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Medical Cannabis Regulation in Lesotho: Global Comparison, Local Challenges and Strategic Recommendations

M. Ntsohi[1], **N. Ebrahim**[1],

1. *School of Pharmacy, Faculty of Natural Sciences, University of the Western Cape, Robert Sobukwe Road, Bellville, South Africa. N. Ebrahim: *Corresponding author: nebrahim@uwc.ac.za*

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ABSTRACT

Background: The regulation of medical cannabis is rapidly evolving globally, as attested by the changing societal attitudes, political shifts, and therapeutic health benefits. Lesotho was one of the first countries in Africa to legalise the cultivation and exportation of cannabis for medicinal purposes. To explore medical cannabis regulations in Lesotho with stringent regulatory authorities, identify the pressing challenges, and attempt to make recommendations addressing them.

Methods: An exploratory-descriptive qualitative research method. A thematic literature review was used to map the relevant data while identifying comparable themes and patterns between Lesotho and other countries. Literature was explored from published online sources, including Google Scholar, PubMed, and Science Direct.

Results: The United States, Europe, Lesotho, and six other countries were explored. Most countries have strict regulatory authorities that comply with international standards on regulation. Although Lesotho complies with the export market, more still needs to be done to regulate medical cannabis globally and locally adequately.

Conclusion: The current medical cannabis regulation in Lesotho is intricate and challenging; Lesotho needs to partner with various stakeholders, such as regulators, government policymakers, and healthcare professionals, to develop systems and inclusive regulatory frameworks for evidence-based therapy that address local healthcare, socioeconomic, and global demands.

Keywords: Medical Cannabis, Regulation, Tetrahydrocannabinol, Cannabidiol, Quality, Lesotho

Introduction

Cannabis, also known as marijuana, dagga, weed, or 'matekoane' in Sesotho (a language spoken in Lesotho), has a very comprehensive denotation that encapsulates at least three species of dioecious annual herbaceous plants in the Cannabaceae family - Cannabis sativa, Cannabis indica, and Cannabis ruderalis [1]. The Lesotho Drug of Abuse Act defines cannabis as any part of the cannabis plant, including seeds, roots and leaves from which cannabis substance has not been taken out [2]. World Health Organisation (WHO) further expounds to indicate that cannabis is a term implying several psychoactive preparations of the plant Cannabis sativa L [3].

In the Kingdom of Lesotho, cannabis was coined as early as the 16th century when it was used as a common staple crop in diverse scenarios such as trading the land [4]. Similarly, across the globe, cannabis has been utilised throughout the generations for various reasons, including religious or spiritual, recreational, industrial (as hemp), and medical purposes, owing to its intricate chemical composition entailing cannabinoids, terpenes and flavonoids [1].

Some researchers use the term medical cannabis interchangeably with pharmaceutical cannabis, while others use them distinctively. Although they may be used interchangeably, medical cannabis refers to the cannabis plant-derived products used to prevent, diagnose, treat, or alleviate diseases, symptoms, or abnormal conditions as prescribed by a qualified health professional, examples of medical cannabis formulations are capsules; oils, edibles, dabbing, tinctures, topicals, vaping and many more [5]. Pharmaceutical cannabis denotes medical cannabis-formulated products that have undergone clinical trials and are registered as a medicine [6].

There are over 120 known phytocannabinoid chemical hybrids in the cannabis plant, which have been isolated; the most researched are delta-9-tetrahydrocannabinol (THC) and cannabidiol (CBD) [7]. CBD was discovered as a non-psychoactive cannabinoid consisting of anti-inflammatory, anti-anxiety, and seizure-reducing properties, while THC, a main psychoactive cannabinoid, was responsible for pain relief, appetite stimulation, and nausea control among others [8,9].

The use of cannabis, including medical cannabis, was deemed illegal for most parts of the world until the recent alteration propagated by the identification of cannabinoid receptors in the human body in the early 1990s [10,11]. The discovery of medical cannabis receptors, the endocannabinoid system and the 2-arachidonoyl glycerol became a game changer in the medical cannabis field and pharmaceutical fraternity, not only in revolutionising the regulatory framework but predominantly as a cornerstone for the treatment of diseases with a clear pharmacological action of the cannabis drug substance [10-13].

According to UNESCO report, the Kingdom of Lesotho has been associated with cannabis cultivation from its inception due to its climatic advantage; the cosmopolitan cannabis species have been grown everywhere in the country with major harvests coming from high mountainous zones in the centre, east, and the western foothill regions of the country along the valleys of numerous streams and rivers [13]. Cannabis crop cultivation has long been recognised as a vital part of the agricultural economy; in the early 2000s, it was estimated that 70% of cannabis in South Africa came from Lesotho [14].

