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The [1]Therapeutics Bill is intended to replace the Medicines Act 1981 and the Dietary Supplements Regulations 1985 to provide for the comprehensive, risk-proportionate regulation of therapeutic products, such as medicines, medical devices, natural health products, and active pharmaceutical ingredients.

Nurse Practitioners New Zealand (NPNZ) the professional organization representing the majority of Nurse Practitioners (NPs) in New Zealand. Of the nearly 650 NPs registered in New Zealand, more than 480 are members of NPNZ.

Nurse practitioners|Mātanga Tapuhi work autonomously and in collaborative teams with other health professionals to promote health, prevent disease, and improve access and population health outcomes for a specific patient group or community. Nurse practitioners manage episodes of care as the lead healthcare provider in partnership with health consumers and their families|whānau. Nurse practitioners combine advanced nursing knowledge and skills with diagnostic reasoning and therapeutic knowledge to provide patient-centred healthcare services including the diagnosis and management of common and complex health conditions. They provide a wide range of assessment and treatment interventions, ordering and interpreting diagnostic and laboratory tests, prescribing medicines within their area of competence, and admitting and discharging from hospital and other healthcare services/settings. As clinical leaders they work across healthcare settings and influence health service delivery and the wider profession.[2]

In preparation for this submission a review of the Therapeutics Bill and the [3]Pae Ora Act 2022 has been undertaken. As defined in the legislation, the purpose of the Pae Ora Act is to provide for the public funding and provision of services in order to—

(a)protect, promote, and improve the health of all New Zealanders; and

(b)achieve equity in health outcomes among New Zealand's population groups, including by striving to eliminate health disparities, in particular for Māori; and

(c) build towards pae ora (healthy futures) for all New Zealanders.

In order to be able to achieve this, the Therapeutics legislation must promote access to healthcare, in order to address inequity. The key to achieving this is to ensure that language and definitions within the legislation are inclusive of all authorized healthcare providers.

1. There are issues with the existing Medicines Act that must be repealed by the new legislation. There have also been examples in more recent legislation (End of Life Choices Act (2019) Including but not limited to Sections 10, 13, 18 and 20) wherein NPs have been excluded by an erroneous definition of

[1] https://www.parliament.nz/en/pb/bills-and-laws/bills-proposed-laws/document/BILL_130084/therapeutic-products-bill
[2] https://www.nursingcouncil.org.nz/Public/Nursing/Scopes_of_practice/Nurse_practitioner/NCNZ
[3] https://www.legislation.govt.nz/act/public/2022/0030/latest/versions.aspx

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the NP scope of practice and therefore prohibited from being able to provide the health service to their patients, many of whom have very limited access to healthcare. **It is critical that patient care and access is not impeded in the new legislation by using a limited definition of medical practitioner – instead it is vital the term 'authorised health practitioner' is consistently applied.**

To facilitate access to therapeutic devices, pharmaceuticals and in general healthcare, the definition and terms within the Act must be inclusive of authorised health practitioners with prescriptive authority including NPs who are authorised prescribers and Registered Nurses who are designated prescribers. Alternatively (and where essential) the legislation must be clear that the statement refers to medical **and** nurse practitioners as authorised prescribers, as defined in the [4]Health Practitioners Competence Assurance Act (2003).

2. Therapeutics in the context of this legislation covers a vast range of products from dressings to appliances, pacing wires. Many of the products captured by the legislation will have nurses (and their patients) as their primary user, far more than medical colleagues. **Further than nurses simply being the end users of products, it is essential that there is nursing input as to what is or is not approved.**

3. Clauses 54 and 55 regarding standing orders. NPNZ agrees that the opportunity to develop and utilise standing orders should remain in the Bill. Nurses are increasingly adopting formal prescribing authorisations at all 3 levels, however, there are still circumstances within which nurses need to be able to operate under the standing order framework. This includes situations for example, within remote and rural communities, and for consumers that experience access to care barriers – notably Māori. **Standing Orders continue to facilitate equity in terms of service provision. NPNZ does not agree that they should be removed at this time.**

4. Clauses 83, 87, 88 and 90 relate to the prescription, supply, and importation of medical devices. These clauses affect nurses who are involved in 'prescribing' or fitting patients for medical devices. The ability to prescribe medical devices best sits with regulatory authorities under the HPCA Act. **In many settings nurses and Nurse Practitioners prescribe, fit, and supply patients with a range of products which fall under the medical advice definition**. Including but not limited to; compression hosiery, stoma related applied devices, urological catheters/devices, protheses, casts/splints, respiratory devices, and wound care products. **All of which are delivered within services where nurses are the responsible and expert clinicians in the assessment, supply, fitting, and management of these devices.**

[4] https://www.legislation.govt.nz/act/public/2003/0048/latest/DLM203312.html

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Nurse practitioners need to retain the ability to design/create, import or secure local or overseas supply of medical devices if required and appropriate. An example was provided by an NP: *"In my own practice, we import a range of therapeutic compression hosiery that we assess for and fit. We do this because we can source these and provide them at a greatly reduced cost to the patient compared with purchasing over the counter."*

NPNZ argues that the HPCA Act and the regulatory agencies/processes are the appropriate vehicle to ensure competent registered nurse and nurse practitioner practice, rather than to specify specific devices and professions within the Bill itself.

