



MCIA

Medicinal Cannabis Industry Australia

Annual Report 2022-23

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.”



MCIA Board



Peter Crock
Chair MCIA



Elisabetta Faenza
CEO, LeafCann Group



Russell Harding
Executive Chairman
and CEO, MedReleaf
Australia



Patty Holmes
Director and
Co-founder, Holmes
and Wilson



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



Peter Koetsier
CEO, Cann Group



Jo Patterson
CEO, BOD
Australia

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 22/23 year with development of policy positions/papers or submissions to:

- Risk-based variations (ODC)
- ODC Transformation project
- Medicinal cannabis reforms (updated TGO 93) and associated guidance
- Royal Commission into Veteran Suicides
- Industry Metrics
- Import process policy paper
- Fees and Charges Consultation Submission (ODC)

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 major activity for Standards Working Group is 2022/23 was a review of the MCIA Code in light of the updated TGO93.

Ongoing activity is focused on advertising compliance and GMP compliance for imports.

The Standards Working Group is also investigating the opportunity for best practice guidance documents and development of tools to assist members in identifying and complying with regulations and standards.

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 2022/23 was around:

- Strategy in regard to Human Research Ethics Committees (HREC) and hosting of workshop to discuss approaches to successfully engaging with HRECs in the area of clinical trials involving unregistered medicinal cannabis therapeutic goods
- Discussions with potential funding bodies for insight into possible funding of an industry wide research strategy

AUSTRALIAN MEDICINAL CANNABIS MARKET AT A GLANCE

2022 TOTAL

AUSTRALIAN
MEDICINAL CANNABIS
MARKET:

48,276 kg

AUSTRALIAN
PRODUCTION:
24,900 kg

IMPORTS:
24,886 kg

EXPORTS:
1,510

2022 UNITS
DISPENSED:
1,679,882
units

PRODUCT
CATEGORY

**ORAL LIQUID
PRODUCT CATEGORY:**
CBD dominant: 54%
Balanced: 24%
THC dominant: 22%

**DRIED FLOWER
PRODUCT CATEGORY:**
CBD dominant/balanced: 3%
THC dominant: 97%

BREAKDOWN OF
UNITS DISPENSED

PRODUCT DOSAGE FORM:
Dried flower: 66%
Oral liquid: 29%
Inhalation*: 4%
Oral other**: 1%

**PRESCRIBER
ACCESS PATHWAY:**
SAS B: 42%
AP: 58%

* Liquid vape product,
**Capsules, pills, wafers



MCIA

Medicinal Cannabis Industry Australia

Source: ODC FOI requests TGA

Chair Report

I am pleased to present this report to the 5th Annual General Meeting of the Medicinal Cannabis Industry Australia (MCIA).

Our industry continues to mature, with the medicinal cannabis ecosystem developing, although challenges remain for patients, prescribers, and companies. I have said previously that our industry's success depends upon a mature approach to policymaking, a commitment to quality, adherence to high ethical standards, and improved access pathways for healthcare consumers.

MCIA continues to be the voice for the legitimate medicinal cannabis industry and works to support a sustainable medicinal cannabis ecosystem.

MCIA's vision is for an innovative, responsible, and legally compliant industry that delivers economic and social value while keeping the focus on patients and medicinal cannabis's therapeutic value. During this year, MCIA has continued to advocate for and implement strategies to achieve this vision.

The final changes to the Therapeutic Goods (Standard for Medicinal Cannabis) (TGO93) came into effect in July this year. The two most impactful changes were the requirement for imported products to meet equivalent Good Manufacture Practice (GMP) quality standards as Australian-made products and the medicinal cannabis product labelling requirements.

MCIA has delivered on several planned initiatives during the year, including ACannabis 2023, the first in-person conference after two years of virtual ones. MCIA welcomed over 400 attendees to its conference and exhibition at CentrePiece in Melbourne in mid-March. In its fourth year, the event brought together participants from the medicinal cannabis ecosystem, including policymakers, governments, global leaders, healthcare professionals, and industry participants, to share knowledge, exchange ideas and showcase leading-edge industry technologies and opportunities. ACannabis 2023 continues establishing its position as the premier Australian medicinal cannabis event.

To promote Australia's profile as a reliable, high-quality source of medicinal cannabis in Europe, which is important for the further opening of medical markets, MCIA partnered with Austrade and Global Victoria to have a presence at the ICBC event in Berlin in July 2022 for an Australian delegation. The ICBC program included a boutique side event, the Global Investment Forum, an educational briefing session for the Australian delegates and the ICBC conference and trade show, which included the Australia pavilion. The attendance of the MCIA was crucial to providing insights into the Australian industry to visitors and direct requests to suitable delegates.

MCIA continues to actively engage 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 quality Australian products to Australian patients in a timely and affordable manner. A significant part of our activity has been 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 held regular meetings with the Office of Drug Control (ODC) and Therapeutic Goods Administration (TGA), and both organisations regularly participate in our member forums as MCIA makes comprehensive submissions to various inquiries.

