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

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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


wholesaler
consumer
TGA
THERAPEUTIC GOOD
Amazing Herbal
retailer
importer/ exporter
manufacturer

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

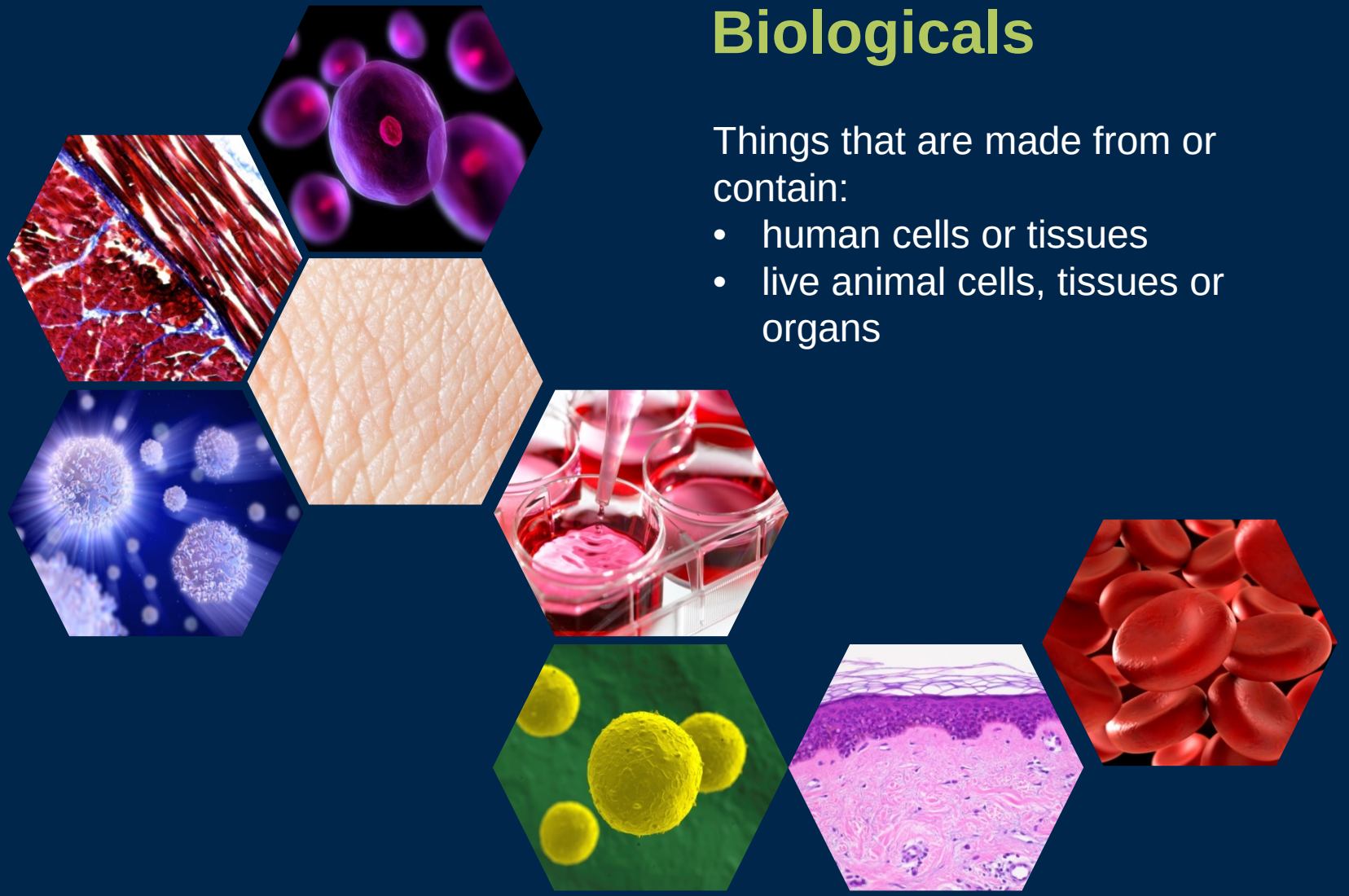
Something used for:

- 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

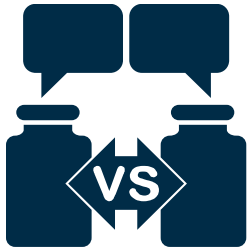
National Industrial Chemicals Notification and Assessment Scheme (NICNAS)

We don’t:

