



The Trans Tasman Therapeutic Products Agency

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MEDSAFE



The Australian and New Zealand Governments have decided

- **To create a single market for therapeutic products (including complementary medicines)**
- **To establish a single regulatory agency to operate in both countries and administer the regulatory scheme**



Scope of the Scheme

- **All medicines and medical devices**
 - including complementary medicines
- **Approvals relating to manufacture, supply, import, export, promotion**
- **Standards**
- **Post-market monitoring**
- **Enforcement**



Currently.....

- Interim Ministerial Council is operational
- Legislation is being drafted
- Consultation is occurring on aspects of the proposed regulatory scheme



Proposed regulatory scheme differs from the current Australian and New Zealand schemes

EXAMPLES

- Product licensing (including export-only)
- New joint labelling standards, advertising scheme
- Risk classes for medicines (Class I and Class II)
- Expanded list of ingredients permitted in Class I medicines
- New definition of “complementary medicine”



Class I Medicines

Are low-risk medicines that:

- Contain permitted ingredients only;
- Do not contain scheduled ingredients;
- Are not required to be sterile;
- Do not carry indications that make an implied or direct reference to a serious disease, disorder or condition; and
- Do not carry indications that offer to treat, cure, prevent or manage a disease, disorder or condition unless specifically permitted.



Obtaining a Class I Medicine Product Licence

The applicant will be required to certify that:

- The medicine is a Class I medicine;
- The medicine is safe for its intended purpose
- The applicant holds evidence to support any claim in relation to the medicine



Transition Begins From 'Go-Live'

At start-up:

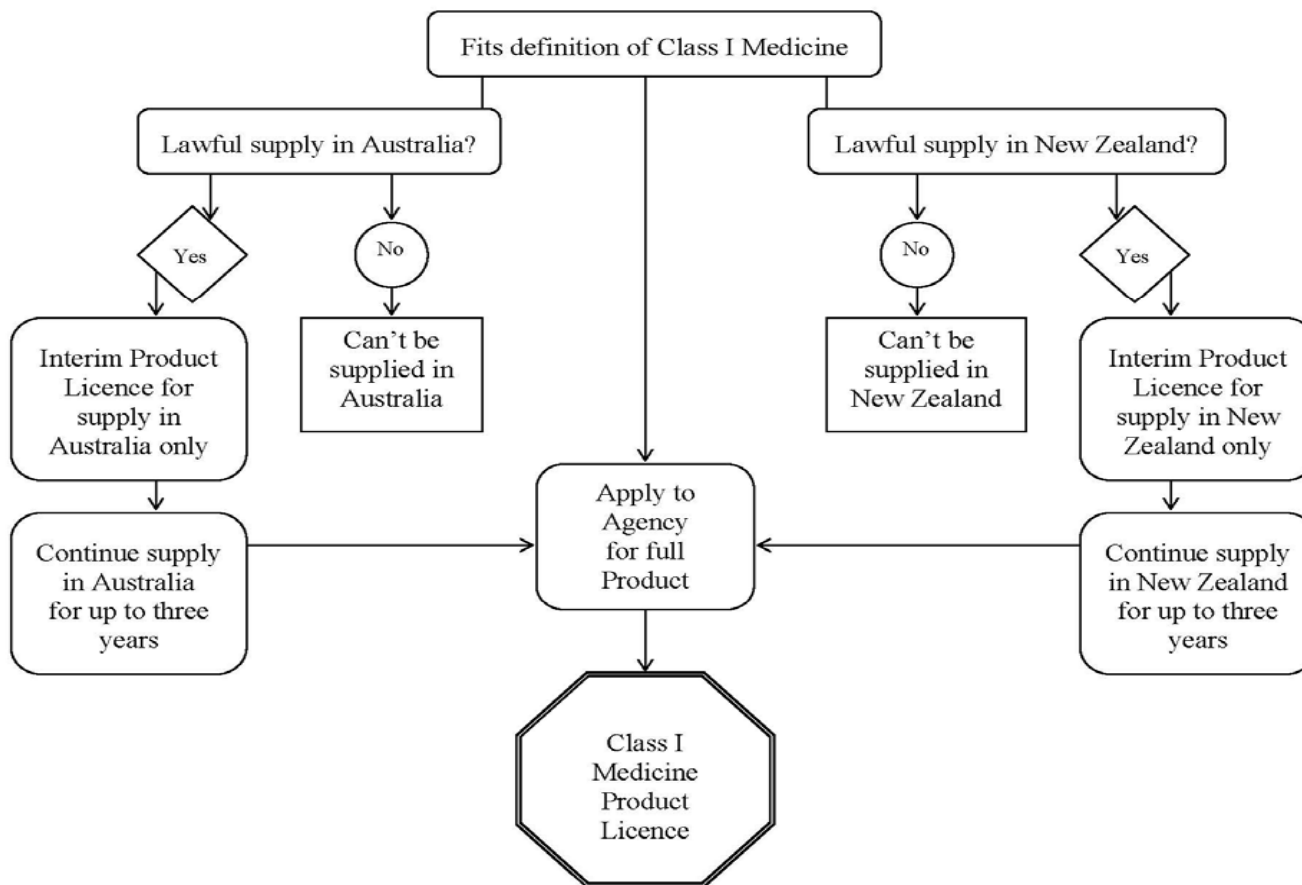
- Transitional approvals for continued supply of products legally on the market in Australia or NZ

