



Australian Government

Department of Health

Therapeutic Goods Administration

SME Assist – ‘Meeting Your Obligations’

Basics of Therapeutic Goods Regulation

Bronwynne Bulless
Director, SME Assist

12 November 2019



TGA Health Safety
Regulation



Disclaimer

This material is provided to you solely for the purpose of providing a record of today's presentation.

The presentation is 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 paper should not be relied upon in any way as representing a comprehensive description of regulatory requirements, and
- b) it cannot guarantee, and assumes no legal liability or responsibility for, the accuracy, currency or completeness of the information contained in the presentation paper.



SME Assist

Provides targeted support for small to medium businesses, start-ups and researchers, including:

- entry level guidance for those new to regulation
- information for research groups who are developing innovative new medicines and medical devices
- tools to help determine if your product is a therapeutic good
- access to workshops, webinars, online materials and other useful resources
- phone and email support
- subscription service





Objectives

To give you:

- an **overview** of therapeutic goods regulation
- information about TGA's SME Assist service
- advice on **where to look** on the TGA website for more information
- helpful links for applications



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*.



← Look out for this symbol

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:

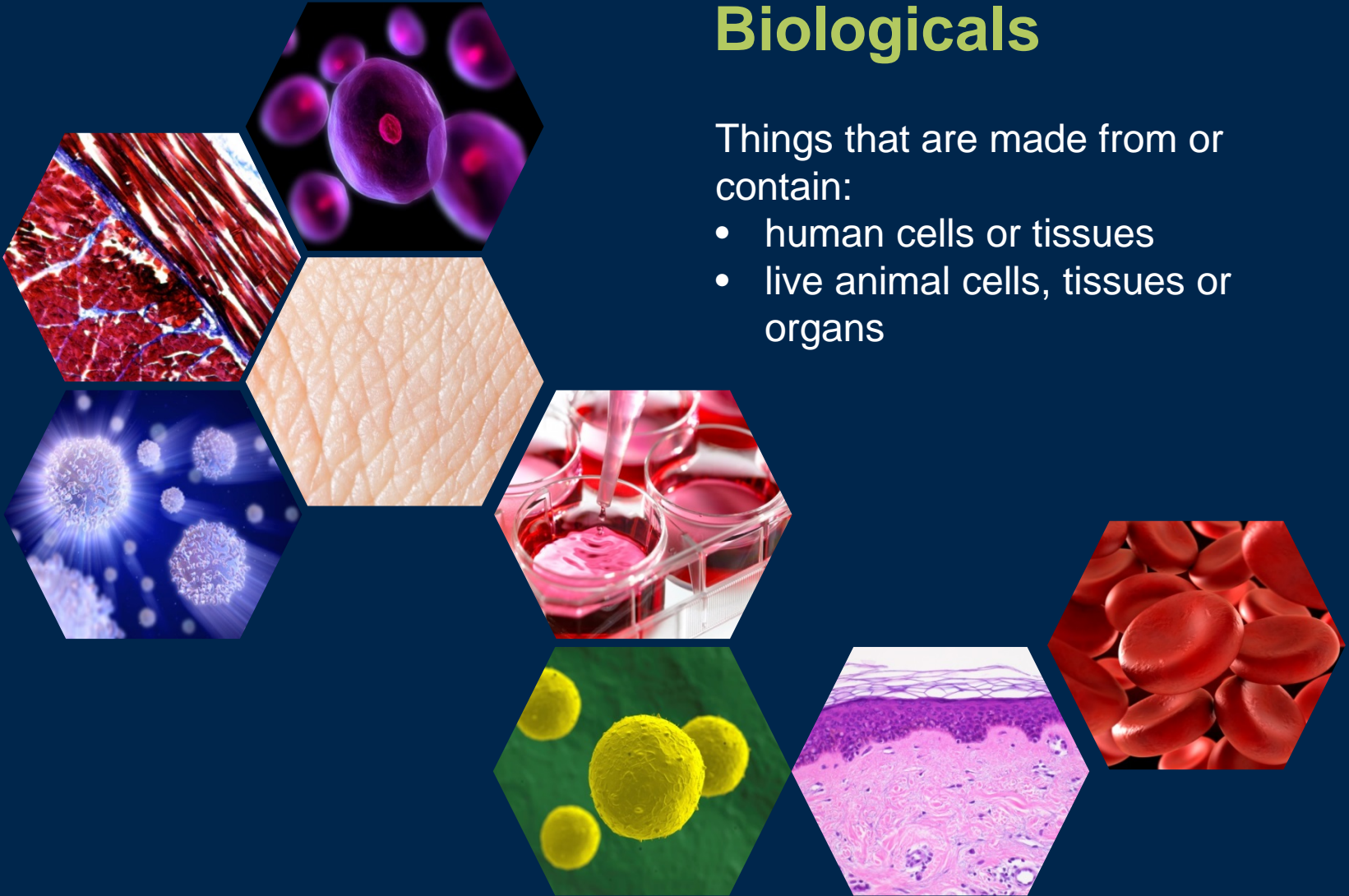
- prescription medicines
- complementary medicines
- over-the-counter medicines
- vaccines
- blood and plasma



