



Australian Government
Department of Health and Ageing
Therapeutic Goods Administration



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**GUIDELINES FOR TRANSITION TO
THE JOINT REGULATORY SCHEME
FOR
CLASS 1 MEDICINES,
CLASS 2 MEDICINES AND
MEDICAL DEVICES**

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GUIDELINE FOR CONVERTING A CLASS 1 MEDICINE INTERIM PRODUCT LICENCE TO A CLASS 1 ANZTPA PRODUCT LICENCE

Scope

This document provides guidance on the policies and practices that will be applied to the transition from interim Product Licences for Class 1 medicines that authorise supply in either Australia or New Zealand (but not both countries) to a full Class 1 product licence issued by the Australian New Zealand Therapeutic Products Authority (ANZTPA) Product Licence authorising supply in both Australia and New Zealand.

Introduction

In December 2003, the New Zealand and Australian Governments signed a Treaty committing to the establishment of a Joint Authority and regulatory scheme for therapeutic products. The prime objective of the Treaty is to safeguard public health and safety in Australia and New Zealand by establishing and maintaining a joint scheme consistent with international best practice for the regulation of the quality, safety, and efficacy of therapeutic products, and of their manufacture, supply, import, export and promotion. The joint scheme will deliver a harmonised approach to the regulation of therapeutic products in Australia and New Zealand.

Under the scheme, a product licensing mechanism will be used to authorise the supply of a product in both New Zealand and Australia. The Product Licence will be issued by the ANZTPA and is referred to in this document as the ANZTPA Product Licence.

As part of the establishment of the ANZTPA under the Treaty, Australia and New Zealand have agreed on transitional arrangements to ensure marketing authorisations previously granted under current New Zealand and Australian legislation remain effective over the transition period. **During the transition period, prior to obtaining an ANZTPA Product Licence, sponsors may supply products only in the country in which they have approval.** Supply in both countries is permitted only after a full ANZTPA Product Licence has been granted by the ANZTPA. Therefore, before the end of the transition period, sponsors need to apply for, and obtain, an ANZTPA Product Licence in order to continue to supply their products after the end of the transition period.

Transitional Class 1 Product Licence

The treaty obligations on both countries mean that at commencement of the ANZTPA, all products lawfully supplied in Australia or New Zealand can continue to be supplied in the country in which they were already being supplied lawfully, for the duration of the specified transition period (proposed to be 3 years).

Existing Australian Listed Medicines

All Listed medicines currently included on the Australian Register of Therapeutic Goods (ARTG) approved for supply in Australia will be granted transitional approval in the form of an Interim Product Licence that permits the continued supply of the product in Australia only. The interim product licence will impose the same conditions as those that applied to the inclusion of that product on the ARTG under the *Therapeutic Goods Act 1989*.

Existing New Zealand Products

Any product supplied in New Zealand that has been granted either Ministerial consent or provisional consent under the *New Zealand Medicines Act 1981* will be granted an Interim Product Licence that permits the continued supply of the product in New Zealand only. Additionally any product that is being lawfully supplied as a dietary supplement in New Zealand prior to the commencement of the ANZTPA and meets the ANZTPA definition of a complementary medicine, will be granted an Interim Product Licence that permits the continued supply of the product in New Zealand only.

Complementary Medicines Transition Database COMET (New Zealand only)

Products that meet the definition of a complementary medicine and are being lawfully supplied in New Zealand prior to commencement of the ANZTPA will be captured on the Complementary Medicines Transition Database – COMET. COMET allows for sponsors to enter information relating to their products, including details relating to its sponsor and manufacturer. Interim Product Licences will be issued only for products on this database prior to commencement of the ANZTPA.

It will be illegal to supply a therapeutic product in Australia and/or New Zealand after commencement of the joint regulatory scheme if the product is not the subject of either an Interim or an ANZTPA Product Licence.

GMP – Interim to Full ANZTPA Product Licence

For products supplied in New Zealand and entered on COMET, the application to convert an Interim Product Licence to an ANZTPA Product Licence will be the same as the process for a new Class 1 medicine. As part of this process, if the product is manufactured in Australia and/or New Zealand, the sponsor will need to certify that the product is manufactured in accordance with the ANZTPA Code of GMP by a manufacturer that:

- holds a full ANZTPA manufacturing licence; or
- holds an interim manufacturing licence, provided that the manufacturer was licensed by either the TGA or Medsafe prior to commencement of the joint scheme.

Obtaining a full ANZTPA Class 1 Product Licence

Sponsors who wish to continue to supply products in Australia or New Zealand beyond the expiry of the transition period, need to apply for (and be granted) a full ANZTPA Product Licence before the end of the transition period, as the interim licence will lapse when the transition period ends.

Sponsor Certifications

Sponsors of Class 1 medicines will apply for a product licence on-line. The sponsor will be required to certify their product conforms to all ANZTPA requirements, including that:

- the medicine is a Class 1 medicine; and
- the medicine is safe for the purpose or purposes for which it is designed to be used; and
- the medicine conforms to every standard (if any) applicable to the medicine; and
- advertising of the medicine complies with the requirements (if any) applicable to it under the Medicine Rule or the Advertising Rule, relating to advertising; and
- the medicine complies with the requirements (if any) applicable to it under the Medicine Rule, and under Orders, relating to the quality and safety; and
- for a medicine manufactured in Australia or New Zealand - each step in the manufacture has been carried out by a person who is the holder of a licence to carry out that step (unless the medicine or manufacturer is exempt from this requirement); and
- the medicine contains no substance that is a prohibited import for the purposes of the Australian and/or New Zealand Customs legislation; and
- the applicant holds information or other evidence that supports any claim made by the applicant in relation to the medicine and complies with the requirements (if any) specified in the Orders; and
- the applicant holds product specifications and labels (draft or actual) for the medicine; and
- the applicant holds data that demonstrates that the specifications attributed to the product by the manufacturer will continue to be met for the duration of the shelf life nominated by the manufacturer under the storage conditions nominated by the manufacturer; and
- all of the manufacturers of the medicine are nominated as manufacturers in the application; and
- the applicant is a resident of, or carries on business in, Australia or New Zealand; and
- the presentation of the medicine is acceptable; and
- the application contains no information that is false or misleading in a material particular.

