
**MINISTRY OF HEALTH**
**PHARMACY AND POISONS BOARD**

# REGULATORY IMPACT STATEMENT

**FOR**

# THE PHARMACY AND POISONS (REGISTRATION OF HEALTH PRODUSTS AND TECHNOLOGIES) RULES 2022

**MARCH, 2022**

This Regulatory Impact Assessment (RIA) has been prepared by the Ministry of Health pursuant to Section 6 and 7 of the Statutory Instruments Act (No. 23 of 2013)

Contents

## CHAPTER 1: INTRODUCTION AND BACKGROUND

### *1.1.What are health products and technologies?*

The Health Laws (Amendment) Act, 2019 defines health products and technologies as:

*health product" includes human and veterinary medicines, medical products, medicinal substances, vaccines, diagnostics, medical devices, blood products, traditional and alternative medicine, therapeutic feeds and nutritional formulations, cosmetics and related products;*

*"health technology" means the application of organized knowledge and skills in the form of devices, medicine, vaccines, procedures and systems developed to solve a health problem and improve the quality of life;*

### *1.2. Legal and regulatory framework*

**Constitutional dispensation**

Article 43 (1) of the Constitution of Kenya 2010 provides that every Kenyan citizen has a right to the highest attainable standard of health including the right to health care services. Article 46 (1)(c) of the Constitution also guarantees consumers the right to protection of their health, safety and economic interests. Similarly, Article 53 and 56 of the Constitution mandates the state to ensure protection of children's and minorities' right to health care.

**Statutory dispensation**

Section 62(1) of the Health Act, 2017 provides for the establishment of a single regulatory body responsible for regulation of health product s and technologies in Kenya. Section 3 of the Pharmacy and Poisons Act, Cap 244 Laws of Kenya provides for the establishment of the Pharmacy and Poisons Board (hereinafter "*the Board*") whose functions are provided for under Section 3B with the primary objective being to regulate the profession of pharmacy and ensure the safety, quality and efficacy of medical and health products and technologies.

Further, section 44 (1) (n) of the Act has expanded the mandate of the Cabinet Secretary responsible for matters health in consultation with the Board to create rules for the effective creation and implementation of a framework for application and harmonization of registration of health products and technologies.

In performance of its function, the Board is tasked under Section 62(1) of the Health Act to do the following:

a) licence health products and health technologies

b) licence manufacturers and distributors of health products

c) conduct laboratory testing and inspection of manufacturing, storage and distribution facilities of health products and technologies

d) control of clinical trials

e) conduct advertising and promotion, post marketing surveillance for quality, safety and disposal of health products and health technologies

f) regulate contractors for medical devices and physical security for products including radioactive material and biological products

**Policy dispensation**

Sessional Paper No 4 of 2012 on National Pharmaceutical Policy, also known as the Kenya National Pharmaceutical Policy (KNPP) was formulated to succeed the Kenya National Drug Policy (KNDP) of 1994. The Policy goal was towards reforming the pharmaceutical sector to ensure universal equitable access to quality essential medicines and HPTs for all Kenyans.

**The Kenya Health Policy 2014-2013**

The policy objective aimed at ensuring that the country attains the highest possible standards of health, in a manner that is responsive to the needs of the people.

The policy identified key action areas to include among others, ensuring effective, safe and affordable Health Products and Technologies (HPTs) are available and rationally used at all times.

The proposed rules seek to actualize the aspirations of both Sessional Paper No 4 of 2012 on National Pharmaceutical Policy and The Kenya Health Policy 2014-2013 through the implementation of the national HPT Policy therein.

### *1.3.Requirements of the Statutory Instruments Act, 2013*

Prior to making a statutory instrument, section 6 and 7 of the Act mandates the Board to prepare a regulatory impact statement in circumstances where the proposed statutory instrument is likely to impose significant cost on the community, or part of the community.

