## CHAPTER 219

# THE TANZANIA MEDICINES AND MEDICAL DEVICES ACT

[PRINCIPAL LEGISLATION]

ARRANGEMENT OF SECTIONS

*Section* *Title*



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**PART III**



**PART IV**

**PROVISIONS REGARDING DRUGS**

*(a) Pharmacy*



*(b) Registration of Drugs, Medical Devices or Herbal Drugs*



*(c) Clinical Trials of Drugs, Medical Devices or Herbal Drugs*



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## PART VIII
## ENFORCEMENT AND LEGAL PROCEEDINGS

*(a) Inspection, Sampling and Analysis*



*(b) Legal Proceedings*



## PART IX
## MISCELLANEOUS PROVISIONS AND SAVINGS



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# CHAPTER 219

# THE TANZANIA MEDICINES AND MEDICAL DEVICES ACT

An Act to provide for the efficient and comprehensive regulation and control of medicines, medical devices, herbal drugs and poisons and to repeal the Food (Control of Quality) Act, 1978, the Pharmaceuticals and Poisons Act, 1978 and to provide for related matters.[1]

[1st July, 2003]
[GN. No. 160 of 2003]

Acts Nos.
1 of 2003
12 of 2004
13 of 2008
1 of 2011
4 of 2013
9 of 2017
8 of 2019

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## PART I
## PRELIMINARY PROVISIONS

Short title
Act No.
8 of 2019 s. 24

**1.** This Act may be cited as the Tanzania Medicines and Medical Devices Act.

Application

**2.** This Act shall apply in the manner in which the Minister may, by order in the *Gazette*, direct.

Interpretation
Act No.
9 of 2017 s. 29

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

"administer" means administering of substance or article to a human being or an animal whether orally, by injection or by introduction into the body in any other way, or by external application, whether by direct contact with the body or not, and any reference in this Act to administering a substance or article shall be construed as a reference to administering it either in its existing state or after it

1 The long Title was amended by Act No.8 of 2019, s. 23

has been dissolved or dispersed in, sprayed, or diluted or mixed with some other substance used as a vehicle for such administration;

"analyst" means a person designated as an analyst by the Minister on advice of the Director General for the purposes of this Act under section 15;

"animal" means all vertebrates, invertebrates or other fauna except man;

"assemble" in relation to a medicinal product includes:

(a) enclosing the product, with or without other medicinal products of the same description in a container which is labelled before the product is sold or supplied; or

(b) where the product, with or without other medicinal products of the same description, is already enclosed in the container in which it is to be sold or supplied, and is labelled before the product is sold or supplied;

"association" includes a body corporate partnership or unincorporated;

"Authority" means the Tanzania Medicines and Medical Devices Authority or by its acronym "TMDA" established by section 4;

"authorised seller of pharmaceutical products" means a person, other than a person lawfully conducting a retail pharmacy business;

"Board" means the Ministerial Advisory Board established under section 9;

"business" includes professional practice and any activity carried on by person or a body of persons in relation to products regulated under this Act;

"certificate" means a certificate issued by the Authority under this Act;

"composition" in relation to a drug products means the ingredients of which it consists, proportions, degree of strength, quality and purity in which those ingredients are contained;

"container" in relation to products regulated under this Act, means a bottle, jar, box, packet, sachet or other receptacle

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which contains or is to contain in it, not being a capsule or other article in which the product is or is to be administered or eaten, and, where any such receptacle is or is to be contained in another such receptacle, includes the former but does not include the latter receptacle;

"controlled drug" means any narcotic drug, psychotropic substance or precursor as listed under section 57;

"dentist" means a person who is registered as a dentist under the Medical, Dental and Allied Health Professionals Act; Cap. 152

"Director General" means the Chief Executive of the Authority appointed under section 8(1);

"dispense" means the supply of a drug, drug product or poison on and accordance with a prescription lawfully given by a medical practitioners, dentists or veterinarian;

"drug", "medicine" or "pharmaceutical product" 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 the symptoms thereof, in man or animal;

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

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

(d) articles intended for use as a component of any articles specified in clause (a), (b) or (c); but does not include medical devices or their components, parts or accessories;

"general sale drug" means any drug whose use does not need the direction or prescription by a medical practitioner, dentist or veterinarian;

"herbal drug" means any labelled preparation in pharmaceutical dosage form that contains as active ingredients one or more substances of natural origin that are derived from plants;

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"human consumption" includes use in the manufacture of food for human consumption and "consume" shall be construed accordingly;

"ingredient" in relation to the manufacture or preparation of a product regulated under this Act includes anything which is the sole ingredient or in combination of that product as manufactured or prepared;

"inspector" means an inspector appointed, authorised or recognised as such under section 79;

"International Drug Control Convention" means-

(a) the Single Convention on Narcotic Drugs, 1961, adopted by the United Nations Conference at New York in March, 1961;

(b) the Protocol, amending the Convention mentioned in sub-clause (a), adopted by the United Nations Conference at Geneva in March, 1972;

(c) the Convention on Psychotropic Substances, 1971, adopted by the United Nations Conference at Vienna in February 1, 1971;

(d) United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances adopted at Vienna on 19th December, 1988; and

(e) any other international drug control convention, or protocol or other instrument amending an International Drug Convention, relating to narcotic drugs, precursor chemicals or psychotropic substances which may be ratified or acceded to by the United Republic after the commencement of this Act;

"label" means any tag, brand, mark, pictorial or other descriptive matter, written, printed, stenciled, marked, embossed or impressed on or attached to a container of any food, drug, cosmetics or medical devices;

"leaflet" means and includes any written information related to food, drug, medical devices or cosmetic products;

"manufacture" includes all operations involved in the production, preparation, processing, compounding, formulating, filling, refining, transformation, packing,

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packaging, re-packaging and labelling of products regulated under this Act;

"manufacturer" means a person or a firm that is engaged in the manufacture of products regulated under this Act;

"medical device" means any instrument, apparatus, laboratory equipment and reagent, implement, machine, appliance, implant, in vitro reagent, or calibrator, software, material or other similar or related article which is intended by manufacturer to be used alone or in combination for human beings or other animals, for the following purpose of-

(a) diagnosis, prevention, monitoring, treatment or alleviation of diseases or compensation for an injury;

(b) investigation, replacement, modification, support, the anatomy or of a physiological process;

(c) supporting or sustaining life;

(d) control of conception; or

(e) providing information for medical or diagnostic purposes by means of vitro examination or specimen derived from the human body or other animal,

except that it does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means;

"medical practitioner" means a person who is registered as a medical practitioner under the Medical, Dental and Allied Health Professionals Act; Cap. 152

"Minister" means the Minister responsible for health;

"narcotic drugs" means any of the substances natural or synthetic referred to in the Single Convention on Narcotic Drugs of 1961 intended for medical and scientific purposes;

"package" in relation to any product regulated under this Act, means any box, packet or any other article in which one or more primary containers of products regulated under this Act are to be enclosed in one or more other boxes, packets or articles in question, the collective number thereof;

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"Permanent Secretary" means the Permanent Secretary responsible for health;

"pharmacopoeia" means a current edition of Tanzania Pharmacopoeia, British Pharmacopoeia, European Pharmacopoeia, United States Pharmacopoeia, the International Pharmacopoeia and any other pharmacopoeia approved by the Authority;

"pharmacy" includes a registered pharmacy department in a hospital, clinic or health centre or a community pharmacy;

Cap. 311 "pharmacist" means a person who is registered as a pharmacist under the Pharmacy Act;

"poison" means a substance specified in the poisons list prescribed under section 57;

"precursor chemicals" means all substances used in the manufacture of Narcotic drugs or Psychotropic substances as provided for under the International Drug Control Conventions;

"premises" includes land, buildings, structures, basements and vessels and in relation to any building includes a part of a building and any curtilage, forecourt, yard, or place of storage used in connection with building or part of that building; and in relation to "vessel", means ship, boat, air craft, and includes a carriage or receptacle of any kind, whether open or closed;

"prescription" means a lawful written direction by a medical practitioner, dentist, or veterinary surgeon for the preparation and dispensation of a drug by a pharmacist;

"prescription medicine" means any drug product required to be dispensed only upon a prescription given by a medical practitioner, dentist or veterinary surgeon or any other person approved by the Minister;

"products regulated under this Act" means drugs, poisons, herbal drugs and medical devices;

"psychotropic substances" means any substance natural or synthetic or any natural material, or any salt or

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preparation of such substance or material referred to in the Convention of Psychotropic Substances of 1971 intended for medical and scientific purposes;

"retail pharmacy business" means a business which consists of or includes the retail sale of drug products but does not include a professional practice carried on by a medical practitioner, dentist or veterinary surgeon;

"sanitary convenience" means a latrine, privy, urinal, water closet, pitlatrine or earth closet;

"sell" or "sale" means sell by wholesale or retail and include import, offer, advertise, keep, expose, display, transmit, consign, convey or deliver for sale or authorise, direct or allow a sale or prepare or possess for purposes of sale, and barter or exchange supply or dispose of to any person whether for a consideration or otherwise;

"substance" means any natural or artificial substance, whether in solid or liquid form or in the form of a gas, vapour or radiation;

"superintendent" for the purpose of this Act, means a person who is a managers and controls the business of a pharmacist;

"Tanzanian National Formulary", "National Formulary" means a compendium known by that name published by the Authority which comprises of drug names, drug formula clinical uses and other information concerning medicines;

"traditional health practitioner" means any person practicing traditional medicine and registered under the Traditional and Alternative Medicine Act; Cap. 244

"treatment" in relation to disease, includes anything done or provided for alleviating the effects of the disease, whether it is done or provided by way of cure or not;

"unfit product" means a product regulated under this Act which violates any provision of this Act; and

"veterinarian" means a person who is registered as a veterinarian or specialist under the Veterinary Act. Cap. 319

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## PART II
## ADMINISTRATIVE AND GENERAL PROVISIONS

*(a) Administration*

Establishment of Tanzania Medicines and Medical Devices Authority Cap.245 Act No. 8 of 2019 s. 25

**4.**–(1) There is hereby established Tanzania Medicines and Medical Devices Authority or by its acronym "TMDA".

(2) The Authority shall be an Executive Agency and shall operate in accordance with the Executive Agencies Act.

(3) The Authority shall have a common seal and the seal of the Authority shall be authenticated by the signature of the Director General or in his absence any person acting on his behalf authorised by him in writing.

(4) The Authority in discharging its functions under this Act, in addition to the functions and powers conferred under sections 5 and 6 shall, take into account the functions as may be specified under the law relating to the establishment of executive agencies.

Functions of Authority Act No. 8 of 2019 s. 26

**5.**–(1) The Authority shall be the regulatory body for the products regulated under this Act, and shall in particular-

(a) regulate all matters relating to quality and safety of drugs, herbal drugs, medical devices and poisons;

(b) regulate in accordance with this Act, the importation, manufacture, labelling, marking or identification, storages promotion, sell of drugs, herbal drugs and medical devices or any materials or substances used in the manufacture of products regulated under this Act.

