



Australian Government

Department of Health

Therapeutic Goods Administration

# SME Assist – ‘Meeting Your Obligations’

## Market Authorisation

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12 November 2019



**TGA** Health Safety  
Regulation



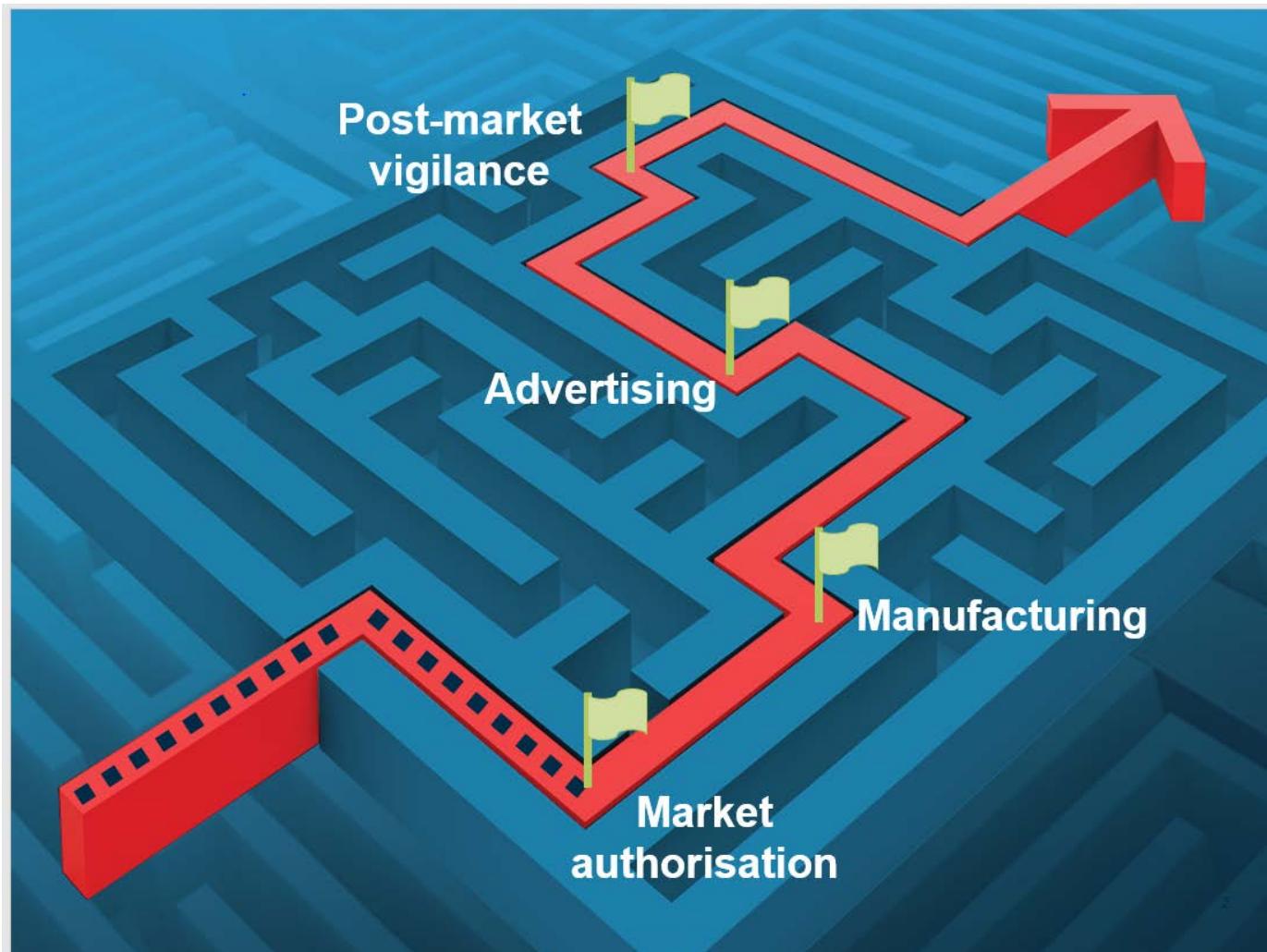
# Disclaimer

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# Market Authorisation