It will be essential to consider funding streams such that if Pharmac listed medical devices that may become generally funded or funded via special authority, nurse practitioners will need to be able to continue to prescribe relevant medical devices via any funding mechanism in place.

NPNZ strongly recommends that consideration is given to the definitions of authorised health practitioner and if they are to be specified, that nurse practitioners are specifically included as authorised prescribers.

Nurse Practitioners and nurses are often the only health practitioners with whom people have contact. This is particularly so in rural and remote areas of Aotearoa, where there are high numbers of Māori and in high density, lower socio- economic urban areas where cost of accessing health care is unaffordable – thus perpetuating inequity and a poorer health outcome.

5. **Nurse Practitioners** are excluded in the current Medicines Act 1981 specifications regarding new Medsafe unapproved medicines (Section 29). Section 29 has at its root the provision of a means for use of experimental drugs that could be put in the 'last hope' category when nothing else seems to be having a therapeutic impact. **This section is no longer fit for purpose and must be eliminated**.

   It has recently been used as a de facto way to manage supply chain disruption experienced because of the global pandemic. This has become increasingly problematic, with disruption to usual supply of medicines and the necessity to utilise substitutes –with many classified as 'new medicines' and falling under Section 29 of the current Medicines Act. Due to the definition of **Medical Practitioner** that exists in the legislation, Nurse Practitioners can not prescribe these medications. **This is a major equity and access to care issue as there are numerous communities where nurse practitioners are the only health practitioner meeting health needs.**

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It is anticipated that global events threatening supply therapeutic devices and pharmaceuticals will continue well into the future. Any new legislation must protect ongoing supply to patients and enable all prescribers to continue to meet the health needs of their patients/ consumers.

NPNZ recommends that the processes for genuinely new and experimental medicines and therapeutic devices are separate and clearly defined as different to management of supply chain issues, clearly defining the scopes of those who may prescribe them.

6. **The Therapeutics Bill sections 114-116 relate to emergency supply. NPNZ recommends that the definition of who may prescribe medications in this circumstance include Nurse Practitioners and RN prescribers.**

7. **Section 226 Regulator's powers in relation to oversupplied persons** sub-section (3):

The only place where the term "Medical Practitioner" occurs in in sub part 3, clause 226. I can see no reason why this should not be 'authorised health practitioner' as this may be an action required by nurse practitioners, who manage care of patients as well as others such as RN prescribers, pharmacists, veterinarians, dentists, and midwives. It is unnecessarily restrictive, given that it serves to prevent abuse of dispended medicinal products (**anyone should be able to report this**).

Oversupplied persons

Clause 226 *gives the Regulator powers in relation to persons who are addicted or habituated to a prescription medicine or pharmacist medicine or who have obtained more of those medicines than is reasonably necessary for their own therapeutic purposes. These powers can be exercised only by the Regulator personally on the advice of a medical practitioner or by a medical practitioner to whom that power has been delegated.*

8. Although there is indication that the bill will not change restrictions on pharmacy ownership currently in the Medicines Act 1981, NPNZ would suggest that requirement for a pharmacist to own a majority stake in a licenced pharmacy be removed. It would be ideal if this could be addressed in this legislation.

The rationale:

This requirement does not apply to any other community health service. For example, general practices, midwifery, private medical, and dental and allied health practices all can have ownership structures that do not require the relevant health practitioner to hold a majority ownership. **For consistency and fairness for all providers, this requirement should be removed.**

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Secondly, removing this requirement opens the opportunities and possibilities for new models of care (in line with national strategic health goals and plans) by facilitating amalgamation and development of new services with inclusive ownership structures, which could include non-traditional parties such as communities and Iwi. **Clearly, pharmacy services require a registered pharmacist, and this could be ensured through contract arrangements, but by levelling the playing field around ownership, we provide opportunities to develop new ways of providing and organising services**.

We are aware of resistance by the Pharmacy groups to this. However, all professions and service providers should have a consistent business environment in which to operate, and more importantly, this is an anomaly that we believe will adversely impact on innovation and service development in the future.

Summary

Supports the updating of the legislation to address inequity and promote improved health outcomes.

Recommends That all language in the legislation describes and defines 'authorised health practitioners as defined under HPCA (2003) to promote access to health care and reduce inequity, to truly be able to achieve Pae ora – healthy future for all

Recommends: the legislation is consistent in its use of 'authorised health practitioner' to define prescribing authority enabled by the legislation. In accordance with the HPCA (2003) these practitioners would be regulated by their duly appointed regulatory agencies.

Recommends that clear processes to address supply chain issues as distinct form the process of introduction of new or experimental medications are included in the legislation to avoid the disadvantage of consumers that has ensue with application of the current Section 29 of the Medicines Act

Disagrees with removal of Standing Orders.

Requests that in addition to the written submission, that **Nurse Practitioners NZ** have a representative delegation that can speak to the Select Committee.

Thank you for the opportunity to comment on the proposed legislation

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