AUDA-NEPAD
AFRICAN UNION DEVELOPMENT AGENCY

THE ACCESS AND DELIVERY PARTNERSHIP
New Health Technologies for TB, Malaria and NTDs

Disclaimer

The Guidance Document is a resource document to assist AU Member States in domesticating the AU Model Law. It is not a legally binding document. It contains practical and informal guidance on the provisions of the AU Model Law, but it does not form part of the AU Model Law. The Guidance Document aims at providing a better understanding of some parts of the AU Model Law, but it is not an exhaustive description of all the provisions in the AU Model Law.

For any enquiries, please contact:

Janet Byaruhanga at AUDA-NEPAD: JanetB@nepad.org

230 15th Road, Randjespark, Midrand, Johannesburg, 1685, South Africa

Office: +27 11 256 3600
Facebook: @nepad.page
Twitter: @nepad_agency
Instagram: @auda_nepad
#TheAfricaWeWant
www.nepad.org

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A GUIDANCE DOCUMENT FOR DOMESTICATION OF THE AFRICAN UNION MODEL LAW ON MEDICAL PRODUCTS REGULATION

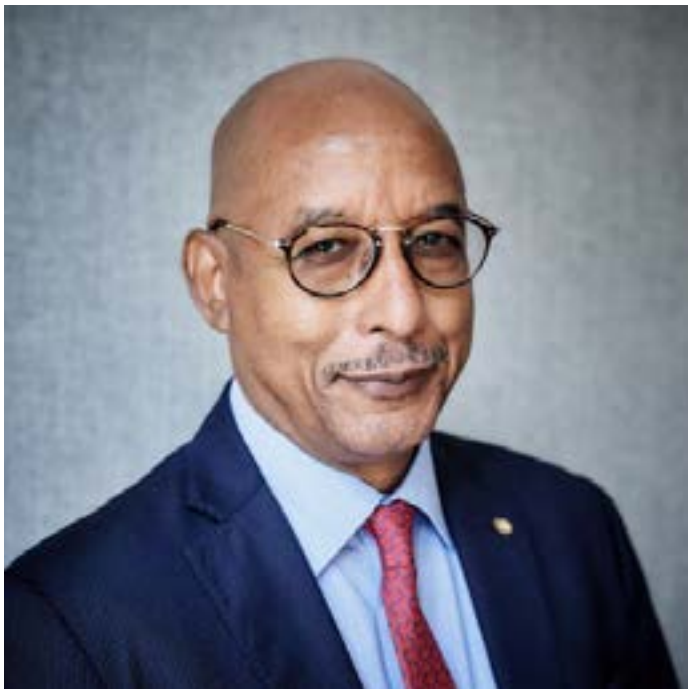
Contents

Acronyms and Abbreviations

ADP	Access and Delivery Partnership
AMA	African Medicines Agency
AMRH	African Medicines Regulatory Harmonization
AU	African Union
AU Model Law	African Union Model Law on Medical Products Regulation
AUDA-NEPAD	African Union Development Agency
ECOWAS	Economic Community of West African States
LMICs	low- and middle-income countries
MoA	Memorandum of Agreement
QCL	Quality Control Laboratory
RECS	regional economic communities
SADC	Southern African Development Community
SF	substandard and falsified
SSFFC	substandard, spurious, falsified, falsely-labelled and counterfeit
TWP-MPRR	Technical Working Group on Medicines Policy and Regulatory Reforms
UNDP	United Nations Development Programme

Foreword

Dr Ibrahim A. Mayaki
Chief Executive Officer of the AUDA-NEPAD



Recognizing the importance of efficient and aligned regulatory systems for access to new health technologies, the African Heads of State and Government at the African Union Summit in January 2016 adopted the African Union Model Law for Medical Products Regulation (AU Model Law). The AU Model Law provides a comprehensive legislative template that can be adapted and adopted by AU Member States and regional economic communities towards regulatory harmonization across the continent, consistent with international standards.

A harmonised legal environment for the regulation of medical products will be a requisite enabler for the effective operation of the continent-wide African Medicines Agency, the establishment of which will be another crucial step towards regulatory harmonization and improved functioning of national regulatory authorities in Africa. Ultimately, it is hoped that these harmonization efforts will result in the achievement of the AU's Pharmaceutical Manufacturing Plan for Africa, which envisions an African people with access to essential quality, safe and effective medical products.

The Guidance Document for Domestication of the African Union Model Law on Medical Products Regulation (Guidance Document) will serve as an important tool to accelerate the harmonization process. The Guidance Document was commissioned by the African Union Development Agency (AUDA-NEPAD), with the support of the Access and Delivery Partnership (ADP), which is a global health project led and coordinated by the United Nations Development Programme (UNDP). AUDA-NEPAD and UNDP are longstanding partners, which have worked together to promote the development of the African Union (AU) Model Law on Medical Products Regulation (AU Model Law), and since its adoption in 2016 by African Heads of State and Government at the AU Summit, its domestication within the national legal and regulatory frameworks of AU Member States.

AUDA-NEPAD and UNDP gratefully acknowledge the roles and contributions of various individuals and institutions in the development and finalization of this Guidance Document.

Grateful thanks are due to Professor Yousuf Vawda, who wrote this Guidance Document. Professor Vawda draws on his experience and expertise as one of the technical experts who contributed to the development and drafting of the AU Model Law since the inception of the process in 2014.

Thanks are also due to Safiatou Simporé, who prepared the Survey on the Status of Domestication of the AU Model Law (the Survey) in Annex 2 of this document.

Representatives from the AU Member States and Regional Economic Communities, in particular the participants of the October 2018 Technical Seminar on Promoting Domestication of the AU Model on Medical Products Regulation, jointly organized by AUDA-NEPAD and UNDP, and the May 2019 Regional Training Workshop on the AU Model Law on Medical Products Regulation, organized by AUDA-NEPAD, are acknowledged for their inputs, information and feedback that contributed to the preparation of the Guidance Document and the Survey.

A draft version of the Guidance Document has been used as a reference document to aid the domestication processes in several AU Member States. This use included the initiative under the Southern African Development Community (SADC) Medicines Regulatory Harmonization Project, supported by the World Bank, which provided technical assistance to Comoros, Madagascar, Namibia and Seychelles, to review and update their legislation in line with the AU Model Law during the period from May to July 2020, and the on-going domestication processes in Ghana and Senegal, which are supported by ADP. Such use has also facilitated additional feedback and inputs from various stakeholders, which have been duly incorporated into this version of the Guidance Document.

Acknowledgements are also due to the African Medicines Regulatory Harmonization (AMRH) Technical Committee on Medicines Policy and Regulatory Reforms.

Finally, the contributions of AUDA-NEPAD and UNDP staff are gratefully acknowledged: Margareth Ndomondo-Sigonda, Janet Byaruhanga and Vanessa Msengezi from AUDA-NEPAD are thanked for their guidance and coordination roles, while Cecilia Oh, Judit Rius Sanjuan, Amitrajit Saha and Desiree Gomez from UNDP are thanked for their technical inputs and support in the development of the Guidance Document and the Survey.

