



**MCIA**

Medicinal Cannabis Industry Australia

# Annual Report 2020-21

A not-for-profit member driven organisation



# Contributing value to the medicinal cannabis industry

MCIA works within six pillars of activity to enhance value to the industry and members, and deliver on the vision of  
*“Building an industry that enhances wellbeing through facilitating access to quality Australian medicinal cannabis products for Australian and global patients, and where the industry and its products are built on sound science and underpinned by industry processes and standards that ensure patients, the medical community and governments have confidence in the sector and its products, services and information.”*



Elevating industry standards and initiatives that enables patient access to trusted products, underpins innovation, and drives a culture of integrity, transparency and fairness across the medicinal cannabis industry.

Targeted advocacy with balanced, contextual and inclusive representation, and promotion of industry issues.

Advocate for key policies and outcomes to support the sector including in areas such as patient access, regulatory efficiency, harmonisation and compliance, product integrity.

Sharing of experiences information and ideas to contribute to a collective knowledge that supports confidence in the medicinal cannabis industry and its products.

Build confidence with patients, doctors, the healthcare sector, community and Government through the MCIA Code of Conduct and other technical guidance documents. Trust and integrity are the cornerstones of a sustainable medicinal cannabis industry.

Identify and support local and global growth opportunities for the industry.

Lift the industry voice to influence policy and regulatory developments, contribute to public debates, promote policy and data through proactive advocacy, and foster industry leaders.

Connect, inspire, and support the medicinal cannabis ecosystem to help build a responsive and agile industry.

Directly interface with government and other key stakeholders.

Increase awareness and knowledge and improve connectivity through networking and information opportunities for members and events such as ACannabis.

Work collaboratively with regulators to promote and shape a framework supportive of delivering Australian quality products to Australian patients in a timely and affordable manner.

Work with our members to develop industry standards, codes of practice, technical guidelines, etc in order to improve transparency, fairness and patient/healthcare practitioner confidence.

# MCIA Board



**Peter Crock**  
Chair MCIA & CEO,  
Cann Group



**Rodney Cocks**  
Chief Executive  
Officer & Director,  
Cronos Australia



**Elisabetta Faenza**  
CEO, LeafCann  
Group



**Russell Harding**  
Executive Chairman  
& CEO, MedReleaf  
Australia



**Carol Ireland**  
CEO and Managing  
Director, Epilepsy  
Action Australia, and  
MCIA/MCC  
collaboration, patient  
advocate

## MCIA Committees

### Board Committees

- Membership Committee
- Communications Committee

### Working Groups

- Policy Working Group
- Research Working Group
- Standards Working Group

# MCIA Working Groups

## Policy Working Group



Chair:  
**Dr Jaroslav Boublik**  
CEO Research & Advisory and  
Chief Scientist, LeafCann Group

The Policy Working Group is responsible for assisting MCIA and the Board develop formal position statements on key policy issues; monitor and report on Federal/State and global legislation/policy trends and recommend MCIA response as appropriate; and develop industry positions/submissions in relation to Government, regulatory and other relevant inquiries and consultation.

The Policy Working Group was very active during 2020/21 with development of policy positions for the following submissions to:

- Medicinal Cannabis Single License and Permit Reform (Office of Drug Control (ODC))
- Scheduling of cannabis for Research into therapeutic use (TGA)
- Medicinal cannabis reforms re import equivalence, compounding, labelling, child resistant packaging (TGA)
- CBD down scheduling to S3 OTC (TGA)
- Victorian Cannabis Inquiry (The Legislative Council's Legal and Social Issues Committee)
- Compounded medicines and good manufacturing practice (TGA)
- Inquiry into the Approval Processes for New Drugs and Novel Medical Technologies in Australia (House of Representatives Standing Committee on Health, Aged Care and Sport)

## Standards Working Group



Chair:  
**Elisabetta Faenza**  
CEO, LeafCann Group

The Standards Working Group is responsible for assisting MCIA and the Board to develop and maintain a self-regulatory, principles-based Code of Conduct for the industry (and any associated Guidelines or Protocols); and inform the development, effective and efficient operation of relevant standards to be adopted across the industry.

The Standards Working Group is undertaking a review of existing standards within legislation or official guidance documents to identify gaps, ambiguities or unworkable requirements. Following this it will investigate development of tools to assist members in identifying and complying with standards, and development of strategies to address gaps.

