AFRICAN UNION MODEL LAW ON MEDICAL PRODUCTS REGULATION

Preamble

We Member States of the African Union:

RECOGNISING that the right to health is an international human right as expressed in Article 25 of the Universal Declaration of Human Rights and Article 12 of the International Covenant on Civil and Political Rights;

REAFFIRMING the right to health guaranteed by Article 16 of the African Charter;

CONSCIOUS of the obligation of states to protect the health of their people towards the attainment of the highest possible physical and mental wellbeing of all;

BEARING IN MIND that it is the duty of the State to regulate medical products and to provide adequate mechanisms for guaranteeing their quality, safety, and efficacy;

MINDFUL of the need to promote and protect the public health of citizens by developing regulatory systems that satisfy minimum regulatory capacity;

FURTHER MINDFUL of the need to implement the policies, legislation, guidelines and related standards as recommended by the World Health Organization (WHO);

REITERATING Assembly Decision {Assembly/AU/Dec.55(IV)} taken during the Abuja Summit in January 2005 which requested the AU Commission to develop a Pharmaceutical Manufacturing Plan for Africa (PMPA) within the framework of the New Partnership for Africa's Development-NEPAD;

FURTHER REITERATING the 19th African Union Assembly decision {Assembly AU/Dec.442(XIX)} on Roadmap for Shared Responsibility and Global Solidarity for the AIDS, TB and malaria response in Africa which among others, emphasises the need to accelerate and strengthen regional medicines regulatory harmonization initiatives and lay foundations for a single African regulatory agency;

RECALLING Executive Council Decision, {EX.CL/Dec.857 (XXVI)} which endorsed the milestones for the establishment of a single medicines regulatory agency in Africa within the context of the African Medicines Regulatory Harmonization (AMRH) Programme, which is part of the framework of the PMPA, and contributes to the development of a healthy human capital for the fulfilment of the African Union's human and social development as enshrined in the Agenda 2063;

CONCERNED that the proliferation of Substandard/Spurious/Falsified/Falsely-labelled/Counterfeit (SSFFC) medical products on the continent poses a major public health threat and **NOTES** that despite the importance of health legislation and medical product regulation in ensuring national public health, regulatory systems of many African countries remain inadequate;

RECOGNIZING the importance of harmonization of policies, legislation and legal frameworks relating to medical products through Regional Economic Communities RECs) and the African Union as an effective way of ensuring access to medical products that are safe, efficacious, and of assured quality to the African population;

CONVINCED that the adoption and domestication of a Model Law on medical products regulation in Africa is essential for the creation of a harmonized regulatory environment on the continent;

HAVE AGREED

To adopt the following African Union Model Law on Medical Products Regulation

African Union Model Law on Medical Products Regulation

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PART I: GENERAL PROVISIONS

Article 1: Short Title

1) The Short Title of this Model shall be‘’Law on Medical Products Regulation”

Article 2: Scope of Application and other laws

1) This law shall apply to all medical products alongside existing laws related to regulation of medical products.
2) In the event of any conflict with any other law on medical products the provisions of this law shall prevail.
3) Provisions of any existing law in conflict with this law shall to the extent of the inconsistency stand repealed or amended.

Article 3: Purpose

The purpose of this Law is to establish an effective and efficient system of medical products regulation and control and ensure that such products meet required standards of safety, efficacy and quality.

Article 4: Definitions

In this Law, unless the context requires otherwise requires:

“advertisement” in relation to a medical product, means any pictorial, visual or otherwise descriptive matter or verbal statements or references:-

a) appearing in a print or electronic publication or medium;
b) broadcast on television or radio; or
c) brought to the notice of members of the public in any manner whatsoever,

which is intended to directly or indirectly advise of the existence and benefits of a medical product, and “advertise” has a corresponding meaning;

“agency/authority” means the National Regulatory Agency/Authority as stated in this law;

“appointing or supervising authority” means the governmental body, minister or official to which the [National] Medical Products Regulatory Agency/Authority is accountable;

“board” means the Board of the National Regulatory Agency/Authority as constituted under this law;

“clinical trial" means any systematic study on pharmaceutical products in human subjects, whether in patients or other volunteers, in order to discover or verify the effects of, and/or identify any adverse reaction to, investigational products, and/or to study the absorption, distribution, metabolism and excretion of the products with the object of ascertaining their efficacy and safety;

“code of conduct” means an official document of the Agency/Authority describing the behaviour expected of staff, members of the Board and Technical Committees, and contractors;

