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Common questions or information that Australian manufacturers need to know about TGA approved goods (medicines, biological and devices)

Current: 27th April 2020

BACKGROUND:

Australian manufacturers are seeking ways they can assist with COVID-19 equipment and supply needs. For many, this is the first time that they have sought to work in the medical sector, and they would like a greater understanding of the regulations around the supply of therapeutic goods in Australia. This document seeks to provide a summary of some publicly available information that they may like to consider.

The Therapeutic Goods Administration (TGA) is part of the Australian Government Department of Health and is responsible for regulating therapeutic goods including prescription medicines, vaccines, sunscreens, vitamins and minerals, medical devices, blood and blood products (https://www.tga.gov.au/). Almost any product for which therapeutic claims are made they must be entered in the Australian Register of Therapeutic Goods (ARTG) before it can be supplied in Australia (https://www.tga.gov.au/tga-basics).

While there is a lot of information on the TGA website, it is often targeted to those who understand the regulatory framework. Due to this, the TGA is now working to develop some easy to understand non-technical / regulatory fact sheets to assist manufacturers who may not be familiar with therapeutic goods regulations. In the meantime, please find some targeted information below, which is derived directly from the TGA website.

Please note, that the TGA website is being updated continuously, particularly during the current pandemic, so please check the TGA website links provided, for the most current information.

To assist Australian manufacturers here are three 'quick-start' TGA services:

1. **COVID-19 Specific TGA Updates** (top of the TGA Home page - *COVID-19: Information on medicines and medical devices*): https://www.tga.gov.au/

2. **SME Assist** (https://www.tga.gov.au/sme-assist)
   To help small to medium enterprises (SMEs), researchers, start-ups and those unfamiliar with regulation to understand their regulatory and legislative obligations, the TGA has set up a dedicated service called *SME Assist*.

   This service has sub-sections for particular topics and links to other websites to get relevant information. There are foundation and advanced sections.

3. **Therapeutic Good On-line Tool** (https://www.tga.gov.au/sme-assist/my-product-therapeutic-good)
   This very useful part of the TGA website suggests that one of the first things a manufacturer should ask is if the good they wish to supply is considered to be a therapeutic good.

   A decision-making tool is provided on the website to help assess if a good is a therapeutic good or not. If the good does appear to be a therapeutic good and a company wishes to supply it, they will need to meet regulatory

requirements based on what class of medical device they wish to supply, what their good manufacturing process (GMP) is, and many other requirements as required by the TGA.

If it is not considered to be a therapeutic good, it is unlikely that it needs to be regulated by the TGA as it will likely be regulated under other legislation instead. Professional advice should always be sought on this matter.

There are many companies that already have TGA approval for each class of device and so for companies that are not already approved, rather than dedicate limited resources and time into the TGA approval process, it may be more efficient and effective to seek out one of these approved suppliers (called Sponsors) and explore ways that they can be worked with.

Please note that before relying on the information on the TGA website, users should carefully evaluate its accuracy, currency, completeness and relevance for their purposes, and should obtain any appropriate professional advice relevant to their particular circumstances. The Therapeutic Goods Administration cannot guarantee and assumes no legal liability or responsibility for the accuracy, currency, completeness or interpretation of the information.

Inquiries to the TGA can be made at:

Email: sme.assist@tga.gov.au Phone: 1800 020 653

Website: https://www.tga.gov.au/

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

MANUFACTURERS MAY ALSO FIND THE FOLLOWING INFORMATION OF ASSISTANCE:

Following are commonly asked questions or information about the TGA.

1. **Is there a presentation that I can watch that summarises what the TGA requirements and processes are?**

Information from TGA Website	Source and further information: TGA Website Link
This is a recent YouTube presentation by the TGA. It features helpful information including a Q&A section. While it is quite long (two hours), it will save you a lot of time navigating the TGA website.	https://youtu.be/EzC-lIlT9zY.

2. **What is the role of the TGA? What are they aiming to achieve and why do products and supplies need to be approved?**

Information from TGA Website	Source and further information: TGA Website Link
It is important that Australians have access to quality therapeutic goods that are safe to use and fulfil their intended purpose. The Therapeutic Goods Administration (TGA), as part of the Department of Health, protects the health and wellbeing of the community by regulating and monitoring all therapeutic goods that are distributed here in Australia. If you are looking to import, supply, export or manufacture a therapeutic good, you will need to meet certain requirements and obligations in accordance with the Therapeutic Goods Act 1989, in addition to any other relevant Commonwealth, state and/or territory legislation. Civil	https://www.tga.gov.au/sme-assist/basics-therapeutic-goods-regulation

and criminal penalties may apply if you do not meet your legal requirements.	
The TGA does not regulate: • veterinary medicines • food • health insurance • cosmetics • chemicals • healthcare professionals	https://www.tga.gov.au/what-tga-doesnt-do

3. I have heard that any therapeutic goods must be approved by the TGA. How do I know what is considered to be a therapeutic good?

