New Zealanders for HEALTH RESEARCH

Ngā Tāngata o Aotearoa mō te Rangahau Hauora

"New Zealand's peak body representing the entire health and medical research pipeline"

Submission on the proposed therapeutics product legislation

Introduction

New Zealanders for Health Research (NZHR) was established in November 2015 to bring about increased investment in health research from government, industry and philanthropy; this provides the overarching context for our response to the proposed therapeutic products legislation. In developing this submission we have consulted with our partners and members as set out at the end of this document (from whom we derive 100% of our funding).

We wish to record our thanks to Chris James, Group Manager, Medsafe for his presentation on the proposals to the NZHR "Health and Prosperity through Clinical Trials" workshop on 22nd March. That both enhanced our understanding of the proposed regime, and assisted us in framing our response.

NZHR analysis

In analysing the impact of the prosed legislation NZHR has focused on what impact it will have on undertaking clinical trials, primarily, but not exclusively as presented on page 89 of the discussion document.

#	Current	Proposed	NZHR response
1.	Objectives of the current regulatory arrangements not fully or clearly articulated	The objectives for the regulatory scheme are that it: 1. meets expectations of risk management and assurance of acceptable safety, quality and efficacy or performance of therapeutic products	Agree with the objectives as listed but believe that the way the objectives are numbered implies an inappropriately ordered hierarchy of importance, that there should be an additional objective relating to innovation, research and development, and that

#	Current	Proposed	NZHR response
		2. results in efficient and cost-effective regulation 3. is flexible, durable, up to date and easy to use 4. ensures high-quality, robust and accountable decision-making 5. is able to sustain capable regulatory capacity 6. supports New Zealand's trade and economic objectives 7. is trusted and respected 8. supports consumer access to, and individual responsibility for, care.	health outcome objectives should be considered at least as important as trade and economic objectives. We submit that the objectives should be set out as follows: 1. meets expectations of risk management and assurance of acceptable safety, quality and efficacy or performance of therapeutic products 2. supports consumer access to, and individual responsibility for, care. 3. supports New Zealand's health and health outcomes objectives 4. supports innovation and investment in health research and development of new therapies and interventions 5. supports New Zealand's trade and economic objectives 6. is trusted and respected 7. results in efficient and cost-effective regulation 8. is flexible, durable, up to date and easy to use 9. ensures high-quality, robust and accountable decision-making 10. is able to sustain capable regulatory capacity
2.		Paragraph 107 of the discussion document states that in broad terms, an applicant for a therapeutic product would need to satisfy the regulator that: • the quality, safety and efficacy or performance of the product are satisfactorily established (s 95(a))	This is potentially problematic for clinical trials because by definition it would not be possible to satisfy these criteria prior to the clinical trial being undertaken. For unapproved products, sufficient pre-clinical data supporting quality, safety and efficacy are likely to be unavailable.

#	Current	Proposed	NZHR response
		• the likely benefits of the product outweigh its likely risks (s 95(b))	We note that paragraph 131 of the discussion document states that the legislation would enable activities that would otherwise be unlawful to be authorised via a licence (s 123(2)). For example, a licence for a clinical trial could also authorise the supply of an unapproved medicine for the purpose of that trial. The one activity a licence could not authorise is one that involves a prohibited product, as these can only be authorised by a permit (s 81). However it is not clear from the discussion document as to the criteria that would used by the licensing mechanism, and we believe that this should be made fully transparent. NZHR's submission is that the use of all putatively therapeutic products should be subject to the following process: 1. review by an independent expert technical committee to determine whether safety risks are such that the trial should not go ahead 2. provided the risks are deemed to be acceptable it would then be permissible for the proposed trial to be submitted for ethics committee approval 3. if the clinical trial receives ethics committee approval then the putatively therapeutic product would automatically be granted approval as an exempt product.