Pre-clearance certificates

Sponsors will be required to obtain certifications from the Managing Director, prior to submitting an application for an ANZTPA Product Licence if:

- a step in the manufacture of the medicine has been carried out outside Australia or New Zealand. In this case, the Managing Director must have certified that the manufacturing and quality control procedures used in each such step are acceptable (unless the medicine or manufacturer is exempt from this requirement); or
- the medicine contains any ingredient of human or animal origin. In this case the Managing Director must have certified that the ingredient/s from the specified source (including country of origin) are satisfactory for use in a human medicine, for example, in terms of minimising the risk of transmission of Transmissible Spongiform Encephalopathies.

ANZTPA Product Licence Application

On receipt of an ANZTPA Product Licence application for a Class 1 medicine, the Managing Director will grant a product licence if:

- the application has been made in the correct form; and
- the application is complete and is accompanied by the correct fee; and
- requisite certifications from the Managing Director have been obtained, prior to submission of the application; and
- key data in the application have been validated by the ANZTPA.

If the decision is to grant a product licence, the Managing Director will provide a copy of the product licence to the applicant. The product licence will be effective from the date specified on the licence.

Post Market Audits

At any time after an ANZTPA Product Licence has been granted for a Class 1 medicine, the Managing Director may:

- audit the licence application to determine whether any or all the matters certified by the applicant are correct; or
- evaluate the quality, safety and efficacy of the medicine; or
- conduct a risk assessment of the medicine.

Having demonstrated compliance with all ANZTPA standards (and having paid the applicable fee), a full ANZTPA product licence will be issued enabling supply in both Australia and New Zealand.

Note: Licensed manufacturers who were manufacturing medicines in Australia and/or New Zealand prior to commencement of the ANZTPA will be able to continue to manufacture under the same terms permitted prior to commencement. A full ANZTPA manufacturing licence will not be granted until the manufacturer has applied to the ANZTPA and successfully passed an audit to ensure compliance with the ANZTPA manufacturing principles. Lawful, unlicensed manufacturers of products meeting the definition of complementary medicine in New Zealand prior to commencement of the ANZTPA will be granted an interim manufacturing approval that will enable them to continue the activities that they were lawfully undertaking prior to commencement of the ANZTPA. An ANZTPA product licence could not be granted for products manufactured by manufacturers holding an interim manufacturing approval until such time as they have demonstrated compliance with ANZTPA manufacturing principles and been granted a full ANZTPA manufacturing licence.

GUIDELINE FOR SPONSORS OF CLASS 2 MEDICINES APPLYING TO CONVERT INTERIM PRODUCT LICENCES TO ANZTPA PRODUCT LICENCES DURING THE TRANSITION PERIOD

1. Scope

At commencement of the joint regulatory scheme, each medicine currently registered in Australia and New Zealand will qualify for a transitional approval. This approval will take the form of an **Interim Product Licence** authorising supply of the medicine in the country in which it was previously registered for the duration of a 3 year transition period.

The sponsor of the medicine must apply for and obtain a full **ANZTPA Product Licence** in order to continue supplying the product beyond the transition period. An ANZTPA Product Licence will authorise supply of the product in both countries.

This document describes the process and requirements for applying to convert an Interim Product Licence to an ANZTPA Product Licence for a Class 2 medicine.

2. Introduction

In December 2003 the New Zealand and Australian Governments signed an Agreement (treaty) committing to the establishment of a joint agency and regulatory scheme for therapeutic products. The prime objective of this Agreement is to safeguard public health and safety in Australia and New Zealand by establishing and maintaining a joint scheme consistent with international best practice for the regulation of the quality, safety, and efficacy or performance of therapeutic products, and of their manufacture, supply, import, export and promotion.

The agency is to be called the Australia New Zealand Therapeutic Products Authority (ANZTPA). As part of the establishment of the ANZTPA under the Treaty, Australia and New Zealand have agreed transitional arrangements for implementation of the scheme. These arrangements are designed to ensure that products being supplied under marketing authorisations granted under the superseded legislation of either country can continue to be supplied during a 3 year transition period.

Under the joint regulatory scheme, product licensing is the mechanism used to grant marketing authorisation to suppliers of therapeutic products.

2.1 Transition from existing approvals to product licences

At commencement of the joint scheme, an Interim Product Licence will be issued for each product that is included in the Australian Register of Therapeutic Goods (ARTG) and for each product for which consent for distribution has been granted in New Zealand. The interim product licence is a transitional approval. It authorises the sponsor to continue to supply the product only in the market in which they previously had approval, but only for the duration of the 3 year transition period. Where the same product is being supplied in both countries, two interim product licences will be issued – one to authorise continued supply in Australia and one to authorise continued supply in New Zealand.

