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GOVERNMENT NOTICE

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ACT NO. 6 OF 2023

Lesotho Medicines and Medical Devices Control Authority Act, 2023

An Act to provide for the establishment of a Lesotho Medicines and Medical Devices Control Authority and its functions; the registration of a medicine or a medical device; licensing of professional personnel and premises dealing with medicines or medical devices; monitoring and regulation of the utilization of a medicine or a medical device; clinical trials and related matters.

Enacted by the Parliament of Lesotho.

PART I - PRELIMINARY

Short title and commencement

1. This Act shall be cited as the Lesotho Medicines and Medical Devices Control Authority Act, 2023 and shall come into operation on a date to be determined by the Minister by notice published in the Gazette.

Interpretation

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

"administer" means administering a medicine or a medical device;

"adulterate" means adding a substance to or abstracting a substance from a medicine in order to affect the composition of the medicine;

"advertisement" means any written, pictorial, visual or other descriptive matter or any verbal statement or reference,

(a) broadcast on television or radio;

(b) appearing in a newspaper, magazine, pamphlet or other publication;

(c) distributed to a member or members of the public; or

(d) brought to the notice of the members of public in any

other manner,

which is intended to promote the sale of a medicine or a medical device and "advertise" has a corresponding meaning;

"analyst" means a person, a body of persons or an organisation appointed under section 41 who has a special knowledge of the action and application of a medicine or a medical device for the purpose of testing, examining or analysing the medicine or medical device;

"applicant" means an applicant for a certificate of registration in respect of a registered medicine or a medical device and an applicant for a licence issued in terms of this Act;

"approved name" means the international non-proprietary name of a medicine or a medical device;

"authorised person" means a medical practitioner, a dentist, a veterinarian or any other person authorised under this Act to prescribe a medicine or a medical device;

"Authority" means the Lesotho Medicines and Medical Devices Control Authority established under section 3;

"Board" means the Board of the Authority, established under section 5;

"certificate" means a certificate of registration issued under section 15 (8) (c);

"certificate of analysis" means a certificate issued by an analyst in terms of section 41 (2);

"chemist" means a professional business which deals with a medicine or medical device from Schedule 0 to Schedule 3, which is owned and managed by a qualified pharmacy technician registered with the Lesotho Medical, Dental and Pharmacy Council;

"Chief Executive Officer" means a person appointed as such under section 13;

"clinic" means a place registered as such under the Public Health Order, 1970[1], where outpatients are given medical treatment or advice;

"clinical outcome" means a measurement of how a patient feels, functions or survives or a clinical measurement of the incidence or severity of a disease;

"clinical trial" means a trial undertaken in order to evaluate the effectiveness and safety of a medicine or a medical device by monitoring its effect on a group of people or a group of animals;

"competent person" includes a juristic person qualified for the task given to him as may be decided by the Board;

"compound" means to manufacture a medicine or a medical device at a small scale;

"counterfeit medicine" means a medicine which is deliberately and fraudulently mislabelled with respect to its identity or source;

"country of origin" means a country where a product was first innovated;

"Dental Surgeon" means a person registered as such under the Medical, Dental and Pharmacy Order 1970;

"Director-General" means the Director-General of Health Services;

"generic product" means a pharmaceutical product intended to be interchangeable with the patented product which is manufactured without a licence from the patent owner and marketed after expiry of the patent or an exclusive right;

"health centre" means a clinic staffed with a group of health professionals to provide health services for the local community;

"holder" means a holder of a certificate of registration in respect of a registered medicine or a medical device;

"hospital" means an institution registered as such under section 81 (1) of the Public Health Order, 1970;

"immediate container" means a container which is in direct contact with a medicine;

"inspector" means a pharmaceutical inspector authorised as such under section 39;

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

"licence" means a licence issued under section 29 (3);

"manufacture" includes purchasing of material, processing, packaging, quality control, release and storage of medicinal products or medical devices and manufacturing has a corresponding meaning;

"medical device" means an instrument, appliance, material, machine, apparatus, implant, diagnostic agent or any matter used or sold for use in -

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

(b) restoring, correcting or modifying any sematic, psychic or organic function; or

(c) the diagnosis or prevention of a pregnancy;

"medical practitioner" means a person registered as such under the Medical, Dental and Pharmacy Order, 1970;

"medicine" means any substance, a mixture of substances or related substances used or sold for use in-

(a) the alleviation, cure, diagnosis, mitigation, modification or treatment of a disease, abnormal physical or mental state or the symptoms thereof in a human being or in an

animal;

(b) restoring, correcting or modifying any somatic, psychic or organic function in a human being or in an animal;

"Minister" means the Minister responsible for health;

"pharmacist" means a person registered as such under the Medical, Dental and Pharmacy Order, 1970;

"pharmacy" means a professional business dealing with a medicine or a medical device owned and managed by a qualified pharmacist registered and licensed under the Medical Dental and Pharmacy Order, 1970;

"pharmaceutical intelligence" means new scientific discoveries relating to medicines;

"pharmacist intern" means a person registered as a pharmacist under the Medical Dental and Pharmacy Council but who has not practiced as such within a period not exceeding one year after graduating;

"pharmacy technician" means a person registered as such under the Medical, Dental and Pharmacy Council;

"prescribe" in relation to a medicine or a medical device means to issue a written or oral instruction for a specific patient to receive a medicine or a medical device specified in the instruction under such conditions as may be determined by a medical doctor, veterinarian or any other person authorised to prescribe and "prescription" has a corresponding meaning;

"register" when used as a noun, means the register referred to in section 15(1) and when used as a verb, means to enter into such a register to approve a medicine for circulation in the local market;

"registration" means registration of a medicine or medical device made in terms of section 15;

"schedule" means a category of a registered medicine or medical device classified by the Minister in terms of section 32;

"sell" means to sell by a manufacturer, a wholesale or a retail and includes to import, offer, advertise, keep, expose, transmit, consign, covey, deliver for sale, authorise, direct, allow a sale, prepare or possess for the purposes of sale and barter or exchange, supply or dispose of to a person, whether for consideration or otherwise and "sale" and "sold" have a corresponding meaning.

