2025

The Legal framework for accessing controlled medicines for pain management in Kenya: a case study of medical cannabis

Arunga, Nancy Shephard
Strathmore Business School
Strathmore University

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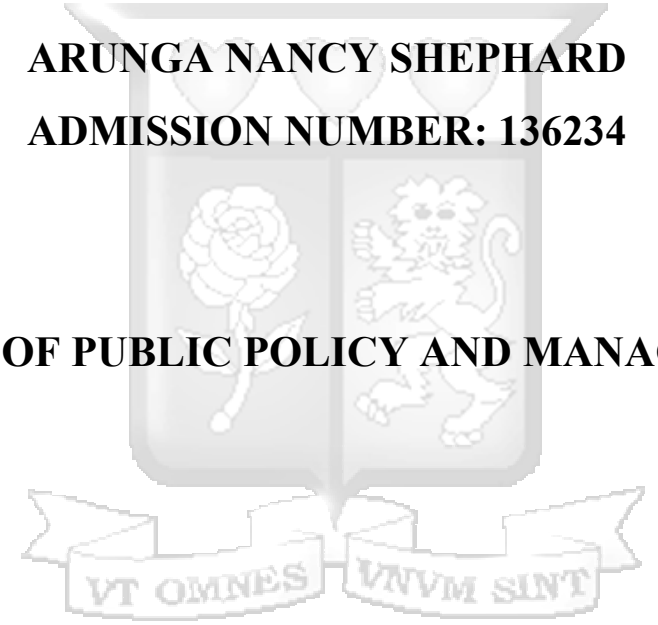
ARUNGA NANCY SHEPHARD
ADMISSION NUMBER: 136234

MASTER OF PUBLIC POLICY AND MANAGEMENT



NOVEMBER 2024

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ARUNGA NANCY SHEPHARD

136234

A DISSERTATION SUBMITTED IN PARTIAL FULFILMENT OF THE REQUIREMENTS FOR THE AWARD OF MASTER OF PUBLIC POLICY AND MANAGEMENT AT STRATHMORE UNIVERSITY

STRATHMORE UNIVERSITY

NAIROBI, KENYA

DECLARATION

I declare that this work has not been previously submitted and approved for the award of a degree by this or any other University. To the best of my knowledge and belief, the thesis contains no material previously published or written by another person except where due reference is made in the thesis itself.

Name: Arunga Nancy Shephard

Signature: 

Date: 24th September 2024

Approval

The proposal of Ms. Arunga Nancy Shephard was reviewed and approved for defence by:

Name of Supervisor: Dr. Ben Ngoye

Faculty Affiliation: Strathmore Business School

Institution: Strathmore University

Signature: 

Date: 13th November 2024

ACKNOWLEDGMENT

I appreciate and thank God for His grace, provision of the resources, and the physical, mental, and emotional ability He gave me during this period of my studies. I most sincerely appreciate my family, friends, and colleagues who have been of great support and encouragement as I worked on my research. Without my supervisor Dr. Ngoye's guidance, support, and encouragement as well as his patience with me, this work would have been impossible. I am grateful to you daktari and may the Lord bless you. I also acknowledge my employer, Pharmacy and Poisons Board and the Strathmore Business School for the support offered during my studies.

DEDICATION

I dedicate this thesis to the Almighty God for giving me the strength to finish this thesis, my daughter Nina for being a darling little girl and cooperating throughout this time

ABSTRACT

The study sought to evaluate the ability of the legislative framework for controlled medicines to effectively structure the process of implementation of access to medical cannabis (MC) for pain management in Kenya. Using Mazmanian and Sabatier's framework, it analyzed the statutory variables within the legislation governing controlled medicines. Through the lens of the Policy Diffusion Theory, the study identified barriers in implementing the policy-legal framework and investigated stakeholder involvement in regulatory framework development and implementation. The main research objective was to evaluate the effectiveness of the legislative framework in facilitating access to MC for pain management in Kenya. The specific objectives were: (1) to evaluate the existing legal framework governing access to MC for pain management in Kenya; (2) to investigate the involvement of stakeholders in shaping and executing the regulatory framework for access to MC as an alternative for pain management; and (3) to identify the barriers to implementation of the policy and legal framework for accessing MC for pain management. Recommendations were then formulated to enhance the policy, legal, and regulatory framework for MC access, with a focus solely on the policy-legal framework, excluding social and scientific considerations and non-medical uses of cannabis. The study utilized a qualitative research methodology, featuring key informant interviews with policymakers, the regulatory authority, healthcare providers, and patient advocates. The findings revealed significant gaps and contradictions between science and Kenya's current legal framework, which provided for medical use as an exception for the use of cannabis; however, this provision had not been operationalized in policy, law, regulations and practice. Looking through the lens of the Mazmanian and Sabatier's framework, it was evident that lack of clarity in the legal provisions and lack of regulations for the implementation of licit use of medical cannabis was a legal barrier that impeded access to MC, pointing to a failure of the statute to structure the implementation process coherently. Furthermore, lack of stakeholder awareness and inconsistent implementation of relevant policies hindered access. However, the study highlighted openness among some stakeholders to explore MC based on research evidence. This was, however, impeded by the lack of a structured proactive mode of stakeholder involvement. Based on the findings, recommendations included legislative reforms to clearly structure access to MC for pain management, developing comprehensive MC policies through structured stakeholder engagement, implementing evidence-based guidelines, and healthcare provider training on MC, along with launching public awareness campaigns to destigmatize MC. The findings aimed to guide policymakers and regulators in refining the regulatory framework and potentially influencing legislative amendments to improve responsible MC access for pain management while preventing abuse and diversion, using policy diffusion to leverage on the experience of other countries that have successfully implemented access to MC.

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LIST OF ABBREVIATIONS AND ACRONYMS

AU	African Union
CND	Commission on Narcotic Drugs
FDA	Food and Drug Administration
HCPs	Healthcare Professionals
HIV&AIDS	Human Immunodeficiency Virus & Acquired Immunodeficiency Syndrome
IDCC	International Drug Control Conventions
INCB	International Narcotics Control Board
KALRO	Kenya Agricultural and Livestock Research Organization
KEBS	Kenya Bureau of Standards
KEHPCA	Kenya Hospice and Palliative Care Association
KEML	Kenya Essential Medicines List
KEPHIS	Kenya Plant Health Inspectorate Service
KMPDC	Kenya Medical Practitioners and Dentists Council
MC	Medical Cannabis
MOH	Ministry of Health
NACADA	National Authority for the Campaign Against Alcohol and Drug Abuse
NACOSTI	National Commission for Science, Technology and Innovation
NGO	Non-Governmental Organizations
NMRA	National Medicines Regulatory Authority
PCP	Palliative Care Provider
PPB	Pharmacy and Poisons Board
PSK	Pharmaceutical Society of Kenya
QOL	Quality of Life
SDGs	Sustainable Development Goals
UHC	Universal Health Coverage
UDHR	Universal Declaration of Human Rights
UN	United Nations
UNODC	United Nations Office on Drugs and Crime
WHO	World Health Organization

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CHAPTER ONE: INTRODUCTION

3.1 Introduction

This chapter serves as the foundation for the study by providing a detailed overview of the research topic, highlighting the legal context surrounding the access to medical cannabis (MC) for pain management in globally and in Kenya, the problem statement, research objectives and the significance of the study. It sets the stage for understanding the challenges and opportunities in regulating controlled substances, particularly focusing on MC. This chapter delves into the global recognition of the right to health, including access to medicines, as articulated in the Universal Declaration of Human Rights (UDHR) and the World Health Organization (WHO) Constitution, and how it intersects with the legal frameworks governing controlled substances. Through a discussion of key policies, international conventions, and the legal environment in Kenya, the chapter underscores the urgency of addressing the barriers to accessing MC in the context of pain management, while balancing the need to prevent misuse and abuse.

3.2 Background of Study

The 1948 Universal Declaration of Human Rights (UDHR) and the 1946 World Health Organization (WHO) Constitution both recognize the right to the highest attainable standard of health, which includes access to medicines. As such, states are obligated to ensure access to affordable and good quality medicines (Oehlke Krista et al., 2017). This obligation extends to controlled substances like medical cannabis (MC) for pain management, as the failure to relieve pain is considered a violation of a fundamental human right and undermines Quality of Life (QOL) (World Health Organization, 2011). The experience of pain decontextualizes an individual, causing them to disengage from all other aspects of reality necessitating palliative care.

Palliative Care is defined by the WHO as “an approach that improves the QOL of patients and their families facing the problems associated with a life-threatening illness through the prevention and relief of pain as well as physical, psychosocial and spiritual support” (WHO, 2020a). Access to controlled medicines is a central theme in palliative care with a focus on optimal pain and symptom control. However, many countries face legislative, regulatory and administrative hurdles that hinder access to controlled medicines, leading to underestimation of a country's need for pain medications (UNODC, 2011). This is demonstrated by the fact that

governments mostly end up enacting legislation and policies that severely limit access to controlled medicines (World Health Organization, 2011).

Opioids, such as morphine, are among those commonly prescribed to manage moderate-to-severe pain in patients with HIV&AIDS, cancer and various other painful disease conditions. However, their misuse and abuse have contributed to the widespread "opioid-epidemic". In response to this crisis, scholars have proposed the use of MC as a potential alternative analgesic to balance out this epidemic. Despite being known as an illicit controlled drug, cannabis, also known as marijuana, has received attention in chronic pain literature, due to its analgesic properties, prompting more patients to seek it for pain relief (Rogers et al., 2019 & Cunningham et al., 2020). For example, a 2018 study in Israel found that cannabis significantly reduced pain and opioid use among cancer patients, with many reporting less reliance on opioids as a result. The study concluded that cannabis could be an effective adjunct to opioid therapy, reducing the risk of opioid dependence while still managing severe pain (Bar-Lev Schleider et al., 2018).

A 2018 Israeli study involving 3000 cancer patients revealed that MC significantly reduced both pain and opioid consumption, particularly among those with advanced or metastatic disease (Davis, 2020). Scholars like Williams (2018) and Kranz (2021) advocate for considering MC as a viable alternative to opioids for pain relief. Similarly, MacCallum et al. (2021), support the introduction of MC as adjunctive therapy, that resulted in lower opioid doses, improved pain-related outcomes and reduced opioid-related harm. Moreover, a recent study by Jeddi et al., (2024) indicated that, compared to opioids, MC may be equally effective for chronic non-cancer pain while leading to fewer discontinuations due to adverse events.

Acknowledging that cannabis use carries risks, Lake et al. (2020) note that it poses lower risks of physical dependence and accidental overdose compared to opioids. However, while opioid overdoses frequently result in death, it is rare for a fatal cannabis overdose to occur (Woodcock, 2023).

Prescription drug overdose is the leading cause of unintentional mortality in the United States, prompting the urgent need for alternative painkillers like MC, which carry lower risks of dependence and overdose compared to opioid-based medicines (Reiman et al., 2017; Lake et al., 2020). Moreover, while opioid overdoses frequently result in death, it is rare for a fatal cannabis overdose to occur (Woodcock, 2023). Consequently, as at December 2020, over 50

countries had legalized MC and established programs for its use, including 33 states in the United States of America (Mahabir et al., 2020).

The UN Commission on Narcotic Drugs (CND), also took a significant step in December 2020 by passing a resolution to remove Cannabis from Schedule IV, which had imposed stringent control measures for over 59 years, effectively discouraging its medical usage (United Nations, 2020). This decision by the CND was founded on WHO recommendations reflecting increased medical use of cannabis for pain treatment and development of new cannabis-related pharmaceutical preparations. Cannabis is now categorized alongside morphine and oxycodone in terms of their potential for abuse and dependence with fewer procedural barriers to its use (WHO, 2020b). This action supports Goal 3 of the Sustainable Development Goals (SDGs) on "ensuring healthy lives and promoting well-being for all at all ages" specifically Target 3.8 which seeks to achieve universal health coverage (UHC) through access to essential medicines.

The African Union (2019) similarly emphasized the importance of considering local provisions for increased production of controlled substances for scientific and medical use especially for pain relief. However, despite scientific evidence supporting the therapeutic benefits of cannabis, its use in pain management remains extremely stigmatized in many countries including Kenya (Ezekiel de Silva & Nilanga Perera, 2020). MC comes as a crude plant form, or a processed pharmaceutical form (PSK, 2020). Access in the context of this study refers to a patient's ability to obtain and use MC upon prescription.

The developed world, in contrast with developing countries, is thus making strides in improving pain management by adopting innovative solutions like MC. However, the same progress is not observed in many developing countries where the gap in pain management persists, largely due to limited access to traditionally controlled drugs such as marijuana (WHO, 2011).

3.3 Policy and Regulatory Framework for Access to Medical Cannabis in Kenya

Building upon the global perspective, this section delves into the specific regulatory framework governing access to MC within the context of Kenya.

The Government of Kenya (2007) in its economic blueprint "the Vision 2030" and the Constitution of Kenya (2010) under Article 43 has prioritized the health sector, to ensure it

meets the highest attainable standards. This right includes access to controlled medicines. This right is further buttressed under Article 21(1) that requires the state to take legislative, policy and other measures to achieve the progressive realization of the rights guaranteed in Article 43. However, the regulatory frameworks surrounding MC present a contrasting picture.

MC is regulated under the International Drug Control Conventions (IDCC) more specifically the 1961 Single Convention on Narcotic Drugs ("the Convention") which emphasizes the importance of a well-balanced approach in order to ensure availability for medicinal usage while reducing diversion and abuse. The National Pharmaceutical Policy, 2012 provides the drug policy backing and seeks to ensure equitable access to essential medicines through the public, faith-based, non-governmental organizations (NGOs) and private providers (MOH, 2012). The policy takes cognizance of the legislative and institutional framework shortcomings to include inadequate provisions for licit use of controlled and psychotropic substances hindering their access and appropriate use; conflicting provisions in other legislative instruments hindering enforcement; and an inadequate legal framework for the regulator. The Government commits in the Pharmaceutical Policy, to update, restructure and harmonize as required all medicines and other relevant legislation, regulations and rules, to create one modern medicines law governing the pharmaceutical sector, formulated according to well-proven models.

The Kenya Palliative Care Policy, 2021, on the other hand domesticates the commitment by African countries to establishing effective domestic and global frameworks for overseeing the accessibility of narcotic drugs and psychotropic substances to alleviate pain and suffering (MOH, 2021). This involves guaranteeing the secure distribution of the most effective and affordable medications to patients in need, as well as providing comprehensive education and training to healthcare professionals on the appropriate utilization of these medications for pain management.

While Kenya is a signatory to the IDCCs, the Narcotic Drugs and Psychotropic Substances (Control) Act No. 4 of 1994 ("Narcotics Act") takes a stringent stance, primarily viewing narcotic drugs through the lens of illicit use. On the other hand, the Pharmacy and Poisons Act, Cap 244 Laws of Kenya that is established to govern licit use remains ambiguous to the extent of access to MC. As with many other countries, the law is restrictive in terms of possession of narcotic drugs, with little focus on medicinal access. The drafters of the Narcotics Act viewed

narcotics and psychotropic substances from the illicit use perspective, a key indicator of the prism with which the legal system approaches these controlled substances whose possession is met with the full force of the law. This is demonstrated by the fact that the Narcotics Act is domiciled in the Ministry responsible for internal security matters, compounded by the fact that the amendments to the Narcotics Act introduced in 2022 only served to further stiffen the penalties (Narcotic Drugs and Psychotropic Substances (Control) Act, n.d.).

However, the Narcotics Act provides for exceptions for possession of narcotic drugs and these include persons in possession of a licence issued pursuant to Section 16 or a medical practitioner, dentist, veterinary surgeon, or registered pharmacist (Healthcare Professionals (HCPs)) who is in possession for medical purposes or a person who possesses the same pursuant to the prescription of a HCP or a person authorized under the regulations. While there are several exemptions for medicinal purposes, there is a lack of specific regulations on the legal possession of controlled substances by patients and HCPs.

According to the Narcotics Act, Cannabis is classified under the First Schedule as a narcotic drug as well as under the Third Schedule as a "prohibited plant" and any cultivation is outlawed. This creates a potential concern over the clarity of the objective of this statute, as it is unclear whether the exceptions for medical purposes extend to prohibited plants.

The Narcotics Act further provides for the establishment of a board to implement the exceptions, whose functions are, inter alia, to "issue licences for the importation, exportation, diversion, sale, manufacture, production or distribution (at stated places); name ports or places in Kenya where any narcotic drug or psychotropic substance may be exported or imported; prescribe the manner in which any narcotic drug or psychotropic substance is to be packed or marked for export; and prescribe the records to be kept by any person in connection with the export, import, receipt, sale, disposal or distribution of narcotic drugs or psychotropic substances". It is, however, curious that this Board has never been established since the inception of the Narcotics Act presenting a lacuna in implementation and interpretation of the law.

