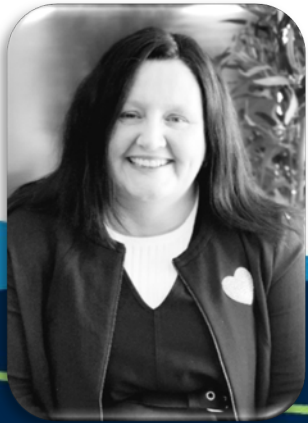




Australian Government  
Department of Health  
Therapeutic Goods Administration

# Medicinal cannabis advertising compliance



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Director, Advertising and  
Compliance Education, and policy ,  
Regulatory Compliance Branch  
Therapeutic Goods Administration



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Advertising Investigator  
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Assistant Secretary, Regulatory  
Service & Drug Control Branch  
Therapeutic Goods Administration



**Rosemary Richards**

Executive Manager  
Medicinal Cannabis Industry  
Australia



**Peter Crock**

CEO – Cann Group Ltd  
Chair - Medicinal Cannabis  
Industry Australia



**Cameron Scadding**

Managing Director  
Source Certain International

**Therapeutic Goods Administration (TGA)**  
**Medicinal Cannabis Industry Australia (MCIA)**  
**Source Certain International (SCI)**

**TGA** Health Safety  
Regulation

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- This webinar is being recorded
- Slides will be made available on the TGA website
- To ask a question to the **speaker** – Please use the **Q&A** tool
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  - Questions will be answered at the end of the presentation
- If you need to contact the moderator – please use the **‘Chat’** function
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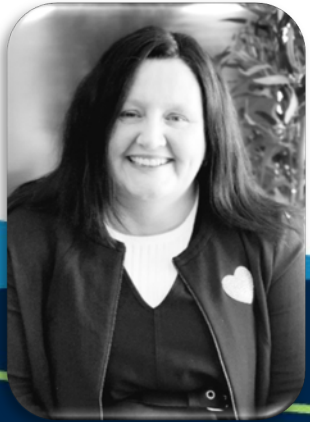
OR

**Dial:** (02) 9338 2221 **Passcode:** 165 601 1620



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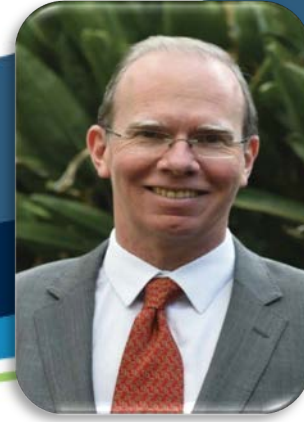
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# Introduction

**George Masri**

Assistant Secretary

Regulatory Services and Drug Control Branch

Health Products Regulation Group

Department of Health





# Today's session

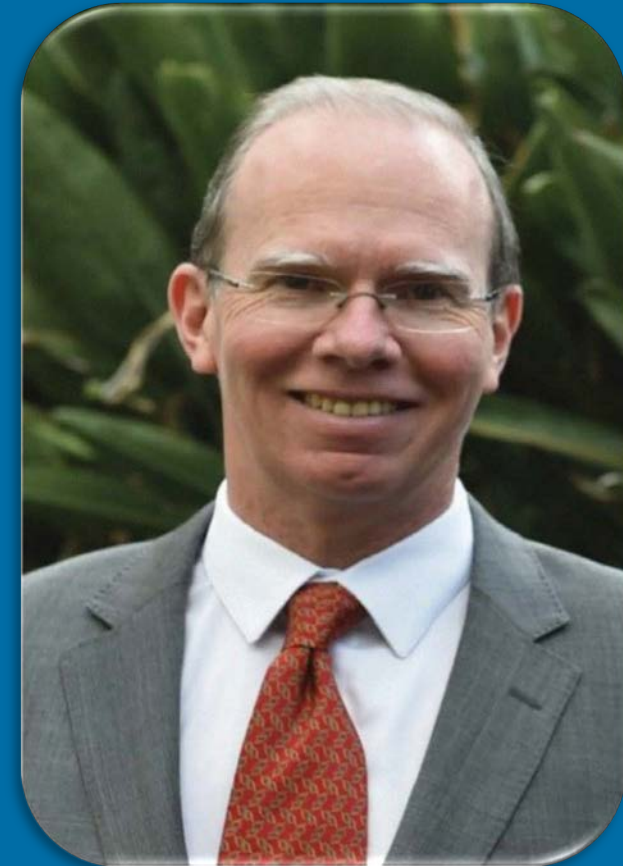
- Assist industry and other interested parties to understand their obligations in regards to advertising medicinal cannabis
- Overview of the advertising requirements
  - Legislative scheme
  - General offences
  - Prohibited and restricted representations
  - Application of the Poisons Standard
  - ASX announcements
  - Media and social media/testimonials

# Introduction

**Peter Crock**

CEO – Cann Group Ltd

Chair - Medicinal Cannabis Industry Australia



# Definition of ‘advertise’

*“... includes make any statement, pictorial representation or design that is **intended, whether directly or indirectly, to promote the use or supply of the goods**, including where the statement, pictorial representation or design:*

- (a) is on the label of the goods; or*
- (b) is on the package in which the goods are contained; or*
- (c) is on any material included with the package in which the goods are contained.”*



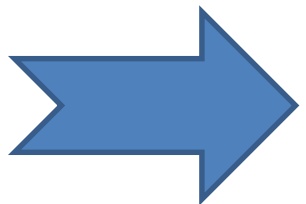
# The difference between advertising and other activities

- Key question: Is it advertising?
  - Material must be considered on a case by case basis
  - Information in one context may become promotional in another context
    - e.g. placement of an ‘informational article’ near an advertisement for a product mentioned in the article
  - Does the material have the effect of persuading consumers as to the qualities of a therapeutic good?
  - Does the material provide supply information about a therapeutic good i.e. does it promote the supply (advertise) a therapeutic good



# Promotion v information

- Use of language - factual vs compelling/call to action
- Inclusion of testimonials
- References to the product
- Comparison information
- Motivates a response
- Creates a sense of urgency



Does it make a consumer want to go out and buy the product?

this does not apply to advice or information given directly to a patient during the course of treatment

# What can you say about your operations?

- Business activities may involve dealing with medicinal cannabis, including importation of finished product or starting materials, cultivation, harvesting and manufacture of finished products in Australia
- Businesses may publicly state (including at conferences) what their operational activities involve **BUT** it is important that the information remains **modest** and **factual** to ensure the material does not become advertising by promoting the use of medicinal cannabis

# ASX announcements

- Continuous disclosure obligations
- ASX announcements should refrain from using promotional materials such as patient testimonials
- Crowd funding activities are not legal requirements for the purpose of the Corporations Act and would be more likely considered advertising or promotional activities

