

Medicinal Cannabis Reforms

Labelling refresher



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1 February 2023



Acknowledgement of Country

I would like to acknowledge the Traditional Owners and Custodians of the lands on which we meet today and pay my respects to Elders past, present and emerging.

I would like to extend that acknowledgement and respect to any Aboriginal and Torres Strait Islander peoples here today.

Welcome

Housekeeping

- This webinar is being recorded
- Webinar will be made available in the upcoming weeks
- Any relevant links will be broadcasted via the chat tool
- Q&A session will occur after todays presentation
- Live poll – how did we go, let us know



Difficulties hearing from computer?

Check your settings located under
“**Audio & Video**” tab located top of your screen:

OR

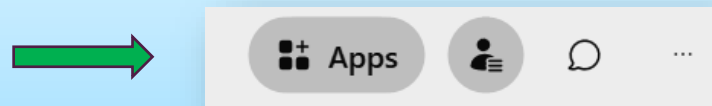
Dial: 02 9338 2221 (+61-2-9338-2221)

Access code: 2654 168 3039

How to ask questions

SLIDO

Slido App



- Click on Apps+ icon
- Select “Slido”
- Open “Q&A” tab to ask questions
- Live Poll (use survey tab when prompted)

OR

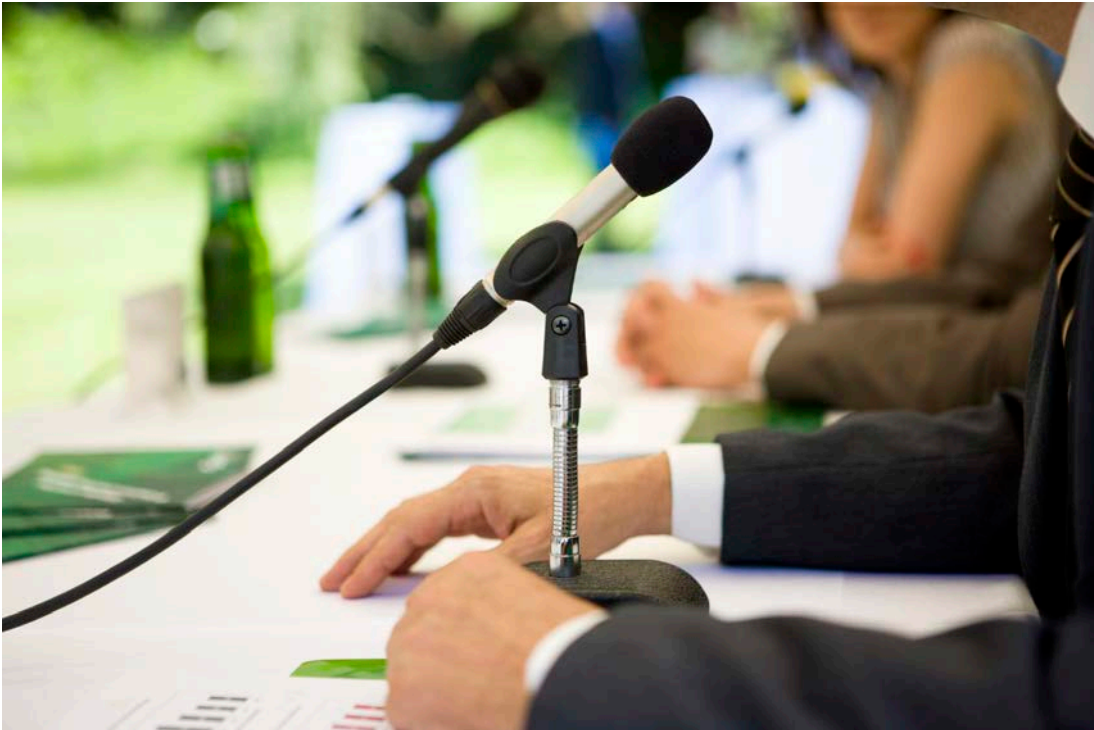
Slido QR

Scan the QR code to access separately from your mobile device



<https://app.sli.do/event/fMQb9bQkfYwTVRKbbk4jpN>

Agenda



- March 2022 reforms to Therapeutic Goods Order (TGO 93) (the quality standard for Medicinal Cannabis)
- Guiding principles
- Basic requirements
- Naming ingredients
- Common queries
- Your questions answered

