THE ZAMBIA MEDICINES AND MEDICAL SUPPLIES AGENCY ACT, 2019

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SCHEDULE

GOVERNMENT OF ZAMBIA

ACT

No. 9 of 2019

Ratact Assprishing Inventoring and cost-effective system for the procurement, storage and distribution of medicines and medical supplies; establish Medical Stores Limited as the Zambia Medicines and Medical Supplies Agency and provide for its functions; and provide for matters connected with, or incidental to, the foregoing.

[12th November, 2019

ENACTED by the Parliament of Zambia

PART I

PRELIMINARY PROVISIONS

1. This Act may be cited as the Zambia Medicines and Medical Supplies Agency Act, 2019, and shall come into operation on the date appointed by the Minister by statutory instrument.

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

"Agency" means the Zambia Medicines and Medical Supplies Agency established in accordance with section 3;

"appointed date" means the date appointed by the Minister under section 1;

"associate" has the meaning assigned to the words in the Anti-Corruption Act, 2012;

"Board" means the Board of the Agency constituted in accordance with section 6;

"Chairperson" means the person appointed as Chairperson of the Board in accordance with section 6

"Company" means the Medical Stores Limited existing in accordance with the Companies Act, 2017, and existing immediately before the appointed date;

"diagnostic Centre" means a laboratory or radiological service, or any other related service;

Enactment

Short title and commencement

Interpretation

Act No. 3 of 2012

- "Director-General" means the person appointed as Director-General of the Agency in accordance with section 14;
- "emoluments" has the meaning assigned to the word in the Constitution:
- "health facility" has the meaning assigned to the words in the Health Professions Act. 2009:
- "Health Professions Council of Zambia" means the Health Professions Council of Zambia established under the Health Professions Act. 2009:
- "hospice" has the meaning assigned to the word in the Health Professions Act, 2009;
- "hospital" has the meaning assigned to the word in the Health Professions Act, 2009;
- "legally disqualified" means the absence of legal capacity as provided in section 4 of the Mental Health Act, 2019;
- "medical supplies" means products or materials used in the delivery of healthcare services and include pharmaceuticals, non-pharmaceuticals, nutraceuticals, vaccines and therapeutic antisera, medical equipment and devices, medical appliances and materials, health technologies, laboratory supplies and reagents, dental materials, hospital consumables, and any other material or equipment as may be necessary for the delivery of healthcare services in Zambia;
- "medicine" means medicine for human use, herbal medicine for human use, a medicinal product for human use or any substance or mixture of substances for human use intended to be used, or manufactured for use, for its therapeutic efficacy or for its pharmacological purpose in the diagnosis, treatment, alleviation, modification or prevention of disease or abnormal physical or mental state or the symptoms of disease in a person;
- "member" means the person appointed as a member of the Board in accordance with section 6;
- "public health facility" means a health facility owned or operated by the Government;
- "relative" has the meaning assigned to the word in the Anti-Corruption Act, 2012;

Cap. 1

Act No. 24 of 2009

Act No. 6 of 2019

"Secretary" means the person appointed as Secretary to the Board in accordance with section 15;

Act No. 3 of 2012

- "supply chain" means a system of organisations, activities, information, and resources involved in moving a product or service from a supplier to a customer;
- "Vice-Chairperson" means the person elected as Vice-Chairperson of the Board in accordance with section 6; and
- "Zambia Qualifications Authority" means the Zambia Qualifications Authority established under the Zambia Qualifications Authority Act, 2011.