Information from TGA Website	Source and further information: TGA Website Link
Therapeutic goods fall under three different categories: • Medicines (including prescription, over-the-counter and complementary medicines, such as paracetamol and echinacea) • Biologicals (something made from or containing human cells or tissues, such as human stem cells or skin) • Medical devices (including instruments, apparatuses and appliances, such as pacemakers and sterile bandages) Therapeutic goods can comprise a broad range of things, such as bandages, pregnancy testing kits, herbal remedies, tissue grafts and paracetamol. The TGA regulates what are known as Other Therapeutic Goods (OTGs), which include items such as tampons and disinfectants.	https://www.tga.gov.au/book-page/my-product-therapeutic-good
What defines a therapeutic good? In relation to the work of the TGA, therapeutic goods are broadly defined as products for use in humans in connection with: • 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 This includes things that are: • used as an ingredient or component in the manufacture of therapeutic goods • used to replace or modify parts of the anatomy	https://www.tga.gov.au/sme-assist/my-product-therapeutic-good#1
Is my product a therapeutic good? A tool has been prepared to help you identify if your product may be a therapeutic good.	Go to this link to help you decide if your good is a therapeutic good: https://www.tga.gov.au/sme-assist/my-product-therapeutic-good

4. **If I need to engage with the TGA, when should I do that?**

Answer from TGA Website	Source and further information: TGA Website Link
When to engage with the TGA There are many reasons you may need to engage with the TGA. This can include meeting your obligations if you are already a sponsor of a therapeutic good, reporting information to the TGA on the safety, efficacy and quality of a product, and where you might be seeking for a product to be authorised for use in Australia. This page provides some information to help you understand at what point you should engage with us, especially where you are considering: • seeking approval to import, export, manufacture or supply a therapeutic good in Australia • conducting research related to a therapeutic good that is not currently registered for use in Australia **Engage early** There is no rule about how early you should engage with the TGA. If you are conducting research with a product for which therapeutic claims are made, or have a product that is likely to be considered a therapeutic good, familiarising yourself with our website and understanding the steps and pathways for market authorisation is a good idea. By the time you are applying for a therapeutic good to be entered in the Australian Register of Therapeutic Goods (ARTG), you should already be looking at our website. The majority of engagement with TGA is likely to be online. You might access information through our website, make applications through TGA Business Services, pay fees or charges, or report adverse events or report issues that might result in a therapeutic goods recall. You can also contact us directly by email or phone.	https://www.tga.gov.au/sme-assist/when-engage-tga

5. **I can switch my production to make the items below, do I need TGA approval to make any of these and what standards or accreditation do I need for each?**
   - Hand sanitiser
   - Surgical masks
   - Gowns
   - Face shields
   - Ventilators

Answer from TGA Website	Source and further information: TGA Website Link
All information and updates relating to COVID-19 and therapeutic goods in Australia	https://www.tga.gov.au/

