Australian Government
Department of Health
Therapeutic Goods Administration

SME Assist – ‘Meeting Your Obligations’
Manufacturing

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TGA Health Safety Regulation

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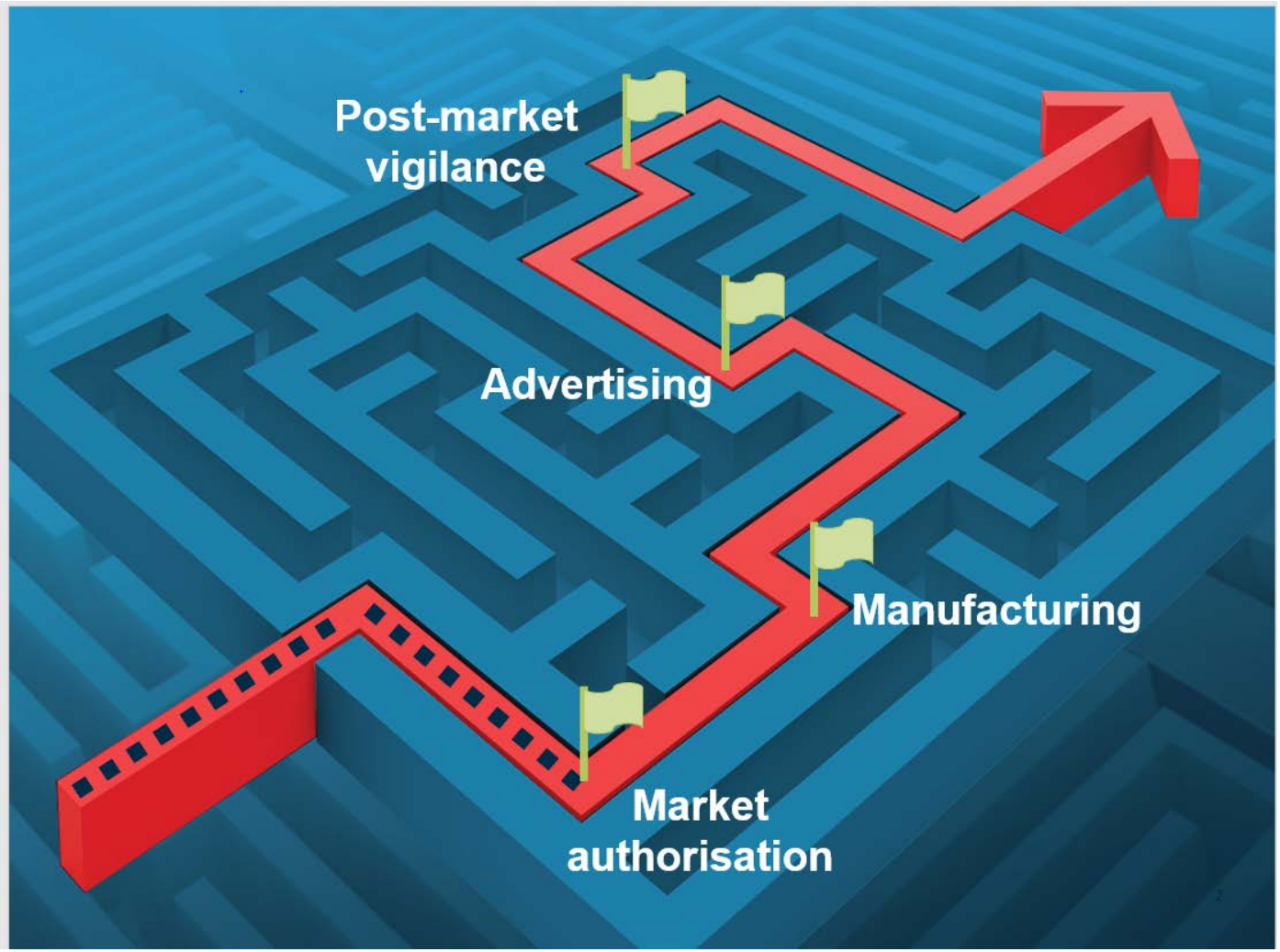

Post-market vigilance
Advertising
Manufacturing
Market authorisation

Manufacturing

Medicines and biologicals

Medical devices

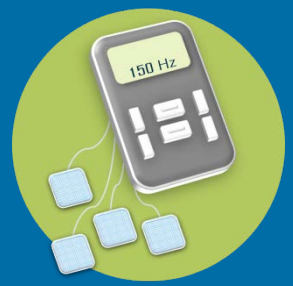
All therapeutic goods

Manufacture

- Any stage involving the production of the therapeutic good
- This can include:
  - producing
  - processing
  - refurbishing
  - assembling
  - packaging
  - labelling
  - testing
  - release for supply

Manufacturing

Assessment



Good manufacturing practice (GMP)

PIC/S Guide to GMP

or

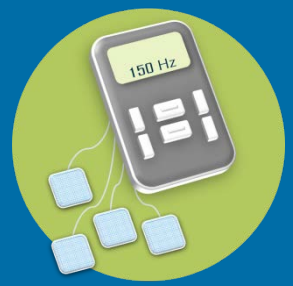
Australian Code of GMP for human blood and blood components, human tissues and human cellular therapy products