Research and develop new therapeutic goods

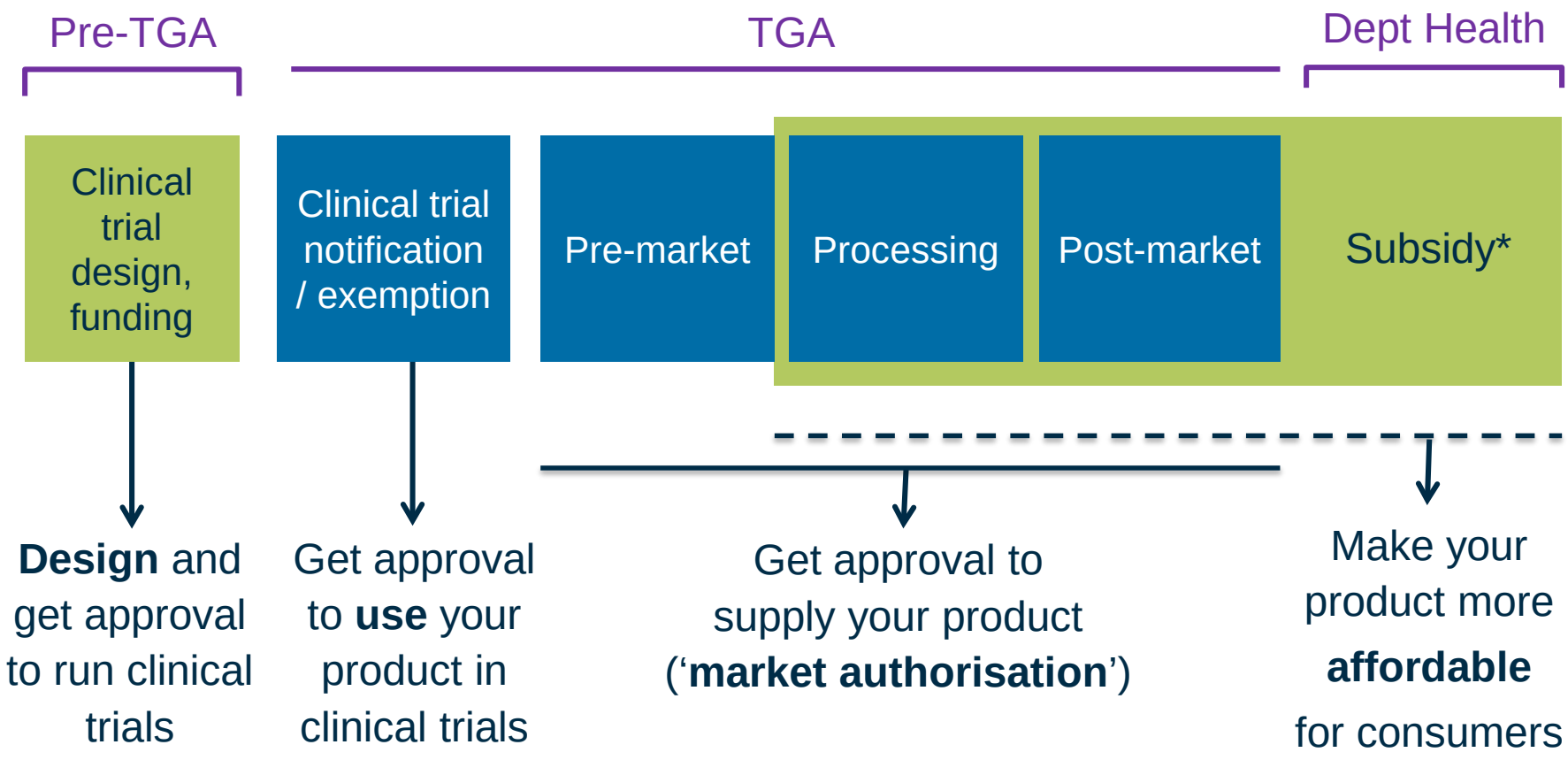
Provide clinical advice to individuals

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

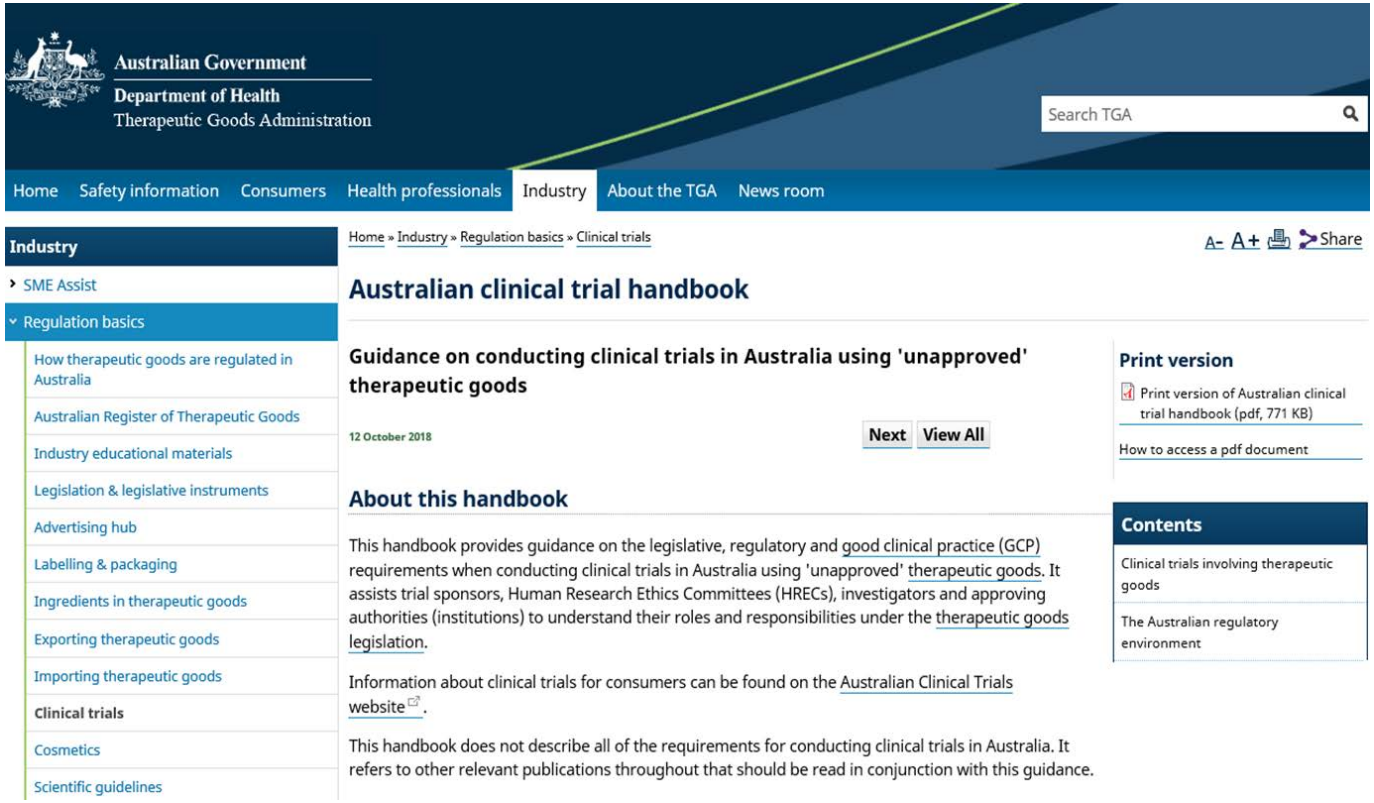
Approving authority

- 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

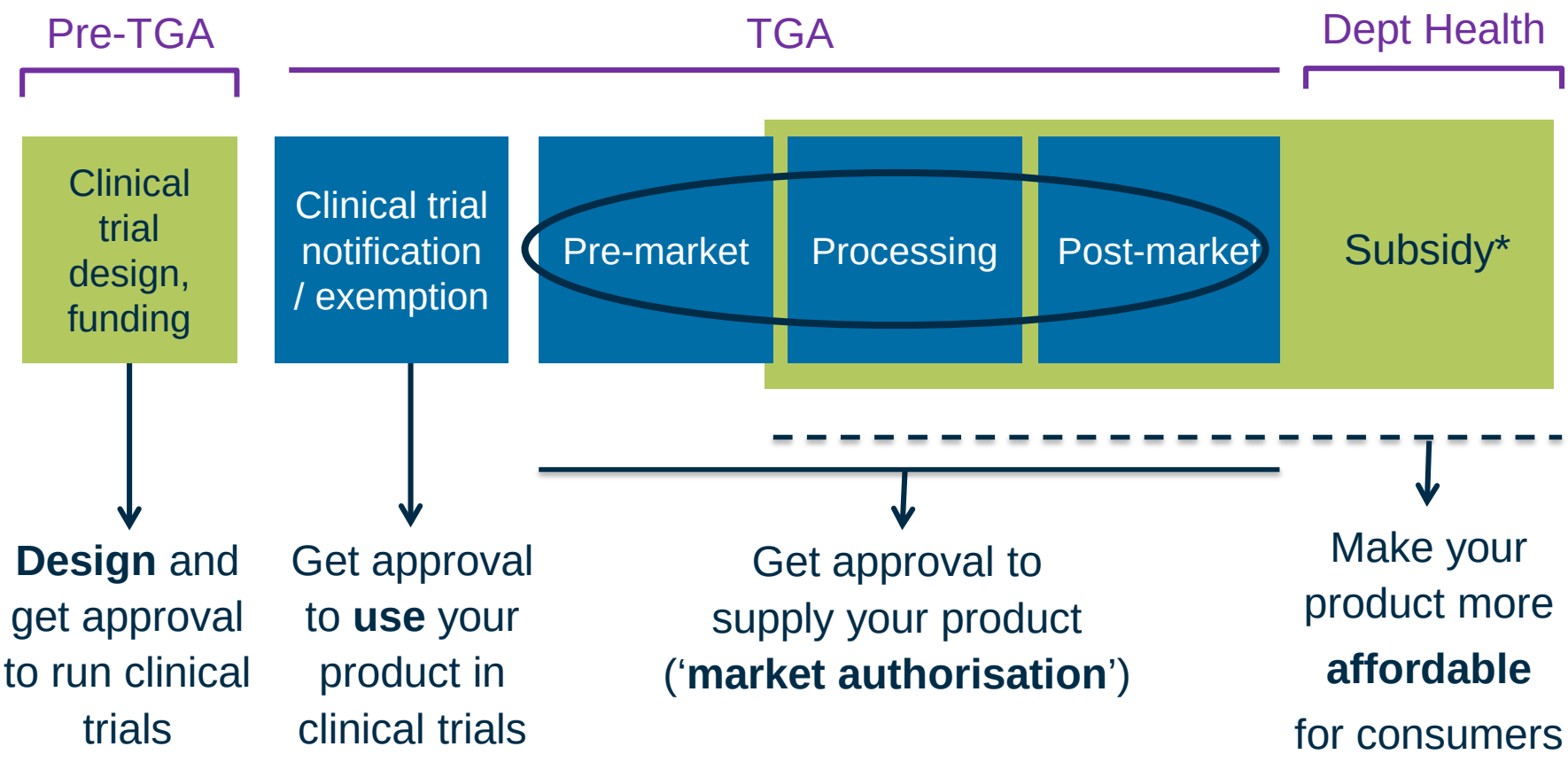
Principal investigator

