



**Model Law on Medical Products Regulation and
Harmonization in Africa**

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African Union



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PREAMBLE

The right to health is a universal and fundamental right which has been recognised and promoted in the Universal Declaration on Human Rights (art. 25); in the International Convention on Civil and Political Rights (art. 12) and in the African Charter on Human and People's Rights (art. 16).

It is the States' highest responsibility is to ensure that people have access to quality health care services, and medical and pharmaceutical products which are in line with the international quality standards.

The existence and effective implementation of health related laws and regulations constitute an essential pillar of any public policy.

The regulations relating to the production and distribution conditions of medical products in Africa are at the helm of public health issues on the continent.

Therefore, the African Union undertook through the Pan African Parliament, African Union Commission and NEPAD Agency to meet the challenge of medical products regulation by preparing a Model Law for Member States intended to be used as a framework for the development or enhancement of out-dated or non-existing national laws.

This Model Law strives to streamline aspects relating to the establishment and governance of National Regulatory Agencies, as well as the operational aspects relating to the various functions assigned to and deployed by these Agencies.

Moreover, the African Union member states reflect a broader vision of achieving the harmonisation of medical products regulation on the continent. This vision is in line with the Union's 19th General Assembly resolution calling for the acceleration and strengthening of regional initiatives pertaining to the harmonisation of medical products regulation, on the one hand, and building the foundation for the creation of an African Regulatory Agency, on the other.

This vision is perfectly in line with the African Union's mandate to work for the protection and promotion of Human and People's Rights.



This Model Law seeks to lay the basis for an efficient and effective regulatory system for medical products, for their harmonisation across regions and the continent, and for the promotion and the expansion of a competitive and efficient pharmaceutical industry in Africa.

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PART I: PRELIMINARY PROVISIONS

1. Short title, Extent and Commencement

- 1) This law shall be cited as a "Law on Medical Products Regulation and Harmonization",
- 2) This Law shall come into operation on such date as the parliament or the relevant authority in charge may declare by notice published in the official Gazette.

2. Application of other laws and consequential amendments

- 1) This Law shall apply to all medical products alongside existing laws on medical products regulation prepared under this Law.
- 2) The provisions of any existing law in conflict with this law shall, to the extent of the inconsistency, stand repealed or amended.

3. Purposes

The purpose of this Model Law is to:

- 1) To protect public health through the establishment of an effective and efficient system of medical products regulation and control at all levels to ensure that medical products circulating in the State meet required standards of safety, efficacy and quality.
- 2) To improve public health by encouraging and facilitating research and developments and regulation of medical products to ensure a secure pharmaceutical supply system.
- 3) To facilitate fair trading practices in the pharmaceutical sector and promote harmonisation of regulation of medical products through regional economic communities recognised by the African Union.

4. Definitions

In this Law, unless the context otherwise requires:

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“advertisement” in relation to a medicine, a scheduled substance and medical devices, includes a representation by any means for the purpose of promoting, directly or indirectly, the sale or disposal of a product regulated by this Law; and “advertise” has a corresponding meaning; this may include pictorial, visual or otherwise descriptive matter or verbal statements or references appearing in a newspaper, a magazine, a pamphlet or other publication;

- a) broadcast on television or radio;
- b) distributed to members of the public; or
- c) brought to the notice of members of the public in any manner, which is intended to promote the sale of that medicine or scheduled substance, and “advertise” has a corresponding meaning;

“agency” means the National Regulatory Authority as stated in this law.

“appeal committee” means the appeal committee of the national regulatory authority as referred to in this law.

“appointing authority” means the authority that is responsible for appointing the staff of the national regulatory authority and its affiliated institutions.

“board” Means the Board of the National Regulatory Agency constituted under this law.

“certificate of registration” means a certificate of registration issued in terms of the laws of the country

“chairperson” means the person elected as chairperson of the Board;

“clinical trial” means an investigation or series of investigations consisting of the administration of one or more medical products of a particular description, the use of a medical device by or under the direction of — (a) a doctor or dentist to one or more of his patients; or (b) two or more doctors or dentists, each product being administered by or under the direction of one or other of those doctors or dentists to one or more of his patients, or by a pharmaceutical company on a multitude of persons where (in any such case) there is evidence that medical products of that description have effects which may be beneficial to the patient or patients in question and the administration of the product or products or the use of the medical device is for the purpose of ascertaining whether, or to what extent the product has, or the products have, those or any other effects, whether beneficial or harmful;

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“committee” means a committee established by the Agency for the performance of specific tasks under this law;

“composition” ,in relation to drug products means the ingredients of which consists, proportions, degree of strength, quality and purity in which those ingredients are contained.

"container", means the bottle, jar, box, packet or other receptacle which contains or is to contain, medicines, cosmetics, micro-biological or devices not being a capsule, cachet, or other article in which the product is or is to be eaten, administered, 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

”contravention” includes failure to comply to set standards, regulations and laws under this Law.

“dentist” Means a person that is duly registered as such under the medical practitioners Law

“dispense”, in relation to a medicine, means to prepare; count out, measure or decant from a bulk supply; mix; dissolve; or disperse, and dispose of, a medicine, for gain or otherwise, for the treatment of a particular person or animal, but does not include the actual administration of the medicine, and “dispensing” has a corresponding meaning;

"doctor" means a person registered under the law governing the medical profession; to diagnose and treat human or animal diseases by drugs or surgical operations.

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

“falsified and substandard medical products” means medical products which do not meet national specifications because of quality system failures and falsified products which have a false representation of identity or source. (All products unregistered with the regulatory authority are equally illegal.)

“Harmonization” means adjustment of differences and inconsistencies among different laws, regulations, methods, procedures, schedules, specifications, or systems of medical products regulation to make them uniform or mutually compatible among the National Regulatory Authorities (NRAs).

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“import” means bringing into the national territory whether on ones body by land, sea or air with the intent to distribute, dispense and retail and consume.

