MINISTRY OF HEALTH

REGULATORY IMPACT STATEMENT

FOR

PHARMACY AND POISONS (AMENDMENT) 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)

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1. INTRODUCTION AND BACKGROUND

1.1. Introduction

Section 44 of the Pharmacy and Poisons Act (hereinafter "Act") mandates the Cabinet Secretary for Health, in consultation with the Pharmacy and Poisons Board (hereinafter "Board") to make Rules giving effect to the Act. Consequently, the Cabinet Secretary has formulated, *inter alia,* the Pharmacy and Poisons (Amendment) Rules 2022 (hereafter "Amendment Rules") amending the Pharmacy and Poisons Rules to give effect to the Act.

1.2. Requirements of the Statutory Instruments Act, 2013

Section 6 of the Statutory Instruments Act 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 statement 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.

2. OBJECT OF THE PROPOSED AMENDMENT RULES

2.1. The general objective of the Amendment Rules is to give effect to section 44 of the Act by regularizing importation, exportation and manufacture of biologicals and all advertisements, promotional material and information relating to health products and technologies.

3. EFFECT OF THE PROPOSED AMENDMENT RULES

3.1. The Amendment Rules seek to amend the Pharmacy and Poisons Rules. The effect of the amendment is to include in the existing statutory instrument provisions regulating importation, exportation and manufacture of biologicals, and the advertisement and promotion of health products and technologies, which provisions are non-existent in the existing legal framework.

3.2. With regard to advertisement and promotion of health products, the effect of the proposed Amendment Rules is to better implement section 36, 37, 38, 39 and 40 of

the Act with regard to promotion and advertisement of health products and technologies.

4. OVERVIEW OF THE PROPOSED AMENDMENT RULES

4.1. The Amendment Rules address importation, exportation and manufacture of biologicals. To this extent, the Amendment Rules seek to prevent substandard lots from reaching the public by reviewing the analytical methods that the manufacturer used, and the specifications of their own test data lot release to ensure the quality of lots in commercial distribution. They also seek to provide for real-time monitoring of the manufacturing, testing, and product quality.

4.2. In addition, the Amendment Rules address advertisement and promotion of health products and technology as follows; elements of advertisement and promotion, specific requirements for advertisement and promotion, advertisement for specific populations, content for promotional advertisement, online advertisement and promotions, and stakeholder responsibility with regard to advertisements and promotions.

4.3. A summary of the Amendment Rules is as follows:

4.3.1. **Scope**

a) As aforestated, the Amendment Rules seek to amend the Pharmacy and Poisons Rules to provide for importation, exportation and manufacture of biologicals.

b) Additionally, the Amendment Rules regularize the promotion and advertisement of health products and technologies. They define advertisement as any written, pictorial, visual or verbal statement with a medical claim designed to promote prescription, supply, sale and consumption of health products through any medium.

c) The Amendment Rules also offer clarity as to what is not an advertisement including factual, accurate, informative announcements and reference material concerning licensed medicines.

4.3.2. **Importation, Exportation and Manufacture of biologicals**

a) The Amendment Rules provide for evaluation by authorised personnel of every batch of imported biologicals before they are released into the market to ensure that they meet the approved specifications. They also require that only persons who have valid import licence can import biologicals into the Kenyan territory.

b) The Amendment Rules also provide for the evaluation by authorised personnel of every batch of exported biologicals prior to their exportation. The Amendment Rules require that only persons with a valid exportation licence can export biologicals.

c) The Amendment Rules also make it mandatory for any person who seeks to manufacture any biologicals that may be used for treatment to obtain a license for the same. Subsequently, each consignment of the biological product

manufactures must be evaluated by an authorised person before its release for distribution.

4.3.3. **Authorisation for Advertisement and Promotion**

a) There is a mandatory requirement under the Amendment Rules that written permission of the Board must be sought by any person who wishes to advertise or promote any drug or poison. The application is to be made to the Board.

b) Additionally, the Amendment Rules provide that no health product or technology shall be advertised or promoted unless registered by the Board. Further, no person shall promote off-label or unregistered indications and materials sent under the guise of personal communications.

