MINISTRY OF HEALTH

PHARMACY AND POISONS BOARD

REGULATORY IMPACT STATEMENT

FOR

PHARMACY AND POISONS (WASTE MANAGEMENT) 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)

Contents

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 in collaboration with the Board formulated, *inter alia,* the Pharmacy and Poisons (Waste Management) Rules 2022 (hereinafter "Rules") to give effect to the objectives of the Act, and in particular ensuring public safety with regard to handling and disposal of pharmaceutical waste to prevent hazardous outcomes.

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 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.

2. OBJECT OF THE PROPOSED RULES

2.1. The general objective of these Rules is to give effect to section 44 of the Act by regulating handling, transportation, storage and disposal of pharmaceutical waste.

2.2. The objective is intended to ensure that there is an enabling regulatory framework to ensure compliance with the Constitution and the Act.

3. OVERVIEW OF THE PROPOSED RULES

3.1. The Rules address four main issues as illustrated herein below:

3.1.1. **Scope of the Rules**

a) The Rules distinguish between what will and will not be considered as pharmaceutical waste. They provide that pharmaceutical waste shall include: waste containing pharmaceuticals that are expired, damages or no longer needed; items contaminated by or containing pharmaceuticals (bottles, boxes); applicable medical devices; substandard and falsified medical products; and obsolete investigational medicinal products. However, the Rules shall not apply to sharps waste, infectious waste, pathological waste, radioactive waste and non-hazardous waste.

b) The Rules also define a waste generator as the person whose activities or activities under his or her direction produces waste or if that person is not known, the person who is in possession or control of that waste. The Rules place responsibility on the waste generator to manage pharmaceutical waste in the manner provided and also to adopt cleaner production measures in the management of pharmaceutical waste.

3.1.2. **Pharmaceutical waste management**

a) The Rules provide certain requirements with regard segregation, packaging, labelling, handling and collection, storage and transportation of pharmaceutical waste.

b) With regard to segregation of pharmaceutical waste, the Rules provide that a waste generator shall segregate any pharmaceutical waste from other forms of medical waste at the point of generation and at all stages thereafter. It is also required that cytotoxic pharmaceutical waste and compressed-container medications (aerosols, inhalers) shall be segregated from other forms of pharmaceutical waste.

c) On the issue of packaging, the Rules provide that a waste generator shall take reasonable steps to ensure that pharmaceutical waste is in a package that is easily identifiable, including being in its original packaging, to aid in identification and prevent reaction between incompatible molecules.

d) The Rules also require that containers and packages for storing pharmaceutical waste shall contain a description of the pharmaceutical waste; name, physical address and telephone contact of the waste generator; and warning or caution statements as may be appropriate.

e) In addition, the Rules state that waste collection and storage bags for pharmaceutical waste needing incineration should not be made of chlorinated plastics. That plastic bags or bin liner used in storage or transport should be legibly labelled with the name of the firm manufacturing the plastic bags or bin liner.

f) Further, the Rules provide that a waste generator shall ensure that pharmaceutical waste is transferred to a person licensed to dispose such pharmaceutical waste in an approved pharmaceutical disposal facility.

g) Moreover, the Rules provide that all pharmaceutical waste shall be stored in a designated quarantine store, marked and put away from usable pharmaceuticals. In addition, any storage used for pharmaceutical waste shall be labelled on the outside.

h) Finally, the Rules require special conditions for transportation of pharmaceutical waste including that onsite transportation of pharmaceutical waste shall be separate from infectious waste, during offsite transportation, a consignment note shall be carried by the driver, and on completion of a journey, the consignee shall affirm receipt and driver shall return consignment note to waste generator.

3.1.3. **Importation and exportation of pharmaceutical waste**

a) The Rules make it an offence to import pharmaceutical waste into the territory of Kenya, attracting a fine of Kshs. 500,000.00.

b) The Rules prohibit exportation of pharmaceutical waste unless the exporter has a valid permit issued by the National Environment Management Authority and a valid prior informed consent document issued by the designated national authority of the receiving country.