A key focus for the Standards Working Group ongoing maintenance of the MCIA Code of Conduct, and development of guidance documents to support the Code. Future activity will include outreach activities around review of the Code and extension of guidance documents.

## Research Working Group



Chair:  
**Melinda Thompson**  
Head of Regulatory Affairs &  
Quality Systems, Source Certain  
International

The Research Working Group is responsible for assisting MCIA and the Board to:

- Facilitate the sharing of knowledge and expertise regarding clinical trials, observation studies, product pathways and related activities
- Identify commercial, regulatory, ethical and legal impediments to the execution of research pertaining to medicinal cannabis in Australia
- Identify opportunities for research collaborations and partnerships that would benefit the industry as a sector and/or the broader community
- Engage with political, regulatory and other stakeholders to facilitate information exchange and educational activities pertaining to medicinal cannabis.

Key focus for the group in 2020/21 was around opportunities for systematic data capture to support research and product registration. The Research Group also provided input into the submission on scheduling of cannabis for research into therapeutic use that was developed by the policy working group.

# Chair Report

It is with pleasure that I present this report to the third Annual General Meeting of the Medicinal Cannabis Industry Australia (MCIA), although once again we are having to meet virtually. Despite the challenging year, the industry has demonstrated its resilience and has continued its rapid development.

The success of our industry depends upon a mature approach to policy-making, a commitment to quality, adherence to high ethical standards; and improved access pathways for healthcare consumers. The past 12 months has seen some significant changes with the reforms to the Narcotic Drug Act, the down scheduling of CBD and rapid and ever increasing growth in SAS B and Authorised Prescriber approvals.

MCIA is the voice for the legitimate medicinal cannabis industry and works to support a sustainable medicinal cannabis industry ecosystem through value chain collaboration.

MCIA's vision is for an innovative, responsible and legally compliant industry delivering both economic and social value while focusing on individual well-being. During 2020/21 MCIA has continued to advocate for and implement strategies to deliver this vision.

MCIA has delivered on a number of planned initiatives during the year including **ACannabis EVOLVE** - the industry's conference. While not able to meet in person, close to 500 participants from across the ecosystem came together to share ideas, learn from each other and explore opportunities for our exciting industry. The conference was very valuable in enhancing the visibility and voice for MCIA and ACannabis has established itself as a valuable platform for education, awareness and information.

MCIA is focused on accelerating access for

patients. As medical research increases, and more countries regulate for the use of medicinal cannabis, we can see the importance of what is effectively a new class of compound in medicine. We share that many people in the patient community are frustrated that more than five years on from the Australian Parliament passing legislation to enable the cultivation of cannabis for medicinal and research purposes, many patients are still not able to readily access Australian product. We announced last year that to elevate activity in this area that we were fostering the development of an Advisory Council.

We are very pleased to be working with Dr Richard Di Natale - a champion of the medicinal cannabis industry - to facilitate the Medicinal Cannabis Health Advisory Council. Richard and his fellow Council members have shown great leadership in initiating discussion and activity with the Colleges and AMA to develop streamlined access pathways and education and training resources for healthcare practitioners and consumers. You can read more details on the Council elsewhere in the MCIA Annual Report, and we look forward to continuing to engage with the Council and to positive outcomes from their activities.

We announced the establishment of a Parliamentary Friends of Medicinal Cannabis Group in the Federal Parliament at last year's AGM. This group provides a non-partisan forum for Members and Senators to meet with representatives of the Australian medicinal cannabis industry, medical experts and patient advocates to raise awareness of the medicinal cannabis industry to Parliamentarians and within the broader community. The first meeting of the Parliamentary Friends of Medicinal Cannabis Group was held in November 2020

and included remarks by the Parliamentary co-chairs and an interactive panel discussion with a range of industry experts spanning patient advocates, research and industry.

MCIA continues to have a very active engagement with the Government, various regulatory authorities and members of Parliament. MCIA has built sound relationships with the regulator and continues to work collaboratively to promote and shape a framework supportive of delivering Australian quality products to Australian patients in a timely and affordable manner. A major part of our activity has been around advocating for key policies and outcomes to support the sector including in areas such as patient access, regulatory efficiency, harmonisation and compliance and product integrity.

