

Regulatory Challenges of Medicinal Cannabis in Australia and the United Kingdom: Insights from a Research Landscape Analysis

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ABSTRACT

The legalisation of medicinal cannabis has increasingly shifted the regulatory debate from whether cannabis should be permitted for medical purposes to how effective governance can ensure safe, equitable and meaningful patient access. Although Australia and the United Kingdom have established legal pathways for medicinal cannabis, legal recognition does not necessarily translate into practical accessibility. Patients may continue to encounter restrictive prescribing requirements, limited professional knowledge and confidence, uncertainty surrounding clinical evidence, product availability and quality, affordability concerns, and regulatory complexity. This study aims to examine the legal and governance frameworks governing medicinal cannabis in Australia and the United Kingdom and to identify the principal regulatory and practical challenges affecting their implementation. A qualitative research landscape analysis was undertaken using Scopus AI Analytics to examine relevant literature on medicinal cannabis regulation, legislation, governance and implementation challenges in the two jurisdictions. The analysis incorporated the Summary, Expanded Summary and Concept Map functions to identify key regulatory relationships and developing areas of research. The findings indicate that the central governance challenge in both jurisdictions is the need to balance regulatory control with meaningful patient access. Australia demonstrates a complex, multi-level regulatory structure involving federal and state or territory authorities, while the United Kingdom operates a more restrictive specialist prescribing framework. Across both jurisdictions, regulatory effectiveness is influenced not only by legislation but also by professional preparedness, clinical evidence, product safety and quality, market availability, affordability and mechanisms for monitoring patient outcomes. The study suggests that medicinal cannabis governance should be understood as an interconnected and adaptive regulatory system rather than a purely legislative exercise. Practically, policymakers should strengthen regulatory coordination, professional education, evidence-based prescribing, product oversight and patient protection while ensuring that regulatory requirements do not unnecessarily impede access. The findings provide a basis for developing more proportionate, responsive and patient-centred approaches to medicinal cannabis governance.

Keywords: Regulatory challenges, implementation barriers, medicinal cannabis, Australia, United Kingdom.

INTRODUCTION

The regulation of medicinal cannabis has emerged as an increasingly important legal, healthcare and public policy issue as jurisdictions move away from traditional prohibition towards controlled frameworks that permit cannabis-based products for therapeutic purposes. Although medicinal cannabis is now legally available in a growing number of countries, legalisation does not necessarily translate into effective or equitable patient access. The implementation of medicinal cannabis regimes requires governments to reconcile competing considerations, including patient access, product safety and quality, clinical evidence, professional accountability, prevention of misuse and diversion, and the need for effective regulatory oversight. Consequently, the central regulatory

challenge is no longer simply whether medicinal cannabis should be legalised, but how legal frameworks can be designed and implemented to ensure that access is clinically appropriate, safe and practically achievable.

Australia and the United Kingdom provide particularly useful jurisdictions for examining the contemporary challenges of medicinal cannabis regulation because both have established lawful pathways for therapeutic cannabis while retaining significant controls over prescribing, supply, professional responsibility and patient access. Australia introduced a national regulatory framework for medicinal cannabis in November 2016 through a multilayered system involving the Commonwealth, state and territory authorities, the Therapeutic Goods Administration (TGA), and relevant professional bodies. At the federal level, the Therapeutic Goods Act 1989 provides the principal regulatory framework for therapeutic goods, while the Poisons Standard establishes the national scheduling framework according to the risks associated with particular substances. The legal effect of the Poisons Standard is implemented through state and territory medicines and poisons legislation, making Australian medicinal cannabis governance a shared and multilayered regulatory responsibility.

Within this framework, medicinal cannabis is subject to controlled-drug regulation through the scheduling system. Cannabis and tetrahydrocannabinol (THC), subject to applicable qualifications and circumstances, are generally treated as Schedule 8 substances when prepared or packed for human therapeutic use. The regulatory framework also provides several pathways for accessing medicinal cannabis, including the Special Access Scheme (SAS), the Authorised Prescriber pathway, and relevant product registration or approval mechanisms. Under the SAS, healthcare practitioners may seek access to unapproved therapeutic goods for individual patients subject to specified requirements, while the Special Access Scheme–Category B (SAS-B) requires medical practitioners to submit an application to the TGA for specified medicinal cannabis products. The Authorised Prescriber pathway provides an alternative mechanism through which appropriately authorised practitioners may prescribe unapproved products for specified patients or classes of patients. The Narcotic Drugs Act 1967 further regulates the cultivation and production of cannabis for medicinal and scientific purposes. Together, these arrangements demonstrate that Australian law has moved from prohibition towards controlled therapeutic access, although the interaction between Commonwealth and state or territory requirements continues to create regulatory complexity.

The expansion of lawful prescribing in Australia has nevertheless not eliminated practical barriers to access. Although prescriptions increased substantially between 2017 and 2024, research continues to identify regulatory complexity, geographical disparities, prescribing requirements, practitioner reluctance, treatment costs, limited clinical evidence and professional uncertainty as significant barriers (MacPhail et al., 2022; Lim & Lim, 2026). Patient access may also be affected by the cost of treatment, uneven availability, prescribing requirements and limited knowledge among healthcare professionals. Gething et al. (2025), for example, identified practitioner reluctance, high costs and dependence on imported products as significant factors contributing to consumer vulnerability and, in some cases, encouraging patients to obtain cannabis through unregulated channels. Concerns regarding the safety, efficacy and appropriate therapeutic indications of medicinal cannabis may also affect its integration into mainstream healthcare (Arnold, 2021). The professional literature has similarly identified difficulties associated with prescribing, safety concerns and the continuing stigma surrounding cannabis as barriers to its integration into mainstream healthcare (Lewis & Flood, 2021). These findings suggest that the effectiveness of medicinal cannabis regulation depends not only on the existence of a legal pathway but also on the capacity of healthcare professionals and institutions to implement regulatory requirements consistently.

The role of healthcare professionals represents another important regulatory dimension. Pharmacists, in particular, occupy a critical position between prescribers and patients because they are involved in the dispensing and provision of information concerning medicinal cannabis. Research has found that Australian pharmacists recognise their important role but may feel inadequately prepared to counsel patients because of limitations in knowledge, education and professional resources (Bawa et al., 2023; Sabmeethavorn et al., 2022). Regulatory changes concerning the supply of low-dose cannabidiol (CBD) products have further expanded the responsibilities of pharmacists and raised questions concerning professional preparedness, consumer information and appropriate safeguards (Hallinan et al., 2022). These developments demonstrate that regulatory effectiveness depends not only on statutory rules but also on the capacity of healthcare professionals and institutions to implement those rules consistently.

The United Kingdom provides a different regulatory model. In November 2018, cannabis-based products for medicinal use in humans (CBPMs) were rescheduled from Schedule 1 to Schedule 2 under the Misuse of Drugs (Amendments) (Cannabis and Licence Fees) (England, Wales and Scotland) Regulations 2018, within the broader framework of the Misuse of Drugs Act 1971 (UK). The reform created a lawful basis for prescribing CBPMs in defined circumstances and represented a significant shift from the previous regulatory position. However, rescheduling did not establish unrestricted access. Most initial prescriptions must be made by a specialist medical practitioner, while many CBPMs remain unlicensed. Consequently, prescribing is also shaped by professional and clinical governance requirements established through bodies such as the National Institute for Health and Care Excellence (NICE), the General Medical Council (GMC), the Medicines and Healthcare products Regulatory Agency (MHRA), and NHS England.

The UK framework illustrates the importance of professional governance in translating legislative reform into meaningful access. NICE guideline NG144 recommends specialist initiation of most CBPMs and provides for subsequent prescribing through shared-care arrangements where appropriate. The GMC's professional standards permit the prescribing of unlicensed medicines where clinically justified but require prescribers to exercise appropriate professional judgement, justify their decisions and ensure patient safety. NHS England has similarly recognised the additional clinical and medico-legal responsibilities associated with prescribing CBPMs, particularly given the limited evidence base and unlicensed status of many products. These requirements may contribute to professional caution and restricted prescribing, notwithstanding the legal availability of medicinal cannabis. Patients may consequently continue to encounter barriers arising from limited NHS funding, bureaucratic procedures, restricted prescribing, supply difficulties and professional uncertainty (Nutt et al., 2020).

Recent UK research further demonstrates that regulatory barriers operate at both institutional and professional levels. Heeg et al. (2024) found that barriers to prescription and the financial cost of medicinal cannabis were among the most frequently reported concerns among healthcare professionals, while training was associated with greater confidence and reduced concern about the evidence supporting medicinal cannabis. At the policy level, the UK Government continues to acknowledge limitations in the evidence base and has maintained restrictions on prescribing by non-specialists. In 2025, the Advisory Council on the Misuse of Drugs commenced a review of the 2018 regulatory changes to assess whether the legislation achieved its intended objectives and to identify unintended consequences. These developments indicate that, despite legal recognition of medicinal cannabis, the UK continues to confront questions concerning evidence, clinical guidance, professional competence, funding, patient access and the appropriate balance between control and therapeutic availability.

Existing studies have generated valuable but largely fragmented insights into these challenges. In Australia, research has examined prescribing trends and regulatory pathways (MacPhail et al., 2022), professional attitudes and knowledge (Bawa et al., 2023), pharmacist experiences (Sabmeethavorn et al., 2022), safety and adverse effects (Arnold, 2021), professional representations of medicinal cannabis (Lewis & Flood, 2021), consumer vulnerability (Gething et al., 2025), and the broader evolution of regulatory oversight (Lim & Lim, 2026). In the United Kingdom, previous scholarship has focused on barriers to prescribing and patient access (Nutt et al., 2020), while more recent research has examined healthcare professionals' knowledge, attitudes and concerns regarding medicinal cannabis (Heeg et al., 2024). Taken together, these studies demonstrate that medicinal cannabis regulation is a multidimensional issue involving law, governance, healthcare professionals, patients, evidence, markets and public perceptions. However, much of the existing literature examines individual components of the regulatory environment or focuses on one jurisdiction, profession or stakeholder group.