3.1.4. **Pharmaceutical waste treatment and disposal**

a) The Rules state that before treatment and disposal, pharmaceutical waste shall be sorted according to dosage form or by active pharmaceutical ingredient, depending on treatment options available. Further, the Rules provide that pharmaceutical waste shall be disposed within one year from the date of registration in the manner set out in the schedule of the Rules.

b) Further, the Rules provide that disposal of pharmaceutical waste shall be done under the supervisions of the Board at a pharmaceutical waste disposal site approved by the National Environment Management Authority. Upon disposal, the Rules state that the Board shall issue a Certificate of Safe Disposal of Pharmaceutical Waste.

4. STAKEHOLDER CONSULTATIONS

4.1. Legal Requirements Relating to Public participation and Consultation

4.1.1. The Constitution of Kenya 2010 and the Statutory Instruments Act 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."

4.1.2. 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 wished 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.

4.1.3. The Statutory Instruments Act 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.*"

4.1.4. 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)

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

4.2. Consultations Undertaken

4.2.1. 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.

4.2.2. The Board in execution of his statutory mandate and in an effort targeted at ensuring its regulatory effectiveness, sought to engage stakeholders, experts and members of public when developing these Rules in order to ensure Kenya's regulatory framework is in line with global standards. The following steps were undertaken to ensure there was effective public participation:

a. In February 2022, the Board published these Rules on for ease of access by stakeholders and members of public.

b. On 20th February 2022, the Board published a notice on its website at https://web.pharmacyboardkenya.org/ as follows:

i. Notifying the general public that it had published the Rules.

ii. Inviting stakeholders and members of public to a virtual meeting to highlight oral submissions from 7th March to 9th March 2022.

iii. Inviting stakeholders and members of public to attend a hybrid meeting at the Board's regional offices between 10th and 11th March 2022 (hereinafter called "meetings").

iv. Inviting all stakeholders and members of public to give feedback to the Rules by:

i. filing an online feedback form on the Board's website https://web.pharmacyboardkenya.org/stakeholder-feedback-form,

ii. Sending an email to feedback@pharmacyboardkenya.org;

iii. Sending feedback to the Board's physical address: 4th Floor, PPB Building along Lenana Road, Nairobi;

iv. Sending feedback via post at P.O. Box 27663-00506, Nairobi.

(Annexure 1 – is a copy of the Notice on the Board's website)

c. 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 comments on the Rules either by filing a feedback form, by email, post or leaving the comments at the Board's offices.

(Annexure 2 – are copies of screenshots from Facebook and Twitter posts)

d. Further, on 21st February 2022, the Board notified the general public of the 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)

e. Additionally, the Board sent correspondence to its mapped stakeholders informing them of the draft Rules and inviting them to attend the meeting and or send their feedback for consideration. *(Annexure 4 – are copies of correspondence sent to various stakeholders)*

i. **Virtual meeting from the Board's headquarters**

4.2.3. On 9th March 2022, the Board conducted a virtual public participation meeting where stakeholders and other members of public attended and gave their feedback for consideration. The said session was chaired by Dr. Wilfred Ochieng and coordinated by Dr. Wanga, Dr. Pamela, Dr. Allan Kyalo and Tom Kauki.

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

4.2.4. At the start of the meeting, the coordinators gave a presentation of the Rules. Subsequently, the coordinators invited comments and feedback from the attendees. The comments and feedback were addressed at the virtual meeting. Subsequently, the Rules were amended as appropriate to incorporate the feedback from the participants.

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

ii. **Hybrid meeting at the Board's headquarters and regional offices**

4.2.5. On 11th March 2022, the Board conducted a hybrid meeting where stakeholders and members of public joined the meeting virtually and physically across the Board's ten (10) regional offices namely Nairobi, Coast, North Rift, South Rift, Upper Eastern, Western, Nyanza and Central.

This session was chaired by Dr. Willis Ochieng and coordinated by Dr. Tom Kauki, Mr. Kauki and Mr. Kiptoo.

(Annexure 7 – is a copy of the agenda of the hybrid meeting and attendance list of stakeholders and members of public)

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

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

iii. **Written submissions from various stakeholders and members of public**

4.2.7. 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 Pharmaceutical Waste Rules also amended as appropriate.