## Medicines and biologicals

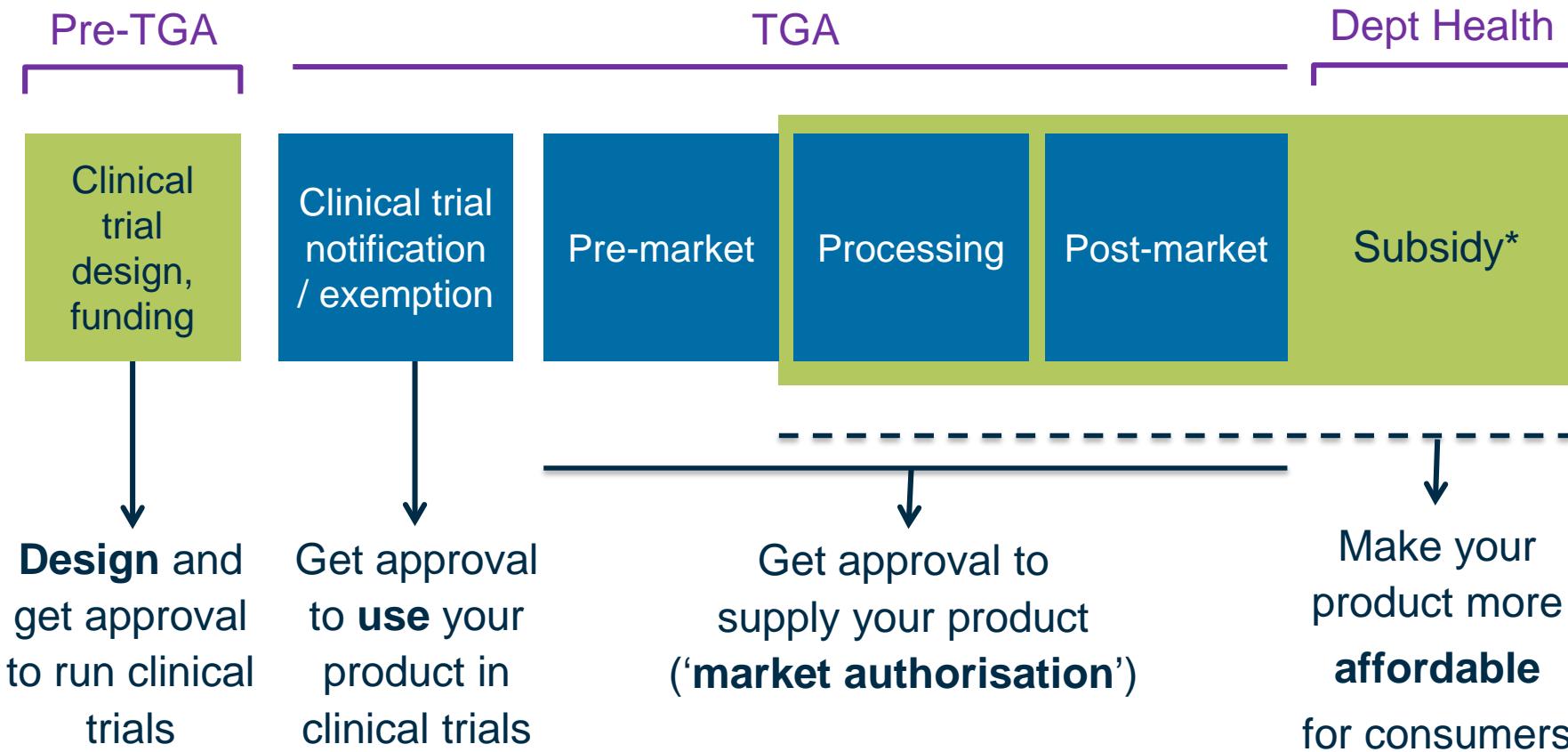


## Medical devices



## All therapeutic goods

# Therapeutic good development lifecycle





# Market authorisation

## Identify your product



Use the [\*\*i\*\* Is my product a therapeutic good?](#) decision tool

Search the [\*\*i\*\* Australian Register of Therapeutic Goods \(ARTG\)](#) for similar products