A research gap therefore remains in developing a broader and more systematic understanding of the interconnected regulatory challenges emerging across Australia and the United Kingdom. In particular, there is a need to move beyond isolated discussions of prescribing, access, safety or professional attitudes and to identify the wider conceptual relationships that characterise the contemporary regulatory landscape. Such an approach is important because regulatory challenges do not occur independently. For example, restrictions on prescribing may interact with limited clinical evidence and professional uncertainty, which may subsequently influence patient access and encourage reliance on private or unregulated markets. Similarly, regulatory complexity may affect pharmacists, prescribers and patients differently while generating common concerns regarding safety,

quality, cost and accountability. A systematic mapping of the research landscape can therefore provide a more comprehensive understanding of how these issues are connected.

Against this background, this study aims to analyse the research landscape concerning the regulatory challenges of medicinal cannabis in Australia and the United Kingdom, with particular emphasis on identifying the principal areas of research, relationships between key concepts within the field. The study uses a structured research-landscape approach incorporating analysis of the research area and examination of a concept map. Rather than treating these analytical components as merely bibliometric outputs, the study uses them to identify the dominant regulatory concerns and areas requiring further scholarly and policy attention. This approach enables the study to examine not only what has been researched but also how different regulatory issues are conceptually connected and where the research agenda appears to be developing.

The study contributes to the literature in three principal respects. First, it provides a cross-jurisdictional synthesis of regulatory challenges in two developed healthcare systems that have adopted different approaches to medicinal cannabis regulation. Second, by integrating the research landscape and concept map, it provides a broader analytical perspective than studies concentrating on a single regulatory issue or stakeholder group. Third, the findings may assist policymakers, regulators, healthcare professionals and researchers in identifying persistent regulatory barriers and areas requiring further investigation. In particular, understanding the relationship between regulatory control and meaningful patient access may contribute to the development of medicinal cannabis frameworks that maintain appropriate safeguards without creating unnecessary barriers to legitimate therapeutic use.

The remainder of this article is structured as follows. The next section describes the research methodology and explains the approach used to analyse the medicinal cannabis research landscape, including the concept map. The subsequent section presents the findings of the analysis for Australia and the United Kingdom. This is followed by a discussion of the principal regulatory challenges and their implications for patient access, professional practice, safety, governance and policy development. The final section concludes the article by highlighting the key findings, research implications and potential directions for future research.

METHODOLOGY

This study employed a qualitative research landscape analysis using Scopus AI Analytics to examine the legal framework, governance arrangements, and challenges or barriers associated with the implementation of medicinal cannabis regulation in Australia and the United Kingdom. The researcher employed Scopus AI Analytics as a preliminary research landscape and thematic mapping tool and to identify relevant scholarly literature, recurring concepts, and research clusters. Scopus AI was selected as an AI-assisted research tool because it enables researchers to explore scholarly literature indexed in Scopus and provides analytical functions designed to support the identification and synthesis of research topics, concepts and areas of scholarship (Elsevier, 2024a, 2024b). This methodological approach builds upon the research strategy adopted in previous studies by Sanek et al. (2025) and Joni et al. (2025), which employed Scopus AI to identify, synthesise, and map relevant academic literature and emerging research themes. In particular, Scopus AI outputs such as the Summary, Expanded Summary, and Concept Map were used to facilitate the identification of conceptual relationships and thematic patterns within the relevant body of literature. The present study adopts a similar approach while extending its application to the comparative legal and regulatory analysis of medicinal cannabis governance in Australia and the United Kingdom.

The analysis was conducted using Scopus AI on 7 September 2026, and this date was recorded as the temporal reference point for the research landscape examined in the study. Recording the search date is particularly important because Scopus AI generates responses dynamically from the content available within the Scopus database, and its outputs may change as new publications are indexed or as the system is updated (Elsevier, 2024a). The analysis was conducted on 7 September 2026 using the following search string:

The search strategy was developed to align directly with the aim of the study, which is to analyse the research landscape concerning the legal framework and governance surrounding medicinal cannabis in Australia and the

United Kingdom and the challenges or barriers that exist in its implementation. The following Boolean search string was entered into Scopus AI on 7 September 2026:

("medicinal cannabis" OR "medical cannabis" OR "medical marijuana") AND (Australia OR "United Kingdom") AND (regulation OR legislation OR "legal framework" OR governance) AND (challenge OR barrier OR issue OR implementation)***

The search string consisted of four principal conceptual components. First, the terms “medicinal cannabis,” “medical cannabis,” and “medical marijuana” were used to capture variations in terminology employed in the scholarly literature. Second, “Australia” and “United Kingdom” established the geographical boundaries of the study. Third, the terms “regulation,” “legislation,” “legal framework,” and “governance” were used to identify literature addressing the legal and institutional dimensions of medicinal cannabis. Finally, “challenge*,” “barrier*,” “issue*,” and “implementation” were incorporated to capture literature concerning difficulties associated with putting medicinal cannabis regulatory frameworks into practice. The use of the asterisk wildcard was intended to capture different word endings, thereby broadening the retrieval of potentially relevant literature. The search strategy was consequently designed to ensure that the retrieved research remained closely connected to the two principal dimensions of the study: regulatory framework and governance, and implementation challenges and barriers.

Scopus AI uses content from the Scopus database and applies artificial intelligence techniques to assist researchers in discovering and understanding relevant research. According to Elsevier, Scopus AI combines semantic/vector search and keyword search to identify relevant documents and uses information such as abstracts and metadata to generate its responses (Elsevier, 2024a, 2026). The platform is designed to help researchers move from a research question towards relevant literature and broader insights into a research field (Elsevier, 2024b). In the present study, this capability was used to explore how the academic literature has addressed medicinal cannabis regulation in Australia and the United Kingdom. Scopus AI was therefore treated as an analytical and discovery tool, rather than as an independent source of legal or empirical evidence.

Scopus AI's Summary function provides a concise synthesis of the research associated with a user's query and identifies key findings and themes within the retrieved literature (Elsevier, 2024a). The Expanded Summary was subsequently examined to obtain a more detailed understanding of the research area. According to Elsevier, the Expanded Summary provides a more extensive synthesis of the research landscape and allows researchers to explore the topic in greater depth than the initial Summary (Elsevier, 2024a). Scopus AI provides a Concept Map to assist researchers in visualising the conceptual relationships within a research topic. According to Elsevier's Scopus AI guidance, the Concept Map is generated from keywords identified from relevant research abstracts and provides a visual representation of the relationships between concepts within the research landscape (Elsevier, 2024a). These outputs were used to identify the principal areas of scholarly attention concerning medicinal cannabis governance, legal regulation, implementation barriers, professional practice, patient access, and regulatory challenges. Rather than reproducing the language of the Scopus AI outputs, the identified themes were subsequently traced to the underlying academic literature and relevant primary legal and regulatory sources. This ensured that substantive legal propositions were based on verifiable sources rather than on AI-generated summaries.

The Concept Map was particularly useful for identifying relationships among three interconnected dimensions of medicinal cannabis governance: (i) access and implementation.; (ii) regulatory challenges (iii) and the legal framework. These dimensions provided the analytical structure for interpreting the Australian and United Kingdom frameworks. The approach also enabled the study to distinguish between the formal legality of medicinal cannabis and the practical conditions under which lawful access can be achieved.

The next analytical functions were subsequently integrated to construct an overall picture of the research landscape. The Summary provided a broad overview of the research area, while the Expanded Summary provided greater detail concerning the principal regulatory and implementation issues. The Concept Map was used to examine the relationships among key concepts. This sequential analytical approach allowed the study to progress from identifying the broad research landscape to examining its conceptual structure. Such an approach is

consistent with the intended purpose of Scopus AI as a tool that assists researchers in navigating and understanding complex research landscapes (Elsevier, 2024a).

For the purpose of analysis, the findings were organised into two principal analytical dimensions: (1) legal framework and governance and (2) implementation challenges and barriers. The first dimension examined the legal and institutional arrangements governing medicinal cannabis, including legislation, regulatory authorities, prescribing mechanisms, professional oversight and product regulation. The second dimension examined difficulties encountered in implementing these frameworks, including patient access, prescribing barriers, professional knowledge and confidence, safety and quality concerns, limitations in clinical evidence, affordability, availability, supply, stigma and regulatory complexity. This categorisation enabled the study to examine whether similar regulatory challenges arise in both jurisdictions and, where appropriate, to identify differences in the way those challenges are represented in the literature.

The study adopted a qualitative interpretive approach to analysing the Scopus AI outputs. The purpose was not to calculate statistical prevalence or establish causal relationships, but to identify and interpret patterns, as well as relationships within the scholarly literature. The concepts and themes generated through Scopus AI were therefore examined in relation to the underlying publications identified by the platform. This distinction is important because Scopus AI is an AI-assisted research tool and its generated responses should not be treated as substitutes for the original scholarly sources. Elsevier emphasises that researchers should exercise critical judgement when using AI-generated outputs and should verify information against the underlying sources (Elsevier, 2024a, 2024b). Accordingly, this study used the original Scopus-indexed publications as the substantive evidence base and the Scopus AI outputs as an instrument for identifying, organising and interpreting the research landscape.

Methodological transparency was maintained by recording the exact search string, search date, analytical functions and principal themes generated during the Scopus AI analysis. The analysis was conducted on 7 September 2026, which constitutes the cut-off date for the research landscape reported in this article. This temporal specification is necessary because the Scopus database is continuously updated and Scopus AI is designed to provide dynamic, current research insights (Elsevier, 2024a, 2026). Consequently, replication of the same search at a later date may produce additional or different results because of changes in the underlying Scopus corpus and developments in the Scopus AI system.