Under the Act, a regulatory impact statement shall contain;

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 proposedlegislation which is to amend an existing statutory instrument the effect on the operation of theexisting statutory instrument;

c) a statement of other practicable means of achieving those objectives, including other regulatoryas 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;

g) a draft copy of the proposed statutory rule

In furtherance of implementation of the foregoing provisions, the Board, in consultation with

the Cabinet Secretary Ministry of Health prepared the Pharmacy and Poisons (Registration of Health Products and Technologies) Rules, 2022 (hereinafter referred to as "*HPT Rules*") which were subjected to stakeholder consultation as required under Section 5 of the Statutory Instruments Act, 2013. The comments and concerns raised during public participation were used to enrich the HPT rules.

## CHAPTER 2: AN OVERVIEW OF THE PROPOSED PHARMACY AND POISONS (REGISTRATION OF HEALTH PRODUCTS AND TECHNOLOGIES) 2022

### 2.1. Brief background

Over time, the Board has observed that the Pharmacy and Poisons Act, Cap 244 Laws of Kenya (hereinafter "the Act") does not have make adequate provision on market authorization (hereinafter "MA") of Health Products and Technologies (hereinafter "HPTs") in Kenya making it difficult for the regulator to effectively regulate HPTs.

According to Section 3A (c) of the Act the powers of the Board with respect to market authorization is to grant or withdraw MA for medical products subject to appropriate conditions and revise such conditions as necessary. Similarly, under section 3B (2)(e) and (f) of the Act, the Board's function is to grant or revoke licenses for the manufacture, importation, exportation, distribution and sale of medicinal substances and to maintain a register of all authorized medicinal substances respectively.

Therefore, the Act does not provide for among others:-

- A register of HPTs,
- Application procedure for MA of HPTs,
- What is to be issued with MA,
- Certificate of Registration,
- Retention of HPTs,
- Periodic renewal of MA,
- Issuance of certificate of MA,
- Suspension and cancellation of MA, and
- Variation of MA

The general objective of the HPT rules is to give effect to Section 3B (2) of the Act and 63(1) of the Health Act, 2017. The key objective is to provide for a legal framework for the application and authorization process for market authorization of HTPs to ensure safety, quality and efficacy of health products and health technologies within the Kenyan market.

### 2.2. The Pharmacy and Poisons (Registration of Health Technologies) Rules

**2022**

### *2.2.1. Part I – Preliminaries*

This part provides for the citation of the HPT Rules together with definitions and interpretation of key terminologies used within the Rules. Some of the terms are equally defined in the Act as well as the Health Act for harmony and ease of reference.

Some of the key terminologies are:

*Blood product- medicinal product based on a blood constituent which is prepared industrially*

*Cosmectics-substance(s) manufactured for use in cleansing, improving or altering the complexion, skin, hair, eyes or teeth*

*"good manufacturing practice certificate" means a document issued by a competent regulatory authority that certifies compliance to good manufacturing practice;*

*"health product" includes human and veterinary medicines, medical products, medicinal substances, vaccines, diagnostics, medical devices, blood products, traditional and alternative medicine, therapeutic feeds and nutritional formulations, cosmetics and related products;*

*"health technology" means the application of organized knowledge and skills in the form of devices, medicine, vaccines, procedures and systems developed to solve a health problem and improve the quality of life*

*Plasma- Liquid part of blood where the blood separates from its cells which only contains blood proteins*

*Product retention- Maintenance of product in the register registered products*

*vaccine- heterogenous class of medicinal substances capable of inducing specific, active and protective host immunity against infectious diseases*

*Registered HPT- a HPT for human use, approved by the Board, and presented into the market in a ready form, in a special package and with a specific name*

### *2.2.2. Part II – Registration of HPTs*

This part provides for the application and authorization process of market authorization of HPTs. It also sets out the prescribed forms and timelines of the different steps of the MA process, validity of the registration certificates and renewal of licenses.

Under this part, the Board is expected to maintain a register of authorized HPTs in the prescribed form in the First Schedule which shall be available to the public for scrutiny, thus enhancing the citizens' right to access to information under Article 35 of the Constitution of Kenya 2010.

