MINISTRY OF HEALTH

PHARMACY AND POISONS BOARD

REGULATORY IMPACT STATEMENT

FOR

THE PHARMACY AND POISONS (GUIDELINES FOR THE CONDUCT OF CLINICAL TRIALS) 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.Definition of Clinical Trials.

The World Health Organization definition of a clinical trial is "*any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes*"

Clinical trial outcomes thus dictate the decisions to be made about health care. International best practice as prescribed under the Declaration of Helsinki demand that "*Every clinical trial must be registered in a publicly accessible database before recruitment of the first subject*".

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 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*"). Section 3A of the Act provides for the powers of the Board to include among others "*grant or withdraw authorization for conducting clinical trials of medical products*"

Further, according to Section 3B of the Act and in relation to regulation of health products and technologies, the Board is mandated to approve the use of any unregistered medicinal substance for purposes of clinical trials and compassionate use as well as approve and regulate clinical trials on medicinal substances.

Section 25A of the Act provides for the substantive law on clinical trials and gives the

Board the power to prescribe guidelines for evaluation of applications to commence clinical trials on pharmaceutical products.

In performance of its function, the Board is also 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 policy acknowledges Kenya's pharmaceutical sector, whose functions include among others, drug research and development, including clinical trials and bioequivalence studies, as a significant contributor to the economy and a key component of healthcare delivery.

International best practices demand that National Regulatory Authorities, in this case, the PPB, impose timelines for assessment of clinical trial applications and maintain a publicly available database of approved and rejected applications. The proposed guidelines thus seek to address the gaps in the regulatory framework on clinical trials,

promote implementation of the constitutional provisions above and ensure Kenya's clinical trial system is compliant with global standards and practice.

Additionally, emerging issues such as COVID-19 have caused delays in subject enrolment and operational gaps which has had a negative impact on clinical trial programmes and data integrity. Therefore, the Guidelines will provide sufficient guidance on clinical trial application, authorization, registration and monitoring process.

Kenya recently signed a Memorandum of Understanding with the pharmaceutical giant, Moderna, for the construction of vaccine a manufacturing plant in Kenya, the first of its kind in Africa. Therefore, the main purpose of the guidelines is to facilitate collaboration of the Ministry of Health and PPB with key stakeholders in ensuring that clinical trials are conducted in accordance with global scientific, ethical and moral standards to guarantee circulation of quality, safe and efficacious medicines, health products and technologies in the Kenyan market.

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 (GUIDELINES FOR THE CONDUCT OF CLINICAL TRIALS) 2022

2.1. Brief background

The general objective of the Guidelines 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 Scope of Application of the guidelines

The guidelines provide that they shall be applicable to: testing of unregistered health products; comparative bioavailability trials; generation of data on a health product that is registered in Kenya based on recognition, reliance or a work sharing arrangement; establish bioequivalence for registration of a generic health product; identify adverse reactions; to generate data on the absorption, distribution, metabolism and excretion of a health product; and to conduct a post-marketing study of a registered health product including the efficacy studies monitoring resistance.

The guidelines shall not apply to clinical trials that among others covers randomised controlled clinical trials relating to behavioural intervention; involves an adult participant in the use of an educational test, survey, interview, or observation of public behavior and involves the collection or evaluation of existing data, documents, or pathological or diagnostic specimens which are publicly available or if the

2.2.2. Part II – Procedure for application for approval to conduct clinical trials

This part provides for the application process for authorization to conduct clinical trials and sets out the prescribed forms and timelines of the different steps of the approval process.

Under this part, the Board is expected to appoint an expert advisory committee for

clinical trials which shall assist in ensuring efficient processing of the applications.

2.2.3. Part III – Investigators and sponsors

This part makes provision for qualifications for appointment as principal investigators and sponsors and sets out their duties and responsibilities.

2.2.4. Part IV – Conduct of Clinical Trials

This part provides for the procedure for the conduct of clinical trials on child participants and the need for issuance of informed written consent before the process. It also sets out formalities on issuance of reports on suspected and unexpected serious adverse drug reactions during clinical trials.

Under this part the Board is also mandated to ensure the establishment of a Data and Safety Monitoring Board whose purpose shall be to among others:

(a) assess the progress of a clinical trial;

(b) assess the safety data of a clinical trial; and

(c) assess the critical efficacy endpoints of a clinical trial

2.2.5. Miscellaneous

The guidelines provide for among others, formalities regarding amendment of protocols, inspection of sites for conducting clinical trials, online clinical trial registries and conduct of clinical trials in special circumstances.

2.2.6. Schedule

The Schedule provides for the standard form for the Application for Approval to Conduct Clinical Trial and labelling requirements.

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 submit their 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 the information 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 Guidelines were virtually tabled for discussion and deliberations by stakeholders on 7th March 2022. On 10th 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 Guidelines is to to provide for the establishment of a robust quality assurance system that will ensure clinical trials carried out in Kenya have guaranteed data integrity as well as the safety and well-being of study participants in furtherance of the provisions of Section 3B (2)(o) and (p) and Section 25A of the Pharmacies and Poisons Act, Cap 244, Laws of Kenya and international best practices.

