National Ethics Advisory Committee
Kāhui Matatika o te Motu

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Hon Peter Dunne (Associate Minister of Health)

National Ethics Advisory Committee (NEAC) advice on compensation for treatment injury in clinical trials

Executive summary

i. The National Ethics Advisory Committee (NEAC) is an independent advisor to the Minister of Health on ethical issues of national significance in the health and disability sector.

ii. NEAC has recently been made aware of two cases where participants in clinical trials have not yet received compensation for treatment injury that occurred in 2012. There is a risk that, if the public becomes aware of the difficulties faced by these participants, it could affect future participation in, and conduct of, clinical trials in New Zealand.

iii. These cases suggest that some companies conducting clinical trials in New Zealand may be failing to comply with NEAC's and Medicines New Zealand's guidance to provide compensation cover for study participants to at least Accident Compensation Corporation (ACC) equivalent standard, and to do so in an expeditious manner.

iv. NEAC has previously recommended, and continues to support, a review of the current statutory exclusion of participants in industry-sponsored clinical trials from ACC compensation for treatment injury, with a view to securing at least ACC-equivalent cover for all injured clinical trial participants. This would provide affected participants with prompt access to treatment, rehabilitation and, where appropriate, financial compensation to cover, for example, loss of earnings.

v. We are aware that the Ministry of Business, Innovation and Employment is undertaking work on possible amendments to the Accident Compensation Act 2001. It would be appropriate to consider the issues NEAC raises in this report as part of that work.

NEAC recommends that you:

a) **Agree** to provide a copy of this report to Hon Nikki Kaye, Minister for ACC. Yes / No

Victoria Hinson
Chair
National Ethics Advisory Committee

Minister's Signature:

Date:

NEAC Contacts:

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Purpose

1. In November 2014, the National Advisory Committee on Health and Disability Support Services Ethics – Kāhui Matatika o te Motu (NEAC) raised the issue of compensation for treatment injury in its initial briefing to you [NEAC report 20140444 refers].

2. This report provides you with further advice on compensation for treatment injury in clinical trials.

Background

About the National Ethics Advisory Committee

3. NEAC is a ministerial advisory committee, established under section 16 of the New Zealand Public Health and Disability Act 2000. NEAC's statutory functions are to:

   - advise the Minister of Health on ethical issues of national significance in respect of health and disability matters
   - determine nationally consistent ethical standards across the health sector
   - provide scrutiny for national health research and health services.

Legislative and policy setting for compensation for treatment injury

4. Section 32 of the Accident Compensation Act 2001 (AC Act) sets out the limited circumstances in which there will be cover for 'personal' (physical) injury suffered as a result of treatment provided as part of a clinical trial. Cover is provided through the Accident Compensation Corporation (ACC) and may include access to treatment and rehabilitation, and financial compensation for loss of earnings and for permanent disability.

5. However, Section 32 (6) of the AC Act specifically excludes from ACC cover any treatment injury from any trial that is conducted 'principally for the benefit of the manufacturer or distributor of the medicine or item being trialled'. Treatment injuries in industry-sponsored clinical trials were covered prior to 1992 under the accident compensation scheme, but were excluded when the Accident Rehabilitation and Compensation Insurance Act 1992 came into force.

6. NEAC understands that this statutory exclusion was motivated by a concern that New Zealand might be targeted by industry seeking to conduct questionable clinical trials here and then leaving New Zealanders to bear the cost. NEAC's view is that this motivation reflects a poor understanding of the clinical trials industry and an unjustifiable lack of confidence in the robustness of New Zealand's regulatory framework.

7. In 2009, NEAC completed work on the ethics of clinical trials, including sector and public consultation. This work confirmed that the legislative framework generates significant issues about compensation for treatment injury for participants in industry-sponsored clinical trials. In response to this, NEAC's advice for researchers, *Ethical Guidelines for Intervention Studies*, established the principle that, if cover under the AC Act will be excluded for the intervention study (many intervention studies are clinical trials), investigators and study sponsors have responsibilities to ensure alternative compensation cover for study participants to at least ACC-equivalent standard. This may include earnings-related compensation.