I hope all Member States and regional economic communities, with the support from relevant stakeholders and partners, will ensure the wide dissemination and use of this Guidance Document.

MODULE I

Introduction

African Heads of State and Ministers for Health have long been concerned about the effective regulation of medical products on the continent. This arose out of the commitment of Member States of the African Union (AU) to "protect the health of their people towards the attainment of the highest possible physical and mental wellbeing of all"[1] through the regulation of medical products and adequate mechanisms for guaranteeing their quality, safety and efficacy. Another reason for the need of regulation relates to the concern about the proliferation of substandard and falsified (SF) products, which pose a major health threat across the continent. One critical measure is to help countries strengthen their regulatory capacity through the mechanism of the African Union Model Law on Medical Products Regulation (Model Law); another is the treaty for the establishment of the African Medicines Agency (AMA).

The AU Model Law process began in early 2014 with the development of a zero draft, on which comment was invited from a range of stakeholders and experts. Subsequently, a first draft was presented at regional stakeholder consultations within the AU regions during the period from 2014 to 2015. The draft was then amended after inputs received at the regional meetings. Next, the draft incorporating the feedback from the regions was submitted through the governance structures of the AU, and the final version of the AU Model Law was officially adopted by African Heads of State and Government at the AU Summit in January 2016, in Addis Ababa, Ethiopia. The AU Model Law provides a template for countries to harmonize their regulatory frameworks and outlines the key functions and standards that should form part of the regulatory system. These provisions will be discussed in greater detail below.

> *A unique feature of the AU Model Law process is the extent of stakeholder consultation and participation in the development of the legislation, which took place during 2014-2015. The AU Model Law process is not an isolated development, but is complemented by partnerships, regional integration initiatives, incorporation of global best practices in medicines regulation, and a pharmaceutical plan for the continent. These elements will go towards ensuring the AU Model Law's relevance and sustainability.*[2]

The AU is now supporting Member States in domesticating the AU Model Law into their national legislation. The African Union Development Agency (AUDA-NEPAD) is coordinating capacity-building and providing technical assistance to enable countries to review their legislation in place on medical products regulation and effect the requisite amendments in order to align them with the AU Model Law. The respective Regional Economic Communities (RECs) are actively involved in facilitating this process.

This guidance document aims to assist countries as they navigate through the domestication process. It provides material on understanding key concepts, guidance on how to draft legislation and a chapter-by-chapter analysis of the AU Model Law, explaining the meaning of each provision and the reason for its inclusion. It also offers useful drafting suggestions. All of these features will enable countries to align their regulatory laws to the AU Model Law and will not only facilitate effective regulation in each country but will also advance the goal of the harmonization of regulatory systems.

1 Article 16, African Charter on Human and Peoples' Rights, https://www.achpr.org/legalinstruments/detail?id=49.

2 African Union Model Law for Medical Products Regulation: Increasing access to and delivery of new health technologies for patients in need, ADP Issue Brief (2017). Available at: https://adphealth.org/upload/resource/AU%20Model%20Law.pdf (accessed on 6 September 2021).

MODULE II

What Does Domestication Mean?

In the legal context, 'domestication' refers to the legislative action taken to incorporate into the national legislation, an agreement or treaty of a regional, continental or international institution. Although the AU Model Law is not a treaty, it requires a similar act of domestication to become domestically binding in an AU Member State. Thus, there will need to be a process at the national level in the individual AU Member States to ensure that the national law is in alignment with the AU Model Law.

When is the AU Model Law regarded as having been domesticated in a country?

The following are the possible scenarios:

a. A country's regulatory law is already in alignment with the AU Model Law.

b. A country adopts the AU Model Law verbatim as its regulatory law.

c. A country adopts all the essential provisions of the AU Model Law.

d. A country adopts some of the provisions but not all the essential provisions.

e. A country does not make any changes to align with the AU Model Law.

In scenarios a, b and c, it is deemed that the country has domesticated the AU Model Law; in scenarios d and e, it is deemed that the country has not domesticated the AU Model Law.

A question that arises is: **What are the essential provisions of the AU Model Law?**

A useful rule of thumb is to clarify if there is anything in the national law that would be an impediment to regional and continental harmonization, which in turn leads to what should be considered 'essential' (i.e. non-negotiable).

The list of essentials should include the following:

- There must be a national authority that has responsibility for regulating medical products.
- The products must include medicines, vaccines, diagnostics and medical devices.
- Approval of medical products must be based on quality, safety and efficacy.
- Assessments must be conducted by appropriately qualified technical experts (or the country may rely on the expertise of another regulator).
- In addition to registration of medical products, the authority must also undertake the licensing of manufacturers, importers, exporters, wholesalers and distributors.
- The authority must also be responsible for the approval of clinical trials and quality and safety surveillance of products circulating in the market.
- There must be in place procedures for regulatory inspection and enforcement, with appropriate powers, as well as fairness, due process and appeal procedures.
- There must be in place mechanisms for regional collaboration, harmonization of guidelines and standards, information sharing and regulatory reliance on decisions made by other agencies.

Where the relevant law of a country contains these basic provisions, this would represent the minimum standard for domestication provided that nothing in other laws of the country bars the remaining provisions in the AU Model Law from being permitted. For example, the law on regulation of medical products of a country may not refer to International Cooperation and Harmonisation (Part VI of the AU Model Law) or Protection of and Access to Information (Article 34 of the AU Model Law). In such instances, where there is nothing to the contrary in any other law of the country, the said law will be deemed to have all the essential provisions of and be substantially aligned with the AU Model Law.

MODULE III

A Note on Legal Drafting

While there are certain conventions (rules) that are followed in the drafting of legal documents, they do not have to be written in archaic and inaccessible language. The following are some guidelines to consider when drafting legislation.[3]

A basic approach

There is no one-size-fits all formula for this task. However, a measure of uniformity may be required, especially in the light of the harmonization process that is taking place across the continent. The AU Model Law should be used as a flexible guide rather than a prescriptive document. The use of plain language, whether in Arabic, English, French or Portuguese, is to be encouraged for reasons elaborated on below.

Legal conventions

Legislation usually follows a standard structure. The following checklist may be useful to ensure that important provisions are not omitted:

- Cover: This typically has the coat-of-arms of the country and the subject of the legislation.
- General explanatory note: This indicates what the legislation is addressing.
- Long title: This is the full name and citation of the legislation.
- Preamble: This provides important background and context to the legislation.
- Arrangement of sections: Similar to a table of contents page, this is often further divided into chapters.
- Definitions and interpretation: This provides the meaning of terms of art (that is, terms that are unique to the subject of this legislation) as well as the interpretation of other commonly used words in the context of this legislation.
- Main and ancillary provisions: The main provisions explain how the subject and main aspects of this legislation are to be dealt with; the ancillary provisions are the supporting sections or clauses that enable the main clauses to function.
- Repeal and amendment of laws: Where new legislation is drafted, it provides that the existing law dealing with the same subject matter will be repealed once the new legislation takes effect. More commonly however, amendments are made to the existing law to replace specific sections.
- Transitional provisions: These are provisions on how the law will be applied during the transition from the existing to the new legislation.
- Short title and commencement: This is a shortened form of the legislation, for common usage, and it also states when the legislation comes into force.
- Schedules: These are lists or catalogues attached to the legislation that contain relevant information on matters referred to in the main body of the legislation.
- Memorandum on Objects: At times, a detailed background of the rationale and evolution of the law is attached to the legislation.

