

c. Licences and Permits

20. Application for licences or permits.
21. Types and issuance of licences or permits.
22. Restriction on dealing in products regulated under this Act.
23. Exemptions when dealing in drugs.
24. Exception when Supplying and dispensing drugs.
25. Suspension, variation and revocation of licence or permits.
26. Licence to sell, supply or dispense specified drugs.
27. Authority to issue Dispensing Certificates.

PART 111

PROVISIONS REGARDING FOOD

a. Registration and Composition Of Food

28. Registration of pre-packaged food.
29. Regulations regarding the composition of food.
30. Prohibition on food adulteration.
31. General protection for purchasers of food.
32. Offences regarding sale, etc. Of unfit food.
33. Food offered as prizes, etc.
34. Examination of food suspected to be unfit for human consumption.
35. Power to seize and dispose of carcass unfit for human consumption.

b. Importation

36. Restriction On importation of food.
37. Application for registration Of importers.
38. Restriction on movement of imported food.

' Milk, Milk Products and Milk Substitutes

39. Rules relating to milk, milk products and milk substitutes.
40. Milk from diseased dairy animals not to be used for human consumption.

d. Premises for Slaughter of Animals and Sale of Meat

41. Restriction on use of premises for slaughter of animals and sale of meat.
42. Regulations regarding premises for slaughtering, slaughter and butchery facilities etc.
43. Transport of meat.

e. Food Hygiene

44. Minister to make regulations regarding food hygiene.
45. Duty to report certain diseases and conditions.
46. Notification of food borne diseases.

PART IV
PROVISIONS REGARDING DRUGS

a. Pharmacy

47. Restriction on Pharmacy business and use of title.
48. Conditions for body corporate to become authorized seller of drugs and poisons.
49. Disposal of stocks by disentitled person -
50. Restrictions on directions by the Authority.

b. Registration of Drugs, Medical Devices or Herbal Drugs

51. Conditions for registration of drugs, medical devices or herbal drugs.
52. Application for registration of drugs, medical devices or herbal drugs.
53. Registration of drugs, medical devices and herbal drugs.
54. Register of drugs, medical devices and herbal drugs.
55. Cancellation and variation of conditions of registration.
56. Drugs, medical devices and herbal drugs to be labelled.
57. Sale of unregistered drugs, medical devices and herbal drugs for specified purposes.
58. Prohibitions, controls and restrictions in respect of drugs, medical devices, herbal drugs, poisons and certain substances.

59. Prohibition of sale of drugs, medical devices or herbal drugs which do not comply with prescribed requirements.
60. Prohibition of the manufacture, sale and distribution of undesirable drugs, medical devices or herbal drugs.

c. Clinical Trials of Drugs, Medical Devices or Herbal Drugs

61. Clinical trials of drugs, medical devices or herbal drugs.
62. Conduct of clinical trials.
63. Application to conduct clinical trials.
64. Authority to cause investigation to be conducted.
65. Conditions to conduct clinical trials.
66. Consent for clinical trials.
67. Supply of information prior to clinical trials, etc.
68. Power of the Authority to stop or suspend clinical trials.
69. Monitoring of clinical trials by the Authority.
70. Reports on clinical trials.
71. Offences and penalties.
72. Renewal and revocation of clinical trial certificate.

d. Dealing in Drugs, Medical Devices, Herbal Drugs or Poisons

73. Import and export of drugs, medical devices, herbal drugs or poisons.
74. Sale and administration of drugs subject to prescription by appropriate practitioners.
75. Prohibition of sale of adulterated or unfit drugs, medical devices and herbal drugs.
76. Counterfeit drug or medical devices.

e. Drugs and Poisons List

77. Drugs, medical devices, herbal drugs and poisons list.
78. Application of the Drugs and Prevention of Illicit Traffic in Drug Act.
79. Provision for non medicinal products.

f Prohibited Drugs

80. Interpretation of "deal in" and "prohibited drugs"
81. Prohibited drugs.

82. Prohibition to deal in prohibited drugs.
83. Forfeiture on conviction and prohibition from driving.
84. Safe custody of forfeited prohibited drugs.
85. Destruction of forfeited prohibited drugs.

PART V

COSMETICS

86. Restriction on manufacture, importation, distribution and sale of cosmetics.
87. Prohibited ingredients.
88. Prohibition of manufacture and sale of certain cosmetics.
89. Counterfeit cosmetics.
90. Power to prohibit the manufacture, importation and distribution of cosmetics in public interest.
91. Penalties.

PART VI

PACKAGING AND LABELLING

92. Labelling of products regulated under this Act.
93. Leaflets.
94. Containers and Packages.

PART VII

PROMOTION

95. Regulation on promotion of food, drugs, medical devices or herbal drugs.
96. Advertisement of products regulated under this Act.
97. Meaning of advertisement.
98. Restriction on food, drugs, medical devices or herbal drugs advertisement.

PART VIII

ENFORCEMENT AND LEGAL PROCEEDINGS

a. Inspection, Sampling and Analysis

99. Powers to seize, forfeit, condemn and destruct unfit products, devices, etc.

THE UNITED REPUBLIC OF TANZANIA



No. 1 OF 2003

I ASSENT,

President

An Act to provide for the efficient and comprehensive regulation and control of food, drugs, medical devices, cosmetics, 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.

I-----I

ENACTED by the Parliament of the United Republic of Tanzania.

PART I

PRELIMINARY PROVISIONS

1. This Act may be cited as the Tanzania Food, Drugs and Cosmetics Act, 2003 and shall come into operation on such date as the Minister may, by notice published in the *Gazette* appoint. Short title and commencement

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

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

"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 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 means and 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 unincorporate;

"Authority" means the Tanzania Food and Drugs Authority, or the acronym "TFDA" established by section 4;

"authorized seller of pharmaceutical products" means a person, other than a person lawfully conducting a retail pharmacy business, who may sell poisons pursuant to section 48;

"Board" means the Ministerial Advisory Board established under section 9 of this Act;

"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 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 77 of this Act;
- "cosmetic" means any article intended to be used by means of rubbing, pouring, steaming, sprinkling, spraying on or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness or altering the appearance and includes any article intended for use as component of a cosmetic; such articles exclude articles intended besides the above purposes for use in the diagnosis, treatment or prevention of diseases and those intended to affect the structure or any function of the body;
- "cream" in relation to food means that part of milk, rich in fat which has been separated by skimming or by any other means;
- "dentist" means a person who is registered as a dentist under the Medical Practitioners and Dentists Ordinance; cap.409
- "Director General" means the Chief Executive of the Tanzania Food and Drug Authority appointed under section 8(l) of this Act;
- "dispense" means the supply of a drug, drug product or poison on and in accordance with a prescription lawfully given by a medical practitioners, dentists or veterinary surgeon;
- "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; or
 - (c) disinfection in premises in which food and drugs are manufactured, prepared or kept, hospitals, equipment and farm houses;
 - (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;
- "food" means any article other than drugs, cosmetics and tobacco used as food or drink for human consumption and includes any substance used in manufacture or treatment of food;

"food borne disease" means any disease of infectious or toxic in nature caused or thought to be caused by consumption of contaminated food;

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

"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;

"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 1 05;

"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, 197 1;
- (d) United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances adopted at Vienna on 19" 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, 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" or "devices" means, an instrument, apparatus, implement, medical equipment, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part or accessory, which is -

- (a) recognized in the Official National Formulary, or Pharmacopoeia or any supplement to them;
- (b) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment or prevention of disease, in man or other animals or;
- (c) intended to affect the structure or any function of the body of man or other animals, and which does not achieve any of its principal intended purposes through chemical action within the body of man or other animals and which is not dependent upon being metabolised for the achievement of any of its principle intended purposes;

"medical practitioner" means a person who is registered as a medical practitioner under the Medical Practitioners and Dentists Ordinance;

"Milk substitutes" means a product manufactured using non milk ingredients to imitate the properties and characteristics of milk;

"Minister" means the Minister for the time being 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,

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

"pharmacopoeia" means a current edition of Tanzania Pharmacopoeia, British Pharmacopoeia, European Pharmacopoeia, United States

Act No. 7
of 2002

- 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;
- "pharmacist" means a person who is registered as a pharmacist under the Pharmacy Act, 2002;
- "poison" means a substance specified in the Poisons List prescribed under section 77;
- "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 cartilage, 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 food, drugs, cosmetics, poisons, herbal drugs and medical devices;
- "psychotropic substances" means any substance natural or synthetic or any natural material, or any salt or 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, pit-latrine 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;

"slaughter facility" means and includes a slaughterhouse, slaughter slab, abattoir and any premises or place habitually used for slaughter of animals for human consumption;

"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 manager and controls the business of a pharmacist;

"Tanzanian National Formulary" "National Formulary" means a compendium known by that name published by the Tanzania Food and Drug 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, 2002;

"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

"veterinary surgeon" means a person who is registered as a veterinary surgeon under the Veterinary Surgeons Ordinance.