PART II

THE ZAMBIA MEDICINES AND MEDICAL SUPPLIES AGENCY

Act No. 13 of 2011

Establishment of Medical

Stores Limited as

Zambia

Medicines and Medical

Supplies

Agency Act No. 10

of 2017

- 3. (1) Despite any other written law, the Medical Stores Limited existing in accordance the Companies Act, 2017, is continued and is deemed to be established under this Act and renamed as the Zambia Medicines and Medical Supplies Agency.
- (2) The Agency is a body corporate with perpetual succession and a common seal, capable of suing and of being sued in its corporate name, and with power, subject to the provisions of this Act, to do all acts and things that a body corporate may, by law, do or perform.
- **4.** (1) The seal of the Agency shall be a device that the Agency may determine and shall be kept by the Secretary.
- (2) The affixing of the seal shall be authenticated by the Chairperson or the Vice-Chairperson and the Secretary or any other person the Board authorises for that purpose.
- Seal of Agency
- (3) A contract or instrument which, if entered into or executed by a person not being a body corporate, would not be required to be under seal, may be entered into or executed without seal on behalf of the Agency by the Secretary or any other person the Board authorises, generally or specifically, for that purpose.
- (4) A document purporting to be a document under seal of the Agency or issued on behalf of the Agency shall be received in evidence and shall be considered to be so executed or issued, without further proof, unless the contrary is proved.
 - 5. The functions of the Agency are to—
 - (a) procure, store and distribute medicines and medical

Functions of Agency

supplies;

- (b) re-package and re-label medicines and medical supplies;
- (c) develop, maintain and manage an efficient and costeffective system of procurement, storage and distribution of medicines and medical supplies;
- (a) ensure timely availability of medicines and medical supplies in public health facilities;
- (ε) establish and maintain strict inventory management systems and security protocols within the Agency and other storage facilities under the control and supervision of the Agency;
- (j) facilitate the selection, forecasting, quantification and supply planning of medicines and medical supplies for health facilities;
- (g) establish a network of storage, packaging and distribution facilities for the provision of medicines and medical supplies to health facilities;
- (h) enter into agreements or establish frameworks with Government and other local and international institutions for purposes of manufacturing medicines and medical supplies as the Board may determine;
- (i) provide information and regular reports on the status and cost-effectiveness of procurement, storage, distribution and value of medicines and medical supplies to the Ministry responsible for health in order to assist with appropriate planning and decision making;
- (j) cooperate and exchange information relating to medicines and medical supplies with relevant stakeholders at district, provincial, national and international level;
- (k) establish and maintain an internal quality assurance system for efficient operations, compliance with regulations and quality of medicines and medical supplies;
- (1) support health facilities to establish and maintain appropriate inventory management systems for medicines and medical supplies; and
- (m) advise the Minister on policies relating to the procurement, storage and distribution of medicines and medical supplies.
- **6.** (1) There is constituted the Board of the Agency consisting of the following part-time members appointed by the Minister:

- (a) a representative each of—
 - (i) the Attorney-General;
 - (ii) the Ministry responsible for health;
 - (iii) the Ministry responsible for finance;
 - (iv) the Pharmaceutical Society of Zambia;
 - (v) the Health Professions Council of Zambia; and
 - (vi) a civil society organisation concerned with matters relating to health; and
- (b) a person from the private sector with experience and knowledge in finance or business management.
- (2) The members, other than the member referred to in subsection (1) (b), shall be nominated by their respective institutions.
- (3) The Minister shall appoint the Chairperson from among the members.
- (4) The members shall elect the Vice-Chairperson from among themselves.
- (5) A person shall not be nominated or appointed as a member if that person—
 - (a) is an undischarged bankrupt;
 - (*t*) is legally disqualified;
 - (c) has been convicted of an offence involving fraud or dishonesty;
 - (a) has been convicted of an offence under any written law and sentenced to imprisonment for a period exceeding six months without the option of a fine;
 - (e) has been found guilty of professional misconduct; or
 - (1) is an employee of the Agency.
 - 7. (1) The Board is the governing body of the Agency.
- (2) Without limiting the generality of subsection (1), the functions of the Board are to—
 - (a) provide strategic direction to the Agency;
 - (b) approve the annual budget estimates and financial statements of the Agency;
 - (c) approve the annual work plan, action plans and activity reports of the Agency;
 - (a) manage, control and administer the assets of the Agency in a manner that promotes the purposes for which the