Before the end of the 3 year transition period, the product licence holder must apply for, and be granted, an ANZTPA Product Licence in order to continue to supplying the product after the end of the transition period. An ANZTPA Product Licence will authorise supply of the product in both markets.

At the commencement of the joint scheme the Australian and New Zealand product registration databases (SIME and SMARTI) will be combined to produce an Interim Register of all Class 2 medicines approved in either country. An Interim Product Licence, based on the data held in the Interim Register, will automatically be issued for each product in the Interim Register. As companies apply for, and are granted, ANZTPA Product Licences during the transition period, an ANZTPA Product Licence Register will progressively be created.

2.2 Transition in relation to applications under consideration at commencement of the joint scheme

At commencement of the scheme, both countries will have marketing authorisation applications under consideration but not yet determined. Transition arrangements for such applications will be as follows:

- An application that has been submitted to the TGA and/or Medsafe under their respective Australian or New Zealand legislation and is under evaluation will, unless withdrawn by the applicant, be determined in accordance with the requirements of that superseded legislation and the transitional provisions of the implementing legislation for the joint scheme. If a decision is made to grant a marketing authorisation, an Interim Product Licence will be issued. The Interim Product Licence will authorise supply of the product in one country only for the duration of the transition period. The licence holder will then be required, before the end of the transition period, to apply for and obtain an ANZTPA Product Licence.
- An applicant may elect to withdraw an application under consideration by the TGA and/or Medsafe at commencement of the scheme, and submit a replacement application that meets all ANZTPA requirements and can therefore be determined in accordance with the requirements of the joint scheme. If a decision is made to grant a marketing authorisation, ANZTPA Product Licence will be issued authorising supply in both countries.

2.3 Preparation for transition

While many medicines are approved and marketed in both countries, there are often differences in the product details for those registrations. In preparation for transition to the joint scheme, sponsors should review their current product ranges and rationalise their marketing authorisations to take advantage of the “single market” opportunities provided by the joint regulatory scheme. The information in this guidance document should assist companies to make informed decisions about the technical profile of the product they wish to market under an ANZTPA Product Licence.

Requirements and decisions in relation to the inclusion of prescription medicines under the Australian Pharmaceutical Benefits Scheme (PBS) administered by the Pharmaceutical Benefits Branch (PBB) of the Australian Department of Health and Ageing or the New Zealand Pharmaceutical Schedule administered by PHARMAC lie outside the joint scheme. Sponsors should contact the PBB or PHARMAC for

further information on their requirements for listing of products on their respective Schedules.

3. Process for Applying to Convert an Interim Product Licence to an ANZTPA Product Licence

An application to convert an Interim Product Licence to an ANZTPA Product Licence will be made by submitting an electronic application and, where required, supporting documents and data.

3.1 The Electronic Application Form

An electronic application form will be provided to capture information about the applicant, product and past regulatory approvals or rejections for the product, and to create a draft electronic database record for the product to which the ANZTPA Product Licence application relates. This database record will be akin to the "Provisional ARTG Record" (PAR) currently required in Australia, but modified to meet ANZTPA requirements.

An outline of the content of the form is shown below.

Part A: Applicant details

- Name and address of Interim Product Licence holder(s) and intended ANZTPA Product Licence holder
- Name and address of applicant (if not the same as above)

Part B: History of past regulatory approvals

- Statement of whether product has previously been approved in Australia only, or New Zealand only, or both Australia and New Zealand
- Approval/File number(s)
- Whether an application relating to the product has ever been rejected in Australia or New Zealand (either in whole or with respect to any matter listed in Part C below) or the subject of regulatory action (with respect to any matter listed in Part C)

Part C: Product particulars

- Product name
- Description of the product (e.g. appearance, dimensions, etc)
- Active ingredient(s)
- Dose form (e.g. tablet, capsule, suspension, etc)

- Strength
- Container/Packaging
- Pack size(s)
- Whether or not the product is a co-marketed product or a generic product
- In the case of a generic product, the innovator(s)/market leader(s) that the product was considered to be bioequivalent with at the time of its registration in Australia and/or New Zealand
- Any delivery devices and reconstitution liquids accompanying the product (and details of any separate approval numbers for these)
- Storage conditions and shelf life
- Formulation for which an ANZTPA Product Licence is being sought
- Sterility and type of sterilisation method (if applicable) for each component
- Name, address and Manufacturer ID of each finished product manufacturer [includes packers, sterilisers and quality control testing sites], manufacturers of the active ingredients (for prescription medicines only), and the steps of manufacture, packaging or testing carried out at each site
- Indications for which an ANZTPA Product Licence is being sought

Part D: Declarations

- Declaration that the proposed formulation and method of manufacture are:
 - the same as the formulation and method of manufacture for the product currently registered in both Australia and New Zealand; OR
 - the same as the formulation and method of manufacture for the product currently registered either in Australia or in New Zealand, and, where different formulations and/or methods of manufacture have been approved in Australia and New Zealand, an explanation of those differences (or a statement that this information is not known to the applicant).
- Declaration that the proposed indications are the same as those currently registered in both Australia and New Zealand OR that information is provided with the application to support the inclusion of indications previously approved in one country but not the other.
- Declaration that the specifications comply with the ANZTPA requirements.
- Declaration that valid GMP clearances are held for each manufacturing, packaging, sterilising and testing site.