- 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



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)

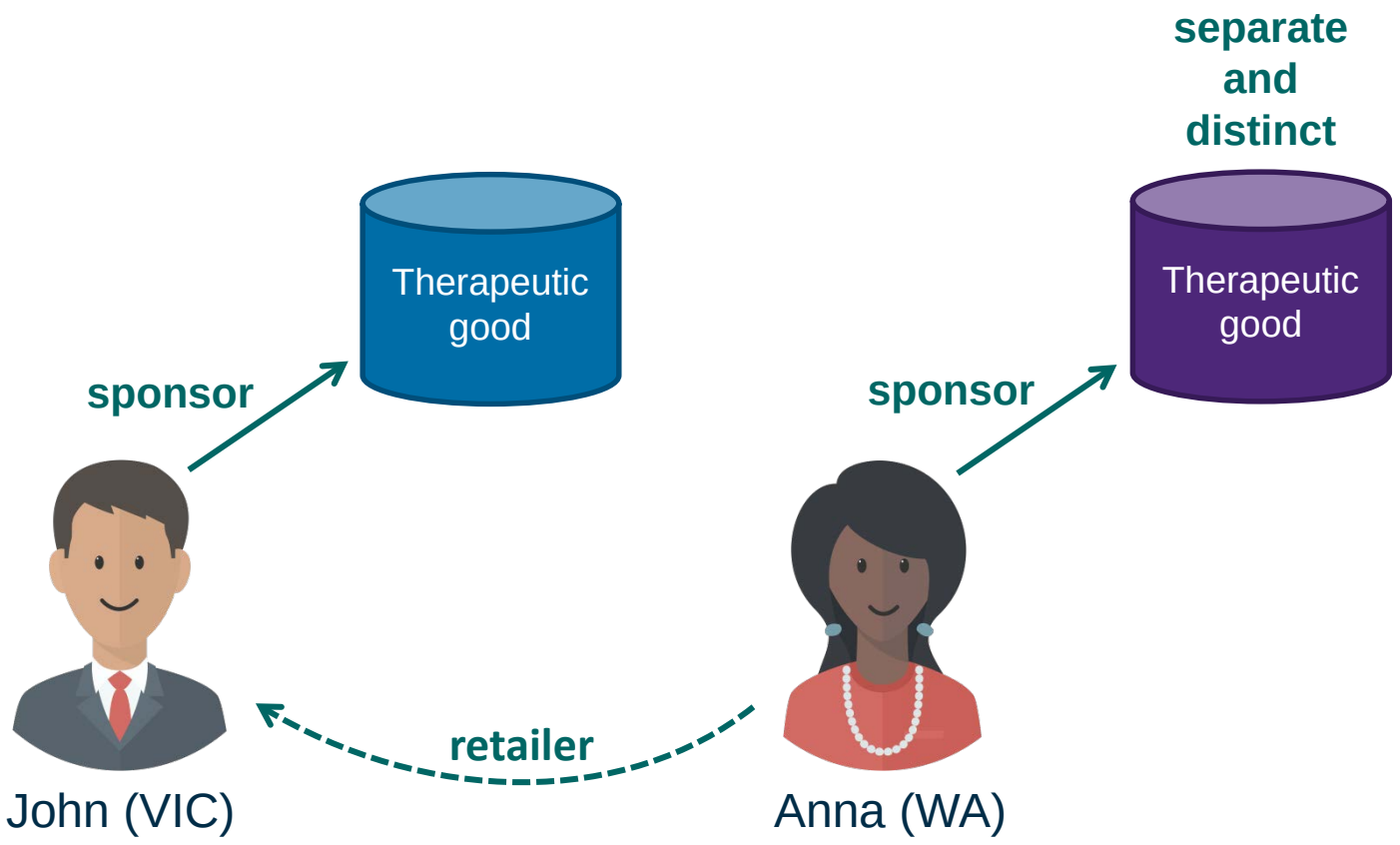
- When market authorisation is granted, the product is added to an **electronic register** of therapeutic goods that can be lawfully supplied in Australia – the ARTG
- It provides information such as the product name, active ingredients, classification and manufacturer
- The ARTG entry is under the **sponsor's 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	ⓘ Therapeutic Goods Act 1989	16
Biologicals	ⓘ Therapeutic Goods Regulations 1990	11A
Medical devices	ⓘ Therapeutic Goods Act 1989	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
• **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