# What is not permitted?

- x Images or pictorial representations of cannabis plants or leaves
- x Images or pictorial representations of medicinal cannabis products
- x Testimonials from consumers and case studies
- x Listing medical conditions suitable for therapy with medicinal cannabis



Care should be taken in re-publishing content such as advertorials

# Do's and Dont's

- ✓ We are a licenced importer and supplier of medicinal cannabis products
- ✓ Our company directors are .....
- ✓ Our portfolio is available at the following link .....
- ✓ Our philosophy
- ✓ Our financial details can be obtained by.....
- ✓ Current research projects
- ✗ We import the highest grade medicinal cannabis products
- ✗ The benefits of our products are.....
- ✗ Our products may be used to treat.....
- ✗ Testimonials from end users
- ✗ Products include CBD oils
- ✗ Pictures of products or cannabis plants



# Requirements for advertising to the public

- Requirements apply to sponsors and other advertisers (e.g. retailers, practitioners)
- *Therapeutic Goods Act 1989* requirements: ss42DL (criminal) or 42DLB (civil)
  - **must not advertise:**
    - **prescription medicines or biologicals**
    - illegal therapeutic goods (not in the ARTG)
  - must not mention serious conditions without prior TGA approval

In addition, s42DM (criminal) or s42DMA (civil) provides an offence for breaching the requirements of the Therapeutic Goods Advertising Code

# Therapeutic Goods Advertising Code

- Advertising must:
  - be accurate, balanced & verified
  - not mislead nor arouse unwarranted expectations
  - not lead to self diagnosis and/or inappropriate treatment
- Other specific requirements include:
  - must not advertise goods as ‘safe’
  - no endorsements by health professionals or government (includes ‘TGA approved or use of the government logo)
  - must not imply that other goods are harmful or ineffectual
  - certain mandatory statements must be included

# Application of the Poisons Standard

- From 1 February 2020 certain cannabidiol (CBD) products are included in Schedule 3 (pharmacist only)
- The new entry in Schedule 3 applies to CANNABIDIOL in oral, oromucosal and sublingual preparations **included in the Australian Register of Therapeutic Goods**
- Cannabidiol **does not appear in Appendix H** to the poisons standard and therefore is **not** permitted to be advertised to the public

# Implying government approval

Do not make reference to government agencies (domestic or foreign), including TGA, in any therapeutic goods advertising or promotional material as this potentially implies endorsement by that agency

This includes:

- x statements such as 'TGA approved' or 'Government endorsed'
- x using the TGA logo or the Commonwealth Coat of Arms
- x statements that a therapeutic good is 'included in the ARTG by the TGA', 'registered by the TGA', 'TGA listed' or similar



# Social media

- You are responsible for the content of any page you create/manage
- Advertisers should monitor their social media feeds for non-compliant posts from third parties
- Consider having an ‘acceptable use policy’ that tells third parties there are requirements and you may remove non-compliant posts
- Be careful about what you are tagged in and remove inappropriate tags
- Do not tag the TGA or a government entity in product-specific posts
  - Express or implied government endorsement of therapeutic goods is prohibited



# Example Facebook ads – clinics



Greenz Medical centre



**Our services include:**

Pain Management  
Management of chronic conditions  
Psychology

Make an appointment to see one of our doctors  
and work out a management plan to suit you.



Greenz Medical Centre

**Tried everything? Still in pain ?**

You can now get your medicinal cannabis  
prescriptions at Greenz Medical Centre. Our range  
of superior quality products will get you back in the  
game.

**Testimonial** “I was barely able to walk to the park,  
now I am completely pain-free and enjoying the  
great outdoors...” Tim, 47



*Guaranteed or your money back*

# Advertising to health professionals

secure the  
advertising



must be **directed exclusively** to health  
professionals (including hospital  
purchasing officers)

advertise  
publicly



ad must comply with all applicable  
requirements in the Act & Code

Examples of health professionals:  
medical practitioners, dentists, pharmacists, nurses (see s42AA)

## Example: Directing exclusively to HPs

A medicinal cannabis supplier has information available to health professionals via its secure website, after confirmation of health professional status. The website displays the following information:

***The materials available here are secured with a username and password issued by the website administrator following confirmation of health professional status***

Click here to provide your AHPRA registration number

A self declaration is not enough to meet the requirement of exclusively to health professionals:

Click here if you are a health professional

# Serious diseases, conditions, ailments or defects

Unauthorized use of prohibited or restricted representations in advertising is a serious breach of the requirements

## Prohibited representations

- Treatment, cure, prevention or diagnosis of e.g.:
  - Depression
  - PTSD
  - Cancer

## Restricted representations

- Epilepsy, seizures/fits
- Neuropathic pain
- Chronic pain
- Opioid addiction
- Anxiety

# Case study: Medicinal cannabis prescription services

- Case: clinic offering medical services, including services involving medicinal cannabis
- Facebook page promoted medicinal cannabis for treating chronic pain, palliative care, epilepsy, chemotherapy induced vomiting/nausea, MS, neuropathic pain, cancer pain, PTSD, depression, fibromyalgia, autism, schizophrenia, Alzheimer's, anorexia & wasting associated illness, Parkinson's Disease, seizure management, Tourette's & tremors

## Details of non-compliance

- Advertising a prescription medicine (breach of s42DL(10), s42DLB(7) of the Act)
- References to serious health conditions (breach of s42DL(7), s42DLB(4) of the Act – restricted representations, breach of s42DL(5), s42DLB(2) - prohibited representations)

## Outcome

- Cease and desist letter – issued with instruction for immediate action
- Advertiser removed all non-compliant advertising



## Case study 2 : Hemp oil

- Case: Individual and their business advertising hemp oil for sale
- The business website and Instagram pages promoted a hemp oil for a list of benefits including reducing pain and inflammation, increasing recovery, improvement of insomnia, recovery from hang-overs, relief of chronic anxiety, boosting the immune system, release of Anandamide and decreased post- surgery or injury recovery time

### Details of non-compliance

- Advertising a therapeutic good not registered on the Australian Register of Therapeutic Goods (ARTG), (breach of sections 42DL(12), 42DLB(9) of the Act)
- Advertising a prescription medicine (breach of s42DL(10), s42DLB(7) of the Act)
- References to serious health conditions (breach of s42DL(7), s42DLB(4) of the Act – restricted representations, breach of s42DL(5), s42DLB(2) - prohibited representations).
- Importation and supply offences (breach of sections 19B and 19D of the Act)