Are you a manufacturer (or considering becoming one)? You may be (or intend to be) a manufacturer of a medicine, biological or other therapeutic good, or you may manufacture medical devices (including in vitro diagnostic (IVD) medical devices). You can find out more about being a manufacturer on our website. If you manufacture, or intend to manufacture, a medicine, biological or other therapeutic good **within Australia** you must have a current licence to manufacture therapeutic goods. If you manufacture medicines, biologicals or other therapeutic goods **overseas**, a sponsor must have appropriate good manufacturing practice (GMP) certification or clearance. If you manufacture medical devices (including IVDs), the level of conformity assessment required matches the level and nature of the risks associated with the use of the device. Self-assessment by the manufacturer is acceptable for low risk devices, whereas for the highest risk devices an assessment of the manufacturer's quality management system and examination of the design of the specific device by a conformity assessment body is required.	https://www.tga.gov.au/sme-assist/when-engage-tga
Good manufacturing practice (GMP) application decision tree	https://www.tga.gov.au/good-manufacturing-practice-application-decision-tree
Hand sanitisers and COVID-19 As a result of the high demand for hand sanitisers, there are now three classes of hand sanitisers – general consumer products ('cosmetics'), therapeutic goods and products with one of two specific formulations (excluded from TGA regulation for the duration of the COVID-19 pandemic). **COVID-19 update: Advertising claims and hand sanitisers** This update is about the kind of advertising claims that can be made in relation to hand sanitisers and COVID-19.	https://www.tga.gov.au/hand-sanitisers-and-covid-19 https://www.tga.gov.au/covid-19-update-advertising-claims-and-hand-sanitisers
COVID-19 advice on surgical masks and gowns: Face masks and gowns which are non-sterile and designed as safety or protective apparel for use in the home or for recreational or occupational use (for example, nursing) are excluded from regulation by the TGA under the Act. Please see *Therapeutic Goods (Declared Goods) Order 2019* as this declares particular goods or classes of goods to be therapeutic goods, or not to be therapeutic goods, for the purposes of the Act.	https://www.tga.gov.au/media-release/covid-19-advice-surgical-masks-and-gowns
Face shields	No current information available on TGA website, although they do appear in the ARTG.
Ventilators In response to the anticipated demand for invasive ventilator medical devices to treat patients requiring respiratory support as a result of infection with COVID-19, a Commonwealth Government taskforce has been working to identify domestic manufacturing capability of these devices. Australia's Chief Scientist, Dr Alan Finkel, has led these efforts and, with support from an expert panel of ICU clinicians from across Australia, has compiled *Ventilator for COVID-19 use in Australia*.	https://www.tga.gov.au/ventilator-covid-19-use-australia

This document, published on the TGA's website on 7 April 2020, details minimum technical requirements for invasive ventilators that would be suitable for supply to and use in Australian hospitals when approved devices are not available during the COVID-19 emergency. The specification was prepared in consultation with the TGA and will serve as a guide to domestic manufacturers seeking to support Australia's efforts in managing the COVID-19 emergency. **Exemption for coronavirus (COVID-19) medical devices**	https://www.tga.gov.au/exemption-coronavirus-covid-19-medical-devices

6. **The materials and equipment that I can import from overseas have FDA approval. Do I still need to get TGA approval for these?**

Answer from TGA Website	Source and further information: TGA Website Link
International agreements and arrangements for GMP clearance The TGA has entered into various international agreements and arrangements with other countries and regulatory authorities to support international regulatory collaboration. Some of these agreements and arrangements allow us to use inspections conducted by these regulatory authorities as part of the GMP clearance process in lieu of performing our own on-site inspection. **United States Food and Drug Administration (US FDA)** We have a cooperation agreement with the US FDA. We accept evidence from the US FDA for GMP clearance applications using the CV pathway, irrespective of the country the inspection is performed in, as long as the inspection was performed using a comparable GMP standard.	https://www.tga.gov.au/international-agreements-and-arrangements-gmp-clearance

7. **What is the TGA approval process and what needs to be approved eg design, manufacturing process and product?**

Answer from TGA Website	Source and further information: TGA Website Link
Overview of applying for market authorisation Market authorisation is the approval given to supply a therapeutic good in Australia, and, in most cases, involves entry on the Australian Register of Therapeutic Goods (ARTG). This information provides an overview of the various steps involved when applying for market authorisation. It is intended for those who are new to therapeutic goods regulation. It is also intended to guide researchers who are developing new innovative products. Please make sure you have read: • Basics of therapeutic goods regulation • Is my product a therapeutic good? **The process varies depending on your therapeutic good**	https://www.tga.gov.au/sme-assist/overview-applying-market-authorisation

If you are a person or organisation applying for market authorisation, you are known as the **applicant**. If market authorisation is granted, you become known as the **sponsor**. As the sponsor, you are also the one who: • obtains the ARTG entry • bears all associated responsibilities • is financially liable for the good	
Overview of medical devices and IVD regulation This information is provided to assist you if you are new to engaging with the TGA and Australia's regulatory framework for medical devices, including in vitro diagnostics (IVD) medical devices. It will introduce you to some of the concepts and terminology used in medical device regulation. This information should be used as a guide only. If you would like further information, please refer to the Australian Regulatory Guidelines for Medical Devices (ARGMD) or contact the TGA. For specific advice on the application of therapeutic goods legislation in particular cases, you may need to seek your own independent advice. **Introduction** Our risk-based approach to regulating therapeutic goods is designed to ensure that the level of regulation matches the risks posed by particular therapeutic goods. Medical devices including IVD medical devices are assessed against the Essential Principles and in line with their intended purpose and risk-based classification. The regulatory framework for medical devices spans the life of the device and includes: • **pre-market assessment:** conformity assessment • **market authorisation:** inclusion in the ARTG • **post-market monitoring:** continuing compliance with all regulatory, safety and performance requirements and standards. **Supplying medical devices** Medical devices must be entered on the ARTG before they can be lawfully: • supplied in Australia • imported into Australia • exported from Australia. A person or company who is legally responsible for supplying a device in Australia is called a sponsor. **What is a medical device?** Medical devices are defined by section 41BD of the *Therapeutic Goods Act 1989* (the Act), and further informed by the *Therapeutic Goods (Articles that are Medial Devices) Specification 2014*. You should refer to this definition for any regulatory purpose, including preparing your application. In summary, medical devices: • are used for humans • are intended to diagnose, prevent, monitor, treat or alleviate a disease or injury, or modify or monitor anatomy or physiological functions of the body • generally achieve their purpose by a physical, mechanical or chemical action.	https://www.tga.gov.au/sme-assist/medical-devices-regulation-introduction