“compassionate use” means access to unregistered medical products in special or emergency situations. In general, either the patient has a severe or life-threatening illness and existing therapy has failed, or the disease is a rare one for which specialist medicines do not have a local marketing authorization. The medical products are still experimental, or at any rate unproven, and the government is not obliged to fund their supply;

“dispense” means to prepare and supply to a patient a course of therapy on the basis of a prescription;

“dispenser” means anyone who dispenses medicines. It is specifically used to mean anyone who is not a graduate pharmacist but is trained to dispense medications, maintain stock records and assist in procurement activities;

“distribution” means division and movement of medical products from the premises of the manufacturer of such products, or another central point, to the end user thereof, or to an intermediate point by means of various transport methods, via various storage and/or health establishments;

“ethics committee/institutional review board” means a multidisciplinary body responsible for reviewing biomedical research for safeguarding the dignity, rights, safety, and well-being of all actual or potential research participants;

“export” includes to deliver or supply within the country for dispatch to a destination outside of the country;

“harmonisation” means alignment or adjustment of differences and inconsistencies among different laws, regulations, methods, procedures, schedules, specifications, or systems of National Medical Products Regulatory Agencies/Authorities;

"import" means bringing into the national territory whether on one’s body, by land, sea or air with the intent to distribute, dispense and retail and consume;

“information management system” means database and transaction management system that is designed to facilitate the storage, organization, and retrieval of information within the Agency/Authority;

“inspection” means an officially conducted examination (i.e. review of the conduct of the trial, including quality assurance, personnel involved, any delegation of authority and audit) by relevant authorities at the site of investigation and/or at the site of the sponsor in order to verify adherence to Good Clinical Practice (GCP) and Good Laboratory Practice (GLP) as set out in this document;

“inspector” means a person authorized to perform inspection activities by the [National] Medical Products Regulatory Agency, pursuant to this Law;

“interchangeable pharmaceutical product” means apharmaceutical product which is therapeutically equivalent to a reference product;

“manufacture” means all operations of purchase of materials and starting materials, preparation of the active pharmaceutical ingredient (API) and of the pharmaceutical product, including packaging and repackaging, labelling and re-labelling, quality control, release, storage and distribution and the related controls.

“market” includes a variety of systems, institutions, procedures, social relations and infrastructures for medical products sale, and barter or exchange or supply or dispose of to a person;

“marketing authorization” means a legal document issued by the competent Agency/Authority for the purpose of marketing or free distribution of a product which has been approved after evaluation for safety, efficacy and quality.

‘‘**medical device**” means any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent or calibrator, software, material or other similar or related article:-

a) intended by the manufacturer to be used, alone or in combination, for humans or animals for:-
    (i) diagnosis, prevention, monitoring, treatment or alleviation of disease;
    (ii) diagnosis, monitoring, treatment, alleviation of or compensation for an injury;
    (iii) investigation, replacement, modification or support of the anatomy or of a physiological process;
    (iv) supporting or sustaining life;
    (v) control of conception;
    (vi) disinfection of medical devices; or
    (vii) providing information for medical or diagnostic purposes by means of *in vitro* examination of specimens derived from the human body; and
b) which does not achieve its primary intended action in or on the human or animal body by pharmacological, immunological or metabolic means, but which may be assisted in its intended function by such means~~;~~.

“medical products” include medicines, vaccines, diagnostics and medical devices.

“medicine” means any substance or mixture of substances used or purporting to be suitable for use or manufactured or sold for use in:-

a) the diagnosis, treatment, mitigation, modification or prevention of disease, abnormal physical or mental state or the symptoms thereof in humans; or
b) restoring, correcting or modifying any somatic or psychic or organic function in humans, and includes any veterinary medicine;

“minister” means the Minister responsible for health matters;

“mutual recognition” means the acceptance of one National Medical Products Regulatory Agency’s certification of standards and procedures for medical product regulation by another National Medical Products Regulatory Agency;

“other regulated products” may include complementary medicines, cosmetics, food and related products;

“pharmacist” means a holder of a degree or diploma in pharmacy from a recognized higher institution of learning and is registered or licensed to practise pharmacy;

“pharmacovigilance” means the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problem;

“pharmacy” means a science and technique of producing and dispensing medical products that links health science with chemical science and aims to ensure the safe and effective use of medical products;

“prescribe” means issue an instruction in writing a certain kind of medical treatment ,or a particular medicine only upon prescription, for a specific patient or animal by a licensed medical practitioner, a dentist or a veterinary Surgeon for the collection of a drug or treatment from a dispensing unit;

