MINISTRY OF BUSINESS, INNOVATION & EMPLOYMENT
HĪKINA WHAKATUTUKI

BRIEFING

ACC cover exclusion for people injured in commercial clinical trials

Date:	16 July 2018	**Priority:**	Medium
Security classification:	**In confidence**	**Tracking number:**	18-19 0136

Action sought		
	Action sought	**Deadline**
Hon Iain Lees-Galloway Minister for ACC	**Approve**, along with the Minister of Health, Hon David Clark, the attached joint response to s 9(2)(a) .	20 July 2018

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

The following departments/agencies have been consulted					
☐ Treasury	☐ MoJ	☐ NZTE	☐ MSD	☐ TEC	☐ MoE
☐ MFAT	☐ MPI	☐ MfE	☐ DIA	☐ TPK	☒ MoH
		☒ Other:	ACC has been informed		

Minister's office to complete:

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☐ See Minister's Notes ☐ Withdrawn

Comments:

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Purpose

1. This briefing provides information on the exclusion from ACC cover for commercial clinical trial related injuries, as background to a proposed response to s 9(2)(a) correspondence proposing the exclusion be removed.

Recommended action

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

a **Note** the s 9(2)(a) proposes that the Accident Compensation Act 2001 exclusion of commercial trial injuries from cover be removed.

Noted

b **Note** that it is uncertain whether removing the exclusion would be beneficial for trial participants, and the risks associated with its removal are potentially significant.

Noted

c **Approve**, along with the Minister of Health, Hon David Clark, the attached joint response to s 9(2)(a) .

Agree/Disagree

d **Agree** to forward this briefing to Hon David Clark for his information.

Agree/Disagree

Hayden Fenwick
Manager, Accident Compensation Policy

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Hon Iain Lees-Galloway
Minister for ACC

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Background

2. On 6 June 2018 s 9(2)(a) , wrote to you as Minister for ACC and Hon David Clark, Minister of Health:

   a. about the lack of certainty that commercial clinical trials participants have that they will be compensated in the event they are injured

   b. proposing that ACC cover be extended to people injured in commercial clinical trials to resolve that uncertainty.

3. In the past, other groups, such as Middlemore Clinical Trials, a large trial provider and the National Ethics Advisory Committee (NEAC) have similarly proposed removing the exclusion.

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

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

5. Commercial trial participants that 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 Ministry of Health administered regulatory settings. 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

   c. sponsors hold sufficient insurance to compensate injured participants.

6. Sponsors opt in to follow Medicines New Zealand Guidelines (Industry Guidelines)[2], which outline how sponsors should approach compensation.

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

Clinical trial related injuries are uncertain but rarely disputed through the courts

8. Between 2009 and 2017 there were approximately 900 clinical trials involving 50,000 people. Over the period 136 adverse events were reported through Medsafe's voluntary system.

9. Two serious events during this period were disputed and publicised. One case faced a significant delay but has been resolved. In respect of the case that has not been resolved, it is uncertain whether it would have been covered by ACC in the absence of the present exclusion, as the dispute concerned whether the disability could be attributed to the trial or underlying health condition.[3] It is not known whether the more recent fatality noted in s 9(2)(a) correspondence is in dispute.

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

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

[3] One case involved a participant injured in a trial for gout medicine, who suffered a severe arterial fibrillation that required hospitalisation and was unable to return to work as a builder following the incident. The other case involved a participant who suffered diabetic lumbar plexus neuropathy following a diabetes medicine trial, which resulted in paralysis and difficulty using his legs.

Trial sponsors should retain responsibility for trial related injuries

10. MBIE considers that the AC Act's exclusion of commercial trial injuries should be retained. The benefits for trial participants of removing the exclusion are uncertain, and the risks, while also uncertain, are potentially significant.

It is uncertain whether injured trial participants would be better off under ACC

11. s 9(2)(a) and others suggest that removing the exclusion would provide clinical trial participants more certain cover, entitlements and timely resolution of claims.

12. However, it is not clear whether removing the exclusion of commercial clinical trials would result in the benefits to participants. In the unresolved case the key point of contention was whether the injury was caused as a result of participation in the trial, or through underlying health factors. Like trial sponsors, ACC would have to determine the circumstances relating to the injury before providing any assistance.