We have continued to hold regular meetings with the Office of Drug Control (ODC) and Therapeutic Goods Administration (TGA), with both these organisations regularly participating in our member forums, and made a number of comprehensive submissions to various inquiries. These are listed elsewhere in the Annual Report, but I would like to single out the outcome of the scheduling of CBD to S3 OTC. I said last year the MCIA submission showed the power of like-minded organisations coming together to express different views, have constructive discussion, supported by investment in evidentiary research to develop a well articulated and robust submission that will deliver improved outcomes for patients, the community and industry. This was demonstrated in the final outcome of the scheduling decision that saw the maximum daily dose increased from 60mg to 150mg, thus providing the industry with a real opportunity to achieve product registration and make available OTC

products to patients.

During the past year, MCIA has also worked closely with the Victorian Government - firstly on a project to help shape the Government's new Industry Development Plan, and secondly to shape support for companies wishing to export. This will not only support Victorian based companies, but the broader medicinal cannabis industry.

Our industry and its products have the opportunity to have a profound impact on the way we treat some conditions, the potential to improve the wellbeing of a wide range of patients, and to contribute positively to Australia's health system. Australia is well placed to lead the world with quality medicinal cannabis, deliver next generation patient wellbeing, and develop a new export industry. MCIA remains focused on improving the access for patients to Australian products underpinned by Australian quality in a timely and affordable manner. The Australian licensed sector will have significant capacity coming online over the next couple of years which should see Australian patients being able to access Australian quality product in a timely and affordable manner. However, it is important as an industry that we provide the stewardship and evidential support to see it become part of healthcare options available to patients.

A critical policy change for the local industry will be the expected equivalence requirements for imported products. TGA initiated consultation on this issue in January 2020 and while the Government response has been somewhat slow we understand that the Government is working towards a policy change that will see a level playing field. It is important that patient access is not disrupted in the transition stage, and again MCIA has

been engaging with TGA on risk mitigation actions to avoid any adverse behaviour during a transition.

While MCIA has made significant progress over the past twelve months, it continues to rely on the support and contribution of our members. I would particularly like to thank our founding members for continuing to do much of the heavy lifting, and all our new members who have joined us over the last year. Your collective support and involvement has enabled MCIA to progress on as many fronts as possible. In particular, I would like to thank my fellow board members -Rodney Cocks, Russell Harding, Elisabetta Faenza, and Carol Ireland, and directors who have since moved on with changes to their roles in the industry - Patty Holmes and Nick Woolf.

I would like to acknowledge the valuable input of our working groups which has seen great contribution from technical and policy people within our member companies to help shape MCIA's policy frameworks and submissions and inputs to industry processed.

Lastly, I invite you all to attend **ACannabis 2022**, which subject to COVID allowing, will be ACannabis hybrid combining virtual and in-person options in March 2022. This event

will enable us to continue the networking and knowledge building created by **ACannabis**. **ACannabis** has put the Australian medicinal cannabis industry centre stage and helped improve communication and understanding of needs and requirements across patients, industry and Government.

I have enjoyed the privilege of leading this very important industry association since its inception, and look forward to working with everyone that is part of this exciting new industry to ensure that it delivers positive outcomes and impact for all.

MCIA wants to be your trusted partner in shaping the Australian industry, facilitating access for patients and enhancing Australia's place in the global medicinal cannabis industry.

I am confident with the MCIA membership and team that we can achieve this.

**Peter Crock**  
Chair  
Medicinal Cannabis Industry  
Australia (MCIA)



# Objectives

Medicinal Cannabis Industry Australia (MCIA) is the peak industry organisation for Australia's licensed medicinal cannabis industry. It represents the mutual interests of members and other stakeholders to build a professional industry based on legitimacy, credibility and recognition for the Australian sector in domestic and international arenas. It acts as the voice for the licensed medicinal cannabis sector.