# Hemp oil cont.

## Outcomes

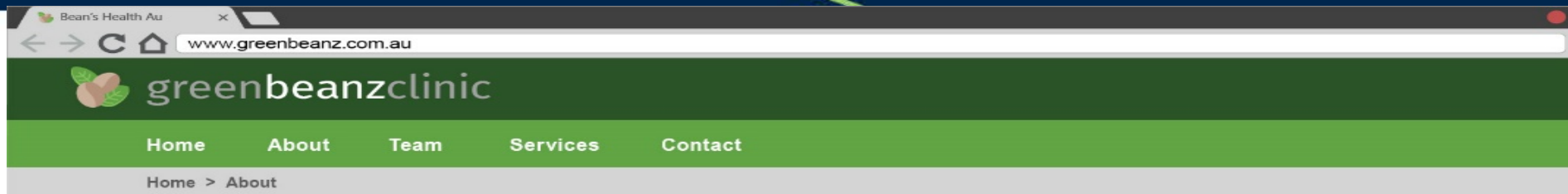
- Cease and desist letter – advertiser to remove non-compliant advertising and cease supply
- Advertiser instructed to close down the website and social media site by removing the uniform resource locator (URL) to ensure that those platforms currently promoting medicinal cannabis could no longer be accessed or viewed by the public
- The TGA further instructed the advertiser to notify what authorisations, licenses or permissions they held to have access to, possess or supply CBD oils in Australia
- Advertiser given infringement notices

# Accurate and balanced information

- ✓ Canberra Epilepsy Group has collated information about the use of medicinal cannabis in certain types of epilepsy. It disseminates the information to their members. The information is an accurate assessment of the full body of evidence relating to efficacy, possible benefits and possible drawbacks (including side effects) of the use of medicinal cannabis

## Accurate and balanced information cont.

- X** North West Child Epilepsy group members receive information from Jackson's Pharmacy advising that the pharmacy can compound various medicinal cannabis products to the formulation specified in a doctor's prescription
- X** North West Child Epilepsy organisation provides its members with a list of compounding pharmacies that can compound various classes of medicines including medicinal cannabis. They advise that Jackson's Pharmacy can compound various medicinal cannabis products with a valid prescription



Are you having difficulties finding access to medical cannabis? We're here for you.

#### About us

Green Banz Clinic is dedicated to improving the quality of life for all our patients, with timely and affordable access to pharmaceutical-grade medical cannabis.

Our certified team of medical experts can help you access cannabis-based products via the Therapeutic Goods Administration's (TGA) Special Access Scheme.

#### About medical cannabis

Medical cannabis is a natural treatment offering relief for patients suffering from chronic health conditions. The TGA has approved the use of medical cannabis for treating over 30 different conditions including:

- chronic pain
- neuropathic pain
- cancer
- anxiety
- insomnia
- arthritis
- fibromyalgia
- depression

#### Testimonials

"I'd tried everything on the market to relieve my back pain, some days I could barely walk. Medical cannabis offered me natural and fast pain relief when nothing else would work!"  
– Erica, 37, mother of 3.

"Medical cannabis treatment has made such a difference to managing my epilepsy. Now it's finally under control and I can get on with living a normal life."  
– Craig, 52, social worker.

#### A clear path to patient access

If you are suffering from a chronic condition and are looking for alternative treatments, medical cannabis could be an option for you.

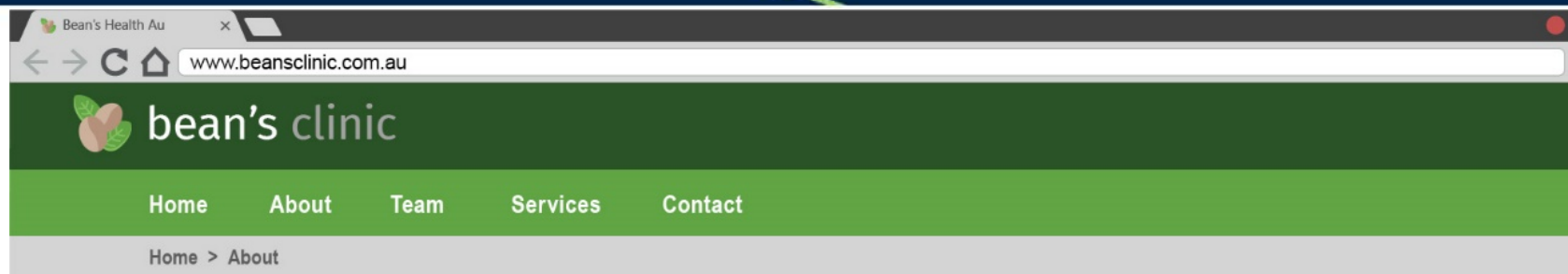
[Make an appointment today](#) to find out if medical cannabis is right for you.



**Book Now**

Non-compliant  
example - clinic





We're here to help you achieve your health and wellbeing goals.

#### About us

Our team of experienced medical practitioners provide personalised guidance, and treatments tailored to your individual needs.  
We specialise in treatments for patients who have been unable to find relief through other options.

#### Medicinal cannabis prescribing

Our specialist doctors will work with you to explore your options and determine the appropriate treatment for your conditions and circumstances. This could include medicinal cannabis therapy.

#### About medicinal cannabis

There are tight restrictions around the manufacture, supply and use of medicinal cannabis within Australia. However, laws exist to allow the prescribing and dispensing of medicinal cannabis products in specific circumstances.

Visit the Therapeutic Goods Administration (TGA) website for [important patient information relating to medicinal cannabis](#).

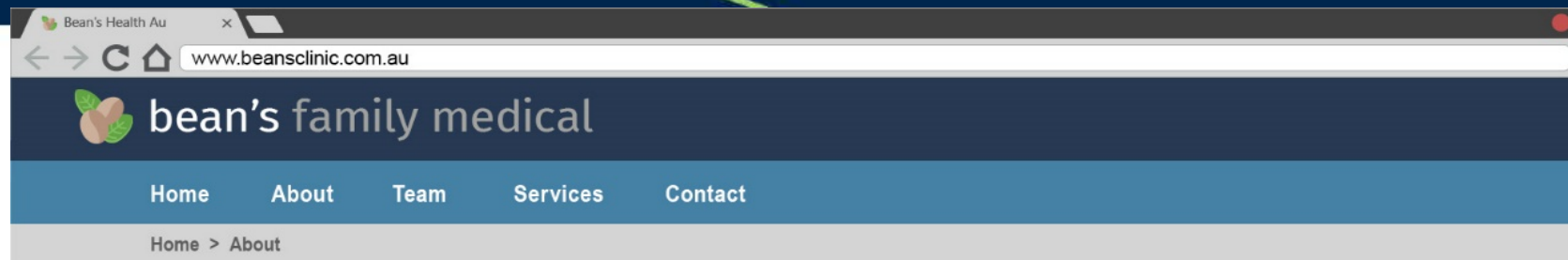
#### We can help

If you are looking for alternative treatments, contact us today for a consultation.  
[Make a booking online](#) and be on your way to feeling better sooner.