There has been a changing of the guard this year. At the TGA, Professor John Skerritt retired from his position of Deputy Secretary Health Products Regulation Group. The medicinal cannabis industry has been very fortunate to have someone of John's integrity, longstanding interest in and passion for medicinal cannabis to help implement regulations for our new and emerging industry. The pathway for the industry has been, and continues to be challenging, but the guidance and pragmatism of John as the ultimate regulator has certainly assisted the industry to

develop and grow, and most importantly, has helped provide the health sector and patients with confidence in this new and exciting medicine. We sincerely thank him for his contribution to our industry and the broader health sector outcomes.

We recently had the opportunity to meet and welcome Professor Tony Lawler as the new Deputy Secretary and MCI look forward to working with him and the TGA team.

At the MCI, founding executive manager Rosemary Richards resigned from her position but continues to work with the MCI as a special advisor. I would like to acknowledge her valuable contribution and commitment to the cause which were crucial to MCI's successful establishment and operation. Following an orderly transition, Patty Holmes has taken the reins as Executive Officer and continues to deliver from the platform established by Rosemary.

Finally, after seven long years in the pressure cooker of a nascent industry, I have decided it is also the right time for me to hand the baton on. I have flagged to the board that I will not seek reappointment as Chair of the MCI. It has been an honour and a privilege, and I hope useful, to be at the forefront of such an important opportunity, to break the shackles and stigma of prohibition, and provide all important access to effectively a new class of compound to medicine in Australia and around the world.

Thank you.

Peter Crock
Chair
Medicinal Cannabis Industry Australia (MCI)



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.

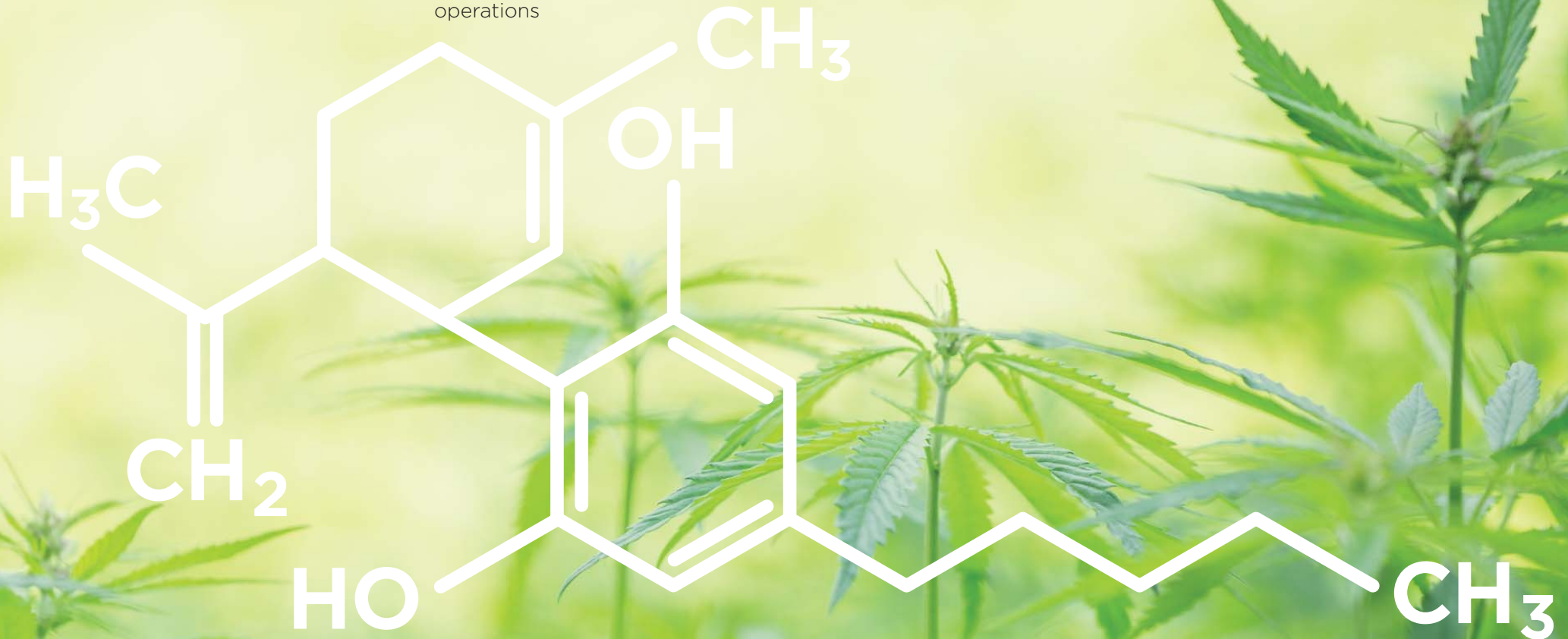
Specific objectives are to:

- 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 2022/23

Government Relations activity

Advocacy/Stakeholder engagement

Beginning FY23 with a strategic planning session in Canberra, discussions focused on the challenges and opportunities facing Australia's medicinal cannabis industry. MCIA's top strategic priorities were confirmed as government relations and education, and throughout the year, MCIA's work focused on furthering these priorities.