The Pharmacy and Poisons Board (PPB) is the Kenyan National Medicines Regulatory Authority (NMRA). It is mandated under the Pharmacy and Poisons Act (Cap 244) as amended in 2019, to regulate licit trade in controlled substances in accordance with the IDCCs

(Pharmacy and Poisons Act, 1957). Additionally, it regulates various activities that inform placement of medicines in the Kenyan market through processes such as marketing authorization and post-marketing surveillance, licensing and inspecting manufacturers, importers, exporters, wholesalers, distributors, pharmacies, and retail outlets. To facilitate this regulatory role, the PPB has developed and implemented several policies, regulations and guidelines to ensure access to safe, quality and efficacious medicines which are available publicly on the organization website (PPB, 2024).

Kenya, as a signatory to the IDCCs, is required to provide, through the PPB, a realistic country estimate of its controlled substances requirements for medical use every year and report periodically on their consumption to the International Narcotics Control Board (INCB). The regulatory framework is clear to the extent of assigning responsibility for ensuring access to controlled substances for medical use to the PPB. It is however unclear as to whether this extends to MC due to the special considerations given to cannabis under the Narcotics Act. This regulatory stance, coupled with societal stigma, has contributed to a perception that MC remains largely banned in Kenya, despite the exceptions provided for medical purposes within existing legislation. As a result, accessing MC for pain management in Kenya presents significant challenges, warranting an in-depth examination of the regulatory framework for access to MC as a potential barrier to MC accessibility for pain management in Kenya.

3.4 Problem Statement

A study by the WHO (2017) highlighted the global issue of inadequate access to controlled medicines for pain management due to various barriers, including policy and legislation factors; affordability; knowledge; societal attitudes. These barriers result in inadequate or undertreated pain in countries with limited access to these medicines. Despite 60 years of IDCCs, ensuring adequate availability of controlled drugs for medical purposes has received far less emphasis compared to efforts to prevent their misuse. This imbalance poses a significant challenge in countries like Kenya where pain relief remains a challenge leading to psychosocial distress exacerbated by stigma and poverty (Ali, 2016). While misuse of controlled substances constitutes a threat to society, regulation is not meant to obstruct their availability for legitimate medical use in patient care (United Nations International Narcotics Control Board, 2015).

African populations, including those in Kenya, endure significant pain from conditions like HIV/AIDS and cancer, yet face limited access to pain medication, as observed by Nchako et al. (2018) and Selman et al., (2013). About 70% of reported cases of Cancer in Kenya are detected at an advanced stage when treatment is no longer helpful; patients therefore often need low-cost interventions to ease their pain (Williams, 2018). This places emphasis on the need for effective pain management to improve QOL. Although affordable and effective interventions exist, there's a gap between scientific evidence and public policy. Furthermore, studies by Huang et al., (2013) and Ochong'a et al., (2021) reveal challenges in accessing and properly using controlled pain medications due to government restrictions, bureaucratic processes and knowledge gaps among HCPs and the general population, which was also observed in Yao et al., (2023). Scholten (2020) similarly observed the prevalence of untreated pain in countries (such as Kenya) where the consumption of opioid analgesics is very low.

The Kenya Palliative Care Policy identifies challenges in palliative care services to include prohibitive laws limiting prescription and access to opioids for palliative care and a poorly defined structure for palliative care stakeholders' engagement and coordination (MOH, 2021b). Additionally, the country's health care system is impeding the attainment of effective patient pain management by focusing on the negative aspects of laws regulating essential medications while ignoring their positive effects (Nyakundi, 2013). The Narcotics Act imposes stricter regulations on cannabis compared to other controlled substances. While the Pharmacy and Poisons Act aligns with IDCCs, the stringent provisions of the Narcotics Act cast doubt on the medical use of cannabis. This legal interplay has fostered a perception that MC is effectively banned in Kenya. Consequently, this ambiguity serves as a barrier to accessing MC for pain management: prescribers hesitate to recommend it, regulators refrain from registering related products, and patients in pain struggle to find it in the market.

In Kenya, strong opioid analgesics include fentanyl patches, morphine ampules for injection, immediate-release oral morphine tablets, sustained-release tablets, and oral morphine solution, available for hospital or home use. These are available but costly and mostly used in private hospitals (Kamonyo, 2018). However, dihydrocodeine (DF-118) and pethidine are more commonly used than oral morphine for pain treatment, even when oral morphine is available. Opioid drugs (morphine-like) are frequently prescribed for the management of moderate to severe cancer pain. However, a significant proportion of cancer patients, ranging from 10% to 15%, fail to achieve enough relief, hence highlighting the necessity for novel analgesics to

safely supplement (Häuser et al., 2023). According to Haroutounian et al. (2016) and Hameed et al. (2023) the use of MC for chronic pain treatment provides improved pain and functional outcomes, along with a notable decrease in opioid usage indicating a potential long-term benefit of cannabis treatment for this patient population.

In recent years, African countries, including South Africa, Malawi, Lesotho, Zambia, Ghana and Zimbabwe, have shown interest in MC initiatives, aligning with global trends towards acceptance of cannabis for pain management. However, despite changes made to Kenya's Pharmacy and Poisons Act in 2019 to implement the IDCCs, the NMRA does not list any registered MC medications. Kenya submitted a country estimate of 200gms for cannabis for the year 2023 (INCB, 2023) compared with Zimbabwe at 6,000,000, Lesotho at 10,901,050, Israel at 97,590,000, Germany at 21,800,000, UK at 406,191,050, USA at 3,000,000 (INCB, 2024). The discrepancy between the global increase in licit cannabis production and Kenya's modest country estimate raises questions about meeting the demand for pain medication.

Given the potential benefits of MC in pain management, it is essential for Kenya to explore innovative approaches to improve access to affordable pain-relieving medicines, aligning with WHO's call to bridge the neglected pain gap in developing countries (WHO 2011). Untreated pain can lead to decreased QOL, increased healthcare costs and societal burdens. Effective regulation and policy frameworks, as emphasized by Ndomondo-Sigonda et al. (2017), are crucial for ensuring access and preventing misuse or diversion of MC. However, the current state of Kenya's NMRA and its alignment with the CND decision remains unclear.

Given the central role that policy and legislation play in ensuring access to controlled medicines, this study evaluated Kenya's legislative framework's effectiveness in facilitating access to MC for pain management. By assessing existing gaps and potentials within the regulatory system, this study sought to contribute to public health promotion, enhance patient access to MC, and ensure its responsible use to address pain-related challenges in Kenya.

3.5 Research Objectives

The main research objective was to evaluate the ability of the legislative framework to effectively structure the process of access to MC for pain management in Kenya.

3.6 Specific Objectives

The specific objectives were:

a) To evaluate the existing legal framework governing access to MC for pain management in Kenya;
b) To investigate the involvement of stakeholders in shaping and executing the regulatory framework for access to MC as an alternative for use in pain management;
c) To identify the barriers to implementation of the policy and legal framework for accessing MC for pain management in Kenya; and

3.7 Research Questions

a) What are the strengths and weaknesses of the current legal framework regarding access to medical cannabis for pain management in Kenya?
b) How have various stakeholders been involved in the development and implementation of the regulatory framework for accessing MC for pain management in Kenya?
c) What are the main barriers faced in implementing of the legal framework for access to MC for pain management in Kenya?

3.8 Scope of the Study

This study focused solely on the legal framework governing the use of MC) for pain management, excluding the social and scientific aspects of pain management. It also excluded other non-medical uses of cannabis, such as its use for research and recreational purposes. The theoretical scope of the study was guided by Policy Diffusion Theory and the framework model proposed by Mazmanian & Sabatier (1983). This framework examined the legal structure with a focus on statutory variables related to the clarity of the statute, the commitment of officials to implement statutory objectives, the biases in decision rules of the implementing agencies towards achieving objectives, and the formal access provided to outsiders to influence the framework. The study did not address the allocation of financial resources for implementation. The methodological scope of the study involved qualitative research, including a review of policy and regulatory documents and interviews with the regulator, HCPs, and policymakers.

3.9 Significance of Study

This study, through its findings and empirical data obtained from various stakeholders, contributes to informing policymakers and regulators involved in all aspects of pain

management, particularly the Ministry of Health, the Pharmacy and Poisons Board, the Ministry of Interior and Coordination, and Parliament. The study aids in the development of legislation that enables access to safe, quality, and efficacious medical cannabis (MC), while ensuring an appropriate balance is maintained against the proliferation of abuse and diversion for non-medical uses of these controlled substances.

By obtaining the views of a variety of stakeholders on the challenges and barriers affecting the implementation of the existing legal framework for MC in pain management, a rich picture emerges, allowing a meaningful comparison between theory and practice. This contributes to a deeper understanding of the use of MC for pain management, particularly in ensuring an appropriate balance between access to these substances and the prevention of abuse.

Healthcare professionals (HCPs) also benefit from the findings, as they inform their prescribing practices, helping them consider MC as an acceptable alternative for pain management. Furthermore, given the high costs of pain management in Kenya, the study reveals that the availability of MC may provide a more affordable alternative for both chronic and non-chronic pain patients in the country.

The theoretical significance of this study lies in its application of Mazmanian and Sabatier's Framework for Policy Implementation and Policy Diffusion Theory. By evaluating the legal and regulatory framework for MC access, the study contributes to the understanding of how policy is translated into practice, particularly in the context of controlled substances in Kenya. Additionally, the study enhances the body of knowledge on policy diffusion, especially how global trends influence local drug policies and regulatory frameworks.

CHAPTER TWO: LITERATURE REVIEW

2.1 Introduction

This literature review focused on the theoretical foundations of the study, followed by empirical literature on legal frameworks governing access to MC for pain management, challenges and barriers in implementation of legal frameworks for accessing MC for pain management, and stakeholder involvement in development and implementation of the regulatory framework for access to MC as an alternative for use in pain management. The correlation between the variables is illustrated at the end by a conceptual framework.

2.2 Theoretical Literature

This study is based on Mazmanian's and Sabatier's Framework for Implementation Analysis and the Policy Diffusion Theory, as outlined below.

2.2.1 Policy Diffusion Theory

Policy Diffusion is defined by Shipan & Volden (2012) as one government's policy choices being influenced by the choices of other governments. It is emphasized that policymakers consistently depend on the knowledge and experiences of those who have previously engaged in policy experimentation, given the interdependence of global systems. This theory offers an opportunity to design policy opportunities and limitations encountered by policymakers across many levels. External influences exert a significant influence on internal policy in all key global policies, including drug policy.

In placing this theory in the context of this study, the AU in its common African position recognizes that the world drug problem requires an "integrated approach to drug supply, demand reduction, and harm reduction strategies, as well as ensuring the availability of controlled substances for medical and scientific use" (AU, 2016). This position is likely to influence Kenya's policy and legal framework, which this study examined.

Policy diffusion involves learning from effective policies, which can lead to positive outcomes, while copying policies may result in inappropriate choices and coercion-based choices are unlikely to be optimal (Shipan & Volden, 2008). The mechanisms of policy diffusion are further enriched in Blatter et al. (2022) who focus on diffusion in democracies such as Kenya to include rights-driven processes where policies diffuse based on legal frameworks such as constitutions,

recognition-driven processes, where policies spread because they are recognized as effective and beneficial or ideology-driven processes, where policies spread based on ideological affiliations between political parties. The theory highlights the role of transnational and national actors in diffusion processes.

Scholars of policy diffusion have begun to explore how country-specific institutional, political, or economic factors influence policymakers' responses to decisions made by other governments (Wasserfallen & Wasserfallen, 2018). Policy adoption and diffusion are influenced by factors such as a nation's problems, political situation, resources, and external peer influence through coercion, competition, learning, and emulation (Mistur et al., 2021). Critics of the diffusion theory note that the focus by scholars on the mechanism of diffusion gives little recognition to the role of institutions in shaping the policy diffusion process (Turnbull, 2017).

The justification for adoption of this theory in this study is motivated by the fact that people would struggle to locate specific instances of policies that were implemented solely for internal reasons, which suggests that policy makers rely on the experiences of those who have previously experimented with policies to justify policy implementation. Since access to controlled substances is a global issue controlled by the IDCCs, this theory provided a framework for examining the current policy framework and formulating appropriate recommendations.

2.2.2 Mazmanian's and Sabatier's Framework for Implementation Analysis

In examining the theoretical underpinnings of policy implementation, Mazmanian & Sabatier (1983) assert that the process involves translating fundamental policy decisions into action, typically embedded within statutes. They outline a series of stages through which policies typically progress, starting with the passage of legislative statutes and culminating in revisions to these statutes based on perceived impacts and feedback. This perspective underscores the interconnectedness of policy formulation and implementation, highlighting the need for policies to address identified problems, set clear objectives, and structure the implementation process effectively (Muller, 2015).

Central to Mazmanian and Sabatier's framework is a spectrum of independent variables shaping the policy implementation process, with legislative and institutional variables playing a crucial role. This study delved into the legislative and institutional variables highlighted within this framework, particularly emphasizing the necessity of unambiguous statutes, seamless decision-making processes, clear responsibilities, and supportive enforcement entities. Additionally, external involvement should tilt toward proponents to facilitate implementation.

Despite the theoretical clarity provided by Mazmanian and Sabatier, the actual implementation of policies often faces challenges due to vague or absent policy objectives (Sandfort & Moulton, 2015). While Sabatier & Mazmanian (1983) propose a linear relationship between policy decisions and implementation, others, such as Sandfort & Moulton (2015) suggest that implementation is a complex process characterized by multidirectional change. This study examined the implementation of the Narcotics Act and the Pharmacy and Poisons Act, focusing specifically on the extent to which implementers incorporate statutory directives into their operations, without delving into broader social dimensions.

Sabatier & Mazmanian (1983) argue that regulatory programs requiring a substantial departure from the status quo are more likely to achieve their objectives. Successful implementation, according to their framework, is hinged on clear objectives, supportive agencies, requisite authority, resources, adherence to statutory provisions, effective leadership, and public support. Similarly, Heddleston (2013) in his study, found that statutory variables such as pro-MC resolutions by the authorizing agent, sympathetic law enforcement and the presence of local regulatory bodies contributed to successful regulations. Conversely, Pal (2014) highlights the inevitability of implementation failures, despite characteristics of successful implementers such as strategic planning, resourcefulness, and goal-oriented knowledge.

Policy clarity emerges as a recurrent theme in implementation literature, with clear statutes being more likely to achieve desired outcomes. Such statutes feature specific objectives, causal explanations, administrative duties, implementation guidelines, and dedicated agencies (Meier & McFarlane, 1995). Similarly, Oikarinen (2018) categorizes research approaches to policy implementation as either top-down, bottom-up, or hybrid, with a recognition that socioeconomic contexts can significantly influence the process. Linder & Peters (1990) assert that clarity remains paramount, particularly in top-down implementation strategies, ensuring compliance among implementing actors.

Kerr (1976) emphasizes the crucial features of effective policy, including the presence of an authorizing agent, prescribed actions under specific conditions, and the intent of implementing agents to execute specified actions. He warns against the most conspicuous form of policy failure—implementation failure—resulting from inadequate planning or effort, leading to ineffective policy transfer or execution.

This theoretical framework supports this study as it will focus on identifying implementation failures of MC legislation, as highlighted by Muller (2015), which may result from inadequate translation of policies into action. Contrary to Ham's (1986) emphasis on external environment and policy design, this study underscores the role of implementers in ensuring successful policy implementation.

2.3 Empirical Literature

2.3.1 Legal Framework Governing Access to MC for Pain Management

The WHO (2003), stressed the importance of comprehensive medicines legislation and regulation, emphasizing the need for legislation that provides both structure and flexibility. The legal framework should empower the NMRA to adapt regulations to the rapid advancements in science and technology within the field of medicines regulation. This authority is similar to the legislative and institutional variables proposed in Mazmanian and Sabatier's framework, essential for successful implementation of statutes.

The IDCCs are fundamental in shaping national drug laws, aiming to prohibit the abuse of controlled substances while ensuring their availability for medicinal use. However, the IDCCs prioritize an enforcement-heavy criminal justice approach, despite the dual obligation to enforce availability for medical purposes (Burke-Shyne et al., 2017b). The INCB (2021) highlights the conditions in the IDCCs under which medical use of MC is permitted, emphasizing the need for States to licence and regulate its production, estimate the country's MC demand, ensure proper medical supervision and monitor their effects and potential diversion to non-medical use. Therefore, clarity in drug laws is essential for implementing agencies such as the PPB as proposed in the Mazmanian and Sabatier theoretical framework.

