Australian Government
Department of Health
Therapeutic Goods Administration

Medicinal cannabis products

Declaration of conformity with Therapeutic Goods Order (TGO) 93

23 March 2017

Unapproved medicinal cannabis products imported into, supplied in as well as those manufactured in Australia must conform with Therapeutic Goods Order No. 93 (Standard for Medicinal Cannabis) (TGO 93) (https://www.legislation.gov.au/Details/F2017L00286).

The TGA has published a guidance document (//www.tga.gov.au/conforming-tgo-93-standard-medicinal-cannabis) that provides a plain English explanation of various requirements of TGO 93 and their application to assist sponsors in complying with their regulatory obligations.

The TGA has developed a declaration form that must be completed for **unapproved medicinal cannabis products** to declare that the product(s) conform to TGO 93. **This should be completed by the medicinal cannabis product manufacturer**.

This form should be completed by medicinal cannabis product manufacturers prior to the supply of any new unapproved medicinal cannabis products in Australia, and also following any material change to medicinal cannabis products (including cannabis plants used in their manufacture) that were the subject of a previous declaration of conformity provided to the TGA where that change could have affected the quality of the products.

The reason for requesting that the medicinal cannabis product manufacturer complete the declaration form is that the person importing or supplying the unapproved medicinal cannabis product(s) in Australia may not be the commercial sponsor of the good (e.g., a medical practitioner). The highly technical nature of TGO 93 means that this person may not be in a position to declare that the product conforms to the standard. The manufacturer of the medicinal cannabis product that has responsibility for quality control testing of the finished product is best placed to declare that the medicinal cannabis product conforms to this standard.

The manufacturer of the medicinal cannabis product(s) should submit the completed form to the

person applying to access the medicinal cannabis product(s) through the available access pathways.

Please note that although the cannabis plant used in the manufacture of the medicinal cannabis product must meet the requirements of Schedule 1 of TGO 93, reduced or rotational testing of the cannabis plant used in the manufacture of the product can be carried out provided that this is justified on good manufacturing practice (GMP) grounds. For example, a manufacturer may be able to justify reducing or not conducting pesticide testing if no pesticides are used in the cultivation of the cannabis plant. The manufacturer should ensure that the product, if tested by the TGA laboratories, will meet all the requirements of the standard.

For unapproved medicinal cannabis products to be accessed via:

- **SAS B and Authorised Prescriber:** The form is submitted to the medical practitioner. The medical practitioner is required to submit this form as supportive documentation to the TGA with their application.
- **Clinical Trials - CTN/CTX:** The form is submitted to the clinical trial sponsor. The Australian clinical trial sponsor should complete the section at the end of the form to include the name of the medicinal cannabis product(s) used in the clinical trial as well as the TGA clinical trial application number and protocol number. The clinical trial sponsor is then required to submit this form as supportive documentation to the TGA with their application or notification, as applicable. In the case of a CTN involving the use of a medicinal cannabis product, the clinical trial sponsor should submit this form via email to clinical.trials@health.gov.au (mailto:clinical.trials@health.gov.au). In the case of a CTX involving the use of a medicinal cannabis product, the clinical trial sponsor should submit this form as part of the CTX application made to the TGA.

Form

This form is available in pdf and Microsoft Word formats. The pdf form can be filled in and saved to your computer using Adobe Reader version 7 or later or any version of Adobe Acrobat Standard or Professional. If you have an earlier version of Adobe Reader you can fill in the form on-screen and print it out but you will not be able to save the completed form.

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

Medicinal cannabis products - Declaration of conformity with Therapeutic Goods Order (TGO) 93 (pdf,109kb) (//www.tga.gov.au/sites/default/files/medicinal-cannabis-products-declaration-of-conformity-with-tgo-93.pdf)

Medicinal cannabis products - Declaration of conformity with Therapeutic Goods Order (TGO) 93 (Microsoft Word,145kb) (//www.tga.gov.au/sites/default/files/medicinal-cannabis-products-declaration-of-conformity-with-tgo-93.docx)

Category: Unapproved therapeutic goods
Tags: cannabis, forms
URL: https://www.tga.gov.au/node/735710 (//www.tga.gov.au/form/medicinal-cannabis-products)