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 and materials.





What we do NOT regulate



VETERINARY
MEDICINES

Australian
Pesticides and
Veterinary
Medicines
Authority
(APVMA)



HEALTH
PROFESSIONALS

Australian
Health
Practitioner
Regulation
Agency
(AHPRA)



HEALTH
INSURANCE

Australian
Prudential
Regulation
Authority
(APRA)



FOOD
STANDARDS

States and
Territories and
Food Standards
Australia New
Zealand
(FSANZ)



COSMETIC AND
CHEMICAL
STANDARDS

National
Industrial
Chemicals
Notification and
Assessment
Scheme
(NICNAS)



We don't:

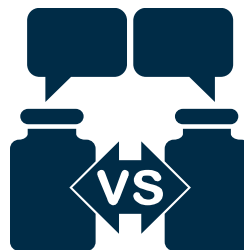
Research and develop new therapeutic goods



Provide clinical advice to individuals



Consider cost effectiveness or recommend one product over another

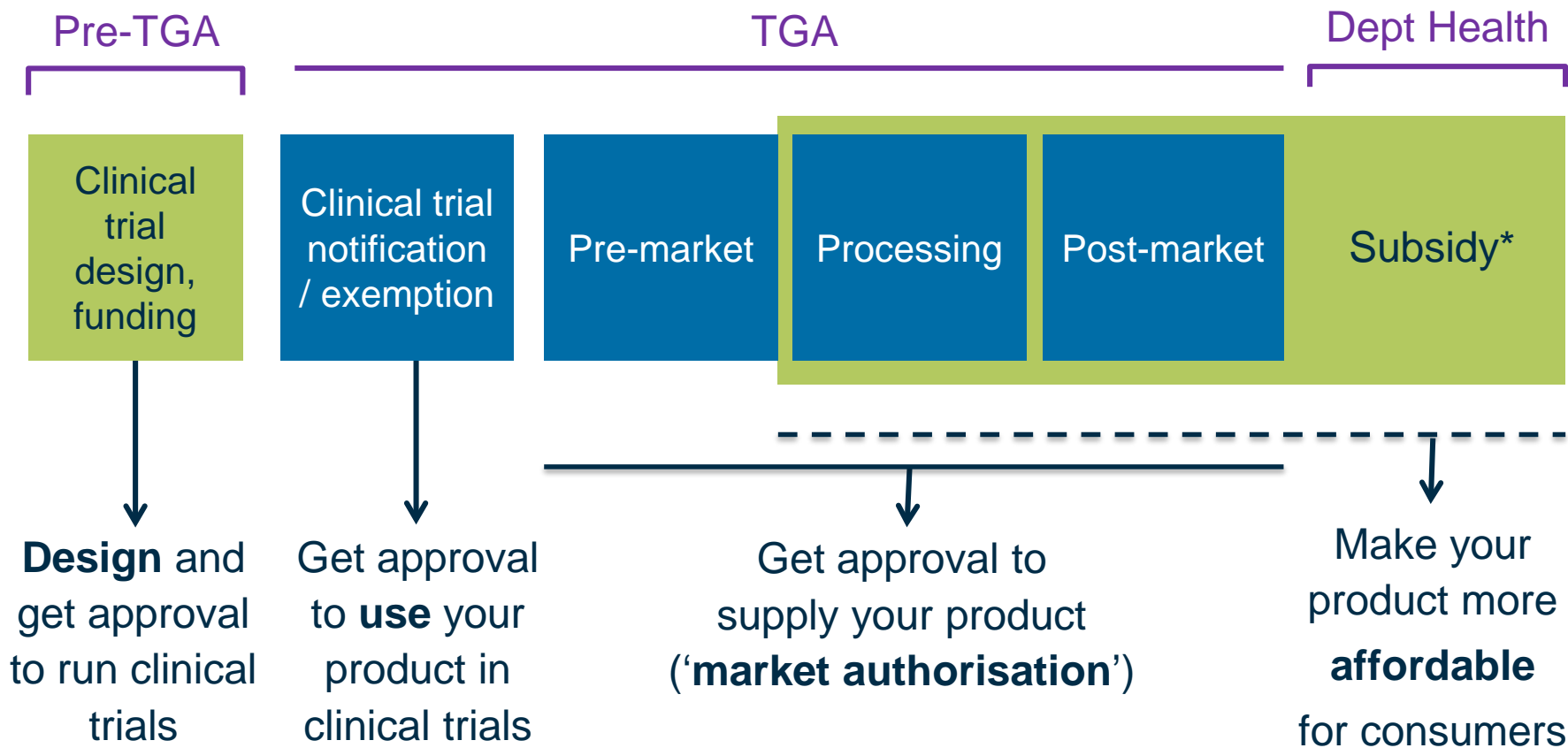


Make decisions about subsidies for therapeutic goods





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 **‘exemption’** scheme

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





Responsibilities under clinical trials schemes

Sponsor

- Overall responsibility for trials conducted
- Submissions to TGA
- Ensure the trial must be in accordance with the Good Clinical Practice, National Statement and procedural protocol
- Safety reporting

Human Research Ethics Committee

- Assess the scientific validity of the trial design, safety and efficacy of the medicine or device, and ethical acceptability of the trial process
- Monitor the conduct of the trial
- Approve the trial protocol

Approving authority

- The institution or organisation at which the trial will be conducted (trial sites)
- Gives the final approval for the conduct of the trial at the site, having due regard to advice from the Human Research Ethics Committee

