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## N O T I C E

The Bill hereunder shall be presented before the House of Representatives for the first reading which will start its session on 13th day of September, 2023 and is gazetted together with its Objects and Reasons for public notice.

**ZANZIBAR**
23rd August, 2023

(Eng. Zena Ahmed Said)
***Secretary to the Revolutionary Council and Chief Secretary***

# A BILL

*for*

## AN ACT TO ESTABLISH THE ZANZIBAR CENTRAL MEDICAL STORES AGENCY FOR THE PROCUREMENT, MANUFACTURE, STORAGE AND DISTRIBUTION OF MEDICINES AND OTHER MATTERS RELATED THERETO

**ENACTED** by the House of Representatives of Zanzibar.

## PART ONE
## PRELIMINARY PROVISIONS

Short title and commencement.

**1**. This Act may be cited as the Zanzibar Central Medical Store Agency Act, 2023 and shall come into operation after being assented to by the President.

Application.

**2.** This Act shall apply to all matters relating to procurement, manufacture, storage and distribution of medicines for public and private health facilities that may require services of the Agency.

Interpretation.

**3**. In this Act, unless the context otherwise requires:

"Agency" means the Zanzibar Central Medical Stores Agency established under section 4(1) of this Act;

"Board" means the Board of Directors of the Agency established in accordance with section 9(1) of this Act;

"Client" means any health facility, institution or person receiving services from the Agency;

"Director General" means the Director General of the Agency appointed in accordance with section 15(1) of this Act;

"Government" means the Revolutionary Government of Zanzibar;

"Health facility" means any institution for the reception and medical treatment of persons who are injured, infirm or suffering from illness, and includes a hospital, health center, dispensary, maternity home, clinic (whether mobile or not), and also any place or premises used for purpose of medical treatment, whether regularly or periodically;

"Medical device" means an instrument, apparatus, implement, medical equipment, machine, implant, in vitro reagent or other similar or related article including any component, part or accessory;

"Medicine" means any substance or mixture of substances manufactured, sold or presented for use in:

(a) the diagnosis, treatment, mitigation or prevention of a disease, disorder, abnormal physical or mental state or symptoms thereof, in human being or animal;

(b) restoring, correcting or beneficial modification of organic or mental functions in human being or animal;

(c) disinfection in premises in which medicines are manufactured, prepared or kept, hospitals, equipment and farm houses; or

(d) articles intended for use as a component of any articles specified in paragraph (a), (b) or (c) and also includes medical devices or their components, parts or accessories;

"Minister" means the Minister responsible for health;

"Medical Store" means a warehouse or special reserved place designated for storing medicines before distribution or moved to another location;

"President" means the President of Zanzibar and Chairman of the Revolutionary Council;

"Unwanted medicine" means medicines that are unfit for human and animal consumption due to expiration, obsolete or their use has been discontinued by the relevant Authorities;

"Warehouse" means a building where medicines may be stored prior to their distribution or moved to another location.

## PART TWO
## ESTABLISHMENT OF THE AGENCY

Establi-shment of the Agency.

**4**.-(1) There is established an Agency to be known as the Zanzibar Central Medical Stores Agency.

(2) The Agency shall, subject to the law, be capable to:

(a) acquire, hold, purchase or dispose any movable and immovable property;

(b) enter into any contract or transaction;

(c) borrow any such sum of money from any financial institution; and

(d) perform any act which an Agency of its nature may by law, be entitled to do.

Seal and Logo of the Agency.

**5**.-(1) There shall be a common seal and logo of the Agency in a shape and size as may be determined by the Board.

(2) The application of the seal and logo of the Agency on any document shall be authenticated by the signature of the Director General or Officer authorized by the Director General.

(3) Any document purported to be an instrument issued by the Agency, sealed with the seal of the Agency and authenticated in accordance with the provision of subsection (2) of this section, shall be deemed to be an instrument of the Agency.

Objectives of the Agency.

**6**. The Agency shall have objectives to:

(a) administer all matters relating to procuring, manufacturing, storing, distribution and selling of medicines made by the Agency; and

(b) ensure quality medicines are continuously available at the affordable price.

Functions of the Agency.