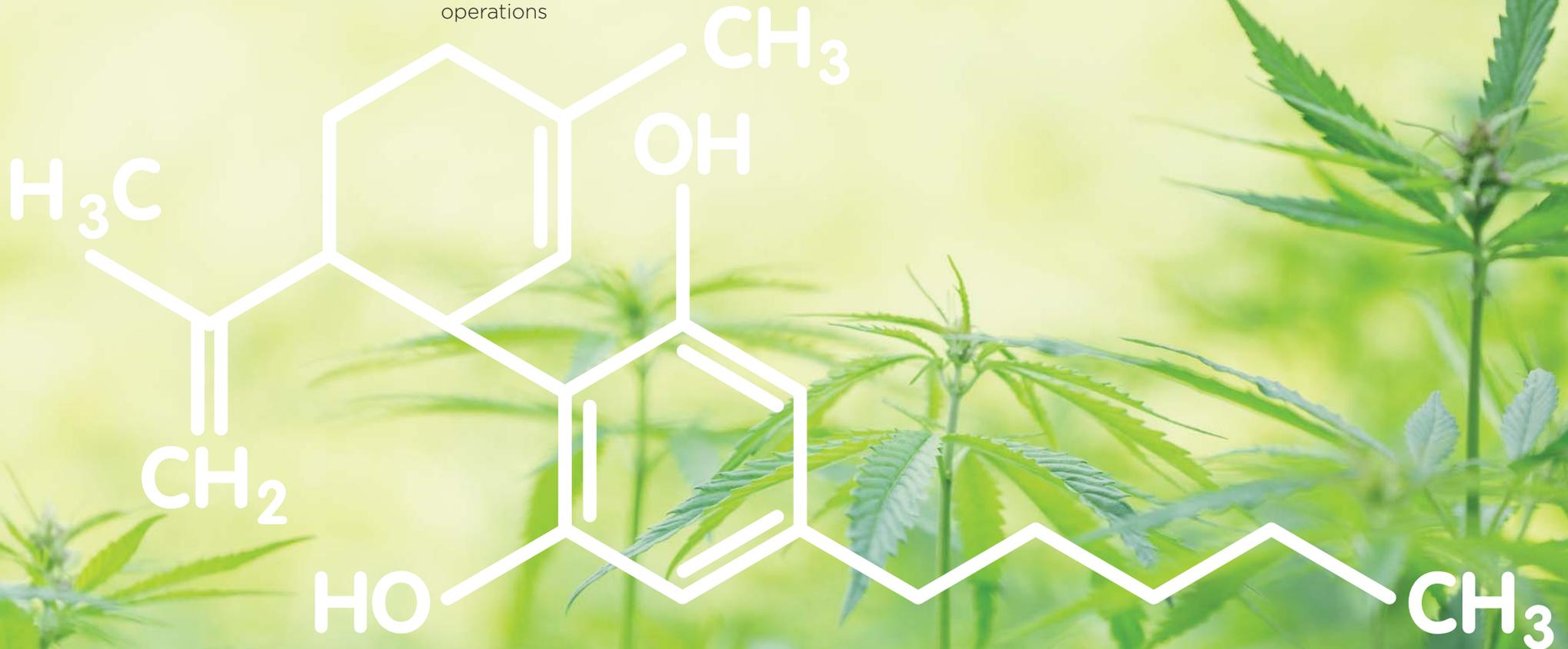
Specific objectives are to:

- facilitate and promote the growth, development and reputation of the medicinal cannabis industry
- promote regulatory consistency across Australia and facilitate a self-regulatory environment that accelerates access for Australian products to Australian and global patients
- promote awareness and confidence in medicinal cannabis
- promote best practices in all aspects of the industry's operations

# Industry Outcomes

MCIA, through its activities, will support/develop:

- Well informed patients, healthcare sector and industry, based on sound data and research
- A better skilled industry - operating at best practice
- Access to more effective tools and processes
- A harmonious and collaborative industry which works to grow the industry within the context of community and environmental responsibility
- Enhanced innovation and leadership
- A legitimate and legally compliant industry



# Highlights of 2020/21

## Medicinal Cannabis Health Advisory Council

Medicinal cannabis has the potential to positively contribute to health outcomes for the community, and the newly established Council will play an important role through engagement with medical experts, patient advocates, and Government to raise awareness of the applications, and barriers to access, for medicinal cannabis.

The Council comprises:

- Dr Richard Di Natale, Chair
- Associate Professor Vicki Kotsirilos, AM, General Practitioner and Honorary Academic, Adjunct Associate Professor, Western Sydney University and La Trobe University
- Professor Iain McGregor, Academic Director of the Lambert Initiative, University of Sydney
- Adjunct Professor Kylie Ward, CEO, Australian College of Nursing
- Carol Ireland, CEO and Managing Director, Epilepsy Action Australia
- Professor Jonathan Cebon, Group Head, Cancer Immunobiology Program, Olivia Newton-John Cancer Wellness & Research Centre (ONJCRI), and former Medical Director of ONJCRI

This group of experts is committed to ensuring that there continues to be a strong focus on facilitating patient access to medicinal cannabis, that there is access to balanced evidence based information for patients, and education and training programs for the medical profession that will enable improved communication and access pathways for medicinal cannabis.

The Council will engage with colleagues from the health, research and patient advocacy sectors to increase awareness of medicinal cannabis to Australians and to support education, awareness, and access to medicinal cannabis.