### *2.2.3. Part III – Miscellaneous*

This part makes provision for registration of HPTs and market authorization in emergency situations and provides for the procedure of undertaking variations and changes to the registered HPTs.

Conditions precedent for registration of HPTs for compassionate use is also highlighted in this part together with timelines, for consideration by the Board as to their safety, efficacy, quality and economic value. Upon successful application, the Board issues a certificate of registration in prescribed Form 4 set out in the First Schedule.

#### *2.2.4. Schedules*

The First schedule provides for the standard forms highlighted in the HPT Rules as follows:-

*Form 1 – Register of health products*

*Form 2 – Application for Registration of health products or technologies*

*Form 4 - Certificate of Registration of Health Product or Technology*

*Form 5 – Notice of intention to withhold, Suspend or Cancel the registration of health product or Technology*

*Form 6 – Notice of intention to withdraw the registration of a health product or Technology*

*Form 7 – Application for Registration/ Renewal of certificate of registration*

## CHAPTER 3: STAKEHOLDER PARTICIPATION

### 3.1. Approach and methodology

The Board in execution of its statutory mandate and in an effort targeted at ensuring its regulatory effectiveness, sought to engage stakeholders, experts and members of public with a view to enhancing regulation of the conduct of clinical trials so as to be aligned with global standards. In doing so, the Board undertook the following steps in ensuring there was effective public participation:

#### *3.1.1. Plenary preparation of the public participation sessions*

A technical committee was formed to undertake the preparations of the anticipated stakeholder engagement sessions. During the meetings the Committee mapped out and issued invitations of the intended consultative sessions to key stakeholders in accordance with the Board's Third Strategic Plan 2020-2025.

#### *3.1.2. Issuance of invitations for public participation*

On 20th February 2022, the Board published among others, the Pharmacy and Poisons (Registration of Health Products and Technologies) Rules 2022, on its website for ease of access by stakeholders and members of public together with the invitation for consultative meetings

on its official website.

In addition, a notice was issued through the *Daily Nation* dated 21st February 2022 inviting stakeholders and members of the public to visit the Board's website to access the draft HPT Rules and to submittheir written comments to the Board's Chief Executive Officer. Copies of the notice in the Daily Nation were posted on notice boards in all the department within the Ministry to disseminate theinformation to the general public.

Similarly, on 21st February 2022, the Board, via its social media platforms, Facebook and twitter, notified the public of the published draft rules and attached the link to the public participation invitation on its website.

### *3.1.3 Conduct of the consultative meetings*

The public consultation sessions were scheduled and took place from 7th March 2022 up to 9th March 2022. The sessions were mainly conducted virtually, with coordination from the Board's Nairobi region.

The draft HPT rules were virtually tabled for discussion and deliberations by stakeholders on 8th March 2022. On 11th March 2022, stakeholders from the Board's Central, North Rift, Upper Eastern, Lower Eastern, Coast, Western and South Rift regional offices converged for deliberations on the draft rules and their attendance recorded as per the table below:

*Table 1: Attendance of public participation sessions in regional offices*

| No. | Region | Stakeholders present |
|---|---|---|
| 1. | Central | 33 |
| 2. | Coastal | 34 |
| 3. | Lower Eastern | 48 |
| 4. | North Rift | 62 |
| 5. | Upper Eastern | 38 |
| 6. | North Eastern | 20 |
| 7. | South Rift | 56 |
| 8. | Western | 63 |

**On both occasions stakeholder feedback was recorded and collated together with**

**written submissions received by the Board on email and by post for deliberations by the technical team on HPT.**

### *3.1.4. Deliberations and outcome*

After receipt of the comments and concerns, the Board deliberated on said feedback to which effect some were adopted and rules amended accordingly while others were rejected with reasons.