“importer” means a person who brings a medical products, medical devices, chemical substances and other related products, into the national territory or causes a medicine, to be brought into the country, and includes a person who - (a) owns the goods brought into the national territory (b) carries the risk for the goods brought into the national territory ; (c) represents to be the one who brought the goods into the national territory or who owns those goods; (d) actually brings the goods into the national territory ; (e) is beneficially interested in any way in the goods brought into the national territory ; or (f) acts on behalf of a person referred to in paragraphs (a) to (e), and “import” and “importation” have a corresponding meaning;

“inspector” means any professional authorized or appointed or recognized to perform inspection activities by the national regulatory Authority pursuant to this law.

“label” when used as a verb, means a brand, mark, a legend or otherwise designate or described, and when used as a noun, means a brand, a legend or, a written, a pictorial or other descriptive matter appearing on or attached to, or belonging to, or accompanying a package containing medical products or chemical substances

“label” means any material which is printed or affixed to a packing material which provides the necessary information about a medical device, medical device includes an insert.

“license” means a certificate issued for a health professional to provide medical or other health related services.

“legal practitioner” means a person that is licensed as a legal practitioner as defined in the national law governing legal practice in the country

“manufacture” in relation to medical products and chemical substances includes any process carried out in the course of making the product inclusive of purchasing of material, processing, packaging, quality control, release and storage of medicinal products and related substances, but does not include dissolving or dispersing the product in, or diluting or mixing it with, some other substance used as a vehicle for the purpose of administering it; rubbing it, spraying it, sprinkling it, or making diagnosis with it. **“manufacturing”** has a corresponding meaning;

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“**manufacturer**” means any person who converts raw materials, components or parts by the use of tools, machines and labour to produce finished products of medicines for human or animal use, cosmetics, medical devices, foods and chemical substances whether on a large or small scale for use or for sale, and any person under whose direction and control such manufacturing takes place

“**medicine**” means a substance or a mixture of substances used or purported to be suitable for use or manufactured or sold for use in - (i) the diagnosis, treatment, mitigation, modification or prevention of a disease, abnormal physical or mental state, or the symptoms thereof, in humans or in animals; or (ii) restoring, correcting or modifying any somatic, psychic or organic function in humans or in animals;

“**medical practitioner**” means a doctor, dentist or veterinary surgeon who is duly licensed to practice in his trade.

“**Ministry**” or “**Minister**” means the Ministry or Minister in charge of Health matters respectively;

“**Mutual recognition**” means the acceptance of one National Regulatory Authority’s certification of standards and procedures for medical product regulation by another NRA;

“**package, re-package**” in relation to any medical products, means any box, packet or other article in which one or more containers of the products are or are to be enclosed, and, where any such box, packet or other article is or is to be itself enclosed in one or more boxes, packets or other articles, includes each of the boxes, packets or articles in question;

“**patient**” means; a) a person treated by the medical practitioner, the dentist, the practitioner, the traditional healer or the registered nurse; and b) in the case of a pharmacist, a person treated by a pharmacist;

“**person**” means any physical or juridical person and means male and female;

“**pharmacist**” means a person who is trained and registered as a pharmacist and has in force a valid practising certificate or license issued under the law governing the pharmacy profession in the country;

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

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“**prescribe**” means - to 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

“**prescription**” means an order issued in writing by a duly licensed medical practitioner instructing for a specific patient or animal to receive a medicine or specified treatment from a dispensing unit.

“**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 on Psychotropic Substances of 1971 intended for medical and scientific purposes;

“**premises**” includes a building, hut, shed, kiosk or tent together with the land on which it is situated and an adjoining land used in connection with it, and a vehicle, conveyance or vessel;

“**public**” includes a section of the public concerned with manufacturing, dispensing, selling or administering, or the issue of prescriptions for medical products, medical devices, chemical substances and related products.

“**register**” means the act of recording in writing the medicines,. Foods, cosmetics, chemical substances, medical devices products registered or any other related products; this also refers to the records kept in terms of this Law

“**regulation**” means a law , decree Acts of parliament, framework, policies, directives and guidelines made under this Law;

“**products regulated under this law**” means pharmaceuticals including human and veterinary medicines, diagnostic products; medical devices; vaccines/biological; complimentary medicines; and as the case may be in a particular member states .

“**sell**” means sell by wholesale or retail, and includes 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

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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;

“substance” means any natural or artificial substance whether in solid or liquid form or in the form of gas, vapour or radiation

“supply” includes having in possession for the purpose of supply;

“supplying” anything in circumstances corresponding to retail sale is a reference to supplying it, otherwise than by way of sale, to a person as being a person who receives it for a purpose other than that of selling or supplying

“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 a cure or not

“vaccines” means any substances administered intravenously or orally to stimulate the production of antibodies and provides immunity against one or several diseases, prepared from the causative agent of a disease, its products, or synthetic substances, treated to act as an antigen without inducing the disease

“Vice-chairperson” means the person elected as vice-chairperson of the Board.



PART II: ADMINISTRATION, GENERAL PROVISIONS AND GOVERNANCE

5. Establishment of the Agency

- 1) There is hereby established the authority to regulate medical products to be the national regulatory agency (the Agency).
- 2) The Agency shall be an autonomous body, with perpetual succession.
- 3) The Agency shall subject to the provisions of this Act, be capable in its name to:
 - a. sue and be sued;
 - b. take, purchase, acquire, hold, and dispose of property whether movable or immovable
 - c. borrow or lend money; or
 - d. Perform such other things or acts, which may lawfully be performed by a corporate body, for the proper performance of its functions and in accordance with provisions of this Act,
- 4) The Agency shall have a common seal.

6. Organs of the Agency

There shall be constituted organs of the Agency which shall include but not limited to the Board, Statutory Committees of the Board, the Head of the Agency, The Management and the Technical Committees.

