Australian Government
Department of Health, Disability and Ageing
Therapeutic Goods Administration

Six monthly report - supply of unapproved therapeutic goods

A step-by-step guide to completing the form

Version 2.1, August 2025

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Overview of the submission process

General information regarding the form

It is a **legal** requirement for sponsors of therapeutic goods supplied under the Special Access Scheme (SAS) and Authorised Prescriber (AP) scheme to provide six monthly reports to the Secretary of the Therapeutic Goods Administration (TGA) under paragraph 47B(1)(c) of the *Therapeutic Goods Regulations 1990*.

Sponsors must provide the report using the approved Six monthly report – supply of unapproved therapeutic goods by a sponsor form following the supply of therapeutic goods exempt, approved or authorised under the SAS and AP schemes. Specified reporting periods are outlined below.

This form is not a requirement for products exempt or approved under the clinical trials schemes.

It is an offence to provide false or misleading information to a Government agency.

The information in this document is provided for guidance only. It should not be relied on to address every aspect of the relevant legislation. You should seek your own independent legal advice to ensure that all of the legal requirements are met.

Step-by-step guide to completing the form

Details of Sponsor

The *Therapeutic Goods Act 1989*, Chapter 1, Section 3, defines a sponsor, in relation to therapeutic goods as:

(a) a person who exports, or arranges the exportation of, the goods from Australia; or

(b) a person who imports, or arranges the importation of, the goods into Australia; or

(c) a person who, in Australia, manufactures the goods, or arranges for another person to manufacture the goods, for supply (whether in Australia or elsewhere);

Please include the name of the sponsor and sufficient information to allow the sponsor to be uniquely identified. The contact details must include information such as the city or suburb of the sponsor's principal place of business in Australia. The Australian telephone number and email address must also be included.

Reporting period

Reporting periods are 1 January - 30 June (inclusive) and 1 July - 31 December (inclusive). Reports must be submitted within 1 month of the end of the relevant reporting period.

Medicinal cannabis products

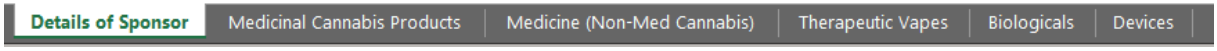
The TGA publishes a list of medicinal cannabis products by active ingredient on our website to support healthcare professionals in safe prescribing and dispensing of 'unapproved' medicinal cannabis products.

This information is captured from sponsor six-monthly usage reports and represents all unapproved medicinal cannabis products supplied in Australia via the Special Access Scheme and Authorised Prescriber scheme during the most recent six-month reporting period.

Products included in reports received by the TGA over 1 month after the reporting period's closure will not be included in website publishing.

Product details

- Relevant product tabs are included on the bottom of the excel document. Please navigate to all relevant tabs and enter the details as per the examples provided.



- Medicinal Cannabis products have an additional requirement of the "Full Cannabinoid Profile"

Medicinal cannabis example

Active ingredient/s (name and strength)	Full cannabinoid profile (Click here for further information on category determination)	Trade name	Category of cannabinoid content	Dosage form (where applicable)	Pack size / total volume (where applicable)	Quantity of packs supplied by Special Access Scheme (SAS) pathway	Quantity of packs supplied by Authorised Prescriber (AP) pathway	Total quantity of packs supplied by pathways
CBD 100mg/mL	CBD >90%, THC<1%, CBG<1% + other cannabinoids	TGA Example	Category 1: CBD medicinal cannabis product (CBD >90%)	Oral Liquid	30mL	100	0	100

Other product example

Active ingredient/s (name and strength)	Trade name	Dosage form (where applicable)	Pack size / total volume (where applicable)	Quantity of packs supplied by Special Access Scheme (SAS) pathway	Quantity of packs supplied by Authorised Prescriber (AP) pathway	Total quantity of packs supplied by pathways
Example Ingredient 20mg	*TGA Example*	*Tablet*	*17*	*50*	*50*	*100*

Step 1: Active ingredient/s (name and strength)

Active ingredients are the therapeutically active components in a product responsible for its physiological or pharmacological action. This includes ingredients such as cannabinoids, vitamins and amino acids that have a physiological or pharmacological effect in the final formulation.

For medical devices, the device name corresponds to the device category such as shoulder replacement system, pacemaker lead or hip replacement system.

Trade/ product names for prescription medicines clearly identify the product. For both medicines and devices, trade names should be unique, and clearly identify the product but be neither promotional nor offensive in relation to general community standards.

Step 2: Full cannabinoid profile / Category of cannabinoid content (medicinal cannabis products only)

Please provide the full cannabinoid profile of the product and use the guide SAS and AP categories for medicinal cannabis products to determine the relevant category of the medicinal cannabis product. The category determination of medicinal cannabis products is based on the proportion of cannabidiol (CBD) content compared with the total cannabinoid content of the medicine.

Step 3: Dosage form

Please use approved dosage form terminology in the TGA code tables, except for novel or new dosage forms

Step 4: Pack size / total volume

Please provide the **pack size** of the unapproved good supplied i.e. 20 tablets/box or 2 inhalers/box

Step 5: Quantity of packs supplied by pathway

Quantity of units *supplied* is the *number* of times the unapproved therapeutic good has been *supplied* under the SAS and AP scheme over the six-month reporting period.

The **total quantity** supplied is the sum of the quantity supplied under the SAS and AP scheme.

Medicinal cannabis products

The six-monthly reports must be an accurate representation of the therapeutic goods supplied by the sponsor under the SAS and AP scheme in the preceding six-month period.

Please include only unapproved products that have been supplied in Australia under the SAS or AP schemes during the defined six month reporting period.

Version history

Version	Description of change	Author	Effective date
V1.0	Original publication	Special Access Section	20 June 2022
V2.0	Updated information for medicinal cannabis category of cannabinoid content.	Business Improvement and Compliance Section	June 2024
V2.1	Minor update to SAS and AP categories for medicinal cannabis products.	Business Improvement and Compliance Section	August 2025

Therapeutic Goods Administration

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