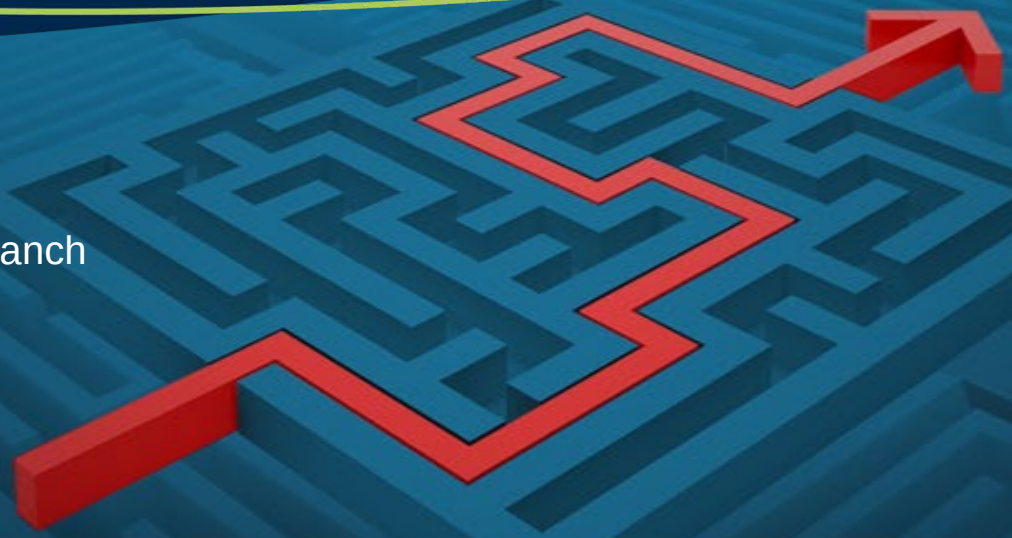
Australian Government
Department of Health
Therapeutic Goods Administration

SME Assist

Help to navigate the regulatory maze



Avi Rebera
Assistant secretary
Regulatory Engagement and Planning Branch

ARCS conference, Sydney
8 August 2019

TGA Health Safety Regulation

Disclaimer

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

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 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 this paper.

Today's objectives

To provide:

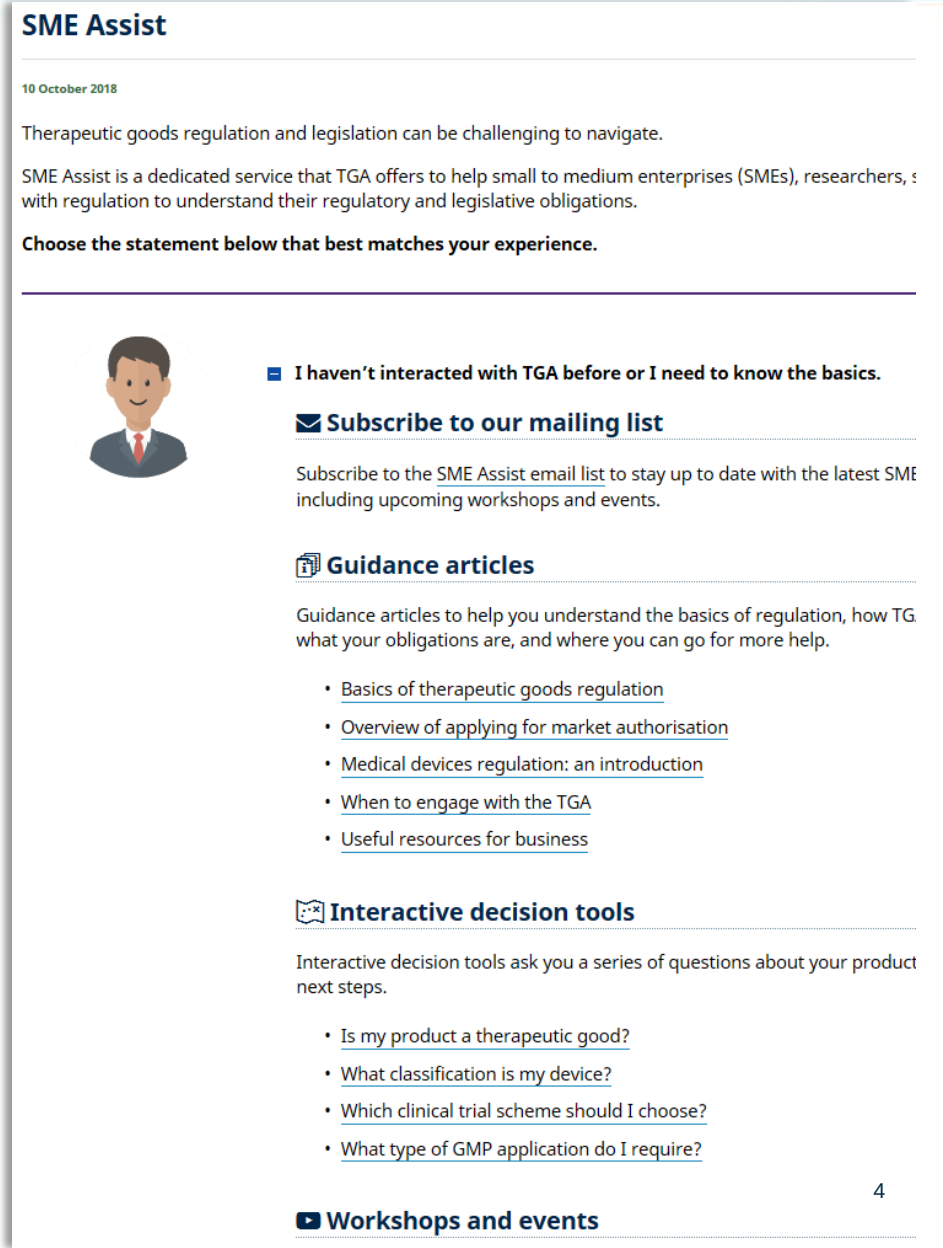
- information on TGA's SME Assist and what the service offers
- details on upcoming SME Assist events
- information on where to find more help

