MINISTRY OF HEALTH

PHARMACY AND POISONS BOARD

REGULATORY IMPACT STATEMENT

FOR

PHARMACY AND POISONS (PHARMACOVIGILANCE AND POST MARKET SURVEILLANCE) 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 (Pharmacovigilance and Post market surveillance) 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 has been progressive in its approach to the realization of socio-economic rights in the context of Article 43 of the Constitution of Kenya which provides that *"every person has the right to the highest attainable standard of health, which includes the right to health care services, including reproductive health care."*

2.2 In light of this, the Kenyan government enacted the Health Act, 2017 whose purpose is to establish a unified health system to coordinate the inter-relationship between national and county government health systems. The aforementioned 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.

2.3 Under Section 15 of the Health Act, the Ministry of Health is mandated to develop policies, laws and administrative procedures in consultation with health stakeholders. On the other hand, Section 63 denotes that there shall be a single regulatory body- in this context, the Pharmacy and Poisons Board- which *"shall conduct….post marketing surveillance for quality, safety and disposal of health products"*

2.4 The Pharmacy and Poisons Board operates under the Ministry of Health as a semi-independent regulatory authority. The Board has 4 Directorates of which the Department of Product Safety is responsible for several Departments including the Department of Pharmacovigilance and Post-market surveillance.

2.5 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 it sets up a National Pharmacovigilance and Post-market Surveillance system to monitor the quality, safety and efficacy of all medical products and health technologies after they have been released in the Kenyan market post-registration.

2.6 This is also in furtherance of Good manufacturing Practices in pharmaceuticals as prescribed by the World Health Organization (WHO) Programme to ensure that pharmaceutical products are consistently produced and controlled according to quality standards. The system is designed to minimize the risks involved in any pharmaceutical production that cannot be eliminated through testing the final product.

2.7 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 Section 3B of the Pharmacy and Poisons Act empowers the Board to *"conduct post-market surveillance of safety and quality of medical products"* and under Section 44(mme) of the aforementioned Act to *"make rules for pharmacovigilance, post market surveillance and Good Manufacturing Practice."*

3.2 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. Under Section 3, the Pharmacy and Poisons Act establishes the Pharmacy and Poisons Board which regulates the practice of pharmacy and manufacture and trade in drugs and poisons and whose function includes: *"to conduct post market surveillance of safety and quality of medical products"*.

3.3 The purpose of the proposed Rules is to:

a) Establish a legal basis for pharmacovigilance and post market surveillance which entails developing a system for detecting, reporting and monitoring adverse drug reactions and substandard and falsified products to improve safety and efficacy of pharmaceutical products in Kenya;
b) Develop a rapid alert and recall system to improve patient care and safety in relation to the use of health products and technologies; and
c) Provide a legal basis for manufacturers and market authorization holders to appoint a qualified person for pharmacovigilance to assess the benefit, harm, effectiveness and risk of a health product or technology, leading to the prevention of harm and maximization of benefits of the health product or technology among others.

3.4 Rule 2 of the proposed Rules defines pharmacovigilance as the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other possible health product related problem. Post-market surveillance is assigned the meaning in the Pharmacy and Poisons Act CAP 244 under Section 2 and is defined as the practice of monitoring the safety and quality of a pharmaceutical drug or medical device after it has been released on the market and is an important part of the science of pharmacovigilance.

3.5 The proposed Rules are arranged as follows:

a) Part I: Preliminary
   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)(mme) of the Pharmacy and Poisons Act.

The Rules apply to health products and technologies manufactured, imported, distributed, marketed, licensed or used in health care practice in Kenya.

The overall goal of the Rules is to improve patient care, public health and safety in relation to the use of health products and technologies.

b) Part II- The National Pharmacovigilance and Post marketing Surveillance System
    i. Under Rule 5, the Board establishes the National Pharmacovigilance Centre which shall set up and manage the Pharmacovigilance and post marketing surveillance system to receive and maintain all relevant information about suspected adverse drug reactions and adverse events to health products or health technologies which have been authorized by the Board.
    ii. Rule 6 espouses that the system shall work with the support of healthcare providers, health regulatory bodies, the pharmaceutical industry, marketing authorization holders, members of the public and other relevant stakeholders.
    iii. Rules 7-12 describe the roles and responsibilities of key stakeholders in the system.
    iv. Rule 13 provides that the National Post-marketing surveillance system shall comprise of the National reporting system for substandard and falsified products; the National pharmacovigilance and Post-marketing Surveillance Technical Working Group; and the Quality Control Testing Laboratory.
    v. Rule 25 establishes a rapid alert system designed to ensure a timely, proportionate, accurate and consistent response to health events arising from sub-standard and falsified medical products which represent a significant threat to health and safety of the public.
c) Part III- General provisions

    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 pharmaceutical safety and safeguard public health.

