

# MEDICINAL CANNABIS

INFORMATION HAND BOOK



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### BASICS OF MEDICINAL CANNABIS

Medicinal cannabis, also known as medical marijuana, is a proven and effective natural treatment option that has been used for centuries to alleviate a wide range of medical conditions.

Cannabis contains over 100 cannabinoids, including THC and CBD, which have been extensively studied and shown to have significant therapeutic properties.

Research has demonstrated that medicinal cannabis can be an effective treatment for a variety of conditions, including chronic pain, muscle spasms, seizures, inflammation, and nausea and vomiting caused by chemotherapy.

It is also increasingly recognised as a potential treatment for mental health conditions such as anxiety, depression, and PTSD.

## USES AND EFFECTIVENESS

#### CHRONIC PAIN

A meta-analysis of 28 randomised controlled studies found that medicinal cannabis was helpful in treating chronic pain, with a statistically significant reduction in pain intensity compared to placebo<sup>(1)</sup>.

#### MULTIPLE SCLEROSIS

Medicinal cannabis has been shown in studies to improve muscle stiffness and pain associated with multiple sclerosis, with one meta-analysis finding that cannabis-based treatments were more effective than placebo in lowering spasticity in persons with multiple sclerosis<sup>(2)</sup>.

#### NAUSEA AND VOMITING

Medical cannabis has been proven to be useful in lowering chemotherapy-induced nausea and vomiting, with one evaluation of 30 randomised controlled trials finding that cannabis-based drugs were more effective than placebo in reducing these symptoms<sup>(3)</sup>.

#### EPILEPSY

A systematic evaluation of 11 randomised controlled studies indicated that cannabidiol (CBD), a non-psychoactive component of cannabis, reduced seizure frequency in persons with treatment-resistant epilepsy<sup>(4)</sup>.

#### ANXIETY AND DEPRESSION

While research on the effectiveness of medicinal cannabis in the treatment of anxiety and depression is limited, some studies have suggested that cannabis may have potential therapeutic effects in these conditions, with one review reporting that cannabis use was associated with reduced symptoms of depression and anxiety in some people<sup>(5)</sup>.

#### SIDE EFFECTS

Like with any prescription, medicinal cannabis can cause adverse effects, the most prevalent of which are dizziness, dry mouth, and lethargy. Nonetheless, research indicates that medicinal cannabis is generally well-tolerated, with one review stating that major side events are uncommon<sup>(6)</sup>.

### MEDICINAL CANNABIS INDUSTRY OVERVIEW

# Medicinal cannabis is one of the fastest-growing industries globally.

The high efficiency and quick effect of medicinal cannabis products for certain health conditions led to a significant increase in demand, becoming an irreplaceable medicine for thousands of patients.

#### THE OPPORTUNITIES

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- The global medicinal cannabis market is estimated to be worth AUD 80 billion (US\$62.6 billion) by 2024.
  Australia's legal cannabis market size is expected to reach AUD 692 million by 2030.
  Compound Annual Growth Rate 30.1%.
  More than 400 legal medical cannabis products available in the market.
  More than 1965 active Authorised Prescribers.
  - Around 150 licenced medicinal cannabis businesses.

### Medicinal Cannabis in Australia

In Australia, medicinal cannabis has been legal for prescription use since 2016. As of 2021, over 70,000 patients have been prescribed medicinal cannabis, with the majority of prescriptions being for chronic pain and spasticity. The number of medicinal cannabis prescriptions in Australia has been steadily increasing, reflecting the growing acceptance of cannabis as a mainstream medical treatment.

With its demonstrated efficacy and growing acceptance, medicinal cannabis is set to become an increasingly common treatment option in Australia and around the world. As further research is conducted, we can expect to discover even more applications for this powerful natural medicine.

\$692M

EXPECTED AUSTRALIA'S LEGAL CANNABIS MARKET SIZE BY 2030 30.1%

COMPOUND ANNUAL GROWTH RATE

'HCPA is the leader in medicinal cannabis business consulting'

### **KEY BUSINESS OPPORTUNITIES**



#### **CULTIVATION AND PRODUCTION**

Cultivation and production of high-quality cannabis from growing to harvesting.