[Make an Appointment](#)

Compliant  
example - clinic



We're here to help you achieve your health and wellbeing goals.

#### About us

We're dedicated to providing you and your family with personalised, professional, quality healthcare. Our team of experienced medical practitioners offer a wide range of medical and support services, tailored to your individual needs.

#### The services we provide

- General practice medicine
- Naturopathy
- Medicinal cannabis prescribing
- Mental health and psychology services
- Care plans and assessments
- Exercise physiology
- Dietetics
- Travel vaccinations

#### Schedule an appointment

Contact one of our friendly team members who will be pleased to assist.

[Make a booking online](#) for the day and time that suits you.

For emergencies ring 000 or attend your closest hospital.



**Make an Appointment**

Compliant  
example - medical  
practice

# Supply of goods not in the ARTG

- Finished medicinal cannabis products not in the ARTG must only be supplied under one of the following ‘alternative pathways’ available via exemption, approval or authority under the TG Act:
  - (a) the authorised prescriber scheme (**AP**) - subsection 19(5);
  - (b) Special Access Scheme B (**SAS B**) - paragraph 19(1)(a);
  - (c) a clinical trial notification (**CTN**) – Regs, Schedule 5A, item 3; or
  - (d) a clinical trial approval (**CTA**) - paragraph 19(1)

# Direct Control requirements

- Exempt medicines are subject to further regulation in the *Therapeutic Goods Regulations 1990*. Sponsor must hold the goods under its 'direct control' until they are the subject of a relevant approval or authorisation under the TG Act
- These additional conditions relate specifically to medicines that are imported as exempt goods or if the medicines are medicinal cannabis products manufactured in Australia under a license issued by the TGA as exempt goods
- See Schedule 5A item 1 (medicines) and item 2 (medicinal cannabis)

# What is direct control?

For a sponsor to be said to maintain 'direct control' any **distribution contract** should (generally) provide for the medicinal cannabis products to:

- a) remain the sponsor's property until they are supplied through an approved alternative pathway
- b) be kept in a warehouse or secured area which is known to the sponsor, and over which the sponsor has some degree of contractual and practical control, and
- c) only be released for supply with approval from the sponsor (with any supply or movement of the goods being specifically notified to the sponsor, so that it maintains appropriate records as required by the conditions)

# Wholesale of medicinal cannabis

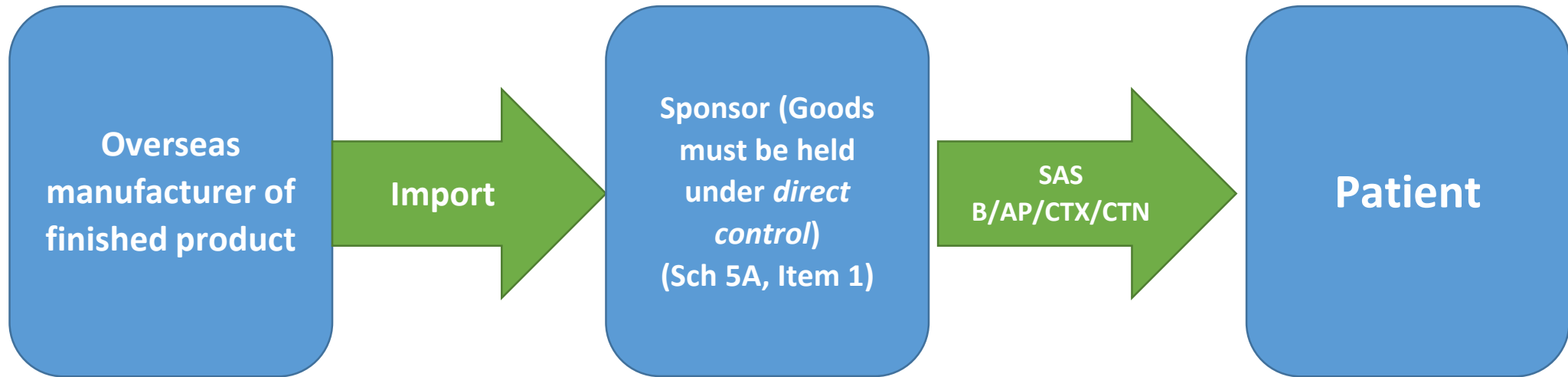
- Wholesale supply of unregistered therapeutic goods, including medicinal cannabis products, is not consistent with the therapeutic goods regulatory framework
- The TG Act also provides for a ‘wholesale supply’ criminal offence where a person who is not the sponsor of medicinal cannabis goods supplies the goods to a person other than the ultimate consumer of those goods unless the goods are listed or registered goods, or via an approved alternative pathway
- This criminal ‘wholesale supply’ offence at section 21 will apply regardless of whether or not the purchaser holds a wholesaling license