“prohibited medical product” means medical products with toxicity or side-effects that outweigh their therapeutic usefulness, so that public health and welfare are protected by prohibiting their production, manufacture, export, import, trade, distribution, supply, possession or use, except in amounts required for medical or scientific research. Prohibited drugs will be determined by the national or supranational registration/licensing authority;

“promotion” means all informational and persuasive activities by manufacturers and distributors, the effect of which is to induce the prescription, supply, purchase, and/or use of medicinal products (For the purposes of this law, promotion includes advertising);

“qualified technical person” means a person responsible for the release of batches of finished product for sale. In certain countries the batch documentation of a batch of finished product must be signed by an authorized person from the production department and the batch test results by an authorized person from the quality control department for batch release;

“Quality Management System” means a set of policies, processes and procedures required for planning and execution of the core business area of an Agency/Authority;

“reference product” means a medical product which has been granted a marketing authorisation by a competent Agency/Authority on the basis of a complete dossier, that is, with the submission of quality, pre-clinical and clinical data;

"scheduled substance" means any medicine or other substance prescribed under Article 21;

"**sell"** means to sell by wholesale or retail, and includes to import, offer, advertise, keep, expose, 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 or supply or dispose of to a person, whether for a consideration or otherwise, and also includes offering or attempting to sell, or receiving for sale, or having in possession for sale, or exposing for sale, or sending or delivering for sale, or causing or allowing to be sold, offered or exposed for sale, and "sale" and "sold" have a corresponding meaning;

"storage" means storing of medical products up to their point of use;

"substandard/spurious/falsified/falsely-labelled/counterfeit medical product" means the like-named products as defined by the World Health Organisation;

"supply" means having in possession for the purpose of supply;

"wholesaler" means sale of goods in large quantities, as for resale by a retailer

PART II: ADMINISTRATION AND GOVERNANCE

Article 5: Establishment of the Agency/Authority

1) The [National] Medical Products Regulatory Agency/Authority hereafter 'the Agency/Authority' is hereby established as a juristic person.

2) The national Agency/Authority shall be an autonomous body.

3) The national Agency/Authority shall be functionally/financially accountable to the line ministry.

4) The Agency/Authority shall be composed of:-

a) The Board of the Agency/Authority
b) The Head of the Agency/Authority
c) The Technical committees of the Agency/Authority

Article 6: Powers of the Agency/Authority

The Agency/Authority shall have the powers to:

1) formulate regulations and guidelines for regulating the manufacture, import and export, distribution, sale and use of medical products;

2) grant or withdraw authorisation for conducting clinical trials of medical products;

3) grant or withdraw marketing authorisation for medical products subject to appropriate conditions and revise such conditions for marketing authorisation as necessary;

4) recall medical products from the market;

5) grant or withdraw licenses to manufacturers, wholesalers, retailers, importers, exporters and distributors;

6) investigate conduct related to the manufacture, import, export storage, distribution, sale and use of medical products;

7) levy, collect and utilize fees for services rendered;

8) prescribe the standards appropriate for new medical products; new uses, dosages, and formulations of existing medical products; and such other categories as may be appropriate;

9) institute administrative, civil and/or criminal proceedings;

10) exercise such other powers as necessary for the performance of its functions.

Article 7: Functions of the Agency/Authority

The Agency/Authority shall have among others, the following functions to:-

1) regulate the manufacture, import and export, storage, distribution, sale and use of medical products;

2) regulate, monitor and inspect personnel and premises that are involved in the manufacture, import and export, storage, distribution, sale, use and disposal of medical products;

3) maintain a register of medical products for which marketing authorisation has been granted;

4) regulate clinical trials of medical products;

5) test medical products regulated under this law;

6) conduct post-marketing surveillance of safety and quality of medical products;

7) regulate the promotion, advertising and marketing of medical products;

8) regulate the use of unregistered medical products for trial purposes or for compassionate use;

9) disseminate information on the quality and safety of medical products to health professionals and the public;

10) disseminate information on medical products to health professionals and to the public in order to promote their responsible use;

11) collaborate with other national, regional and international institutions on medical products regulation;

12) perform such functions as may be assigned by the Board.

Article 8: Establishment of the Board

1) The Board of the Agency/Authority is hereby established.

2) The Board of the Agency/Authority and its Chairperson shall be appointed by the appointing authority, under terms to be determined by regulation.

