



Medicinal cannabis advertising compliance



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Introduction

Lucy Haslam

Chair – Australian Medicinal Cannabis Association



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

Teresa Nicoletti

Lawyer, Director and Company Secretary

Australian Medicinal Cannabis Association (AMCA)



Introduction

Danielle Chifley

Director – Medicinal Cannabis Section
Office of Drug Control



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.”*

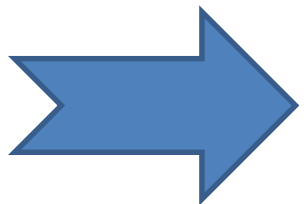


The difference between advertising and other activities

- 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 Don'ts

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

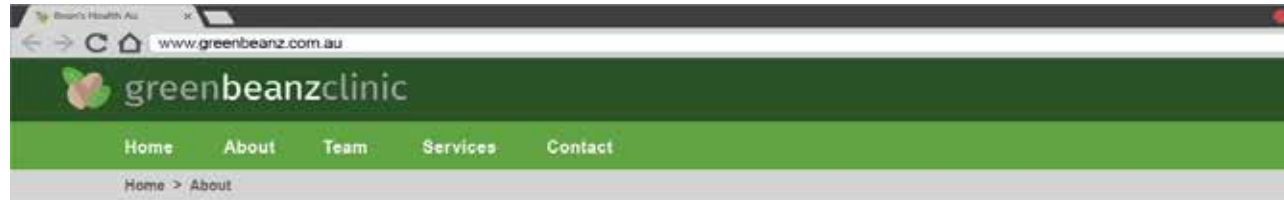
- Cease and desist letter – advertiser to remove non-compliant advertising and cease supply
- Advertiser instructed to close down the website and social media site by removing the uniform resource locator (URL) to ensure that those platforms currently promoting medicinal cannabis could no longer be accessed 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

ü 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



Non-compliant
example - clinic

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

About us

Green Beanz 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.