- Declaration of the TSE and viral status of any ingredients of animal or human origin, including materials used in the manufacturing process which may not be present in the finished product.
- Declaration regarding patents (if applicable).
- Declaration regarding embryos/stem cells.
- Declaration that the content of the proposed product information document complies with ANZTPA requirements (see section 4.12) and otherwise is:
 - (1) identical to the current Australian PI; or
 - (2) identical to the current New Zealand data sheet; or
 - (3) a hybrid¹ of the current Australian and New Zealand documents.
- Declaration that the proposed Consumer Medicine Information is consistent with the proposed product information document and meets ANZTPA requirements.
- Declaration that the proposed Package Insert (if any) is consistent with the proposed product information document.
- Declaration that the proposed labelling complies with the Managing Director's Order on labelling and all relevant ANZTPA guidelines.
- Declaration that the proposed labelling for a Class 2 OTC medicine complies with the labelling requirements of the Australia New Zealand Therapeutic Products Advertising Code.
- Declaration that the proposed quality control specifications for the active ingredient(s), excipients, finished product and packaging (including test procedures) are the same as those currently approved in Australia and/or New Zealand (apart from any changes necessary to meet the ANZTPA standards) or that information on both countries is not known to the sponsor.

3.2 Information to be supplied as separate supporting data

The following information should be supplied as supporting data with an application to convert from an Interim Product Licence to an ANZTPA Product Licence:

- Copies of GMP clearances for each manufacturing, packaging, sterilising and testing site. See Section 4.2 for further information;
- Quality control specifications for the active ingredient(s), excipients, finished product and packaging (including an indication of the test procedures used), where these differ from previously approved specifications. See sections 4.3 to 4.5 for further information;
- A copy or mock-up of the proposed labelling for Class 2 OTC medicines. See Section 4.11 for further information;

¹ Instructions for preparing hybrid PI documents are provided in this document in section 4.12

- Electronic copies (in Microsoft Word or Rich Text format) of the draft product information (PI) document and relevant source documents. See Section 4.12 for further information;
- An electronic copy of the proposed Consumer Medicine Information (CMI) document in Microsoft Word or Rich Text format. See Section 4.13 for further information; and
- An electronic copy of the proposed Package Insert (if applicable) in Microsoft Word or Rich Text format.

3.3. History of past approvals and rejections

In most cases where the same application has been submitted to both the TGA and Medsafe the final decisions by the Australian and New Zealand regulators to approve or reject the application have been the same. In some cases, however, there may be differences in the indications or some other product details approved in the two countries.

There are, however, some cases where a product has been approved in one country and rejected, or recommended for rejection and subsequently withdrawn, in the other. Part B of the application form is designed to capture the history of approvals and rejections in both countries.

If the product has previously been approved for registration in either Australia or New Zealand but rejected for registration in the other country, the applicant may apply for an ANZTPA Product Licence but should identify and explain why the product was rejected in one country and provide reasons why an ANZTPA Product Licence authorising supply in both countries should now be issued or state why this information is not known to the sponsor. Each case will be considered on its own merits.

4. Determining Product Details and Documentation Requirements for Applications to Convert from Interim to ANZTPA Product Licences

The following sections provide further detail on the determining the product details to be included in applications to convert from Interim Product Licences to ANZTPA Product Licences and the documentation required to support the application.

It should be noted that, in general, only product details previously approved in one country or the other can be included on the ANZTPA Product Licence. Changes to product details can only be made through the product licence conversion process where these are necessary to meet ANZTPA requirements. A sponsor wishing to make other changes should first obtain an ANZTPA Product Licence using the process described in this guideline, then submit an application to vary that product licence through the normal ANZTPA product licence variation mechanism.

If the product being transitioned is not identical to the Australian or New Zealand product (other than in respect of changes necessary to meet ANZTPA requirements), the application will be rejected.

4.1 Product formulation

Where there is only one Interim Product Licence authorising supply of the product in either Australia or New Zealand, the formulation proposed for the ANZTPA Product Licence must be the same as that previously approved.

Where there are two Interim Product Licences for the same product (one for Australia and one for New Zealand) and the registered formulations are identical, the formulation proposed for the ANZTPA Product Licence must be the previously approved formulation.

Where there are two Interim Product Licences and the products have different formulations, the applicant may propose either formulation in the application for an ANZTPA Product Licence. Alternatively, the applicant may wish to apply for two separate ANZTPA Product Licences for the two formulations. In this case, different product names will be required to distinguish between the different formulations and the sponsor should contact the ANZTPA for further advice.

4.2 Site of manufacture

Only manufacturing sites (and processes carried out at those sites) approved by either the TGA or Medsafe and meeting ANZTPA requirements will be accepted in an application to convert from an Interim to an ANZTPA Product Licence. A subsequent application to vary the ANZTPA Product Licence will be required to add new sites of manufacture.

The name and address of each site and the manufacturing steps carried out at each site are to be included in the application form, together with a declaration that a current and valid GMP clearance is held for each site. Applicants should not include previously approved manufacturing sites if they are no longer required.

The applicant should provide a declaration that both the formulation and its method of manufacture are the same as currently registered in Australia and/or New Zealand. Manufacturing process and control data should not be submitted during the licence conversion process.

Where the same ingredient manufacturers and finished product manufacturers, packers, sterilisers and quality control testing sites are approved in both countries, those approvals may be carried over automatically to the ANZTPA Product Licence. However, the applicant should confirm (or provide supporting evidence) that each site has acceptable and up-to-date GMP status that meets ANZTPA requirements. Where this cannot be provided, that site should not be included in the application.

If there are different sites approved for Australia and New Zealand, the applicant may apply to have all of the sites approved provided there is up-to-date evidence of acceptable GMP for each site for the operations carried out.