3) The Board shall consist of at least nine but not more than eleven members, to include the following:-

a) five members who each have expertise in at least one of the following:- medicine, pharmacy, nursing, veterinary medicine and public health;
b) one member appointed on account of his or her knowledge of the law;

c) one member appointed on account of his or her knowledge of financial matters and/ or accounting;
d) one representative from the pharmaceutical industry association
e) one representative from civil society or the community.

Article 9: Functions of the Board

1) The Board shall have the functions to:-

a) provide strategic guidance to the Agency/Authority in the discharge of its functions.
b) approve the strategic and annual work plan and budget of the Agency/Authority;
c) review the annual reports presented by the Agency/Authority;
d) monitor and evaluate activities of the Agency/Authority;
e) establish such committees as it deems necessary for the functioning of the Board;
f) recommend persons for appointment as the head of the Agency/Authority to the appointing authority;
g) approve the appointment or removal of senior management officers of the Agency/Authority;
h) perform such functions as maybe assigned by the supervising authority.

2) The Board shall provide the appointing authority with an annual report to be tabled in Parliament.

Article 10: Management of the Agency/Authority

1) Appointment of officers of the Agency/Authority

a) The Head of the Agency/Authority shall be appointed by the appointing authority on recommendation of the Board and shall hold a suitable qualification in medicine, pharmacy, nursing, veterinary medicine or public health.

b) The Head of the Agency/Authority shall be the chief executive officer and shall be accountable to the Board for the management of the business and affairs of the Agency/Authority.

c) The senior officers of the Agency/Authority shall be appointed by the Board on the recommendation of the Head of the Agency/Authority;

2) Duties and Responsibilities of the Head of the Agency/Authority

The Head of the Agency/Authority shall be responsible for:-

a) management of the business and affairs of the Agency/Authority;

b) implementation of this law governing the activities of the Agency/Authority and report to the appointing authority through the Board;

c) execution of the decisions and directives of the Board and makingperiodic reports to the Board.

3) Directorates of the Agency/Authority

The Agency/Authority shall have directorates to facilitate execution of its operations and functions as it may deem fit, which may include:

a. Planning, Monitoring and Evaluation~~,~~ Research and Statistics.
b. Product Evaluation and Registration.
c. Inspectorate and Law Enforcement.
d. Post-marketing Surveillance.
e. Quality Control.
f. Harmonisation and International Cooperation.
g. Human Resources, Administration and Finance.

Article 11: Technical Committees

1) The Head of Agency/Authority shall, with the approval of the Board, set up Technical Committees to facilitate the work of the Agency/Authority as may be deemed appropriate.

2) The reports of Technical Committees shall form the basis for decision-making by the Agency/Authority.

Article 12: Funding of the Agency/Authority

1) The funding of the Agency/Authority shall consist of:-

a) funds appropriated by the State;

b) fees received for services rendered;

c) income that the Agency/Authority may receive from investments;

d) grants and donations.

2) The Agency/Authority may, subject to the provisions of any other written law and the approval of the Minister responsible for finance raise by way of loans from any source in or outside the country, such money as it may require for the discharge of its functions.

3) The receipt of funds by the Agency/Authority shall at all times be subject to the objectives of this law and shall be free from conflict of interest.

PART III: NATIONAL REGULATORY SYSTEM

Article 13: Marketing Authorisation

1) All medical products, circulating in the area of jurisdiction of this law must be registered and have a valid marketing authorisation and certificate of conformity unless otherwise exempted.

2) The Agency/Authority may from time to time determine that a medical product or category of medical products or part of any class or category of medical products shall be subject to exemption from marketing authorisation in terms of this law.

3) Any such determination shall be published in official government publication by the head of the Agency/Authority and shall come into operation on the date stipulated in the notice.

4) In the case of a medical product which was available for sale in the area of jurisdiction of this law immediately prior to the date of publication by which it is subject to marketing authorisation in terms of this law, the provisions of Art. 13 (1) shall come into operation if no application for marketing authorisation of such medical product is made within the period of twelve months immediately succeeding that date, on the expiration of that period.

5) The provisions of Art. 13 (1) shall not apply in respect of the sale of any medical product compounded by a pharmacist for a particular patient in the course of carrying professional activities in a quantity not greater than the quantity required for treatment as determined by an authorised prescriber or the pharmacist if:-

a) such medical product does not contain any component the sale of which is prohibited by any law or any component in respect of which an application for marketing authorisation has been rejected; and

b) the active component of such medical product appears in another medical product which has been authorised in terms of this law.