Ask the manufacturer of the device

Look at labels, instructions and advertising material

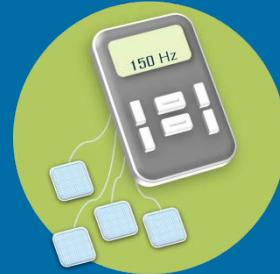
Use the **Is my product a therapeutic good?** and [\*\*i\*\* What classification is my medical device?](#) decision tools

Search the [\*\*i\*\* ARTG](#) for similar products



# Market authorisation

Consult the **Australian Regulatory Guidelines** to find out what's required in your application



ARGCM

Complementary medicines

ARGOM

Over-the-counter medicines

ARGPM

Prescription medicines

ARGB

Biologics

ARGMD

Medical devices



# Market authorisation

## International assessment

### Comparable overseas regulators for **prescription medicines**

These currently include:

- Canada
- European Union
- Japan
- Singapore
- Switzerland
- United Kingdom
- United States of America



### Comparable overseas regulators

These currently include:

- Canada
- European notified bodies
- Japan
- United States of America
- Certificates and reports issued under the Medical Device Single Audit Program





# Market authorisation

## Ingredients and indications



**What does it contain?**

Example:

- Permissible ingredients
- Substances in the Poisons Standard

**What claims are you making?**

Example:

*'Helps promote general health and wellbeing' versus 'cures diabetes'*





# Market authorisation

## Labelling requirements



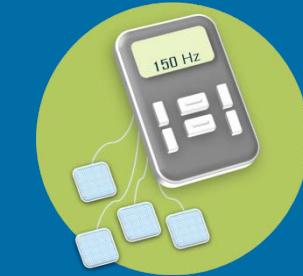
**Prescription medicines:**  
TGO 91 labelling Order



**Non-prescription medicines:**  
TGO 92 labelling Order



**Biologics:**  
TGO 87 labelling Order



Essential Principles 13.1, 13.2, 13.3  
(labelling)



Essential Principle 13.4  
(instructions for use)



Part 10.2 of the  
Therapeutic Goods  
(Medical Devices) Regulations 2002  
(sponsor information)



# Market authorisation

## Online application

- Create an account in TGA Business Services (TBS)
- Log into your TBS account
- Complete relevant fields and agree to the declaration
- Review and submit
- Pay application fees





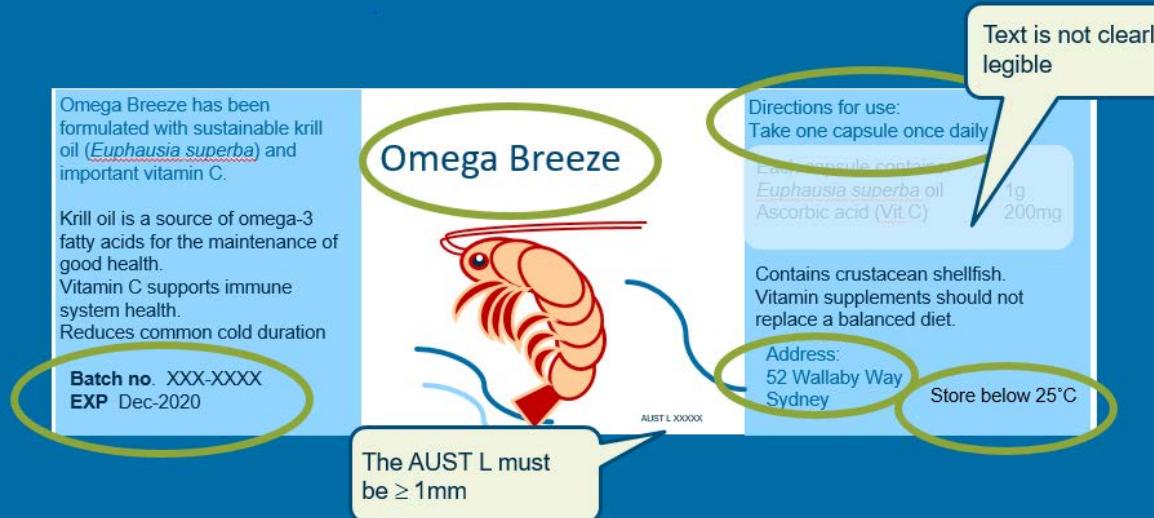
# CASE STUDY: Alex and her listed medicine label





