[Chap6304]CHAPTER 63:04
MEDICINES AND RELATED SUBSTANCES

ARRANGEMENT OF SECTIONS

SECTION

Act 8, 2013,
S. I. 8, 2016,
S.I. 9, 2017,
Act 39, 2018.

AN ACT to provide for the registration, regulation of the sale, distribution, importation, exportation, manufacture and dispensing of medicines and related substances, and matters incidental thereto.

[Date of Commencement: Parts I to V: 1st February, 2016;
Parts VI to XIII: 17th February 2017.]

PART I
Preliminary (ss 1-2)

1. Short title

This Act may be cited as the Medicines and Related Substances Act.

2. Interpretation

In this Act, unless the context otherwise requires-

"analyst" means a person with a degree in-

(*a*) chemistry;
(*b*) microbiology;
(*c*) pharmacy;
(*d*) pharmaceutical science;
(*e*) biomedicine;
(*f*) medical and pharmaceutical biotechnology, or an equivalent degree with proven technical competency in the analysis of medicine;

"Authority" means the Medicines Regulatory Authority established under section 3;

"Board" means the Board of the Authority, established under section 6;

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

(*a*) discover or verify the clinical, pharmacological or pharmacodynamic 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;

"controlled substance" means a prohibited substance or medicine listed in Schedules 1A, 1B, 1C, 1D, or 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 human body, for the purpose of cleansing, beautifying or altering the appearance; or

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

"counterfeit product" means-

(*a*) a medicine;

(*b*) a cosmetic;

(*c*) a related substance; or

(*d*) a product-

(i) with correct ingredients,

(ii) with incorrect ingredients,

(iii) without active ingredients,

(iv) with insufficient ingredients, or

(v) with fake packaging;

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

"dentist" means a person registered as a dentist under the Botswana Health Professions Act (Cap. 61:02);

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

"dispensary" means any premises in which an authorised dispenser stores, handles, and dispenses medicine listed under Schedule 1, 2 or 3;

"distribution" means any practice whose activities involve the-

(*a*) handling;

(*b*) storing; or

(*c*) supplying,

of medicine for wholesale to pharmacies or dispensaries;

"emergency prescription" means medicine supplied by a pharmacist in a pharmacy, in an emergency, for a specified period of time and without a prescription;

"illicit substance" means any substance, natural or synthetic, which has been declared as an illicit substance by the Minister;

"inspector" means a person authorised in writing by the Medicines Regulatory Board and published in the *Gazette* as such, to inspect pharmaceutical operations;

"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;

"medicated feed" means a mixture of premix and animal feed;

"medical device" means an instrument, apparatus, implement, implant, medical equipment, machine, contrivance, or other related article, which is-

(*a*) used in the diagnosis, mitigation, treatment or prevention, of disease in man or animals; or

(*b*) used to affect the structure or function of the body of man or animals, and does not achieve any of its intended principal purposes through chemical action within the body, and is not dependent upon being metabolised for the achievement of any of its principal intended purposes;

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

"medical representative" means a person who promotes, markets, or advertises medicines;

"medicine" means-

(*a*) any substance, mixture 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*) herbal tea, or 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;

(*g*) any medical device; or

(*h*) any premix;

"narcotic medicine" means any substance, 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 Surgeon Council to carry out designated duties relating to veterinary medicine under the supervision of a veterinary surgeon;

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

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

"pharmacy" means premises, labelled as such, licensed by the Medicines Regulatory Authority for the storing, dispensing, and selling of medicines, 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;

"precursor chemical" means a substance, including its salts, isomers, derivatives, and analogues, that may be used frequently in the illicit synthesis or manufacture of narcotic medicines, psychotropic medicines, and illicit substances as provided for under the United Nations Convention Against the Illicit Traffic in Narcotic Drugs and Psychotropic Substances, 1988;

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

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

"prohibited substance" means any plant, preparation or substance, or mixture of substances, which has been declared as a prohibited substance by the Minister, by Order published in the Gazette;

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

"technician" means a person with a diploma or higher national diploma in-

(*a*) laboratory technology;

(*b*) medical or clinical laboratory;

(*c*) medical or clinical engineering; or

(*d*) animal health, or an equivalent related diploma with proven technical competency in the analysis of medicine, or the repair and management of medical devices; and

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

PART II
Medicines Regulatory Authority (ss 3-5)

3. Establishment of Authority

There is hereby established an authority to be known as the Medicines Regulatory Authority, which shall be a body corporate capable of suing and being sued and, subject to the provisions of this Act, of performing such acts as bodies corporate may, by law, perform.

