MEDICINES AND RELATED SUBSTANCES CONTROL ACT, 2016

(Act 9 of 2016)

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AN ACT

Entitled

AN ACT to provide for the establishment of a Medicines Regulatory Authority; registration of medicines and medical devices; the control of medicines and scheduled substances, and to provide for incidental matters.

ENACTED by the King and Parliament of Swaziland.

PART I

PRELIMINARY

Short title and commencement

1. (1) This Act may be cited as the Medicines and Related Substances Control Act, 2015.

(2) This Act shall come into force on a date to be appointed by the Minister in the Gazette.

(3) The Minister may determine different dates for the coming into force of different provisions of this Act.

Interpretation

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

"adulterated medicine" means a medicine−

(a) which has a strength, purity or quality that is different or falling below that which it purports or is represented to possess;

(b) which has its substance−

(i) mixed or packed in a manner that reduces its quality or strength; or

(ii) substituted wholly or partly; or−

(c) which is contained in a container that contains a poisonous or deleterious substance which may render its contents injurious to health.

(d) contaminated with physical and chemical contaminants

"adulterated medical device" means a medical device which consists in whole or in part of an impure or decomposed substance; or if the medical device has been manufactured, prepared, packed or stored under insanitary conditions whereby it has been contaminated or rendered injurious to health.

"advertisement", in relation to medicines, medical devices or scheduled substances, means any written, pictorial, visual or other descriptive matter or verbal statement or reference−

(a) appearing in any audio, visual, electronic or print media; or

(b) distributed to members of the public;

(c) brought to the notice of members of the public in any manner whatsoever; or

(d) which is intended to promote the sale of that medicine, medical device or scheduled substance, and "advertise" and "advertising" have corresponding meanings;

"analyst" means an person appointed as an analyst in terms of section 59;

"approved name", in relation to a medicine, means the international non-proprietary name (INN) of that medicine or, where no such name exists, that other name as the authority may determine, not being a brand or trade name registered under any other act;

"authorised prescriber" means a person authorised by the Act to prescribe any medicine;

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

"clinical trial" means an investigation in respect of a medicine or medical device for use in humans or animals that involves human or animal subjects and that is intended to discover or verify the clinical, pharmacological or pharmacodynamic effects of the medicine, identify any adverse events, study the absorption, distribution, metabolism and excretion of the medicine or ascertain its safety or efficacy***;***

"complementary medicine" means a substance or mixture of substances prepared and used or purported to be suitable for use in –

(a) the diagnosis, treatment, mitigation, modification, or prevention of a disease, abnormal physical or mental state or the symptoms of abnormal physical or mental state, in humans or animals; or

(b) restoring, correcting or modifying any somatic, psychic or organic function in humans or animals, in accordance with the principles of−

(i) homeopathy;

(ii) traditional or alternative medicinal practices; or

(iii) herbal medicine;

"compound" means to prepare, mix, combine, package and label a medicine as a result of a prescription for an individual patient by a pharmacist or other person authorised in terms of this Act;

"counterfeit" means a medicine or medical device for which there is a false representation in relation to its identity or source. This applies to the medicine or medical device, its container, or other packaging and labelling information. Counterfeiting can apply to both branded and generic medicines and medical devices. Counterfeit medicines and medical devices may include products with the correct components or with the wrong components, without active ingredients, with incorrect amounts of active ingredients or with false packaging. Counterfeit medicines and medical devices do not include substandard batches of or quality defects or non-compliance with GMP or GDP in legitimate medical products.

"dispense" means the interpretation and evaluation of a prescription, the selection, manipulation or compounding of the medicine, the labelling and supply of the medicine in an appropriate container as prescribed by the Act and the provision of information and instructions to ensure the safe and effective use of medicine by the patient and "dispensing" has a corresponding meaning;

"dispenser" means a person registered as a dispenser under the Pharmacy Act;

"dentist" means a person registered as a dentist under the Medical and Dental Practitioners Act, 1970;

"export" includes deliver or supply within the Kingdom of Swaziland for dispatch to any destination outside the Kingdom;

"health facility" means any place where health care services are provided to members of the public and includes a hospital, health centre or clinic situated in either the public or the private sector;

"hospital pharmacy" means any place licensed under the Pharmacy Act, which is situated inside a health facility where services pertaining to the profession of a pharmacist are provided to members of the public, but does not include a retail pharmacy, a wholesaler or a manufacturer;

"immediate container", in relation to a medicine or scheduled substance, means a container which is in direct contact with the medicine or substance;

"import" means bring a medicine, medical device or scheduled substance into the Kingdom of Swaziland or cause a medicine, medical device or scheduled substance to be brought into the Kingdom of Swaziland for purposes other than personal use;

"interchangeable multi-source medicines" means medicines that contain the same active substances which are identical in strength or concentration, dosage form and route of administration and meet the same or comparable standards, with regard to therapeutic equivalence;

"inspector" means a person appointed under Section 59 to be an inspector;

"label", when used as a verb, means brand, mark or otherwise designate or describe, and when used as a noun means any brand or mark or any written, pictorial or other descriptive matter appearing on, or attached to, or packed with and referring to any article or the package containing an article;

"manufacture" means carry out operations including purchasing of material, processing, production, packaging, release, storage or shipment of medicines, medical devices and scheduled substances in accordance with quality assurance and related controls, and "manufacturing" has a corresponding meaning;

"manufacturer" means any place licensed under the Pharmacy Act where medicines or scheduled substances are manufactured but does not include a hospital pharmacy, a retail pharmacy or a wholesaler;

"medical device" means any instrument, appliance, material, machine, apparatus, implant or diagnostic reagent−

(a) used or purporting to be suitable for use or manufactured or sold for use in−

(i) the diagnosis, treatment, mitigation, modification, monitoring or prevention of disease, abnormal physical or mental states or the symptoms of abnormal physical or mental state; or

(ii) restoring, correcting or modifying any somatic or psychic or organic function; or

(iii) the diagnosis or prevention of pregnancy,

and which does not achieve its purpose through chemical, pharmacological, immunological or metabolic means in or on the human or animal body but which may be assisted in its function by such means; or

(b) declared by the Minister, in consultation with the Authority, by notice in the Gazette to be a medical device, and includes any part of or an accessory of a medical device;

"medical practitioner" means a person registered as a medical practitioner under the Medical and Dental Practitioners Act, 1970;

"medicinal purpose" means for the purposes of the treatment or prevention of a disease or some other definite curative or therapeutic purpose, but does not include the satisfaction or relief of a habit or craving for the substance used or for any other such substance, except where the substance is administered or used in a health facility maintained wholly or partly by the Government or approved for such purpose by the Minister;

"medicine"−

(a) means any substance or mixture of substances which is used, or is manufactured, sold or represented as suitable for use, in−

(i) the diagnosis, treatment, mitigation, modification, prevention of diseases or any abnormal physical or mental state or symptoms of any abnormal or mental state in humans or animals; or

(ii) restoring, correcting or modifying a physical, mental or organic function in humans or animals; and

(b) includes a complementary medicine; or

(c) means a substance or mixture of substances declared by the Minister, in consultation with the Authority, by notice in the Gazette to be a medicine or a complementary medicine, and excludes a veterinary drug and medicinal substance.

"Minister" means the Minister responsible for health;

"narcotic*"* means a medicine -

(a) regulated by the Single Convention on Narcotics of 1961 as amended by the 1972 protocol; or

(b) registered as such by the Authority;

"nurse" means a person registered as a nurse under the Nurses and Midwives Act of 1965.

"package" means a container in or by which an original immediate container of a medicine is enclosed, covered, contained or packed, but excludes bulk boxes in which that original immediate container or the package is transported;

"pharmacy" means any place licensed under this Act where services pertaining to the profession of a pharmacist are performed and includes a hospital pharmacy, retail pharmacy, manufacturer or wholesaler;

"pharmacist" means a person registered as a pharmacist under the Pharmacy Act;

"pharmacy assistant" means a person registered as a pharmacy assistant under the Pharmacy Act.

"pharmacy intern" means a person registered as a pharmacy intern under the Pharmacy Act;

"pharmacy technician" means a person registered as a pharmacy technician under the Pharmacy Act;

"pharmacy technologist" means a person registered as a pharmacy technologist under the Pharmacy Act;

"pharmacovigilance" means the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other medicine-related problems;

"precursor" means a substance –

(a) that can be used to manufacture a medicine; or

(b) that is registered as such by the Authority;

"prescribe" means published by regulation under this Act and "prescribed" has a corresponding meaning;

"psychotropic" means a medicine or substance –

(a) controlled by the Convention on Psychotropic Substances of 1971; or

(b) registered as such by the Authority;

"Register" means the medicines register kept in terms of section 22;

"Registrar" means the Registrar of the Authority appointed under sections 19;

"registered name", in relation to a registered medicine or medical device, means the name under which that medicine or medical device is registered;

"retail pharmacy" means any place licensed under the Pharmacy Act where services pertaining to the profession of a pharmacist are provided to members of the public, but does not include a hospital pharmacy, a manufacturer or a wholesaler;

"scheduled substance" means any medicine or other substance prescribed by the Minister in the First Schedule;

"sell" means sell by wholesale, retail or internet trader, and includes offer, advertise, keep, expose, transmit, consign, convey or deliver for sale or authorize, import or export, direct or allow a sale, or prepare or possess for purposes of sale, and barter or exchange or supply or dispose of to a person, whether for a consideration or otherwise; and "sale" and "sold" have corresponding meanings;

"therapeutic equivalence" is determined from comparative bioavailability, pharmacodynamic, clinical or in vitro studies which meet the criteria for bioequivalence determined by the Authority and refers to medicines which are pharmaceutically equivalent i.e. contain the same amount of active substances in the same dosage form, meet the same or comparable standards and are intended to be administered via the same route and after administration in the same molar dose, their effects with respect to both efficacy and safety are essentially the same;

"Tribunal" means the Medicine and Related Substances Control Appeals Tribunal established under section 67;

"this Act' means the Medicines and Related Substances Control Act, 2015 and any regulations published under this Act;

"undesirable medicine" includes medicines or substances which are substandard, adulterated, counterfeit or expired or which are subject to registration under this Act but are not registered or approved for use by the Authority.