## Submissions

- Submission to the TGA: Potential reforms to medicinal cannabis manufacturing, labelling and packaging requirements

**JANUARY 2021**

- MCIA Submission to the Office of Drug Control: Medicinal Cannabis Permit Reform

**DECEMBER 2020 & MAY 2021**

- MCIA Submission to THA: Consultation on TGA Guidelines for compounded medicines and good manufacturing practice (GMP) - Guide to the interpretation of the PIC/S guide to GMP for compounded medicinal products

**DECEMBER 2020**

## Code of Conduct

Medicinal cannabis has an important role to play in improving health outcomes. MCIA believes that patients should have easy and affordable access to a quality controlled, true to label, compliant product that is already demonstrating the potential to positively contribute to a broad range of conditions. MCIA works to help the industry develop a culture of doing things the right way, ethically, with integrity, and in full compliance with the law. This will build the trust and confidence of all communities with which MCIA members engage.



What is the promise?	
• Plant-derived cannabinoid medicine which delivers on what is promised	
• All medicine is produced ethically and complies with the expected Australian regulatory standards	
• The Australian Medical Cannabis industry and all of its stakeholders are committed to transparency	

The MCIA Code has been developed to help build confidence with patients, regulators and the community. The Code will also contribute to and support a well-functioning medicinal cannabis industry.

The Code addresses issues that have potential to impact on the integrity and reputation of the medicinal cannabis industry. The Code will assist MCIA members to be recognised as committed to developing and operating in an industry that is built on trust, accountability, and assurance. The Code aims to promote high standards of integrity across the medicinal cannabis industry so that patients and healthcare professionals can have confidence in their dealings with the Industry and its members and their products.



# Highlights of 2020/21

## Advocacy/Stakeholder engagement

- Held the first meeting of the Parliamentary Friends Group for Medicinal Cannabis (Nov 2020)
- Submissions to the ODC, TGA, and Minister of Health, followed by response and engagement on implementation
- Engagement with TGA re advertising guidelines, import protocols, scheduling, testing and compliance, and representation on key TGA Working Groups
- Engagement with the ODC on the implementation of regulatory reforms and improvements, in particular, in regard to the single licence and permit reforms
- Briefing papers and policy statements
- Engagement with the State and Federal Government, regulatory authorities, Advisory Councils and members of Parliament
- Engagement with patient advocacy groups, medical sector and other community stakeholders

## Representation

- Presented to the Minister Hunt's Medicinal Cannabis Advisory Council
- Member of the TGA Industry Working Group on GMP
- Meetings with various Ministers, Minister's advisers, ODC and TGA

## Industry insights

- Provides members with information and insights to navigate, often complex, industry issues
- Working with MTPConnect to develop a White Paper for the Medicinal Cannabis Industry (scheduled for release in late 2021). This critical piece of work provides a base for the industry to develop good metrics around its contribution to the health, economy and export revenue of Australia.

## Events

- Joint event with FreshLeaf Analytics and release of the FreshLeaf Analytics H1 2021 Report on Medicinal Cannabis Patient, Product and Pricing Analysis  
**APRIL 2021**
- ACannabis EVOLVE - an Industry led Australian medicinal cannabis conference bringing together the industry's ecosystem, held virtually on 16 & 17 March, with 500 participants from across the value chain. Around 50% of the delegates were from the healthcare practitioner or consumer sectors.  
**MARCH 2021**
- Joint workshop with TGA in regard to advertising compliance  
**MARCH 2021**
- Member Forums - introduced in the COVID environment to enable ongoing member contact and networking  
**SEPTEMBER 2020, NOVEMBER 2020 & MAY 21**

- Parliamentary Friends of Medicinal Cannabis Group - inaugural event comprising remarks by the Parliamentary co-chairs and an interactive panel discussion "Ready, willing and able - Medicinal Cannabis - Australia's next growth story". The panel comprised a range of industry experts spanning patient advocates, research and industry:
  - Elisabetta Faenza, MCIA Director & CEO, LeafCann Group
  - Peter Crock, MCIA Chair & CEO, Cann Group - *industry perspective*
  - Dr Richard Di Natale, Chair, MCIA HCP/Patient Advisory Council - *healthcare/patient perspective*
  - Professor Iain McGregor, The Lambert Initiative University of Sydney - *research perspective*
  - Carol Ireland, CEO, Epilepsy Action Australia - *patient advocacy perspective*

**NOVEMBER 2020**

