MINISTRY OF HEALTH

PHARMACY AND POISONS BOARD

REGULATORY IMPACT STATEMENT

FOR

PHARMACY AND POISONS (TRANSPORTATION OF PHARMACEUTICALS) RULES, 2022

2022

This Regulatory Impact Statement (RIS) has been prepared by the Ministry of Health in consultation with the Pharmacy and Poisons Board pursuant to Section 6 and 7 of the Statutory Instruments Act (No. 23 of 2013)

1.0 PREFACE

1.1 This Regulatory Impact Statement *(hereinafter "the Statement")* has been prepared in compliance with Sections 6 and 7(1) and (2) of the Statutory Instruments Act, 2013 requirement for Regulatory Impact Statement on the proposed Pharmacy and Poisons (Transportation of Pharmaceuticals) Rules, 2022 *(hereinafter "the Rules").*

1.2 The purpose of the Statement is to enable Members of Parliament, and the Kenyan Community to be informed of the environmental, social and economic implications of the implementation of the proposed Rules.

2.0 INTRODUCTION

2.1 The Constitution of Kenya is heralded as the bedrock for transformational change in human rights with the entrenchment of a comprehensive Bill of Rights including the Right to Health for every Kenyan guaranteed under Article 43. It follows therefore that the safety of drugs in the distribution and supply-chain management should be guaranteed so as to ensure every Kenyan "*the highest attainable standard of health*".

2.2 In addition, Article 46 of the Constitution on Consumer Protection is an integral part of the fundamental right to health as it ensures that medical products made available in Kenya are of reasonable quality to achieve Universal Health Coverage. Further, consumers have the right "*to the protection of their health...*"which entails guaranteeing the safety of pharmaceutical products on transit up to consumption by the Kenyan consumer.

2.3 The Health Act under Section 3 recognizes the role of health regulatory bodies established under any written law. To that extent therefore, the Health Act, 2017 reinforces the regulatory function of the Pharmacy and Poisons Board established under Section 3 of the Pharmacy and Poisons Act, CAP 244 and which is empowered under Section 44(1)(f) and (ff) to "*make rules for the importation, exportation, transport and labeling of drugs and poisons.*".

2.4 Section 6 of the Statutory Instruments Act, 2013 provides that if a proposed instrument is likely to impose significant cost on the community or a part of the community, the regulation making authority shall, prior to making the statutory instrument, prepare a regulatory impact statement about the instrument. Section 7 provides the contents of regulatory impact statements to include:

a) a statement of the objectives of the proposed legislation and the

reasons for them;

b) a statement explaining the effect of the proposed legislation, including in the case of a proposed legislation which is to amend an existing statutory instrument the effect on the operation of the existing statutory instrument;
c) a statement of other practicable means of achieving those objectives, including other regulatory as well as non-regulatory options;
d) an assessment of the costs and benefits of the proposed statutory rule and of any other practicable means of achieving the same objectives;
e) the reasons why the other means are not appropriate;
f) any other matters specified by the guidelines; and
g) a draft copy of the proposed statutory rule.

3.0 STATEMENT OF OBJECTIVES AND OVERVIEW OF THE PROPOSED RULES

3.1 The primary objective of the proposed Rules is to facilitate better carrying out of the purposes and provisions of the Pharmacy and Poisons Act, CAP 244. The Pharmacy and Poisons Act establishes the Pharmacy and Poisons Board under Section 3 which is empowered to make rules for the effective implementation of the Act and in particular, as envisaged in Section 44(1)(f) and (ff), for the Cabinet Secretary for Health to in consultation with the Board *"make rules for the importation, exportation, transport and labeling of drugs and poisons."*

3.2 The Purpose of these Rules therefore is to specify the basic requirements for:

a) The transportation of pharmaceuticals;
b) The security of pharmaceuticals while on transit; and
c) Accounting for the pharmaceuticals within the possession of transporters**.**

3.3 Further, the Rules seek to regulate transportation operations in order to: Maintain the quality and safety of the pharmaceutical products throughout the distribution channels from manufacture to consumption; License transporters by enhancing partnership/support systems; and provide for enforcement through inspection, audit and monitoring of transport operations in pharmaceuticals.