PART II - THE MEDICINES AND MEDICAL DEVICES CONTROL AUTHORITY

Establishment of the Medicines and Medical Devices Control Authority

3. (1) There is established a body to be known as the Medicines and Medical Devices Control Authority.

(2) The Authority is a body corporate with perpetual succession and a common seal and may -

(a) acquire, hold, dispose of movable or immovable property;

(b) sue and be sued; and

(c) subject to this Act, exercise rights, powers and privileges and perform all acts that bodies corporate may by law perform.

Functions of the Authority

4. The functions of the Authority are to -

(a) regulate the manufacture, import and export, storage, distribution, sale and use of medicines and medical devices;

(b) ensure that medicines and medical devices that are circulating in the country are of good quality, efficacy and safe use, by regulating the pharmaceutical industry; and

(c) perform such other functions in relation to this Act as the Board may direct.

The Board of the Authority

5. There is established a Board which is the governing body of the Authority.

Composition of the Board

6. (1) The Board shall comprise of the following members who shall be appointed by the Minister by notice published in the Gazette:

(a) the Head of Pharmaceutical Services in the Ministry of Health;

(b) a medical practitioner nominated by the Medical Dental and Pharmacy Council;

(c) four pharmacists who have expertise in pharmaceutics, pharmacology, pharmacy practice and pharmaceutical analysis and who shall be nominated by the Medical, Dental and Pharmacy Council;

(d) the Director of Livestock Services or his representative from the Ministry of Agriculture and Food Security;

(e) the Head of Legal Department in the Ministry of Health;

(f) a radiation physicist, who shall be nominated by the Lesotho Medical, Dental and Pharmacy Council; and

(g) a diagnostic radiographer, who shall be nominated by the Lesotho Medical, Dental and Pharmacy Council.

(2) The members shall elect from among their number, a Chairperson and a Deputy Chairperson, who shall be removed through majority of votes of Board members.

(3) The Minister shall cause the names of the members to be pub-

lished by notice in the Gazette.

(4) The Board may, when necessary, invite a person with relevant expertise on an ad hoc basis to advise the Board on a particular issue but this person shall not vote.

Functions of the Board

7. (1) The functions of the Board are to -

(a) advise the Minister on matters relating to medicine and medical device;

(b) issue a license to a person who deals in medicines;

(c) make recommendations to the Minister on classification of a medicine or medical device into Schedules to be used by the specified groups of health care personnel and veterinarian;

(d) approve the appointment and removal of the staff of the Authority which is made by the Chief Executive Officer;

(e) consider approving the recommendations of the Chief Executive Officer, relating to terms and conditions for employment of the staff of the Authority;

(f) perform any other duty in relation to the functions of the Authority;

(g) provide strategic guidance to the Authority in the discharge of its functions;

(h) approve the strategic and annual work plan and budget of the Authority;

(i) review the annual reports presented by the Chief Executive Officer;

(j) monitor and evaluate activities of the Authority; and

(k) establish such committees as it deems necessary for the function of the Board.

Tenure of office

8. (1) A member, except an ex-officio member, shall hold office for a period of three years from the date of his appointment.

(2) A member, except an ex-officio member, shall hold office for not more than two consecutive terms.

Remuneration of members of the Board

9. A member shall receive such remuneration and allowances as may be determined by the Minister in consultation with the Minister responsible for finance.

Meetings of the Board

10. (1) The Board shall meet at least quarterly in a year and at such places as may be determined by the Chairperson or whenever the business of the Board requires.

(2) The Chairperson may, at any time, convene a special meeting of the Board on a written request of not less than three members.

(3) The Chairperson shall preside at all meetings of the Board and in his absence, the Deputy Chairperson shall preside and if both the chairperson and the Deputy Chairperson are not present, members present shall elect from among themselves one of their members to preside.

(4) A quorum for a meeting of the Board shall be two thirds majority of the members voting.

(5) A decision of the Board shall be constituted by the majority of the members present and voting and in the event of an equality of votes, the person presiding shall have a casting vote.

(6) A decision made or an act done by the Board shall not be invalid by reason of a vacancy in the Board or because a person who is not entitled to be a member sat or acted as a member at the time when the decision was made.

Vacation of office of a member of the Board

11. (1) A member shall vacate his office if he -

(a) has been absent from three consecutive meetings without leave of the Board;

(b) has been convicted of a criminal offence or an offence under this Act;

(c) has neglected his duties as a member;

(d) has been engaged in a misconduct;

(e) is mentally or physically incapable of performing his duties as a member;

(f) is disqualified from carrying on his profession;

(g) resigns;

(h) is an unrehabilitated insolvent;

(i) ceases to be a citizen of Lesotho; or

(j) becomes a member of Parliament.

(2) The Minister may, where the office of a member becomes vacant before the expiration of the period for which the member was appointed, appoint another person to hold office for the remainder of the period of which that member was appointed.

Disclosure of interest

12. (1) If a member of the Board or any person related to the member -

(a) tenders for, acquires or holds a direct or indirect pecuniary interest in a contract with the Authority or in any application for the registration of a medicine under consideration by the Authority;

(b) knowingly acquires or holds a direct or indirect pecuniary interest in a company or an association of persons applying for the registration of a medicine by the Authority; or

(c) has an interest in the pharmaceutical or health care industry,

which results in his private interest coming or appearing to come into conflict with his duties as a member, the member shall disclose the interest or fact to the Board.

(2) A member who discloses such interest in terms of subsection (1) shall not take part in the consideration or discussion of or vote on any question before the Authority which relates to a contract, right, interest or registration of a medicine referred to in subsection(1).

(3) A person who fails to comply with this provision commits an offence and is liable on conviction to a fine not exceeding Five Thousand Maloti or to imprisonment for a period not exceeding one year or both.

PART III - ADMINISTRATION

Chief Executive Officer

13. (1) There shall be a Chief Executive Officer of the Authority who -

(a) is appointed by the Board on a competitive basis;

(b) is a pharmacist; and

(c) has managerial experience.

(2) The Chief Executive Officer shall attend meetings of the Board but shall not vote and shall not be paid a sitting allowance.