The common unfettered cannabis products used in Lesotho are associated with recreational use, food supplements, complementary medicine, traditional or herbal medicines, cosmetics, (hair and beauty) and beverages which can be found in some community pharmacy front shops and other retail outlets most of which are produced by Basotho small and medium enterprises [15,16]. Basotho had been relying on matekoane for various health conditions, while others depended on it for survival, making it difficult for the government to impose harsh restriction policies [13,17].

The Lesotho government did not enforce cannabis regulation until 2001, when the first Lesotho Drug of Abuse Bill was drafted following the United Nations (UN) and the International Narcotic Control Board (INCB). Therefore, in 2008, the Lesotho Drug of Abuse Act was released, which repealed the Lesotho Dangerous Medicine Act of 1973 and aimed to ensure the

availability of some drugs for medicinal purposes [2]. The regulatory framework amendment commenced a new era in the Kingdom, succeeded by medical cannabis licensure.

The recent release of the Lesotho Drug of Abuse (Cannabis) Regulation of 2018 significantly facilitated operations related to the issuing of licenses and renewals of the cannabis drug substance [18]. Prohibition Partners conveyed that the medical cannabis growth from the Kingdom of Lesotho has attracted foreign investors worldwide, including mature global markets such as the United States, Europe, Australia, Canada, Israel, New Zealand, South Africa and the United Kingdom [17].

Lesotho's medical cannabis market value is estimated to reach at least US$3.39 million by the end of 2024, with a cumulative annual growth rate of 1.66% from 2024 to 2029, culminating in a value of US$3.68 million by 2029 [19]. The bullish exponential trajectory in the Lesotho medical cannabis market is overwhelmingly accompanied by great difficulties facing health products regulation, therefore, this article explores the challenges of medical cannabis regulation in Lesotho in comparison with the global standards and provides strategic recommendations.

Methods

The method used to conduct this study was exploratory-descriptive qualitative research, which utilised a thematic systematic review to map and evaluate relevant literature, and identify comparable themes and patterns between Lesotho and stringent regulatory authorities and other countries with which Lesotho trades medical cannabis. The study design and strategies involved recognising information in the public domain relevant to the study, including Google Scholar, PubMed and Science Direct. In particular, data regarding the current health policies regulating medical cannabis in Lesotho was identified and compared to that of international markets where Lesotho trades.

The study selection was predominantly on the current health policies regulating medical cannabis in the Kingdom of Lesotho. The scope was broadened by comparing the Lesotho regulatory policies with the founding members of the International Council for Harmonization (ICH) actively involved in stringent medical cannabis regulatory policies which are EU and US. Other relevant countries that Lesotho trades medical cannabis with are; Australia, Canada, Israel, New Zealand, South Africa, and the United Kingdom. Exclusion criteria were limited to stated countries and data on the English language.

Data analysis

Thematic comparative and descriptive analyses were used to categorically read through various data sources and summarise relevant themes and patterns of the non-numeric information. The identified comparable themes and patterns related to the study objectives were collated into categories, and then coded, and the tabular summaries were developed as shown in Tables 1, 2, and 3.

Table 1: Common themes and patterns of Lesotho, the United States and the European Union findings

Common themes & patterns	Lesotho	United States	European
Legalisation or decriminalisation of medical cannabis as per INCB	Medical cannabis is legalised mainly for exportation [24].	At least 38 States have legalised cannabis for medical purposes [29].	Medical cannabis is legal in EU Member states [30].
Regional/ national regulatory bodies regulating medical cannabis	Lesotho Narcotic Bureau (LNB), Lesotho Medicine and Medical Device Control	Food and Drug Administration (FDA); Drug Enforcement Administration (DEA) [31].	European Medicine Agency (EMA), member states regulatory agencies [32].

