



Australian Government

Department of Health

Therapeutic Goods Administration

TGO 93 testing and regulation of medicinal cannabis

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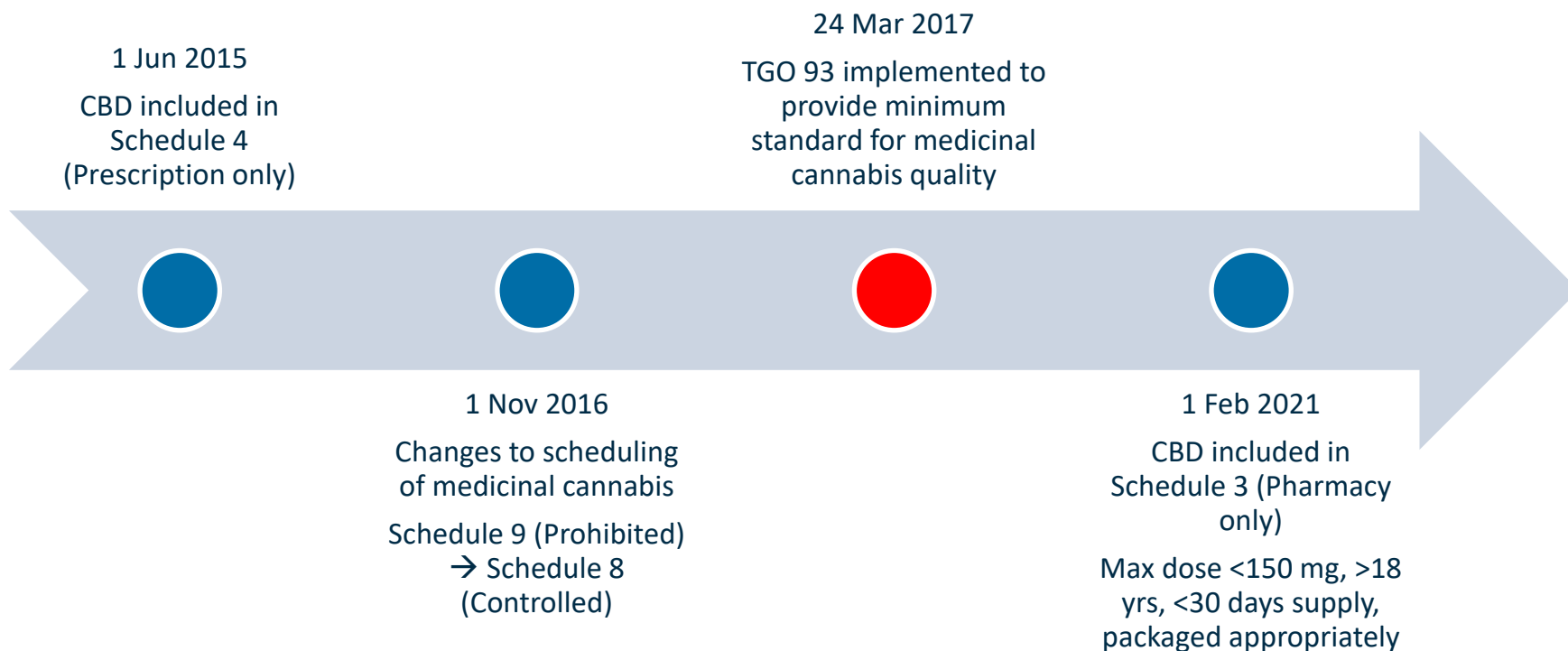


TGA Health Safety
Regulation

18/11/2021



Medicinal cannabis regulation history





Access to medicinal cannabis

- For products not registered on the ARTG, medicinal cannabis can be accessed via one of the unapproved medicines pathways:
 - Special Access Scheme
 - Authorised Prescriber
 - Clinical Trial





Who controls the quality?

- Most medicinal cannabis products are unapproved therapeutic goods (TGA has not assessed them for safety, quality or effectiveness)
- The TGA is responsible for governing regulatory standards for medicinal cannabis products in Australia.
- Compliance required for imported and locally produced/supplied medicinal cannabis.
- Responsibility rests with the sponsor.