Article 14: Consideration of Applications for Marketing Authorisation

1) Every application for marketing authorisation of medical products shall be submitted to the head of the Agency/Authority in a prescribed form and shall be accompanied by the prescribed particulars, samples of the relevant medical products, particulars of a qualified technical person and the prescribed application fee.

2) The Agency/Authority shall prescribe the standards appropriate for new medical products; new uses, dosages, and formulations of existing medical products; interchangeable multi-source medicines (otherwise known as generic equivalents); and such other categories as may be appropriate.

3) The Agency/Authority may prescribe standards and procedures for referencing, relying upon or otherwise weighing, the marketing assessments and approvals of other medical product regulatory authorities or assessment mechanisms.

4) The Agency/Authority shall approve a medical product if it is satisfied;

a. that it is suitable for the intended purpose in respect of its quality, safety and efficacy; and

b. that marketing authorisation is in the public interest.

5) If the Agency/Authority is not so satisfied it shall notify the applicant in writing of the reasons why it is not so satisfied and the applicant shall furnish the Agency/Authority with a response within one month of notification.

6) If no such response is submitted by the applicant within the said period, or if after consideration of any comments so submitted, the Agency/Authority is still not satisfied, it shall reject the application.

7) The Agency/Authority shall publish the medicines register in the official government publication and the official website of the Agency/Authority.

Article 15: Licensing of Manufacturers, Importers, Exporters, Wholesalers and Distributors

1) No person shall manufacture, import, export, supply, store, distribute or sell at wholesale level any medical product, unless the person has been issued with a licence by the Agency/Authority.

2) The conditions of a licence for the manufacture, import, export, wholesale, and distribution of medical products shall be stipulated in guidelines issued by the Agency/Authority which shall provide for the issuance, renewal, suspension, exemptions or exceptions, cancellation and revocation of such licences.

3) Provisions shall be made for all manufacturers, importers, exporters, wholesalers and distributors to comply with Good Manufacturing Practice (GMP) and Good Distribution Practice (GDP) and any other good practices as stipulated in the guidelines.

4) The supervising authority shall designate ports of entry for medical products imported into the jurisdiction.

5) The Agency/Authority shall maintain a register of all licensed premises and shall publish same in the official government publication and the official website of the Agency/Authority.

Article 16: Post-Marketing Surveillance and Safety Monitoring

The Agency/Authority shall undertake the following functions:-

1) Pharmacovigilance

a. There shall be established a national Pharmacovigilance Programme as a function of the Agency/Authority to monitor and report on the safety of medical products.

b. The Programme shall undertake:-

i) monitoring and analysis of adverse effects or events relating to products regulated under the Law;
ii) identifying and reporting adverse events relating to clinical trials;
iii) establishing causality, taking remedial actions, and reporting to international safety monitoring systems;
iv) appropriate regulatory action when necessary, including but not limited to revising the marketing authorisation or labelling/warning requirements of the medical product.

c. The Agency/Authority shall issue guidelines to provide for mandatory reporting and submission of periodic safety updates by the manufacturers and distributors, and voluntary reporting by health care professionals and the public.

2) Quality Monitoring

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

3) Recall and Withdrawal of Medical Products

a. Whenever the Head of the Agency/Authority finds that any medical product does not conform with the standards of identity, strength, quality and purity, or any other requirement specified in the documentation for registration, the Head of the Agency/Authority shall:-

   i) instruct the licensee to discontinue the sale of the remainder of the batch and, so far as is practicable;
   ii) recall any portion of the batch already sold.

b. The Agency/Authority shall by order, published in the official government publication, withdraw and strike off a medical product from the register which on the latest available scientific evidence are shown to be hazardous to public health and welfare, or are unsafe, inefficacious or of unacceptable quality.

c. Upon the occurrence of the event in Art. 16(3)(b) above the Agency/Authority shall issue notice to the public on medical products withdrawn from the market.

d. The information shall be disseminated as widely as possible, including through use of electronic media.

4) Disposal of Medical Products

If the Agency/Authority is of the opinion that it is not in the public interest that a medical product be made available to the public, the Agency/Authority may direct that such products be withdrawn from the market and disposed of in accordance with relevant laws and in the manner stipulated in the regulation.