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

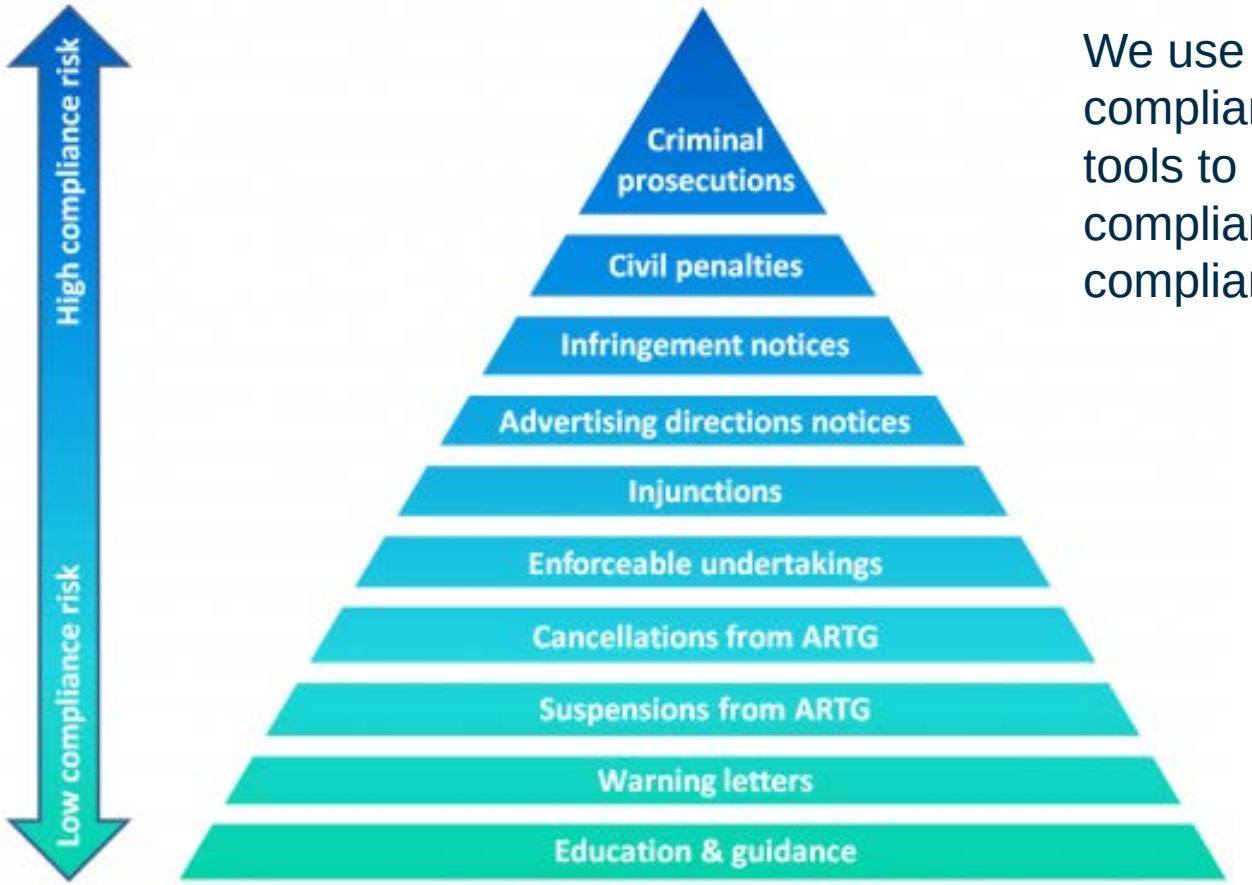
Medical devices (not including *in vitro* diagnostics)

Class	Risk	Examples
Class I	Low	Tongue depressors, slings
Class I – supplied sterile Class I – incorporating a measuring function Class IIa	Low-medium	Some bandages, wound dressings, catheters Medicine cups with defined units Intravenous tubing, syringes for infusion pumps
Class IIb	Medium	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