"veterinary medicines" means any substance or mixture of substances which is used, or is manufactured, sold or represented as suitable for use, in:

(a) the diagnosis, treatment, mitigation, modification or prevention of disease, or abnormal physical or mental state or the symptoms of disease or abnormal physical or mental state in animals;

(b) restoring, correcting or modifying any physical mental or organic functions in animals; or

(c) manipulating morphology, natural development and breeding of an animal.

"veterinary surgeon" means a person registered as a veterinary surgeon in terms of the Veterinary Surgeons Act, 1997.

"wholesaler" means any place licensed under the Pharmacy Act where medicines and scheduled substances are purchased from a manufacturer and sold or distributed to a retail pharmacy, a hospital pharmacy or a person authorised to sell medicine to the public but does not include a hospital pharmacy, a retail pharmacy or a manufacturer.

PART II

MEDICINES REGULATORY AUTHORITY

Establishment of the Medicines Regulatory Authority

3. (1) There shall be established, within one year of coming into force of this Act, an Authority to be known as the Medicines Regulatory Authority.

(2) The Authority shall be a juristic person.

Composition of the Authority

4. (1) The Authority shall consist of not less than five members and not more than nine members to be appointed by the Minister in the prescribed manner and shall consist of −

(a) the person responsible for the national pharmaceutical services in the ministry responsible for health, who shall be a pharmacist, or a representative of that Pharmacist;

(b) a pharmacist engaged in the private sector;

(c) a pharmacist engaged in the public sector;

(d) a medical practitioner who is a specialist physician;

(e) the Director of Health Services or a representative of that Director;

(f) a person with special knowledge of the action and application of medicines in the human body such as a pharmacologist who holds a postgraduate qualification in pharmacology;

(g) the Director of Veterinary Services or a representative of that Director;

(h) an admitted attorney with over seven years' experience; and

(i) a representative appointed by the Minister of Finance

(2) The members of the Authority shall, in the first official meeting of the Authority, elect one member as chairperson and another as vice-chairperson of the Authority, and the vice-chairperson shall exercise the functions of the chairperson during any period that the chairperson is unable to exercise such functions.

Functions of the Authority

5. (1) The Authority shall perform the functions conferred to it by this Act.

(2) The Authority may advise the Minister or furnish a report to the Minister on any matter referred to it by the Minister or any matter arising from the application of this Act.

Powers of the Authority

6. The Authority shall, subject to this Act have the powers to–

(a) purchase, hire, lease or otherwise acquire, immovable and movable property necessary or convenient for the performance of the functions of the Authority;

(b) maintain, alter and improve the property of the Authority;

(c) sell, exchange, lease, mortgage, dispose of, turn to account or otherwise deal with property of the Authority, or any part of property of the Authority, which is not required for the purposes of the Authority for a consideration that the Authority may determine;

(d) insure against losses, damages, risks and liabilities which the Authority may incur;

(e) administer the assets of the Authority or any assets to be held in trust for the Authority and to settle the liabilities of the Authority;

(f) raise or borrow money to enable the Authority to carry out any of its functions or to exercise any of its powers, with approval from the Minister;

(g) employ, upon such terms and conditions as the Authority may consider fit, persons who are necessary for conducting its affairs, and to determine the conditions of services of such persons;

(h) determine the manner in which decisions of the Authority or any of its committees are made;

(i) institute, defend and proceed with any legal action in its own name;

(j) require any person registered under this Act to furnish the Authority with information that the Authority requires;

(k) generally, do all such things that are necessary, conducive or incidental to the exercise of the powers and the performance of the functions of the Authority under this Act or any other enactment.

Special Powers of the Authority

7. (1) Where the Authority considers it necessary for the purpose of carrying out its functions and exercising its powers under this Act, the Authority may, by notice in writing issued by the Chairperson, served on any person, require that person−

(a) to furnish the Authority, in the case of a body corporate, by a director or competent employee or agent of the body corporate,

within the time and in the manner specified in the notice, any information specified in the notice;

(b) to produce to the Authority, or to a person specified in the notice acting on its behalf in accordance with the notice, any document specified in the notice; or

(c) to appear before the Authority at a time and place specified in the notice to give evidence, either orally or in writing, and produce any document or class of document specified in the notice.

(2) The Chairperson or, in the absence of the Chairperson the Vice-Chairperson, shall have the power to administer an oath or affirmation to a person appearing before the Authority as a witness.

Term of office

8. (1) Subject to section 9, a member of the Authority shall hold office for a period not exceeding five years, on such terms and conditions that the Minister may determine.

(2) A retiring member shall be eligible for reappointment as a member for not more than two terms.

Disqualification from membership

9. A person is not qualified to be appointed a member of the Authority if that person−

(a) is a declared insolvent or bankrupt;

(b) has made an assignment to or arrangement or composition with creditors that has not been rescinded or set aside;

(c) has, in terms of any law in force in Swaziland, within the past five years immediately preceding the date of appointment, been convicted of a criminal offence of which dishonesty is an element; or

(d) has been disqualified in terms of any law from carrying on the profession in respect of which that person was appointed to be a member; or

(e) is not a citizen of Swaziland and is not ordinarily resident in Swaziland.

Vacation of office of a member

10. (1) A member of the Authority shall vacate office and the office of a member of the Authority shall become vacant if the member−

(a) is declared insolvent under any law relating to insolvency;

(b) is of unsound mind or is in any other way mentally incapacitated;

(c) is absent from three consecutive meetings of the Authority without leave or without a justifiable excuse;

(d) is convicted of an offence under this Act or is convicted of any criminal offence of which dishonesty is an element;

(e) is sentenced by a competent court to a term of six months imprisonment or more without an option to pay a fine;

(f) becomes disqualified in terms of Section 9;

(g) is deemed by the Minister, in consultation with the Authority, to have violated the internal rules of conduct prescribed by the Authority and published by notice in the Gazette;

(h) vacates the office or ceases to hold the qualification by virtue of which the member was appointed to the Authority; or

(i) fails to comply with the provisions of Section 11(1).

(2) A member may resign from office after three months from the date of submission of a written notice of resignation to the Minister.

Disclosure of interest

11. (1) Where a member of the Authority has commercial interests related to the pharmaceutical or health care industry, which interest includes, but is not limited to, any consultancy, paid or unpaid, any research grant from which the member directly or indirectly benefits, or any equity holding or any executive or non-executive directorship or any other payment or benefit in kind, that member shall−

(a) as soon as possible disclose that interest; and

(b) not be present or participate in any proceedings or deliberations of the Authority in relation to that matter.

(2) A member who intentionally fails to comply with sub-section (1) commits an offence and is liable, on conviction, to a fine not exceeding ten thousand Emalangeni or to imprisonment for a period not exceeding two year or to both.

Filling of vacancies

12. (1) Where the office of a member becomes vacant before the expiry of the term of office, the Minister, shall in terms of section 4 appoint another member to replace the member who vacates office,

(2) A member appointed under this section shall fall in the same category as the person the member is to replace and shall hold office only for the unexpired part of the term of office.

Meetings and proceedings of the Authority

13. (1) The Authority shall ordinarily meet for the despatch of business at such times and place as the Authority may determine, and shall meet at least four times in each calendar year.

(2) Subject to this Act the Authority shall regulate its meetings and procedures as required.

(3) The Chairperson may, at any time, convene a special meeting of the Authority to be held at such time and place as the Chairperson may determine, and shall, upon a written request by the Minister or a written request signed by not less than four members of the Authority, convene a special meeting within thirty days after the date of receipt of the request, at such time and place as the Chairperson may determine.

(4) The chairperson, or, in the absence of the chairperson, the vice-chairperson shall preside at all meetings of the Authority.

(5) Where both the Chairperson and Vice-Chairperson are absent from a meeting of the Authority, the members present may elect any member to be an acting chairperson for that meeting.

(6) The Vice-Chairperson of the Authority may perform any function of the chairperson during any period where the Chairperson is for any reason unable to perform that function.

(7) A majority of members shall form a quorum at a meeting of the Authority.

(8) All acts, matters or things authorised or required to be done by the Authority shall be decided by a majority vote at a meeting of the Authority at which a quorum is present.

(9) At all meetings of the Authority each member present shall have one vote on a question before the Authority and, in the event of an equality of votes, the Chairperson shall have, in addition to a deliberating vote, a casting vote.

(10) The validity of any act or proceedings of the Authority shall not be affected by any vacancy or absence among its members or any defect in the appointment Authority.

Committees of the Authority

14. (1) The Authority may appoint−

(a) from among its members an executive committee; and

(b) any other committees that it may consider necessary,

to investigate and report to it on any matter within the purview of the Authority under this Act.

(2) The executive committee may, subject to the directions of the Authority, exercise all the powers and perform all the functions of the Authority during periods between meetings of the Authority, but shall not have the power, save in so far as the Authority otherwise directs, to set aside or vary any decision of the Authority.

(3) Any action taken or decision made by the executive committee shall be subject to review at the first ensuing meeting of the Authority.

(4) The vesting or imposition of any functions or powers in other committees appointed under this section shall not divest the Authority of those functions and powers, and the Authority may amend or withdraw any decision of any committee in the exercise of its functions.

(5) Where the Authority establishes a committee other than the executive committee, the Authority−

(a) shall appoint at least one member of the Authority to be a member of that committee and shall designate that member, or one of those members, as the case may be, to be the Chairperson of that committee; and

(b) may appoint persons who are not members of the Authority to be members of the committee.

Remuneration and expenses of the members of the Authority or committees

15. A member of the Authority or a committee of the Authority shall be paid from the funds of the Authority any remuneration, fees and allowances that the Minister, in consultation with the Minister responsible for finance, may determine.

Funds of the Authority

16. (1) The initial funding required to enable the Authority to commence its functions shall be appropriated for that purpose from the Consolidated Fund.

