Australian Government
Department of Health
Therapeutic Goods Administration

SME Assist ‘Meeting Your Obligations’

Supplying Medicinal Cannabis in Australia

Therapeutic Goods Administration (TGA)
21 October 2021

TGA Health Safety Regulation

Welcome

- This webinar is being recorded
- Slides will be made available on the TGA website
- Questions – please use the **Q&A** tool when I open this function
  - Q&A will occur after todays presentation
  - Your questions are only visible to the panel
- If you need to contact the moderator – please use the **'Chat'** function
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Australian Government
Department of Health
Therapeutic Goods Administration

SME Assist ‘Meeting Your Obligations’
Supplying Medicinal Cannabis in Australia

Steven-Smith Fleury, Klara Koelmeyer &
Kevin Eager

Therapeutic Goods Administration (TGA)
21 October 2021

TGA Health Safety Regulation

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This material is provided to you solely for the purpose of providing a record of what TGA representatives spoke about at today's presentation.

The papers are not legislative in nature and should not be taken to be statements of any law or policy in any way.

The Australian Government Department of Health (of which the TGA is a part) advises that:

a) the presentation papers should not be relied upon in any way as representing a comprehensive description of regulatory requirements, and

b) cannot guarantee, and assumes no legal liability or responsibility for, the accuracy, currency or completeness of the information contained in the presentation paper.

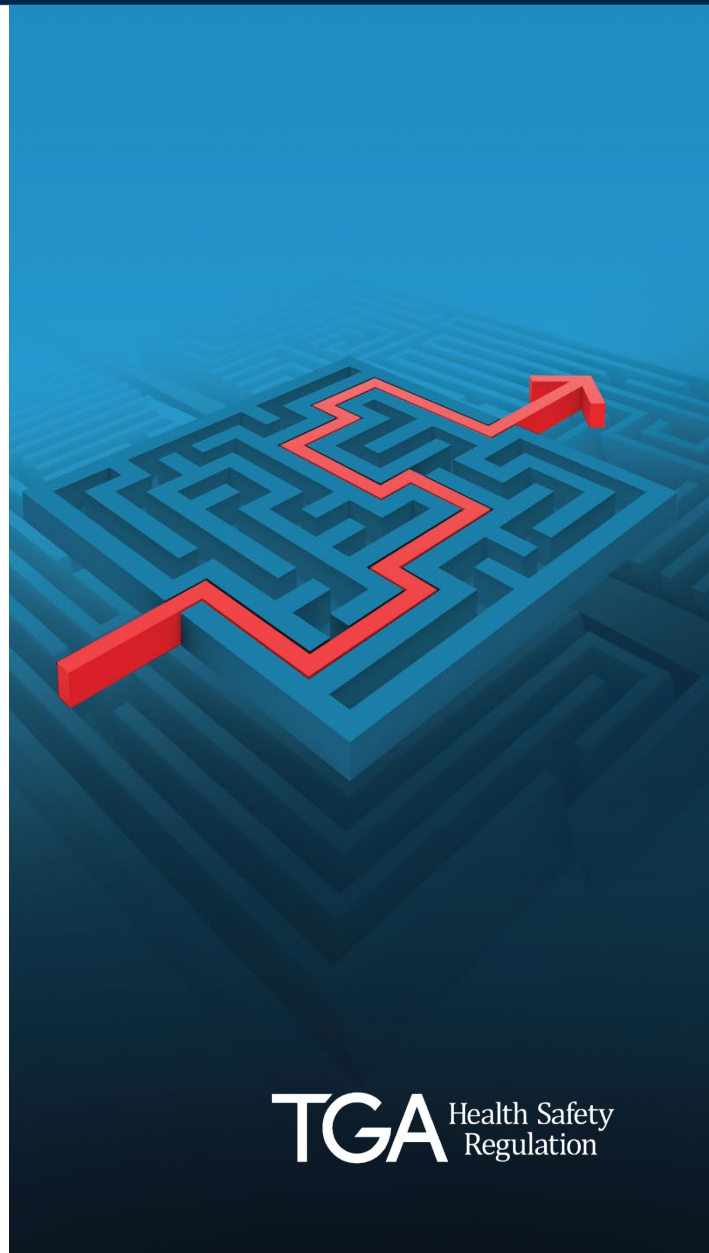
Schedule

13:05	PART I: Basics of therapeutic goods regulation
13:30	PART II: Supplying medicinal cannabis
15:15	**Break**
15:30	PART III: Q&A session
16:30	**Close**

Objectives

To give you general information about:

- therapeutic goods regulation in Australia
- the role of TGA
- TGA's SME Assist service
- how to supply medicinal cannabis in Australia
- where to find help



TGA Health Safety Regulation

SME Assist

- **Aimed** at small to medium enterprises (SMEs), start-ups, researchers and those unfamiliar with therapeutic goods regulation
- **Assists** users with navigating the ‘regulatory maze’
- **Offers** a range of support including:
  - guidance articles
  - interactive decision tools
  - educational workshops across Australia
  - recorded presentations on regulatory obligations
  - email and phone assistance
  - a subscription service to keep up-to-date with news and events

tga.gov.au/sme-assist
sme.assist@tga.gov.au
1800 020 653

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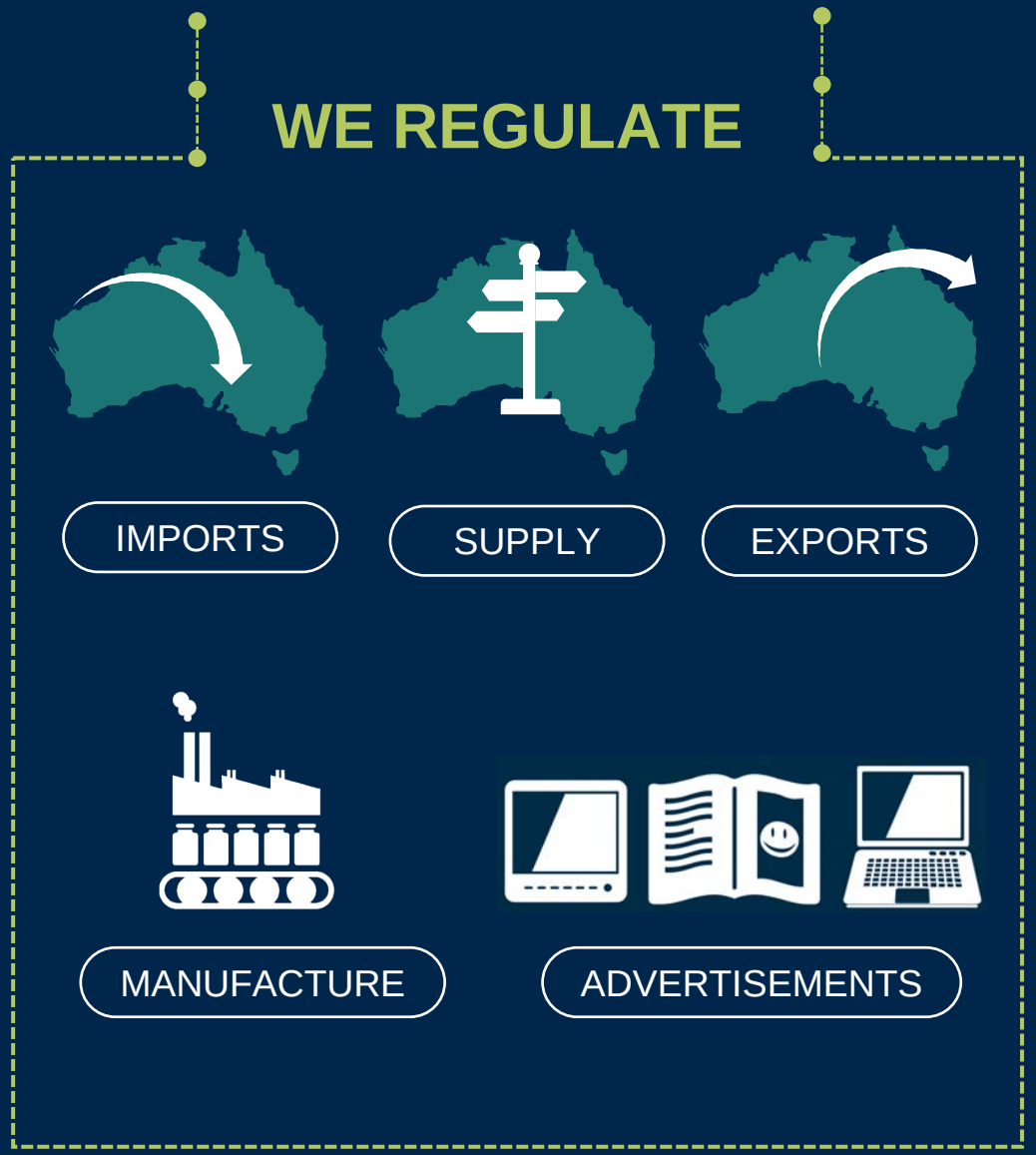
Basics of Therapeutic Goods Regulation