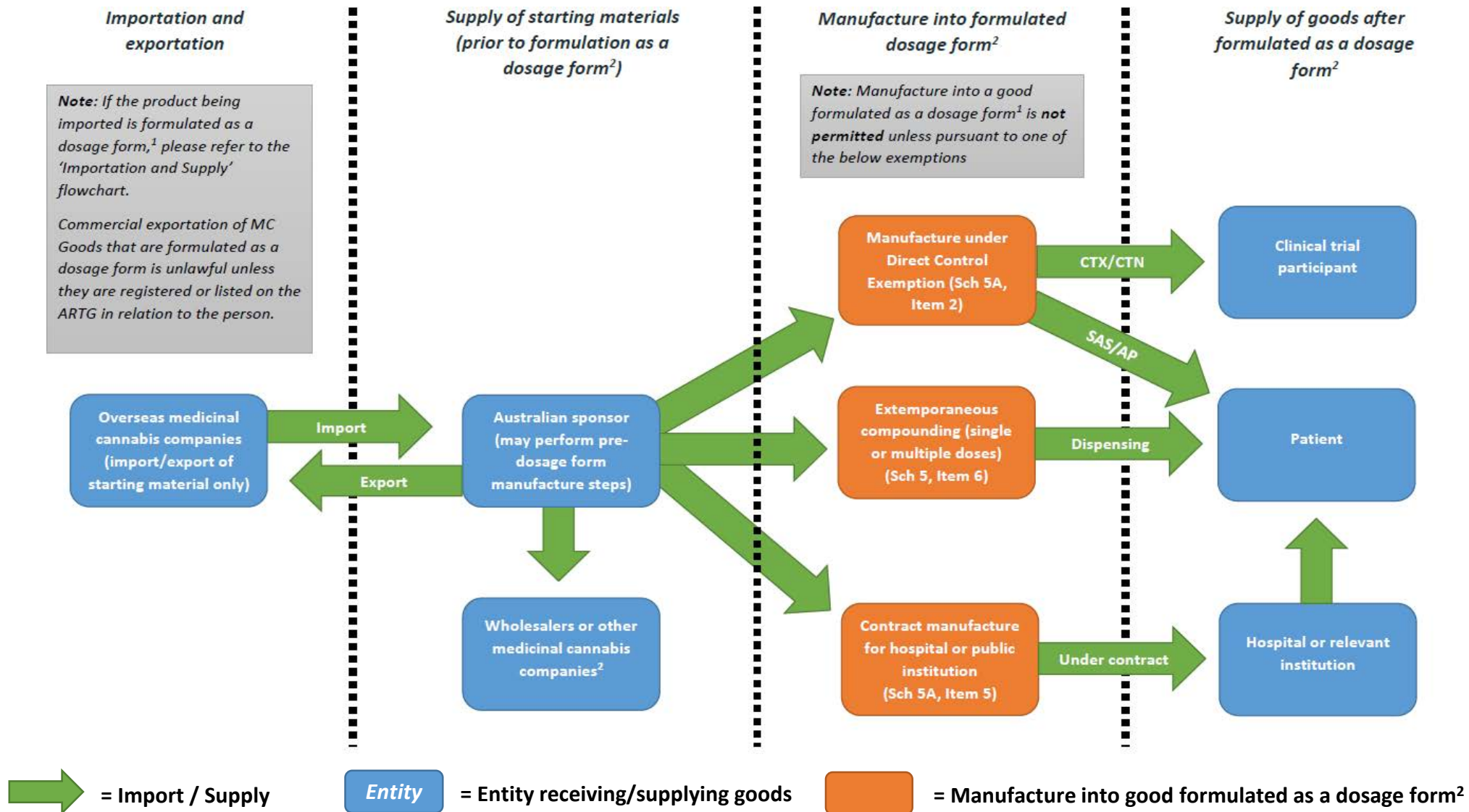


**The flow charts on the  
next 3 slides are  
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be reproduced**

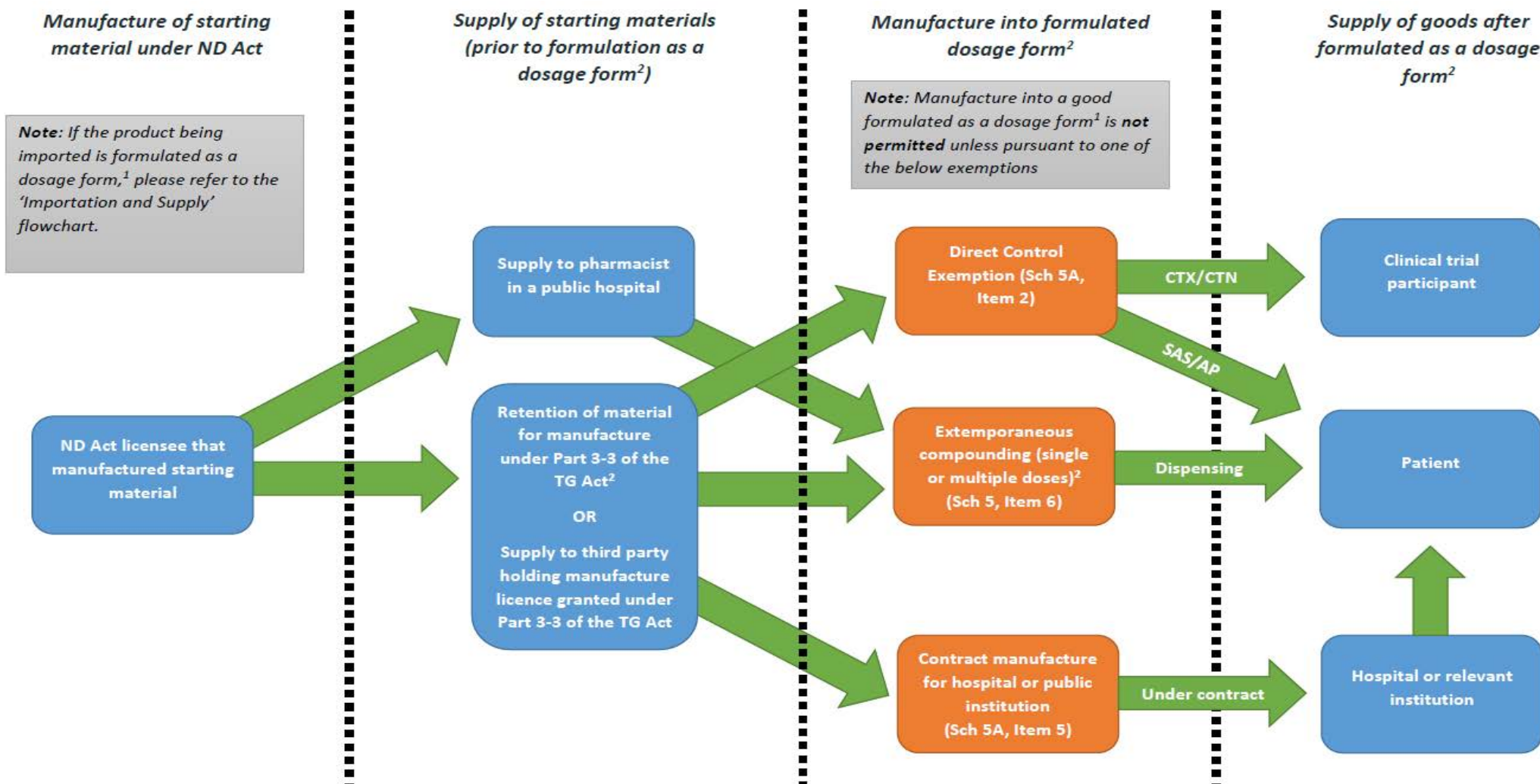
# Importation and supply of MC Goods



## Domestic manufacture and supply of MC Goods from imported starting materials



# Domestic manufacture and supply of MC Goods from starting materials produced in Australia



# Website and link references

TGA Advertising hub

[www.tga.gov.au/advertising-hub](http://www.tga.gov.au/advertising-hub)

TGA Advertising guidance for businesses involved with medicinal cannabis products

<https://www.tga.gov.au/publication/advertising-guidance-businesses-involved-medicinal-cannabis-products>

Case study - Medicinal cannabis prescription services

<https://www.tga.gov.au/case-study-medicinal-cannabis-prescription-services>

# More information



TGA website [www.tga.gov.au](http://www.tga.gov.au)



TGA Facebook <https://www.facebook.com/TGAgovau/>



TGA Twitter <https://twitter.com/TGAgovau>



TGA YouTube <https://www.youtube.com/channel/UCem9INJbMSOeW1Ry9cNbucw>



TGA topics blog <https://www.tga.gov.au/blogs/tga-topics>



TGA LinkedIn <https://www.linkedin.com/company/therapeutic-goods-administration/>