The purpose of the Guidelines is to:-

i. Provide for requirements, procedure and timelines for assessment of Clinical Trial applications
ii. Provide for the assessment of safety data, critical efficacy and progress of a clinical trial, through an established Data and Safety Monitoring Board
iii. Provide for modalities around implementation of accelerated evaluations during emergency situations, epidemics and outbreaks
iv. Define roles of the Ethical Committees at both national and county levels
v. Complement the existing legal framework by allowing the Pharmacy and Poisons Board (hereinafter *"the Board"*) to recognize and use relevant clinical trial decisions, reports or information from other regulatory authorities or regional or international bodies;

4.2. Statement on the Effect of the Proposed Regulations

Generally, the proposed **Guidelines** are neither in contravention of any constitutional provisions nor do they have any retrospective effect on any constitutional provisions. Additionally, the Guidelines neither infringe on the public's fundamental rights and freedoms nor impose additional costs and taxes on the targeted pharmaceutical players. The guidelines are thus but additional safeguards to the statutory provisions on clinical trials under Section 25A of the Act.

4.2.1. Effects on the Public Sector

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

4.2.2. Effects on the private sector

It is expected that key players in the pharmaceutical industry together with health service providers will stand to benefit from a better regulated sector in the promotion of quality, safe and efficacious medicines, health products and technologies.

4.2.3. Effects on fundamental rights and freedoms

Article 31 (c) of the Constitution of Kenya guarantees that information relating to the private affairs of clinical trial participants, including child participants, shall be safeguarded and not unnecessarily revealed.

Similarly, the freedom of conscience will be guaranteed as the guidelines mandatorily require applicants seeking authorization to conduct clinical trials to submit participants' informed written consent or from their legal representatives.

It is also envisioned that the CT Guidelines shall have a positive impact on the on the fundamental rightsand 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 Guidelines will also promote and protect consumers' right to protection of their health, safety and economic interests since the Board, through its Ethical Committees, will have adequately assessed and registered quality, safe and efficacious medicines, health products and technologies. 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 clinical trials, which records will be readily available to the

public.

4.2.4. Impact on existing legal framework

The guidelines 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 guidelines shall complement existing legislation and administrative guidelines on the conduct of clinical trials in Kenya.

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 (Guidelines for the Conduct of Clinical Trials) 2022

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

i. **Improved monitoring of authorization to conduct clinical trials.**

The guidelines provide clear provisions on the registration formalities of and timelines regarding applications to conduct clinical trials. Requirements to prepare safety reports and the appointment of Expert Ethics Committee and the Data Safety and Monitoring Board guarantee an assurance of close monitoring of authorization procedure, thus promoting the Board's integrity.

ii. **Enhanced consumer protection:** it is apparent that improved monitoring of the authorization process will enhance consumer protection as health and medicinal products will be quality and effective assured.

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

The proposed guidelines do not limit the fundamental rights and freedoms set out under the Constitution of Kenya 2010.

Rather, the guidelines promote the full enjoyment of:

(a) the right to the highest attainable standards of health as stipulated under Article 43 of the Constitution.

(b) consumers' right to protection of their health, safety and economic interests as guaranteed under Article 46; and

(c) protect the citizen's freedom of conscience as well the right to access to information to make informed decisions.

iv. **Complementing existing legal frameworks:** The draft Clinical Trials Guidelines 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 guidelines neither conflict nor have any negative effect on existing legislation. Additionally, the guidelines do not have a retrospective effect on any constitutional provisions.

5.2. Financial Cost

Implementation of the proposed guidelines do not impose additional costs or taxes on industry players 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 guidelines.

6.1. Option one: Maintenance of the Status Quo

The guidelines are responsive to the globally acceptable standards for the conduct of clinical trials.

By maintaining the status quo, the legal requirements under Sections 63 of the Health Act, 2017 and Section 3A, 3B and 25A of the Pharmacy and Poisons Act, Cap 244 Laws of Kenya, will not be fulfilled.

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 (Guidelines for the Conduct of Clinical Trials) 2022 will yield the following benefits: promotion of fundamental rights and freedoms such as the freedom of conscience, right to access to information and the right to the highest attainable standards of health among others and improved monitoring of authorization to conduct clinical trials.

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 guidelines will be undertaken through the existinginstitutional 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 (Guidelines for the Conduct of Clinical Trials) 2022 are extremely necessary. The guidelines provide a framework that ensures protection of fundamental rights and freedoms including freedom of conscience, right to access to information and the right to the highest attainable standards of health.

In view of the above conclusion, it is recommended that the Pharmacy and Poisons (Guidelines for the Conduct of Clinical Trials) 2022 be adopted.

ANNEXURES

(i) The Pharmacy and Poisons (Guidelines for the Conduct of Clinical Trials) 2022

(ii) The comprehensive public participation report

(iii) Minutes of Virtual Stakeholder Meetings

(iv) Stakeholder Meetings Attendance List

(v) Stakeholder Comments\Reports