The role of TGA

We **regulate** and **monitor** all therapeutic goods in Australia to ensure that they are safe to use and fulfil their intended purpose.

It is our mandate to fulfil this service, as set out by the *Therapeutic Goods Act 1989*.



We regulate **therapeutic goods**

Something used for:

- preventing, diagnosing, curing or alleviating a disease, ailment, defect or injury
- influencing, inhibiting or modifying a physiological process
- testing the susceptibility of persons to a disease or ailment
- influencing, controlling or preventing conception
- testing for pregnancy
- replacing or modifying a part of the anatomy

Medicines

These include:

- prescription medicines
- over-the-counter medicines
- complementary medicines
- vaccines
- blood and plasma

Biologicals

Things that are made from or contain:

- human cells or tissues
- live animal cells, tissues or organs

Medical devices

These generally have a physical or mechanical effect on the body or are used to measure or monitor functions of the body. They include:

- instruments
- appliances
- materials

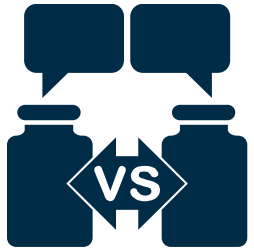
What we do NOT regulate

We also don't:

- Research and develop new therapeutic goods

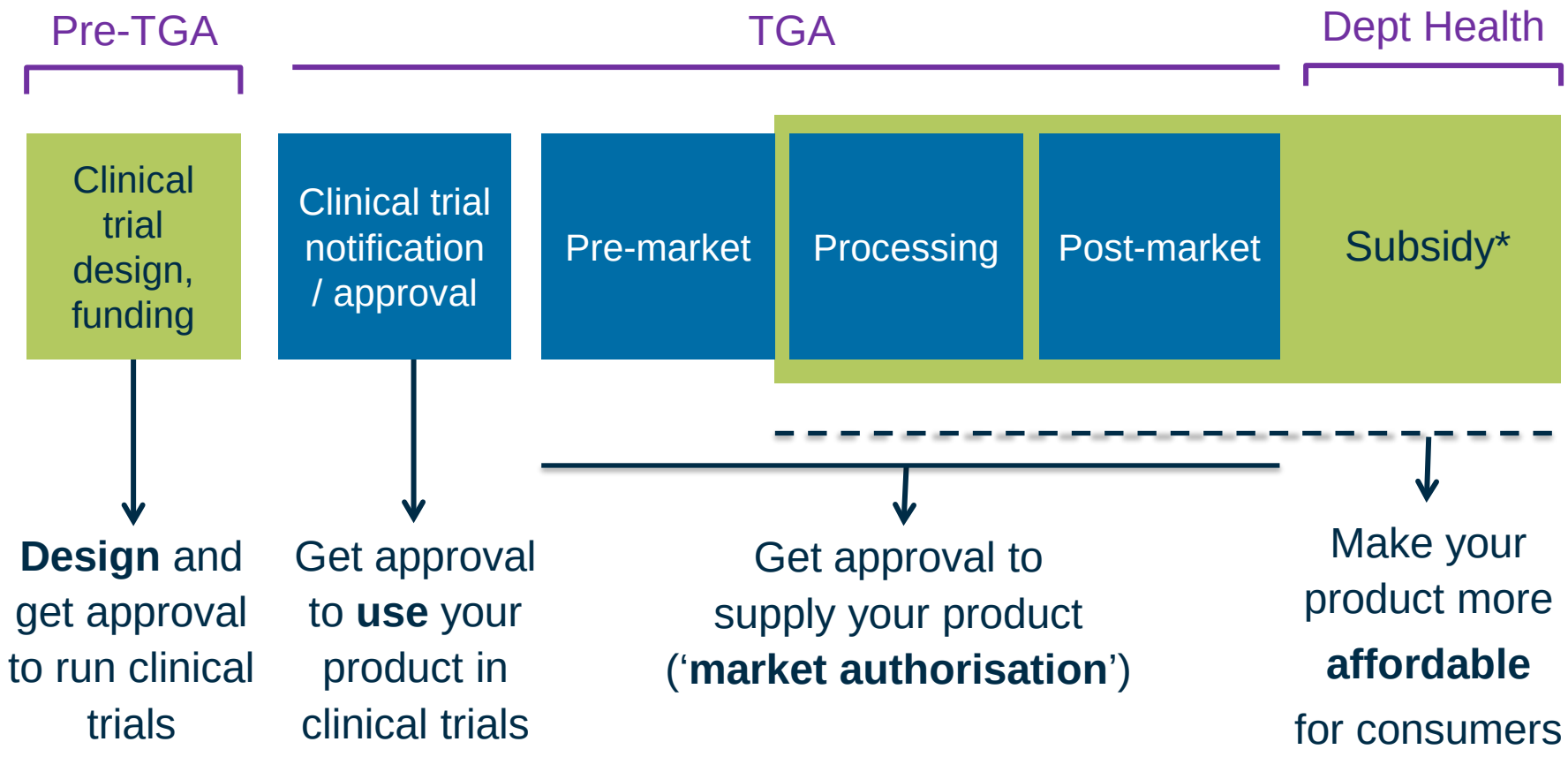
- Provide clinical advice to individuals