# Market authorisation

## Labelling requirements





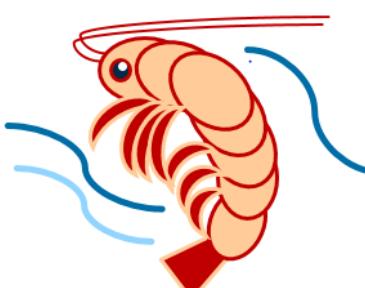
2122	EUPHAUSIA SUPERBA OIL	A	<p>Only for use in oral medicines.</p> <p>The medicine requires the following warning statement on the medicine label:</p> <ul style="list-style-type: none"><li>- (SFOOD) 'Derived from seafood'</li><li>or</li><li>- (SHELL) 'Contains crustacean shellfish'.</li></ul>
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Omega Breeze has been formulated with sustainable krill oil (*Euphausia superba*) and important vitamin C.

Krill oil is a source of omega-3 fatty acids for the maintenance of good health.  
Vitamin C supports immune system health.  
Reduces common cold duration

Batch no. XXX-XXXX  
EXP Dec-2020

**Omega Breeze**



60 capsules

AUST L XXXXX

Directions for use:  
Take one capsule once daily

Each capsule contains:  
*Euphausia superba* oil 1g  
Ascorbic acid (Vit C) 200mg

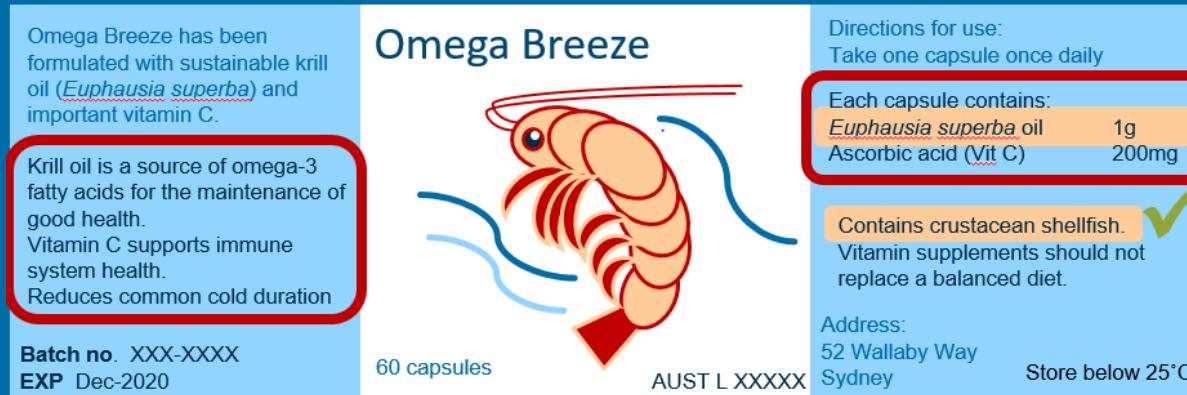
Contains crustacean shellfish. Vitamin supplements should not replace a balanced diet.