Article 17: Regulatory Inspection and Enforcement

1) Appointment, Authorisation and Recognition of Inspectors

a) The Agency/Authority shall:-
   i. recommend to the appointing authority the appointment of inspectors with relevant qualifications in pharmacy or related sciences, and with knowledge and experience in the inspection of medical products and facilities for the manufacture, storage, and transportation of medical products; and
   ii. authorise such inspectors to perform such functions as are stipulated under this Law.

b) All inspectors appointed under this Law shall have a valid identification during the performance of their duties.

c) All inspectors appointed under this Law shall be bound by a code of conduct.

d) Inspectors exercising any powers conferred upon them by this Law shall produce, on demand, a duly authenticated document confirming their authority to exercise the power so conferred upon them.

2) Powers of Inspectors

a) Inspectors appointed under this Law may at all reasonable times, enter any;

i. premises which is on the register of premises;
ii. other premises in respect of any person who is licensed under this Law;
iii. premises used in the manufacture, marketing, or distribution of a medical product that is the subject of a marketing authorisation or licensing request;
iv. premises suspected of or dealing in products regulated in terms of this Law.

b) Inspectors may, at all reasonable times:

i. examine or inspect any certificate of marketing authorisation, licence, book, electronic information storage system or other document on the premises and, for that purpose, may do such other things, including the taking of extracts from documents in the possession of the person as may be necessary to effect the examination or inspection; and
ii. take samples for analysis, or for other examination of any medical products or of any substance capable of being used in the manufacture of medical products.

c) Inspectors may:-

i. seize and detain any medical products, substances or articles consisting of, or containing any prohibited substances which they have reasonable cause to suspect is liable to forfeiture under this Law;
ii. seize and detain any medical products, articles, records or other items which appear to them to constitute or contain evidence of a contravention of any provisions under this law;
iii. close the premises found to be in contravention of this Law; and
iv. recommend the institution of administrative, civil and/or criminal proceedings.

3) Search and seizure

a) Notwithstanding anything to the contrary contained in any other law, if any inspectors have reasonable grounds for believing that any person is in unlawful possession of any prohibited medical product, they may, in terms of a search warrant: -

i. Enter upon any premises on which such person is believed to be present; or
ii. Search such premises or person; provided that the search is conducted with regard to decency and decorum.

b) Any prohibited medical product in the possession of such person shall be seized, and legal proceedings instituted as stipulated in terms of this Law

Article 18: Control of Clinical Trials of Medical Products

1) No person shall conduct clinical trials of medical products in humans without the relevant clearance from the National Ethics Committee/Institutional Review Board and authorisation of the Agency/Authority

2) All clinical trials shall be conducted in accordance with guidelines issued by the Agency/Authority, including provisions for Good Clinical Practice (GCP) and Good Laboratory Practice (GLP).

3) A person shall not sell, dispense, supply, assemble or manufacture medical products for the purpose of clinical trial or medical research on a medical product unless the person is authorised to do so or has been granted an exemption by the Agency/Authority.

4) The Agency/Authority shall maintain a register of all clinical trials conducted in its jurisdiction.

Article 19: Control of Promotion and Advertisement of Medical Products

1) All promotion and advertisement of medical products shall be approved by the Agency/Authority.

2) The Agency/Authority shall issue guidelines relating to the promotion and advertising of medical products and for an enforceable Code of Marketing Practice.

Article 20: Quality Control Laboratory

2) There shall be established a National Quality Control Laboratory as part of the Agency/Authority.

3) The Laboratory shall perform all functions relating to the quality of products regulated under this Law and shall in particular perform the following:-

a. analyse medical products and any other regulated products that may be deemed to constitute a medical product for the purpose of this Law;

b. conduct research and training; and

c. undertake such other function as shall be determined by the Agency/Authority.

4) In performing its functions, the Agency/Authority may utilise any accredited Laboratory within or outside the country for analysis of medical products and attendant functions.

5) The Agency/Authority shall appoint Analysts with relevant qualifications, knowledge and experience in the analysis of medical products and authorise such analysts to perform such functions as stipulated under this law.

Article 21: Scheduling, Classification and Control of Medical Products

1) The scheduling and classification of any medical product or substance shall be determined by the Agency/Authority and published in the official government publication.

2) Control of medical products shall be based on the scheduling status of substances, as allocated by the Agency/Authority, as follows:-

a) Scheduled substances that will be available for general sales, in any retail outlet;

b) Scheduled substances that will be available on the professional advice of a pharmacist, without a prescription from an authorised prescriber, and available only in licensed pharmacies;

c) Scheduled substances that will be available only on the prescription of an authorised prescriber, and dispensed by a pharmacist or licensed dispenser;

d) Scheduled substances that will be available only on the prescription of an authorised prescriber, and dispensed by a pharmacist or licensed dispenser, subject to the control measures prescribed in accordance with either the Single Convention on Narcotic Drugs of 1961, the Convention on Psychotropic Substances 1971, and the UN Convention against Illicit Traffic Drug and Psychotropic Substances, 1988;

e) Scheduled substances that may not be sold, except in accordance with a permit for the purposes of education, analysis or research, or for individual patient purposes.