Background

- The 2016 review of Medicines and Medical Devices Regulation (MMDR) highlighted that small to medium enterprises (SMEs) can find navigating the ‘regulatory maze’ a **challenge**
- We need to:
  - make the regulation process **easier to understand**
  - provide better **support services** for SMEs
- Consultations were held in 2016 with:
  - Industry organisations
  - Government departments

SME Assist

- Launched 9 June 2017 by the Hon Greg Hunt MP, Minister for Health
- **Targets** the needs of:
  - SMEs
  - start-ups
  - researchers
  - those unfamiliar with therapeutic goods regulation
- **Informs** therapeutic R&D groups
- **Assists** users to understand their regulatory and legislative obligations



SME Assist

10 October 2018

Therapeutic goods regulation and legislation can be challenging to navigate.

SME Assist is a dedicated service that TGA offers to help small to medium enterprises (SMEs), researchers, s with regulation to understand their regulatory and legislative obligations.

Choose the statement below that best matches your experience.

I haven't interacted with TGA before or I need to know the basics.

Subscribe to our mailing list

Subscribe to the SME Assist email list to stay up to date with the latest SME including upcoming workshops and events.

Guidance articles

Guidance articles to help you understand the basics of regulation, how TG what your obligations are, and where you can go for more help.

- Basics of therapeutic goods regulation
- Overview of applying for market authorisation
- Medical devices regulation: an introduction
- When to engage with the TGA
- Useful resources for business

Interactive decision tools

Interactive decision tools ask you a series of questions about your product next steps.

- Is my product a therapeutic good?
- What classification is my device?
- Which clinical trial scheme should I choose?
- What type of GMP application do I require?

Workshops and events

Since launch, there has been:

116,000 visitors to the SME Assist web page

424 subscribers to SME Assist emails

32,500 uses of interactive decision tools

241 email enquiries answered

11 'Meeting Your Obligations' workshops held across Australia

643 attendees at workshops

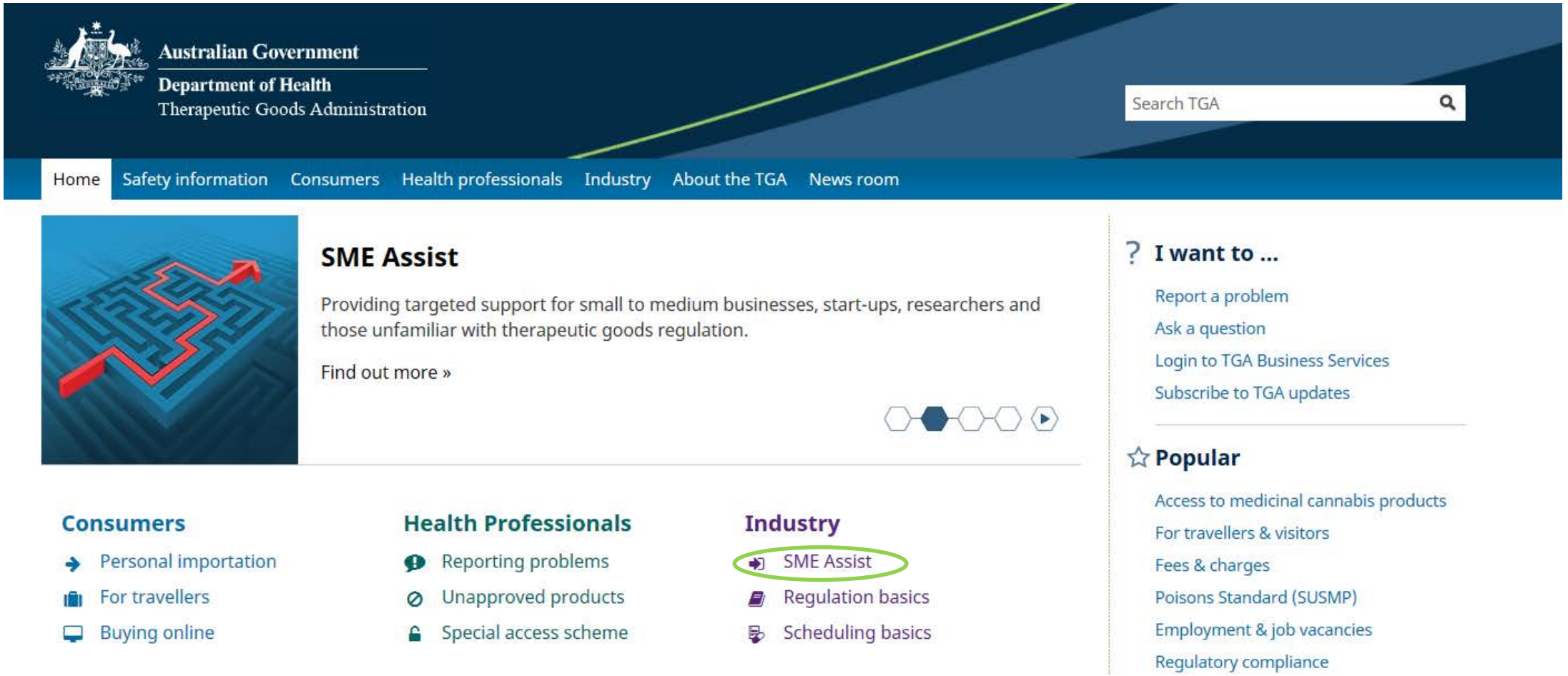
2 educational webinars

We have also worked in partnership with:

- universities (Flinders, Macquarie, QUT), industry organisations (AusBiotech), research organisations (CSIRO, TRI) and the QLD Government