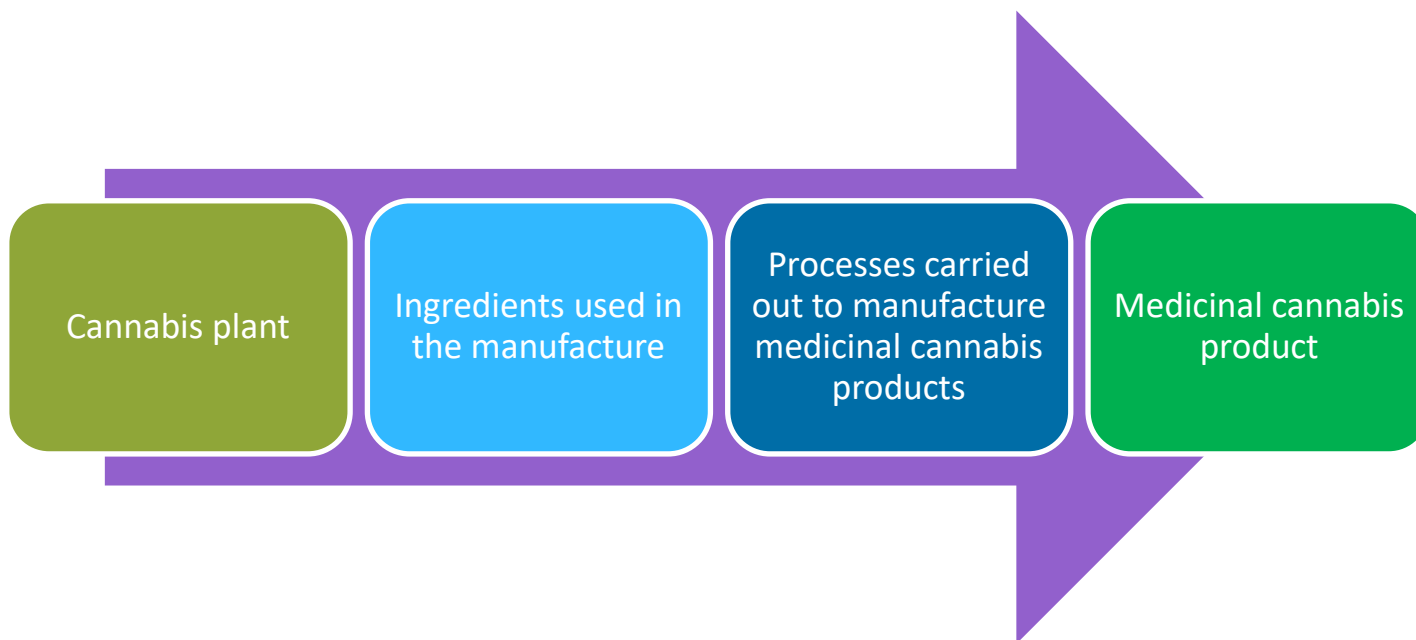
Sponsor responsibility

- The supplier of medicinal cannabis is considered the sponsor of that product in Australia.
- If sourced from overseas, the sponsor may also be the importer of the medicine.
- The sponsor must ensure that their products comply with all applicable quality standards.
 - TGO 93 (Standard for medicinal cannabis)
 - TGO 100 (Microbiological standards for medicines)
- Sponsors are currently required to lodge a declaration form to declare that the products conform to TGO 93





What does TGO93 apply to?



medicinal cannabis products means therapeutic goods that contain, or are manufactured from, any part of the cannabis plant.



