Australian Government
Department of Health
Therapeutic Goods Administration

Six monthly report - supply of unapproved therapeutic goods

A step-by-step guide to completing the form

Version 1.0, June 2022

TGA Health Safety Regulation

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

Sponsor information

- 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.

Form template and examples

Active ingredient/s (name and strength) or device name (i.e category)	Trade name	Category of cannabinoid content (medicinal cannabis products only)	Dosage form* (where applicable)	Quantity per dosage unit (where applicable)	Quantity of units supplied by pathway (Not applicable to nicotine vaping products)		
					Special access scheme	Authorised prescriber	Total
Example 1: CBD 10mg	Trade 1	Category 1	Capsules	30 capsules	0	40	60
Example 2: Nicotine in solution form	Trade 2	N/A	Vape pen	2 inhalers/box	N/A	N/A	N/A
Example 3: Shoulder replacement system	Trade 3	N/A	N/A	N/A	5	0	5
Example 4: ABC Injection 3mg	Trade 4	N/A	Vial for injection	2mL/vial	100	100	200

Step 1: Active ingredients and trade name

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: Category of cannabinoid content (medicinal cannabis products only)

Active ingredient categories for medicinal cannabis products. The category determination of products is in accordance with the ***stated content of active ingredients*** specified on the product label.

Step 3: Dosage form

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

Step 4: Quantity per dosage unit

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

Step 5: Quantity of units 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.

Nicotine products

Step 5 - quantity of supply is not required for nicotine vaping products.

Sponsors are only required to provide the brand and nicotine concentration of each kind of nicotine vaping product supplied in Australia in the relevant period.

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

Therapeutic Goods Administration

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