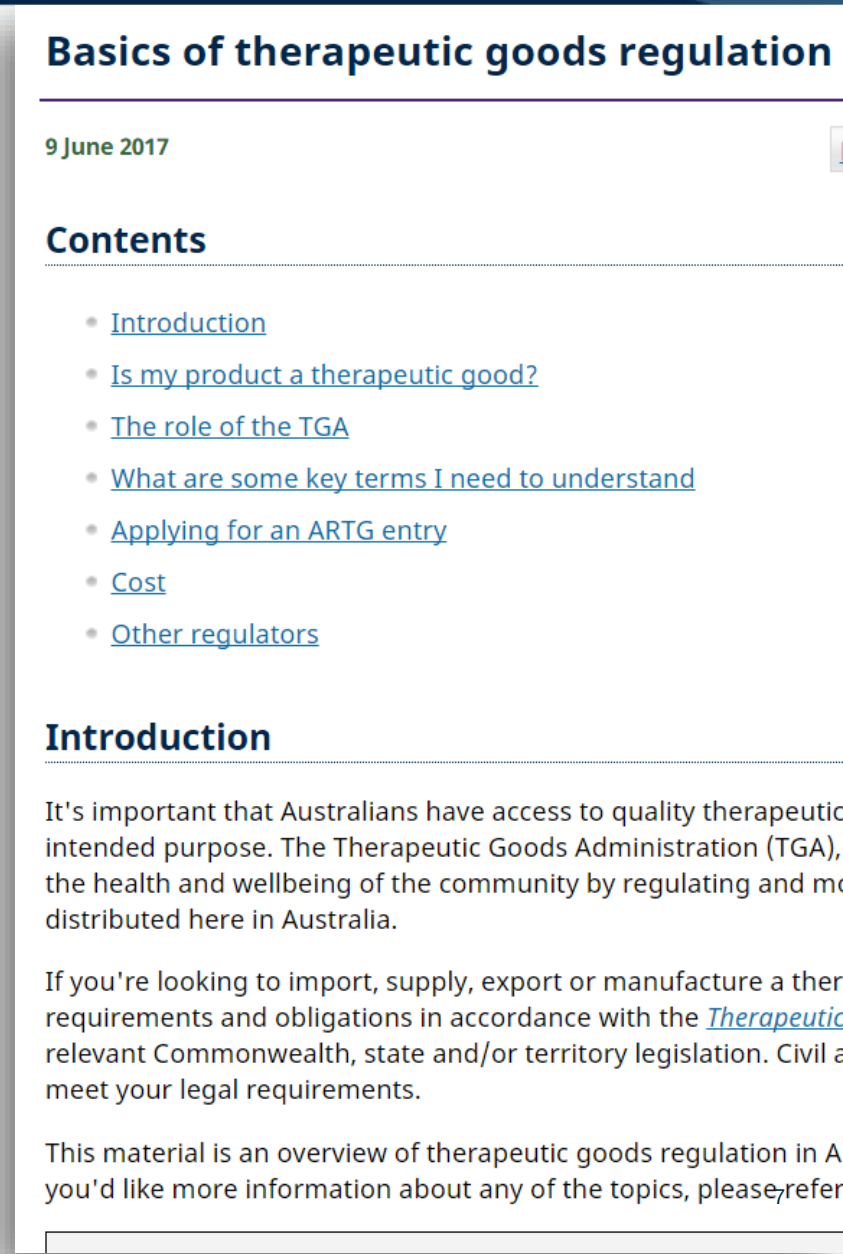
Australian Government
Department of Health
Therapeutic Goods Administration

SME Assist



Guidance articles

- **Various introductory topics:**
  - basics of regulation
  - market authorisation
  - when to engage with TGA
  - medical devices overview
  - useful resources (signposting to other services)
- **Case studies** (e.g. herbalist, importer and researcher)
- Information is written in plain English and targeted at beginners