Act No. of
2002

Cap 376

PART H

ADMINISTRATIVE AND GENERAL PROVISIONS

a. Administration

4.-(1) There is hereby established the Tanzania Food and Drugs Authority or by the acronym "TFDA".

(2) The Authority shall be an Executive Agency and shall operate in accordance with the Executive Agencies Act, 1997.

(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.

Establishment of
Tanzania
Food and
Drugs Authority Act
No. 30,
1997

Functions
of the Au-
thority

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 food, drugs, herbal drugs, medical devices, poisons and cosmetics;
- (b) regulate in accordance with this Act, the importation, manufacture, labelling, marking or identification, storages promotion, sell and distribution of food, drugs, cosmetics, 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 globally, are 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 organizations and other stakeholders;
- (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;
- ü establish and maintain the Tanzania National Formulary and Tanzania Pharmacopoeia;
- (k) provide the public with unbiased information on products regulated under this Act;
- (l) prescribe standards of quality in respect of products regulated under this Act, manufactured or intended to be manufactured or imported into or exported from the United Republic;
- (m) maintain registers prescribed under this Act;
- (n) be responsible for its human resource management and development;

- (o) promote, monitor and ensure successful implementation of the provisions of this Act;
- (p) attend to and, where possible, take legal measures on complaints made by consumers against manufacturers of products regulated under this Act;
- (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;
- (r) 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.

(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 Inter Ministerial Anti Drug Commission established by the Drugs and Prevention of Illicit Traffic in Drugs Act, 1995;
- (c) the Fisheries and Forestry and Bee keeping divisions in the Ministry responsible for fisheries and bee keeping matters;
- (d) the Tanzania Bureau of Standards established by Standard Act, 1975;
- (e) the Directorate of Veterinary Services in the Ministry responsible for Livestock Development; or
- (f) any 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 food, drugs, medical devices, herbal drugs.

Act No.9 of
1995

Act No.6 of
1970

Act No.3 of
1975

6. For the better performance of its functions, the Authority in addition to the powers granted under the Executive Agencies Act, 1997 shall subject to this Act have powers to:

Powers of
the Author-
ity
Act No. 30,
1997

- (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;
- (d) regulate its own procedures;

Sources of
fund and
its manage-
ment

7.-(1) The funds and resources of the Authority shall, in addition to those provided for under the Executive Agency Act, 1997 include:

- (a) interest from deposits;
- (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, 1997,

(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.

(4) Without prejudice to the generality of the financial provisions under this Act, the Authority shall establish a General Fund into which all money 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.

Appoint-
ment and
tenure of
the
Director
General
Act;
No. 30 of
1997

8.41) There shall be a Director General appointed by the Minister on the advice of the Civil Service Commission as provided for under section 9 of the Executive Agencies Act, 1997 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 purpose of assisting the Civil 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, organization, 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, 1997;
- (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 maybe specified in his instrument of appointment and shall be eligible for re-appointment.

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

- (a) misconduct, or
- (b) failure or inability to perform the functions of his office arising from infirmity of body or mind; or
- (c) incompetence

Act No. 3 of 1997 (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, 1997 in respect of any disciplinary action against him or in respect of the decision of the Minister made under subsection (6) of section 9 of the Executive Agencies Act, 1997 to terminate his appointment may, in accordance with such Procedure 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.

Establishment of the Board 9-41) There shall be established a Ministerial Advisory Board which shall consist of:

- (a) the Permanent Secretary who shall be the Chairman;
- (b) not more than twelve other members appointed by the Minister; and
- (c) the Director General who shall be the Secretary to the Board.

(2) The Schedule to this Act shall have effect as to appointments, composition and procedure of the Board, tenure of office of its members, termination of their appointment, the Proceedings of the Board and other matters in relation to the Board and its members.

(3) The Minister may by order published in the *Gazette*, amend, vary or replace all or any of the provisions of the First Schedule except the appointment of the Chairman.

(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.

10. The powers and functions of the Board shall be as provided for under the Executive Agencies Act, 1997.

Powers
and
functions
of the
Board

11.-(I) The Director General shall, in consultation with the Permanent Secretary determine the organizational structure of the Tanzania Food and Drugs Authority and the distribution of responsibilities as he deems fit.

Establish-
ment of Di-
rectorates
and ap-
pointment
of Direc-
tors and
other ern-
ployees of
the Author-
ity

(2) Subject to subsection (1), the Director General shall upon consultation with the Minister responsible for civil 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 civil 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 will 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 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 Civil 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; or
- (b) incoinpetence; 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 Civil 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 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) Any 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 superannuation 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.

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.

Establishment of Technical Committees of the Authority

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

14.-41) There is hereby established within the Authority, the Laboratory to be known as the Tanzania Food and Drugs Authority Laboratory.

Establishment of the 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, cosmetics, 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) analyse foods, food packaging materials and raw materials used in manufacture of food;
- (c) conduct research and training; and
- (d) do such other function as shall be determined by the Authority.

(3) The Minister may on advise of the Director General, by order published in the *Gazette* establish such other Food, Drug and cosmetics Laboratories to carry out the functions entrusted to the Tanzania Food,

Drug and Cosmetics 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 Tanzania Food and Drugs Authority shall take in cognisance the existence of the Government Chemical Laboratory Agency for analysis of food, drugs, cosmetics 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 Food and Drug 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 food, drugs, herbal drugs, medical devices and poisons for analysis or tests and the forms of the Laboratory's reports.
- (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.

Appoint-
ment 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.

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, 1972 or Income Tax Act, 1973.

Exemption from Taxation Acts Nos. 20 of 1972 and 33 of 1973

17. No person shall manufacture for sale, import, export, distribute, sell, offer or expose food for human consumption, drugs, cosmetics, medical devices for human consumption or use unless he complies with the provisions of this Act.

control of manufacturing, importation, export, sell etc.

b. Registration of Premises

18.-(I) No person shall manufacture for sale, sell, supply or store products regulated under this Act except in premises registered under this section for that purpose.

Registration of premises

(2) Every application for registration or renewal of registration of premises shall be made to the Authority in the 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,
- (d) shall have the final say on the location and name of the proposed premises;

(4) Any person who contravenes or fails to comply with this section, commits an offence and upon conviction is liable to a fine of not exceeding five million shillings or to imprisonment for a term of not exceeding two years or to both such fine and imprisonment.

Change of
business
ownership
or any
other
change

19.-(I) Any 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

Applica-
tion for
licences or
permit

20.-(I) Any 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.

(2) Where an application is made for a licence or permit under this Part in relation to food, 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 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) that the substances he intends to use are of a quality satisfactory of the standards prescribed by the Authority in respect of the product he proposes to manufacture;
- (iii) 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;
- (iv) 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;

-
- (v) that he is not disqualified in any other way from holding a licence or a person whose licence is suspended;
 - (vi) that he has adequate expertise or skill or has personnel qualified to execute the business for which he is seeking to be licensed;
 - (vii) 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;
 - (viii) that he meets in all respects such other requirements which may be prescribed in respect of manufacturers of products regulated under this Act;
- (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 safe-keeping of, and the maintenance of adequate records in respect of products regulated under this Act stored in or distributed from those premises;
 - (v) if 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;
 - (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 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 veterinary surgeon 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 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) Every 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

21--Q The Authority, shall subject to sub section (2) upon an application made, issue the following licences or permits-

- (a) manufacturing licence;
- (b) wholesale licence;
- (c) retail licence; or
- (d) any other licence or permit as the Authority may deem fit for the purpose of this Act.

(2) If the Authority is satisfied that the applicant is a fit and proper person to carry on any business set out in sub section (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.

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

(4) Where the Authority considers that the applicant is not fit and proper person to whom a licence or permit should be issued for carrying on of any business specified under this section it shall refuse to issue a licence.

22.-41) Notwithstanding the provisions of this Act or any other written laws, no person shall, on or after the appointed day, manufacture for sale, sell, offer, supply or import any product regulated under this Act unless -

**Restriction
on
dealings in
products
regulated
under this
Act**

- (a) the product is registered in accordance with the provisions of this Act;
- (b) the person holds the appropriate licence or permit required and issued by the Authority.

(2) No person shall 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; or
- (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) Any 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 upon 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 such fine and imprisonment.

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

Exemptions when dealing in drugs

23.-(I) The provisions of section 22 shall not apply to -

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

- (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 veterinary surgeon 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 veterinary surgeon for administration to a particular animal or group of animals under the care of that other veterinary surgeon;

(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 veterinary surgeon;

(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;

- (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 household 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, 2002, which relates to a herbal drug specifically prepared for administration, or supply to this particular patient.