Finally, human oversight was maintained throughout the analytical process. The researcher critically assessed the information generated by Scopus AI, examined the underlying scholarly publications and interpreted the identified concepts and themes in accordance with the research aim. This approach recognises that AI-generated research summaries may contain errors or incomplete interpretations and should therefore be subjected to human verification and scholarly judgement (Elsevier, 2024a). Scopus AI was therefore treated as an assistive research technology for literature discovery and thematic organisation, while responsibility for legal interpretation and the final conclusions remained with the researchers.

RESULT AND DISCUSSION

Overview of the Research Landscape: Legal Framework, Governance and Implementation Challenges

The research landscape reveals that medicinal cannabis governance in Australia and the United Kingdom is shaped by a common regulatory tension: both jurisdictions have moved away from an absolute prohibition of medicinal cannabis while retaining substantial controls over prescribing, supply, professional responsibility, product quality, and patient access. The legalisation or rescheduling of medicinal cannabis has therefore not resulted in unrestricted access. Instead, access is mediated through a combination of statutory controls, regulatory classifications, professional requirements, clinical guidance, and administrative procedures.

Although both jurisdictions have established legal pathways for medicinal cannabis, the existence of a legal framework has not necessarily resulted in straightforward or equitable access for patients. The research landscape identified through the Scopus AI analysis indicates that regulatory complexity, prescribing requirements, professional uncertainty, patient access, safety and quality concerns, and the limited development of clinical

evidence are interconnected rather than isolated problems. The findings therefore suggest that the effectiveness of medicinal cannabis regulation should not be assessed solely by whether a jurisdiction has legalised medicinal use. Instead, attention must also be directed towards how the regulatory framework operates in practice and whether it enables healthcare professionals to prescribe appropriately while allowing patients to obtain safe, effective and affordable products.

In Australia, the research landscape demonstrates that medicinal cannabis regulation has developed through a multi-layered governance structure. Medicinal cannabis became legally accessible within the Australian therapeutic goods framework in November 2016, with the Therapeutic Goods Administration (TGA) playing a central federal regulatory role. Prescribing has primarily occurred through mechanisms including the Special Access Scheme–Category B (SAS-B), under which practitioners apply to the TGA to prescribe a category of medicinal cannabis product for an individual patient and a specified indication. The regulatory system also interacts with state and territory requirements and professional oversight arrangements (MacPhail et al., 2022). The literature therefore identifies regulatory complexity as a central characteristic of the Australian model. This finding is consistent with Lim and Lim (2026), who describe the Australian framework as involving the TGA, state health departments and multiple professional oversight bodies. Although prescribing has expanded substantially since 2016, the continued interaction between federal requirements, state-level arrangements and professional responsibilities creates a regulatory environment that can be difficult for practitioners and patients to navigate.

The development of the Australian framework also illustrates an important distinction between legalisation and regulatory accessibility. MacPhail et al. (2022) found that the regulatory framework had generated substantial growth in medicinal cannabis prescribing during its first five years. However, the existence of a legal prescribing pathway does not necessarily mean that patients can access treatment easily. The SAS-B pathway, in particular, places administrative responsibilities on prescribers and requires them to navigate regulatory requirements before treatment can be supplied. The literature consequently identifies administrative complexity and regulatory navigation as significant implementation barriers. This suggests that regulation can become an access barrier when compliance requirements are sufficiently demanding to discourage or delay prescribing. The regulatory objective of ensuring appropriate oversight must therefore be balanced against the practical burden imposed on healthcare professionals.

The rapid expansion of medicinal cannabis prescribing in Australia provides further evidence of this tension. MacPhail et al. (2022) documented a substantial increase in prescribing following the establishment of the regulatory framework, demonstrating that legalisation created a pathway for the rapid development of medicinal cannabis use. More recent evidence indicates that this growth has continued. Lim and Lim (2026) report that prescriptions increased from 231 in 2017 to more than one million by early 2024, although significant barriers remain, including treatment costs, uneven availability in remote areas and variable knowledge among healthcare professionals. The results therefore indicate that increasing utilisation should not be interpreted as evidence that regulatory challenges have been resolved. Rather, the expansion of prescribing has exposed a second generation of regulatory problems involving affordability, equity, professional capability, supply and integration into mainstream healthcare.

One of the most significant themes identified in the analysis is prescriber reluctance. The implementation of medicinal cannabis regulation depends heavily upon healthcare professionals being willing and sufficiently confident to prescribe. Australian evidence demonstrates that professional knowledge and attitudes can influence this process. Karanges et al. (2018), in a survey of 640 Australian general practitioners, examined knowledge, attitudes, perceived therapeutic effects and harms, and willingness to prescribe medicinal cannabis. The study illustrates the importance of professional knowledge and confidence in determining whether a legal regulatory pathway translates into actual clinical access. The regulatory problem is therefore partly institutional and partly professional: even where legislation permits medicinal cannabis prescribing, uncertainty about evidence, safety, appropriate indications and professional responsibility may discourage clinicians from using the available pathways.

This issue is reinforced by the literature concerning the integration of cannabis into mainstream healthcare. Lewis and Flood (2021) identified the continuing transition of cannabis from a prohibited substance towards a

recognised therapeutic product within Australian healthcare discourse. This transition involves not merely a change in legal status but also a change in professional attitudes and clinical norms. The persistence of stigma and uncertainty can therefore slow regulatory implementation even after legislative reform has occurred. The literature's identification of stigma, media representation and lack of clinical guidance as implementation barriers is significant because it demonstrates that regulatory effectiveness is influenced by factors extending beyond legislation itself. A formally permissive framework may remain functionally restrictive if healthcare professionals lack confidence in the evidence or continue to associate cannabis primarily with its history as a prohibited drug.

The patient-access dimension represents another major finding. The Australian literature indicates that patients can encounter several layers of difficulty between legal entitlement and actual access, including prescriber reluctance, administrative processes, cost and product availability. Gething et al. (2025) provide particularly strong evidence on this issue. Their analysis of submissions from patients, carers and families identified three major barriers: healthcare practitioners' reluctance to prescribe, the high cost of medicinal cannabis and its access process, and dependence on imported products that can contribute to shortages and product substitution. These findings demonstrate that patient access is not determined by legislation alone. Instead, access is the outcome of interaction among regulatory requirements, professional behaviour, market conditions and the financial capacity of patients.

The relationship between regulatory barriers and unregulated access is particularly important. The analysis indicates that some Australian patients continue to obtain cannabis through unregulated or illicit channels despite the existence of a legal medicinal cannabis framework. This finding raises a significant regulatory paradox: regulation intended to protect patients may become ineffective if the legal pathway is perceived as too difficult, expensive or inaccessible. Gething et al. (2025) similarly found that barriers to regulated access had contributed to patients seeking unregulated cannabis for therapeutic purposes. From a regulatory perspective, this creates an important policy concern because unregulated products may lack reliable information regarding composition, potency, quality and provenance. Consequently, restrictive access mechanisms may unintentionally undermine some of the very safety objectives that regulation is intended to achieve.

Safety and quality therefore emerge as another important component of the research landscape. The literature demonstrates concerns regarding product safety, efficacy, quality and adverse-event monitoring. These concerns are understandable given the historical limitations of the evidence base and the rapid expansion of medicinal cannabis markets. Wang et al. (2024), in a systematic scoping review of global medicinal cannabis safety-monitoring systems, found substantial variation in monitoring systems, including differences in terminology, data collection, causality assessment and institutional responsibility. Their analysis identified 24 monitoring systems comprising databases and registries and concluded that post-marketing surveillance would benefit from more centralised, consistent and accessible approaches. This finding is particularly relevant to the Australian context because it demonstrates that legal access must be accompanied by effective pharmacovigilance if regulators are to identify adverse events and evaluate the real-world safety of medicinal cannabis.

The safety issue also illustrates the broader relationship between evidence, regulation and prescribing. Clinicians require reliable evidence to determine whether medicinal cannabis is appropriate for particular patients, while regulators require evidence to determine how products should be controlled. At the same time, evidence generation may be constrained by the historical regulatory status of cannabis. Wang et al. (2024) note that historical legislative resistance contributed to limited preclinical data and that existing adverse-event monitoring systems remain inconsistent. The result is a regulatory cycle in which limited evidence contributes to professional caution, professional caution limits prescribing, and limited prescribing and fragmented monitoring may constrain the development of robust real-world evidence. Breaking this cycle requires regulatory systems capable of supporting both appropriate access and systematic evidence generation.

The research landscape also highlights the important role of pharmacists in implementing medicinal cannabis regulation. Pharmacists occupy a critical position in the regulatory chain because they are responsible for dispensing products and may be required to provide patients with information concerning their use. The role of pharmacists becomes particularly significant in a regulatory environment in which product types, prescribing requirements and safety considerations are evolving. The literature supplied in the Scopus AI results indicates

that pharmacist knowledge, attitudes and experiences are therefore relevant to the effective implementation of medicinal cannabis regulation. This suggests that regulatory frameworks should not focus exclusively on prescribers and regulators but should recognise pharmacists as important actors in ensuring safe and appropriate use.

The analysis identifies a related concern regarding the commercialisation of medicinal cannabis. As medicinal cannabis markets expand, the regulatory challenge shifts from simply establishing legal access towards ensuring that commercial growth does not compromise patient welfare. Gething et al. (2025) demonstrate how policy and market factors can interact to create consumer vulnerability, particularly where high costs, supply problems and unequal access exist. This finding suggests that market expansion should be accompanied by appropriate consumer-protection mechanisms, quality controls and safeguards against inappropriate prescribing. The growth of the medicinal cannabis industry therefore creates a need for regulatory frameworks that balance commercial availability with therapeutic integrity.