8. What does Class 1 and Class 2 mean?

<table>
<tr><th>Answer from TGA Website</th><th>Source and further information: TGA Website Link</th></tr>
<tr><td>

What classification is my medical device?

Medical devices are classified according to the level of harm they may pose to users or patients. The following tool will assist in determining the classification of a medical device that is not an In Vitro Diagnostic device. There are separate classification rules for IVD devices.

<table>
<tr><th>Medical Device Classification</th><th>Level of Potential Harm</th></tr>
<tr><td>Class I</td><td>Lowest</td></tr>
<tr><td>Class Is, Class Im</td><td>Low</td></tr>
<tr><td>Class IIa</td><td>Low to Moderate</td></tr>
<tr><td>Class IIb</td><td>Moderate to High</td></tr>
<tr><td>Class III, AIMD</td><td>High</td></tr>
</table>

</td><td>https://www.tga.gov.au/sme-assist/what-classification-my-medical-device#109</td></tr>
<tr><td>

Classification of medical devices (not IVD medical devices)

Medical devices, other than IVD medical devices, are classified with regard to their intended purpose. In particular, the classification rules take into account the degree of invasiveness in the human body, the duration and location of use, and whether the device relies on a source of energy other than the body or gravity.

Examples of devices with different classifications are summarised in the following table.

<table>
<tr><th>Class</th><th>Risk</th><th>Examples</th></tr>
<tr><td>Class I</td><td>Low</td><td>Surgical retractors, tongue depressors</td></tr>
<tr><td>Class I - supplied sterile
Class I - incorporating a measuring function
Class IIa</td><td>Low-medium</td><td>Hypodermic needles, suction unit</td></tr>
<tr><td>Class IIb</td><td>Medium-high</td><td>Lung ventilator, blood bags, condoms</td></tr>
</table>

</td><td>https://www.tga.gov.au/sme-assist/medical-devices-regulation-introduction</td></tr>
</table>

Class III	High	Heart valves, major joint replacement implants, devices containing medicines or tissues, cells or substances of animal, biological or microbiological origin	
AIMD (Active Implantable Medical Devices)	High	Implantable defibrillator	

9. What exemptions are in place at the moment and how do you apply for your product/supply to be exempt?

Answer from TGA Website	Source and further information: TGA Website Link
Exemption for coronavirus (COVID-19) medical devices The *Therapeutic Goods Act 1989* (the Act) provides that the Minister for Health (or his delegate) may exempt certain kinds of medical devices that are not included in the Australian Register of Therapeutic Goods from various provisions of the Act so that those devices can be made available urgently to deal with public health emergencies. On 22 March 2020, the Secretary, as delegate of the Minister, made the *Therapeutic Goods (Medical Devices—Face Masks and Other Articles) (COVID-19 Emergency) Exemption 2020*, to support the purchase of certain kinds of medical devices by the Australian Government Department of Health for the National Stockpile. The exemption continues to support the Australian Government's rapid response to the COVID-19 emergency by facilitating access to certain kinds of medical devices intended to assist in reducing the transmission of infection between individuals, particularly patients and health care professionals.	https://www.tga.gov.au/exemption-coronavirus-covid-19-medical-devices

10. I do not understand some of the key terms used by the TGA. Can you please explain some of these?

Answer from TGA Website	Source and further information: TGA Website Link
If you have not previously been involved in regulation of therapeutic goods, here are some key terms that might be useful to know. • Australian Register of Therapeutic Goods (ARTG) • Conformity assessment (for medical devices) • Good manufacturing practice (GMP) (for medicines and biologicals) • Indication / intended use / intended purpose • Manufacture • Post market monitoring • Sponsor • Supply	https://www.tga.gov.au/book-page/what-are-some-key-terms-i-need-understand