With the increasing demand for medicinal cannabis products, there is a
pressing requirement for more streamlined and economical production
methods. To meet this demand, numerous companies are now investing in
innovative production processes due to the Australian government's stringent
regulations governing the cultivation and production of medicinal cannabis.



#### MANUFACTURE

Cannabis extraction and supply of finished products. Manufacture of finished dosage forms: dried flower, oil, tablets, etc.

- The Australian government has implemented strict regulations for the manufacture of Medicinal cannabis products, which has led to a growing number of companies investing in GMP-compliant facilities and manufacturing processes.
- The global cannabis extract market is expected to reach USD 28.5 billion by 2027, with a compound annual growth rate (CAGR) of 16.6% from 2020 to 2027, according to a report by Grand View Research.



#### **AUTHORISED PRESCRIBER**

Becoming an authorised prescriber of medicinal cannabis.

Authorised prescribers are healthcare practitioners who have been approved by the Therapeutic Goods Administration (TGA) to prescribe medicinal cannabis to patients with specific medical conditions. This includes general practitioners, specialists, and nurse practitioners.

### The legalisation of medicinal cannabis in Australia has opened up various business opportunities in the cannabis industry.



#### DISPENSARY

Dispensaries are retail outlets that sell medicinal cannabis products to authorised patients.

• Dispensaries require significant investment and expertise in navigating complex regulations, but can be a lucrative business opportunity as the number of dispensaries in Australia is still relatively low.



#### IMPORT

Importation of GMP-compliant cannabis products, manufacture into finished product and supply through authorised pathways.

 According to a report by FreshLeaf Analytics, the value of imported medicinal cannabis products in Australia increased from AUD 38.3 million in 2019 to AUD 52.3 million in 2020.



#### EXPORT

Exportation of medicinal cannabis products or extracts of cannabis.

- Australia is predicted to become the largest cannabis flower exporter globally, with an estimated 11% market share by 2025, according to a report by Prohibition Partners.
- As of August 2021, the TGA had issued 119 licences to export medicinal cannabis products from Australia to other countries, according to a report by Mondaq.



#### RESEARCH

Cannabis research and clinical trials on plant extracts, cannabis products, and cannabinoids to evaluate the safety and effectiveness of cannabis medicine.

 In 2020, the Australian government announced AUD 2 million in funding for medicinal cannabis research to support clinical trials and studies to evaluate the safety and effectiveness of medicinal cannabis products.



## HOW WE CAN HELP YOU

Australia has a robust federal and state regulatory framework enforcing strict requirements for medicinal cannabis businesses. Complying with regulations and understanding industry developments can be challenging. That's why our specialists at HCPA are here to support you through the entire process.

We provide an all-in-one solution and support you in every stage of your business formation - from business planning, registration, finding site location, developing facility design, and getting all the required licenses and permits.

### **HCPA SOLUTION**

We offer consulting solutions to all stakeholders:

- · Cultivators and Producers
- Manufacturers
- Importers and Exporters
- Distributors
- Scientific Researchers
- Medical Practitioners

#### **BUSINESS PLANNING**

We provide complete information on market analysis, regulatory requirements, and recommendations necessary to plan and structure your business. We will assist you in developing the business plan required for getting your license.

#### LICENCES AND PERMITS

We will explain the whole process and assist you to get all the licences and permits such as ODC, TGA and relevant State licencing required to start your medicinal cannabis business - from preparing the licence applications to developing the required documentation.

#### FACILITY DESIGN AND BUILD

HCPA will assist you in locating an appropriate site for your business operations, designing the facility in compliance with the regulatory requirements, getting the required planning and building permits, and organising the construction of your facility.

#### DISPENSARY

Our team of experts are here to provide unparalleled guidance, helping you conquer regulatory challenges and assist you in setting up your own dispensary.

#### **QUALITY MANAGEMENT SYSTEM**

We will assist you in developing and refining a quality management system within your organisation in order to meet the regulatory requirements and ensure the high quality of all business operations, processes and procedures.

#### **EQUIPMENT & PERSONNEL**

Our team will guide you in recruiting suitable staff and finding relevant equipment for your business.

#### **TRAINING & SUPPORT**

If you struggle with certain aspects of running your business, our professional consultants will support and mentor you through training online, over the phone or face-to-face.

#### **AUTHORISED PRESCRIBER**

If you are a medical practitioner looking to become an authorised prescriber, we will explain the application pathways and guide you through the registration process.