3) Regulations shall be issued by the Minister, after consultation with the Agency/Authority, dealing with:-

a. the requirements for a legal prescription for a scheduled substance;

b. the recognition of categories of authorised prescribers;

c. the licensing of dispensers other than pharmacists;

d. the records to be kept in relation to scheduled substances sold on the professional advice of a pharmacist or on prescription of an authorised prescriber;

e. the control measures to be implemented in relation to substances scheduled as psychotropic or narcotic substances;

f. the process of obtaining permits for access to scheduled substances, for purposes of education, analysis or research or for individual patients' purposes;

g. the licensing of importers, exporters and manufacturers of psychotropic or narcotic substances and the reporting requirements for such substances.

4) No person shall import, export or manufacture any substances scheduled as a psychotropic or narcotic substance unless in possession of a specific licence issued by the Agency/Authority for this purpose.

5) The Agency/Authority shall collect such data as are necessary on the importation, exportation and manufacture of psychotropic or narcotic substances as are required for reporting to the International Narcotics Control Board, as outlined in regulations.

Article 22: Prohibition of Substandard/Spurious/Falsified/Falsely-labelled/Counterfeit (SSFFC) Medical Products

1) No person shall manufacture, import, export, supply, store, distribute or sell any SSFFC medical products.

2) The Agency/Authority shall issue guidelines stipulating procedures for handling SSFFC medical products in collaboration with other relevant institutions.

PART IV: OFFENCES AND LEGAL PROCEEDINGS

Article 23: Offences

Any person who:-

1) Obstructs or hinders any inspector in the exercise of his or her powers or the performance of his or her duties under this law; or

2) With fraudulent intent, tampers with any sample taken in terms of this law; or

3) Makes any false or misleading statement in connection with any medical product or scheduled substance: -

a) In an application for marketing authorization thereof; or

b) In the course of an application for a manufacturing, importing, exporting, storage, sale or distribution license thereof; or

c) In the course of the sale thereof; or

4) Sells any medical product or scheduled substance upon the container of which a false or misleading statement in connection with the contents is written; or

5) Generally with regard to medical products and scheduled substances, contravenes any provision of the following sections, or fails to comply with any condition imposed thereunder, namely;

a) Art. 13;

b) Art. 15;

c) Art. 16 (3) and 16 (4);

d) Art. 18;

e) Art. 19;

f) Art. 21;

g) Art. 22; or

6) In any other manner, contravenes the provisions of this Law, shall be guilty of an offence.

Article 24: Penalties

1) Any person who is convicted of an offence referred to in Art. 23 shall be liable to a fine and/or imprisonment.

2) The court convicting any person of an offence under this Law may, upon the application of the prosecutor, declare any medicine or scheduled substance in respect of which the offence has been committed to be forfeited to the State.

3) In addition to any civil and/or criminal penalties imposed on a person in respect of any contravention in terms of this Law, further administrative penalties may be imposed as stipulated in Regulations.

PART V: ADMINISTRATIVE APPEALS PROCEDURES

Article 25: Establishment of an Administrative Appeals Committee

1) An Administrative Appeals Committee shall be established by the appointing authority to hear and determine appeals lodged by persons aggrieved by the decisions of the Agency/Authority.

2) The Administrative Appeals Committee shall consist of:-

a) a judge or a legal practitioner who has practiced as such for a period of at least seven years, and shall be the chairperson of the committee;

b) practitioners who are registered as specialists in the area of medicine, pharmacy, nursing, veterinary medicine and public health, one of whom may be called upon depending on the nature of the complaint;

c) any other specialist in the area of the appeals.

Article 26: Administrative Appeals Procedures

1) Any person who is aggrieved by a decision of the Agency/Authority may appeal in the manner, and within the period, prescribed, against such decision, to an Administrative Appeals Committee.

2) The decision of the Administrative Appeals Committee is final.

PART VI: INTERNATIONAL COOPERATION AND HARMONISATION OF REGULATION OF MEDICAL PRODUCTS

Article 27: International Cooperation

1) The Agency/Authority shall cooperate with other national, regional and continental medical products regulatory agencies.

2) The Agency/Authority shall share pharmaceutical intelligence on products that pose public health risks with other agencies at the regional, continental and global level.