For prescription medicines, evidence of acceptable GMP may be a cross reference to evidence on a TGA or Medsafe file or database (where that evidence is still current and valid), a current ANZTPA manufacturing licence, a previous TGA GMP clearance that is still current, or a new or updated GMP certificate from a recognised overseas regulatory authority.

For OTC and complementary medicines, applicants must provide a valid pre-clearance number for each finished product manufacturer. Expired GMP clearances should be renewed before the ANZTPA Product Licence application is submitted. Evidence of the GMP status of manufacturers of starting materials need not be submitted. However, these manufacturers should be specified in Part C of the electronic application form. It is the responsibility of the manufacturer of the finished product to ensure that all starting materials (actives and excipients) are manufactured to an acceptable standard of GMP.

4.3 Quality control specifications

The applicant will need to ensure that the specifications for the active and inactive ingredients, finished product and packaging comply with the standards set in Managing Director's Orders. This may, in some cases, require changes to be made to the currently approved specifications.

4.4 Specifications for active ingredients and finished product

Where only one Interim Product Licence exists for a product, or where there are Interim Product Licences under which the specifications for the active ingredient(s)/finished product are identical, these specifications must be applied to the product for which the ANZTPA Product Licence is being sought (subject to any necessary modifications to meet applicable standards set by Managing Director's Orders).

Where there are two Interim Product Licences with differences in the approved active ingredient or finished product specifications, the applicant should choose one or other set of specifications, and may make only those changes that are required in order to meet ANZTPA standards. Where one set of specifications is more stringent or comprehensive than the other, this set should be chosen for the ANZTPA Product Licence unless an alternative approach can be justified (with supporting information). There may be a particular test requirement currently required in one country but not the other. This requirement should be carried over to the harmonised specifications providing it is consistent with ANZTPA guidelines or Managing Director's Orders.

4.5 Specifications for excipients

Specifications for excipients approved in both countries are usually pharmacopoeial but can be "in house" provided they adequately control the relevant quality parameters.

If there is only one Interim Product Licence, or there are two Interim Product Licences under which the specifications for the excipients are identical, these specifications must be applied to the product for which the ANZTPA Product Licence is being sought (subject to any necessary modifications to meet ANZTPA standards set by Managing Director's Orders).

Where there are two Interim Products Licences with differences in the approved excipient specifications, one or other set of specifications should be chosen. The only permissible modifications to that set of specifications will be those that are required to meet ANZTPA standards.

Where one set of specifications is more stringent or comprehensive than the other, this set should be chosen for the ANZTPA Product Licence unless an alternative approach can be justified (with supporting information).

4.6 TSE and virus requirements

If a product contains an ingredient of animal or human origin, the application should include the appropriate declarations (or references to previous declarations or evidence provided to the TGA or Medsafe) about the product's compliance (e.g. its sourcing, preparation and processing) with ANZTPA requirements regarding freedom from TSE agents and hazardous viruses. These requirements will be set out in ANZTPA guidelines.

4.7 Packaging

Where the packaging specified under two Interim Product Licences for a product is different, the applicant should decide which packaging (both the immediate container and the primary pack) is to be used for the product for which the ANZTPA Product Licence is being sought. The packaging selected for the product must comply with any applicable ANZTPA standards contained in Managing Director's Orders.

Because Australia and New Zealand have significantly different climates (New Zealand lies within ICH Climatic Zones I and II, whereas Australia falls within Zones II, III and IV), the approved packaging for a particular product may have been different in each country. Where the climatic conditions significantly influence the stability of a product, packaging suited to Australian conditions is likely to be as protective as, or more protective than, that needed for New Zealand conditions and should therefore be used for the product covered by the ANZTPA Product Licence.

4.8 Shelf life and storage conditions

For many products approved in both Australia and New Zealand, the shelf life and storage conditions are already harmonised.

When seeking an ANZTPA Product Licence for a product for which there is only one Interim Product Licence, or for which there are two Interim Products Licences with the same product shelf life and storage conditions, the applicant should specify the currently approved storage conditions and shelf life in the application.

Where there are two Interim Product Licences with different shelf life and storage condition statements, the less restrictive set of requirements (i.e., longer shelf-life/higher storage temperature) may be adopted for the ANZTPA Product Licence. In such cases, the shelf life and storage conditions approved in one country must be used together.

An applicant will not, as part of the process of converting from an Interim Product Licence to an ANZTPA Product Licence, be able to seek a longer shelf life for a product than that previously approved in either country. The applicant must first obtain an ANZTPA Product Licence using the previously approved shelf life, before submitting a Product Licence Variation application for a shelf life extension.

The required ANZTPA labelling statements for storage conditions will be set out in a Managing Director's Order.

4.9 Indications

Where a product has previously been approved in Australia and in New Zealand, there will be two Interim Product Licences. In some cases, the approved indications for the product may be different in the two countries.

If the indications approved in Australia and New Zealand are not substantially the same, the sponsor may either:

- choose to adopt the narrower range of common indications for the ANZTPA Product Licence. In this case, the sponsor will need to submit details of the indications approved in the two countries and provide a statement that the narrower set of indications is accepted by the sponsor; or
- submit information relating to approval of the additional indications in the broader range of indications. The information required will depend on the history of approval of the indications, but may include MAAC, MEC or ADEC minutes, or evidence of approval of the indication(s) in other countries.

The following is a guide to the process for applying for an ANZTPA Product Licence where the applicant is seeking inclusion of the broader range of indications.

