

**RMI Submission on the
Guidelines for Transition to the Joint Regulatory
Scheme for Class 2 Medicines**

PREAMBLE

The Researched Medicines Industry Association of New Zealand (RMI) is the professional and trade organisation of New Zealand’s research-based pharmaceutical industry. Its 18 member companies are engaged in the research, development, manufacture and marketing of prescription medicines and the ongoing improvement of medical and scientific knowledge about their products.

SUBMISSION

1. Transition period of 3 years for industry.

- 1.1 At commencement of the joint regulatory scheme, medicines with consent to distribute in New Zealand will be granted an Interim Product Licence allowing continued supply of the medicine in New Zealand for the duration of the transition period.
- 1.2 The proposed Guidelines state that the transition period will be 3 years (p.7) and that “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 supplying the product after the end of the transition period” (p. 8).
- 1.3 The RMI considers the proposed 3 year time frame is insufficient for industry to harmonise existing approvals, apply for and receive approval for full ANZTPA Product Licences. This is especially so where product ranges are extensive, a product is a low priority and/or there is a significant lack of conformity between the existing approvals in New Zealand and Australia.
- 1.4 To meet the information requirements for a straight forward conversion from two Interim Product Licences to an ANZTPA Licence (including supporting documents and data) will require a significant investment in time. In addition to collating existing material, the licence holder will need, as appropriate, to update specifications to ANZTPA requirements and to generate new material to meet ANZTPA requirements for labelling, Product Information, Consumer Medicine Information and Package Insert. Licence holders may also need to provide additional information to justify decisions relating to choice of specifications or to include a broader range of indications.

- 1.5 The time required to prepare an application for an ANZTPA product Licence will increase markedly when the medicine concerned has had an application for approval (of the medicine or of an indication) rejected or recommended for rejection and withdrawn in one country. In addition where significant differences exist in respect to safety information the ANZTPA PI will involve a significant re-write.

The RMI recommends that there be a 5 year transition period for product licence holders to apply for and be granted a full ANZTPA Product Licence.

2. Transition period of 3 years for the Authority.

- 2.1 The RMI also considers that a 3 year transition period will be insufficient for the Authority to process all applications for ANZTPA Product Licences especially where an application may require some evaluation. Indeed, the Joint Agency Establishment Group itself acknowledges in the May 2006 Fees and Charges consultation document (para 128) that "...there remains considerable uncertainty regarding the actual number of licences to be issued under the joint scheme (interim and full Authority licences) and the rate of transition...". In addition it is noted that transitional work in assessing interim product and manufacturing licences for conversion to full ANZTPA licences will be performed from within Authority staffing levels (para 71).
- 2.2 Despite the proposal that full ANZTPA licences must be applied for and granted within the transition period, there is no indication in the Guidelines of the timelines for approval of applications for a full ANZTPA licence by the Authority. This further supports the view that the JAEG cannot determine the workload the Authority will face in assessing applications for full ANZTPA licences and cannot, therefore, realistically commit to meeting their obligations to process all applications within the transition period.

Thus, the RMI strongly recommends that the transition period for application and granting of an ANZTPA Product Licence be 5 years and that the product remains legally able to be supplied under an Interim Product Licence until the application is granted (or otherwise) by the Authority.

- 2.3 The RMI understands the desire to complete the transition to a single regulatory authority as quickly as possible. However, imposing an unrealistic timeframe to ensure companies do not "drag their feet" in applying for an ANZTPA licence is not the answer.

3. Transition period for product in the market place.

- 3.1 Following the granting of a full ANZTPA Product Licence, product in the supply chain for each country will, to some degree, be non-compliant with the ANZTPA licence - this may be limited to non-compliant labelling or be more significant such as different formulations in each market. There will by necessity be a lead time (subject to a variety

of factors including batch size, sales volumes, etc) until product fully compliant with the ANZTPA licence can be supplied. For example, industry experience from mergers has shown that it takes up to 3 years to phase out existing labelled stock and introduce new labelling.

The RMI, therefore, strongly recommends that this issue is covered in the transition guidelines and proposes a 3-year phase in period for stock following the granting of an ANZTPA Product Licence to ensure continuity of supply and to minimise write-offs.

4. Documentation required for ANZTPA licence application.

- 4.1 The RMI also has a number of concerns re the information requirements (including supporting documents and data) to convert from an Interim to a full ANZTPA Product Licence.
- 4.2 A particular issue is the time and difficulty involved in determining the regulatory history of older products which may have been grandfathered and/or have had a number of sponsors over time.

The RMI recommends, therefore, that consideration be given to limiting the time period over which the regulatory history is required by the Authority.

5. Costs associated with converting to an ANZTPA Licence

- 5.1 Industry has also expressed concern regarding costs associated with converting from an Interim Product Licence to a full ANZTPA licence. The RMI acknowledges and supports the JAEG's Proposal 33 in the Fees and Charges Consultation Paper: that " the Authority will not charge a fee to convert from an interim product licence to a full ANZTPA product licence, provided the application does not require an evaluation to be undertaken" .
- 5.2 However, it is not clear from the guidelines what is considered to be "evaluation" and the RMI seeks clarification from the JAEG regarding this. For example, will approval of draft Product Information, which is a hybrid of the existing New Zealand data sheet and Australian PI, attract a fee for evaluation?

The RMI strongly recommends that the cost structure, and the associated timelines for approval, for applications for a full ANZTPA licence which require evaluation be promulgated as soon as possible to allow companies to budget for these charges.

- 5.3 If companies are unable to effectively budget for these costs, the transition of products from Interim to full ANZTPA Product Licences will be delayed and this will have a negative impact on the ANZTPA's workflow and cashflow.

6. Variations to Interim Product Licences

- 6.1 At the recent ANZTPA Information Meetings it was evident that the JAEG do not anticipate that variations would be performed on interim licences. Sponsors would need to wait until the ANZTPA Licence was granted before making submissions to change registered details.
- 6.2 At a minimum, CMC variations must be permissible in order to ensure continuity of supply. Manufacturing changes are constantly being made i.e. manufacturing sites / equipment / methods. Approval of these changes cannot be delayed because harmonisation is incomplete or there is clinical evaluation which needs to be performed to gain an ANZTPA licence.
- 6.2 Short supply situations, albeit not a common occurrence, do happen and industry needs to be able to perform variations to ensure continued supply from both a contractual and patient safety perspective.
- 6.3 In addition, important safety related issues need to be able to be acted on i.e., urgent Product Information safety updates.

The RMI strongly recommends that the proposed transition guidelines are updated to include the capacity to perform variations on interim product licences. At a minimum, the Authority must allow variations for manufacturing changes and safety updates to ensure continued supply and patient safety.

7. NZ Licences with Provisional Consent or Labelling Exemptions

- 7.1 The RMI notes that no information is given to outline how New Zealand products with provisional consent and or labelling exemptions that expire post the issue of an interim licence (but before the end of the transition period) will be handled.

The RMI recommends that on issue of an interim licence, products which are subject to provisional consent or a labelling exemption, are given one expiry date i.e., the provisional consent or labelling exemption expires at the same time as the interim licence.

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