



Industry Development Plan

Developing a Medicinal Cannabis
Industry in Victoria
2018–2021

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Minister's foreword

Victoria's medicinal cannabis industry is set to flourish. This plan shows how strong support from the Victorian Government will position Victoria as the Australian hub for medicinal cannabis innovation.

Victoria's leadership has driven national reform on medicinal cannabis. Patients can now access life changing medicines to treat a range of medical conditions.

Going forward, patient access will be underpinned by the establishment of a secure and reliable local industry. This government is committed to development of Victorian medicinal cannabis businesses that are capable of supplying both domestic and international markets.

Victoria has existing strengths in both agricultural and medical R&D. We will work with doctors, researchers, industry and the Commonwealth to facilitate the development of the industry.

Driving the industry forward will create jobs, attract investment, and develop a full range of high quality, locally produced products to meet patient needs.

The Hon. Jaala Pulford
Minister for Agriculture
Minister for Regional Development

01

Introduction

Across the world, innovative medicinal cannabis products are changing the lives of patients who suffer from a number of medical conditions that are unresponsive to other treatments.

With the recent legalisation of medicinal cannabis, Victoria is well-placed to develop a productive new medicinal cannabis industry. This industry will establish Victoria as a responsible supplier of high quality medicinal cannabis to patients in need, both in Australia and across the world.

WHAT IS MEDICINAL CANNABIS?

Medicinal cannabis is the broad term for cannabis products that have been legally cultivated or manufactured for medical purposes.

This can include medical-grade herbal products or purified pharmaceuticals from extracts of the Cannabis Sativa plant.¹

Cannabis plants contain a number of different compounds called cannabinoids and terpenes, which have various effects when introduced into the human body.

The main cannabinoids used are cannabidiol (CBD) and tetrahydrocannabinol (THC).²

HOW IS MEDICINAL CANNABIS REGULATED?

All stages of the process from cultivation to manufacturing, distribution and patient access are tightly regulated, principally by the Commonwealth Government, to ensure that medicinal cannabis products of a reliable quality are available to patients who need them most.

Access to medicinal cannabis only occurs through licensed pharmacists to patients with a prescription from a medical practitioner.

As the industry develops over the coming years, legislation is expected to evolve.

Victoria's first legal crop of cannabis was harvested by the Victorian Government for medicinal use, making Victoria the first State in Australia to produce medicinal cannabis locally. This crop is undergoing development into a pharmaceutical product for eligible children suffering from severe intractable epilepsy.

“This landmark reform means Victorian families will no longer have to decide between breaking the law and watching their child suffer.”

Premier of Victoria, Daniel Andrews



Legislation provides **patients** access to life changing medication



Leading pharmaceutical research and development gives the **public confidence** in the quality of products