(c) ensure that evidence of existing and new adverse events, interactions and information about pharmacovigilance of products being monitored, analysed and acted upon;

(d) ensure that, clinical trials on drugs, medical devices and herbal drugs are being conducted in accordance with prescribed standards;

(e) foster co-operation between the Authority and other institutions or organisations and other stakeholders;

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(f) approve and register products regulated under this Act, manufactured within or imported into, and intended for use in the United Republic;

(g) examine, grant, issue, suspend, cancel and revoke certificates and licences or permits issued under this Act;

(h) appoint inspectors and order inspection of any premises;

(i) promote rational use of drugs, medical devices and herbal drug;

(j) establish and maintain the Tanzania National Formulary and Tanzania Pharmacopoeia;

(k) provide the public with unbiased information on products regulated under this Act;

(l) maintain registers prescribed under this Act;

(m) be responsible for its human resource management and development;

(n) promote, monitor and ensure successful implementation of the provisions of this Act;

(o) attend to and, where possible, take legal measures on complaints made by consumers against manufacturers of products regulated under this Act;

(p) do such acts or take such measures as are, in the opinion of the Authority, necessary or expedient for the prevention of health hazards to consumers which may result from the consumption or use of low or bad quality products regulated under this Act; and

(q) carry out such other functions as may be conferred upon the Authority by any written law or as are incidental to the performance of its functions under this Act.

(2) In the performance of its functions, the Authority shall, as far as is practicable, maintain a system of consultation and cooperation with-

(a) any government institution dealing in atomic energy;

(b) the Drugs Control and Enforcement Authority established by the Drug Control and Enforcement Act; Cap. 95

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(c) the Fisheries and Forestry and Bee keeping divisions in the Ministry responsible for fisheries and bee keeping;

(d) the Tanzania Bureau of Standards established by the Standards Act;

Cap. 130

(e) the Directorate of Veterinary Services in the Ministry responsible for Livestock Development; or

(f) a body or Institution established by or under any other written law and having functions similar to those specified in subsection (1) or having functions which relate to drugs, medical devices and herbal drugs.

Powers of Authority

Cap. 245

**6.** For the better performance of its functions, the Authority in addition to the powers granted under the Executive Agencies Act, shall subject to this Act have powers to-

(a) enter or remove any name from any register prescribed under this Act or, subject to such conditions as the Authority may impose, restore it thereto;

(b) hire and terminate services;

(c) condemn and order destruction or disposal in any way any product regulated under this Act found to be unfit for its intended use; and

(d) regulate its own procedures.

Sources of funds and its management

Cap. 245

Acts Nos:
13 of 2008 s. 47
4 of 2013 s. 53
Cap. 245

**7.**–(1) The funds and resources of the Authority shall, in addition to those provided for under the Executive Agencies Act, include-

(a) interest from deposits; and

(b) proceeds derived from sell of assets and any other source of income identified by the Authority and legally obtained.

(2) The funds and resources of the Authority shall be applied for the purposes for which the Authority is established and managed as provided for under the Executive Agencies Act.

(3) The financial year of the Authority shall start on the first day of July of each year and end on the last day of June of the next following year.

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(4) Without prejudice to the generality of the financial provisions under this Act, the Authority shall establish a General Fund into which all monies received by it shall be paid and out of which all payments required to be made by the Authority shall be effected.

(5) Subject to the approval of the Board, the Authority may invest any monies in such a manner as it deems fit.

Appointment and tenure of Director General
Cap. 245

**8.**–(1) There shall be a Director General appointed by the Minister on the advice of the Public Service Commission as provided for under section 9 of the Executive Agencies Act, from among persons who possess the relevant qualifications, experience and competence to manage efficiently and effectively, the affairs of the Authority in accordance with modern management standards and he shall hold the office on such terms and conditions of service as the Minister may specify in the instrument of appointment.

(2) For the purposes of assisting the Public Service Commission to select the best candidate for appointment as Director General, the Board shall submit to the Commission a short list of candidates who submitted their applications for such office under an open and competitive system, together with an objective assessment of the suitability of each candidate, and the Board shall be entitled to be represented, either by one of its members or by any other person appointed by the Board for that purpose at the proceedings of the Commission for selecting a candidate to be appointed.

(3) The Director General shall be the head of the Authority and shall be responsible for the day to day operations of the Authority, the proper management of its funds, property and business and for the personnel management and development, organisation, control and discipline of the employees of the Authority.

(4) The Director General shall-

(a) be the Authority's accounting officer with such financial responsibilities as may be provided for under the Executive Agencies Act; and
Cap. 245

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(b) perform his functions in accordance with an Annual Performance Agreement concluded between him and the Permanent Secretary.

(5) Whenever the Director General is not in the office or is prevented by illness or other reasonable cause from discharging his functions under this Act, such functions shall be discharged by any other official appointed by him on his behalf or delegated by him on his behalf to perform such administrative or professional functions.

(6) The Director General shall hold office for five years or for such period as may be specified in his instrument of appointment and shall be eligible for re-appointment.

(7) The Minister may, after consultation with the Public Service Commission, and on the recommendation of the Permanent Secretary, terminate the appointment of the Director General for-

(a) misconduct;

(b) failure or inability to perform the functions of his office arising from infirmity of body or mind; or

(c) incompetence.

(8) Where the Director General is aggrieved by the decision of the Permanent Secretary made under subsection (2) of section 5 of the Executive Agencies Act, in respect of any disciplinary action against him or in respect of the decision of the Minister made under subsection (6) of section 11 of the Executive Agencies Act, to terminate his appointment may, in accordance with such procedures as may be prescribed, appeal to the Minister from the decision of the Permanent Secretary or to the Prime Minister from the decision of the Minister, as the case may be.

Cap. 245
Cap. 245

Establishment of Board
Act No. 12 of 2004 Sch.
Cap. 245

**9.**–(1) There shall be established a Ministerial Advisory Board in accordance to the Executive Agencies Act.

(a) [Omitted.]

(b) [Omitted.]

(2) [Omitted.]

(3) [Omitted.]

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(4) In appointing the members of Board, the Minister shall have due regard to the need to include in its membership, persons who are not in the public service and persons who are representative of the interests of the Authority's stakeholders.

(5) A member of the Board, other than an ex-officio member, shall hold an office for a period not exceeding three years or for such shorter periods as may be specified in his instrument of appointment.

(6) The Director General may participate in each deliberation, except in matters affecting his own interest, but he shall have no right to vote.

Powers and functions of Board Cap. 245

**10.** The powers and functions of the Board shall be as provided for under the Executive Agencies Act.

Establishment of Directorates and appointment of Directors and other employees of Authority

**11.**–(1) The Director General shall, in consultation with the Permanent Secretary determine the organisational structure of the Tanzania Medicines and Medical Devices Authority and the distribution of responsibilities as he deems fit.

(2) Subject to subsection (1), the Director General shall, upon consultation with the Minister responsible for public service, on such terms and conditions, appoint for each directorate persons who possess relevant qualifications and experience to be directors.

(3) For the purposes of assisting the Director General to select the best candidates for appointment as directors, the Director General shall cause to be submitted to him by a body approved by the Minister responsible for public service a short list of candidates who shall submit their applications for such office, under an open and competitive system, together with an objective assessment of the suitability of each candidate.

(4) The Director General and directors shall constitute a management team under the chairmanship of the Director General, which shall advise the Director General on all matters concerning the management and functions of the Authority.

(5) The Director General shall engage such number of other employees as he may consider necessary or desirable

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for the efficient and effective discharge of the functions of the Authority and on such terms and conditions of service as he may determine in accordance with any directions issued by the Minister responsible for public service.

(6) The Director General shall be responsible for the discipline and control of the employees of the Authority and may terminate the appointment of an employee for-

(a) misconduct;

(b) incompetence; or

(c) failure or inability to perform the functions of his office arising from infirmity of body or mind.

(7) An employee of the Authority who is aggrieved by the decision of the Director General in respect of any disciplinary action against him or the termination of his appointment may, in accordance with such procedure as may be prescribed by the Public Service Commission, appeal to the Permanent Secretary against the decision.

Transfer of staff and their rights

**12.**–(1) With effect from the date on which the Act establishing the Authority comes into force, any person who, on that date holds a public office in a department in relation to which the Authority is established shall, except as may otherwise be determined by the Director General with the approval of the Permanent Secretary in respect of any such person, become an employee of the Authority; but the provisions of this subsection shall not be construed as affecting the appointment to the public service of any person who by virtue of this subsection, does not become an employee of the Authority nor his eligibility to continue to hold that office.

(2) Nothing in this section shall operate so as to prevent any employee of the Ministry of Health, the National Food Control Commission, the Pharmacy Board or any government institution from resigning or being dismissed.

(3) The terms and conditions of employment of any employee transferred from the Ministry of Health, the National Food Control Commission, the Pharmacy Board or any other

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government institution to the Authority shall not be less favourable than those enjoyed by that employee immediately prior to the date on which the transfer was made.

(4) An employee of the Ministry of Health, the National Food Control Commission, the Pharmacy Board or any other government institution-

(a) whose service continues with the Authority; or

(b) whose service is transferred to the Authority,

shall be deemed to be continuous for the entire period from the date of first appointment with the respective Ministry or government institution.

(5) Where an employee whose service with the Authority is deemed to be continuous is a member of any statutory, voluntary, pension or any other superanuation scheme, such employee shall continue to be governed by the same laws and regulations governing such schemes and his service for the purpose of such scheme, shall be deemed to be service with the Authority and the Authority shall contribute to such scheme accordingly.

(6) Where an employee of the Ministry of Health, the National Food Control Commission, the Pharmacy Board or any government institution whose service is not transferred to the Authority, his service shall be transferred to the respective Ministry or government institution which shall determine his employment status under the same laws and regulations governing his services prior to his transfer to the Pharmacy Board or the National Food Control Commission.

Establishment of Technical Committees of Authority

**13.**–(1) There shall be established by the Authority, Technical Committees responsible for advising the Director General on matters related to the Authority's functions under this Act.

(2) The functions and composition of the Technical Committees shall be set out in the regulations.

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Establishment of Laboratory Act No. 8 of 2019 s. 27

**14.**–(1) There is hereby established within the Authority, the Laboratory to be known as the Tanzania Drug Authority Laboratory.

(2) The Laboratory shall perform all functions relating to the quality of products regulated under this Act and shall in particular perform the following:

(a) analyse drugs, medical devices, herbal drugs, raw materials, drug adjuvant, packaging material, drug delivery systems, systemic diagnostic agents and any other product that may be deemed to constitute a drug product for the purpose of this Act;

(b) conduct research and training; and

(c) do such other function as shall be determined by the Authority.

(3) The Minister may, on advice of the Director General, by order published in the *Gazette,* establish such other drug laboratories to carry out the functions entrusted to the Tanzania Drug Authority Laboratory by this Act or any regulations made thereunder.

(4) The Minister may, on the advice of the Director General, by notification in the *Gazette* appoint any other laboratory or institution to perform such functions as he may specify for the purposes of enforcement of this Act.

(5) In performing its functions, the Authority shall take in cognisance the existence of the Government Chemical Laboratory Agency for analysis of drugs and medical devices and wherever necessary shall seek the assistance of that Laboratory.

(6) The Minister may on the advice of the Director General by order published in the *Gazette*, make rules prescribing-

(a) the functions of the Tanzania Drug Authority Laboratory and the local area or areas within which such functions may be carried out;

(b) the procedure for the submission to the said Laboratory of samples of articles of drugs, herbal drugs, medical devices and poisons for analysis or tests and the forms of the Laboratory's reports; and

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(c) such other matters as may be necessary or expedient to enable the said Laboratory to carry out its functions.

(7) The Minister may in case of any dispute regarding analytical results appoint any laboratory or qualified person to authenticate the analytical results.

Appointment of analysts

**15.**–(1) The Minister may, on advise of the Director General by notice published in the *Gazette*, appoint such persons as he thinks fit, having the necessary qualifications to be Analysts for the purposes of enforcement of this Act.

