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N O T I C E

The Bill following hereunder shall be presented before the House of Representatives for the first reading which will start its session on 23rd day of November 2016, and is gazetted for the public notice incorporating together with its objects and reasons.

ZANZIBAR
01 November, 2016

(Dr. ABDULHAMID Y. MZEE)
Secretary to the Revolutionary Council and Chief Secretary

A BILL
for
AN ACT TO AMEND THE FOOD, DRUGS AND COSMETICS ACT NO. 2 OF 2006

PART I
PRELIMINARY PROVISIONS

1. This Act may be cited as the Zanzibar Food, Drugs and Cosmetics (Amendment) Act, of 2016 and shall come into operation immediately upon being assented to by the President. Short title and commencement

2. This Act shall be read together as one with the Zanzibar Food, Drugs and Cosmetics Act No. 2 of 2006, hereby referred to as "Principal Act". Construction

PART II
AMENDMENT PROVISIONS

Amend-ment of section 2

3. Section 2 of the Principal Act is hereby amended by-

(a) deleting the interpretation of the word "Principal Secretary";

(b) deleting the interpretation of the word "Registrar" and replacing it by the word "Executive Director "in this section and where ever it appears;

(c) deleting the interpretation of the word "Board" and replacing it by the word "Agency" in this section and wherever it appears except when it refers to Advisory Board;

(d) adding the following new words in interpretation in alphabetical order:

"Agency" means the Zanzibar Food and Drugs Regulatory Agency established under section 4 of this Act;

"Board" means the Advisory Board of the Agency as established under section 7 of this Act;

"Chairperson" means a Chairperson of the Board appointed under section 5A(1)(a) of this Act, and include any person performing the functions of the Chairperson;

"Executive Director" means Executive Director of the Agency appointed under the provisions of section 8 of this Act;

"feed" means any substance or product, including additives, whether processed, partially processed or unprocessed, intended to be used for oral feeding to animals and fish;

"Government" means the Revolutionary Government of Zanzibar;

"Health facility" means health services or care that are provided in health care centers such as hospitals, clinics, outpatient care centers and specialized care centers such as birthing centers and psychiatric care centers;

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

"retail food business" means the handling and processing of food and its storage at the point of sale or delivery to the final consumer and includes distribution terminals, catering operations, canteens, institutional catering, restaurants and other similar food service operations, shops, supermarkets, distribution centers and wholesale outlets.

Amendment of section 3

4. Section 3 of the Principal Act is hereby repealed and replaced with the new section as follows-

Establishment of the Agency

3.-(1) There is hereby established the Government agency to be known as Zanzibar Food and Drugs Agency or by its acronyms ZFDA.

(2) The Agency shall be semi-autonomous with perpetual succession and common seal and shall be capable in its name of-

(a) borrowing and lending money;

(b) taking, purchasing or otherwise acquiring, holding, charging and disposing of movable and immovable property; and

(c) doing or performing all such other acts which are lawfully be done by an Agency.

Amend-ment of section 4

5. Section 4 of the principal Act is hereby amended as follows-

(a) in sub section (1) by-

(i) deleting the word "prescribe" in paragraph (k) and replacing it by the word "regulate";

(ii) deleting paragraph (s) and replacing it by the following-

"(s) control and where necessary take legal measures on improper disposal of products regulated under this Act";

(b) adding new paragraph (t) as follows-

"(t) conduct post marketing surveillance of safety and quality of medical products;"

(c) by repealing sub section (2) and replacing it by the following-

"(2) In the performance of its functions, the Agency shall-

(a) maintain a system of consultation and cooperation with National, International and with other public and private institutions established by or under any other law and having functions similar to those specified in sub section (1) of this section or having functions which relates to food, animal feed, drugs, medical devices, herbal drugs and cosmetics;

(b) recognize and comply with the National, Regional, Continental and International Standards;

(c) take proper measures to ensure effective National and International cooperation to combat the production, circulation and use of falsified and substandard of products regulated under this Act; and

(d) foster National and International cooperation and harmonization of regulations of medical products.