Principal investigator

- Personally supervises the trial at that site
- Must conduct the clinical trial in accordance with the clinical trial protocol
- Must monitor safety
- Must comply with record management and reporting requirements for adverse events



Australian clinical trial handbook

The screenshot shows the Australian Government Department of Health Therapeutic Goods Administration website. The main navigation bar includes links for Home, Safety information, Consumers, Health professionals, Industry (selected), About the TGA, and News room. A search bar is located in the top right corner.

The breadcrumb trail is: Home » Industry » Regulation basics » Clinical trials.

The main heading is "Australian clinical trial handbook". Below it is the sub-heading "Guidance on conducting clinical trials in Australia using 'unapproved' therapeutic goods" with a date of 12 October 2018. There are "Next" and "View All" buttons.

The "About this handbook" section states: "This handbook provides guidance on the legislative, regulatory and good clinical practice (GCP) requirements when conducting clinical trials in Australia using 'unapproved' therapeutic goods. It assists trial sponsors, Human Research Ethics Committees (HRECs), investigators and approving authorities (institutions) to understand their roles and responsibilities under the therapeutic goods legislation." It also mentions that information for consumers can be found on the Australian Clinical Trials website.

A second paragraph states: "This handbook does not describe all of the requirements for conducting clinical trials in Australia. It refers to other relevant publications throughout that should be read in conjunction with this guidance."