(2) The Minister, when appointing Analysts under subsection (1), shall take into account not to appoint a person who has any interest in the manufacture, import or sale of any product regulated under this Act.

Exemption from taxation

**16.** Notwithstanding any other written laws, no stamp duty or any tax shall be chargeable on receipt, contract, instrument or other document given or executed by the Authority or on behalf of the Authority or by any person in respect of any functions done or performed under this Act, but nothing in this section shall be construed to exempt any person from liability to pay income tax, stamp duty on any power of attorney, or on any document otherwise liable under the Stamp Duty Act or Income Tax Act.

Cap. 189
Cap. 332

Control of manufacturing, importation, export, sell etc.
Act No. 8 of 2019 s. 28

**17.** A person shall not manufacture for sale, import, export, distribute, sell, offer or expose drugs, medical devises for human consumption or use unless he complies with the provisions of this Act.

*(b) Registration of Premises*

Registration of premises

**18.**–(1) A person shall not manufacture for sale, sell, supply or store products regulated under this Act except in premises registered under this section for that purpose.

(2) Every application for registration or renewal of registration of premises shall be made to the Authority in the

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prescribed form, and shall be accompanied by such fee as the Authority may prescribe.

(3) The Director General or any person in his behalf-

(a) shall register the premises if he is satisfied that the prescribed requirements for which the premises is intended have been complied with;

(b) shall keep registers in the prescribed form of all premises registered under this section;

(c) may, for good and sufficient reasons refuse to register, or may cause to be deleted from the register, any premises which are or have become unsuitable for the purposes for which they were registered; and

(d) shall have the final say on the location and name of the proposed premises.

(4) A person who contravenes or fails to comply with this section, commits an offence and on conviction shall be liable under section 61 of the Economic and Organised Crime Control Act.

Cap. 200

Change of business ownership or any other change

**19.**–(1) A change of ownership of the business or any other change of a registered premises shall be notified to the Authority.

(2) Registration of premises registered under section 18 shall cease to have effect upon the expiration of thirty days from the date of changing the ownership of the business of products regulated under this Act.

*(c) Licences and Permits*

Application for licence or permit Act No. 8 of 2019 s. 29

**20.**–(1) An application for a licence or permit under this Act shall be made to the Authority in the prescribed form and shall be accompanied by such fee as may be prescribed in the regulations.

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(2) Where an application is made for a licence or permit under this Part in relation to drugs, medical devices or herbal drug, the Authority shall, before issuing the licence or permit to which the application relates, consider the following-

(a) in the case of application for manufacturing products regulated under this Act-

(i) the premises in which the applicant proposes to manufacture the respective products have been inspected and registered by the Authority for that purpose;

(ii) he has sufficient financial resources such as would enable him, in relation to the manufacture of products regulated under this Act, to maintain the standards of quality prescribed by or under this Act;

(iii) that he has not, within twelve months immediately preceding his present application, been convicted of an offence under this Act or any other written law relating to quality standards of products regulated under this Act;

(iv) that he is not disqualified in any other way from holding a licence or a person whose licence is suspended;

(v) that he has adequate expertise or skill or has personnel qualified to execute the business for which he is seeking to be licensed;

(vi) that he has adequate facilities such as would enable him to maintain the standards of quality prescribed in relation to the manufacture of the products for which he is seeking to be licensed; and

(vii) that he meets in all respects such other requirements which may be prescribed in respect

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of manufacturers of products regulated under this Act; and

(b) in the case of an application for the licence or permit to sell products regulated under this Act-

(i) the premises on which products regulated under this Act, of the description to which the application relates will be stored;

(ii) the equipment are available for storing the products regulated under this Act on those premises;

(iii) suitability of the equipment and facilities which are used for distributing the products regulated under this Act;

(iv) the arrangements made or to be made for securing the safekeeping of, and the maintenance of adequate records in respect of products regulated under this Act stored in or distributed from those premises;

(v) where the Authority is satisfied that it is in the public interest that a licence to sell product under this Act should be issued or renewed, the Authority may, on application made to it in writing on prescribed forms, and on payment of the prescribed fee, issue to the applicant a licence in the form prescribed, or renew the licence as the case may be; and

(vi) a separate licence under this section shall be required in respect of each set of premises in which the business is carried on.

(3) Subject to subsection (2)(b), a licence or permit to sell drugs shall be issued or renewed under this section only if the person applying for or holding the licence or permit is or has, a registered pharmacist in control of the distribution of the drugs.

(4) Subject to the conditions specified under subsection (2)(b) and any other conditions which the Authority may

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prescribe, a wholesale licence or permit to sell veterinary drugs shall only be issued or renewed if the person applying for or holding the licence or permit is or has, a pharmacist or a veterinarian in direct control of the distribution of veterinary drugs.

(5) The Director General shall keep registers of all licence or permit issued by the Authority under this section.

(6) The Authority may refuse to issue or renew, or may revoke, a licence or permit under this section, for any good and sufficient reason relating either to the applicant, licensee, quality, safety or efficacy of products or to the premises in which the business is, or is proposed to be carried on.

(7) A licence or permit issued under this section shall expire on the 30th day of June next following the date of issue.

Types and issuance of licences or permits Act No. 1 of 2011 s. 59

**21.**–(1) The Authority, shall subject to subsection (2) and upon an application, issue the following licences or permits-

(a) manufacturing licence;

(b) wholesale licence;

(c) retail licence in food, cosmetics and veterinary medicines and veterinary devices; or

(d) any other licence and permit as the Authority may deem fit for the purposes of this Act.

(2) The word "wholesale licence" as used in subsection (1) (b), means a licence for dealing in wholesale in the business relating to veterinary medicines, and includes importation of human medicines and medical devices.

(3) Where the Authority is satisfied that the applicant is a fit and proper person to carry on any business set out in subsection (1) may issue to the applicant the licence or permit appropriate to such business subject to such general or special conditions as the Authority may consider appropriate to impose.

(4) A licence or permit issued under subsection (1) shall be in the form and manner as set out in the regulations made under this Act.

(5) Where the Authority considers that the applicant is not fit and proper person to whom a licence or permit should be

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issued for carrying on of any business specified under this section it shall refuse to issue a licence.

Restriction on dealings in products regulated under this Act

**22.**–(1) Notwithstanding the provisions of this Act or any other written laws, a person shall not, on or after the appointed day, manufacture for sale, sell, offer, supply or import any product regulated under this Act unless-

(a) the product is registered in accordance with the provisions of this Act; and

(b) the person holds the appropriate licence or permit required and issued by the Authority.

(2) A person shall not in the course of any business carried on by him-

(a) sell or manufacture any product regulated under this Act except in accordance with a licence granted for that purpose;

(b) manufacture or assemble any product regulated under this Act except in accordance with a manufacturer's licence granted for that purpose; or

(c) sell, supply, import or export any product by way of wholesale dealing or retail except in accordance with licence or permit granted by the Authority for that purpose.

(3) A person who contravenes the provisions of this section relating to the manufacture, importation or wholesale of products regulated under this Act, commits an offence and on conviction shall be liable to a fine not exceeding five million shillings or to imprisonment for a term not exceeding two years or to both.

(4) A person who contravenes the provisions of this section relating to retail sale of products regulated under this Act, commits an offence and on conviction shall be liable to a fine not exceeding five hundred thousands shillings or to imprisonment for a term not exceeding three months or to both.

Exemptions when dealings in drugs

**23.**–(1) The provisions of section 22 shall not apply to-

(a) anything done by a medical practitioner or dentist which-

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(i) relates to a drug product specially prepared for administration or supply to his particular patient; or

(ii) relates to a drug product specially prepared by that dentist at the request of another dentist for administration to a particular patient of that other dentist; or

(iii) relates to a drug product specially prepared by that medical practitioner at the request of another medical practitioner for administration to a particular patient of that other medical practitioner.

(b) anything done by a veterinarian which-

(i) relates to a drug product specially prepared for administration to a particular animal which is under his care; or

(ii) relates to a, drug product specially prepared by him at the request of another veterinarian for administration to a particular animal or group of animals under the care of that other veterinarian;

(c) anything which is done in a pharmacy and is done by or under the supervision of a pharmacist and consists of preparing, dispensing, assembling or procuring a drug product in accordance with a prescription given by a medical practitioner, dentist or a veterinarian;

(d) anything which is done in a pharmacy by or under the supervision of a pharmacist and consists of-

(i) preparing or dispensing a non-prescription drug for administration to a person where the pharmacist is requested by or on behalf of that person to do so in accordance with the pharmacist own judgment as to the treatment required and that person is present in the pharmacy at the time of the request in pursuance of which that product is prepared or dispensed;

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(ii) preparing a stock of drug products with a view to dispensing them as mentioned in paragraph (c) or in paragraph (d)(i);

(e) anything which is done in a hospital pharmacy by or under the supervision of a pharmacist and consists of preparing a stock of drug products with a view to dispensing them as mentioned in paragraph (c); or

(f) the importation of a drug product by any person for administration to himself or to any persons who are members of his house-hold or the importation of a drug product where it is specially imported by or to the order of a medical practitioner or dentist for administration to his patient:

Provided that, either case the quantity so imported shall be not greater than is reasonably necessary for the purpose and is not of commercial value; or

(g) the importation of a drug product in such circumstances as may be specified by the Authority;

(h) the importation of any drug, medical devices or poison for purposes of research institution; or for the purpose of obtaining samples for registration.

(i) anything done by a traditional health practitioner registered under the Traditional and Alternative Medicines Act, which relates to a herbal drug specifically prepared for administration, or supply to this particular patient.

Cap. 244

Repealed

**24.** [Repealed by Act No. 1 of 2011 s.60.]

Suspension, variation and revocation of licences or permits

**25.**–(1) Subject to Part II Subpart (c), the Authority may suspend a licence for such period as it may determine, or may revoke, or vary any provisions of such licence.

(2) The suspension or revocation of a licence or permit under this section may be limited to products of one or more descriptions, or to any particular premises or to a particular part of any premises.

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(3) The Authority may, on the application by the holder of a licence or permit under this Part, vary the provisions of the licence or permit in accordance with any proposals contained in the application, if the Authority is satisfied that the variation will not affect the safety, quality or efficacy of such products.

Repealed

**26.–27**. [Repealed by Act No. 1 of 2011 s. 60.]

## PART III

Repealed

**28.–46**. [Repealed by Act No. 8 of 2019 s. 30.]

## PART IV
## PROVISIONS REGARDING DRUGS

*(a) Pharmacy*

Repealed

**47.–48**. [Repealed by Act No. 1 of 2011 s.60.]

Disposal of stock by disentitled person

**49.**–(1) Notwithstanding anything contained in the foregoing provisions of this Part-

(a) a person who having been permitted or licensed under this Act to possess or sell any drug, becomes for any reason disentitled to possess or sell that drug may, with the consent of the Authority may impose, within ninety days from the date of his disentitlement, disposed any stocks of drugs lawfully acquired by him prior to the disentitlement; and

(b) the person or representative of any deceased person who immediately before his death was lawfully in possession of any licence to deal with drug under this Act and any lawfully appointed liquidator, receiver or other person dealing with the property of any person who has ceased to be entitled to possess any licence to deal with drug under this Act may, with the written permission, and subject to the directions of the

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Authority, sell that drug to a licensed wholesale dealer or to any authorised seller of drugs.

(2) A person who carried on business or practices as a pharmacist in contravention of this section, commits an offence and on conviction shall be liable to a fine not less than one million shillings or to imprisonment for a term not less than six months or to both.