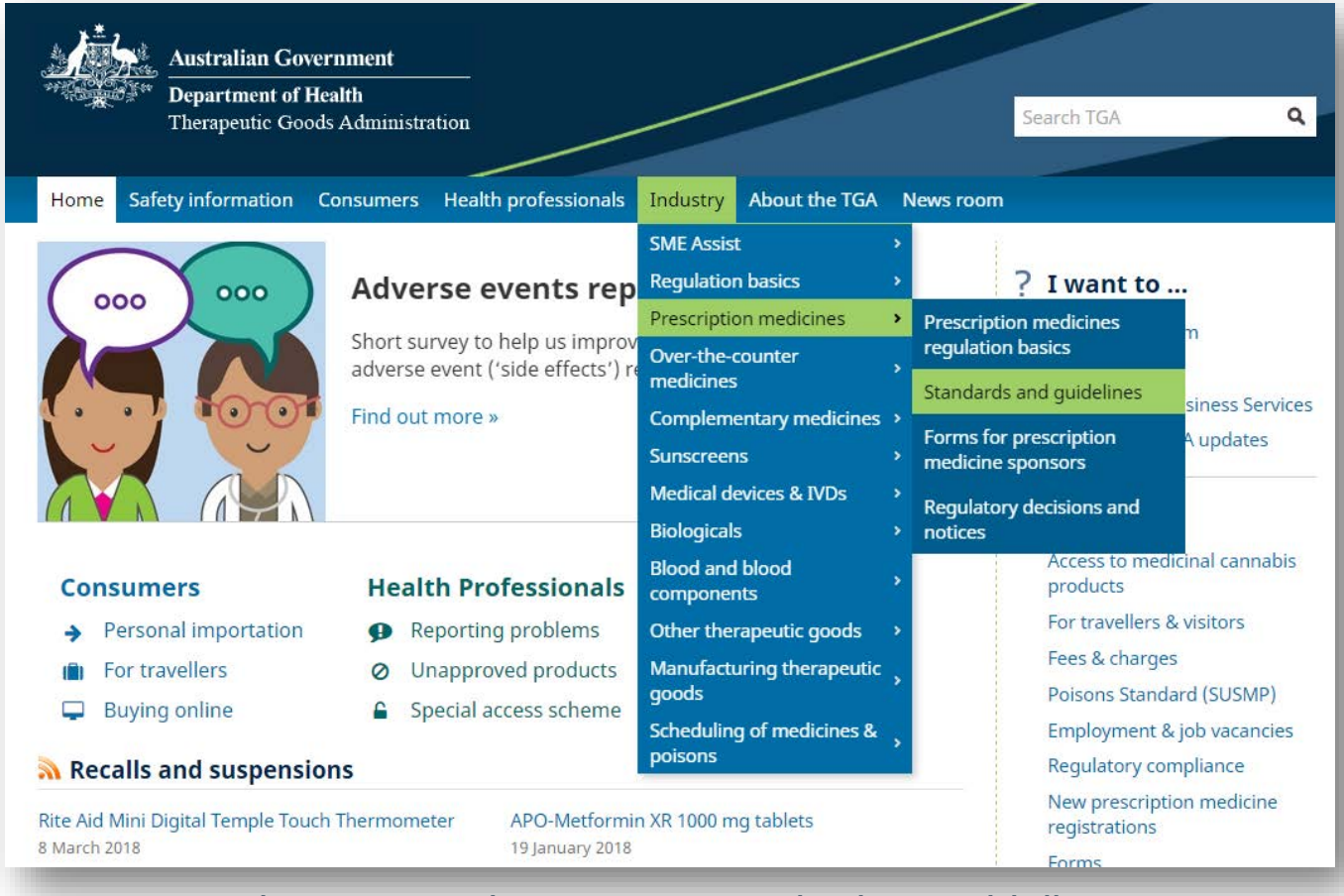
Helpful links for applications

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

- ⓘ **ARGCM** for **complementary medicines**
- ⓘ **ARGOM** for **over-the-counter medicines**
- ⓘ **ARGPM** for **prescription medicines**
- ⓘ **ARGS** for **sunscreens**
- ⓘ **ARGMD** for **medical devices**
- ⓘ **ARGB** for **biologicals**
- ⓘ **ARGATG** for **advertising therapeutic goods**

