

White Paper Series

The Complexities of the Medicinal Cannabis Market from an Australian Viewpoint

Part 1: On the fence between prescription and over-the-counter: why medicinal cannabis is a unique market segment

SASHI ANANTHAM, Senior Consultant, Management Consulting Group

JACK SHEPPARD, Consultant, Management Consulting Group

AMANDA BALTZER, Consultant, Management Consulting Group

WAI FONG CHAN, Analyst, Management Consulting Group



Table of contents

Introduction to the White Paper Series	3
Part 1	4
Medicinal cannabis market complexities	4
Formulations and the over-the-counter aspects of medicinal cannabis	4
Intellectual property protection	5
Clinical trials and regulations	5
Sales and marketing	6
Market access and prescribing considerations	7
Conclusion	7
References	8

Introduction to the White Paper Series

Medicinal cannabis shares common characteristics with both prescription and over-the-counter (OTC) markets, making it a unique market segment with specific restrictions and complexities. Since the start of the new millennium, there has been an upturn in countries that have fully or partially de-criminalised or legalised medicinal cannabis on federal and/or regional levels. This has resulted in substantially new economic activity from what was previously an illegal trade. At present, there is no uniformity in the legalisation of medicinal cannabis across these countries. This creates complexities in a market which is somewhat burdened by limited yet growing clinical evidence. This is largely due to historical restrictions on cannabis research, and affected by concerns over the enforceability of medicinal cannabis patents. The white paper series aims to delve into these complexities by comparing the legalisation and commercialisation process of medicinal cannabis across selected countries.

In this white paper series, we will evaluate the medicinal cannabis market in Australia and how it compares to five other Organisation for Economic Co-operation and Development countries, namely Canada, Germany, New Zealand, United Kingdom and the United States. The research will illuminate the similarities and differences to both the pharmaceutical and OTC markets, and the type of hurdles that are faced by manufacturers. Globally, access and uptake of medicinal cannabis is a recent development, especially when compared to established pharmaceutical therapy areas. When compared to OTC markets such as probiotics, or vitamins, the medicinal cannabis market shows some similarities and peculiarities including but not limited to brand-agnostic regulations, patient-driven advocacy of product use and formulation-agnostic indication claims.

Throughout the series, we will discuss in detail the various regulatory pathways that countries and regions have implemented, the various routes for market access to medicinal cannabis, global reimbursement trends, importing and exporting pathways, advocacy, and lastly, how all of these aspects have affected the current pharmaceutical market. In the subsequent parts of this series, each of the following sections will be discussed in detail and updated regularly to account for the highly dynamic medicinal cannabis market.

Insights will be generated from IQVIA's commercial expertise and historical global medicinal cannabis client engagement experience. Client specific or confidential information will not be included in any reports. This series is fully funded by IQVIA and has not been financed by third-parties.

Part 1: On the fence between prescription and over-the-counter: why medicinal cannabis is a unique market segment

Medicinal cannabis market complexities

Medicinal cannabis was legalised in Australia at the federal level in 2016 and the market is expected to grow. Globally, medicinal cannabis sales have increased since the 1990s when a selection of US states legalised medicinal cannabis use; this was shortly followed by Canada’s federal legalisation in 2001. Since then, North America and Europe’s medicinal cannabis industries have boomed. However, there is no consensus on the exact sales value or figures on consumption because these differ greatly across the sources^{1,2,3,4,5,6,7}. Since medicinal cannabis is primarily sold with prescription, this makes it similar to that of traditional pharmaceuticals. Yet, a substantial portion of the marketing and sales activities undertaken by the medicinal cannabis manufacturers resemble that of over-the-counter market behaviours. The numerous forms and formulations are the primary driver of this distinction.

Formulations and the over-the-counter aspect of medicinal cannabis

Medicinal cannabis comes in multiple forms, each with multiple formulations, and are all covered under the umbrella-term of medicinal cannabis (Fig. 1). The cannabis plant contains over one hundred cannabinoids, but the primary therapeutic molecules are cannabidiol (CBD) and tetrahydrocannabinol (THC). The various formulations can include everything from crude plant extracts, which contain all cannabinoids isolated from that specific strain, to purified CBD or THC. The formulations are generally based off the CBD:THC ratio and are labelled as such, similar to the vitamin market, where the molecule is more recognisable than the brand. There are several therapeutic ratios, and this can vary markedly depending on the intended therapeutic use or indication.

Figure 1: Medicinal cannabis forms and combinations.