#	Current	Proposed	NZHR response
			If this is deemed to be too open a process then, although not favoured by NZHR the circumstances under which the regulator would be permitted to not grant a license should be clearly articulated (ie it should not be allowed to be, or be seen to be, a discretionary and/or arbitrary process) Where a putatively therapeutic product is demonstrated by a clinical trial to be efficacious its approval as an exempt product should continue after the conclusion of the trial so that trial participants are able to continue to benefit while awaiting the conclusion of the formal approval process. We note that it is considered unethical for a sponsor to discontinue supply of a therapeutic product to a clinical trial patient if the patient responds to the product, even after the trial has ended
3.		p.45 The Bill would enable the regulator to charge fees to cover any costs not covered by government funding (s 256). The split between the costs recovered from industry and those met by the government has not yet been decided.	NZHR submits that clinical trials should not attract additional compliance costs. There are already too many disincentives to investment in clinical trials which government policy should be seeking to mitigate rather than aggravate.
4.		Paragraph 337 of the document notes that there would be interfaces between the Therapeutic Products Act, the Human Tissue Act 2008, the Human Assisted Reproductive Technology Act 2004 (HART) and the Hazardous Substances and New Organisms (HSNO) Act 1996. Before the Therapeutic Products Bill is introduced to Parliament, further work will be needed to clarify those interfaces and this work will be informed by	The Environmental Protection Authority Act should be added to list of Acts where there are interfaces with the proposed legislation. No additional barriers should be introduced to involving genetically modified organisms in clinical trials.

#	Current	Proposed	NZHR response
		the feedback on the draft Bill. In relation to the HSNO interface, the policy intent is that HSNO controls on new organisms (which includes human cell lines) would continue to apply. Likewise, the Human Assisted Reproductive Technology Act 2004 would apply alongside the Therapeutic Products Act.	
5.	Conducting a clinical trial of a therapeutic product not necessarily a controlled activity requiring an authorisation.	Conducting a clinical trial of a therapeutic product would be a controlled activity requiring an authorisation. It is intended that the approval would take the form of a licence that could authorise the supply of the product(s) being trialled to the specified clinical trial site(s) as well as the trial itself.	Supported subject to comments in row 2 above.
6.	Medical device and cell and tissue trials require an ethics approval only.	Medical device and cell and tissue researchers will work within a regulated trial environment.	Supported
7.	Clinical trials of a medicine require approval for trials of unapproved medicines only.	All clinical trials of a medicine would require approval	Supported subject to comments in row 2 above.
8.		The new scheme would take a risk-based approach to licensing so that greater scrutiny would be given to applications to trial novel products being used for the first time in humans and high-risk products, than applications for trials researching new uses for approved products or comparing approved products.	Supported subject to comments in row 2 above.
9.	Although ethics approval for clinical trials is established practice it is	Ethics approval would be legally required for authorised trials unless an ethics approval body certifies that ethics approval is not required.	Supported

#	Current	Proposed	NZHR response
	not specifically mandated legally.		
10.	No single accessible register of clinical trials in New Zealand.	It is envisaged these would include a requirement for registration of specified trial information in a publicly accessible registry that could be entered via the search portal on the World Health Organization's International Clinical Trials Registry Platform. The regulator would be required to maintain a publicly accessible register of licences. This system would therefore provide.	Supported in principle. Currently there is no reliable and comprehensive single source of New Zealand clinical trials information, as illustrated by both NZHR[1] and ANZCTR[2] reports, which gives rise to inconsistent information about New Zealand's clinical trials landscape. Furthermore the World Health Organization's International Clinical Trials Registry Platform has very limited capacity for undertaking other than very basic analysis. NZHR believes that there should be a comprehensive record of all clinical trials conducted in New Zealand which includes all therapeutic interventions, and which is not restricted only to trials involving therapeutic products. There should be consultation with the sector to determine the fields to be included in the register, the register should be fully searchable, and there should be built in requirements to ensure that data entry is accurate and complete.
11.		The regulator would be able to grant or refuse an application for a clinical trial licence without first seeking advice from the Health Research Council, as is currently required for approvals under the Medicines Act 1981. This is consistent with the	Not supported in principle. As stated in row 2 above NZHR maintains that the use of all putatively therapeutic products should be subject to review by an independent expert technical committee to determine whether the likely benefits of the product

[1] https://www.nz4healthresearch.org.nz/wp-content/uploads/2019/02/Clinical-trials-in-New-Zealand-NZHR-op-ed-130319-V2.pdf
[2] http://www.anzctr.org.au/docs/NZ_Report_2006-2015.pdf

#	Current	Proposed	NZHR response
		principle of independent decision-making. The regulator instead would have the flexibility to seek expert advice on a trial application from an individual or committee, or to determine the application using its own in-house resources.	outweigh its likely risks, and the circumstances under which the regulator would elect to not accede to the committee's determination should be clearly articulated.

18th April 2019

Chris Higgins
Chief Executive | New Zealanders for Health Research
+64 27 292 8433 mobile | ceo@nz4healthresearch.org.nz
www.nz4healthresearch.org.nz

NZHR partners and members

Platinum

Gold

Silver

Bronze

Chrome

Foundation