The United Kingdom presents a somewhat different regulatory configuration but demonstrates a similar gap between legal availability and practical access. Cannabis-based products for medicinal use became legally prescribable by specialist doctors from 1 November 2018, following amendments to the Misuse of Drugs Regulations 2001. The regulatory change created a legal route for specialist doctors registered with the General Medical Council to prescribe cannabis-based products for medicinal use under controlled circumstances. Most such products remain unlicensed, and prescribing is subject to additional restrictions. Thus, contrary to the initial Summary's indication that UK information was not specified, the Expanded Summary and supporting literature demonstrate that the United Kingdom has an established legal and regulatory framework, although its implementation remains highly restrictive.

The principal UK challenge identified in the research landscape is therefore not the absence of legislation but the limited translation of legislative reform into routine clinical access. Nutt et al. (2020) observed that, despite the legalisation of cannabis-based products for medicinal use, patients continued to experience substantial difficulties obtaining prescriptions, with very limited NHS prescribing at the time of their study. They identified barriers including concerns regarding the scientific evidence, prescriber attitudes and the institutional reluctance to incorporate medicinal cannabis into routine clinical practice. This is analytically significant because it demonstrates that the UK experience mirrors an important feature of the Australian experience: legal reform represents only the first stage of regulatory implementation.

The UK framework also demonstrates the importance of specialist prescribing as a regulatory gatekeeping mechanism. The 2018 regulatory changes restricted prescribing of unlicensed cannabis-based medicinal products to doctors on the General Medical Council specialist register. The UK Government justified this restriction partly by reference to the limited evidence base and the unlicensed status of most products. While specialist prescribing provides an additional layer of clinical oversight, it may simultaneously reduce the number of healthcare professionals able or willing to prescribe medicinal cannabis. The resulting tension between patient protection and access is therefore comparable to the Australian situation, although the institutional mechanisms differ. Australia relies heavily on regulatory pathways such as SAS-B, whereas the UK places greater emphasis on specialist clinical authority.

The UK experience also demonstrates how evidence uncertainty can become a regulatory barrier. Nutt et al. (2020) identified perceived deficiencies in scientific evidence as an important reason for limited prescribing and argued for patient-centred evidence-generation approaches, including patient-reported outcomes, pharmacoepidemiology and n-of-1 studies. The significance of this finding extends beyond the UK because it illustrates the reciprocal relationship between evidence and regulation. If the evidence base is considered insufficient, regulators may impose stricter controls; however, overly restrictive access can also limit opportunities to generate real-world evidence concerning effectiveness and safety. A sustainable regulatory framework must therefore manage uncertainty without allowing evidentiary limitations to become an indefinite justification for restricting access.

The comparison between Australia and the United Kingdom consequently reveals both convergence and divergence. The two jurisdictions differ in their regulatory architecture, but both demonstrate a common

implementation problem: the legalisation or rescheduling of medicinal cannabis does not automatically produce meaningful patient access. Australia has developed a relatively active prescribing environment but continues to experience regulatory complexity, cost, supply, professional knowledge gaps and unequal access. The UK has established a legal route for specialist prescribing but has experienced more limited integration into mainstream healthcare, particularly within the NHS. These differences suggest that regulatory success should be assessed using more than one indicator. The existence of legislation, the number of prescriptions, the number of authorised prescribers and the availability of products are useful indicators, but they should be complemented by measures of affordability, equity, safety, professional confidence and patient experience.

Overall, the literature indicates that the major regulatory challenge in both jurisdictions lies in achieving an appropriate balance between control and access. Excessively restrictive regulation may delay or prevent access to potentially beneficial treatment, while insufficient regulation may expose patients to risks relating to product quality, inappropriate prescribing, adverse effects and commercial exploitation. The Australian and UK experiences therefore demonstrate that medicinal cannabis regulation should be viewed as an ongoing process of regulatory adaptation rather than a single legislative event. As markets expand and clinical experience accumulates, regulators must continually adjust prescribing requirements, professional guidance, safety monitoring and patient-protection mechanisms.

The findings further suggest that the implementation of medicinal cannabis regulation is best understood as an interdependent governance system. Legal rules influence prescribing; prescribing depends upon professional knowledge and confidence; professional practice affects patient access; access is influenced by product availability and cost; and all of these factors are connected to the evidence base and safety-monitoring mechanisms. Consequently, a weakness at one point in the regulatory chain can produce effects elsewhere in the system. The central lesson from the underlying literature is therefore that effective medicinal cannabis regulation requires coordination across legislation, regulatory agencies, healthcare professionals, patients and markets. Australia demonstrates the challenges of managing a rapidly expanding and multi-level regulatory system, while the United Kingdom demonstrates how restrictive implementation can persist even after formal legal recognition. Together, these findings reinforce the importance of designing regulatory frameworks that are sufficiently cautious to protect patients but sufficiently responsive to facilitate legitimate therapeutic access.

The Concept Map

The concept map generated by Scopus AI (Figure 1) reveals several interconnected themes relevant to the regulation of medicinal cannabis in Australia and the United Kingdom. At the centre of the map is medicinal cannabis governance, which is connected to three principal themes: legal framework, regulatory challenges, and access and implementation. The legal framework theme identifies Australia and the United Kingdom as the principal jurisdictions examined, whereas regulatory challenges are linked to broader issues of decriminalisation and policy debates. The access and implementation theme further highlights the clinical pathway and the role of general practitioners. These interconnected themes suggest that the effectiveness of medicinal cannabis regulation cannot be assessed solely by the existence of a legal framework. Rather, attention must also be given to how the framework is implemented, how patients gain access to medicinal cannabis, and how healthcare professionals participate in its delivery.

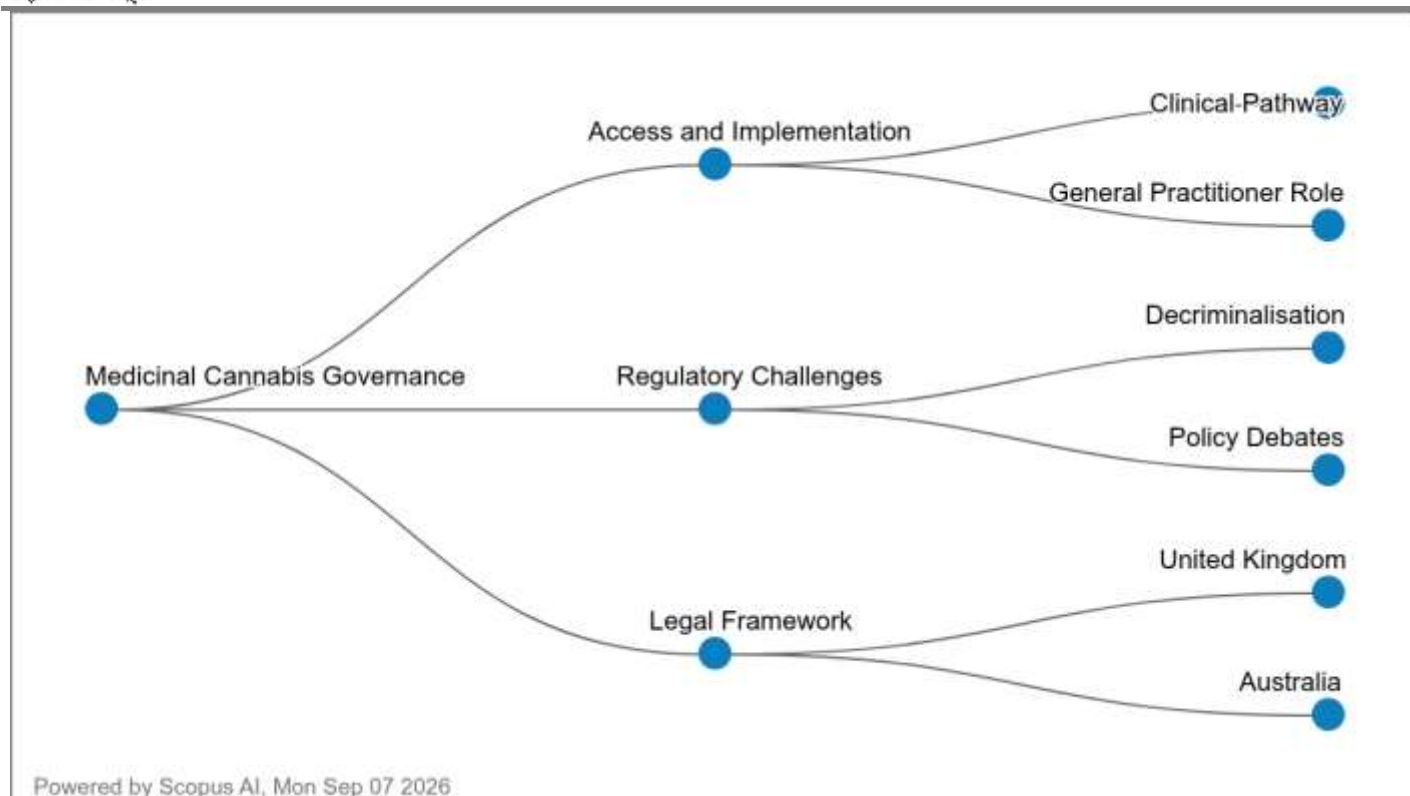


Figure 1: The Scopus AI-generated concept map

Medicinal Cannabis Governance

The results indicate that medicinal cannabis governance is characterised by a multi layered regulatory structure in which legal classification, regulatory institutions, professional oversight and policy objectives interact to determine how medicinal cannabis is controlled and incorporated into healthcare systems. The international literature demonstrates that there is no single model of medicinal cannabis governance, with jurisdictions adopting different approaches according to their drug control policies, healthcare structures and public health priorities. Belackova et al. (2018) identify several regulatory dimensions relevant to medicinal cannabis, including legal status, production and supply controls, prescribing arrangements, product regulation and mechanisms for monitoring use. Similarly, Cox (2021) demonstrates that jurisdictions may establish separate regulatory pathways for medicinal and non-medicinal cannabis, reflecting different policy objectives and risk considerations.

