New Zealand
Association of Clinical Research

Health Committee
Level 10 Bowen House
Parliament Buildings
Molesworth Street
Wellington 6160
New Zealand

02-Mar-2023

Re: Therapeutic Products Bill impact on clinical trials

To the Health Committee,

The New Zealand Association of Clinical Research (NZACRes) is a professional members organisation. Our network reaches over 800 clinical researchers in Aotearoa and internationally. We represent clinical researchers from every part of the sector including Te Whatu Ora investigative sites, private research sites, pharmaceutical companies, contract research organisations (CROs) and other vendors involved in clinical trials.

The proposed Therapeutic Products Bill (TPB) will protect, promote and improve the health of all New Zealanders by providing for acceptable safety, quality and efficacy of medicines or performance of medical devices across their life cycle. NZACRes acknowledges and supports the purpose of the TPB and recognises the magnitude of the undertaking in replacing the Medicines Act 1981.

The importance of clinical trials must not be underestimated. Clinical trials offer people in New Zealand the opportunity to access therapies that would not otherwise be available to them and, as such, are an important part of overall healthcare for New Zealanders. Additionally, the conduct of clinical trials can save the public healthcare system money. In a 2019 report, the economic contribution of clinical trials in New Zealand was estimated to be approximately $150 million/ year[1]. This report did not estimate the contribution from trials of other therapeutic products so the overall sector economic contribution is likely to be significantly higher.

It is essential that New Zealand remains an attractive and competitive clinical trials destination. In order to do so, it is imperative that the approval timelines are preserved and that any new processes do not create unnecessary barriers to conducting clinical research in New Zealand. After reviewing

[1] Siddharth, P. (2020). The value of clinical research with modern medicines in New Zealand: Economic contribution and wide-ranging benefits.

the TPB and on behalf of our membership, NZACRes requests consideration of the following recommendations.

Key recommendations for consideration:

1. Omitted from the TPB: regulatory timeline. Section 30(4) of the Medicines Act 1981 requires that the Director-General shall determine every application for his approval under this section within 45 days after the receipt of the application. Rapid regulatory review is currently one of the key advantages of conducting clinical trials in New Zealand and we ask that the 45 day review timeline is carried through into the TPB if regulatory approval is required in addition to licensing.

2. Sections 15 and 16 Therapeutic Purpose and Therapeutic Product. The definition of therapeutic purpose includes (g) investigating a human physiologic process. Together with section 16, the present wording of the TPB would classify all lab kits as therapeutic products. Clarification around the requirement to register laboratory equipment for diagnostics as part of a clinical trial is required. Commonly, samples and tests that are not part of the standard of care could be used to generate study data but are not used for clinical decision making. We request further clarification regarding clinical trial diagnostic kits that are not used for clinical decision making, and request that they be exempt from requiring a license or being listed under this application if the tests are not performed in New Zealand.

3. Section 36 Clinical Trial (2)(b) indicates that post-investigation activities, after the information gathering phase has ended, are not part of a clinical trial. Several processes take place after the data generation phase of a study, e.g. returning unused investigational product to the country of origin for disposal, unblinding, destruction of surplus back up samples. We request clarification regarding the licensing requirements for the conduct of these activities.

4. Section 152 Content of a license. We request confirmation that only one license is required per clinical trial and that the license can cover all of the activities required for a clinical trial to be conducted in New Zealand, such as:

    a. Importing, exporting and supply of investigational products and devices;

    b. Importing, exporting and supply of placebo, controls or comparators and;

    c. Importing and exporting lab kits and samples

5. Sections 157 & 159 Criteria for Licensees and Responsible Persons. Further clarity around the definition of the Licensee for the purpose of conducting a clinical trial is required. We would like further information on who the licensee is intended to be and if the new bill will essentially follow the current Medsafe system where an applicant becomes the NZ Sponsor for the purposes of conducting the clinical trial. It is unclear if under the proposed bill the licence holder could be any party appropriate for the study; including pharmaceutical companies, biotech companies, CROs, academic institutions, health authorities or individual investigators.