7. Powers and Functions of the Agency

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

- 1) regulate, monitor and enforce the use, manufacture, import and export, distribution and sale of all medical products for human use;
- 2) regulate and enforce conformance with prescribed standards of quality, safety and efficacy;
- 3) regulate, monitor and inspect personnel, premises and practices that are involved in the manufacture, promotion, procurement, storage, distribution and sale of such medical products for compliance with defined codes of practice and other requirements;
- 4) provide regulations for controlling the manufacture, import and export, distribution and use of medical products and necessary steps to prevent misuse and abuse;

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- 5) take necessary steps to prevent importation, distribution or sale to the public of substandard or adulterated medical products and other regulated products;
- 6) take reasonable steps to ensure that only duly authorized persons are involved in importing, exporting manufacturing, stocking, selling, distributing or otherwise dealing in the regulated products;
- 7) inspect and license all manufacturing premises, importing agents, wholesalers, distributors, transport vessels, medical stores and dispensing areas within health facilities, pharmacies and retail outlets dealing in the regulated products;
- 8) maintain an inventory of provisionally authorised/registered regulated grant, after due assessment, Marketing Authorisation licenses or registration status for medical products meant for human use, whether locally manufactured or imported, and whether destined for the national market or export;
- 9) cancel the authorizations or registration licenses of, or cause regulated products that are detrimental to public health to be recalled from the market;
- 10) regulate the maintenance of proper books and records of authorized medical products and ensure that they are kept up to date;
- 11) levy fees for Marketing Authorisation and other authorisation related to regulated products;
- 12) publish lists of provisionally authorised regulated products meant for human use and provide public information from time to time about products that have been issued with Marketing Authorisations;
- 13) monitor and inspect the market for presence of illegal, substandard or adulterated medical products meant for human use;
- 14) provide a process for sampling, analysing and testing regulated products that includes processes for production and manufacture and distribution and monitor and enforce compliance with labelling requirements;
- 15) ensure that the promotion, advertising and marketing of regulated products meant for human use is in accordance with the product information approved by the Agency;
- 16) approve the use of unregistered and unauthorized medical products for trial purposes or for compassionate use;
- 17) oversee clinical trials on medical products;
- 18) establish a functional system for pre-and post-marketing surveillance of safety, quality, efficacy, and effectiveness of medical products and to optimize the risk-benefit balance;

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- 19) disseminate information on regulated products for human use to health professionals and to the public in order to promote their rational use;
- 20) give due attention to the implementation of conventions on narcotics, psychotropic drugs, radioactive pharmaceutical and poisons, which the country is signatory to.
- 21) Devise appropriate strategies for staff retention and for the qualitative development of professionals who are in service.
- 22) collaborate with the academia, research institutions and development partners, in the area of research on regulatory science and drug development ;
- 23) maintain a system of consultation and cooperation with other government Ministries and institutions, the private sector and civil society on proper implementation of this Law;
- 24) establish mechanisms for monitoring and reviewing implementation of this Law;
- 25) continuously review rules, regulations, guidelines and procedures pertaining to implementation of this Law and make amendments when necessary in order to keep pace with changing times and industry demands.

8. Establishment of the Board

- 1) There shall be established a Board for the Agency.
- 2) The appointing authority shall, upon recommendation of the relevant stakeholders, appoint the Chairperson and Members of the Board, who shall be entrusted to provide oversight on activities and affairs of the Agency and to exercise all functions and powers conferred upon them under the provisions of this law.
- 3) The members of the Board, may include :
 - a. Representative from the Ministry responsible for Health
 - b. One registered pharmacist from academia,
 - c. One Legal Counsel
 - d. One representative of the medical association
 - e. One representative of the pharmacy association
 - f. One representative from civil society
 - g. The Head of the Agency.
- 4) The Board shall discharge its functions and powers under the supervision of the appointing authority;

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- 5) The members of the Board shall hold office for a term of three years and thereafter shall be eligible for reappointment for one additional term only;
- 6) A member of the Board may resign their office by writing addressed to the appointing authority;
- 7) The members of the Board shall be paid such allowances as may be determined by the appointing authority;
- 8) The Board shall designate one of its members as Vice-Chairperson to act as Chairperson during the absence of the chairperson;
- 9) The Chairperson shall preside over the Board, call for meetings, determine the agenda of the Board meetings in consultation with the Head of the Agency;
- 10) By a two-thirds (2/3) majority vote of the full membership of the board, recommend to the Appointing Authority for removal any member of Management or Board, in either case only for acts incompatible with the Agency's or Board's rules or regulations; and
- 11) Without prejudice to the provisions of this Law, the Board shall issue its own rules of procedure for the conduct of meetings, and establish a code of conduct governing the activities of the Board and members of the Board.

9. Powers and Functions of the Board

- 1) The Board shall have the powers and functions to:
 - a. Provide strategic guidance to the Agency in the discharge of its functions.
 - b. Approve regulations for implementation of this Law;
 - c. Approve the strategic and annual work plan and budget of the Agency;
 - d. Review the quarterly reports presented by the Agency;
 - e. Monitor and evaluate implementation of Agency;
 - f. Establish, encourage and promote training programmes for the employees of the Agency and appropriate persons from public or private organizations/institutions
 - g. Establish ad hoc committees whenever it deems necessary;
 - h. Approve the appointment or removal of Heads of Departments of the Agency;
- 2) The Board shall uphold the autonomy of the Agency.



10. Appointment of the Head of the Agency

- 1) The Head of Agency shall be appointed by the appointing authority on recommendation of the Board.
- 2) The Board shall advertise the position through a public advertisement in collaborations with appropriate national agencies, interview and select before recommendation to the appointing authority.
- 3) The nominee shall possess as minimum a degree in Pharmacy or any of the health and physical sciences but with knowledge and experience in the management of medical products and medical products regulatory systems.
- 4) The conditions of employment shall be on such terms and conditions as the Agency, with the approval of the Government may approve.
- 5) The Head of Agency shall be appointed to serve on such terms and conditions as shall be set out in the letter of appointment.

11. Duties and Responsibilities of the Head of Agency

- 1) The Head of Agency shall be the Chief Executive Officer and shall be responsible to the Board for the management of the business and affairs of the Agency as well as for the execution of the decision and directives of the Board.
- 2) The Head of the Agency shall be responsible for the day to day operations of the agency, the proper management of its fund, property and business and for the personnel management and development, organisation, control and discipline of the employees of the Agency.
- 3) The Head of the Agency shall be a member of the Board but shall have no voting powers.
- 4) In the event the Head of the Agency is not in the office or is prevented by illness or other reasonable course from discharging his functions under this Law, 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, management or professional functions.