(3) The Chief Executive Officer shall be the Secretary of the Board.

Functions of the Chief Executive Officer

14. The functions of the Chief Executive Officer shall, subject to the general supervision and control of the Board, be to -

(a) manage the staff, affairs and assets of the Authority;

(b) supervise and control the activities of an employee of the Authority in the course of his employment;

(c) enter into the register all registered medicines and medical devices;

(d) keep and maintain a medicine and a medical device register;

(e) employ staff of the Authority on such terms and conditions, and with the approval of the Board as may be necessary for conducting the affairs of the Authority; and

(f) carry out any other duties imposed on him under this Act.

PART IV - REGISTRATION AND LICENSING

Registration of a medicine and a medical device

15. (1) No person shall sell, manufacture, distribute, dispense, import, export or handle a medicine or a medical device, unless the medicine or medical device is registered with the Board and the person is issued with a licence to do so by Board.

(2) A person who wishes to register a medicine or medical device with the Authority in terms of subsection (1), shall submit an application for registration in such a manner and on such a form as may be determined by the Minister by regulations.

(3) An application submitted in terms of subsection (2) shall be ac-

companied by -

(a) particulars on the safety, quality and therapeutic efficacy of the medicine or medical device;

(b) a sample of the medicine or medical device, where appropriate; and

(c) such an application fee as may be determined by the Minister.

(4) The Board shall register the medicine or medical device which is sold, manufactured, distributed or circulated in the country if -

(a) it is in the public interest;

(b) the medicine or the medical device, meets the required safety, quality and therapeutic efficacy approved by the Board;

(c) the premises at which the medicine or medical device is manufactured, complies with current good manufacturing practices set by the Authority and is issued with the license.

(d) a person handling the medicine or medical device is issued with a license under section 29 (3).

(5) The Chief Executive Officer shall, within a minimum of ninety days of receiving an application referred to in subsection (3), submit the application with the approved particulars and where appropriate, with a sample medicine or medical device to the Board for consideration.

(6) On receiving the application, the Board -

(a) shall undertake an investigation regarding the medicine or medical device;

(b) may inspect a manufacturing plant to ensure that all the conditions, requirements and standards set out for reg-

istration of a medicine or a medical device are met; and

(c) may require further or additional information relating to the application.

(7) The Board shall, after consideration of an application, and if it is satisfied that a medicine or a medical device complies with subsection (4), approve the registration of the medicine or the medical device with such terms and conditions as it may consider necessary.

(8) The Chief Executive Officer shall, within thirty days of receipt from the Board's approval or disapproval of registration of a medicine or a medical device inform the applicant of the approval;

(9) Where the registration of the medicine or medical device has been approved by the Board, the Chief Executive Officer shall -

(a) register the medicine or the medical device; and

(b) issue a certificate of registration of the medicine or the medical device.

(10) The medicine or the medical device shall be registered under a name approved by the Board and shall be allocated with a registration number.

(11) Where the application is not approved by the Board, an applicant may within a period of thirty days after such disapproval, lodge an appeal, in writing, to the Appeals Committee under section 43.

(12) The Authority shall issue guidelines on the manufacturing, import and export of medicines and medical devices.

(13) A person who contravenes subsection (1) commits an offence and is liable on conviction to a fine not exceeding Fifty Thousand Maloti or imprisonment for a period not exceeding ten years or both.

Prohibition of sale of an unregistered medicine or a medical device

16. (1) No person shall sell a medicine or medical device unless the medicine or medical device is registered in terms of section 15.

(2) Subject to subsection (1), the Minister may, on the recommendation of the Board and by notice published in the Gazette, declare the medicine or medical device available in Lesotho, to be subject for registration.

(3) Where a declaration notice in terms of subsection (2) is made in relation to the medicine or medical device which immediately before the date of publication of this Act -

(a) was available for sale in Lesotho, the notice shall come into operation on a date to be appointed by the Minister by notice published in the Gazette; and

(b) was not available for sale in Lesotho, the notice shall come into operation on the date of publication in the Gazette.

(4) Notwithstanding subsection (1), a person may sell an unregistered medicine or medical device if the medicine or medical device was available in Lesotho before a declaration notice is published in terms of subsection (2) and an application for registration of the medicine or medical device is submitted to the Board and an application fee is paid.

(5) An unregistered medicine or medical device sold in terms of subsection (4) shall continue to be on sale until -

(a) the Board has approved the application for registration and the medicine or medical device shall be sold as a registered medicine or medical device;

(b) the Board has not approved the application for registration of the medicine or the medical device;

(c) the medicine or the medical device is not allowed for sale in Lesotho;

(d) the application for registration is withdrawn by the applicant;

(e) the application for registration has lapsed; or

(f) the Board withdraws in writing, the right to sell the unregistered medicine or the medical device.

(6) A person who contravenes sub-section (1) commits an offence and is liable on conviction to a fine not exceeding Fifty Thousand Maloti or to imprisonment for a period not exceeding ten years or to both.

Sale of an unregistered medicine or medical device

17. (1) The Board may, in writing, authorise a person to sell a specified quantity of a particular medicine or medical device which is not registered, for a specified period and to a person or institution determined by the Board.

(2) The medicine or medical device sold in terms of subsection (1) shall be used for the specified purpose and only in a manner determined by the Board.

(3) The Board may by notice in writing withdraw an authorisation made in terms of subsection (1) where the medicine is not used for the specified purpose.

Renewal of registration

18. (1) A holder of a certificate of registration may submit an application for renewal of certificate of registration of a medicine or a medical device to the Board, six months before the expiry of the original registration.

(2) The application submitted in terms of sub-section (1) shall be accompanied by a prescribed renewal fee.

Transfer of certificate of registration

19. (1) The certificate of registration is transferable.

(2) Where a holder of a certificate wishes to transfer the certificate, he shall submit an application to the Board for approval to transfer the certificate to another person who qualifies to apply for the registration of a medicine or medical device.

(3) An application made pursuant to subsection (2) shall be -

(a) submitted to the Board in a form determined by the Minister by regulations;

(b) accompanied by a copy of the certificate to be transferred; and

(c) accompanied by a transfer fee determined by the Minister by regulations.