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

5. ASSESSMENT OF THE IMPACT OF THE PROPOSED RULES

5.1. Statement of the Impact of the proposed Rules

Need for the Rules

5.1.1. The primary purpose of the Rules is to facilitate better carrying out of the purposes and provisions of the Act. The Act was enacted to control the profession of pharmacy and the trade in drugs and poisons in Kenya.

5.1.2. Based on the foregoing, healthcare services inevitably create pharmaceutical waste that may itself be hazardous to public health and the environment. Safe methods for managing pharmaceutical waste are therefore essential and should be an integral feature of healthcare services. The purpose of the Rules is to regulate the management of pharmaceutical waste.

5.1.3. Management of pharmaceutical waste entails taking all practical steps to ensure that pharmaceutical waste is managed in a manner that protects human health and the environment against the adverse effects which may result from pharmaceutical waste.

5.1.4. In both the short and long term, the actions involved in implementing safe pharmaceutical waste management programmes require a multi-sectoral

cooperation and interaction at all levels. Establishment of Rules on safe management of pharmaceutical waste, training of personnel and raising public awareness are essential elements of safe pharmaceutical waste management.

5.1.5. With the enactment of the Rules, there will be a well-established legal framework for management of pharmaceutical waste at all levels of healthcare. The Rules will apply to all persons whose activities or activities under their direction produces waste, or persons in possession or control of that waste.

i. Impact on the Fundamental Rights and Freedoms

5.1.6. 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]

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

5.1.8. In promulgating the Rules, the Cabinet Secretary must not restrict, limit or diminish the Bill of Rights unless the action is justified under Article 24(1) of the Constitution.[3]

5.1.9. There is no negative impact of the Rules on the fundamental rights and freedoms. Upon analysis of the Rules, the following are discernible:

5.1.10. The Rules provide for:

i. Environmental rights: The right to a clean environment is guaranteed by the Constitution.[4] The State is required to manage the environment in a sustainable manner, and to eliminate processes that are likely to endanger

[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] Articles 42, 69 & 70 of the Constitution of Kenya 2010.

the environment. The Rules seek to ensure that pharmaceutical waste is properly handled, stored and disposed in order to protect human health and the environment.

ii. Economic and Social rights: The right to economic and social rights is also guaranteed by the Constitution.[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. Actualisation of this right goes hand in hand with ensuring that pharmaceutical waste is properly disposed to prevent instances of infections and disease arising from mismanagement of such waste.

ii. Impact on the Private Sector

5.1.11. Private sector comprises largely of non-governmental health service providers including members of the medical, dental, pharmacy and nursing professionals. It also includes dealers in health products and technologies as well as consumers of those health products and technologies. The main sources of pharmaceutical waste are from households, hospitals and community pharmacies.

5.1.12. It is anticipated that the Rules would positively impact on the private sector by providing a legally recognized means of disposing health products and technologies, an area that has long been unregulated leading to uncertainty as to the appropriate and legally recognized means of disposing pharmaceutical waste which has resulted to pollution. Definition of what constitutes pharmaceutical waste provides a good guidance of what type of waste the Rules apply to. In addition, provisions for segregation, packaging, labelling, handling, collection and transportation of pharmaceutical waste will serve the purpose of preventing harm or injury to health service providers as well as members of public.

5.1.13. By succinctly providing for management of pharmaceutical waste, it is anticipated that there will be a general increase in environmental pollution. It is also anticipated that there will be a decrease in injuries and infections from improperly disposed pharmaceutical waste.

5.1.14. Despite these benefits, the Rules many increase the costs of disposal of pharmaceutical waste. This is because the Rules are specific as to the means of packaging, labelling, handling and collection, storage and transportation, and disposal of pharmaceutical waste. However, these cost implication is minimal and does not outweigh the benefits.

[5] Article 43 Ibid.

iii. Impact on the Public Sector

5.1.15. The improvement in the management of disposal of pharmaceutical waste is the natural output of the proposed Rules. The Rules are expected to provide solution to disposal of pharmaceutical waste that forms a substantial part of hazardous waste in the country.