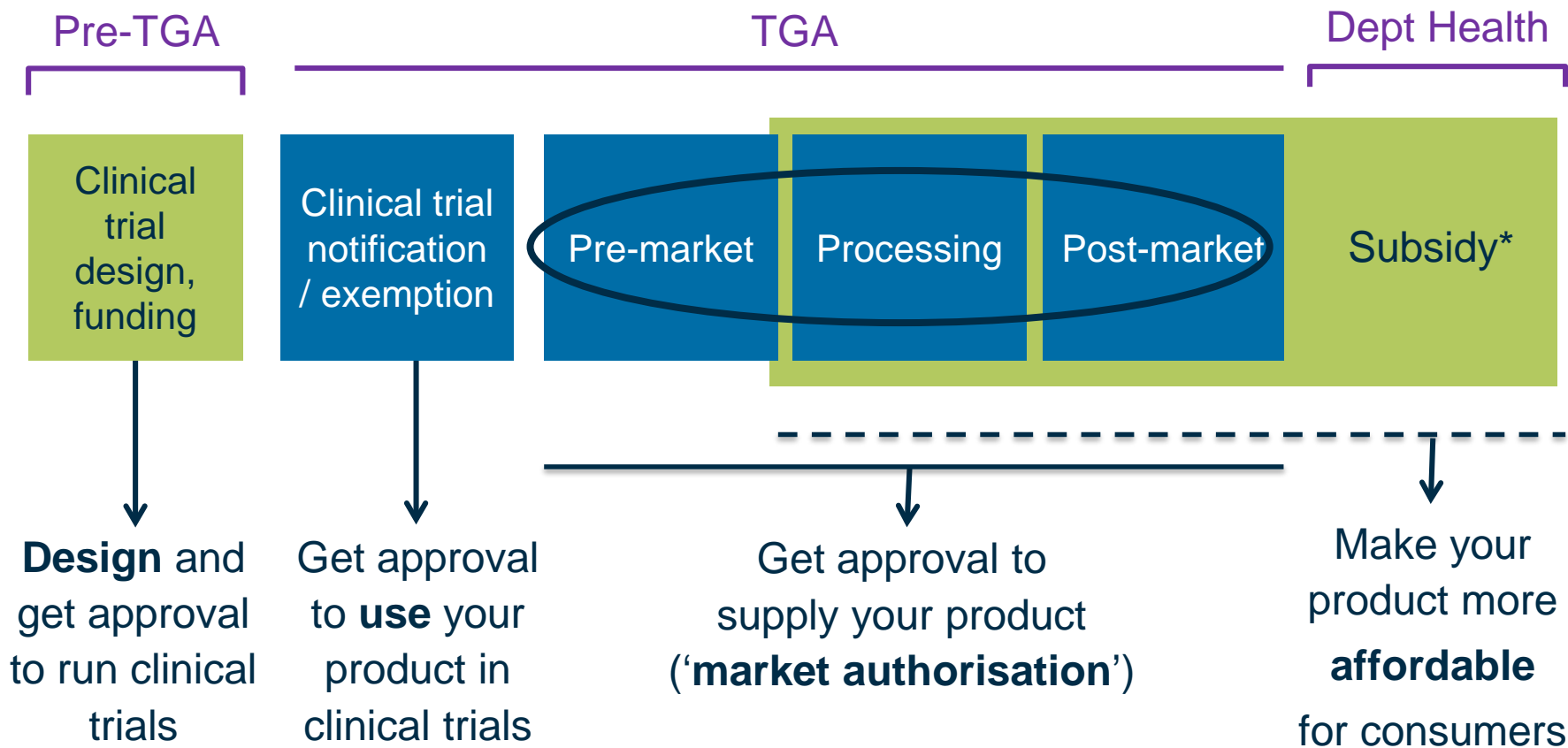
On the right side, there is a "Print version" section with a PDF icon and the text "Print version of Australian clinical trial handbook (pdf, 771 KB)" and a link "How to access a pdf document". Below that is a "Contents" section with two items: "Clinical trials involving therapeutic goods" and "The Australian regulatory environment".

The left sidebar contains a navigation menu under "Industry" with "SME Assist" and "Regulation basics" (expanded). Under "Regulation basics", there are links for: "How therapeutic goods are regulated in Australia", "Australian Register of Therapeutic Goods", "Industry educational materials", "Legislation & legislative instruments", "Advertising hub", "Labelling & packaging", "Ingredients in therapeutic goods", "Exporting therapeutic goods", "Importing therapeutic goods", "Clinical trials", "Cosmetics", and "Scientific guidelines".





