DIETITIANS BOARD
Te Mana Mātanga Mātai Kai

Dietitians NZ
Ngā Pukenga Kai Ora o Aotearoa

Clerk of the Committee
Health Committee
Parliament Buildings

3 March 2023

To the Clerk of the Health Committee

Joint Submission on the Therapeutic Products Bill

1. The Dietitians Board of New Zealand (the Responsible Authority under the HPCA Act 2003) and Dietitians New Zealand Incorporated (the professional association for Dietitians) are pleased to jointly submit on the Therapeutic Products Bill. There are 1025 Registered Dietitians in New Zealand who would be covered by the provisions of the Bill; 853 practising and 683 of whom are prescribers (as at January 31 2023).

Position

2. The Dietitians Board of New Zealand and Dietitians NZ support the intent of the Bill to modernise our medicines regime and to broaden the scope to include medical devices, natural health products, and active pharmaceutical ingredients.

3. While supporting the overall tenor and direction of the Bill and recognising the need for a robust and internationally accepted regulatory regime; we do have some concerns and questions about the Bill, and these are outlined below.

4. In particular, we note that much of the implementation and regulatory detail is to be provided for in Regulations still to be drafted. This makes it difficult to assess fully the operational effects and workability of the Bill in its entirety and its fit with corresponding legislation.

Scope Of Practice under the HPCA Act

5. The scope of practice for Registered Dietitians is relevant to the draft Bill –
6. *"Dietitians are registered health practitioners who evaluate scientific evidence about food and nutrition and translate it into practical strategies. Dietitians work in partnership with individuals, whānau, communities and populations, in states of health and disease, to support optimal health and well-being.*

7. *Dietitians use their knowledge, skills and judgment in a variety of contexts, which includes promoting and protecting public health, directing and delivering medical nutrition therapy services, and managing food and health systems. They may perform a variety of functions, including policy development, leadership, management, research, education, and communication roles.*

8. *Dietitians with a prescribing endorsement are able to prescribe Special Foods and approved nutrition-related medicines.*

9. *Dietitians are accountable for ensuring that their practice is consistent with the Dietitians Board's competency requirements, Code of Ethics and Conduct, and relevant legislation."*

Restricted Activity

10. Dietitians have a restricted activity as part of their scope of practice under Section 9 of the Health Practitioners Competence Assurance Act 2003 (HPCA A). The restricted activity is for the prescribing of enteral and parenteral nutrition where the feed is administered through a tube into the gut or central venous catheter.[1] This activity is restricted because it is highly specialised and has been noted for its ability to cause risk or harm to the public.

11. Dietitians are highly trained health practitioners who are responsible for the feeding of and nutritional health needs of patients in their care and/or under the care of a specialist multi-disciplinary health team (such as gastroenterology, renal health, paediatric or metabolic health teams).

12. The administration of food and therapeutic agents via a feeding tube aims to maximise nutritional uptake by the patient and requires knowledge of physiology, metabolism, biochemistry, and nutrition. Nutrition is a key part of treatment and returning the person to a state of optimum health.

Part 2 Interpretation

13. As noted earlier, the Dietitians Board and Dietitians NZ support modernisation of the regulatory regime for medicines and the incorporation of devices and NHPs under the one regulatory regime.

14. Currently nutritional products prescribed by dietitians for individuals by way of exclusive or partial feeding via a feeding tube are included in the Food Standards Code (Standard 2.9.5, Foods for Medical Purposes) and therefore it appears these would not be included in this Bill. This is despite their prescription being a restricted activity, having a clear therapeutic purpose and carrying a risk of harm from administration.

[1] Health Practitioners Competence Assurance (Restricted Activities) Order 2005 (SR 2005/182) (as at 01 July 2005) – New Zealand Legislation

15. Conversely, it appears that foods with added vitamins and/or minerals, e.g., orange juice with calcium added, would be included in this draft Bill because supplemented foods are not currently included in the Food Standards Code. It is not clear whether this Bill would supersede the current New Zealand Food (Supplemented Food) Standard 2016.

16. This is confusing and appears to contradict the authorisation for Registered Dietitians, who are permitted under their scope of practice to prescribe enteral and parenteral nutrition.

17. Greater clarity is required in the Bill relating to Foods for Medical Purposes (currently covered in the Food Standards Code) and supplemented foods (not currently included in the Food Standards Code). Foods for medical purposes are often compounded and dispensed by Pharmacists or hospital foodservice personnel, and as mentioned previously, have a clear therapeutic benefit and carry a risk of harm.

18. We recognise that the regulations will follow this legislation but do want to bring the Committee's attention for the need to differentiate between NHPs for medical purposes and those for general public use. Following bariatric surgery, patients require life-long supplementation in levels greater than that currently included in 'off-the shelf' vitamin and mineral supplements. We note that there has been no allowance for bariatric specific supplements in the Therapeutic Good Administration (TGA) in Australia. This increases the pill burden for many bariatric patients, increasing costs and decreasing compliance. This can lead to significant nutritional deficiencies and ill health.

