Australian Government
Department of Health
Therapeutic Goods Administration

Supply and Distribution of Therapeutic Goods

Navigating the regulatory landscape

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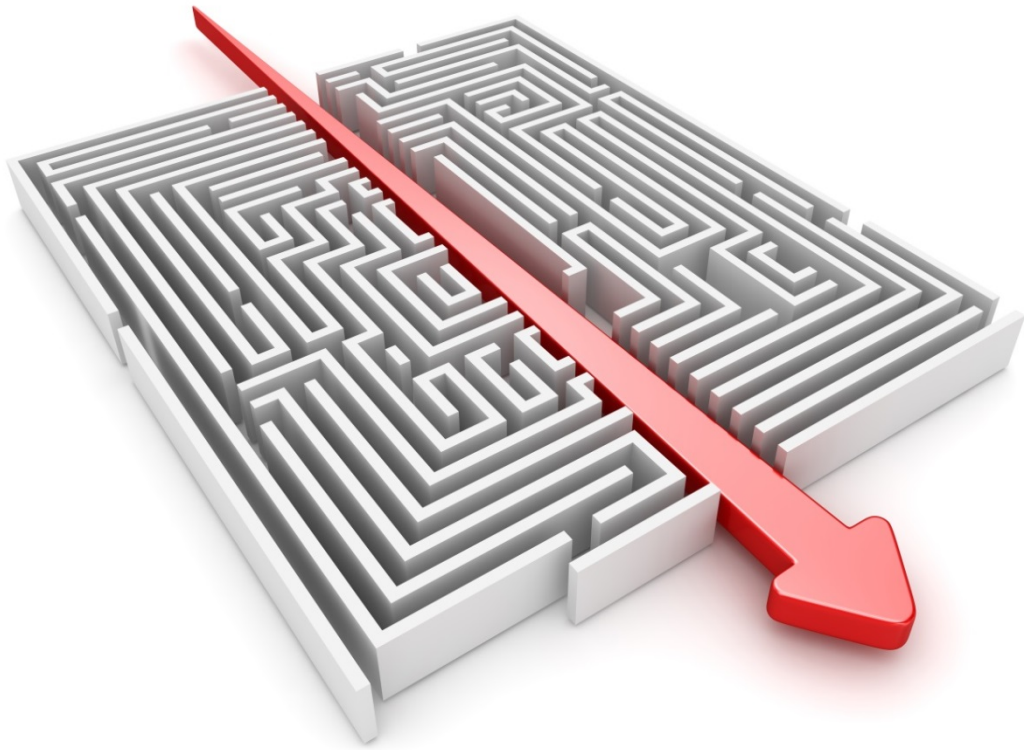
TGA Health Safety Regulation

Overview

- Supply & Distribution of Medical Devices
- Supply & Distribution Medicines
  - Domestic Supply
  - Supply from overseas
- Medicine Sponsor's Responsibilities
  - Release For Supply
  - Transportation
  - Wholesale distribution
- Good Distribution Practice



Supply & Distribution of Medical Devices

- ***ISO13485:2016: clause 7.5.11 "Preservation of Product"***

'The organization shall document procedures for preserving the conformity of product to requirements during processing, storage, handling, and distribution. Preservation shall apply to the constituent parts of a medical device.

The organization shall protect product from alteration, contamination or damage when exposed to expected conditions and hazards during processing, storage, handling and distribution…'

- What does this mean?
  - The *manufacturer* is responsible for overall compliance with this clause and therefore distribution.
  - The *sponsor* is responsible for the product on the market and reporting any issues to the manufacturer and TGA.
  - Contracts must be in place to outline responsibilities.