Basics of therapeutic goods regulation

9 June 2017

Contents

Introduction

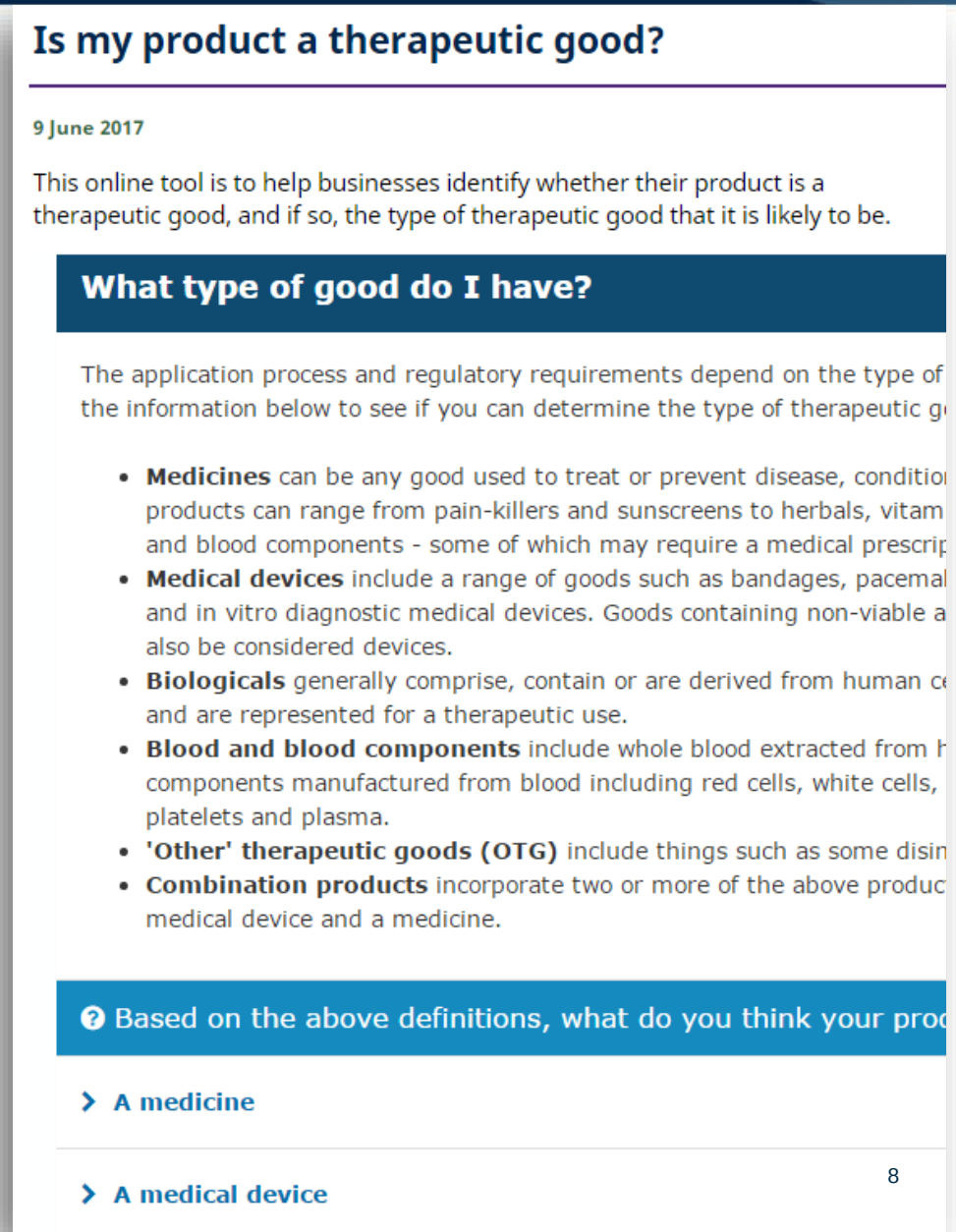
It's important that Australians have access to quality therapeutic
intended purpose. The Therapeutic Goods Administration (TGA),
the health and wellbeing of the community by regulating and mo
distributed here in Australia.

If you're looking to import, supply, export or manufacture a ther
requirements and obligations in accordance with the *Therapeutic*
relevant Commonwealth, state and/or territory legislation. Civil a
meet your legal requirements.

This material is an overview of therapeutic goods regulation in A
you'd like more information about any of the topics, please refer

Interactive decision tools

- **Designed to help SMEs and researchers:**
  - better navigate regulatory processes
  - understand the regulation of specific products
- **Current interactive tools include:**
  - Is my product a therapeutic good?
  - What classification is my device?
  - Which clinical trial scheme should I choose?
  - What type of GMP application do I require? (manufacturing medicines)
  - What do I require to have a listed medicine in the ARTG?



Is my product a therapeutic good?

9 June 2017

This online tool is to help businesses identify whether their product is a therapeutic good, and if so, the type of therapeutic good that it is likely to be.

What type of good do I have?

The application process and regulatory requirements depend on the type of
the information below to see if you can determine the type of therapeutic g

- **Medicines** can be any good used to treat or prevent disease, conditio
products can range from pain-killers and sunscreens to herbals, vitam
and blood components - some of which may require a medical prescrip
- **Medical devices** include a range of goods such as bandages, pacemal
and in vitro diagnostic medical devices. Goods containing non-viable a
also be considered devices.
- **Biologicals** generally comprise, contain or are derived from human c
and are represented for a therapeutic use.
- **Blood and blood components** include whole blood extracted from h
components manufactured from blood including red cells, white cells,
platelets and plasma.
- **'Other' therapeutic goods (OTG)** include things such as some disin
- **Combination products** incorporate two or more of the above produc
medical device and a medicine.