Empirical data supports the importance of having well-structured and flexible frameworks for MC.

Oehlke Krista et al. (2017) noted the failure of many countries to update their drug control systems to accommodate modern treatment approaches like controlled substances for chronic pain management. They advocate for adapting frameworks to incorporate MC as a viable pain management therapy. In contrast, Burke-Shyne et al. (2017a), criticized the lack of consideration drug control gives to international human rights law, highlighting the ongoing human rights violations despite its inclusion in the UN Charter.

Sznitman (2020) observed that Israel's regulatory framework applied similar requirements to MC as other controlled substances such as opioids to ensure access. This was contrary to the Americas where stringent regulation hindered patient enrollment to MC programs unlike in Israel. This has resulted in a more successful implementation compared to other regions. According to the Israeli Ministry of Health (2019), the medical cannabis program has enrolled over 30,000 patients by 2019, showing its effectiveness in providing access to MC for pain management. This case is contrasted with countries in North America where regulations have been much stricter, limiting patient enrollment and access (Smith, 2013). A study by Lucas (2008) also found that Canada's medical cannabis program, despite early successes, has been criticized for slow bureaucratic processes, hindering access for patients in need.

Similarly, South Africa's MC framework aims to align access of cannabis products with other controlled medicines (Medicines Control Council, 2017). According to Clark et al. (2021), however, 60% of South African healthcare providers surveyed were unfamiliar with cannabis as a treatment option for pain, showing that the regulatory framework, while progressive, has not yet achieved full integration into medical practice. This highlights the need for better educational initiatives and clearer guidelines for healthcare providers to ensure that patients benefit from the legal access to MC.

Dania Putri (2020) suggests that African governments should use the opportunity to further decolonize drug control measures while strengthening the legal foundation for MC initiatives. This is particularly relevant in light of historical barriers to MC access that were rooted in colonial-era policies. A 2018 African Union report revealed that several African countries with emerging MC legal frameworks showed positive impacts on pain management and access to cannabis products, but these frameworks are still in early stages of development, with limited patient enrollment and lack of formalized treatment options. The MC regulatory framework

and its practical implementation must be explained so that it may be responsive to patient needs while upholding medical practice and ethical standards (Schlag et al., 2020). Cohen (2009a) argues for medical marijuana approval to be regulated under existing pharmaceutical laws subject to scrutiny by the Food and Drug Administration (FDA) for safety and efficacy.

According to Kippenberg (2010), certain HCPs believe that the existing legislation in Kenya effectively forbids the use of morphine. The reluctance to use narcotic drugs is due to the severe penalties outlined in the Narcotics Act and the ambiguity surrounding proper prescription procedures. The Act does not give guidance on lawful possession of controlled drugs by HCPs and patients. Recent data from the Kenyan Ministry of Health (2018) showed that morphine prescription rates have dropped by 30% in the last decade, indicating that restrictive legal frameworks are directly affecting healthcare providers' ability to treat patients in need of pain relief. There is no clear guidance for HCPs on prescribing controlled drugs, leading to uncertainty in clinical practice.

Smith (2013), highlights the conflict between state MC law and federal classification of marijuana as Schedule I, posing challenges to the validity of both MC laws and marijuana law enforcement efforts. This creates a conflict between access to MC and criminal justice. This situation is replicated in the Kenyan context whereby the legal framework governing licit access to MC seems to be made unclear by the stringent requirements under the framework governing illicit use. This lack of clarity and consistency presents an implementation challenge for both the implementing agencies and the target groups.

2.3.2 Barriers in Implementation of Legal Frameworks for Accessing MC for Pain Management

A study by Lohman et al., (2010), emphasized that countries, under international human rights law, have a duty to provide pain relief medications as part of the right to health. Failure to ensure access to adequate pain relief could constitute a breach of the duty to prevent cruel, inhuman, and degrading treatment. However, as noted by Xu & Gao (2017), deviations in policy execution occur in several ways: ceremonial, attached, alternate, delayed, and uneven implementation. These deviations stem from factors both within and outside the policy itself, leading to inconsistencies in the enforcement of MC access laws.

In addition to the Lohman et al., (2010), highlighted that despite the availability of affordable and efficient pain management medications, millions worldwide suffer moderate to severe pain annually without receiving any appropriate treatment. Key obstacles to effective pain management include inadequate drug supply systems, lack of pain treatment policies, insufficient healthcare professionals training, overly strict drug control regulations, fear among HCPs of legal repercussions, and high pain treatment costs. These limitations not only fail to supply necessary medications and alleviate pain but also violate human rights.

Similarly, Kippenberg (2010) identified several significant obstacles to the accessibility of crucial palliative care medications. These barriers encompass the failure to effectively implement the existing medicines policy, concerns among HCPs regarding the prescription of opioid medications, the absence of a centralized procurement system for morphine, and the exorbitant cost associated with this drug.

Regarding access to controlled substances in African countries, the INCB (2012) identifies inadequate capacity to estimate actual licit narcotic requirements, insufficient training of national drug control administrators and deficient legal and regulatory frameworks as factors hindering access to necessary controlled medicines for pain treatment. This inability to accurately predict licit requirements leads to shortages and low availability of these substances for medical use. Clark et al. (2021) similarly identified legal, regulatory and socio-political barriers to accessing opioids, akin to those for MC. They point to lack of explicit laws, inadequate education among policymakers and clinicians about the benefits of opioids access, restrictive international controls and bureaucratic barriers.

Critically assessing the role of INCB, Burke-Shyne et al. (2017) argue that the INCB endorsement of restrictive drug control systems, driven by the "war on drugs" undermined access to controlled medicines and the right to benefit from scientific progress. They note that restrictions on research of cannabis in the US have hindered assessment of its medical benefits. Duvall (2019) and Dania Putri (2020) highlight historical barriers to MC, rooted in the colonial-era demonization and prohibition of the plant. This prohibition, driven by economic interests in favoring other lucrative drugs like alcohol and coffee, marginalized and stigmatized cannabis users across various regions.

Despite policy and legislative progress, emotional barriers persist in prescribing MC (Schlag et al., 2020). Sznitman & Bretteville-Jensen (2015) similarly observed the fear that legalization of MC was likely to result in cannabis use for recreational purposes. However, Scholten (2020) argues that the burden of pain-related disease far outweighs concern about non-medical cannabis use.

According to WHO (2017), regulatory barriers impede access to controlled medicines, such as limitations on prescription durations and dispensing outlets, and restrictions on exports and imports. These regulations were available but often poorly implemented and enforced, hindering access to information thereby obstructing the right to health (Burke-Shyne et al. 2017a; Maxwell, 2018). The integration of MC into palliative care has been delayed due to lack of clinical research data, inadequate knowledge, and confusing regulatory frameworks, exacerbated by political and public opinions that either stigmatize or praise it (Cyr et al., 2018). In Kenya, Kippenberg (2010), identifies misconceptions about drug control laws, apprehension of legal consequences, and persistent use of the term "dangerous drugs" to describe controlled pain medications as a barrier.

Importing controlled medicines involves a cumbersome process due to stringent regulations outlined in IDCCs. For instance, the Single Convention mandates that controlled substances be available for medical and scientific use, subject to national regulations. It sets out three key criteria for countries to follow in their national regulations: (a) only authorized/licensed individuals can dispense controlled substances under the Convention; (b) controlled substances can only be transported between authorized institutions or individuals as per national law; and (c) a medical prescription is necessary for dispensing controlled substances. However, countries often impose additional conditions, hindering access. Similarly, the 1971 Convention on Psychotropic Substances aims to ensure access to psychotropic substances for medical use.

The INCB estimates that 5.5billion people lack or have limited access to these medicines, with 92% morphine consumption concentrated in a small fraction of the global population. Regulatory frameworks, entrenched in criminal justice perspectives, exacerbate these challenges, as seen in the classification of cannabis as a Schedule I narcotic, hindering research progress (National Academies of Sciences et al., 2017).

2.3.3 Stakeholder Involvement in Development and Implementation of The Regulatory Framework for Access to MC as An Alternative for Use in Pain Management

According to Savage et al., (2016), despite ongoing discussions surrounding cannabis, many pain specialists and researchers advocate for thorough research on cannabinoids. They emphasize the importance of understanding herbal cannabis's clinical potential to guide drug development and evaluate outcomes, a sentiment also supported by medical leadership.

Cohen (2009b) argues that political advocacy should not overshadow scientific evidence in determining marijuana's suitability as a pharmaceutical agent. He suggests that decisions about its medical use should follow standard drug-approval processes, with final authority resting with NMRAs like US FDA. This sentiment is echoed by Paul-Emile (2010), who highlights the risks of legislating drugs without enough empirical knowledge.

Lucas (2008) notes that court challenges from patients benefiting from MC but were vulnerable to arrest and persecution due to its controlled status resulted in the establishment of centralized MC programs in Canada. However, the program had faced criticism from the medical establishment, law enforcement, and patients. Lohman et al., (2010) point out that excessive regulations and HCPs lack of knowledge contribute to undertreatment of pain, emphasizing the need for improved prioritization of pain management medications.

In order to ensure adequate policies in a rapidly changing MC regulatory environment, Ruheel et al. (2021) stress the importance of considering stakeholder feedback and involving HCPs in policymaking to ensure effective regulation of MC and utilization by patients. They argue that addressing consumer needs and involving HCPs can overcome barriers like religious opposition and communication gaps between researchers and policymakers. Advocacy efforts by civil society have effectively facilitated increased importation of morphine into the nation. The inclusion of palliative care and pain management in many national documents, particularly those pertaining to individuals with cancer and HIV/AIDS, has been secured (Ali, 2016).

Ablin et al. (2016) and Lamonica et al. (2016), highlights the necessity of HCPs involvement in both the policy development and implementation process to address gaps occasioned by stakeholders' confusion and misinterpretation in MC regulation.

The analysis by Kim (2016) suggests that public opinion largely influences the spread of MC laws, rather than elected officials' political philosophy or the government's budgetary health. There is therefore need for governments to prioritize user needs and fund research to ensure safe and timely access backed by scientific evidence (Lucas, 2008; Taylor, 2016). The discussion on MC use in Kenya should first align with the law, requiring well-structured, sober discussions among all stakeholders (Weru, 2019).

2.4 Research Gap

The key findings from the review of literature indicate that generally, access to controlled substances, including MC, is marred by several barriers of access despite scientific evidence of its medical benefits. The literature indicates legal frameworks as both a barrier and enabler in enabling access to MC globally. It emphasizes the human right nature of ensuring access to MC and the importance of stakeholder involvement at both policy development and implementation. Most of the studies have focused on the scientific evidence of MC use in pain management and the attitudes and social barriers [non-statutory variables] to access of controlled substances such as opioids, including morphine, with a focus on palliative care.

Limited studies have however been done on the statutory variables of implementation of MC legislation for use in pain management enabling access to these substances for pain management in Kenya. To arrive at a deeper understanding of the statutes' implementation structure, this study focused on evaluating the implementation of MC legislation in Kenya as an enabler of access to MC for pain management.

Table 2.1: Research gaps

Study	Focus	Methodology	Key Findings	Research Gap
Sznitman (2020)	Medical cannabis regulation in Israel	Qualitative interviews with healthcare providers	Israel's MC regulatory framework is effective, but bureaucratic barriers hinder widespread access	Limited focus on statutory framework in non-Western countries
Burke-Shyne et al. (2017)	International drug control systems	Case studies of multiple countries	Legal frameworks are seen as both enabling and restricting access to controlled substances	Lack of country-specific analysis of MC legislation implementation, especially in Kenya
Lohman et al. (2010)	Barriers to accessing pain relief worldwide	Survey and interviews with healthcare providers	Barriers include regulatory frameworks, lack of training, and cost	Limited focus on the role of legislation in enabling access to controlled substances

Study	Focus	Methodology	Key Findings	Research Gap
Kippenberg (2010)	Access to morphine in Kenya	Policy analysis and expert interviews	Ambiguities in Kenyan drug control laws contribute to under prescription of morphine	Lack of focus on MC legislation implementation in Kenya
Putri (2020)	African decolonization of drug control	Literature review and policy analysis	Advocates for the decolonization of drug policies to improve access to controlled substances in Africa	Lack of empirical studies on MC regulation in African countries
Cohen (2009a)	Medical marijuana regulation in the U.S.	Literature review and policy analysis	Advocacy for standardized regulation and scientific approval of MC	Focus on Western countries, with limited research on Kenya and other African nations
Medicines Control Council (2017)	Medical cannabis access in South Africa	Policy review and national surveys	Strong regulatory framework but limited access due to bureaucratic hurdles and lack of awareness	Gaps in regional analysis of MC policy in Africa

2.5 Conceptual Framework

This study investigated the ability of the legal framework to structure implementation by evaluating the effectiveness of the existing legal and policy framework, identification of barriers in implementation and obtaining insights into stakeholder involvement and their impact. The conceptual framework, under figure 1, illustrates visually how these elements of the legal framework interact to impact access to MC for pain management, highlighting the key relationships and dependencies among these variables. The policy and legal frameworks influence access to MC, stakeholder involvement shapes the development and implementation of these policies while implementation barriers can affect the effectiveness of the legal framework. It identifies the independent variables (implementation challenges, legal framework, and stakeholder participation) and the dependent variable (access to MC), showing how these elements interact to affect access.

The implementation barriers include the clarity of the regulatory framework, which affects how easily MC can be accessed, regulatory barriers that stem from national and international drug control regulations, and bureaucratic processes that delay access. Additionally, the knowledge gap and attitudes of policymakers and healthcare professionals (HCPs) influence how effectively MC is prescribed and accessed.

The policy and legislative framework addresses the strengths and weaknesses of the laws governing MC access. A strong framework ensures better access, while weak or ambiguous laws and international controls limit access to MC for medical purposes. International regulations, like the Single Convention on Narcotic Drugs, also impact a country's ability to regulate MC.

Stakeholder participation includes the roles of policymakers, HCPs, and civil society/patient advocates. Policymakers create laws, HCPs prescribe and manage MC, and patient advocates push for reforms and awareness. Effective collaboration among these groups is crucial for improving access to MC.

The dependent variable, access to MC for pain management, is influenced by the interaction of the independent variables. The effectiveness of the legal framework, participation of stakeholders, and resolution of implementation barriers determine how well MC is integrated into healthcare systems and made available to patients in need

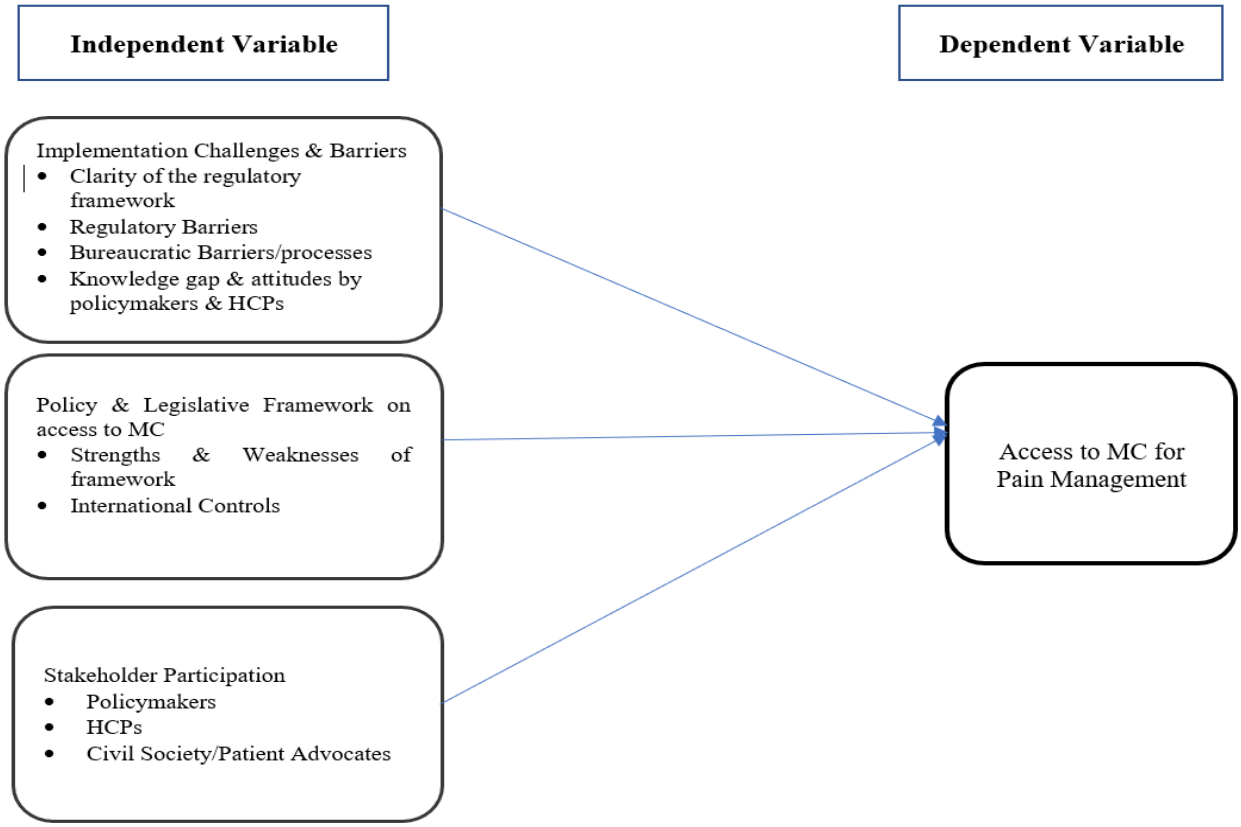

Figure 1: Conceptual Framework

CHAPTER THREE: RESEARCH METHODOLOGY

3.1 Introduction

This chapter outlines the research methodology used in conducting this study. In more detail, it outlines the philosophy guiding the research, the adopted research design, the study population and sampling, methods of data collection, data analysis, data quality control and ethical considerations.