Cancellation or amendment of registration

20. (1) The Board may cancel or amend the registration of the medicine or the medical device if -

(a) it is not in the public interest to register the medicine or medical device;

(b) the retention fee is due and it is not paid;

(c) the holder of a certificate fails to comply with the set conditions of registration determined by the Board;

(d) the medicine or medical device no longer complies with the requirements set out by the Board;

(e) there are false or misleading advertisements in relation to the medicine or medical device; and

(f) the premises under which the medicine or medical device is manufactured, fail to comply or meet the required standards set out by the Board.

(2) The Board shall, before cancelling or amending the registration of a medicine or medical device -

(a) give notice to the holder informing him of the intention to cancel or amend;

(b) give the holder an opportunity of appearing before the Board and being heard;

(c) specify the grounds on which the cancellation or amendment is to be made;

(d) provide for the holder to indicate reasons why the Board should not cancel or amend the registration; and

(e) if necessary direct the Chief Executive Officer to cancel or amend the entries in the register.

Notification of registration, cancellation or amendment of a medicine or the medical device

21. (1) The Minister shall, by notice published in the Gazette, notify the public of the registration, cancellation or amendment of the medicine or the medical device.

(2) The notice referred to in sub-section (1) shall specify -

(a) in the case of a registration of the medicine or medical device,

(i) the name under which the medicine or medical device is registered;

(ii) the active components of the medicine or the medical device;

(iii) the name of the applicant;

(iv) the name of the manufacturer;

(v) the registration number allocated to the medicine or medical device; and

(vi) the conditions, if any, under which the medicine or medical device is registered;

(b) in the case of a cancellation or variation of the registration of the medicine or the medical device,

(i) the name under which the medicine or the medical device is registered;

(ii) the name of the applicant; and

(iii) the registration number allocated to the medicine or the medical device.

Medicines Register

22. (1) The register shall contain the name and all relevant particulars of every -

(a) registered medicine;

(b) registered complimentary medicine;

(c) registered medical device;

(d) registered cosmetic;

(e) licensed person dealing with medicines or medical devices;

(f) licensed premises dealing with medicines or medical devices;

(g) registered nutriceutical; and

(h) registered related substance.

(2) The Chief Executive Officer shall keep the register in electronic form.

Amendment and cancellation of entries into a Register

23. (1) A person may, in a prescribed form and accompanied by a prescribed fee, submit an application to the Chief Executive Officer to amend or cancel a medicine in a register.

(2) The Chief Executive Officer shall, sixty days after receipt of an application submitted in terms of subsection (1), submit the application to the Board for consideration.

(3) If the Board grants its approval in respect of an application submitted to it in terms of subsection (1), the Chief Executive Officer shall enter the amendment or cancellation in the register.

Retention fee

24. (1) A holder of a certificate shall pay an annual retention fee in a form and manner determined by the Minister for a registered medicine or a medical device.

(2) The Minister shall set an annual retention fee which shall be levied on all registered medicines or medical devices.

Purchase and sale of the medicine and the medical device by a wholesaler

25. (1) A wholesaler shall purchase a medicine or medical device only from the manufacturer or from the primary importer of the finished product.

(2) The wholesaler shall sell the medicine or medical device to the retail sector or another wholesaler depending on the authorised category of Schedules by the Board.

(3) Where the medicine or medical device lacks safety, quality and efficacy, the importer or wholesaler, shall return the medicine or medical device to the manufacturer from whom the medicine or medical device was obtained and shall claim and be entitled to a refund.

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

(5) A person who contravenes sub-section (1) commits an offence and is liable on conviction to a fine not exceeding Sixty Thousand Maloti or to imprisonment for a period not exceeding twelve years or to both.

Return of undesirable medicine and medical device

26. (1) If the Board is of the opinion that it is not in the public interest that a medicine or medical device be made available to the public, it may, by written notice, direct a person who is in possession of such medicine or medical device, to return any quantity of such medicine or medical device to the manufacturer or in the case of any imported medicine, to the importer concerned or to deliver or send it to any other person designated by the Board.

(2) The Board may, by notice in writing, direct a manufacturer or importer of such medicine who has in his possession any quantity of the medicine, including any quantity returned, delivered or sent to him in pursuance of a directive under subsection (1), or any other person to whom any quantity of such medicine has been so returned, delivered or sent, to deal with or dispose of that quantity in such a manner as the Board may determine.

(3) A person who fails to comply with this section commits an offence and is liable on conviction to a fine not exceeding Fifty Thousand Maloti or to imprisonment for a period not exceeding ten years or both.

Licencing of a person handling a medicine or a medical device

27. (1) A person shall not manufacture, dispense, sell, distribute or import a medicine or a medical device unless -

(a) he is issued with a licence by the Board;

(b) the premises on which the medicine or the medical device is manufactured, sold or distributed complies with conditions and standards determined by the Board.

(2) A person shall be issued with a licence in terms of subsection (1) depending on his qualification, registration under such terms and conditions as may be prescribed by the Board.

(3) A person who fails to comply with subsection (1) commits an offence and is liable on conviction to a fine not exceeding Fifty Thousand Maloti or to imprisonment for a period not exceeding Ten years or to both.

Application for a licence

28. (1) A person shall make an application in writing to the Board for a licence to manufacture, dispense, sell, distribute or import a medicine or a medical device in a manner determined by the Board.

(2) The Board may, where necessary, request an applicant to furnish it with further information.

(3) The Board shall, where satisfied that the prescribed requirements and conditions for application of a licence are met and within thirty days after receiving an application and on payment of a prescribed fee, issue a licence to the person who made the application.

(4) Where an application for a licence is made by a registered company, the Board shall issue a licence only if one of the shareholders and directors of the company is a pharmacist and a citizen of Lesotho.

(5) The Board may refuse to issue a licence where an application does not meet the prescribed requirements and conditions.

(6) The Board shall, within thirty days after the decision to refuse to issue a licence, inform the person who made the application in writing, with reasons for such refusal.

(7) A licence issued in terms of subsection (3) shall be valid for a period of one year and is subject to renewal under the same terms and conditions of a previous application.