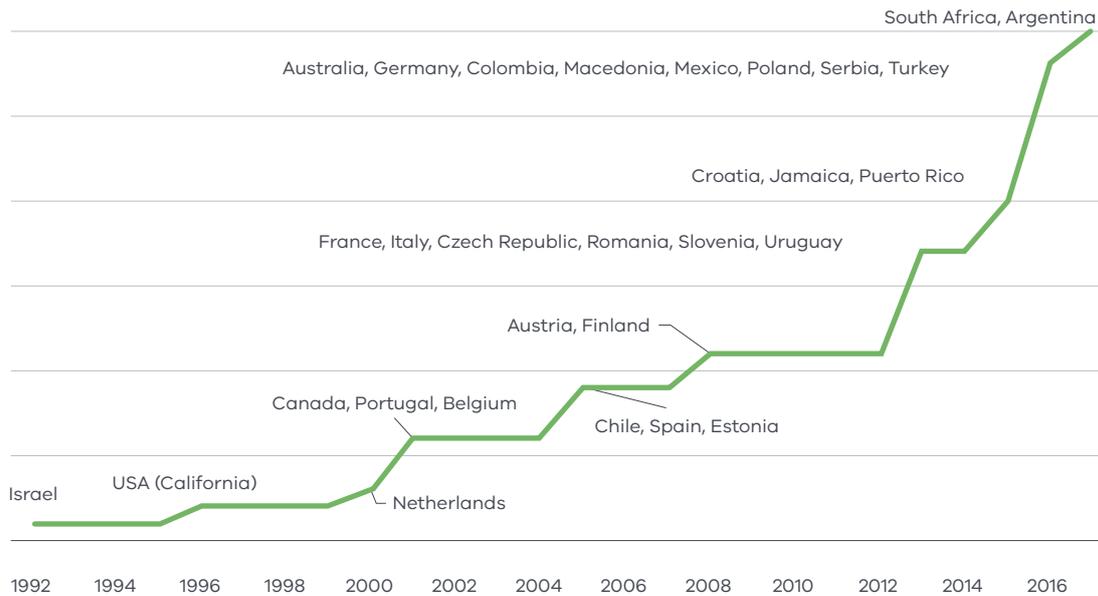


This growth industry will leverage Victoria's **advanced manufacturing** a med-tech capabilities

THE INTERNATIONAL MARKET

In a global context, the legal use of medicinal cannabis has grown rapidly over the last decade, with use of medicinal cannabis or pharmaceutical products containing cannabinoids legal in 30 countries as shown in Figure 1 below.³

Figure 1: Legalisation of medicinal cannabis globally



To date, global exporters of medicinal cannabis have been confined to the Netherlands, United Kingdom, United States and Canada. These suppliers have emerged in large part because of a supportive policy environment.

With the announcement that Australia will establish an export market, Victoria is well positioned to supply products to patients around the world.

“The Victorian Government is committed to developing this dynamic and rapidly growing industry.”

THE OPPORTUNITY FOR VICTORIA

The Victorian Government is committed to developing this dynamic and rapidly growing industry. By building on our existing strengths, such as Victoria's advanced manufacturing and med-tech capabilities, we are well-placed to develop a responsible industry that provides patients with reliable, effective, life-changing medicines.

This Industry Development Plan aims to guide the development of the Victorian medicinal cannabis industry from its emerging status to that of an established industry that is ready to supply both a domestic and international market. The Victorian Government will monitor this plan throughout its duration, responding to challenges and opportunities as they emerge.



Job creation

High-value jobs are expected to evolve from the industry



High domestic market share

Potential for significant market share with expertise and infrastructure around **agricultural and medical R&D**



Potential international market

A new export industry could allow Victoria to meet the needs of **thousands more patients globally**

02

The future of the industry

The Victorian Government supports the development of a productive medicinal cannabis industry in Victoria. This vision includes Victorian firms producing high-quality medicinal cannabis products for domestic and global patients, and establishing Victoria as an export hub. This competitive new Victorian industry will contribute to the productivity of the state and the creation of new jobs along the industry's supply chain.

Medicinal cannabis will be cultivated, manufactured, and distributed in a competitive marketplace by licensed companies. Cultivation will occur in secure and tightly controlled environments. All stages of the supply chain from cultivation, manufacturing, wholesaling and distribution will be subject to strict regulations. Good Manufacturing Practice (GMP) will apply to the manufacturing process, helping to ensure that Australia's products meet the highest standards of quality and reliability.

Distribution within Australia will occur through licensed pharmacists to patients with a prescription from a medical practitioner, similar to the process of other medicines and pharmaceutical products. Both quality assured whole plant products and pharmaceutical-grade products will be available to patients, in a range of formulations, ensuring that Australia's products meet the diverse range of needs of Australian and overseas patients.

“Good Manufacturing Practice (GMP) will apply to the manufacturing process, helping to ensure that Australia’s products meet the highest standards of quality and reliability.”

WHICH PATIENTS ARE LIKELY TO BENEFIT FROM MEDICINAL CANNABIS?

Patients with various conditions that do not respond to conventional treatments may benefit from use of medicinal cannabis. To date, few products have been approved by the Therapeutic Goods Administration (TGA). In part, this is due to evolving evidence from formal clinical trials, which will continue to develop the science over time.