- Consider cost effectiveness or recommend one product over another



- Make decisions about subsidies for therapeutic goods

Therapeutic good development lifecycle



*subsidisation is not guaranteed and will not be granted prior to ARTG inclusion

Clinical trials

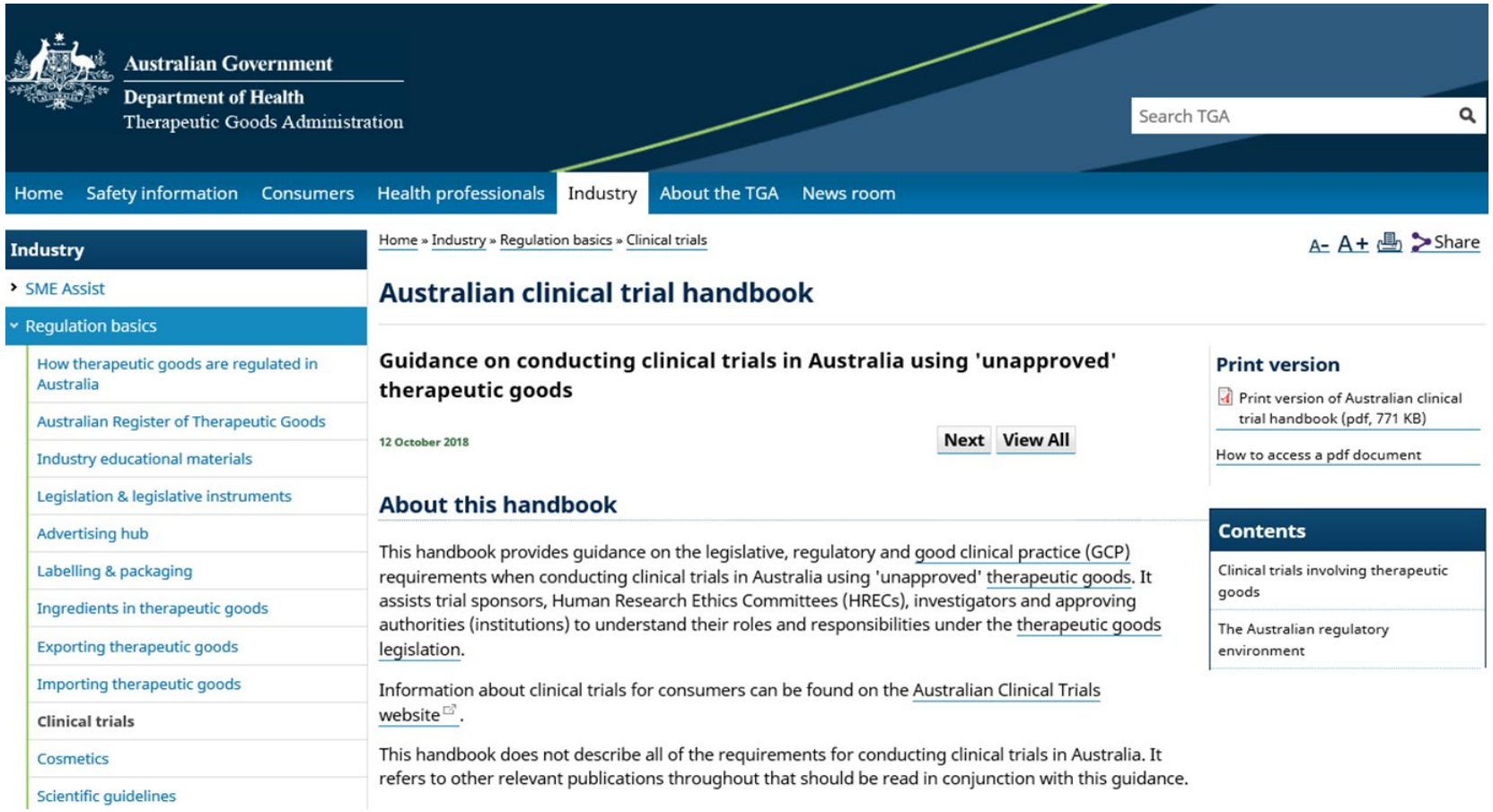
Two pathways for accessing ‘unapproved’ therapeutic goods for experimental purposes in humans: ‘**notification’** scheme and **‘approval’** scheme

The CTA scheme replaced the CTX scheme from 2 Nov 2020

The use of therapeutic goods in a clinical trial conducted under these schemes must be in accordance with:

- the International Council for Harmonisation of technical requirements for pharmaceuticals for human use, Guidelines for Good Clinical Practice the National Statement on Ethical Conduct in Human Research
- the procedural protocol as approved by the Human Research Ethics Committee responsible for monitoring the conduct of the trial

Australian clinical trial handbook



Market authorisation

The **approval** given to supply a therapeutic good in Australia.

sale, exchange,
gift, lease, loan,
hire or hire
purchase

If you want to do one or more of the following:

- **manufacture** therapeutic goods for supply within Australia or elsewhere
- **import** therapeutic goods into Australia
- **export** therapeutic goods from Australia
- **arrange** for the import, export or manufacture of therapeutic goods

… you will need to apply for market authorisation through the TGA.

Australian Register of Therapeutic Goods (ARTG)

- When market authorisation is granted, the product is added to an **electronic register** of therapeutic goods that can be lawfully supplied in Australia – the ARTG
- It provides information such as the product name, active ingredients, classification and manufacturer
- The ARTG entry is under the **sponsor's name**

Separate and distinct products have their own ARTG entry

- Every ARTG entry is unique (**separate and distinct**).
- This ‘uniqueness’ is defined in a certain way depending on what type of therapeutic good you have.
- These definitions can be found in the legislation:

Product type	Where to look	Section
Medicines	ⓘ Therapeutic Goods Act 1989	16
Biologicals	ⓘ Therapeutic Goods Regulations 1990	11A
Medical devices	ⓘ Therapeutic Goods Act 1989	41BE

ARTG entries

Medicines

- Each **separate and distinct** medicine will usually have its own ARTG entry.
- Definitions are found in 16(1) and 16(1A) of the *Therapeutic Goods Act 1989*.
- Medicines which are taken to be separate and distinct will depend on the medicine type and can include characteristics such as:
  - different active ingredients
  - different directions for use
  - a different dosage form
  - a different formulation, composition or design specification

Benefit vs. risk approach

Therapeutic goods are regulated based on the level of **risk** they pose.

Goods that pose a **higher risk** of adverse events or are used for more serious illnesses are more tightly regulated than those that pose a **lower risk**.

Benefits must outweigh risks!

Benefit vs. risk approach

Medicines

Listed AUST L	Assessed Listed AUST L(A)	Registered AUST R
• **No** pre-market evaluation • Can only have **permissible indications** • Can only contain pre-approved, lower risk **permissible ingredients** • Require pre-approved **GMP**	• Pre-market evaluation required for **intermediate** and **permissible indications** • Can only contain pre-approved, lower risk **permissible ingredients** • Require pre-approved **GMP**	• Pre-market evaluation **required** • Sponsor needs to provide **data** to demonstrate safety, quality and efficacy • May contain **other substances** (e.g. poisons) • Fees are higher, as they may require more monitoring

Our work is **ongoing**

Our work doesn’t stop when a product reaches the market.

It continues over the lifetime of every therapeutic good.

