



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



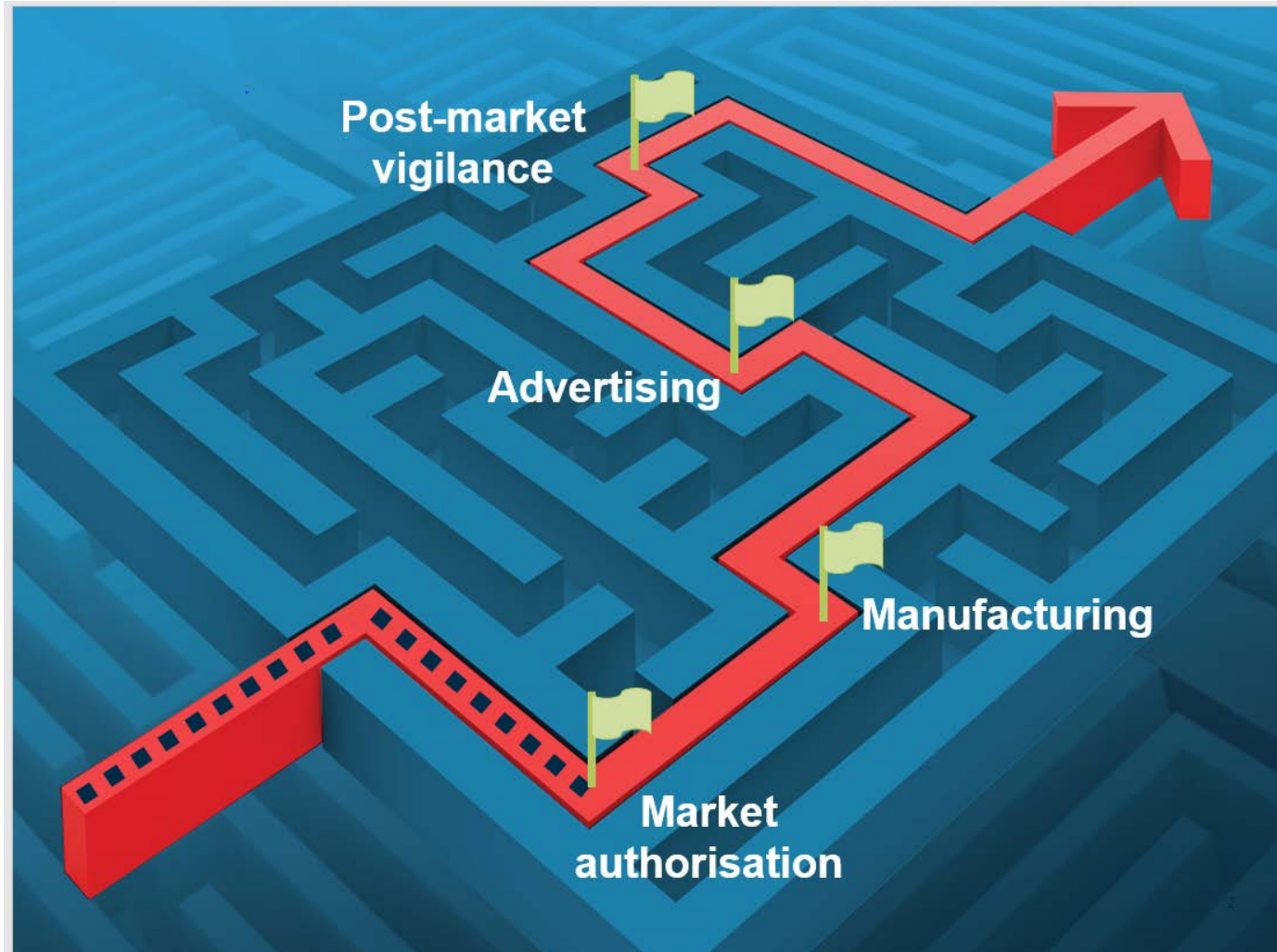
Disclaimer

This material is provided to you solely for the purpose of providing a record of today's presentation.

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- 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.