3.2 Research Philosophy

Chowdhury (2014) explains interpretivism as the philosophy that puts meaning in a person's character and participation in social and cultural life. This philosophy is based on Max Weber's verstehen, where researchers aim to understand the motives and meanings behind people's actions, behavior and interactions in society and culture. According to interpretivism, value-free data cannot be collected because enquirers utilize their own preconceptions to influence the investigation process, and the researcher interacts with the human subjects of the investigation, affecting both sides' views. Essentially, this philosophical and research paradigm is concerned with the uniqueness of a certain circumstance, which contributes to the underlying desire for contextual depth.

In this study, data was collected on the stakeholders' diverse views regarding the barriers and challenges they face in implementing the legal framework for accessing MC for pain management in different contexts to derive indicators such as perception of effectiveness of the frameworks, identification of barriers and solutions proposed. By comparing the theory with practice, the researcher gained a fuller understanding of the issues around implementation of the legal framework and was better placed to contribute to the body of knowledge on access to MC.

Arguments for interpretivism assert that truth and knowledge are based on people's experiences as well as their understanding of them (Ryan, 2018). According to Bryman (2012), it is possible that a researcher who adopts an interpretative posture will arrive at unexpected conclusions, or at least conclusions that appear surprising from an external perspective, that is, from outside the social environment being investigated. This philosophy was crucial in this study as it aimed to demonstrate how stakeholders perceive and interpret the world concerning MC access for

pain management. This provided the common understanding necessary for successful implementation of MC programs in Kenya.

3.3 Research Design

The research design involved selecting an appropriate strategy that aligned with the research objectives as observed by McNabb (2018), which in this study included interviewing individuals with experience in pharmaceutical policy making, regulation and pain management implementation to address inaccessibility of MC in Kenya. A qualitative methodology was used for this study to assist in gaining a rich and deeper understanding of the problem of inaccessibility of MC for management of pain in Kenya. Key informant interviews of individuals selected based on their experience in pharmaceutical policy making, regulation and implementation of pain management strategies were done in order to appreciate the issues associated with the problem. This study therefore used qualitative research methodology as the most suitable approach as guided by the research questions and research objectives.

3.4 Population and Sampling

A research population is a large collection of individuals or objects that constitutes the main focus of a research (Biggam, 2008). This study targeted the government officials responsible for policy, the NMRA, HCPs, civil society organizations, and other key stakeholders to determine the current state of implementation of MC legal framework, the barriers, how to overcome hurdles, and how to ensure the balance between access and abuse is maintained.

Sampling plays a crucial role in qualitative research as it entails the deliberate selection of a cohort of participants who possess the potential to offer significant insights pertaining to the research questions. In qualitative research, participant selection is determined by the research objectives and is highly dependent on the researcher's discretion to select the right sampling technique (Shaheen et al., 2018). Purposive sampling is chosen for this study to ensure that participants selected align with the research objectives, contributing to a sample that is rich in information. By employing various purposive sampling strategies, the study captured a diverse range of perspectives, maximizing the richness of the data collected and enhancing the comprehensiveness of the analysis.

In this regard, the study interviewed representatives from key organizations involved in pharmaceutical policymaking, regulation of medicines, healthcare provision and Civil Society, as they play crucial roles in the implementation and oversight of MC programs for pain management in Kenya. This step gathered insights into the variables of policy-legal effectiveness, challenges faced and potential solutions. The regulatory authority, PPB, has a total staffing of 194 staff. The sample was drawn from the heads based on specific criteria such as legal expertise, experience in regulation of controlled medicine drawn from the relevant department i.e. the product evaluation and registration department, licit control unit, drug crime and investigation division and any other representative identified by the PPBs management. Emphasis was laid on the licit control unit owing to their expertise in licit control.

The Ministry of Health is organized into 6 directorates; the study focused on one directorate and one division as a representative sample. The HCPs were drawn from palliative Medicine specialists. The Kenya Medical Practitioners and Dentists Council (KMPDC) register of licensed local practitioner as at 27th March 2024 revealed only two persons registered as palliative medicine specialists that informed the sample (KMPDC, 2024). Palliative Care Providers (PCP) institutions in Nairobi formed part of the population. (KEHPCA, 2024). A representative from the management of the largest patient advocacy group, in view of the institution's active involvement in patient advocacy formed part of the population and sample to offer insights on the patient needs and stakeholder involvement. The specific sample size was as indicated in Table 3.2 below:

Table 3.2: Sample Size

Sample Category	Organization/Representative	Total No.	Sample Size
Pharmaceutical Policy Maker	Health Standards, Quality Assurance and Regulation	4	2
	Health Products & Technologies	1	1
	Total	5	3
Regulation of Medicines	Product evaluation and registration Department	1	1
	Legal Department	2	1
	Licit Control Unit	2	2
	Drug Crime & Investigation Unit	2	1
	Total	7	5
Healthcare Provision	Palliative Medicine Specialists	2	1
	Pharmaceutical Society of Kenya	2	2

Sample Category	Organization/Representative	Total No.	Sample Size
	HCPs from PCP institutions: a) Freestanding b) Public c) Private	3	3
	Total	7	6
Civil Society & Advocacy	Palliative Care Association	1	1
	TOTAL	18	15

3.4.1 Sampling Approach

Sampling in qualitative research is crucial as it determines the cohort of participants who will provide insights aligned with the research objectives. Since this study aimed to explore the implementation of the MC legal framework, barriers, and stakeholder involvement, purposive sampling was used. This method was effective for selecting participants who have knowledge and experience relevant to the study's objectives (Shaheen et al., 2018). By using various purposive sampling techniques, the study aimed to gather a rich and diverse range of perspectives from those directly involved in the policy, regulation, healthcare, and civil society spheres.

3.4.2 Sampling Strategy

The sample will be drawn from the following categories:

Policy and Regulatory Body

- Representatives from the Ministry of Health (MOH), particularly the Health Standards, Quality Assurance and Regulation Directorate, and the Health Products and Technologies Department. The specific focus will be on the officers who are involved in policy decisions related to MC, as well as those overseeing pharmaceutical regulations.
- Representatives from the Pharmacy and Poisons Board (PPB), particularly the Product Evaluation and Registration Department head, Legal Department Officers, Licit Control Unit, and Drug Crime and Investigation Unit. Since the PPB has a total of 194 staff, the sample will be drawn from the heads of these departments based on specific criteria, such as legal and scientific expertise and experience with controlled medicines. The emphasis will be on the Licit Control Unit due to their direct involvement with the regulation of controlled substances like MC.

Healthcare Providers (HCPs)

- Palliative care specialists, including those from palliative medicine (as registered by the Kenya Medical Practitioners and Dentists Council - KMPDC, 2024) and those practicing in Palliative Care Providers (PCP) institutions in Nairobi.
- The umbrella body for Pharmacists, specifically the heads of the institutions, was also included as they play a crucial role in policy development, advocacy on regulation of medicines, including MC.
- Healthcare workers in three major PCP institutions in Nairobi: freestanding, public and private.

Civil Society and Advocacy

- A representative of one of the Palliative Care Associations due to their active involvement in patient advocacy and stakeholder engagement in MC discussions.

3.5 Data Collection Methods

Data was collected through face-to-face or telephone interviews, to allow for in-depth insights and personal interactions with the participants, as recommended by McNabb (2018). Structured interviews containing a mix of both open-ended and closed questions were used to gather primary data effectively. The open-ended questions sought deeper clarification and deepened an understanding of the issues in MC access. Additionally, focus group discussions (FGDs) were held with the regulator. These FGDs provided an opportunity for discussion with the regulator on their perspectives on the legal and regulatory framework, barriers to MC access and the role of stakeholder involvement in shaping the regulatory framework. Different interview guides were developed for the different key informants to ensure focused collection of data. A sample of the Interview and FGD Guides may be found in Appendix A.

The FGDs and face-to face interviews took approximately 14 days to cater for access to government officials whose schedules are often unpredictable, while ensuring a rapport is established with the participants.

In order to undertake a critical review and analysis of the policy and legislative framework, using Mazmanian's framework, secondary data was gathered from the policies and legislation that guide use of controlled substances such as MC in pain management, including international

laws, laws of Kenya, Sessional Papers, Pharmaceutical Policy papers, Ministry of Health Strategic Plans, Pharmacy and Poisons Board Strategic Plan, National Dailies and published literature on the matter. This assisted in assessing the effectiveness of the policy and legal framework through identification of the strengths, weaknesses, gaps and opportunities in the Kenyan context. Additionally, respondent organizations; websites, reports, data banks among others provided secondary data.

3.6 Data Analysis

The data collected from interviews, focus group discussions (FGDs), and secondary sources were analyzed using a combination of content analysis and thematic coding techniques, as outlined in the conceptual framework. Each of these data sources were analyzed systematically to address the research questions and achieve the study's objectives.

3.6.1 Interview Data Analysis

The interview data obtained from key informants was analyzed using content analysis to identify themes, patterns, and relationships related to the research objectives. Specifically, the analysis focused on variables such as perceived barriers to MC access, suggested improvements, and the roles of stakeholders in policy implementation. Cross-case matrices were employed to compare data across different stakeholder groups, such as government officials, healthcare providers, and civil society representatives. This allowed for a nuanced understanding of how each group perceives the legal framework for MC and its challenges.

To analyze the qualitative data, deductive coding was applied. Deductive coding involved reviewing raw data to identify patterns in similar phrases, words, or relationships, and categorizing them into themes and sub-themes based on pre-defined categories derived from the conceptual framework. For this study, categories such as access barriers, regulatory challenges, and stakeholder perspectives were used as initial coding categories, which were refined as the data was analyzed.

3.6.2 FGD Data Analysis

The data collected from the focus group discussions (FGDs) was also analyzed using the same approach. The FGD data was transcribed and coded in line with the main themes identified during the interviews, such as legal framework, barriers to MC access, stakeholder

involvement, and implementation challenges. Thematic analysis was applied to identify key insights, particularly focusing on the collective perspectives of the regulator representatives regarding regulation of MC access within the healthcare system. The group dynamics from the FGDs provided additional context and richness to the data, allowing for a deeper understanding of the issues discussed.

3.6.3 Secondary Data Analysis

The secondary data was analyzed through document analysis, which involved reviewing policy and legal documents, reports, and publications related to the regulation of controlled substances, including MC. The analysis focused on assessing the effectiveness of the legal framework, identifying gaps or inconsistencies, and understanding how the legislation aligned with international standards and human rights obligations. The secondary data helped contextualize the primary data and provide a broader understanding of the legal and regulatory environment surrounding MC access.

Through these combined methods of analysis, the study synthesized findings from interviews, FGDs, and secondary data, provided a comprehensive picture of the challenges and opportunities in implementing the MC legal framework in Kenya. The findings were used to identify key themes and insights that informed recommendations for improving the regulatory framework and enhancing access to MC for pain management.

3.7 Research Quality

To test the validity and reliability of the data collection instruments, a pilot test of the interview guide was conducted with a small sample drawn from the target population. The pilot involved three respondents, which represented approximately 10% of the intended sample size for the study. This small sample helped verify the clarity, relevance, and comprehensibility of the interview questions. The pilot respondents were selected based on their familiarity with the topic, ensuring that they can provide valuable feedback regarding the effectiveness of the interview guide.

The feedback received from these pilot respondents was used to make necessary adjustments to the interview guide, ensuring that it is well-structured and capable of eliciting the required information for the main study. By piloting with a small group, any issues with the phrasing of

questions, the length of the interview, or the structure of the guide were addressed, improving the overall data collection process.

Additionally, variations in question delivery and response recording were minimized to ensure consistency and reliability in how data is captured during the actual interviews. To further enhance the reliability of the interviews, participants in the face-to-face interviews were asked for consent to record the sessions. The recordings served to ensure accuracy in capturing responses and were used for data analysis.

Finally, member checking was employed, where the interview findings were shared with participants to verify the accuracy of the data and to clarify any potential misinterpretations. This process helped ensure objectivity, reduces bias, and enhances the credibility and trustworthiness of the study's findings.

3.8 Ethical Considerations

To protect research participants, ethical approval was successfully sought from the Strathmore Institutional Ethics Review Committee and a research permit from the National Commission for Science, Technology and Innovation (NACOSTI) before field work. The study participants were fully informed about the study details to enable an informed decision on participation, and they signed a written consent form to signify their agreement as recommended by Lammasniemi (2018). As part of the details of informed consent, the participants were informed of the confidential nature of the study. Additionally, confidentiality and anonymity of the respondents was ensured by registering their data by category as opposed to the specific interviewees' names. The Sample Introduction Letter and Consent form is annexed as Appendix B and Appendix C respectively. The budget used in conducting the study is attached as Appendix D.

CHAPTER 4: PRESENTATION OF RESEARCH FINDINGS

4.1 Introduction

This chapter presents the findings of the study evaluating the legislative framework's ability to effectively structure the process of access to MC for pain management in Kenya. Using a qualitative design, data was collected through interviews and FGDs with key stakeholders including policymakers, regulators, HCPs, and civil society/patient advocates. Additionally, relevant documents such as the Pharmacy and Poisons Act and the Narcotics Act were reviewed. The findings are organized according to the study's objectives.

4.1.1 Response Rate

All 15 planned responses were successfully collected, resulting in a 100% response rate. This included 2 FGDs involving 7 participants (46.7%) and 8 interviews (53.3%). According to Mugenda and Mugenda (2003), a response rate of 50% is sufficient for analysis, thus the study exceeded the required measures for data analysis and reporting.

4.1.2 Demographic Data

The study included participants playing various roles within Kenya's healthcare sector, bringing significant experience and expertise. They were drawn from key organizations involved in pharmaceutical policymaking, regulation of medicines, healthcare provision and Civil Society. All participants held advanced degrees, including Bachelor of Pharmacy (B. Pharm), Bachelor of Medicine and Bachelor of Surgery (MBChB), and multiple master's degrees, with professional experience ranging from 12 to 23 years. The sample sizes are tailored to ensure a focused and detailed examination of each role's contribution to the healthcare system.

Table 4.3: Demographic Data

Code	Age Range	Education Level	Years of Experience
Category A- Policy Makers			
A01	40-50	• BPharm • Masters in clinical pharmacy	22-25 years in service
A02	40-55	• MBChB • Masters in public health	22 years in service
Category B – Regulator			

Code	Age Range	Education Level	Years of Experience
B01	45-50	• BPharm • Masters in pharmacy	22 years in service
B02	35-40	• Bachelor of Laws • Master of Laws	15 years in practice
B03	40-50	• BPharm • Masters in health systems management	15-20 years in service
B04	40-50	BPharm	25 years in service
Category C – HCPs			
C01	45-55	MBChB, Specialized in Palliative Care	12 years in palliative care
C02	40-50	BPharm	15-20 years' experience
C03	40-50	MBChB	15-30 years of practice
Category D – Civil Society			
D01	45-50	• MBChB • 2 master's degrees • Fellowship	14 years in palliative care

4.2 Legal Framework governing access to MC for Pain Management in Kenya

The legal and policy framework governing MC in Kenya is guided by both national and international laws. Key national statutes include the Pharmacy and Poisons Act and the Narcotic Drugs and Psychotropic Substances (Control) Act, 1994. The Pharmacy Act classifies cannabis as a Part I poison, restricting its sale and importation to authorized entities, while the Narcotics Act categorizes cannabis as a narcotic drug, prohibiting its cultivation and trafficking with limited allowances for medicinal use by licensed individuals and medical practitioners. The Narcotics Act provides for the establishment of a Board to govern licit use and specifies the functions of this board. However, it was established that this Board has never been put in place as PPB is recognized as the national competent authority as per Article 116 of the Single Convention and is implementing licit control.

