

RMI Submission on the Australia New Zealand Therapeutic Products Regulatory Scheme (Medicines) Rule 2006

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.

The RMI's submission is written in the context of the limited information available to stakeholders at the time. While the Rule is largely complete, the overarching legislation and the majority of technical orders are not available. Further, the Rule does contain a number of "Drafter's Notes" highlighting points to be addressed in the future.

Thus, the RMI anticipates the opportunity to be involved through further consultation in the ongoing drafting and finalising of the Medicines Rule.

SUBMISSION

AUSTRALIA NEW ZEALAND THERAPEUTIC PRODUCTS REGULATORY SCHEME (MEDICINES) RULE 2006

3.09 Provisional product licence

- (1) *If the Authority decides to not grant a product licence to an applicant in respect of a medicine, on the grounds that there is insufficient information about the safety or efficacy of the medicine available to justify the grant of a licence that is not provisional, but considers that:*
- (a) *there is clinical need for a medicine of that kind for the prevention or treatment of a life-threatening disease, disorder or condition; and*
 - (b) *the medicine offers a likely superior therapeutic benefit over existing treatments (if any); the Authority may grant to the applicant a provisional product licence in respect of the medicine.*

The RMI strongly supports the granting of a provisional product licence in respect of a medicine in the circumstances outlined in 3.09 (1). However, as the Rule is currently written, the suitability of a medicine for provisional licensing is solely at the discretion of the Authority. Consequently, this may deter applicants from applying for a product licence for a medicine with insufficient safety or efficacy data even though it fulfils (a) and (b) above, because of concern that the application will be rejected under 3.25 (2) (c).

Therefore, the RMI recommends that an applicant for a product licence, which fits the criteria in 3.09 (1), has the option to apply for a provisional licence.

3.09 Provisional product licence

(3) Subject to this Rule a provisional product licence has effect for:

(a) a period of 2 years from the date of its commencement....

And

(4) ...the Authority may extend the period mentioned....for a further period not exceeding 2 years from the expiry of the original period.

(5) A provisional licence that has been extended under subsection (4) cannot be further extended.

The RMI is concerned that circumstances may prevail whereby a licence holder is unable to generate sufficient safety or efficacy data within the maximum 4 year duration of a provisional product licence. To remove the medicine from the market could be considered unethical and if there is no alternative medicine available will compromise patient treatment. In such circumstances, and where the Authority is satisfied that the licence holder has been adequately meeting the requirements of subsection 3.09 (6) (a) regarding ongoing study and testing of the medicine, the RMI recommends that at the discretion of the Managing Director an extension of the product licence may be granted.

The RMI recommends that subsection 3.09 (5) be amended to:

“A provisional licence that has been extended under subsection (4) cannot be further extended except on the order of the Managing Director where clinical need has been established

3.28 Reduction of evaluation fee where evaluation period exceeded

(1) If the evaluation of a Class 2 Medicine (other than an evaluation to which section 3.30 applies) is not completed within 255 working days after notification under paragraph 3.26 (3) (b), the applicable total evaluation fee under section 3.27 is reduced by one quarter.

The RMI supports legislating the timeframe by which an evaluation for a Class 2 Medicine must be completed. However, the RMI is disappointed that the nominated evaluation period of 255 working days is greater than that of other international regulatory bodies i.e. the proposed evaluation period does not meet international best practice.

The RMI recommends that for the licensing of Class 2 medicines the evaluation period meets international best practice – the stipulated review time (excluding clock stops) by the EMEA is 210 days for new medicine applications.

3.31 Priority evaluation

The RMI supports the Authority giving priority to the evaluation of a Class 2 medicine under the conditions outlined in 3.31 (1).

The RMI recommends that an applicant for a product licence, which fits the criteria in 3.31 (1), has the option to apply for priority evaluation.

Additionally, there are instances where it may be justified for a priority evaluation for a new indication for an existing medicine and the other aspects of subsection 3.31 [(b), (c) and (d)] apply.