MEDICINAL CANNABIS		
Formulations	Ratios	Routes of Administration
<ul style="list-style-type: none"> • Crude plant extracts • Synthetic cannabinoids • Extracted cannabinoids • Pure cannabinoids 	<ul style="list-style-type: none"> • 1:1 THC:CBD ratio • 1:2 THC:CBD ratio • 1:3 THC:CBD ratio • 1:4 THC:CBD ratio • 1:10 THC:CBD ratio • 1:20 THC:CBD ratio • CBD only (or synthetic) • THC only (or synthetic) 	<ul style="list-style-type: none"> • Tincture • Raw oil • Buccal spray • Transdermal gel • Transdermal patches • Suppositories • Capsules • Dried plant material
<p><i>Medicinal cannabis can be any mix of these options which all require different clinical studies, have different biological effects, and have clinical evidence in different indications</i></p>		

The two branded products Sativex and Epidiolex have CBD:THC ratios of 1:1 and 1:0 respectively. These brands have followed the general prescription product route to market. The vast array of other medicinal cannabis products are akin to OTC products, where purchasing relies on the molecule ratio rather than the brand, and this speaks to the fact that the market is in its infancy.

“Medicinal cannabis shares common characteristics with both prescription and OTC markets, making it a unique market segment with specific restrictions and complexities.”

Each of these formulations can be supplied to patients in multiple forms, e.g. tinctures, raw oils, buccal sprays, transdermal gel/patches, suppositories, capsules, and dried plant material; all of which differ in their rate of onset, and bioavailability of the active components (Fig. 1). These various combinations of forms and routes of administrations create complexities when it comes to clinical trials, intellectual property, regulations and genericisation. Although some products have gone through the traditional prescription pharmaceutical route to market, there appears to be companies that are leveraging a more OTC-like approach.

Intellectual property protection

As an emerging market, the medicinal cannabis industry presents immense opportunities for innovation. However, given the long history of legalising access, it is of no surprise that there would be challenges surrounding the securing of intellectual property (IP) rights. Prior to the legalisation of medicinal cannabis in Australia, it was difficult for innovators to obtain patent protection for subject matter relating to cannabis plants because the *Patents Act 1990* (Cth) provides that a patent may not be

granted for a subject matter that would be “contrary to law”. Since the legitimisation of medicinal use, patents relating to cannabis related subject matter may be granted because there is now a legal use for the invention. Medicinal cannabis related products and the plants that they are derived from are eligible for protection across a range of IP rights, including plant patents, plant breeder rights and trademarks. In particular, patent protection is available in Australia for newly identified, naturally-occurring proteins and small molecules isolated from cannabis plants as long as the patentability requirements are satisfied, specifically the novelty, usefulness, non-obviousness, and inventive step. This contrasts markedly with the situation in the US where naturally-occurring proteins are not eligible for patent protection. There is also a strong interest in IP protections relating to the processing and production techniques of cannabis extract, and for the use of the aforementioned extracts and derivatives as adjuvants to existing therapies and treatments. The factors and complexities that manufacturers and growers need to consider when securing IP rights will vary across countries. Therefore, the importance of adopting a multi-faceted approach in protecting medicinal cannabis will not only help maximise the benefits of the new invention but can help reduce the risk of potential infringement and secure a competitive advantage. Overall, IP protection for medicinal cannabis appears to mimic the framework being used for prescription medications.