(8) Where the Board has refused to issue an applicant with a license in terms of subsection (5), the person who made the application may lodge an appeal against the decision of the Board to the Appeals Committee.

Cancellation, suspension or amendment of a license

29. (1) A licence issued in terms of section 28 (2) may be cancelled, suspended or amended if -

(a) the holder of the license fails to follow the terms and conditions prescribed; or

(b) the Board considers that it is in the public interest.

(2) Where a holder of a license is not satisfied with the decision of the Board to cancel, suspend or amend the license or the conditions and requirements under which a license was issued, he may lodge an appeal against such a decision to the Appeals Committee.

Importation and exportation of a medicine or a medical device

30. (1) No person shall import or export a medicine or medical device unless the -

(a) person is licensed in terms of this Act to import or export;

(b) person in the case of an unregistered medicine or medical device, is authorised by the Board to import or export the medicine or the medical device; and

(c) container or package in which the medicine or the medical device is contained in, bears a label written in Sesotho or English;

(d) medicine or medical device is registered in terms of this Act or as determined by the Board; and

(e) medicine or medical device complies with the Board's requirements for quality, efficacy and safety.

(f) a certificate for such import or export has been issued to him by the Board upon payment of such fee as may be determined by the Minister.

(2) A person who fails to comply with this provision commits an offence and is liable on conviction to a fine not exceeding Forty Thousand Maloti or to imprisonment for a period not exceeding eight years or both.

PART V - POST MARKETING SURVEILANCE AND SAFETY MONITORING

Pharmacovigilance

31. (1) The Authority shall -

(a) monitor and analyse adverse effects or events relating to a medicine or medical device regulated under this Act;

(b) establish casualty, take remedial actions and report to international safety monitoring system; and

(c) take appropriate regulatory action when necessary, including but not limited to revising the marketing authorisation, labelling or warning requirements of a medicine or medical device.

(2) The Authority shall issue guidelines to provide for mandatory reporting, submission of periodic safety updates by manufactures and distributors and voluntary reporting by health professionals and the public.

Quality Monitoring

32. (1) The Authority may institute a risk-based testing scheme consisting of sampling of medicines and medical devices throughout the supply chain, to identify the products most at risk or likely to be falsified or sub-standard and shall take appropriate action to protect the public health, including enforcement measures under this Act.

(2) In performing its functions, the Authority shall utilise the National Pharmaceutical Quality Control Laboratory or any accredited laboratory within or outside the country for analysis of medicines and medical devices.

Recall, non-release or non-dispensation of a medicine or medical device

33. The Board shall, where it considers that a medicine or medical device is not fit for consumption, cause the Minister to declare, by notice published in the Gazette, that the medicine or medical device -

(a) is prohibited for sale to the public;

(b) is recalled from the market if it is already on sale to the public;

(c) be returned to the manufacturer; or

(d) be disposed off in a prescribed manner.

PART VI - NATIONAL REGULATORY SYSTEM

Classification of Schedules of a medicine or a medical device

34. (1) The Minister shall, on the recommendation of the Board and by notice published in the Gazette, classify a registered medicine or medical device into the following Schedules:

(a) Schedule 0;

(b) Schedule 1;

(c) Schedule 2;

(d) Schedule 3;

(e) Schedule 4;

(f) Schedule 5;

(g) Schedule 6;

(h) Schedule 7; and

(i) Schedule 8.

(2) The Minister shall in classifying the registered medicine or medical device, take into consideration, who -

(a) utilises the registered medicine or medical device;

(b) acquires the registered medicine or medical device;

(c) manufactures the medicine or medical device;

(d) sells the medicine or medical device;

(e) distributes the medicine or medical device;

(f) imports the registered medicine or medical device; and

(g) dispenses the medicine or medical device.

(3) The Minister may, on the recommendation of the Board and by notice published in the Gazette, amend the Schedules referred to in sub-section (1).

Control of a scheduled medicine or a medical device

35. The Minister may, on the recommendation of the Board, make regulations for the control, handling, prescription and dispensing of a scheduled medicine or medical device.

Generic substitution

36. (1) A pharmacist or person issued with a license to sell a medicine or medical device, under section 29 (3) -

(a) upon dispensing a medicine or medical device to a person in possession of a prescription inform the person of the benefits of substituting the prescribed medicine or the medical device with a generic medicine or medical device; and

(b) may, subject to subsections (2) and (3), dispense or sell the generic medicine or medical device instead of the medicine or medical device on the prescription.

(2) A pharmacist who dispenses or sells the generic medicine or medical device in terms of subsection (1) (b), shall record the brand name or the name of the manufacturer of the generic medicine or medical device in the pre-

scription book or in any other permanent record required to be kept in the prescribed manner.

(3) A pharmacist shall not dispense or sell the generic medicine or medical device if -

(a) the person who is issued with a prescription, has written on the prescription in his own hand the words "no substitution" next to the medicine or the medical device prescribed;

(b) the patient expressly objects to the generic medicine or medical device;

(c) the retail price of the generic medicine or medical device is higher than that of the medicine or medical device specified on the prescription; or

(d) the Board has declared that the medicine or medical device cannot be substituted.

(4) A pharmacist who sells a generic medicine or medical device in accordance with this Act, does not incur a greater liability in respect of that sale than the liability which he would have incurred had he sold the medicine or medical device specified in a prescription.

(5) The Minister may, on the recommendation of the Board, and by notice published in the Gazette, declare a medicine or medical device not to be a generic medicine or medical device.

Labelling

37. (1) A person shall not sell a medicine or medical device unless the immediate container or the package in which the medicine or the medical device is sold in, bears a label written in Sesotho or English and sets out the -

(a) registered name and registered number of the medicine or medical device; and

(b) particulars of and information about the medicine or

medical device, except where a medical doctor, dentist or veterinarian indicates on the prescribed form that a container or package in which the medicine or the medical device is dispensed, shall not be labelled.

(2) A person who sells the medicine or the medical device, in a container which bears a false or misleading statement in connection with the contents, commits an offence and is liable on conviction to a fine not exceeding Thirty Thousand Maloti or imprisonment for a period not exceeding six years or both.