Based on the above definitions, what do you think your proc

› A medicine

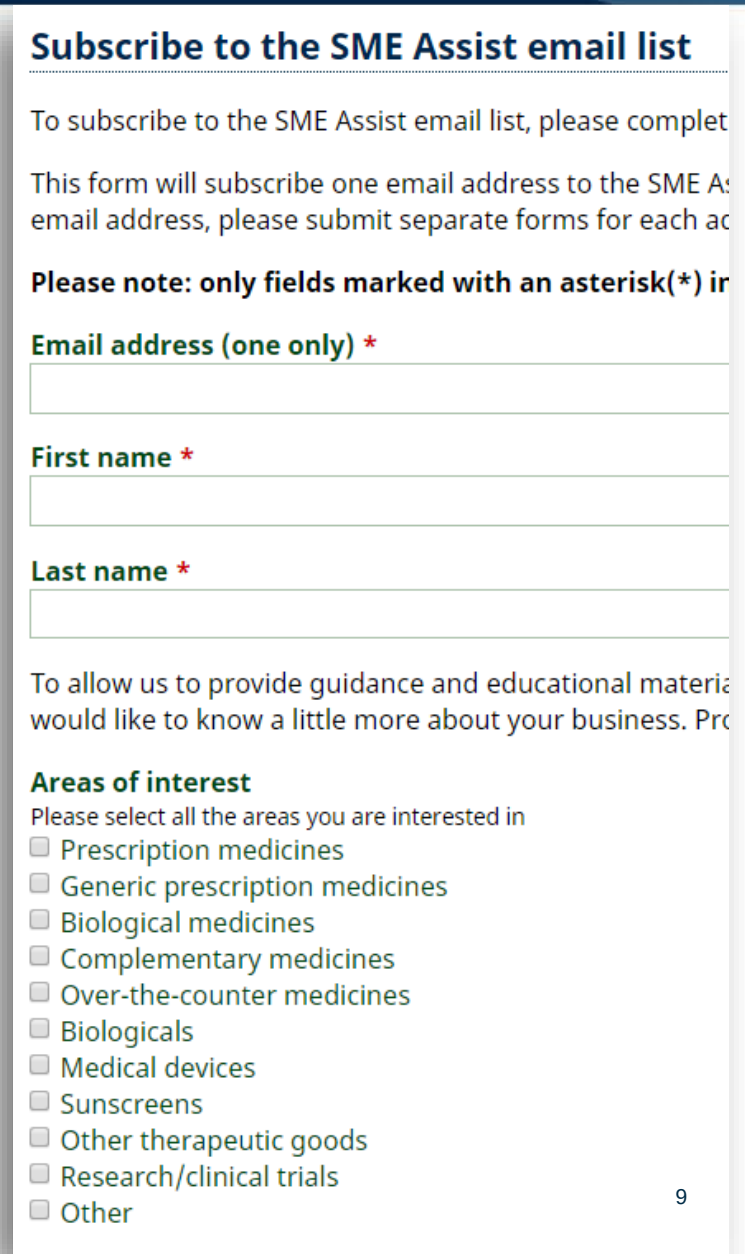
› A medical device

Phone and email support

- Provides tailored and efficient assistance to SMEs and researchers
- Enquiries answered directly or forwarded to relevant area

Subscription service

- Keeps subscribers informed about what's coming up and what's new to SME Assist, including:
  - upcoming workshops, webinars and events
  - new online resources and tools
  - news and information relevant to SMEs



Subscribe to the SME Assist email list

To subscribe to the SME Assist email list, please complet

This form will subscribe one email address to the SME As
email address, please submit separate forms for each ac

Please note: only fields marked with an asterisk(*) ir

Email address (one only) *

First name *

Last name *

To allow us to provide guidance and educational materia
would like to know a little more about your business. Pro

Areas of interest

Please select all the areas you are interested in

- ☐ Prescription medicines
- ☐ Generic prescription medicines
- ☐ Biological medicines
- ☐ Complementary medicines
- ☐ Over-the-counter medicines
- ☐ Biologicals
- ☐ Medical devices
- ☐ Sunscreens
- ☐ Other therapeutic goods
- ☐ Research/clinical trials
- ☐ Other

Upcoming events

- **Continued rollout** of 'Meeting Your Obligations' workshops:
  - Perth (October 2019)
  - Melbourne and Adelaide (November 2019)
  - Sydney, Brisbane and Melbourne (2020 - dates to be confirmed)
- Addition of **new guidance articles** and decision tools:
  - Overview of ingredients
  - Researcher considerations
- Development of further **webinars** on specific topics
- Increased **social media** presence