Scenario 1: *Indication approved in one country, no application for that indication EVER considered in the other country*

The ANZTPA Product Licence will be able to include an indication approved only in one country, provided no application for that indication has ever been considered in the other country.

Example: Company X chose to apply to extend the indications for Product A in Australia but not NZ. An application was lodged with the TGA but not with Medsafe and an extension of indications was approved in Australia. No application was ever lodged in NZ. Company X may have the extended set of indications included under the ANZTPA Product Licence for Product A.

Example: Company X chose to apply for a certain set of indications for Product A in Australia but applied for a wider set of indications in New Zealand. No application was EVER made to the TGA to extend the indications in Australia to match those approved in New Zealand. Company X may have the broader New Zealand-approved set of indications included under the ANZTPA Product Licence for Product A.

Scenario 2: *Same indications applied for in both countries but not approved EXACTLY as per application in one country*

If an application to extend the indications for a product has previously been submitted in both countries and approved as per the application in one country but not in the other, and the sponsor wishes to use the broader set of indications on the ANZTPA Product Licence, the sponsor will need to provide a brief statement of the regulatory history of the product covering:

- Details of previous application(s) made to the TGA or Medsafe for approval of the indication(s) concerned;

- An explanation for why approval may previously have been sought and/or granted only in one country;
- Details of any application(s) withdrawn and the reasons for such withdrawal;
- Copies of TGA or Medsafe evaluation reports, ADEC or MAAC minutes and TGA or Medsafe approval (or rejection) letters regarding the indication(s) concerned; and
- Evidence that the indication(s) concerned has been evaluated and approved by other comparable regulatory authorities in the European Union, Canada or the United States of America, together with a copy of the approved product information document from those countries.

For example: *Company Y markets Product B in Australia and New Zealand. In Australia, Company Y applied for an extension of indications and this extension was granted exactly as stated in the application. In New Zealand, Medsafe did not agree to extend the indications in full, extending it in a smaller class of patients. Company Y will not be automatically able to include the extended, Australian indication for Product B. If the indication is to be included as part of the full licence application, additional information will be required (see above). Alternatively, the company may use the more restrictive (NZ) indications.*

Scenario 3: Indications have been narrowed in one country

In some cases, indications for a product will have been narrowed in one country, while the original broader set of indications remains approved in the other country. A narrowing of indications may occur in response to new evidence of a poor risk–benefit profile, adverse events specific to a condition, submission of a Safety-Related Notification (SRN) or some other reason.

If the sponsor wishes to ‘reinstate’ the indication that was removed, the sponsor should submit a justification for including the broader set of indications at the time they apply for an ANZTPA Product Licence.

For example: *Company Z markets product C in Australia and New Zealand for conditions P and Q. After review by ADEC and ADRAC, the indication in Australia was narrowed, and now does not include condition P. In New Zealand, Medsafe chose to retain the indication. Company Z will not be automatically able to include condition P in the indications for Product C and a justification for including the broader set of indications should be submitted.*

4.10 Dosage and directions for use

Where the same dosage and directions for use have been approved in both countries, these should be used in the application. Where different dosages and/or directions for use have been approved in the two countries, the details proposed for the ANZTPA product licence must be consistent with those approved in one country or the other (not a combination of the two) with no extension of dose range, age range or other details.

4.11 Labelling

An application for an ANZTPA Product Licence must include a declaration of compliance with the ANZTPA labelling requirements set out in the Managing Director's Order and with any relevant ANZTPA guidelines.

The labels for co-marketed products (also known as 'clones') should contain the same information as the parent product apart from the brand name, product licence number and product licence holder details.

For Class 2 OTC and complementary medicines, a declaration should also be provided indicating compliance with labelling requirements in the Australia New Zealand Therapeutic Products Advertising Code. For Class 2 OTC and complementary medicines the applicant should also submit:

- a draft of the proposed label, marked to show changes from the currently approved Australian and New Zealand labels, and a justification for these changes; and
- copies of the currently approved Australian and New Zealand labels marked to show any differences between them.

4.12 The Product information (PI) document

A product information (PI) document (equivalent to the Australian "PI" or New Zealand "data sheet") will be required for every 'prescription medicine' and 'pharmacist only medicine' (see Part 7 of the Medicines Rule). The ANZTPA requirements for PI documents will be set out in an order and/or guidelines and will be based on the current Australian requirements for the PI. Data sheets for products approved only in New Zealand will need to be re-formatted of the Australian format has not already been adopted.

When applying for an ANZTPA Product Licence, the applicant will be required to submit a draft PI document and will also be required to submit documents to show how the draft was derived.

The proposed PI should incorporate the most recent, relevant and sound information available from the NZ Data Sheet and Australian PI. Where possible, text should be copied directly from the source document. Where this is not possible, new text should be clearly marked as such. New text should only be added for the purpose of complying with ANZTPA requirements. Other changes to the PI will require ANZTPA approval and a Product Licence Variation will need to be submitted after an ANZTPA Product Licence has been granted.

In addition to an electronic copy (in Microsoft Word or Rich Text format) of the referenced PI, the applicant should submit an electronic clean copy of the proposed PI and a declaration that the only changes made to the document were those necessary to meet ANZTPA requirements.

All contraindications, warnings and precautions included in either country's PI document must be included in the ANZTPA PI document. If an agency has previously agreed to the removal of a precaution, warning or contraindication, then details of that decision must be included with the application.

