MINISTRY OF BUSINESS, INNOVATION & EMPLOYMENT
HĪKINA WHAKATUTUKI

EVENT BRIEFING

Meeting with Mr Richard Stubbs, NZACRes, 14 February 2019

Date:	5 February 2019	**Priority:**	Low
Security classification:	In Confidence	**Tracking number:**	2228 2018-19

Action sought		
	Action sought	**Deadline**
Hon Iain Lees-Galloway Minister for ACC	**Note** the contents of this briefing before your meeting on 14 February 2019.	13 February 2019

Contact for telephone discussion (if required)				
Name	**Position**	**Telephone**		**1st contact**
Hayden Fenwick	Manager, Accident Compensation Policy	04 896 5479	s 9(2)(a)	✓
Suzy Morrissey	Principal Advisor	s 9(2)(a)		

The following departments/agencies have been consulted
ACC, Treasury, Ministry of Health

Minister's office to complete:

- ☐ Approved
- ☐ Noted
- ☐ Seen
- ☐ See Minister's Notes
- ☐ Declined
- ☐ Needs change
- ☐ Overtaken by Events
- ☐ Withdrawn

Comments

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EVENT BRIEFING

Meeting with Mr Richard Stubbs, 14 February 2019

Date:	7 February 2019	**Priority:**	Low
Security classification:	In Confidence	**Tracking number:**	2228 2018-19

Purpose

You are meeting with Mr Richard Stubbs, President of the NZ Association of Clinical Research, at your office on Thursday, 14 February 2019.

Mr Stubbs requested this meeting to discuss the potential for ACC to provide coverage for treatment injuries to sponsored (commercial) clinical trial participants in the period prior to the sponsor's final acceptance of responsibility.

This briefing provides background information and talking points for the meeting, covering:

- the current arrangements for clinical trials and treatment injuries, and
- the role of the health system in clinical trials.

Recommendations

The Ministry of Business, Innovation and Employment recommends that you:

a **Note** the contents of this briefing and attached talking points.

Noted

Hayden Fenwick
Manager, Accident Compensation Policy, Labour, Science and Enterprise
4 / 2 / 19

Hon Iain Lees-Galloway
Minister for ACC
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Background

Purpose of meeting

1. You are meeting with Mr Richard Stubbs on 14 February, in your office, from 10 – 10.30 am.

2. Mr Stubbs requested this meeting to discuss the potential for ACC to provide coverage for treatment injuries to sponsored (commercial) clinical trial participants in the period prior to the sponsor's final acceptance of responsibility.

3. Mr Stubbs has previously corresponded and met with the Minister for Health regarding the exclusion itself. It is possible that he may raise the broader exclusion issue in the meeting.

Attendees

4. Mr Stubbs is the President of the NZ Association of Clinical Research (NZACRes).

5. Officials from MBIE (Suzy Morrissey, Principal Advisor, Accident Compensation Policy) and ACC (James Anderson, Senior Policy Officer, Scheme Direction and Settings) will also attend.

Talking points

6. Talking points are attached as **Annex 1**. These cover the current provisions of the ACC scheme in relation to treatment injuries from sponsored (commercial) clinical trials.

Items for discussion

Clinical trial sponsors are responsible for compensating people injured as part of their trials

7. The Accident Compensation Act 2001 (the AC Act) has since 1992 excluded cover for injuries related to clinical trials undertaken principally for the benefit of the company (section 32(6)), referred to hereafter as 'commercial trials'.

8. Approximately half of all clinical trials are commercial trials which are sponsored, for example, by pharmaceutical companies seeking market access for a medicine. A limited set of clinical trial circumstances have ACC cover, namely where written consent is not obtained, the trial is undertaken without ethics approval, or where the trial is principally for public benefit. Public benefit trials, for example, can be undertaken by an academic focusing on improving medicines or treatment delivery to vulnerable communities.

9. Commercial trial participants who are injured must seek redress from trial sites and sponsors. If disputes arise, participants can seek redress through the courts. This arrangement is underpinned by regulatory settings administered by the Ministry of Health. In approving clinical trials, statutorily convened Health and Disability Ethics Committees (HDECs)[1] require trial applicants to confirm that:

    a. injuries attributable to participation in a trial will be compensated to a level equivalent to what ACC would provide in similar circumstances

    b. trial participants retain rights to pursue legal remedies, and

[1] Health and Disability Ethics Committees are Ministerial committees established under section 11 of the New Zealand Public Health and Disability Act 2000.

c. sponsors hold sufficient insurance to compensate injured participants.

