Submission to the proposed repeal of the Therapeutic Products Act 2023

Thank you for the opportunity to comment in the repeal of the Therapeutic Products Act 2023, which will be replaced by the previous legislation - the Medicines Act 1981 and the Dietary Supplements Regulations 1985 in the interim.

Note: In addition to this written submission, the College and NPNZ seeks to present before the Select Committee.

Background

The College of Nurses Aotearoa (NZ) Inc. The College is a leading national professional nursing organisation. We are fully committed to te Tiriti o Waitangi. We are a leading voice for support, advancement, and valuing of the nursing profession.

Nurse Practitioners New Zealand (NPNZ) is a division of the College of Nurses Aotearoa representing Nurse Practitioners professional and practice issues **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.

The Nurse Executives Aotearoa (NEA) is an inclusive organisation of nurse leaders from across the whole of health. NEA encourages robust, professional korero and the opportunity to be active participants in identifying the future direction of the nursing profession and health system.

The College and NPNZ represent a substantial and increasing number of authorized nurse practitioners (NPs) - (there are now approximately 800 nationally) and designated registered nurse (RN) prescribers. To support and inform this submission the College Board, Fellows, and wider membership have been consulted on its development. Members of Nurse Executives Aotearoa and Nurse Practitioners NZ have also been consulted.

1. The Therapeutic Products Act allowed for the wider contribution of nurses to health service delivery; we have waited so long for revision. At a time when we need nurses to be enabled, this repeal puts up barriers to progress. The scope of the new act was far greater than the previous which was outdated and no longer fit for purpose. Key concerns with the old legalisation are the issues with Section 29 of the Medicines Act. We are seeking clarification as to why the Act must be repealed in its entirety - rather than keeping those clauses of the new Act which are working well.

2. It is not clear what will happen to therapeutic products. There is the potential for harm if oversight allows vested interest and product dumping. We are not averse to innovation and opportunity, but in a country that is in severe financial restraint, it is critical that approval processes and reporting of harm continues.

3. As defined in the legislation, the purpose of the Pae Ora Act 2022 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.

4. In order to be able to achieve this, 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. Definitions within the Medicines Act 1981 and associated legislation are outdated and no longer appropriate for the delivery of accessible and equitable health care to the people of Aotearoa.

5. There are issues with the existing Medicines Act that had been addressed in new legislation. It is critical that patient care and access is not impeded by using a limited definition of medical practitioner – instead, it is vital the term 'health practitioner' is consistently applied. The repeal of the Therapeutic Products Act and reverting to the Medicines Act creates a major barrier to equity and access as the old legislation predates the development of the Nurse Practitioner Role as an Authorised prescriber, and a health practitioner that increasingly leads care – improving access to high quality health care for many people in Aotearoa.

6. Section 29 of the Medicines Act is a significant barrier to access to medicines for the New Zealand public. Under Section 29, nurse practitioners are unable to prescribe new medicines or extend prescribing if already prescribed by a medical practitioner. This means any new medicine that is brought in for example to replace a medicine that is in short supply but has not been formally approved, is unable to be prescribed by a nurse practitioner. This is a significant barrier to accessing basic medicines and limits nurse practitioner practice in a way that was not foreseen. This Section of the existing legislation must be specifically identified and removed from any new legislation.

7. Under the Medicines Regulations 1984, Section 44a, a Medical Officer of Health is charged with authorising any person to administer a vaccination who has satisfied the medical officer of health they meet certain conditions. This regulation requires a medical officer of health to oversee the practice of predominantly registered nurses (and some pharmacists) in most New Zealand vaccination programmes. Requiring a medical officer of health to oversee the practice of health practitioners who are accountable and responsible to their own professional bodies under the HPCA is old-fashioned, inappropriate and puts a significant burden on the medical officer of health who, in theory, is required to ensure every single one of these practitioners is safe to practice. Moving forward, it is essential this requirement is removed with any new legislation. As per point 2 above, health practitioners who have completed the appropriate training should be able to prescribe and administer medicines within their scope of practice and this should include vaccinations. Because of the 'list' system, vaccinations are unable to be added or changed easily, limiting this as an option for appropriately trained health practitioners and as a result creating a barrier to easy access to vaccination.

8. 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. Nurse prescribers are excluded in the current Medicines Act 1981 specifications in regard to new medicines (Section 29).

9. 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**. It has recently been used as a de facto way to manage supply chain disruption, experienced as a result of the global pandemic. This has become increasingly problematic, with disruption to usual supply of medicines and the necessity to utilise substitutes –some of which are classified as 'new medicines' and fall under Section 29 of the Current Medicines Act.

Due to the definition of Medical Practitioner that exists in the legislation, neither RN prescribers nor NPs can prescribe these medications This is a major equity issue as there are numerous communities where nurse practitioners and nurses are the only health practitioner meeting health needs .

10. 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. *Refer Appendix for detailed list of issues raised by members in relation to Section 29 barriers to NPs being able to appropriately meet patient needs.*

11. The College 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.

12. Further, the College seeks to include a legislative addition indemnifying any prescriber, nurses included, of a medicine governed by section 29, from prosecution by the Health and Disability Commissioner or other relevant party. The approval requirements for a supplier of a medicinal product are onerous and those supplying a product simply to make up a deficit in availability of the usual approved product are not going to go to the effort of seeking that approval for such a small market as that in Aotearoa.