Therapeutic good development lifecycle



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



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.





Market authorisation

Sponsor

- Once you've obtained market authorisation, you become known as the **sponsor**
- The sponsor bears all associated responsibilities and is financially liable for the therapeutic good

*Remember, you will have **ongoing responsibilities** even after approval has been given. It is a continuous process.*





Help to achieve market authorisation

- **Use of international assessments from comparable overseas regulators**
 - Prescription medicines: Canada, European Union, Japan, Singapore, Switzerland, United Kingdom, United States of America
 - Medical devices: Canada, European notified bodies, Japan, United States of America and certificates and reports issued under the Medical Devices Single Audit Program
- **Priority review and provisional approval pathways for prescription medicines**





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**





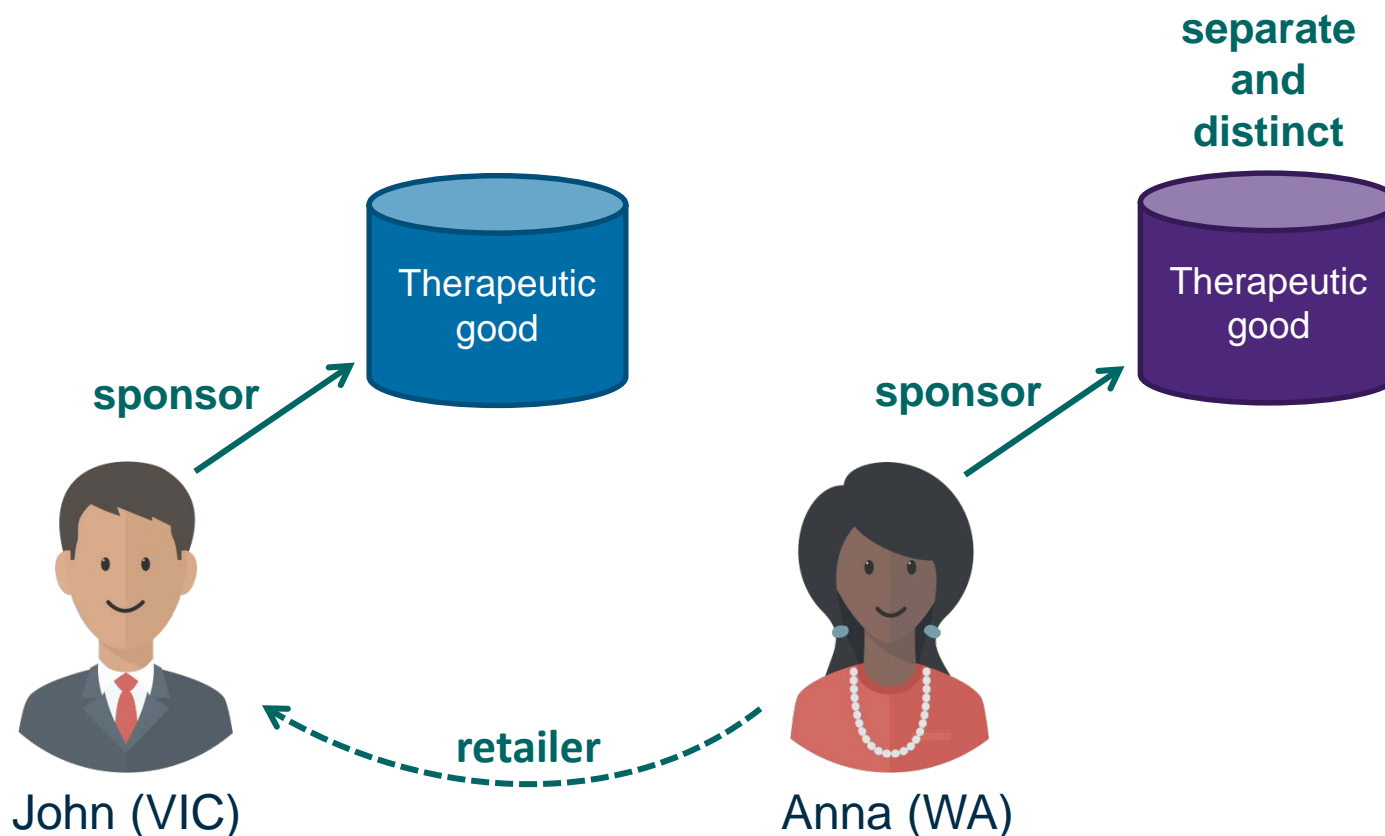
Separate and distinct products have their own ARTG entry