4. Functions of Authority

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, and

(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;

(*b*) ensure that cosmetics manufactured in, imported into, or exported from Botswana are safe to use;

(*c*) perform sampling and establish a laboratory or other facilities for-

(i) the 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, and

(ii) the inspection of privately owned medicine quality control laboratories;

(*d*) grant, renew, suspend or cancel, after due assessment, marketing authorisations for medicines, whether locally manufactured or imported and whether intended for local use or export;

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

(*f*) inspect or cause to be inspected, and license all domestic manufacturing premises, exporters, importers, wholesalers, distributors, clinics and hospital pharmacies, retail pharmacies, dispensaries and other outlets where medicines are dispensed or stored;

(*g*) inspect or cause to be inspected, premises where medicated feeds are used, handled or stored;

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

(*i*) ensure that the advertising of medicines is in accordance with this Act;

(*j*) monitor and review the implementation of this Act;

(*k*) prepare, modify or amend and publish any guidelines intended to be applied, or to be adopted in connection with the manufacture, testing, sampling, use, or safe disposal of any medicine;

(*l*) benchmark against 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;

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

(*n*) conduct post marketing surveillance and control chemical precursors;

(*o*) do those things, or enter into those transactions that are expedient or necessary for the proper and efficient discharge of the functions of the Authority;

(*p*) control and monitor import, export, use, storage, and dispensing of controlled substances;

(*q*) grant approval of the use of medicine for clinical trials or medical research; and

(*r*) inspect and license privately owned medicine quality control laboratories.

5. Appointment of officers and employees

(1) The Authority shall have a Chief Executive Officer, appointed by the Minister on the recommendation of the Board, and on terms and conditions determined by the Board.

(2) The Chief Executive Officer shall, subject to such directions as may be given by the Board, be charged with the management and control, administration and organisation 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, subject to the provisions of this Act, delegate the exercise of any of his or her powers under this Act, to any senior officer of the Authority.

(5) The Chief Executive Officer shall appoint other officers and employees of the Authority.

(6) The Chief Executive Officer may resign from office by notice in writing addressed to the Minister, and may be removed from office by the Minister.

PART III
Establishment of Board of Authority (ss 6-13)

6. Establishment and functions of Board

(1) There is hereby established a Board of the Authority, to be known as the Medicines Regulatory Board which, subject to the provisions of this Act, 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.

7. Membership

(1) 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*) pharmaceutical industry;
(*c*) business management;
(*d*) medicine;
(*e*) pharmacy;
(*f*) veterinary medicine; and
(*g*) two other areas as may be determined by the Minister.

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

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

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

(5) The Minister shall cause appointments to the Board to be published by notice in the *Gazette*, within 30 days of the appointments.

8. Tenure of office

A member shall hold office for a period of three years and shall be eligible for re-appointment for not more than two consecutive terms.

9. Disqualification

A person shall not be appointed as a member or shall not continue to hold office, who has-

(*a*) in terms of a law in force in any country-
(i) been adjudged or otherwise declared bankrupt and has not been discharged, or

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

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

(i) of a criminal offence in any country, or

(ii) of a criminal offence for which he or she has not received a free pardon and notwithstanding that the sentence has been suspended, which, if committed in Botswana, would have resulted in a criminal offence having been committed, the penalty for which would be at least six months imprisonment without the option of a fine.

10. Removal and resignation of members

(1) The Minister may remove a member from office where the member-

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

(*b*) is inefficient;

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

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

(*e*) has failed to comply with the provisions of sections 12 (1) or 13.

(2) A member may resign from the Board by giving 30 days notice, in writing, to the Minister.

(3) The office of a member shall become vacant-

(*a*) where the member does not appeal within 30 days from the date the member was convicted of an offence referred to under section 9 (*b*);

(*b*) where the member appeals, within 30 days from the date a ruling against the member is made on an appeal made in respect of a conviction against the member under section 9 (*b*);

(*c*) where the member communicates his or her resignation, in writing, to the Minister, in accordance with subsection (2);

(*d*) where a period of 30 days has elapsed from the date the member is given notice in writing by the Minister to vacate office; or

(*e*) where a member is removed by the Minister on the grounds of misconduct in terms of subsection 10 (1) (*d*).

11. Filling of vacancy

(1) Where the office of a member becomes vacant before the expiry of the member's term of office, the Minister may, in accordance with section 7, appoint another person to be a member in place of the member who has vacated 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 would otherwise have held office is less than six months.