13. To repeal the whole Act to address concerns in regard to vitamins and wellness supplements seems excessive, as the scope of the therapeutic products programme is much broader than this. There is insufficient detail for what will replace the Act.

For further information, please contact:

Kate Weston - Executive Director College of Nurses Aotearoa
executivedirector@nurse.org.nz 027 225 8287

Appendix One - Issues with Section 29 Medicines Act 1981

The following are excerpts from NPs describing the challenges and workarounds they have in place simply to provide everyday care to people. The time taken to rectify the issues arising from out-of-date legislation means people are missing out on timely care and the costs to our system already under pressure are exacerbated.

- An aged care provider with a nurse led service and 12 NPs. In the past issues were uncommon with rarely used drugs. Now daily struggles with routine medications going on and off S29, Morphine, Oxycodone, Furosemide, Paracetamol. Developing a time-consuming work around with pharmacy and primary care.
- Told I can no longer prescribe Vit B12 injections as the previous iteration of Hydroxocobalamin is no longer available and needs to be Neo-B12 which is a section 29 - very frustrating for those patients who have been on this medication and now I need to get a GP to prescribe or re-prescribe it.
- I manage 1500 patients many of whom are on drugs under Section 29 some initially prescribed by a specialist who will see them every 6-12mth. This creates a barrier to timely prescription of medications and the loss of continuity of care as any GP that is asked to do these scripts will not know the patient as we do.
- I write to you out of sheer frustration regarding section 29 medications and the need for medical practitioners to sign off these prescriptions. I am an NP of 8 years' experience working in aged care and primary care. The PHC practice is entirely staffed by NPs. We do have a GP who assists us to cover on call and has been obliging by signing scripts / completing special authority that we aren't currently allowed to do. There are several PHC practices that do not have GPs and this number is increasing.
- B12 injections, Morphine elixir, Sofradex ear drops are just some everyday prescription items on the S29 list which becoming more problematic. The list keeps growing as supply issues continue, causing not just double handling of scripts for GPs, pharmacists and patients who may or may not be able to pick up a script at some future point. Phone calls, emails and conversations are constant. We never know what's next or which pharmacy still has remaining stock of the original drug or not. This disjoints care

and is much worse in rural areas where it may be weeks between visits to town for patients.

- I can prescribe Clozapine an antipsychotic needing special monitoring or medications for rapid tranquillisation for an agitated psychotic person, or benzodiazepines but cannot prescribe melatonin for sleep.
- People stable for years on psychiatric medications I routinely prescribe but then the medication is made a section 29 due to supply issues. They must either change clinicians, I find a medical colleague willing to prescribe or they need to switch medications, often leading to relapse. **I cannot stress enough how unfair and potentially disruptive this is on these people's and their whanau lives.** Especially the negative impact on employment, finances, relationships- it is massive.

These stories provide some insight into the problems Section 29 is now creating at a time when our health resources are too sparse to be squandered to comply with outdated legislation. While worsening access for already vulnerable populations and adding needless pressure onto our workforce creating inefficiency, expense and additional burn out risk.

Section 29 is currently a significant barrier to nurse practitioners achieving good patient outcomes.

- The risks include:
  - Increasing reliance on unapproved medicines.
  - Disruption of care impacting on patient flow and access to care.
  - Additional workload with already high and risky workload demands.
  - Medicolegal and patient consent risks.
  - NPs unable to practice within their prescribed scope leading to frustration and potentially exit from the workforce – particularly from primary care where we need them most.

We cannot continue to ignore this issue. College of Nurses, NPNZ and NEA request that Section 29 is urgently and rapidly repealed.

Appendix Two - Extracts: Medicines Act (1981)

Nurse Practitioners and Registered Nurse Designated prescribers are excluded in the current Medicines Act specifications in regard to new medicines. This has become increasingly problematic with disruption to usual supply of medicines and the necessity to utilise substitutes –some of which are " new medicines" Due to the definition of Medical practitioner that exists in the legislation , neither RN prescribers nor NPs can prescribe these medications This is a major equity issue as there are numerous communities where nurses and NP are the only health practitioner that they have access to , who are now unable to meet patients health needs

https://www.legislation.govt.nz/act/public/1981/0118/latest/DLM53790.html

Medicines Act 1981

29 Exemption for medicine required by medical practitioner.

(1)Neither section 20 nor section 24 shall prevent—

(a)the supply by any person to any medical practitioner, on the medical practitioner's request, of any medicine required by that medical practitioner for the treatment of a particular patient currently under that medical practitioner's care; or

(b)the administration by any medical practitioner of any such medicine to any such patient.

(2)Every person who, for the purposes of subsection (1), sells or supplies to any practitioner any medicine that is a new medicine by virtue of paragraph (a) of the definition of the term new medicine in section 3(3) before the consent of the Minister to the distribution of that medicine has been published under the Legislation Act 2019 shall, as soon as practicable after the end of every month in which he has so sold or supplied any such medicine, report that sale or supply to the Director-General in writing, naming the practitioner and patient, describing the medicine, and identifying the occasion when and the place where the medicine was so sold or supplied.

(3)Without limiting section 48, if any person fails to comply with subsection (2), the Minister may, in the manner prescribed in that section but without complying with subsection (2) of that section, prohibit that person from selling and supplying any new medicine to which subsection (2) applies before the consent of the Minister to the distribution of that medicine has been published under the Legislation Act 2019.