Regulatory compliance framework

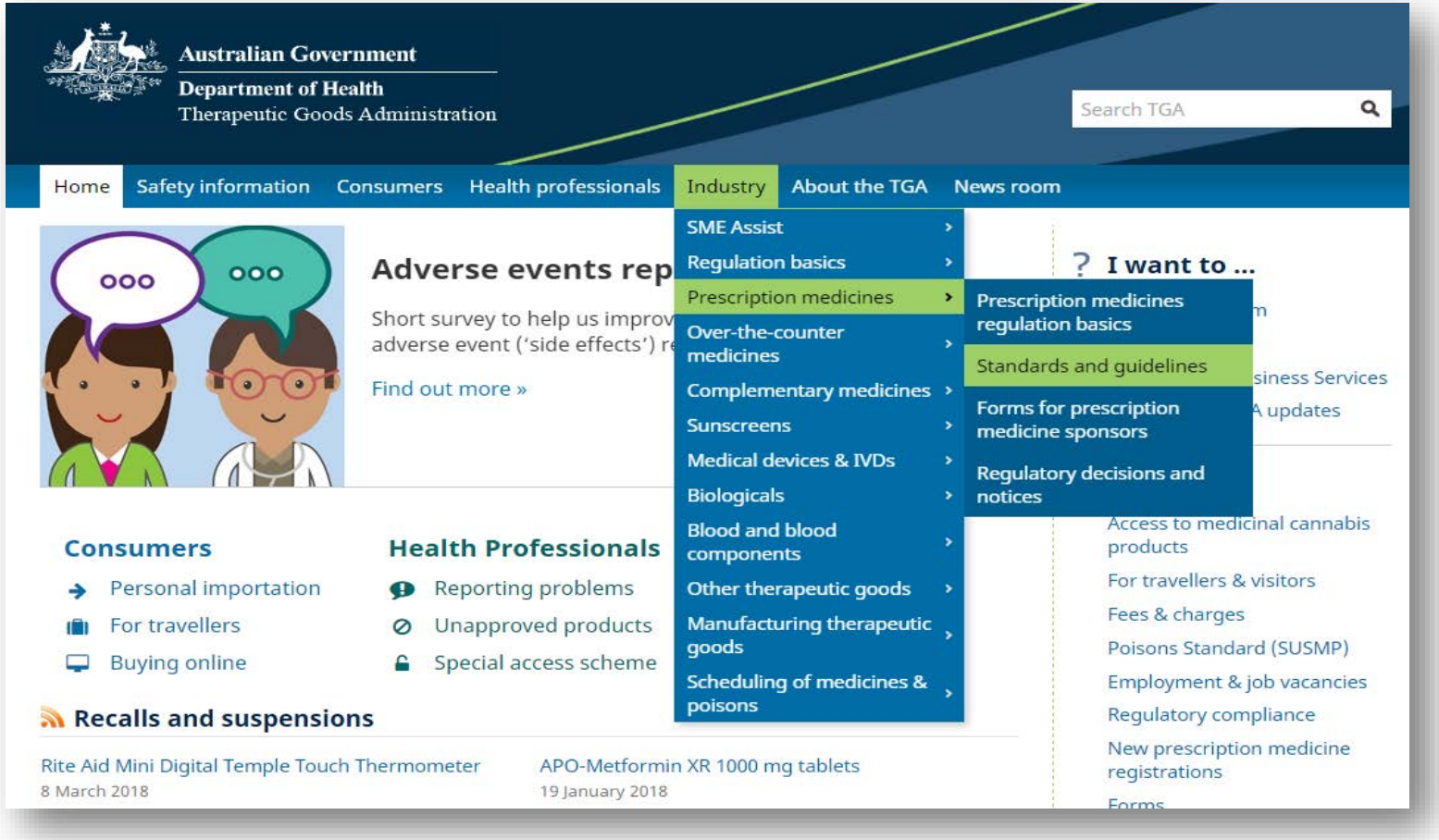
We use a range of compliance and enforcement tools to address alleged non-compliance to encourage compliance with the Act

Australian Regulatory Guidelines

- All types of therapeutic goods have their own **Australian Regulatory Guidelines** to assist applicants and sponsors with the process of applying for market authorisation.
- Note that these are guidance documents only.

ARGCM for **complementary medicines**
ARGOM for **over-the-counter medicines**
ARGPM for **prescription medicines**
ARGS for **sunscreens**
ARGMD for **medical devices** (currently under review)
ARGB for **biologicals**
ARGATG for **advertising therapeutic goods** (updated)

Australian Regulatory Guidelines



Industry > Product type > Standards & guidelines

TGA Business Services (TBS)

About the TGA > TGA Business Services

Fees and charges

The TGA is required to recover its costs through fees and charges for a majority of activities that fall within the scope of the *Therapeutic Goods Act 1989*, including the TGA's public health responsibilities.

Fees

- For a service e.g.
  - application
  - product evaluation
  - audit
  - certificates
  - advertising approval

Charges

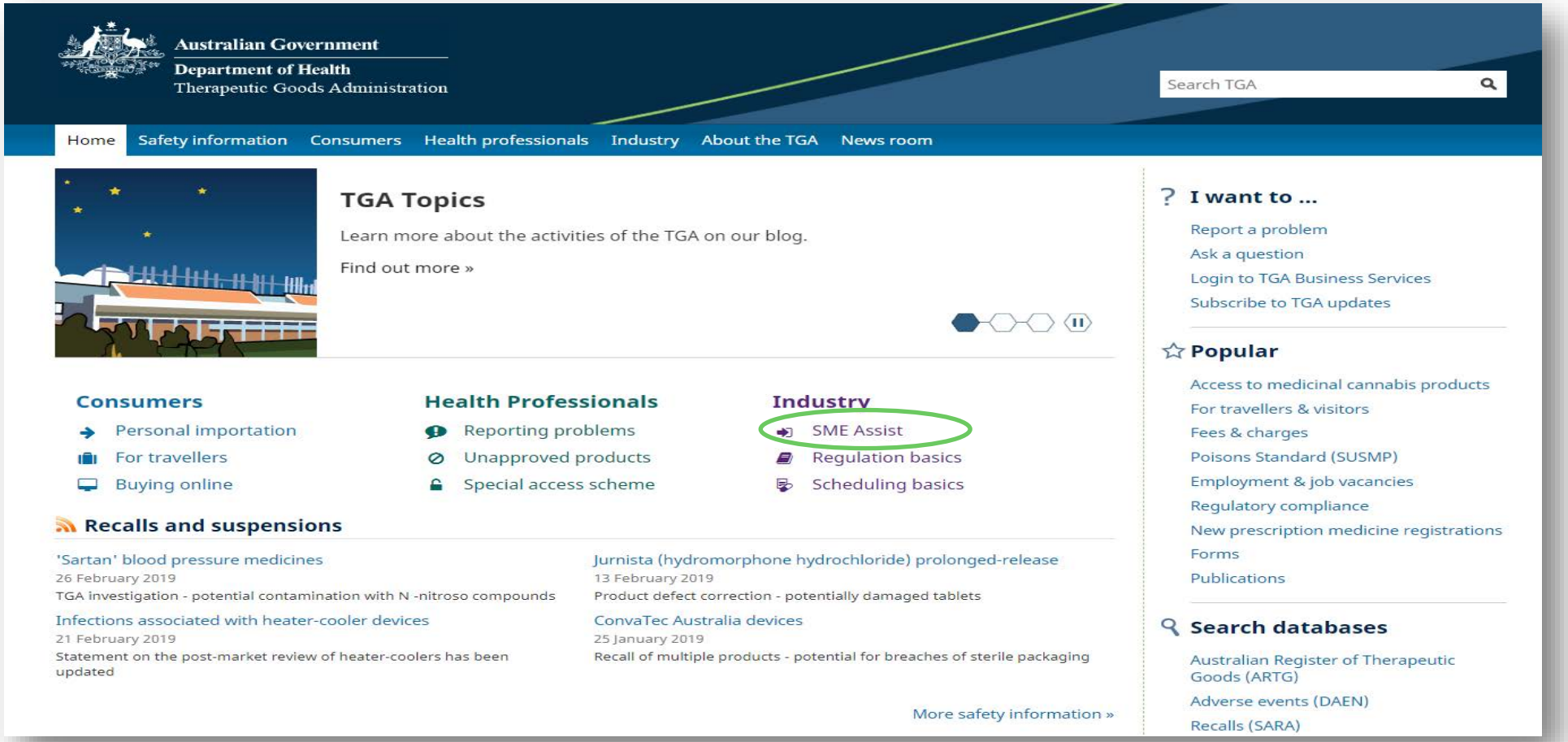
- Tax imposed on the regulatory industry
- Applied annually