24-(1) A medical practitioner, dentist or veterinary surgeon, or a member of the staff of a hospital, dispensary or similar institution who has been authorized to do so by the general or special order of the Minister, on the advice of the Authority may supply or dispense a prescription drug for the purpose of medical, dental or veterinary treatment, as the case may be, subject to the following conditions -

**Exception
when
supplying
and
dispensing
drugs**

- (a) the drug shall be distinctly labelled with the name and address of the person by whom it is supplied or dispensed;

(b) the following particulars shall, within twenty four hours after the drug has been supplied or dispensed, be entered in a book used regularly for the purpose, and which shall be called the Prescription Book -

(i) the date on which the drug was supplied or dispensed;

(ii) the name, strength and the quantity supplied;

(iii) the name and address of the person to whom the drug was supplied;

(iv) the name and address of the person by whom the prescription was given.

(2) Where an authorized seller of drugs supplies a prescription drugs, shall enter its particulars in a Prescription Book kept in accordance with the provisions of this section.

(3) Any person to whom subsection (1) applies and who supplies or dispenses any prescription drug in a manner contrary to this section, commits an offence and upon conviction is liable to a fine of not less than one hundred thousand shillings or to imprisonment for a term not exceeding one month, or to both such fine and imprisonment.

Suspension,
variation
and
revocation
of licences
or permits

25.-(1) Subject to Sub Part 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.

(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.

Licence to
sell,
supply or
dispense
specified
drugs

26.-(1) Notwithstanding any of the provisions of this Act, relating to sell, supply or dispensing of drugs and if it is in the public interest so to do, the Minister may, on advise of the Authority and by order published in the

Gazette, allow any person or group of persons to be licensed by the Authority to sell, supply or dispense such drugs as may be specified and under such conditions as may be prescribed in the regulations.

(2) The Minister may in addition to any other conditions, require such a person to possess specified qualifications or training as the case may be.

27.-(1) The Authority may, when it is in the public interest and upon an application being made in a prescribed manner and subject to such conditions as may be prescribed in the regulations made under this Act, issue a dispensing certificate to a practising medical practitioner, dentist or veterinary surgeon to dispense drugs, which he is entitled to prescribe.

Authority
to issue
Dispens-
ing
Certifi-
cates

(2) Upon application being made to the Authority pursuant to subsection (1), the Authority may issue a dispensing certificate subject to such conditions as it may deem necessary and for such duration of time as it may prescribe.

(3) The Authority may, where it is satisfied that the applicant did not or is not fulfilling the conditions issued by it may suspend, revoke or withdraw the dispensing certificate issued under subsection (1) of this section.

(4) In this section "public interest" means and includes facilitation of accessibility of the public to drugs within a specified area.

PART III

PROVISION REGARDING FOOD

(a) Registration and Composition of Food

28.-(1) No person shall manufacture, import, distribute, sell or expose for sale pre-packaged food unless that food or food product has been registered by the Authority

Registra-
tion of
pre-
packaged
food

(2) Every application for registration of pre-packaged food shall be made to the Authority in a prescribed manner together with the prescribed application fees.

(3) The Authority shall register any pre-packaging food or food product if it is satisfied that, that food or food product complies with

prescribed standards and the manufacturing operations for such food complies with the Prescribed current Good Manufacturing Practice requirements.

(4) 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 pre-packaged food or food product.

Regulations regarding the composition of food

29.-(1) The Minister may, after consultation with the Authority, make regulations prescribing standards to be complied with by manufacturers with regard to the composition of food or its microbiological or chemical or physical standards.

(2) Without prejudice to the generality of the power conferred by subsection (1), the Minister may in those regulations -

- (a) require, prohibit or regulate the addition to food or extraction from it of any specified substance or any substance of any specified category, or the use of any substance as an ingredient in the manufacture or preservation of that food;
- (b) prohibit, restrict or regulate the importation, manufacture or sale, possession for sale, offer or exposure for sale or the consignment or delivery, of food or any of its ingredients which do not comply with those regulations;
- (c) Prohibit or regulate the importation of any food which, in his opinion, is or may be prejudicial to public health;
- (d) prohibit, restrict or regulate the importation, exportation or use of any specified materials, or materials of any specified category, in the manufacture of apparatus or utensils intended for use in the manufacture or preservation of food;
- (e) prescribe or provide for methods of analysis for the purpose of ascertaining the presence in any food, or the absence from it, of any specified substance, or the quantity of any substance present in any food.

(3) In making regulations under this section, the Minister shall have regard to the desirability of restricting, so far as is practicable, the use in the manufacture of food or substances of no nutritional value as foods.

30--(1) No person shall with intent to cause food to be sold for human consumption -

Prohibi-
tion on
food
adultera-
tion

- (a), add any substance to the food, use any substance as an ingredient of that food in its manufacture or abstract any constituent from it; or
- (b) subject the food to any other process or treatment, so as, in any such case, to produce food of a quality below the prescribed standard, whether or not that food thereby becomes injurious to health;
- (c) if that food does not comply with requirements prescribed by the Authority.

(2) Subject to this section, no person shall distribute, sell or offer, expose or advertise for sale for human consumption, or have in his possession for the purpose of distribution or sale, any food manufactured in contravention to subsection (1).

(3) Any person who contravenes any of the provisions of subsection (1) or (2), shall be guilty of an offence and shall be liable on conviction to a fine of not less than one million shillings or to imprisonment for a term not more than six months or to both such fine and imprisonment.

(4) Where, in proceedings for an offence under this section, it becomes necessary to determine whether or not any article of food is injurious to health, regard shall be not only to the probable effect of that article on the health of a person consuming it, but also to that probable cumulative effect of articles of substantially the same composition on the health of a person consuming those articles in ordinary quantities.

31.-(1) Any person who sells any food which is not of the nature, substance or quality of the food demanded by the purchaser shall be guilty of an offence.

General
protection
for
purchasers
of food

(2) Where regulations made under section 29, contained provisions prescribing the composition of, or prohibiting or restricting the addition to, any food, or the extraction from it, of any substance, a purchaser of that food shall, unless the contrary is proved, be deemed, for the purposes of subsection (1), to have demanded a food complying with the provisions of the regulations.

(3) In any proceedings for an offence under subsection (1), it shall not be a defence for the defendant to allege that the purchaser bought for analysis or examination and therefore was not prejudiced.

(4) In this section, references to sale shall be construed as references to sale for human consumption.

Offences
regarding
sale, etc.
of unfit
food

32.-- 1) Any person who-

- (a) distributes, sells, or offers or has in his possession for the purpose of distribution, sale or manufacture for sale; or
- (b) deposits with, or consigns to, any person for the Purpose of distribution or sale or manufacture for distribution or sale, any food intended, but unfit, for human consumption, shall be guilty of an offence.

(2) Where any food in respect of which an offence under paragraph (a) Of subsection (1) has been committed, if the unfit food or food products was distributed or sold to the offender by some other person, that other person, shall also be guilty of an offence.

Food
offered
as prizes,
etc

33.-(1) The Provisions of sections 32 and 34 shall apply in relation to-

- (a) any food intended for human consumption which is offered as a prize or reward or donation in connection with any entertainment to which the public are admitted, whether or not on payment of money, as if such food were or had been, exposed for sale by each person in the organization of the entertainment;
- (b) any food intended for human consumption which is offered as a prize or reward, donation or given away for the Purposes of advertisement, or in furtherance of any trade or business, as if the food were, or had been, exposed for sale by the person offering or giving it away;
- (c) any food intended for human consumption which is exposed or deposited in any Premises for the purpose of being so offered or given away as if the food were, or had been, exported for sale by the occupier of the Premises.

(2) in this section, the expression „entertainment" includes any social gathering, amusement, exhibition, performance, game, sport, lottery or trial of skill.

34.-(1) Any inspector may, at all reasonable times, examine any food intended for human consumption which has been distributed, sold, or is offered or exposed for sale or is in the possession of, or has been deposited with or consigned to, any person for the purpose of distribution or sale or manufacture for sale, if it appears to him to be unfit for human consumption, may seize it and remove it in order to have it dealt with in a manner provided for in this Act.

Examina-
tion of
food
suspected
to be unfit
for human
consump-
tion

(2) An Inspector who seizes any food under subsection (1) shall inform the person in whose possession the food was found of his intention to have it disposed of in a prescribed manner.

(3) if it appears to the inspector that any perishable food examined by him is unfit for human consumption he shall condemn the food and order destruction of the same or dispose of in a prescribed manner.

(4) When it appears to the inspectors that any non-perishable food examined by him is unfit for human consumption he shall take that food to the court for farther action, and if the court is satisfied that, that food is unfit for human consumption, the court shall condemn the food and order for its destruction or disposal in a prescribed manner, and if the court is not satisfied that the food is unfit for human consumption, it may order for further actions to be taken.

(5) When the court orders for the destruction or disposal of any food which has been declared unfit for human consumption, that destruction or disposal shall be done at the owners cost.