(2) Other funds of the Authority shall consist of−

(a) moneys that may be payable to the Authority from money appropriated from the Consolidated Fund;

(b) fees that are prescribed; and

(c) other money and assets that may vest in or accrue to the Authority, whether in the course of its functions or otherwise.

(3) The Authority shall not accept any donation or bequest without the approval of the Minister.

Accounts of Authority and audit of accounts

17. (1) The Authority shall keep proper accounts and other records relating to accounts in respect of its funds, including any particular accounts and records that the Minister may direct.

(2) The accounts of the Authority shall be examined and audited by an auditor appointed by the Authority with the approval of the Minister.

Annual report of the Authority

18. (1) The Authority shall, as soon as possible and in any case not later than six months after the end of the financial year concerned, submit to the Minister a report of the affairs of the Authority during each financial year.

(2) A report submitted under subsection (1) shall include a copy of the Authority's balance sheet and income and expenditure account.

Appointment of the Registrar

19. (1) The Authority shall nominate a person to be appointed by the Minister as the Registrar of Medicines and Related Substances.

(2) The Registrar shall be appointed on such terms and conditions as the Minister may, in consultation with the Authority, determine.

(3) The Registrar shall be a qualified Pharmacist, with a minimum of seven years' experience and shall also be a Secretary and an ex officio member of the Authority.

Duties and responsibilities of the Registrar

20. (1) Subject to this Act and the general supervision and control of the Authority, the Registrar shall−

(a) be responsible for the day-to-day administration of the Authority;

(b) implement the policies and programmes approved by the Minister or agreed upon by the Authority;

(c) manage the funds and property of the Authority;

(d) administer, organize, supervise and generally control the staff of the Authority;

(e) on the instructions of the Chairperson, convene meetings of the Authority and any committee the Authority and maintain records of any meetings;

(f) keep the Minister informed about the activities of the Authority; and

(g) keep records of all the transactions of the Authority.

(2) The Registrar shall represent the Authority in the day-to-day dealings of the Authority with Government and other third parties.

(3) The Registrar may, for specific matters, delegate some of the powers and prerogatives of the Registrar to the staff of the Authority holding administrative posts, subject to the approval of the Authority.

(4) Where the Registrar is temporarily absent from Swaziland or is temporarily incapacitated from performing the functions of the office of the Registrar, the Authority shall appoint a suitably qualified person to act as Registrar during that period of absence or incapacity.

(5) A person appointed under subsection (4) may exercise all the powers conferred upon the Registrar.

Other officers and employees

21. The Authority shall, on such terms and conditions as the Authority may, with the approval of the Minister, determine, employ other persons as the Authority may consider appropriate for the effective discharge of the functions of the Authority.

PART III

REGISTRATION

Medicines and medical devices register

22. (1) Subject to subsection (2), the Registrar shall keep and maintain a register, to be known as the Medicines and Medical Devices Register.

(2) The Registrar shall enter into the register−

(a) any information or particulars of a medicine or medical device which the Authority has approved for registration, including the conditions, if any, under which that medicine or medical device has been registered;

(b) any cancellation of the registration or variation of the conditions of registration of any medicine or medical device in terms of this Act; or

(c) any information which has been prescribed in the regulations.

(3) The register shall be divided into the following parts−

(a) Part I which shall relate to medicines which are not complementary medicines or medical devices;

(b) Part II which shall relate to medical devices; and

(c) Part III which shall relate to complementary medicines.

Unregistered medicines and medical devices.

23. (1) A person shall not advertise, sell or supply any medicine or medical device unless that medicine or medical device has been registered under this Act.

(2) Where a medicine was registered with conditions, a person shall not advertise, sell or supply that medicine unless under those condition.

(3) The Minister shall prescribe procedures for speedy registration of −

(a) medicines which are listed in the Swaziland essential medicines list; and

(b) medicines or medical devices which are considered by the Minister, after consultation with the Authority, to be essential for national health.

(4) The Registrar shall ensure that an application in respect of a medicine which appears on the latest Swaziland essential medicines list or medicine which does not appear on the essential medicines list but which, is considered by the Minister in consultation with the Authority, to be essential for national health, is subject to the prescribed procedures in order to expedite the registration thereof.

(5) Subsection (1) shall not apply in relation to the sale of a medicine compounded by a medical practitioner, dentist, veterinary surgeon, nurse, pharmacist, pharmacy technologist, pharmacy technician, pharmacy assistant or dispenser in accordance with that scope of practice, where that medicine or medical device–

(a) is for treatment of a particular person or animal for a period not exceeding thirty days, at a time;

(b) complies with the requirements for labelling under section 34;

(c) is not advertised for sale in Swaziland; or

(d) does not contain any component which is prohibited from sale.

Application for registration of medicines or medical devices

24. (1) An application for registration of a medicine or medical device shall be made to the Registrar in the prescribed form and manner.

(2) An application under this section may be made by any person and shall−

(a) be accompanied by such information, fee, sample or material; and

(b) designate the information to be considered appropriate

as may be required by the Authority or set out in regulations.

Request for supplementary information

25. (1) Where an application submitted under section 24 is incomplete, the Registrar shall notify the applicant in writing requesting further information within the time that the Registrar may specify.

(2) Where an applicant does not supplement the application with the requested information within the time specified under subsection (1), the application shall be rejected.

(3) The rejection of an application under sub section (2) shall not bar an applicant or any other person from making a subsequent application in relation to the same medicine or medical device.

Evaluation of applications

26. (1) Where an application for registration meets the requirements of section 24, and section 25 where applicable, the Registrar shall convey that application to the Authority for evaluation.

(2) When evaluating applications, the Authority shall consider all relevant factors including−

(a) the expected adverse effects;

(b) the therapeutic efficacy for the indication for which the medicine or medical device is intended;

(c) the quality as measured against specific requirements as may be prescribed;

(d) whether the medicine or medical device is banned or severely restricted by an international convention or a treaty or agreement which binds Swaziland;

(e) status of the medicine or medical device under registration schemes of other countries; or

(f) any other information that may be specified by the regulations.

Condition for sale of unregistered medicines or medical devices

27. (1) Where a medicine or medical device which was available for sale in Swaziland immediately before the date of commencement of this Act but has not been registered, a person may sell that medicine or medical device if an application for the registration of that medicine or medical device is made within two years immediately after the date of commencement of this Act until notification is published in the Gazette–

(a) that the application for the registration of that medicine or medical device has been withdrawn; or

(b) that the application for the registration of that medicine or medical device has lapsed due to failure to pay the annual retention fee for the right to sell an unregistered medicine or medical device; or

(c) that the Authority has approved the registration of that medicine or medical device or rejected the application, as the case may be.

Approval of applications for registration

28. (1) If after the consideration of any application referred to it under section 26 and after any investigation or enquiry which it may consider necessary, the Authority is satisfied that the medicine or medical device under consideration−

(a) is required in public interest;

(b) is suitable for the purpose for which it is intended; and

(c) is suitable with respect to its safety, quality and therapeutic efficacy,

the Authority shall approve the registration of that medicine or medical device and assign a name under which the medicine or medical device shall be registered under.

(2) Notwithstanding subsection (1), the Authority shall not approve the registration of any medicine or medical device manufactured outside Swaziland, unless a valid certificate of registration in respect of that medicine or medical device issued by the appropriate authority established for the registration of medicines or medical devices in the country of origin is produced before the Authority and the Authority is satisfied by the authenticity of the certificate.

(3) Where the medicine or medical device has not been so registered in the country of origin, evidence that the medicine or medical device was manufactured in that country and reasons why it was not registered in that country shall be produced to the satisfaction of the Authority before the Authority can approve registration of the medicine or medical device.

Decision on application for registration

29. (1) Where the Authority approves registration of a medicine or medical device the Registrar shall−

(a) assign a registration number to the medicine or medical device or in the case of renewal if possible re-assign the same medicine or medical device number;

(b) register the medicine or medical device in the register of medicines and medical devices;

(c) publish the registration in the gazette; and

(d) issue a registration or re-registration certificate to the applicant.

(2) If the Authority approves registration in accordance with section 24 with conditions or safeguards, including those regarding duration of registration, manufacture, storage, transport, import, export, packaging, repackaging, labelling, distribution, sale, use, or disposal, the Registrar shall−

(a) assign a registration number to the medicine or medical device, or in the case of renewal, re-assign the same number if possible;

(b) list the medicine or medical device in the register of medicines and medical devices;

(c) publish the registration in the Gazette; and

(d) issue to the applicant or an authorised representative or agent of the applicant a registration or re-registration certificate,

with the conditions or safe guards included.

(3) Where registration of a medicine or medical device was not approved by the Authority the Registrar shall−

(a) decline registration of a medicine or medical device notifying the applicant of the reasons for that refusal; and

(b) not issue a registration or re-registration certificate where registration or re-registration has been declined.

(4) Refusal of registration of a medicine or medical device under this Act shall not prevent an applicant or any other person from making a subsequent application in relation to the same medicine or medical device.

Amendment of entries in the register

30. (1) An entry made in the register in relation to any medicine or medical device may, on application by the holder of the certificate of registration issued in respect of that medicine or medical device, be amended by the Registrar with the approval of the Authority.

(2) An application under this section shall be made to the Registrar in the prescribed form and shall be accompanied by the prescribed application fees.

(3) After receipt of an application in terms of this section the Registrar shall within seven days forward the application to the Authority for its consideration.

(4) Where an application under this section is granted the Registrar shall within seven days make the required amendments in the register and, where necessary, cancel the existing certificate of registration in respect of such medicine or medical device and issue a new certificate of registration in respect of that medicine or medical device.

Cancellation and variation of registration

31. (1) The Registrar may cancel the registration or vary the conditions of registration of a medicine or medical device if the Authority determines that–

(a) the registration was secured as a result of a mistake or through fraudulent means;

(b) the registration was secured in contravention of this Act;

(c) it is not in the interest of the public that the registered medicine or medical device should be made or continue to be made available to the public;

(d) it is in the public interest to vary the conditions of registration of the medicine or medical device;

(e) any conditions subject to which the registration was granted have been breached; or

(f) subsequent to the registration the Registrar or the Authority has become aware of new facts or an unforeseen change in circumstances which require cancellation.