4.3.4. **Specific requirements for Advertisement and Promotion**

a) The Amendment Rules provide classifications for advertisement of different forms of poisons to the general public. However, the Amendment Rules prohibit advertisement of controlled, narcotic and psychotropic substances to the general public in any format.

b) Additionally, the Amendment Rules classify promotional advertisements that are to be directed towards healthcare practitioners qualified to prescribe, dispense, handle or supply medicines. Further, they provide the means by which medical devices may be advertised.

c) Further, the Amendment Rules put specific conditions for advertisement to targeted groups including pregnant and lactating mothers and children and minors.

4.3.5. **Online Advertisements and Promotions**

a) The Amendment Rules set requirements for online advertisement and promotion. Firstly, a company or institution wishing to conduct an online advertisement and promotion shall ensure there are two windows, one for healthcare practitioners whose access shall be restricted and another for the general public. Secondly, such company or institution shall be operated, maintained and regulated by authorized market authorization holders, manufacturers, distributors or their appointed representatives. Thirdly, the Amendment Rules limit online advertisement to health products and technologies that are of a lower public health risk.

b) In addition, the Amendment Rules state that if an advertisement is conducted by press releases and product launches, it shall ensure press releases for new chemical entities and health technology innovations are allowed only once and that the use of brand names is not dramatized. Further, if an advertisement is conducted through promotional meetings, it shall ensure that no unregistered health product is displayed or circulated and further that approval of the Board for the promotional meeting is obtained in advance.

5. STAKEHOLDER CONSULTATIONS

5.1. Legal Requirements Relating to Public participation and Consultation

5.1.1. The Constitution of Kenya 2010 and the Statutory Instruments Act 2013 require that there be consultations in making a law or an instrument that is likely to affect people. What is the extent of the consultations? Are consultations by 'sampling' good enough? These matters have come before Courts for interpretation of the meaning of "public participation."

5.1.2. The law does not expressly provide that records of all consultative meetings be kept but requires that public participation be done to ensure that the outcome is an instrument that truly reflect the wishes and consensus of all stakeholders in line with Article 10 of the Constitution of Kenya 2010, which declares, as one of the national principles of governance, *"patriotism, national unity, sharing and devolution of power, the rule of law, democracy and participation of the people."* But there must be evidence of such consultation, hence keeping of records is paramount.

5.1.3. The Statutory Instruments Act 2013 also includes the following meaning of public participation, *"public participation" means involvement by the regulation making authority of persons or stakeholders that the statutory instrument may directly or indirectly apply to."*

5.1.4. In **Moses Munyendo & 908 others v Attorney General & another [2013] eKLR** the Court rendered the following view of the issue:

> *"As concerns the pre-parliamentary or consultative stage, the Permanent Secretary has given evidence on how different stakeholders were consulted. Some of the organisations consulted include the following; Kenya National Federation of Cooperatives, National Cotton Growers Association, Meru Central Diary Co-operative Union Limited, Cereal Growers Association and the Horticultural Farmers and Exporters Association. The organisations consulted are, in my view, broadly representative of agricultural interests in the country. This evidence is not controverted by the petitioners. Furthermore, I do not think it is necessary that every person or professional be invited to every forum in order to satisfy the terms of* ***Article 10.*** *Thus the contention that by the first petitioner, "I am aware that majority of Kenyans producers, processors, professionals or policy makers have not been invited to any stakeholders' meetings to enrich any of the law" is not necessarily decisive of the lack of public participation."* (Emphasis added)

5.1.5. The Cabinet Secretary for Health in consultation with the Board sought to work within the above understanding in making these Rules.

5.2. Consultations Undertaken

5.2.1. At the heart of the Regulatory Impact Statement, is the understanding that there must be consultation with those people who are likely to be affected by the statutory instrument.

5.2.2. Based on the foregoing, the Cabinet Secretary in consultation with the Board and in an effort targeted at ensuring regulatory effectiveness, sought to engage

stakeholders, experts and members of public with a view to enhancing the Amendment Rules so as to align the Kenya's regulatory framework with global standards. Based on the foregoing, the following steps were undertaken to ensure effective public participation:

1. In February 2022, the Board published the Amendment Rules for ease of access by stakeholders and members of public.
2. On 20th February 2022, the Board published a notice on its website at https://web.pharmacyboardkenya.org/ notifying the general public that it had published the Amendment Rules. Via the notice, the Board invited the stakeholders and members of public to a virtual meeting to highlight oral submissions from 7th March to 9th March 2022. Further, stakeholders and members of public were given an option of attending a hybrid meeting at the Board's regional offices between 10th and 11th March 2022 (hereinafter called "meetings"). Additionally, the Board invited all stakeholders and members of public to make comments on the Amendment Rules as follows:
    i. By filing an online feedback form on the Board's website https://web.pharmacyboardkenya.org/stakeholder-feedback-form;
    ii. By email through feedback@pharmacyboardkenya.org;
    iii. By sending feedback to the Board's physical address: 4th Floor, PPB Building along Lenana Road, Nairobi; and
    iv. By sending feedback via postal Address: P.O. Box 27663-00506, Nairobi.