Due to the international controls imposed on cannabis, the review of national laws was done against the benchmark of the International Drug Control Conventions (IDCCs). The IDCCs outline five key conditions under which medical use of Cannabis is permitted. These conditions emphasize the need for clear regulatory frameworks that allow for MC while ensuring proper supervision and preventing misuse. As part of the study, the five conditions were compared with the policy-legal framework in the country both in terms of the law and practice with findings on Table 4.4 below.

A comparison was also done between the functions of the board set out under Section 16 of the Narcotics Act and the provisions under the Pharmacy Act with regards to licit control with the findings captured under Table 4.5.

4.2.1 Strengths of the Current Legal Framework

The regulatory approach under the national statutes provides a structured mechanism for controlling the distribution and use of cannabis, ensuring it remains within legal confines for authorized medical purposes. The theoretical framework by Mazmanian and Sabatier (1983) underscores the importance of clear and consistent legal and policy guidelines for successful policy implementation.

Participants in the study acknowledged that there was no specific regulation or guideline that relates to regulation of MC. However, at a minimum the regulation of cannabis would follow the same structured guidelines and monitoring mechanisms that currently exist for regulation of other controlled substances. A review of these guidelines revealed that there was lack of clarity specifically with regards to cannabis.

It was, however, clear in terms of strengths that the minimum requirements applicable for controlled medicines to wit; product registration and authorized persons were provided for under the Act. These aspects ensure that there is a foundational structure to build upon for the integration of MC into pain management practices. This was supported by the participants who stated that "*Person must be registered by the PPB; establishment registered; product must also be registered by the PPB to ascertain quality, safety and efficacy; The source of the product has to be ascertained, Good Manufacturing Practices complied with; Indicate intention to deal*

with this product; premises are then inspected to ascertain capacity to keep records, have professionals on record".

4.2.2 Weaknesses of the Current Legal Framework

Despite these strengths, the study identified several weaknesses within the current legal framework. The lack of a comprehensive legal framework to support the use of MC for pain management was a significant concern among participants. One participant stated, "*So, for now, cannabinoid use, medicinal cannabinoid. Yeah. There's no legal instrument that supports using medicinal cannabinoids*." Another mentioned, *"However, as a country, our legal framework classifies cannabis as an illegal substance. So, you are liable to prosecution if you are found in possession.*" This ambiguity within existing laws contributes to negative social attitudes towards MC and creates substantial barriers to its medicinal use.

Participants in the study also emphasized the need for legislation to align with policy directives – by implication therefore, that there's misalignment. One participant noted, "*It's only that the legal environment in Kenya does not allow any of that. Remember, a policy needs to be based on current legislation, or legislation should be crafted to support policy."* This underscores the need for better alignment between existing laws and policy frameworks to create a more cohesive environment for the implementation of MC for pain management.

Additionally, participants stated that there was need to develop regulations specifically for MC to adjust with the regulatory trends world over and provide a clear framework. One participant stated, *"We need regulations that will adjust with the regulatory trends world over and provide a clear framework."* These regulations should ensure that Kenya remains adaptable to global standards while maintaining local relevance.

According to the participants and review of literature, there is no framework in place to facilitate access to MC by meeting all the conditions specified by the IDCCs. For example, the Pharmacy Law only provides for the function of implementing the IDCCs but does not provide details on the how to in the form of regulations and guidelines. A participant supported this position and stated that *"The Act is insufficient as it provides for a mention of licit under only one part under Section 3B of the Act*".

Additionally, the participants acknowledged that the law did not prescribe the allowable limits of MC, aspects of dosing and handling of the product to provide confidence to the prescribers and the users. This was further exacerbated by the available policies on pain management that did not consider MC as an option for pain management resulting in the same not being provided for in the national or hospital formularies. The KEML, 2023 for example, contained only 6 opioids, and some opioids were too weak for management of severe pain of scores above 7 that were not responsive to weak opioids. This challenge was pegged on the weakness in the legal framework among other reasons to wit *"there should be change in law to touch on which specific types would be made legal for medicinal use".*

The participants indicated that the Narcotics Act as it is now, was amended in 1994 and failed to bring on board important components on licit use that had been provided for under the Dangerous Drugs Act (DDA) that was repealed by the Narcotics Act. It was their view that the DDA provided more clarity on the requirements for handling of narcotic drugs for licit use. One participant remarked, *"The Dangerous Drugs Act provided clearer guidelines on how narcotics should be handled for licit use, which the current Narcotics Act fails to address adequately."*

Table 4.4: IDCCs vs Kenyan Laws

S/N	IDCC	Kenyan Laws (Statement and intent)	In practice
1.	Licensing and Regulation of Production	Under the Narcotics Act, cultivation of cannabis is illegal. On the other hand, the Pharmacy Act provides for manufacture of medicinal Substances and requirement for licensing health products, which include narcotic drugs such as Cannabis. Manufacture under the Pharmacy Act is defined to include "…packaging, blending, mixing, assembling, distillation, processing, changing of form or application of any chemical or physical process in the preparation of a medicinal substance or product".	It was explained that MC would be regulated like other controlled substances, however it was apparent that the regulator was yet to receive any applications for registration or manufacture of the MC product and as such there were no licensed manufacturers or products on the website. A participant stated that *"for MC, there has never been intent from organizations for medical use. The intent has only come for industrial and recreational purposes and no person has met the requirements anyway".* However, when it came to production of MC, it was clarified that the regulator's role only kicked in at the point of processing or changing form as in the definition of manufacture. It was noted that the involvement of the regulator was restricted as cultivation was outrightly outlawed

S/N	IDCC	Kenyan Laws (Statement and intent)	In practice
			in the Narcotics Act with no provision for exceptions and even if it was not, regulation of cultivation would fall under the purview of other government agencies.
2.	Estimation of National Demand	No provision in the national law.	It was noted that Kenya submits national estimates to INCB annually. However, it was explained that estimating the demand was challenging since no one was currently importing MC, and accurate estimation would only be possible if it were being used within the country. This was evidenced by participants noting that *"the legal framework was enabling, however most of the requests for authorization received by the regulator were for recreational use, explaining why there were no registered MCs in the database for the regulator."* It was suggested that further research was needed to determine who might require MC domestically. There was a disconnect between the regulator and the stakeholders in terms of the demand for MC. Participants stated that *"People call wondering*

S/N	IDCC	Kenyan Laws (Statement and intent)	In practice
			whether they can legally get MC in the country, giving testimonies of how they accessed them in other countries, and it worked to ease their pain"; Stakeholders noted the need for MC as follows: *"Increasing options for patients; for example, for Cannabis, you do not have as much constipation like morphine, so if someone has constipation, they can stop using it and still get pain relief".* Additionally, another participant supported this, *"...To avoid misuse of opioids, it is important to introduce alternative. Cannabis does not replace the pain killer; it supplements the pain killer owing to the way it works."* In the meantime, it was noted that other pain-relief products such as morphine and pethidine are being used as issues related to cannabis remain unresolved, as illustrated by participants' observation that

S/N	IDCC	Kenyan Laws (Statement and intent)	In practice
			"professionals are not ready to get involved due to the bureaucracies. Most people view these products as one of the products they do not want to deal with due to stigma." *"Make it explicit on the allowed limit within the Act for medical use"* to scale up palliative care in the country. *"The law should be explicit so as to the allowable limit we can. Dosing and handling?"* *"...having it within the medicines schedule to give people confidence that it can be imported, stocked. There has been no direct invitation from the regulator when reviewing medicines scheduling"* The participants advocated for an increase in the quota for MC, through their involvement. The participants provided the example of the increase in quotas for morphine upon their involvement. *"I haven't been involved in the legal conversations. But*

S/N	IDCC	Kenyan Laws (Statement and intent)	In practice
			with the regulator, the quota for morphine used to be very low. We advocated for the increase in this quota to ensure availability".
3.	Proper Medical Supervision	The Pharmacy Act makes provision for authorized persons who may handle Poisons, including narcotic drugs. There is a lack of clarity on the specific details as relates to MC. The Narcotics Act provides for the regulation-making powers of the cabinet Secretary for Interior to prescribe conditions on the conditions for issuance of authorizations and prescriptions. However, the regulations are not in place.	There is need to incorporate the use of medical cannabis in clinical practice for pain management through *".... education and sensitization to deconstruct the misbelief about the drug from leadership, prescribers, patients, societies and communities at large. People will understand that this is a normal drug as long as it is prescribed".* However, the law should be amended to provide *"Limitation on handling, prescribing, dispensing…"* MC can fit into existing treatment for patients with severe pain but there is fear among HCPs on handling narcotics generally. The HCPs were of the view that in using MC, *".... Assess pain on whether it is mild, moderate or severe. It would fall in the severe pain category with better side effect profile.*

S/N	IDCC	Kenyan Laws (Statement and intent)	In practice
			Scores above 7 or pain not responsive to weak opioids" The regulator adopts a multi-agency approach in dealing with supervision e.g. Anti-narcotics Unit, NACADA, County Governments, this is especially when doing audits and surveillance. This was noted to be due to abuse of prescription medicine for non-medical use resulting in criminality.
4.	Monitoring and Reporting	In terms of monitoring the effects, the Pharmacy Act and regulations provides for the establishment and implementation of a national vigilance system.	Monitoring and reporting are implemented by the regulator and HCPs for all medicines. The participants concurred that "*For morphine and fentanyl, this is done by doctors, we can extend this to cannabis to ensure monitoring use, making sure it is being prescribed by the right people which makes provision for follow-up and reporting any Adverse drug event*" The regulator "*organizes trainings and awareness for HCPs on vigilance and record maintenance*".

S/N	IDCC	Kenyan Laws (Statement and intent)	In practice
5.	Ensuring Availability for Medical and Scientific Use	The Pharmacy Act makes provision for regulation of licit use of narcotic, psychotropic substances in accordance with the IDCCs. However, there are no specific details provided in regulations on implementation of this provision of the law, presenting a gap.	There is no registered MC in the regulator's database on the website. *"Cannabis is scheduled as a part 1 poison but is unclear on how to handle… The Act is silent as it only mentions the extracts and resins. Therefore, if found in the market being marketed as a medicine it will be impounded. An Inspector looks at registration, permits for import, who is handling, how is it being conveyed."* There is fear among HCPs on handling narcotics generally. According to them, *"use of the word Controlled makes people want to use it. But the systems and infrastructure do not exist."* It is therefore necessary to improve the law *"…to make cannabis an essential drug and have it included as part of pain control in the Essential Medicines List"*

The findings under Table 4.4 above, demonstrate that the Kenyan legal framework is yet to be aligned fully to the conditions prescribed under the IDCCs.

Table 4.5: Comparison between Narcotics Act and Pharmacy Act

S/N	Narcotics Act	Pharmacy Act	Assessment of consistency/inconsistency between the Acts
a)	Issuance of licences for the importation, exportation, diversion, sale, manufacture, production or distribution (at stated places);	Makes provision for the requirement to obtain import or export licences for importation or exportation of any poisons and this is expounded in the Pharmacy and Poisons Rules. Licence to Manufacture medicinal substances is provided for and the requirement to obtain a license for wholesale dealer and obtain premises registration. The Act does not explicitly provide for sale; however it provides for the requirement for poisons to be handled by specified persons authorized by the PPB. No provision in relation to diversion. No regulations specific to Narcotics.	Inconsistent. The Narcotics Act addresses import/export of narcotic drugs, while the Pharmacy Act is broader on the general requirements. However, there is lack of specific provisions/regulations on specifics as it relates to narcotics.
b)	Naming ports or places in Kenya where any narcotic drug or psychotropic substance may be exported or imported	The definition of health products and technologies includes narcotics. There is no provision in the law making this requirement. The Cabinet Secretary however is empowered to make	Inconsistent. The Pharmacy Act lacks detailed provisions for the export/import of narcotics, while the Narcotics Act defines this requirement.

S/N	Narcotics Act	Pharmacy Act	Assessment of consistency/inconsistency between the Acts
		rules with regards to importation and exportation of Poisons which are available but not clear on additional conditions for narcotic drugs. The ports are not specified in schedules or regulations. However, a gazette notice was availed that provided for the ports of entry and exit of medicines.	
c)	Prescribing the manner in which any narcotic drug or psychotropic substance is to be packed or marked for export	No provision. The only specification available in the law is the general rules with regards to labelling and it is applied for import only.	Inconsistent. The Pharmacy Act lacks detailed packing/marking provisions for narcotics, while the Narcotics Act requires such regulations. Participants acknowledged that "*while there were no specific regulations in place, there was the possibility of introducing rules tailored to labeling requirements for certain products. For instance, when invoicing for narcotics, these should be invoiced separately. Furthermore, the next entity in the supply chain should be clearly indicated on the* invoice *to ensure proper controls are in place, thereby exonerating all parties from liability".*

S/N	Narcotics Act	Pharmacy Act	Assessment of consistency/inconsistency between the Acts
d)	Prescribing the records to be kept by any person in connection with the export, import, receipt, sale, disposal or distribution of narcotic drugs or psychotropic substances	Provides for the records to be documented, including the requirement to maintain a Poisons Book and Prescriptions Book. This is not specific to narcotic drugs. Safe Disposal Regulations are available for disposal of pharmaceutical waste.	Partially consistent. Both Acts require record-keeping, but the Narcotics Act lacks enforceable regulations specific to narcotic drug records. There is need to provide more detail in regulations concerning record-keeping for narcotic drugs. *"The PPB as the implementer of the Pharmacy Act has domesticated Guidelines which specify that the importers/exporters provide returns to the PPB via the permit number indicating where they were distributed and specifying the quantities. These assist in making returns to the INCB. This component is lacking and should be included in the Act and its regulations for enforceability".* *"It is a requirement to keep records of psychotropic & narcotic drugs which should be updated regularly and produced for inspection*

S/N	Narcotics Act	Pharmacy Act	Assessment of consistency/inconsistency between the Acts
			when need arises. It is a requirement to keep them under lock and key. The Dangerous Drugs Act was clearer on the requirements for handling". *"In terms of possession, it is unclear on how much someone can possess in order to possess it legally and not be deemed to be a peddler. With other controlled medicines it is known practice, you don't carry medicines that are more than 30 days"*

The findings under Table 4.5. indicate that the Pharmacy Act which governs licit control of MC and other controlled medicines is largely inconsistent with the provisions under the Narcotics Act that relate to licit use. The Pharmacy Act should be aligned to make better provisions for licit use of MC and ensure clarity in the statute.

4.3 Barriers to Implementation of the Policy and Legal Framework for Accessing MC for Pain Management

Despite growing recognition of MC's potential benefits, several challenges impede its adoption for pain management in Kenya. Participants identified a deficient legal framework as a primary obstacle. The existing laws categorize cannabis as illegal for most purposes, complicating its integration into mainstream medical practice. For instance, Participant D stated, *"The legal framework is not supportive of MC use, making it hard for patients to access treatment."* This sentiment was echoed by ten out of fifteen participants, highlighting widespread concern over the current legal restrictions.

Regulatory barriers also emerged as a significant challenge, with six participants citing issues related to accessibility and affordability. Participant C noted, "*The regulatory environment makes it difficult to obtain MC, even for those who qualify for its use."* The lack of clear policies and guidelines on pain treatment was another commonly mentioned barrier, as pointed out by Participant C, who said, *"There are no specific policies on how to incorporate MC into pain management protocols."* Two participants shared similar views on this issue.

A participant explained that the existing challenges when it comes to access to existing controlled medicine opioids such as morphine included the fact that "*professionals are not ready to get involved due to the bureaucracies. Most people view these products such as morphine as one of the products they do not want to deal with due to stigma*". This was raised as a concern for the mainstream controlled medicines as HCPs *"fear handling narcotics*"; therefore, this begs the question as to how MC is likely to be treated as a participant stated that MC "*has a lot of interest and controversies"*. According to 3 participants, the legal framework was enabling, however most of the requests for authorization received by the regulator were for recreational use, explaining why there were no registered MCs in the database for the regulator.