The expansion of the market is evolving rapidly. Patient uptake will rely on expert medical advice and the results of ongoing clinical trials.

It is projected that the uptake of medicinal cannabis for treatment of epilepsy, HIV/AIDS, multiple sclerosis, cancer and chronic pain will grow throughout the life of this plan.

Victoria’s industry will aim to supply half of Australia’s market for medicinal cannabis. This is an ambitious goal, but would mean that by 2028, Victoria could provide medicinal cannabis products to 83,000 of the 166,000 potential patients across Australia.

03

Expected outcomes

Victoria's current strengths as a location to develop and grow high value businesses make it well-placed to grow and sustain a new medicinal cannabis industry.

Alongside the critical health benefits for patients, developing this new industry would generate a wide variety of direct and indirect benefits for the State. Some of these are shown in as shown in Figure 2 below.

Figure 2: Benefits of a strong medicinal cannabis industry



“A thriving medicinal cannabis industry has the potential to create up to 500 new Victorian jobs along the supply chain, from cultivation through to sales, by 2028.”

WHAT ARE THE BENEFITS OF A MEDICINAL CANNABIS INDUSTRY IN VICTORIA?

A local medicinal cannabis industry will help ongoing access to medicinal cannabis for Victorian patients who are in need, as well as encourage innovation, growth and employment opportunities in Victoria.

A thriving medicinal cannabis industry has the potential to create up to 500 new Victorian jobs along the supply chain, from cultivation through to sales, by 2028.⁴ These new jobs will be created across key industry sub-sectors including agriculture, manufacturing, wholesaling, R&D and distribution.

In addition to meeting the needs of the Australian market, Victoria is well positioned to grow the industry through global exports. With Victoria’s existing infrastructure, Melbourne’s large life-sciences cluster, and existing agriculture R&D facilities, Victoria is well-placed to become the hub for medicinal cannabis and an attractive location for international investment.

By 2028, if Victorian producers meet the needs of 83,000 Australian patients and develop a strong foothold in key export markets, the industry’s economic contribution to the state could reach \$90 million per year.⁵

04

Key actions for government

The Victorian Government will take eight key actions to facilitate the development of the new medicinal cannabis industry.



01

Promote collaboration and networking between key stakeholders



02

Streamline regulatory requirements



03

Develop and disseminate clinical guidance and education materials



04

Licence Victorian Government intellectual property



05

Use the existing pharmaceutical supply chain to develop export markets



06

Set up an online one-stop-shop for industry, doctors and patients



07

Facilitate medicinal cannabis clinical trials



08

Facilitate labour force requirements



01 Promote collaboration and networking between key stakeholders

ACTION OVERVIEW

Promote actions that encourage collaboration and networking between key stakeholders, including relevant government agencies, universities and research institutes, and medical professionals. Any activities that facilitate the development of international connections in the medicinal cannabis industry will also be promoted and shared within a medicinal cannabis industry network.

Key steps required:

Identify key stakeholders across industry and research, including governments, universities, key industry players and medical professionals



Identify core strategies and issues for each key stakeholder



Facilitate actions that promote collaboration and networking between stakeholders



One example may be to partner with key stakeholder groups to attract international conferences to Victoria for researchers and healthcare professionals, with a focus on medicinal cannabis



Canvass feasibility of opening a business park with shared facilities, security costs, potentially co-located with existing R&D facilities

Benefits

- Develop a shared understanding of key industry issues and challenges
- Promote knowledge sharing across industry
- Understanding of medical needs by industry may result in development of better products, an increase in medical practitioner confidence to prescribe medicinal cannabis



02 Work with Therapeutic Goods Administration (TGA) and Office of Drug Control (ODC) to streamline Commonwealth and state regulations

ACTION OVERVIEW

By working with the Commonwealth's TGA and ODC to streamline Commonwealth and state regulations, the Victorian Government will aim to avoid duplication and reduce red tape for industry. Reducing inefficiencies created by complex regulations will benefit patients, medical professionals and industry.