Fees and charges

Annual Charge Exemption (ACE) scheme

- Allows for the exemption of annual charges until a product first generates turnover
- All new entries are eligible
- Sponsors are to make a declaration each year to confirm that their entry had $0 turnover in the previous financial year and have never previously made revenue

SME Assist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Regulation basics
Scheduling basics
Recalls and suspensions
'Sartan' blood pressure medicines
26 February 2019
TGA investigation - potential contamination with N -nitroso compounds
Infections associated with heater-cooler devices
21 February 2019
Statement on the post-market review of heater-coolers has been updated
Jurnista (hydromorphone hydrochloride) prolonged-release
13 February 2019
Product defect correction - potentially damaged tablets
ConvaTec Australia devices
25 January 2019
Recall of multiple products - potential for breaches of sterile packaging
More safety information »
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Access to medicinal cannabis products
For travellers & visitors
Fees & charges
Poisons Standard (SUSMP)
Employment & job vacancies
Regulatory compliance
New prescription medicine registrations
Forms
Publications
Search databases
Australian Register of Therapeutic Goods (ARTG)
Adverse events (DAEN)
Recalls (SARA)

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Supplying Medicinal Cannabis in Australia

Unapproved products

- Medicines not included on the ARTG are known as 'unapproved' medicines
- They have not been evaluated by the TGA for quality, safety and effectiveness
- Any Australian medical practitioner can apply via the Special Access Scheme (SAS) or Authorised Prescriber(AP) pathway to prescribe unapproved products including medicinal cannabis
- Medical practitioners can apply to become an Authorised Prescriber of a specific unapproved medicinal cannabis product to specific patients with a particular medicinal condition or symptom
- Lodge SAS and AP applications and notifications to TGA and state/territory health departments (if relevant)
- A sponsor is responsible for meeting their regulatory requirements

Scheduling

- The **Poisons Standard** provides a uniform approach to control the availability and accessibility of substances
  - includes provisions about containers and labels with a view to promoting uniform labelling and packaging requirements

- Medicines and poisons are classified into **Schedules**
  - in accordance with the level of regulatory control required to protect public health and safety

The Schedules

Schedule 1	Not currently in use
Schedule 2	Pharmacy medicine
Schedule 3	**Pharmacist Only Medicine**
Schedule 4	**Prescription Only Medicine OR Prescription Animal Remedy**
Schedule 5	Caution
Schedule 6	Poison
Schedule 7	Dangerous Poison
Schedule 8	**Controlled Drug**
Schedule 9	Prohibited Substance
Schedule 10	Substances of such danger to health as to warrant prohibition of sale, supply and use

Cannabis scheduling

Cannabis and tetrahydrocannabinol

- Under certain circumstances, cannabis (including seeds, extracts, resins and the plant or any part of the plant) and tetrahydrocannabinol (when extracted from cannabis) when prepared or packed for human therapeutic use, are 'Controlled Drugs' under **Schedule 8**

Cannabidiol

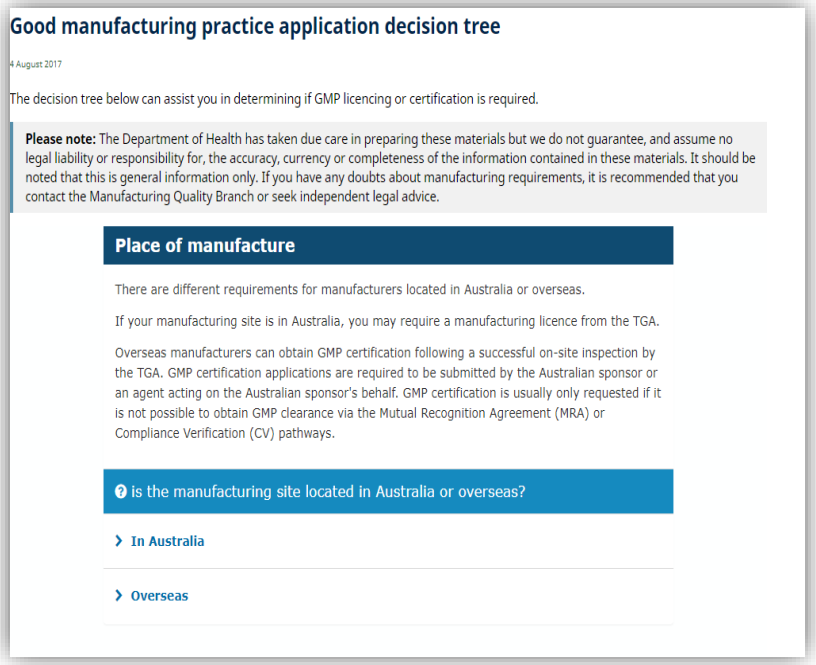
Schedule 4	Schedule 3 (Low dose CBD)
In preparations for therapeutic use or analytical and scientific research where: • cannabidiol comprises 98 per cent or more of the total cannabinoid content of the preparation; and • any cannabinoid, other than cannabidiol, must be only those naturally found in cannabis and comprise 2 per cent or less of the total cannabinoid content of the preparation **except** when included in **Schedule 3**.	In oral, oromucosal and sublingual preparations included in ARTG when: • the cannabidiol is either plant derived or, when synthetic, only contains the (-)-CBD enantiomer; and • the cannabidiol comprises 98 per cent or more of the total cannabinoid content of the preparation; and • any cannabinoids, other than cannabidiol, must be only those naturally found in cannabis and comprise 2 per cent or less of the cannabinoid content of the preparation and of which tetrahydrocannabinol (THC) can only comprise 1 per cent of the total cannabinoid content; and • specified restrictions on dose, packaging, pack size and intended users are satisfied

Other substances

- Nabiximols, nabilone and dronabinol are listed as ‘Controlled Drugs’ in **Schedule 8** of the Poisons Standard
  - S8 substances also require a prescription from an Australian-registered medical practitioner to obtain and possess within Australia

TGA's manufacturing requirements

- Manufacture includes processing, packaging, labelling, testing, release for supply, assembling, storage, sterilising
- Therapeutic goods must be manufactured by a TGA approved manufacturer
- Manufacturers must comply with the principles of Good Manufacturing Practice (GMP)
  - GMP is used internationally to describe a set of principles and procedures which helps ensure that each batch of a therapeutic good is safe, reliable and of consistent high quality
- Manufacturers must obtain a licence/clearance/certificate for the manufacturing steps they perform and the type of medicine produced
- See manufacturing medicines on TGA's website which includes step-by-step guides
- Use the '**Good Manufacturing Practice Application'** decision tool



Good manufacturing practice application decision tree

4 August 2017

The decision tree below can assist you in determining if GMP licencing or certification is required.

Please note: The Department of Health has taken due care in preparing these materials but we do not guarantee, and assume no legal liability or responsibility for, the accuracy, currency or completeness of the information contained in these materials. It should be noted that this is general information only. If you have any doubts about manufacturing requirements, it is recommended that you contact the Manufacturing Quality Branch or seek independent legal advice.

Place of manufacture

There are different requirements for manufacturers located in Australia or overseas.

If your manufacturing site is in Australia, you may require a manufacturing licence from the TGA.

Overseas manufacturers can obtain GMP certification following a successful on-site inspection by the TGA. GMP certification applications are required to be submitted by the Australian sponsor or an agent acting on the Australian sponsor's behalf. GMP certification is usually only requested if it is not possible to obtain GMP clearance via the Mutual Recognition Agreement (MRA) or Compliance Verification (CV) pathways.

is the manufacturing site located in Australia or overseas?