Australian Regulatory Guidelines



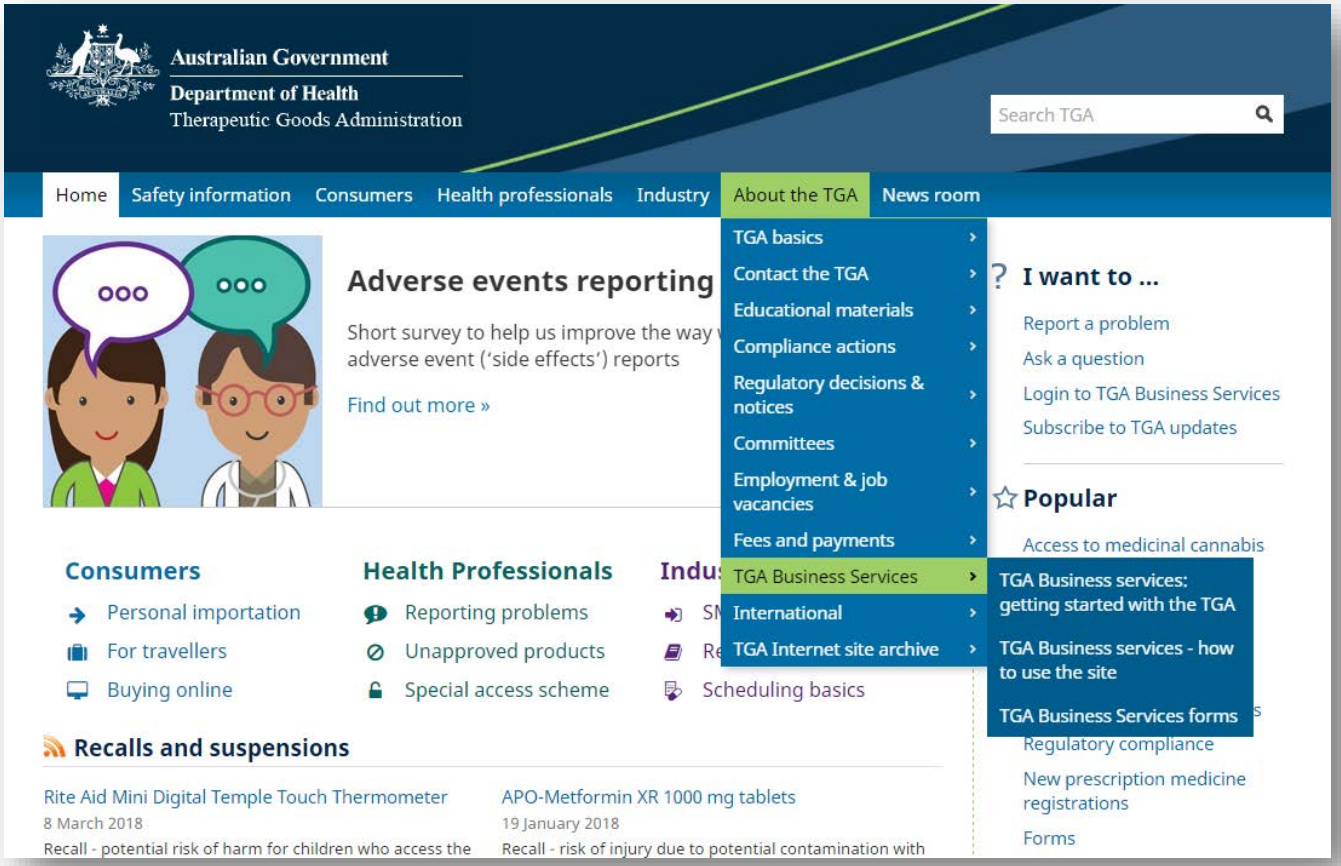
Industry > Product type > Standards & guidelines