Drafting in plain language

Drafting in plain language is an important recent trend, allowing for legal documents (whether contracts or legislation) to be understood by a wider range of individuals, and not only by legally qualified individuals. As a start, it is important that the draft be grammatically correct. Ensure that unnecessary words, phrases and clichés are omitted. The structure of sentences should be brief and readable. It is vital to use precise language (i.e. find the best word to convey the exact meaning), in order to avoid confusion and disputes over interpretation. However, care should be taken not to oversimplify language to the extent that it loses meaning. Careful attention also needs to be paid to punctuation; for example, a comma or full stop incorrectly placed can drastically change the meaning of a sentence.

Legal and Policy Coherence

It is important that there are no conflicting provisions between this law and other applicable laws, as well as

3 In this document, the terms “legislation” and “law” are sometimes used interchangeably. Generally, however, the term “legislation” is used to describe the law that is made by parliaments. Legislation is also referred to as statute law, statutes or Acts of Parliament. The term is also used to describe the act of making a new law. For the purposes of this Guidance Document, the term legislation is used when referring to the draft law or Bill that is being drafted to domesticate the AU Model Law into the law of the country.

within this law. Conflicting provisions can lead to disputes, requiring clarification by a court. Significantly, they can impede a government's ability to discharge its functions, such as service delivery to its population. Alignment of this law with a country's constitution is important, given that the latter is the supreme law of the country. Finally, this law should also be aligned with other existing legislation, even though its scope will be confined to the subject matter at hand. This is important for policy, legal and implementation coherence.

Application of these guidelines to the AU Model Law process

First, the draft legislation for each country must be responsive to national needs and must also be capable of harmonization and alignment with those of others, as well as with regional and continental initiatives. There is, in fact, a high level of alignment and synergy between the AU Model Law and the AMA Treaty, so this is not a major hurdle. Second, as indicated above, it must be expressed in precise language to avoid ambiguities, using plain language where possible. Finally, the legislation must be in line with sound constitutional and human rights values, especially the rights to life, health and dignity. It must pay attention to ethical concerns such as the avoidance of conflicts of interest. Finally, it must promote accountability through clear provisions relating to transparency in the functioning of the relevant public agencies and public participation in decision-making.

MODULE IV

AU Model Law: Chapter-by-Chapter Analysis

Structure of the AU Model Law

The AU Model Law consists of a Preamble and ten Parts. The Parts are further divided into thirty-five Articles. Each Part and Article are discussed below, in terms of the meaning, significance and rationale of the individual section.

Title

The long title of the AU Model Law is the **African Union (AU) Model Law on Medical Products Regulation**.

Preamble

A Preamble is an important political statement outlining the intentions of the drafters and the background to the law. It provides the framework for the AU Model Law and affirms the AU mandate to spearhead its implementation. It references key international human rights instruments relevant to health and medicines as well as important decisions and declarations made by the AU in pursuance of the goals of protecting the right to health, developing regulatory systems and promoting pharmaceutical manufacturing on the continent. It also records significant concerns, including the proliferation of SF products.

Important note: There was an error in the printed version of the AU Model Law in the first paragraph of the Preamble. The reference to 'Article 12 of the International Covenant on Civil and Political Rights' should instead read 'Article 12 of the International Covenant on Economic, Social and Cultural Rights'.

> **Drafting Suggestion**
>
> It is advisable to adopt a shorter version of this Preamble and include details of the specific country context in the national legislation.

Part I: General Provisions

Article 1: Short Title

The Law on Medical Products Regulation.

Article 2: Scope of Application and other laws

The purpose of this provision is to bring the national law in line with the AU Model Law. To the extent that provisions in existing national law are in conflict with those in the AU Model Law, these provisions must be repealed or amended. This is because the country has signed the AU Model Law, through its Head of State, which obliges it to apply the AU Model Law within the country.

> **Drafting Suggestion**
>
> This law shall apply to all medical products. In the event of any conflict with any other law on medical products, the provisions of this law shall prevail.

Article 3: Purpose

The purpose states clearly why the legislation is being put in place; it is to establish an effective and efficient system of medical products regulation and control on the triple requirements of safety, efficacy and quality.

> **Drafting Suggestion**
>
> The principle that medicines will be registered for use only when they have met the requirements of quality, safety and efficacy is non-negotiable.
>
> Other language can be used to suit a country's unique needs; for example, instead of 'medical products', a country's law may regulate 'medicines', or 'health technologies' or 'medical products, food and cosmetics', as the case may be.

Article 4: Definitions

This is an important provision in any legislation where meaning is given to the key terms or concepts used. The meaning may be different from the commonly understood meaning, so the legislation must be interpreted in accordance with the definitions provided. The AU Model Law provides for the definitions of terms typically used in laws relating to regulation of medical products.

Drafting Suggestion

It is important that national legislation, in using the terms in the AU Model Law, defines them in exactly the same way as the AU Model Law, in the interest of uniformity and harmonization.

If a country decides, for example, to include food or cosmetics in its regulatory law, then it would be able to add these to the definitions without altering the effect of the law. It could take the following approach: modify the title of the act to relate to 'medical products, food and cosmetics'; add definitions of 'food' and 'cosmetics'; and include detailed provisions to indicate how food and cosmetics will be regulated.

Part II: Administration and Governance

Article 5: Establishment of the Agency/Authority

There are two aspects to this provision. First, it proposes to establish a [National] Medical Products Regulatory Agency/Authority, which is a juristic person (with legal capacity) which is autonomous (independent of), but functionally and financially accountable to, the line ministry (usually the ministry responsible for health). Second, it proposes that the Authority[4] will be composed of the Board, the Head of the Authority and the Technical Committees.

It is useful to clarify several points here.

First, the issue of independence. The reason for this provision is to enable the Authority to perform its functions without interference from any party. This not only relates to independence from the executive arm of government, but also from other interested parties, such as the pharmaceutical industry, patient groups and others. Medical products regulation is a scientific function, informed by the criteria of quality, safety and efficacy of the regulated products, and not by extraneous social, economic or political factors. Therefore, guaranteeing its independence is the best way to ensure that these criteria are met. However, the independence of the Authority does not mean that it is a free agent to do as it pleases. Independence and accountability can co-exist. According to the AU Model Law, the "Authority shall be functionally/financially accountable to the line ministry". The Authority must therefore assure the ministry that it has carried out its legislative mandate and must account for all funds that it has received. The Authority can also be censured for deviating from its mandate.