12. Disclosure of interest

(1) Where a member is present at a meeting of the Board or any committee of the Board at which any matter which is the subject of consideration and in which matter the member is directly or indirectly interested in a private capacity, the member shall forthwith upon 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 under 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 the Board makes a decision which benefits that member directly or indirectly, that decision shall be void to the extent to which it benefits the member.

(4) A person 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.

13. Confidentiality

(1) A member shall not disclose any confidential information relating to the affairs of the Board, which he or she acquired during the performance of his or her duties under this Act.

(2) Notwithstanding the provisions of subsection (1), a member may disclose information relating to the affairs of the Board 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) Any 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 IV
Meetings and Proceedings of Board (ss 14-18)

14. Proceedings of Board

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

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

(3) Meetings of the Board shall be held at such places and times as the Board may determine and shall be convened by the Chairperson or Secretary of the Board.

(4) 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.

(5) A decision of the Board on any matter shall be by a majority of the members present and voting at the meeting and, in the event of an equality of votes, the Chairperson shall have a casting vote in addition to his or her deliberative vote.

(6) At any meeting of the Board, a *quorum* shall be constituted by not less than one half of the members of the Board.

(7) The Chairperson of the Board shall cause minutes of the meetings of the Board to be taken and recorded.

(8) The Board may co-opt one or more persons qualified or able to assist it in its functions, to attend any meeting of the Board, but such persons may not vote on any matter before the Board.

(9) The Authority shall provide the Secretary for the Board.

(10) The Secretary shall keep minutes of each meeting of the Board, which shall be submitted for acceptance at the next meeting of the Board.

15. Validity of decisions

An act or decision or proceeding of the Board shall not be invalid on account of the appointment of any member being defective, if the act was done, or the decision, or the proceedings took place, in accordance with a majority vote of the persons who were at the time entitled to act as members.

16. Committees

(1) The Board may appoint committees either of a general or special nature consisting of such number of members, with such qualifications, as the Board may determine

(2) The Board may delegate any of its powers, functions or duties under this Act to a committee appointed in terms of subsection (1).

(3) The provisions of sections 12, 13 and 17 shall, with the necessary modifications, apply to a member of a committee.

17. Remuneration

A member shall be paid out of the funds of the Board such allowances as the Minister may determine.

18. Indemnity of members

No civil or criminal proceedings may be instituted against a member in respect of anything done by the member in the discharge of his or her duties as a member

PART V
Financial Provisions (ss19-22)

19. Funds of Authority

(1) The revenue of the Authority shall consist of-

(*a*) moneys appropriated by Parliament for the purposes of the Authority;
(*b*) grants and donations that the Authority may receive;
(*c*) income that the Authority may receive from investments; and
(*d*) fees charged in terms of this Act.

(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 money as it may require for the discharge of its functions.

(3) The Authority may, subject to the approval of the Minister, invest in such manner as it considers appropriate, such of its 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, with the approval of the Minister.

20. Financial year

The financial year of the Authority shall be a period of twelve months ending on the 31st of March each year.

21. Accounts and audit

(1) The Authority shall maintain proper books of accounts and statement of accounts in respect of each financial year relating to the expenditure of the Authority and shall in each financial year prepare a statement of such accounts

(2) The Authority shall submit its books of accounts and statement of accounts to an auditor appointed by the Authority, who shall audit the accounts within two months of the end of the financial year or such extended time after the financial year, as the Minister responsible for finance may direct

(3) An auditor appointed under subsection (2) shall report in respect of the accounts for each financial year, in addition to any other matter on which the auditor considers it pertinent to report on, whether or not-

(*a*) the auditor has received all the information which, to the best of his or her knowledge were necessary for the performance of his or her duties as auditor;
(*b*) the accounts and related records of the Board have been properly kept and represent a true and fair view of the transactions and financial affairs of the Authority; and
(*c*) the Authority has complied with all the financial provisions of this Act with which it is the duty of the Authority to comply.

(4) The auditor shall forward a report made under subsection (3) and a copy of the audited accounts within 14 days of the completion thereof, to the Authority.

22. Annual report

(1) The Board shall, within three months of the receipt of the audited accounts, submit to the Minister, a comprehensive report on the activities of the Board and the Authority during the preceding year, together with the audited accounts and auditor's report submitted inaccordance with section 20 (3).

(2) The Minister shall lay a copy of the annual report before the National Assembly not later than three months from the date of its submission.