*See Annexture 1 – Comprehensive Public Participation Report*

## CHAPTER 4: IMPACT ASSESSMENT OF THE RULES

### 4.1. Statement of objectives and reasons

The primary objective of the Rules is to facilitate and regulate the profession of pharmacy and ensure the safety, quality and efficacy of health products and health technologies in accordance with the Health Act, 2017, the Pharmacies and Poisons Act, Cap 244, Laws of Kenya and international best practices.

The purpose of the rules is to:

Provide for the requirements and procedure of applications for licensing of market authorization for HPTs

To provide for timelines for the validity of licenced HPTs within the Kenyan market

Regulate the periodic renewal and variation of market authorization for HPTs

**The Rules are geared towards addressing the lack of proper structures that provide for the requirements, procedure and timelines for market authorization of HPTs.**

### 4.2. Statement on the Effect of the Proposed Regulations

Generally, the proposed rules are neither in contravention of any constitutional provisions nor do they have any retrospective effect on any constitutional provisions. Additionally, the rules neither infringe on the public's fundamental rights and freedoms nor impose additional costs and taxes.

#### *4.2.1. Effects on the Public Sector*

The HTP Rules shall have a positive impact on the public sector by enhancing coherence and streamlining registration and market authorization of HTPs which will greatly contribute to improvement of service delivery in the pharmaceutical industry.

#### *4.2.2. Effects on the private sector*

The rules seek to curb the prevalent unauthorized online marketing and sale of unregistered HPTs. The Board has previously received complaints from private industry stakeholders to the effect that third parties have been actively marketing and selling their products without their consent.

Thus, it is expected that key players in the pharmaceutical industry together with health service providers will stand to benefit from a better regulated HPT sector in the promotion of safer, quality and affordable HPTs.

#### *4.2.3. Effects on fundamental rights and freedoms*

It is envisioned that the HPT Rules shall have a positive impact on the fundamental rights and freedoms through promotion of economic and social rights of the citizenry as contemplated under Article 43 of the Constitution and ensuring accessibility to high standards of safe and

quality health care services.

The Rules will also promote and protect consumers' right to protection of their health, safety and economic interests since the Board will have adequately assessed and registered safe, quality and affordable HPTs. Further, consumers' right to access to information under Article 46(1) and 35 of the Constitution are guaranteed as the Board will have a register of all registered and authorized HPTs, which records will be readily available to the public.

#### *4.2.4. Impact on socio-economic aspects*

Globally, there has been a paradigm shift in trading with emerging trends such as e-commerce. The pharmaceutical industry has not been exempted from move to the online space as industry players have invented online pharmacies.

Notwithstanding the ease of business that is attributed to the trade, it has equally posed a threat to the pharmaceutical industry with the Board observing an increase in unauthorized online advertisement, promotion and sale of HPTs including Prescription Only Medicines (POMs). Inadequate regulation of the online space is not only a threat to the health of consumers but also the regulator's overall accountability mandate.

As such, implementation of the HPT Rules together with the rules on advertisement of medicinal substances will sufficiently regulate the online space for pharmaceuticals.

#### *4.2.5. Impact on existing legal framework*

The rules have been prepared and enacted in accordance with Constitutional provisions and are not in any way in contravention with the Pharmacy and Poisons Act, Cap 244 Laws of Kenya or any other written law. Therefore, in furtherance of achieving their primary objective, the rules shall complement existing legislation and administrative guidelines on market authorization of HPTs.

## CHAPTER 5: 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.

### 5.1. Benefits of the Pharmacy and Poisons (Registration of Health Products and Technologies) Rules 2022

The approval of the proposed rules is deemed to have the following accruing benefits:

i. **Enhanced consumer protection:** Registration of market authorization for HPTs will guarantee circulation of safe, quality, effective and affordable health products and technologies within the pharmaceutical industry.