12. Management

- 1) The staff of the Agency shall be under the management of the Head of the Agency.
- 2) The Agency shall have directorates and/or units to facilitate execution of its operations and functions as it may deem fit and may include:
 - a. Planning, Monitoring and Evaluation; Research and Statistics
 - b. Product Evaluation and Registration
 - c. Inspectorate and Law enforcement
 - d. Pharmacovigilance Centre
 - e. Quality Control Laboratory
 - f. Harmonization and International Cooperation
 - g. Human Resource Development, Administration and Finance
 - h. Other directorates or departments as may be required for the proper performance of the functions of the Agency

13. Technical Committees

- 1) The Head of Agency shall with the approval of the Board, set up Technical Committees to facilitate the work of the Directorates as may be deemed appropriate.
- 2) Technical Committees, where possible, shall be chaired by a person appointed by the Board upon recommendations of the Agency.
- 3) Technical expertise of members shall be the major criteria for their appointment.
- 4) The corresponding directorate and/or department will function as the Secretariat to the Committee.
- 5) The report of Technical Committees shall be the basis for decision making by the Agency.
- 6) Membership of Technical Committees shall be coterminous with the term of the Board.
- 7) Members of the Committees shall be free of conflict of interest and shall sign declarations to same.



14. Sources of Funds

- 1) The funds of the Agency shall include:
 - a. such fees as are payable in terms of regulations made under this Law; and
 - b. such moneys as may be payable to the Agency from moneys appropriated for the purpose by a law enacted by Parliament; and
 - c. interest from deposits; and
 - d. proceeds derived from the sale of assets and any other source of income identified by the Agency and legally obtained; and
 - e. such other moneys and assets as may vest in or accrue to the Agency, whether in the course of its functions or otherwise.
- 2) The Agency shall not accept any donation or bequest without the approval of the Board after consultation with the Minister responsible for finance.
- 3) The funds and resources of the Agency shall be applied for the purpose for which the Agency is established and managed as provided for under the law,
- 4) The Agency 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 Agency shall be effected.
- 5) Subject to the approval of the Board, the Agency may invest any monies in such a manner as it deems fit.

15. Accounts and audit Accounts and audit

- 1) The Agency shall keep proper accounts and other records relating thereto in respect of its funds.
- 2) The accounts of the Agency shall be examined and audited by the government auditor or a by an external auditor as the Board may determine.

16. Annual Reports

- 1) The Agency shall keep proper accounts and other records relating to the affairs of the agency.
- 2) The Agency shall produce a written annual report at the end of each financial year.

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- 3) The Agency shall submit a report to the Minister, not later than ... in each year, relating to the activities of the Agency during the previous financial year, and shall include a copy of the Agency's balance sheet and income and expenditure account.
- 4) The Minister shall table the said annual report before the National Parliament.

17. Restriction of liability

- 1) The Agency, a committee or a member of staff of the Agency or of any such committee is not liable for any loss or damage arising out of, or in connection with, the performance of the Agency's or the committee's or the member's duties under this Law, or in respect of any act or thing done in good faith by the Agency or any such committee or member in the exercise of the powers or the performance of functions under this Law.
- 2) The Agency, a committee or a member of staff of the Agency or of any such committee shall however be liable for any loss or damage if the loss or damage is due to the Agency's, the committee's or the member's wilful misconduct, gross negligence or failure to comply with this Law or a direction or decision given under it.

18. Exemption from Taxation

- 1) 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 Board or on behalf of the Board or by any person in respect of any functions done or performed under this Act.
- 2) 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 national income tax Laws.

19. Declaration and Conflict of interests

- 1) A member of staff of the Agency, of Board or of a committee appointed by the Agency shall declare any interests related to regulated medical products.
- 2) A member with conflict of interest shall recuse themselves from any discussion or decision-making to which the said interests relate or may relate.

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- 3) The Agency shall promulgate regulations and guidelines for declaration of conflict of interest that shall be applicable to all members of the Board, Committees and staff of the Agency.
- 4) A person who knowingly fails to disclose or declare their interest commits an offence and is liable to conviction under governing Laws of the country.

20. Remuneration of members of the Board, Committee and Staff of the Agency

- 1) A member of the Board, staff of the Agency or of a Committee shall be paid from funds of the Agency.
- 2) The Agency shall promulgate financial rules, regulations and procedures as may be approved by the Minister responsible for Health, after consultation with the Minister responsible for Finance.

PART III: NATIONAL REGULATORY SYSTEM

21. Scheduling of Medical Products

- 1) The schedule status of any medical product shall be determined by the Agency as may be promulgated in the regulations in accordance with international conventions and acceptable standards.

22. Marketing Authorization

- 1) No medical product whether manufactured locally or imported shall be put into use in the country unless it is fully registered by The Agency
- 2) The Agency shall approve a medical product if it is satisfied;
 - a. with its quality, safety and efficacy;
 - b. that the medical product is suitable for the intended purpose;
 - c. that it complies with the prescribed requirements; and
 - d. that marketing authorization is in public interest.
- 3) The registration shall be done in accordance with regulations promulgated by the Agency providing for the issuance, renewal, variation, validity, exemption, suspension, cancellation and revocation of such licenses.

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- 4) The Agency shall publish the medicine registers in the official government gazette and the official website of The Government and The Agency.

23. Licensing Manufacturers, importers, Exporters, Wholesalers, Distributors and Retail outlets

- 1) No person/organization shall manufacture, supply, store, distribute or sell any medical product, unless the person/organization has been issued a license by the Agency.
- 2) The conditions of a license for the manufacture of medical products shall be stipulated in regulations promulgated by the Agency that shall provide for the issuance, renewal, suspension, exemptions or exceptions, cancellation and revocation of such licenses.
- 3) Provisions shall be made for all manufacturers, importers, exporters, wholesalers and distributors to comply with Good Manufacturing Practice (GMP), Good Distribution Practice (GDP), Good Storage Practice (GSP), Good Warehousing Practice (GWP) as stipulated in the regulations

24. Permits for Importers, Exporters, Wholesalers, Distributors and Retail outlets

- 1) No person/organization shall import, export, store, distribute or sell any medical products, unless the product is duly registered by the Agency, and the person/organization has been issued a permit by the Agency for the same.
- 2) The conditions of a permit for the supply, storage, distribution, or sale of medical products shall be stipulated in regulations promulgated by the Agency that shall provide for the issuance, renewal, suspension, exemptions or exceptions of, cancellation and revocation of such permits.
- 3) Provisions shall be made for the promulgation of regulation to govern donations of medical products.

