

**DISCUSSION PAPER: WORKFLOW PRACTICES WITHIN THE
DRUG SAFETY AND EVALUATION BRANCH (DSEB) OF THE TGA**

RESEARCHED MEDICINES INDUSTRY ASSOCIATION OF NEW ZEALAND

SUBMISSION JANUARY 2006

Debbie Wyber
Manager, Technical & Scientific Affairs
Researched Medicines Industry Association
19th January 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 19 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 acknowledges that while the Discussion Paper was initiated by the TGA, feedback provided will also flow through into the development of business practices for the Australia New Zealand Therapeutic Products Authority (ANZTPA). Our submission, therefore, is written in the context of an operational ANZTPA.

This submission follows the order of the Discussion Paper where "Options and Issues for Consideration" have been identified to streamline processes for evaluation of applications and to increase transparency of decision-making.

Application Entry Process (AEP)

The RMI strongly supports streamlining the AEP, reducing AEP timeframes and assisting ANZTPA to plan allocation of resources.

To achieve this objective, the RMI supports the following options identified in the Discussion Paper:

- Sponsors could provide 2-3 months' notice to the Australia New Zealand Therapeutic Products Authority (ANZTPA) of their intention to lodge an application, within a specified quarter. At this time, sponsors would submit an application summary with the minimum information needed to allow the ANZTPA to assess the resource requirements and identify any issues which may need to be addressed prior to submission.
- A pre-submission meeting to discuss the proposed application would be optional (and could be at the request of either the sponsor or the ANZTPA).
- At the time of making the application, sponsors would complete an administrative checklist and confirm that they have fulfilled all submission requirements (including any agreed outcomes from any pre-submission meeting).
- Applications would not be screened in accordance with a full Application Entry Process, as currently employed by the TGA, but would be accepted for evaluation within 10 working days.
- The RMI supports the current practice of priority evaluation of applications where the medicine is indicated for the treatment or diagnosis of a serious, life-threatening or severely debilitating disease or condition and there is clinical evidence that the medicine may provide an important therapeutic gain. The RMI recommends that the ANZTPA set a time limit for the evaluation of priority applications, as the EMEA proposes.

Additional Information and Data

The RMI supports the following options for streamlining the handling of applications, including requests for further data, to the advantage of both the sponsor and the regulator:

- Having a fixed evaluation period aligned with international best regulatory practice – the stipulated review time (excluding clock-stops) by the CHMP is 210 days for new medicine applications and 30, 60 or 90 days for variations (depending on type).
- Within a maximum of 135 days after commencement of the evaluation, the ANZTPA would supply a consolidated list of formal questions to the sponsor (rather than the current TGA practice of rolling Section 31 requests). Informal questions should continue to be raised on an ad hoc basis and the evaluation process continue (i.e. no stopping of the clock) while the sponsor is sourcing the answer to these informal questions.
- Notwithstanding the stated preference for a consolidated list, where there are significant differences among the evaluation areas in the time taken to complete the preliminary evaluation (as is the situation currently in New Zealand), there may be an advantage in receiving separate lists of questions from each evaluation area.
- The sponsor would be expected to respond to formal questions within an agreed timeframe, not normally exceeding 6 months.
- Where a major clinical question is asked, requiring the collection of new data that will take more than 6 months to obtain, a sponsor should not be required to withdraw the application (or have it rejected) unless the need for this data was flagged at a pre-submission meeting or as part of any Application Entry Process. (This would also apply, as appropriate, to questions asked by the ADEC/MAAC.)
- The preliminary draft evaluation reports should be provided to the sponsor at the same time as the consolidated list of formal questions. Supplementary data could be provided at the same time as the sponsor's response to the formal questions. This would streamline the process of responding to formal questions and the evaluation report and would be of advantage to both the sponsor and regulator.
- If, after evaluating the sponsor's response to the questions, the regulator requires more information, further questions may be put to the sponsor. However, any such questions must be directly related to the original consolidated list of formal questions and must not be "new" questions.

ADEC Process

Under the ANZTPA, the Australian Drug Evaluation Committee (ADEC) and New Zealand's Medicines Assessment Advisory Committee (MAAC) will be replaced by a single committee.

The RMI supports the following options to streamline the ADEC/MAAC process

- Sponsors should have the opportunity to provide additional information directly to the ADEC/MAAC during the meeting.
- Sponsors could elect to either have an appropriately qualified expert available to respond to any specific questions the Committee has regarding the application, or sponsors could make a 10 minute presentation to provide clarification of issues identified in the evaluation report and to respond to questions raised by the Committee.
- The Committee should be an expert advisory committee, not a representative committee, with members having expertise in medical practice, pharmaceutical chemistry, pharmacology, statistics or pharmacovigilance. This structure would mirror the structure of New Zealand's MAAC and is consistent with the terms of reference of the existing MAAC and ADEC.

Transparency

The RMI supports the following options for improving the transparency of the regulator's decision making processes to the benefit of both industry and consumers, while ensuring there remains appropriate protection of confidential commercial information:

- Publishing edited minutes of the ADEC/MAAC meetings or the full resolutions in relation to each application for registration (excluding confidential commercial information and negative resolutions).
- Publishing a summary of the decision made by the regulator's delegate and the rationale for that decision, except when the application has been rejected by the regulator.
- The Committee gives advice only and the final decision is made by the regulator. Thus, publishing both the Committee's advice and the

regulator's decision would enhance transparency. As negative decisions will not be published, the ADEC/MAAC advice should not be published until the regulator's decision is also published.

- The summary provided by the regulator could include the approval letter, provisional register record (currently the ARTG), CMI, PI, standard conditions of registration and particular conditions of registration.
- The RMI does not object in principle to the publishing of copies of the evaluation reports (edited to exclude confidential information). The FDA currently publishes edited reports. However, to do so would require a significant investment in time for both the regulator (which may impact negatively on evaluation timelines) and the sponsor. Further, under the cost recovery model proposed for the ANZTPA this would represent an additional cost to industry. Similarly, development of a document such as the EMEA's EPAR could also have significant resource implications.
- The RMI strongly supports publishing the CMI and PI on the regulator's website as this provides an up-to-date, regulated, single source for all CMI and PI which is publicly available and free of charge to the end-user.