10. Sponsors can opt in to follow Medicines New Zealand guidelines. These are industry guidelines,[2] which outline how sponsors should approach compensation.

11. New Zealand's approach in this area is broadly consistent with arrangements in other countries such as Australia and the United Kingdom.

However there has been some pressure to remove this exclusion from ACC coverage

12. In July 2018 you received correspondence from s 9(2)(a) s 9(2)(a) who was seeking the removal of the exclusion. We provided advice for you that stated there was an insufficient case for removing the AC Act exclusion of commercial trial-related injuries at that time (and we are not aware of any facts to suggest this has changed).

13. Mr Stubbs has also previously sought removal of the exclusion. The Ministry of Health (MoH) has advised that Mr Stubbs met with Hon David Clark on this matter during the National Ethics Advisory Committee (NEAC) Consultation on Draft Ethical Standards for Health and Disability Research, and that he made a formal submission.

14. MoH also advise that NEAC plan to revisit advice they previously provided in 2015 on the ethical considerations relating to ACC and commercial clinical trial exclusion and re-issue it to Minister Clark.

15. The Clinical Trial Inquiry, conducted by the Health Committee in 2011, recommended that both public and private sector clinical trial sponsors have secure indemnity agreements in line with international best practise (recommendation 36). In its response (paragraphs 57-58), the previous government noted the NEAC requirement for 'at least ACC-equivalent standard' compensation to provide reasonable protection for participants in commercial trials.

Treatment injuries can be complex but appropriate arrangements are in place

16. Although ACC does not generally cover treatment injuries arising from commercial clinical trials, it does cover treatment injuries arising from other types of treatment, and the AC Act provides ACC with nine months, instead of the usual four, to decide whether to accept the claim (section 57).

17. During the period before any claim is accepted by ACC, treatment may be provided through the health service, and change to coverage by ACC prior to acceptance would represent a significant change. As well as creating a precedent, any change would create a further difference between the treatment of claimants in commercial trials and non-commercial trials, as well as creating a different between claimants in commercial trials and all other claimants. Any change would also require legislative change.

18. The extended period to consider a claim reflects the complexity of treatment injuries and may go some way to explaining the delay in acceptance of claims by the organisers of commercial trials.

19. Mr Stubbs is proposing that ACC coverage is provided to trial participants for this period prior to acceptance by the organisers.

20. There have been a small number of cases (two in 2016) where there was a delay in getting

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2 Medicines New Zealand (2015). Guidelines on Clinical Trials Compensation for Injury resulting from Participation in an Industry-sponsored Clinical Trial.

compensation. However the expectation is that the Medicines New Zealand guidelines, which require a 'simple and expeditious procedure', should ensure any delays are limited.

Further support for current arrangements could be provided

21. As the Act excludes injuries from clinical trials, providing ACC coverage, even for a limited time, would require legislative change. It would also burden ACC (and the state) with additional costs, both actual and administrative, which would contravene the policy intention of the exclusion.

22. Instead, options to support the current arrangement, whereby the trial organisers are expected to bear any costs of treatment injury, could be considered. These might include:

    a. Requiring new clauses in trial contracts that require the trial organiser to cover participants' costs in the period before causation is established, and the claim is accepted, or rejected by the courts.

    b. Requiring trial organisers to have contracts with a third party Accredited Employers Program (AEP) provider to provide coverage for trial participants in the period before causation is established, and the claim is accepted by them, or rejected by the courts. The question of a refund for the trial organiser, in the case of a claim being subsequently rejected, would need to be considered.

    c. Requiring trial organisers to pay a bond to ACC that would be used to fund any pre-decision treatment. This would represent an extension of current ACC obligations.

    d. Requiring either the manufacturer, distributor, or local agent to have arrangements in place that match the timeframes, as well as the support for treatment and entitlements, that apply to ACC.