The Australian framework illustrates a particularly complex form of governance because regulatory responsibility is distributed between the federal Therapeutic Goods Administration (TGA), state and territory authorities and relevant professional bodies. Since the legalisation of medicinal cannabis in 2016, Australia has progressively expanded its regulatory framework, while retaining significant controls over prescribing, product access and professional practice (Lim & Lim, 2026; MacPhail et al., 2022). The United Kingdom adopts a different governance structure. Following the rescheduling of cannabis-based products for medicinal use in November 2018, medicinal cannabis can be prescribed by specialist doctors who meet the relevant professional requirements, while most cannabis-based medicinal products remain unlicensed and subject to additional regulatory controls. Consequently, governance in the UK is strongly dependent on specialist clinical oversight and the interaction between drug control legislation, medicines regulation and professional standards.

These jurisdictions demonstrate that medicinal cannabis governance is not simply a question of whether cannabis is legally recognised for therapeutic purposes. Rather, governance encompasses the institutional allocation of regulatory authority, the classification and control of cannabis products, prescribing requirements, professional accountability, product standards and mechanisms for ensuring patient safety. The comparative literature further indicates that regulatory boundaries become particularly important where medicinal and non-medicinal cannabis markets coexist. Experiences from Canada and Switzerland demonstrate that governments must continuously

negotiate the institutional and policy boundaries between medical and non-medical cannabis in order to maintain appropriate public health objectives and prevent regulatory overlap or policy drift (Cox, 2021; Sznitman et al., 2025). Thus, the findings support an understanding of medicinal cannabis governance as an evolving system of legal, institutional and professional controls, rather than as a single legislative intervention.

The analysis further reveals that the principal governance challenge is the need to balance control, therapeutic availability, public health protection and regulatory adaptability. The Australian experience demonstrates that a multi-level governance model can facilitate the rapid expansion of medicinal cannabis while simultaneously generating coordination difficulties and administrative complexity. Lim and Lim (2026) highlight continuing challenges involving federal and state regulatory responsibilities, professional knowledge, supply arrangements and the integration of medicinal cannabis into mainstream healthcare. MacPhail et al. (2022) similarly demonstrate substantial growth in prescribing following the introduction of the Australian regulatory framework, while their analysis illustrates the importance of examining whether prescribing practices remain consistent with regulatory expectations. These findings suggest that regulatory expansion does not necessarily resolve governance problems; instead, increased utilisation can expose weaknesses in coordination, professional guidance and regulatory oversight. Comparable issues are evident internationally. In the United States, the coexistence of federal prohibition and state level medical cannabis programmes creates a fragmented regulatory environment in which legal status and regulatory responsibilities may differ according to jurisdiction (Mead, 2019). In Canada, the coexistence of medical and non-medical cannabis regimes raises questions concerning the continuing rationale, effectiveness and public health consequences of maintaining separate regulatory pathways (Cox, 2021). The Brazilian experience similarly illustrates how weaknesses in formal governance may encourage patients and patient organisations to develop alternative forms of bottom-up governance to secure therapeutic access (Pereira, 2025). These comparative findings are significant for Australia and the UK because they demonstrate that effective medicinal cannabis governance requires more than detailed legislation. It requires clear allocation of institutional responsibilities, consistent regulatory standards, evidence informed decision making, professional competence, effective monitoring and mechanisms for responding to changes in scientific knowledge and patient needs. The emerging literature also indicates that governance must remain adaptive because medicinal cannabis regulation continues to evolve in response to new evidence, changing patterns of use and concerns regarding safety and public health (Hmamouchi, 2025, 2026). Accordingly, the results suggest that the quality of medicinal cannabis governance should be evaluated not only by the existence of a legal framework but also by the coherence of the regulatory system, the clarity of institutional responsibilities and its capacity to reconcile therapeutic objectives with appropriate control. This provides an important foundation for examining the subsequent dimension of the study, namely whether these governance arrangements are successfully translated into meaningful, safe and equitable access and effective implementation.

Overall, the analysis indicates that the major regulatory challenge in both jurisdictions lies in achieving an appropriate balance between control and access. Excessively restrictive regulation may delay or prevent access to potentially beneficial treatment, while insufficient regulation may expose patients to risks relating to product quality, inappropriate prescribing, adverse effects and commercial exploitation. The Australian and UK experiences therefore demonstrate that medicinal cannabis regulation should be viewed as an ongoing process of regulatory adaptation rather than a single legislative event. As markets expand and clinical experience accumulates, regulators must continually adjust prescribing requirements, professional guidance, safety monitoring and patient-protection mechanisms.

The findings further suggest that the implementation of medicinal cannabis regulation is best understood as an interdependent governance system. Legal rules influence prescribing; prescribing depends upon professional knowledge and confidence; professional practice affects patient access; access is influenced by product availability and cost; and all of these factors are connected to the evidence base and safety-monitoring mechanisms. Consequently, a weakness at one point in the regulatory chain.

The Relationship between Medicinal Cannabis Governance, Access, and Implementation

The analysis identifies a strong relationship between medicinal cannabis governance and patient access, demonstrating that the existence of a legal framework does not necessarily guarantee effective implementation or meaningful access. Medicinal cannabis governance encompasses more than the legalisation or authorisation

of cannabis for therapeutic purposes; it includes the institutional structures, regulatory requirements, professional responsibilities and administrative mechanisms through which access is delivered. The literature indicates considerable variation in governance models, ranging from separate medical and non-medical access pathways to government-controlled systems and multi-level regulatory arrangements. Cox (2021), for example, demonstrates that Canada maintains distinct mechanisms for medical and non-medical cannabis, with the medical framework retaining a gatekeeping role for health professionals. Similarly, the Quebec experience illustrates how governance structures can be designed to prioritise public health objectives through institutional separation, independent oversight and restrictions on commercialisation (Rychert et al., 2026). These findings suggest that governance is fundamentally an access mechanism: regulatory decisions concerning who may prescribe, what products may be supplied, how products are monitored and which institutions are responsible for oversight directly influence the extent to which patients can obtain medicinal cannabis. Consequently, the effectiveness of a medicinal cannabis framework should not be assessed solely by whether legislation permits medicinal use, but by whether its governance arrangements establish a practical, coherent and sufficiently accessible pathway from legal authorisation to treatment. This distinction is particularly important because a highly restrictive framework may protect against inappropriate use but simultaneously create administrative and professional barriers that undermine the therapeutic purpose of legalisation.

Australia provides a clear illustration of the relationship between regulatory design and practical access. Since medicinal cannabis was legalised at the federal level in 2016, Australia has developed a multi-layered governance structure involving the Therapeutic Goods Administration (TGA), state and territory health authorities and professional regulatory bodies. The principal access pathway has historically involved the Special Access Scheme, particularly Category B (SAS-B), through which medical practitioners obtain authorisation to prescribe particular medicinal cannabis products. MacPhail et al. (2022) found substantial growth in medicinal cannabis prescribing during the first five years of the regulatory scheme, demonstrating that the framework was capable of facilitating significant expansion in access. Nevertheless, the expansion of prescribing has occurred within a regulatory environment characterised by multiple approval requirements and overlapping federal and state responsibilities. Lim and Lim (2026) similarly identify regulatory complexity, coordination gaps, rural availability, cost and variations in professional knowledge as continuing challenges despite the substantial expansion of access. The Australian experience therefore demonstrates a paradox of implementation: regulatory liberalisation can substantially increase the number of patients receiving medicinal cannabis while simultaneously producing procedural and institutional barriers that prevent access from becoming equally available to all patients. The governance framework may be legally operational but practically difficult to navigate. This is particularly significant for patients who require affordable and continuous treatment, because the effectiveness of access depends not merely on whether a prescription can legally be issued, but also on whether a qualified practitioner is willing and able to prescribe, whether the product is available, whether the patient can afford it and whether the regulatory process can be completed without disproportionate administrative burdens. The relationship can therefore be conceptualised as governance → prescribing pathway → professional decision-making → product availability → patient access, with weaknesses at any stage capable of limiting the effectiveness of the overall system.

A further finding is that health professionals constitute a critical implementation link between medicinal cannabis governance and actual patient access. Although legislation establishes the formal right or pathway to obtain medicinal cannabis, prescribing and dispensing decisions are frequently delegated to health professionals. Gardiner et al. (2019), in a systematic review of 26 studies, found that health professionals generally supported medicinal cannabis in practice but reported substantial deficiencies in their own knowledge and expressed concerns about patient and societal harms. This finding is important because regulatory systems that impose professional gatekeeping without simultaneously providing adequate education, clinical guidance and institutional support may unintentionally transform professional uncertainty into an access barrier. The Australian evidence illustrates this problem particularly clearly. Martin et al. (2025) found that inadequate knowledge among general practitioners affected their willingness to engage with medicinal cannabis, while rural residence and lower income were associated with additional barriers to access. Telehealth services could reduce geographical barriers but did not eliminate financial barriers. Thus, professional governance and clinical capacity are not secondary considerations but essential components of implementation. The same relationship can be observed beyond Australia. Withanarachchie et al. (2026), examining medicinal cannabis access in New Zealand, found demographic and socioeconomic disparities in prescription access and reported that some groups were

less likely to seek prescriptions because of anticipated physician refusal. These findings reinforce the proposition that access is partly produced through interactions between regulatory rules and professional behaviour. A legal framework may formally permit medicinal cannabis, but if practitioners lack confidence in the evidence, remain concerned about liability or adverse effects, or are insufficiently trained to prescribe it, the practical availability of treatment remains constrained. Effective governance must therefore incorporate professional education, clear prescribing guidance, accountability mechanisms and opportunities for continuing clinical development.

The results further demonstrate that implementation barriers are not confined to regulatory complexity but extend to equity, affordability and the broader social determinants of access. The governance of medicinal cannabis determines not only whether treatment is legally available but also the conditions under which patients can obtain and sustain treatment. In Australia, the literature identifies cost, geographical location, practitioner availability, regulatory procedures and product supply as interconnected barriers.