The participants indicated that abuse of controlled medicines for illegal activities to achieve side effects was a real barrier to access as the abuse of prescription only medicine for non-prescription use was on an all-time high resulting in stricter controls being put in place with the potential of limiting access: "*Kenya is accused of being too strict; a lot of bureaucracies that limit access to controlled products. Availability is not an issue. Access may be an issue as*

not everyone is allowed to dispense these products. People are finding it easy to use Prescription products for abuse instead of heroine"

The main issue according to some participants that hindered access was sensitization. This was pegged on ambiguity and lack of knowledge within the existing legal framework contribute to implementation challenges; *"stakeholders need sensitization on the need for this product to be done by the Ministry of Health to ensure the prescribers are aware and this product, MC is demystified instead of fearing to prescribe and dispense*". The study also identified socio-political and emotional barriers, including negative social attitudes and stigmatization surrounding cannabis use. These barriers are compounded by the deficient legal frameworks that inadequately support MC use for pain management, resulting in regulatory barriers and inadequate training for healthcare providers.

Insufficient training of healthcare officials was also identified as a significant barrier. Participant A and C pointed out, "*Healthcare providers often lack the necessary training and knowledge to confidently recommend and prescribe MC."* This concern was echoed by six participants who emphasized the need for comprehensive training programs for healthcare professionals. Inadequate training limits the ability of HCPs to integrate MC into pain management effectively. Participant I mentioned, "*Without proper training, even those willing to consider MC are unsure about its dosage, potential interactions with other medications, and overall efficacy.*" These findings align with strategies in countries with more established MC programs. Participants in C further highlighted, "*Public education is crucial to changing perceptions and attitudes towards MC. Without it, stigma and misinformation will continue to hinder acceptance."*

All the participants shared similar concerns, highlighting the need for structured educational programs and comprehensive training programs that provide healthcare professionals with the knowledge and skills needed to prescribe and manage MC treatments effectively. *"CMEs in various forms should be organized to create forums to educate HCPs on what they can do and options for their patients*" Additionally "*training in the health courses for pain management. Students are not well taught on the pain scale and the kind of painkillers to combine to take care of the pain that comes in between".*

The need for public education campaigns and awareness-raising initiatives to address misconceptions and promote evidence-based decision-making was re-emphasized. As one participant mentioned, *"I feel number one is education. Like what are the benefits? What are the benefits of what already is in place for pain management or pain management options? So, cannabis over let's say morphine, fentanyl, whatever."* This emphasis on education underscores the importance of disseminating accurate information to various stakeholders.

One participant noted, "*There's a deeply ingrained societal view of cannabis as a harmful drug. This perception extends to its medical use, creating barriers to acceptance."* Another respondent emphasized the need for public education: "*We need to differentiate between recreational use and medical use in the public eye. This can only be achieved through comprehensive education campaigns."* Cultural attitudes also play a significant role in shaping perceptions. As one participant highlighted, "*In some communities, there's a stigma attached to cannabis use due to historical and cultural beliefs. Overcoming this requires sensitivity and tailored communication strategies."*

Additionally, participants were in agreement that the lack of access to MC was also caused by the delayed integration of MC into palliative care policies and the essential medicines lists, thus putting it in a non-priority place when it came to prescribing practices and procurement in health facilities. According to Category B participants, while *"the legal framework was enabling, however most of the requests for authorization received by the regulator were for recreational use, explaining why there were no registered MCs in the database for the regulator."* The lack of policy integration directly impacted both prescribing practices and procurement decisions in health facilities. This policy gap is further emphasized by another participant who noted that *"There are no specific policies on how to incorporate MC into pain management protocols."*

One participant stated, *"Cultivation is illegal. I can just say cultivation is illegal. It's illegal under this 1994 Act. It is illegal to cultivate, to process, and to trade with all those."* This quote reinforces the legal barrier to accessing MC, as the regulator confirmed that indeed cultivation, processing, and trade of cannabis are prohibited under the current legal framework. "*The law is available for manufacture. However, cultivation is illegal under the Narcotics Act".* This creates a barrier for access to a more affordable alternative for pain management under the 1994 Narcotic Drugs and Psychotropic Substances (Control) Act. This was supported by the

participants in Category C who stated *"Consider amendment to lift the ban on cultivation to allow processing and reduce cost of healthcare"* while another stated that *"Government is keen on local manufacturing agenda to increase our capacity as a country and even trade in the region. If cultivation can be done in a controlled way for purposes of extracting the derivatives, riding on the local manufacturing agenda and take care of the opportunities in the region. Consider amendment to the law including putting controls in the law".*

In terms of operationalization of the CND decision to reschedule Cannabis as advised by the WHO, it was a finding that "*there is still no agreement on the threshold of THC in terms of the allowable limits. WHO says 0.2% THC. However, …… is yet to interrogate this and set the allowable limits. Since 2018, Kenya has been allocated 1gm of cannabis resin. However, to date no one has ever applied for a molecule for registration of cannabis resin or THC and CND".*

The study found varying perceptions towards MC among Kenyan stakeholders, ranging from openness based on research evidence to hesitancy due to perceived illegality. These mixed attitudes mirror the global discourse on MC. This dichotomy highlights the ongoing tension between anecdotal evidence, observational studies, and the gold standard of randomized controlled trials in shaping perceptions of MC.

It was further noted from the participants that the socio-political landscape presented additional barriers, with entrenched cultural attitudes and stigmatization surrounding cannabis use affecting public perception and acceptance of MC. Participant D explained, "*Cannabis is still stigmatized, and this affects how people view its medical use."* This was a common theme, with four participants discussing the socio-political challenges.

Participant A stated that "*One of the major symptoms in Cancer is pain. In the management of cancer patients, there's undertreatment especially in public service. Factors include…. Misconception on addiction. The fear of addiction is more. There is assumption that all opioids are addictive".* Participants C remarked, *"Many people still view cannabis solely as an illegal drug, not as a potential medicine."* Five out of fifteen participants shared similar views, emphasizing the need for public education campaigns to address misconceptions and deeply rooted stigmas associated with cannabis use. *"Some Physicians believe the myth that cannabis*

is only for recreation and abuse. Can't be used. The Patient & community believe that those who use are not very smart and need to be ostracized".

One participant expressed openness to considering MC, stating, "*So, for me as an individual, I would go for it just based on the research that has been done, which shows that it is useful, that it will be useful, especially in palliative care.*" This quote reflects a positive attitude toward the use of medical cannabis, based on available research evidence. However, another participant highlighted the hesitancy among some HCPs, stating, *"But now that is where I feel like maybe we haven't managed to operationalize it, to make it part of the treatment policies, yes, to explore because of that, maybe it's a fear of the illegality. Like this is not allowed, this is outlawed."* This suggests that concerns over the perceived illegality of medical cannabis may contribute to reluctance among healthcare providers.

4.4 Involvement of Stakeholders in Shaping and Executing the Regulatory Framework for Access to MC as an Alternative for Use in Pain Management

The participants revealed that the involvement of stakeholders in the policy making process was a potential area of improvement as engagements were done but in their view it could be done better. This was characterized by the lack of a formal framework within which to involve stakeholders, that entailed definitive timelines for consultation and discussion on emerging issues and new areas of regulation, and in particular for MC to ensure that policy changes that prioritize patient access to MC as a therapeutic option are put in place. Parti cants in Category B agreed that on stakeholder involvement, *"It is done however the frequency is not structured. The recommendation is to structure the period of regulatory review. This is because innovation often precedes regulation"*

It was the view of the participants that an improvement in this area would result in effective regulation and transparency in the process of ensuring access to MC, as the stakeholders would offer insights into clinical application of MC and its potential benefits for pain management. This aligns with earlier evidence where participants noted that *"professionals are not ready to get involved due to the bureaucracies."* Additionally, the participants expressed that there was lack of clarity in the information that informed the country estimates submitted to the INCB, which pointed towards low involvement of stakeholders on this front. This lack of stakeholder engagement echoes the earlier sentiment where a participant emphasized that *"stakeholders need sensitization on the need for this product to be done by the Ministry of Health to ensure*

the prescribers are aware and this product, MC is demystified." It was their view that their involvement would ensure the alignment of such guidelines with international standards and local healthcare needs.

The participants expressed the advantages that they had experienced in ensuring availability of other controlled substances such as morphine with one going further to state that *"For oral morphine I have been involved in a lot of conversation to have oral morphine available on KEMSA system. There is a program running in Kenyatta National Hospital (KNH) to ensure production is done in KNH. Before 2012, morphine tablets and powder were in the KEML. It means the counties can now prioritize this to ensure availability*".

The participants were of the view that the regulator needed to do more in terms of being the initiator of conversation with stakeholders as currently it was from stakeholder to regulator. This therefore presented room for improvement. On the regulator's side there was concurrence on this front in that indeed periodic stakeholder engagement was carried out but in an unstructured manner. This is supported by evidence that *"stakeholders need sensitization on the need for this product to be done by the Ministry of Health to ensure the prescribers are aware and this product, MC, is demystified instead of fearing to prescribe and dispense."* The focus was more on government multi-agency efforts to combat diversion and abuse of the controlled products already available in the market.

Upon a keen study of the relevant laws accessible on the Kenya Law reports website, it was evident that to effectively shape the regulatory framework for MC in Kenya, it is crucial for various stakeholders to play critical roles. *"Consider multi-agency approach in regulating cultivation and manufacture/production for medical use rather than importing".* Additionally, *"Not a lot of work has gone into MC. I am aware about efforts that have gone. However, generally there is need to have joint stakeholder engagement to ensure we are speaking one voice on MC"* This coordinated approach would leverage the expertise of various agencies to develop a comprehensive regulatory framework. Category D participant "*I have been involved in more of the advocacy to stakeholders. For oral morphine I have been involved in a lot of conversation to have oral morphine available on KEMSA system. Before 2012, morphine tablets and powder were in the KEML. From 2023 now KEML has morphine oral solution available. It means the counties can now prioritize this to ensure availability".*

It was evident from the participants that they were unable to provide information to patients on where to get MC as some already had experience that the treatment worked for them. *"Patients calling .... asking whether they can get MC in Kenya as it has worked".* It was the view of participants in Category C and D, *"MC still needs a lot of advocacy, champions. The more people are talking about it, the more people understand, the more we can implement changes that are going to be beneficial to improving access.* Another participated supported this position by stating "*Medical cannabis could revolutionize pain management in Kenya, offering relief to many patients. However, this requires careful regulation to prevent misuse and ensure safety."*

It was a unanimous view that the patient needed to be prioritized by making MC available as an option for management of pain. A participant stated that " *for pain management increasing options for patients is needed; for Cannabis, you do not have as much constipation like morphine, so if someone has constipation, they can stop using it".* Another participant was of the view that "*..it could be cheaper than morphine and eventual economic impact. More options available to the patient".*

Stakeholder participation is vital in policy discussions and strategy development to address the legal, medical, and social dimensions of MC integration. As one participant highlighted, "*Policy needs to be based on current legislation or crafted to support policy,"* underscoring the importance of harmonizing laws with policy directives to create an enabling environment for MC use. It was further proposed that there is need to "*Look at the EAC regional block as we interrogate MC policies. Looking at things as a block. This can be an avenue to bring this to the fore at the EAC level as our neighbor, Uganda has relaxed its policies and laws on cannabis to allow for medical use"*

On the regulatory approaches to make cannabis available for medical use, category B proposed that *"Continue multi-agency conversation, develop guidelines for the product, consult stakeholders on the product and develop policy on medical use of Cannabis"*

CHAPTER FIVE: DISCUSSION, CONCLUSION, AND RECOMMENDATIONS

5.1 Introduction

This chapter provides an in-depth discussion of the study findings in relation to the existing body of literature on medical cannabis (MC) for pain management. Using Political Theory and Mazmanian and Sabatier's Framework for Policy Implementation Framework, it examines the adequacy of the current legal framework, the main barriers to its implementation, the involvement of stakeholders, and offers actionable recommendations to enhance the policy, legal, and regulatory framework in Kenya.

5.2 Discussion of the Findings

5.2.1 Legal and Policy Framework Governing Access to MC for Pain Management in Kenya

The study findings indicate that the current legal framework in Kenya is ambiguous with regard to medical use of cannabis. There are general provisions under the Narcotics Act that allow for scientific and medicinal use, however, there are no clear or detailed policy instruments, legislation or operational guidelines to facilitate access to MC for pain management. According to Mazmanian and Sabatier's framework, this lack of clarity in policy objectives and legal provisions significantly impedes implementation. Without well-defined statutory goals and implementation guidelines, policy implementation becomes inconsistent or symbolic at best.

The study revealed that the Kenyan legal framework is yet to align fully to the conditions prescribed under the IDCCs. On some aspects, the Kenyan law presents a lack of clarity and there is low commitment to implement statutory objectives. This is demonstrated by the provisions donating powers to make regulations for medical use of narcotics but the same has not been implemented by the relevant authorities. Law is available but the users are not aware.

The participants' emphasis on the need for legislation to align with policy directives echoes a key finding by Kilmer and MacCoun (2017) in their review of processes for establishing MC programs. They argue that successful MC programs require harmonious interaction between laws, regulations, and policies specific to medical use. The misalignment in Kenya, where policies like the Palliative Care Policy exist without supportive legislation addressing MC use, creates a paradoxical situation that impedes HCPs and patients from accessing this treatment

option. The findings established that indeed MC had the potential to provide a cheaper alternative for pain management and in particular to improve QOL for patients at the end of life. However, the lack of regulations and guidelines to create an enabling environment for access to MCs both by patients and HCPs, resulted in a notable access gap that should be addressed through review of the entire regulatory framework. This misalignment is not just a technical issue but can lead to stigma. As highlighted under the findings, while there are acts implementing the Palliative Care Policy, the lack of clarity on MC use aspects in the Pharmacy and Poisons Act and Narcotics Act contributes to this misalignment.

The lack of a comprehensive legal instrument to support MC use in Kenya represents a significant weakness in the current regulatory framework. The findings indicated that the law regulating medical use classifies cannabis as a health product and therefore the rules that applied to medicines extended to this product, including the requirements for registration of the product and licensing of qualified persons. It was clear however, that given the stigma around this product occasioned by the recreational abuse, there were no registered products on the regulator's database and in fact any applications received were rejected for lack of a regulatory framework. This gap is not unique to Kenya but is observed in various African countries grappling with cannabis policy reform. For instance, DeCloedt (2022) provides a nuanced analysis of South Africa's journey towards legalizing cannabis for medical use. Despite making strides, they note that gaps in the legal framework persist, hindering effective implementation. This comparative perspective underscores the complexity of reforming cannabis laws and the need for comprehensive legislative overhauls rather than piecemeal changes.

The literature review revealed that indeed the legal framework as set up lay emphasis on illegality more than access. This is evidenced by the provisions of the Narcotics Act which specify that regulations for medical use will be made by the Cabinet Secretary responsible for internal security. On the other hand, the issue that the cabinet secretary responsible for health will publish regulations relates to aspects of rehabilitation. It is crucial that regulation making powers for medical use of narcotics such as MC are given to the Cabinet Secretary for Health under the Pharmacy Act or the Narcotics Act as it may be to facilitate access for health purposes.

The legal framework, as a key strength, made provision for pharmacovigilance systems to monitor adverse events and apportioned responsibilities to the different players across the supply chain. Monitoring mechanisms to prevent diversion and abuse, as highlighted in the Kenyan study, aligns with recommendations from other jurisdictions. In Australia, Oldfield et al. (2021) emphasized the importance of pharmacovigilance systems to monitor adverse effects, track usage patterns, and prevent misuse. They argue that such systems not only safeguard public health but also generate valuable data to inform ongoing policy refinements. For Kenya, the application of such monitoring systems to extend to MC could help build public trust and demonstrate commitment to responsible MC use.

The Narcotics Act specifies that regulations for medical use will be made by the Cabinet Secretary responsible for internal security. On the other hand, the issue that the cabinet secretary responsible for health will publish regulations relates to aspects of rehabilitation. This creates an overemphasis on control rather than access for health purposes. The regulations are also not in place, despite the Act being in force for the past 30 years.

This lack of clarity in the regulatory framework presents skepticism among the potential users, the regulator and the law enforcement agencies, leading to the inaccess of MC for pain management. The analysis of the current legal framework reveals several strengths and weaknesses that significantly impact the implementation of medical cannabis policies. The framework demonstrates positive elements in regulatory approaches, guidelines and monitoring, and initiatives and policies. However, these strengths are counterbalanced by notable weaknesses including deficient legal frameworks, regulatory barriers, stigmatization, and inadequate training.