Common themes & patterns	Lesotho	United States	European
Medical cannabis products, registration and scheduling	Schedule I. Single Convention of 1961, no approved or registered product [2].	DEA, FDA. Schedule I. Approved products. (Marinol, Syndros, Cesamet, Epidiolex and Sativex) [31].	Schedule I. Approved and registered products include Marinol, Syndros, Cesamet, Epidiolex, and Sativex [32].
Medical cannabis use, benefits or adverse events	Medical cannabis use is illegal [2].	Medical cannabis is legal [6]. Epilepsy, anorexia, appetite stimulant, multiple sclerosis [33]	EMA. Epilepsy, anorexia, appetite stimulant, multiple sclerosis [32].
Quality control & quality assurance; GMP, GLP, GAP/GACP	LNB issues licences and has regulatory responsibilities [18]	FDA and DEA give guidance on quality requirements [34].	EMA, EU GMP, Competent Authorities (CA), and member state agencies [35].
Medical cannabis pharmacovigilance system, R&D	Not yet established [2,24].	FDA pharmacovigilance and adverse event reporting system [33].	EMA-EudraVigilance was established and includes member state regulatory agencies [35].
Global import & export, harmonisation & standardisation	Companies register with LNB, get EU GMP for exportation	FDA. DEA gives guidance on the import and export of cannabis-derived preparations [33,34]	EMA, member state agencies distinctively handle imports, exports and standardisation [35]

Results

The results in Tables 1, 2 and 3 showcase the identified common themes and patterns in the current medical cannabis regulation amongst the countries trading with Lesotho and the selected countries. Firstly, the major results shown in Tables 1, 2 and 3 portray an overview of the cross-cutting themes and trends regarding the legislation or decriminalisation of medical cannabis as per the INCB.

Secondly, Tables 1 to 3 show the establishment of regional or national regulatory agencies responsible for overseeing the handling of cannabis, licensing of companies for the cultivation of cannabis for medical purposes, ensuring safe and quality medical cannabis products, reporting to INCB on the consumption of medical cannabis, mitigation and diversion and drug trafficking related to illegal use of medical cannabis amongst others.

Thirdly, Tables 1, 2 and 3 illustrate comparable regulatory measures on medical cannabis product registration, integration into the healthcare service delivery system, scheduling, and labelling from seed to the market. Fourthly, Tables 1 to 3 demonstrate the medical cannabis use, benefits, adverse events, and pharmacovigilance (PV) measures available to mitigate risks or balance risks with benefits and standardised research and development (R&D). Lastly, all three Tables below compare and display the safety, efficacy and quality aspects of medical cannabis from cultivated seed to imported or exported consumable or marketed medical cannabis products. Quality control checks, quality assurance, international standardisation (ISO) and other harmonisation values including current Good Manufacturing Practices (cGMP), Good Laboratory Practices (GLP), Good Agricultural Practices and or Collecting Practices (GAP/GACP), Good Clinical Practices (GLP), PV guidelines, pharmacopoeia, stringent regulatory requirements and local regulatory requirements.

Table 2: Common themes and patterns in Australia, Canada and Israel

Common themes and patterns	Australia	Canada	Israel
Legalisation or decriminalisation of medical cannabis as per the INCB	Medical cannabis is legal for use [36].	Medical cannabis is legal for use [37].	Medical cannabis is legal for use [38,39].
Regional/national regulatory bodies regulating medical cannabis	Therapeutic Good Administration (TGA) [36].	Health Canada [37].	Israel Medical Cannabis Agency (IMCA) [38].
Medical cannabis products, registration and scheduling	Oils, tinctures, sprays, capsules. Cesamet, Epidiolex, Sativex	Marinol, Syndros, Epidiolex, Sativex, Tinctures (Cannabis Oils)	Epidiolex, Sativex, Tinctures (Cannabis oils)
Medical cannabis use, benefits or adverse events	Epilepsy, anorexia, appetite stimulant, multiple sclerosis [36].	Epilepsy, anorexia, appetite stimulant, multiple sclerosis [37].	Epilepsy, anorexia, appetite stimulant, multiple sclerosis [40].
Quality control & quality assurance; GMP, GLP, GAP/GACP	Australia Register of Therapeutic Goods (ARTG)/TGA [36].	Health Canada [37].	IMCA [38-40].
Medical cannabis pharmacovigilance system, R&D	Pharmacovigilance under ARTG/TGA like conventional medicines [36].	Pharmacovigilance under Health Canada is like conventional medicine [37].	Pharmacovigilance under the Israel Ministry of Health, IMCA
Global import & export, harmonisation & standardisation	TGA, imports, exports, harmonisation and standardisation [36].	Health Canada, imports, exports, harmonisation & standardisation [37].	IMCA, imports, exports, harmonisation and standardisation [38-40]

Table 3: Common themes and patterns in New Zealand, South Africa and the United Kingdom