8. Medicines New Zealand[1] made a matching improvement to its own guidance, noting that compensation should be no less than would be awarded for similar injuries by New Zealand's accident compensation scheme (*Researched Medicines Industry Guidelines on Clinical Trials Compensation for Injury Resulting from Participation in an Industry-Sponsored Clinical Trial*, 2008, paragraph 4.1).

9. NEAC's advice to researchers on providing at least ACC-equivalent cover for clinical trial participants will be revisited in 2015 as part of its review of *Ethical Guidelines for Intervention Studies*.

Previous NEAC recommendation to review current statutory exclusion

10. In 2010, NEAC provided advice to the then Minister of Health recommending a review of the current statutory exclusions of participants in industry-sponsored clinical trials from ACC compensation for treatment injury. This recommendation was part of NEAC's advice in response to the Health Select Committee's inquiry into improving New Zealand's environment to support innovation through clinical trials.

11. A copy of NEAC's original advice is appended (paragraphs 46 – 57 contain the advice on compensation for treatment injury).

Advice

12. While NEAC's and Medicines New Zealand's guidance clearly state a requirement of at least ACC-equivalent cover, the recent experience of two participants, which have been brought to the attention of NEAC, would suggest that this expectation is not being met. NEAC understands that the Ministry of Health has advised you on the details of these cases and so we only briefly outline the cases here.

13. The first case involves a male participant who took part in a trial for gout medicine in 2012. As a result of the trial treatment he suffered [redacted] following the incident and to date has not received compensation.

14. The second case, which also took place in 2012, involves a male participant who took part in a diabetes trial administered by the [redacted] Currently, there is the possibility of mediation with the clinical trial company by the end of year to reach an agreement about compensation but, at the time of writing, no date has been set.

15. NEAC notes that these two cases suggest a failure to meet Medicines New Zealand's expectation of a 'simple and expeditious procedure' in relation to the provision of compensation for injury caused by participation in clinical trials.[2] This delay in the provision of compensation means that these individuals have not been supported to access

[1] Medicines New Zealand is the industry association representing companies engaged in research, development, manufacture and marketing of prescription medicines.
[2] As noted in the preamble of the *Researched Medicines Industry Guidelines on Clinical Trials Compensation for Injury Resulting from Participation in an Industry-Sponsored Clinical Trial* (2008).

appropriate treatment and rehabilitation services, including vocational rehabilitation, which, in at least one of these cases, has resulted in a further loss of income.

16. There is a risk that, if the public becomes aware of the difficulties faced by some clinical trial participants in receiving an adequate level of rehabilitation and compensation for treatment injury, it could affect future participation in, and conduct of, clinical trials in New Zealand.

Review of current statutory exclusion

17. Based on its previous work, NEAC considers that section 32 (4) - (6) of the AC Act continues to generate the following issues:

    a. by stating a statutory exclusion of participants in industry-sponsored clinical trials from ACC cover it disadvantages these people compared to participants in all other research in New Zealand

    b. it consequently requires researchers, ethics committees and research locality organisations (eg, DHBs) to secure indemnity cover for study participants and researchers through private sector insurance

    c. it sends a negative signal about whether New Zealand welcomes the conduct of industry-sponsored clinical trials.

18. NEAC continues to support a review of the current statutory exclusion of participants in industry-sponsored clinical trials from ACC compensation for treatment injury. NEAC believes that this review should be based on the principles that policy should be justifiable to those affected by it, and should secure at least ACC-equivalent cover for all clinical trial participants.

19. This could be achieved by:

    a. repealing the statutory exclusion, in section 32 of the AC Act, of participation in industry-sponsored clinical trials, or

    b. extending ACC cover to participants in industry-sponsored clinical trials without repealing the section 32 exclusion, for example, by requiring industry to purchase ACC cover through payment of levy for the clinical trials it conducts in New Zealand.

20. We are aware that the Ministry of Business, Innovation and Employment is considering possible limited amendments to the AC Act to increase the workability of the legislation. It would be appropriate to consider the issues NEAC has raised about compensation for treatment injury as part of that work and to assess the policy options.

21. NEAC is available to discuss the issues raised in this report upon request.

Ends.