Advertisement

38. (1) A person shall not -

(a) advertise, publish, distribute or in any other manner bring to the notice of the public or cause, to be advertised, publish, distribute or in any other manner cause to bring to the notice of the public, a false or misleading information relating to medicine or medical device; or

(b) in an advertisement, publication, distribution or in any other manner that brings notice to the public, make a claim that the therapeutic quality, efficacy and effect of the medicine or medical device is that other than which is stated by the Board in terms of this Act or state or suggest that the medicine or medical device should be used for a purpose under circumstances or in a manner that is not stated by the Board in terms of this Act; or

(c) advertise a medicine or a medical device without the approval of the Authority.

(2) A person who makes a false or misleading statement -

(i) in an application for registration of a medicine or medical device or in any other application required under this Act; and

(ii) in the course of the sale of the medicine or med-

ical device;

commits an offence and is liable on conviction to a fine not exceeding Forty Thousand Maloti or to imprisonment for a period not exceeding eight years or to both.

Adulteration of medicines

39. (1) No person shall adulterate a medicine or medical device for sale.

(2) A person who contravenes subsection (1), commits an offence and is liable on conviction to a fine not exceeding Ten Thousand Maloti or imprisonment for a period not exceeding two years or both.

Counterfeit medical products

40. (1) No person shall -

(a) manufacture, sell, distribute, dispense, import, export or expose for sale, a counterfeit medical product;

(b) own, possess or control a counterfeit medical product in transit, trans-shipment, free-trade zone, bonded warehouse and in other situations of international commerce;

(c) introduce into the distribution chain, a counterfeit medical product by any means, including but not limited to manufacturing, selling, delivering, distributing, importing, donating, storing or otherwise supplying others with a counterfeit medical product;

(d) own, possess or control a counterfeit medical product which is likely to enter the distribution chain;

(e) design, produce, print, sell, deliver, distribute, import, export, donate or otherwise supply others with a package, label or any material intended for use for a counterfeit medical product;

(f) manufacture, transport or distribute an equipment, a

component, a documentation or any material, used in the production of or to accompany the distribution of a counterfeit medical product with the knowledge to the fact that they may or are likely to be used for such purposes;

(g) provide a service such as an on-line service, electronic sale platform, electronic payment or transportation where he has reasonable grounds to believe or notice has been given to him by the appropriate authorities that the service is exploited by a person engaged in a counterfeit medicine; and

(h) conspire to commit, attempt to commit, aid, abet, counsel, facilitate in the usage of or incite an offence set forth in subsection(3) in the usage of a counterfeit medical product as provided for in paragraph (a), (b), (c), (d), (e) and (f).

(2) A person who contravenes subsection (1) commits an offence and is liable on conviction to a fine not exceeding Fifty Thousand Maloti or to imprisonment for a period not exceeding ten years or both.

(3) Where a person is convicted of an offence under subsection (2), the court -

(a) shall order that the counterfeit medical product be forfeited to the State, unless the counterfeit medicine is further required as an exhibit at a trial; and

(b) may order that a vehicle, aircraft, vessel, boat, animal, receptable container or thing in or upon which a medicine was found or was used for the purpose of manufacturing or in connection with the counterfeit medicines, be forfeited to the State.

Inspectors

41. (1) The Board shall appoint an inspector to perform the functions and exercise the powers conferred on him under section 40.

(2) The Board shall issue an inspector with an identity document, authorising him to act as such.

(3) An inspector shall, upon inspection of premises under this Act, produce an identity document to a person in charge of the premises.

Functions and powers of inspectors

42. (1) An inspector may with or without the presence of a police officer-

(a) inspect personnel and premises dealing with a medicine or a medical device to determine and ensure that all requirements and conditions for licencing of the personnel and premises are complied with;

(b) collect such information as he deems necessary for the performance of his function under this Act; and

(c) at reasonable times -

(i) enter upon and inspect any premises, vehicle, vessel or aircraft in or on which there is suspected to be the medicine or medical device which contravenes a provision of this Act;

(ii) seize the medicine or medical device, book, record or a document found in or on any premises, vehicle, vessel or aircraft which contravenes a provision of this Act; and

(iii) take a sample of the medicine or medical device, as he may consider necessary and submit it to the relevant authorities for analysis.

(2) Where an inspector takes a sample in terms of subsection (1) (c) (iii), he shall ensure that the sample is,

(a) taken in accordance with the prescribed procedure and form and in the presence of a person in charge of the

medicine or medical device and if the person in charge for any reason is absent, in the presence of any other witness;

(b) immediately packed, sealed and labelled in a manner prescribed by the Board; and

(c) submitted to an analyst with a certificate of inspection signed by him.

(3) A person who distracts an inspector in the performance of his functions commits an offence and is liable on conviction to a fine not exceeding Fifty Thousand Maloti or to imprisonment for a period not exceeding ten years or to both.

(4) Where an inspector suspects that the premises within which a medicine or a medical device is sold is in contravention of the provisions of this Act, the inspector may close the premises.

Analysts

43. (1) The Board, may appoint an analyst to examine or analyse samples of a medicine or medical device taken by an inspector under section 40 (1) (c) (iii) to determine the safety, quality and purity of pharmaceuticals, animal and plant products manufactured for consumption, export and import.

(2) The analyst to whom a sample is taken to, shall, after receiving the sample, examine or analyse the sample within a prescribed period and shall in writing state the result of the examination or analysis and issue a certificate of analysis to the Board.

(3) The Minister may where necessary, designate any place as an analytical laboratory

(4) A person who with fraudulent intent, tampers with a sample of a medicine or medical device provided for under this section commits an offence and is liable on conviction to a fine not exceeding Fifty Thousand Maloti or to imprisonment for a period not exceeding ten years or both.

Clinical trials

44. (1) A person shall, before a medicine or medical device is released to the public, make an application to the Board to conduct a clinical trial in order to determine the safety and therapeutic effect of the medicine or the medical device.

(2) A clinical trial may be conducted by using -

(a) a group of human beings if the medicine or medical device to be assessed is intended for human consumption; and

(b) a group of animals if the medicine or the medical device to be assessed is intended for animal consumption.