3) The supervising authority shall take appropriate measures to ensure effective bilateral, regional and international co-operation to combat the production, circulation and use of SSFFC medical products, illicit drugs, narcotics and psychotropic substances.

Article 28: Regulatory Harmonisation Initiatives

1) The Agency/Authority shall participate in regional and continental medical products regulatory harmonization initiatives.

2) The appointing authority and/or the Agency/Authority, as the case may be, shall take such measures to ensure effective co-operation with their counterparts in other countries to:-

a) harmonise registration of medical products, inspections, quality management systems, information management systems, joint evaluations, joint inspections and any other regulatory activities as may be appropriate;

b) provide for the use of accredited quality control laboratories within the harmonisation framework;

c) provide for the recognition of regional, continental and other international technical guidelines;

d) provide for harmonisation of the data requirements for evidence of quality, safety, and efficacy of medical products and the grounds on which authorisation for distribution shall be granted within the region;

e) provide for mutual recognition of marketing authorisation decisions;

f) share summary evaluation and inspection reports;

g) participate in common post-marketing surveillance conducted In accordance with nationally and internationally recognised standards;

h) provide for cooperation with other regulatory agencies/authorities for the purpose of strengthening national regulatory capacity;

i) establish networks with other regulatory agencies/authorities and collaborate in protecting public health through enforcement activities;

j) establish exchange programmes with other medical products regulatory agencies/authorities so as to keep abreast of evolving scientific development in the field of medical products; and

k) provide for any necessary legal mechanisms for regulatory harmonisation.

l) Provide for transparency and information sharing through:-

i. Establishment of a quality management system based on common regional and continental requirements to ensure efficiency;

ii. The creation a national information management system which allows for sharing information at regional and continental levels in accordance with national laws, bilateral and multilateral agreements

PART VII: MONITORING AND EVALUATION

Article 29: Monitoring and Evaluation of National Regulatory System

1) The Agency/Authority shall create a monitoring and evaluation system charged with reviewing and assessing the performance of the Agency/Authority.

2) The Agency/Authority shall prepare periodic reports and present to the supervising authority through the Board of the Agency/Authority.

3) The supervisory authority shall report on the performance of the Agency/Authority to relevant governing bodies at regional and continental levels.

PART VIII: REGULATIONS AND GUIDELINES

Article 30: Regulations

1) The appointing authority shall have the power to make regulations necessary for the efficient carrying out of the objectives of this Law, in consultation with the Agency/Authority.

2) The Agency/Authority shall, within a reasonable time before any regulation is made under Art. 30 (1), cause the text of the regulation, together with a notice declaring the intention to make the regulation to be officially published, inviting stakeholders to furnish any comments or representations thereon.

Article 31: Guidelines

1) The Agency/Authority shall have the power to issue guidelines necessary for the carrying out of the objects and purposes of this Law.

2) The Agency/Authority shall, within a reasonable time before any guideline are made under Art. 31 (1), cause the text of the guideline, together with a notice declaring the intention to make the guideline to be officially published, inviting stakeholders to furnish any comments or representations thereon.

PART IX: MISCELLANEOUS PROVISIONS

Article 32: Declaration and Conflict of Interests

1) A member of staff of the Agency/Authority, of the Board or of a committee shall declare any interests related to any medical products, or which may be relevant to any decision-making.

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

Article 33: Restriction of Liability

1) The Agency/Authority, the Board, a committee member or a member of staff of the Agency/Authority is not liable for any loss or damage arising from any decision made or act carried out in good faith in the exercise of powers or performance of functions under this Law and other applicable laws.

2) The Agency/Authority, the Board, a committee member or a member of staff of the Agency/Authority shall however be liable for any loss or damage if the loss or

damage is due to wilful misconduct, gross negligence or failure to comply with this Law and other applicable laws.

Article 34: Protection of and Access to Information

1) No person shall disclose to any other person/institution any information acquired by him in the exercise of his powers or the performance of his functions under this Law and relating to the business or affairs of any person, or use such information for self-gain or for the benefit of his employer;

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

a) for the purpose of the exercise of his powers or the performance of his functions under this Law with the written authority of the Agency/Authority;

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

c) if it is in the public interest.

Article 35: Regulation of Other Related Products

The Agency/Authority may regulate other related products, not covered by this Law. The appointing authority shall issue regulations for such related products to ensure that they comply with prescribed standards.

PART X: COMMENCEMENT

The law shall commernce in accordnace with the legislative proceedures of each state.