35.-41) An Inspector may seize, and cause to be disposed of in such manner as he may think fit, the carcass or any part of the carcass, Of ally animal received into a butchery facility or cold stores for the purpose of sell for human consumption which on examination is found to be diseased or unfit for human consumption, and no compensation shall be payable to the owner of that carcass or any part of it.

power
seize and
dispose of
carcass
unfit for
human
consump-
tion

(2) Where, in pursuance of subsection (1), any carcass or a part of it is seized by an inspector, he shall, before causing it to be disposed of record or cause to be recorded-

- (a) a description or other Particulars as will suffice to identify the carcass Or Part of it; and
- (b) the grounds upon which the seizure was effected.

(3) For the purpose of this section, the inspector may deal with poultry, game and fish in the same manner as if the poultry, game and fish were carcasses or animals for slaughter.

b. Importation

**Restziction
on
importa-
tion of
food**

36.-(1) No person shall on or after the appointed day, carry on the business of an importer of food unless he is registered by the Authority under section 37 as an importer of food.

(2) The Authority shall cause to be kept and maintained in the prescribed manner a register containing -

- (a) the name of every registered importer of food;
- (b) the date of registratiofi;
- (c) the kind or kinds of food in respect of which he is registered as an importer;
- (d) chemical composition, microbiological and physical status of the food he imports; and
- (e) such other particulars as the Authority may, from time to time, prescribe.

(3) The provisions of section 37 shall be complied with, by every person registered as an importer of food on every occasion he proposes to import food which was not included in his original application for registration.

**Applica-
tion for
registra-
tion of
importers**

37.-(1) Every application for registration as an importer of food shall be addressed to the Director General and shall be in a prescribed form and manner.

(2) Upon receipt of an application for registration, the Director General shall, as soon as is practicable, proceed to consider the application and grant registration if he is satisfied that -

- (a) the composition of the food proposed to be imported is not of a quality below the specifications prescribed under this Act;
- (b) importation and consumption of the food proposed would enhance or contribute in any other way to the national effort to improve the nutritional status of the people of Tanzania;
- (c) the food or its products and practices related there to does not in any way contravene the provisions of this Act.

38.-(1) Without prejudice to any power of examining food conferred by this Part, any person authorized in writing in that behalf by the Authority may give directions to the person in possession of any food which is imported for human consumption, prohibiting or restricting its removal or delivery -

Restriction on movement of imported food

- (a) during any period of not more than seventy-two hours; and
- (b) if within that period the authorized person so requires, until that person has notified the authorized person of the name of the person to whom, and the address to or at which, he proposes to send or deliver that food.

(2) Any person who, fails to comply with any direction given under subsection (1), or who, in a notification under that subsection, knowingly makes any false statement, shall be guilty of an offence.

c. Milk, Milk Products and Milk Substitutes

39.-4 1) The Minister may, after consultation with the Authority and other institutions dealing with matters related to milk, milk products or milk substitutes and with such other person as he may determine, make rules for the purposes of -

Rules relating to Milk, Milk products and Milk substitutes

- (a) regulating the addition to milk intended for human consumption, any water or colouring matter, or any dried or condensed milk or liquid reconstituted from condensed milk;

- (b) regulating the extraction of any matter or substance from milk intended for distribution or sale for human consumption;
- (c) regulating in any other way the composition and other dealings in milk, milk products and milk substitutes.

(2) Rules made under this section shall be published in the *Gazette*.

Milk from diseased dairy animals not to be used for human consumption

40. No person shall -

- (a) sell, or offer or expose for sale, for human consumption; or
- (b) use in the manufacture of food for sale for human consumption, the milk of any dairy animal which to his knowledge has tuberculous milk, or is suffering from emaciation due to tuberculosis or from tuberculosis of the udder, or any infection of the udder or teats which is likely to convey diseases, or from any comatose condition, any septic condition of the uterus, anthrax or any other zoonotic diseases so diagnosed;
- (c) sells or offer or expose for sale or use or use in the manufacture of food for human consumption the milk from any treated dairy animal during its withdrawal period.

(2) Any person who contravenes this section shall be guilty of an offence.

(3) In any proceedings under this section, an accused person shall be deemed to have known that a dairy animal was diseased, if he could with reasonable diligence have ascertained that fact.

d. Premises for Slaughter of Animals and Sale of Meat

Restrictions on use of premises for slaughter of animals and sale of meat

41.-41) No person shall use any premises for slaughter of animals or cause or permit any animal to be slaughtered with intent to supply, sell, offer or expose for sale meat for human consumption, unless that premises is registered by the Authority.

(2) Any person who contravenes any of the provisions of this Act shall be guilty of an offence.

42.-41) The Minister shall, on advice of the Director General after consultation with the Minister responsible for Livestock Development, make regulations relating to premises for the slaughter of animals or birds and sale of meat for human consumption and may, by such regulations:

- (a) prescribe the methods, instruments or appliances which may be used to carry out slaughtering;
- (b) provide for and regulate the inspection of slaughter and butchery facilities to determine whether or not they are suitable for the intended purpose;
- (c) provide for the disposal, treatment or processing of waste matters, refuse and by-products resulting from the slaughtering of animals or birds in slaughterhouses;
- (d) prescribe places and circumstances in which an animal or bird may be slaughtered in a place other than a slaughterhouse, and any action or actions to be taken in the event of every such slaughter,
- (e) prescribe the manner in which carcasses and viscera are to be marked or labelled upon their being detained or seized under Part VIII;
- (f) regulate treatment and disposal of any animal, carcass or viscera, or any part of them, in relation to which a breach of this Act has been committed and the offender convicted;
- (g) prescribe or provide for any matter in relation to slaughter and slaughter facilities which appears to him to be necessary for the proper maintenance of quality standards in respect of meat intended for human consumption.

(2) Regulations made under this section may require acts or things to be performed or done to the satisfaction of a prescribed person and may empower a prescribed person to issue directions to any other person requiring acts or things to be performed or done, imposing conditions and prescribing periods and dates upon, within or before which such acts or things shall be performed or done or such conditions shall be fulfilled.

Regulations regarding slaughtering, slaughter and butchery facilities, etc.

(3) No regulation made under this section relating to any slaughter facility shall be so framed or construed as to deny to any religious community reasonable facilities for obtaining food, the flesh of animals or birds slaughtered by the method specially required by their religion.

(4) The Authority for the purpose of performing its functions under Sub Part (d) of Part III of this Act shall establish and maintain a system of consultation and cooperation with any person or body of persons, whose functions are related to those of the Authority or whose participation or collaboration in the work of the Authority is likely to advance the better and more effective furtherance of the objects specified under Sub Part (d), and in particular the institutions responsible for Hide and Skin Trade Act, 1963 and the Animal Diseases Ordinance, 1960.

Act No.68
of 1963,
Cap. 156

Transportation
of meat

43.-(I) Subject to subsection (2), no person shall convey or cause to be conveyed any meat or meat product from a slaughter facility or cold store in any vehicle unless such vehicle has been approved in writing for that purpose by the Authority.

(2) Subsection (1) shall not apply to the transport of meat or meat products in hermetically sealed containers or in other containers of a type approved by the Authority.

(3) The Authority or, as the case may be, an inspector designated for that purpose by the Authority, may refuse to approve any vehicle, tray or load-carrying part of which is not covered; or which has no proper provisions for preventing contamination or which is considered for any other reason to be unsuitable for the carriage of meat or meat products.

(4) If at any time the Authority considers that any vehicle approved under subsection (1) of this section has ceased to be suitable for carrying meat or meat products, it may revoke the approval of that vehicle.

(5) Any person who contravenes this section is guilty of an offence and shall be liable on conviction to a fine of not less than one hundred thousand shillings or to imprisonment for a term not exceeding three months or to both such fine and imprisonment.

e. Food Hygiene

44.(1) The Minister may, after consultation with the Authority make regulations designed to secure the observance of sanitary and cleanly conditions and practices and wholesome methods in connection with -

Minister to
make
regula-
tions
regarding
food
hygiene

- (a) the sale of food for human consumption;
- (b) the manufacture, transport, storage, packaging, marking, exposure for sale, service or delivery of food intended for human consumption.

(2) Without prejudice to the generality of the power conferred by subsection (1), the Minister may make regulations -

- (a) prohibiting, restricting or regulating the sale, or storage, possession or exposure for sale, of any specified food, in anyplace in the United Republic by any specified person or category of persons;
- (b) impose requirements as to the construction, layout, drainage, equipment, maintenance, cleanliness, ventilation and extraction of fumes or heat, lighting, water-supply and use of premises in, at or from which food for human consumption is manufactured or stored, or sold, offered or exposed for distribution or sale;
- (c) imposing requirements as to the provision, maintenance and cleanliness of sanitary and washing facilities in connection with those premises, the disposal of refuse and the maintenance and cleanliness of apparatus, equipment, furnishings and utensils used in such premises, and in particular, the regulations may impose requirements that every sanitary convenience situated in such premises be supplied with water through a suitable flushing appliance;
- (d) prohibiting or restricting spitting on or, in any other way, littering premises where food for human consumption is manufactured or stored, or sold, offered, or exposed, for distribution or sale;
- (e) imposing requirements as to the clothing to be worn by persons engaged to work in those premises;

- (f) requiring the periodic medical examination of persons engaged in those premises or a category of them, the immunization of those persons against any special disease and prohibiting the employment or continued employment of any of them found to be suffering from any specified disease;
- (g) regulating generally the treatment and disposal of any food which is unfit for human consumption or any food which is condemned by an inspector under section 34 or which is, in any other way, found by an inspector to be manufactured, distributed, or sold, or offered or exposed for sale, contrary to any of the provision of this Act.

