

Session 4A

# TGA update: GMP and Advertising

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# TGA update on Advertising and GMP

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**Australian Government**  
**Department of Health and Aged Care**  
Therapeutic Goods Administration

[tga.gov.au](http://tga.gov.au)



## Advertising trends

- 12% of suspected advertising breaches relate to medicinal cannabis
- Common advertising breaches:
  - Promotion of medicinal cannabis as a prescription medicine
  - References to serious medical conditions and government endorsements
  - Testimonials and endorsements
- Online advertising on websites and social media
  - Use of hashtags naming medicinal cannabis or medical conditions
  - Eligibility assessments or questionnaires
  - Blog posts or articles
- Promotion on third parties' platforms, such as media outlets
- Mass communications, such as email or text message marketing



# Advertising enforcement update

## Enforcement action

- Disrupting and deterring unlawful advertising of medicinal cannabis is a TGA priority.
- In 2022-23:
  - issued 101 infringement notices (over \$1.2 mil) to 7 entities
  - 45% of total infringement notices issued relate to medicinal cannabis
- In 2023-24 to date:
  - 1 civil penalty proceeding initiated against clinic and individual
  - issued 18 infringement notices (over \$231k) to 4 entities

# TGO93

Therapeutic Goods (Standard for  
Medicinal Cannabis) (TGO 93)  
Order 2017

*Updated quality requirements*  
*TGA Compliance activities*



# TGO93 updates

## Implementation of GMP evidence requirements for overseas medicinal cannabis manufacturers

- Each step of manufacture outside Australia must be in accordance with GMP.
- Australian sponsor must obtain/hold acceptable written evidence
- TGA will recognise certification by specified foreign regulators



- TGA inspection can be requested (certificate not a clearance)
- ‘Starting material’ exemption **when going to a GMP site**
  - ‘Starting material’ for this purpose is ‘plant material’; or ‘oil extracted directly from the cannabis plant’ (this is the first extraction only)



# TGO93 Compliance activities

## TGA inspections of overseas medicinal cannabis manufacturers

- Australian sponsors have applied for TGA inspections of medicinal cannabis manufacture outside Australia.
- Since 1 July 2023, TGA inspectors have inspected six overseas manufacturing sites to confirm compliance with GMP requirements.
- 5 certificates of 'Compliance with GMP for the purposes of TGO93' have been issued following the assessment of acceptable GMP at the sites.
- 1 sites is still under review.



# TGO93 Compliance activities

## TGA investigations of reports of non-compliance with TGO93

- Since 1 July 2023, there have been 7 investigations of reports of non-compliance with TGO93.
- The reports include
  - Reports of poor quality medicinal cannabis from patients,
  - Reports of poor product labelling (including expiry dates) healthcare practitioners,
  - Reports from whistleblowers,
  - Report from a regulatory agency.
- Investigations included 4 for products manufactured locally and 3 products manufactured overseas
- Three investigations have been closed and four are ongoing
- Additional compliance activities to help detect, address and report on noncompliance with the requirements of TGO93, including requesting documentation from sponsors and their manufacturers are planned in 2024.

## Report a breach

- [Report a breach | Therapeutic Goods Administration \(TGA\)](#)

The links below are for reporting:

- counterfeit (fake) medicines and medical devices
- suspicious or illegal activity
- non-compliant advertising.

[Report a perceived breach or questionable practices](#)

Report counterfeit products, suspicious or illegal activity.

[Report non-compliant advertising](#)

Make a report about non-compliant advertising.