- 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	 <u>Therapeutic Goods Act 1989</u>	16
Biologicals	 <u>Therapeutic Goods Regulations 1990</u>	11A
Medical devices	 <u>Therapeutic Goods Act 1989</u>	41BE



Sponsorship example





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 have to outweigh risks!



Benefit vs. risk approach

Medicines

Listed AUST L	Assessed Listed AUST L(A)	Registered AUST R
<ul style="list-style-type: none">• No pre-market evaluation• Can only have permissible indications• Can only contain pre-approved, lower risk permissible ingredients• Require pre-approved GMP	<ul style="list-style-type: none">• Pre-market evaluation required for intermediate and permissible indications• Can only contain pre-approved, lower risk permissible ingredients• Require pre-approved GMP	<ul style="list-style-type: none">• 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



Benefit vs. risk approach

Medicines

	AUST L	AUST L(A)	AUST R
Prescription	none	none	always
OTC	some	none	most
Complementary	most	some	some





Benefit vs. risk approach



Medical devices (not including *in vitro* diagnostics)

Class	Risk	Examples
Class I	Low	Tongue depressors, slings
Class I – supplied sterile	Low-medium	Some bandages, wound dressings, catheters
Class I – incorporating a measuring function		Medicine cups with defined units
Class IIa	Medium	Intravenous tubing, syringes for infusion pumps
Class IIb		Lung ventilators, medical device disinfectants, some implantable devices (e.g. urethral stents)
Class III	High	Heart valves, devices containing medicines or tissues, cells or substances of animal, biological or microbiological origin
Active implantable medical device (AIMD)	High	Implantable defibrillators

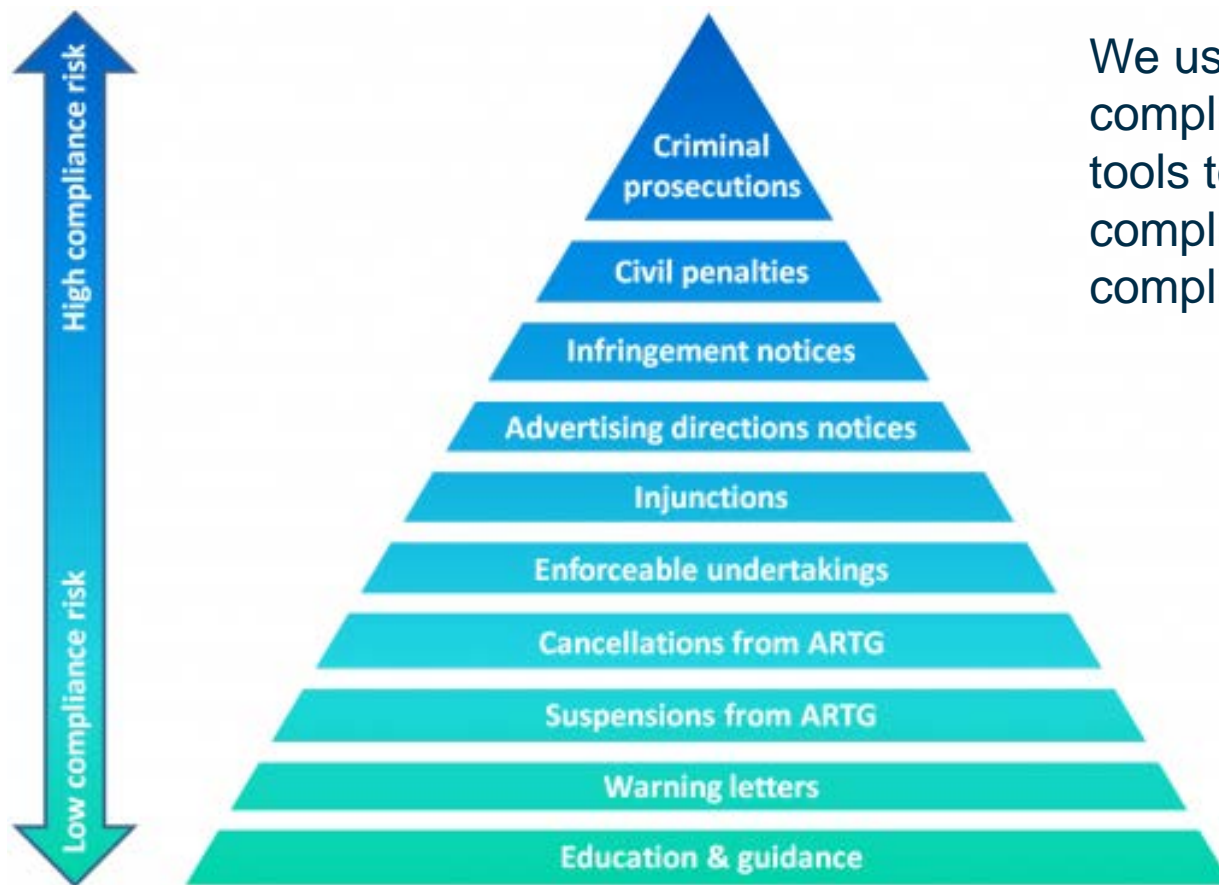
[In vitro diagnostics classification](#)

