



Ms Becci Slyfield
Support Officer
Clinical Risk Management
Medsafe
Ministry of Health
PO Box 5013
Wellington

30 November 2009

RE: REQUEST FOR COMMENTS ON PROPOSED UPDATES TO THE NEW ZEALAND GOOD CLINICAL RESEARCH PRACTICE GUIDELINE

Dear Ms Slyfield

Thank you for the opportunity to comment on the proposed New Zealand Good Clinical Research Practice Guideline.

NZBIO is New Zealand's national industry association representing bio-based industries and organisations. With approximately 300 members, NZBIO actively represents the interests of the scientists, entrepreneurs, investors, companies and service providers that are active in driving and supporting New Zealand's rapidly growing bioeconomy. NZBIO's members include a number of human therapeutics, diagnostics and medical technology companies, as well as a number of research organisations and service providers who are actively pursuing activities in clinical research and commercialisation.

With reference to the consultation document, we support the majority of the recommendations and would like to acknowledge the excellent work that has been done to date. We would also like to emphasise the importance of New Zealand being able to build a successful Clinical Trials Sector. In order to accomplish this we will need to work closely with our counterparts in Australia whose Clinical Trials Sector is already valued at \$AU450m per annum. A key to success will be ensuring that the New Zealand and Australian systems, regulations and processes are harmonised.

Page 5, Section 2.1.1, 3rd bullet point

"If any substance is administered to human beings for a therapeutic purpose as part of a trial where clinical endpoints are assessed...."

The nature of Phase I and IIa clinical trials is that they are conducted in healthy volunteers and/or patient groups. This is normally done to investigate the safety, pharmacokinetic or pharmacodynamic properties of the drug and as such are not considered "therapeutic" trials. Current wording provides some ambiguity relating to these trials and generates a potential 'loop-hole' around which it could be argued that approval under Section 30 of the Medicines Act is not required.

Page 5, Section 2.1.1, 4th bullet point

We support a robust regulatory framework for clinical trials involving medical devices, most notably Class II & III devices, to ensure patient safety and efficacy. We also recognise that due to the nature of medical devices and the large range and diversity of products, that it will be important to ensure that the regulatory process does not limit the ability for medical devices to continue to be trialled in New Zealand. We do believe that proposed notification to Medsafe by email of such trials being conducted could be strengthened. We would suggest that a system of Medical Device Clinical Trial Register, or similar, is initiated. We also suggest that ethical approval for such trials be given subject to evidence of registration of the trial with Medsafe.

Page 7, Section 2.1.4, Table

We believe that further consideration could be undertaken to clarify when SCOTT approval is required. In some instances it could be interpreted as incongruous with the need for scientific assessment and safety of the clinical trial. For example, a medicine registered for use at dose 'x' in an adult population, which is then proposed for a clinical trial at lower dose 'y' in a paediatric population requires approval under s30 of the Medicines Act, based on the use of the unapproved dose, rather than its use in a different population. If the approved dose 'x' were to be used in the paediatric population, the trial would proceed with no regulatory assessment, which could expose patients to side-effects.

Similarly, a new indication or dosage regimen does not require SCOTT approval; however, there may be significant toxicity implications with regard to total exposure in some of these cases.

Page 8, Section 2.2

NZBIO supports the principle of an accreditation scheme for clinical trial sites, particularly for Phase I units, to bring the local requirements in line with international standards (e.g., Medicines and Healthcare Regulatory Agency, MHRA), but we would like to make the following observations.

We do not wish to create a significantly more restrictive environment within New Zealand which may in the long-term discourage placement of clinical trials in this country. Therefore we would recommend that a system similar to that in the UK, be considered

To ensure that clinical trials held in New Zealand attract both international and local investors it will be important to ensure that the regulations and their implementation are both transparent and in line with international practice.

It will be important that all information provided to Medsafe for this purpose is not only maintained in confidential manner but it is also perceived to be maintained in a confidential manner. To achieve this all potential conflicts of interest will need to be eliminated from the process.