3.4 The proposed Rules are arranged as follows:

a) Part I: Preliminaries

This part stipulates that the proposed rules are made by the Cabinet Secretary for Health, in consultation with the Board, in exercise of the powers conferred by section 44(1)(f) of the Pharmacy and Poisons Act. These Rules apply to all persons authorized to use, store, distribute and transport pharmaceuticals.

Rule 2 defines transit as the period during which pharmaceuticals are in the process of being carried, conveyed, or transported across, over or through a passage or route to reach the destination.

Vehicles means trucks, vans, buses, minibuses, cars, trailers, aircraft, railway carriages, boats, motorcycles and other means which are used to convey pharmaceuticals.

b) Part II- Requirements for transportation

The Rules prescribe the requirements for transportation as follows:

i. Licence: Any person wishing to engage in the business of transporting pharmaceuticals shall make an application to the Board as set out in the First Schedule.
ii. The pre-requisite documents for licensure are stipulated at Part II Rule 5(2) of the Rules for completeness of an application.
iii. For enforcement, Rule 6 provides that a license issued under these Rules may be revoked, suspended or modified if violations are detected.
iv. Rule 7 places responsibility upon the consignor to verify the type of pharmaceuticals and possession authorizations of the consignee before commencing transport of pharmaceuticals.
v. Rule 8 provides that the consignor shall ensure security of the pharmaceuticals during transportation including: Lockable doors, intruder alarm, security cleared delivery drivers, dispatch & arrival records among others.

c) Part III- Categories of transport modes

This Section stipulates the minimum conditions for transport of pharmaceuticals by air, sea and road transport.

i. For Air transport, the transporter must ensure that pharmaceutical products handling meets the IATA requirements for aircrafts; time and temperature sensitive label is affixed on all shipments booked as time

and temperature sensitive cargo; acceptance checklist for time and temperature sensitive shipments are executed; temperature excursions and time taken to deliver the consignment is recorded and the Board through an authorized officer(s) is notified on the arrival of the shipment at the Port of Entry for pre-clearance inspection.

ii. For Sea transport, the transporter is to ensure that the pharmaceuticals are packaged in a refrigerated container for transporting temperature sensitive cargo in accordance with the manufacturer's storage specifications; and the import of pharmaceuticals must be through a Gazetted/recognized Ports of Entry that are equipped to handle the products.

Upon arrival at the port of entry, the pharmaceuticals shall be removed from the transporting vessel as soon as possible and moved to a safe and suitable temperature-controlled storage location to minimize the risk of temperature related damage and theft.

Finally, a transporter by sea is to notify the Board through an authorized officer(s) on the arrival of the shipment for pre-clearance inspection, report excursions or any other deviations.

iii. For Road transport, the transporter is to ensure that the vehicles and equipment used to transport pharmaceuticals are suitable for the purpose and appropriately equipped. The design and use of vehicles should aim to minimize the risk of errors on products being distributed and tracking devices and engine kill buttons ought to be installed on vehicles to beef up security. In addition, the transporter is to use dedicated vehicles and equipment so as to minimize contamination,

d) Part IV- Specifications

This part prescribes specific responsibilities upon the transporter in relation to loading and receiving bays, transport and delivery vessels, monitoring of storage conditions during transit, temperature controlled vehicles, calibration, insulated containers/carriages, emergencies and contingency planning, record keeping and standard operating procedures: Every transporter of pharmaceuticals is required to develop, domesticate and maintain procedures on correct transport of pharmaceuticals

Further, this part prescribes the offences and penalty provisions that give enforcement powers and enable the Board to execute its mandate and implement all activities to address transportation of

pharmaceuticals.