Address:  
52 Wallaby Way  
Sydney

Store below 25°C

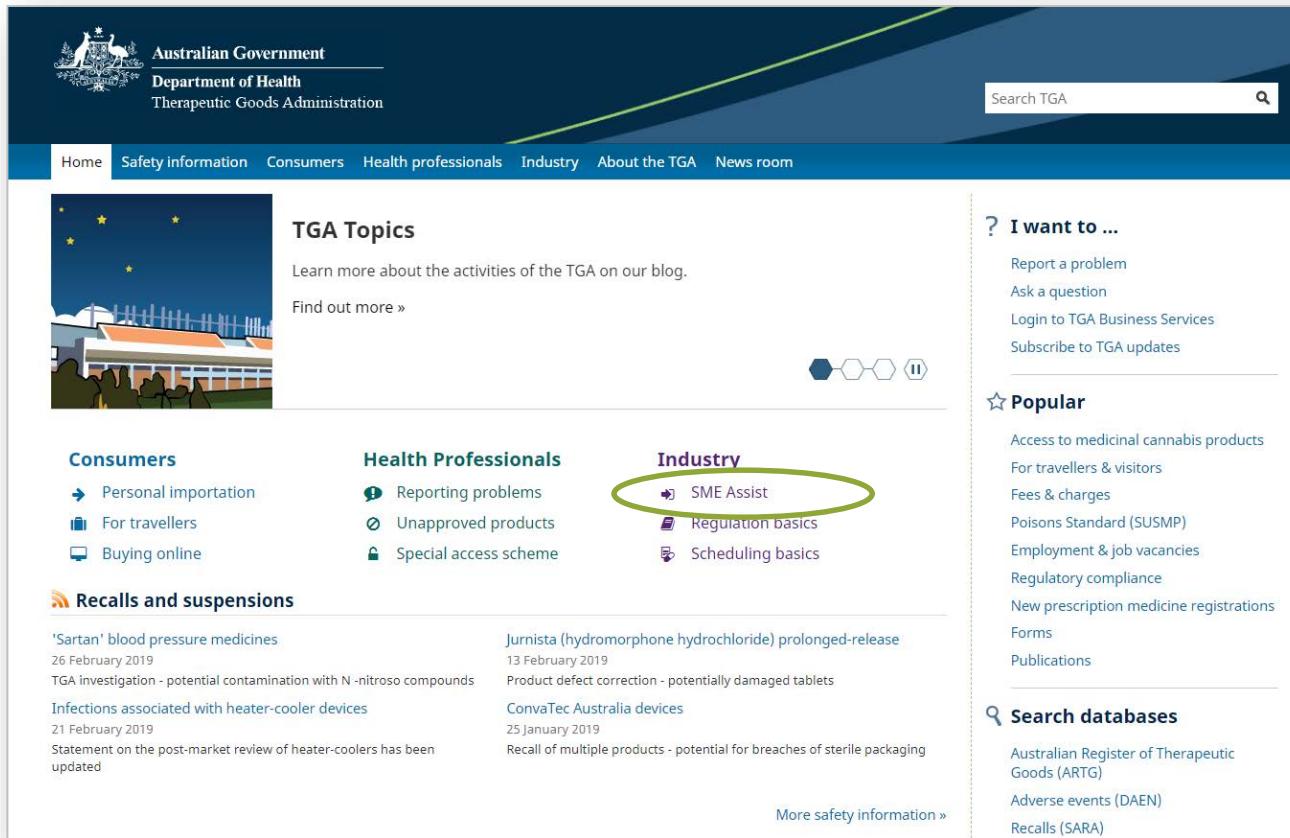


7	Decrease/reduce/relieve common cold duration	Scientific or Traditional	Label statement: If symptoms persist, talk to your health professional.  Product presentation must not imply or refer to serious forms of respiratory disorders/diseases, such as: asthma, pneumonia, COAD, COPD, influenza.  Label statement: Adults only, OR Not to be used in children under 2 years of age without medical advice.
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# SME Assist



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- For travellers
- Buying online

**Health Professionals**

- Reporting problems
- Unapproved products
- Special access scheme

**Industry**

- SME Assist
- Regulation basics
- 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 products
- For travellers & visitors
- Fees & charges
- Poisons Standard (SUSMP)
- Employment & job vacancies
- Regulatory compliance
- New prescription medicine registrations
- Forms
- Publications

**Recalls and suspensions**

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

[More safety information »](#)

**Search databases**

- Australian Register of Therapeutic Goods (ARTG)
- Adverse events (DAEN)
- Recalls (SARA)



## SME Assist

[www.tga.gov.au/sme-assist](http://www.tga.gov.au/sme-assist)

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