MINISTRY OF HEALTH
MANATŪ HAUORA

133 Molesworth Street
PO Box 5013
Wellington 6140
New Zealand

9 January 2020

NZ for Health Research
PO Box 25-716
St Heliers
Auckland

Dear Mr Higgins

Thank you for your letter about fee waivers for the assessment of clinical trials for public good.

The Ministry of Health (the Ministry) is committed to supporting research and researchers in New Zealand. Along with the initiatives you note in your letter that the Ministry is undertaking to implement the New Zealand Health Research Strategy (NZHJRS), the Health Research Council (HRC) announced on 1 December 2019 its new 2020 Health Delivery Research Investment Round with a new project and a people focused pipeline approach to developing both research and researchers.

I am advised by Medsafe that section 30 of the Medicines Act 1981 requires that clinical trials can only be approved for *new* medicines on the recommendation of the HRC of New Zealand. This function is delegated to Medsafe, the New Zealand medicines regulator. In practice this amounts to around 150 trials per year. Since the law mandates that all trials for new medicines require a full assessment, a fee is charged to pay the clinical experts who advise Medsafe about the scientific validity of the trial and the need for significant amendments. The fee also covers any subsequent protocol amendments.

As you may be aware, Medsafe is required to recover its costs through the fees and charges for all activities that fall within the scope of the Medicines Act 1981 (the Act). While the ability to waive fees in some instances is an important consideration of the regulator, it is important to note that any application for which the full fee is not paid is in fact being supported by the applicants who do pay the full fee. This is also known as 'cross-subsidisation'. The extent of cross-subsidisation is monitored closely and has recently been the subject of regulatory audits internationally (for example the Therapeutic Goods Administration (TGA) in Australia). The waiving of fees for clinical trials is quite unusual when compared to other countries. For example, we note the TGA does not operate a fee waiver system.

I am advised that Medsafe has not imposed an additional fee but rather has reduced the fee from $7500 to $1000 to reduce cross-subsidisation in response to:

- increased request for fee waivers
- increased requests for further information from the HRC committees
- increased numbers of protocol amendments, the fee for which is included in the up-front charge.

Medsafe advises that 15 trials were given a fee waiver in the last 12 months. This number represents 10% of the trials that have been assessed by Medsafe in the last 12 months. Of the 15 trials given fee waivers only five were using new medicines previously unapproved in New Zealand. These were all multinational trials.

I am also advised that seven trials granted fee waivers were proposing to use unapproved medicines, while there was an approved version marketed in New Zealand. If the approved version was used an assessment from Medsafe would not be required under the Medicines Act 1981. Medsafe's analysis also shows most of the trials that had fee waivers had funding from companies or governmental agencies, such as HRC, and four trials were supported by charitable donation.

Medsafe supports innovation and works to minimise barriers to conducting clinical trials for cutting edge therapies. However, I am advised that the clinical trials for cutting edge therapies are generally supported by pharmaceutical companies and are not usually eligible for fee waivers.

Medsafe has confirmed that for any ground-breaking clinical trial that the investigator does not have the reduced fee they will still consider waiving the entire fee. Medsafe will also be working with HRC to ensure that the criteria for applying for a fee waiver are appropriate and are applied consistently.

I trust this information helps clarify the fee waiver process.

Yours sincerely

Dr Ashley Bloomfield
Director-General of Health

New Zealanders for
HEALTH RESEARCH
Ngā Tāngata o Aotearoa mō
te Rangahau Hauora

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5th December 2019

Dear Ashley

Removal of fees waiver for public good clinical trials

I am writing to express NZHR's concern about what appears to be a new arbitrarily imposed Medsafe policy to remove the current fees waiver opportunity for non-funded collaborative trials and charge $1000 + 2% transaction fee for these trials, and to request that the decision be reversed.