TGO 93 reforms

The quality standard for Medicinal Cannabis Products - introduced in March 2022

- GMP requirements, microbiological quality requirements and **Labelling/Packaging** changes apply to all products released for supply on or after 1 July 2023.
- Clarifications made in December 2022 make clear that the labelling changes apply to all medicinal cannabis products that are **finished products**.
- Compliance obligations are on the importer/sponsor.



TGO 93 section 15

- Apply to finished products only
- Section 15(2) sets out compulsory information for products (other than extemporaneously compounded products)
- Section 15(3) sets out the compulsory information for extemporaneously compounded products
- All information needs to be legible, visible and durable (section 15(4))
- All other general labelling obligations (e.g. Poisons Standard) **continue to apply**



Labelling guiding principles

Labels should facilitate the quality use of medicines by consumers and health professionals

- Precise obligations are in section 15 of TGO 93
- Deliberately avoids being over prescriptive, given the nature of unapproved Medicinal Cannabis Products
- TGO 91 and TGO 92 can be considered as best practice if further guidance required



Descriptions of ingredients on labels



Key points

- Carefully follow the applicable sections of TGO 93
- You will need to know:
 - The name of species or hybrid species
 - What part of the plant does the product come from
 - If a preparation, the type of preparation
 - How much THC/CBD is in the product
 - The weight of the extract and minimum dry weight of the plant part from which the extract came (if applicable)

Describing plant preparations

Isolates

Follow section 15(2)(f):

'each 1mL contains tetrahydrocannabinol (THC) 20mg and cannabidiol (CBD) 10mg'

Extracts

Follow sections 15(2)(f) and 15(2)(g):

'*Cannabis sativa* leaf dry extract 50mL, derived from *Cannabis sativa* leaf dry 300g minimum, containing tetrahydrocannabinol 1000 mg (20mg/mL)'

Essential oils

Follow sections 15(2)(f) and 15(2)(g)(i), (ii), (iii), (iv):

'*Cannabis indica* leaf essential oil, containing 25mg THC/mL'



Describing plant material

Dried flower

Follow section 15(2)(f) and 15(2)(h):

Cannabis indica dry leaf 10g minimum, containing THC 10% w/w, CBD 2.5% w/w”

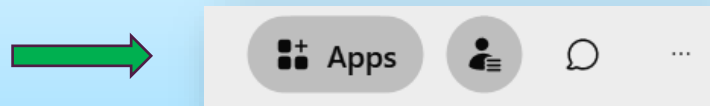
- Hybrids should be described using normal plant nomenclature:
E.g. *Cannabis sativa x indica* hybrid
- Plant parts: e.g. root, leaf, flower



Question 'App' is now open

SLIDO

Slido App



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OR

Slido QR

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Some common queries...

- Layout/font size
- What contact details are required?
- Primary/secondary packaging
- Units of measure
- Blister pack information



Further information

TGO 93 guidance and FAQs
available on the TGA website



medicinalcannabisreforms@health.gov.au



Survey - Poll

How did we go?

We'll be back with you in **1 minute**.

1. Please open SLIDO *(located from your APPS icon)*
2. Open the POLL tab
3. Complete short survey
4. We'll then commence Q&A



Anonymous or Open responses welcome





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Vanessa Caig
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Q&A

More information



| | | |
|--|-----------------|---|
|  | TGA website | https://www.tga.gov.au |
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|  | TGA Twitter | https://twitter.com/TGAgovau |
|  | TGA YouTube | https://www.youtube.com/channel/UCem9INJbMSOeW1Ry9cNbucw |
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Australian Government

Department of Health and Aged Care
Therapeutic Goods Administration