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Mr L. Andrews Assistant Commissioner Productivity Commission GPO Box 1428 Canberra City ACT 2601

Dear Mr Andrews,

Regarding the Productivity Commission's draft research report for the Annual Review of Regulatory Burdens on Business: Manufacturing and Distributive Trades

I would like to provide the Commission this update on the NHMRC's involvement in the harmonisation of multi-centre ethical review, referred to in your draft report at page 60.

The National Health and Medical Research Council (NHMRC) is Australia's principal agency for funding health and medical research, for developing health advice for the Australian community, health professionals and governments, and for providing advice on ethical behaviour in health care and in the conduct of health and medical research.

Scientific and ethical reviews of research proposals are important steps in the approval of research involving humans in Australia.

As you have noted in your draft report, the Australian Health Ministers Advisory Council agreed that NHMRC should establish a process for the harmonisation of multi-centre ethical review. NHMRC is developing a framework for the harmonisation of reviews involving multiple research centres and is not involved in the operational aspects of conducting reviews. This work is informed by a reference group which includes Medicines Australia.

Currently NHMRC is conducting focus groups in all States and Territories to determine stakeholder views on the critical elements of a harmonised system. Issues under consideration including recognition/accreditation of ethics committees, insurance and indemnity, costs and fees.

Looking forward, our commitments include:

2008-09

- Consult extensively with stakeholder groups and jurisdictions on the essential elements and model for a harmonised national system of multi centre ethical review (HoMER)
- Promote the harmonisation process with researchers, sponsors and institutions
- Facilitate pilots of essential elements of HoMER supporting mutual recognition and single ethical review
- Develop an accreditation process for Human Research Ethics Committees (HRECs) involved in multi-centre review
- Report to AHMAC on development and staged implementation of essential elements

2009-2010

- Implement outstanding elements of HoMER
- Facilitate enabling and supporting elements for HoMER operation

We will be working with State and Territory governments and other stakeholders to achieve a national system within this timeframe and will provide further updates on this project on our website at www.nhmrc.gov.au.

Yours sincerely

Dr Clive Morris

Chief Knowledge and Development Officer