As I expect you are aware section 3.5.1 of Medsafe's November 2018 Guideline on the Regulation of Therapeutic Products[1] state that a waiver may be considered for a clinical trial conducted for the public good. As far as we are aware this guideline remains current, but Medsafe's interpretation of how it should be applied has changed.

We understand that when NZACRes President Julie Jones raised this directly with Medsafe in October of this year Medsafe's response was that:

- the fees are not new
- it was considered unfair for some parties to be subsidising others entirely and that they therefore believe that applicants should pay the reduced fee or the full fee, depending on whether or not the study is commercial
- the change in practice was linked to the outcome of the 2018 fees review consultation process[2]
- they would be concerned that if a study couldn't afford a $1000 fee then perhaps it couldn't afford to properly conduct the trial as a whole
- there will be a full review of the fees structure when the new Therapeutics Products Act comes into force (in a number of years time)

NZHR's response is as follows:

- we acknowledge that the provision for fees has been there for a long time, but as far as we're aware this is the first time since 2005 that Medsafe has augmented the fees waiver policy for "public good" clinical trials
- the Fees Review consultation document did refer to adjusting the' standard' waiver under regulation 61, but our understanding is that this referred to new or changed medicines applications, not clinical trials
- even though $1000 may not seem a lot it actually imposes a significant barrier to those seeking public good clinical trials funding, and puts trials at risk of becoming

[1] Guideline on the Regulation of Therapeutic Products in New Zealand Part 11: Clinical trials – regulatory approval and good clinical practice requirements Edition 2.0 November 2018.
[2] https://www.medsafe.govt.nz/consultations/FeesReview2018.asp

financially unviable and/or of not going ahead because delays in securing additional required funding mean they fail to meet internationally determined registration deadlines.

- This in turn means there are lost opportunities for DHBs to realise the financial and resource benefits of patients participating in clinical trials, and patients suffer unnecessarily as a result of missing out on cutting edge therapies which may otherwise be available to them through the clinical trial
- despite being mandated by the Health Research Strategy a commitment to health research being embedded in health service delivery is a long way off and District Health Boards are typically yet to value clinical trials sufficiently to feel that contributing an additional $1000 per trial can be justified
- the HRC and the Ministry of Health are to fund a study on clinical trial systems and data infrastructure in New Zealand's public healthcare system. The purpose of this initiative is to realise the potential for clinical trials research in New Zealand, and is an important part of implementing the New Zealand Health Research Strategy 2017-2027. As you're aware, this initiative aims to provide an evidence-base to inform the development of an infrastructure roadmap and operating model to support a sustainable and nationally coordinated clinical trials enterprise in New Zealand, and contribute to improved and more equitable health outcomes for New Zealanders. The study will include both an analysis of existing clinical trial capability and recommendations co-designed with stakeholders, to inform policy[3]. NZHR's view is that Medsafe's decision to impose fees for "public good" clinical trials is at best premature and contemplating any change in practice should have been deferred until the outcomes of this exercise were known and ratified.
- there is significant underinvestment in health research in New Zealand[4] [5] and potentially shifting costs into an already under-resourced environment will unnecessarily and unjustifiably put additional strain on New Zealand's health research funding infrastructure.
- imposition of the additional fees is inconsistent with the Ministry of Health's obligations to implement the Health Research Strategy.

NZHR is happy to discuss this further and provide specific examples if that will be helpful. We look forward to a response in due course

Kind regards

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cc Chris James, Group Manager, Medsafe
Ian Town, Chief Science Advisor, Ministry of Health
Patricia Anderson, Chief Advisor, Health Research Council of New Zealand

[3] https://www.hrc.govt.nz/news-and-events/request-proposals-enhance-nzs-clinical-trials-coming-soon
[4] https://www.nz4healthresearch.org.nz/wp-content/uploads/2019/06/government-health-research-investment-trajectories-090619.pdf
[5] The New Zealand Health Research Prioritisation Framework . Appendix 1. Page 22.