(3) Regulations made under this section shall be published in the *Gazette*.

Duty to
report
certain
diseases
and
conditions

45.-41) Every person who works in direct contact with food in food processing and handling operations and who -

- (a) is suffering from a septic sore, diarrhoea, chronic cough or septic sorethroat; or ,
- (b) to his knowledge is suffering from, or is a carrier of typhoid or paratyphoid fever, any salmonella infection, dysentery or any staphylococcal infection liable to cause food poisoning, shall not be allowed to handle food and shall be required to take necessary measures including seeking medical attention and reporting the matter to the employer where applicable.

(2) Upon being informed of the circumstances specified in subsection (1), every employer or occupier shall forthwith stop the employee from handling food and cause such employee to be attended by a medical practitioner and shall keep records related to such incidence.

(3) The employer shall be required to notify the Authority without delay.

Notifica-
tion of
food borne
diseases

46.-(I) Where a medical practitioner or any other person becomes aware, or suspects, that a patient under his care is suffering from food poisoning, he shall, without delay, send to the Medical Officer of Health of the area in which the patient ordinarily resides, a report stating -

- (a) the name, age and sex of the patient, and the address of the residence of that patient; and
- (b) particulars of the food poisoning from which the patient is, or is suspected to be suffering.

(2) Upon receipt of the report, the medical officer of health shall immediately take all necessary measures to investigate and prevent or put to a stop occurrences of food poisoning within the area under his jurisdiction and report such actions and measures to the Authority in a prescribed manner.

(3) Subject to subsection (2) of this section and section 45(3), the Authority shall prescribe a manner in which food borne incidence shall be reported.

PART IV PROVISIONS REGARDING DRUGS

a. Pharmacy

47.-41) No person other than a pharmacist either alone or in association with other persons shall, on or after the coming into effect of this Act carry on the business of a pharmacist.

Restriction
on
pharmacy
business
and use of
title

(2) No person shall manufacture for sale, sell, supply or dispense any drug except under the immediate supervision of a pharmacist.

(3) Subject to subsections (1) and (2), no person other than a pharmacist shall assume, take, exhibit, or in any way make use of any title, emblem, or description reasonably calculated to suggest that he is a pharmacist.

(4) The name and certificate of registration of the pharmacist having control of the business shall be conspicuously exhibited in the premises.

(5) Where the body is an association -

- (a) a copy of the certificate of its registration under the Business Names (Registration) Ordinance or the Companies Ordinance or any other charter or instrument establishing such association, shall be lodged with the Authority;

Cap 212

- (b) the business shall be under the management of a superintendent who shall be a pharmacist and also a member of its body of directors who is not acting in a similar capacity for any other body corporate;
- (c) in each set of premises for the retail sale of drugs, the business shall be carried on by the superintendent .

(6) Where the body is a partnership -

Cap 213

- (a) a copy of the certificate of its registration under the Business Name (Registration) Ordinance, if any, shall be lodged with the Authority;
- (b) one or more of the partners shall be a pharmacist; and
- (c) it shall comply with the provisions of subsection (5)(c).

(7) For the purpose of subsection (3), the use of any of the titles "pharmacist", "druggist", "dispensing chemist", "pharmacist" or "drug chemist", or a similar word or combination of words in any language, shall be deemed to be reasonably calculated to suggest the owner of the business or the person having control of the business on the premises is a pharmacist.

(8) Nothing in this section shall extend to or interfere with the emergency supply of drug for use within twenty four hours to particular person by qualified medical practitioner, a dentist or a veterinary surgeon for the purpose of medical, dental or veterinary treatment.

(9) Any person who contravenes this section, commits an offence and is liable upon conviction:

- (a) in case such a person is an individual to a fine of not less than one million shillings or to imprisonment for a term not less than six months, or to both such fine and imprisonment;
- (b) in case such a person is an association, or firm or body corporate to a fine of not less than five million shillings.

(10) Notwithstanding the provision of subsection (2), no prescription drug can be supplied or dispensed without the supervision of a pharmacist.

48.-(1) Any body corporate carrying on business comprising the sell of drugs shall be an authorized seller of drugs within the meaning of this Act if -

Conditions
for body
corporate
to become
authorized
seller of
drugs and
poisons

- (a) with regard to the keeping, selling, dispensing and compounding of drugs the business is under the management of a superintendent who -
 - (i) is a pharmacist;
 - (ii) has signed, and sent to the Director General a statement in writing on behalf of the body corporate stating his name and specifying whether or not he is a member of that body; and
 - (iii) is not at the time acting in similar capacity for any other body;
- (b) in each set of premises for the sell of drugs, the business is carried on either under the personal supervision of the superintendent or subject to his directions under the personal control of another pharmacist;
- (c) the name and certificate of registration of the superintendent or of some other pharmacist having control of the business is conspicuously exhibited in the Premises.

(2) Where -

- (a) a body corporate which is an authorized seller of drugs has been convicted of an offence under this Act; or
- (b) any member of the body corporate or any of its officers or any officer employed by it in carrying on the business, has been convicted of any criminal offence, or has been guilty of misconduct which, in the opinion of the Authority renders him or would, if he were a pharmacist, render him unfit to be on the register, the Authority may inquire into the matter and may, subject to this Act, direct that-
 - (i) the body corporate cease to be an authorized seller of drugs, and be disqualified, for a period specified in the direction from being an authorized seller of drugs or,
 - (ii) any or all of the premises of drugs and the body corporate be removed from the register of premises and be disqualified for a Period specified in the direction from being registered.

(3) The Authority may if it deems necessary, either on its own motion or on application by the body corporate concerned, direct the cessation of any disqualification imposed under this section.

Disposal
of stocks
by
disentitled
person

49.-4 1) Notwithstanding anything contained in the foregoing provisions of this Part-

- (a) any 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 and subject to any conditions or directions which the Authority may impose, within ninety days from the date of his disentitlement, dispose any stocks of drugs lawfully acquired by him prior to the disentitlement;
- (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 Authority, sell that drug to a licensed wholesale dealer or to any authorized seller of drugs.

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

Restric-
tions on
directions
by the
Authority

50.41) 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 facts 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 must 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) if 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;
- (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 the responsibility, knowledge or diligence of that body as a whole.

b. Registration of Drugs, Medical Devices or Herbal Drugs

51.-(I) 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;

Condi-
tions for
registra-
tion of
drugs,
medical
devices or
herbal
drugs

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

Applica-
tions for
registra-
tion of
drugs,
medical
devices or
herbal
drugs

52.-(1) Every 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 from time to time.

(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.

(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).

Registra-
tion 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, a medical device or a 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) if 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;
- (b) if 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) If 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
- (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 51 shall apply accordingly.

Register of
drugs,
medical
devices
and herbal
drugs

54-(I) 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;
- (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.
- (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.-(I) 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; or

-
- (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 96.
 - (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) if the Authority is satisfied that the applicant supplied false information in connection with his application for registration of any product it shall reject registration or remove the product from the register.
 - (g) it is in the public interest to vary the conditions of 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) If -
- (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.

(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--Q Subject to the provisions of this section, no person shall 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 veterinary surgeon for the treatment of a particular person or animal and supplied by that medical practitioner, dentist or veterinary surgeon 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 veterinary surgeon, shall be labelled with the registered name of the drug, medical device or herbal drug.

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

Sale of unregistered drugs, medical

(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.

devices, and herbal drugs for specified purposes

(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, 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).

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

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

(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; or

(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, if 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.

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

59.-41) 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) No person shall -

- (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;
- (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 the manufacture, sale and distribution of undesirable drugs, medical devices or herbal drugs.

60.-(I) 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 notifi

cation in the *Gazette* prohibit the manufacture, sale or distribution of such drugs or medical devices.

(2) Any 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 and upon conviction is 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 such fine and imprisonment.

c. Clinical Trials of Drugs, Medical Devices or Herbal Drugs

61.-41) 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 veterinary surgeon 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.

Clinical trials of drugs, medical devices or herbal drugs

(2) Subject to the provisions of this Part, no person shall, 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 authorizes 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 authorized 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.

Conduct
of clinical
trials

62. No person shall conduct a clinical trial of any drug, medical device or herbal drug without the written authorization of the Director General.

Applica-
tion to
conduct
clinical
trials

63.-(1) Any 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, veterinary surgeon 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
investiga-
tion to be
conducted

64.-(1) Upon the receipt of an application in terms of subsection (1) of section 63, the Authority shall cause to be conducted such investigations to authenticate the safety, efficacy and quality of a drug, medical device or herbal drug and if 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) Any person who is aggrieved by a decision of the Authority of not granting authorization for the conduct of clinical trial may make his representation within sixty days to the Authority.