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 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*

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

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); Pharmaceutical Society of Kenya (PSK); Health regulatory bodies including: the Ministry of Health and the National Drug Regulatory Authority (NDRA); the Council of Governors; Distributors of Health products and equipment; Public Procurement Agencies such as the Kenya Medical Supplies

[2] Section 2 Statutory Instruments Act

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 (Pharmacovigilance and Post-Market surveillance) 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 (Pharmacovigilance and Post-market Surveillance), Rules 2022 and submitted by 7th March, 2022. On 9th March, 2022, the Board conducted the virtual participation exercise on the Pharmacy and Poisons (Pharmacovigilance and Post-market Surveillance), Rules 2022 from 9.00-10.30am. *(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 10th March, 2022, oral submissions on the Pharmacy and Poisons (Pharmacovigilance and Post-market surveillance) 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 Pharmacovigilance is the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other possible health product related problem. On the other hand, post-market surveillance is the practice of monitoring the safety and quality of a pharmaceutical drug or medical device after it has been released on the market and is an important part of the science of pharmacovigilance.

5.1.2 The Kenyan Pharmacovigilance program was officially launched in June 2009 and Kenya joined the World Health Organization programme in 2010 as the 98th member. Since then, the Pharmaceutical industry in Kenya has experienced exponential growth over the last few years with increased access to medicinal products in Kenya. However, this is not well matched with the pharmacovigilance and post-market surveillance capacity to monitor drug safety.

5.1.3 There are over 10,000 products registered in the Kenyan market. Despite their obvious benefits, they are known to have a possibility of causing adverse events which can be serious or fatal. The safety and quality of these health products and medical technologies must be continuously monitored by key players in the industry to ensure patient safety as a central component in attainment of Universal Health Coverage in Kenya. Moreover, there should be concerted efforts to curb the existence of substandard and falsified medical products in the Kenyan market.

5.1.4 Globally, adverse drug reactions and poor product quality contribute significantly to morbidity and mortality and have a huge impact on the health care system. Therefore, implementing regular tracking is critical to ensure that health products and medical technologies continue to meet the required standards whilst in the market post-registration.

5.1.5 Since Pharmacovigilance was introduced in Kenya, there have been 14403 individual case safety reports made accounting for

0.06% of the total reports made worldwide[3]. With legal provisions in place, there shall be increased rapid alerts as a result of availability of mechanisms and structures for reporting thereby increasing patient care.

5.1.6 The most notable achievement of the Kenyan pharmacovigilance program was carried out in September 2011[4].The PPB recalled more than 15,000 of batches of antiretroviral drugs sold by Hetero Drugs Limited in India. The drugs were found to be a counterfeited version of WHO prequalified medicines and had been donated by Medicines Sans Frontiers (MSF) to a local nongovernmental organization. The irregularities such as discoloration, 14 moulding, and breakages were reported by patients and health workers to the PPB. The company was obligated to recall all the drugs that had been quarantined.

5.1.7 In late September 2011, the World Health Organization issued a detailed statement recommending that patients contact their treatment provider, highlighting that genuine Hetero products with the same batch number were also circulating, and that treatment regimens should not be stopped indiscriminately. This exercise revealed the loopholes in the supply chain management of pharmaceuticals in Kenya.

5.1.8 Inevitably, more stringent controls with legal backing need to be made to safeguard the safety and quality of health products and medical technologies post registration. Be that as it may, the uptake of pharmacovigilance and post marketing surveillance has been slow due to lack of legal backing yet it goes without saying that legal backing is essential to policy choices (or lack thereof), infrastructure, institutional authority and resources to address pharmaceutical safety and safeguard public health.