Second, it is possible that a country may not have the resources or capacity to set up a wholly new independent structure. In this instance, the AU Model Law must be applied flexibly. For instance, the regulatory function may be housed within a larger government department. Nevertheless, its independence should be safeguarded, to ensure no interference in its functioning. An example is the Republic of Seychelles, with a small population and a small number of personnel in their regulatory system. It has adapted this aspect of the AU Model Law to create a Medical Products Regulatory Service within the Public Health Authority of the Ministry of Health.

Drafting Suggestion

Ideally, a country should establish an Authority along the lines proposed in the AU Model Law. In reality, because of various factors, such as history, and the lack of resources and expertise, the country may have to modify or adjust according to its needs and resources available. Nonetheless, it is important that the regulatory body is fit for purpose, that is, able to carry out its functions, and that it does so independently, i.e. without any interference in its mandate.

Article 6: Powers of the Agency/Authority

The Authority has wide powers under the AU Model Law, which may be incorporated into national law, as appropriate. Such powers include: granting/withdrawing authorization for medical products, clinical trials and licences to various actors in the supply chain; investigating and prosecuting offences; levying fees; and prescribing standards for categories of products.

Since the Authority is charged with the regulation of medical products, Article 6 enables it to prepare the regulations that facilitate the implementation or carrying out of its functions for the consideration of the Minister. The power to legally approve ('make') the regulations is given to the Minister (appointing authority) in terms of Article 30.

4 The AU Model Law uses the formulation of "Agency/Authority" to denote that countries may choose the term that is most suited or appropriate to the national context and circumstances. In the Guidance Document, where the term "Authority" is used, it is understood to also mean "Agency".

Drafting Suggestion

The AU Model Law provides for a range of powers. A country may not wish to give the Authority all of these powers, or it may wish to give it additional powers (e.g. to regulate disinfectants and poisons in addition to medical products). The national legislation can therefore be amended accordingly.

Article 7: Functions of the Agency/ Authority

The AU Model Law gives the Authority similarly wide functions (in implementing the powers mentioned above). They include: maintenance of a medical products register; conducting post-marketing surveillance; regulation of the promotion and advertising of medical products; the use of unregistered medicines; dissemination of a range of information to health professionals and the public; and collaboration with institutions at the national, regional and international levels.

Finally, the Authority also has the function of appointing or removing its senior management officers. The Authority appoints the Head through its Board.

Drafting Suggestion

Countries can tailor their national legislation to their specific needs, giving their Authority fewer or more functions, provided that these functions are within the ambit of the intent of the AU Model Law. It is advisable, however, to keep the scope of its functions wide because it may be subsequently decided that the Authority could undertake additional functions (e.g. regulation of veterinary products). This will avoid having to go back to parliament to amend the law.

Article 10: Management of the Agency/Authority

The Head of the Authority shall be appointed by the appointing authority on recommendation of the Board. He or she must hold a suitable qualification in medicine, pharmacy, nursing, veterinary medicine or public health. He or she shall be accountable to the Board for the management of the business and affairs of the Authority (including implementation of this law and execution of the decisions of the Board).

This is a useful distribution of power as neither the minister nor the Board has exclusive authority over the Head. Other senior officers shall be appointed by the Board on the recommendation of the Head.

The Authority shall have a range of directorates for its operations (Planning, Monitoring and Evaluation, Research and Statistics; Product Evaluation and Registration; Inspectorate and Law Enforcement; Post-marketing Surveillance; Quality Control; Harmonization and International Cooperation; and Human Resources, Administration and Finance).

Furthermore, with the approval of the Board, the Head shall set up Technical Committees as appropriate, whose reports shall form the basis of regulatory decision-making by the Agency.

Drafting Suggestion

Not all regulatory bodies will have the full range of management structures and functions. Hence, applied flexibly, the national authority shall have the freedom to decide and set up the appropriate directorates and technical committees according to its specific needs, resources and capacity.

Article 12: Funding of the Agency/ Authority

The Authority's funding shall be raised from the following sources: the state; fees for services; income from investments; grants and donations; and loans (with the approval of the minister responsible for finance).

All funds must be raised in accordance with this law, and free from conflicts of interest. Therefore, the Authority should not accept donations or the like from any person, industry or institution that has an interest in its functions.

Drafting Suggestion

Ensuring sustained funding of a regulatory body in low- and middle-income countries (LMICs) can be a challenge. Regulatory authorities in LMICs are not in the same position as the European Medicines Agency and the United States Food and Drug Administration, which can be self-sufficient owing to the volume of applications and the high rate of fees charged. Rather, regulators in LMICs largely depend on contributions from the state, supplemented by user fees. For the sustainability and independence of the regulator, it would be unwise to be dependent on a single source of funding.

Part III: National Regulatory System

Article 13: Marketing Authorisation[5]

There are three important aspects to this provision:

a. All medical products must be registered and have a valid marketing authorisation and certificate of conformity, unless the Authority exempts them from these requirements by publishing a notice to this effect in an official government publication.

b. Where a product was being sold in the country prior to the requirement for registration coming into effect, an application for marketing authorisation must be made within 12 months of the notice requiring registration, and if no application is made, the product may not be sold after the expiration of the 12-month period.

c. Another exemption from registration is when the product is compounded by a pharmacist for a particular patient in the quantity determined by an authorised prescriber, provided that: the product does not contain any prohibited component for which an application for marketing authorization has been rejected; and the active component of such a product is present in another authorised product in terms of this law.

Drafting Suggestion

Going forward, all medical products will have to apply for, and obtain, a marketing authorisation. If the Authority is being established for the first time, or such products were not required to be registered previously, then the products already on the market will have to be registered after publication of a government notice requiring their registration within a specified period; if such products are not so registered, they will have to be removed from the market.

Compounding by a pharmacist is permitted, but under strict conditions that may be provided for in regulations.

Article 14: Consideration of Applications for Marketing Authorisation

The Authority **must** prescribe the appropriate standards for new products; in the case of medicines, for example, this includes the new uses, dosages and formulations. It **may** also prescribe standards and procedures for referencing, relying on or otherwise weighing the assessments and approvals of other regulatory authorities or assessment mechanisms.

The application must be in the prescribed form, together with the prescribed particulars, the prescribed fee, samples of the product, and particulars of a qualified technical person.

The Authority must approve a product if it is satisfied that it is suitable for the intended purpose with respect to its quality, safety and efficacy, and that marketing authorisation is in the public interest.

If it is not so satisfied, it must notify the applicant in writing of the reasons. The applicant shall have one month to respond. If no such response is submitted by the applicant within the said period, or if the Authority is still not satisfied, it shall reject the application.

The Authority must publish the register of approved medical products in the official government publication and on the official website of the Authority.

Drafting Suggestion

The marketing authorisation procedure outlined here is for cases where the regulator has the capacity (or limited capacity) to assess the medical products in order to be satisfied of their safety, efficacy and quality. Where this is not the case, the regulator may refer to, or rely on, the regulatory decisions of another, established regulator. These are some of the available regulatory pathways, for which there should be an enabling provision in the law. Usually, the country will subsequently enter into a memorandum of agreement (MoA) with the country of the established regulator.