(3) The annual report shall include an update on the extent to which progress has been made on the activities of the Authority and any other relevant information which the Minister may request.

PART VI
Control Over Registration, Import, Export, Manufacture, Distribution, Sale and Dispensing of Medicines (ss 23-37)

23. Registration of medicines

(1) No person shall-

(*a*) import;
(*b*) export;
(*c*) manufacture;
(*d*) distribute;
(*e*) sell;
(*f*) promote;
(*g*) advertise;
(*h*) store; or
(*i*) dispense,

any medicine or cosmetic, unless the medicine or cosmetic is registered by the Authority.

(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.

(3) The Authority may, in such special circumstances as it considers appropriate-

(*a*) exempt, in writing, any medicine or cosmetic from the requirements of subsection (1); or
(*b*) by order published in the *Gazette*, declare any medicine or cosmetic to be a banned medicine or cosmetic, in which case the medicine or cosmetic shall not be registered or if already registered, such registration shall be cancelled.

(4) Medicine in relation to which an exemption may be made in terms of subsection (3) may include-

(*a*) medicine which has not been registered but was prescribed outside Botswana for a patient's personal use;
(*b*) medicine 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*) medicine intended for re-export in the form and packaging that it was imported; or
(*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.

(5) An application for a medicine referred to under subsection (4) (*a*) and (*b*) to be exempted from registration shall be made in the prescribed form and shall be accompanied by the prescribed fee.

(6) Any person who manufactures, imports, exports, distributes, sells, promotes, advertises, stores, prescribes, or dispenses any medicine or cosmetic banned in terms of subsection (3) (*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.

24. Application for registration

(1) An application for the registration of a medicine or cosmetic shall be submitted to the Authority in the prescribed form and shall be accompanied by the prescribed fee, and any further information that the Authority may consider necessary in order to process the application.

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

(3) In considering an application for registration the Authority shall consider the safety, efficacy, and quality of a medicine or cosmetic.

(4) Where the Authority registers a medicine or cosmetic, the person who applied for the registration shall submit information to the Authority annually, in the prescribed manner accompanied by a prescribed fee.

(5) Where the holder of market authorisation is aware of a safety, efficacy or quality problem which could have detrimental effects on public health, the holder of the market authorisation shall, in consultation with the Authority, recall the medicine or cosmetic.

(6) Any person who contravenes subsection (5) commits an offence and is liable to a fine not exceeding P100 000 and to imprisonment not exceeding 10 years, or to both.

(7) The Authority may, without prior consultation from the holder of market authorisation, recall a medicine or cosmetic.

25. Maintenance of register

(1) The Authority shall maintain a register in which it shall record-

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

(*b*) the cancellation of the registration or variation of the conditions of registration of any medicine 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.

26. Pharmaceutical operations

(1) No person shall practise as a pharmacist or operate a pharmacy or a dispensary on any premises unless-

(*a*) the person has applied for and been issued with a licence in respect of the said premises for operating the pharmacy or dispensary;

(*b*) the premises, in the case of a pharmacy, are under the continuous supervision of a pharmacist; and

(*c*) in the case of a dispensary, the person is authorised in writing by the Director of Health Services or the Director of Veterinary Services as the case may be, to dispense.

(2) An application for a licence under subsection (1) shall be made by a pharmacist who is resident in Botswana, and shall be made in the prescribed form and accompanied by the prescribed fee.

(3) The retailing of Schedule 3 medicine, shall be through a pharmacy duly licensed as such under this Act.

(4) A person who contravenes the provisions of this section commits an offence and is liable to a fine not exceeding P15 000, or to imprisonment for a term not exceeding three years, or to both.

(5) Where the Authority is of the view that a pharmacy or dispensary is not being operated in accordance with good professional standards, the Authority may, in writing, suspend the licence issued in terms of subsection (2) pending compliance with any directions the Authority considers necessary, or cancel the licence where the non-compliance continues.

(6) Where a licence is cancelled under subsection (5), the licence holder shall dispose of the stock within six months and in a manner approved by the Authority.

(7) Where there is a change in the ownership of a pharmacy, the owner shall notify the Authority as soon as is practicable after the change of ownership.

27. Manufacturing of medicines

(1) The manufacture of medicine may only be undertaken in an establishment licensed by the Authority.

(2) A person who wishes to manufacture medicines shall apply in the prescribed form and pay the prescribed fee to the Authority, and shall supply any further information which the Authority may require to satisfy itself that the premises to be used are suitable for the purpose and will be operated in accordance with standards of good practice in the manufacture and quality control of medicines.