**7**.-(1) The Agency shall have the functions, to:

(a) procure, store and distribute medicines to client;

(b) manufacture or cooperate with medicines manufacturing companies during manufacturing of medicine;

(c) verify and maintain the quality and safety of medicines during procuring, manufacturing, storage and distribution of medicines to client;

(d) develop, maintain and manage an efficient and cost effective system of procurement, storage and distribution of approved medicines required for use by the client;

(e) apply, in so far as they are applicable, sound commercial principles in procurement, storage and distribution of medicines in order to maintain a self-sustaining revolving fund for the operation of the Agency;

(f) identify medicine needed in the country;

(g) set the price of medicines to be distributed by the Agency;

(h) register and maintain records of the client;

(i) conduct research relating to functions of the Agency;

(j) collaborate with national, regional and international institutions in the implementation of the strategic continuous availability of medicine;

(k) collaborate with private sectors in manufacturing, procuring, distributing, storing, controlling and conducting research on medicine; and

(l) perform any other function conferred under this Act.

(2) Without prejudice the functions provided under subsection (1) of this section, the Agency may receive any donation of medicines given to the Government.

(3) The Agency may, after approval of the Board, enter into agreement with any institution with similar interests for improving its efficiency and quality of services in accordance with the provisions of this Act.

Powers of the Agency.

**8**. In performing its functions, the Agency shall have powers, to:

(a) enter and inspect any premise which is provided with the services of the Agency;

(b) restrain the distribution of medicine to health facility which contravenes the medicines distribution and storage guidelines;

(c) require information from any client in order to identify the quantity that is required to be procured;

(d) refuse to receive medicine which do not meet standards issued by relevant authority; and

(e) exercise any power conferred under this Act.

## PART THREE
## ADMINISTRATION AND MANAGEMENT OF THE AGENCY

Establi-shment and Compo-sition of the Board.

**9**.-(1) There shall be the Board of Directors of the Agency which shall be composed of the following members:

(a) Chairperson who shall be appointed by the President;

(b) Director General of the Agency;

(c) Chief Government Pharmacist;

(d) State Attorney from Attorney General's Chambers;

(e) Representative from tertiary hospitals;

(f) Pharmaceutical personnel from private sector; and

(g) Technical financial person from Ministry responsible for Finance.

(2) Save for Chairperson and ex-officio members, other members of the Board shall be appointed by the Minister upon consultation with respective institutions based on experience, knowledge and gender equality.

Qualifi-cations of the Chairperson.

**10**. A person shall qualify to be appointed as a Chairperson, if that person has:

(a) at least first degree in the field of health sciences from the institute recognized by the Government;

(b) working experience of not less than seven years in matters related to health sciences;

(c) competence in supervising matters of the institution effectively and efficiently; and

(d) high level of integrity.

Secretary of the Board.

**11**.-(1) The Board shall appoint an staff of the Agency to be Secretary of the Board.

(2) Aperson shall qualify to be appointed as a secretary of the Board if that person:

(a) has at least first degree in the field of law from the institute recognized by the Government or qualify to be corporate secretary; and

(b) has working experience of not less than three years in the public service.

(3) The Secretary of the Board shall be accountable to the Board and shall:

(a) in consultation with the Chairperson, prepare the agenda of the meeting of the Board;

(b) take accurate minutes of the meetings of the Board;

(c) maintain the correct and sufficient records of meetings of the Board;

(d) give proper notifications of the meetings of the Board to the members; and

(e) perform any other function as directed by the Board.

Functions of the Board.

**12**. Board shall have the following functions:

(a) overseeing operations of the Agency;

(b) advising the Minister on the development of the policies and strategies relating to services provided by the Agency;

(c) reviewing and approve policies, business and operational plan, budget, reports and auditing financing statements of the Agency;

(d) providing strategic guidance;

(e) ensure the good governance, sound policies and practice are in place and implemented;

(f) ensuring the efficient use of resources of the Agency; and

(g) perform any other function conferred by this Act.

**13**. The Board shall have a general supervisory power in respect of the performance of the functions of the Agency, and in particular shall have power to: Powers of the Board.

(a) establish Staff Regulations and Financial Regulations for the Agency;

(b) approve the organizational structure of the Agency;

(c) recommend to the relevant authority, any alteration in salaries, wages or other terms and conditions of service of employees of the Agency;

(d) approve fees, rates and other charges related to the services rendered by the Agency;

(e) recruit and appoint staff of the Agency in accordance with the Public Service Act, No. 2 of 2011; and

(f) take disciplinary actions against any staff in accordance with the Public Service Act, No. 2 of 2011.

**14**.-(1) The provisions relating to the proceedings of the Board shall be as prescribed in the Schedule of this Act. Proceedings of the Board.

(2) The Minister may, by order published in the Gazzette, amend the Schedule made under the provisions of subsection (1) of this section.

**15**.-(1) There shall be the Director General of the Agency who shall be appointed by the President. Appointment of the Director General.