Constitution of Board of Agency

Functions of Board Agency is established;

- (e) provide policy guidance and direction in order to ensure the efficient performance of the functions of the Agency;
- (1) monitor and evaluate the performance of the Agency against budgets and plans; and
- (g) advise the Minister on matters relating to the procurement, warehousing and distribution of medicines and medical supplies, and recommend appropriate policy and legislative interventions.
- **8.** The Board may, by direction in writing and on the conditions the Board considers necessary, delegate to the Director-General any of its functions under this Act.

- (1) Subject to the other provisions of this Act, a member shall hold office for a period of three years and may be re-appointed for one further period of three years.
- (2) A member may resign on giving one month's notice, in writing, to the Minister.
- (3) A member shall, on the expiration of the period for which the member is appointed, continue to hold office until a successor is appointed, but in no case shall the further period exceed four months.
 - (4) The office of a member becomes vacant if the member—
 - (a) dies;
 - (b) resigns;
 - (c) is absent, without reasonable excuse, from three consecutive meetings of the Board of which the member has had notice;
 - (a) is adjudged bankrupt;
 - (e) becomes legally disqualified;
 - (1) is found guilty of professional misconduct;
 - (g) is convicted of an offence under any written law and sentenced to imprisonment for a period exceeding six months without the option of a fine;
 - (h) ceases to hold the office by virtue of which the member was appointed;
 - (1) ceases to be a representative or holder of an office in, or member of, the institution which nominated the member;

Delegation of functions of Board

Tenure of office and vacancy

or

- (j) is removed by the Minister for good cause on the following grounds:
 - (i) the member acts dishonourably, improperly, fraudulently, dishonestly or disorderly; or
 - (ii) the institution which the member represents withdraws its support of the member as its representative and informs the Minister accordingly.
- (5) The Minister may, where the office of a member becomes vacant before the expiry of that member's term of office, appoint another person to be a member in place of the member whose office becomes vacant, but that other member shall hold office only for the unexpired term of that office.
- **10.** (1) Subject to the other provisions of this Act, the Board may regulate its own procedure.
- (2) The Board shall meet for the transaction of business at least once every three months at a place and time that the Board may determine.

Proceedings of Board

- (3) A meeting of the Board may be called by the Chairperson on giving notice of not less than fourteen days, and shall be called by the Chairperson if not less than one-third of the members so request in writing, except that if the urgency of a particular matter does not permit the giving of the notice, a special meeting may be called on giving a shorter notice.
- (4) Four members shall constitute a quorum at a meeting of the Board.
 - (5) There shall preside at a meeting of the Board—
 - (a) the Chairperson;
 - (b) in the absence of the Chairperson, the Vice-Chairperson;
 - (c) in the absence of the Chairperson and the Vice-Chairperson, such other member as the members present may elect for the purpose of that meeting.
- (6) A decision of the Board on any question shall be by a majority of the members present and voting at the meeting and, in

the event of an equality of votes, the person presiding at the meeting shall have a casting vote in addition to that person's deliberative vote.

- The Board may invite any person, whose presence is in its opinion desirable, to attend and to participate in the deliberations of the meeting of the Board, but that person shall not have a vote.
- A member who is for any reason unable to attend a meeting of the Board may, in writing, nominate another person from the same organisation to attend the meeting in that member's stead and that person shall be considered to be a member for the purpose of that meeting.
- (9) The validity of any proceedings, acts or decisions of the Board shall not be affected by any vacancy in the membership of the Board or by any defect in the appointment of any member or by reason that any person not entitled to do so, took part in the proceedings.
- 11. (1) The Board may constitute committees that it considers necessary and delegate to the committees such of its functions as it considers appropriate.

The Board may appoint, as members of a committee. persons who are or are not members of the Board, except that at least one member of a committee shall be a member of the Board.