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



About the TGA > TGA Business Services

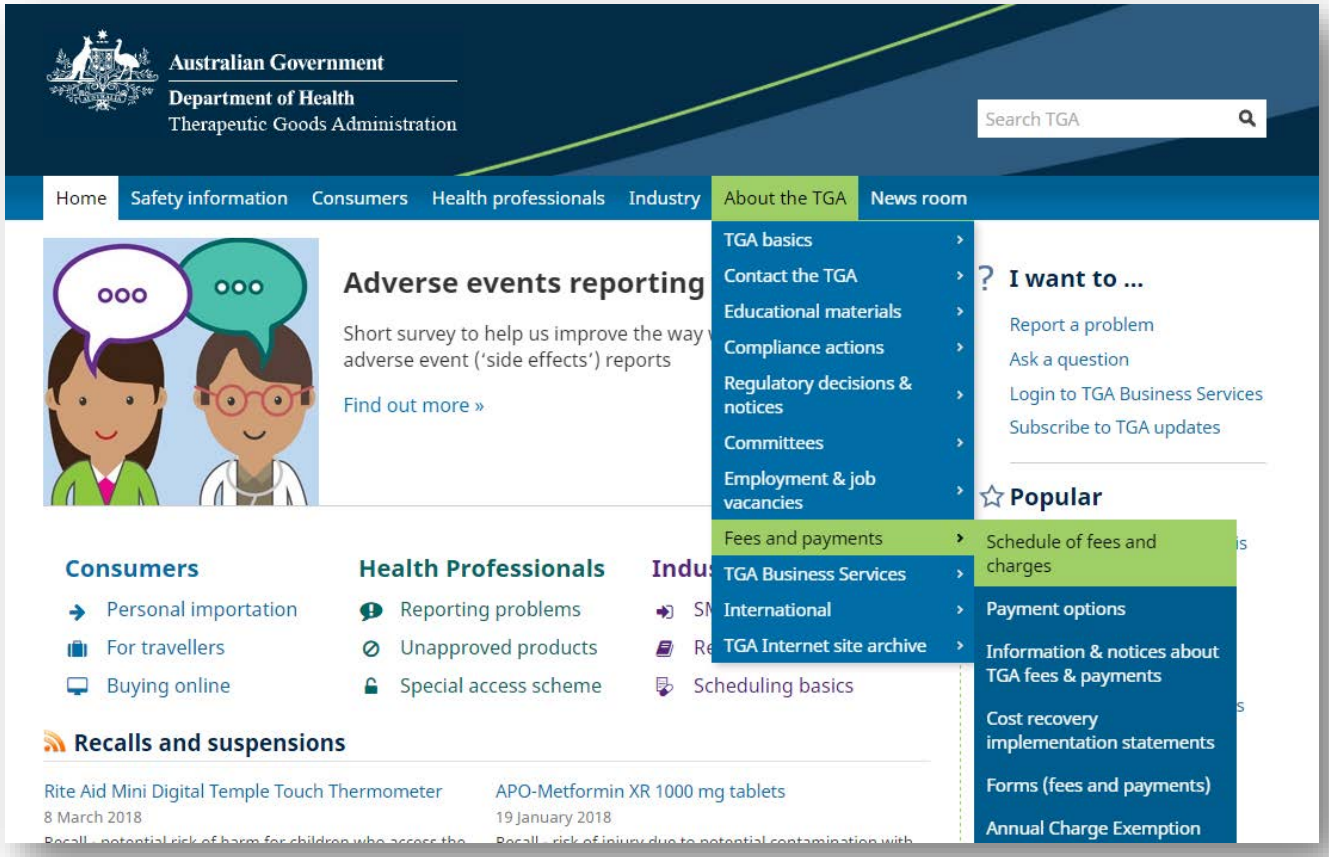
TGA Business Services

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



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

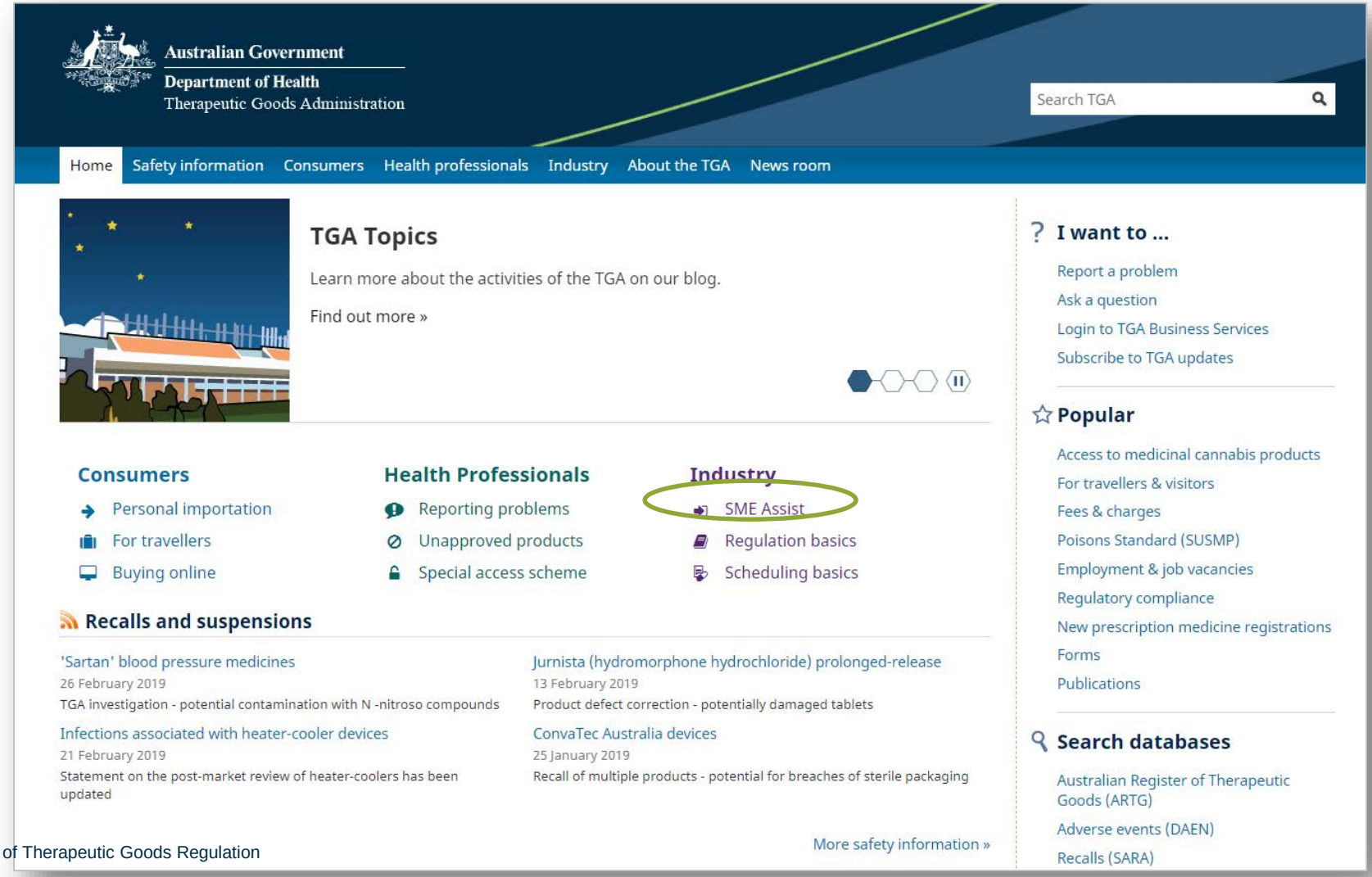
- Tax imposed on the regulatory industry
- Applied annually

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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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
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Recall of multiple products - potential for breaches of sterile packaging
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SME Assist

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

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