4.0 PUBLIC PARTICIPATION

3.1 The Constitution of Kenya recognizes as well as mandates public law making bodies to promote and facilitate public participation in the law making process. This is anchored in Article 174(c) f the Constitution of Kenya and is designed *"to give powers of self-governance to the people and enhance the participation of the people in the exercise of the powers of the State and in making decisions affecting them"*.

3.2 The Constitutional Court of South Africa set out the threshold of public participation in ***Doctors for Life International Vs. The Speaker of the National Assembly*** [1] emphasized the "special meaning" of public participation and held that the effect of public participation should be that all parties interested in legislation should feel that they have been given a real opportunity to have their say, that they are taken seriously as citizens and that their views matter and will receive due consideration.

3.3 Suffice to note, the objective of public participation is both symbolical and practical; the persons concerned must be manifestly shown the respect due to them as concerned citizens, and the legislators must have the benefit of all inputs that will enable them to produce the best possible laws.

3.4 In point of fact, public participation is a key component of Kenya's constitutional architecture. The Constitution offers an expansive role of the public in the conduct of public affairs by placing a high value on public participation in the law-making process.

3.5 Article 10(2) of the Constitution requires public participation as part of every public policy, law making and governance process in the country. Further, Article 232 provides for the values and principles of public service. Among the principles is the involvement of the public in the policy making process.

3.6 Public participation is also a requirement of the legislative process under the Constitution. Article 118(1)(b) mandates Parliament to *"facilitate*

[1] 2006 (12) BCLR 13999 (CC)

public participation and involvement in the legislative and other business of Parliament and its committees"

3.7 The Statutory Instruments Act defines public participation as the *"involvement by the regulation making authority of persons or stakeholders that the statutory instrument may directly or indirectly apply to."*[2] It is imperative that all statutory instruments meet the dictates of the Act to the extent that the regulation making authority facilitates public participation.

3.8 The Statutory Instruments Act further provides that in determining whether any consultation that was undertaken is appropriate, the regulation making authority shall have regard to all relevant matters, including the extent to which the consultation: drew on the knowledge of persons having expertise in fields relevant to the proposed statutory instrument; and ensured that persons likely to be affected by the proposed statutory instrument had an adequate opportunity to comment on its proposed content.

3.9 Evincibly, public participation should not be treated as a mere formality for the purpose of fulfillment of the constitutional dictates. Moreover, it must not be equated with consultation. Meaningful public participation must take into account the quantity and quality of the governed to participate in their own governance.

3.10 In the making of these proposed Rules, the Pharmacy and Poisons Board facilitated public participation in the following manner:

a) Communication of the scope and intention of the Rules through dissemination of adequate information including the Draft rules and matrices available on the Board's website at https://web.pharmacyboardkenya.org/
b) Identification and determination of the stakeholders as it relates to the persons concerned or likely to be affected by the draft Rules. The Board ensured intentional inclusivity and diversity
c) Consultation and notification to all mapped stakeholders concerned or likely to be affected by the Rules including stakeholders in academia; research institutions such as Kenya Medical Research Institute (KEMRI) and the National Quality Control Laboratory; Kenya Association of Pharmacists (KAPI);

[2] Section 2 Statutory Instruments Act

Pharmaceutical Society of Kenya (PSK); Health regulatory bodies including: the Ministry of Health and the National Drug Regulatory Authority (NDRA); the Council of Governors and County Governments; Distributors of Health products and equipment; Public Procurement Agencies such as the Kenya Medical Supplies Agency (KEMSA); Pharmacists and other health care providers; and the general public.

d) Consideration, in good faith of the input of the public and all the views received as part of the public participation programme was recorded, further deliberated upon, incorporated and the outcome recorded.

3.11 Demonstrably *"Participation of the people necessarily requires that the information be availed to the members of the public whenever public policy decisions are intended and the public be afforded a forum in which they can adequately ventilate them."* **Republic Vs. The Attorney General & Another Ex parte Hon. Francis Chachu Ganya [2013] eKLR**.