During transition period:

- Full product licences (allowing supply in both countries) issued by the Agency when compliance with Agency standards demonstrated

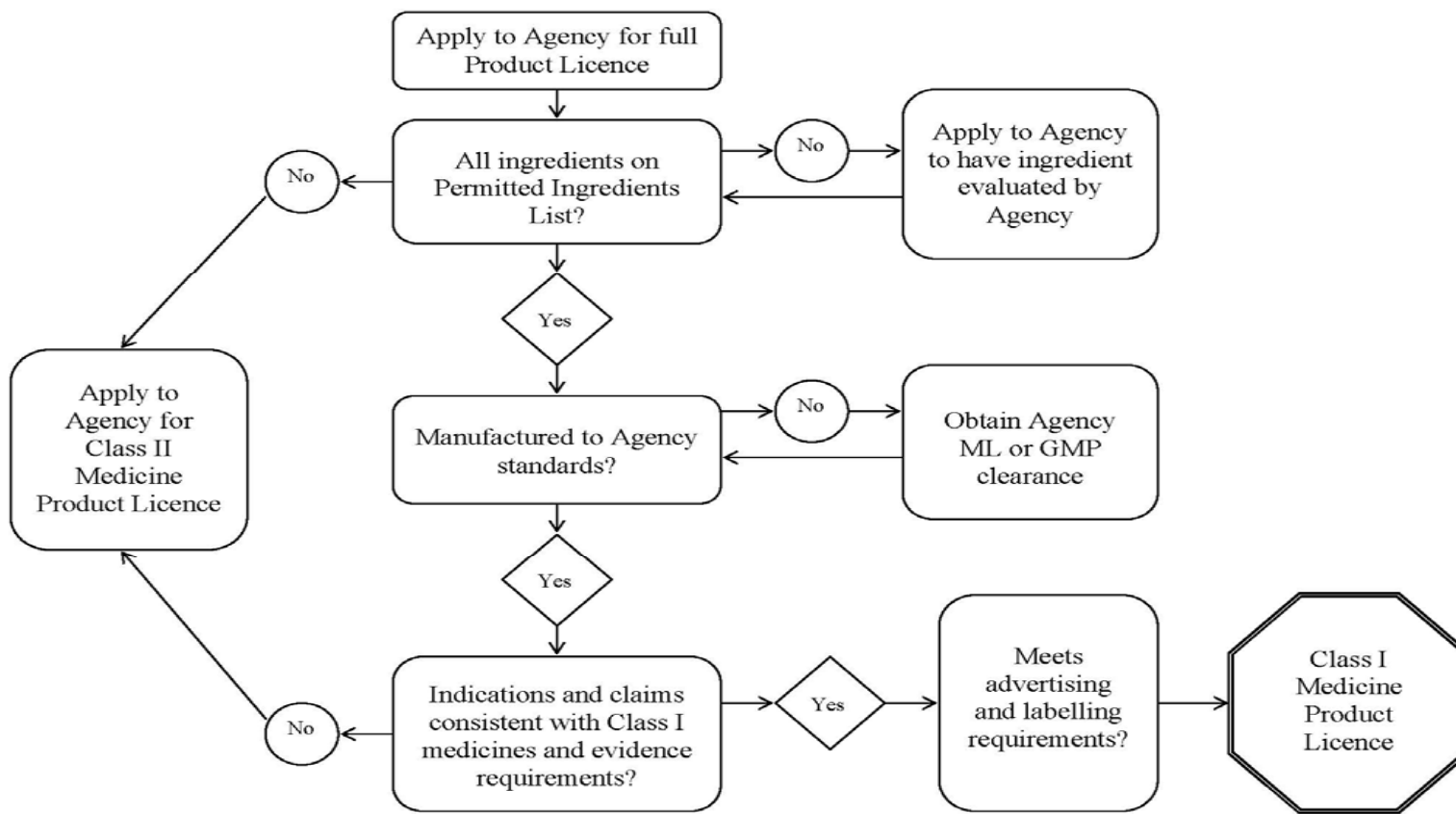


Class I Medicines at Commencement





Class I Medicines During Transition





Getting ready.....

- Obtain information about products from overseas manufacturers/suppliers
- Enter product details on COMET database (not necessary for products already on the ARTG)
- Decide the claims you will wish to make for the products and ensure you hold appropriate evidence to support those claims



Information and updates

- www.jtaproject.com
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