Conformity assessment

Essential Principles

Manufacturing

Manufacturer evidence



Australian manufacturer:

⇨ **manufacturer** needs to obtain GMP **licence** and forward onto sponsor

Overseas manufacturer:

⇨ **sponsor** needs to obtain GMP **clearance** for their manufacturer

Market authorisation application

Include manufacturer evidence

Certificate or declaration of conformity

Submit manufacturer evidence **first**

Then submit market authorisation application

Manufacturing

International agreements and arrangements

Mutual recognition agreements (MRA)

There is a list of countries and their regulatory bodies that have an MRA or equivalent arrangement with Australia. These include:

- United States
- Canada
- Singapore
- United Kingdom

Comparable overseas regulators (CORs)

These currently include:

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

Manufacturing

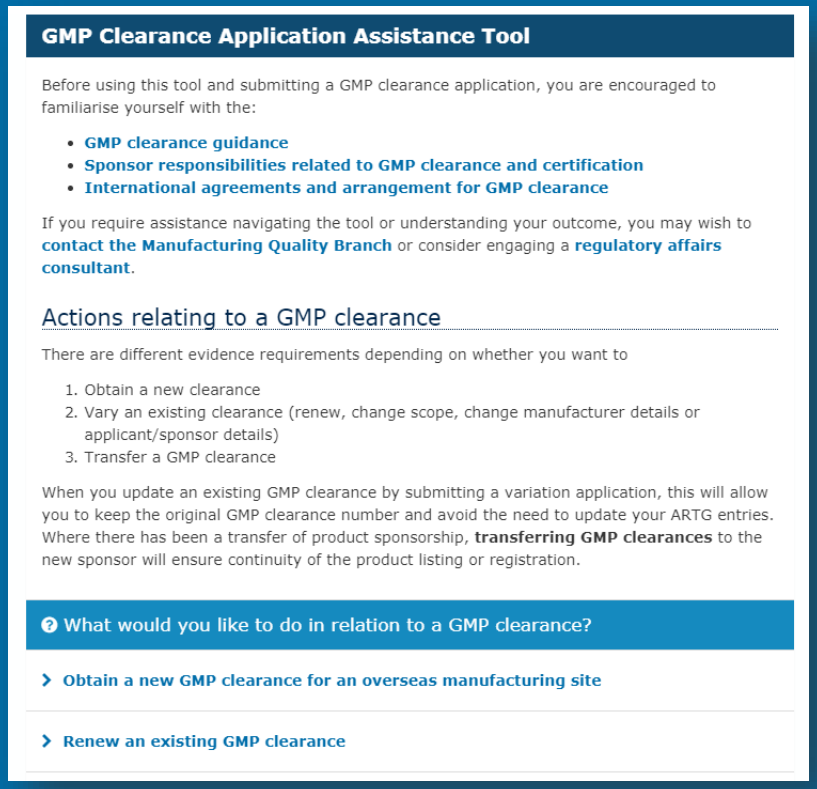
Inspections

Can happen at any time during the market authorisation process (pre-market, processing, post-market)

CASE STUDY:
Susie's GMP Clearance

- ✓ **Regulated as a medicine in Portugal**
- ✓ **Manufacturer recently inspected**
- ✓ **GMP certificate**

Susie uses the GMP clearance application assistance tool



GMP Clearance Application Assistance Tool

Before using this tool and submitting a GMP clearance application, you are encouraged to familiarise yourself with the:

- **GMP clearance guidance**
- **Sponsor responsibilities related to GMP clearance and certification**
- **International agreements and arrangement for GMP clearance**

If you require assistance navigating the tool or understanding your outcome, you may wish to **contact the Manufacturing Quality Branch** or consider engaging a **regulatory affairs consultant**.

Actions relating to a GMP clearance

There are different evidence requirements depending on whether you want to

1. Obtain a new clearance
2. Vary an existing clearance (renew, change scope, change manufacturer details or applicant/sponsor details)
3. Transfer a GMP clearance

When you update an existing GMP clearance by submitting a variation application, this will allow you to keep the original GMP clearance number and avoid the need to update your ARTG entries. Where there has been a transfer of product sponsorship, **transferring GMP clearances** to the new sponsor will ensure continuity of the product listing or registration.

What would you like to do in relation to a GMP clearance?