TGO93 specified tests: Plant material

Specified tests			
Column 1 Item	Column 2 Parameter	Column 3 Test method	Column 4 Limits
1	Aflatoxins	Ph Eur 2.8.18	Not more than 2 µg/kg of aflatoxin B1 and not more than 4 µg/kg for the sum of aflatoxins B1, B2, G1, G2
2	Foreign matter	Ph Eur 2.8.2	Not more than 2.0%
3	Heavy metals	Ph Eur 2.4.27	Not more than 3.0 ppm of arsenic Not more than 0.5 ppm of cadmium Not more than 5.0 ppm of lead Not more than 0.5 ppm of mercury
4	Ochratoxin A	Ph Eur 2.8.22	Not more than 20 µg/kg
5	Pesticides	Ph Eur 2.8.13	Not more than the limits specified in Ph Eur 2.8.13
6	Total ash	Ph Eur 2.4.16	Not more than 20.0%

With the exception of item 2 of this table, each limit specified in column 4 applies on a dried basis.



TGO93 specified tests: Finished Products

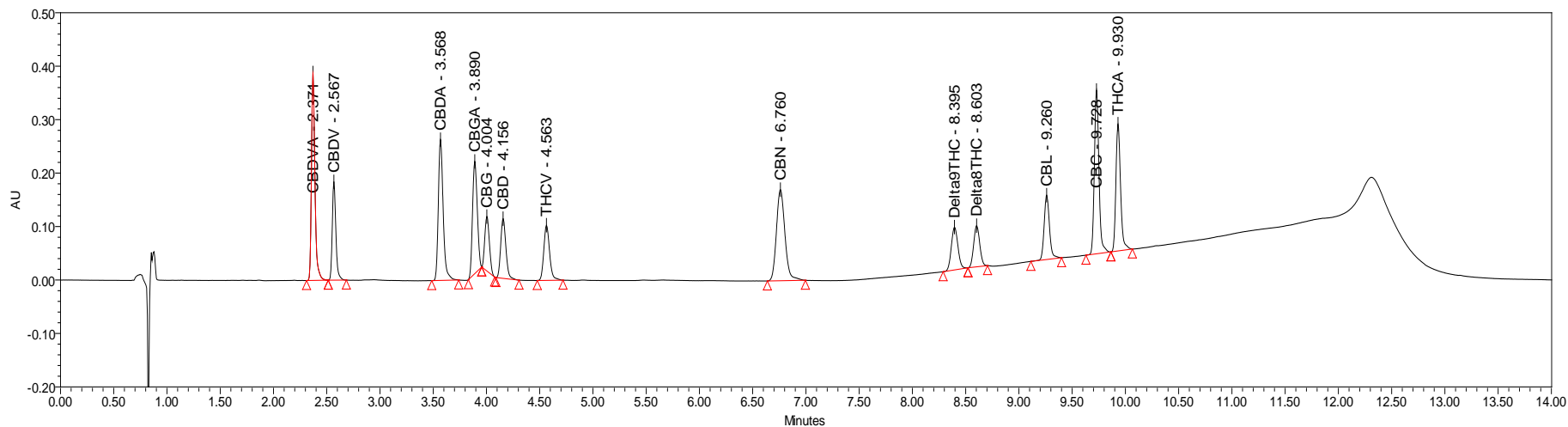
- Finished Products:
 - Assay of the active ingredients – finished product
 - Herbal final form:
80.0 – 120.0% of stated content
 - Tablets, capsules:
90.0 – 110.0% of stated content.
 - Any other dosage form (such as oils):
90.0 – 110.0% of stated content.





UPLC method for cannabinoids

- Published on TGA website: <https://www.tga.gov.au/resource/test-method-uplcc01-cannabinoids>
- Currently validated for 13 cannabinoids
- Plant samples extracted with ethanol (multiple extractions combined)
- Oil samples dispersed into isopropyl alcohol





Recent testing surveys

- Testing of products marketed to the paediatric population.
- Targeted CBD only oil products.
- Requirement: 90.0 – 110.0% of the stated content of active ingredients.
- All products found to contain appropriate levels of CBD

- Testing of plant material finished products for compliance with schedule 1 tests
- Tests conducted were Aflatoxins, Heavy Metals, Ochratoxin A and Pesticides
- Testing was outsourced to National Measurement Institute (NMI)
- All testing showed the products complied with TGO 93 for these tests.

- Testing reports can be found on the TGA website at: <https://www.tga.gov.au/tga-laboratory-testing-reports>



Thank You





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