(2) A notice under this section shall state the grounds upon which the notice of cancellation or variation is based.

(3) Before effecting any cancellation or variation under sub-section (1), the Registrar shall give the party to whom the registration was granted thirty days to make submissions as to why the registration should not be cancelled or varied.

(4) Where no submissions are submitted after the expiry of the time stated in subsection (3), the Registrar shall publish the notice of cancellation or variation in the Gazette and the cancellation or variation shall be effective after twenty one days from the date of publication.

(5) Where after considering the submissions submitted under subsection (3) the Authority considers that the registration still has to be cancelled or varied, the Registrar shall, within seven days after the decision was issued by the Authority inform the person upon whom the registration was granted, of the decision of the Authority and the Registrar shall thereafter publish the decision in the Gazette.

(6) Subject to section 66, a cancellation or variation or registration shall be effective after the expiry of twenty one days from the date of first date of publication and the Registrar shall thereafter amend the register of medicines and medical devices accordingly.

Changes regarding registered medicines or medical devices

32. (1) Where there is a change in the trade name, label, or use of a registered medicine or medical device the registration certificate holder shall make a written application to the Registrar requiring the Registrar to effect that change in the register of medicines and medical devices.

(2) Where the proposed change is not in contravention of this Act or other applicable legislation or any international convention or treaty or agreement which binds Swaziland the Registrar shall effect the change in the register.

(3) Where necessary the Registrar may issue the applicant with a new certificate which includes the changes effected by the Registrar.

(4) Where a change is proposed to the formulation, active ingredient or concentration of a registered medicine a new application for registration shall be made.

Transfer of certificates of registration

33. (1) A certificate of registration may with the approval of the Authority, be transferred by the holder of that certificate to any other appropriate person.

(2) Application for approval of the transfer of a certificate of registration shall be made to the Registrar on the form approved and provided by the Authority and shall be accompanied by the certificate of registration in question and the prescribed application fees.

(3) The Registrar shall, as soon as practicable after the receipt of any application, submit the application to the Authority for consideration.

(4) If the Authority grants approval for application submitted to it under subsection (3), the Registrar shall make the necessary entries in the register relating to the person to whom the certificate of registration is transferred, cancel the existing certificate of registration and issue a new certificate of registration on the form approved and provided by the Authority to that person in respect of the relevant medicine or medical device.

PART IV

LABELLING, SALE AND SPECIAL PERMITS

Labelling

34. (1) A person shall not sell any medicine or medical device unless the immediate container and the package in which it is sold are labelled with its registered name, registered number and any other prescribed particulars.

(2) A registered medicine or medical device which is sold by–

(a) a medical practitioner, dentist or veterinary surgeon for the treatment of a particular person or animal and supplied by that medical practitioner, dentist or veterinary surgeon for that person or animal; or

(b) a pharmacist for the treatment of a particular person or animal and supplied by that pharmacist in accordance with a prescription given by a medical practitioner, dentist or veterinary surgeon,

may be sold without being labelled with the registered number of the medicine or with the other prescribed requirements but shall be labelled with the registered name of the medicine unless the medical practitioner, dentist or veterinary surgeon, as the case may be, specifically directs that it shall not be labelled with the registered name.

(3) The Minister may, after consultation with the Authority, by regulation, provide for exemptions to subsection (1).

(4) A person who contravenes subsection (1) commits an offence and shall be liable, on conviction, to a fine not exceeding five thousand Emalangeni or imprisonment for a period not exceeding two years or both.

Advertising of medicines or medical devices

35. (1) A person who advertises–

(a) an unregistered medicine or medical device; or

(b) any medicine or medical device in a manner that –

(i) is false or misleading or is intended to deceive;

(ii) employs false or misleading comparisons with other medicine or medical device;

(iii) is contrary to approved uses or label instructions and any other conditions of registration of the medicine or medical device; or

(iv) is contrary to other conditions that may be prescribed by regulations,

commits an offence.

(2) A person shall not advertise−

(a) any schedule 2 medicine to the public without the approval of the Authority;

(b) schedule 3, 4, 5 and 6 medicines to the public.

Sale of medicines and medical devices to comply with certain requirements

36. (1) A person shall not sell any medicine or medical device, which has been registered under this Act or in respect of which the Authority has authorised the sale as contemplated in section 36, unless that medicine or medical device complies with the prescribed requirements.

(2) Where a medicine or medical device is required by this Act to be provided with any information, that information shall be written, printed or otherwise marked on a label which is attached or fixed to the package of that medicine; or packed with, and refers to that medicine.

Registrar to make certain information available

37. (1) Where a medicine, or medical device has been registered under this Act the Registrar shall, as soon as practicable, make available to medical practitioners, dentists, pharmacists, veterinary surgeons and the person who applied for registration of the medicine or medical device any information which the Registrar considers necessary, and which may include−

(a) the name and number under which that medicine or medical device is registered and the conditions, if any, subject to which that medicine is registered;

(b) the therapeutic efficacy and effect of that medicine or medical device; or

(c) the purpose for which, the circumstances under which and the manner in which that medicine or medical device should be used.

(2) Where registration of a medicine or medical device is been cancelled under this Act the Registrar shall, as soon as practicable, notify medical practitioners, dentists, pharmacists veterinary surgeons and the person who applied for registration of the medicine or medical device of the cancellation of the registration of the medicine or medical device.

(3) The provisions of subsections (1) and (2) shall not apply, in respect of veterinary medicines, which are regulated by the Regulation and Control of Veterinary Drugs and Medicinal Substances Regulations published in terms of the Animal Diseases Act 7 of 1965.

Prohibition of the sale of undesirable medicines or medical devices

38. (1) Where the Authority resolves that it is not in the interest of the public that a registered medicine be made available to the public, the Authority may, through the Registrar,–

(a) by notice in writing transmitted by registered post to any person, direct that person; or

(b) by notice in the Gazette or local newspaper, direct all persons−

(i) not to sell, supply or deliver that medicine or medical device to any person for any reason whatsoever; or

(ii) to return the medicine or medical device to the manufacturer of the medicine or medical device or, in the case of an imported medicine or medical device, to the entity that imported the medicine or medical device or to supply or deliver that medicine or medical device to a person approved by the Authority for that purpose.

(c) by notice in writing, direct any person to whom any medicine or medical device has been so returned, delivered or sent, to deal with, dispose of or destroy that medicine or medical device in a manner that the Authority may determine.

(2) A person shall not sell, advertise or supply a medicine, medical device or a scheduled substance, which is the subject of a notice under subsection (1), unless the notice is withdrawn by the Authority or set aside on appeal.

(3) A person who contravenes this section commits an offence and is liable, on conviction, to a fine not exceeding thirty thousand Emalangeni or to imprisonment for a period not exceeding twenty years or both.

PART V

CONTROL OF MEDICINES AND SCHEDULED SUBSTANCES

Control of medicines and scheduled substances

39. (1) Subject to this section, a person shall not sell, possess or manufacture any medicine or scheduled substance, except in accordance with the prescribed conditions.

(2) The Minister may, on the recommendation of the Authority, prescribe the scheduled substances and amend such schedule.

(3) A schedule 0 substance may be sold in a retail business outlet.

(4) A person shall not sell a schedule 1 substance−

(a) unless that person is a pharmacist, pharmacist intern, pharmacy technician, pharmacy technologist, pharmacy assistant or a dispenser acting in the scope of that practice;

(b) unless that person is a manufacturer, wholesaler, retail pharmacy or hospital pharmacy and is selling the substance to any person who may lawfully possess that substance;

(c) unless that person is a medical practitioner or dentist, who is authorised−

(i) to prescribe that substance for use in humans;

(ii) or licensed under section 47 to compound and dispense that substance;

(d) unless that person is a veterinary surgeon who may prescribe, compound or dispense that substance for purposes of the treatment of an animal;

(e) unless that person is a pharmacist or nurse−

(i) who may prescribe only the scheduled substances identified in the Schedule for that purpose;

(ii) who is a holder of a licence issued under section 47, to compound and dispense the scheduled substances referred to in paragraph (e) (i);

(f) to any person under the age of fourteen years except upon a prescription issued by−

(i) an authorised prescriber and dispensed by a pharmacist, pharmacist intern, pharmacy technician, pharmacy technologist, pharmacy assistant, or dispenser acting in accordance the scope of such practice;

(ii) a veterinary surgeon for use in animals;

(iii) a person who is the holder of a licence issued under section 47; or

(iv) on a written order disclosing the purpose for which that substance is to be used and bears a signature known to the seller as the signature of a person known to that seller and who is above the age of fourteen years;

(5) A person shall not sell a Schedule 2, Schedule 3, Schedule 4, Schedule 5 or Schedule 6 substance unless that person is−

(c) a pharmacist, pharmacist intern, pharmacy technician, pharmacy technologist, pharmacy assistant or a dispenser acting in accordance with the scope of practice, and is authorised to sell only schedule 2 substances without a prescription;

(b) a pharmacist, pharmacist intern, pharmacy technician, pharmacy technologist, pharmacy assistant, or a dispenser, acting in accordance with scope of practice, upon a written prescription issued by an authorised prescriber or on the verbal instructions of an authorised prescriber who is known to that pharmacist, pharmacy intern, pharmacy technician, pharmacy technology, pharmacy assistant, or a dispenser;

(c) a manufacturer, wholesaler, retail pharmacy or hospital pharmacy to any person who may lawfully possess that substance;

(d) a medical practitioner or dentist, who−

(i) is authorised to prescribe that substance for use in humans; or

(ii) licensed under this Act to compound or dispense that substance.

(e) a veterinary surgeon who is licensed under this Act to prescribe, compound or dispense that substance;

(f) a nurse who -

(i) is authorised to prescribe only the scheduled substances identified in the Schedule for that purpose; or

(ii) is licensed under this Act to compound and dispense the scheduled substances referred to in subparagraph (i).