Restrictions on directions by Authority

**50.**–(1) Where an act or omission which, under this Part, may be made the ground of a direction by the Authority involving the seizure or restriction of the right of a person to have his name registered, is an act or omission on the part of an employee of the person, the Authority shall not give any such direction unless proof is given to its satisfaction of some or more of the fact specified in subsection (2) and the Authority is of the opinion that, having regard to the facts so proved, that person ought to be regarded as responsible for the act or omission.

(2) The facts for which the Authority shall be satisfied before giving the direction referred to in subsection (1) are-

(a) that the act or omission in question was instigated or connived at by that person;

(b) that person or his employee had been guilty, within twelve months immediately preceding the date when the act or omission concerned occurred, of similar act or omission and that person had, or reasonably ought to have had knowledge of that previous act or omission;

(c) where the act or omission concerned was a continuing act or omission, that the said person had, or reasonably ought to have had, knowledge of its continuance; and

(d) in case of criminal offence which is an offence under this Act, that the person had not exercised due diligence to enforce the execution of the Act.

(3) In this section, references to the responsibility, knowledge or diligence of the owner of the business shall, if the owner is an association, be construed as references to

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the responsibility, knowledge or diligence of that body as a whole.

*(b) Registration of Drugs, Medical Devices or Herbal Drugs*

Conditions for registration of drugs, medical devices or herbal drugs

**51.** The Authority shall approve the registration of a drug, medical device or herbal drug if it considers that-

(a) the availability of that drug is in the public interest; and

(b) it is safe, efficacious and of acceptable quality;

(i) in the case of a drug which is intended for use in human beings in relation to its effect on the health of man;

(ii) in the case of a veterinary drug in relation to its effect on the health of animals, consumers of food of animal origin, the environment and users; and

(iii) in the case of a medical device in relation to its safety and efficacy;

(c) the premises and manufacturing operation complies with the current good manufacturing practices requirements as provided in the regulations; and

(d) it complies with any other requirements as may be prescribed by the Authority.

Applications for registration of drugs, medical devices or herbal drugs

**52.**–(1) An application for the registration of a drug or medical device or herbal drug shall be submitted to the Director General in the prescribed manner and shall be accompanied by application fees, samples and such other particulars as are prescribed in the application guidelines issued by the Authority, and any other information as the Authority may require.

(2) As soon as possible after receiving an application in terms of subsection (1), the Director General shall notify the applicant that the application has been received.

(3) The Authority may charge any applicant such costs as it may incur for the purposes of carrying out Good Manufacturing Practice inspection or laboratory investigations prior to registration of any drug product.

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(4) An application in terms of subsection (1) may, at any time be withdrawn by the applicant but such withdrawal shall not entitle the applicant to the refund of the application fees referred to in subsection (1).

Registration of drugs medical devices or herbal drugs

**53.**–(1) The Authority may, on application made and after conducting such investigation which it may consider necessary and if it is satisfied that the drug, medical device or herbal drug in question is suitable for the purpose for which it is intended, and if it complies with the prescribed requirements it shall approve the registration of that drug or medical device or herbal drug subject to such conditions as it may impose.

(2) Where the Authority-

(a) refuses to approve the registration of a drug, medical device or herbal drug; or

(b) approves registration of a drug subject to conditions fixed in terms of subsection (1), the Director General shall inform the applicant in writing of such decision and the reasons thereof.

(3) Without the prejudice of subsection (1)-

(a) where the applicant is not so satisfied with the decision of the Authority he may, within sixty days after the date of the notification furnish the Director General with his representations; and

(b) where after consideration of any comments so submitted the Authority is satisfied with the representations, it may approve the registration of such drug, medical device or herbal drug or if it is still not satisfied it shall reject the application.

(4) Where the Authority approves the registration of any drug, medical device or herbal drugs, the Director General shall-

(i) enter in the register the prescribed particulars of the drugs, medical devices or herbal drug and any condition or particulars as it may deem fit;

(ii) allocate a registration number to the drug, medical devices or herbal drug; and

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(iii) issue to the applicant a certificate of registration in the prescribed form showing the registration number of that drug, medical device or herbal drug and any conditions subject to which it is registered.

(5) Notwithstanding the applicants proposed drug name, the Authority shall have power to reject a proprietary name on the grounds that it constitutes a safety hazard, misleading, is established based on International Non-proprietary Names (INN) stems for related substances, or for any other reason which the authority shall determine and every drug shall be registered under such a name or names as the Authority may approve.

(6) Where the Authority approves, refuses to approve or cancels the registration of a drug, medical device or herbal drug, the Director General shall cause to be published in the *Gazette* notification of such approval or refusal and shall in such notice specify, the name under which such drug is registered, the qualitative and quantitative content of its active components, the name of the registrant and the registration number.

(7) A certificate of registration issued under subsection (4) shall, unless earlier suspended or revoked, and subject to payment of prescribed annual retention fees be valid for a period of five years from the date of issue and may thereafter be renewed.

(8) Notwithstanding the provisions of subsection (7), where the application for renewal is made after the expiration of the period of validity of the certificate of registration of a drug, medical device or herbal drug, the application shall be considered as a fresh application and the provisions of section 31 shall apply accordingly.

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Register of drugs, medical devices and herbal drugs

**54.**–(1) Subject to the provisions of subsection (2), the Director General shall keep a register, to be known as the drugs, medical devices and herbal drugs register in a form approved by the Authority, in which he shall enter-

(a) the particulars of any drug or medical device or herbal drug which the Authority has directed him to register, including the conditions, if any, subject to which that drug or device has been registered; and

(b) the cancellation of the registration or variation of the conditions of registration of a drug, medical device or herbal drug.

(2) The drugs, medical devices or herbal drug register shall have the following parts-

(a) Part I relating to human drug products;

(b) Part II relating to veterinary drug products;

(c) Part III relating to herbal drugs;

(d) Part IV relating to medical devices; and

(e) any other point as the Authority may determine.

(3) The Minister may prescribe any other products to form part of the Register.

Cancellation and variation of conditions of registration

**55.**–(1) Where the Authority is of the opinion that-

(a) any person has failed to comply with the conditions subject to which a drug, medical device or herbal drug has been registered;

(b) the annual fee payable for the retention of the registration of a registered drug, medical device or herbal drug referred to this Act has not been paid;

(c) a registered drug, medical device or herbal drug does not comply with any prescribed requirement;

(d) a registered drug, medical device or herbal drug has been advertised in the United Republic in an advertisement which is false or misleading or does not comply with the provisions of section 71;

(e) it is not in the public interest that a registered drug, medical device or herbal drug should be made or continue to be made available to the public;

(f) where the Authority is satisfied that the applicant supplied false information in connection with his application for

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registration of any product it shall reject registration or remove the product from the Register; or

(g) it is in the public interest to vary the conditions or registration of a registered drug, medical device or herbal drug, the Director General shall give notice thereof in writing to the person by whom or on whose behalf the application for the registration of that drug, medical device or herbal drug was made; the Director General shall give notice to the person concerned under this subsection and may vary, amend or cancel the registration concerned forthwith.

(2) A notice given in terms of subsection (1) shall-

(a) specify the grounds on which the opinion of the Authority is based; and

(b) indicate that the person to whom it is directed may, within one month after the receipt thereof, submit to the Director General any representations he may wish to put forward in connection with the matter.

(3) Where-

(a) no representations are submitted in terms of paragraph (b) of subsection (2); or

(b) after consideration of any representations submitted in terms of paragraph (b) of subsection (2), the Authority is of the opinion for any reason specified in subsection (1) that the registration of the drug or device or herbal drug should be cancelled or the conditions of registration be varied, the Director General shall cancel, amend or vary the conditions of registration of that drug, medical device or herbal drug as the case may be.

(4) On the cancellation or variation of the conditions of registration of a drug, medical device or herbal drugs in terms of the provisions of subsection (1) or subsection (3), the Director General shall cause to be published in the *Gazette* notification of that cancellation or variation of conditions.

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(5) Notwithstanding subsection (4), the Director General shall not publish notification of such cancellation or variation of conditions until the period for the lodging of an appeal has expired or, if the person has appealed against the decision of the Authority, until such time as the appeal has been abandoned or determined in terms of that section.

Drugs, medical devices, herbal and drugs to be labelled

**56.**–(1) Subject to the provisions of this section, a person shall not sell any registered drug or medical devices unless it is labelled with its registered name and registered number, in addition to any other prescribed requirements.

(2) Labelling of containers and direction for use shall be in English or Kiswahili or both.

(3) A registered drug or medical device which is sold by-

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

(b) a pharmacist for the treatment of a particular person or animal and supplied by that pharmacist in accordance with a direction given by a medical practitioner, dentist or veterinarian, shall be labelled with the registered name of the drug, medical device or herbal drug.

Sale of unregistered drugs, medical devices, and herbal drugs for specified purposes

**57.**–(1) The Authority upon application made to it may, authorise the sell, or supply, import or export of unregistered drugs, medical devices or herbal drugs for a specific purpose.

(2) In granting any authority in terms of subsection (1), the Authority may fix conditions subject to which a specified drug or medical device and may be so distributed, including conditions relating to the use of that drug or medical device by the purchaser.

(3) Where any conditions are fixed in terms of subsection (2), relating to the use of the drugs, medical devices or herbal drugs by the purchaser, the person to whom the authority is granted in terms of subsection (1) shall not sell that drug,

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medical devices or herbal drug unless he is satisfied that the purchaser is aware of and able to comply with the conditions so fixed.

(4) The Authority may at any time withdraw any authority granted in terms of subsection (1).

Prohibitions, controls and restrictions in respect of drugs medical devices, herbal drugs poisons and certain substances

**58.**–(1) The Minister may, after consultation with the Director General make regulations to prohibit, control or restrict-

(a) the manufacture, compounding, dispensing, possession, sale or use of any drugs or medical devices and herbal drugs poison or any substance; or

(b) the manufacture, possession, sale or use of-

(i) any substance which is used, or manufactured, sold or presented as suitable for use, for cosmetic purposes or for the dressing of wounds or the stanching or absorbing or bleeding or other discharges from the body;

(ii) any substance, medical device or article which is used, or is manufactured, sold or presented as suitable for use, for any purpose which brings it into contact with the body or any part thereof, where in the opinion of the Director General, such regulations are desirable in order to prevent infection or allergy or any other harmful effect resulting from that use; or

(iii) any medical device or article which is used, or manufactured, sold or presented as suitable for use, in the diagnosis or treatment of any physical or mental state in man if, in the opinion of the Director General, such regulations are desirable in the public interest.

(2) The regulations referred to in subsection (1), may prescribe the precautions to be taken by a person in possession of a drug, medical device herbal drug, poison or any substance to ensure its safe custody and the action to be taken by such person in the event of the destruction, loss or theft, thereof.

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Prohibition of sale of drugs, medical devices, or herbal drugs which do not comply with prescribed requirements

**59.**–(1) The Authority may prescribe requirements with which any drugs or medical devices or component thereof must comply, including requirements as to the composition, therapeutic suitability and effect, purity or other properties and the conditions under which any drugs, medical devices or herbal drugs shall be prepared as stipulated in the pharmacopoeia.

(2) A person shall not-

(a) sell any drug, medical devices or herbal drugs in respect of which requirements referred to in subsection (1) have been prescribed unless that drugs, medical devices or herbal drugs complies with such requirements; or

(b) prepare any drug, medical devices or herbal drugs in respect of which conditions referred to in subsection (1) have been prescribed otherwise than in accordance with such conditions.