(3) The manufacture of medicines shall be under the continuous supervisory control of a registered pharmacist who possesses such practical experience as the Authority may prescribe.

(4) Where the Authority is satisfied that the conditions of any licence are not being observed, or that the manufacture of any medicine is not being carried out in accordance with the provisions of this Act or standards of good practice in the manufacture and quality control of medicines, the Authority may, after notice in writing to the licence holder, cancel the licence issued under this section.

(5) Where the Authority cancels a licence in terms of subsection (4), the licence holder shall cease all manufacturing.

(6) 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.

28. Import, export,distribution or sale of medicines

(1) No person shall import, export, distribute or sell medicines except in accordance with a licence issued for the import, export, distribution or sale of medicines in terms of this Act.

(2) A person who wishes to import, export, distribute or sell medicines shall apply to the Authority, in the prescribed form accompanied by such fee as may be prescribed and such information as the Authority may require.

(3) The person referred to under subsection (2) shall be resident in Botswana.

(4) The import, export, distribution or sale of medicines in terms of this section shall be under the continuous supervisory control of a pharmacist, or veterinary surgeon.

(5) A person authorised in terms of this Act to import, export, distribute, or sell medicines shall not import, export, distribute, sell, or keep in storage contrary to such conditions as may be prescribed, any medicine after the date of expiry indicated on the package of the medicine.

(6) A person who contravenes the provisions of this section commits an offence and is liable-

(*a*) in the case of importing, exporting or selling medicine to a fine not exceeding P100 000, or to imprisonment for a term not exceeding 10 years, or to both; or

(*b*) in the case of import, export, distribution, or selling medicine, dispensing or keeping in storage contrary to such conditions as may be prescribed, any medicine after the date of expiry indicated on the package of the medicine, to a fine not exceeding P100 000, or to imprisonment for term not exceeding 10 years, or to both.

29. Record keeping

(1) An importer, exporter, manufacturer, distributer, dispenser, or user of veterinary medicinal products shall keep, in the prescribed form, records of all transactions or activities relating to the medicines 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.

30. Variation of authorisation

(1) No person to whom authorisation has already been granted under this Act shall effect any changes to the manufacturing process, labelling, or packaging of a medicine, except with the prior authorisation of the Authority.

(2) An application for authorisation referred to under subsection (1) shall be in the prescribed form and shall be accompanied by a prescribed fee.

(3) A person who contravenes the provisions of subsection (1) 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.

31. Importation of generic products

Where the Minister responsible for trade has, in terms of the Cap. 68:03 Industrial Property Act, authorised the exploitation of a patent medicine, the Authority may grant an applicant who satisfies all other requirements for the registration and importation of medicine under this Act, a licence to import that medicine.

32. Post-marketing surveillance

(1) A person whose medicine has been registered or exempted from registration under this Act shall report to the Authority, in the prescribed manner, any adverse reactions to the medicine.

(2) The following shall be reported to the Authority in the prescribed manner-

(*a*) any adverse reaction in a human to any registered medicine which report shall be made by the person with respect to whom the registration was granted;

(*b*) any adverse reaction in an animal to any medicine, which report shall be made by the person who administered the medicine;

(*c*) any adverse reaction in a human to any veterinary medicine ingested through eating an animal that was treated with a veterinary medicine, or was fed medicated feed; premix;

(*d*) any adverse reaction in a person to veterinary medicine through the handling of that medicine;

(*e*) lack of expected efficacy of a veterinary medicine or medicines used in humans, in relation to the indications claimed for the medicine; and

(*f*) any adverse reaction in an animal to a medicine used for humans where the use of that medicine in animals has been allowed.

33. Withdrawal of licence

(1) The Authority may withdraw a licence issued in terms of section 28 or 31 where the Authority is satisfied that the medicine is being imported, exported, distributed or sold otherwise than in accordance with the conditions of a licence issued under this Act.

(2) Where the Authority decides to withdraw a licence in terms of subsection (1), the Authority shall issue written notice to the importer, exporter, distributor or seller-

(*a*) stating the manner in which the importer, exporter, distributor or seller has contravened the provisions of the Act; and

(*b*) allowing the importer, exporter, distributor or seller 21 days within which to comply with the Act.

(3) Where the importer, exporter, distributor or seller does not, within 21 days of the written notice, comply with the requirement which led to the notice to withdraw the licence being issued, the Authority shall withdraw the licence or suspend the licence for a specified period pending compliance with any conditions set by the Authority.