Clinical trials and regulations

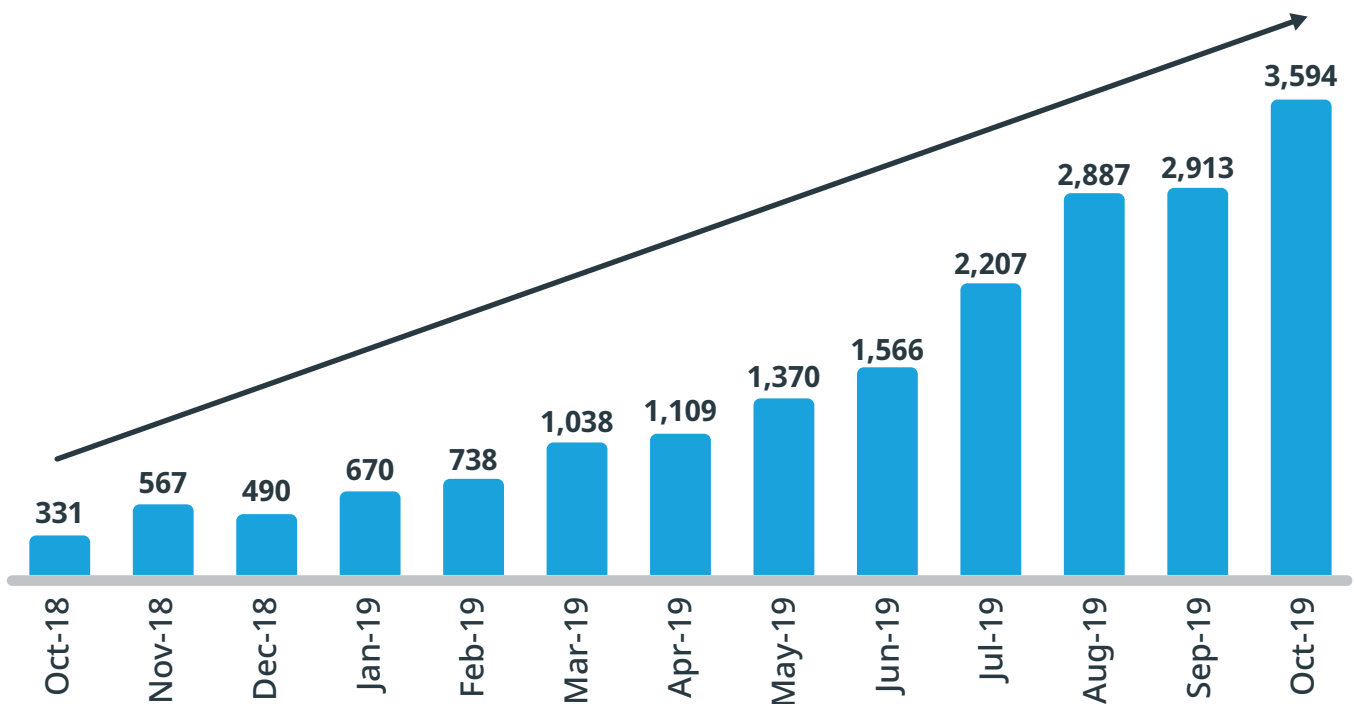
Similar to IP protection, medicinal cannabis clinical trials are subjected to certain considerations and challenges. For example, medicinal cannabis is generally not viewed at the product level, but rather the efficacious CBD:THC ratio is the focal point of the study, and the two primary molecules that make up the trial compound are generic in nature, i.e. they are not considered novel or new chemical entities, therefore only plant breeders rights can be used as IP protection. There is freedom to operate if another product is able to achieve the same ratio.

Hence, when a specific CBD:THC ratio is approved for use for a given indication, e.g. chronic pain, any product that contains the specific ratio can be marketed for that target indication. Manufacturers compete on variations in product quality, concentration, shelf life, delivery format, excipient profile etc. The time, effort, and finances invested into a clinical trial to generate evidence could readily be co-opted by competitors with limited or no clinical program. This naturally causes consternation amongst manufacturers, whose hesitance to invest restricts the availability of high-quality clinical evidence that would support broader cannabis use. This in particular makes the medicinal cannabis market resemble OTC markets more than prescription markets, where clinical trials provide a unique advantage. Moreover, manufacturers who duplicate original claims backed by clinical evidence without an investment of their own are able to undercut prices substantially and could potentially be viewed as generics by regulatory bodies. If public reimbursement was ever considered for medicinal cannabis, it is therefore likely that exclusivity and price premium would be difficult to achieve under the current regulatory framework in Australia.

Sales and marketing

Sales and marketing of medicinal cannabis reflects many similar aspects of both traditional prescription pharmaceutical and OTC marketing. Although medicinal cannabis is only available with a prescription, the labelling and 'approved indications' remain very similar to the OTC market. In the traditional prescription market, the approved marketing indications are for a specific product. However, the indications for medicinal cannabis worldwide tend to be based on the trials and research conducted on the molecule formulation as with the OTC market, rather than the brand itself, like in the prescription market. Overall, the brand level familiarity in Australia and more mature markets globally is not at the same level as the prescription market, as the patient and prescriber knowledge still lies at the molecule level. The medicinal cannabis market has similarities with both the prescription and OTC market however it may be moving towards a more prescription based environment in the near future as certain brands become better recognised, although this remains to be seen.

Figure 2: The Growth of Special Access Scheme (Category B) approved applications for medicinal cannabis.



Source: TGA. (2019). Authorised prescribers. Accessed from: <https://www.tga.gov.au/form/authorised-prescribers>

Market access and prescribing considerations

Although medicinal cannabis has been legal for nearly two decades in many regions of North America, and more recently in Australia and regions of Europe, it is still not as accessible as the traditional pharmaceutical market. This is due to a number of factors, including but not limited to its transition to a legal compound, the stigma surrounding its use, and the restrictions on Research & Development.