(3) The Director General may, by notice in writing, require any person who manufactures, sells, administers or prescribes any drugs, medical devices or herbal drug on whose direction any drugs, medical devices or herbal drugs are administered to furnish him with information which that person has in his possession.

Prohibition of manufacture, sale and distribution of undesirable drugs, medical devices or herbal drugs

**60.**–(1) Where the Minister on advice of the Director General is satisfied that the use of any drug, medical devices or herbal drug is likely to involve any risk to human being or animal or that any drug, medical device or herbal drug does not have therapeutic value claimed or purported to be claimed for it or it contains ingredients and in such a quantity for which there is no therapeutic justification and that in the public interest it is necessary or expedient so to do, the Minister may, by notification in the *Gazette* prohibit the manufacture, sale or distribution of such drugs or medical devices.

(2) A person whether by himself or by any other person on behalf manufactures, sells or distributes any drugs, medical devices or herbal drug in contravention of this provision or any notification issued under this section, commits an offence

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and on conviction, shall be liable to a fine of not less than one million shillings or to imprisonment for a term of not less than six months or to both.

*(c) Clinical Trials of Drugs, Medical Devices or Herbal Drugs*

Clinical trials of drugs, medical devices or herbal drugs

**61.**–(1) In this Part, "clinical trial" means an investigation or series of investigations consisting of a particular description by, or under the direction of a medical practitioner, dentist or veterinarian to the patient or animal where there is evidence that drugs, medical devices, or herbal drugs of that description has effects which may be beneficial to and safe to the patient or animal in question and the administration of the drugs, medical devices or herbal drugs is for the purpose of ascertaining beneficial and harmful effects.

(2) Subject to the provisions of this Part, a person shall not, in the course of a business carried on by him-

(a) sale or supply any drugs, medical devices or herbal drugs for the purpose of a clinical trial; and

(b) procure, import, manufacture or assemble any drugs, medical devices or herbal drugs for sale or supply for the purpose of clinical trial unless-

(i) he is the holder of a product registration which authorises the clinical trial in question, or he does it to the order of the holder of such a licence, and in either case, he does it in accordance with the product registration; and

(ii) a "certificate" for the purpose of this section, in this Act referred to as a "Clinical Trial Certificate", has been issued in writing to him certifying that, subject to the conditions of the certificate, the Authority has authorised the clinical trial in question and that a certificate is for the time being valid and the trial is to be carried out in accordance with that certificate or instruction issued in writing by the Director General.

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Conduct of clinical trials

**62.** A person shall not conduct a clinical trial of any drug, medical device or herbal drug without the written authorisation of the Director General.

Application to conduct clinical trials

**63.**–(1) A person wishing to conduct a clinical trial of a drug, medical device or herbal drug shall submit to the Authority an application in the prescribed form, signed by him and accompanied with a prescribed fee, an Ethical Clearance Certificate issued by any approved institute for medical research and any relevant information as provided under the guidelines for registration of drugs for clinical trial.

(2) Where a clinical trial is to be conducted in a hospital, veterinary institution or other designated institution, the application referred to in subsection (1) shall be countersigned by a medical superintendent or medical officer, veterinarian of such medical or veterinary institution.

(3) For the purpose of this section, a designated institution includes a medical or veterinary institution, or any other approved institution.

Authority to cause investigation to be conducted

**64.**–(1) Upon the receipt of an application in terms of subsection (1) of section 43, the Authority shall cause to be conducted such investigations to authentify the safety, efficacy and quality of a drug, medical device or herbal drug and where it is satisfied that the drug, medical device or herbal drug is reasonably safe, efficacious and of acceptable quality, the Authority shall register the product for the purposes of clinical trials.

(2) Subject to the provisions of subsection (1), the Director General shall issue Clinical Trial Certificate for the approved products.

(3) A person who is aggrieved by a decision of the Authority of not granting authorisation for the conduct of clinical trial may make his representation within sixty days to the Authority.

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(4) Where no such representation is submitted by the applicant within the said period or if after consideration of any comments so submitted the Authority is still not satisfied it shall reject the application.

Conditions to conduct clinical trials

**65.** A clinical trial of any drug, or medical device or herbal drug authorised in terms of section 43 shall be subject to such specific and general conditions as the Authority may impose and, for the safety of all persons, or animals taking part in such trial, the person conducting the trial shall observe strictly all the conditions imposed subject to which the trial was authorised.

Consent for clinical trials

**66.** Where the Director General grants written authorisation under section 44 for the conduct of a clinical trial of a drug, medical device or herbal drug, such trial shall not take place until-

(a) in the case of a drug, medical device or herbal drug for the treatment of adult persons, the voluntary written consents of all such persons taking part in the clinical trial have been freely obtained;

(b) in the case of a drug, medical device or herbal drug for the treatment of minors or persons under legal disability the voluntary written consents of their parents or legal guardians, have been freely obtained; and

(c) in the case of a drug, medical device or herbal drug for the treatment of animals, the voluntary written consent of the owners of all animal taking part in the clinical trial have been freely obtained, by the person conducting the trial.

Supply of information prior to clinical trials, etc.

**67.** Whenever a clinical trial of any drug, medical device or herbal drug is authorised in terms of the provisions of section 46, the person conducting the trial shall, before commencing the trial-

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(a) inform all persons taking part in the trial or persons whose animals will take part in the trial about;
  (i) the aims and objectives of the clinical trial and the way in which it will be conducted; and
  (ii) the possible risks, discomforts and other adverse effects that may result therefrom;
(b) ensure in such amounts as may be prescribed, by the Authority all persons or animals taking part in the trial against any injury or risk of injury that may be sustained during the trial; and
(c) sign an indemnity in such form as may be prescribed, indemnifying the Government and the Authority from liability in respect of any injury or adverse effect which may be sustained by any person or animal, directly or indirectly, as a result of the conduct of the trial and which occurs or reveals itself at the time of the trial or subsequently.

Power of Authority to stop or suspend clinical trials

**68.**–(1) Where at any stage during the clinical trial of any drug, medical device or herbal drug authorised in terms of the provisions of section 46, the Authority is satisfied that having due regard to the initial risks, discomforts or other adverse effects caused to persons or animals taking part in the trial it is in the public interest to stop or suspend the trial, the Authority shall order the person conducting clinical test to stop or suspend the trial immediately.

(2) Without prejudice to subsection (1), the Authority may, on any other reasonable cause suspend, vary or stop any clinical trial.

(3) The Authority shall notify the person conducting the trial of its decision and the reasons for such decision.

Monitoring of clinical trials by Authority

**69.** The Authority shall monitor such clinical trial from the beginning to the end in order to ensure adequate protection of the general public against any risks or adverse effects from the clinical trial of any drug authorised in terms of the provisions of section 43, as to satisfy itself that all specific and general

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conditions subject to which the trial was authorised are being strictly observed by the person conducting the trial and that to all intents and purposes the trial will achieve its aims and objectives.

Reports on clinical trials

**70.**–(1) The Authority may require the person conducting the trial to submit to it such reports as it may direct.

(2) In addition to the report referred to in subsection (1), the person who is conducting the trial shall, immediately report to the Authority of any serious or adverse effects or reaction observed during the trial.

Offences and penalties

**71.** A person who contravenes the provisions of this Part, commits an offence and on conviction, shall be liable to a fine of not less than ten million shillings or to imprisonment for a term of not less than five years or to both.

Renewal and revocation of clinical trial certificate

**72.**–(1) Subject to the provisions of this section, every Clinical Trial Certificate unless previously renewed or revoked, shall expire at the end of the authorised period of the trial.

(2) A certificate, if it has not been revoked, may, on the application of the holder of the certificate be renewed by the Authority for a further approved period.

*(d) Dealing in Drugs, Medical Devices, Herbal Drugs or Poisons*

Import and export of drugs, medical devices, herbal drugs or poisons

**73.**–(1) A person, other than a person issued with a licence or permit under the provisions of this Act, may not import or export into Mainland Tanzania any drugs, medical devices, herbal drugs or poisons.

(2) Subject to subsection (1), the Authority may, where it is in the public interest so to do, authorise parallel importation of any drug.

(3) Notwithstanding the provisions of this Act, any *bona-fide* tourist or visitor who enters into, or person normally resident, who re-enters the United Republic, may bring with him such quantity of any drug as may be required during a

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period of twenty one days for the medical treatment of himself, any member, or partner travelling with him.

(4) A person shall not import any drug with shelf life more than twenty four months whose remaining shelf life is less than 60% and a drug with shelf life of less or equal to twenty four months whose remaining shelf life is less than 80%.

(5) Where any person imports any drug, medical devices, herbal drugs or poison, contrary to the provisions of this Act, the Authority may order destruction or re-export of such drug, medical devices, herbal drugs or poisons at his own expenses.

(6) A person who contravenes the provisions of this section commits an offence and on conviction, shall be liable to a fine of not less than one million or to imprisonment for a term of not less than six months or to both.

(7) In this section "parallel importation" means importing a drug into the country without authorisation of the drug registration holder from another country where it is legitimately placed.

Repealed

**74.** [Repealed by Act No. 1 of 2011 s.60.]

Prohibition of sale of adulterated or unfit drugs, medical devices and herbal drugs

**75.**–(1) A person shall not-

(a) add any substance to, or subtract any substance from a drug so as to affect adversely the composition of the drug with intention of selling the drug in that changed state;

(b) sell, supply, offer or expose for sale, supply, or have in his possession for the purpose of sale or supply, any drug, medical devices, herbal drug or poison product whose composition has been affected by the addition thereto or subtraction there from of any substance; or

(c) sell or supply any drug, medical devices, herbal drug or poison product which is not of the nature or quality demanded by the purchaser.

(2) A person shall not-

(a) offer for sale;

(b) procure for sale;

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(c) sell; or

(d) administer to any person or animal, any drug which is unfit for intended purpose.

(3) All drugs which are unfit for intended purpose shall be kept in separate place labelled "unfit for intended use" marked in red.

(4) For the purposes of this Act, a "drug which is unfit for intended use" means a drug which has expired, which is not safe, efficacious or of undesired quality even before the expiry date.

(5) Where a drug, medical device, herbal drug or poison is sold or supplied pursuant to a prescription given by an appropriate practitioner, subsection (1) shall have effects as if-

(a) any reference to the "purchaser" includes a reference to the person for whom the drug, medical devices, herbal drugs or poisons was prescribed by an appropriate practitioner; and

(b) for the words "demanded by the purchaser" shall be substituted by the words "specified in the prescription".

(6) A person who contravenes the provisions of this section, commits an offence and on conviction shall be liable-

(a) where such a person is an individual, to a fine of not less than five hundred thousand shillings or to imprisonment for a term of not less than three months or to both; or

(b) where such a person is an association or body corporate, to a fine of not less than three million shillings.

Counterfeit drugs, medical devices or herbal drugs

**76.**–(1) A person shall not manufacture, import, supply, possess or offer for sale any counterfeit drug, herbal drug or medical device.

(2) A person who deals in or manufactures counterfeit drugs, herbal drugs, medical devices, commits an offence and on conviction, shall be liable to fine of not less than five million shillings or to imprisonment for a term of not less than two years or to both.