- A person serving as a member of a committee shall hold office for a period that the Board may determine.
- Subject to any specific or general direction of the Board, a committee may regulate its own procedure.
- The Agency shall pay to a member or a member of a committee allowances that the Emoluments Commission may, on

the recommendation of the Minister, determine.

- (1) A person who is present at a meeting of the Board or a committee at which any matter is the subject of consideration. and in which matter that person or that person's relative or associate is directly or indirectly interested in a private capacity shall, as soon as is practicable after the commencement of the meeting, disclose that interest and shall not, unless the Board or the committee otherwise directs, take part in any consideration or discussion of, or vote on, any question relating to that matter.
- A disclosure of interest made under subsection (1) shall be recorded in the minutes of the meeting at which it is made.

Committees

Allowances

Disclosure of interest

- 14. (1) The Board shall appoint, through a competitive and transparent process, a Director-General who shall be—
 - (a) the chief executive officer of the Agency; and

Director-General

- (b) responsible for the day-to-day administration of the Agency.
- (2) A person qualifies for appointment as Director-General if that person—
 - (a) holds a bachelor's degree, or an equivalent qualification, which is accredited or recognised and validated by the Zambia Qualifications Authority;
 - (b) holds a postgraduate degree in business management, public health, pharmacology, pharmacy, supply chain management or a related field, which is accredited or recognised and validated by the Zambia Qualifications Authority;
 - (c) has at least five years' experience working at a senior management level;
 - (a) is of proven integrity; and
 - (e) has not been convicted of an offence involving fraud or dishonesty.
- (3) The Director-General shall attend meetings of the Board and of a committee, and may address those meetings but shall not vote on any matter.
- (4) The Board may, whenever the Director-General is for any reason unable to perform the functions of the Director-General, appoint an acting Director-General to perform the functions of the Director-General.
- **15.** (1) The Board shall appoint a Secretary who shall perform board secretarial functions.
- (2) The Agency may appoint other staff of the Agency that the Agency considers necessary for the performance of the functions of the Agency.

Secretary and other staff

16. (1) The Emoluments Commission shall, on the recommendation of the Board, determine the emoluments of the

Emoluments and other conditions of service of Director-General, Secretary and other staff

Immunity

Director-General, Secretary and other staff of the Agency.

- (2) The Board shall determine the conditions of service, other than emoluments, of the Director-General, Secretary and other staff of the Agency.
- 17. (1) An action or other proceeding shall not lie or be instituted against a member, a member of a committee or a member of staff of the Agency for, or in respect of, an act or thing done or omitted to be done in good faith in the exercise or performance of a power or function conferred by or under this Act.
- (2) Despite anything to the contrary contained in any other written law, where a judgment or court order is obtained against the Agency, no execution, attachment or process of any nature shall be issued against the Agency or against any property of the Agency, but the Minister or the Director-General shall cause to be paid out of the Consolidated Fund or revenue of the Agency such amounts of moneys as may, by judgment or court order, be awarded against the Agency to the person entitled to the money.

PART III

THE MEDICINES AND MEDICAL SUPPLIES FUND

- **18.** (1) There is established the Medicines and Medical Supplies Fund to support the procurement of medicines and medical supplies for public health facilities.
- (2) Subject to the Public Finance Management Act, 2018 and without limiting the generality of subsection (1), the Fund shall be administered by the Minister responsible for health and applied for the purposes of—
 - (a) ensuring availability of medicines and medical supplies in public health facilities;
 - (b) procuring and distributing medicines and medical supplies for emergency purposes for public health facilities; and
 - (c) for such other purposes as the Board may determine.
 - (3) The Fund consists of—
 - (a) monies that Parliament may appropriate for the purposes of the Fund;
 - (*t*) monies received by the Fund from donations and grants from any source, with the approval of the Minister; and
 - (c) other monies that may vest in, or accrue to, the Fund from the National Health Insurance Scheme or any other

Establishment of the Medicines and Medical Supplies Fund Act No. 1 2018 source.