(4) Where the Authority withdraws or suspends a licence in terms of this section, the importer, exporter or distributor shall forthwith cease all operations in respect of which the licence was issued.

(5) A person who knowingly supplies an importer, exporter, distributor, dispenser or seller-

(*a*) to whom a licence to carry out the import, export, distribution operation, sale or authorisation to dispense has not been issued; or

(*b*) whose licence to operate the import, export, distribution operation or sale or authorisation to dispense, as the case may be, has been withdrawn, commits an offence and is liable to a fine not exceeding three years, or to both.

(6) Where the Authority withdraws a licence issued in terms of this section, an inspector may close the premises from which the import, export, distribution operation or sale was being carried out.

34. Medicines in transit

(1) Where medicines are to be imported into Botswana in the course of transit to another country, the importer shall, before the importation of the medicine, notify the Authority of the intended importation, in writing, stating-

(*a*) the type and quantity of the medicines to be imported;

(*b*) the expected time of arrival and expected time of departure of the medicines;

(*c*) the expected mode of transport and place of arrival and departure of the medicines; and

(*d*) the ultimate destination of the medicines.

(2) The importer shall, within 48 hours of the medicines leaving Botswana, notify the Authority, in writing, of the departure of the medicines, stating the date, time of the departure and the time of exit.

(3) No Schedule 1A, 1B, or 1C medicine, or precursor chemical which is in Botswana in the course of transit to another country, shall be permitted to pass through Botswana whether or not the consignment is removed from the conveyance in which it is carried, unless an export authorisation in respect of the medicine is presented to and approved by the Authority.

(4) An importer shall provide the Authority with proof that authority for the medicine in transit through Botswana to enter the intended country of destination has been granted by the customs department and where applicable, the authority responsible for regulating the registration of medicines in that country

(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.

35. Counterfeit products

(1) No person shall import, export, manufacture, distribute, sell, promote, advertise, store or dispense, any counterfeit product.

(2) A person who contravenes subsection (1), commits an offence and is liable to a fine not exceeding P 100 000, or to imprisonment for a term not exceeding 10 years, or to both.

36. Designation of ports

The Minister, in consultation with the Authority, may designate ports through which medicines and cosmetics may be imported or exported.

37. Disposal of unwanted medicine

(1) A person in possession of unwanted medicine shall dispose of the medicine in the manner prescribed by regulations.

(2) In this section, "unwanted medicine" means a medicine which has expired, is substandard, banned, or is a counterfeit.

PART VII

Classification of medicines, and control of certain classes of medicines (ss 38-47)

38. Classification and description of medicines

(1) Medicines shall be classified according to the following classifications and descriptions, which shall be specified in the regulations-

(*a*) Schedule 1 medicine – a medicine which is or contains a prescribed psychotropic medicine, and must 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 must be kept by the dispensing pharmacist for a minimum of three 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;

(iii) 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;

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

(v) 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 medicines;

(*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 or in the case of veterinary medicine, a livestock advisory centre under the control of a paraprofessional;

(*c*) Schedule 3 medicine – a medicine which may be sold from a pharmacy without prescription, in the case of veterinary medicine, or sold from a livestock advisory centre without prescription; and

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

(2) The dispensing of Schedule 1A, Schedule 1B, Schedule 1C, Schedule 2 and Schedule 3 medicines, shall be by a pharmacist through a pharmacy, a livestock advisory centre or through an institution approved by the Director.

(3) The Minister, acting in consultation with the Directors, may by regulations, provide for medical practitioners, veterinary surgeons, dentists, pharmacy technicians or other health personnel to dispense such medicines to the extent or in the circumstances specified in the regulations.

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

(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.

39. Prescriptions

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

(2) The Minister, acting in consultation with the Director of Health Services and the Director of Veterinary Services, may by regulations, authorise limited powers of prescription of medicines to pharmacists, nurses, paraprofessionals and other health personnel.

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

(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) A person who brings in a prescription 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 any inspector appointed in terms of this Act, a certified copy of the prescription under which it was issued.

(6) A person who contravenes-

(a) the provisions of 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) the provisions of subsection (5) 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.

(7) A prescriber shall keep a copy of each prescription issued by him or her, for a prescribed period.

40. Validity of prescriptions

(1) A prescription for a Schedule 1A, Schedule 1B or Schedule 1C medicine is valid for only thirty days and shall not be dispensed more than once in succession.