(3) The Board shall, in determining an application made under subsection (1) -

(a) consider whether the clinical trial will provide relevant information relating to the safety or therapeutic effect of the medicine or medical device; and

(b) request the person who wishes to conduct a clinical trial to provide the information that may be considered and requested by the Board relating to the participant in the clinical trial.

(4) A person shall, in submitting an application under subsection (1), provide all information related to the assessed medicine or a medical device to the -

(a) Board;

(b) person on whom the clinical trial is conducted on;

(c) guardian of a minor, in the case where the person whom the clinical trial is conducted on is a minor; or

(d) owner of an animal, in the case where the clinical trial

is conducted on an animal.

(5) The Board shall monitor the clinical trials to ensure that the participants are safe and that the objectives of the trial are achieved.

(6) The Board shall suspend or stop the clinical trial if it considers it necessary -

(a) for the interest and safety of the participant; and

(b) in the public interest.

(7) A manufacturer shall,

(a) within thirty days of completion of a clinical trial, provide the Board with a report with details on the findings of the trial in terms of ethical considerations; and

(b) ninety days after the clinical trial has been completed, provide the Board with a report of the findings in terms of clinical considerations.

(8) The Board shall, within ninety days of receipt of the report furnish the Minister with the report and make a recommendation about the medicine or medical device.

(9) A person who fails to comply with this section commits an offence and is liable on conviction to a fine not exceeding One Million Maloti or to imprisonment for a period not exceeding Twenty-five years or to both.

PART VII - APPEALS PROCEDURES

Appeals Committee

45. (1) The Minister shall appoint an Appeals Committee which shall be responsible for hearing Appeals against decisions of the Board.

(2) The Appeals Committee shall be appointed on an adhoc basis to deal with matters brought on appeal by an applicant.

Composition

46. (1) The Appeals Committee shall comprise of the following members:

(a) one legal expert with five years experience in law, who shall be nominated by the Law Society and who shall be the Chairperson;

(b) one pharmaceutical specialist and medical device expert who shall be nominated by the relevant professional councils; and

(c) one practitioner who is registered as a specialist in medicine, nursing, veterinary medicine or public health, and may be called upon depending on the nature of the appeal.

(2) No member shall have a direct or indirect interest in the affairs of the appellant or respondent.

Appeal

47. (1) Any person aggrieved by a decision of the Board may, within 14 days of receipt of the decision, in the prescribed manner and upon payment of the prescribed fee, appeal against such decision to the Appeals Committee appointed by the Minister for the purposes of the appeal concerned.

(2) An appeal shall -

(a) be in writing;

(b) state reasons for appealing; and

(c) give an address to which notices may be sent.

(3) The Appeals Committee may, after hearing the appeal -

(a) confirm, set aside, vary or reverse the decision of the Board; and

(b) direct the Board to execute the decision of the Appeals Committee.

(4) The decision of the Appeals Committee shall be in writing and a copy of the decision shall be furnished to the appellant and the Board.

Remuneration

48. The members of the Appeals Committee shall be paid such sitting allowance as may be determined by the Minister, after consultation with the Minister responsible for finance.

PART VIII - INTERNATIONAL COOPERATION AND HARMONISATION OF REGULATION OF MEDICAL PRODUCTS

Participation in regulatory harmonization schemes

49. The Authority shall participate and cooperate with regional, continental and international medicines regulatory authorities.

Harmonization of regulatory requirements and activities

50. (1) The Minster shall take appropriate measures in line with the SADC protocol or other international health protocols to ensure the effective cooperation with Ministers responsible for health and other health agencies in other countries of the region to -

(a) harmonize the registration of a medicine or a medical device, inspection, Quality Management System, Information Management System, evaluation, joint inspection and other regulatory activities as may be necessary;

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

(c) provide for the recognition of regional and international technical guidelines developed and published by the World Health Organisation and the International Conference on Harmonisation of Technical Requirement for Registration of Pharmaceuticals for Human Use;

(d) provide for the harmonization of data requirements for evidence of quality, safety and efficacy of a medicine and the grounds on which authorisation for distribution shall be granted within the region;

(e) provide for any necessary legal mechanisms for regulatory harmonisation of enforcement.

(2) The Authority shall take such measures that may ensure mutual recognition of regulatory decisions.

(3) The Authority shall take such measures to share summary evaluation and inspection reports.

(4) The Authority shall participate in a common post-market surveillance conducted in accordance with national, regional and internationally recognised standards at regional level.

(5) The Authority shall provide for cooperation with other regulatory authorities for the purpose of strengthening national regulatory capacity.

(6) The Authority shall establish networks with other medical products regulatory authorities or agencies and collaborate in protecting public health through enforcement activities.

(7) The Authority shall establish exchange programmes with other medicines regulatory authorities or agencies so as to keep abreast with the ever evolving scientific development in the field of medical products.

Transparency and information sharing

51. (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 the Authority shall provide to and share regulating information relevant on medical products.

(3) The Authority shall establish a paper and an electronic web

based copy including but not limited to regulations, laws, forms, applications or list of registered medicines.

International cooperation

52. (1) The Authority shall share information on pharmaceutical intelligence with other medical products regulatory authorities and agencies at regional, continental and international level.

(2) The Authority shall take proper measures to ensure effective bilateral, regional and international cooperation to combat the production, circulation and use of falsified and substandard medicines.

PART IX - FINANCE

Funds and assets of the Authority

53. The funds and assets of the Authority shall consist of,

(a) such sums as may be provided for by Parliament;

(b) all monies and property that may from time to time be borrowed, donated, lent or granted to the Authority by the government or any other foreign government or international organization;

(c) all investments or property acquired or vested in the Authority and all monies earned or arising from investments or property of the Authority; and

(d) monies lawfully raised or borrowed by the Authority.

Accounts

54. (1) The Authority shall keep proper books of accounts and records relating to its fund.

(2) The accounts kept in terms of subsection (1) shall be prepared in accordance with the financial reporting standards issued, adopted and published by the Lesotho Institute of Accountants.