By addressing these identified weaknesses, particularly through legislative reforms and enhanced stakeholder engagement, Kenya can develop a more supportive regulatory environment for the use of MC in pain management. This approach aligns with Mazmanian and Sabatier's emphasis on clear, consistent legal and policy guidelines, as well as the necessity for adaptive, responsive legislation as highlighted by the WHO and other regulatory bodies. Policy Diffusion theory offers additional insights into the need to emulate global trends that reflect a growing movement toward decriminalization and regulation of medical cannabis—particularly in countries such as Canada, Germany, and South Africa. Kenya may exercise

transnational learning or emulation to adopt policies and legislation that promote access to MC for pain management.

5.2.2 Barriers to Implementation of the Policy and Legal framework for Accessing MC for Pain Management in Kenya

The study findings identified legal barriers, information gaps, and lack of training for healthcare professionals as key challenges to accessing MC in Kenya. These findings resonate with international studies, suggesting common hurdles even in jurisdictions with legal MC. For example, Boehnke et al. (2019), surveying HCPs in U.S. states with legal MC, found that many lack knowledge and training on MC, leading to reluctance in recommending it. This knowledge gap is not limited to countries new to MC. In Israel, which has one of the oldest and most established MC programs, Ablin et al. (2016) reported that many physicians feel unprepared to prescribe MC due to insufficient training.

The Kenyan context adds another layer of complexity to the legal prohibition of cannabis due to the historical stigma associated with cannabis. The lack of formal guidelines on how healthcare institutions and practitioners should legally engage with controlled substances fosters uncertainty and fear of legal repercussions. This institutional hesitation demonstrates how an inadequately resourced policy, even if well-intentioned, may remain dormant due to poor implementation design. From a Political Diffusion perspective, this also illustrates how policy diffusion may fail not just due to lack of adoption, but also due to poor adaptation to local contexts, which results in symbolic compliance rather than real reform.

The information gaps highlighted in the study findings also reflect broader issues in MC research and dissemination. The participants largely seemed unaware about the legal environment in Kenya and were uncertain as to whether MC was legal or illegal. It was clear that despite their conviction that the product had therapeutic value, fear of legal consequences overrode the attempt to prescribe. Abrams (2018) notes that despite growing evidence of MC's efficacy, particularly in pain management, translation of this research into clinical practice remains a challenge globally. In Kenya, where access to current research may be limited, these information gaps are likely more pronounced, underscoring the need for targeted knowledge dissemination strategies.

The study's revelation of the undertreatment of pain in Kenya, particularly in public healthcare facilities, aligns with a critical global health disparity highlighted by Knaul et al. (2018). Their comprehensive analysis revealed a significant global gap in access to palliative care and pain relief, with the burden falling disproportionately on low- and middle-income countries. This disparity is not just a matter of resource constraints but is also intertwined with policy barriers, including restrictive drug control laws.

The study found varying perceptions towards MC among Kenyan stakeholders, ranging from openness based on research evidence to hesitancy due to perceived illegality. These mixed attitudes mirror the global discourse on MC. For example, in the U.S., Boehnke et al. (2019) found that while some HCPs were receptive to MC based on patient reports and emerging research, others remained skeptical due to limited clinical trial data and regulatory concerns. This dichotomy highlights the ongoing tension between anecdotal evidence, observational studies, and the gold standard of randomized controlled trials in shaping perceptions of MC.

Kenyan participants noted that entrenched cultural attitudes and stigmatization surrounding cannabis use significantly affect public perception and acceptance of MC. It was their view that “many people still viewed cannabis solely as an illegal drug, not as a potential medicine”, emphasizing the need for public education campaigns to address misconceptions.

These findings align with strategies in countries with more established MC programs. In Canada, Capler et al. (2017) found that public education campaigns were vital in destigmatizing MC and promoting evidence-based attitudes among both the public and healthcare providers. They noted that effective campaigns went beyond just disseminating information; they also addressed deeply rooted stigmas associated with cannabis use. Participants highlighted that, "Public education is crucial to changing perceptions and attitudes towards MC. Without it, stigma and misinformation will continue to hinder acceptance."

However, changing perceptions is complex, especially in contexts with a history of strict drug prohibition. Barry & Glantz (2017), analyzing international trends in cannabis legalization, argue that shifts in public and professional attitudes often precede and drive legal changes, rather than the reverse. This suggests that in Kenya, targeted education efforts might be necessary to build public and professional support before significant legal reforms can be successfully implemented.

In addition to socio-political barriers, the study identified insufficient training of healthcare officials as a significant challenge. Inadequate training limits the ability of healthcare providers to integrate MC into pain management effectively. This issue is not unique to Kenya. In the U.S., Boehnke et al. (2019) found that many healthcare providers felt unprepared to discuss MC with patients due to gaps in their medical education. Similarly, in Canada, Capler et al. (2017) noted that training programs for healthcare providers were essential in ensuring the successful implementation of MC policies.

The study identified gaps in knowledge, compliance concerns, and prescribing practices as key challenges to implementing an MC program in Kenya. The policy-legal framework was unclear to this extent resulting in confusion amongst potential prescribers and users. These challenges echo into experiences in countries with more mature MC programs, indicating that they are not merely teething problems but ongoing issues requiring continuous attention.

However, implementation challenges in Kenya are compounded by the current overemphasis on illegality of cannabis for recreational use. Thomson et al. (2024) found that in Zimbabwe, despite legal reforms, the historical criminalization of cannabis created a chilling effect, with healthcare providers wary of legal repercussions. This suggests that in Kenya, legal reforms must be made to make clear regulatory provisions accompanied by clear protocols and protections for HCPs to overcome this legacy of criminalization.

5.2.3 Involvement of Stakeholders in Shaping and Executing the Regulatory Framework for Access to MC as an Alternative for use in Pain Management

The study findings emphasize the importance of a multi-stakeholder approach in developing MC policies, aligning with recognized best practices globally. The study found that key stakeholders, including HCPs, patient advocacy groups and civil society organizations—are largely excluded from the policymaking and implementation processes. Where stakeholder engagement exists, it is often informal, reactive, or peripheral. The regulator acknowledges the absence of a structured way to engage stakeholders, yet they do engage them in various capacities. For example, the regulator always consulted with the Ministry of Health before making any changes to the regulatory framework. However, the engagement process lacks a

formalized structure, leading to inconsistencies and gaps in stakeholder involvement. This indicates a clear area for improvement in the regulatory process.

According to the findings, stakeholder involvement in the development and implementation of the regulatory framework for accessing MC for pain management has been less structured. Patient advocates reported involvement to some extent, although it remains unstructured and *ad hoc*. For example, while patient advocates have managed to convince the regulator to increase the portion of morphine administered to patients for pain management, this success was achieved despite the lack of a structured engagement process. Mazmanian and Sabatier highlight the critical role of supportive coalitions and sustained political leadership in bridging the gap between policy design and execution. In Kenya's case in this study, the lack of political will and stakeholder alignment severely hampers the implementation of any progressive reform on MC access.

In this study, the potential role of MC in addressing the undertreatment of pain becomes particularly salient. According to the findings, the participants pointed to the fact that as stakeholders they would be happy to combine the mainstream opioids with MC to reduce risks of opioid dependence while improving the QOL of their patients. Political Diffusion Theory reinforces this finding on stakeholder involvement by suggesting that policy diffusion often depends on active policy entrepreneurs—advocates or institutions that champion reforms by drawing on international best practices. The lack of structured engagement of such actors in Kenya's policy landscape may explain the stagnation of cannabis-related reforms despite increasing global momentum.

The study found minimal involvement of key stakeholders, particularly HCPs, in the legislative process. As Mazmanian and Sabatier suggest, lack of supportive structures limits the policy's ability to transition from paper to practice. From a policy diffusion standpoint, the absence of strong policy transnational advocacy may explain why Kenya has not embraced reforms seen in other countries.

5.3 Conclusion

The study revealed significant weaknesses in the current legal framework, primarily the lack of a comprehensive legal framework for medical use of cannabis presenting the perception of

the illegality of MC exacerbated by the classification of cannabis as an illegal substance under the Narcotics Act. This aligns with Mazmanian and Sabatier's framework, which emphasizes that unclear legal provisions can derail effective policy implementation. This identified legal barrier, compounded by information gaps and lack of healthcare provider training, severely restricts access to MC. As evidence increasingly supports MC's role in pain management, particularly in reducing opioid use. Kenya has an opportunity to address this gap by integrating MC into its healthcare system. The Policy diffusion approach can deepen the understanding of policy makers when it comes to integrating MC into the health care system as it will offer the opportunity to understand the pros and cons and establish the balance between scientific advancements, pain management and potential for abuse

The study highlights that stakeholder involvement in shaping and executing the regulatory framework for MC access for pain management has been largely unstructured. Although patient advocates have to some extent been involved, these have occurred in the absence of a systematic engagement process. This lack of coordinated stakeholder engagement continues to hinder effective implementation of policy implementation and reforms in response to the rapidly changing scientific environment.

The study also illuminates pathways for progress. The openness of some stakeholders to MC, based on their understanding of international research evidence, suggests a foundation for change. The emphasis on stakeholder involvement, public education, and developing clear guidelines resonates with successful strategies in countries like Canada, Israel, and Australia. These countries demonstrate that inclusive policy development, robust educational initiatives, and evidence-based regulations are key to establishing effective, patient-centered MC programs. Political Diffusion Theory explains the broader international dynamics and Kenya's resistance to global policy trends, while the Mazmanian and Sabatier framework provides a nuanced lens into why implementation continues to falter at the national level.

The implementation of the policy and legal framework for MC faces numerous barriers, these include deficient and ambiguous legal framework, absence of clear policies and a challenging socio-political landscape. Additional obstacles such as bureaucracies, fear and stigma associated with handling controlled substances, high treatment costs and the potential for abuse of controlled medicines for illegal activities, further complicate progress. Moreover, the

delayed integration of MC into national palliative care policies underscores the need for a more coordinated and comprehensive approach to reform.

In conclusion, while the path to integrating MC for pain management in Kenya is fraught with legal, educational, and cultural challenges, it is also rich with opportunities for effective implementation of MC policy-legal framework. By learning from global experiences, engaging diverse stakeholders, and prioritizing evidence-based policies, Kenya can work towards a compassionate, effective approach to MC that prioritizes patient well-being while ensuring public safety. The journey will require continuous policy refinement and legal reforms, ongoing research and a commitment to education at all levels. Until such a time that the Mazmanian approach combined with policy diffusion is applied, interventions in pain management will continue to be unstructured and driven more by fear of abuse than public health concerns. But the potential benefits – improved pain management, reduced opioid dependence, and enhanced quality of life for patients – make this a journey worth undertaking.

5.4 Limitations and Suggestions for Further Research

While this study provides valuable insights, several limitations should be considered to contextualize the findings and guide future research. The study did not extensively examine public perceptions and societal attitudes towards MC and related social issues, which are key to understanding policy acceptance. Societal barriers were out of scope for this study; however, it was a recurrent theme during the data collection and is a potential area for further in-depth study. Future research should consider exploring societal attitudes and including patients to capture lived experiences.

5.5 Recommendations

Based on the findings, discussion, and an understanding of the study's limitations, the following recommendations are proposed to enhance the policy, legal, and regulatory framework for accessing MC for pain management in Kenya:

1. **Legislative Reform:**

Initiate a comprehensive process to amend laws such as the Pharmacy and Poisons Act and the Narcotic Drugs and Psychotropic Substances (Control) Act to clearly make provision for cannabis for medical use. This reform should address the five conditions under the IDCCs for

medical use: licensing and regulation of production, estimation of national demand, proper medical supervision, monitoring and reporting, and ensuring availability for medical and scientific use.

Develop and implement regulations on licit control of narcotic drugs and psychotropic substances in line with the IDCCs so as to expound on the provision in the Pharmacy Act provide clarity in regulations on the allowable limits of THC and CBD for medicinal use, controls applicable for MC, provisions on prescribing, dosing and handling.
In view of the fact that the Government is keen on local manufacturing agenda and universal healthcare, consider amending the law to provide for a multi-agency approach in regulating cultivation and manufacture for medical use rather than importing to increase our capacity as a country and even trade in the region.

Ensure the legislative reform process is transparent and engages legal experts, healthcare professionals, patient advocates, and other stakeholders. This will ensure the new laws address medical needs while incorporating safeguards against misuse and aligning with policy directives.

Implement clear legal protocols and protections for HCPs to overcome the legacy of cannabis criminalization. This will encourage more providers to engage with MC without fear of legal repercussions.

2. **Policy Development:**

Develop structured, inclusive policies for MC use through stakeholder engagement. This should involve patient groups, healthcare professionals, policymakers, and academics, ensuring commercial interests do not overshadow public health goals. Policies should cover access, affordability, quality control and patient education.

Integrate MC as a useful product in palliative care policies and the essential medicines lists. This includes increasing the quota for cannabis resin from 1gm. Additionally, ensure policies are informed by international best practices, adapting successful elements from countries with established MC programs while considering the unique Kenyan context.

Implement regular reviews of MC policies and guidelines to ensure they remain relevant and responsive to emerging research and real-world clinical experiences. This iterative process can help adapt the regulatory framework to evolving medical and scientific knowledge.

3. **Guidelines and Training:**

Integrate MC education into medical curricula to improve physicians' confidence in prescribing MC for pain management and continuing professional development programs for healthcare professionals, emphasizing both theoretical knowledge and practical, case-based learning to build confidence and competence in prescribing MC.

Developing clear guidelines, training programs, and incorporating MC into essential medicines lists as key regulatory approaches. This aligns with global best practices but also require tailoring to the Kenyan context. Effective guidelines should go beyond just dosage and indications; they should also cover patient selection criteria, monitoring protocols, and strategies to minimize risks like dependence or misuse. Guidelines should be living documents, responsive to emerging research and real-world clinical experiences.

Provide specific training on compliance with legal and regulatory requirements to mitigate healthcare providers' fears of legal repercussions and ensure consistent implementation practices.

4. **Public Education:**

Public support is often a precursor to successful policy implementation, so these public awareness campaigns should aim to build broad-based support for MC reforms. The campaigns should de-stigmatize MC and promote its therapeutic potential. These campaigns should address misconceptions and deep-rooted stigmas associated with cannabis use.

Utilize local leaders, patient testimonials, and culturally resonant messaging to effectively shift public perceptions. Law enforcement would need to be sensitized on the licit side of cannabis and the benefits based on its formulation.

5. **Stakeholder Engagement:**

Encourage a multi-stakeholder approach in developing and implementing MC policies. Engaging diverse stakeholders, including patients, healthcare providers, regulators, and cannabis producers, can ensure the regulations are patient-centered and practical.

The stakeholder engagement process should be carefully structured to prioritize patient welfare and public health outcomes over commercial interests. Adopting a more structured engagement process, as highlighted in the Mazmanian's framework, would ensure that all relevant stakeholders, including patient advocacy groups, healthcare providers, and policymakers, are systematically involved. This includes putting in place a structure for the period of regulatory review to keep up with regulatory trends as innovation so often precedes regulation. This approach can help mitigate potential conflicts and ensure the policies serve the broader community's needs.

Foster dialogue with policymakers to align legal and policy frameworks with health goals, ensuring a supportive environment for MC use in pain management.

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APPENDICES

APPENDIX A: SAMPLE INTERVIEW & FOCUS GROUP DISCUSSION GUIDES

A. MINISTRY OF HEALTH

S/N	QUESTION
1.	In view of the decision by CND to implement the recommendation by the WHO to recategorize Cannabis in view of its therapeutic benefits, has the MOH considered revising its policies to facilitate access to MC for NCDs and in particular palliative care? To what extent has this been operationalized in-country?
2.	How do you perceive the clarity and effectiveness of pain management policies in facilitating access to MC for pain management?
3.	What gaps/weaknesses do you see in these policies and regulations if at all (be specific on the policy and the gap)?
4.	In view of CND decision, how can we incorporate the use of medical cannabis in clinical practice for pain management?
5.	How should cannabinoids fit into existing treatment for those medical conditions for which they may be used (e.g. as an adjunctive treatment or as a first-line treatment)?
6.	What is delaying the integration of MC into palliative care?
7.	Our neighbor, Uganda has relaxed its policies and laws on cannabis to allow for medical use. It is something the country is also considering in particular to ensure control over diversion and abuse? If no, why? If yes, how?
8.	In your view, are there any systemic issues or gaps in the implementation of regulatory measures that hinder access to controlled medicines currently that would impact access to MC for pain management?
9.	Countries like Israel apply similar requirements to MC as other controlled substances like opioids to ensure access. Is this something the MOH can consider in influencing the policies on access to this product?
10.	What do you reckon the PPB can do better in ensuring access to controlled substances such as MC?
11.	If cannabis is made available for medical use, how will governments address the possible reluctance of physicians to prescribe cannabis for ethical or medico-legal reasons and uncertainty about clinical indications and dosing, particularly where any physician is

S/N	QUESTION
	authorised to prescribe cannabis preparations? Would guidelines and training be provided, and, if so, by whom?
12.	How might governments permit the manufacturing and distribution of cannabis for medical purposes? Should governments contract private companies? Might patients be allowed to grow their own cannabis for medical purposes? How should cannabis be distributed to patients? Could this be done through any pharmacy, specific pharmacies or other distribution channels?
13.	What additional strategies or policies, if at all, do you believe could improve access to controlled medicines for pain management while ensuring compliance with regulations?