5.1.16. Amongst the benefits to flow from the Rules is a clarification of the waste that falls within the context of pharmaceutical waste. Further, the Rules define who is a waste generator and place responsibility upon that person with regard to management of pharmaceutical waste.

5.1.17. The Rules, as read with the Act, ensure the Board is able to perform its mandate to regulate handling, storage and disposal of pharmaceutical waste. Previously, despite the Act placing this mandate on the Board, there was no legal framework in place to enable the Board effectively perform this mandate. The instant Rules help address this issue.

5.1.18. 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.

6. 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.

6.1. Benefits of the Pharmacy and Poisons (Pharmaceutical Waste Management) Rules 2022

i. Definition of what constitutes pharmaceutical waste: The Rules clarify what amounts to pharmaceutical waste. This clarification is important as it separates pharmaceutical waste, which is under the mandate of the Board, with other types of waste which are under the mandate of other government agencies.

ii. Management of pharmaceutical waste: The Rules enhance management of pharmaceutical waste by putting measures to enable segregation, packaging, labelling, handling and collection, storage and transportation, and importation and exportation of pharmaceutical waste.

iii. Facilitation of Fundamental rights and freedoms: The proposed Rules will enhance the rights to a clean and healthy environment and highest standards of health as provided guaranteed in the Constitution.[6]

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

iv. Complementing existing legal framework: The proposed Rules do not propose to have any new legislation enacted or any existing laws being amended. They complement other laws including the Constitution and the Act to make their implementation more effective.

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

7. ALTERNATIVE OPTIONS

7.1. 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[7] 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."*

7.2. 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:

7.2.1. Policy

Instead of prescribing Rules, some matters are better left to policy. The Ministry of Health has in collaboration with the Board has had policy mechanisms developed from time to time to guide disposal of pharmaceutical waste. These mechanisms, though not law, inform what is or is not permissible with respect to management of pharmaceutical waste. The policy mechanisms are as follows:

i. Health Care Waste Management Standard Operating Procedures. First Edition. Ministry of Health. Government of Kenya. June 2016.

ii. Health Care Waste Management Strategic Plan 2015 – 2020. Ministry of Health. Government of Kenya, April 2015.

iii. National Guidelines for Safe Management of Health Care Waste. Ministry of Medical Services and Ministry of Public

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

Health and Sanitation. Government of Kenya, January 2011.

iv. Kenya National Guidelines on Safe Disposal of Pharmaceutical Waste. Republic of Kenya. Ministry of Health. 2001.

v. Safe Management of Wastes from Health-care activities. Second Edition. World Health Organisation. 2014.

The Rules seek to address those issues of disposal of pharmaceutical waste that cannot be sufficiently addressed under the Rules.

7.2.2. **Self-regulation**

The government may allow, in appropriate cases, for the sector to regulate itself up to a certain threshold. For instance, in the current Rules, sector players have been left to choose the means of disposal of pharmaceutical waste provided the same is approved.

7.2.3. **Information or guidance**

Information approaches-education and persuasion- can be used to achieve certain objectives. 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.[8]

7.2.4. **Recommendations**

This involves providing advisory guidance as to appropriate action in order to implement specified policy objectives. Guidance may for instance be provided on the issue of proper disposal of pharmaceutical waste. However, there is need, for health and safety purposes an environmental conservation or protection, to prescribe regulation such as the instant Rules for purposes of enforceability.

7.2.5. **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 disposal of pharmaceutical waste because of several factors including the high number of professionals all who are governed under different Codes of conduct and also the fact

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

that the "waste producers" include non-professionals to whom the Codes of conduct are not applicable.

8. COMPLIANCE AND IMPLEMENTATION

8.1. Institutions

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

9. CONCLUSION

9.1. Based on the analysis in this Statement, the Pharmacy and Poisons (Waste Management) Rules 2022 are extremely necessary. The Rules offers socio-economic, environmental and legal benefits which include clarity means of disposal of pharmaceutical waste and clarity of responsibility with regard to disposal of such waste, which benefits far outweigh the costs of the Rules.

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

9.3. Recommendation

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