(4) If 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.

Condi-
tions to co-
duct cli-
nical trials

65. Any clinical trial of any drug, or medical device or herbal drug authorized in terms of section 63 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 authorized.

66. Where the Director General grants written authorization under section 64 for the conduct of a clinical trial of a drug, medical device or herbal drug, no such trial shall take place until - Consent for clinical trials

- (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; and
- (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, as the case may be, have been freely obtained; and
- (c) in the case of a drug, medical device or herbal drug for the treatment of animal's, 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.

67. Whenever a clinical trial of any drug, medical device or herbal drug is authorized in terms of the provisions of section 66, the person conducting the trial shall, before commencing the trial - Supply of information prior to clinical trials, etc.

- (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 there from;
- (b) ensure in such amounts as may be prescribed, from time to time, 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 the
Authority
to stop or
suspend
clinical
trials

68.-41) If at any stage during the clinical trial of any drug, medical device or herbal drug authorized in terms of the provisions of section 66, 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.

Monitor-
ing of
clinical
trials by
the
Authority

69.-The Authority shall monitor such clinical trial from the beginning to the end so in order to ensure adequate protection of the general public against any risks or adverse effects from the clinical trial of any drug authorized in terms of the provisions of section 63, as to satisfy itself that all specific and general conditions subject to which the trial was authorized 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.-(I) 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.-Any person who contravenes the provisions of this part, commits an offence and upon conviction is 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 such fine and imprisonment.

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 authorized period of the trial.

Renewal and revocation of Clinical Trial Certificate

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

d Dealing in Drugs, Medical Devices, Herbal Drugs or Poisons

73.-(1) No person, other than a person issued with a licence or permit under the provisions of this Act, may import or export into Mainland Tanzania any drugs, medical devices, herbal drugs or poisons.

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

(2) Subject to subsection (1), the Authority may if 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 period of twenty-one days for the medical treatment of himself, or any member, or partner travelling with him.

(4) No person shall 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) If 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) Any person who contravenes the provisions of this section commits an offence and upon 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 such fine and imprisonment.

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

Sale and
adminis-
tration of
drugs
subject to
prescrip-
tion by
approp-
riate
practi-
tioners

74--(I) Subject to the Provisions of this section, no Person shall sell by retail, or supply in circumstances corresponding to retail sale or administer, other than to himself, a drug product of a description or a class specified by order made by the Minister and published in the *Gazette* except in accordance with a Prescription given by appropriate practitioner.

(2) In this Part "appropriate Practitioner" means a medical practitioner, dentist, veterinary surgeon and any other person as the Minister may by Order published in the *Gazette* specify.

(3) Any Person who contravenes the provisions of this section commits an offence and upon conviction is liable to a fine of not less than one hundred thousand shillings or to imprisonment for a term not exceeding three months or to both such fine and imprisonment.

Prohibi-
tion of sale
of
adultera-
ted or
unfit
drugs,
medical
devices
and herbal
drugs

75--(I) No Person shall -

(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; or

(b) sell or supply, Or offer or expose for sale or 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) No person shall -

(a) offer for sale;

(b) Procure for sale;

(c) sell;

(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 or which is not safe or 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) Any person who contravenes the provisions of this section, commits an offence and shall be liable on conviction -

(a) if 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 such fine and imprisonment;

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

76.-41) No person shall manufacture, import, supply, possess or offer for sale any counterfeit drug, herbal drug or medical device.

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

(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;
or

- (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; or
- (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; or
- (d) it has been substituted wholly or in Part by another drug substances; or
- (e) it Purports to be it is a Product of manufacturer of whom it is not truly product.

(5) 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.

e. Drugs and Poisons List

Drugs,
medical
devices,
herbal
drugs and
Poisons
list

77.--(I) 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 advise of the Director General in the like manner, amend or vary the list, from time to time, 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.

78.-(I) Without derogating the provisions of the Drugs and Prevention Of Illicit Traffic in Drugs Act, 1995, no person shall manufacture, import, sell or use any controlled drug for medicinal or scientific purpose unless he complies with the provisions of this Act.

Applica-
tion of the
Drugs and
prevention
of Illicit
Traffic in
Drugs Act,
1995
No.9
1995

(2) The provisions of the Drugs and Prevention of Illicit Traffic in Drugs Act, 1995 in relation to offences and penalties shall apply *mutatis mutandis* to offences committed under this Act.

(3) The provisions of this Act, shall be in addition to and not in derogation of the Drugs and Prevention of Illicit Traffic in Drugs Act, 1995, or any other written laws having functions similar to those specified under this Act.

(4) Notwithstanding the provision of subsection (6), any 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 shall upon conviction be liable to a fine of not less than fifty thousand shillings, or to imprisonment for a tecin not exceeding six months or to both such fine and imprisonment.

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 -

Provisions
for non
medicinal
products

- (a) are manufactured, sold, supplied, imported or exported in a manner similar to drugs; or
- (b) are used as ingredient in the manufacture of drugs; or
- (c) if 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*

Interpre-
tation of
• "deal in"
and "pro-
hibited
drugs"

80. In this Part "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 "prohibited drugs"⁶⁶ means any drug declared to be a prohibited drug in terms of the provisions of section 81 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 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.

Prohibi-
tion to
deal in
prohibi-
ted drugs

82.-41) No person shall deal in any prohibited drugs unless he holds a permit issued by the Authority.

(2) Any person who contravenes the provisions of subsection (1), commits an offence and upon 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 upon 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 such fine and imprisonment.

83.-(1) Where any person is convicted of any offence under the provisions of section 82, the court -

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

(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, 1985 and the Evidence Act, 1967, shall, *mutatis mutandis*, apply.

Forfeiture on conviction, and prohibition from driving Acts No.9 of 1985 and No.6 of 1967

(2) In any prosecution under the provisions of section 82, if it 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 provisions of the Road Traffic Act, 1973 shall, *mutatis mutandis*, apply in respect of any such prohibition.

Act. No. 30 of 1973

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.

Safe custody of forfeited prohibited drugs

85.-41) 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.

Destruction of forfeited prohibited drugs

(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 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
COSMETICS

Restriction on manufacture, importation, distribution and sale of cosmetics

86. No cosmetics shall be sold, given, manufactured, imported, stored or exhibited for the purpose of being sold or given unless the cosmetic conforms to requirements prescribed by the Authority.

Prohibited ingredients

87.-(I) Whenever the Authority considers it necessary or desirable in the public interest that any ingredient should be declared to be prohibited, the Minister may, on advice of the Director General by notice in the *Gazette* declare such ingredient to be a prohibited ingredient and may in like manner amend or revoke such notice.

(2) Except as otherwise provided in the regulations, a cosmetic shall not contain any prohibited ingredients.

(3) Only approved substances may be used to colour cosmetics.

88. No person shall himself or by any other person on his behalf -

(a) sell, supply or distribute cosmetics that contain poisonous or harmful substances that might injure users under normal conditions;

(b) manufacture or hold cosmetics under in sanitary conditions, using non-permitted colours, or including any filthy, putrid or decomposed substance;

(c) sell, or stock or exhibit or offer for sale or distribute any cosmetic which has been imported or manufactured in contravention of any of the provisions of this Act.

Prohibition of manufacture and sale of certain cosmetics

89. For the purpose of this Act, a cosmetic shall be deemed to be counterfeit if -

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

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

(c) the label or container bears the name of an individual or company purporting to be the manufacturer of the cosmetic which individual or company is fictitious or does not exist; or

(d) it purports to be the product of a manufacturer of whom it is not truly his product.

Counterfeit cosmetics

90. Without prejudice to any other provisions contained in this Act, if the Minister on advice of the Director General is satisfied that the use of any cosmetic is likely to involve any risk to human being or that it contains ingredients of such a type and quantity which there is no justification and that in the public interest it is necessary or expedient to prohibit, the Minister may, by notification in the *Gazette* prohibit the importation, manufacture and sale of such a cosmetic.

Power to prohibit the manufacture, importation and distribution of cosmetics in public interest.

Offences
and
penalties

91. Any person whether himself or on behalf of another person manufactures, imports, sells or distributes -

- (a) any counterfeit cosmetic as referred to in the provision of section 89, commits an offence and upon conviction is liable to a fine not exceeding one million shillings or to imprisonment for a term not exceeding six months or both such fine and imprisonment;
- (b) any cosmetic other than cosmetic referred to under the provisions of section 88, the import of which is prohibited, commits an offence and upon conviction is liable to a fine of not less than five hundred thousands shillings or to imprisonment for a term of not less than three months or both such fine and imprisonment.

PART VI

PACKAGING AND LABELLING

Labelling
of products regulated under this Act

92.-41) No person shall, 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 122.