(g) a pharmacist who is authorised to prescribe only the scheduled substances identified in the Schedule for that purpose.

(6) Sale of medicine under subsection (5) shall only take place under the condition that−

(a) all the prescribed particulars of every sale shall be recorded in the prescribed manner in a prescription book or other permanent record required to be kept in the prescribed manner;

(b) the authorised prescriber who has given verbal instructions regarding the supply of a Schedule 2, 3 or 4 substance to a pharmacist, pharmacist intern, pharmacy technician, pharmacy technologist, pharmacy assistant, or dispenser to dispense a prescription shall, within seven days after giving the instructions, furnish the person who dispensed the medicine with a prescription confirming the instructions;

(c) the treatment period shall not exceed seven days in the case of verbal instructions;

(d) if a prescription is not presented for dispensing within thirty days of issue it shall no longer be dispensed;

(e) in the case of a schedule 2 substance, that substance shall only be supplied to a person under the age of fourteen years under the requirement of section 39 (4) (f).

(f) in the case of a schedule 2, schedule 3 or schedule 4 substance, that sale may be repeated if the person who issued the prescription indicates on the prescription the number of times it may be dispensed, and that the prescription may not be repeated more than five times;

(g) in the case of a schedule 5 substance, the sale shall not be repeated more than five times, and then only if the authorised prescriber has

indicated on the prescription the number of times and the intervals at which it may be dispensed;

(h) in the case of a schedule 6 substance, it shall not be repeated without a new prescription being issued;

(i) in an emergency in which the health or life of a patient is at stake, a person registered under the Pharmacy Act and employed by a wholesaler may, on receipt of a telephonic or telefaxed or other electronic request, supply a schedule 6 substance to a pharmacist, medical practitioner, dentist, veterinary surgeon or nurse, without a written order, except that−

(i) it shall be the responsibility of that pharmacist, medical practitioner, dentist, veterinary surgeon, nurse or other person to ensure that the person employed by a wholesaler receives a written order within seven days.

(ii) the schedule 6 substance shall be supplied in the smallest unit sales pack available;

(iii) a permanent record is made and kept of that supply;

(j) in an emergency a person registered under the Pharmacy Act may sell any schedule 5 or schedule 6 substance in a quantity not greater than that required for continuous use for a period of forty eight hours, on the verbal instructions of a medical practitioner, dentist, veterinary surgeon or nurse, who is known to that pharmacist, and the prescriber who has given the verbal instructions, shall within seventy two hours after giving the instructions furnish to the person who dispensed the prescription a written prescription confirming the instructions;

(k) in an emergency a person registered under the Pharmacy Act may sell a schedule 2, schedule 3 or schedule 4 substance on a non-recurring basis for a period not exceeding thirty days in accordance with the original prescription in order to ensure that therapy is not disrupted, and that person shall be satisfied that an authorised prescriber initiated the therapy, with the intention that the therapy be continued, and that the particulars of that sale are recorded in a prescription book or other prescribed permanent record;

(l) a person registered under the Pharmacy Act may sell a greater or a lesser quantity of a schedule 1, schedule 2, schedule 3 or schedule 4 substance than the quantity prescribed or ordered, according to the therapeutic pack in the original container of that substance as supplied to that person, but the quantity so sold shall not exceed or be less than, twenty five per cent of the quantity specified in the prescription or order in question;

(m) any seller referred to in this subsection shall retain the prescription or order concerned for a period of not less than five years as from the date of that sale;

(n) a schedule 6 substance may only be sold if the course of treatment does not exceed thirty consecutive days;

(o) the sale of a Schedule 5 substance by a manufacturer or wholesaler and the sale of a Schedule 6 substance by a manufacturer, wholesaler, retail pharmacy or hospital pharmacy shall be recorded in a register which shall be kept in the prescribed manner, and shall be balanced to show clearly the quantity of every schedule 5 or schedule 6 substance remaining in stock as on the last day of March, June, September and December of each year, and that balancing shall be completed within the fourteen days following each of the said dates;

(p) the person who dispenses a prescription shall endorse on the prescription the date of sale and the quantity of the substance sold, and when it is repeated, the date of sale and the quantity of the said substance sold, and the last seller shall retain the prescription for a period of not less than five years as from the date of the last sale;

(q) any schedule 1, schedule 2, schedule 3 or schedule 4 substance for the treatment of any animal may be supplied by any person other than a veterinary surgeon registered in terms of the Veterinary Surgeons Act, 1997, upon a written prescription issued by a veterinary surgeon or on the verbal instructions of a veterinary surgeon.

Sale of scheduled substances for analytical purposes

40. (1) A person, other than a pharmacist, pharmacist intern, pharmacy technician, pharmacy technologist, pharmacy assistant or dispenser acting in accordance

with such scope of practice, shall not sell a schedule 1, schedule 2, schedule 3, schedule 4, schedule 5 or schedule 6 substance for analytical purposes, manufacture of foods, cosmetics, educational or scientific purposes, unless a permit, issued in accordance with the prescribed conditions has, subject to subsection (2), been issued by the Authority, for that purpose.

(2) The Authority may, revoke any permit issued under this section if the conditions on which that permit was issued, are not complied with or if it is in the public interest.

Possession of schedule 7 and 8 substances and manufacture of schedule 5 and 6 substances

41. (1) A person, other than the Authority or a medical practitioner pursuant to subsection (2), shall not acquire or possess a schedule 8 substance.

(2) The Authority shall only allow a medical practitioner to provide a schedule 8 substance, on the prescribed conditions, for the treatment of a particular patient of that medical practitioner and upon any conditions that the Authority, may impose.

(3) A person shall not−

(a) acquire, use, possess, manufacture, or supply any schedule 7 or schedule 8 substance; or

(b) manufacture any schedule 5 or schedule 6 substance−

unless that person has been issued with a permit by the Authority, for that acquisition, use, possession, manufacture, or supply.

(4) A person shall not manufacture, use or supply any schedule 5 or schedule 6 substance for any purposes other than medicinal purposes, unless that person has been issued with a permit by the Authority for that manufacture, use or supply with any conditions that may be imposed.

(5) The Authority may−

(i) acquire; or

(ii) issue a permit with such conditions as the Authority may determine, to a medical practitioner, analyst, researcher or veterinary surgeon to acquire or use−

a Schedule 7 or Schedule 8 substance for the treatment or prevention of a medical condition in a particular patient, or for the purposes of education, analysis or research;

(a) subject to the conditions or requirements stated in such permit, authorise the administration outside any health facility of any Scheduled substance or medicine for the satisfaction or relief of a habit or craving to the person referred in such authority.

(6) The period of validity of a permit issued in terms of this section shall not exceed a period of twelve months from the date of issue.

(7) The Authority may where any condition on which the permit was issued is not being complied with, at any time revoke or amend a permit issued under this section.

(8) Notwithstanding anything to the contrary contained in this section, a person shall not sell or administer any scheduled substance or medicine for any purpose other than medicinal purposes.

Permit to import and export schedule 5, 6, 7 and 8 substances

42. (1) A person shall not import or export a−

(a) schedule 5, schedule 6, schedule 7 or schedule 8 substance; or

(b) any substance which becomes subject to international control under the 1961 Single Convention on Narcotic Drugs or the 1971 Convention on Psychotropic Substances,

unless a permit has been issued to that person by the Authority.

(2) A permit shall not be issued under this section unless the applicant has furnished the Registrar with the prescribed annually required information and complies with all the prerequisite conditions stated in the permit.

(3) A permit issued under this section shall specify that the holder of that permit shall not deviate from the conditions set out in the in the permit.

(4) The Minister may, on the advice of the Authority, by notice in the Gazette prescribe any other substance which requires a permit under this section to import.

(5) A permit issued under this section shall be in the prescribed manner and subject to any conditions as may be determined by the Authority.

(6) A permit issued under subsection (1) shall not be issued for any purpose other than the satisfaction or relief of a habit or craving to a patient in respect of that substance or medicine.

(7) The validity period of a permit issued under this section shall not exceed a period of six months from the date of issue.

(8) The Authority shall refuse to issue a permit under this section where−

(a) the Authority, is not convinced that the applicant is capable of keeping or storing the substance or medicine in a satisfactory manner in order to prevent the loss of the substance or medicine;

(b) the use of that substance or medicine has not been authorised under this Act;

(c) the Authority, is of the opinion that the annual importation quota for that substance has been exceeded or will be exceeded;

(d) it is not in public interest that such permit should be issued;

(e) the applicant did not comply with any of the conditions under which a previous permit was issued; or

(f) the applicant has failed to comply with any of the conditions provided in the regulations.

(9) Where an application for a permit under this section is refused, the applicant shall be furnished with the reasons for that refusal.

(10) Refusal of a permit under this section shall not prevent an applicant or any other person from making a subsequent application.

(11) Subsection (1) shall not apply to any preparation which contains a substance which is specifically exempted from all control measures for obtaining import or export permits by the 1961 Single Convention on Narcotic Drugs.

(12) Any importation or exportation exempted by subsection (11) shall be authorised by the Authority.

Authority to prescribe medicines and scheduled substances

43. A nurse, medical practitioner, dentist or veterinary surgeon, shall not prescribe a medicine or scheduled substance without the authority of the relevant professional body.

Authority to issue a permit in relation to schedule 1-5 substances

44. Notwithstanding anything to the contrary contained in this section, the Authority may, after consultation with the Pharmacy Council, issue a permit to any person or organisation performing a health service, authorising that person or organisation to acquire, possess, use or supply any specified Schedule 1, Schedule 2, Schedule 3, Schedule 4 or Schedule 5 substance, and that permit shall be subject to any conditions that the Pharmacy Council may determine.