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

Anyone conducting any of the above categories of businesses will require a licence issued by the Authority, and the conditions of the licence shall be stipulated in guidelines issued by the Authority.

The Authority provides for issuance, renewal, suspension, exemptions or exceptions, cancellation and revocation of such licences.

Provision must be made for all categories of businesses to comply with Good Manufacturing Practice, Good Distribution Practice and any other good practices as stipulated in the guidelines.

5 Spelling is consistent with usage in AU Model Law.

The Authority shall designate ports of entry for imported medical products.

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

> **Drafting Suggestion**
>
> Even where a small country does not currently have manufacturing facilities for medical products (for example), it will still be useful to include such provisions in the legislation so as to avoid having to amend the law later, when the country has developed manufacturing capability.

Article 16: Post-Marketing Surveillance and Safety Monitoring

This Article involves four different but interrelated functions:

Pharmacovigilance

The Authority must establish a national Pharmacovigilance Programme to monitor and report on the safety of medical products, including: analysis of adverse and other events relating to products generally, and in clinical trials; investigating causes, taking remedial actions, and reporting to international safety monitoring systems; taking appropriate regulatory action when necessary, including revising the marketing authorization or labelling requirements; and issuing guidelines for mandatory reporting by the manufacturers and distributors, and voluntary reporting by health care professionals and the public.

Quality Monitoring

The Authority may institute a risk-based testing scheme (e.g. sampling of medical products throughout the supply chain) to identify at-risk or sub-standard/falsified products and shall take appropriate action.

Recall and Withdrawal of Medical Products

When any product does not conform with standards of identity, strength, quality and purity, or any other specified requirement, the Authority must instruct the licensee to discontinue the sale of the remainder of the batch and recall any portion of the batch already sold.

Where the latest scientific evidence shows a product to be hazardous to public health, unsafe, inefficacious or of unacceptable quality, the Authority shall by notice in an official publication, withdraw and strike off that medical product from the register, issue a notice to this effect to the public and disseminate the information widely.

Disposal of Medical Products

If the Authority considers that it is not in the public interest that a medical product be made available to the public, it may direct that the product be withdrawn from the market and disposed of in the manner prescribed.

> **Drafting Suggestion**
>
> Far from being a luxury, post-marketing surveillance and safety monitoring are critical functions of the regulator. The adverse side effects of an approved medical product may only become known years after it has been placed on the market. Diverse populations may react differently to the same product. It is therefore vital to include these provisions in the law.

Article 17: Regulatory Inspection and Enforcement

This Article deals with three different powers: appointment, authorization and recognition of inspectors; powers of inspectors; and search and seizure.

Appointment, Authorization and Recognition of Inspectors

The Authority must recommend to the relevant minister the appointment of inspectors with relevant qualifications in pharmacy or related science and with knowledge and experience in the inspection of products and facilities and authorize them to perform such functions as stipulated under this law.

Inspectors shall be bound by a code of conduct, have valid identification during the performance of their duties, and shall produce, on demand, a duly authenticated document confirming their authority.

Powers of Inspectors

Inspectors may, at all reasonable times, enter the following types of premises: those on the register of premises; other premises in respect of any person licensed under this law; premises used in the manufacture, marketing or distribution of a medical product that is subject to a marketing authorization or licensing request; and premises suspected of or dealing in products regulated by this law.

They may at all reasonable times: examine or inspect any certificate of marketing authorization, licence, book, electronic information storage system or document on the premises, including the taking of extracts of same to effect examination or inspection; and take samples for analysis or for other examination of any medical products

or substances capable of being used in the manufacture of medical products.

They may also: seize and detain any products, substances or articles containing any prohibited substances that they have reasonable cause to suspect is liable to forfeiture under this law; seize and detain any items that appear to constitute evidence of a contravention under this law; close the premises found to be in contravention of this law; and recommend the institution of administrative, civil and/or criminal proceedings.

Search and seizure

Inspectors, in possession of a search warrant, and on reasonable grounds for believing that any person is in unlawful possession of any prohibited medical product, may enter upon any premises where such person is believed to be present or search such premises or person with due regard to decency and decorum.

> **Drafting Suggestion**
>
> For a regulatory authority to be effective, it must not only have good rules in place, but also the power to enforce them. This is the role of the inspectorate. However, they are not a law unto themselves. For the regulatory authority to gain respect for its integrity and authority, it must be even-handed and follow due process. Inspectors have wide powers, for example, to enter and search premises and seize items, but they must be guided by the law, act with restraint, and in the case of entry, search and seizure, conduct these only on reasonable grounds, and they must obtain a proper warrant before they act.

Article 18: Control of Clinical Trials of Medical Products

All clinical trials of medical products in humans cannot be conducted without the relevant clearance from the National Ethics Committee/Institutional Review Board and authorisation by the Authority. They shall be conducted in accordance with guidelines issued by the Authority (including provisions for Good Clinical Practice and Good Laboratory Practice).

No person can sell, dispense, supply, assemble or manufacture medical products for a clinical trial or medical research unless authorised or exempted by the Authority.

The Authority must maintain a register of all clinical trials conducted in the country.

> **Drafting Suggestion**
>
> Clinical trials are increasingly important for the pipeline of new medical products. These trials often exclude certain groups, such as women or research subjects from LMICs. It is therefore important that African countries participate in such trials. Hence, there is need for proper oversight over clinical trials through ethics and regulatory approvals.
>
> Not having the capacity to oversee the ethics and regulatory approval processes should not disqualify a country from hosting a site for a clinical trial, if desired. The country may consider entering into a MoA with a partner within the region to oversee the approvals.

Article 19: Control of Promotion and Advertisement of Medical Products

The Authority must issue guidelines relating to the promotion and advertising of medical products and for an enforceable Code of Marketing Practice and must approve all promotional and advertising material.

Article 20: Quality Control Laboratory

The Authority must establish a National Quality Control Laboratory to perform the following functions, among others: analyse medical products or any other regulated products that may be deemed to constitute a medical product for the purpose of this law; conduct research and training; and appoint analysts with relevant qualifications to perform these functions.

The Authority may use any accredited laboratory within or outside the country for analysis of medical products and attendant functions.

> **Drafting Suggestion**
>
> If, for example, a country does not have the resources and capacity to set up a Quality Control Laboratory (QCL), but instead relies on the facilities of another country or countries, the law should state that, in the absence of having its own QCL, the country will utilize the facilities of another country.

Article 21: Scheduling, Classification and Control of Medical Products

The Authority is also responsible for the scheduling and classification of medical products and their publication in the official government publication.

Control of medical products will be based on the scheduling status allocated by the Authority:

- scheduled substances that are available for general sale in any retail outlet
- scheduled substances that are available on the professional advice of a pharmacist, without a prescription from an authorized prescriber, and available only in licensed pharmacies
- scheduled substances that are available only on the prescription of an authorized prescriber, and dispensed by a pharmacist or licensed dispenser
- scheduled substances that are available only on the prescription of an authorized prescriber, and dispensed by a pharmacist or licensed dispenser subject to the control measures in:
    - the Single Convention on Narcotic Drugs of 1961
    - the Convention on Psychotropic Substances of 1971, or
    - the United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances of 1988
- scheduled substances that may not be sold except in accordance with a permit (presumably from the minister responsible for health) for the purposes of education, analysis or research, or for individual patient purposes.