› In Australia

› Overseas

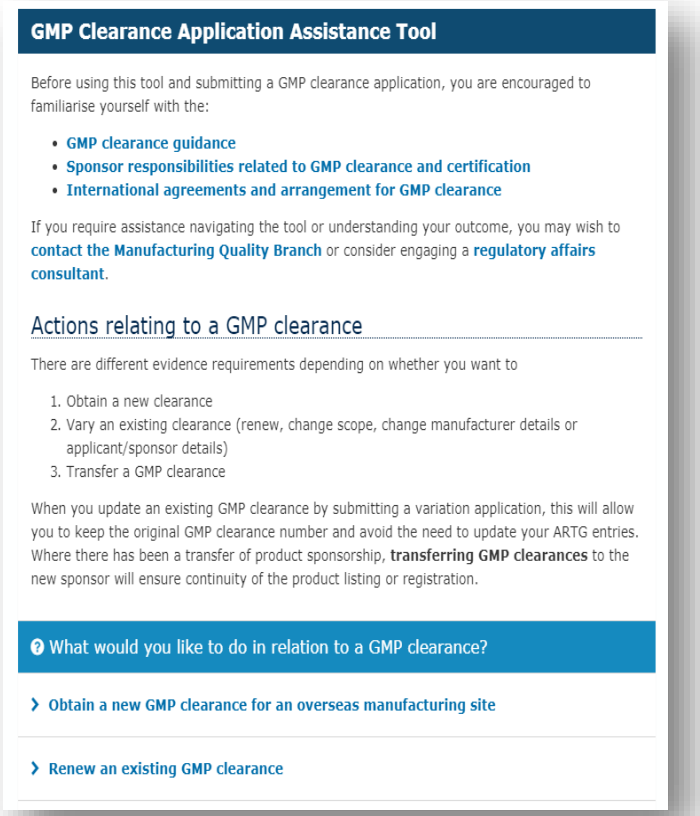
Australian and overseas manufacturers

- **Australian** manufacturers need to obtain **GMP licences**
  - must undergo an inspection prior to approval
  - manufacturer obtains the licence and provides details to sponsor
  - sponsors include this in their market authorisation application
  - inspections can happen at any time during market authorisation to ensure compliance

- Sponsors of medicines on the ARTG obtain **GMP clearances** for their overseas manufacturers
  - can be obtained in various ways such as Mutual Recognition Agreement (MRA) by a recognised country
  - must be recently inspected by the overseas regulator to TGA standards
  - sponsors include this in their market authorisation application

- Use the '**GMP clearance application**' assistance tool

- A **GMP certificate** is obtained by the manufacturer as a result of an overseas TGA inspection.



The Office of Drug Control (ODC)

- Regulates and provides advice on the import, export and manufacture of controlled drugs
  - as well as cultivation of cannabis for medicinal purposes to support Australia's obligations under International Drug Conventions

- A manufacturing licence issued by ODC differs from a GMP license issued by TGA
  - an ODC issued manufacturing licence applies to the separation or extraction of cannabis extract or of the Active Pharmaceutical Ingredient (API) from the cannabis and/or resin
  - GMP licence issued by the TGA applies to the manufacturing of a medicine for human use

- There are currently three types of licences under the *Narcotic Drugs Act 1967* relating to medicinal cannabis:
  - medicinal cannabis licence authorising cultivation or production or both
  - cannabis research licence authorising cultivation or production or both for research purposes
  - manufacturing licence authorising the manufacture of a drug or product

- This will move to a single licence framework in December 2021, meaning one licence would capture all three activities. More information on this is available on the ODC's website, www.odc.gov.au.

Import/export of therapeutic goods containing medicinal cannabis

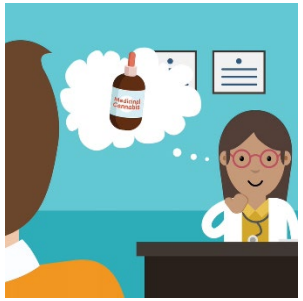
- Medicinal cannabis products for import/export between countries (including those made from low THC cannabis) is tightly controlled and subject to international drug conventions
  - approval must be granted by the national governments of both the importing and exporting countries before shipment can occur

- **Import**
  - can occur if a medical practitioner considers a medicinal cannabis product to be suitable for a particular patient (SAS/AP)

- **Export** can occur provided domestic supply is not affected, the following products are eligible for export if granted a licence and permit to export
  - medicinal cannabis products in Australia under a GMP licence
  - medicinal cannabis products included as export-only, or registered, on the ARTG
  - extracts of cannabis (or extracts of cannabis resin) manufactured under a licence and permit that are not in the final dosage form

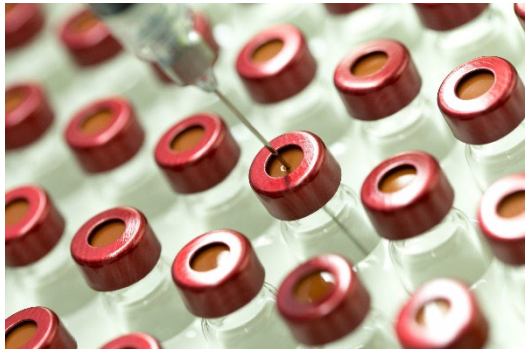
- Export of medicinal cannabis (extracts and preparations) is not permitted unless the product is listed as export-only or registered on the ARTG and the exporter holds a licence and permit to export drugs from the ODC

- **Wholesale** supply of any finished therapeutic goods that are not included on the ARTG, including medicinal cannabis products, is not consistent with the therapeutic goods regulatory framework.



Supply as a prescription medicine

- Sponsors can submit an application to include prescription only medicinal cannabis preparations in the ARTG
- Applications are individually evaluated for safety, quality and efficacy
- Must meet all legislative requirements for therapeutic goods as set out in applicable legislation
- Information on the application process and data requirements is available in the Australian Regulatory Guidelines for Prescription Medicines
- There are currently only 2 approved products



Application process for prescription medicines

- An application must be submitted to TGA which includes
  - data that support the quality, safety and efficacy of the product for its intended use
  - description of type of data outlined in Australian Regulatory Guidelines for Prescription Medicines - see also TGA adopted international guidelines
  - evidence of Good Manufacturing Practice is required
  - completed forms
  - payment of fees

- Examples include:
  - an application to register a new medicine
  - an application to registration an additional indication, dose form or strength

Pre-application activities

- Approved terminology for medicines (ingredient names)
  - Look at how to propose a new ingredient name - https://www.tga.gov.au/proposing-new-ingredient-name
- Pre-submission meetings
  - Look at requirements outlined in pre-submission planning form - www.tga.gov.au/form/pre-submission-planning-form-ppf
- Other considerations
  - Product Information (PI)
  - Consumer Medicine Information (CMI)
  - Patent certification and data exclusivity

Application categories

- Category 1 application
  - A new medicine or a change to a medicine
- Comparable Overseas Regulator (COR) report-based process:
  - Builds on previous Category 2 process
- Category 3 application and Minor Variations

- There are statutory processing times
  - Regulation 16A to 16G of the Therapeutic Goods Regulations 1990

Category 1 applications

- New chemical/biological entity or biosimilar medicine
- Changes to a medicine that create a separate and distinct good on the ARTG
- Some examples include:
  - extensions of indications (Type C)
  - new generic products (Type D)
  - major variations such as applications for new dosage forms, new strengths (Type F)
  - minor variation (Type G and H)
  - amendments to the Product Information (Type J)

Category 1 evaluation - key phases and milestones

Phase	Description
1. Pre-submission	Applicant provides necessary information on scope and scale of their application. Assists TGA's resource planning
2. Submission	TGA completes activities in preparation for application evaluation. Letter of application acceptance
3. First round assessment	Evaluator(s) assess the dossier
4 Consolidated Section 31 requests	TGA will consolidate all questions from our evaluator(s) and send to applicant. Stop Clock. NB: 'Rolling questions' used for Priority applications
5. Second round assessment	TGA evaluator(s) assess the application in view of the response to questions
6. Expert advisory review	Delegate may seek independent advice after having considered all evaluation reports
7 TGA Decision	TGA delegate makes a decision
8. Post-decision	Administrative and regulatory activities are completed e.g. ARTG entry, PI finalisation

Comparative Overseas Regulator (COR) applications

- Open to applications where the medicine has received full overseas marketing approval following a de novo evaluation.