    (Annexure 1 – is a copy of the Notice on the Board's website)
3. On 21st February 2022, the Board published notices on its Facebook and twitter handles, @Pharmacy and Poisons Board and @ppbkenya respectively, inviting stakeholders and general public to attend the meetings, and calling for feedback on the Amendment Rules.

    (Annexure 2 – are copies of screenshots from Facebook and Twitter posts)
4. Further, on 21st February 2022, the Board notified the general public of the draft Rules via a newspaper advertisement on the *Daily Nation* and invited both the general public and stakeholders to attend the meetings and submit feedback.

    (Annexure 3 – is a copy of the Newspaper advertisement on the Daily Nation)
5. Additionally, the Board sent correspondence to its mapped stakeholders informing them of the Amendment Rules and inviting them to attend the meeting and or send their feedback for consideration. *(The bundle marked Annexure 4 contains copies of correspondence sent to various stakeholders)*

Virtual meeting from the Board's headquarters

5.2.3. On 7th March 2022, the Board conducted a virtual public participation meeting where stakeholders and other members of public attended and gave their feedback for consideration with regard to the Amendment Rules. The meeting was chaired

by Dr. Jacinta Wasike and coordinated by Dr. Nancy Cherotich, Dr. Abdul, Dr. Allan Kyalo and Dr. Muite.

(Annexure 5 – is a copy of the agenda of the virtual meeting and attendance list of stakeholders and members of public)

5.2.4. At the start of the meeting, the coordinators made a presentation of the Amendment Rules for the benefit of stakeholders and members of public. Subsequently, the coordinators invited comments and feedback from the attendees. The comments and feedback were addressed at the virtual meeting. Subsequently, the Amendment Rules were amended as appropriate to incorporate the feedback from the participants.

(Annexure 6 – are copies power point presentation and a schedule addressing comments and feedback from the virtual meeting)

Hybrid meeting at the Board's headquarters and regional offices

5.2.5. On 10th March 2022, the Board conducted a hybrid meeting where stakeholders and members of public joined the meeting virtually and physically across the ten (10) regional offices namely Nairobi, Coast, South Rift, North Rift, South Rift, Lower Eastern, Upper Eastern, Western, Nyanza and Central. This session was chaired by Dr. Jacinta Wasike and coordinated by Dr. Nancy Cherotich, Dr. Abdul and Dr. Muite.

(Annexure 7 – is a copy of the agenda of the hybrid meeting and the attendance list for the said meeting)

5.2.6. The session began by a presentation on the Amendment Rules. Subsequently, the coordinators invited comment and feedback from the attendees. The comments and feedback was considered and the Amendment Rules were amended as appropriate.

(Annexure 8 – are copies of power point presentation and schedule addressing comments and feedback from the hybrid meeting)

Written submissions from various stakeholders and members of public

5.2.7. Further to the comments and feedback received from both the virtual and hybrid meetings referred above, the Board also received comments and feedback via email, post and through its website in form of letters and written submissions. The Board deliberated on the feedback and the Amendment Rules also amended as appropriate. The feedback received by the Board was from several stakeholders including:

i. Mission for Essential Drugs and Supplies (MEDS);

ii. Federation of Kenya Pharmaceutical Manufacturers (FKPM);

iii. Kenya Medical Laboratories Technicians and Technologists Board (KMLTTB); and

iv. Kenya Association of Pharmaceutical Industry (KAPI).