25. Market Surveillance and Safety monitoring

1) Establishment of a Pharmacovigilance Centre

- a. There shall be established a national Pharmacovigilance Centre as part of the Agency to monitor and report on the safety of medical products.
- b. The Center shall be responsible for:-
 - (i) Monitoring and analysis of adverse effects or events for products regulated under the Law;

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- (ii) take appropriate regulatory action when necessary;
 - (iii) monitoring of clinical trials, identify and report adverse events; and ensure that they conform with ethical principles for medical research involving human subjects;
 - (iv) provide for means for establishing causality, taking remedial actions and report to international safety monitoring systems.
- c. The Agency shall promulgate regulations to provide for mandatory reporting by the industry (manufacturers and distributors) and health care professionals, and submission of periodic safety updates.

2) Quality Monitoring

- a. The Agency shall ensure that there is in place, throughout the supply chain in the country, a testing scheme consisting of sampling of high risk medical products, from wholesalers and retailers, assessed as being most at risk of likely to be falsified and upon identifying the presence of falsified medical products the Agency shall take appropriate action to protect public health and take enforcement action under this Law.

3) Risk Assessment and Management

- a. For the purpose of maximizing protection of public health, the Agency shall implement a programme of risk-based inspection of medical products throughout the manufacturing, distribution, compounding, dispensing, clinical trials activities and pharmacovigilance.
- b. The Agency will assess the risk of any scientific data presented to it and make an informed decision on whether that product will be recalled and/or withdrawn from circulation or not.
- c. The Agency shall take appropriate enforcement action upon determining that compliance is not being achieved or cannot be achieved or that an unacceptable risk to public health exists.

4) Recalls or withdrawal of medical products

- a. Whenever the Head of the Agency finds that any portion of any medical product does not conform to the standards of identity, strength, quality and purity, or any other



requirement specified in the documentation for registration, the Head of the Agency 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 shall by order published in the Gazette issue notices withdrawing from the medical products market in the country any medical products stocked or retailed but 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. The information shall be disseminated as wide as possible, including through use of electronic media.

5) Disposal of undesirable medical products

- a. If the Agency is of the opinion that it is not in the public interest that a medicine be made available to the public, the Agency may:
 - (i) by notice in writing handed or transmitted by registered post or electronically to any person direct that person; or
 - (ii) by notice in the Gazette direct any person, to:
 - i. return any quantity of that medicine in his or her possession to the manufacturer, supplier or importer of that medicine or scheduled substance; or
 - ii. deliver or send that medicine to any other person designated by the Agency.
- b. The Agency may, by notice in writing, direct:
 - (i) any manufacturer, supplier or importer of a medical product who has any quantity of that medical product, including any quantity returned to him or her in pursuance of a direction made under subsection (a); or
 - (ii) any other person to whom any quantity of a medical product has been delivered or sent to dispose of that quantity in such manner, subject to regulations made, as the Agency may determine.
- c. A person may not sell a medicine which is the subject of a notice under subsection (a), unless the notice has been withdrawn by the Agency or set aside on appeal.

26. Control of Clinical Trials of Medical Products

- 1) No person/organization shall conduct clinical trials in medical products on humans or animals without the authorization of the Agency.



- 2) No clinical trials shall be conducted in the absence of informed consent by all participants.
- 3) The conditions for authorization of such clinical trials shall be stipulated in regulations promulgated by the Agency that shall provide for the issuance, renewal, suspension, cancellation and revocation of such authorizations, including review by an ethical committee.
- 4) Provisions shall be made for inspection of clinical trial sites in accordance with Good Clinical Practice (GCP) and Good Laboratory Practice (GLP) as provided for by regulations.

27. Control of Drug Promotion and Advertisement

- 1) No person/organization shall advertise or promote any medical product without authorization by the Agency.
- 2) The Agency shall promulgate regulations that:-
 - a. provide for guidelines and procedures for approval of advertising and promotional activities or materials,
 - b. establish standards for determining when any advertising or promotional activity or material is false or misleading.

28. Establishment of Quality Control Laboratory

- 1) There shall be established a National Quality Control Laboratory as part of the Agency.
- 2) 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. do such other function as shall be determined by the Agency
- 3) The Agency may appoint any other laboratory or institution to perform such functions as it may specify for the purposes of enforcement of this Law.
- 4) In performing its functions, the Laboratory shall take cognisance of the existence of any accredited Laboratory within or outside the country for analysis of medical products.



- 5) In case of dispute regarding analytical results, the Agency shall follow procedure as prescribed in the regulations.

29. Control of Narcotic drugs, Psychotropic Substances and Precursors

- 1) Control of Narcotics drugs, Psychotropic Substances and Precursors in accordance with legislation on dangerous drugs and relevant treaties to which the State subscribes, including the Single Convention on Narcotic Drugs of 1961 as amended by the 1972 Protocol, the Convention on Psychotropic Substances 1971 adopted in 1988, and the UN Convention against Illicit Traffic Drug and Psychotropic Substances, 1988
- 2) No person/organization shall import, export, transit into or out of the country, manufacture, store, distribute, sell, prescribe, dispense, or administer any narcotic drug or psychotropic substance, unless the person/organization has been issued a special license for such purpose by the Agency.
- 3) This special license shall be in addition to any license, permit or other requirement or restriction.
- 4) No person/organization shall dispense or administer any narcotic drug or psychotropic substance except in accordance with a valid prescription from a licensed health care practitioner authorized to prescribe such products.
- 5) The conditions for issuance of a special license for the import, export, transit, manufacture, storage, distribution, sale of narcotic drugs or psychotropic substances shall be stipulated in regulations promulgated by the Agency that shall provide for the issuance, renewal, suspension, cancellation and revocation of such special licenses.
- 6) The conditions for the prescribing, dispensing, administration and reporting of narcotic drugs and psychotropic substances shall be stipulated in regulations promulgated by the Agency.
- 7) The Agency shall collect data on licit narcotics drugs and psychotropic substances and report to the International Narcotics Control Board (INCB) as provided for in the regulations.

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- 8) The Minister shall, on advice by the Agency, by regulations published in the Gazette declare lists of narcotics and psychotropic substances.