TGA Instagram <https://www.instagram.com/tgagovau/?hl=en>



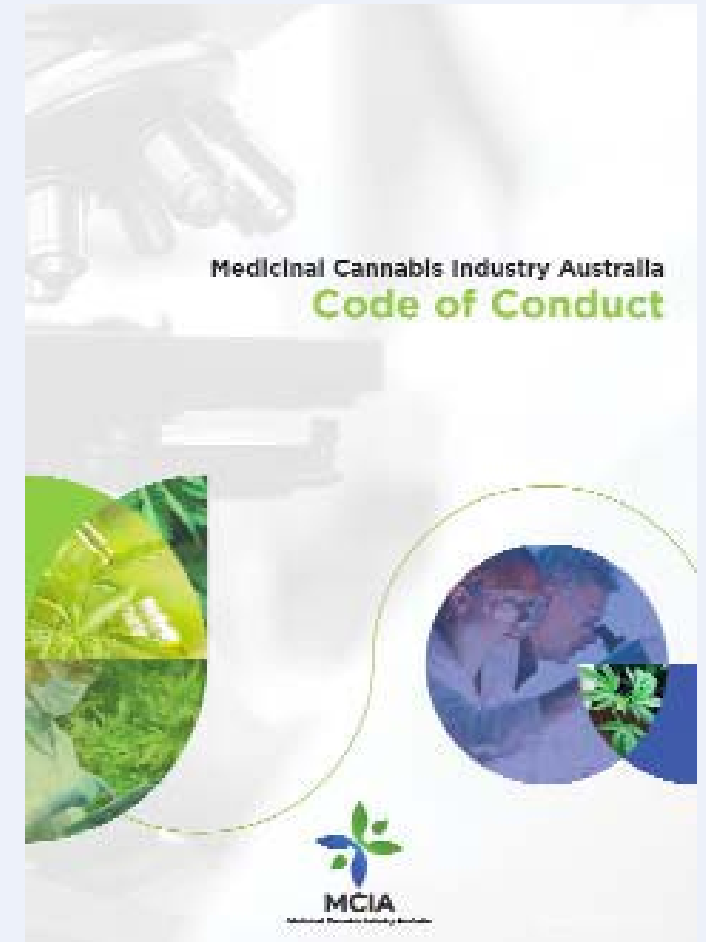


# MCIA Code

*Building a trusted Australian Medicinal Cannabis Sector*



Medicinal Cannabis Industry Australia



## MCIA Vision

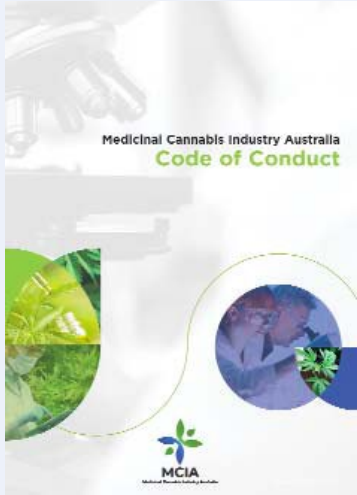
Build an industry that enhances wellbeing through facilitating access to quality Australian medicinal cannabis products for Australian and global patients.

The Australian 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.



## The code supports the vision

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.



- Developed through MCIA's Standards & Regulatory Affairs Working Group, stakeholder and member consultation
- Developed to:
  - Govern members' promises of quality and safety around product
  - Deliver an industry built on transparency and integrity
  - Build confidence with doctors and healthcare sector, and patients
- Contributes to and supports a well-functioning medicinal cannabis industry



**MCIA**

**Medicinal Cannabis Industry Australia**

*Shaping the industry for patient wellbeing*



**ΔCANNΔBIS**  
**EVOLVE** CONFERENCE  
**2021**

[www.acannabis.com.au](http://www.acannabis.com.au)

16 & 17 MARCH 2021

**TGA Webinar**  
March 2021

How a collaborative, cohesive and disciplined industry  
will result in a trusted and valuable Australian cannabis brand.

# Today's Discussion

**1**

State of Play

**2**

Integrity Matters

**3**

Social Licence

**4**

Building Trust

**5**

Working Together to Deliver



# 1 State of Play – Where did we Come From?

## Where did this industry come from?

- Regulators, Patients, Doctors, Cultivators.
- Popularity
  - Patients want access to medicine.
  - This does not mean that, by default, it is universally accepted as a good idea.
- Illegal background.

**Being cannabis and being popular is not enough.  
We need to deliver a medicine that works.  
We cannot assume the trust of stakeholders.**



# 1 State of Play – The Backdrop

## Where did this industry come from? Where is it going?

- Law changed to allow prescription of medical cannabis in November 2016.
- In January 2018 the government announced the opening of the export market to Australian cannabis.
- Narcotics Drug Act completed and reform is afoot.
- How does it compare to US & Canada?

**It is critically important that the industry is able to cut through the noise and deliver.**

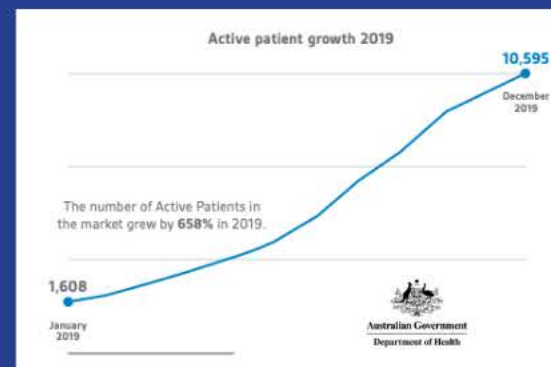
## Canada's legal marijuana industry turns two: what has changed?

Global News October 17, 2020

NEWS • NATIONAL •

6:00am, Oct 18, 2020

## 'Tide is turning': New Zealand's cannabis referendum sparks debate in Australia



<https://freshleafanalytics.com.au/wp-content/uploads/2020/03/Freshleaf-Q1-2020-Report.pdf>

Review of the Narcotic Drugs Act 1967  
Final Report  
Professor John McMillan AO  
10 July 2019

AUSTRALIA

## Australia Moves to Allow CBD Sales Over the Counter, Calls for Public Input

Today, cannabidiol is in Schedule 4, and therefore allowed only with a prescription.

APR 24, 2020 5:22PM EDT

Cannabis Council of Canada  
Licensed, Regulated, Trusted.

## Congratulations Canada on the Second Anniversary of Cannabis Legalization

It's hard to believe that two years have passed since Canada made history with the legalization of adult-use cannabis. As Canada's national association of licensed cannabis producers and on behalf of thousands of our employees, the Cannabis Council of Canada would like to THANK Canadians, our customers and our governments for their confidence and trust. To help commemorate two years in the life of a start-up sector, we've put together a report card that highlights our collective successes and emphasizes places where progress is ongoing.