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(3) For the purposes of this Act, a drug, medical device or herbal drug shall be deemed to be counterfeit if-

(a) it is manufactured under a name which belongs to another drug;

(b) it is an imitation of, or is a substitute for, another drug, medical device or herbal drug resembles another drug or medical device likely to deceive or bears upon its label or container the name of another drug, medical device or herbal drug unless it is plainly and conspicuously marked so as to reveal its true character and its lack of identity with such other drug, medical device or herbal drug;

(c) the label or container bears the name of an individual or company purporting to be a manufacturer of the drug, medical device or herbal drug which individual or company is fictitious or does not exist;

(d) it has been substituted wholly or in part by another drug substances; or

(e) it purports to be a product of manufacturer of whom it is not truly product.

(4) It shall be a defence in any prosecution for an offence under subsection (1), if it is proved to the satisfaction of the court that the accused, not being a person selling the drug, medical devise or herbal drug to which the false or misleading advertisement which is the subject of the prosecution relates, did not know and could not reasonably be expected to have known, the advertisement was in any respect' "false" or "misleading" unless it is proved that, the accused failed on demand by the Director General, an inspector or a police officer, to furnish the name and address of the person at whose instance the advertisement was published or distributed or was brought to the notice of the public.

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*(e) Drugs and Poisons List*

Drugs, medical devices, herbal drugs and poisons list

**77.**–(1) The Minister may on advise of the Director General by order in the *Gazette*, declare lists of substances or articles which shall be treated as drugs, herbal drugs, medical devices or poisons for the purposes of this Act.

(2) The list of drugs declared under subsection (1) of this section, shall be divided into but not limited to "controlled drugs", prescription drugs" and "general sale drugs".

(3) The Minister may on the advice of the Director General, in the like manner, amend or vary the list, as he deems proper.

(4) Subject to such conditions as the Minister may prescribe in the regulations made under this Act, any general sale drug may be sold either by way of retail or wholesale in an open shop.

Application of Drugs Control and Enforcement Act
Cap. 95

**78.**–(1) Without derogating the provisions of the Drugs Control and Enforcement Act, a person shall not manufacture, import, sell or use any controlled drug for medicinal or scientific purpose unless he complies with the provisions of this Act.

Cap. 95

(2) The provisions of the Drugs Control and Enforcement Act in relation to offences and penalties shall apply *mutatis mutandis* to offences committed under this Act.

Cap. 95

(3) The provisions of this Act, shall be in addition to and not in derogation of the Drugs Control and Enforcement Act, or any other written laws having functions similar to those specified under this Act.

(4) Notwithstanding the provision of subsection (6), a person who contravenes or fails to comply with any provisions or regulation under this Act relating to the keeping of books or the issuing, or dispensing of prescriptions containing controlled drugs to which this Act applies, commits an offence and on conviction, shall be liable to a fine of not less than

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fifty thousand shillings, or to imprisonment for a term not exceeding six months or to both.

Provisions for non medicinal products

**79.**–(1) The Minister, on the advise of the Director General may cause the regulations to be published in the *Gazette* specifying any description or classes of articles or substances which-

(a) are manufactured, sold, supplied, imported or exported in a manner similar to drugs;

(b) are used as ingredients in the manufacture of drugs; or

(c) where used without proper safeguards, are likely to be a risk to the public health or to be dangerous or injurious to animals.

(2) The Minister on advice of the Director General shall provide that subject to such exceptions and modification as may be specified under the provisions of this Act, including those relating to offences and penalties have effect to such description or classes of articles or substances as if those provisions apply to drugs.

*(f) Prohibited Drugs*

Interpretation of "deal in" and "prohibited drugs"

**80.** In this Part-

(a) "deal in" in relation to any prohibited drug, includes to possess, sell or perform any act, whether as a principal, agent, carrier, messenger or otherwise, in connection with the delivery, collection, importation, exportation, transshipment, conveyance, supply, administration, manufacture or transmission of such drugs; and

(b) "prohibited drugs means any drug declared to be a prohibited drug in terms of the provisions of section 61 of this Act.

Prohibited drugs

**81.** Whenever the Authority considers it necessary or desirable in the public interest that any drugs should be declared to be prohibited drug, the Minister may on advice of the Director

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General, by notice published in the *Gazette* declare such drug to be a prohibited drug and may in like manner amend or revoke such notice.

Prohibition to deal in prohibited drugs

**82.**–(1) A person shall not deal in any prohibited drugs unless he holds a permit issued by the Authority.

(2) A person who contravenes the provisions of subsection (1), commits an offence and on conviction shall be liable to imprisonment for a term of not less than five years and notwithstanding anything to the contrary contained in any other law for the time being in force, the court shall not order that the operation of the whole or any part of the sentence be suspended.

(3) Where on conviction the convicted person satisfies the court that there are special circumstances in the particular case, which circumstances shall be recorded by the court, why such a sentence should not be imposed, the convicted person shall be liable to a fine of not less than five million shillings or to imprisonment for a term of not less than one year or to both.

Forfeiture on conviction, and prohibition from driving
Acts Nos.

**83.**–(1) Where any person is convicted of any offence under the provisions of section 62, the court-

(a) shall order that any drugs to which the conviction relates be forfeited to the Government; and

(b) may order that any vehicle, aircraft, vessel, boat, animal, receptacle, container or thing in or upon which such drugs was found, be forfeited to the Government and the provisions of the Criminal Procedure Act, and the Evidence Act, shall, *mutatis mutandis*, apply.

Cap. 20
Cap. 6

(2) In any prosecution under the provisions of section 62, where is established to the satisfaction of the court that the convicted person used any motor vehicle to convey the products regulated under this Act, which the conviction relates, the court may order that the convicted person or, where the motor vehicle concerned was driven by another person, that other person, be prohibited from driving all classes of motor vehicles for a period not exceeding fifteen years and the appropriate

Cap. 168

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provisions of the Road Traffic Act, shall, *mutatis mutandis*, apply in respect of any such prohibition.

Safe custody of forfeited prohibited drugs

**84.** Subject to the provisions of section 83, the Director General shall keep such forfeited drugs into a safe custody until such date of disposal.

Destruction of forfeited prohibited drugs

**85.**–(1) Within seven days of the receipt from the court of any consignment of forfeited prohibited drugs, the Director General shall communicate in writing to the Inspector General of Police, the Commissioner of Customs and the Attorney-General, the full particulars of prohibited drugs meant for destruction including their quantity and all other relevant information, which shall, in every material particular, correspond strictly with the particulars furnished to the Director General by the court at the time of delivery.

(2) Within fourteen days of the written communication referred to in subsection (1), the Director General shall appoint a date and time, which shall not be before the expiry of the period within which an appeal against the conviction concerned may be noted, for the total destruction, by incineration, or any other approved method of destruction.

(3) Where an appeal has been noted, pursuant to subsection (2), the forfeited prohibited drugs shall not be destroyed until such time as the appeal has been abandoned or determined, whereupon the provisions of this subsection shall apply.

(4) For the purposes of this Act, the Director General shall whenever necessary, constitute a panel comprising of a drug inspector, a public health officer, government officer from government institution responsible for environment and a police officer to supervise the destruction of all prohibited drugs forfeited to the Government.

(5) On the date and time appointed by the Director General in terms of subsection (2), the panel referred to in subsection (4) shall supervise the destruction of forfeited prohibited drugs

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and shall, immediately after the destruction, subscribe to and sign a joint declaration in the prescribed form, attesting to the total destruction of such drugs.

(6) Within fourteen days of the destruction of any prohibited drugs forfeited to the Government, the Minister shall upon the advice of the Director General, cause to be published in the *Gazette* for general public information, the joint declaration referred to in subsection (5).

## PART V

Repealed

**86.–91.** [Repealed by Act No 8 of 2019 s. 31.]

## PART VI
## PACKAGING AND LABELLING

Labelling of products regulated under this Act

**92.**–(1) A person shall not, in the course of a business operated by him, sell or supply or have in his possession for purposes of selling or supplying any product regulated under this Act in a container or package which is not labelled in accordance with the regulations made under section 96.

(2) Without prejudice to subsection (1), a person shall not in the course of a business carried on by him, sell or supply, drug, medical device or herbal drug of any description in a container or package which is labelled or marked in such a way that-

(a) falsely describes the product; or

(b) is likely to be misleading as to the nature, efficacy or quality of the product or as to the uses or effects of the product of that description.

(3) A person who contravenes the provisions of subsection (2), commits an offence and on conviction shall be liable-

(a) where such a person is an individual, to a fine of not less than five hundred thousand shillings or to imprisonment for a term of not less than three months or to both; or

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(b) where such a person is an association or body corporate, to a fine of not less than three million shillings.

Leaflets

**93.**–(1) A person shall not, in the course of a business carried on by him, supply or have in his possession for the purpose of supplying together with drug, medical devices, or herbal drug a leaflet relating to such drug, medical devices or herbal drug which does not comply with the regulations made under section 96.

(2) Without prejudice to subsection (1), a person shall not, in the course of a business carried on by him, supply or supply together with drug, medical devices or herbal drug, or have in his possession for the purpose of supplying a leaflet which-

(a) falsely describes medical drug, drug device or herbal drug or cosmetics to which it relates; or

(b) is likely to be misleading as to the nature, efficacy and quality of such product.

(3) A person who contravenes the provisions of this section, commits an offence and on conviction shall be liable-

(a) where such a person is an individual, to a fine of not less than one hundred thousand shillings or to imprisonment for a term of not less than one month or to both; or

(b) where such a person is an association or body corporate, to a fine of not less than one million shillings.

Containers and packages

**94.**–(1) A person shall not pack a product regulated under this Act in a container or package which will alter its efficacy, safety, quality or nutritional value of such a product.

(2) A person who contravenes the provisions of this section, commits an offence.

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## PART VII
## PROMOTION

Regulations on promotion of drugs, medical devices or herbal drugs

**95.** The Minister on the advice of the Director General, may make regulations to regulate any promotional activities connected to drugs, medical devices or herbal drugs.

Advertisement of products regulated under this Act

**96.**–(1) Without prejudice to provisions of this Act, a person shall not publish, distribute or in any other manner bring to the notice of the public or cause or permit to be published or distributed or to be so brought to the notice of the public any false or misleading advertisement of products regulated under this Act, except in accordance to the code of conduct for promotion of such products as provided in the regulations.

(2) Where any drug, medical device or herbal drug has been registered subject to the condition that it shall be available to a medical practitioner, a dentist or a veterinarian, a person shall not advertise that drug, medical devices or herbal drugs other than-

(a) in a medical, dental, veterinary or pharmaceutical journal; or

(b) to members of the medical, dental, veterinary or pharmacy profession.

Meaning of advertisement

**97.**–(1) In this Part, "advertisement" includes every form of advertising, whether in a publication, or by the display of any notice or by means of any catalogue, price list, letter, whether circular or addressed to a particular person, or by the exhibition of a photograph or a cinematograph film, or by way of sound recording, sound broadcasting, or television or any other means of communication.

(2) Notwithstanding anything contained in subsection (1), "advertisement" does not include spoken words except-

(a) words forming part of a sound recording or embodied in a soundtrack associated with a cinematograph film;

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(b) words broadcast by way of sound broadcasting or television or transmitted to subscribers to a diffusion service; and

(c) anything spoken in public.

(3) Except as regulations made under the provisions of section 96 may otherwise provide, for the purposes of this Part, the following shall not constitute an advertisement-

(a) the sale or supply, or offer for sale or supply, of a medical devices or herbal drugs in a labelled container or package; and

(b) the supply, together with drugs, medical devices or herbal drugs of a leaflet relating solely to the use of the drugs supplied.

Restriction on drugs, medical devices or herbal drugs advertisement

**98.**–(1) A person shall not advertise any product regulated under this Act in a manner that is false, misleading or deceptive or is likely to create erroneous impression regarding its character, value, quantity, composition, merit, safety or efficacy as the case may be.