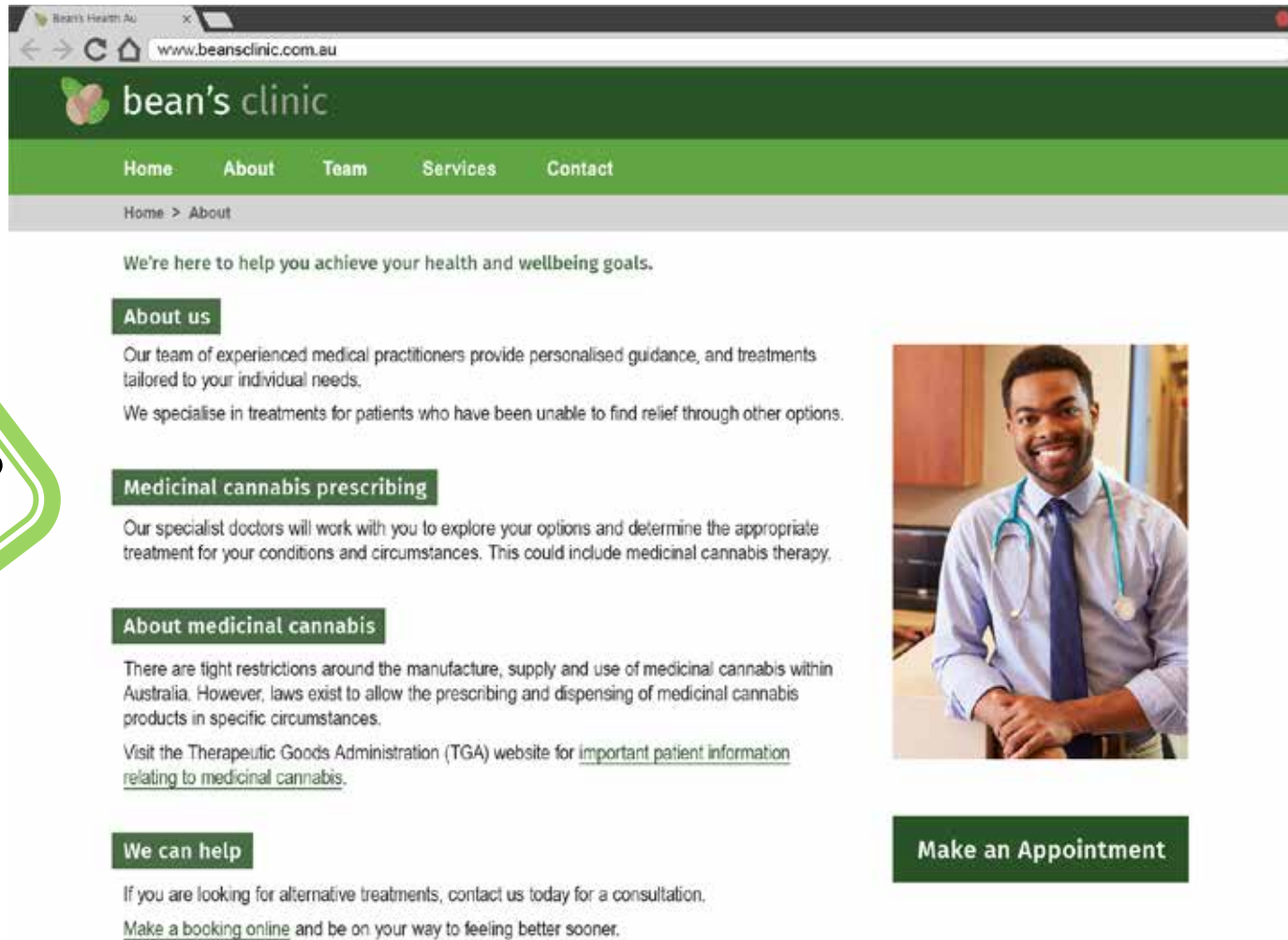
A clear path to patient access

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



The screenshot shows the website for 'bean's clinic' at www.beansclinic.com.au. The navigation menu includes Home, About, Team, Services, and Contact. The 'About' page is active, displaying the following content:

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.