(2) A person shall qualify to be appointed as the Director General, if that person has:

(a) at least first degree in the field of pharmaceutical sciences, supply chain, procurement, business administration or any other related field from any institution recognized by the Government;

(b) working experience in any field specified under paragraph (a) for a period of not less than five years; and

(c) high integrity.

Functions of the Director General.

**16**.-(1) The Director General shall be the Chief Executive Officer of the Agency and shall be responsible for the supervision of day to day functions of the Agency.

(2) In performing his functions, the Director General shall be responsible for:

(a) accountability of income and expenditure of the Agency;

(b) proper management of the funds and properties of the Agency;

(c) implementing strategic plan, business plan and operational plan of the Agency;

(d) managing the affairs of the Agency in an efficient and effective quality service delivery;

(e) act as the chief advisor to the Government on all issues related procure, manufacture, storage and distribution of medicines for public health facilities;

(f) ensuring the effective use of staff and other resources of the Agency;

(g) maintain the register of clients of the Agency;

(h) implement the national policies relating to medicine; and

(i) perform any other functions for better implementation of the provisions of this Act.

Departments, Units and Divisions of the Agency.

**17**.-(1) The Agency shall establish departments, unit and divisions as may deem necessary in accordance with the provisions of the Public Service Act, No. 2 of 2011.

(2) The heads of departments and units shall be appointed by the Board upon recommendations of the Director General who shall be persons with relevant knowledge and sufficient experience to perform the functions in their respective department and unit and shall be accountable to the Director General.

(3) The heads of divisions shall be appointed by the Director General based on their related qualifications and experiences and shall be accountable to the heads of their respective departments.

Staff of the Agency.

**18.** The Agency may, upon such terms and conditions, employ staff in accordance with the provisions of the Public Service Act, No. 2 of 2011.

## PART FOUR
## PROCUREMENT, MANUFACTURE, STORAGE AND DISTRIBUTION OF MEDICINES

Procurement of medicines.

**19.** The Agency shall procure medicines subject to the provisions of the Procurement and Disposal of Public Assets Act, No.11 of 2016.

Manufacture of medicines.

**20**.-(1) The Agency shall manufacture medicine subject to the Good Manufacturing Guidelines prescribed by the relevant authority.

(2) The Agency shall, in manufacturing of medicines, consider such types of medicines which are commonly used or needed and they are of affordable prices.

Medical Stores.

**21**.-(1) There shall be Medical Stores which shall be owned by the Agency and shall be used for storage of medicines.

(2) The Agency may establish other medical stores in any area when it is necessary.

Storage of the medicines.

**22**.-(1) The Agency shall have the duty to store medicine procured by the Agency, obtained by any other way or owned by public or private institutions.

(2) Storage of medicine shall comply with the guidelines for the proper handling of medicines that will be issued by the Agency.

(3) The Agency shall store medicines in its stores or other stores recognized by the Agency.

Storage of medicines of private institutions.

**23**. The Agency may store medicine of private institutions through special arrangement and subject to regulations made under this Act.

Distribution of medicines.

**24**.-(1) The Agency shall distribute medicines according to the needs of the client.

(2) Without prejudice the provisions of this Act, the Agency may use any institution to distribute medicines.

(3) Distribution of medicines to any client shall be made after the client fulfilled the procedures as prescribed in the regulations made under this Act.

## PART FIVE
## FINANCIAL PROVISIONS

Sources of funds of the Agency.

**25**.-(1)The funds and resources of the Agency shall consist of:

(a) such sums as may be approved by the House of Representatives;

(b) such fees or charges payable to the Agency for services rendered;

(c) such lawful grants, gifts, donations, contributions, loan, bequests or investment as may be received from any person or institution; and

(d) any such other money that may be legally received or acquired by the Agency whether in the course of its operations or otherwise.

(2) All financial transactions of the Agency shall be made and governed in accordance with the provisions of the Public Finance Management Act, No.12 of 2016.

(3) The Agency shall retain certain percentage of money collected from the services rendered by the Agency as determined by the Minister responsible for finance.

Budget of the Agency.

**26**.-(1) The Director General shall, in respect of every financial year, prepare and submit to the Board for deliberation and approval, the estimates income and expenditure of the Agency for the next financial year in accordance with the provisions of the Public Finance and Management Act, No. 12 of 2016.

(2) Upon the deliberation and approval of estimates, the budget of the Agency shall be dealt as part of the budget of the Ministry.