Key steps required:

Ensure there is a clear understanding of the roles of the state and Commonwealth Governments in regulating medicinal cannabis



Avoid duplication of processes that would require both Commonwealth and State approval

Benefits

- Avoid unnecessary administration for patients, industry and government
- Reduce confusion for patients and medical practitioners about access pathways



03 Develop and disseminate clinical guidance and education materials for medical practitioners, pharmacists and health professionals

ACTION OVERVIEW

Working with the Commonwealth Government, develop and disseminate clinical guidance and related education materials about medicinal cannabis. This will assist medical practitioners to make appropriate clinical decisions and ensure that clinical practice guidelines are consistent with legislation.

Key steps required:

Identify the appropriate medical bodies and key specialists in each field to provide input



Confirm the key conditions to be included



Work with the TGA and ODC to facilitate the development of clinical guidelines



Consult with medical bodies and specialists to receive feedback on preliminary guidelines and support ongoing testing



Once developed, inform clinicians of their availability and point of access

Benefits

- Increase clinicians' understanding of medicinal cannabis
- Increase clinicians' confidence to prescribe medicinal cannabis where they assess this to be clinically appropriate



04 Licence Victorian Government intellectual property

ACTION OVERVIEW

Develop scheme for licensing Victorian Government intellectual property (IP) regarding strains of medicinal cannabis to allow companies to operate competitively within the sector.

Key Steps required:

Investigate current schemes for medicinal cannabis IP licensing in other jurisdictions



Develop a scheme for IP licensing relevant to the Victorian medicinal cannabis market



Test this IP scheme with key stakeholder groups



Evaluate initial uptake of IP and adjust where necessary

Benefits

- Promote a competitive market through access to medicinal cannabis IP created by government research and development
- Victoria attracts domestic and overseas industry investment



05 Use the existing pharmaceutical supply chain to develop export markets for medicinal cannabis products

ACTION OVERVIEW

Using the existing supply chain is likely to increase the speed at which export markets can be developed. If successful, Victoria could become a medicinal cannabis hub, leading to the creation of additional jobs in the state.

Key steps required:

Determine key relationships in the existing pharmaceutical or agricultural supply chains that could be leveraged for the export of medicinal cannabis



Understand and identify how medicinal cannabis is able to fit into the industry and where extra steps need to be taken

Benefits

- Fast-track the development of a profitable export market in line with regulatory controls
- Make high quality medicines available to patients in other countries
- A larger export market may mean more jobs for Victorians



06 Set up an online one-stop-shop for industry, doctors and patients providing general information and outlining state and Commonwealth government approval processes

ACTION OVERVIEW

Cultivators, manufacturers, suppliers, doctors and patients will be able to access relevant information and requirements at a virtual government one-stop-shop. General information and relevant links will be provided on medicinal cannabis, including regulations for cultivation, research, manufacturing, imports and patient access, as well as for intellectual property (IP) applications.

Key steps required:

Identify all the approvals and information required from cultivating cannabis through to patient access



Create a document library with up-to-date information



Set up an easy to navigate website, with links to relevant websites and information from government, industry and peak bodies



Decide which agency(s) will home the website and be responsible for its maintenance



Go live with website initially and determine if a 'shop front' is required for face-to-face interaction

Benefits

- Increase awareness about regulation and required approvals for companies and investors
- Facilitate patient access by providing up-to-date information and neutral clinical guidance for medical practitioners



07 Facilitate medicinal cannabis clinical trials

ACTION OVERVIEW

Support for clinical trials will generate evidence to inform medical practitioners, health professionals, government and the public about the use of medicinal cannabis to treat a range of conditions.

Key steps required:

Support medicinal cannabis researchers and companies to navigate the establishment of clinical trials in Australia



Identify linkages between industry and universities to partner on future clinical trials



Identify sources of potential funding for clinical trials by industry, universities and government



Work together with clinicians, industry, and patients to identify priority clinical trials in which Australian patients could participate

Benefits

- Fast-track the development of new medicinal cannabis products to treat a range of conditions
- Improve the accuracy of dosage information for a range of conditions
- Increase medical practitioner confidence in new products
- Increase investor confidence, promoting industry development



08 Facilitate labour force requirements

ACTION OVERVIEW

Growth and employment in the medicinal cannabis industry will be supported by facilitating access to an appropriate labour force, encompassing local and international staff.

