

**CONSULTATION ON REGULATORY ARRANGEMENTS FOR CLINICAL
TRIALS AND ACCESS TO UNAPPROVED THERAPEUTIC PRODUCTS**

**RESEARCHED MEDICINES INDUSTRY ASSOCIATION OF NEW ZEALAND
SUBMISSION**

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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 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.

CLINICAL TRIALS UNDER A JOINT TRANS TASMAN REGULATORY AGENCY

The RMI strongly supports the retention of New Zealand's existing clinical trials approval process. Key features of the current New Zealand system are the emphasis on patient/volunteer safety and the speed and rigour of the review process.

Specifically, the retention of the SCOTT (Standing Committee on Therapeutic Trials) is important. The SCOTT performs the technical/scientific review and makes a recommendation about the safety of the medication AND the validity of the study protocol.

If, under a joint regulatory agency, all scientific reviews are done in Australia there is concern that the high level of expertise within New Zealand for the scientific review of clinical trials could be lost.

Under a joint regulatory agency, it will be possible to harmonise which trials require scientific review. The RMI recommends that scientific review should be confined to products or procedures that do not have an established safety record. This is also consistent with the current requirements under Section 30 of the Medicines Act 1981.

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 review recommends (R.10) the time frames for scientific

review of 21 calendar days for Phase 1 trials and 30 calendar days for all other trials. The RMI supports these time frames as maximum periods for the review of safety of the medication and validity of the protocol.

The RMI strongly recommends that scientific and ethics reviews continue to be conducted in parallel.

The RMI supports trans-Tasman mutual recognition of scientific reviews (safety and the validity of the protocol) performed by either the SCOTT or an approved "Scientific Assessment Panel" (SAP). Where scientific review is performed by an HREC, which is not a SAP, the RMI recommends that trans-Tasman recognition of this review is limited to Phase IV studies only i.e. validity of the protocol (if scientific review of Phase IV trials is required).

The RMI recommends retaining the current New Zealand Health Research Council structure for ethics review of the study protocol – with 6 regional ethics committees in addition to a national committee that provides ethics review of trials being conducted in more than one region. There are also a number of additional HRC accredited ethics committees.

The use of National Ethics Advisory Committee (NEAC) application forms provides consistency in the data provided to ethics committees (and reduces the costs of providing such data) and the RMI recommends that a standardised application form be used in both New Zealand and Australia.

In conclusion, the RMI strongly recommends the following:

- The Rules, under which the Joint Agency operates, clearly define those clinical trials for which approval must be sought
- The SCOTT is retained in New Zealand for the provision of scientific review of clinical trials (i.e. safety of the medication and validity of the study protocol)
- There is trans-Tasman recognition of scientific reviews conducted by either the SCOTT or a Scientific Assessment Panel only for all Phase I – III clinical trials
- New Zealand retains the current system of ethics review, including 1 multi-region/national and 6 regional ethics committees
- There is a common trans-Tasman application form for ethics review
- There is no trans-Tasman mutual recognition of ethics reviews
- Scientific and ethics reviews are conducted in parallel
- Maximum time frames for scientific review (safety and validity of the protocol) of 21 calendar days for Phase 1 trials and 30 days for all other

trials with the overall time to approval being no greater than currently legislated in New Zealand.

- The system should uphold ICH standards and guidelines without imposing unnecessary “local” requirements and follow internationally accepted audit and pharmacovigilance processes.

UNAPPROVED THERAPEUTIC GOODS NOT FOR USE IN CLINICAL TRAILS

The RMI supports the development of regulatory mechanisms that provide for the limited use of unlicensed medicines to individual patients under controlled conditions. In line with risk assessment principles, the level of regulatory control should be consistent with the potential risks to patients. The Australian Special Access Scheme (SAS) appears to provide an appropriate degree of protection for patients suffering from life-threatening and serious medical conditions. However, elements of the New Zealand “Section 29” system could be retained for supplies to patients suffering from less serious medical conditions.

CONCLUSION

We have the opportunity with the introduction of the joint trans-Tasman regulatory agency to further develop an internationally competitive market for clinical research with the highest standards of clinical research and patient safety. **To ensure New Zealand can retain and grow its clinical research industry, ongoing consultation with stakeholders, including the RMI and its member companies, will be necessary.**