(Annexure 9 – are copies of the comments and feedback received from various stakeholders alongside a schedule addressing the same)

6. ASSESSMENT OF THE IMPACT OF THE PROPOSED AMENDMENT RULES

6.1. Statement of the Impact of the proposed Amendment Rules

Need for the Regulations

6.1.1. With regard to biologicals, the Amendment Rules seek to prevent substandard lots from reaching the public. By providing for reviewing of the analytical methods that the manufacturer used, and the specifications of their own test data, the Amendment Rules ensure the quality of lots in commercial distribution. Further, the Amendment Rules provide real-time monitoring of the manufacturing, testing, and product quality.

6.1.2. With regard to Advertisement and Promotion of health products and technologies, the Amendment Rules also seek to facilitate their regulation. Advertisement and promotion of health products and technologies remains an important means of creating awareness and disseminating information to the general public and healthcare professionals.

6.1.3. Advertisement based on sound standards and ethics has many benefits - advertisements provides information about medicinal products, the conditions they treat and what health benefit they can be expected to provide. Advertising refreshes consumer awareness, aids decision making by simplifying choosing a medicine for an identified healthcare need when consumers are pursuing their healthcare requirements, and enhances distinctiveness of specific medicine benefits (e.g. treatment outcomes). Reach is also enhanced through consumer education. Advertising also provides a means of updating society on the latest advances and availability of medicines.

6.1.4. Advertisements and promotions can also, if not carried out correctly, mislead consumers and in turn affect their health. Unethical advertisements and advertisements that are based on false claims also negatively affect the lives of consumers.

6.1.5. In the past few years, there has been a large increase in the number of advertisements and promotions across all mediums and media in Kenya indeed, a welcome activity. However, there has also been an increase in the advertisement of unregistered medicines, medicines with otherwise little safety, quality and efficacy-related data and advertisements and promotions, including on social media platforms, that are misleading. This development poses a great threat to the safety of the consumers – something that is unacceptable because of the risk posed to the general public.

6.1.6. With the proposed amendment to the Pharmacy and Poisons Rules, there will be a well-established legal framework for advertisement of drugs, pharmaceutical preparations and therapeutic substances, an area which had until now remained unregulated.

i. Impact on the Fundamental Rights and Freedoms

6.1.7. The Constitution declares that: -

> *"The Bill of Rights is an integral part of Kenya's democratic state and is the framework for social, economic and cultural practices."*[1]

Further, the Constitution provides that: -

> *"It is a fundamental duty of the State and every State organ to observe, respect, protect, promote and fulfil the rights and fundamental freedoms in the Bill of Rights."*[2]

6.1.8. The obligation to observe these and other Constitutional provisions therefore means that the Ministry, including the Board, being public entities are required to ensure compliance with the imperatives set out in the Constitution which includes developing the instant Amendment Rules. The Bill of Rights is a great masterpiece of normative order which guarantees citizens the necessary rights and freedoms without which the purpose of Government would be a nullity.

6.1.9. The Constitution also requires that in promulgating the Amendment Rules, the Board must not restrict, limit or diminish the Bill of Rights unless the action is justified under Article 24(1) of the Constitution.[3]

6.1.10. At this point it is notable that there is no negative impact of the Amendment Rules on the fundamental rights and freedoms. Upon analysis of the Amendment Rules, the following are discernible:

i. Consumer protection rights: Consumer protection is a right recognised by the Constitution.[4] The State is required to ensure that consumers have the information necessary for them to gain full benefit from goods and services, and to protect the health safety and economic interests of consumers. The Amendment Rules seek to regularize advertisement of health products and devices to ensure protection of consumers.

ii. Economic and Social rights: The right to economic and social rights is also a Constitutional issue.[5] The State is mandated to ensure that every person has access to the highest standard of health, which includes the right to health care services. To guarantee this right, the Amendment Rules seek to prevent substandard lots from reaching the public by ensuring that only those batches that have been analysed and tested are commercially distributed. Further, actualisation of this right goes hand in hand with ensuring proper regulation of advertisement and promotion of medical products and technologies. The regulation will help ensure that information available to both members of public and health care providers is correct and sufficient to enable right

[1] Article 19(1) of the Constitution of Kenya 2010
[2] Article 21(1), Ibid.
[3] Article 24(1) provides that – "A right or fundamental freedom in the Bill of Rights shall not be limited except by law, and then only to the extent that the limitation is reasonable and justifiable in an open and democratic society based on human dignity, equality and freedom, taking into account all relevant factors…"
[4] Article 46 of the Constitution of Kenya 2010.
[5] Article 43 of the Constitution of Kenya, 2010.

decision making when making a decision on the appropriate health care product or technology.

ii. Impact on the Private Sector

6.1.11. Private sector comprises largely of non-governmental health service providers including members of the medical, dental, pharmacy and nursing professionals. With regard to promotion and advertisement of health products and technologies, private sector also includes mainstream media, social media, e-commerce platforms and the general public.