Audit

55. (1) The accounts of the Authority shall be audited by the Auditor-General or by an independent auditor authorised by him under the Audit Act, 1973 and in accordance with the requirements and qualifications provided for under the Lesotho Institute of Accountants Act, 1977.

(2) The accounts of the Authority shall be prepared for auditing not later than three months after the end of the financial year.

Reporting of audited accounts

56. (1) The Authority shall, after the close of each financial year, but not later than six months, submit the following documents to the Board-

(a) an annual report on the activities of the Authority during the preceding year, including the assessment relating to the achievement of the objectives of the Authority, compliance policies, procedures and criteria established by the Board and the effectiveness of the administration of the Authority;

(b) audited financial statements;

(c) an income statement for the preceding financial year and

(d) a balance sheet showing the assets and liabilities of the Authority at the close of the year.

(2) The Board shall submit a copy of the annual report and audited accounts of the Authority to the Minister, who shall submit it to Parliament fourteen days after receipt of the report.

PART X - REGULATIONS AND GUIDELINES

Code of Ethics

57. (1) The Board may formulate a code of ethics relating to the marketing policies of pharmaceutical and medical devices companies.

(2) Any code of ethics formulated by the Board in terms of subsection (1) shall be adopted and complied with by pharmaceutical and medical devices companies.

(3) A person who fails to comply with the code of ethics commits an offence and is liable on conviction to a fine not exceeding Ten Thousand Maloti or imprisonment for a period not exceeding two years or both.

Preservation of secrecy

58. A person shall not -

(a) disclose to any other person information acquired by him in the exercise of his powers or in the performance of his functions under this Act; or

(b) use such information for self-gain except for purposes of legal proceedings when so required to do so by a competent court.

Regulations

59. (1) The Minister may, make regulations for carrying out the provisions of this Act into effect.

(2) Without prejudice to the generality of subsection (1), the Minister may -

(a) prescribe a person or a group of persons who may apply for the registration of the medicine or medical device;

(b) prescribe the forms to be used in an application for registration of a medicine or medical device and the particulars which must be furnished with such application;

(c) prescribe the circumstances in which or the conditions under which and a person to whom the medicine or medical device is made available to the public;

(d) prescribe, in consultation with the Minister responsible

for finance;

(i) a fee payable to the Authority in respect of registration of the medicine or the medical device; and

(ii) any other fee payable in terms of this Act;

(e) prescribe the minimum standards of good manufacturing practices to be followed in the manufacture of the medicine or the medical device.

PART XI- MISCELLANEOUS

Exemptions

60. The Minister may by notice published in the Gazette, on the recommendation of the Board, and subject to such conditions as he may specify, exempt a medicine or medical device from the operation of any or all of the provisions of this Act.

Existing staff

61. (1) A public officer who is employed in the Ministry of Health and who deals with regulation of medicine may, if he shows interest, be employed with the Authority upon the commencement of this Act.

(2) Where a public officer is employed in the Authority in terms of sub-section (1), he shall be deemed, upon employment to the Authority, to have retired from the Public Service from the date of assumption of his duties with the Authority and shall be entitled to such terminal benefits due to him, under the appropriate legislation.

(3) A public officer who does not wish to be employed with the Authority may be re-deployed in the public service subject to availability of a suitable position in the public service.

(4) Where no suitable position is available in the public service, the public officer referred to in subsection (3) shall be deemed to have retired from the public service and shall be entitled to such terminal benefits as may be due

under the applicable law.

Inconsistency with other legislation

62. In the event of any inconsistency between the provisions of this Act and the operation of any other law, the provisions of this Act shall prevail to the extent of the inconsistency.

NOTE

1. Act No. 12 of 1970

GOVERNMENT NOTICE NO. 15 OF 2023

The Parliament of Lesotho

Statement of Objects and Reasons of the Lesotho Medicines and Medical Devices Control Authority Act, 2023

(Circulated by the Authority of the Minister responsible for health Honourable Selibe Mochoboroane)

The purpose of the Act is to establish a Medicines Regulation Authority which will be a statutory body responsible for regulation and control of medicines and medical devices. The Authority shall regulate the manufacture, sale and use of medical products and ensure that such products meet the required standards of safety, efficacy and quality thus protect and promote public health. The Authority shall also ensure the appropriateness of information provided to the public and health professionals concerning medical products.

The Act provides for establishment of the Board which shall be the governing body of the Authority. The functions of the Board among others shall be to advice the Minister on matters relating to medical products into Schedules, declare and exempt any article as a medical product.

According to the Act it is an offence to manufacture, sell, distribute or circulate in the country a medical product which is not registered. Sale and use of unregistered medical products is prohibited safe where allowed by the Board. The Board may authorize sale of unregistered medical products for a specified purpose and only for a specified period. The Act also provides for licensing of personnel handling medical products depending on their qualifications. The premises on which the medical product is manufactured, sold or distributed is also licensed and has to comply with the required standards.

It is an offense to import and export medical products unless a person is licensed by the Authority, the medical product is registered and complies with Boards requirements for quality, efficiency and safety, the container or package in which the medical product is contained in bears a label written in Sesotho and English and a certificate is issued by the Board.

The Act also provides for scheduling of registered medical products in accordance with set international standards. Medical products are classified from

Schedule 0 to Schedule 8. The purpose for classification is to regulate who utilizes, acquires, manufactures, sells, distributes, imports and dispenses medical product to ensure safety of the public.

Under the Act is an offence to have a medical product which is not in the public interest. Where a product already in the market is considered not fit for consumption, the Authority shall prohibit its sale, recall the product from the market and return the product to the manufacture or dispose it off.

The Act provides for appointment of inspectors who will determine that all requirements and conditions for licensing of the personnel and premises are complied with. The inspector will control and regulate compliance with good manufacturing practices, good clinical practices and good laboratory practices to ensure that medical products are of good quality, safety and efficacy.

The Act provides for monitoring of advertisements and promotion of medical products entering the market. The Act also allows monitoring of clinical trials for new products unregistered and registered products for the protection of participants. The Act prevents illegal sale or use of substandard, spurious, falsely labelled, falsified and counterfeit medical products.

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