Lim and Lim (2026) report that monthly treatment costs may be substantial and that rural and remote patients can experience difficulties arising from uneven availability and limited clinical expertise. Martin et al. (2025) similarly found that lower income and rural residence can restrict access even where legal pathways exist. These findings are consistent with broader international evidence showing that formal legalisation can coexist with structural inequities. In Colombia, for example, the implementation of the medical cannabis framework has been associated with a gap between the legislative objective of improving access and the structural, socioeconomic and health-system barriers experienced in practice (Marín Arroyave & León Cruz, 2025).

The Brazilian experience provides another important illustration. Pereira (2025) describes a context of weak legal governance in which patient associations developed alternative bottom-up mechanisms to facilitate access to medicinal cannabis. While such arrangements may improve access for some patients, they also demonstrate the consequences of a governance system that does not adequately translate legal recognition into reliable and equitable pathways. The implication is that implementation should be evaluated through an accessibility and equity lens, rather than through legislation alone. A governance model may be considered formally successful when it establishes a lawful route to medicinal cannabis, yet substantively unsuccessful if that route is inaccessible to patients because of cost, geography, professional reluctance, administrative burdens or socioeconomic disadvantage. Accordingly, access should be understood as a multidimensional outcome involving legal eligibility, affordability, geographical availability, professional accessibility, product availability and continuity of treatment.

Overall, the findings indicate that the relationship between medicinal cannabis governance, access and implementation is best understood as an interdependent regulatory chain rather than a linear relationship between legislation and patient access. The governance framework establishes the rules and institutional responsibilities; implementation determines how those rules operate through regulators, health professionals, pharmacists, suppliers and healthcare institutions; and access represents the ultimate practical outcome for patients. The evidence from Australia demonstrates that a relatively developed regulatory framework can produce substantial growth in prescribing while continuing to experience fragmentation, professional knowledge gaps, financial barriers and inequitable access.

International evidence from Canada, Colombia, Brazil and New Zealand further demonstrates that different governance models generate different implementation problems, but a common issue remains the potential gap between formal legal availability and meaningful access. The results therefore suggest that effective medicinal cannabis governance requires a balance between regulatory control and accessibility. Excessive procedural requirements may discourage prescribing and encourage patients to seek alternative or informal sources, whereas insufficient oversight may expose patients to concerns relating to product quality, safety, inappropriate prescribing and commercialisation.

Governance should consequently be designed as an adaptive system that integrates regulatory clarity, professional competence, patient protection, affordability, supply reliability, monitoring and equity. The central finding of this analysis is therefore that legalisation is only the starting point of medicinal cannabis reform; the effectiveness of reform ultimately depends on the quality of governance mechanisms through which legal access is implemented in practice. In this sense, access should be regarded not merely as an outcome of governance but

also as an indicator of whether the governance framework is achieving its intended public health and therapeutic objectives.

The Relationship between Medicinal Cannabis Governance and Regulatory Challenges

The results demonstrate that regulatory challenges in medicinal cannabis governance arise largely from the distinctive legal and institutional complexity associated with regulating a substance that occupies a position between controlled drug regulation and therapeutic medicine. Unlike conventional medicines, medicinal cannabis is governed simultaneously through drug control legislation, medicines regulation, professional standards and public health considerations. The comparative literature shows considerable variation in how jurisdictions reconcile these competing objectives. Belackova et al. (2018) demonstrate that medicinal cannabis regulatory models differ according to the legal status of cannabis, the role of healthcare professionals, product controls, supply arrangements and mechanisms for monitoring use. More recent analysis similarly shows that regulatory pathways and the availability of regulator approved cannabis medicines remain highly variable internationally, with only a limited number of cannabis-based medicines receiving formal regulatory approval across major regulatory jurisdictions (Jardim & Delgado Charro, 2025). This diversity creates an inherent regulatory challenge because policymakers must determine how cannabis products should be classified, which products should qualify as medicines, what evidence should be required before approval and how medicinal use should be distinguished from non-medical use. In Australia and the United Kingdom, medicinal cannabis has consequently been incorporated into existing controlled drug and therapeutic goods frameworks rather than being regulated through an entirely independent system. This approach provides mechanisms for controlling supply and protecting public health, but it also creates regulatory layers that can make the system difficult for practitioners, patients and industry participants to navigate. The challenge is therefore not simply the absence of regulation, but the complexity, interaction and adaptability of existing regulatory regimes. Where different legislative and institutional requirements operate simultaneously, regulatory uncertainty may emerge concerning prescribing, product approval, professional responsibility and permissible therapeutic use. Thus, the results suggest that regulatory complexity is a fundamental governance issue because the effectiveness of medicinal cannabis regulation depends on whether different components of the legal framework operate coherently rather than independently.

Australia provides a particularly important example of this regulatory complexity. Following the legalisation of medicinal cannabis at the federal level in 2016, responsibility for governance has involved the Therapeutic Goods Administration, state and territory authorities and professional regulatory bodies. The resulting framework has enabled a substantial expansion of medicinal cannabis prescribing, but its multi-level character has also created coordination and implementation challenges. Lim and Lim (2026) identify continuing difficulties associated with the interaction between federal and state regulatory requirements, professional knowledge, product supply and the integration of medicinal cannabis into mainstream healthcare. MacPhail et al. (2022) similarly demonstrated rapid growth in medicinal cannabis prescribing during the first five years of the Australian framework, particularly through the Special Access Scheme Category B pathway. The significance of these findings is that regulatory expansion itself can generate new governance pressures. As the number of patients, prescribers and products increases, regulators must ensure that the framework remains capable of maintaining appropriate standards of prescribing, product quality, safety monitoring and professional accountability. The problem is therefore one of regulatory capacity as well as regulatory design. A framework that is sufficiently restrictive to control potential harms may impose administrative burdens that discourage appropriate prescribing, whereas a framework that facilitates rapid expansion may face difficulties in ensuring consistent clinical standards and monitoring. Evidence from Australian practitioners illustrates this tension. Dobson et al. (2024) identified four major influences on prescribing: the clinical capabilities required to prescribe, the status of medicinal cannabis as an unapproved therapeutic good in many circumstances, negative professional attitudes towards prescribers and divergent beliefs regarding its clinical utility. These findings demonstrate that regulation operates through professional behaviour as well as statutory rules. Even where legislation establishes a lawful pathway, uncertainty regarding clinical evidence, professional responsibility and appropriate prescribing practice can influence how that pathway operates in practice. Regulatory challenges therefore arise not only from the formal complexity of Australian law but also from the interaction between regulatory requirements and the professional discretion of those responsible for implementing them.

The United Kingdom presents a different but related regulatory challenge. Cannabis remains a controlled drug under the Misuse of Drugs Act 1971, while amendments to the Misuse of Drugs Regulations 2001 in November 2018 created a legal pathway for cannabis-based products for medicinal use to be prescribed by specialist doctors. Nevertheless, only a limited number of cannabis-based medicinal products have marketing authorisation, meaning that most products prescribed within the specialist framework remain unlicensed. The UK framework therefore attempts to reconcile two regulatory objectives: maintaining strict controls over cannabis as a controlled substance while permitting carefully restricted therapeutic use. The House of Commons Library (2025) confirms that cannabis-based medicines can be prescribed by specialist doctors, but that few products have product licences. This creates an important regulatory distinction between legal availability and regulatory approval. A product may be legally prescribed within the specialist framework without having undergone the conventional marketing authorisation process applicable to fully licensed medicines. Consequently, prescribers must operate within a regulatory environment in which evidence, clinical responsibility and professional confidence are particularly important. Nutt et al. (2020) identified concerns regarding the evidence base, prescriber willingness, professional education, funding and institutional arrangements as significant barriers to the implementation of the 2018 reforms. Although these findings should be interpreted in their historical context, they remain relevant to understanding why legislative reform did not automatically produce widespread clinical adoption. The UK experience therefore illustrates a central regulatory paradox: the government may create a lawful pathway without creating the institutional and professional conditions necessary for that pathway to be routinely used. This distinction is particularly important when evaluating the effectiveness of medicinal cannabis legislation. Regulatory success cannot be measured solely by the enactment of legislation or the removal of cannabis from a more restrictive legal category; it must also be assessed according to whether the resulting framework provides sufficient clarity regarding prescribing responsibilities, product standards, clinical evidence and professional accountability.

A further regulatory challenge identified by the results concerns quality, safety, efficacy and the regulation of an expanding range of cannabis products. Medicinal cannabis regulation must address not only whether cannabis may be used therapeutically but also what constitutes an acceptable medicinal product, how its cannabinoid content and potency should be controlled, what manufacturing standards should apply and what evidence should be required to establish safety and efficacy. Jardim and Delgado Charro (2025) found that the regulatory landscape for cannabis-based medicines remain complex and that relatively few products have received formal approval across major regulatory agencies. Their findings also highlight the market gap created when consumer cannabis products become available more rapidly than evidence based medicinal products can be developed and approved. This creates a significant governance problem because regulators must distinguish between products that are manufactured and evaluated as medicines and products marketed with therapeutic claims without equivalent regulatory scrutiny. Product diversity further complicates this task because differences in cannabinoid composition, concentration, formulation and route of administration may influence both therapeutic effects and risks. At the same time, regulators face the continuing difficulty of making policy decisions in an area where the evidence base is developing and remains uneven across conditions and products. These issues have ethical as well as technical implications. Sagy et al. (2018) emphasised that medical cannabis raises ethical questions concerning patient autonomy, informed decision making, evidence of benefit and harm, and the responsibilities of healthcare professionals. Regulatory uncertainty may therefore produce two opposing risks: excessive restriction may prevent potentially beneficial treatment from reaching patients, while insufficient regulation may expose patients to products of uncertain quality or encourage inappropriate therapeutic claims. The regulatory challenge is consequently one of proportionate regulation, in which controls are sufficiently robust to protect patients without unnecessarily preventing legitimate therapeutic innovation. This requires continuous review of product standards, manufacturing requirements, clinical evidence and post market monitoring as the medicinal cannabis market evolves.