6.1.12. In relation to importation, exportation and manufacture of biologicals, the enhanced measures will ensure safety to members of the public. The measures will also give assurance to health care providers of the quality of health products.

6.1.13. Secondly, studies show that when prescribing medicinal products and technologies, health care providers have a great reliance on promotions and advertisements leading to less appropriate prescribing.[6] A systemic review of empirical studies on the effects of promotion on physician behaviour found that physicians with greater exposure to promotions and advertisements had a higher prescription volume, prescribed more costly medicines, had more a rapid adoption of new medicines, including those without therapeutic value, and made more requests for formulary inclusion of drugs without established therapeutic advantages.[7]

6.1.14. Based on these studies, it is evident that unregulated promotion and advertisement of health products and technologies has a negative impact on how health care providers prescribe medical products and technologies hence the importance of the Amendment Rules. The Amendment Rules also have the effect of ensuring that sufficient regulatory framework to minimise risks to the health care providers.

6.1.15. Secondly, with regard to mainstream media, social media and advertisement on e-platforms, studies indicate that although most of the advertisements provided the product's brand and generic name; other information needed for rational prescribing, such as contraindications, interactions, side-effects, warnings and precautions were less commonly provided.[8] Thus, failing to provide adequate information on e-commerce platforms has the effect of disenfranchising and putting at risk of the consumers of those health products and technologies. The Amendment Rules will have the effect of regulating this sector in order to ensure that advertising and promotion is proper in order to minimize adverse effects on consumers.

[6] Norris, P., Herxheimer, A., Lexchin, J., & Mansfeld, P. (2005). Drug promotion: What we know, what we have yet to learn. In W. H. O. and Health Action International (Ed.). Geneva.

[7] Wazana, A. (2000). Physicians and the pharmaceutical industry: Is a gift ever just a gift? JAMA, 283, 373–380.

[8] European Federation of Pharmaceutical Industries and Associations. (2007). EFPIA Code on the promotion of prescription-only medicines to, and interactions with, healthcare professionals.

6.1.16. Finally, the culmination of the Amendment Rules is to protect consumers of health products and technologies by ensuring that the existing regulatory framework gives effective protection.

iii. Impact on the Public Sector

6.1.17. Improved regulation of importation, exportation and manufacture of biologicals will ensure real-time monitoring of the manufacturing and testing of biologicals to ensure that the products are of the required quality.

6.1.18. In addition, advertising and promotion of health products and technologies is the natural output of the Amendment Rules. The Amendment Rules are expected to address the problem of inappropriate use of health products and technologies by not only lack of information but also misleading promotional information.

6.1.19. The Rules, as read with the Act, ensure the Board is able to perform its mandate to regulate advertisement and promotion of health products and technologies. Previously, despite the Act placing this mandate on the Board, there was no comprehensive legal framework in place to enable the Board effectively perform this mandate to protect consumers. The instant Amendment Rules help address this issue.

6.1.20. Finally, it is envisaged that there will be a rise in costs of implementing the Rules: liaising with related government agencies, monitoring and enforcing compliance with the Rules are expected to lead to a rise in costs of implementation.

7. COST-BENEFIT ANALYSIS

7.1. This section seeks to assess the changes proposed by the Amendment Rules in terms of their costs and benefits to justify the proposals pursuant to section 7(d) of the Statutory Instruments Act.

7.2. Benefits of the Pharmacy and Poisons (Amendment) Rules 2022: -

a) Regulation of importation, exportation and manufacturing of biologicals – The Amendment Rules require that persons dealing with biologicals, including their manufacture, exportation or importation, to have a valid licence. The also require those biologicals to be evaluated and approved before they can be distributed. This provisions of the Amendment Rules are critical in ensuring that quality of lots released to the public.

b) Definition of what constitutes advertisement: The Amendment Rules provide clarity as to what amounts to advertisement of health products as any written, pictorial, visual or verbal statement with a medical claim designed to promote prescription, supply, sale, consumption of health products through any medium.

c) Facilitation of Fundamental rights and freedoms: The Amendment Rules will enhance access to economic and social rights and the right to highest attainable standards of health as guaranteed by the Constitution.[9]

[9] Article 42 and 43 of the Constitution of Kenya, 2010.

d) Complementing existing legal framework: The Amendment Rules do not propose to have any new legislation enacted but seek to amend the existing legal framework to address the legal gap for advertisement and regulation of health products and technologies. They complement other laws including the Constitution and the Act to make their implementation more effective.