23. It is not clear that ACC would be able to accommodate any of these options and they do not represent MBIE advice or recommendations.

24. Trial organisers currently have liability, it is international standard practise, and there is insufficient evidence of perverse outcomes currently occurring in New Zealand to justify a major change to current practise.

The role of the health system

25. The health system in New Zealand provides treatment to all those in medical need. Trial participants who require healthcare for treatment injuries receive treatment from the health system. Treatment is not withheld during any claim assessment or dispute period. There may be a change to their treatment provider if a claim is accepted and the trial organiser commences payment. There are not considered to be any negative consequences for trial participants arising from the health system.

26. The impact on the health system of any changes to liability for treatment injury would need to be considered.

Mr Stubbs may be keen to broaden your discussion

27. Mr Stubbs has previously corresponded and met with the Minister for Health regarding the exclusion itself. It is possible that he may raise the broader exclusion issue in your meeting. Talking points are also provided on this topic in case it should occur.

28. In our view, shifting the compensation arrangements to ACC would not necessarily offer additional certainty of compensation to trial participants, or provide faster determination of cover for treatment injury claims. The low number of known disputes does not suggest an

urgent problem and there would be practical issues in determining how to calculate an appropriate levy. Overall there does not appear to be a case for removing the exclusion.

Consultation

29. ACC, the Ministry of Health, and the Treasury were consulted on this briefing.

Annex 1: Talking points

- Current arrangements do not appear to be acting as a deterrent to either trial participants or trial organisers.
- The burden of responsibility on trial organisers (rather than the state) is standard industry practise internationally.
- Any changes to move the burden to ACC (even temporarily) would require legislative change and represent a major change to the policy intention.
- It would create a difference in pre-acceptance treatment for those claimants participating in commercial trial and other (non-participant) claimants.
- The benefit of making such a change, compared to the administrative and financial costs, is unclear at this time.
- Changes to support the current arrangements (such as requiring trial organisers to accept initial costs or provide initial treatment on a no-liability, temporary basis or requiring trial organisers to comply with the same decision timeframes as ACC) could be considered but further consultation would be required.

Suggested questions for you

- Can you tell me what NZACRes or the sector has undertaken or could consider undertaking with respect to this issue?
- Are there other options we should consider rather than just ACC?

Should the issue of broader clinical trial exclusion be raised

- It is not clear that shifting the compensation arrangements to ACC would necessarily offer additional certainty of compensation to trial participants.
    - Injury claims not accepted by sponsors under current arrangements, may equally be declined by ACC, as they would still have to determine the circumstances relating to the injury before providing any assistance.
- It is also uncertain whether the determination of cover for treatment injury claims would be faster if managed by ACC.
    - Determining cover for treatment injury claims can be more complex than for other claims, and the AC Act accordingly gives ACC a longer period (nine months as compared to four months) to decide whether to accept a claim of this nature.
- Given the small number of known disputes in this area, it is not clear that commercial trial sponsors are not taking responsibility for injuries relating to their trials and that people who are injured are missing out on compensation.
- If the accident compensation scheme was expanded to cover commercial clinical trials participants, and a levy was introduced to cover the costs of those injuries, it would be important but also challenging to establish levies that fairly reflect the differing risks of different types of clinical trials.
    - Appropriately risk-adjusted levies would be important, for instance, to avoid incentivising more risky as opposed to less risky trials seeking to be located in New Zealand, which would place greater pressure on the regulatory system governing trials.

- Setting such levies would be challenging given the limited information on the numbers and severity of trial related injuries, and the small scale of the New Zealand trial industry.

- The Health and Disability Ethics Committees have updated the informed consent template wording for commercial trials (s 9(2)(a) was concerned that participants may not understand the lack of ACC coverage for clinical trial treatment injuries).

- An exposure draft of the Therapeutic Products Bill, developed by the Ministry of Health, has been released for consultation. The Bill is designed to update the regulatory scheme around medicines, medical devices and other therapeutic products in New Zealand.

  - The Bill will also strengthen the regulatory oversight of clinical trials and address a number of issues in the clinical trial regulatory system, including gaps in the ethics approval coverage of trials of therapeutic products other than medicines (e.g. devices).

  - Consultation on the exposure draft of the Bill closes on 18 April 2019.