Finally, the findings indicate that regulatory challenges should be understood as dynamic governance problems rather than temporary obstacles associated with the initial legalisation of medicinal cannabis. Both Australia and the United Kingdom demonstrate that once medicinal cannabis is incorporated into the healthcare system, regulators must continuously adjust the relationship between drug control, medicines regulation, professional practice, scientific evidence and patient protection. Australia illustrates the difficulties associated with a rapidly expanding and multi-level regulatory system, where increased prescribing places greater demands on coordination, professional competence, safety monitoring and regulatory oversight. The UK illustrates a different

problem in which a formally established specialist prescribing pathway remains constrained by the limited number of licensed products, evidence considerations and professional gatekeeping. These differences nevertheless point to a common conclusion: regulatory effectiveness depends on the coherence between legal rules and the institutions responsible for implementing them. Fragmented responsibilities can produce uncertainty; insufficient professional guidance can discourage appropriate prescribing; inadequate product regulation can undermine patient safety; and slow adaptation can leave legislation disconnected from scientific and clinical developments. The results therefore support a governance model based on regulatory clarity, inter agency coordination, evidence informed decision making, professional education, proportionate product regulation and continuous evaluation. Such an approach is particularly important because medicinal cannabis regulation is not static. As scientific evidence develops, new formulations enter the market and patient demand changes, existing regulatory frameworks must be capable of adaptation without compromising safety or legal certainty. For Australia and the United Kingdom, the central regulatory challenge is consequently not whether medicinal cannabis should be regulated, but how regulation can remain sufficiently controlled, coherent and evidence informed while responding to the evolving therapeutic, clinical and public health dimensions of medicinal cannabis. This finding provides an important basis for the subsequent analysis of access and implementation, because regulatory complexity, evidence uncertainty and professional ultimately determine how effectively the legal framework is translated into practice.

The Relationship between Medicinal Cannabis Governance and Legal Framework

The results demonstrate that the legal framework is the fundamental component through which medicinal cannabis governance is established, defining the legal status of cannabis, the institutional allocation of regulatory authority, the conditions under which medicinal use is permitted, and the mechanisms through which production, supply and prescribing are controlled. At the international level, medicinal cannabis regulation operates within the broader framework of international drug control, particularly the United Nations Single Convention on Narcotic Drugs 1961, which permits the use of controlled narcotic drugs for medical and scientific purposes subject to regulatory controls.

National legal systems subsequently translate these international obligations into different regulatory models. Belackova et al. (2018) demonstrate that medicinal cannabis frameworks can be understood through two central dimensions: the regulation of cannabis supply and the authorisation of patients to access cannabis for therapeutic purposes. These dimensions are important because a legal framework must simultaneously regulate the production and quality of cannabis products and establish lawful mechanisms through which patients can obtain them. The international literature illustrates considerable variation in how these objectives are balanced. Canada, for example, developed a distinct framework for medical cannabis before subsequently introducing the Cannabis Act 2018, which established a broader legal framework for both medical and non-medical cannabis (Cox, 2021). The United States presents a substantially different model because federal law continues to prohibit cannabis while individual states have established their own medical cannabis regimes, creating a complex relationship between federal and state law (Mead, 2019).

These comparative experiences demonstrate that the legal framework does more than determine whether medicinal cannabis is lawful. It establishes the boundaries within which regulatory institutions, healthcare professionals, patients and commercial actors operate. Consequently, the results indicate that the legal framework should be regarded as the structural foundation of medicinal cannabis governance, because subsequent regulatory arrangements concerning licensing, prescribing, product standards, cultivation, supply and professional accountability depend upon the legal classification and statutory authority established by the state.

The existence of a legal pathway, however, does not necessarily indicate that the framework is simple or coherent. Rather, medicinal cannabis frequently remains subject to multiple layers of controlled drug legislation, medicines regulation and healthcare regulation, creating the possibility of overlapping responsibilities and regulatory uncertainty. This finding provides the conceptual basis for examining how these legal arrangements operate specifically in Australia and the United Kingdom.

In Australia, the legal framework is characterised by a combination of federal therapeutic goods and controlled drug legislation together with state and territory regulation of medicines and prescribing. The federal framework

was substantially established following amendments to the Narcotic Drugs Act 1967 in 2016, which facilitated the cultivation and production of cannabis for medicinal and research purposes under Commonwealth licensing and regulatory controls. The Therapeutic Goods Act 1989 provides the principal federal framework for regulating therapeutic goods, while the Therapeutic Goods Administration (TGA) administers important aspects of medicinal cannabis regulation. Most medicinal cannabis products accessed in Australia remain unapproved therapeutic goods rather than products included in the Australian Register of Therapeutic Goods (ARTG). Consequently, access is commonly facilitated through regulatory pathways such as the Special Access Scheme (SAS) and Authorised Prescriber (AP) scheme.

Under the SAS, for example, access to unapproved medicinal cannabis may occur on a case-by-case basis, with SAS-B requiring an application to the TGA for approval to supply an unapproved product to an individual patient. This structure demonstrates that Australian governance distinguishes between legal recognition of medicinal cannabis and ordinary marketing authorisation of a medicine. The distinction is significant because the TGA states that it has not assessed the quality, safety, efficacy or performance of unapproved products accessed through the SAS or AP pathways in the same manner as products included in the ARTG. The framework therefore incorporates controlled flexibility: patients may obtain access to products that have not received full marketing approval, but access is subject to specific regulatory pathways and professional responsibilities. The Australian model can consequently be characterised as a regulated access framework rather than unrestricted legalisation.

The legal framework also extends beyond patient access to cultivation, production and manufacture, with the Office of Drug Control playing an important role in the regulation of cannabis as a controlled drug. The continuing evolution of the Australian framework is evident from recent regulatory reviews concerning unapproved medicinal cannabis products and concerns about whether existing oversight remains appropriate as the number and variety of products increase. Thus, Australia's legal framework demonstrates the advantages and limitations of a multi layered model: it provides several lawful mechanisms for medicinal use while simultaneously creating a regulatory structure that requires interaction between therapeutic goods regulation, controlled drug regulation and state and territory requirements.

The United Kingdom adopts a different legal framework in which medicinal cannabis remains embedded within a relatively restrictive controlled drugs regime. The critical legislative change occurred on 1 November 2018, when cannabis-based products for medicinal use in humans were moved into Schedule 2 of the Misuse of Drugs Regulations 2001, thereby creating a lawful route for their prescription in strictly controlled circumstances. The reform did not amount to general legalisation of cannabis. Cannabis continued to be controlled under the Misuse of Drugs Act 1971, while products that did not satisfy the statutory definition of cannabis-based products for medicinal use remained subject to the existing controlled drug restrictions. The framework specifically permits specialist doctors on the General Medical Council specialist register to prescribe cannabis-based products for medicinal use, while general practitioners cannot independently initiate prescriptions for unlicensed cannabis-based medicinal products.

The legal framework also distinguishes between licensed and unlicensed products. The UK Government explains that, apart from products such as Sativex, most cannabis-based products for medicinal use have historically been unlicensed, and the regulatory framework therefore imposes additional restrictions on their prescribing and supply. This produces a governance model based strongly on specialist professional gatekeeping and controlled prescribing. The legal framework consequently seeks to reconcile two potentially competing objectives: maintaining strict control over cannabis as a controlled drug while allowing specialist clinicians to use cannabis-based products where there is a clinical justification.

The distinction between the Australian and UK models is therefore significant. Australia has developed multiple access pathways for unapproved medicinal cannabis products through the therapeutic goods regulatory system, whereas the UK has established a more narrowly defined specialist prescribing pathway within its controlled drugs regime. Nevertheless, both frameworks demonstrate that legal recognition is accompanied by substantial regulatory conditions. The UK framework is currently also subject to further scrutiny: in 2025, the Advisory Council on the Misuse of Drugs initiated a review of the impact of the 2018 changes, including whether the reforms achieved their intended effects and whether they produced unintended consequences. This continuing

review illustrates that medicinal cannabis legislation is not static; legal frameworks must evolve as evidence, clinical practice, patient demand and regulatory experience develop.

Comparatively, the findings reveal that Australia and the United Kingdom have adopted different legal mechanisms to achieve a similar governance objective: permitting controlled therapeutic use while maintaining the regulatory controls associated with cannabis as a controlled substance. Australia's framework is characterised by a broader regulatory architecture involving therapeutic goods legislation, controlled drug legislation, federal regulatory agencies and state and territory requirements. Its principal legal challenge lies in managing the interaction between these different layers while ensuring that the framework remains capable of controlling an expanding market and maintaining appropriate standards for unapproved products. The UK framework is comparatively more centralised around controlled drug legislation and specialist prescribing, with access strongly dependent on the professional judgement of specialist doctors and the regulatory status of individual products. The two systems therefore differ not only in the scope of legal access but also in the way regulatory authority is exercised. This distinction is consistent with the broader regulatory literature, which emphasises that medicinal cannabis frameworks can be structured along different combinations of supply controls and patient authorisation mechanisms (Belackova et al., 2018).

Importantly, neither model represents unrestricted access. In Australia, legal access to many products is dependent on specific regulatory pathways such as the SAS and AP schemes, while in the UK, specialist prescribing and additional controls constrain access to cannabis-based medicinal products. The comparative findings therefore challenge the assumption that the legalisation of medicinal cannabis necessarily produces straightforward patient access. Instead, legalisation creates the legal possibility of access, while the detailed architecture of the legal framework determines the conditions under which that possibility can be realised.