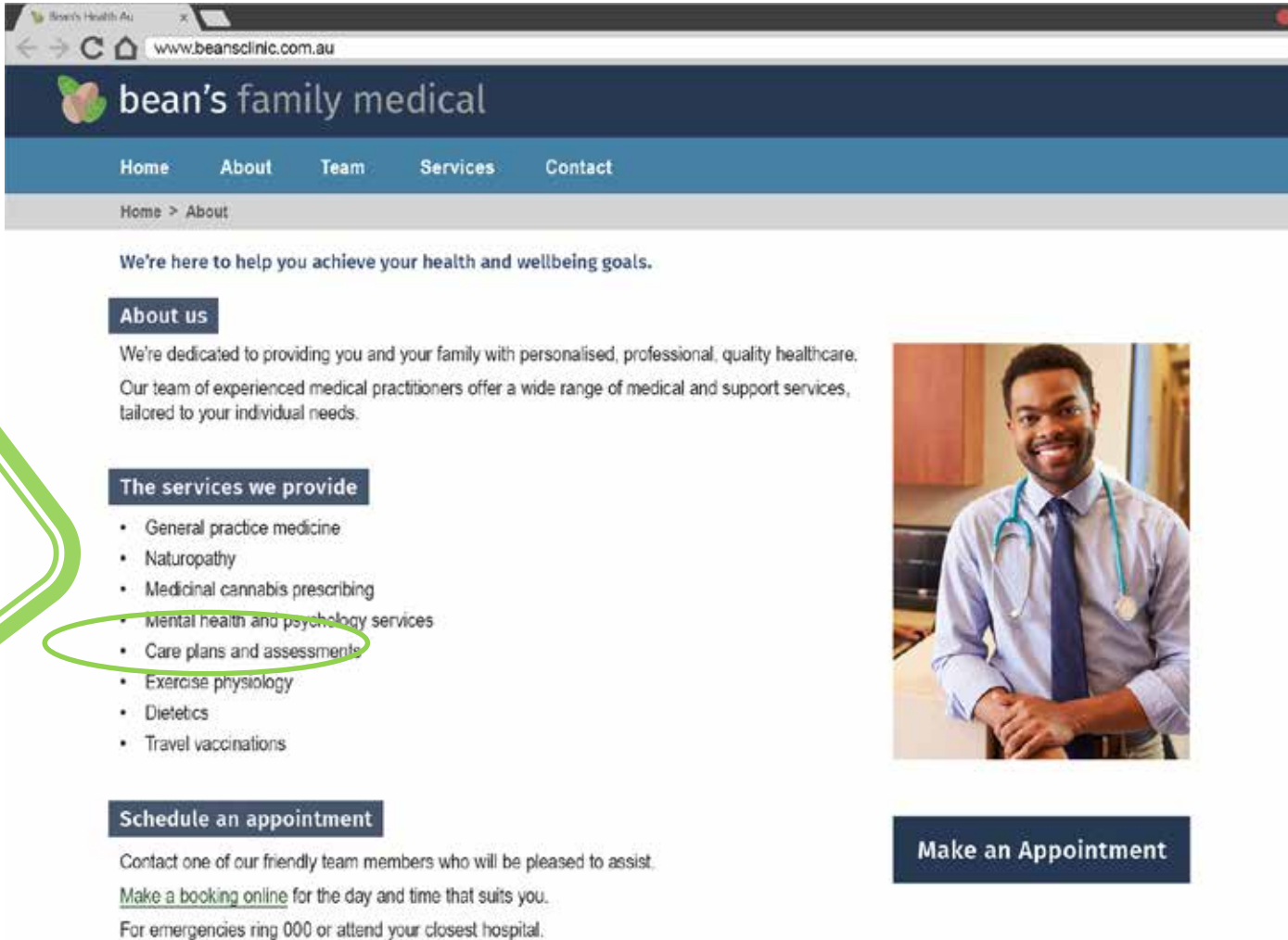
About medicinal cannabis
There are tight restrictions around the manufacture, supply and use of medicinal cannabis within Australia. However, laws exist to allow the prescribing and dispensing of medicinal cannabis products in specific circumstances.
Visit the Therapeutic Goods Administration (TGA) website 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