Possession of certain medicines and scheduled substances

45. (1) Notwithstanding anything to the contrary contained in this Act a person may possess−

(a) a schedule 0, schedule 1 or schedule 2 substance for medicinal purposes; or

(b) a schedule 3, schedule 4, schedule 5 or schedule 6 substance if the medicine or substance was supplied in terms of a prescription issued by an authorised prescriber;

(2) A medicine or scheduled substance may be possessed by a medical practitioner, dentist, veterinary surgeon, or nurse, for the purposes of administering it in accordance with his or her scope of practice.

(3) A medicine or scheduled substance may be possessed for sale by a person registered under the Pharmacy Act, a pharmacy licensed under that Act, or a person who is the holder of a permit or licence issued under section 44 or section 47 respectively.

(4) Any medicine or scheduled substance which contains alcohol may be sold by a medical practitioner, dentist, veterinary surgeon, nurse or person registered under the Pharmacy Act, for medicinal purposes only.

Publication of information relating to a medicine, medical device or scheduled substance

46. Notwithstanding the provisions of preceding sections, the Authority may, if it considers it expedient and in the public interest, disclose information in respect of prescribing, dispensing, administration and use of a medicine, medical device or scheduled substance.

PART VI

LICENCES

Licences

47. (1) Subject to this section, the Authority may on application in the prescribed manner and on payment of the prescribed fee issue to a−

(a) medical practitioner, dentist or nurse a licence to compound and dispense medicines;

(b) manufacturer, a licence to manufacture a medicine, medical device or scheduled substance;

(c) wholesaler, a licence to act as wholesaler or distributor of a medicine, medical device or scheduled substance; or

(d) manufacturer, wholesaler, retail pharmacy or hospital pharmacy, a licence to import or export, a medicine or medical device in accordance with the Custom and Exercise Act of 1971.

(2) A licence issued−

(a) under subsection (1) shall be issued under the regulations and upon any conditions applicable to acceptable quality assurance principles and good manufacturing and distribution practices that the Authority may determine; and

(b) under subsection (1) (a) shall not be issued to an applicant unless the applicant successfully completes a supplementary course in dispensing practise determined by the Pharmacy Council.

(3) A person shall not compound or dispense a medicine or scheduled substance unless that person is−

(a) is a holder of a licence issued under this section or the Pharmacy Act; or

(b) a veterinary surgeon licensed as a veterinary surgeon under the Veterinary Surgeons Act 8 of 1997.

(4) A person shall not manufacture, act as a wholesaler or distribute, import, export a medicine unless that person is a manufacturer, wholesaler, retail pharmacy or hospital pharmacy who is a holder of a licence issued in terms under (1).

(5) The Authority may, after an application made to it, issue a licence to any person or entity that satisfies the requirements to hold that licence.

(6) An application for a licence under this Act shall be made to the Registrar in the prescribed form and manner.

(7) An application for a licence under this section shall be accompanied by the prescribed fee and any information, samples and material that may be required by the Registrar or set out in the Regulations.

(8) Subsections (3) and (4) shall come into operation twelve months after the date of operation of all the sections of this Act.

(9) A person who contravenes subsection (1) commits an offence and shall be liable, on conviction, to a fine not exceeding twenty thousand Emalangeni or to imprisonment for a period not exceeding ten years or to both.

Request for supplementary information

48. (1) Where an application submitted under section 47 is incomplete, the Registrar shall notify the applicant in writing, requesting further information within the time that the Authority may specify.

(2) Where an applicant does not supplement the application with the requested information within the time specified, the application shall be rejected.

(3) The rejection of an application under subsection (2) shall not bar an applicant or any other person from making a subsequent application in relation to the same medicine or medical device.

Evaluation of applications

49. (1) Where an application for a licence meets the requirements of sections 47, or 48 where applicable, the Registrar shall convey that application to the Authority for evaluation.

(2) Where necessary the Authority may require an Applicant under this section or any person to furnish it with any information, document, material, sample or anything which may be relevant to the application.

(3) Where the Authority has finalised its evaluation of an application it shall, not later than fourteen days, advise the applicant of its decision, which shall be written and shall include reasons for that decision.

(4) Subject to an outcome of an appeal under this Act or a decision of the court, a person shall not issue a licence under this Act where an application for that licence was refused by the Authority.

(5) A person who contravenes subsection (4) commits an offence and shall be liable, on conviction, to a fine not exceeding twenty thousand Emalangeni or to imprisonment for a period not exceeding ten years or to both.

(6) A licence issued under this section may be accompanied by any condition that the Authority may state in the licence or that maybe prescribed in the regulations.

Period of validity and renewal of licences

50. A licence issued under section 47 shall be valid for the prescribed period, which shall not exceed three years, but may be renewed on application in the prescribed manner and before the prescribed time or such later time as the Authority, as the case may be, may allow and such application shall be accompanied by the prescribed fee.

Suspension or revocation of licences

51. (1) The Authority may suspend for a specified period or revoke a licence issued under this Act if the Authority determines that–

(a) the licence was obtained as a result of a mistake or through fraudulent means;

(b) the licence was secured in contravention of this Act;

(c) the acts performed pursuant to the licence are undesirable on the grounds of harm to human health;

(d) the holder of the permit has been convicted of an offence which, in the opinion of the Authority, is of such a nature that renders the holder of licence unfit to hold that licence;

(e) any conditions subject to which the licence was issued have been breached; or

(f) subsequent to issuing the licence the Authority becomes aware of new facts or an unforeseen change in circumstances which require suspension or revocation.

(2) Before effecting any suspension or revocation under sub-section (1), the Authority shall give the party to whom the licence was issued thirty days to submit written justification as to why the licence should not be suspended or revoked.

(3) Notice of suspension or revocation of a licence under this section shall be published in the Gazette and the suspension or revocation shall be effective twenty-one days after the first date of publication.

Reimbursement of registration or license application fees

52. Where a license issued under this Act has been suspended, amended or revoked, reimbursement of any amount paid in respect of that registration or license shall not be made to any person.

Substitution with an interchangeable multi-source medicine

53. (1) Subject to subsections (2), (3) and (4), a pharmacist, pharmacist intern, pharmacy technician, pharmacy technologist, pharmacy assistant or dispenser or a person who is a holder of a licence issued under section 47 shall, before dispensing a branded medicine to a person who is in possession of a prescription which prescribes a branded medicine,−

(a) inform that person of the benefits of substituting the branded medicine by an interchangeable multi-source medicine which has similar composition with that branded medicine, and shall, in the case of that substitution, take reasonable steps to inform the person who prescribed the medicine of that substitution; and

(b) with the consent of that person dispense the interchangeable multi-source medicine instead of the prescribed branded medicine.

(2) Where consent is not obtained under subsection (1) (b) the dispenser shall record this fact on the prescription or dispenser's record.

(3) When an interchangeable multi-source medicine is dispensed by a dispenser, the dispenser shall note the brand name and where no brand name exists, the name of the manufacturer of that interchangeable multi-source medicine in the prescription book.

(4) A person authorised to dispense a prescription under this Act shall not sell or dispense an interchangeable multi-source medicine−

(a) if the person prescribing the medicine has written, in the handwriting of that person on the prescription the words ***'no substitution'*** next to the item prescribed;

(b) if the retail price of the interchangeable multi-source medicine is higher than that of the prescribed medicine; or

(c) where the medicine or product has been declared not substitutable by the Authority.

(5) A person who contravenes this section commits an offence.

(6) This section shall not apply in relation to a dispensary or pharmacy which is owned by the Government.

Supply of affordable medicines

54. (1) The Minister may upon recommendation of the Authority−

(a) prescribe a pricing system for all medicines and scheduled substances sold in Swaziland to ensure the affordability of medicines;

(b) prescribe the conditions under which any medicine which is identical in composition, meets the same quality standards and which originates from any site of manufacture of the original manufacturer and is intended to have the same proprietary name as that of another medicine already registered in Swaziland, but which is imported by a person other than the person who is the holder of the registration certificate of the medicine already registered, may be imported;

(c) prescribe the registration process for medicine referred to in paragraph (b).

(2) This section shall not be construed to undermine any rights attached to any medicine or medical device.

Purchase and sale of medicines by wholesalers

55. (1) A wholesaler shall not purchase or receive medicine for distribution from any source other than from the original manufacturer or from the primary importer of the finished product.

(2) Subsection (1) shall not be construed to prevent the return of medicines for credit purposes, to the manufacturer or wholesaler from which that medicine was initially obtained.

(3) Any wholesaler may in the prescribed manner and on the prescribed conditions be exempted by the Authority from the provisions of subsection (1).

Clinical trials

56. (1) A person shall not conduct a clinical trial of any medicine or medical device without the approval of the Authority.

(2) A person desiring to initiate or conduct a clinical trial in respect of an unregistered medicine, a new indication or new dosage regimen of a registered medicine or substance, shall apply to the Authority on the prescribed form and pay the prescribed fees.

(3) Clinical trials shall be conducted in accordance with guidelines for good clinical practice as may from time to time be determined by the Authority.

(4) Where the clinical trial is in respect of animals, the application shall specify the kinds of animals that will be subjected to the trial.

(5) A person conducting the clinical trial shall submit progress reports to the Authority after every six months from the date when the clinical trial was started and thirty days after the completion or termination of the clinical trial.

(6) The Authority may request additional information, inspect a clinical trial or withdraw the authorisation to conduct a clinical trial if the Authority is of the opinion that the safety of the subjects of the trial is compromised, or that the scientific reasons for conducting the trial have changed.

Prohibition of disclosure of information.

57. (1) A person shall not, without the consent in writing given by the Minister, publish or disclose to any person, otherwise than in the course of the person's duties, the

contents of any document, communication, or information which relates to, and which has come to the person's knowledge in the course of, that person's duties under this Act, unless the disclosure is made to a police officer pursuant to an investigation or an order of the court.

(2) A person who contravenes subsection (1) commits an offence and is liable, upon conviction, to a fine not exceeding twenty thousand Emalangeni or to imprisonment for a period not exceeding ten years, or to both.