3.12 The Board has met the two facets of dissemination of information to the public. First, the Board provided an explanation of the rules that is intended to be passed and the rationale behind the proposed Rules in order to adjudge their efficacy or efficiency.

3.13 Second, the proposed Rules have been made readily available in formats accessible to the public. The proposed rules can not only be accessed but also downloaded from the Board's website.

3.14 Through a Notice on the Board's website on 20th February, 2022 and vide Public Notice dated 21st February, 2022, imprinted on the *Daily Nation,* as well as on the Board's social media platforms on 21st February 2022- Facebook @Pharmacy and Poisons Board and Twitter @ppbkenya, the Board notified the general public that it had developed six (6) sets of draft Pharmacy and Poisons Rules 2022 under the Pharmacy and Poisons Act aimed at facilitating effective implementation of the Act. Among the Rules was the Pharmacy and Poisons (Transportation of Pharmaceuticals) Rules, 2022.

3.15 The Board invited all stakeholders and members of the public to make comments on the draft Rules and submit written submissions in the prescribed matrix format available on the Board's website. The matrix had an entry for the proposed changes and justification to be

filled in by the public and was available at https://web.pharmacyboardkenya.org/stakeholder-feedback-form.

3.16 Written submissions were to be made to the Board's email address at feedback@pharmacyboardkenya.org, by post at P.O. Box 27663-00506, Nairobi or by dropping comments to the Physical address in the 10 Regional offices including the Main office at 4th Floor, PPB Building along Lenana Road, Nairobi. This was set to take place within the span of two weeks and was expected to come to a close by Close of Business, Monday, 7th March, 2022.

3.17 In addition, stakeholders and members of public were informed that they would be required to highlight oral submissions from 7th to 11th March 2022 in the following manner:

a) Virtual meetings from 7th to 9th March, 2022 following link https://us02web.zoom.us/meeting/register/tZModeGupjOiHN3flJ_9LT5qsz-rZ888UY9G ; and
b) Physical meetings in the 10 Regional Offices from 10th to 11th March, 2022 accessible through the link https://web.pharmacyboardkenya.org/regional-offices/

3.18 Subsequently, and in line with the Notices, the Board undertook public participation where stakeholders and other members of public attended and gave their feedback for consideration with regard to the draft Rules.

3.19 Written submissions were made by the public on the Pharmacy and Poisons (Transportation of Pharmaceuticals), Rules 2022 and submitted by 7th March, 2022. On 8th March, 2022, the Board conducted the virtual participation exercise on the Pharmacy and Poisons (Transportation of Pharmaceuticals), Rules 2022 from 2.00-4.00pm. ***(Appendix 1 is a Copy of the attendees on the virtual meeting)***

3.20 On 22nd February, 2022 a written memorandum was sent to various stakeholders inviting them for the physical participation exercise. Consequently, on 11th March, 2022, oral submissions on the Pharmacy and Poisons (Transportation of Pharmaceuticals) Rules, 2022 were made physically in the 10 Boards' regional offices. ***(Appendix 2 is a copy of the attendees on the physical meeting)***

3.21 All the feedback ensuing from the virtual and physical meetings was collated. The Board took into consideration all the views received from the public. Thereafter, the Board deliberated on the said comments and proposals and the results and outcome of the participation recorded. ***(Appendix 3 is a copy of the Public Participation Report)***

5.0 ASSESSMENT OF THE IMPACT OF THE PROPOSED RULES

5.1 Need for the Rules

5.1.1 Distribution is an important activity in the integrated supply-chain management of pharmaceutical products. One of the key aspects of the distribution process of pharmaceuticals is transportation. It is imperative that transportation and handling of pharmaceutical products is regulated to ensure the quality and identity of the products during all aspects of the distribution process.