bean's family medical

Home About Team Services Contact

Home > About

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)

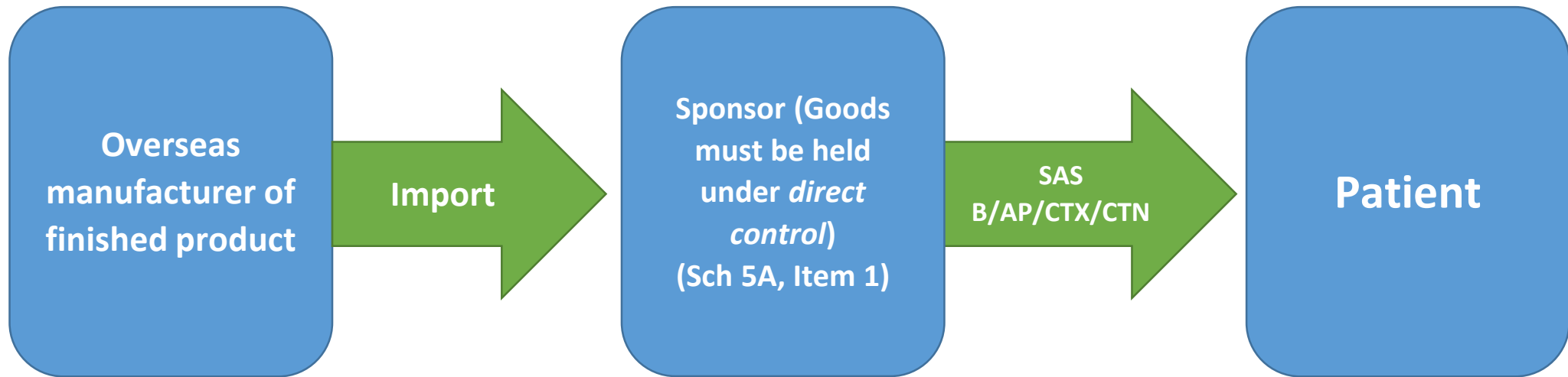
Wholesale of medicinal cannabis

- 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

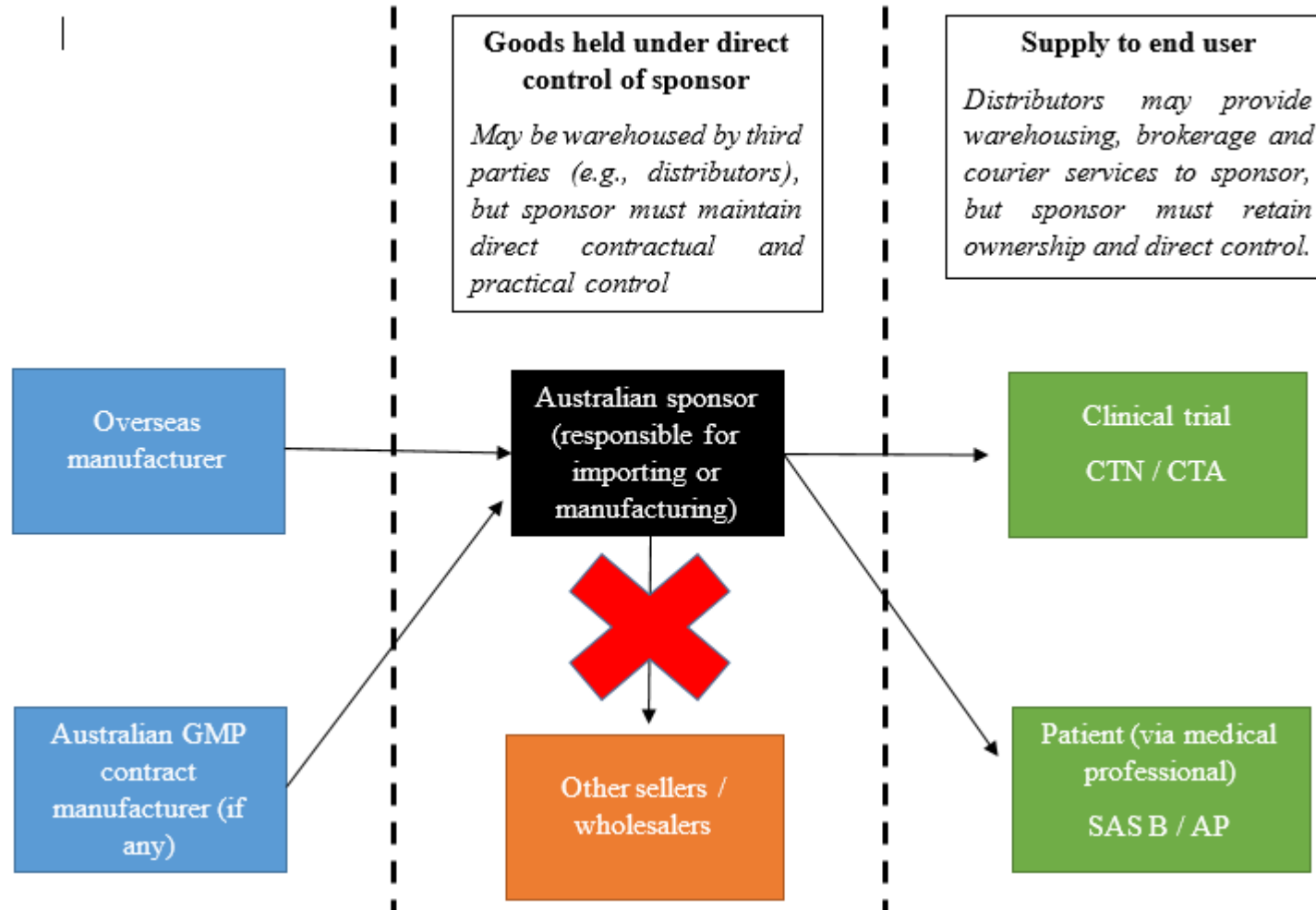


The flow charts on the next 2 slides are copyright and must not be reproduced

Importation and supply of MC Goods



Direct control and domestic supply of MC Goods



Website and link references

TGA Advertising hub

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>

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?



Rowena Love

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More information



TGA website www.tga.gov.au



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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>





Australian Government

Department of Health
Therapeutic Goods Administration