(2) Without prejudice to subsection (1), no person shall in the course of a business carried on by him, sell or supply, food, drug, medical device, herbal drug or cosmetics 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) Any person who contravenes the provisions of subsection (2), commits an offence and upon conviction shall be liable -

- (a) if 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 such fine and imprisonment; and

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

93.-(1) No person shall, in the course of a business carried on by him, supply or have in his possession for the purpose of supplying together with food, drug, medical devices, or herbal drug a leaflet relating to such food, drug, medical devices or herbal drug which does not comply with the regulations made under section 122.

Ixadlets

(2) Without prejudice to subsection (1), no person shall, in the course of a business carried on by him, supply or supply together with food, drug, medical devices or herbal drug, or have in his possession for the purpose of supplying a leaflet which:

- (a) falsely describes food, 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) Any person who contravenes the provisions of this section, commits an offence and upon conviction shall be liable -

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

94.(1) No person shall 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 .

Contai-
ners and
Packages

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

PART VII

PROMOTION

Regulations on promotion of food, drugs, medical devices or herbal drug

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

Advertisement of products regulated under this Act

96.-(1) Without prejudice to provisions of this Act, no person shall 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) If 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 veterinary surgeon, no person shall advertise that drug, medical devices or herbal drugs other than: -

- (a) in a medical, dental, veterinary or pharmaceutical journal;
- (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 cinematography film;
- (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 122 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 food, drug, medical devices or herbal drugs in a labelled container or package; and
- (b) the supply, together with food, drugs, medical devices or herbal drugs of a leaflet relating solely to the use of the drugs supplied.

98.-41) No person shall 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.

Restricti-
on on
food,
drugs,
medical
devices
or herbal
drugs
advertis-
ment

(2) No person shall carry out any promotion activities on products regulated under this Act, except and after getting a written approval from the Authority

(3) No person shall advertise or sell by retail any food, drugs, medical devices or herbal drugs in connection with any bonus, offer or discount.

(4) Any person who contravenes the provisions of this section, commits an offence and upon conviction is liable to -

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

PART VIII

ENFORCEMENT AND LEGAL PROCEEDINGS

a. Inspection, Sampling and Analysis

99.-(I) 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 owners cost.

Powers to
seize, tor-
feit
condemn
and dest-
ruct unfit
products

(2) If 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) Any 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 term not exceeding six months or to both such fine and imprisonment.

(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 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.

Provisi-
Ons regar-
ding
inspection
of meat

1 00--~ 1) The Minister upon the advice of Director General shall, by notice published in the *Gazette*, authorise an inspector in relation to every slaughter facility or category of slaughter facilities, and every cold store, or category of cold stores, for the purposes of inspecting carcasses and viscera dealt with at the slaughter facility or slaughter facilities or, as the case may be, the cold store or cold stores.

(2) The Authority shall devise and cause to be provided a means of reproducing distinctive marks for use at all slaughter facilities and cold stores, so devised as to indicate the identity of the slaughter facility or cold store, and of the inspector.

(3) The inspector shall affix or impress the device provided under subsection (2) to or on any carcass or a part of it in every case in which he has inspected the whole carcass with all the viscera at the place of slaughter, and when the carcass or a part of it has appeared to him to be free of disease, sound, whole some and fit for human consumption, and the device shall not be used in any other way.

(4) Any person who makes use of a device identical with or similar to any device provided under subsection (2) with intent to deceive any person, 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 three months or to both such fine and imprisonment.

101.-~I) Subject to the provisions of this section and any regulations made under section 122, any inspector may take samples for analysis, for other examination of any food, drugs or medical devices, cosmetics, and herbal drug or of any substance capable of being used in the manufacture of food, drugs, cosmetics' 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 place which he is authorized to enter for the purposes of ensuring compliance with this Act. Power to
take
OR samples

(2) Where the food, drugs, cosmetics, 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 bulk of the food, drugs, cosmetics, medical devices and herbal drugs.

(4) Any person who fails to comply with any demand made by an inspector under this section, commits an offence and upon conviction is 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 such fine and imprisonment.

Right to submit sample to an analyst

102. Any inspector who has procured any food, drugs, cosmetics, medical devices and herbal drugs or other substance for use in the manufacture of food, drugs, cosmetics, medical devices and herbal drugs may submit a sample of it to an analyst for analysis.

Provisions regarding the taking of samples for analysis

103.-- 1) Where an inspector who has taken a sample of any food or substance under the provisions of section 102 considers that it should be analysed, he shall forthwith divide that sample into at least three parts, each part to be marked and sealed or secured in the manner permitted by its nature and shall -

- (a) with respect to one part of the sample, comply with the provisions of subsection (2); and
 - (b) with respect to the remaining parts of the sample, comply with the provisions of subsection (3).
- (2) (a) if the sample was obtained by purchase from a dealer in the food or substance concerned, the inspector shall permit the vendor to select and take one part from the three parts;
- (b) if the sample was obtained by purchase from an automatic machine:
- (i) if there appears on the machine the name and address, within the United Republic, of its proprietor, the inspector shall give one part of the sample to that person;
 - (ii) in any other case, the inspector shall give one part to the occupier of the premises on which the machine stands or to which it is affixed;
- (c) if the sample is of any food or substance consigned from outside the United Republic and was taken by that officer before delivery to the consignee, he shall give the one part of the sample to the consignee;
- (d) if the sample is of any food or substance in transit from a consignor within the United Republic to a consignee within or

outside the United Republic, the inspector shall give the one part of the sample to that consignor;

- (e) if none of the presiding paragraphs of this subsection apply, the inspector shall give one part of the sample to the person appearing to him to be the owner of the food or substance from which the sample was taken.

(3) The inspector shall, unless he subsequently decides not to have an analysis made, personally submit to the analyst one of the remaining parts of the sample and retain the other or others for future comparison.

(4) In every case to which subsection (2), applies, the inspector shall inform the person to whom the part of the sample is given that the sample was taken for analysis by the analyst.

(5) Where any sample taken for analysis consist of the contents of an unopened package, the inspector may retain the packing material and, if he decides to have an analysis made, deliver the sample to an analyst.

(6) Any part of a sample which is to be given to any person under this section may be given either by delivering it to him or to his agent, or by sending it to him by post in a registered packet, but if after reasonable inquiry the inspector is unable to find the person to whom the part of the sample is to be given or ascertain his name and address, he may, in lieu of giving that part to that person, retain it.

(7) If it appears to the inspector that any food or substance a sample of which he has taken for analysis was manufactured or put into its wrapper or container by a person, other than one to whom any part of the sample required to be given, having his name and an address in the United Republic displayed on the wrapper or container, the inspector shall, unless he subsequently decides not to have an analysis made, within three days after taking that sample, send to that person a notice informing him that the sample has been taken by him and where the sample was taken or, as the case may be from whom it was purchased.

104. Where an inspector procures a sample consisting of food or substance contained in unopened packages, and the division into parts of the food or substance in the packages:

Where
division of
sample
into parts
impracti-
cable

(a) is not reasonably Practicable; or

(b) might affect the composition or impede the proper analysis of the contents,

the inspector shall be deemed to have complied with the provisions of section 103(2) if he divides the containers into the requisite number of lots and deals with each lot as if it were a part in the manner Provided by that section, and references in this Act to a part of a sample shall be construed accordingly.

**Appoint-
ment,
authorisa-
tion and
recogni-
tion of
inspectors**

105.-(I) For the Purpose of this Act, the Authority may -

(a) appoint any pharmacist, medical Practitioner, health officer, food technologist, pharmaceutical technicians 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 sub-section (1) shall be recognised as authorised officers under this Act.

(3) When appointing Or authorizing inspectors, the Authority shall take into account 'lot to appoint or authorize an inspector who has interest in the manufacture, Importation or sale of any Product regulated under this Act.

**Powers of
inspectors**

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

(ii) 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 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 food, drug, cosmetics, 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, foods, cosmetics, 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;
 - (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 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* authorize such officers or persons, to be public prosecutors for the purposes of this Act.

(3) Any 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 upon conviction is 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 such fine and imprisonment.

Power to call information regarding composition of products regulated under this Act

107.-(I) 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;
- (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;
- (c) particulars of any investigation carried out by or to the knowledge of the person carrying in the business concerned, for the purpose of determining whether and to what extent the substance, or any product formed when the substance is used in the preparation of food nutritionally enriches that food or becomes injurious to, or in any way affects health;
- (d) particulars of any investigations carried out by or to the knowledge of the person carrying on the business concerned for the purpose of determining the cumulative effect on the health of a person consuming the food in ordinary quantities.

(3) Save for the purposes of any proceedings for an offence against this Act, and subject to the provisions of section 120, 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) Any 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) Any person who fails to comply with the requirements of any order made under subsection (1), commits an offence.

b. Legal Proceedings

108.-(1) In every case in which a sample for analysis is delivered to the analyst under section 103, 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.

Certificate
of
analysis

(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) Any person who, for the purpose of advertisement, uses any certificate of analysis he obtained under this section, commits an offence and upon conviction is 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 such fine and imprisonment.

