Australian Government
Department of Health
Therapeutic Goods Administration

Consultation: Therapeutic Goods Order No. 93 (Standard for Medicinal Cannabis)

24 November 2016

This consultation closed on 16 January 2017.

Invitation to comment

The TGA sought comments from interested parties on the draft Therapeutic Goods Order (TGO) No. 93 Standard for Medicinal Cannabis and draft guidance on TGO No. 93.

Consultation documents

How to access a pdf or Word document (//www.tga.gov.au/accessing-documents-website)

Draft TGO No. 93

Draft Therapeutic Goods Order No. 93 (Standard for Medicinal Cannabis) - November 2016 (pdf,76kb) (//www.tga.gov.au/sites/default/files/consultation-therapeutic-goods-order-no-93-standard-medicinal-cannabis-tgo.pdf)

Draft Therapeutic Goods Order No. 93 (Standard for Medicinal Cannabis) - November 2016 (Microsoft Word,123kb) (//www.tga.gov.au/sites/default/files/consultation-therapeutic-goods-order-no-93-standard-medicinal-cannabis-tgo.docx)

Draft guidance

Draft Guidance on Therapeutic Goods Order No. 93 (Standard for Medicinal Cannabis) - November 2016 (pdf,251kb) (//www.tga.gov.au/sites/default/files/consultation-therapeutic-

goods-order-no-93-standard-medicinal-cannabis-guidance.pdf)

Draft Guidance on Therapeutic Goods Order No. 93 (Standard for Medicinal Cannabis) - November 2016 (Microsoft Word,100kb) (//www.tga.gov.au/sites/default/files/consultation-therapeutic-goods-order-no-93-standard-medicinal-cannabis-guidance.docx)

Timetable

Document released for consultation on **Thursday, 24 November 2016**.

Interested parties should respond by close of business **Monday, 16 January 2017**.

Feedback will be released following consideration of submissions. (See 'What will happen').

About the consultation

The TGA proposes to adopt a standard (TGO 93) specifying the minimum requirements for the quality of medicinal cannabis products. The order applies to medicinal cannabis products and ingredients used in the manufacture of those products including, but not limited to, the cannabis plant.

This guidance document provides a plain English explanation of various requirements of Therapeutic Goods Order (TGO) No. 93 *Standard for Medicinal Cannabis* (TGO 93) and their application to assist sponsors in complying with their regulatory obligations.

The documents are being released for comment, input and feedback from all parties affected.

Background

The Australian Government made a decision to facilitate access to medicinal cannabis products to appropriate patients for medical conditions where there is evidence to support its use, effective from 1 November 2016.

To ensure that unapproved medicinal cannabis products are appropriately accessed by patients under the *Therapeutic Goods Act 1989* (the Act), it is important, among other things, to have appropriate regulatory controls to ensure that the quality of the medicinal cannabis products and ingredients used in the manufacture of those products including, but not limited to, the cannabis plant are acceptable.

Content of submissions

Submissions may address any, or all, of the proposals to be included in Therapeutic Goods Order 93 and the guidance to this Order.

In addition, submissions might include information on the suitability of:

- The test requirements and limits outlined in Schedule 1 *Specified Tests* in TGO 93.
- The proposed assay limits for the various dosage forms of medicinal cannabis products in TGO 93.
- The proposed limit of greater than or equal to 1.0% w/w or w/v above which the individual cannabinoids must be considered to be an active ingredient and controlled as such for the purposes of TGO 93 i.e., controlled at the proposed assay limits.

Enquiries

Any questions relating to submissions should be directed to the Experimental Products Section of the Pharmacovigilance and Special Access Branch by email to mctgo.consultation@health.gov.au (mailto:mctgo.consultation@health.gov.au) or by telephone to 02 6232 8661.

What will happen

All submissions will be placed on this website unless marked confidential or indicated otherwise in the submission form (see Privacy information).

Submissions will be reviewed by the TGA and feedback on submissions will be provided through this website.

Privacy information

- The TGA collects your personal information in this submission in order to:
  - contact you if the TGA wants to seek clarification of issues raised in your submission or to check whether you consent to certain information that you have provided being made publicly available.
  - help provide context about your submission (e.g. to determine whether you are an individual or a director of a company or representing an interest group).
  - Seek feedback about how the consultation was undertaken.
- Please do not include personal information about other individuals in the body of your submission. Personal information in this context means information or an opinion about an individual whose identity is apparent, or can reasonably be ascertained, from the information or opinion.
- More information on consultations (//www.tga.gov.au/about-consultations) and privacy (//www.tga.gov.au/privacy) is included in the submission form and on our website.

Category: Medicinal cannabis
URL: https://www.tga.gov.au/node/732940 (//www.tga.gov.au/consultation/consultation-therapeutic-goods-order-no-93-standard-medicinal-cannabis)