Regulations regarding scheduling of medical products shall be issued by the Minister after consultation with the Authority. The matters to be covered in the regulations are:

- requirements for a legal prescription for a scheduled substance
- recognition of categories of authorized prescribers
- licensing of dispensers other than pharmacists
- records of scheduled substances sold on the professional advice of a pharmacist or on prescription of an authorized prescriber
- control measures to be implemented for scheduled psychotropic or narcotic substances
- process of obtaining permits for access to scheduled substances for purposes of education, analysis or research, or for individual patients' purposes
- licensing of importers, exporters and manufacturers of psychotropic or narcotic substances, and the reporting requirements for such substances.

Import, export or manufacture of any substance scheduled as psychotropic or narcotic are prohibited unless a person is in possession of a specific licence issued by the Authority for this purpose.

The Authority must collect necessary data on importation, exportation and manufacture of psychotropic or narcotic substances for reporting to the International Narcotics Control Board, as outlined in the regulations.

Important notes:

1. Article 21(2)(d) is a repeat of 21(2)(c).
2. The correct name in Article 21(2)(e) is the "United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances of 1988".

> **Drafting Suggestion**
>
> Careful attention must be paid to drafting these provisions.
>
> One problem is whether the schedule is part of the Act, and hence may only be updated by the parliament. Since many schedules are frequently updated and amended, it would be impractical to table amendments in parliament each time the schedules are updated. This problem may be resolved by not placing the schedules in the body of the Act but rather as annexures, which the Minister is usually empowered to amend by regulation. All that will be required will be to publish the changes, after calling for public comment, in the official government publication, rather than amending the Act itself.

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

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

The Authority shall issue guidelines stipulating procedures for handling such products, in collaboration with other relevant institutions.

Important note:

For various reasons, the World Health Organization has, subsequent to the adoption of the AU Model Law, changed to the shorter form "**Substandard and Falsified (SF) Medical Products".**

Drafting Suggestion

It is recommended that the new terminology 'Substandard and Falsified (SF) Medical Products' be used in national legislation.

It is also recommended that the term 'counterfeit' not be used because it would constitute a misuse of an intellectual property term in a medical products regulatory law. (The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) applies the term 'counterfeit' in relation to trademark and copyright violations, and not patent-related matters.)

Part IV: Offences and Legal Proceedings

Article 23: Offences

The provision lists the following acts as offences:

- obstructing or hindering to any inspectors from performing their duties
- fraudulently tampering with any sample taken under this law
- making false or misleading statements regarding a medical product or scheduled substance:
  - in the applications for marketing authorization
  - in the course of the application for a manufacturing, importing, exporting, storage, sale or distribution licences thereof or
  - in the course of the sale thereof.
- selling any medical product/scheduled substance in the container of which a false or misleading statement in connection with the contents is written
- contravening the provisions of this law in any way; in particular, relating to:
  - marketing authorisation (section 13)
  - licensing of manufacturers (section 15)
  - recall, withdrawal and disposal of medical products (section 16)
  - control of clinical trials (section 18)
  - control of promotion and advertisements (section 19)
  - scheduling, classification and control of products (section 21) and
  - prohibition of SF products (section 22).

Drafting Suggestion

The general rule is that the failure to comply with the provisions of the law is regarded as an offence. Some actions may also be offences under the common law of a country; for example, a person who falsely labels a medical product can be charged for the common law offence of fraud, or in terms of this law. In addition, specific actions can be listed as offences under this law, just as they are listed under the AU Model Law.

Article 24: Penalties

Committing any of the offences can result in the person who is convicted being punished with a fine, imprisonment, or both.

If a person is convicted, the court can, upon the request of the prosecutor, declare any medical product or scheduled substance seized by the authorities, to be forfeited to the state.

In addition to criminal and civil penalties imposed by the court, administrative penalties may be imposed, and must be stipulated in regulations.

Drafting Suggestion

This law should not spell out the details of the period of imprisonment or the amount of the fines, because these may change depending on circumstances such as the state of the economy or devaluation of the currency, among other things.

The responsible minister should be authorised to make regulations from time to time in order to respond to these changes in circumstances.

Further, the advantage of having civil and administrative penalties is useful when dealing with offending corporate entities, which can be punished for particularly offensive conduct by having substantial administrative fines imposed on them.

Article 25: Establishment of an Administrative Appeals Committee

An appeal may be lodged against a decision of the Authority by any aggrieved person. An Administrative Appeals Committee shall be established, consisting of the following parties: a judge or a legal practitioner who has practised for at least seven years, who shall be the Chairperson of the Committee; practitioners from one of the disciplines relevant to the appeal (medicine, pharmacy,

nursing, veterinary medicine, or public health); and any other specialist in the relevant discipline.

> **Drafting Suggestion**
>
> Countries may constitute the Administrative Appeals Committee according to their respective needs and capacities, provided that the Committee comprises knowledgeable and independent members. For example, where judges are not available, a practising or academic lawyer may preside over the hearing.

Article 26: Administrative Appeals Procedures

The Authority may issue guidelines prescribing the procedure and timeframe for lodging an appeal.

The decision of the Administrative Appeals Committee will be final, subject to the law relating to review by the courts.

Part VI: International Cooperation and Harmonisation of Regulation of Medical Products

Article 27: International Cooperation

The Authority shall cooperate with other national, regional and continental regulatory agencies by:

- Sharing pharmaceutical intelligence on products that pose public health risks.
- Taking appropriate measures for effective bilateral, regional and international cooperation to combat the production, circulation and use of SF products, illicit drugs, narcotics and psychotropic substances.

> **Drafting Note**
>
> While a country can still engage in international cooperation (as most countries do) without an express provision in the medicines regulatory law, it is useful to state this expressly in the law, so that there can be no debate later or delay in efforts to establish international cooperation.

Article 28: Regulatory Harmonisation[6] Initiatives

The Authority shall participate in regional and continental harmonization initiatives and take the following measures to give effect to this commitment:

- Harmonise the registration of medical products, inspections, quality management systems, information management systems, joint evaluations, joint inspections and any other regulatory activities as may be appropriate.
- Provide for the use of accredited quality control laboratories within the harmonisation framework.
- Provide for the recognition of regional, continental and international technical guidelines.
- Provide for the harmonisation of data requirements for evidence of quality, safety and efficacy of products, and the grounds on which authorization for distribution shall be granted within the region.
- Provide for mutual recognition of marketing authorisation decisions.
- Share summary evaluation and inspection reports.
- Participate in post-marketing surveillance conducted in according with nationally and internationally recognized standards.
- Provide for cooperation with other regulators to strengthen national regulatory capacity.
- Establish networks with other regulators to protect public health through enforcement activities.
- Establish exchange programmes with other medical products regulators to keep abreast of evolving scientific developments on medical products.
- Provide for legal mechanisms for regulatory harmonisation.
- Provide for transparency and information sharing by:
    - establishing a Quality Management System on common regional and continental requirements; and
    - creating a national information management system, which allows for sharing at regional and continental levels in line with relevant laws and agreements.