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 108, 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.

Evidence
of analysis

(2) In any proceedings for an offence under this Act, if 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) If 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.

(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.

**Presump-
tions**

110-(I) 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, cosmetics or herbal drug commonly used by man or animal, or any article commonly used in the manufacture of drugs, cosmetics, 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, cosmetics, medical devices, herbal drugs or 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, cosmetics, 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, cosmetics, medical device and herbal drug commonly used by man or animal which is found on any premises or in any vessel where that drug cosmetics, 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.

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

When warrant may be pleaded as defence

- (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; and
- (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 -
 - (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 113, 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 em-
ployers or
OWN 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.

Offences
in reia-
tion to
warranti-
es or
certifica-
tes 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 upon conviction is 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 such fine and imprisonment.

(2) Any person who, having sold any article or substance in respect of which a warranty might be pleaded under the provision of section 111 gives to the purchaser a false warranty in writing, commits an offence and upon conviction is 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.

114.-41) 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 paid by the person convicted.

Recovery
of expenses
incidental
to taking
samples

(2) All expenses recoverable under this section shall be recovered in the same manner as a fine is recovered.

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 food, drug, cosmetics, medical device, herbal drug or other article with respect to which the offence was committed be forfeited to the government.

Forfeiture

(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.

(3) Any food, 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.

116.-41) Any person aggrieved by a decision of the Authority may appeal to the Minister against that decision.

Appeals

(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.

Act No. 16
of 1967

(4) Where the Attorney General intervenes in any suit or matter in pursuance of subsection (3), the provisions of the Government Proceedings Act, 1967 shall apply in relation to the proceedings of that suit or matter as if it had been instituted by or against the Government.

Prohibi-
tion to
carry on
business
or to dis-
pose of
any
product
pending an
appeal

117.-(I) When 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 or abandoned or withdrawn.

(2) When 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
of me-
mbers of
the
Authority
etc.

118. Any thing done by the Director General, any member of the Board, the Directors, an inspector or any other person 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.-41) 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) If 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.

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

Notifica-
tion of
convic-
tions

- (a) the name of the offender;
- (b) the address, if any, of the place where the offence was committed;
- (c) the nature of the offence;
- (d) the kind of product involved; and
- (e) the fine, forfeiture or other penalty imposed.

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.

Power to
delegate

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

Regula-
tions

- (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, cosmetics, herbal drug or poisons;
- (c) providing for the better regulation of the manufacture, compounding, sell or advertising of foods, drugs, medical device, herbal drug and poisons.
- (d) the safe custody, storage and transport of foods, medical devise drugs, herbal drug and poisons;
- (c) the regulation of the manufacture, importation, exportation, distribution and labelling of food, drugs, device, herbal medicines, cosmetics and poisons;

- (f) the regulation of the prices of both manufactured and imported food, drugs, medical devices herbal drug and poisons;
 - (g) regulating of containers or packaging material in which food, 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;
 - (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;
- Cap. 32
- O) the conduct of inquiries under this section shall be in accordance with the Inquiries Ordinance;
 - (k) provide a code of conduct for food and drug inspectors;
 - (l) prescribing the grounds for suspension or cancellation of a licence issued or registration granted under this Act;
 - (m) provide regulations for registration of food, drugs, medical devices and herbal drugs;
 - (n) provide regulations on the establishment of laboratories for testing and analysing drugs, food, cosmetics or herbal drugs;
 - (o) provide regulations on minimum requirements of Good Manufacturing Practice;
 - (p) provide regulations on conditions for undertaking clinical trials;
 - (q) provide for minimum requirements for a product leaflet;
 - (r) provide regulations on drug promotional activities for product regulated under this Act;
 - (s) provide regulations for controlling of manufacturing, selling, possessing and distribution of narcotic drugs and psychotropic substances;
 - (t) provide regulations on the disposition of narcotic and psychotropic substances;
 - (u) provide regulations on prohibition of manufacture, sell and distribution of herbal drug;
 - (v) provide regulations on sampling procedures, analysis and treatment of the analysis results;

- (w) provide schedules for inspectors identity card, conditions to be provided in the card and commitment form;
- W provide regulations on recall of products which do not comply with any section of this Act;
- (Y) Provide regulations for the categories of drugs;
- W provide regulations for destruction of unfit food, drugs, medical devices, cosmetics, herbal drug and poisons; and
 - (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 particulars to be registered in relation to persons permitted to import food;
 - (cc) Prescribing functions, composition and number of the Technical Committees;
 - (dd) 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.

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

(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.

Repeal
Act Nos.9
of 1978
and
10 of 1978

125. The Pharmaceuticals and Poisons Act, 1978 and the Food (Control of Quality) Act, 1978 are hereby repealed.

Transitional and
savings
provisions

126.-(1) Notwithstanding the repeal of the Pharmaceuticals and Poisons Act, 1978 and the Food (Control of Quality) Act, 1978, 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.

(2) All officers appointed pursuant to the Food (Control of Quality) Act, 1978 or the Pharmaceuticals and Poisons Act, 1978 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..

—————
SCHEDULE
—————

APPOINTMENTS, COMPOSITION AND PROCEDURE OF THE BOARD

(Made Under section 9)

Composi-
tion of
Board

1.---(1) The Board shall consist of

(a) a Chairman, who is the Permanent Secretary in the Ministry responsible for health;

- (b) a legally qualified person holding office in the Attorney-General's Chambers nominated in that behalf by the Attorney-General;
 - (c) Chief Medical Officer;
 - (d) Director of Veterinary Services;
 - (e) Director of National Food Security;
 - (1) the Chief Government Chemist;
 - (g) Director of Tanzania Bureau of Standards;
 - (h) a representative from the Local Government;
 - (i) Director of the Tanzania Food and Nutrition Center;
 - (j) the Director General of Medical Services in the Revolutionary Government of Zanzibar;
 - (k) a representative from the Ministry responsible for beekeeping and fisheries matters;
 - (1) the Director General of the Tanzania Atomic Energy Commission.
 - (m) one member vested with the knowledge of products regulated by the Authority who is not in the public service appointed by the Minister;
2. The Board when dealing with a specific matter for which extra expertise is required may co-opt persons who have the relevant expertise; such co-opted persons shall cease to be members when the matter is determined and shall have no right to vote. Co-option of Members
- 3.--- 1) A member appointed under paragraphs (b), (h), (k) and (m). Tenure of office
- (a) shall unless his appointment is sooner terminated by the Minister, or he ceases in any other way to be a member, hold office for a period of not more than three years but may be eligible for re-appointment; or
 - (b) may at any time resign his office by giving notice in writing addressed to the Minister, and from the date specified in the notice or, if no date is so specified from the date of the receipt of the notice by the Minister, he shall cease to be a member.
- (2) In the case of a member who is a member by virtue of his holding some other office, he shall cease to be a member upon his ceasing to hold that office.
4. It a member of the Board who is a member by virtue of his holding some other office is unable for any reason to attend any meeting of the Board, he may nominate another person from his organization to attend the meeting in his place. Proxy representation
5. Where any appointed member ceases to be a member for any reason before the expiration of his term of office, the appointing authority may appoint another person in his place and the person so appointed shall hold office for the remainder of the term of office of his predecessor. Ceasing member
6. The Board shall hold its meetings as often as the Chairman may determine, but not less than twice in each financial year. Meetings of the Board

Quorum and decisions of the Board 7. Matters proposed at a meeting of the Board shall be decided by a majority of the votes of the members present at voting and in the event of an equality of votes the Chairman shall have a second or casting vote in addition to his original or deliberative vote.

Minutes of Board meeting 8.--~ 1) The Board shall cause to be recorded and kept minutes of all business conducted or transacted at its meetings, and the minutes of each meeting of the Board shall be read and confirmed or amended and confirmed at the next meeting of the Board and signed by the Chairman and Secretary at the meeting.

(2) Any minute purporting to be agreed by the Chairman at a meeting of the Board shall, in the absence of proof of error, be deemed to be a correct record of the meeting whose minutes they purport to be.

Vacancies, etc. not to invalidate proceedings 9. The validity of any act or proceeding of the Board shall not be effected by any vacancy among its members or by any defect proceedings in the appointment of any of them,

Orders, Directions, etc. of the Board 10. All orders, directions, notices or other documents made or issued on behalf of the Board shall be signed by the Director General or any person acting on that behalf

Proof of the Document 11. Any document purporting to be under the hand of the Chairman, Director General or any person acting on his behalf as to *My* resolution of the Board or as having been issued on behalf of the Board, shall be receivable in all courts or tribunals or other bodies authorized to receive evidence and shall, unless the contrary is shown, be deemed, without further proof, to be sufficient evidence of what is contained in the document.

The Board may regulate its own proceedings 12. Subject to the provisions of this Schedule, the Board may regulate its own proceedings.

Passed in the National Assembly on the 10th February, 2003

.....
Clerk of the National Assembly