(2) A person shall not carry out any promotion activities on products regulated under this Act, except and after getting a written approval from the Authority.

(3) A person shall not advertise or sell by retail any drugs, medical devices or herbal drugs in connection with any bonus, offer or discount.

(4) A person who contravenes the provisions of this section, commits an offence and on conviction shall be liable to-

(a) where such a person is individual, a fine of not less than one hundred thousand shillings or to imprisonment for a term of not less than two weeks or to both such fine and imprisonment; or

(b) where such person is a body corporate or association, to a fine of not less than one million shillings.

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# PART VIII
# ENFORCEMENT AND LEGAL PROCEEDINGS

*(a) Inspection, Sampling and Analysis*

Powers to seize, forfeit condemn and destruct unfit products

**99.**–(1) The Authority may, if satisfied that any product regulated under this Act is unfit for the intended use, seize, forfeit and condemn such product and declare it unfit for intended use and shall order that product to be destructed at the owner's cost.

(2) Where it appears to any inspector that any product regulated under this Act, whether or not seized under subsection (1), is unfit for intended purpose or that any provision of this Act, has been contravened in relation to that product regulated under this Act, he may-

(a) affix to that product a mark, seal or other designation; or

(b) destroy or dispose of that product in any other way at the owner's cost.

(3) A person who-

(a) sells, offers or exposes that product regulated under this Act for sale;

(b) deposits or consigns that product regulated under this Act to any person for the purpose of distribution, sale or manufacture for sale;

(c) uses that product regulated under this Act in any other way; or

(d) removes, alters or obliterates the mark, seal or other designation with intent to deceive any person,

commits an offence and on conviction shall be liable to a fine of not less than one hundred thousand shillings and not exceeding one million shillings or to imprisonment for a term not exceeding six months or to both.

(4) Before any product regulated under this Act is destroyed or disposed of in any other way under subsection (2), the inspector concerned shall record a description and such other

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details as will suffice to identify that product and, subject to the procedure prescribed by this Act for the treatment of that product found to be unfit for human consumption, he shall forward a report connected with that product to the Authority.

Repealed

**100.** [Repealed by Act No 8 of 2019 s. 32.]

Power to take samples Act No. 8 of 2019 s. 33

**101.**–(1) Subject to the provisions of this section and any regulations made under section 96, an inspector may take sample for analysis or for the examination of any drugs or medical devices and herbal drug or of any substance capable of being used in the manufacture of drugs, herbal drug, medical devices which appears to him to be intended for sell or to have been sold for use by man or animal which is found by him on or in any premises, stall, vehicle, vessel, conveyance, aircraft or a place he is authorised to enter for the purposes of ensuring compliance with this Act.

(2) Where the drugs, medical devices or herbal drugs which the inspector intends to take, is kept for retail sale in unopened packages, the sample shall consist of the whole of any one package.

(3) When taking any sample under this section, the inspector shall take any necessary measures to satisfy himself that the sample taken is a representative sample of the drugs, medical devices and herbal drugs.

(4) A person who fails to comply with any demand made by an inspector under this section, commits an offence and on conviction, shall be liable to a fine of not less than one hundred thousand shillings or to imprisonment for a term of not less than two weeks or to both.

Submission of sample for analysis Act No. 8 of 2019 s. 34

**102.** An inspector who has taken into possession drugs, medical devices and herbal drugs or other substance for use in the manufacture of drugs, medical devices and herbal drugs may submit a sample of it for analysis.

Repealed

**103.** [Repealed by Act No 8 of 2019 ss. 35.]

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Repealed

**104.** [Repealed by Act No 8 of 2019 ss. 36.]

Appointment, authorisation and recognition of inspectors
Acts Nos.
9 of 2017 s. 30
8 of 2019 s. 37

**105.**–(1) For the purposes of this Act, the Authority may-

(a) appoint any pharmacist, medical practitioner, health laboratory practitioner, health officer, pharmaceutical technician or any public officer as an inspector;

(b) authorise any inspector or officers appointed under any written laws whose functions relate to the functions of the Authority to perform specific functions as inspectors under this Act; and

(c) publish in the *Gazette*, inspectors appointed under this Act.

(2) The inspectors or officers referred to under paragraph (b) of subsection (1) shall be recognised as authorised officers under this Act.

(3) When appointing or authorising inspectors, the Authority shall take into account not to appoint or authorise an inspector who has interest in the manufacture, importation or sale of any product regulated under this Act.

Powers of inspectors
Act No.
8 of 2019 s. 38

**106.**–(1) For the purposes of ensuring compliance under this Act, an inspector or inspectors may-

(a) at all reasonable times, enter:

(i) any set of premises which is on the register of premises;

(ii) any premises in which any person whose name is entered in any register under this Act, carries on any business; and

(iii) any premises in respect of which any person is licensed under this Act;

(b) at any time enter any premises, stall, vehicle, vessel, or conveyance, any premises suspected to be dealing with products regulated under this Act for the purposes of ensuring compliance with this Act;

(c) examine or inspect any certificate of registration, licence, book, electronic information storage system or other document in the premises and, for that

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purpose, he may do such other things, including the taking of extracts from documents in the possession of the person, as may be necessary to effectual the examination or inspection;

(d) seize and detain any drugs, medical device, herbal drug, substance or article consisting of, or containing any poison which he has reasonable cause to suspect is liable to forfeiture under this Act;

(e) seize and detain any drug, product, medical device, herbal drug, article, record or other thing which appears to him to constitute or contain evidence of a contravention of any provision of this Act;

(f) close the premises found to contravene the law and institute criminal proceedings; and

(g) order the return to the country of origin of any product regulated under this Act imported into the country in contravention of the provisions of this Act.

(2) The Director of Public Prosecutions may, on the request of the Authority and upon being satisfied that there are officers or persons who possess the relevant knowledge and training in matters related to prosecution, by notice published in the *Gazette*, authorise such officers or persons, to be public prosecutors for the purposes of this Act.

(3) A person who-

(a) willfully delays or obstructs an inspector in the exercise of his powers under this section; or

(b) refuses or fails without reasonable excuse, to give any information which he is lawfully required to give under this section; or

(c) gives any information which is false in a material particular or which he reasonably believes to be untrue,

commits an offence and on conviction shall be liable to a fine of not less than five hundred thousand shillings or to imprisonment for a term of not less than three months or to both.

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Power to call information regarding composition of products regulated under this Act
Act No. 8 of 2019 s. 39

**107.**–(1) The Director General may order, in writing, any person who carries on a business which includes the manufacture, importation, sell or use of substances of any kind specified in the order, to furnish to him, within a period specified in the order, any specified particulars of the composition and use of those substances sold in the course of that business or used in the manufacture of product regulated under this Act.

(2) without prejudice to the generality of subsection (1), an order made under that subsection may require the following particulars to be furnished in respect of any substance, namely-

(a) particulars of the composition and the chemical nature of the substance; and

(b) particulars of the manner in which the substance is used or proposed to be used in the manufacture of products regulated under this Act;

(3) Save for the purposes of any proceedings for an offence against this Act, and subject to the provisions of section 94, no particulars furnished in accordance with an order made under subsection (1), and no information relating to any individual business obtained by means of those particulars, shall, without the previous written consent of the person carrying on the business concerned, be disclosed to anyone.

(4) A person who discloses any particulars or information or fails to comply with the requirements set under the provisions of this section, commits an offence.

(5) A person who fails to comply with the requirements of any order made under subsection (1), commits an offence.

*(b) Legal Proceedings*

Certificate of analysis

**108.**–(1) In every case in which a sample for analysis is delivered to the analyst under section 77, the analyst shall cause it to be analysed as soon as is practicable and shall give to the person who requested the analysis to be made a certificate specifying the result of the analysis in the prescribed form.

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(2) A certificate of the result of an analysis given by the analyst under subsection (1), shall be signed by the head of the laboratory but the analysis may be made by any person acting under his instructions.

(3) A person who, for the purpose of advertisement, uses any certificate of analysis he obtained under this section, commits an offence and on conviction shall be liable to a fine of not more than one hundred thousand shillings or to imprisonment for a term of not less than two weeks or to both.

Evidence of analysis

**109.**–(1) In any proceedings for an offence under this Act, the production by one of the parties of a document purporting to be a certificate of the analyst given under the provisions of section 82, or a document supplied to him by the other party as being a copy of that certificate shall be sufficient evidence of the facts stated in it, unless, in the former case, the other party requires that the person who made the analysis be called as a witness.

(2) In any proceedings for an offence under this Act, where a defendant intends to produce a certificate of the analyst, or to require, under subsection (1), that the person who made the analysis be called as a witness, he shall give notice of that intention to the other party, together, in the former case, with a copy of the certificate, three days before the date fixed for hearing of the case and if the notice is not given, the court may, if it thinks fit, adjourn the hearing on terms which it considers proper.

(3) Where any relevant method of analysis has been prescribed under this Act, evidence of an analysis carried out by that method shall be preferred to be evidence of any other analysis or test.

(4) In any proceedings under this Act, where a sample has been procured in circumstances which necessitates the requirement that it be divided into parts, the part of the sample retained by the person who took it shall be produced at the hearing.

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(5) A certificate of the result of an analysis transmitted by an analyst under this section shall be signed by the head of the Laboratory but the analysis may be made by any person acting under the direction of the head of the Laboratory and any certificate so transmitted by the analyst shall be sufficient evidence of the truth of the facts stated in it unless any party to the proceedings requires that the person who made the analysis be called as a witness.

Presumptions

**110.**–(1) For the purpose of this Act-

(a) any article commonly used for human consumption shall, if sold or offered, exposed or kept for sale, be presumed until the contrary is proved, to have been sold or, as the case may be, to have been or to be intended for sale for human consumption;

(b) any article commonly used for human consumption, and any article commonly used for the manufacture of products for human consumption which is found in any premises or in any vessel, vehicle or container used for the manufacture, storage, transport or sale of that article or those products, shall be presumed, until the contrary is proved, to be intended for sale, or for manufacturing products for sale for human consumption;

(c) any substance capable of being used in the composition or manufacture of any article commonly used for human consumption, which is found in any premises or vessel where that article is manufactured shall, until the contrary is proved, be presumed to be intended for that use;

(d) any drug, medical device or herbal drug commonly used by man or animal, or any article commonly used in the manufacture of drugs, medical devices or herbal drugs for use by man or animal, which if is found on any premises or in any vessel, vehicle, aircraft or container used for the manufacture, storage, transport or sell of that drugs, medical devices, herbal drugs or

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article, shall be presumed, until the contrary is proved, to be intended for sell or as the case may be for the manufacture of drugs, medical devices and herbal drug for use by man or animal;

(e) any substance capable of being used in the compounding or manufacturing of any drug product, medical device and herbal drug commonly used by man or animal which is found on any premises or in any vessel where that drug, medical devices, or herbal drug is manufactured shall be presumed to be intended for that use.

(2) Where any product regulated under this Act is sold, or deposited with or consigned to any person for the purpose of sale for use by man or animal in an unopened package, any person who appears from any statement on or attached to the package to have enclosed it in that package shall, until the contrary is proved, be deemed to have imported, manufactured or enclosed such products.