4.12.1 Products approved only in Australia

For products approved only in Australia, the previously approved PI should only require minor editing to include, for example:

- the structure of each active ingredient and its Chemical Abstracts Service (CAS) Number (where not already included);
- the New Zealand address of the licence holder.

4.12.2 Product approved only in New Zealand

For products approved only in New Zealand, the previously approved Data Sheet may require re-formatting, but should require little change to the actual content.

4.12.3 Products approved in both countries

For products approved in both countries, the applicant may choose to use either the Australia PI or the New Zealand data sheet as the source document, amended to meet ANZTPA requirements as described above.

Alternatively, the applicant may prepare a new draft PI document from the two existing documents. In this case, the referenced PI should state the source document (Australian PI or New Zealand data sheet) that provided the information, including the heading under which the information appears in that source document. The ANZTPA may request justification for any changes made.

PI and CMI documents are not required for 'pharmacy only' and 'unscheduled' medicines. Where a PI and/or CMI is available for such a product, draft documents must be included in the application for the ANZTPA Product Licence. These documents must comply with all relevant requirements for PI and CMI and must be consistent with the product details.

The product information document and CMI for co-marketed (also known as 'cloned') products should contain the same information as those of the parent product apart from the Brand Name and other brand-specific information about the product's description, presentation licence holder, scheduling and date of approval.

The draft product information document submitted with an application to convert from an Interim to an ANZTPA Product Licence will be approved with granting of the ANZTPA Product Licence. Where a submitted draft is not acceptable, further information may be sought from the applicant and advice may be sought from an expert advisory committee.

The Product Licence Number and new date of approval for the PI should be added prior to publication.

4.12.4 Generic medicines

The product information document for a generic medicine is often derived from that of an innovator product, although there is no regulatory requirement for the documents to be the same. The generic medicine sponsor must submit a draft PI for the generic medicine that meets ANZTPA requirements. As for any other medicine,

the product information for a generic medicine should contain all information relevant to the safe, appropriate use of the medicine.

4.13 The Consumer Medicine Information (CMI) document

A Consumer Medicine Information document (“CMI”) based on, and consistent with, the approved product information document will be required for most prescription medicines (see part 7 of the Medicines Rule). The ANZTPA requirements for CMI documents will be set out in guidelines based on the current New Zealand guidelines. When applying for an ANZTPA Product Licence the applicant will be required to submit:

- an electronic copy of the proposed CMI document (in Microsoft Word or Rich Text Format) based on the new draft product information document; and
- a declaration that the proposed Consumer Medicine Information is consistent with the proposed product information document and meets ANZTPA requirements.

4.14 Bioequivalence and interchangeability

The ANZTPA Product Licence application for a generic medicine should clearly state whether the generic medicine is interchangeable with the corresponding innovator product(s) (or market leader if appropriate) in Australia and/or New Zealand. If a generic is not interchangeable in one of the two countries, there must be a suitably worded warning statement such as "Not interchangeable for any other brand in (either) Australia/New Zealand" on the product label and in the product information document.

The information required to be submitted with an application to convert from an Interim to an ANZTPA Product Licence for a generic medicine will vary, depending on whether the generic medicine has been approved in one country or both, and its status with regard to interchangeability.

Where there are two or more brands of a medicine registered in a particular market, but none is the true “innovator product”, the “market leader” is the reference product for bioequivalence and interchangeability purposes.

4.14.1 Applications for which additional data to support interchangeability are not required

Identical product registered in both countries

No additional data to support interchangeability is required for applications to convert from an Interim to an ANZTPA Product Licence where:

- an innovator product is to be marketed under different brand names by the same company or different companies. In this case, the two products will be interchangeable and either can be a reference product;
- a generic product is supplied in both countries and marketed under different brand names by the same or different companies. In this case, whatever

interchangeability status applies to the "parent" generic product for which bioequivalence data were submitted to the TGA and/or Medsafe will also apply to the co-marketed generic product; or

- a generic product is distributed in both countries by the same company or by companies that are effectively the same organisation and can share the necessary supporting data, and the generic product is considered interchangeable with the corresponding innovator product in both Australia and New Zealand. In this case, that interchangeability status can be carried through to the ANZTPA Product Licence irrespective of which innovator (Australian or New Zealand) version is marketed in the future in either or both countries.

Where a generic product with the same formulation is registered in both countries but by different companies that have no commercial relationship, these companies and the manufacturers concerned will need to work out amongst themselves who will have the marketing rights in which country, who will apply for the necessary ANZTPA Product Licences, what the brand names will be, and who will have the rights to use any bioequivalence data. The ANZTPA will not concern itself with commercial disputes between different companies.

4.14.2 Applications for which additional data to support interchangeability are required

Different generic formulations registered in the two countries by the same company

Where a company markets different formulations of the same generic medicine in the two countries and the formulation in one country cannot be assumed to be bioequivalent to the innovator product in the other country, the company will need to decide which formulation(s) it wishes to market in the future.

If the applicant decides to discontinue one formulation, for example, the current formulation on the New Zealand market and replace it with the current "Australian formulation", the applicant will need to provide evidence that this formulation is interchangeable with the New Zealand innovator product (if still available) or the market leader. This evidence might be data to prove that the Australian and New Zealand innovator/market leader formulations are identical or are so similar that bioequivalence can reasonably be assumed.

Where a bioequivalence linkage between the groups of products in the two countries is not possible, (e.g. because the New Zealand innovator formulation is no longer available) the applicant may need to carry out a new bioequivalence study to confirm bioequivalence between the generic formulation and the leading generic brand in New Zealand. Otherwise, the current New Zealand generics may be interchangeable with each other but the new generic from Australia will not automatically be interchangeable with the other New Zealand generics.