### Cannabis Legalization Report Card

Issue	Grade	Rationale
Support for Cannabis Legalization	B+	Recent public support for legalization has remained despite uncertainty about the structure of the Cannabis Act, with the percentage of Canadians in opposition declining modestly year-over-year to only 24%.
Keeping cannabis away from Children and Youth	B+	While Canadians remain concerned about risks of youth consumption, preliminary estimates from Statistics Canada suggest cannabis use among 15- to 19-year-olds has risen over the first year of legalization by 8.4%.
Combating the Illicit Market	C-	Uncompetitive pricing, namely due to scarce supplies and wholesale markups, presents a barrier to further integration of the illicit market. As a result, the legal market accounts for only 55.6% of all cannabis sales spending country-wide.
Consumer Awareness	C	Industry initiatives related to its ability to communicate product attributes, effects, and responsible use to consumers – including the extensive differentiation between products in potency and price. To this end, 62% of Canadians support increased communication capability for license holders.
Government Leadership	B+	Canadians are generally aligned with the nation's leadership role in the sector, with 71% supporting a greater role in promoting the industry globally and fewer than 10% of respondents expressing opposition to global market leadership.
Cannabis Amnesty	D	Unfortunately, just under 5% of eligible Canadians have successfully applied to the Cannabis Record Suspension Program. This result calls for a modest change in approach, providing every 10% of Canadians support deletion of criminal records for personal possession.
Jobs and the Economy	C+	As one of the fastest-growing sectors in the country, the cannabis industry has created employment throughout multiple sectors and most regions of the country. Sustained growth in medical employment has offset production-related job reductions, while continued illicit market operations and licensees to export support the sector's full economic impact, including for Indigenous and diverse communities.
Medical Patient Access	D	Cannabis medicine, unlike other medicines, is subject to an excise tax. This contributes to an affordability problem, resulting in 50% of patients being as though they must use cannabis from the illicit market. In tandem, 70% of Canadians support selling medical cannabis products in public and private drug plans.
Justice and Law Enforcement	B+	Overall community compliance with legislation is recognized, and 85% of Canadians demonstrate a strong awareness of the rules of driving under the influence. Similarly, fewer cannabis consumers report an interaction with law enforcement related to driving under the influence.
Research, Development, and Innovation	D	The Task Force that preceded legalization noted further research was required to "test and compare" different therapies to ensure safety requirements and potential delays in the issuance of Research Licenses are increasing Canada's global leadership in cannabis research.

For additional detail on the report card, please visit our website at [cannabis-council.ca](https://cannabis-council.ca)

Research, Development, and Innovation

D

Medical Patient Access

D



## 2 Integrity Matters

### The Important Questions

#### Critical Attributes

- Is it safe?
- Does it contain what it is meant to contain?
- Is it consistent?
- Is it only ending up in the hands of those that it should?

**Does it do what it claims to do?  
Are these claims supported  
and are they trusted?**



INTEGRITY & PROMISE



SECURITY

SOCIAL LICENCE

3

## Social Licence

All Stakeholders Responsibility

### What are the risks?

- Issues to address:
  - Illegal growing
  - Pesticide contamination
  - Mycotoxins
- Issues for those with compromised immunity
- Not delivering a product that does what it is meant to do?
- Note delivering a product with what it is meant to have in it?

**So, what about advertising in this context?**

#### Markets

## CannTrust Breach Will Damage Legal Pot Market: Cannabis Weekly

By [Kristine O'wram](#)

14 July 2019, 22:00 GMT+8 Updated on 15 July 2019, 17:00 GMT+8

- ▶ Shortages, high prices likely to worsen after sales halted
- ▶ 'A massive issue that's actually really easy to fix:' Kopf

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## CannTrust's regulatory breach seen damaging trust in the legal pot market

*CannTrust's sales halt is only going to exacerbate the already chronic problem of product shortages and high prices in the legal market*



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## Social Licence

Advertising & Risk

### What are the risks?

- False and misleading claims?
- More broader threats to reputation?

**One stakeholder, one misstep and the whole industry could get hurt.**

**Cannatrek's 'Seed to Patient' set to shake up Australia's medicinal cannabis market**



*Does the drug company know my identity if I take medical cannabis? Do the doctor and pharmacist share this information with the company without me knowing it?*



*Who is making these claims and what are they based on?*

**Pete Evans fined \$25,000 by Therapeutic Goods Administration over coronavirus claims relating to BioCharger**

Posted Fri 24 Apr 2020 at 4:27pm, updated Fri 24 Apr 2020 at 4:44pm



Pete Evans's Facebook Live video drew the TGA's attention to the BioCharger. (YouTube: The Magic Pill)

A NEW FILM BY PETE EVANS



THE  
**MAGIC**  
PLANT



*A magic plant like a magic COVID killing machine?*

*Pete, the self appointed industry expert???*

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## Building Trust

### Expectations

- The regulator, the prescriber, the community and most importantly the patient has an expectation when it comes to control of this new industry.
- Control is more than just access (to grow, distribute, to prescribe etc.)
  - It is also about what gets to market – safety and efficacy.
  - It is also about how we do this?

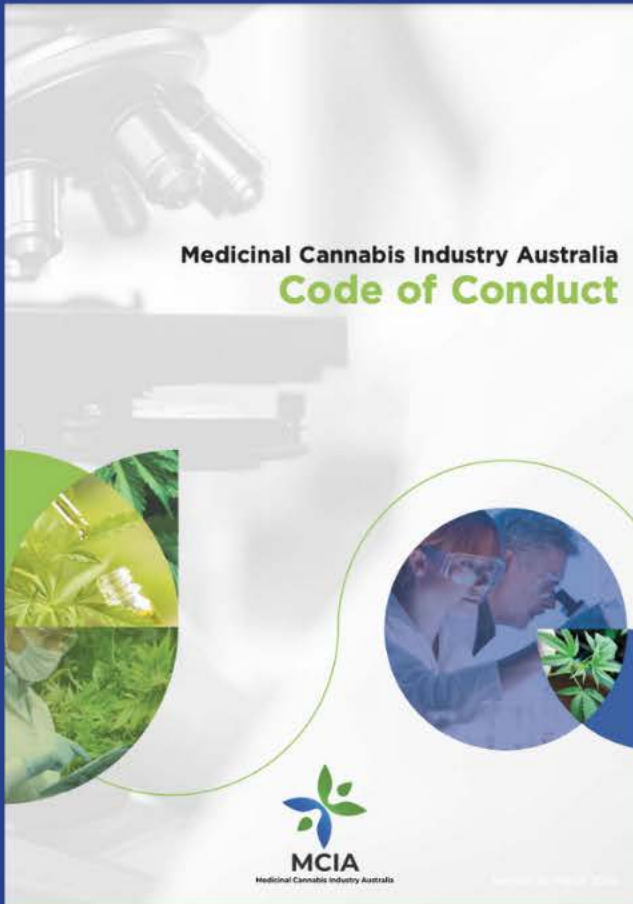
**Trust is not guaranteed and you are only as good as your worst behaviour.**