6. Section 5 of the Principal Act is hereby amended by repealing paragraph (d) and replacing it by the following- Amendment of section 5

(d) perform any other act as may be conferred under this Act or any other law.

7. The Principal Act is hereby amended by adding new sections 5A and 5B immediately after section 5 as follows- Addition of new sections 5A and 5B

Establishment of Board

5A.-(1) There is hereby established Advisory Board of the Zanzibar Food and Drugs Agency which shall be composed of the following members-

(a) Chairperson who is appointed by the President;

(b) Executive Director of the Agency;

(c) Chief Government Pharmacist;

(d) other members appointed by the Minister from:

(i) Ministry responsible for Trade;

(ii) Ministry responsible for Finance.

(iii) State Attorney from Attorney General Chambers ; and

(iv) Zanzibar Chamber of Commerce and Industries.

(2) A person shall not be eligible to be appointed as chairperson unless he holds relevant knowledge and experience for a period of not less than ten years in health and allied sciences.

(3) The Minister shall, before appointing members under paragraph (d) of sub section (1) of this section, seek consultation with the respective institutions, and ensure that the members have sufficient knowledge, experience and qualifications in related field.

(4) The Board shall appoint a qualified lawyer from the Agency to be the Secretary of the Board.

(5) The provisions of the Schedule to this Act shall have effect as to the tenure of office of members, cessation of membership, proceedings of meeting of the Board and other related matters to the Board.

Powers and duties of the Board

5B.-(1)The Board shall have a general advisory power in respect to the performance of the functions of the Agency, and in particular shall have power to-

(a) advice the functions of the Agency in relation to inspection, registration, quality control, quality management system on the products and services regulated under this Act;

(b) provide strategic guidance to the Agency in the discharge of its functions;

(c) advice the strategic and annual work plan and budget for the Agency;

(d) advice sound corporate governance, policies, framework and practices are in place and implemented;

(e) secure and ensure efficient use of resources, including advice on annual budget of the Agency;

(f) review operational, financial, audit and any other report of the Agency;

(g) to propose staff establishment and staff development plan to be prepared by the management within financial resources of the Agency in line with Public Service Act; and

(h) to do any other functions as it deems necessary for the efficiency and effectiveness in the performance of its activities under this Act.

(2) In the discharge of its functions under this Act, the Board shall be answerable to the Minister.

Amend-ment of section 6

8. Section 6 of the Principal Act is hereby repealed and replaced by new section as follows-

Appointment of Exccutive Derector.

6.-(1) There shall be an Executive Director of the Agency who shall be appointed by the President.

(2) A person shall qualify to be appointed as an Executive Director if he-

(a) is a Zanzibari;

(b) is a holder of at least a master degree of pharmaceutical sciences or its equivalent or any other related field from a recognized University; and

(c) has at least seven years working experience in the related field.

(3) The Executive Director shall be the Chief Executive Officer of the Agency and shall be responsible for the management affairs and the day to day operation of the Agency.

Amend-ment of section 7

9. Section 7of the Principal Act is hereby repealed and replaced by the new section as follows-

Departments of the Agency

7.-(1) There is hereby established Departments of the Agency as follows-

(a) Food Safety Control;

(b) Medicine, Cosmetic and other Medical Products;

(c) Laboratory Services; and

(d) Cooperate Services.

(2) The Agency may establish other Departments or Units as may deem necessary.

Amend-ment of section 12

10. Section 12 of the Principal Act is hereby repealed and replaced by the following-

Technical Committees

12.-(1) Agency may establish Technical Committees and assign responsibility for each committee with the intent to facilitate execution and performance of operational functions of the Agency as it may deem fit.

(2) The Technical Committee established under sub section (1) of this section, may regulate its own proceedings.

