Medicinal Cannabis Reforms

Changes to TGO 93 and regulations explained

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Welcome

- This webinar is being recorded
- Today's presentation will be made available on the TGA website
- Any links mentioned on the slides will be broadcasted to the audience
- A Q&A session will take place in the last 30 minutes of this session.
- If you need to contact the moderator – please contact me via the private **'Chat'** function
- Closed Captions [CC]

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Agenda

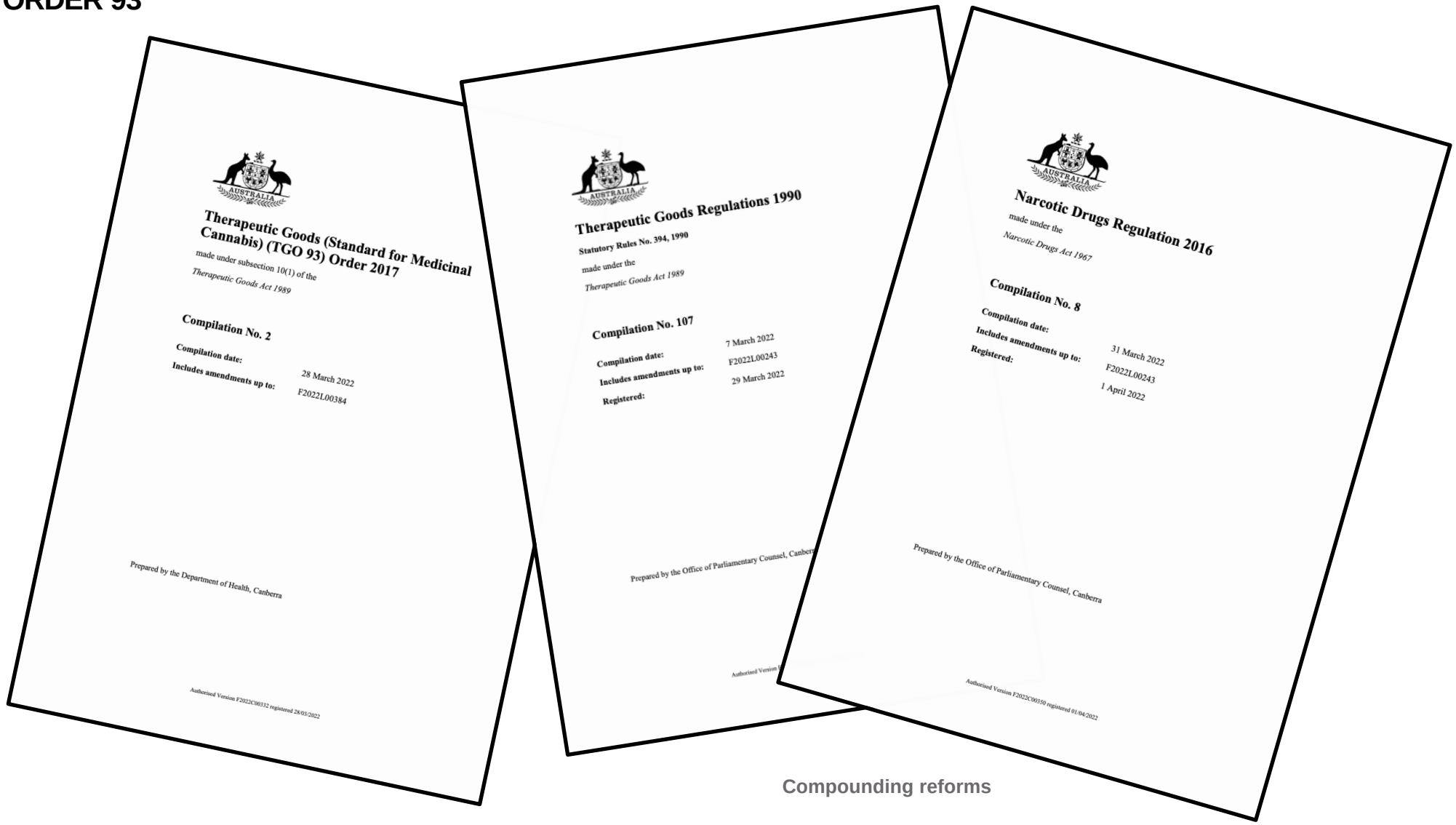
Following a public consultation in 2020/21, the TGA is improving the rules around the supply of unapproved medicinal cannabis products in Australia.