- Must be from a country/jurisdiction determined to be 'comparable'

COUNTRY OR JURISDICTION	REGULATORY AUTHORITY
Countries	
Canada	Health Canada
Singapore	Health Science Authority Singapore (HSA)
Switzerland	SwissMedic
United Kingdom	Medicines and Healthcare products Regulatory Agency (MHRA)
United States	Food and Drug Administration (FDA)
Jurisdictions	
European Union	European Medicines Agency (EMA) - centralised and decentralised processes

  - COR approach A (target time frame of 120 working days)
  - COR approach B (target time frame of 175 working days)
- Applications may relate to:
  - New prescription medicines e.g. New Chemical Entities (NCE) and generics
  - Extensions of Indications
  - Changes to Product Information

Priority review pathway

- Faster assessment of eligible prescription medicines that have a full dossier and substantial evidence
  - target time frame of 150 working days
  - implemented on 1 July 2017

- A Determination step is required before submitting an application for Priority Review
  - this step is a formal process to allow TGA to assess the medicine against the eligibility criteria for this pathway
  - also need to satisfy administrative requirements

- Eligibility criteria:
  - must be a new prescription medicine OR an already registered medicine with a new indication AND
  - for the treatment, prevention or diagnosis of a life-threatening or seriously debilitating condition AND
  - no therapeutic goods are on the ARTG OR if already included on the ARTG, this medicine provides a significant improvement in efficacy or safety compared to those goods AND
  - there is substantial evidence demonstrating that the medicine provides a major therapeutic advance
  - for full details see Regulation 16R of the Therapeutic Goods Regulations 1990

Provisional approval pathway

- Allows sponsors to apply for *time-limited* provisional registration on the ARTG.
- Provides earlier access to certain promising new medicines where TGA assess that the benefit of early availability of the medicine outweighs the risk inherent in the fact that additional data are still required.
- Includes new prescription medicines or new uses for already registered prescription medicines (new indications)
- Determination step - Eligibility criteria are:
  - new prescription medicine or new indications
  - for treating a serious condition
  - favourable comparison against existing therapeutic goods
  - major therapeutic advance
  - evidence of a plan to submit comprehensive clinical data
- Guidance published on the TGA website - https://www.tga.gov.au/provisional-approval-pathway-prescription-medicines

Requirements and guidance for dossier submission

- Structure and format
- Content
  - Technical data requirements (Appendix A – specific mandatory requirements https://www.tga.gov.au/book-page/appendix-specific-mandatory-requirements
  - Australian and international adopted guidelines
- Justification for data gaps
- Administrative requirements

Common Technical document (CTD)

- A set of specifications for a dossier to support the registration of medicines
- General dossier requirements - www.tga.gov.au/publication/general-dossier-requirements
- eCTD specifications - www.tga.gov.au/book-page/ectd-preparation-tools

More information on our website

- Australian Regulatory Guidelines for Prescription Medicines
  https://www.tga.gov.au/publication/australian-regulatory-guidelines-prescription-medicines-argpm

- Standards & guidelines for prescription medicines
  https://www.tga.gov.au/standards-guidelines-prescription-medicines

- Forms for prescription medicine sponsors
  https://www.tga.gov.au/forms-prescription-medicine-sponsors

- Regulatory decisions and notices
  https://www.tga.gov.au/regulatory-decisions-and-notices-prescription-medicines

Final Hints and Tips:

1. Check if your product is a therapeutic good and what type (e.g. OTC/Prescription)
2. Decide whether you want to have it approved in your name to supply it in Australia
3. Understand the legal requirements for your product to be approved and your legal responsibilities of being a sponsor
4. Find out what type of therapeutic good the product is and review the relevant guidelines
5. Determine if it meets a particular submission pathway and application type
6. Understand the dossier/submission requirements and ensure you have ALL required data
7. Understand what it will cost you
8. Seek further advice if you need it!

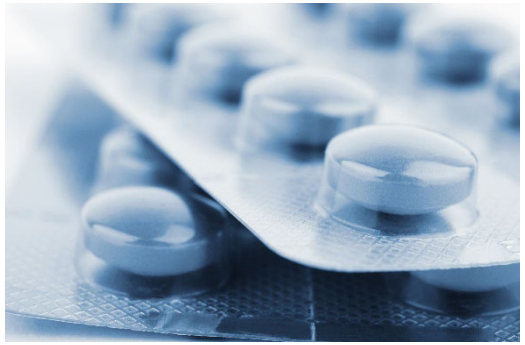
Keep your details up to date with TGA (TBS)

Post registration publication

Australian Public Assessment Report (AusPAR) by TGA

- An AusPAR provides information about:
  - the submission, the TGA's evaluation of the company data submitted
  - the considerations that led the TGA to approve or not approve an application.

Supply as an over-the-counter (OTC) medicine



- Low-dose CBD products:
  - containing a maximum of 150 mg/day
  - for use in adults 18 years and over
  - used in oral, oromucosal and sublingual preparations
  - packed in blister or strip packaging or in a container with child-resistant closure
  - containing no more than 30 days supply in a pack
  - that meet specified formulation requirements and;
  - are approved by TGA and included in the ARTG

- Can be supplied over-the-counter by a pharmacist, without a prescription.

Application process for OTC medicines

- An application must be submitted to TGA to register a low dose S3 CBD-containing medicine on the ARTG
- Fully evaluated for safety, efficacy and quality
- N5 application level
- Full dossier (i.e. Modules 1, 2, 3, 4 & 5) in Common Technical Document format
- Guidance documents on TGA website outline the process and data requirements

Information and data requirements

- **Module 1: A**dministrative info
- **Module 2:** Overviews & summaries
- **Module 3:** Quality
  - complete module 3.2.s or a DMF if manufactured by a 3rd party
  - product must be **manufactured** in a TGA licensed/ cleared GMP facility, like all other medicines
- **Module 4:** Non-clinical
  - pharmacology, pharmacokinetics, toxicology study reports

OTC medicines registration basics

- Overview of OTC medicines registration
- OTC medicines registration process
  Step-by-step guide
- Process to change a registered OTC medicine
  Step-by-step guide
- Changing an OTC medicine: using the Changes Tables
- Fees and payments
- Target evaluation times
- Supporting information

Application and dossier requirements

- Mandatory requirements for an effective application
- General dossier requirements
- OTC Dossier documents matrix
- CTD Module 1: OTC medicines
- Common Technical Documentation (CTD)
- Preparing an OTC application cover letter