30. Control of Falsified and Substandard medical products

- 1) No person/organization shall manufacture, import, export, transport, store/warehouse, supply, possess or offer for sale any falsified and/or substandard medical products.
- 2) The Agency shall promulgate regulations stipulating procedures for handling falsified and substandard medical products.

PART IV: REGULATORY INSPECTION AND ENFORCEMENT

31. Appointment, authorization and recognition of inspectors

- 1) The Agency shall:
 - a. appoint an inspector with a degree in pharmacy or any of the health and physical sciences but with knowledge and experience in the inspection of medical products
 - b. authorise any inspector or officers appointed under any written laws whose functions relate to the functions of the Agency to perform specific functions as inspectors under this Law; and
 - c. publish in the Gazette inspectors appointed under this Law.
- 2) When appointing or authorizing inspectors, the Agency shall take into account the skills and competency of such need to appoint or authorize an inspector.
- 3) Any officers appointed as inspector shall be recognised as authorised officers under this Law and be bound by a code of conduct.

32. Powers of Inspectors

- 1) An inspector or inspectors appointed under this Law may; at all reasonable times, enter;
 - a. any set of premises which is on the register of premises;
 - b. any premises in which any person whose name is entered in any register under this Law, carries on any business; and
 - c. any premises in respect of which any person is licensed under this Law;

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- 2) at any time enter any premises, stall, vehicle, vessel, or conveyance, any
 - a. premises suspected to be dealing with products regulated under this Law for the purposes of ensuring compliance with this Law;
 - b. examine or inspect any certificate of registration, license, 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 effect the examination or inspection;
- 3) take sample for analysis, or for other examination of any medical products or of any substance capable of being used in the manufacture of medical products as provided for in the regulations.
 - a. seize and detain any medical products, substance or article consisting of, or containing any banned substances which he has reasonable cause to suspect is liable to forfeiture under this Law;
 - b. seize and detain any medical products, article, record or other thing which appears to him to constitute or contain evidence of a contravention of any provisions under this law;
 - c. close, with the assistance of the police, the premises found to contravene the law; and
 - d. institute administrative, civil and/or criminal proceedings;
- 4) An inspector exercising any power conferred upon him by this Law shall produce on demand a duly authenticated document which shows that the inspector has the authority to exercise the power so conferred upon him.

33. Search and seizure

- 1) Notwithstanding anything to the contrary contained in any other law, if any inspector, customs officer, or police officer has reasonable grounds for believing that any person is in unlawful possession of any prohibited medicine, they may, with a search warrant:
 - a. enter upon any land where such person is believed to be, and there require him to produce for his inspection such prohibited medicine; or
 - b. search such person or any animal in his possession, and enter and search any land, building, vehicle, aircraft, train, vessel or boat in the possession or use of such person, and open and search any receptacle, container or thing in the possession of such person: Provided that a person shall be searched only by a person of like sex and done with the strictest regard to decency and decorum.

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- 2) Any prohibited medicine in the possession of such person shall be seized and, unless the officer is satisfied that such person will appear and answer any charge which may be preferred against them, arrest and detain them.
- 3) Any person who is arrested and detained and any prohibited medicine which is seized shall be taken as soon as practicable before a court of competent jurisdiction to be dealt with according to law.

PART V: OTHER REGULATED PRODUCTS

34. Regulation of technologies and related health care products

- 1) The Agency shall put in force regulations for related medical products and technologies including vaccines and biological; veterinary medicines; medical devices; traditional and complementary medicines; food and dietary products to ensure that they are of quality, safety and efficacious according to internally established standards.

PART VI: OFFENCES AND LEGAL PROCEEDINGS

35. Offences relating to possession, false information and contravention of notice or condition

It is an offence for any person/Institution:–

- 1) to be in possession of any medical products for the purpose of selling, supplying or exporting it in contravention of this Law;
- 2) to contravene any conditions prescribed for the purpose of this Law;
- 3) to be in possession of any medical product knowing or having reasonable cause to suspect that it was imported in contravention of this Law;
- 4) to make, when making an application or a declaration under this Law or giving any information he is required to give under this law, a statement which he knows or has reason to believe is false in a material particular;
- 5) to provide document, when required to avail the Agency with any document under this Law, which he knows or has reason to believe is forged or altered;
- 6) to fail to comply, without reasonable excuse, with a requirement imposed by a notice given under this law;
- 7) to sell, supply, or deliver any medicine in contravention of a notice directed to them; or

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- 8) to fail to comply without reasonable excuse with a notice given under this Law.
- 9) to re-label, re-package, alter a batch and/or lot numbers, alter manufacturing and/or expiry dates on any regulated medical products.
- 10) any person guilty of an offence under the preceding subsection shall be liable on conviction to a fine or to imprisonment or to both.

36. Offences relating to unlawful trading in medical products

It is an offence for any person:–

- 1) to sell, supply or import any medical product in contravention of any regulation made under this Law;
- 2) to be in possession of any medical product, otherwise than for the purpose of performing or exercising a duty or power imposed or conferred by or under this Law or any other written law, knowing or having reasonable cause to suspect that it was sold, supplied or imported in contravention of this Law or any regulation/order made under this Law;
 - a. to import any medical products in contravention of this Law;
 - b. to manufacture, sell or distribute any medicine, whether through another, in contravention of this Law or any notification issued under this Law;
 - c. to deal in or manufacture counterfeit medical products;
 - d. to distribute or advertise any medicine in contravention of any prescribed condition;or
 - e. to attempt, conspire with another, incite, or be accessory after the fact to the commission of, any offence under this Law relating to unlawful trading in medical products.
 - f. willfully delay or obstruct an inspector in the exercise of his powers under this section; or
 - g. refuse or fail without reasonable excuse, to give any information which he is lawfully required to give under this section; or
 - h. give any information which is false in a material particular or which he reasonably believes to be untrue.
 - i. sells, offers or exposes that product regulated under this Law for sale;
 - j. deposits or consigns that product regulated under this Law to any person for the purpose of distribution, sale or manufacture for sale;
 - k. uses that product regulated under this Law in any other way; or removes, alters or obliterates the mark, seal or other designation with intent to deceive any person.
 - l. Repackages that product regulated under this law for purposes of exportation for sale, distribution or use.