   Unlike previously, with the periodic retentions and variations of MAs consumers will be guaranteed of safe HPTs in the online space where the HPTs are marketed and sold.

ii. **Improved monitoring of authorized HPTs:** clear provisions on the requirements and registration formalities of authorized HPTs and timelines therein present an opportunity provide a clear and reliable platform for close monitoring of HPTs circulating in the market. Similarly, with the provisions on variations and retention of HPTs as well as maintenance of a register of authorized HPTs, the public is at liberty to scrutinize records therein for any mishaps. Indeed the instrument seeks to provide for a more systematic, structured and transparent avenue of the mode of monitoring market authorization of HPTs.

iii. **Promotion of Fundamental Rights and Freedoms:**

   The proposed HPT rules do not limit the fundamental rights and freedoms set out under the Constitution of Kenya.

   Rather, the rules promote the full enjoyment of the right to the highest attainable standards of health as stipulated under Article 43 of the Constitution. The rules also safeguard consumers' right to protection of their health, safety and economic interests as guaranteed under Article 46.

iv. **Complementing existing legal frameworks:** The draft HPT Rules 2022 do not propose to have any new legislation enacted or any of the existing laws being amended. They complement other laws making their implementation more effective.

It is therefore clear that the Rules neither conflict nor have any negative effect on existing legislation. Additionally, the rules do not have a retrospective effect on any constitutional provisions.

### 5.2. Financial Cost

Implementation of the proposed rules neither impose additional costs or taxes on the Market

Authorization Holders (MAHs) nor do they implicate consumers in any manner. This is because there are existing administrative guidelines in place that are already operational and the costs and fees therein shall continue to apply until communicated otherwise through appropriate channels.

## CHAPTER 6: CONSIDERATION OF ALTERNATIVES

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, administrative measures and developing the proposed HPT Rules 2022.

### 6.1. Option one: Maintenance of the Status Quo

The HPT Rules 2022 are responsive to the current e-commerce dynamics. In the absence of these rules, emerging issues in the pharmaceutical industry of unauthorized marketing and sale of unregistered HPTs in online pharmacies will remain insufficiently regulated.

By maintaining the status quo, the legal requirements under Sections 63 of the Health Act, 2017 and Section 3B of the Pharmacy and Poisons Act, Cap 244 Laws of Kenya, will not be fulfilled. In addition, the challenges identified such as absence of an evaluation and monitoring platform for HPTs, will persist.

### 6.2. Option two: Administrative Measures

Administrative measures involve issuance of directives and circulars to the various planning authorities. This is a non-regulatory measure which if applied, will depend on the good will of pharmaceutical practitioners to implement the provisions of the principal Act. 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.

### 6.3. Option three: Formulating the Proposed Pharmacy and Poisons (Registration of Health Products and Technologies) Rules, 2022

The Pharmacy and Poisons (Registration of Health Products) Rules, 2022 will yield the following benefits: enhanced consumer protection, improved monitoring of marketing authorization of HPTs and promotion of fundamental rights and freedoms such as the right to access to information and the right to the highest attainable standards of health among others.

The assessment of the cost and benefits in chapter 5, indicates that the benefits of formulating the rules outweigh the costs. Therefore, option three was selected as the preferred option.

## CHAPTER 7: COMPLIANCE AND IMPLEMENTATION

### 7.1. Institutions

It is the duty of the regulator to assess the adequacy of the institutional framework and other incentives through which the rules will take effect and design responsive implementation strategies that make the best use of them.

Implementation and enforcement of these rules will be undertaken through the existing institutional framework at national level (Ministry of Health and Pharmacy and Poisons Board) and the county level (county governments).

## CHAPTER 8: CONCLUSION AND RECOMMENDATION

Based on the analysis in this report, the Pharmacy and Poisons (Registration of Health Products and Technologies) Rules 2022 are extremely necessary. The rules provide a framework that ensures protection of fundamental rights and freedoms including consumer rights and the right to the highest attainable standards of health. The rules also offer both socio-economic and legal benefits which far outweigh the financial costs of the rules.

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

**ANNEXURES**

i. The Pharmacy and Poisons (Registration of Health Products and Technologies) Rules 2022

ii. The comprehensive public participation report

iii. Minutes of Virtual Stakeholder Meetings

iv. Stakeholder Meetings Attendance List

v. Stakeholder Comments\Reports