### **GROWTH ADVISORY SERVICES**

In a fast-paced and competitive industry, achieving success can be challenging. At HCPA, our specialists are committed to providing tailored support for your business growth. We understand the complexities of the modern business world and offer a full suite of services, including market research, business strategies and operational execution.

Whether you're a startup aiming for rapid growth or an established enterprise seeking to enhance your market position, our experts will work closely to create effective strategies that drive tangible results.

With HCPA as your dedicated partner, you can confidently navigate the dynamic business landscape and pursue your goals with assurance. Together, we'll empower your business to thrive and prosper amidst the everevolving industry.

# GROWING PROFITABILITY

Experience the power of our customized solutions, propelling your business towards resounding success in this thriving sector. Together, we will navigate challenges and unlock the full potential of your enterprise.

Embrace a transformative journey with us as we tailor strategies to suit your unique needs, ensuring unparalleled growth and achievement in the ever-evolving business landscape.

### **HCPA SOLUTION**

Growth advisory

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- Strategy development.
- Business transformation.
- Service delivery improvement.
- Business turnaround.
  - Profit improvement program for busiensses.

If you're interested in exploring the opportunities presented by the medicinal cannabis industry in Australia, now is the time to act. Þ

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Contact us today to learn more about how we can help you navigate the regulatory landscape and establish your presence in this exciting and rapidly growing industry.

1. Lynch ME, Campbell F. Cannabinoids for treatment of chronic non-cancer pain: a systematic review of randomized trials. Br J Clin Pharmacol. 2011 Nov;72(5):735-44.

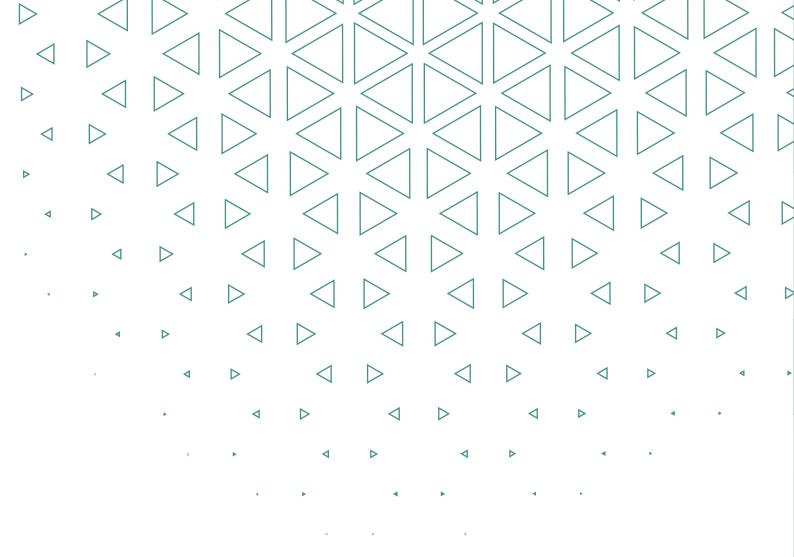
2. Brouwer N, Mekhail N, Verrico L, et al. Medical cannabis in multiple sclerosis: A systematic review. Med Clin (Barc). 2018 Apr 23;150(8):311-318.

3. Smith LA, Azariah F, Lavender VT, et al. Cannabinoids for nausea and vomiting in adults with cancer receiving chemotherapy. Cochrane Database Syst Rev. 2015 Nov 12;(11):CD009464.

4. Lattanzi S, Brigo F, Trinka E, et al. Efficacy and safety of cannabidiol in epilepsy: a systematic review and meta-analysis. Drugs. 2018 Nov;78(17):1791-1804.

5. Cuttler C, Spradlin A, McLaughlin RJ. A naturalistic examination of the perceived effects of cannabis on negative affect. J Affect Disord. 2018 Feb;235:198-205.

6. MacCallum CA, Russo EB. Practical considerations in medical cannabis administration and dosing. Eur J Intern Med. 2018 Mar;49:12-19.





#### **Health Care Providers Association**

ABN 26 625 498 179

60 Albert Road, South Melbourne VIC 3205 www.hcpassociation.com.au enquiries@hcpassociation.com.au

#### 03 9084 7427

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