VICTORIA
State Government

MCIA
Medicinal Cannabis Industry Australia

The Medicinal Cannabis Industry Opportunities and Future Direction

May 2022

Acknowledgements and Disclaimer

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This report is compiled from work undertaken by MCIA in conjunction with Rhys Cohen Consulting for the Victorian Department of Jobs, Precincts and Regions to help inform a review of the Victorian Government's Industry Development Plan for medicinal cannabis. This report pulls together a summary of the feedback from industry consultations and highlights areas of priority. It is provided to assist the industry in its planning and strategy. The publishing of this report does not imply any endorsement by the Victorian Government of the priorities and areas for strategic action, nor does it imply that the Victorian Government will continue to invest in the sector.

The authors acknowledge the help and contribution of DJPR, and other Victorian Government representatives, in compiling this report and would also like to thank industry and other stakeholders for their time and input to the report.

The report has been prepared based on information provided or reported to the consultants in good faith and/or obtained by the consultants from a range of sources and assumed to be accurate and reliable. The report contains general information only. This report is provided as a Review of the Victorian medicinal cannabis industry and therefore MCIA and/or the consultants can accept no responsibility if any of the information within this report is used for other purposes.

The analyses made and the findings presented do not necessarily represent the views of MCIA, nor any person or organisation within the contact group or any other party.

Introduction

This report has been drawn from a review of the development of the medicinal cannabis industry in Victoria undertaken for the Department of Jobs, Precincts and Regions (DJPR) by Medicinal Cannabis Industry Australia (MCIA) and Rhys Cohen Consulting in October 2021.

The Victorian Government released an Industry Development Plan (IDP) in 2018 to guide the development of a local medicinal cannabis industry. As this plan was for the period 2018-2021, the Victorian Government were seeking to assess Victoria's support of the industry to date and determine the needs of the industry that reflect the current business and regulatory environments in Australia and overseas. The IDP has been successful in guiding the development of a new industry in Victoria and creating an attractive environment for private investments. However, medicinal cannabis is still an emerging industry, with uncertainties around patient demand, evolving regulations, and production capacities.

A key component of the review included targeted stakeholder engagement with 30 Victorian based companies and organisations including licensed companies, R&D organisations, medical groups and prescribers, patient advocate groups and Government to help develop recommendations regarding future investment and activities that the Victorian Government could consider to support the local industry.

The review captured stakeholder perspectives of how the landscape has changed since the IDP was developed, the opportunities and challenges for the industry and opportunities for further support by the Victorian Government. It was aimed at providing DJPR with insights on the current and future needs of the industry, to inform government policy and potential future investment aimed at maximising the industry's growth. This will build on the achievements to date and identify future activities that will support continued growth of the industry.

This report provides a summary of the stakeholder views and has been developed to assist MCIA and the broader industry with engagement around opportunities and challenges with Government, and across the medicinal cannabis ecosystem. It help inform the industry's future strategic planning.

Australia's medicinal cannabis regulatory framework

Medicinal cannabis was legalised in Australia in 2016 through amendments to the Narcotic Drugs Act 1967 (ND Act) which established the medicinal cannabis scheme enabling cannabis to be treated as a medicine in compliance with the Single Convention on Narcotic Drugs 1961. The ND Act provides pathways for the supply of medicinal cannabis (cultivation, production, manufacture and trade) through a licence and permit scheme, and seeks to balance domestic supply with patient access, community protection and international obligation.

There were 153 ODC licences as at March 2021, although under the framework at this time companies held multiple licences i.e. cultivation, manufacture and/or research. Since December 2021 companies are being migrated to a new single licence system. At this time, Victoria accounted for around 30% of licence and permit holders in Australia, and was the largest State accounting for 43 licences (followed by NSW with 42 and Queensland with 33). Not all licensed producers have, or intend to, commence commercial-scale cultivation or manufacturing activities.