Key steps required:

Identify potential companies in the medicinal cannabis sector for partnership and sponsorship



Promote existing migration schemes that will support experienced foreign staff and investors contributing to Victoria's industry



Assist companies, particularly new entrants to the sector, to identify and train local staff, particularly in medicinal cannabis production related jobs



Work with industry to advocate to the Federal Government on skilled occupations needed to support industry growth

Benefits

- Promote entry into the medicinal cannabis industry, particularly for smaller companies
- Create new local jobs
- Support migration and employment of experienced workers from the global medicinal cannabis industry where required
- Increase the development of agricultural research and development

05

Looking forward

The development of a medicinal cannabis industry presents many opportunities for Victoria, with potential to create hundreds of new jobs and bring a range of economic benefits to the State. These benefits include growing State output, the creation of new jobs in manufacturing, agriculture, and R&D, the creation of a new export market and an increase in international investment.

Victoria's existing strengths in both agricultural and medical R&D, coupled with Australia's reputation for producing high-quality pharmaceuticals, means that Victoria is well-placed to succeed in a competitive international market.

Australia's existing reputation for producing high-quality pharmaceuticals under GMP regulations also puts Victoria in a strong position to export globally, and to become the medicinal cannabis hub.

WHAT ARE THE NEXT STEPS FOR GOVERNMENT?

Implementing the key government actions set out in this plan will be an important step in the development of Victoria's new medicinal cannabis industry. Three key areas of focus include:

Streamlining state and Commonwealth regulation

By working together with the ODC and TGA to streamline regulations, the Victorian Government can help key stakeholders navigate the regulatory environment.

Increasing professional and public knowledge

Guidance needs to be provided to improve knowledge of the safe use of medicinal cannabis, and to ensure that products are prescribed appropriately.

Providing industry support and integration

The development of the industry may be assisted by licencing Victorian Government IP, or promoting networking and collaboration between key stakeholders.

WORKING TOWARDS A SUSTAINABLE MEDICINAL CANNABIS INDUSTRY

A Victorian medicinal cannabis industry will improve the quality of life for patients suffering from a range of conditions, both in Australia and abroad. With a medicinal cannabis industry based in Victoria, Australian patients requiring treatment for conditions such as epilepsy, multiple sclerosis, HIV/AIDs, cancer and chronic pain will benefit from easier access to a range of reliable and locally-produced medicinal cannabis products.

This plan sets out key government actions to grow a new medicinal cannabis industry in Victoria. By delivering these actions, we can help to ensure:



Victoria is a safe and responsible supplier of medicinal cannabis



Victorians have legal access to life-changing treatments



New high-value jobs are created for Victorians

ENDNOTES

- 1 Whiting P, Wolff R, Deshpande S et al, June 2015, Cannabinoids for Medical Use: A Systematic Review and Meta-analysis, <http://jamanetwork.com/journals/jama/fullarticle/2338251>.
- 2 Borges et al, 2013, Understanding the Molecular Aspects of Tetrahydrocannabinol and Cannabidiol as Antioxidants, *Molecules* 18(1): 12663-12674.
- 3 Cannabis Laws & Scheduling in Europe, <http://www.medicalmarijuana.eu/legal/>; California Proposition 215 (1996), Compassionate Use Act of 1996; South Africa Health, 2016, Medicinal Cannabis, <http://sahealth.sa.gov.au>; Turkey Law Register, <http://www.hukukturk.com>; Reuters, 2017, Argentina lawmakers approve cannabis oil for medicinal use, <http://www.reuters.com/article/us-argentina-cannabis-idUSKBN170391>.
- 4 Industry assumptions were developed to inform the industry development plan. The main assumption was that the medicinal cannabis industry would be a competitive market place.
- 5 The predicted volume of medicinal cannabis produced was influenced by estimates of daily doses required across different conditions.