Market Authorisation



Medicines and biologicals



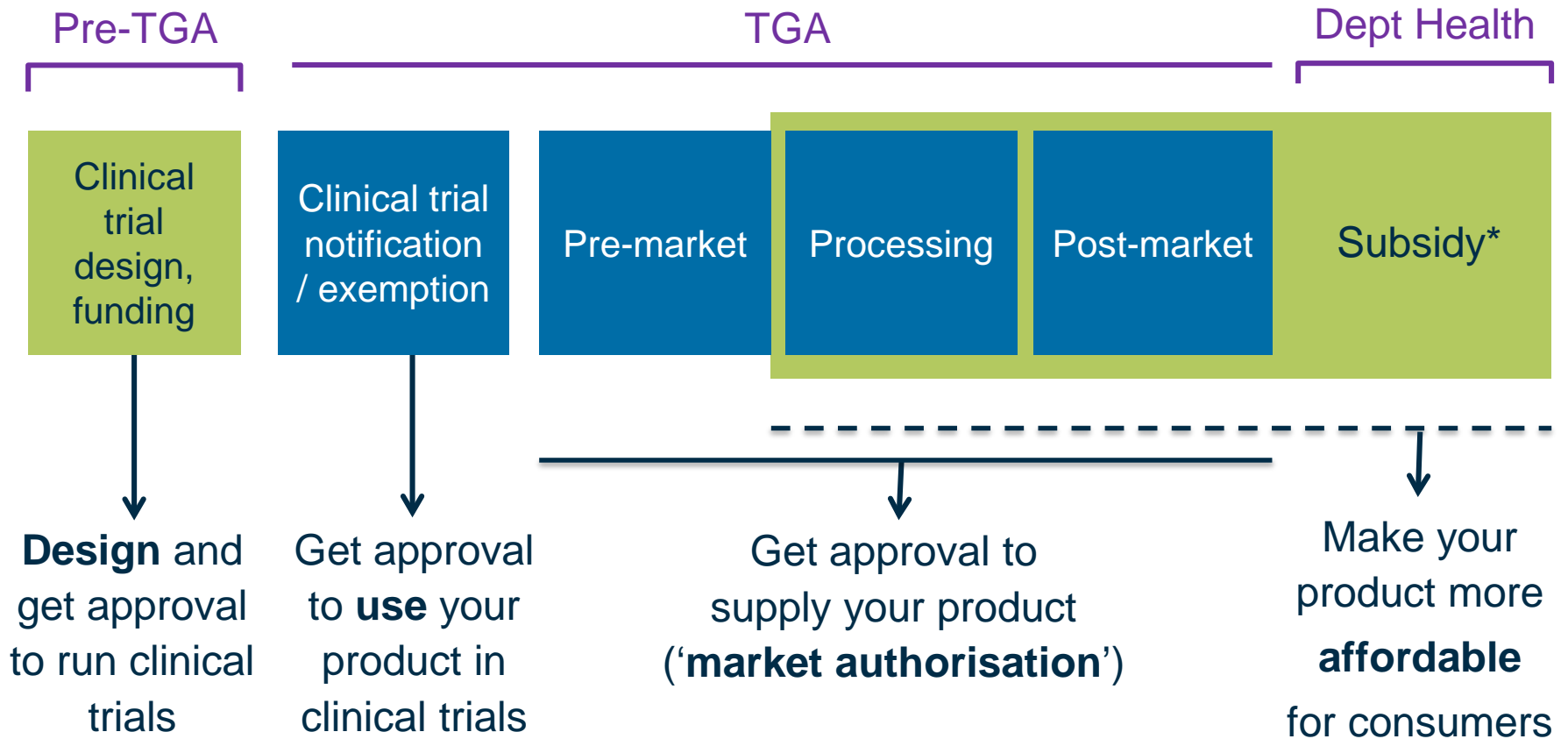
Medical devices



All therapeutic goods



Therapeutic good development lifecycle





Market authorisation

Identify your product



Use the **① Is my product a therapeutic good?** decision tool

Search the **① 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 **① What classification is my medical device?** decision tools

Search the **① 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

Biologicals

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



Biologicals:
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

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

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

AUST L XXXXXX

The AUST L must be $\geq 1\text{mm}$

Text is not clearly legible



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"> - (SFOOD) 'Derived from seafood' <p>or</p> <ul style="list-style-type: none"> - (SHELL) 'Contains crustacean shellfish'.
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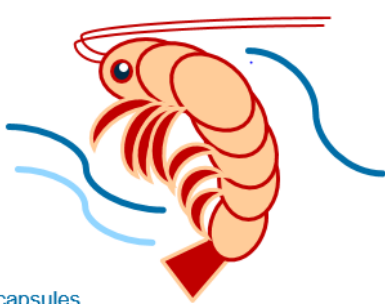
The permissible ingredients determination – we must include the warning statement 'Derived from seafood' or 'Contains crustacean shellfish'.

Omega Breeze has been formulated with sustainable krill oil (*Euphausia superba*) and important vitamin C.

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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:

<i>Euphausia superba</i> 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



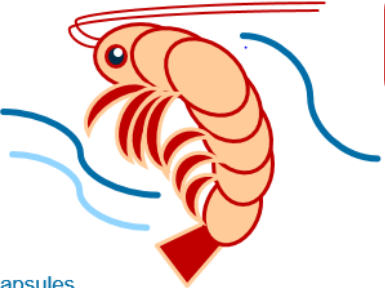
7	<p>Decrease/reduce/relieve common cold duration</p> <p>The permissible indications determination – label must include ‘Adults only’ AND an ‘if symptoms persist...’ statement.</p>	Scientific or Traditional	<p>Label statement: If symptoms persist, talk to your health professional.</p> <p>Product presentation must not imply or refer to serious forms of respiratory disorders/diseases, such as: asthma, pneumonia, COAD, COPD, influenza.</p> <p>Label statement: Adults only, OR Not to be used in children under 2 years of age without medical advice.</p>
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SME Assist

The screenshot shows the TGA website interface. At the top left is the Australian Government logo and text. A search bar is on the top right. A navigation menu includes Home, Safety information, Consumers, Health professionals, Industry, About the TGA, and News room. The main content area features a 'TGA Topics' section with a 'Find out more >' link. Below this are three columns: 'Consumers' (Personal importation, For travellers, Buying online), 'Health Professionals' (Reporting problems, Unapproved products, Special access scheme), and 'Industry' (SME Assist, Regulation basics, Scheduling basics). The 'SME Assist' link is circled in green. A 'Recalls and suspensions' section lists recent events. On the right, there are sections for '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), and 'Search databases' (Australian Register of Therapeutic Goods (ARTG), Adverse events (DAEN), Recalls (SARA)).



SME Assist

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