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





Helpful links for applications



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

- ① [ARGCM](#) for **complementary medicines**
- ① [ARGOM](#) for **over-the-counter medicines**
- ① [ARGPM](#) for **prescription medicines**
- ① [ARGS](#) for **sunscreens**
- ① [ARGMD](#) for **medical devices**
- ① [ARGB](#) for **biologicals**
- ① [ARGATG](#) for **advertising therapeutic goods**



Australian Regulatory Guidelines

The screenshot shows the Australian Government Department of Health Therapeutic Goods Administration website. The navigation bar includes: Home, Safety information, Consumers, Health professionals, **Industry**, About the TGA, and News room. A search bar labeled 'Search TGA' is in the top right. The 'Industry' dropdown menu is open, listing: SME Assist, Regulation basics, **Prescription medicines**, Over-the-counter medicines, Complementary medicines, Sunscreens, Medical devices & IVDs, Biologicals, Blood and blood components, Other therapeutic goods, Manufacturing therapeutic goods, and Scheduling of medicines & poisons. The 'Prescription medicines' sub-menu is also open, listing: Prescription medicines regulation basics, **Standards and guidelines**, Forms for prescription medicine sponsors, and Regulatory decisions and notices. On the left, there is a section for 'Adverse events reporting' with an illustration of two people and a 'Find out more' link. Below that are sections for 'Consumers' (Personal importation, For travellers, Buying online) and 'Health Professionals' (Reporting problems, Unapproved products, Special access scheme). At the bottom, there are recall notices for 'Rite Aid Mini Digital Temple Touch Thermometer' and 'APO-Metformin XR 1000 mg tablets'.

Industry > Product type > Standards & guidelines



Other Guidance

- Subscribe to the TGA Guidelines email list to receive regular updates of new guidance material, for example:
 - [Medical device cyber security guidance for industry](#)
 - [Comparable overseas regulators \(CORs\) for prescription medicines](#)
 - [Comparable overseas regulators \(CORs\) for medical devices](#)
 - [Advertising guidance for businesses involved with stem cells and other human cell or tissue \(HCT\) products](#) ⓘ





TGA Business Services

The screenshot shows the TGA website header with the Australian Government logo and navigation menu. The 'About the TGA' menu is open, listing various services. 'TGA Business Services' is highlighted in green. Below the menu, there are sections for 'Consumers', 'Health Professionals', and 'Industry'. A 'Recalls and suspensions' section is also visible at the bottom.