(2) A prescription for a Schedule 2 medicine may be repeated a maximum of six times and is valid, for initial dispensing, for a period of three months 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.

41. Labelling of medicines

Any medicine imported, manufactured or dispensed within Botswana shall be labelled in accordance with such requirements as the Authority may prescribe.

42. Storage and safe custody

(1) No person shall possess a Schedule 1A, 1B, 1C, or Schedule 2 medicine unless the medicine has been prescribed to the person or the person is authorised by this Act to store, administer, dispense or obtain such medicines.

(2) Any person who is authorised in terms of this Act to be in possession of Schedule 1A, 1B, 1C, and Schedule 2 medicines, shall store such medicines in a place to which members of the public do not have access and in such manner as may be prescribed.

(3) Any person who is in possession of a prescription preparation shall keep such medicine in a place where children do not normally have access.

43. Import and export of narcotics,psychotropics and precursors

(1) Any person who wishes to import or export a Schedule 1A, 1B or 1C medicine, or a precursor chemical, shall apply to the Authority in the prescribed form accompanied by a prescribed fee.

(2) Any person who imports or exports a Schedule 1A, 1B or 1C medicine, or a precursor chemical shall, 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.

(3) Any person who imports or exports a Schedule 1A, 1B, or 1C medicine, or a precursor chemical, shall within seven days of such import or export, provide such information, in the prescribed form, to the Authority as the Authority may require.

(4) A person who contravenes the provisions of-

(*a*) subsection (1) or subsection (2) 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 (3) commits an offence and is liable to a fine not exceding P20 000, or to imprisonment for a term not exceeding three years, or to both.

44. Records of narcotics, psychotropics and precursors

(1) A person who-

(*a*) imports;
(*b*) exports;
(*c*) manufactures;
(*d*) distributes; or
(*e*) sells,

Schedule 1A, 1B, or 1C medicines, or precursor chemicals, 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 under subsection (1) shall be hand written, in indelible ink, and shall 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 under 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 the prescribed manner.

(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.

45. Alteration of psychotropic substances or packaging

(1) A person in control of any psychotropic substance, narcotic substance, or precursor chemical stored in a bonded warehouse or whilst in transit shall not subject such psychotropic substance, narcotic substance, or precursor chemical to any process which would change the nature of that psychotropic substance, narcotic substance, or precursor chemical.

(2) A person in control of any psychotropic substance, narcotic substance, or precursor chemical, stored in a bonded warehouse or whilst in transit shall not alter the packaging of such psychotropic substance, narcotic substance, or precursor chemical without the approval of the Authority.

(3) 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.

46. Advertising and promotion of medicines

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

(2) The advertising or promotion of medicine which may be dispensed on prescription only shall be disseminated solely through professional journals and magazines, or only to persons authorised to dispense, prescribe or administer such medicines.

(3) The advertising or promotion of medicine 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.

(4) 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.

47. Inspection of premises

(1) All premises where medicines or medicated feeds are stored, used, handled, dispensed, manufactured or sold, and any vehicle,transshipment, or receptacle in which medicines are transported, shall be subject to inspection with or without prior arrangement with the person in control of the premises, vehicle, transshipment or receptacle by an inspector authorised by the Authority, in writing, and such inspector shall be given unhindered access to such premises with the right to take samples of any medicines on the premises, without payment, and to carry out any investigation that the inspector considers necessary.

(2) The licence holder of any premises referred to in subsection (1), or the person in charge of the premises, shall on demand by an inspector, provide any economic or statistical information required of the licence holder, and provide all other necessary assistance required by the inspector for the performance of the inspector's duties.

(3) An inspector may seize medicines found on premises, a vehicle, transshipment, or receptacle where the medicines are held in contravention of the provisions of this Act.

PART VIII
Control over Veterinary Medicinal Product Related Matters (ss 48-50)

48. Preparation of premix

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

(2) A person who contravenes subsection (1) 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.

49. Feed mills

(1) No person shall operate a feed mill except in accordance with a licence issued by the Department of Veterinary Services.

(2) A person who contravenes 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.

50. Control over residue limits

(1) 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 the animal is not slaughtered for consumption before the prescribed withdrawal period has elapsed, and the prescribed maximum residue limit allowable in meat has fallen within the limit allowed.

(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 three years, or to both.

(3) The Director of Veterinary Services may prescribe prohibited substances for use in animals.