## 5 Working Together to Deliver

### MCIA Code of Conduct



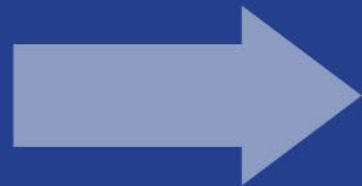
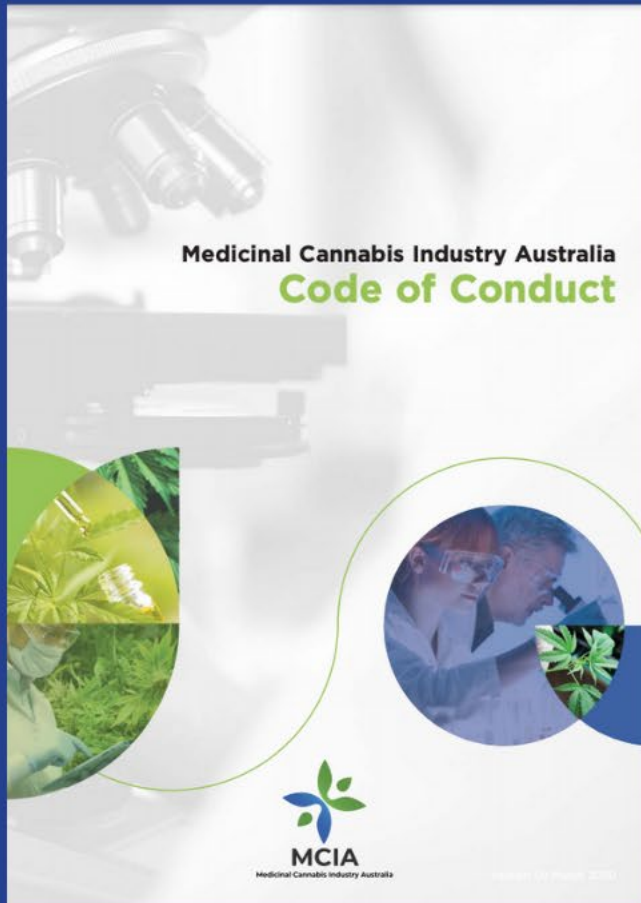
#### What is the promise?

- Plant derived cannabinoid medicine that delivers on what is promised.
- All medicine is produced ethically and complies to the regulatory standard expected for an Australian medicine.
- The Australian Medical Cannabis industry and all of its stakeholders are committed to transparency.



# 5 Working Together to Deliver

## Key Elements



## Australian Quality

Plant Derived + Regulated + True to Label + Trusted

Innovative and developed & delivered with a sector that demonstrates ethical behaviour

Assurance/outcome	Code Practice/Requirement	Standard/Ref document <sup>1</sup>
Clean/safe/ stability	Raw materials production aligned with good agricultural practices (refer 3.2) Produced in compliance with good manufacturing practice as related to the jurisdiction of interest and compliant with pharmacovigilance obligations as part of ongoing safety surveillance.	TGO93 <sup>2</sup> GMP EU GMP
Truth in label i.e. product is what is claimed	Accurately labelled as required by the relevant standard Listed in accordance with ARTG or other standard requirements as appropriate and to provide appropriate communication to the patient and doctor in relation to its use as a medicine.	TGO91 TGO92 TGO93 GMP
Data to support labels and available for verification	Data to back up labels and substantiate the products safety, stability and origin should be easily retrievable so that it can be supplied on request within a reasonable timeframe e.g. stability, pesticides, contaminants, composition, expiry, etc as required by relevant standard. Further to the information supplied or generally available, a company should, upon reasonable request and within reasonable scope, provide doctors/ healthcare professionals with additional accurate and relevant information about products, including company information.	Certificate of analysis Stability data TG093 ICH Q1A, Q1B, Q3A, Q6A
Supplied in a secure manner	Supplied through secured supply chains that are in accordance with medicines/poisons requirements. Supplied in accordance with Quality Risk Management and Pharmaceutical Quality System requirements and guidelines.	TG093 EU GMP ICH Q9, Q10
Verifiable - Australian quality, diversion,	Supported by quality systems to verify: - Australian quality - product compliance with medicines/poisons requirements - compliance with diversion requirements under licence/ permit	ODC TG093 GMP ICH Q7
Ethical and appropriate advertising	Marketed in accordance with TGA advertising guidelines and in a responsible and appropriate manner and in accordance with Section 3.4 of this Code.	

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Thank you and we look forward to contributing  
further to the workshop.

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Today's speakers are currently reading over your submitted questions.

We'll be back shortly for **Q&A**

We appreciate your participation to complete our live poll.

**LIVE POLL**



# Questions?



**Nicole Mclay**

Assistant Secretary  
Regulatory Compliance Branch  
Therapeutic Goods Administration



**Eric McIntosh**

Advertising Investigator  
Regulatory Compliance Branch  
Therapeutic Goods Administration



**George Masri**

Assistant Secretary , Regulatory  
Service & Drug Control Branch  
Therapeutic Goods Administration



**Rosemary Richards**

Executive Manager  
Medicinal Cannabis Industry  
Australia



**Peter Crock**

CEO – Cann Group Ltd  
Chair - Medicinal Cannabis  
Industry Australia



**Cameron Scadding**

Managing Director  
Source Certain International

# More information



TGA website [www.tga.gov.au](http://www.tga.gov.au)



TGA Facebook <https://www.facebook.com/TGAgovau/>



TGA Twitter <https://twitter.com/TGAgovau>



TGA YouTube <https://www.youtube.com/channel/UCem9INJbMSOeW1Ry9cNbucw>



TGA topics blog <https://www.tga.gov.au/blogs/tga-topics>



TGA LinkedIn <https://www.linkedin.com/company/therapeutic-goods-administration/>



TGA Instagram <https://www.instagram.com/tgagovau/?hl=en>





# Website and link references

TGA Advertising hub

[www.tga.gov.au/advertising-hub](http://www.tga.gov.au/advertising-hub)

TGA Advertising guidance for businesses involved with medicinal cannabis products

<https://www.tga.gov.au/publication/advertising-guidance-businesses-involved-medicinal-cannabis-products>

Case study - Medicinal cannabis prescription services

<https://www.tga.gov.au/case-study-medicinal-cannabis-prescription-services>



**Australian Government**

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**Department of Health**  
Therapeutic Goods Administration