B. HEALTHCARE PROVIDERS (HCPs)

S/N	QUESTION
1.	Do you have any document that guides the medication that you prescribe for your patients to manage pain?
2.	In your opinion, can you prescribe MC for your patients in palliative care?
3.	What would prevent you from prescribing MC?
4.	How might prescriptions be limited? How should monitoring of patient outcomes and adverse events be carried out, and by whom?
5.	How should cannabinoids fit into existing treatment for those medical conditions for which they may be used (e.g. as an adjunctive treatment or as a first-line treatment)?
6.	Are there any barriers or challenges you face when prescribing or administering MC for pain relief?
7.	How do you as stakeholders perceive the role of regulatory authorities in ensuring equitable access to controlled medicines like MC?
8.	If you had to change something about the current policy and legal framework for access to MC. What would it be?
9.	Are there any systemic issues or gaps in the implementation of regulatory measures that hinder access to MC for pain management?
10.	What regulatory approaches can be used to make cannabis available for medical use?

S/N	QUESTION
11.	From the HCP perspective, what has been your experience in accessing controlled medicines, particularly MC or other, for pain management in Kenya?
12.	If cannabis is made available for medical use, how will governments address the possible reluctance of physicians to prescribe cannabis for ethical or medico-legal reasons and uncertainty about clinical indications and dosing, particularly where any physician is authorised to prescribe cannabis preparations? Would guidelines and training be provided, and, if so, by whom?
13.	How might prescriptions be limited? How should monitoring of patient outcomes and adverse events be carried out, and by whom?
14.	How should cannabinoids fit into existing treatment for those medical conditions for which they may be used (e.g. as an adjunctive treatment or as a first-line treatment)?
15.	Are there any successful models or practices from other regions or countries that could be adapted to improve MC accessibility in Kenya?

C. PATIENT ADVOCATES

S/N	QUESTION
1.	To what extent have you participated in the development of policies on controlled medicines access?
2.	What has been your role in shaping policies and laws on ensuring availability of MC?
3.	What challenges have you faced in your efforts to shape policies and laws on ensuring availability of MC?
4.	How do you as stakeholders perceive the role of regulatory authorities in ensuring equitable access to controlled medicines like MC?
5.	What are your views concerning access to MC in Kenya?
6.	What policy changes or initiatives would you like to see implemented to enhance access to controlled medicines?
7.	What regulatory approaches can be used to make cannabis available for medical use?
8.	From the patient perspective, what has been your experience in accessing controlled medicines, particularly MC or other, for pain management in Kenya?

S/N	QUESTION
9.	How can policymakers and other stakeholders better support patients in accessing the pain relief they need?
10.	Can you share any experiences that highlight the impact of MC availability (or lack thereof) on patients' quality of life and pain management?
11.	Are there any successful models or practices from other regions or countries that could be adapted to improve MC accessibility in Kenya?

D. FOCUS GROUP DISCUSSION GUIDE

- Brief Overview of the Study and Its Objectives
- Ground Rules for Discussion (confidentiality and open-sharing)

S/N	QUESTION
I.	*CURRENT REGULATORY FRAMEWORK*
1.	What is the process of placing a controlled substance such as MC in the Kenyan market? Where is the process documented?
2.	How does the PPB oversee the distribution and dispensing of controlled medicines like MCin Kenya?
3.	The Narcotics Act provides for establishment of a board to govern licit use through: • Issuance of licences for the importation, exportation, diversion, sale, manufacture, production or distribution (at stated places); • naming ports or places in Kenya where any narcotic drug or psychotropic substance may be exported or imported; • prescribing the manner in which any narcotic drug or psychotropic substance is to be packed or marked for export; and • prescribing the records to be kept by any person in connection with the export, import, receipt, sale, disposal or distribution of narcotic drugs or psychotropic substances How is the PPB concerned with the aforementioned aspects of regulation envisioned under the Narcotics Act?
4.	How does PPB collaborate with HCPs and law enforcement agencies to monitor and regulate controlled substances?
II.	*INTERNATIONAL ALIGNMENT & NATIONAL IMPLEMENTATION*

S/N	QUESTION
	To what extent has the PPB operationalized the CND decision to reschedule Cannabis as advised by the WHO to make MC available for medical use?
5.	The IDCCs are fundamental to shaping national drug laws. To what extent has the PPB enforced the conditions and requirements for making MC available? Any challenges?
III.	*REGULATORY APPROACHES AND INNOVATION*
6.	What regulatory approaches can be used to make cannabis available for medical use?
7.	The Country has for the past 2 years provided an estimate of 200gms for Cannabis and Cannabis resin. What informs the estimates submitted? What are the considerations given to justify the proposals? Are they documented?
8.	What mechanisms are in place to ensure the safe and appropriate use of these substances?
9.	How do you ensure that legal decisions regarding controlled medicines balance public safety concerns with the rights of patients to access adequate pain management?
10.	How often does the PPB update its regulatory framework in view of the rapid advancements in science and technology? And what is the level of involvement of stakeholders in this process?
11.	Has the PPB received any applications for registration of products containing Cannabis? How has the PPB handled such products?
IV.	*POLICY, CHALLENGES AND OPPORTUNITIES*
12.	How do you balance the need for strict regulation of controlled medicines with ensuring adequate access for patients in pain?
13.	Countries like Israel apply similar requirements to MC as other controlled substances like opioids to ensure access. Is this something the PPB can consider in regulation of this product?
14.	What strategies are being considered or implemented to streamline the regulatory process for accessing controlled medicines for legitimate medical purposes?
15.	What types of medicinal products or cannabis preparations should be allowed?
16.	What forms of cannabis preparations should be allowed?

S/N	QUESTION
17.	For which medical conditions should treatment with cannabis preparations or medicinal products be permitted?
18.	How might governments permit the manufacturing and distribution of cannabis for medical purposes? Should governments contract private companies? Might patients be allowed to grow their own cannabis for medical purposes? How should cannabis be distributed to patients? Could this be done through any pharmacy, specific pharmacies or other distribution channels?
19.	If cannabis is made available for medical use, how will governments address the possible reluctance of physicians to prescribe cannabis for ethical or medico-legal reasons and uncertainty about clinical indications and dosing, particularly where any physician is authorised to prescribe cannabis preparations? Would guidelines and training be provided, and, if so, by whom?
20.	How might prescriptions be limited? How should monitoring of patient outcomes and adverse events be carried out, and by whom?
21.	How should cannabinoids fit into existing treatment for those medical conditions for which they may be used (e.g. as an adjunctive treatment or as a first-line treatment)?
22.	What challenges have you encountered in regulating access to controlled medicines, MC, for pain management?
23.	What challenges do you foresee in the implementation of MC policies?
24.	What challenges have you encountered in regulating access to controlled medicines, MC, for pain management?
25.	Are there any successful models or practices from other regions or countries that could be adapted to improve MC accessibility in Kenya?
26.	In your view, what recommendations would you have for the policy makers at Afya House to ensure MC for pain management?

Summary of Key Discussion Points

Thank you and Next Steps

APPENDIX B: INTRODUCTION LETTER

To Whom It May Concern

RE: INTRODUCTION AND INVITATION TO PARTICIPATE IN A RESEARCH STUDY ON THE LEGAL FRAMEWORK FOR ACCESSING CONTROLLED MEDICINES FOR PAIN MANAGEMENT IN KENYA

I am a Postgraduate Student of Public Policy and Management at Strathmore University. I am reaching out to you to introduce myself and extend an invitation to participate in a research study focusing on the legal framework for accessing controlled medicines for pain management in Kenya, specifically examining the case of medical cannabis (MC).

The purpose of this study is to evaluate the ability of the legislative framework to effectively structure the process of access to controlled medicines, particularly medical cannabis, for pain management in Kenya. The specific objectives of this study include: (1) Examining the current legal and regulatory framework surrounding the use of MC for pain management in Kenya, (2) investigating the involvement of stakeholders' in shaping and executing the regulatory framework for access to MC as an alternative for use in pain management (3) identifying any challenges or barriers to implementation of the framework, and (4) formulating recommendations for the improvement of the policy, legal and regulatory framework for accessing MC for pain management in Kenya.

This research is towards a Masters thesis of the candidate and participating in the research has no foreseeable risk. Ethical approval has been received from the Strathmore University Ethics Committee. Your participation in this study is entirely voluntary, and your insights are invaluable contributing to the body of knowledge on access to controlled medicines for pain management. If you choose to participate, you may be involved in either an interview or a focus group discussion, based on your preference and availability. All information shared will be treated with strict confidentiality.

Before proceeding with the study, I kindly request your consent to participate. Attached to this letter is a consent form. Please review this document carefully, and if you agree to participate, kindly sign and return the consent form to me at your earliest convenience.

Should you have any questions or require further clarification regarding the study, please do not hesitate to contact me at nancyrng@gmail.com or +254 728 723 145.

Thank you for considering participating in this research study.

Yours faithfully,

Arunga N.S

APPENDIX C: CONSENT FORM

PROPOSED STUDY: The Legal Framework for Accessing Controlled Medicines for Pain Management in Kenya: A Case Study of Medical Cannabis

SECTION 1: INFORMATION SHEET

Investigator: Arunga Nancy Shephard
Institutional affiliation: Strathmore Business School (SBS)

SECTION 2: INFORMATION SHEET – THE STUDY

2.1 Why is this study being carried out?

The purpose of this study is to evaluate the ability of the legislative framework to effectively structure the process of access to controlled medicines, particularly medical cannabis (MC), for pain management in Kenya.

2.2 Do I have to take part?

No. Taking part in this study is entirely optional and the decision rests only with you. If you decide to take part, you will participate in an interview or a focused group discussion to get information on implementation of the current legal framework for access to controlled medicines, your involvement in shaping and executing the regulatory framework for access to MC as an alternative for use in pain management, identify any challenges or barriers to implementation of the framework and suggest any recommendations for the improvement of the policy, legal and regulatory framework for accessing MC for pain management in Kenya. If you are not able to answer any of the questions, you are free to pass on to the next question. You are free to decline to take part in the study at any time without giving any reasons.

2.3 Who is eligible to take part in this study?

- The Ministry of Health (MOH)
- The Pharmacy and Poisons Board (PPB)
- Health Care Providers (HCPs)
- Patient Advocates/Civil Society

2.4 Who is not eligible to take part in this study?

- Recreational Users of Cannabis

2.5 What will taking part in this study involve for me?

You will be approached and requested to take part in the study. If you are satisfied that you fully understand the goals behind this study, you will be asked to sign this informed consent form and then taken through the interview guide.

2.6 Are there any risks or dangers in taking part in this study?

There are no risks in taking part in this study. All the information you provide will be treated as confidential and will not be used in any way without your express permission.

2.7 Are there any benefits of taking part in this study?

The information will be used to improve the policy and regulatory framework for access to controlled substances, in particular MC for pain management.

2.8 What will happen to me if I refuse to take part in this study?

Participation in this study is entirely voluntary. Even if you decide to take part at first but later change your mind, you are free to withdraw at any time without explanation.

2.9 Who will have access to my information during this research?

All research records will be stored in securely locked cabinets and password protected laptops. That information may be transcribed into our database, but this will be sufficiently encrypted and password protected. Only the people who are closely concerned with this study will have access to your information. All your information will be kept confidential.

2.10 Who can I contact in case I have further questions?

You can contact me, **Arunga Nancy** at SBS, or by e-mail nancy.arunga@strathmore.edu or by phone +254 728 723 145. You can also contact my supervisor**, Dr. Ben Ngoye**, at the Strathmore Business School, Nairobi, or by e-mail bngoye@strathmore.edu or by phone +254 715 395 882.

If you want to ask someone independent anything about this research please contact:

The Secretary–Strathmore University Institutional Ethics Review Board, P. O. BOX 59857, 00200, Nairobi, email ethicsreview@strathmore.edu Tel number: +254 703 034 418.

I, _____, have had the study explained to me. I have understood all that I have read and have had explained to me and had my questions

answered satisfactorily. I understand that I can change my mind at any stage.

Please tick the boxes that apply to you on participation in the research study

☐ I AGREE to take part in this research

☐ I DON'T AGREE to take part in this research

Participant's Signature: **Date:_____/_____/____**

_____ ***DD /MM/YYYY***

Participant's Name: **Time: _____/_____**

(Please print ***name)*** ***HR/MN***

I, _____(Name of person taking consent) certify that I have followed the SOP for this study and have explained the study information to the study participant named above, and that s/he has understood the nature and the purpose of the study and consents to the participation in the study. S/he has been given opportunity to ask questions which have been answered satisfactorily.

Investigator's Signature: **Date: _____/_____/_____**

_____ ***DD /MM /YYYY***

Investigator's Name: **Time: _____/_____**

_____ ***HR/MN***

(Please print name)

APPENDIX D: PROPOSED STUDY BUDGET

No	Item	Cost (KSHS)
1.	Data collection and analysis	5,000
2.	Thesis Printing and binding	10,000
3.	Miscellaneous	10,000
	Total	**25,000**

APPENDIX E: ETHICAL APPROVAL

Strathmore UNIVERSITY

20th May 2024

Ms Arunga Nancy,
nancy.arunga@strathmore.edu

Dear Ms Arunga,

RE: Legal Framework for Access to Controlled Medicines for Pain Management in Kenya: A Case Study of Medical Cannabis

This is to inform you that SU-ISERC has reviewed and **approved** your above **SU-masters** proposal. Your application reference number is **SU-ISERC2225/24.** The approval period is from **20th May 2024 to 19th May 2025.**
This approval is subject to compliance with the following requirements:

i. Only approved documents including (informed consents, study instruments, MTA) will be used.
ii. All changes including (amendments, deviations, and violations) are submitted for review and approval by SU-ISERC.
iii. Death and life-threatening problems and serious adverse events or unexpected adverse events whether related or unrelated to the study must be reported to SU-ISERC within 72 hours of notification.
iv. Any changes anticipated or otherwise that may increase the risks or affected safety or welfare of study participants and others or affect the integrity of the research must be reported to SU-ISERC within 72 hours.
v. Clearance for the export of biological specimens must be obtained from relevant institutions.
vi. Submission of a request for renewal of approval at least 60 days prior to the expiry of the approval period. Attach a comprehensive progress report to support the renewal.
vii. Submission of an executive summary report within 90 days of completion of the study to SU-ISERC.

Before commencing your study, you will be expected to obtain a research license from National Commission for Science, Technology, and Innovation (NACOSTI) https://research-portal.nacosti.go.ke/ and obtain other clearances needed.

Yours sincerely,

Mr Ambrose Rachier,
Chairperson; SU-ISERC

Ole Sangale Rd, Madaraka Estate. PO Box 59857-00200, Nairobi, Kenya. Tel +254 (0)703 034000
Email admissions@strathmore.edu www.strathmore.edu

APPENDIX F: RESEARCH PERMIT

REPUBLIC OF KENYA

NATIONAL COMMISSION FOR SCIENCE,TECHNOLOGY & INNOVATION

Ref No: **763251**

Date of Issue: **23/May/2024**

RESEARCH LICENSE

This is to Certify that Ms.. Nancy Arunga of Strathmore University, has been licensed to conduct research as per the provision of the Science, Technology and Innovation Act, 2013 (Rev.2014) in Nairobi on the topic: THE LEGAL FRAMEWORK FOR ACCESSING CONTROLLED MEDICINES FOR PAIN MANAGEMENT IN KENYA: A CASE STUDY OF MEDICAL CANNABIS for the period ending : 23/May/2025.

License No: **NACOSTI/P/24/35527**

763251

Applicant Identification Number

Director General
NATIONAL COMMISSION FOR SCIENCE,TECHNOLOGY & INNOVATION

Verification QR Code

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See overleaf for conditions