SME Assist
Help to navigate the regulatory maze

Avi Rebera
Assistant secretary
Regulatory Engagement and Planning Branch

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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
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
SME Assist

Providing targeted support for small to medium businesses, start-ups, researchers and those unfamiliar with therapeutic goods regulation.

Find out more »
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
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 product as determined by this tool.

- **Medicines** can be any good used to treat or prevent disease, condition, or injury. Products can range from pain-killers and sunscreens to herbas, vitamins, and blood components - some of which may require a medical prescription.
- **Medical devices** include a range of goods such as bandages, pacemakers, and in vitro diagnostic medical devices. Goods containing non-viable materials that are not normally metabolized in the body may also be considered devices.
- **Biologics** generally comprise, contain, or are derived from human cells and are represented for a therapeutic use.
- **Blood and blood components** include whole blood extracted from blood donors or components manufactured from blood including red cells, white cells, platelets, and plasma.
- **‘Other’ therapeutic goods (OTG)** include things such as some disinfectants, contraceptives, and other items.
- **Combination products** incorporate two or more of the above products, where one product is intended to perform a medical device function and another product is intended to perform a medicine function.

Based on the above definitions, what do you think your product is?

- 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
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](http://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:

<table>
<thead>
<tr>
<th>Product type</th>
<th>Where to look</th>
<th>Section</th>
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<tr>
<td>Medical devices</td>
<td><img src="#" alt="Therapeutic Goods Act 1989" /></td>
<td>41BE</td>
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</tbody>
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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)
- **ARBG** for *biologics*
- **ARGATG** for *advertising therapeutic goods* (updated)
SME Assist

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