Information and data requirements

- **Module 5: Clinical efficacy & safety**
  - Clinical trial reports, with studies conducted in accordance with Good Clinical Practice (GCP) guidelines
  - Dose ranging trials expected
  - A paucity of high quality published trials (meta-analyses and RCTs) with the majority of the literature for analysis being lower quality explorative studies or case series with no placebo control
  - Literature based approaches unlikely to yield sufficient data alone, more likely to be supportive
  - All literature searches must be systematic and not use anecdotal sources
  - Observational studies – inherent limitations, at best would be supportive only

Information and data requirements

- The safety & efficacy data submitted must support the product for its intended use including the patient population and dosage
- Any indication will need **robust clinical evidence**
- Indication must be for OTC use i.e. **suitable for a pharmacist** consultation:
  - indications for serious medical conditions (e.g. epilepsy, anxiety disorders) and/or that require the on-going monitoring or intervention of a doctor are not appropriate for OTC use
- Relevant European Guidelines and ICH guidance documents should also be referred to for assistance
- Application and evaluation fee
- Target timeframe is 210 working days, however, can be less if data is of good quality
- Refer to Australia Regulatory Guidelines for Over-the-Counter Medicines (ARGOM)

Advertising requirements apply to all therapeutic goods

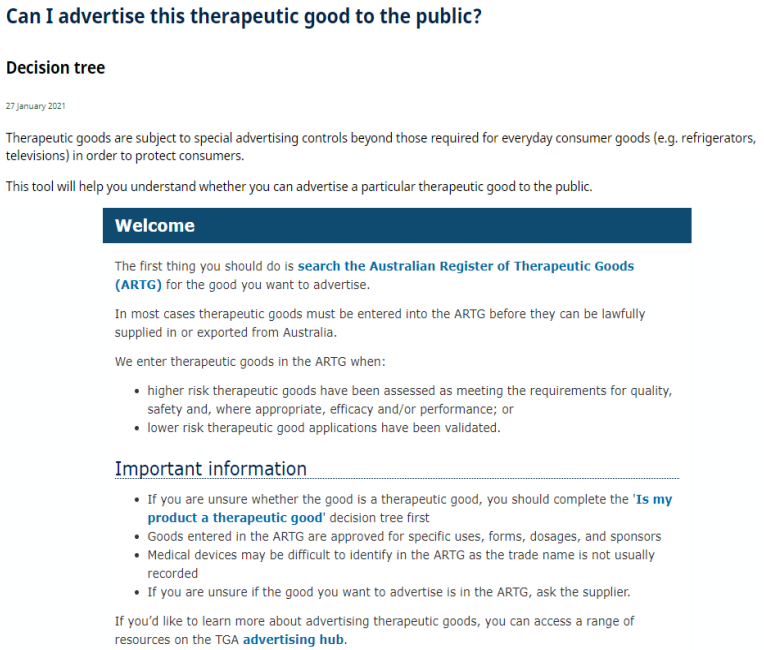
Advertising is any promotional material

Therapeutic Goods Act 1989
Therapeutic Goods Regulations 1990
Therapeutic Goods Advertising Code (No. 2) 2018

Advertising restrictions

- **Restrictions apply when advertising:**
  - pharmacist only medicines (except those included in Appendix H of the Poisons Standard)
  - prescription medicines
  - prohibited or restricted representations (unless approved by TGA)
  - to health professionals
  - for health services

- **For help:**
  - use the ‘Can I advertise this therapeutic good to the public?’ decision tool
  - refer to ‘complying with advertising requirements’



Can I advertise this therapeutic good to the public?

Decision tree

27 January 2021

Therapeutic goods are subject to special advertising controls beyond those required for everyday consumer goods (e.g. refrigerators, televisions) in order to protect consumers.

This tool will help you understand whether you can advertise a particular therapeutic good to the public.

Welcome

The first thing you should do is **search the Australian Register of Therapeutic Goods (ARTG)** for the good you want to advertise.

In most cases therapeutic goods must be entered into the ARTG before they can be lawfully supplied in or exported from Australia.

We enter therapeutic goods in the ARTG when:

- higher risk therapeutic goods have been assessed as meeting the requirements for quality, safety and, where appropriate, efficacy and/or performance; or
- lower risk therapeutic good applications have been validated.

Important information

- If you are unsure whether the good is a therapeutic good, you should complete the '**Is my product a therapeutic good**' decision tree first
- Goods entered in the ARTG are approved for specific uses, forms, dosages, and sponsors
- Medical devices may be difficult to identify in the ARTG as the trade name is not usually recorded
- If you are unsure if the good you want to advertise is in the ARTG, ask the supplier.

If you’d like to learn more about advertising therapeutic goods, you can access a range of resources on the TGA **advertising hub**.

Australian Government
Department of Health
Therapeutic Goods Administration

SME Assist

www.tga.gov.au/sme-assist
1800 020 653
sme.assist@tga.gov.au

More information – Social media

	Website	https://www.tga.gov.au
	Facebook	https://www.facebook.com/TGAgovau/
	Twitter	https://twitter.com/TGAgovau
	YouTube	https://www.youtube.com/channel/UCem9INJbMSOeW1Ry9cNbucw
	Topic blogs	https://www.tga.gov.au/blogs/tga-topics
	Linkedin	https://www.linkedin.com/company/therapeutic-goods-administration/
	Instagram	https://www.instagram.com/tgagovau/?hl=en

Websites and Contacts

TGA Info	info@tga.gov.au
Over-the-counter (OTC) medicines	otc.medicines@health.gov.au
Prescription medicines	application.entry.team@health.gov.au
The Office of Drug Control (ODC)	dcs@health.gov.au
Advertising	tga.advertising@health.gov.au
TGA Manufacturing	gmp@health.gov.au
Unapproved products	medicinal.cannabis@health.gov.au

Resource links

Clinical trials	https://www.tga.gov.au/clinical-trials
Clinical trial handbook	https://www.tga.gov.au/resource/australian-clinical-trial-handbook
SME Assist – market authorisation	https://www.tga.gov.au/sme-assist/overview-applying-market-authorisation
ARTG	https://www.tga.gov.au/australian-register-therapeutic-goods
Therapeutic Goods Act 1989	https://www.legislation.gov.au/Series/C2004A03952
Overview of medical devices and IVD regulation	https://www.tga.gov.au/sme-assist/medical-devices-regulation-introduction
In vitro diagnostics classification	https://www.tga.gov.au/book-page/ivd-classification-examples
Compliance management	https://www.tga.gov.au/hubs/compliance-and-enforcement/compliance-management
Schedule of fees and charges	https://www.tga.gov.au/schedule-fees-and-charges
Notice of final decision	https://www.tga.gov.au/scheduling-decision-final/notice-final-decision-amend-or-not-amend-current-poisons-standard-cannabidiol
ARGOM	https://www.tga.gov.au/publication/australian-regulatory-guidelines-otc-medicines-argom-0
Medicinal cannabis	https://www.tga.gov.au/medicinal-cannabis

How did we go?

LIVE POLL

15 minute break followed with Q&A

Danielle Chifley	The Office of Drug Control (ODC)
Kevin Eager	Over-the-Counter (OTC) medicines
Gaelene Pyke	Over-the-Counter (OTC) medicines
Nicole McLay	Advertising
Myra Kochardy	Advertising
Klara Koelmeyer	Prescription medicines
Adam Cook	Scheduling
Sukanya Lingaratnam	Experimental Products Section (EPS)
Maurice Makdessi	Manufacturing

Q&A with these TGA specialists

Q&A

To ask a question, please use the **Q&A Tool**

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Australian Government

Department of Health

Therapeutic Goods Administration