Supply & Distribution of Medicines

Therapeutic Goods Act 1989 Section 3

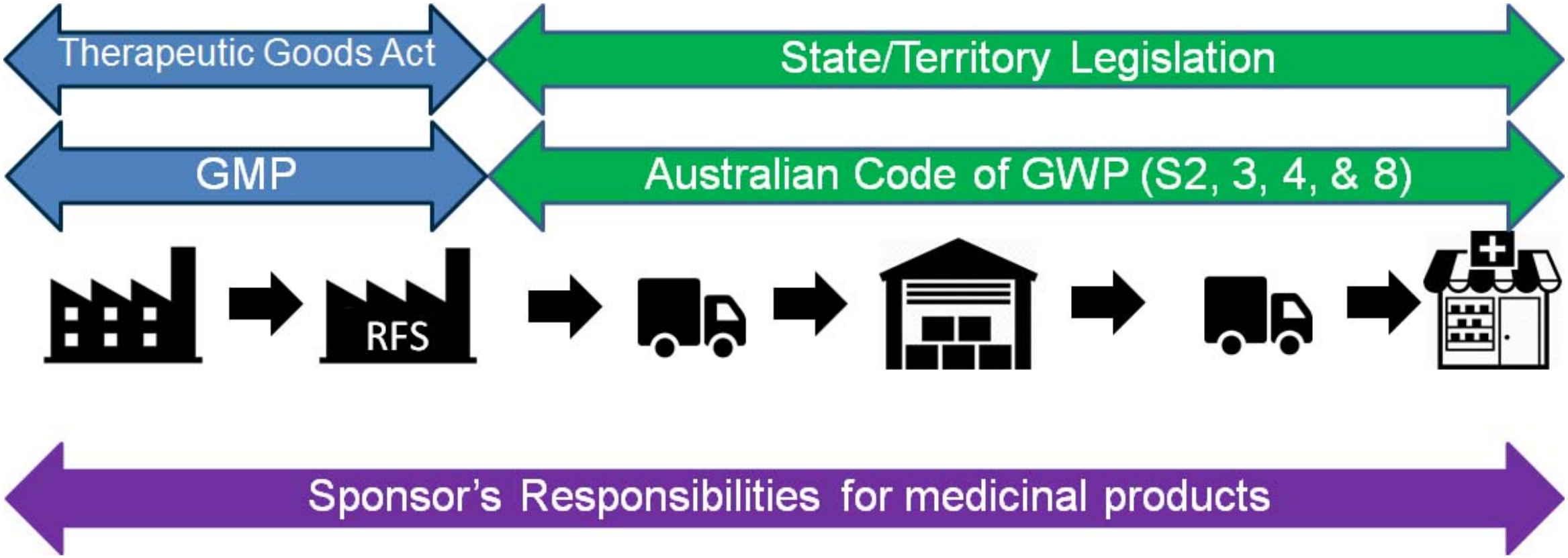
*'**manufacture**, in relation to therapeutic goods that are not medical devices, means:*

(a) to produce the goods; or

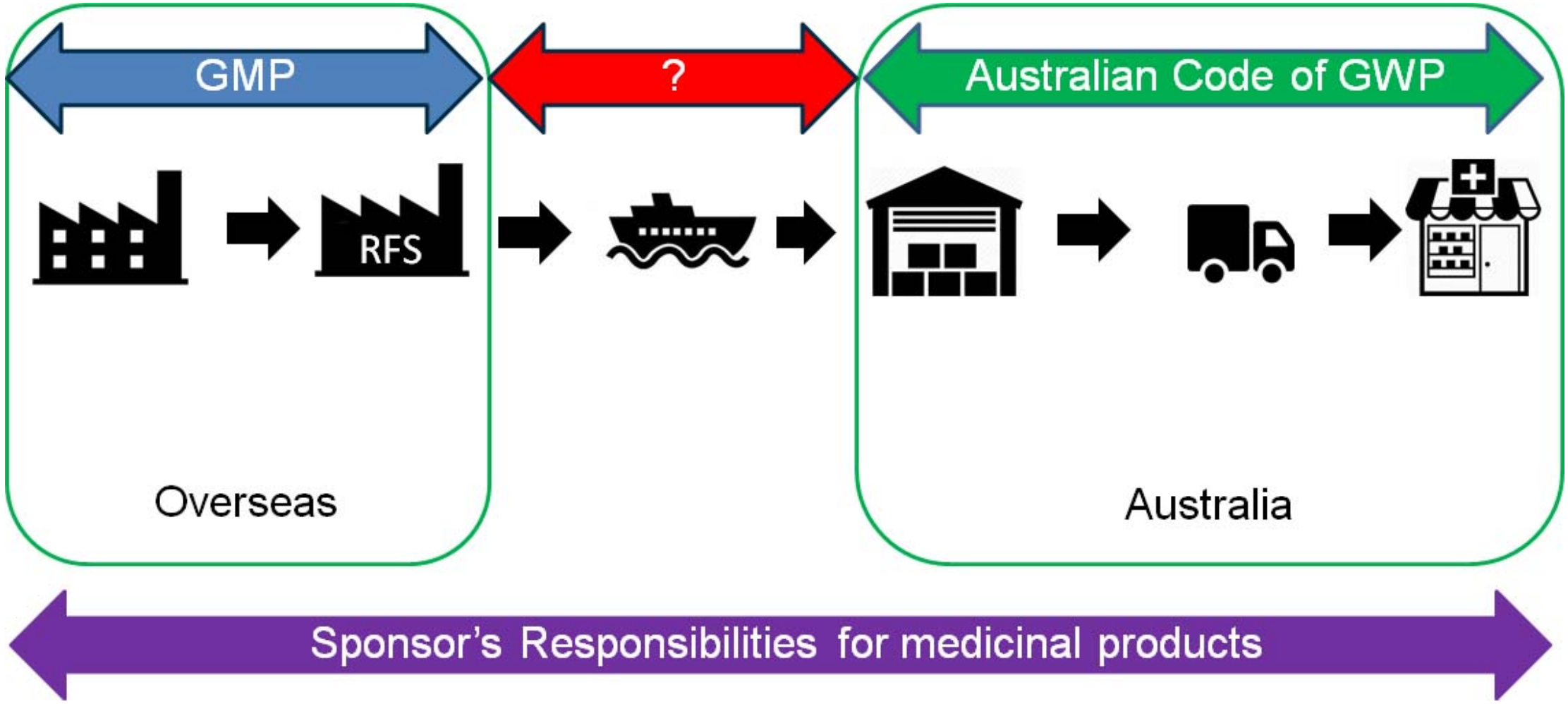
(b) to engage in any part of the process of producing the goods or of bringing the goods to their final state, including engaging in the processing, assembling, packaging, labelling, storage, sterilising, testing or releasing for supply of the goods or of any component or ingredient of the goods as part of that process.'