(4) A person who uses a prohibited substance in contravention of subsection (3) is liable to a fine not exceeding P500 000, or to imprisonment for a term not exceeding three years, or to both.

PART IX
Controlled Substances (ss 51-55)

51. ...

[*39 of 2018, s. 2.*]

52. ...

[*39 of 2018, s. 3.*]

53. ...

[*39 of 2018, s. 4.*]

54. ...

[*39 of 2018, s. 5.*]

55. ...

[*39 of 2018, s. 6.*]

PART X

Medicines in Clinical Trials and Medical Research (ss 56-57)

56. Sale, etc. of medicine for clinical trial or medical research

(1) A person shall not sell, dispense, supply, assemble, or manufacture medicine for the purpose of a clinical trial or medical research on a medicine unless the person is authorised to do so or has been granted an exemption by the Authority.

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

(3) 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 medicine for a clinical trial or medical research.

(4) A person who contravenes 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.

57. Monitoring

(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 the 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, the licence holder shall report the adverse reaction to the Authority, in the prescribed manner.

(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 XI

Sale, Manufacture, Labelling, etc. of Cosmetics (ss58-63)

58. Sale of cosmetics

(1) No person shall sell any 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 by the Authority.

(3) The Minister, acting on the advice of the Authority, may by statutory instrument, 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.

59. Unsanitary conditions

(1) No person shall 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.

60. Therapeutic claims in cosmetics

No person shall 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.

61. Ingredients

No manufacturer or importer shall 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.

62. Labelling of cosmetics

No person shall sell a cosmetic unless it is labelled in the prescribed manner.

63. Safety of cosmetics

(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 request.

(3) If the Authority determines that the evidence submitted by a manufacturer under subsection (1) is not sufficient, the Authority shall notify the manufacturer in writing to that effect, and the manufacture 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) Every manufacturer and importer shall provide the Authority with such documentation and information as may be prescribed, within a prescribed period.

(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 two years, or to both.

PART XII

Establishment of National Medicines and Therapeutics Board (s 64)

64. National Medicines and Therapeutics Board

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

(2) 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;
(*h*) determine the content of lists of medicines within the national formulary which may be availed in government health facilities;
(*i*) approve the medicines to be included in treatment protocols; and
(*j*) undertake training on the rational use of medicines.

(3) The board consists of the following people and their alternates, appointed by the Minister in writing-

(*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 of Health;
(*g*) the Head of Central Medical Stores;
(*h*) a public health specialist representing District Health Teams;
(*i*) a representative of the Department responsible for health, in the Ministry of 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; and
(*m*) a veterinary surgeon representing the veterinary medical products control board.

(4) 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.

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

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

(7) The Minister shall cause appointments to the Board to be published by notice in the *Gazette*.

(8) The provisions of sections 9, 10, 11, 12, 13, 14, 15, 16, 17 and 18 shall apply to this Part, with the necessary modifications.

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

PART XIII
General (ss 65-69)

65. Appeals Committee

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

(3) 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.

(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 Chairperson of the Appeals Committee shall determine the procedure to be followed in hearing an appeal.

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

(8) 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.

(9) The provisions of sections 12, 13, 17 and 18 shall, with the necessary modifications, apply to a member of the Appeals Committee.

66. Offences generally

(1) A person who contravenes the provisions of this Act or who-

(*a*) prescribes any Schedule 1 or Schedule 2 medicine without being authorised by this Act;

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

(*c*) otherwise contravenes the provisions of this Act for which a penalty is not provided, 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 or any regulation made under it, 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

67. Repeal of Cap. 63:04

The Drugs and Related Substances Act, hereinafter referred to as "the repealed Act", is hereby repealed.

68. Savings and transitional provisions

(1) All subsidiary legislation made under the repealed Act and in force immediately prior to the coming into operation of this Act shall, in so far as it is not inconsistent with the provisions of this Act, continue in force as if made under this Act.

(2) The repeal of the Act shall not be construed as invalidating any process undertaken in terms of the repealed Act.

(3) Notwithstanding the repeal of the Act, proceedings commenced under the repealed Act shall be dealt with, inquired into and determined in accordance with that repealed Act.

69. Regulations

The Minister may make regulations for the better carrying out and giving effect to the provisions of this Act, and without prejudice to the generality of the foregoing, such regulations may provide for-

(*a*) any matter to be prescribed under this Act;

(*b*) the procedure for the registration of medicines, and the cancellation or suspension of such registration;

(*c*) 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

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

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

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

(*g*) the inspection of premises under this Act; or

(*h*) 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.