6 Spelling is consistent with usage in AU Model Law.

Drafting Note

While harmonisation entails a range of activities, in most cases, all that is required is for the law to include provisions to make these possible. Countries with limited capacity should be able to participate in regional and continental initiatives, and also to rely on decisions made by other agencies

Part VII: Monitoring and Evaluation

Article 29: Monitoring and Evaluation of National Regulatory System

The Authority must create a monitoring and evaluation system to review and assess the performance of the national regulatory system.

It shall prepare periodic reports and present them to the ministry responsible through its Board.

The government representative shall report on the Authority's performance to the governing bodies of the relevant regional or continental oversight structures.

Drafting Note

It is important that an independent monitoring body or system be set up to review the work of the Authority, as a check on the mandate of the Authority and to ensure accountability. It does not have to be an elaborate body or system but must be sufficiently resourced to carry out this function.

Part VIII: Regulations and Guidelines

Article 30: Regulations

Regulations are usually made by the minister responsible for health, in consultation with the Authority, to further the objectives of the Act.

Article 31: Guidelines

Guidelines are usually issued by the Authority, also to further the objectives of the Act.

In general, both require, within a reasonable time, the publication of the text of the regulation or guidelines (as the case may be) in the official government publication, notifying of the intent to officially publish them, and inviting stakeholders to furnish any comments or representations for consideration.

Drafting Suggestion

Regulations and Guidelines are important aspects of legislation that play distinct roles in conveying the law. Regulations and Guidelines must cover all the core regulatory functions. The table below reflects how these primary, secondary and tertiary levels of legislation relate to one another, the responsible authority for their enactment, and their specific functions.

This table represents a template – the details may differ from country to country.

Features of the Law	Act	Regulations	Guidelines
Level	Primary	Secondary	Tertiary
Passed by	Parliament	Minister	Authority
Enactment by	President: by notice in official publication	Minister: by notice in official publication	Authority: by notice in official publication
Function	Authoritative statement on the law	Implementation of provisions of the Act	Procedures or Information for specific matters
Hierarchy	Must comply with the country's Constitution and align with other legislation	In addition, must comply with provisions of the Act on which they elaborate	In addition, must comply with relevant regulations
Example	Medicines Act	Regulation specifying procedures for an application for the registration of a medicine.	Guidelines specifying the list of documents to be supplied in the dossier in such an application.

Part IX: Miscellaneous Provisions

Article 32: Declaration and Conflict of Interests

All staff, Board and committee members are required to declare any interests related to medical products or to any decision-making of the Authority; any identified conflicts of interest must be managed in accordance with established guidelines.

> **Drafting Suggestion**
>
> This is an important provision to ensure that the regulatory process is free of influence from any party.
>
> The Guidelines on Declaration and Conflict of Interests are another example of tertiary legislation.

Article 33: Restriction of Liability

The Authority, the Board, committee members and staff shall not be personally liable for any losses to another party for any decision made in good faith and in accordance with all laws.

However, they shall be liable for such losses due to willful misconduct, gross negligence or non-compliance with any law.

> **Drafting Suggestion**
>
> This is an important indemnity both to protect individuals acting in good faith, and to encourage individuals with expertise to offer their services in the public interest, without fearing personal liability for mistakes made in good faith.

Article 34: Protection of and Access to Information

The general rule is that there shall be no disclosure of information on the business or affairs of any person, obtained in the course of work with the Authority, or the use of such information for self-gain or the benefit of one's employer.

The exceptions to this rule are that a person may disclose information:

- for the exercise of powers and functions under this law, with the written permission of the Authority
- when required to do so by any competent court, or under any law or
- if it is in the public interest.

> **Drafting Suggestion**
>
> It is important to make such exceptions for the proper administration of the regulator and in the interest of justice, as well as in the public interest, which is best served by the transparency of the work of the regulator.

Article 35: Regulation of Other Related Products

The Authority may regulate other medical products, not covered by the AU Model Law.

As defined in Article 4, 'other regulated products' may include complementary medicines, cosmetics, food and related products. The range of products could also be extended to include traditional health products, blood and blood products, and food supplements, among others.

> **Drafting Suggestion**
>
> Countries should decide what products they want to regulate and include them in the law.
>
> They also have the option of including other products subsequently, but this will require an amendment to the law through parliament.

Part X: Commencement

The law shall commence in accordance with the legislative procedures of the country.

> **Drafting Suggestion**
>
> While this usually occurs when the President signs the Bill, different legal systems may approach this process differently.

Annex 1: 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

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

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

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

3) 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.

4) 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:-

3) 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;

4) 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;

5) 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;

d) 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 commence in accordance with the legislative procedures of each state

Annex 2: Status of Domestication of the African Union Model Law on Medical Products Regulation – Survey Results

Introduction

The African Medicines Regulatory Harmonization (AMRH) initiative, within the framework of the African Union (AU) Pharmaceutical Manufacturing Plan for Africa, set a target in its AMRH Strategic Framework (2016-2020) to domesticate the AU Model Law in at least 25 AU Member States by 2020.[7] To accelerate achievement of this target, AMRH established the Technical Working Group on Medicines Policy and Regulatory Reforms (TWG-MPRR) to support and guide the domestication process. Pursuant to the recommendation of the TWG-MPRR, the African Union Development Agency (AUDA-NEPAD) is coordinating legal capacity-building and providing technical assistance to enable countries to review their existing legislation on medical products regulation and effect the requisite amendments in order to align them with the AU Model Law. At the Fifth Meeting of the TWG-MPRR held in Midrand, South Africa, in October 2018, the TWG-MPRR agreed to undertake a survey to determine the status of the domestication process of the AU Model Law in Member States.

AUDA-NEPAD and the Access and Delivery Partnership (ADP) collaborated on the conduct of a survey and the consolidation of the responses from AU Member States and Regional Economic Communities (RECs) on the status of the AU Model Law domestication process in the individual AU Member States. The responses are compiled in this report, which aims to provide a snapshot of the status of the domestication process at the national level. This report, in analysing the survey responses, also aimed to identify the key challenges faced by AU Member States in the domestication process and their technical assistance needs.

This report is based on self-reported information from AU Member States and is intended as a working document that is updated as new information becomes available.

Methodology

Information in this report was compiled from the responses provided by representatives of AU Member States to a survey questionnaire. Supplemental information was also obtained from participants during training sessions and workshops organized by AUDA-NEPAD, during the period from September 2018 to June 2019. As noted above, information in this report is self-reported.