Subscribe to SME Assist (www.tga.gov.au/sme-assist-email-list) to be notified about dates for upcoming workshops and information about other TGA events

Other stakeholder events

SME Assist will be providing information sessions at:

- Bio Connections Australia Conference, Melbourne August 2019
- ATSA Independent Living Expo, Canberra August 2019
- Bridge Program Symposium, Melbourne October 2019
- GMP Forum, Melbourne November 2019

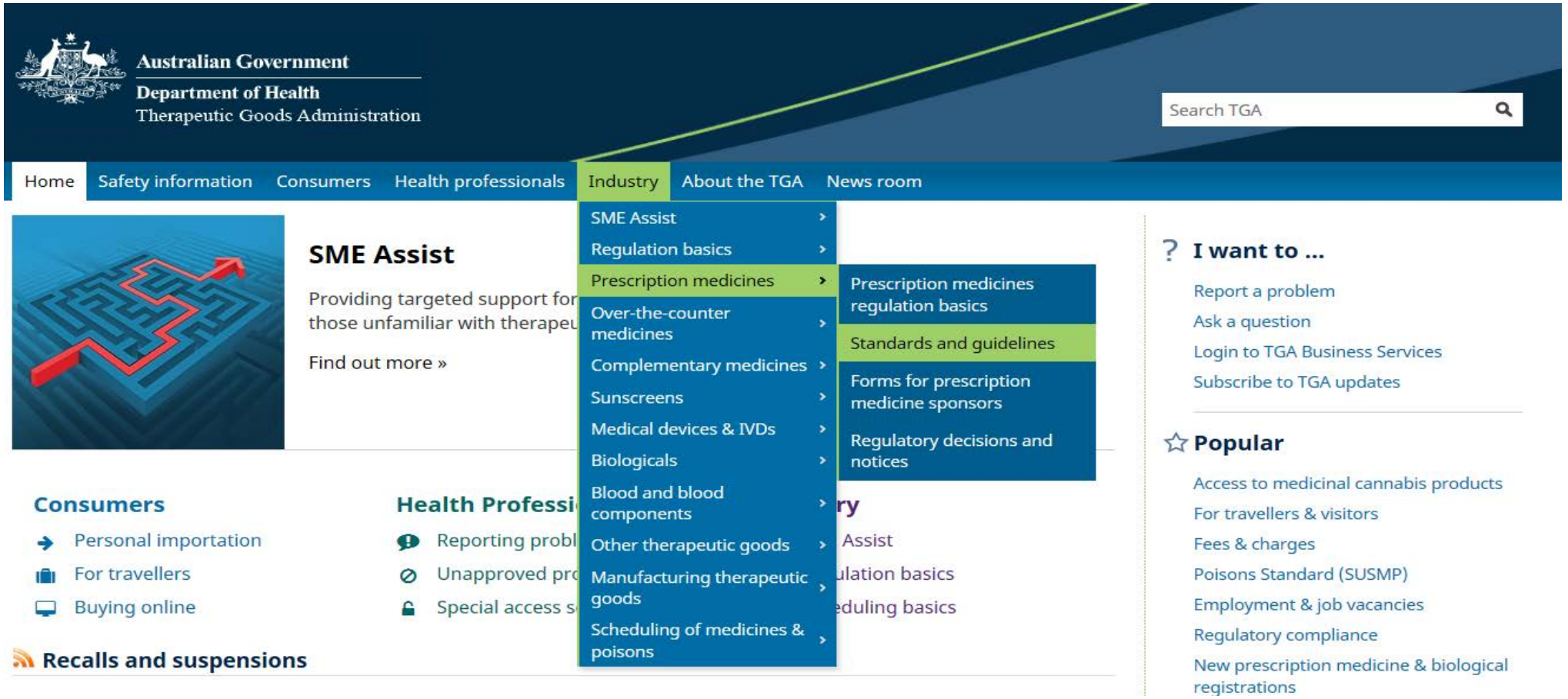
Some key links

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

Australian Regulatory Guidelines



Industry > Product type > Standards & guidelines

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 Government
Department of Health
Therapeutic Goods Administration

SME Assist

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

Australian Government

Department of Health

Therapeutic Goods Administration