Addition of new section 13A

11. The Principal Act is hereby amended by adding new section 13A immediately after section 13 as follows-

Appointment of Analyst

13A.-(1)The Executive Director may, upon advice of the Board, by notice published in the Gazette, appoint a qualified person among chemist, food scientist, pharmacist, microbiologist, biotechnologist, scientist, biochemist, laboratory technician, engineer or any related field to be Analyst for the purpose of enforcement the provisions of this Act

(2) A person shall not qualify to be appointed as Analyst under the provisions of sub section (1) of this section, if that person has an interest in the storage, manufacture, import or sale of any product regulated under this Act.

Repealing of section 14

12. Section 14 of the Principal Act is hereby repealed.

Addition of sections 15A, 15B and 15C

13. The Principal Act is hereby amended by adding new sections 15A, 15B and 15C immediately after section 15 as follows-

Transparency and Information sharing

15A.-(1) The Agency may establish quality management system based on International Standards to improve efficiency and transparency.

(2) The Agency may set up systems to provide for the creation of a regional information management system with which it may share relevant regulatory information.

(3) The Agency may establish paper and electronic web-based copies including but not limited to regulations, laws, forms, applications and registers of medical products.

Protection and access to information

15B.-(1) A person shall not be allowed to disclose to any person or institution any information acquired by him in the exercise of his powers or the performance of his functions under this Act relating to the business or affairs of any person or use such information for self-gain or for the benefit of his employer.

(2) A person may be permitted to disclose information-

(a) for the purpose of the exercise of his powers or the performance of his functions under this Act with the written authority of the Agency;

(b) when required to do so by any competent court or under any law; or

(c) if it is for the public interest.

Monitoring and Evaluation frame work

15C.-(1) The Agency shall establish a Monitoring and Evaluation frame work charged with reviewing and assessing the performance of the Agency.

(2) The Agency shall prepare quarterly, semi-annual and annual reports and present to the Board.

Amendment of section 20

14. Section 20 of the Principal Act is hereby amended as follows-

(a) in sub section (3), by deleting the word **"two"** appears between the word **"than"** and **"million"** and replace it by the word **"three";** and

(b) in sub section (4), by deleting the word **"two"** appears between the word **"than"** and **"hundred"** and replace it by the word **"three"**.

Amendment of section 27

15. Section 27(2) of the Principal Act is hereby amended by adding the words **"retail food business"** in paragraph (b) between the words **"sale"** and **"or"**.

Addition of new sections 60A, 60B and 60C

16. The Principal Act is hereby amended by adding new sections 60A, 60B and 60C immediately after section 60 as follows-

Pharmacovigilance

60A.-(1) The Agency shall establish a pharmacovigilance programme to monitor and report on the safety of medical products.

(2) Subject to subsection (1) of this section, the programme shall undertake-

(a) monitoring and analysis of adverse effects or events relating to products regulated under this Act;

(b) identifying and reporting adverse events relating to clinical trials;

(c) establishing causality, taking remedial actions, and reporting to international safety monitoring systems; and

(d) appropriate regulatory action when necessary, including but not limited to revising the marketing authorisation or labelling requirements of the medical product.

(3) The Agency may issue guidelines to provide for mandatory reporting and submission of periodic safety updates by the manufacturers and distributors, and voluntary reporting by health care professionals and the public.

Quality Monitoring

60B. The Agency may institute a risk-based testing scheme consisting of sampling of medical products throughout the supply chain, to identify the products that are most at risk or likely to be falsified or sub-standard, and shall take appropriate action to protect public health, including enforcement measures under this Act.

Recall and Withdrawal of Medical Products

60C. Whenever the Executive Director finds that any medical product does not conform with the standards of identity, strength, quality and purity or any other requirement specified in the documentation for registration, shall-

(a) order the licensee to discontinue with the sale of the remainder of the batch and, so far as is practicable; and

(b) recall any portion of the batch already sold.