Australian Government
Department of Health
Therapeutic Goods Administration

Search TGA

Home Safety information Consumers Health professionals Industry **About the TGA** News room

Adverse events reporting
Short survey to help us improve the way we handle adverse event ('side effects') reports
Find out more »

Consumers
→ Personal importation
📁 For travellers
💻 Buying online

Health Professionals
👤 Reporting problems
🚫 Unapproved products
🔒 Special access scheme

Industry
📄 Scheduling basics

Recalls and suspensions

Rite Aid Mini Digital Temple Touch Thermometer 8 March 2018 Recall - potential risk of harm for children who access the	APO-Metformin XR 1000 mg tablets 19 January 2018 Recall - risk of injury due to potential contamination with
---	--

About the TGA dropdown menu items:
 TGA basics
 Contact the TGA
 Educational materials
 Compliance actions
 Regulatory decisions & notices
 Committees
 Employment & job vacancies
 Fees and payments
TGA Business Services
 International
 TGA Internet site archive
 Scheduling basics

I want to ...
 Report a problem
 Ask a question
 Login to TGA Business Services
 Subscribe to TGA updates

Popular
 Access to medicinal cannabis
 TGA Business services: getting started with the TGA
 TGA Business services - how to use the site
 TGA Business Services forms
 Regulatory compliance
 New prescription medicine registrations
 Forms

About the TGA > TGA Business Services



TGA Business Services

The TGA's online system where you submit and manage your applications including:

- apply for market authorisation
- submit clinical trial notifications
- advise us of adverse events
- view, cancel or transfer your current ARTG entries and generate certificates
- pay/review invoices
- update your details

Every sponsor needs to have an account.





Fees and charges

The screenshot shows the Australian Government Department of Health Therapeutic Goods Administration website. The navigation menu is open, highlighting the path: **About the TGA** > **Fees and payments** > **Schedule of fees and charges**. Other menu items include TGA basics, Contact the TGA, Educational materials, Compliance actions, Regulatory decisions & notices, Committees, Employment & job vacancies, TGA Business Services, International, and TGA Internet site archive. The main content area features sections for Adverse events reporting, Consumers (Personal importation, For travellers, Buying online), Health Professionals (Reporting problems, Unapproved products, Special access scheme), Industry (Scheduling basics), and Recalls and suspensions (Rite Aid Mini Digital Temple Touch Thermometer, APO-Metformin XR 1000 mg tablets).

About the TGA > Fees and payments > Schedule of fees and charges



Fees and charges

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

Australian Government
Department of Health
 Therapeutic Goods Administration

🔍

Home
Safety information
Consumers
Health professionals
Industry
About the TGA
News room

TGA Topics

Learn more about the activities of the TGA on our blog.

Find out more »

Consumers

- [➔ Personal importation](#)
- [📁 For travellers](#)
- [💻 Buying online](#)

Health Professionals

- [🗨️ Reporting problems](#)
- [🚫 Unapproved products](#)
- [🔒 Special access scheme](#)

Industry

- [➔ SME Assist](#)
- [📖 Regulation basics](#)
- [📄 Scheduling basics](#)

📡 Recalls and suspensions

<p>'Sartan' blood pressure medicines 26 February 2019 TGA investigation - potential contamination with N-nitroso compounds</p> <p>Infections associated with heater-cooler devices 21 February 2019 Statement on the post-market review of heater-coolers has been updated</p>	<p>Jurnista (hydromorphone hydrochloride) prolonged-release 13 February 2019 Product defect correction - potentially damaged tablets</p> <p>ConvaTec Australia devices 25 January 2019 Recall of multiple products - potential for breaches of sterile packaging</p>
--	--

? I want to ...

- [Report a problem](#)
- [Ask a question](#)
- [Login to TGA Business Services](#)
- [Subscribe to TGA updates](#)

☆ Popular

- [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 \(SARA\)](#)

Basics of Therapeutic Goods Regulation
[More safety information »](#)



SME Assist

www.tga.gov.au/sme-assist

1800 020 653

sme.assist@tga.gov.au



Australian Government

Department of Health
Therapeutic Goods Administration