(3) If any person having information, which to that person's knowledge has been published or disclosed in contravention of subsection (1), unlawfully publishes or communicates that information to any person, that person commits an offence and is liable, upon conviction, to a fine not exceeding ten thousand Emalangeni or to imprisonment for a term not exceeding two years, or to both.

Registers as evidence

58. (1) A certificate signed by the Registrar certifying that–

(a) an entry of the name of a medicine in the Register kept in under section 22 shall be accepted as evidence that the medicine is registered in terms of this Act unless the contrary is proved; or

(b) the name of a medicine has been cancelled from, or does not appear in, the Register kept under section 22 shall be accepted as evidence that the medicine is not registered under this Act unless the contrary is proved.

(2) A document purporting to be a certificate signed by the Registrar, setting forth the matters referred to in paragraph (a) or (b) of subsection (1) or any other records kept by the Registrar under this Act shall be admissible in any proceedings on its production by any person as *prima facie* proof of the facts stated in that document.

PART VII

ENFORCEMENT

Inspectors and analysts

59. (1) The Authority may appoint inspectors and analysts from persons that the Authority may consider suitable and necessary for the proper enforcement of the provisions this Act.

(2) The Registrar shall furnish an inspector with a certificate signed by the Registrar certifying the inspector to act as such.

(3) An inspector shall, when required by a person who is affected by the exercise or performance by the inspector of any power or function under this Act, show the certificate of that inspector to that person.

Powers of inspectors and analysts

60. (1) On instruction of the Authority, an inspector or officer may, when the premises are open for business, for the purpose of ensuring compliance with this Act, without a warrant and upon presentation of an identification document of that inspector or officer–

(a) carry out periodic inspections of all establishments which import, export, manufacture, pack, repack, label, store, sell, distribute, use or advertise medicines, substance, devices or articles, to determine whether the provisions of this Act are being complied with;

(b) require production, inspection, examination or copying of certificates, permits, licences, records or any other document relating to the provisions this Act;

(c) take samples of any scheduled substances to which this Act relates and, as may be prescribed, submit such samples for analysis; and

(d) seize any equipment, medicine, device, document, record, or other thing which the inspector believes has been used in or will be used, or which appears to afford evidence of a contravention of this Act.

(2) After executing the duties under sub-section (1) (d), an inspector, customs officer or police officer shall−

(a) prepare an inventory in the prescribed form and give a copy of that inventory to the owner or the person in lawful custody of that item; and

(b) promptly return the seized item to that person after the necessary inquiry or prosecution is completed and the item has been declared legal.

(3) An inspector, customs officer or police officer, executing their duties under this Act, shall not enter into or search a private residence unless the inspector,

customs officer or police officer believes on reasonable ground that there is in that dwelling house evidence relating to contravention of this Act or any other law.

(4) A sample taken under subsection (1) (c) shall be−

(a) taken according to the prescribed method−

(i) in the presence of the person who is in charge of the medicine, medical device or substance, or

(ii) in the presence of a witness; and

(b) divided into three parts,−

(i) one part shall be sent to an analyst, together with the prescribed certificate which has been duly signed in by an inspector, customs officer or police officer;

(ii) one part shall be sent by registered post, together with a copy of the certificate, to the owner or seller of the medicine, medical device or substance or representative of that owner or seller; and

(iii) the other part shall be kept by the inspector, customs officer or police officer for reference purposes.

(5) An analyst who receives a sample sent under this section shall upon receiving the sample, test, examine or analyse the sample and record the test results, examination or analysis in the prescribed form.

(6) An inspector, customs officer or police officer executing duties under this Act shall report contravention of this Act to the Registrar or the Authority.

(7) An owner or a person who was in lawful possession of a medicine, medical device or substance from which a sample was taken under this section shall be entitled to compensation.

(8) A claim for compensation under subsection (7) shall be made in writing, supported by any evidence that may be required and shall be directed to the Registrar.

(9) The decision of the court in legal proceedings instituted under this Act shall prevail over that of any inspector or analyst or customs or police officer in regard to the disposition of an item seized under sub-section (1) (d).

Inspection of private residences

61. (1) Subject to sub-section (2) an inspector, customs officer or police officer, under this Act, shall not enter any private residence except with the consent of the occupier or under the authority of a warrant.

(2) If an inspector, analyst, customs officer or police officer believes on reasonable grounds that the delay in obtaining a search warrant would defeat the object and purpose of the search, the inspector, analyst, customs officer or police officer may enter and search any private residence and any person or thing found in that private residence.

(3) If it appears to a magistrate upon an application made by an inspector, analyst, customs officer or police officer that there are reasonable grounds to believe that−

(a) there is in a private residence anything in respect of which this Act applies;

(b) entry into any private residence is necessary for a purpose relating to the administration of this Act; and

(c) entry to any private residence has been refused or there are reasonable grounds to believe that entry will be refused−

the magistrate may at any time sign and issue a warrant authorising any inspector, analyst, customs officer or police officer to enter and search that private residence subject to conditions that may be specified in the warrant.

(3) An inspector, customs officer or police officer may use any force that may be reasonably necessary to execute a warrant under this section.

Inspection of vehicles

62. (1) In this section, "vehicle" includes a motor vehicle as defined in the Road Traffic Act, 2007, and a vessel, trailer , aircraft or wagon.

(2) For the purposes of ensuring compliance with this Act and the regulations, an inspector, customs officer or police officer may−

(a) require a person operating a vehicle to stop the vehicle; and

(b) carry out an inspection of that vehicle.

(3) An operator of a vehicle shall immediately stop that vehicle when requested or signalled to do so by an inspector, customs officer or police officer who−

(a) displays the official badge or an identity of being an inspector, customs officer or police officer; or

(b) is in or near a vehicle that is readily identifiable as a government vehicle.

(4) For the purposes of carrying out an inspection under this section, a inspector, customs officer or police officer may−

(a) request that any compartment of the vehicle or a container in or on the vehicle be opened, and

(b) exercise any of the powers under section 60.

PART VIII

OFFENCES, PENALTIES AND PROCEEDINGS

Offences and penalties

63. (1) A person who−

(a) obstructs;

(b) provides false information to;

(c) fails to comply with an order, requisition or direction lawfully made or given by;

(b) fails to answer any question reasonably asked by;

(c) prevents or attempts to prevent another person from complying with an order, requisition or directions by or from answering any question from;

an inspector, customs officer or police officer in pursuance of this Act, commits an offence and is liable, on conviction, to a fine not exceeding fifteen thousand Emalangeni or to imprisonment for a period not exceeding five years or to both.

(2) A person who−

(a) manufactures, packs, repacks, labels, sells, stores, distributes, possesses or uses a medicine or substance in Swaziland which is not registered under this Act; or

(b) sells or distributes a medicine, medical device or substance−

(i) without an approved label attached to it; or

(ii) which does not meet the specifications as stated when the product was registered; or

(c) advertises a medicine or substance which is either, not registered, or in manner that is misleading or inaccurate;

(d) without a licence, performs a function for the performance of which, a licence is required;

(e) imports or exports a medicine or substance without a valid permit;

(f) fails to comply with any conditions of registration, licence, or permit;

(g) transports a medicine or substance contrary to the provisions of this Act;

(h) stores or disposes of any medicine or substance or the waste emanating from any medicine or substance in a manner that may harm human or animal health or the environment or in a manner contrary to this Act;

(i) fails to keep records which are required under this Act,

(j) with fraudulent intent, tampers with any sample under this Act;

(k) knowingly sells a medicine, medical device or substance that is known to be counterfeit;

(l) uses a report or certificate, which was issued by an inspector or analyst, for purposes of business or advertising;

(m) sells or uses a veterinary medicine for treatment of a person;

commits an offence and is liable, on conviction, to a fine not exceeding thirty thousand Emalangeni or to imprisonment for a period not exceeding fifteen years or to both.

(2) A person who intentionally provides false information or knowingly makes a misleading or false statement for the purpose of registration, obtaining a licence or a permit under this Act, commits an offence and is liable, on conviction, to a fine not exceeding thirty thousand Emalangeni or to imprisonment for a period not exceeding fifteen years or to both.

(3) A person who−

(a) adulterates a medicine;

(b) knowingly keeps and an adulterated medicine for sell, supply or treatment of another person;

(c) knowingly sell, supply or expose for sale or supply an adulterated medicine ; or

(d) knowing uses an adulterated medicine for the treatment of another person

commits an offence and is liable, on conviction, to a fine not exceeding forty thousand Emalangeni or to imprisonment for a period not exceeding twenty years or to both.

General penalties and proceedings

64. (1) A person who commits an offence under this Act for which no penalty is specifically provided is liable, on conviction, to a fine not exceeding one hundred thousand Emalangeni or to imprisonment for a period not exceeding twenty-five years or to both.

(2) An attempt to commit an offence under this Act shall constitute an offence and may be dealt with in the same manner as if the attempted offence was committed.

(3) A person who aids, abets, counsels or procures an offence under this Act or conspires to commit that offence commits the offence so aided, counselled or procured or conspired to be committed.

(4) In a prosecution for an offence under this Act a certificate purporting to be signed by the Registrar or any officer authorised by the Registrar for that purpose to the effect that on a day specified in the certificate−

(a) a medicine or substance was not registered under this Act; or

(b) the accused person or any other named person was not the holder of a permit or certificate under this Act−

shall in the absence of evidence to the contrary be sufficient evidence of the issues stated in the certificate.

Additional penalties

65. Where after convicting a person the court is satisfied that the convict acquired monetary benefits as a result of the commission of the offence, the court may, in addition to the normal sentence−

(a) order the convicted person to pay to the Government any part of that money which the court may impose after considering the monetary benefit acquired by the convicted person;

(b) disqualify the convicted person from holding any licence, certificate or permit; or

(c) order the Registrar to suspend or cancel, for any period of time, any licence, certificate or permit issued under this Act.

PART IX

APPEALS

Appeals

66. (1) A person, who is aggrieved or affected by a decision of the Authority under this Act, may, within twenty one days after the date of publication of that decision, appeal by notice in writing to the Minister stating the grounds upon which the appeal is based.