17. The Principal Act is hereby amended by adding new section 61A immediately after section 61 as follows- Addition of new section 61A

Disposal of medical products

61A. Subject to section 61(1) of this Act, the Agency may direct that such products be withdrawn from the market and disposed of in accordance with relevant laws and in the manner stipulated in the regulations made under this Act.

Addition of new section 73A

18. The Principal Act is hereby amended by adding a new section 73Aimmediately after section 73 as follows-

Report adverse drugs reaction

73A. Public and private health facility shall report adverse drug reaction to the Agency.

Addition of new section 93A

19. The Principal Act is hereby amended by adding new section 93A immediately after section 93 as follows-

Illegal possession of labels

93A. A person who possesses labels which are suspected to be illegal commits an offence.

Addition of new section 119A

20. The Principal Act is hereby amended by adding a new section 119A as follows-

Declaration and conflict of interests

119A.-(1) A staff of the Agency, member of the Board or Committee shall declare any interest related to any products or which may be relevant to any decision making.

(2) Identified conflicts of interest shall be appropriately managed in accordance with published guidelines.

Amend-ment of section 123

21. Section 123 of the Principal Act is hereby amended by repealing paragraphs (f) and (x) thereof.

Addition of new section 124A

22. The Principal Act is hereby amended by adding a new section 124A as follows-

Compounding of offences

124A.-(1) The Executive Director may compound an offence committed by a person under this Act or its regulations

by requiring him to pay the fine prescribed for such an offence, provided that the person-

(a) admits in writing that he has committed an offence and shall take due care not to repeat the same; and

(b) pays other sums payable under this Act or its Regulations.

(2) Subject to provisions of sub-section (1) of this section, no subsequent prosecution for the alleged offence shall be instituted against the person.

23. The Schedule of the Principal Act is hereby repealed and replaced by the following- Amend-ment of Schedule

SCHEDULE
PROCEEDINGS OF THE ADVISORY BOARD
[Under section 5A(5)]

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1. The Chairperson shall preside at every meeting of the Board, in the absence of the Chairperson, the Vice Chairperson shall preside the meeting and in the absence of the Vice Chairperson, the members present shall elect one amongst them to preside the meeting. Meetings of the Board.

(2) Notice attached with the documents of the meetings of the Board shall be issued and submitted to the members at least seven days before the meeting.

(3) The Board shall ordinarily meet at least once in every three months for the transaction of its business, and in case of emergency, the Board may meet any time.

(4) The Chairperson may at any time convene a special meeting of the Board, upon request in writing by majority of the members, provided that the special meetings shall not exceed the quarterly meetings.

Vice Chairperson

2. The Board shall elect one among its members to be Vice Chairperson.

Decisions of the Board

3.-(1) The decision of the Board shall be determined by votes of majority of the members present and voting, and in the event of an equality of votes, the Chairperson or a person presiding the meeting, shall have a casting vote.

(2) Notwithstanding sub paragraph (1) of this paragraph, decision may be made by the Board by circulation of papers to the members whereby each member shall express his views in writing provided that, any member may require that any such decision to be deferred for discussion at a full meeting.

(3) A circular resolution in writing signed by members for the time being in Zanzibar but who shall not be less than five members, shall be effectual as a decision made at meeting.

Quorum of the meeting

4. More than half of the total number of members shall form a quorum for a meeting of the Board.

Minutes of the meetings

5. The Secretary shall record and keep minutes of all business conducted or transacted in the meeting of the Board, which shall be read and confirmed by the Board at the next meeting and signed by the Chairperson and Secretary.

Tenure of members of the Board

6. The members of the Board save for ex-officio member shall, unless his appointment is sooner terminated or otherwise ceases to be a member, hold office for a period of three years from the date of his appointment, and may be eligible for reappointment for another term.