5.1.2 Indeed, transportation should be regarded as an extension of the storage activities and each journey should be treated as unique, with the length and complexity, as well as any seasonal variations being considered when choosing the packing method and mode of transport. There is little point in storing products appropriately if they are compromised by inappropriate transportation.

5.1.3 Various quality issues are cropped up during transportation and distribuition operations of pharmaceutical products, which may result into gross dangers to public health and safety. Such quality issues include: Product mix-up during transportation; deterioration of product quality; discolouration of formulation; microbial contaminations; label mutilation; loss of product integrity; and abnormal delay among others.

5.1.4 Furthermore, transportation of pharmaceuticals is crucial as inter-individual differences in drug transportation expression can result in variability in drug response and safety.

5.1.5 To the extent that the Board has a direct mandate of ensuring safety of pharmaceutical products, in line with its mission to *"safeguard the health of the public by ensuring that medicines and health products comply with acceptable standards of quality, safety and efficacy,"* the Board has the responsibility to ensure that the

handling of pharmaceutical products does not affect quality, safety and efficacy of the products.

5.1.6 In keeping with international best practices of handling pharmaceutical products, including the World Health Organization (WHO) Programme Distribution guidelines it is imperative that these Rules are enacted as a necessary reform to protect and promote public health.

5.1.7 The WHO Good Distribution Practices denotes that regulation of transportation and products in transit is an important activity in the integrated supply-chain management of pharmaceutical products. This ensures the quality and identity of pharmaceutical products during all aspects of the distribution process from manufacture to consumption. WHO recommends the regulation of vehicles, equipment and shipment containers handling pharmaceuticals as well as guidelines for the transportation and products in transit.

5.1.8 The transportation of pharmaceuticals in Kenya requires a more comprehensive and robust legal framework to deal with the inadequacies in the sector. Legislation and institutional regulations and systems play a key role in assuring the quality, safety, and efficacy of medical products. In contrast, inefficient regulatory systems can be a barrier to access of safe, effective and quality medical products.

5.1.9 The principles upon which the draft Rules have been established is to ensure consistency, efficiency, clarity and effectiveness in transportation of pharmaceuticals. The Rules are drafted in a manner as to provide for collaboration with other agencies and stakeholders in implementing and ensuring compliance. This is so as to promote the existing synergies with various stakeholders.

5.1.10 The Rules provide the scope and mandate of transporters of pharmaceuticals and their consequent licensure; the inspection of transport vessels for suitability; and monitoring of the transport operations of pharmaceuticals in Kenya. Further, they outline the responsibilities and enforcement powers of the Board and authority to take actions if needed all

in a bid to ensure that the same is implemented throughout the supply-chain of drugs and medicines in Kenya.

5.1.11 The objective of the Rules is to ensure that transportation of pharmaceuticals is supported by a comprehensive set of legal provisions, regulations and guidelines which provide the necessary mandate to implement all activities related to this regulatory function.

5.2 Effect on the Public Sector

The proposed Rules will affect the public sector in the following ways:

a) The Government will establish a coherent and regulated environment for streamlined oversight and supportive strategies towards improvement of transportation of pharmaceuticals in Kenya.

b) The Government will have a well-organized policy and implementation structure of distribution of pharmaceuticals in the different modes of transport by air, sea and road thereby promoting regulation and better coordination of the health sector.

c) Improved public health and safety as a result of safe, quality and efficacious medicines due to reduced transportation limitations thereby ensuring affordability and availability of medicines in Kenya.

d) Increased opportunities for public and private sector partnership for investments and building synergies in the development and management of transportation of pharmaceuticals.

e) Increased collaboration and cooperation in transportation of pharmaceuticals research, identifying gaps in handling of pharmaceuticals and information sharing with all stakeholders including regional and international partners.

f) Increased costs of implementing the Rules due to licensure fees and the need to liaise with related government agencies for monitoring and enforcing compliance with the Rules.