- 19. The Minister may, by statutory instrument, on the recommendation of the Agency, make regulations to provide for—
 - (a) the manner of financing programmes and activities to which the Fund shall be applied;

Administration of Fund

- (b) fiscal controls and accounting procedures governing the Fund;
- (c) reporting procedures for matters relating to the Fund;
- (a) investment of the monies of the Fund; and
- (e) any other matter necessary for the efficient operation, administration and management of the Fund.
- **20.** (1) The Agency shall cause to be kept proper books of accounts and other records relating to the accounts of the Fund.
- (2) The Auditor-General or an auditor appointed by the Auditor-General shall audit the Fund annually.

Accounts and audit of Fund

- (3) The fees for the audit of the Fund shall be paid from the Fund.
- 21. (1) The Ministry responsible for health shall, as soon as is practicable, but not later than ninety days after the end of a financial year, submit to the Minister responsible for finance, a report concerning the activities relating to the Fund during that financial year.

Annual report of Fund

- (2) The report referred to in subsection (1) shall include information on the financial affairs of the Fund and there shall be appended to the report—
 - (a) an audited statement of financial position;
 - (b) an audited statement of comprehensive income; and
 - (c) such other information as the Minister responsible for finance may require.
- (3) The Minister responsible for finance shall, not later than seven days after the sitting of the National Assembly next after receipt of the report referred to in subsection (1), lay the report before the National Assembly.

PART IV Financial Provisions Funds of Agency

- 22. (1) The funds of the Agency consist of monies that may—
 - (a) be appropriated to the Agency by Parliament for the purposes of the Agency;
 - (b) be paid to the Agency by way of fees, grants or donations; or
 - (c) otherwise vest in, or accrue to, the Agency.
- (2) The Agency may, subject to the approval of the Minister—
 - (a) accept monies by way of grants or donations from any source within or outside Zambia;
 - (*t*) raise by way of loans or otherwise, monies that the Agency may require for the performance of its functions; and
 - (c) charge and collect fees in respect of—
 - (i) programmes, seminars, publications, consultancy and other services provided by the Agency; and
 - (ii) procurement services, storage and distribution of medicines and medical supplies.
- (3) The Agency shall pay from the funds of the Agency—
 - (a) emoluments of members of staff of the Agency;
 - (b) reasonable travelling and other allowances for the members and members of a committee when engaged in the business of the Agency at rates that the Emoluments Commission may, on the recommendation of the Minister, determine; and
 - (c) any other expenses incurred by the Agency in the performance of its functions.
- (4) The Agency may, subject to the approval of the Minister, invest, in a manner that the Agency considers appropriate, funds of the Agency that the Agency does not immediately require for the performance of the Agency's functions.
- 23. The financial year of the Agency shall be a period of twelve months ending on 31st December of each year.

Financial year

24. (1) The Agency shall cause to be kept proper books of account and other records relating to its accounts.

Accounts and audit of Agency

- (2) The Auditor-General or an auditor appointed by the Auditor-General shall audit the accounts of the Agency annually.
- (3) The Agency shall pay the fees for an audit of the Agency's accounts.

25. (1) The Agency shall, as soon as is practicable but not later than ninety days after the end of a financial year, submit to the Minister a report concerning the Agency's activities during that financial year.

Annual report of Agency

- (2) The report referred to in subsection (1) shall include information on the financial affairs of the Agency and there shall be appended to that report—
 - (a) an audited statement of financial position;
 - (b) an audited statement of comprehensive income; and
 - (c) such other information as the Minister may require.
- (3) The Minister shall, not later than seven days after the first sitting of the National Assembly next after receipt of the report referred to in subparagraph (1), lay the report before the National Assembly.