ODC licences & permits - March 2021	Victoria (No) Licences	Victoria (No) Permits	Australia (No) Licences	Australia (No) Permits
Total	43	18	153	53
Cultivation	19	2	66	
Manufacturing	16	7	57	
Research	8	9	30	

Australia's regulatory framework

Therapeutic Goods Administration (TGA)	**Patient access**	**Special Access Scheme or Authorised Perscriber**
Therapeutic Goods Administration (TGA) / Office of Drug Control (ODC)	**Manufacture**	**Manufacturing Licence - *Theraputic Goods Act*** **Manufacturing Licence - *States & Territories*** **Manufacturing Licence - *Narcotic Drug Act***
Office of Drug Control (ODC)	**Cultivation & production**	**Cultivation Licence - *Narcotic Drug Act***

Four main patient access pathways
- Registration inthe ARTG
- Special Access Scheme (SAS) pathways
- Authorised Perscriber (AP) pathway
- Clinical Trials Notifcation (CTN) scheme

GMP underpins domestically manufactured API and products
- TGO 93 sets minimum requirements for quality for domestic and imported products

Australia's regulatory pathway

Feb 2016
Federal Government amends the Narcotic Drugs Act 1967 to regulate cultivation & manufacture of cannabis for medical & scientific use.
Imported medicinal cannabis legally available

Apr 2016
Victorian Government passes the Access to Medicinal Cannabis Act 2016 to enable access to defined patient groups

Feb 2017
First cannabis research licence under the ND Act

Mar 2017
The first medicinal cannabis licence under the ND Act

Feb 2018
The export of medicinal cannabis products legalised through the Commonwealth Narcotic Drugs Amendment (Cannabis) Regulations 2018

July 2018
Federal Government streamlines patient access to medicinal cannabis

Sept 2019
First Australian medicinal cannabis export sent to Germany

Dec 2020
TGA decision to down-schedule low-dose CBD products to Schedule 3

May 2021
Epidyolex becomes first cannabis medicine to be listed on the PBS

Jun 2021
Narcotic Drugs Amendment (Medicinal Cannabis) Bill 2021 passed

Nov 2021
Changes to SAS B & AP pathways

Dec 2021
ODC single licence & permit reforms implimented

Mar 2022
Medicinal cannabis reforms - imports, packaging & labelling, and compunding

The TGA is responsible for specifying standards for medicinal cannabis products imported, produced and/or utilised in Australia. Therapeutic Goods Order (TGO) 93 is the standard for medicinal cannabis products. TGO 93 applies to both domestic and overseas manufacturers to enable all medicinal cannabis products imported, manufactured or supplied in Australia to meet the quality controls provided by the standard.

Under the Customs (Prohibited Imports) Regulations, all medicinal cannabis products including API products require a licence and permit to import to Australia. All imports must comply with TGO 93 GMP requirements.

The Federal Government legalised exports of medicinal cannabis in 2018 through the Narcotic Drugs Amendment (Cannabis) Regulations 2018. The export opportunity was further supported by the Export Control Legislation Amendment Bill 2020 which assisted to remove unnecessary and unintended regulatory barriers imposed on Australia's exports.

There have been a number of key reviews leading to improvements in the regulatory framework since 2016 including to the licence and permit system, patient access, and products.

The medicinal cannabis industry continues to develop and grow as the regulatory framework evolves, and patient demand increases. The industry has seen significant investment in cultivation and manufacturing facilities, as well as clinical research trials since legalisation in 2016.

McMillan Review	• Tabled in 2019, implementation in 2 parts in 2020 and 2021 • Reduce regulatory burden on industry • Greater flexibility in administration of regulation • Single licence and permit reforms
Senate inquiry on patient access	• Education and training • Improvements to SASB pathway processes • State/Commonwealth interaction • Cost impacts
CBD down-scheduling	• CBD S3 Over-the-counter from Feb 2021 • Products need to be registered on the ARTG • CBD >98% of total cannabinoid content and maximum daily dose up to 150mg • Product form, packaging and advertising restrictions
Import equivalence	• Imports to comply with TGA GMP • SAS/AP approval required for compounding • New labelling and packaging requirements (safety)

What industry stakeholders said

Dealing with the regulators (ODC and TGA) can be challenging.