13. The determination of 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 the claim (refer section 57).

14. Moreover, the industry is incentivised to provide fair and timely compensation, given the risk of reputational damage associated with a participant disputing a claim through the courts or publicising a negative experience. The industry relies on people trusting that trials will be safe and that redress will be forthcoming if anything goes wrong. With only two known disputes since 2009, if there are issues, they are not widespread.

Removing the exclusion would increase cost pressure, but by how much is uncertain

15. Removing the exclusion would expand the Treatment Injury Account. ACC data on adverse reactions to approved medicines indicate that removing the exclusion could see some high cost claims, but it is difficult to know how many claims could be made given current data.

16. s 9(2)(a) correctly points out that any costs for clinical trial related injuries could be reclaimed through a levy on trial sponsors, however, there are a number of considerations:

    a. it would set a precedent – ACC does not currently levy registered health professionals for treatment injuries but an introduction of a Treatment Injury Account levy for clinical trials could create expectations for levies on other health providers

    b. it would depart from common international practice – sponsors tend to be based outside of New Zealand and operate internationally, and the imposition of a levy may be seen as an additional cost to existing insurances

    c. pricing would be difficult – we are unable to reliably estimate the number and cost of commercial trial related injuries given the voluntary nature and extent of information reported to Medsafe's adverse event register.

A no-fault approach could incentivise higher risk trials in New Zealand

17. The exclusion was introduced to address concerns that a no-fault approach in this area could incentivise international pharmaceutical companies to conduct a greater number of higher risk trials in New Zealand, and the potential for this to exacerbate cost pressure.

18. New Zealand has broadly consistent liability arrangements to other comparable countries.

19. If the exclusion was removed under the current funding arrangement, commercial clinical trial sponsors' trial injury costs would be met by the Treatment Injury Account funded by earners and the Crown. This would provide trial sponsors with an advantageous price point for conducting trials in New Zealand in comparison to other countries.

20. If an ACC levy was introduced to recover trial related injury costs, unless it was suitably risk-adjusted, less risky trials would subsidise the costs of more risky trials over time. This would incentivise the location of more risky as opposed to less risky trials in New Zealand. This in turn would place greater pressure on, and require greater resourcing for, HDECs.

Improvements to the trial regulatory system

Disclosure of trial related compensation arrangements has been improved

21. s 9(2)(a) points out that the HDECs' informed consent template could be improved to make it clearer that compensation is not available from ACC, and that compensation from sponsors and/or sites is made according to Industry Guidelines.

22. As of this week, the HDECs have updated the template wording for commercial trials to address the issue of insufficient information being provided to participants in clinical trials under the current system.

Legislation is being developed to strengthen regulatory oversight of clinical trials

23. The Ministry of Health is currently developing an exposure draft for a Therapeutic Products Bill, intended to redesign the regulatory scheme for therapeutic products and replace the Medicines Act 1981 and its associated regulations. The Therapeutic Products Bill would, for example, strengthen the regulatory oversight of clinical trials through additional information, reporting and monitoring requirements, including the power to audit trials and revoke trial approvals.

24. The Bill would 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 (eg devices), which creates ambiguities in respect of the AC Act exclusion provision. The consultation process on the exposure draft will provide an opportunity for further discussion and consideration of the issues.

Officials are exploring other potential improvements

25. In addition to the measures outlined above consideration could be given to expanding indemnity insurance requirements for sponsors to also include trial sites.

26. Ethics approval requires sponsors to have indemnity insurance, but there is no equivalent requirement for trial sites. This has the potential to leave injured participants without a clear compensation pathway where a trial site, as opposed to the medicine being trialled, causes an injury.

Next steps

27. A draft response to s 9(2)(a) is attached for your and the Minister of Health, Hon David Clark's approval at Annex 1. The response addresses the concern raised by s 9(2)(a) regarding the HDEC template and states that there is an insufficient case for removing the AC Act exclusion of commercial trial related injuries at this time.

Annexes

Annex 1: Draft response to s 9(2)(a)

Annex 2: 6 June 2018 letter from s 9(2)(a)