PART V

GENERAL PROVISIONS

26. (1) A person shall not, without the consent in writing given by or on behalf of the Agency, otherwise than in the course of duties of that person, publish or disclose to any other person, the contents of any document, communication or information, which relates to, or which has come to the knowledge of that person in the course of that person's duties under this Act.

Prohibition of publication or disclosure of information to unauthorised persons

- (2) A person who contravenes subsection (1) commits an offence and is liable, on conviction, to a fine not exceeding two hundred thousand penalty units or to imprisonment for a term not exceeding two years, or to both.
- **27.** The Minister may, by statutory instrument, make regulations that are—
 - (a) required to be made by this Act; or
 - (b) necessary for the better carrying out of the provisions of this Act.
 - 28. The Schedule applies to matters specified in the Schedule.

Regulations

Savings and transitional provisions

(Section 28)

SAVINGS AND TRANSITIONAL PROVISIONS

1. (1) The Company shall be deemed to be established as an Agency in accordance with section 3 on the appointed date.

Effective date of establishment of Agency

(2) Subject to subparagraph (3), the Corporate Insolvency Act, 2017, and the Companies Act, 2017, do not apply to the conversion.

Act No. 9 of 2017 Act No. 10 of 2017

(3) Despite subparagraph (2), the Agency shall, as soon as practicable after the conversion, notify the Registrar appointed in accordance with the Patents and Companies Registration Agency Act, 2010, of the conversion and the Registrar shall remove the Company from the register of companies kept and maintained at the Patents and Companies Registration Agency.

Act No. 15 of 2010

- (4) For the purposes of this paragraph "conversion" means the establishment of the Company as the Agency in accordance with this Act and the resolution of the Company.
- **2.** (1) On conversion, employees of the Company shall be paid their terminal benefits.

Transfer of staff

- (2) On or after the appointed date, the Minister may, by statutory instrument, approve arrangements under which employees of the Company shall be re-engaged by the Agency.
- (3) Where a person is re-engaged in accordance with the arrangements made under subsection (2), the terms and conditions of service of that person with the Agency shall be no less favourable than those applicable while in the Company.

Transfer of assets and liabilities

- 3. (1) On or after the appointed date, there shall be transferred to, vest in and subsist against the Agency by virtue of this Act and without further assurance, the assets, rights, liabilities and obligations which immediately before the appointed date were the assets, rights, liabilities and obligations of the Company.
- (2) Subject to subparagraph (1), every deed, bond or agreement, other than an agreement for personal service, to which the Company was a party immediately before the appointed date whether or not of a nature that rights, liabilities and obligations could be assigned, shall, unless its subject matter or terms make it impossible that it should have effect as modified, as provided under this paragraph, have effect as if—
 - (a) the Agency had been party to it;
 - (b) for any reference to the Company there were substituted,

- with respect to anything required to be done on or after the appointed date, a reference to the Agency; or
- (c) for any reference to a member of staff of the Company, not being a party to it and beneficially interested, there were substituted, with respect to anything required to be done on or after the appointed date, a reference to such member of staff of the Agency as the Agency shall designate.
- (3) Where under this Act, any assets, rights, liabilities and obligations of the Company are considered to be transferred to the Agency in respect of which transfer a written law provides for registration, the Agency shall make an application, in writing to the appropriate registration authority for registration of the transfer.
- (4) The registration authority referred to in subparagraph (1) shall make such entries in the appropriate register as shall give effect to the transfer and, where applicable, issue to the transferee concerned a certificate of title in respect of the property or make necessary amendments to the register and shall endorse the deeds relating to the title, right or obligation concerned and registration fees or other duties shall not be payable in respect of the transaction.
- **4.** (1) Any legal proceedings or application of the company pending immediately before the appointed date by or against the Company may be continued by or against the Agency.

(2) After the appointed date, proceedings in respect of any rights, liability or obligation which was vested in, held, enjoyed, incurred or suffered by the Company may be instituted by or against the Agency.

Legal proceedings