The first survey questionnaire was sent to selected AU Member States in September 2018, prior to the Technical Seminar on the AU Model Law, jointly organized by AUDA-NEPAD and ADP in Midrand, South Africa in October 2018. The Technical Seminar was attended by legal and regulatory experts from 13 AU Member States: Burkina Faso, Côte d'Ivoire, Egypt, Eswatini, The Gambia, Lesotho, Malawi, Mozambique, Namibia, Rwanda, Seychelles, United Republic of Tanzania, and Zimbabwe. The survey questionnaire and the Technical Seminar presented an opportunity to obtain and compile information from a group of AU Member States, reported to be "early implementers"; namely Member States that had begun the process of reviewing national legislation to align national legal provisions with those in the AU Model Law. Technical experts representing the several AU Member States and RECs at the Technical Seminar in October 2018 provided additional information to the information collected through the survey questionnaire.

The second survey was conducted prior to the May 2019 Regional Training Workshop for Legal Experts and Regulators from 25 Member States of the Southern African Development Community (SADC) and the Economic Community of West African States (ECOWAS), organized by AUDA-NEPAD in Johannesburg, South Africa. In preparation for the regional training workshop, AUDA-NEPAD sent the survey questionnaire to the AU Member States of the SADC and ECOWAS regions. The information received was compiled prior to the meeting and presented for confirmation by the workshop's expert participants from the national government. In addition, the information provided the basis for further discussion and consultation on national strategies, which enabled workshop participants to develop national roadmaps to facilitate the domestication process in their respective countries.

The survey questionnaire is reproduced below.

7 For more information, see: https://www.nepad.org/publication/amrh-summarized-strategic-framework-2016-2020.

Survey Questionnaire

Country: Focal contact:	
1.	What was your country's involvement/participation in the AU Model Law process leading up to its adoption in January 2016?
2.	What process, if any, was undertaken in your country to domesticate the AU Model Law? What was the consultation process adopted? What was the legislative process? What was the role of your Regional Economic Communities (RECs) in these processes?
3	Did you engage technical experts? a. If so, were they local, international or both? b. Can you provide their names and, if possible, contact details? c. What was the exact nature of the assistance?
4.	Did you consider the AU Model Law adequate with regard to your specific needs?
5.	What gaps if any, did you identify? What adjustment may be required to fill them?
6.	How have you addressed the gaps you have identified?
7.	What lessons would you share with countries seeking to domesticate the AU Model Law?
8.	Please provide electronic copies of the law on medical products regulation before and after domestication, and any other official legal, regulatory or related information, including draft bills.

Summary of survey results

Responses were received on the status of domestication from a total of 26 AU Member States. The survey results indicate variances in the status of the domestication process between the AU Member States.

In general, there are three categories of countries:

a. Domestication process completed

Several countries reported that national legislative processes have concluded with the adoption of the relevant legal instrument or legislation that is aligned with the AU Model Law or has adopted the essential provisions of the AU Model Law.

Four countries – Malawi, Mozambique, Rwanda and South Africa – have reported completion of the domestication process.

In some countries, there are remaining issues or challenges to the effective implementation of the AU Model Law at the national level. These included, in some cases, the need for human and financial resources to enable the establishment of the national regulatory authority and to facilitate the exercise of its functions. Another issue reported by countries concerns the provisions relating to substandard and falsified (SF) drugs, for which some countries have requested additional technical assistance.

b. Domestication process ongoing

A number of countries reported that national consultation processes are ongoing, indicating that national stakeholders are being consulted on the domestication of the AU Model Law. Some countries also report that a draft law or bill is undergoing the legislative process for adoption.

Thirteen countries reported they are in process of domestication; they are: Benin, Burkina Faso, Burundi, Côte d'Ivoire, Egypt, Eswatini, Gambia, Lesotho, Namibia, Seychelles, United Republic of Tanzania, Zambia and Zimbabwe.

c. **Domestication process not commenced**

A number of countries reported that neither the national consultation process nor legal drafting has begun as yet.

Nine countries reported that they have not yet started the domestication process: Cabo Verde, Comoros, Ghana, Guinea, Madagascar, Mali, Niger, Senegal and Togo.

It is to be noted that in some of these countries, while there has yet to be a formal process of reviewing the relevant national legislation to ensure alignment with the AU Model Law, there is already a legal and regulatory framework in place for medical products regulation. For example, Ghana reported that the process of domestication has not yet started, but a regulatory framework is currently in place by virtue of the provisions of the Public Health Act of 2012 and the guidelines thereunder.

Based on the survey responses, the following additional observations on the AU Model Law domestication process may be made:

- **Diversity of national approaches**: The domestication process may differ from country to country, depending on several factors, such as the existing national law, the national needs and priorities, as well as the resources available. It was also noted that in some countries, it may be determined that the establishment of a separate national regulatory authority may not be needed where key regulatory functions can be satisfactorily performed by an existing government agency.
- **Political awareness and support**: Survey respondents highlighted the need for political awareness and support for the domestication process, noting that national processes can be hastened when responsible ministers were made aware of the issue by AUDA-NEPAD and the RECs.
- **Multisectoral national consultation:** Survey respondents emphasized the usefulness of organizing national consultations and dialogues that include all relevant government agencies beyond health and non-governmental stakeholders, including civil society and the private sector.
- **Regional coordination and technical support**: The survey responses highlighted the relevance of the role and support provided by the RECs, being the regional platforms that can enable work-sharing and peer-to-peer learning.
- **Resources:** Survey respondents also emphasized the need for both financial and human resources to support national consultations and legal reform, technical assistance and the effective functioning of the regulatory authorities.

Summary of results

The table below provides a summary of the survey results and the responses provided by 26 AU Member States on the status of the AU Model Law domestication process at the national level.

The table focuses on the following components:

- Status of domestication – whether completed, ongoing or not started
- Legislation available – whether the country has shared relevant legislation or legal instrument
- National consultation – whether a national consultation on the AU Model Law has taken place
- Technical assistance – whether technical assistance has been provided, involving national or international experts.

	Country	Completed	Ongoing	Not started	Legislation available	National consultation	Technical assistance
1	Benin		X		Y		International
2	Burkina Faso		X		Y	Y	Both national and international
3	Burundi		X			Y	International
4	Cabo Verde			X			
5	Comoros			X	Y		International
6	Côte d'Ivoire		X		Y	Y	Both national and international
7	Eswatini		X		Y	Y	Both national and international
8	Egypt		X			Y	
9	Gambia		X		Y		
10	Ghana			X	Y		
11	Guinea			X	Y		
12	Lesotho		X				
13	Madagascar			X			
14	Malawi	X			Y	Y	Both national and international
15	Mali			X	Y		
16	Mozambique	X			Y	Y	Both national and international
17	Namibia		X		Y	Y	National
18	Niger			X	Y		
19	Rwanda	X			Y	Y	
20	Senegal			X			
21	Seychelles		X			Y	
22	South Africa	X			Y		
23	Togo			X	Y		
24	United Republic of Tanzania	X Zanzibar	X Tanzania Mainland		Y	Y	Both national and international
25	Zambia		X		Y		
26	Zimbabwe		X		Y	Y	Both national and international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