Tanzania
1. Principal Legislation
The principal legislation that specifically addresses the counterfeit medicines in Tanzania is 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 (No. 1 of 2003) (cited as the Tanzania Food, Drugs, and Cosmetic Act, 2003 pursuant to its Section 1, hereafter referred to as “Tanzania Food, Drugs, and Cosmetic Act, 2003”).

2. Website Links
Tanzania Food, Drugs, and Cosmetics Act, 2003

3. Extract of the legislation related to counterfeit medicines
Tanzania Food, Drugs, and Cosmetics Act, 2003
Section 3
3. Interpretation
3. In this Act, unless the context otherwise requires –

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


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

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

(d) United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances adopted at Vienna on 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 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 managers 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.

Section 76
76. Counterfeit drugs, medical devices or herbal drugs

(1) 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 device 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.

Section 92
92. Labelling of products regulated under this Act

(1) 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.

Section 93
93. Leaflets
(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.

(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.

Section 94
94. Containers and Packages
(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.

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

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

Section 96
96. Advertisement of products regulated under this Act
(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.

Section 97
97. Meaning of advertisement
(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.

Section 98
98. Restriction on food, drugs, medical devices or herbal drugs advertisement
(1) 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.

(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.

Section 112
112. Sale, etc. by employers or agents
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.

Section 115
115. Forfeiture
(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.

(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.

Section 122
122. Regulations
(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 –

(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;
(e) 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;

(j) 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;

(x) 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.

Section 123
123. General penalty
(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.

(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.