Therapeutic Products Bill: NZHR oral submission to the Health Committee

Thanks for the opportunity to present the New Zealanders for Health Research submission on the Therapeutic Products Bill.

If you've had an opportunity to review the material I sent to most Health Committee members in mid-February you'll be aware that New Zealanders for Health Research is committed to bringing about best possible health for all New Zealanders, and we're on a mission to increase investment in health research as an essential and embedded component of all parts of New Zealand's health system, responsive to New Zealanders' unique health imperatives.

In pursuit of this aim we have long advocated for development of New Zealand's clinical trials sector. Initially this took the form of advocating for concerted implementation of the recommendations following the Health Committee's 2011 clinical trials review (which sadly never happened), and latterly we contributed to the recommendations of the Liggins Institute led 2022 review of clinical trials infrastructure. We're happy to observe that in contrast to what happened after 2011 there is strong evidence that the recommendations of the 2022 review will be fully embraced by Manatū Hauora, Te Whata Ora and Te Aka Whai Ora alike.

Furthermore there is evidence from the analysis in our 2022 opinion poll report that the clinical trials sector is enjoying a new sense of momentum.

We are concerned therefore that this momentum doesn't become compromised by legislation and regulations which put a brake on the sector at the very time that it ought to be picking up speed.

However, before moving on to those issues we want to address the fundamental issue of who the legislation is intended to benefit.

In our written submission we recommended that clause 4, "Principles guiding exercise of powers under Act", should be expanded to reflect the full set of objectives originally proposed by Medsafe, as amended by and in the order recommended by NZHR.

What we particularly mean is that there should be an additional clause 4 b (i) which states that "regulation of therapeutic products should support consumer access to, and individual responsibility for, care", as originally proposed by Medsafe.

Health consumers should be at the heart of the legislation, and this should therefore be made explicit. We are aware of Patient Voice Aotearoa's submission on the Bill which expresses concern that the Bill will cause patients to be denied access to life saving medicine which is only available from overseas suppliers, and we need to ensure that we avoid these sorts of unintended consequences for therapeutic products where, although the evidence supports their safety and effectiveness, they don't meet Pharmac's cost/benefit thresholds.

Moving on to clinical trials per se we think that how the proposed legislation will impact on clinical trials is opaque, and given that many products used in clinical trials are not yet purported to be therapeutic, there should be a separate section in the legislation which deals with clinical trials directly and specifically.

The second main point in our written submission is that we shouldn't be imposing unnecessary additional burdens on the conduct of clinical trials. We already have robust processes governing the conduct of clinical trials and we submit that if those conducting clinical trials are required to obtain a license as the Bill currently requires, then this

should be a mostly automatic and rapid process, provided that ethics committee approval has been provided.

In support of this we draw attention to NZHR member submissions and points as follows:

MSD's, ie Merck's, submission states that "requiring communications relating to clinical trials to comply with the same restrictions as an advertisement, including the prohibition against distributing an advertisement relating to an unauthorised product, may mean that it would be very difficult, if not impossible, to conduct clinical trials in New Zealand."

Douglas Pharmaceuticals submission states that "clarification is required on whether a permit can only be applied for once an ethics approval is in force for the trial. This would mean a sequential process that may unnecessarily delay clinical trial initiation. We, [ie Douglas] propose that the process for requesting clinical licence and permit approval run concurrently".

The Malaghan Institute of Medical Research has observed to us that "a main concern is the potential for a major increase in the logistical burden and costs of running cancer trials that involve new medicines. The Bill implies greater regulation of medicines imported for clinical trials (involving a new business unit), and it is proposed that the costs of this new business unit are met through fees/levies. There is no clear idea how much these fees will be, but they could be high – and if so would have a chilling effect on cancer trial conduct in Aotearoa. This could particularly affect the increasingly-common 'platform trials', which often involve a large number of new medicines, each given to a small number of people with a specific molecular subtype of cancer (i.e. so-called 'personalised', or 'precision' medicine).

"In some cases a single-digit number of cancer patients per year might receive one of these new medicines in New Zealand. Such trials are often

run by non-profit cooperative clinical trial groups (usually internationally-based). An additional cost & logistical burden will simply mean that NZ will be unable to participate. For example, a specific logistical burden is the new requirement for a 'NZ sponsor' of a new medicine. While this might work well for new 'blockbuster' drugs from large multinational pharmaceutical companies, it is unlikely to work for smaller pharmaceutical firms that make a new molecularly-targeted medicine, as such companies cannot be expected to maintain a New Zealand presence for an investigational drug given to a handful of patients each year."

"Clinical trials are already highly regulated, including Standing Committee on Therapeutic Trials (SCOTT), Gene Technology Advisory Committee (GTAC) and Health and Disability Ethics Committee (HDEC) review, and these committees are best placed to assess patient risk. Adding a new NZ-specific regulatory processes for drugs that have already been through these and equivalent regulatory processes overseas (e.g. in USA, Europe, UK or Australia) seems inappropriate".

It could be argued, say Malaghan, that "approved clinical trials that have been reviewed by HDEC, SCOTT and GTAC should be exempt from the new regulation entirely. Otherwise, it will be very important that a fee exemption mechanism is included for public good trials (including co-operative trials, and investigator-initiated trials run with NZ grant funding, e.g. from the HRC)".

Furthermore NZHR adds that all trials which go through the Therapeutic Products Legislation regulatory processes should be fast tracked, and there should be regulations which require the regulator to provide approval within specified short-as-possible time frames.

Thanks again for the opportunity to present this afternoon.

END

NZHR's full written submission can be read here https://nz4healthresearch.org.nz/wp-content/uploads/2023/03/NZHR-submission-re-therapeutic-products-bill-final-050323.pdf

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

24th February 2023