When warrant may be pleaded as defence

**111.**–(1) In any proceedings for an offence which consists of selling, offering, exposing or advertising for sale or having in possession for the purpose of sale, any drug, medical device, herbal drug or substance, it shall be a defence for the defendant to prove that-

(a) he purchased it as being an article or substance which could lawfully be sold or dealt with under the name or description or for the purpose under or for which he sold or dealt with it, and with a written warranty to that effect;

(b) he had no reason to believe, at the time when the alleged offence was committed, that it was something other than what he says it was in paragraph (a); and

(c) it was then in the same state as when he purchased it.

(2) A warranty shall only be a defence in proceedings under this Act if:

(a) the defendant-

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(i) has, not later than three days before the date of the hearing, sent to the prosecutor a copy of the warranty with a notice that he intends to rely on it and specifying the name and address of the person from whom he received it; and

(ii) has also sent a similar notice to the person from whom he received the warranty; and

(b) in the case of a warranty given by a person resident outside Tanzania, the defendant proves that he had taken reasonable steps to ascertain, and did in fact believe in, the accuracy of the statement contained in the warranty.

(3) A defendant who is an employee or agent of the person who purchased the article or substance under a warranty may rely on this section in the same way as his employer or principal would have done had he been the defendant.

(4) The person by whom the warranty is alleged to have been given may appear and give evidence at any hearing, and the court may, if it thinks fit, adjourn the hearing.

(5) For the purposes of this section and of the provisions of section 87, a name or description entered in an invoice shall be deemed to be a written warranty that the article or substance to which the entry refers can be sold or dealt with in any other way under that name or description by any person without contravening this Act.

Sale, etc, by employers or agents

**112.** For the purposes of this Act, any person who, whether on his own account or as the employee of another person, sells, offers, exposes or advertises for sale, or has in his possession for sale, any product regulated under this Act shall be deemed to sell, offer, expose or advertise for sale, or have in his possession for sale, that product regulated under this for intended purpose, and if that person is an employee or agent of some other person, that other person shall subject to this Act, be under the same liability as if he had himself sold, exposed or advertised that product regulated under this Act.

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Offences in relation to warranties or certificates of analysis

**113.**–(1) A defendant who, in any proceedings under this Act, willfully applies in relation to any article or substance a warranty or certificate of analysis given in relation to any other article or substance, commits an offence and on conviction, shall be liable to a fine of not less than three hundred thousand shillings or to imprisonment for a term of not less than one month or to both.

(2) A person who, having sold any article or substance in respect of which a warranty might be pleaded under the provision of section 85 gives to the purchaser a false warranty in writing, commits an offence and on conviction, shall be liable to a fine of not less than three hundred thousand shillings or to imprisonment for a term of not less than one month unless he proves that when he gave the warranty he had reason to believe that the statements or description contained in it were accurate.

Recovery of expenses incidental to taking samples Cap. 200

**114.** Where a person is convicted of an offence under this Act, the court may order that all expenses incidental to the taking of any sample or the making of any analysis of any product regulated under this Act in respect of which the conviction is obtained shall be treated in the manner provided under section 61 of the Economic and Organised Crime Control Act.

Forfeiture

**115.**–(1) In any proceedings for an offence under this Act, the court before which the offence is tried shall, in addition to any order or sentence it makes or imposes, order that any drug, medical device, herbal drug or other article with respect to which the offence was committed be forfeited to the Government.

(2) An order of forfeiture may be made by the court under this section whether or not any person has been convicted of the offence alleged to have been committed.

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(3) Any drug, medical devices, herbal drug or other article in respect of which an order for forfeiture is made under this section shall be deemed to be free from any rights of any person.

Appeals

**116.**–(1) A person aggrieved by a decision of the Authority may appeal to the Minister against that decision.

(2) The Authority may appear as respondent and be heard on any appeal against its decision.

(3) Notwithstanding the provisions of this section, the Attorney General shall have the right to intervene in any suit or matter instituted by or against the Authority for public interest.

(4) Where the Attorney General intervenes in any suit or matter in pursuance of subsection (3), the provisions of the Government Proceedings Act, shall apply in relation to the proceedings of that suit or matter as if it had been instituted by or against the Government.

Cap. 5

Prohibition to carry on business or to dispose of any product pending an appeal

**117.**–(1) Where a decision of the Authority or of a court in any proceedings under this Act, makes it unlawful for a person to carry on any business which he was lawfully carrying on at the date when that decision was given, or to use any premises for any purpose for which he was lawfully using at that date, he shall not carry on that business and shall not use the premises for the purpose, and if any appeal is lodged, until the appeal is finally disposed of, abandoned or withdrawn.

(2) Where the Authority or a court in any proceedings declares a product to be unfit for the intended purpose the owner shall not manufacture for sale, sell, supply or distribute that product, and if any appeal is lodged, until the appeal is finally concluded.

Liability to members of Authority etc.

**118.** Anything done by the Director General, any member of the Board, the Directors, an inspector or any other person

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empowered to perform any function under this Act shall, if done in good faith in execution or purported execution of his function under this Act, shall not render the Director General, Directors, that member, the inspector or that other person personally liable for the matter or thing done.

Protection of informers

**119.**–(1) Subject to this subsection, no complaint made in respect of an offence under this Act shall be admitted in evidence and no witness in any proceedings for an offence under this Act shall be obliged or permitted to disclose the name or address of any informer or state any matter which might lead to his discovery, and, if any books, documents or any other papers which are in evidence or liable to inspection in those proceedings contain any entry in which any informer is named or described or which might lead to his discovery, the court shall cause all those passages to be concealed from view or to be obliterated so far as may be necessary to protect the informer from discovery, but no further.

(2) Where the court, after full inquiry into the case, is satisfied that the informer willfully made in his information a statement which he knew or believed to be false in a material particular, or which he did not believe to be true, or if it appears to the court that justice cannot be fully done, it may require the production of the original information and permit inquiry and require full disclosure concerning the informer.

Notification of convictions

**120.** Where any person is convicted of any offence against this Act, relating to the sale or manufacture for sale of any product regulated under this Act, the Director General may cause to be published in any news paper or newspapers widely circulating in the United Republic-

(a) the name of the offender;

(b) the address, if any, of the place where the offence was committed;

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(c) the nature of the offence;
(d) the kind of product involved; and
(e) the fine, forfeiture or other penalty imposed.

Power to delegate

**121.** The Minister may, upon consultation with the Authority when he considers fit and proper by order published in the *Gazette*, delegate to any other person, institution or body of persons some of the functions or powers of the Authority conferred upon it by this Act.

Regulations

**122.**–(1) The Minister on the advice of the Authority, may make regulations with respect to any of the following matters or for any of the following purposes-

(a) prohibiting the sell of any specified drug, medical device or herbal drugs product except on a prescription lawfully given by a dentist, medical practitioner or veterinary surgeon;
(b) prohibiting, regulating or restricting the sell of any drug, medical device, herbal drug or poisons;
(c) providing for the better regulation of the manufacture, compounding, sell or advertising of drugs, medical device, herbal drug and poisons;
(d) the safe custody, storage and transport of medical devise drugs, herbal drug and poisons;
(e) the regulation of the manufacture, importation, exportation, distribution and labelling of drugs, device, herbal medicines, cosmetics and poisons;
(f) the regulation of the prices of both manufactured and imported drugs, medical devices herbal drug and poisons;
(g) regulating of containers or packaging material in which medical device, herbal drug or poisons may be contained;
(h) exempting any person from any of the provisions of this Act relating to the sell, supply or dispensing of drugs or herbal medicines;

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(i) prescribing the forms, the manner, the procedure and the fees payable in respect of applications for licences or registration and registers to be kept under this Act;

(j) the conduct of inquiries under this section shall be in accordance with the Commission of Inquiries Act; Cap. 32

(k) provide a code of conduct for drug inspectors;

(l) prescribing the grounds for suspension or cancellation of a licence issued or registration granted under this Act;

(m) provide regulations on minimum requirements of good manufacturing practice;

(n) provide regulations on conditions for undertaking clinical trials;

(o) provide for minimum requirements for a product leaflet;

(p) provide regulations on drug promotional activities for product regulated under this Act;

(q) provide regulations for controlling of manufacturing, selling, possessing and distribution of narcotic drugs and psychotropic substances;

(r) provide regulations on the disposition of narcotic and psychotropic substances;

(s) provide regulations on prohibition of manufacture, sell and distribution of herbal drug;

(t) provide regulations on sampling procedures, analysis and treatment of the analysis results;

(u) provide schedules for inspectors' identity card, conditions to be provided in the card and commitment form;

(v) provide regulations on recall of products which do not comply with any section of this Act;

(w) provide regulations for the categories of drugs;

(x) provide regulations for destruction of unfit drugs, medical devices, herbal drug and poisons;

(y) provide regulations for registration of food, drugs, medical devices and herbal drugs;

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(z) provide regulations on the establishment of laboratories for testing and analysing drugs, food, cosmetics or herbal;

(aa) prescribing the manner and the procedure of hearing appeals by the Authority against a decision of an inspector in relation to registration of premises;

(bb) prescribing functions, composition and number of the Technical Committees; and

(cc) regulating, prescribing or providing for any matter or thing which is required or permitted to be regulated, prescribed or provided for by or under this Act.

(2) The power to make regulations under this section in relation to product regulated under this Act, includes the power to make rules in the *Gazette* in relation to any category of such products or any particular product.

General penalty

**123.**–(1) A person who, commits an offence under this Act for which no specific penalty is provided on conviction shall be liable to a fine of not exceeding one million shillings or to imprisonment for a term of not exceeding six months or to both.

(2) Where the court is of the opinion, in the case of a second or subsequent offence, that a fine will not meet the circumstances of the case and that the offence was committed through the personal act, default or culpable negligence of the accused person, it may, in lieu of or in addition to any fine, impose a sentence of imprisonment for a term not exceeding twelve months.

## PART IX

## MISCELLANEOUS PROVISIONS AND SAVINGS

Minister's power to amend, vary or exclude products

**124.** The Minister may, on the advise of the Authority and subject to such conditions as the Authority may recommend, exclude any product regulated under this Act from the operation of any or all provisions of this Act and may, in a like manner, amend or withdraw such products.

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Reference to TFDA to be construed as reference to TMDA
Act No. 8 of 2019 s. 40

**125.** Unless the context requires otherwise, any reference in any written law to the "Tanzania Food, Drugs and Cosmetics Authority or by its acronym "TFDA" shall be construed as reference to "Tanzania Medicines and Medical Devices Authority or by its acronym TMDA.

[s. 124A]

Repeal
Acts Nos. 9 of 1978
10 of 1978

**126.** [Repeals the Pharmaceuticals and Poisons Act and Food (Control of Quality) Act.

[s. 125]

Transitional and savings provisions
Act Nos. 9 of 1978
10 of 1978

**127.**–(1) Notwithstanding the repeal of the Pharmaceuticals and Poisons Act and the Food (Control of Quality) Act any subsidiary legislation, licence, certificate and any other administrative order, direction or instruction made, given or issued under or in pursuance of the provisions of the respective Acts which are in force on the commencement of this Act, shall be deemed to have been made, given or issued under or in pursuance of the provisions of this Act, and shall remain in force until revoked, replaced or rescinded by subsidiary legislation, licence, certificate or any administrative order, directions or instruction made or issued under this Act.

Act Nos. 10 of 1978
9 of 1978

(2) All officers appointed pursuant to the Food (Control of Quality) Act or the Pharmaceuticals and Poisons Act to perform functions in relation to food and drugs, shall continue to perform those functions in so far as this Act relates to them, unless their appointments are revoked or their appointment cancelled and shall for that purpose, be deemed to be inspector appointed under this Act.

[s. 126]

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