In Australia, there are several ways in which patients can access medicinal cannabis. First, patients can enrol in clinical trials for certain medical conditions (e.g. multiple sclerosis, chemotherapy induced nausea and vomiting, epilepsy), however trial availability is limited, thus restricting total patient numbers. Next, an Authorised Prescriber (AP) Scheme exists that allows eligible medical practitioners to become APs of medicinal cannabis products for specific patients (or classes of patients) with certain medical conditions without further Therapeutics Goods Administration approval - 46 APs exist as of October 2019.⁹

A Special Access Scheme (SAS) also exists for practitioners to provide medicinal cannabis once all clinically appropriate treatment options have been exhausted for a given patient's condition. Patients are assessed on a case by case basis and between October 2018 to October 2019, 19,480 patients have accessed medicinal cannabis via this scheme (only numbers for Category B of the SAS are publicly available) (Fig 2)⁹.

The rules that govern which doctors can become APs or prescribe via the SAS are changing, state by state. In November 2019 for instance, Western Australia also allowed GPs to prescribe medicinal cannabis¹⁰, as is the case in New South Wales and Victoria. To date, individual consumers cannot apply to obtain approval to import unapproved medicinal cannabis products⁹.

As the medicinal cannabis landscape evolves, changes are expected to the way products can be prescribed and accessed by patients. If the TGA were to approve and list medicinal cannabis on the Australian Register of Therapeutic Goods, most of the above schemes will likely be replaced by the standard means of access to prescription medication. This will make the medicinal cannabis more akin to the prescription market overall.

CONCLUSION

In this white paper, we have seen that the medicinal cannabis market has several characteristics in common with prescription and OTC medicines making it a unique market segment. Overall, market access for medicinal cannabis appears to have more similarities with prescription medicines whereas clinical trials (or lack thereof), regulations and marketing are currently more aligned to the OTC market. IP protection has similarities with both market types. However, expected legislative changes and the demand for more robust clinical evidence means that the medicinal cannabis market is likely to remain in a constant state of flux. Therefore, the level of similarity to the prescription and OTC markets may change as well.

The next iterations of our white paper series will focus on exploring the topics discussed here (intellectual property protection, clinical trials and regulations, sales and marketing, market access) in more depth, with comparisons of Australia vs. other reference markets. Recent changes to the Australian medicinal cannabis market will also be monitored and discussed.



References

1. IQVIA MIDAS sales data
2. Health Canada
Accessed from: <https://www.canada.ca/en/health-canada/services/drugs-medication/cannabis/research-data/medical-purpose.html>
3. Grand View Research. (2019). Legal Marijuana Market Worth \$66.3 Billion By 2025 CAGR: 23.9%.
Accessed from: <https://www.grandviewresearch.com/press-release/global-legal-marijuana-market>
4. PharmOut. (2019). Cannabis Industry Growth Predictions for 2020- 2025.
Accessed from: <https://www.pharmout.net/cannabis-industry-market-growth-and-predictions-2020-2024/>
5. Imarc Group. (2019). Global Medical Cannabis Market to Reach US\$ 44.4 Billion by 2024, Fostered by Investments in Clinical Trials and R&D.
Accessed from: <https://www.imarcgroup.com/global-medical-cannabis-market>
6. GlobalNewswire. (2019). Medical Marijuana Market To Reach USD 148.35 Billion By 2026 | Reports And Data.
Accessed from: <https://www.globenewswire.com/news-release/2019/05/20/1829108/0/en/Medical-Marijuana-Market-To-Reach-USD-148-35-Billion-By-2026-Reports-And-Data.html>
7. BusinessWire. (2019). Global Medical Marijuana Market 2020-2024 | Evolving Opportunities With Aphria Inc. and Aurora Cannabis Inc.
Accessed from: <https://www.businesswire.com/news/home/20191201005080/en/Global-Medical-Marijuana-Market-2020-2024-Evolving-Opportunities>
8. Therapeutics Goods Administration (2019). Access to medicinal cannabis products.
Accessed from: <https://www.tga.gov.au/access-medicinal-cannabis-products-1>
9. Therapeutics Goods Administration. (2019). Authorised prescribers.
Accessed from: <https://www.tga.gov.au/form/authorised-prescribers>
10. WAtoday. (2019). Rules relaxed as WA GPs get go-ahead to prescribe medical cannabis.
Accessed from: <https://www.watoday.com.au/national/western-australia/rules-relaxed-as-wa-gps-get-go-ahead-to-prescribe-medical-cannabis-20191112-p539va.html>

CONTACT US

iqvia.com/contactus

SASHI ANANTHAM

Senior Consultant

Management Consulting, Strategic Insights & Analytics

E: sashindran.anantham@iqvia.com

AMANDA BALTZER

Consultant

Management Consulting, Strategic Insights & Analytics

E: amanda.baltzer@iqvia.com

JACK SHEPPARD

Consultant

Management Consulting, Strategic Insights & Analytics

E: jack.sheppard@iqvia.com

LOCATIONS

Level 8, 201 Pacific Highway
St Leonards, NSW
Australia

Level 2, 606 St Kilda Road
Melbourne, VIC
Australia