- What does this mean?
  - License to manufacture (GMP) required for all steps up until the point of release for supply (RFS)
  - Post release – things get interesting!

Domestic Supply Chain for Medicines



International Supply Chain for Therapeutic Goods



Sponsor's responsibilities - RFS

- Supply information to the Authorised Person:
  - Marketing Authorisation Details, conditions of registration & updates
  - Relevant batch certification:
    - Certificate of Conformance
    - Certificate of Analysis
    - RFFP package
  - Complete and **reviewed** Product Quality Reviews*
  - Ongoing stability data & updates*
  - Significant batch deviations
  - Approved artwork specifications

*Refer TGA RFS guidance

Sponsor's responsibilities - RFS

- Significant changes to manufacturing processes and ongoing validation
- Product release & expiry specifications
- Marketplace feedback/signals
  - Complaints, recalls, adverse events
- Supply chain details and approved manufacturers/suppliers (all contracts)*
- Transport arrangements

- In addition, sponsors should:
  - Ensure Quality/Technical Agreements are in place
  - Assess continued suitability of the AP
  - Monitor Compliance of manufacturer
  - Facilitate the AP's approval of other manufacturers*
- Maintain clearances for overseas sites

*Refer TGA RFS guidance

Sponsor's responsibilities - Transportation

- Ensure appropriate contracts are in place:
  - Understand the (approved) supply chain and responsibilities
  - Transport between manufacturer and warehouse
    - Transport methods should be validated (conditions and security)
    - Shipments should be monitored and results checked
    - Don't use stability data in lieu of good transport conditions!
  - Be aware of managing shipments "under quarantine"
  - PIC/S PE009-13 Annex 15 contains new guidance for validation of transportation

Sponsor's responsibilities - Wholesale Supply

- Provide relevant information and instructions regarding your product.
- Due diligence:
  - Ensure the wholesaler holds an appropriate licence/permit from state State/Territory Health Authority
    - NB: not all States/Territories regulate the wholesale of medicines in the same manner.
  - Verify compliance with Australian Code of Good Wholesaling Practice for Medicines in Schedules 2, 3, 4 & 8 (2011) NB: Does not apply to Devices or Listed medicines
  - Review product storage and distribution methods – are they in accordance with label requirements?

Good Distribution Practice (GDP)

- Concept of ‘falsification’ (2011/62/EU)
  - Any medicinal product with a false representation of: …

  (c) its history, **including the records and documents relating to the distribution channels used.**

- Emphasis on Supplier Qualification
- Emphasis on Customer Qualification
- Emphasis on maintaining appropriate storage conditions throughout entire supply chain.
  - **Must** transport products under labelled storage conditions

Summary

- Sponsors and Manufacturers have shared responsibilities for distribution
- Distribution (preservation) of medical devices is the responsibility of the *Manufacturer*
- Sponsors of medicinal products have significant role in ensuring products are manufactured, released and distributed in accordance with MA requirements, GMP and GWP.
  - GWP may not apply to all medicines
  - Quality/Technical Agreements and regular communication are critical.
- GDP requirements add additional level of complexity above domestic requirements.

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