Common themes and patterns	New Zealand (NZ)	South Africa	United Kingdom
Legalisation or decriminalisation of medical cannabis as per the INCB	Medical cannabis use is legal [41]. NZ Medicinal Cannabis Agency (NZMCA)	Legalised for personal use [42].	Medical cannabis use is legal [43.44].
Regional/national regulatory bodies regulating medical cannabis	NZMCA, NZ Medicine and Medical Devices Safety Authority (NZMMDSA) [41,45].	SAHPRA in partnership with the Department of Health, South Africa [42].	Medicine Health Product Regulatory Agency (MHRA) [43].
Medical cannabis products, registration and scheduling	NZMCA and NZMMDSA. Epidiolex, Sativex, Tinctures (Cannabis oils)	No SAHPRA-approved products yet. Compassionate pre-approval by SAHPRA [42].	MHRA, Department of Health and Social Care (DHSC), Home Office. Marinol, Syndros, Cesamet, Epidiolex, & Sativex

Common themes and patterns	New Zealand (NZ)	South Africa	United Kingdom
Medical cannabis use, benefits or adverse events	Epilepsy, anorexia, appetite stimulant, multiple sclerosis [41,45].	SAHPRA, provisional approval for specific use [42].	Epilepsy, anorexia, appetite stimulant, multiple sclerosis [43,44].
Quality control & quality assurance; GMP, GLP, GAP/GACP	NZMCA and NZMMDSA handle the Quality Management System	SAHPRA handles the Quality Management System	MHRA handles the Quality Management System [43-46].
Medical cannabis pharmacovigilance system, R&D	NZMMDSA, NZCMA as per conventional medicine [41].	SAHPRA as per pharmaceutical or conventional medicine [42].	MHRA, as per conventional medicine [43-46].
Global import & export, harmonisation & standardisation	NZMMDSA, NZMCA, NZ Medical Cannabis Council (NZMCC), imports, exports, standardisation [41,45].	SAHPRA has developed regulatory guidelines for imports and exports [42].	MHRA and the Home Office control the drug licensing system with DHSC. Imports, exports, harmonisation, standardisation [43].

Discussion

The important themes identified with Lesotho, the strict regulatory authorities and other trading partners include that they all have legislations of medical cannabis which are in line with the UN and the INCB, as shown in Tables 1, 2 and 3. The legalisation of cannabis for medicinal use complies with the precepts of the INCB in all countries. All the countries were found to be in harmony with the Single Convention on Narcotic Drugs Substances of 1961, the Single Convention on Narcotic Drugs as amended by the 1972 protocol, the Convention Against Illicit Psychotropic Substances of 1971 and the UN Conventions Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances of 1988 [20-22].

Lesotho and all other countries have established a national body or an agency that regulates medical cannabis in line with INCB and WHO recommendations [20,23]. The Lesotho Narcotic Bureau (LNB) was established by the Lesotho Drug of Abuse Act 2008 and the Lesotho Drug (Cannabis) Regulation of 2018 to handle licensing, audits, renewal of licenses, and reporting of data to the INCB on medical cannabis imports and exports [2,18].

Lesotho medical cannabis is categorised under Schedule I as per the INCB, it has been declared a prohibited drug substance, hence the local use is illegal and inaccessible [2]. Conversely, Tables 1, 2 and 3 show that in line with the UN and INCB, most of the authorities have developed policies permitting the local use of medical cannabis products. The majority of the countries have approved and registered medical cannabis products with scheduling based on THC and CBD content, however, Lesotho does not have an approved or registered medical cannabis product, be it cannabis oil, CBD-dominant products or THC-dominant products, despite producing them in the country [18,24].

Medical cannabis has been found therapeutically significant in the treatment of diseases like cancer-induced anorexia, AIDS-associated weight loss, multiple sclerosis and severe epilepsy, which have motivated approval from most regulatory agencies, as shown in Tables 1, 2 and 3, except in Lesotho. WHO reported that Lesotho is ranked first and second in the world in the total deaths of epilepsy patients and AIDS-related deaths, respectively [25,26]. The WHO further reported that Lesotho has the highest suicide rate in the world, while the reasons are multi-layered, limited access to mental healthcare services and access to quality medicines take precedence [27]. What if the legal use of medical cannabis in the country

could facilitate saving the lives of Basotho, especially in clinically proven conditions like epilepsy, AIDS and cancer?

The imports/exports target markets perform their quality checks in Lesotho through stringent regulatory authority reliance pathways such as the European Medicines Agency (EMA). EMA has successfully granted some of the Lesotho companies with EU GMP certificates, enabling them to trade internationally. Lesotho companies consistently endeavour to comply with the EU international quality standards (pharmacopoeia, guidelines, GMP, GLP, GAP/GACP and ISO) to import/export medical cannabis in a standardised and harmonised manner.

