REPUBLIC OF KENYA
Ministry of Health

Medical Device Regulatory Convergence Project (MDRC) workshop

TITLE: **GUIDELINE FOR DEVELOPMENT, REVIEW AND APPROVAL OF REGULATORY INSTRUMENTS**

VENUE: **FOUR POINTS, NAIROBI**

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Introduction

Pharmacy and Poisons Board is Kenya's National Medicines Regulatory Authority mandated to regulate practice of pharmacy and ensure access to quality, efficacious and affordable health products and technologies.

The Board is established under the Pharmacy and Poisons Act Cap 244 Laws of Kenya (hereinafter "**the Act**")

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Mandate

Mission: To protect and promote the health of the public by regulating the profession of pharmacy and ensuring access to quality, safe and efficacious and affordable health products and technologies

Mandate…cntd

The objective of the Act is to make better provision for the control of the profession of pharmacy and the trade in drugs and poisons

The Act establishes the Board of PPB and elaborately sets out the powers and functions thereunder

It has additional functions in relation to regulation of the profession of pharmacy

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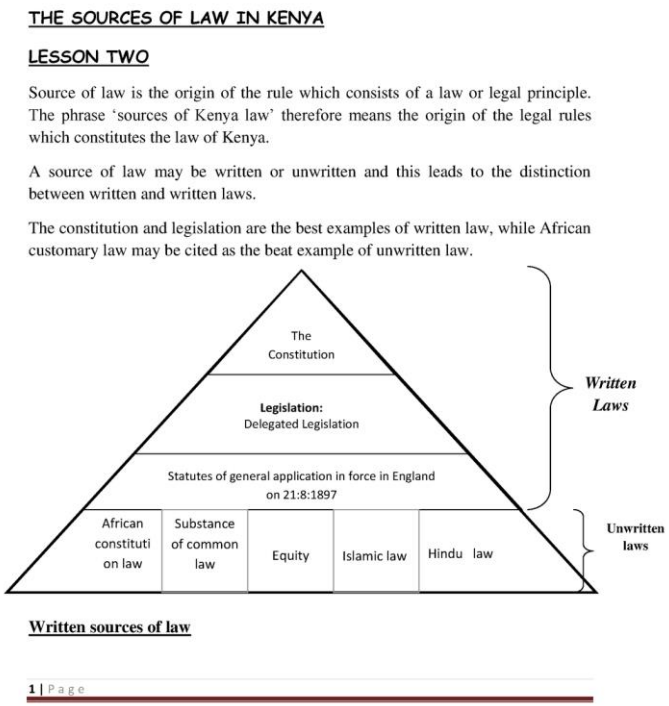
Legal Framework



THE SOURCES OF LAW IN KENYA

LESSON TWO

Source of law is the origin of the rule which consists of a law or legal principle. The phrase 'sources of Kenya law' therefore means the origin of the legal rules which constitutes the law of Kenya.

A source of law may be written or unwritten and this leads to the distinction between written and written laws.

The constitution and legislation are the best examples of written law, while African customary law may be cited as the beat example of unwritten law.

Written sources of law

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Constitution of Kenya, 2010

Pharmacy and Poisons Act, Cap 244.

The Health Act, 2017.

Public Health Act

Regulatory instruments pathway

Legal Framework…cntd

Right to health enshrined under Article 43 (1) (a) which guarantees every person the right to the highest attainable standard of health, which includes the right to healthcare services, including reproductive health care.

Legal Framework…cntd

- Anchor provision-Section 44 of the Act mandates the CS, after consultation with the Board, to make listed rules thereunder. (a-m)

Subsidiary legislation

Subsidiary legislation under the Act

For better functioning, the Act has a set of the following subsidiary legislations thereunder;

1. The Poisons List Confirmation order 1961
2. Pharmacy and Poisons (Prohibited medicines) order 1963
3. PPB (Control of Drugs) Rules, 1989

Subsidiary legislation …cntd

4. The Pharmacy and Poisons(Conduct of Enquiries) Rules, 1985 (EDC)
5. The Pharmacy and Poisons (Parallel Imported Medical substances) Rules, 2019

Anchor Health Statutes

Health Act, 2017

Seeks to provide for regulation of health products and technologies and for connected purposes

Section 62 obliges Parliament to create a single regulatory body for regulation of health products and health technologies.

PPB 2022 regulatory instruments

Developed under Statutory Instruments Act 2013

1. Pharmacy and Poisons (Guidelines for the conduct of Clinical Trials) Rules, 2022;
2. Pharmacy and Poisons (Transportation of Pharmaceuticals) Rules, 2022;
3. Pharmacy and Poisons (Amendment) Rules, 2022

PPB 2022 regulatory instruments

4. Pharmacy and Poisons (Pharmaceutical Waste Management) Rules, 2022;
5. Pharmacy and Poisons (Pharmacovigilance and Post-Market Surveillance) Rules, 2022;
6. Pharmacy and Poisons (Registration of Health Products and Technologies) Rules, 2022; and

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Pharmacy and Poisons Board

Ensuring the provision of safe, quality and efficacious pharmaceutical products and services

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PPB experience S.I development..

Public participation

Art 10 & 232 public engagement in policy making

The Board acknowledges centrality and constitutional dictates of public participation. Stakeholders took a central role in shaping of the draft rules.

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PPB experience S.I development..

The public was notified of the proposed rules through the Board's website on 20th February, 2022 and vide Public Notice dated 21st February, 2022, imprinted on the *Daily Nation,* as well as on the Board's social media platforms on 21st February 2022- Facebook @Pharmacy and Poisons Board and Twitter @ppbkenya.

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PPB experience S.I development..

On 22nd February, 2022 a written memorandum was sent to various stakeholders inviting them for the physical public participation exercise.

PPB experience S.I development..

Written submissions were made by the public on the 6 Draft Pharmacy and Poisons Rules 2022 and submitted by 7th March, 2022 with [92] submissions.

PPB experience S.I development..

- Between 7th to 9th March, 2022, the Board conducted the virtual participation exercise on the draft Rules 2022 with [1250] attendees.
- All the feedback ensuing from the virtual and physical meetings was collated. The Board took into consideration all the views received from the public.

PPB experience S.I development..

- Regulatory Impact Statements and Explanatory Memoranda of the 6 set of proposed Rules in compliance with Sections 6, 7(1) and (2) and Section 11 respectively of the Statutory Instruments Act were published for the public and uploaded on the Board's website.

PPB experience S.I development..

- Public participation report was thereafter generated outlining all the steps undertaken in compliance with the law.
- The final draft version of the rules was generated incorporating public views
- The Committee on Delegated Legislation engaged for pre-publication scrutiny.

- Statutory instruments are legally enforceable
- Harness technology for efficiency-hybrid systems
- Partnership with development partners
- Enhance mandate on the ML3 journey

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THANK YOU

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