37. Reasonable belief

- 1) Where the holder of a manufacturer's license is charged with an offence in respect of any medical product which has been manufactured or assembled by them, in circumstances where they are not the holder of a product license which is applicable to that medical product, but the medicine was manufactured or assembled to the order of another person, it shall be a defence for the holder of the manufacturer's license to prove that they believed, and had reasonable grounds for believing that the other person in question was the holder of a product license applicable to that medicine, and that the medical products were manufactured or assembled in accordance with that product license.

38. Administrative Sanctions

- 1) Any person/organization who cause or takes any action, or any failure to act, that violates any provision of this law or any regulation promulgated under this law may be subject to enforcement action in accordance with the provisions of this Part.
- 2) Notwithstanding any civil and/or criminal penalties, further administrative penalties may be imposed.

39. Lack of knowledge

- 1) It shall be a credible defense on a charge of false or misleading advertisement that the accused, not being a person selling the medicine 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 that the advertisement was in any respect 'false' or 'misleading', unless it is proved that the accused failed on demand by the Head of the Agency, 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.



PART VII: ADMINISTRATIVE APPEALS PROCEDURES

40. Appeal Procedures

- 1) A person who is aggrieved by a decision of the Agency may appeal in the manner, and within the period, prescribed, against that decision to the Appeal Committee
- 2) The Agency must appoint an appeal committee to hear an appeal lodged by any such aggrieved person
- 3) The Appeal Committee shall consist of -
 - a. A judge, or a legal practitioner who has practiced as such for a period of at least five years, and who must be the chairperson of the committee;
 - b. A pharmacologist or other person with special knowledge of the actions and applications of medical products; and
 - c. If the appeal relates to a medicine, a medical practitioner who is registered as a specialist in the country in which he or she is practicing, and a pharmacist.
 - d. The Agency may not appoint a person as a member of an appeal committee, if that person has a direct or indirect interest in the affairs of the appellant or the Agency.
- 4) The Appeal Committee must hear the appeal on the date, at the place and at the time determined by the appeal committee, and the appeal committee must notify the appellant and the Agency in writing prior to that date of such date, place and time.
- 5) The Appeal Committee may, for the purposes of the determination of an appeal -
 - a. summon a person, who:
 - b. may be able to give material information concerning the subject of the appeal; or
 - c. the appeal committee believes has in their possession or under their control any document or thing, which may have a bearing on the subject of the appeal, to

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appear before the appeal committee at a date, place and time specified in the summons, to be interrogated or to produce that document or thing, and retain for examination any document or thing produced by that person;

- d. administer an oath to, or accept an affirmation from, a person called as a witness at the appeal; and
 - e. call a person present at the hearing of the appeal as a witness and examine them and require them to produce any document or thing in their possession or under their control.
- 6) The chairperson of the appeal committee must determine the procedure to be followed at the hearing of an appeal.
 - 7) The appeal committee may, after hearing an appeal -
 - a. confirm, set aside or vary the relevant decision of the Agency; and
 - b. direct the Agency to execute the decision of the appeal committee in connection with the appeal.
 - 8) The decision of the Appeal Committee is final.
 - 9) The decision of the Appeal Committee must be in writing and a copy of the decision must be furnished to the Minister responsible for Health, to the appellant and to the Agency.

PART VIII: HARMONIZATION OF REGULATION OF MEDICAL PRODUCTS AND INTERNATIONAL COOPERATION

41. Participation in regulatory harmonization schemes

- 1) The Agency shall participate and cooperate with any regional or continental medical products regulatory agencies.
- 2) The Minister responsible for Health matters shall ensure the Agency's participation in regional and continental medical products regulatory harmonization activities.



- 3) The Minister responsible for Health shall report the performance of the Agency in regional and continental council of Ministers of Health meetings.

42. Harmonization of regulatory requirements and activities

The Minister responsible for Health and the Agency shall take such measures to ensure effective co-operation with the Ministers responsible for Health and the Agency in other countries of the region to:

- 1) Harmonize registration of medical products, Inspections, QMS, IMS, Joint Evaluations, Joint Inspections and any other regulatory activities as may be appropriate.
- 2) Provide for the use of accredited quality control laboratories within the harmonization framework.
- 3) Provide for the recognition of regional and other international technical guidelines developed and published by the World Health Organization, and the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use.
- 4) Provide for harmonization of the data requirements for evidence of quality, safety, and efficacy of medical products and the grounds on which authorization for distribution shall be granted within the region.
- 5) Provide for any necessary legal mechanisms for regulatory harmonization and enforcement.
- 6) The Minister and Agency shall take such measures that may ensure mutual recognition of regulatory decisions.
- 7) The Agency shall take such measures to share summary evaluation and inspection reports.
- 8) The Agency shall participate in a common post market surveillance conducted in accordance with national and internationally recognized standards at regional level.
- 9) The Agency shall provide for cooperation with other regulatory authorities for the purpose of strengthening national regulatory capacity;
- 10) The Agency shall establish network with other regulatory authorities and collaborate in protecting public health through enforcement activities; and
- 11) The Agency shall establish exchange programmes with other medical products regulatory authorities so as to keep abreast with the ever evolving scientific development in the field of medical products.



43. Transparency and Information sharing

- 1) The Agency shall provide for the establishment of a Quality Management System based on common regional requirements to improve efficiency and transparency;
- 2) The Agency shall set up systems to provide for the creation of a regional information Management system to which it shall provide and share relevant regulatory information;
- 3) The Agency shall establish paper and electronic web based copies including but not limited to regulations, laws, forms, applications, list of registered drugs;

44. International Cooperation

- 1) The Agency shall share information on pharmaceutical intelligence with other agencies at regional and continental levels as may be provided in the regulations.
- 2) The Minister responsible for Health shall take proper measures to ensure effective bilateral, regional and international co-operation to combat the production, circulation and use of falsified and substandard medical products, illicit drugs, narcotics and psychotropic substances.

PART IX: MONITORING AND EVALUATION

45. Monitoring and Evaluation of National Regulatory System

- 1) The Agency shall create a monitoring and evaluation unit charged with reviewing and assessing the performance of the system.
- 2) The Agency shall prepare periodic reports and present to the Minister responsible for Health.