Most authorities have well-established and harmonised national regulatory systems for conventional medicines, including product authorisation, registration, post-market surveillance, PV systems and R&D. With the upsurge of medical cannabis deregulation, the same countries utilised existing systems to manage medical cannabis like pharmaceutical medicines. On the contrary, the recently launched Lesotho Medicine and Medical Devices Control Authority (LMMDCA) is not capable of regulating pharmaceutical medicine in harmony with global standards due to inadequate conventional regulatory systems, absence of legal provisions for marketing authorisation or product registration, non-existence of the PV system and deficient standardised research and development initiatives [18,28].

Cannabis use in various parts of the world was found to be classified under some of the following categories: recreational, industrial (hemp), food supplements, cosmetics, spiritual or religious, herbal or traditional and of course, medical purposes. Most countries, including the US and EU have cannabis legislation specific to each category. On the other hand, Lesotho's cannabis regulation does not succinctly give a distinction between different categories and uses of cannabis; instead, all cannabis is wrapped under Schedule 1 substance [2].

In the same vein, some countries have amicably structured tactics to give differentiation on medical cannabis scheduling and accessibility. Medicinal cannabis with high content of THC (THC-dominant) products is often accessed only with a doctor's prescription, the same with those consisting of a 1:1 ratio with CBD. Further, most countries have allowed CBD-dominant products to be sold over the counter. The classification of medicinal cannabis based on its THC or CBD content has brought an unwavering liberation of medical cannabis in a global community. In Lesotho, legal access to any form of medical cannabis is denied.

To strengthen the Lesotho medicinal cannabis regulation, the country needs to adopt some of the stringent regulatory authority measures applicable to the Basotho people to align with the international regulatory bodies and markets while also providing a legally conducive environment for the accessibility of medical cannabis for the local and global markets. Some of the fundamental recommendations are as follows:

LMMDCA should be strategically developed, financed and technically furnished to carry out the tasks of the national regulatory body. LNB and LMMDCA need to be sufficiently equipped to handle the processes of medical cannabis harmoniously, taking into consideration global quality and safety standards in all the processes.

The guidelines and regulations need to be developed to facilitate LNB and LMMDCA's administration of medical cannabis for local and global markets. In the case of local use of medical cannabis, guidelines need to be drafted to guide the public on the use of medical cannabis while also highlighting the roles of practitioners and practices. The LNB and LMMDCA should be capacitated in order to handle marketing authorization, product registration, and licensing. Equally important, the PV system should be established for post-market surveillance, reporting and monitoring.

Furthermore, guidelines and policies should be developed with specificity in terms of CBD or THC content of the products that can be legally used by the public without consulting a medical doctor and of the products that can only be accessed by patients strictly with a prescription from the qualified and licenced medical practitioner as well as dispensed from designated licensed pharmacies and qualified registered pharmacists.

Lesotho in collaboration with the African community needs to invest more in cannabis

R&D. Standardised R&D is required to validate evidence-based therapies and clinical trials highlighting the benefits and risks of the cannabis drug substance. This will pave the way for the citizens to benefit from the therapeutic effects of medical cannabis. The medical cannabis trading strategy should be revisited to ensure it provides more inclusive economic opportunities, as the current approach primarily benefits global investors, with limited participation from the local population.

Healthcare professionals training on medicinal cannabis should be drafted in line with the proposed guidelines. Additionally, education and awareness should be made regarding the benefits and risks of medicinal cannabis and the proposed practices and regulations in the country. Issues of stigmatisation and crime ideology should be addressed. The integration of medical cannabis into the healthcare system could also be useful. Medical cannabis could be another option of treatment and patients meeting the proposed stipulated criteria should be given a chance to use medical cannabis legally under healthcare professional guidance.

Conclusion

Lesotho and all other countries involved in this study portrayed compliance with the UN and INCB concerning the scheduling, licensing, cultivation, importation and exportation of medical cannabis. All the countries have an established national regulatory body or agency as recommended by the WHO. Importantly, the Lesotho-registered companies obtained EU GMP certification which has facilitated them to trade medical cannabis globally through the stringent reliance pathways.

The Lesotho Narcotic Bureau (LNB) and the Lesotho Medicine and Medical Devices Control Authority (LMMDCA) in comparison with other countries lack the fundamental dynamics necessary for a robust regulatory system of medical cannabis, such as a standardised system, regulatory guidelines, and R&D initiatives which could have facilitated coherent authorisation, registration, and monitoring of pharmaceutical companies. Therefore, the strategic implementation of the recommended traits, particularly the strengthening and capacitation of LNB and LMMDCA, will serve as a major cornerstone in development of medical cannabis regulation in Lesotho.

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Ethical considerations

None to report.

Conflict of interest

No conflict of interest to declare

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