

PROPOSED CLINICAL TRIAL REGULATORY ARRANGEMENTS UNDER THE AUSTRALIA NEW ZEALAND THERAPEUTIC PRODUCTS AUTHORITY

1. PREAMBLE

- 1.1 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.

2. CLINICAL TRIAL ASSESSMENT (CTA) SCHEME

- 2.1 The RMI agrees with the proposed list of criteria for clinical trials that will follow the CTA route, including trials in Australia or New Zealand involving the first administration in humans of a "new" substance(s).
- 2.2 It is proposed that all CTA applications will undergo a scientific review by the ANZTPA. The RMI recommends that the ANZTPA give consideration to allowing this review to be performed by third parties, accredited by the ANZTPA, such as the New Zealand HRC's Standing Committee on Therapeutic Trials (SCOTT).
- 2.3 A feature of the current New Zealand system is the speed with which clinical trial applications are approved. This provides a competitive edge internationally. However, the Consultation Document proposes that the ANZTPA will make a decision within 45 working days of receipt of the CTA application. Such a lengthy time to approval will impact negatively on the international competitiveness of New Zealand in attracting clinical trials, particularly Phase 1 trials.
- 2.4 The RMI, therefore, recommends that the maximum time frame for review of a CTA application by the ANZTPA be 21 working days. The RMI further recommends that there is no provision for the ANZTPA to "stop the clock" unless a sponsor takes more than 5 working days to respond to a question raised by the Authority.
- 2.5 The RMI strongly supports the proposal that the scientific review by the ANZTPA and the ethics review by the HREC(s) be conducted in parallel.

3. CLINICAL TRIALS CERTIFICATION (CTC) SCHEME

- 3.1 The RMI strongly supports the proposal that where an ethics committee in New Zealand requires assistance with the clinical or technical content of an application, the committee can refer the application to the SCOTT before making its decision.
- 3.2 What will need to be clarified under this proposal is how the costs of running the SCOTT will be met. Will they be funded from the CTC application fee or will payment by the sponsor to the HRC be required if an ethics committee refers an application to the SCOTT?

4. ETHICAL REVIEW

- 4.1 The RMI supports the requirement that clinical trials conducted in both Australia and New Zealand will still have to obtain approval from accredited ethics committee in each country.

Submission on behalf of the Researched Medicines Industry Association

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