6. Section 158 (g) and (i) Criteria for granting license – (g) ethics approval and (i) any other criteria in the rules. Clarification around the required approvals to conduct clinical trials is needed. In order to preserve the approval timelines, it is essential that licensing under the TPB and ethics approval can occur in parallel. Likewise, if regulatory approval is required in addition to licensing this should also occur in parallel.

7. Section 158(h) Criteria for granting license – unauthorised products. Post-trial access to unapproved products is an important consideration for placing trials in a country. In some cases, continued access after a study is an ethical requirement and currently can be supplied under Section 29 of the Medicines Act 1981. The TPB should not be prohibitive to ensure access for patients following their participation in a clinical trial. It should be confirmed whether section 158(h) would permit post-trial access to an unapproved product. As the bill stands, it appears that a license or permit would be required for continued access and this may not be feasible in such situations. We request further information and confirmation that provision of unlicenced investigational product can be provided on compassionate grounds as needed, either through individual patient access or a more extensive access programme. We request a suitable named patient supply replacement mechanism to section 29 of the Medicines Act 1981 that would cover patients in this situation.

8. Section 193 and 194 Advertisement and Advertising. The definition of an advertisement (s193) appears to be broad and potentially means any communication about a product could be thought of as promoting a product, such as, the communications between the sponsor and investigator relating to a clinical trial. We recommend that the bill is amended to reflect the definition of an advertisement contained within the Medicines Act 1981: "*any words, whether written, printed, or spoken, and any pictorial representation or design, used or appearing to be used to* ***promote the sale*** *of medicines or medical devices or the use of any method of treatment; and includes any trade circular, any label, and any advertisement in a trade journal*". Section 194 stipulates that only products with New Zealand authorisation may be advertised. Since many therapeutic products are unauthorised products, we are concerned that clinical trials recruitment advertisements under the catchment of section 193 may unintentionally breach section 194.

9. Sections 195 improper inducements to health practitioners and Section 14 Interpretation (induce). During the course of a clinical trial, investigative sites receive payments which are proportional to the number of subjects screened and enrolled. Sponsors may also provide valuable non-investigational, comparator medications or devices or donate equipment to sites at the end of a clinical trial. It is unclear what is considered to be a "benefit" according to section 195 in the context of clinical trials and clarification is required. Furthermore, during the recruitment phase, investigative sites are contacted regularly to encourage the enrolment of eligible participants in the clinical trial. Enrolment in a study is a clinical decision made by the investigators per study protocol. Section 195(3) states that a health practitioner […] makes a favourable clinical decision about a therapeutic product if they make a clinical decision that the product is appropriate for a patient […]. Section 14 defines "induce" and the definition includes to request, instruct, persuade, encourage, assist, or coerce. We are concerned that under the broad definitions of both "induce" and improper

inducements, investigative sites, sponsors and CROs may unintentionally breach section 195 during the course of normal recruitment activities.

10. Schedule 1 sections 29 and 30 – licenses for existing clinical trials. These sections indicate that existing clinical trials will be required to obtain a licence within either 6 or 12 months after commencement of the TPB, depending on their current approval status. We believe this will be a substantial amount of additional work and cost for all parties involved. Furthermore, clinical trials participants may suffer adverse events if consistent access to the investigational product is disrupted. Any protocol deviations related to dosing delays can impact the integrity of the study data collected. We suggest that, in the event that approval is not granted within the given timeframe, that there is provision for continuation of activities until such time the application has been reviewed e.g. a bridging license. An exemption should also be offered to studies that are closing within a short time after the commencement of the TPB.

Thank you for your consideration and we welcome the opportunity to make an oral submission to answer any questions the committee may have.

Sincerely,

The NZACRes Executive Committee

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