Some of the challenging regulatory processes or restrictions identified by industry include:

- Regulatory authorisations are involved at multiple steps
- Turnaround times are drawn out and variable, even for repeat activity by the same applicant
- Delays with issuing and amending licenses and permits
- Pipeline management that is making it extremely difficult to be responsive to the needs of Australian patients

The impact of these inefficiencies and delays include:

- Severely limiting the operational efficiency of companies
- High level of business uncertainty with consequential impacts on product supply, employment and growth
- Reduced patient access and increased cost of access
- Increased costs to business which will further impact patients
- Lack of confidence by patients and healthcare professionals in respect of the ongoing availability of Australian produced products.

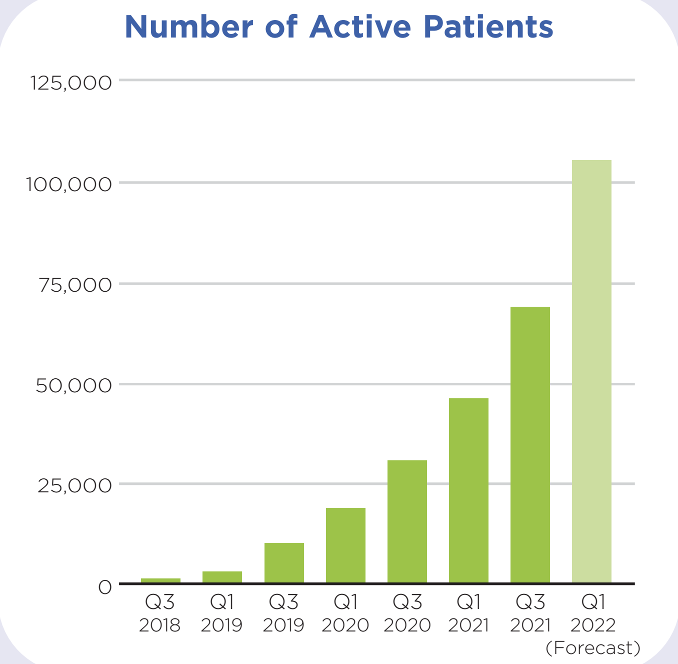
Australia's medicinal cannabis market

Since legalisation in 2016, the Australian medicinal cannabis industry has experienced and is expected to continue to experience rapid growth while still in early stages of development.

The Australian medicinal cannabis industry has potential to become a significant sector within the Australian economy - servicing not only Australian patients and the increasing demand for medicinal cannabis, but also expanding its focus to be a global exporter of a premium Australian grown and made medicine. The medicinal cannabis industry provides an opportunity for the Australian economy to reverse the focus on commodities and own the entire value chain, where leading Australian businesses grow, process and manufacture world leading medical cannabis products for the global market. Australia has the natural resources and technology for cannabis cultivation, a strong reputation for safe, clean and sustainable products, and the innovative capability to process and manufacture pharmaceutical grade products.

Prohibition Partners forecast the value of Australia's cannabis market will jump from around US$40 million ($AUD50-55 million) in 2020 to US$1.23 billion (approximately $AUD1.6 billion) by 2024[1]. Active patient numbers are forecasted to be 90,000 at the end of 2021, up from 70,000 at the end of Q3 2021[2].