(3) The estimates of income and expenditure of the Agency shall be prepared subject with the provisions of the Public Finance Management Act, No. 12 of 2016 and any other directives as may be issued by the Government from time to time.

(4) The Director General shall insure that all payments made out of the Agency's fund are correctly made and properly authorised and adiquate control is maintained over its property and over the incurring of liabilities by the Agency.

Opening Bank Account.

**27**. The Agency shall open bank account in accordance with the Public Finance Management Act, No. 12 of 2016 and deposit its money for the performance of its functions.

Account and audit.

**28**.-(1) The Agency shall properly keep and maintain books of accounts which include all financial records and transactions for every financial year.

(2) All accounts of the Agency shall be audited in accordance wih the provisions of the Public Finance Management Act, No. 12 of 2016 and other relevant financial laws.

Annual report of the Agency.

**29**. The Agency shall, in accordance with the Public Finance Management Act, No. 12 of 2016 submit to the Minister an annual report in respect of that year containing:

(a) copy of the audited accounts of the Agency together with the auditor's report relating to such accounts;

(b) a report of performance against key targets of the Agency and any other related information;

(c) a report on operations of the Agency during that financial year; and

(d) any other information on the activities of the Agency as the Minister may require.

## PART SIX
## MISCELLANEOUS PROVISIONS

Mistaken distribution and collection of medicines.

**30.-**(1) The client shall have the duty to inform the Agency on the mistaken distribution of medicines by the Agency subject to the regulations made under this Act.

(2) The Agency may collect from the client any medicine if the medicine distributed:

(a) is more than the requested quantity;

(b) has defects;

(c) is recalled by relevant authorities;

(d) is expired; or

(e) is distributed by mistake.

Disposal of unwanted medicines.

**31**. The Agency may dispose unwanted medicines subject to the provisions prescribed under relevant laws.

Ethics to Officers of the Agency.

**32**. Subject to the Public Service Act, No. 2 of 2011 or any other law relating to codes of conduct and ethics, the Agency shall issue guidelines for the performance of the functions of the Officers of the Agency.

**33**.-(1) The Agency shall register all clients in accordance with the provisions provided under the Regulations made under this Act. Registration of clients.

(2) Subject to the provisions of subsection (1) of this section, the Agency shall prepare special register which shall contain all necessary information of the of clients.

**34**.-(1) The Minister may make Regulations for the better implementation of the provisions of this Act. Regulations.

(2) Without prejudice to the generality of subsection (1) of this section, the Minister may make regulations on:

(a) ordering and receiving of medicines;

(b) storage and warehousing of medicines;

(c) distribution and collection of medicines;

(d) manufacturing of medicines; and

(e) fees and charges from the services rendered by the Agency.

## SCHEDULE

## PROCEEDINGS OF THE BOARD
**[Made under section 14(1)]**

**1**. The members of the Board shall, in their first meeting of the Board, select one member among them to be a Vice Chairperson of the Board. Vice Chairperson.

**2**. Save for an ex-officio member, the Chairperson and other members of the Board shall hold office for a term of three years from the date of their appointment and may be eligible for re-appointment for another term only. Tenure of members of the Board.

**3**.-(1) The Board shall meet every three months on ordinary meeting and may meet for the extraordinary meetings at any time when the need arises for discharging of its functions. Meeting of the Board.

(2) All meetings of the Board shall be presided by the Chairperson, in his absence, the Vice Chairperson shall preside the meeting of the Board and where the Chairperson and Vice Chairperson are absent, the members present shall elect one member among them to preside the meeting.

Quorum.

**4**. The quorum of all meetings of the Board shall be more than half of a total number of its members.

Decisions of the Board.

**5**. The decisions of the Board shall be made by consensus, where there is no consensus, the decisions shall be made by votes, and where there is an equal vote, the Chairperson shall have a casting vote.

Procedures of the meetings.

**6**. Without prejudice the provisions of this Act, the Board shall have power to regulate its own procedures in respect of the meetings and the proper conduct of its activities including committees of the Board.

Co-opted member.

**7**. The Board may co-opt any person to attend in any deliberations of the meeting of the Board as an expert but the co-opted person shall have no right to vote.

Minutes of meetings of the Board.

**8**. The minutes of meetings of the Board shall be confirmed by the Board at the next meetings and signed by the Chairperson and Secretary.

Disclosure of interest.

**9**.-(1) The member of the Board who has direct or indirect personal interest in a matter being considered or about to be considered by the Board shall, as soon as possible after the relevant facts have come to his knowledge, disclose the nature of his interest at the beginning of the meeting of the Board.