Cessation of member-ship

7.-(1) A member of the Board shall cease to hold office if he-

(a) dies;

(b) is unable to perform the function of his office;

(c) commits misbehavior or misconduct;

(d) convicted of a criminal offence involving fraud, dishonest or moral turpitude;

(e) failed to disclose his interest in issue discussed in the meeting;

(f) absents himself from three consecutive meetings without the leave of Chairperson; or

(g) resigns by given written notice to the appointing authority and the reasons thereof.

(2) If a member of the Board, save for ex-officio members, ceases to be a member for any reason provided under sub section (1) of this section, before the expiration of his term of office, the appointing authority shall appoint another person in his place and the person so appointed shall hold office for the remaining term of office of his predecessor.

Disclaimer of interest of members

8. A member who directly or indirectly has interest in issue to be discussed in the meeting of the Board, shall declare the nature of his interest to the Board and shall refrain from participating in the deliberation of the matter in issue.

OBJECTS AND REASONS

The object of this Bill is to make amendment to the Zanzibar Foods, Drugs and Cosmetics Act, No. 2 of 2006. The amendments are made in order to comply with the recommendations of the African Union Model Law on Medical Products Regulation together with East African Sector al Council on Legal and Judicial Affairs. It has been resolved that, all African Union and East African Member States have to establish an autonomous body in order to regulate the manufacture, import, trade, sale and export of all human and veterinary medicines, medical devices and other health supplies, various pharmaceutical products as well as human food and animal feeds, vitamins and other nutritional supplements for both local use and export to the regional and international market.

Based upon the said recommendations, the amendments are made to reform the Zanzibar Foods, Drugs and Cosmetics Board to regulate the aforementioned products in order to promote the management of health delivery systems and better planning mechanisms to ensure easy access to affordable, safe and quality human and veterinary medicine, human food and animal feeds and other related products within the African community.

The proposed agency shall work as semi-autonomous institution to develop regulatory framework, policies, standards, guidelines and procedures for undertaking safety and quality veterinary medicines and food for human and animal feeds and other related products. The proposed amendments will improve the powers of the Agency to perform its functions effectively and efficiently including controlling mechanism in counterfeit medical products and other related products for human consumption and animal feed including food for human and animals.

This Bill is divided into two parts.

Part One is about preliminary provisions which include short title and commencement date and also construction of this amendment Act with the Zanzibar Foods, Drugs and Cosmetics Act, No. 2 of 2006 to be referred as Principal Act.

Part Two is about amendment provisions which contain amendment of various sections such as-

(a) amendment of section 2 by deleting some words and replacing with other interpretations and adding new interpretation of certain words;

(b) amendment of section 3 by establishing the Zanzibar Food and Drugs Agency;

(c) amendment of section 4;

(d) amendment of section 5 by repealing and replacing paragraph (d);

(e) adding new sections 5A and 5B immediately after section 5. Section 5A is about establishment of the Advisory Board with new composition and qualifications of members including Chairperson and other related matters of the Board thereof. Section 5B is about powers and duties of the Board;

(f) amendment of section 6 which is about appointment of Executive Director as Chief Executive officer of the Agency.

(g) amendment of section 7 which is about establishment of Departments of the Agency;

(h) amendment of section 12 which is about establishment of Technical Committees and other Committees of the Board;

(i) addition of new section 13A which is about appointment of Analysts;

(j) repealing of section 14 thereof;

(k) addition of sections 15A, 15B and 15C;

(l) amendment of section 20;

(m) amendment of section 27(2) by adding the words retail food business in paragraph (b) in order to regulate those who are dealing with that business.

(n) addition of new sections 60A, 60B, 60C, 61A, 73A, 93A, 109A and 124A; and

(o) repealing the whole Schedule and replacing it by the new one which provides for proceedings and other related matters of the Board thereof.

17th October, 2016

(MAHMOUD THABIT KOMBO)
Minster for Health

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