5.3 Effect on the Private Sector

The proposed Rules will affect the private sector in the following ways:

a) The Pharmaceutical industry players including private pharmacies, pharmaceutical associations, distributors and manufacturer as well as professionals and other health care providers shall stand to benefit from a better regulated pharmaceutical sub-sector and conducive operating environment.

b) Transport sector actors shall have a more regulated system promoting the integrity of pharmaceuticals in transit.

c) Private sector actors shall have an opportunity to partner with the Government and government agencies for synergy in the development and management of the pharmaceutical sub-sector in transportation of Pharmaceuticals.

d) Increased investment due to new local and foreign direct investment owing to better regulation of transportation of pharmaceuticals.

e) Production and supply consistence of quality, safe and efficacious health products and medical technologies.

f) Increase the trust of patients on medication and health care system.

g) Increased opportunities for players in academia and research institutions to monitor the quality of medical products in the market taking into account the transportation of such products.

h) Increased opportunities for education training in transportation of pharmaceuticals and their effective communication to the public.

5.4 Effect on Fundamental rights and Freedoms

The Constitution of Kenya is heralded as the bedrock for transformational change in human rights with the entrenchment of a comprehensive Bill of Rights. The proposed rules shall have a positive impact on rights and freedoms of individuals as follows:

a) The Right to Health for every Kenyan guaranteed under Article 43 shall be enhanced as the safety of drugs in the market shall be

guaranteed to ensure every Kenyan "*the highest attainable standard of health*".

b) By ensuring safe transit of pharmaceuticals and reducing quality issues arising due to inappropriate transportation, the Rules shall promote Article 46 of the Constitution on Consumer Protection as medical products made available in Kenya shall be of reasonable quality to achieve Universal Health Coverage. Further, consumers have the right "*to the protection of their health...*"which shall be guaranteed as the safety of pharmaceutical products in the Kenyan market shall be ensured.

6.0 COST-BENEFIT ANALYSIS

This section seeks to assess the changes proposed by the Rules in terms of their costs and benefits to justify the proposals pursuant to section 7(d) of the Statutory Instruments Act. The benefits of the Pharmacy and Poisons (Transportation of Pharmaceuticals) Rules 2022 include:

a) Improved efficiency and effectiveness of transportation of pharmaceuticals in Kenya: Clarification of specifications of transporters of pharmaceuticals by air, road and sea tranposrt, coordinated mechanism with other agencies in transport and responding to the needs of the Kenyan populace with respect to ensuring safe, quality and efficacious health products and medical technologies.

b) Integrated and collaborative approach of implementing the transportation of pharmaceuticals system: Identification of the institutional framework that provides clarity and uniformity on the processes of the system.

c) Facilitation of fundamental rights and freedoms: The proposed Rules will facilitate the full enjoyment of the right to property as stipulated under Article 43, and 46 of the Constitution of Kenya. The instruments do not limit the fundamental rights and freedoms set out under the Constitution.

d) Improved public health and safety: The proposed Rules shall enhance the system for transportation of pharmaceuticals through handling transportation limitations that may lead to deficiencies in the quality, safety, efficacy or effectiveness.

e) Complementing existing legal framework: The proposed Rules do not propose to have any new legislation enacted or any existing laws amended. They complement other laws including the Constitution, the Pharmacy and

Poisons Act and various guidelines to make their implementation more effective.

It is expected that resources would be required for operationalization of the Rules which will include human resource and operation costs for enforcement as well as creation of awareness of the Rules to different stakeholders in the pharmaceutical sub-sector. More resources will go to the implementation of the wider system for transportation of pharmaceuticals. The government will also incur costs in the identification, mapping, assessment, status review and monitoring of the Rules across the country.