This distinction is particularly relevant to governance because excessive fragmentation may create uncertainty and administrative burdens, whereas excessive restriction may limit the practical utility of the legal framework. At the same time, insufficient regulation could undermine product quality, patient safety and public confidence. Effective legal governance therefore requires an appropriate balance between flexibility and control, with clearly defined institutional responsibilities and mechanisms for adapting the law to emerging evidence and regulatory experience.

Overall, the results indicate that the legal framework is both an enabling mechanism and a potential source of constraints within medicinal cannabis governance. In Australia and the United Kingdom, legislation has moved beyond absolute prohibition by creating lawful pathways for medicinal use, but both jurisdictions have retained significant controls reflecting the continuing classification of cannabis as a controlled substance.

The Australian model demonstrates how medicinal cannabis can be integrated into a therapeutic goods framework through mechanisms for accessing both approved and unapproved products, while the UK model demonstrates how medicinal cannabis can be incorporated into a controlled drugs regime through specialist prescribing. The principal contribution of this comparison is therefore the identification of a legalisation–regulation continuum, rather than a simple distinction between prohibition and legalisation. At one end, prohibition prevents lawful therapeutic access; at the other, a highly permissive system may create concerns regarding misuse, product quality and commercialisation. Australia and the UK occupy intermediate positions in which medicinal use is legally recognised but remains subject to substantial regulatory conditions.

The effectiveness of these frameworks consequently depends on whether the law is sufficiently clear to guide regulators and healthcare professionals, sufficiently flexible to respond to scientific and clinical developments, and sufficiently protective to safeguard patients and public health. Recent regulatory reviews in both jurisdictions demonstrate that this process remains ongoing: Australia has been reviewing the safety and regulatory oversight of unapproved medicinal cannabis products, while the UK has been reviewing the consequences of the 2018 reforms.

The findings therefore suggest that the legal framework should not be viewed as a fixed set of rules but as the institutional foundation through which medicinal cannabis governance is continuously negotiated and implemented. This finding also provides the basis for the subsequent analysis of regulatory challenges and access

and implementation, because the complexity, scope and design of the legal framework directly influence whether medicinal cannabis can be delivered in a manner that is safe, coherent, accessible and responsive to patient needs.

CONCLUSION

This study examined the regulatory frameworks, governance arrangements and implementation challenges associated with medicinal cannabis in Australia and the United Kingdom through a qualitative research-landscape analysis supported by Scopus AI. The analysis of the Summary, Expanded Summary and Concept Map demonstrates that medicinal cannabis regulation has developed considerably in both jurisdictions, but that legal recognition does not necessarily translate into meaningful, equitable or routine patient access. The central finding is that legalisation should be understood as the beginning of regulatory implementation rather than its endpoint. The effectiveness of medicinal cannabis reform ultimately depends on the coherence of the legal framework, the capacity of regulatory institutions, the preparedness of healthcare professionals, the availability and affordability of products, the strength of clinical evidence, and the mechanisms established to protect patient safety.

The comparative findings reveal both similarities and differences between Australia and the United Kingdom. Australia has developed a relatively active medicinal cannabis market within a multi-layered governance structure involving federal regulators, state and territory authorities and professional bodies. The expansion of prescribing demonstrates that the Australian framework has successfully created a lawful pathway for substantial growth in medicinal cannabis use.

Nevertheless, the Australian experience continues to be affected by regulatory complexity, overlapping responsibilities, administrative requirements, professional knowledge gaps, cost, geographical inequalities, product availability and supply-related difficulties. In contrast, the United Kingdom has adopted a more restrictive model centred on specialist prescribing, while cannabis remains subject to controlled-drug regulation and most cannabis-based medicinal products remain unlicensed. Consequently, the UK experience demonstrates a different form of implementation challenge: although a legal pathway exists, restrictive prescribing arrangements, evidence uncertainty, professional confidence, funding and institutional reluctance can limit the translation of legal reform into routine clinical access.

Despite these institutional differences, the two jurisdictions demonstrate a common regulatory tension between control and access. Regulatory controls are necessary to address risks relating to misuse, diversion, product quality, adverse effects and inappropriate prescribing. However, excessive regulatory requirements may create administrative, professional and financial barriers that prevent eligible patients from accessing lawful treatment. The findings therefore indicate that patient access should not be conceptualised as a simple consequence of legalisation. Rather, it is the outcome of an interconnected regulatory chain involving legal rules, regulatory authorities, prescribing pathways, healthcare professionals, product availability, affordability and patient circumstances. A weakness at any point in this chain may reduce the effectiveness of the overall framework.

The study also demonstrates that professional capacity is a critical component of medicinal cannabis governance. The legal authority to prescribe does not automatically result in professional willingness or confidence to prescribe. Limited knowledge, uncertainty concerning clinical evidence, concerns about safety and professional responsibility, and insufficient training may discourage healthcare professionals from using available regulatory pathways. Pharmacists are similarly important because they operate at the interface between the regulatory system and patients through dispensing and patient counselling. These findings suggest that effective governance must extend beyond legislation and institutional structures to include professional education, clinical guidance, continuing professional development and clear accountability mechanisms.

Another significant finding concerns the relationship between clinical evidence and regulation. Evidence uncertainty may encourage regulators and healthcare professionals to adopt cautious or restrictive approaches. However, overly restrictive access may simultaneously limit opportunities to generate real-world evidence concerning the effectiveness and safety of medicinal cannabis. This creates a regulatory cycle in which limited evidence contributes to professional caution, professional caution restricts prescribing, and restricted prescribing may constrain the development of broader clinical and real-world evidence. The findings therefore support an

evidence-informed but adaptive regulatory approach in which uncertainty is managed through appropriate safeguards, monitoring and continuing research rather than treated as a permanent justification for restricting therapeutic access.

Theoretically, the study contributes to the understanding of medicinal cannabis regulation by demonstrating that legalisation is not a single legal event but an ongoing process of regulatory implementation. The effectiveness of reform depends upon the interaction between legislation, administrative institutions, professional governance, and clinical practice. Practically, the findings suggest that policymakers should focus not only on changing the legal status of medicinal cannabis but also on developing the supporting governance infrastructure necessary to make lawful access workable.

Several limitations should be acknowledged. First, the research landscape component relies on Scopus AI Analytics as a supplementary tool for identifying literature and thematic relationships. Although the outputs were subject to human review and the underlying sources were independently examined, AI-assisted mapping may not capture all relevant scholarship or legal materials.

Second, the research landscape represents a temporal snapshot based on the Scopus AI analysis conducted on 7 September 2026. Because Scopus is continuously updated and Scopus AI generates dynamic outputs, subsequent searches may produce additional publications, different conceptual relationships. The findings should therefore not be interpreted as a permanently fixed representation of the literature.

Third, the study is limited by the search strategy and database coverage. The search was deliberately constructed around medicinal cannabis, Australia and the United Kingdom, regulatory concepts and implementation challenges. While this approach ensured alignment with the research objectives, potentially relevant studies using different terminology or indexed outside the selected conceptual boundaries may not have been captured. Similarly, reliance on Scopus-indexed literature may exclude relevant government reports, professional guidance, unpublished research and other forms of grey literature.

Fourth, the qualitative interpretive approach does not establish statistical prevalence or causal relationships between regulatory arrangements and patient outcomes. The identified relationships should therefore be understood as patterns and conceptual associations within the literature rather than evidence that a particular regulatory mechanism directly causes a particular outcome. This limitation is consistent with the methodological purpose of the study, which was to identify patterns and relationships rather than to conduct statistical testing.

Future research should build upon these findings through empirical and comparative studies involving patients, healthcare professionals, regulators and other stakeholders. Patient-centred research would be particularly valuable in determining how regulatory requirements affect actual experiences of access, affordability, continuity of treatment and satisfaction with medicinal cannabis services. Research involving doctors and pharmacists could further investigate whether education, clinical guidelines and professional support translate into greater confidence and more consistent prescribing and dispensing practices.

Further studies should also undertake jurisdiction-specific legal and regulatory analysis to examine how statutory provisions, regulatory guidelines and professional standards operate in practice. Comparative research could extend the analysis beyond Australia and the United Kingdom to other jurisdictions that have legalised medicinal cannabis while retaining restrictions on recreational cannabis use. Such research would enable identification of different regulatory models and determine which governance mechanisms are associated with more effective and equitable access.

Future research could extend the analysis through detailed examination of state and territory legislation in Australia and the devolved legal arrangements within the United Kingdom. Empirical research involving prescribers, pharmacists, patients, regulators, and other stakeholders would also assist in determining how legal requirements operate in practice. Further research could examine the effectiveness of shared-care arrangements, the impact of professional education, the operation of medicinal cannabis driving laws, and the relationship between regulatory burden and patient access.

Finally, research should additionally investigate the relationship between regulatory barriers and unregulated access. The present research landscape suggests that when lawful medicinal cannabis pathways are perceived as too costly, restrictive or difficult to navigate, some patients may turn towards unregulated sources. Further empirical investigation is required to establish the extent of this relationship and to determine whether proportionate regulatory reform can improve legitimate access while reducing reliance on unregulated markets.

Overall, the experiences of Australia and the United Kingdom demonstrate that the central challenge of medicinal cannabis regulation is not simply the transition from prohibition to legal recognition, but the development of a regulatory system that can reconcile patient access, safety, professional accountability, evidence, market regulation and public health protection. The findings indicate that effective governance requires a balance between regulatory control and therapeutic accessibility. A system that is excessively restrictive may undermine the purpose of legalisation by creating practical barriers to treatment, whereas insufficient oversight may expose patients to safety, quality and misuse risks. Medicinal cannabis regulation should therefore be understood as an ongoing process of adaptive, evidence-informed and patient-centred governance. The principal lesson from Australia and the United Kingdom is that the success of legal reform should ultimately be measured not by the existence of legislation alone, but by whether that legislation is translated into a coherent, safe, affordable and equitable pathway through which patients can obtain appropriate therapeutic treatment.

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