- **Obtain a new GMP clearance for an overseas manufacturing site**
- **Renew an existing GMP clearance**

GMP clearance is usually issued for manufacturers of:

- non-sterile Active Pharmaceutical Ingredients (APIs)
  - e.g. APIs manufactured by chemical synthesis or ‘classical’ fermentation
- non-sterile finished products
  - e.g. tablets or oral liquids
- sterile or biotech APIs
  - e.g. APIs manufactured by biotechnology fermentation/cell culture, or APIs that are sterilised
- sterile or biotech finished products
  - e.g. injections, lyophilisates or recombinant products
- contract testing laboratories or contract sterilisers

Three possible options for GMP clearance

1) GMP clearance through a mutual recognition agreement (MRA) desktop assessment

Use this if:

- the manufacturing site is located within the borders of an MRA country **and**
- the site has been inspected by that country's regulatory authority

2) GMP clearance through a compliance verification (CV) desktop assessment

Use this if:

- the manufacturer does not meet the criteria for MRA **and**
- the site has been inspected by a regulatory authority that has an agreement or arrangement with TGA

3) GMP certification via a TGA on-site inspection

Use this if:

- MRA and CV pathways are not applicable **or**
- no acceptable evidence from a recognised regulatory authority is currently available
  (e.g. for products that are not considered medicines in the country of manufacture)

Notes about the MRA pathway

- The overseas regulator must meet TGA standards for GMP codes
- The overseas regulator must have recently inspected the manufacturing site to TGA standards
- Evidence must be current, accurate and complete, and translated to English if necessary

Susie submits her GMP clearance application through TGA Business Services (TBS)

- She logs into TBS and selects **Clearance Application**
- She provides the required details, including:
  - Client details
  - Product details
  - Evidence
- She pays the associated fees, agrees to the declaration and submits her application

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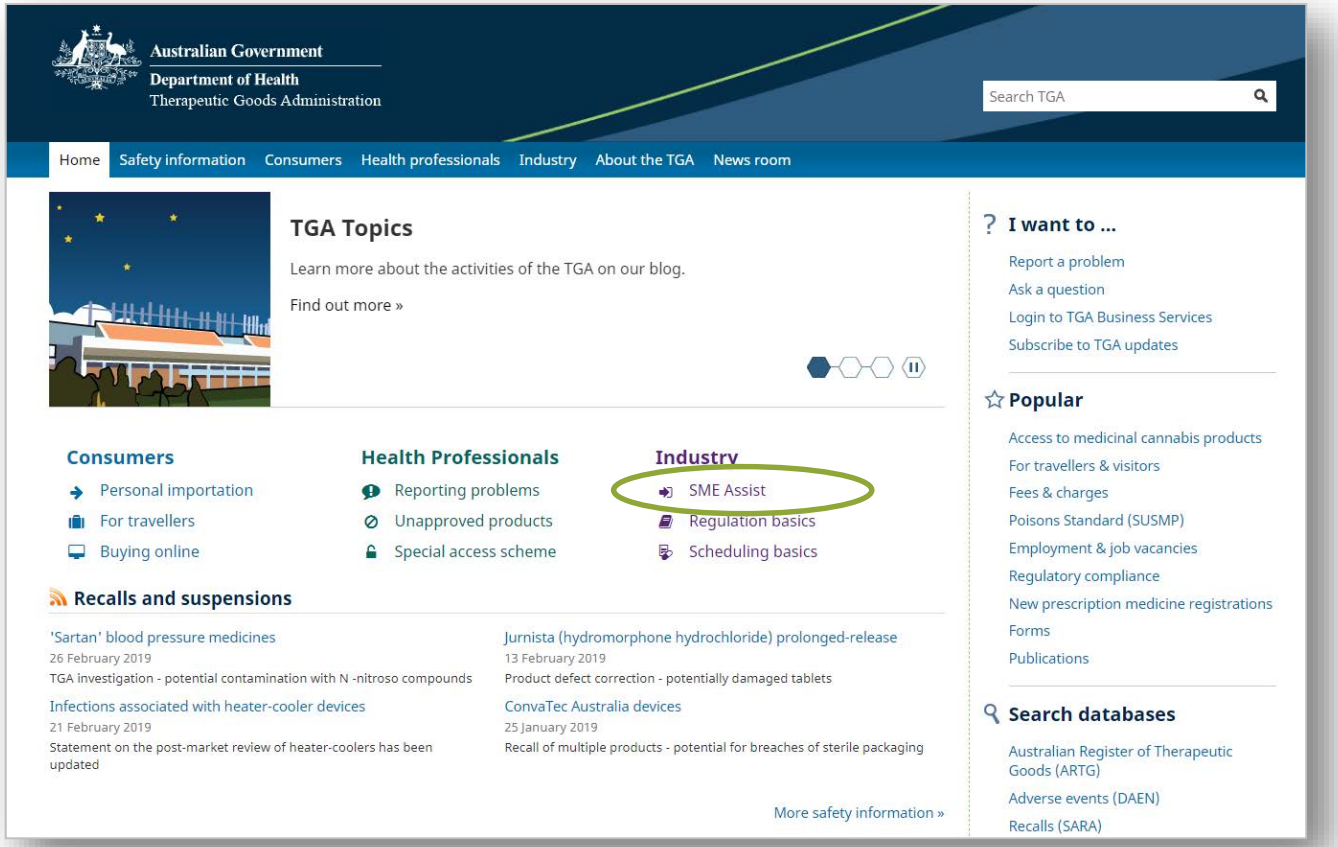
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26 February 2019
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Infections associated with heater-cooler devices
21 February 2019
Statement on the post-market review of heater-coolers has been updated
Jurnista (hydromorphone hydrochloride) prolonged-release
13 February 2019
Product defect correction - potentially damaged tablets
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