7.3. It is therefore clear that the Rules do not conflict or have any negative effect on the existing legislation.

8. ALTERNATIVE OPTIONS TO THE PROPOSED AMENDMENT RULES

8.1. Regulation is not the only means of effective Government policy. There are other ways of dealing with problems, including at the very least no action in the appropriate circumstances. Regulations often come with costs and other consequences. To quote Peter Mumford[10] statement:

> *"Regulatory interventions are necessary for sustaining the environment, saving lives, protecting consumers and vulnerable social and economic groups, and promoting better economic performance by, for example, safeguarding competition in the marketplace. There are however, costs associated with any regulatory intervention and these will vary depending on how well the regulatory regime is designed, implemented and administered."*

8.2. There are a number of options that are also available, more so because Rules or Regulations cannot deal with all matters. Some of the options that may be exploited include:

8.2.1. Policy

Instead of prescribing Rules, some matters are better left to policy. The Ministry of Health has in collaboration with the Board developed the following Guidelines for promotion and advertisement of pharmaceutical products and technologies:

i. Guidelines for Lot Release of Vaccines by Regulatory Authorities;

ii. Guidelines for Regulatory Lot Release of Biological Products;

iii. Guidelines for Advertisement and Promotion of Health Products and Technologies;

iv. Guidelines on Advertising and Promotion of Medicines; Pharmaceutical Regulatory Authority; and

v. Advertising of medicines: Guidance for providers offering medicinal treatment services Medicines and Healthcare Products Regulatory Agency (MHRA).

The Amendment Rules seek to address those issues of advertisement of medical products and technologies that cannot be sufficiently addressed under the Guidelines.

8.2.2. Information or guidance

[10] Mumford, Peter, 2003, 'What Constitutes Good Regulation for Services?' Ministry of Economic Development, Wellington New Zealand, p. 2.

Information approaches – education and persuasion – can be used to achieve certain objectives including on proper advertisement and promotion of health products and technologies. Strategies which attempt to address perceived problems by providing more information, or changing the distribution of information can improve market functioning by enabling people to make better informed decisions.[11]

8.2.3. **Recommendations**

This involves providing advisory guidance as to appropriate action in order to implement specified policy objectives. Guidance may for instance be provided on proper advertising and promotion of health products and technologies. However, there is need, due to the health risks involved to prescribe regulation such as the instant Rules for purposes of enforceability.

8.2.4. **Codes of conduct**

Codes of conduct prescribe guidelines or standards for action or behaviour in specified contexts. These are ideal for matters that are difficult to monitor on continuous basis. However, such Code of Conduct is not sufficient to regulate promotion and advertisement of health products and technologies. Further, considering that some of the players involved in advertising and promotion of health products and technologies such as the e-commerce platforms are not under any professional body, it is not practicable to develop Codes of conduct in this regard.

9. COMPLIANCE AND IMPLEMENTATION

9.1. Institutions

The implementation and enforcement of the Amendment Rules will be undertaken through the existing legal framework within at the Ministry of Health and Board.

10. CONCLUSION

10.1. Based on the analysis in this Statement, the Pharmacy and Poisons (Amendment) Rules 2022 are extremely necessary. The Rules offer socio-economic and legal benefits which are essential in ensuring consumers of health products and technologies, and in particular biologicals, are of the right quality and further ensuring protecting health consumers from lack of information or misleading advertisements.

10.2. The Amendment Rules provide a framework for ensuring that the people of Kenya enjoy the fundamental rights and freedoms guaranteed under the Constitution.

10.3. **Recommendation**

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

[11] OECD Report. *Alternatives to Traditional Regulation,* (Glen Hepburn) found at https://www.oecd.org/gov/regulatory-policy/42245468.pdf (accessed on 24th March 2022)

ANNEXURES SEPARATELY UPLOADED