Since the roll out of the new structures will be phased over a number of years, this budget can be spread out and financed in piece meal. This is a cost payable by the Ministry of Health and does not implicate the user in any manner

7.0 STATEMENT ON REGULATORY AND NON-REGULATORY OPTIONS

The Statutory Instruments Act requires a regulator to carry out an informed evaluation of a variety of regulatory and non-regulatory policy measures by considering relevant issues such as costs, benefits, distributional effects and administrative requirements. Rules and regulations should be the last resort in realizing policy objectives. The options considered under this part are: maintenance of the status quo, developing the Rules and other practical options.

Option one: Maintenance of the Status Quo

The proposed Rules are responsive to the current needs in the pharmaceutical sub-sector and to maintain the quality and safety of pharmaceutical products throughout the distribution channel from manufacture to consumption. In the absence of these regulations, these emerging issues in transport of pharmaceuticals will not be addressed effectively.

By maintaining the status quo, the legal requirements under Section 44(1)(f) and (ff) of the Pharmacy and Poisons Act CAP 244 will not be fulfilled. In addition, the challenges identified such as product mix-up during transportation and deterioration of product quality will persist.

Option two: Developing the Rules

The proposed Rules will yield the following benefits: Maintain the quality and safety of the pharmaceutical products throughout the distribution channel from manufacture to consumption; ensure the licensure of transporters thereby enhancing partnership, collaboration and support systems in the transport industry in Kenya; provide a basis for enforcement through inspections and

monitoring of transport operation; enhance the security of pharmaceuticals while on transit; and provide a system for accounting for the pharmaceuticals within the possession of transporters.

The assessment of the cost and benefits indicates that the benefits of formulating the regulations far outweigh the costs, therefore, option two was selected as the preferred option.

Option three: Other practical options

These can entail administrative measures, self-regulation or policy directives. Administrative measures involve issuance of directives and circulars to the various market players in transportation of pharmaceuticals. This is a non-regulatory measure which if applied, will depend on the good will of pharmaceutical stakeholders to implement the provisions of the proposed Rules. Administrative measures are subjective, not binding and may be challenged in a court of law. In addition, some administrative measures issued in the past and have not achieved the desired objectives.

Self-regulation shall entail allowing, in appropriate cases, for the sector to regulate itself up to a certain threshold. This will also heavily rely on the stakeholders' good will.

Finally, the Ministry of Health has in collaboration with the Board had policy mechanisms developed from time to time to guide the sector including:

a) Guidelines for good distribution practices for Pharmaceuticals (July 2006): These guidelines set out appropriate steps for meeting the responsibilities of wholesalers and retailers in the pharmaceutical industry. They incorporate transport as a key element that should be regulated to ensure safety of pharmaceutical products including the particulars of recommendations to be adhered to in delivery.
b) Guidelines for transportation of Pharmaceuticals in Kenya (July 2019): These guidelines relevant to the degree that they offer guidance on transport risk assessment, modes of transport, temperature control regulations and security for pharmaceuticals during transit.

However, the above policies have not been effective. There is need for legislation and institutional regulations as the same play a key role in assuring the quality, safety, and efficacy of medical products. In contrast, inefficient regulatory systems can be a barrier to access of safe, effective and quality medical products.

8.0 COMPLIANCE AND IMPLEMENTATION

Institutions

The implementation and enforcement of these Rules will be undertaken through the existing legal framework within the Ministry of Health and Pharmacy and Poisons Board. The County Governments shall also play a key role.

9.0 CONCLUSION AND RECOMMENDATION

Based on the analysis in this Statement, the Pharmacy and Poisons (Transportation of Pharmaceuticals) Rules 2022 are extremely necessary. The Rules offers benefits which shall lead to quality, safe and efficacious medicines in Kenya leading to the attainment of Universal Health Coverage.

In addition, the Rules provide a framework for ensuring that the people of Kenya enjoy the fundamental rights and freedoms guaranteed under the Constitution.

Recommendation

In view of the above conclusion, it is recommended that the Pharmacy and Poisons (Transportation of Pharmaceuticals) Rules 2022 be adopted.