Government relations activity during the year included regular meetings with the Assistant Minister for Health and Ageing, Ged Kearney, to discuss the key issues facing the medicinal cannabis industry, such as the driving laws for medicinal cannabis patients, pharmacy compounding, the difficulties of ARTG schedule 3 registration and the lack of published industry data.

Additional initiatives were undertaken with the Minister for Agriculture, Fisheries and Forestry, Murray Watt, and Minister for Trade, Tourism, and Investment Minister, Don Farrell. These interactions focused on the trade imbalance with Canada and the potential biosecurity risk of imported dried plant material, among others.

MCIA continued its government relations activity by regularly meeting with government figures from the TGA and the ODC to address key concerns within the industry. Throughout the year, MCIA conducted and attended numerous sessions with key bodies throughout the industry.

A core activity for MCIA is working with regulators and other stakeholders to help shape the regulatory environment, specifically in the areas of:

- TGA Regulatory Compliance Branch on the implementation and compliance with medicinal cannabis reforms (TGO 93), specifically about the GMP and labelling requirements
- TGA Advertising through ongoing engagement with TGA on advertising guidelines and compliance, including an FOI request on medicinal cannabis advertising complaints
- ODC to improve the availability of medicinal cannabis industry data

Other activities include:

- Development of 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

Submissions

MCIA has worked closely with industry bodies, medical professionals, and patients this year to build several submissions to continue supporting the growth and recognition of the medicinal cannabis ecosystem.

Some of these submissions across the year include:

- Submission to Improving Access to Medicinal Cannabis Bill 2023
- Submission to Greens on Legalise Cannabis Bill
- Submission to Royal Commission into Defence and Veteran Suicide
- Submission to the Office of Drug Control, Medicinal Cannabis Program Regulatory Fees and Charges Review Consultation
- Submission to the public consultation on the review of Guidelines on compounding of medicines by the APHRA Pharmacy Board



Highlights of 2022/23

Industry governance

Medicinal cannabis has an important role to play in improving health outcomes and has demonstrated its potential to positively contribute to a broad range of conditions. MCIAs supports easy and affordable patient access to a quality-controlled, true-to-label, compliant product. A core focus for MCIAs is working with industry to develop a culture of doing things the right way, ethically, with integrity, and in full compliance with the law, to build the trust and confidence of all communities with which MCIAs members engage.

Grant Funding

The financial viability of MCIAs is a prerequisite for all other activities, so additional funding opportunities must be investigated. MCIAs successfully applied for an Agricultural Trade and Market Access Cooperation grant for \$250,000 to assist Australian medicinal cannabis companies in securing global markets for medicinal cannabis products. MCIAs also successfully applied for an Export Market Development Grant for \$20,000 to assist with overseas exposure of Australian capabilities.

Supporting Industry growth

MCIAs has increased its activity around quantifying industry metrics and continues to provide members with information and insights to navigate often complex industry issues.

MCIAs partnered with Austrade and Global Victoria to have a presence at the ICBC event in Berlin in July 2022 for an Australian delegation. The ICBC program included a boutique side event, the Global Investment Forum, an educational briefing session for the Australian delegates and the ICBC conference and trade show, which included the Australia pavilion. The attendance of the MCIAs was crucial to providing insights into the Australian industry to visitors and direct requests to suitable delegates. This initiative helped profile Australia as a reliable, high-quality source of medicinal cannabis in Europe, which is important for the further opening of medical markets.

Education

In March of this year, MCIAs and Epilepsy Action Australia (EAA) announced a collaboration to support and develop CanGuide's position as the source of trusted information on cannabis-based medicines for patients and healthcare professionals and to deliver outcomes beneficial to the Australian medicinal cannabis industry.

Prescribers and others have identified a trusted information platform as a key industry need, and this partnership is seeking the funding required to develop this valuable, necessary resource.

The service will be delivered via the CanGuide website and the HealthShare platform, which is integrated into the clinical software of 90% of Australian GPs.

Patient access

MCIAs continues to actively work with Drive Change and other stakeholders to advocate for changes to driving laws, which has been identified as a major barrier to increased patient access. Direct state advocacy activities include MCIAs submissions to Victorian and NSW Government inquiries.



Highlights of 2022/23

Building the medicinal cannabis ecosystem

Engagement and networking

MCIA hosted its ACannabis conference and exhibition at CentrePiece in Melbourne in mid-March. In its fourth year, the event brought together participants from the medicinal cannabis ecosystem, including policymakers, governments, global leaders, healthcare professionals, and industry participants, to share knowledge, exchange ideas and showcase leading-edge industry technologies and opportunities. ACannabis 2023 successfully brought the industry together and continues establishing its position as the premier Australian medicinal cannabis event.

MCIA workshop events held during the year include:

- Understanding Clinical Trials and Insurance Requirements
- Tips and tricks for the OTC market, product registration and the advertising environment for Schedule 3 CBD
- Tips for successfully engaging with Human Research Ethics Committee



MCIA
ACANNABIS
14 & 15 MARCH 2023
www.acannabis.com.au