[1] 'Oceania Cannabis Report' second edition published in April 2020
[2] FreshLeaf H2 2021 report https://freshleafanalytics.com.au/report-h2-2021/



The medicinal cannabis sector will deliver broad benefits across the community including:

- Economic benefits for regional, state and the national economy
- New medicine for patients across a wide range of conditions
- Improved wellbeing for patients
- Potential savings for the Australian healthcare sector
- Employment opportunities
- Export revenue

Patient access

Patient demand in Australia for medicinal cannabis has increased significantly over the last two years driven by factors such as access pathway reforms, price reductions, and the development of scientific evidence across indications and patient groups. Continuing to reduce barriers to domestic patient access is a key priority for industry.

There are two key patient access pathways: the Special Access Scheme Category B (SAS-B) and Authorised Prescriber Scheme (AP Scheme).

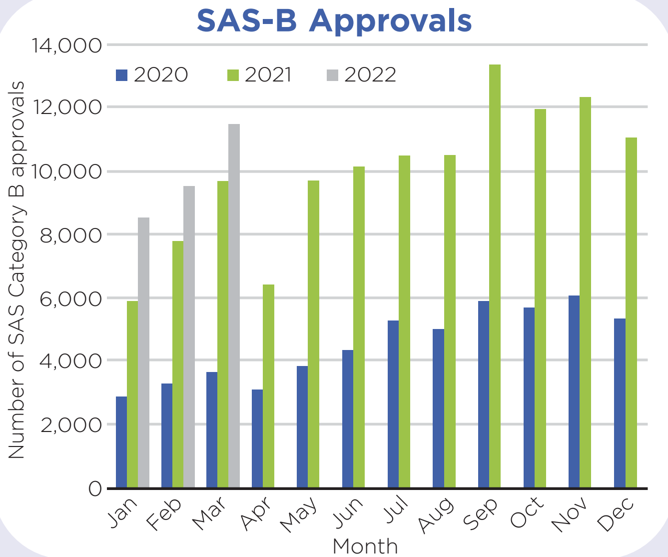
Medicinal cannabis dominates SAS-B activity, with over 220,000 SAS-B applications having been approved by February 2022. This pathway evolved to provide access to unregistered medicines on an ad hoc basis for exceptional circumstances, but for medicinal cannabis is now a pathway for a medicine being prescribed routinely. While the application process has improved, it does not yet provide a seamless solution for prescribers.

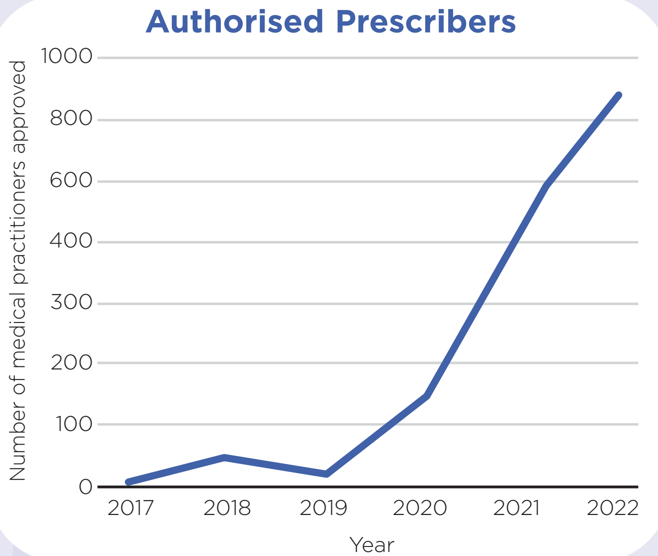
Common SAS-B indications:

- Chronic pain (over 50%)
- Anxiety
- Insomnia & sleep disorders
- Cancer pain & symptom management
- Neuropathic pain
- PTSD
- Depression
- Epilepsy

What industry stakeholders said

Stakeholders saw the SAS pathway as not being 'fit for purpose' as cannabis is no longer exceptional and occasional.





There were 843 active Authorised Prescribers (Feb 2022).