- GMP level playing field
- Packaging, labelling, microbiological
- Compounding changes
- Other refinements
- Your questions answered

What has changed?

THERAPEUTIC GOODS ORDER 93

GMP
Labeling
Child-resistant closures
Microbiological standards
Other clarifications



Compounding reforms

GMP level playing field (s13 TGO 93)

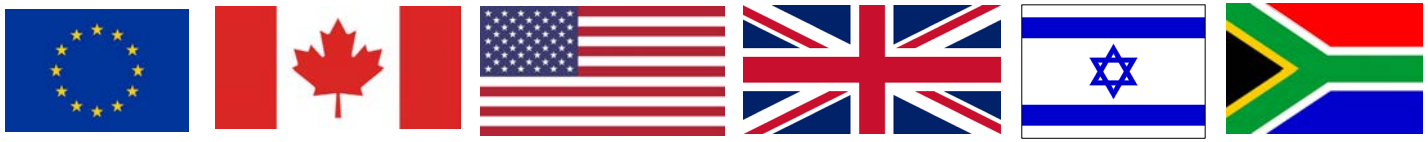
- *New requirement:*

  each step of manufacture, in relation to a medicinal cannabis product, that occurs outside Australia must meet one of the GMP standards set out in section 13(2) of TGO 93

- Brings overseas products in line with requirements on local manufacturers
- Flexibility to follow a local GMP code (country dependent), or Australian PIC/S
- Does not apply to plant material or oil extracted directly from the cannabis plant
- Obligation to ensure compliance belongs to the importer/sponsor

GMP level playing field - evidence

- Local sponsor must obtain/hold acceptable written evidence (s13(2))
- TGA will accept evidence from specified foreign regulators in country of manufacture:



- Other countries or evidence not available → request TGA inspection
  - The TGA will provide a certificate. It will not be a clearance process.
- Further countries may be added in the future.

Labelling, packaging and quality improvements

- Child-resistant packaging required unless the product is only plant material (TGO 93 s 14)
- Updated labelling requirements in line with TGO 91 and GMP practices (TGO 93 s 15)
- Providing greater certainty to patients and prescribers, facilitating recall processes
- All microbiological requirements now in TGO 93 s16

Reforms to compounding

- Changes to regulations bring extemporaneously compounded medicinal cannabis in line with other medicinal cannabis products.
- Pharmacists must ensure that prescriptions:
  - have Special Access Scheme approval or
  - were prescribed by an Authorised Prescriber
- Cannabis that is cultivated or manufactured domestically can be supplied for the extemporaneous compounding of medicinal cannabis products.

Compounding: information for prescribers

Prescribing a compounded ‘unapproved’ medicinal cannabis product

1

Consultation with patient

If an ‘unapproved’ compounded medicine is deemed clinically appropriate for your patient, select an ‘**active ingredient category**’ that is clinically suitable for your patient’s condition.

2

TGA approval

The **SAS/AP Online System** is the preferred method of submission to reduce processing times.

3

Write a prescription for your patient

Write a prescription for your patient in accordance with relevant State and Territory legislation.

Medical practitioners should consider individual legal and professional responsibilities when a compounded medicine is prescribed and subsequently compounded and dispensed.

TGO 93 clarifications

- The TGA puts the safety of Australians first
- TGO 93 has always
  - prohibited synthetic cannabis products
  - required medicinal cannabis products to be made from the cannabis plant only, without chemical modification.
- TGO 93 s 8 reworded to avoid any confusion
- Decarboxylation is not modification or transformation.
- Products containing chemically derived Delta-8 THC/other synthetic ingredients are:
  - Schedule 9 drugs and
  - non-compliant with TGO 93

Timelines and transition

- GMP requirements
- Labelling/packaging changes
- Microbiological quality requirements

*Apply to all products released for supply **on or after 1 July 2023***

- Compounding changes

*All product extemporaneously compounded and supplied **on or after 28 April 2022***

- All other amendments to TGO 93

*Apply **immediately***

Australian Government
Department of Health

Further information

TGO 93 guidance available on the the TGO website

Australian Government
Department of Health

Further information

Questions?

Contact us

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Australian Government

Department of Health

Therapeutic Goods Administration