

3 March 2023

Committee Secretariat
Therapeutic Products Bill
Parliament Buildings
Wellington
email: health@parliament.govt.nz

Submission in response to: the Therapeutic Products Bill
From: Physiotherapy New Zealand

Tēnā koutou katoa

Physiotherapy New Zealand (PNZ) is grateful for the opportunity to make a submission on the Therapeutic Products Bill on behalf of our members. We support most of the Bill that replaces the current Medicines Act and aims to provide a flexible regulatory regime for natural products.

We are however concerned that, as acknowledged in the feedback in the House by Members representing the views of Rongoa Māori practitioners and from Tae Ora Tinana the PNZ Māori Physiotherapy group that insufficient consultation has occurred with groups representative of a wide range of Māori both urban and rural which has resulted in little consideration of the impact on their practices.

We therefore request that the time be taken before the Bill goes to it's next reading for far wider consultation with Māori groups across the Motu.

Whilst physiotherapists are not direct prescribers of medication they may under standing orders be delegated this care. There are two Physiotherapy Board New Zealand standards¹ that safeguard the public safety when physiotherapists are involved with patients and prescription medicines:

- 1) Giving advice about medication standard
- 2) Physiotherapists administering prescription medicines standard

Along with physiotherapists who are also Rongoa Māori practitioners, physiotherapists may also use, sell or advise patients on the use of NHPs. The PBNZ is likely to need to review the two standards to include NHPs. The inclusion of medical devices into the Bill will also likely impact on some physiotherapists. It appears from the definitions of medical devices that equipment such as acupuncture needles and sports and exercise monitoring equipment are now included. To date physiotherapists have not been asked for input into the Bill and how the requirements will work in practice; this will require further consideration.

¹ Physiotherapy Board of New Zealand. Physiotherapy Standards Framework. Physiotherapy Standards. Giving advice about medication standard. Physiotherapists administering prescription medicines standard.

Specific Comments

The following is specific feedback provided by PNZ members that PNZ submits requires further consideration:

Section 54

1(a)(ii) - this clause appears to limit standing orders to authorised indications only. This may be too limited and may need to be broadened to off-label use/indications as well, provided the prescriber remains responsible. The “Physiotherapists administering prescription medicines standard” clearly states the responsibilities of care physiotherapists are required to take. For example, many prescription medications may be considered off-label use in children, where standing orders may apply in hospital settings or in travelling sports team situations. Other examples include off-label use of anti-depressants (e.g. venlafaxine) for neuropathic pain. This also appears at odds with clause 85 which specifically states that unauthorised and off-label medications can be administered by a health professional.

Clause 85

3.a. the use of the word “and” at the end of this clause appears to state that only health practitioner prescribers for that medication can administer a prescription medicine. This appears at odds with existing standing order arrangements from the Medicines Act 1981, Medicines (standing order) regulations 2002 and section 54 on standing orders in the proposed regulations and will not work in practice in situations where the prescriber is not present/available (e.g. in some prehospital / hospital settings where a physiotherapist or other health practitioner that is not a prescriber (e.g. paramedic, nurse) needs to administer prescription medicine or in a travelling sports team environment where the only health practitioner present may be a physiotherapist.

Suggested amendment:

(3) However, they are allowed to do so only if—

(a) they are a health practitioner prescriber for that medicine and they administer it to a patient of the practitioner; **or**

(b) they administer it to a patient of, and at the request of, another health practitioner prescriber for the medicine; and

(c) if it is a medicine that requires compounding, it is lawfully compounded for that patient; and

(d) if it is a medicine that does not have a NZ authorisation for any indications, the special case requirement is complied with.

Medical devices

A number of physiotherapists deliver acupuncture, within their scope of practice. Whilst this does not involve the administration of any prescription medicines it does require the use of acupuncture needles. The acupuncture needles sold in NZ are CE marked and are deemed safe for the EU market (27 member states, ~447 million

population). Will these products need to be re-examined by the regulator under the bill? And if so, would healthcare be withheld until approved?

Physiotherapists working in a variety of areas including sports and cardiorespiratory use diagnostic devices to monitor heart and respiratory performance and medical devices to administer medicines, such as bronchodilators, for respiratory conditions. The Bill is unclear as to the specific devices that are covered and therefore the implications for physiotherapy practice. We recommend further clarification be given of the exact devices covered under the Bill along with consultation with those groups of physiotherapy practitioners whose practice is likely impacted to ensure practicable solutions are found to managing health and safety concerns.

Natural Health Products

The term NHP is ambiguous. Many physiotherapists use massage/topical creams with arnica/beeswax for example. These are not administered via intravenous, intramuscular or oral means, therefore are they included and therefore will their effectiveness need to be shown by clinical trials before use?

We therefore recommend that a clearer definition of NHPs covered by the Bill or a more comprehensive list the types of NHPs covered, for example taking into account their application and risk to patient safety be provided.

Rongoa Māori

Tae Ora Tinana representing Māori physiotherapists and PNZ members are very concerned that the lack of representative consultation across Rongoa Māori practitioners working in various different care settings e.g. rural and Māori patients receiving these services, is a breach of Te Tiriti o Waitangi obligations. We therefore recommend that time be taken now to address this issue and to fully consider the implications of this Bill on Rongoa Māori practice and the risk the current Bill poses to further increasing health inequities for Māori.

A practical threat to Rongoa Māori relates to the process of traditional remedies (natural health products NHP as defined in the Bill) used in Rongoa Māori needing to undergo costly and time-consuming testing and regulation, which could make it more difficult and expensive for Rongoa Māori practitioners to provide their services. Consultation on this requirement would be helpful to ensure that public safety is met in a culturally appropriate manner.

About PNZ

PNZ, alongside our Te Tiriti partnership group Tae Ora Tinana, is the national professional membership organisation for physiotherapists and physiotherapy students. We provide our members with advocacy, education, information, and services as well as promoting physiotherapy to the general public. First incorporated in 1924 Physiotherapy New Zealand Incorporated currently has a membership of over 4,700 physiotherapists. PNZ members work across all aspects of the health and disability system including the current DHBs, private practice, education, private sector, occupational health, and disability.

Thank you for the opportunity to submit on this matter. If the Committee requires further information the primary contact for matters relating to this submission is:

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We would appreciate the opportunity to present an oral submission.

Ngā mihi,



Mark Quinn
President



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