In December 2020, the TGA agreed to amend the scheduling for cannabidiol (CBD) to down-schedule low dose CBD products to Over-the-Counter (OTC) Schedule 3 (S3). This decision allows low-dose CBD-containing products, up to a maximum of 150 mg/day, for use in adults that have been approved by the TGA, to be supplied over-the-counter. This will be accompanied by the advice of a pharmacist, without a prescription. Products will be required to be approved by the TGA and included on the Australian Register of Therapeutic Goods (ARTG), along with a number of other restrictions. While the announcement provides an opportunity for the industry to develop S3 products, there remain questions over the ability to meet the evidentiary requirements for the proposed registration pathway.

What industry stakeholders said

While recognising the OTC CBD S3 opportunity, stakeholders had reservations around whether investing in clinical trials would result in sufficient evidence to enable registration, and concerns around the risk of future regulatory uncertainty.

Driving Laws

Current driving laws mean that legally-prescribed medicinal cannabis patients may face criminal sanctions for driving with a detectible level of THC in their saliva despite not being impaired. A Medicinal Cannabis and Safe Driving Working Group (Working Group) was established to consider approaches on managing medicinal cannabis and safe driving in Victoria following the introduction of the Road Safety Amendment (Medicinal Cannabis) Bill 2019 (the Bill) by Hon Fiona Patten MP. Representatives on this Working Group included Members of Parliament, Senior Government Executives and medical professionals. The Working Group's report to government will inform future parliamentary debate.

What industry stakeholders said

Stakeholders see driving laws are a significant barrier to patient access due to a drug driving regulatory framework that treats patients taking legally prescribed medicinal cannabis containing THC in the same manner as users of some illicit drugs i.e. criminalising the presence of the drug regardless of impairment.

Evidence and education

Building evidence is key to the development of the medicinal cannabis industry. The development of robust and conclusive evidence that medicinal cannabis is an effective treatment for a range of indications is an important driver for increasing the number of patients accessing medicinal cannabis and improving the confidence of the healthcare sector to prescribe these products.

The opportunity to support demand growth and patient access through increased evidence, is widely recognised by stakeholders. The commitment from industry to demonstrating the safety and efficacy of products through clinical trials is seen as paramount to the success of the industry in the long-term. There is also growing interest from the academic and clinical communities into the various clinical indications for which medicinal cannabis may prove effective.

Access to balanced, evidence-based information for patients, and education and training programs for the medical profession, were identified as key issues for facilitating patient access to medicinal cannabis. As the body of evidence continues to grow regarding the potential clinical applications of medicinal cannabis, this need for training and education will increase.

What industry stakeholders said

The ability for medicinal cannabis companies to expand the scope of clinical research is hindered by cost, capability, complexity, and risk.

Research stakeholders experienced difficulties in navigating the many various commercial players who might support trial work.

Researchers encountered a number of challenges, particularly in relation to accessing products of suitable quality and supply continuity. Research stakeholders noted that finding and securing access to appropriate, high-quality GMP investigational products for clinical trials is difficult, and takes more time and resources compared to other medicines.

There is opportunity for greater collaboration between medicinal cannabis companies and the research/medtech sector.

Medicinal cannabis ecosystem

Australia's medicinal cannabis industry is still young and evolving, and is expected to benefit significantly from the development of a sustainable ecosystem. With the potential to create both direct and indirect economic benefits, a strong medicinal cannabis industry would be of substantial value to Australia.

Experiences across a number of other areas of innovation, such as agtech, have demonstrated the value in creating sustainable growth through the clustering of entrepreneurial activity around areas of excellence. Fostering innovation through leveraging the strengths of a sector, along with funding support, will assist with ecosystem development and fast-track growth and commercialisation. Networking and collaboration are critical to unite and integrate the medicinal cannabis ecosystem to meet the needs of companies and patients, and enable a high-growth, internationally competitive industry.

Connecting, inspiring, and supporting the medicinal cannabis ecosystem will help build a responsive and agile industry with a focus on building capability to meet opportunities; creating conditions to drive innovation; enhancing efficiencies and sustainability; and strengthening connectivity to build capability and optimise industry performance.