Page 11, Section 2.3.4, paragraph 3

We are aware due to the size of the sector there is the potential for perceived conflicts of interest in relation to the approval of clinical trials. It will be important going forward to ensure that the playing field for all applicants is both perceived to be and is fair and equitable.

To achieve this we would recommend that following the recommendation of SCOTT to the Director-General, the applicants are furnished with a list of the reviewers involved in the application as well as any declarations of conflict of interest.

We would also recommend that if a trial is declined an appeal process is put in place to facilitate further discussion around the decision.

Page 12 Section 3.1, 4th paragraph

"The principal investigator should be resident in New Zealand, competent in the field of study as evidenced by curriculum vitae, and have qualifications and experience recognized within New Zealand."

In line with NZBIO's objective to ensure that New Zealand is an international player in this sector, we support the requirement for suitably qualified and experienced principal investigators, registered with the New Zealand Medical Council, in all areas of clinical research. We caution against this section excluding valuable specialist skills acquired overseas.

In line with our earlier stated objectives of being able to compete on the world stage and being involved in leading edge technology, we are concerned that this current requirement could severely hamper international leaders in the field coming to New Zealand and New Zealand experts going offshore to seek international experience and qualifications.

The economic viability of the sector is dependent on New Zealand being recognised internationally as a place where international experience is valued and supported and the current emphasis could lead to the exclusion rather than the inclusion of specialist knowledge.

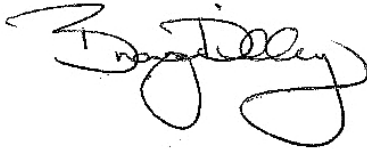
As identified in the Primorus submission, the requirement for an NZ recognised qualification would exclude the Diploma in Pharmaceutical Medicine, a specialist qualification established by the Royal College of Physicians, London. This qualification is the primary qualification for Pharmaceutical Physicians to conduct phase I trials as recommended by the ABPI (1) and is a requirement to meet the rigorous Medicines and Healthcare Regulatory Agency (MHRA) (UK regulatory body) guidelines (produced in Response to the TeGenero incident in the UK) for conducting First in Human trials (2) and fulfil Medsafe's intentions to an international standard.

Many other international qualifications would also be excluded given the international nature of pharmaceutical medicine and the considerable steps in harmonisation introduced through guidelines such as GCP. The International Federation of Associations of Pharmaceutical Physicians (IFAPP) fosters the development and international recognition of Pharmaceutical Medicine as a medical specialty and the development of training and continuing education programmes in Pharmaceutical Medicine around the world. It currently has 28 international members, predominantly from Europe, Asia, US, South America and Australia (<http://www.ifapp.org/home/about-ifapp>).

The Council for Education in Pharmaceutical Medicine (CEPM), a sub-committee of the IFAPP, is concerned with establishing and harmonizing postgraduate courses in Pharmaceutical Medicine globally, promoting mutual recognition of Diplomas in Pharmaceutical Medicine and to obtain the recognition of the title of Physician Specialist in Pharmaceutical Medicine internationally. Recognition of an internationally recognised and comprehensive program such as this could only be beneficial to clinical development in NZ.

We would be happy to facilitate access to key participants of the Human Therapeutics industry in New Zealand to assist you in your further work if this would be of assistance. In the interim please do not hesitate to contact me if I can assist you in any way.

Kind regards

A handwritten signature in black ink, appearing to read 'Bronwyn Dilley', with a stylized flourish at the end.

Bronwyn Dilley

Chief Executive

References

1. **ABPI.** ABPI Guidelines for Phase 1 Clinical Trials. [Online] http://www.abpi.org.uk/publications/pdfs/phase1_guidelines.pdf.
2. **MHRA.** Clinical trials for medicinal products: Phase 1 Accreditation Scheme. [Online] <http://www.mhra.gov.uk/Howweregulate/Medicines/Medicinesregulatorynews/CON2033112>.
3. **FACULTY OF PHARMACEUTICAL MEDICINE OF THE ROYAL COLLEGES OF PHYSICIANS OF THE UNITED KINGDOM.** Standing Orders. [Online] <http://www.fpm.org.uk/faculty/StandingOrders.pdf>.