The RMI recommends that subsection 3.31 is amended to include an application for a new indication

3.31 Priority evaluation

(2) A decision to give priority to an evaluation:

(a) does not require the Authority to complete the evaluation within a shorter period than if priority was not given to the evaluation

The RMI believes that a fundamental benefit of a priority evaluation option is that the evaluation is completed in a shorter period. Thus, to maximise the value of a priority evaluation option under the Authority, a time frame, which is shorter than the standard period, should be stated in the Rule.

The RMI recommends that the Authority be required to complete an evaluation given priority within a shorter period than if priority was not given.

3.42 Conditions applicable to all product licences

Offshore manufacturing

(13) (a) (iii) if evidence delivered to the Authority under subparagraph (ii) ceases to be current – deliver to the Authority, within 20 working days after the evidence ceases to be current, a copy of the evidence that is updated and current;

The timeframe of “within 20 working days after the evidence ceases to be current” does not reflect the reality of current overseas practice where audits are not consistently conducted on time and after the audit the evidence is not provided by the regulatory authority in a timely manner. 90 calendar days would be a more realistic timeframe.

The RMI recommends that 3.42 (13) (a) (iii) be amended to read as follows:

“if evidence delivered to the Authority under subparagraph (ii) ceases to be current – deliver to the Authority within 90 calendar days after the evidence ceases to be current, a copy of the evidence that is updated and current”

3.49 Variation – Class 2 medicine

Variations to Class 2 medicines (with the exception of those covered in *Section 3.50 – shorter evaluation period in certain cases*) have a default time-line of 255 working days which is not in line with international best practice. The stipulated review times for variations under the EMEA are 30, 60 or 90 days.

The RMI recommends that timelines for evaluation of variations are stipulated within the Rule and that these timelines meet international best regulatory practice.

The RMI also notes that the criteria for variations in the draft Rule are much the same as those currently in force under the TGA. Such changes as minor clinical amendments to Product Information for safety related updates which do not fall under the criteria outlined in Section 3.49 (2) or (3), must be evaluated in the standard 255 working days timeframe. For small changes this evaluation timeframe is excessive. Safety changes which require evaluation should be available to prescribers in a reasonably short timeframe and not 255 working days as with the current TGA process.

The RMI recommends that there should be an additional category for minor clinical/safety changes not meeting the criteria of 3.49 (2) or (3) which are evaluated within a timeframe commensurate with the complexity and volume of data provided i.e. a timeframe of 90 calendar days

5.06 Medicine used for an experimental purpose (Clinical Trial Assessment Scheme)

And

5.07 Medicine used for experimental purpose (Clinical Trial Certification Scheme)

A feature of the current New Zealand system is the speed with which clinical trial applications are approved. This provides a competitive edge internationally.

The RMI recommends that the Rule stipulates that scientific review of Phase 1 trials is completed within 21 calendar days and 30 calendar days for all other trials.

The RMI also recommends that scientific and ethics reviews are conducted in parallel.

The RMI supports trans-Tasman mutual recognition of scientific review of studies conducted under the Clinical Trial Certification Scheme where these are performed by either the SCOTT (Standing Committee on Therapeutic Trials, see below) in New Zealand or, in Australia, a scientific review committee approved by the Authority. If the scientific review is performed by an ethics committee which has not been approved by the Authority the RMI recommends that trans-Tasman recognition of the scientific review is limited to Phase IV studies only.

The RMI recommends that New Zealand retains the current Health Research Council structure for ethics review of the study protocol with scientific review conducted by the SCOTT.

The RMI recommends that the New Zealand specific legislation replacing the Medicines Act 1981 retains the role of the SCOTT.

The RMI opposes trans-Tasman mutual recognition of ethics reviews of clinical trials.

Part 10 Orphan medicines

*10.01 (2) For subsection (1), a disease or condition is **rare** if it is likely to affect not more than a total of 2,400 people in Australia and New Zealand at any one time.*

The RMI recommends that to maintain the ongoing currency of the definition of an orphan disease that it is stated in the Rules as a prevalence rather than the total number of affected individuals. Further, the definition of an orphan disease in the Rule should be consistent with international best practice.

The RMI recommends the prevalence for orphan disease designation be 7.5 affected individuals per 10,000 of population.

Dated : 14 August 2006