Global opportunities

While domestic demand is fuelling Australian growth, access to international markets will assist medicinal cannabis to maximise their significant investments. The Australian medicinal cannabis industry has competitive advantages in quality, product integrity/safety, and its regulatory framework. Facilitating access to export markets is a key industry priority to support the sustainability of Australian cultivation and manufacturing businesses. The Australian regulatory framework enables competitive access to preferential export markets, but also comes with a high-cost supply base. Building scale through supplying both domestic and export markets is therefore critical.

To successfully navigate the regulatory and market environments, Australian medicinal cannabis companies need to be informed, agile, and well resourced. The legalisation of access to medicinal cannabis around the world is an evolving process, with many countries pursuing either initial legalisation or regulatory reforms.

Regulatory and market environments are complex and constantly evolving in the medicinal cannabis space. This presents companies with additional uncertainty and risk, as well as the potential for sudden opportunities which need to be taken advantage of in an agile fashion.

Potential export markets

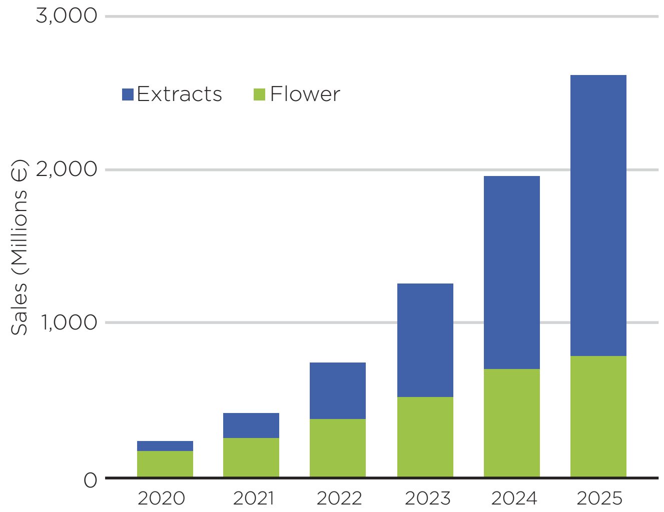
Country	2020 Population (million)	2020 Projected market value (AUD million)
France	66.5	15
UK	67.3	14
Germany	83.6	12
Italy	60.2	12
Poland	38	3

Source: Statista 2021

As legal markets across the globe continue to evolve, companies need to pay attention to some key underlying complexities. Patient access to medicinal cannabis as a treatment option is largely via special access pathways which may be subject to ad hoc regulatory changes. This means that companies operating in the supply and distribution of medicinal cannabis products need to accept and work within this inherent regulatory uncertainty.

Europe has emerged as the most promising export market for Australian medicinal cannabis products, with a number of companies having commenced exports to the United Kingdom, Denmark, France and Germany, among others. The industry is well positioned to access these valuable European markets due to the ability to meet GMP requirements.

Projected sales of medical cannabis in Europe



Source: Prohibition Partners

Factors shaping the Australian market

The Australian medicinal cannabis industry is poised for substantial growth. While still in its infancy the industry is maturing and is now in a position to build on the foundations that have been laid. Medicinal cannabis products are increasingly being recognised as effective; there is growing demand for medicinal cannabis treatments; and markets continue to open as more countries authorise the use and trade of medicinal cannabis products.

The sector is responding to changing market conditions, however rigid regulations have not enabled the agility that companies require to respond to market opportunities. Nor do the patient access pathways enable demand to grow in line with community expectations.

The focus for future planning should be demand-led, with support to facilitate access to Australian and global opportunities.

This requires a “patient first” focus i.e. improve patient access and export capabilities to drive growth. A demand-led approach will require action to address the regulatory barriers for companies, healthcare professionals, researchers and patients to expand access and improve affordability to enable industry growth.

