on prescribing by different cadres of clinical staff and pharmacists; and

(h) determine the content of lists of medicines within the national formulary which may be availed in Government health facilities; and

(i) approve the medicines to be included in treatment protocols.

Composition of board

77. (1) The board shall consist of the following people and their alternates, 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 medical products control board;

(n) a veterinary surgeon representing the public sector;

(o) a veterinary surgeon representing veterinary association or union in Botswana;

(p) a veterinary surgeon representing the Veterinary Surgeon's

Council; and

(q) a representative of the Attorney General's Chambers.

(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, 17, 20, 21, 22 and 81 shall apply to this Part, with the necessary modifications.

(7) A clinical pharmacist from the Botswana Essential Medicines Action Programme shall be the Secretary of the board.

PART XVI – *Appeals*

Appeals Committee

78. (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) pharmaceutical industry;

(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) 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 time, date and place.

(5) 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.

(6) The Committee shall issue guidelines setting out the procedure to be followed in an appeal hearing, and such guidelines shall be made accessible to the public.

(7) The provisions of sections 15, 21, 22 and 81 shall, with the necessary modifications, apply to a member of the Appeals Committee.

Decisions of Appeals Committee

79. (1) 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.

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

(3) 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 XVII – *Miscellaneous Provisions*

International cooperation and regulatory harmonisation

80. For purposes of international cooperation and regulatory harmonisation with comparable regulatory authorities, the Authority shall –

(a) cooperate with other national, regional and international medical products regulatory authorities;

(b) share pharmaceutical intelligence on products that pose public health risks with other authorities at the regional and international level;

(c) take appropriate measures to ensure effective bilateral, regional and international co-operation to combat the production, circulation and use of substandard or falsified medical products;

(d) participate in regional and continental medical products regulatory harmonisation initiatives;

(e) harmonise registration of medical products, inspections, quality management systems, information management systems, joint evaluations, joint inspections and any other regulatory activity as may be appropriate;

(f) provide for the use of accredited quality control laboratories within the harmonisation framework;

(g) provide for the adherence of regional and other international technical guidelines;

(h) provide for harmonisation of data requirements for evidence of quote safety, efficacy of medical products and the grounds on which authorisation for distribution shall be granted within the region;

(i) provide for mutual recognition of marketing authorisation decisions;

(j) share summary evaluation and inspection reports;

(k) participate in common post-marketing surveillance conducted in accordance with national and internally recognised stands;

(l) provide for recognition or reliance on vigilance-related decisions, reports or information from other countries, regional or international bodies;

(m) provide for cooperation with other regulatory agencies or authorities for the purpose of strengthening national regulatory capacity;

(n) establish networks with other regulatory agencies or authorities and collaborate in protecting public health through enforcement activities;

(o) establish exchange programmes with other medical products regulatory agencies or authorities to keep abreast of evolving scientific development in the field of medical products;

(p) advise on any necessary legal mechanism for regulatory harmonisation;

(q) provide for recognition and use of laboratory testing-related decisions, reports or information from other regulatory, regional and international bodies;

(r) provide for recognition or reliance on regulatory decisions made by other regulatory bodies;

(s) provide for transparency and information sharing through –

(i) the establishment of a quality management system based on common regional requirements to ensure efficiency, and

(ii) the creation a national information management system which allows for sharing information at regional and continental levels accordance with

national laws, bilateral and multilateral agreements; and

(t) take appropriate measures to ensure effective co-operation with comparable regulatory authorities outside Botswana.

Indemnity

81. 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.

General offences and penalties

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

(a) prescribes any Schedule 1 or Schedule 2 human medicine or in the case of veterinary medicine, Schedule 1, 2, 3, 4, POM-VP and VPS without being authorised by this Act; or

(b) obstructs or fails to comply with any reasonable request by the Authority, in the exercise of its functions under this Act,

commits an offence and without prejudice to the person's liability in terms of subsection (2), is liable to a fine of P10 000, or to a term of imprisonment not exceeding one year, or to both.

(2) Any person who imports, exports, manufactures, distributes, sells, dispenses, prescribes or advertises any medicine or other substance falsely purporting to be, or intended to or likely to induce anyone to a mistaken belief that it is a registered medicine, commits an offence and is liable to a fine of P100 000, or to imprisonment for 10 years, or to both.

(3) Where any person is convicted of an offence under this Act, the court may, at the request of the Authority, order any medicine or other substance in respect of which the offence was committed to be seized and disposed of as the Authority may require, and the Authority may at the same time withdraw any approval or authorisation previously given by the Authority to that person.

Obstruction of authorised officer or inspector

83. A person who –

(a) obstructs or hinders an authorised officer or inspector in the performance of his or her functions under this Act;

(b) with fraudulent intent tampers, with a sample seized in terms of this Act; or

(c) when asked by an authorised officer or inspector for an explanation or information relating to a matter within his or her knowledge, gives an explanation or information which is false or misleading, knowing it to be false or misleading,

commits an offence and is liable –

(i) for a first offence, to a fine not exceeding P100 000, or to imprisonment for a term not exceeding two years, or to both, or

(ii) for a second or subsequent offence, to a fine not exceeding P200 000, or to imprisonment for a term not exceeding three years, or to both.

Administrative penalties

84. In addition to criminal penalties that may be imposed on a person who contravenes any provision of this Act, the Authority may impose such administrative penalties as may be prescribed, as it considers necessary.

Regulations

85. (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 medicines, and the cancellation or suspension of such registration;

(b) the procedure for obtaining the approval of the Director in any matter where the approval of the Director 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) the 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 or medical research on any medicine, or any scientific or medical experiments in relation to habit-forming medicines;

(h) facilitation of traceability and prudent use of veterinary medicine; and

(i) prohibited substances.

Repeal of Cap. 63:04

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

Savings and transitional provisions

87. (1) Notwithstanding the repeal effected under section 86, 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 it is 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) Any 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 license or registration within such time as may be prescribed.