5.2 Effect on the Public Sector

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

[3] Pharmacovigilance, Summary Report July-September 2020
[4] Cohn, Von Schoen-Angererb, Jambert, Arreghini and Childs, 2013

a) The Government will establish a coherent and regulated environment for streamlined oversight and supportive strategies towards improvement of pharmacovigilance and post-market surveillance in Kenya.

b) The Government will have a well-organized policy and implementation structure through the establishment of the National Pharmacovigilance and Post-market surveillance system for the regulation and better coordination of the health sector.

c) Improved public health and safety as a result of a highly upgraded system for detecting, reporting and monitoring medical products released into the Kenyan market post-registration.

d) Increased opportunities for public and private sector partnership for investments and building synergies in the development and management of pharmacovigilance and post market surveillance.

e) Increased collaboration and cooperation in pharmacovigilance and post market surveillance research, science and technology and information sharing with all stakeholders including regional and international partners.

f) Increased costs of implementing the Rules due to 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) 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 Pharmacovigilance and Post market surveillance.

c) Increased investment due to new local and foreign direct investment owing to better regulation of health products and medical technologies post registration.

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

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

f) Contribute to the assessment of benefit, harm, effectiveness and risk of a health product or technology, leading to the prevention of harm and maximization of benefits of the health product or technology.

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

h) Enhance monitoring of status of market authorization of medical products and health technologies in Kenya.

i) Increased opportunities for education training in post-marketing surveillance programs and activities 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 recalling sub-standard and falsified medical products, 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 post registration shall be ensured.

c) Article 35 of the Constitution obligates the State to disseminate adequate information to the Kenyan people. This shall be enhanced as the rapid alert and recall system shall be made available to the public detailing health products and medical technologies that are of poor quality thereby increasing patient care and safety. Further, the distribution of information shall lead to improve drug prescribing and regulation.

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 (Pharmacovigilance and Post-market Surveillance) Rules 2022 include:

a) Improved efficiency and effectiveness of pharmacovigilance in Kenya: Clarification of functions of the roles of the national and county pharmacovigilance units, coordinated mechanism for preparation of pharmacovigilance and post market surveillance plans 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 Pharmacovigilance and Post-market surveillance 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, 46 and 35 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 detecting, reporting and monitoring adverse drug reactions and products that do not meet market authorization requirements including reasons relating 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 National Pharmacovigilance and Post-market Surveillance system. 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 the science relating to the detection, assessment, understanding and prevention of adverse effects including those that may be primarily caused by substandard and falsified products. In the absence of these regulations, these emerging issues will not be addressed effectively.

By maintaining the status quo, the legal requirements under Section 63 of the Health Act, Section 3B and Section 44(1)(mme) of the Pharmacy and Poisons Act CAP 244 will not be fulfilled. In addition, the challenges identified such as absence of a streamlined rapid alert and recall system among others, will persist.

Option two: Developing the Rules

The proposed Rules will yield the following benefits: Establish a legal basis for pharmacovigilance and post market surveillance which entails developing a system for detecting, reporting and monitoring adverse drug reactions to improve safety and efficacy of pharmaceutical products in Kenya; Develop a

rapid alert and recall system to improve patient care and safety in relation to the use of health products and technologies; and Provide a legal basis for manufacturers and market authorization holders to appoint a qualified person for pharmacovigilance to assess the benefit, harm, effectiveness and risk of a health product or technology, leading to the prevention of harm and maximization of benefits of the health product or technology among others.

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 Pharmacovigilance and Post-market surveillance. 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 the Establishment of the qualified persons for Pharmacovigilance (December, 2018)
b) Guidelines on the Safety and Vigilance of medical products and health technologies (December, 2019)
c) Guidelines for Monitoring, Reporting and Managing Adverse events following Immunization in Kenya
d) Guidelines for Post-marketing surveillance of Medical Products and Health Technologies in Kenya (January, 2022)
e) Guidelines for recall and Withdrawal of Medical Products and Technologies (January, 2022)

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 (Pharmacovigilance and post-market surveillance) Rules 2022 are extremely necessary. The Rules offers benefits which shall lead to quality, safe and efficacious health products and medical technologies.

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 (Pharmacovigilance and post-market surveillance) Rules 2022 be adopted.