Australia is well positioned to be a major player in the global market for medicinal cannabis based on the Australian framework which supports legitimacy, safety and quality. Growth of the medicinal cannabis industry will be driven by a combination of organic growth in the Australian market, access to export markets, and improved scale and commercialisation of companies.

Greater mainstream acceptance of cannabis as a medicine will also be key to driving growth, including the implementation of a streamlined prescriber pathway which better reflects the safety and effectiveness of medicinal cannabis. The down-scheduling of low dose CBD and the promise of non-prescription access through pharmacies has helped provide legitimacy to cannabis as a 'medicine for the masses'.

Increased investment in R&D and innovation and building evidence around the efficacy of medicinal cannabis products will support organic growth. Access to independent and validated education and the continued building of robust clinical evidence will improve the confidence of the healthcare sector to prescribe medicinal cannabis. This will be supported by longer term 'normalisation' of medicinal cannabis as some products become ARTG registered medicines.

A key focus for companies now is to be scalable. Demand for manufactured products and services is evident, but companies are limited by current throughput capacities and economies of scale. Technological solutions are available in the form of infrastructure and more automated processes, but the investment costs are significant and companies require access to capital to be able to take advantage of these opportunities for increased capacity, scale, and efficiencies.

Greater collaboration to build a sustainable ecosystem is required for the development of a sustainable ecosystem which supports innovation, knowledge and investment.

Strategic themes for shaping future growth of the Australian medicinal cannabis industry

Realising the medicinal cannabis opportunity can be achieved by enabling demand through:

- Improving patient access via enhanced prescriber pathways
- Building evidence and education to provide prescriber and patient confidence
- Reducing red tape to enhance industry agility and efficiency
- Developing knowledge and supporting companies to access export markets

But it is also necessary to address the constraints on the industry delivering on this opportunity including:

- Patient and prescriber barriers to access
- Rigid regulations unaligned to commercial practices
- Lack of access to capital to invest in new technologies, R&D and clinical trials
- Under-developed linkages between medicinal cannabis companies and the broader biotech/medtech ecosystem limiting opportunities for innovation and synergies

If these constraints can be addressed, the benefits will be significant. However, there is a risk of the industry not being able to maintain momentum if some of these constraints cannot be addressed in the short term.

Impact and the strategic levers

Strategic levers

A sustainable ecosystem through collaboration
Greater connectivity and improved collaboration between industry, government, researchers, and education and training institutions to support innovation and unlock the growth potential of the industry

An agile and productive regulatory environment
Streamlined regulatory requirements to support patient access and industry development, and improved State/Federal dialogue regarding medicinal cannabis regulation

Improved industry capability, scale and competitiveness
Greater capacity and efficiency of medicinal cannabis companies, and more diverse, specialised and accessible R&D service providers

Easier and more affordable access for Australian patients
Reduced barriers for prescribers and patients, and improved affordability and reliability of supply

Greater confidence and demand through medical scientific research
Robust evidence verifying medicinal cannabis as an effective treatment for a range of indications and providing evidence to support doctor confidence in prescribing

Better patient outcomes through prescribers education
Independent, balanced, evidence-based educational materials to inform prescribers

Expand export opportunities
Build on Australia's competitive advantages and leverage the Australian brand

Delivering impact

An economically and scocially sustainable industry delivering benefits through:

- **Expanded footprint**
- **Increased efficiency, scale and capability**
- **GDP and export revenue growth**
- **Increased employment opportunities**
- **Improved access for patients and positive contribution to health outcomes of Australians**
- **An innovative, collaborative and cohesive medicinal cannabis ecosystem**

For further information

For further information on medicinal cannabis or to get involved with the industry please contact:

MCIA Medicinal Cannabis Industry Australia

Medicinal Cannabis Industry Australia
PO Box R1826
Royal Exchange NSW 1225
E rosemary.richards@mcia.org.au
P 61 9427 6999