Alternatively, the sponsor could elect to include a suitably worded warning statement such as "Not interchangeable for any other brand in (either) Australia/New Zealand" on the product label and in the product information document.

An ANZTPA Product Licence will authorise supply of a product in both countries. If the sponsor wished to obtain two ANZTPA Product Licences (using different brand names) and market one product only in Australia and one product only in New Zealand, the bioequivalence and interchangeability issues described above will still need to be resolved for each product.

Generics registered in only one country

If a sponsor wishes to claim bioequivalence and interchangeability for a generic product that is registered in either Australia or New Zealand (but not both), the application to convert from an Interim to an ANZTPA Product Licence will need to include evidence that the generic product is bioequivalent to the corresponding innovator product in the other country, or, if that is not possible because the innovator product is no longer available in that country, the applicant may need to provide evidence that it is bioequivalent to the leading generic brand marketed in that country. Alternatively, the sponsor may elect to include a suitably worded warning statement such as "Not interchangeable for any other brand in (either) Australia/New Zealand" on the product label and in the product information document.

4.14.3 Other interchangeability issues

Medicines currently non-interchangeable in both New Zealand and Australia

For medicines deemed to be non-interchangeable in both countries (e.g. warfarin, phenytoin), the sponsor will be able to apply for an ANZTPA Product Licence authorising supply in both countries, but non-interchangeability will be maintained and a suitable statement will be required on the label and in the product information document.

Medicines currently non-interchangeable in New Zealand but interchangeable in Australia

These medicines will be regarded as interchangeable when supplied (in either Australia or New Zealand) under the authorisation of an ANZTPA Product Licence.

OTC or complementary medicine generics

Where a generic OTC or complementary medicine has been approved in either Australia or New Zealand without bioequivalence data, these data will not be required to support an application for an ANZTPA product licence.

TRANSITION TO THE JOINT REGULATORY SCHEME FOR MEDICAL DEVICES

Introduction

Transitional arrangements will be required to give sponsors and manufacturers of medical devices in Australia and New Zealand time to achieve compliance with regulatory requirements under the joint scheme to be administered by the Australia New Zealand Therapeutic Products Authority (ANZTPA). These arrangements will be based on the principles set out in the Agreement².

Defined Transition Period

The transition period for medical devices is three (3) years from the commencement of the joint regulatory scheme.

Interim Product Licences

- A sponsor who is legally supplying medical devices in Australia or New Zealand prior to commencement of the joint scheme will be issued with an interim product licence.
- If a medical device being supplied in New Zealand prior to commencement of the joint scheme is included on WAND, the sponsor of the product will be issued an interim product licence authorising continued supply in New Zealand only.
- If a medical device is included on the Australian Register of Therapeutic Goods (ARTG) prior to commencement of the joint scheme, the sponsor of the product will be issued an interim product licence authorising continued supply in Australia only.
- An interim product licence will be valid until the end of the transition period.
- An interim product licence will authorise the continued supply of the medical device only in the jurisdiction in which it was previously being lawfully supplied.
- If the holder of an interim product licence wishes to continue supplying the medical device beyond the transition period, they must apply for and obtain an ANZTPA product licence and must meet all the requirements of the joint scheme.
- Following commencement of the joint scheme, anyone who supplies a medical device (other than one which is specifically exempted from product licensing), without holding either an interim or an ANZTPA product licence authorising them to do so, will be acting unlawfully and will be exposed to potential enforcement action by the Authority.

² The *Agreement between the Government of Australia and the Government of New Zealand for the establishment of a joint scheme for the regulation of therapeutic products*.

NEW ZEALAND

Interim Manufacturing Approvals for Manufacturers Not Previously Required to be Licensed

- New Zealand manufacturers of medical devices who:
 - are lawfully manufacturing medical devices prior to commencement of the joint scheme; and
 - do not hold a manufacturing licence because they are not required to do so,will be permitted to continue their manufacturing activities until the end of the transition period.
- An interim database of unlicensed manufacturers will be established prior to the commencement of the joint scheme to record the details of these manufacturers.
- During the transition period, an Interim Product Licence (authorising supply in New Zealand only) will be granted for a medical device that is manufactured by a New Zealand manufacturer after commencement of the scheme, provided ANZTPA labelling and advertising standards are met.
- Manufacturers wishing to continue manufacturing medical devices beyond the end of the transition period must, within 2 years of commencement of the joint scheme, apply to the Authority for an ANZTPA conformity assessment certificate. They must then meet all the requirements of the joint scheme so that a conformity assessment certificate can be granted before the end of the transition period.

AUSTRALIA

Interim Conformity Assessment Certificate

- Any manufacturer who is required to hold a valid conformity assessment certificate issued by the TGA prior to commencement of the joint scheme will be issued an interim conformity assessment Certificate. Interim conformity assessment certificates will be valid for the transition period.
- If the holder of an interim conformity assessment certificate wishes to continue manufacturing the medical devices beyond the end of the transition period they must, before the end of the transition period, apply to the Authority for an ANZTPA conformity assessment certificate and must meet all the requirements of the joint scheme.

Manufacture of Class I (non-sterile, non-measuring) medical devices

Manufacturers who produce only Class I medical devices that are not supplied sterile and do not have a measuring function, do not need a conformity assessment certificate to continue their manufacturing activities under the joint regulatory scheme.