(2) The Minister shall, within twenty one days of receiving the notice of appeal under this section, appoint an appeals tribunal, according to section 67, which shall hear and determine the appeal.

Medicine and related substance control appeals tribunal

67. (1) There shall be a Medicine and Related Substance Control Appeals Tribunal whose functions shall be to hear appeals against the actions and decisions of the Registrar or Authority under this Act.

(2) The Tribunal shall be appointed by the Minister and shall consist of−

(a) a Chairperson who shall be a legal practitioner of not less than ten years experience in the practice of law;

(b) a deputy Chairperson who shall be a legal practitioner of not less than seven years experience in the practice of law; and

(c) three other members possessing the necessary and relevant expertise or experience in relation to the case concerned.

(3) The Tribunal shall be duly constituted for its work by the Chairperson, and in the absence of the Chairperson the deputy Chairperson, and two other members.

(4) The Tribunal shall be independent in the performance of its functions and any person who interferes with the functions of the Tribunal in any manner, commits an offence.

(5) The Tribunal shall be appointed for the purpose of the appeal or appeals concerned.

(6) The members of the Tribunal shall be removed from office in the same manner as members of the Authority.

(7) The Minister shall designate a person, who is not a member, to serve as secretary to the Tribunal and that person shall serve in that capacity in accordance with the ethical standards appropriate of that office.

(8) A member of the Tribunal may recuse oneself on one's own motion, or on application by any interested person, for any of the reasons for which a judge or magistrate may recuse oneself or may be required to recuse oneself in accordance with the law applicable in Swaziland.

(9) Where a member of the Tribunal becomes aware that a party to the appeal or any person who has an interest in the appeal, is a close relative or associate of the member, or of any person who has an influence on the member, that member shall−

(a) as soon as possible disclose that interest; and

(b) not be present or participate in any proceedings or deliberations of the Tribunal in relation to that matter.

(10) A member of the Tribunal who intentionally fails to comply with subsection (9) commits an offence.

(11) The Tribunal may, after hearing an appeal,−

(a) confirm, set aside or vary the decision of the Authority or Registrar; and

(b) direct the Authority or Registrar to execute the decision of the Tribunal.

(12) The decision of the Tribunal shall be in writing and shall state the reason for the decision and each party shall be furnished with a copy of the decision.

(13) A member of the Tribunal shall be paid such remuneration and allowance as the Minister in consultation with the Minister responsible for finance may determine.

(14) The powers of the Tribunal and the manner and procedure for appeals before the Tribunal shall be prescribed.

(15) The aggrieved party may take the case to court in the event the aggrieved party is not satisfied with the decision of the Appeals Tribunal.

PART X

HARMONIZATION OF REGULATION OF MEDICINES AND RELATED SUBSTANCES AND INTERNATIONAL COOPERATION

Participation in regulatory harmonization schemes

68. (1) The Authority shall participate and cooperate with any regional or continental Medicines regulatory agencies.

(2) The Minister shall promote the Authority's participation in regional and continental medicines regulatory harmonization activities.

(3) The Minister shall report the performance of the Authority in regional and continental council of Ministers of Health meetings.

Harmonization of regulatory requirements and activities

69. The Minister and the Authority shall take such measures to ensure effective co-operation with the Ministers responsible for Health and the Medicines Regulatory Authorities in other countries of the region to:

(a) Harmonize Registration of medical products, Inspections, Quality Management System, Information Management System, Joint Evaluations, Joint Inspections and any other regulatory activities as may be appropriate;

(b) Provide for the use of accredited quality control laboratories within the harmonization framework;

(c) Provide for the recognition of regional and other international technical guidelines developed and published by the World Health Organization, and the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use;

(d) Provide for harmonization of the data requirements for evidence of quality, safety, and efficacy of medical products and the grounds on which authorization for distribution shall be granted within the region;

(e) Provide for any necessary legal mechanisms for regulatory harmonization and enforcement;

(f) Ensure mutual recognition of regulatory decisions and to share summary evaluation and inspection reports;

(g) Participate in a common post market surveillance conducted In accordance with national and internationally recognized standards.

Transparency and Information sharing

70. (1) The Authority shall provide for the establishment of a Quality Management System based on common regional requirements to improve efficiency and transparency.
(2)The Authority shall set up systems to provide for the creation of a regional information Management system to which it shall provide and share relevant regulatory information.
(3)The Authority shall establish paper and electronic web based copies including but not limited to regulations, laws, forms, applications, list of registered medicines.

International Cooperation

71. (1) The Authority shall share information on pharmaceutical intelligence with other agencies at regional and continental levels as may be provided in the regulations.

(2) The Minister shall take proper measures to ensure effective bilateral, regional and international co-operation to combat the production, circulation and use of falsified and substandard medical products, illicit drugs, narcotics and psychotropic substances.

PART XI

FORMS, REGULATIONS AND INDEMNITIES

Regulations

72. (1) The Minister may make regulations or issue any order or notice to give effect to any of the purposes of this Act.

(2) In particular and without prejudice to the generality of subsection (1) the regulations made under this section may prescribe all or any of the following matters; −

(a) anything which is to be or may be prescribed under this Act;

(b) the authorization, regulation, control, restriction or prohibition of the−

(i) manufacture;

(ii) advertising;

(iii) distribution;

(iv) alteration;

(v) decanting;

(vi) packaging;

(vii) labelling;

(viii) repackaging;

(ix) compounding;

(x) dispensing;

(xi) possession;

(xii) import and export;

(xiii) storage;

(xiv) transportation;

(xv) sale;

(xvi) use; and

(xvii) dumping and other disposal−

of any medicine, medical device or substance or class of medicine, medical device or substance;

(c) ban, restrict or severely restrict the import, export and use of medicine, medical devices or scheduled substances;

(d) the designation of places as ports of entry or exit, where medicine, medical devices or scheduled substances may be presented for inspection and admit into and exit from Swaziland;

(e) the form, type and content of any application, certificate, licence, permit, authorization, receipt, or other documents or thing done under this Act;

(f) the information to be considered proprietary information and how this information shall be maintained;

(g) the procedures and criteria to be followed by the Registrar and the Authority when considering the grant, review, variation, suspension, renewal and revocation of registration, licences, and any permits under this Act;

(h) the period of validity of registration, licences, and permits granted or issued under this Act;

(i) the requirements which any medicine, medical device, substance or any component of a medicine, medical device or substance shall comply in regard to composition, therapeutic suitability and effect, purity or any other property;

(j) the pharmacological classification of medicines, medical devices or substances;

(k) the requirements for the containers and labels of certain medicines, medical devices or scheduled substances;

(l) the storage and the proper disposal of certain medicines, medical devices and scheduled substances and their containers;

(m) advertising of medicines, medical devices or scheduled substances;

(n) precautions and work safety measures to be taken for protection from injury, ill health and death of persons exposed to medicines, medical devices or scheduled substances during their manufacture, transport, storage and use;

(o) the form, content and manner of keeping and maintaining registers, inventories and records;

(p) the notification of cases or suspected cases of poisoning, intoxication, injury, illness and death of persons and animals that have been exposed to certain medicines, medical devices or scheduled substances;

(q) the duties and responsibilities of persons responsible for any medicines, medical devices or substances or for premises on which such medicines, medical devices or scheduled substances are kept;

(r) criteria and requirements for laboratories designated under this Act;

(s) the procedures to be followed for submitting samples for analysis under this Act and the methods of sampling, testing and certifying of medicines, medical devices and scheduled substances;

(t) the procedures to be followed where any equipment, medicine, medical device or scheduled substance, document, record, or other thing is seized under this Act;

(u) the destruction of medicines, medical devices or scheduled substances manufactured, modified, imported, stored, transported or used contrary to this Act;

(v) the payment of fees on applications for registration, permits and licences under this Act, on the carrying out or issue of the same, charges for any analysis required under this Act and any other fees or charges for carrying out the purposes and provisions of this Act and calculation of interest that shall accrue on unpaid fees and charges;

(w) the provision by applicants for registration under this Act of bonds or other forms of security for securing their compliance with the obligations under the terms and conditions of their registrations or permits or their compliance with provisions of this Act;

(x) compliance with and the implementation of obligations of Swaziland under bilateral and multilateral treaties, convention or agreements;

(y) the registration of medicine or scheduled substances which have been registered with other authorities or similar bodies elsewhere with acceptable repute and standing;

(z) the fees payable in respect of anything done under this Act;

(aa) penalties for contravention of regulations, any rules made or any conditions attached to any registrations, licences or permits effected, given or issued under the regulations; and

(bb) the manner of filling an appeal to the Medicine and Related Substances Appeals Tribunal and the procedure of the Tribunal.

(cc) the control of Narcotics drugs, Psychotropic Substances and Precursors in accordance with legislation on dangerous drugs and relevant treaties to which the State Swaziland subscribes, including the Single Convention on Narcotic Drugs of 1961 as amended by the 1972 Protocol, the Convention on Psychotropic Substances 1971 adopted in 1988, and the UN Convention against Illicit Traffic Drug and Psychotropic Substances, 1988.

(dd) the mandatory pharmacovigilance reporting by the manufacturers, wholesalers and health care professionals, and the submission of periodic safety updates.

Indemnity of Government and officers

73. (1) The Government shall not be liable in respect of anything done or omitted to be done in good faith in the exercise of a power or duty under this Act.

(2) No action shall lie against the Authority, Registrar, Inspector or analyst or any government official in respect of any act done or omitted to be done in good faith in the purported exercise of any powers under this Act.

(3) Subsection (1) and subsection (2) shall not prevent the Registrar, Inspector or analyst or any government official from being accountable for failing to perform their duties.

Exemptions

74. The Authority may, in writing, exempt, subject to any conditions that may specify any medicine, medical device or substance from the operation of any or all of the provisions of this Act.

Repeals

75. Sections 3, 4, 5 and 15 of the Opium and Habit Forming Drugs Act, 1922 will be repealed on dates to be determined by the Minister and published by notice in the Gazette.

FIRST SCHEDULE