(2) A disclosure of interest shall be recorded in the minutes of the meeting and the member making such disclosure shall not:

(a) be present during the deliberations of the Board for the making of the determination; or

(b) influence any other member in the making the determination.

**10**. The member shall cease to hold office upon the occurrence of one of the following: Cessation of membership.

(a) resignation;

(b) if he is absent without reasonable excuse for three consecutive meetings of the Board;

(c) if he becomes incapacitated to perform his duties by reasons of physical or mental health;

(d) if he is terminated by the Minister where he does not meet expectation of the Agency;

(e) if he ceases to be a representative of the institution which nominated that member; or

(f) death.

**11**. The Board may form committees to carry out specific functions as may deem necessary. Committees of the Board.

**12**.-(1) The Board may, if deems fit for the proper discharging of its functions, delegate some of its functions to a committee of the Board. Delegation of the functions of the Board.

(2) Where the Board delegates its functions under subsection (1) of this section, it shall give directives in writing as may be necessary to ensure the proper performance of the functions.

**13**. The Chairperson and other members of the Board shall be entitled to be paid such allowances in accordance with the Public Service Act, No. 2 of 2011 and other relevant laws. Allowances of the members.

## OBJECTS AND REASONS

The objects and reasons of this Bill is to enact a law that will enable the establishment of the Zanzibar Medical Stores Agency to strengthen the availability of medicines, medical supplies and other health commodities services in the country.

The Agency will be an independent entity that will work under the Ministry responsible for health issues that will focus on the implementation of its responsibilities under the terms of the laws.

Before this Bill was drafted, in 2008 the Government formulated a Medicine Policy that led to the establishment of the Department of the Chief Government Pharmacist where the Central Medical Store (CMS) was part of that Department. The department was given, among other things, the responsibility of managing medicines, medical supplies and other related health commodities for hospitals and public health facilities. In carrying out its duties, in 2011 the CMS was upgraded to a full department and given the responsibility of receiving, storing and distributing medicines, medical supplies and other health commodities.

However, there have been challenges in achieving the goals of sustainable availability of medicines due to various reasons including the department's lack of legal capacity to procure medicines and medical supplies, not having the authority to make operational decisions as well as the failure to participate in the 'Pooled Bulk Procurement' of medicines and medical supplies through regional and international cooperation.

In solving these challenges, this proposed Bill establishes an Agency that will be able to procure, manufacture, store and distribute medicines, medical supplies and other health commodities. This step will enable the Agency to achieve the Government's goals of strengthening health services in the country. In addition, the established Agency will be a legal entity to approve the needs of medicines in the country, to assess and receive medicines donated by local and foreign stakeholders.

Therefore, the Government decided to establish the Zanzibar Medical Stores Agency, which will deal with the continuous availability of medicines, medical supplies and other health commodities in the country as well as the strengthening of economic development and commercially self-sustainability as specified in this Bill.

This Bill will lead to the establishment of an Agency that will be known as the Zanzibar Central Medical Stores Agency, which is an independent institution that will be under the Ministry responsible for health issues. This Agency will be supervised by the Board of Directors and managed by the Director General who will be the Chief Executive Officer appointed by the President. Also, in this Bill there are departments, units and divisions that will be headed by a person who will be appointed in accordance with the provisions of this Bill and the laws related to the Public Service. Heads of departments and units will be answerable to the Director General in carrying out their daily duties.

**This Bill is divided into six parts**:

***Part One***: is about preliminary provisions that provide for short title, application and commencement date, interpretation of words.

***Part Two***: provides for the provisions relating to establishment of the Agency, seal and logo of the Agency, objectives of the Agency, functions and powers of the Agency.

***Part Three***: is about the Administration and Management of the Agency and among things provides for establishment of the Board, functions and powers of the Board, proceedings of the Board, appointment of the Director General, functions and powers of the Director General, Department, Units and Divisions of the Agency and Staff of the Agency.

***Part Four***: deals with the provisions relating to procurement, manufacture, storage and distribution of medicines by the Agency.

***Part Five***: provides for financial provisions which includes sources of funds, budget of the Agency, power of the Agency on retention of money, opening of bank account of the Agency, account and audit and annual report of the Agency.

***Part Six***: describes miscellaneous provisions including mistaken distribution and collection of medicines, disposal of unwanted medicines, registration of clients and powers of the Minister to make regulations.

At the end there is a Schedule which provides for the proceedings of the Board.

***ZANZIBAR***
23rd August, 2023.

(HON. NASSOR AHMED MAZRUI)
***Minister for Health***
***ZANZIBAR***

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