46. Monitoring and Evaluation of Regulatory Harmonization Schemes

- 1) The unit in charge of monitoring and evaluation shall monitor the progress of the Agency made in regards to NMRAs participation in regulatory harmonization schemes and the application use of such schemes and processes into national regulatory systems.



PART X: REGULATIONS

47. Application of Model Regulations

There shall exist model regulations annexed to this Act, to facilitate implementation by the member state.

48. Powers to Make Regulations

- 1) The Minister responsible for Health shall have powers to make regulations in various matters on the recommendations of the Agency, including:-
 - a. governing testing of medical products;
 - b. governing the location of pharmaceutical plants or testing facilities, including prohibiting or regulating the construction, installation, use, operation or changing of such plants or testing facilities;
 - c. governing the keeping of information, records and documents by persons who manufacture, offer for sale, sell medical products and other medical products
 - d. prescribing appliances and minimum health and safety standards in any pharmaceutical plant or storage facility;
 - e. prescribing standards or requirements for medical appliances or products;
 - f. prescribing the contents of labels or marks that may be placed on or with medical products, appliances and products;
 - g. prescribing fees to be paid to designated persons or organizations for the testing or labelling of medical products, appliances and products and prescribing by whom the fees shall be paid;
 - h. regulating the installation, testing, maintenance and repair of appliances any pharmaceutical plant;
 - i. regulating the testing of any medicine or medical technology appliance or equipment;
 - j. designating persons or organizations to test medical appliances and products;
 - k. Providing for the placing of a prescribed label or mark on or with medical products, appliances and products that conform to the prescribed standards;

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- l. providing for information to be reported by persons who manufacture, offer for sale, sell or lease medical products, appliances or products, including the frequency, time and manner for reporting;
 - m. the manufacture, compounding, dispensing, possession, sale or use of any medical products; or the manufacture, possession, sale or use of:-
 - a) any substance which is used, or manufactured, sold or presented as suitable for use for the dressing of wounds or the stanching or absorbing or bleeding or other discharges from the body; or
 - b) any medicine 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 Agency, such regulations are desirable in order to prevent infection or allergy or any other harmful effect resulting from that use; or
 - c) any medicine 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 Agency, such regulations are desirable in the public interest.
 - d) The regulations referred to in sub-section (a), may prescribe the precautions to be taken by a person in possession of any medicine to ensure its safe custody and the action to be taken by such person in the event of its destruction, loss or theft.
- 2) In making such regulations, the Minister on advice of the Agency shall use the model regulations as a reference.

PART XI: MISCELLANEOUS PROVISIONS

49. Internet Vigilance

- 1) Every distributor, vendor, importer or exporter of medical products who is trading on the internet must be registered in the countries in which he does business.

PART XII: STATUTORY AND TRANSITIONAL ARRANGEMENTS



50. Preservation of secrecy

- 1) No person shall, except for the purpose of the exercise of his powers or the performance of his functions under this Law, or for the purpose of legal proceedings under this Law, or when required to do so by any competent court or under any law, or with the written authority of the Agency, or if it is in the public interest, 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; provided that a disclosure may be permitted in order to promote transparency and the right of the public to timely, accessible and accurate information.

51. Statutory instrument governing transitional matters

- 1) In order to facilitate the effective translation of this "Model Law" into national substantive law of states as well as its application, the competent national authorities of the States shall take all relevant steps for transitional arrangements to avoid a situation of a "legislative vacuum"

52. List of repeals

- 1) The competent State authorities shall take all relevant steps to repeal or amend national regulations that are contrary to the provisions contained in the "Model Law" regardless of the nature of these regulations (Legislative or regulatory).



53. Statement of Objects and Reasons

Access to affordable, safe, quality and efficacious medical products on the African continent has been challenging for decades. This is partly attributed to weak or inexistent medical products regulatory systems in most African countries. Studies have shown that the majority of African countries either lack or have weak legislation and regulations to protect the public against hazards associated with the use of poor quality and unsafe medical products.

The poor access to medical products had necessitated the inception of efforts by the African Union (AU) through the 55th Decision of the AU in 2005 and the subsequent endorsement of the Pharmaceutical Manufacturing Plan for Africa (PMPA) in 2007 by the AU Ministers of Health. The PMPA provides a framework for improving medicines access to the African population. The 19th AU Assembly decision on Roadmap for Shared Responsibility and Global Solidarity for AIDS, TB and Malaria response in Africa, further emphasizes on the need to accelerate and strengthen the implementation of the PMPA and regional medicines regulatory harmonization initiatives that lay a foundation for a single African regulatory agency.

The national medicines regulatory agencies (NMRAs) are mandated to regulate medical products within their national territories. On-going efforts on regional harmonization of medical products are hampered by the fact that member states do not mutually recognise decisions made by other agencies. In addition, national legislations do not contain provisions that impose obligations to harmonise regulatory requirements and procedures for regulation of medical products. Admittedly, this has a negative effect on regional harmonisation efforts being undertaken by regional economic communities (RECs). The varying determination and commitment by Member States to domesticate regional treaties calls for national implementing policies, legislation and regulations that enable Member States to fulfil treaty obligations on regional medicines regulation.

Noting the above challenges, the meeting of the Pan African Parliament Committee on Health Labour and Social Affairs (PAP–CHLSA) of July 2011 proposed that a Model Law is required to address legislative gaps that hamper effective medicines regulation and regional harmonization. The development of the Model Law also aimed at ensuring a systematic approach for the development of a harmonized legislation on medicines regulation in African



countries that supports the African Union course of promoting local production of pharmaceuticals with a view to protect public health and contribute to economic growth.

The Model Law on Medical Products Regulation and harmonization in Africa inter alia seeks to:- i) Provide a comprehensive guide to member states in the review and/or development of national legislation; ii) Provide a framework to support member states and RECs in their endeavour to harmonise medical products regulation; and iii) Provide an enabling regulatory environment for the private sector to deliver quality, safe and efficacious medical products and technologies to the African population.

In order to facilitate the implementation of regional and national harmonisation efforts, the model Law will be accompanied by model regulations which will be developed based on identified needs by countries and their respective RECs.