19. We agree that the Regulator should be able to reclassify an NHP as a medicine at the request of the sponsor. We also suggest reclassification should be determined by the Regulator on the grounds of new evidence (reported benefits or harms) to support proportionate regulation and to protect the public. However, the lack of specificity in the Bill and the deferral of a long list of issues to be addressed in secondary legislation is concerning.

20. There will be other issues that emerge from such an omnibus Bill and have the potential to generate unintended consequences or contradict existing clauses because they are yet to be operationally tested. For example: the transitional arrangements for Responsible Authorities to update scopes of practice with the Therapeutic Products Bill.

21. Even with a long lead time to 2026 for implementation of all regulatory functions of the Bill, the Responsible Authorities, established currently as registered charities, may not be a suitable vehicle to manage the mandate the Bill imposes on them given like jurisdictions' requirements for clear governmental oversight of medicines control, safety, and administration, end-to-end in the supply chain.

22. Other functions and operational clauses are still to be fully set out:

- Approved Health benefit claims for products to claim a therapeutic purpose- clause 61 and 62 defines permitted health claim but the Rules for clause 62 standardising claims are yet to be developed.
- Transition times for NHPs
- Build of and regulations governing the Regulator and administration costs of the new regime and how these will be shared.
- Cost recovery of manufacturing license and importation fees for ingredients for NHPs
- Proportionality of market authorisation of NHP costs and how these will be derived.
- Labelling requirements of NHPs – including risks, contraindications and therapeutic claims
- NZ Australian harmonisation of market authorisations and requirements for supply and sale including changes to the Food Standards Code.

Part 3 Dealing with therapeutic products

23. Dietetic Prescribing
24. Dietitians are authorised prescribers – that is, they are independent prescribers and utilise their skills and dietetic knowledge to inform their prescribing practice. They are not required to have prescriptions counter-signed except when training or under supervision in their first year of registration following graduation.

25. Dietitians are often the only allied health practitioner within a clinical setting or health team that holds prescribing and dispensing rights. Since 2015 and updated by gazette notice in 2017[2], dietitians who have completed the standards and training set by the Board and who complete annual re-certification requirements to maintain their prescribing endorsement are permitted to prescribe and authorise subsidised dispensing of approved nutrition-related medicines, in addition to all Special Foods.

26. The Dietitian Prescriber Endorsement is held by over 680 dietitians and enables people to receive prescribed treatments and medicines directly from the dietitian without having to be seen by another treating health practitioner.

27. The Board surveyed all dietitians in 2022 about extending prescribing rights further to allow for a wider range of therapeutic products to be prescribed and administered. The survey also asked about how dietitians address equity concerns for those patients who need medicines that are either unapproved or unfunded for dietetic purposes. Some patients or clients rely on a secondary referral to a General Practitioner, thereby delaying treatment and adding in extra cost to the treatment regime for the individual concerned. Community care could be enhanced, and inequities reduced if the dietitian had wider approved and funded access to greater nutrition related medicines, medical devices, and natural health products.

[2] https://gazette.govt.nz/notice/id/2017-gs1092

28. The Dietitians Board will be providing advice this year to Manatū Hauora (Ministry of Health) recommending an expansion of prescription medicines and products for dietitians. This Bill recommends that those decision-making powers reside with the Board itself. While this provides for a more flexible and responsive system it removes the additional safety net of classification and agency checks and balances held by Medsafe on behalf of the Crown. We discuss this is further detail on pages 6-8.

29. We support the standardisation of product labelling and components for supply and manufacture. We support the Bill's proposal that for a product to be ascribed a therapeutic level, it must incorporate a sufficient dose or amount of an evidence based and therapeutic substance and that the useability of it as a health product must be recognisable to a consumer as a therapeutic product.

30. The deferral of activities to be covered by Regulations covering form and function of the Regulator means we cannot be certain as to the impacts on market availability and access, impacts on dietetic practice, how costs will be attributed, impacts on boundary issues such as prescribing of altered or blended foods for a therapeutic purpose or on how the Dietitians Board should respond to the development of new professional standards governing practice that will change with the passage of the new Act.

31. The lack of timeframes and detail which will follow in the regulations makes it difficult to know how smaller regulators are expected to respond and to what degree we should be engaging with the profession on the tsunami of new product rules and regulation that is about to sweep in. Some dietitians who supply NHPs and combine NHPs with orthodox medicines and enteral feeds, will find themselves having to navigate a complex web of rules and regulations.

32. What educative processes will be engaged to assist health practitioners navigate their way through the cascade of new rules?

33. What education will be provided to Responsible Authorities to implement new prescriber rules and to monitor the use of products that are now deemed therapeutic and prior to the Bill may have been deemed 'off-the shelf' sports supplements with a for sale customer approach of 'caveat emptor'?

Part 9 Regulator

34. Clause 14 defines health practitioner but does not define professional bodies or coverage. See also clause 343 (7) (j). The term professional bodies captures membership organisations such Dietitians NZ and Te Kāhui Manukura o Kia Ora (Māori dietitians rōpū). Responsible Authorities regulate the dietetic profession. Registration is mandatory. Membership of a professional body is usually voluntary. It is confusing and risks capturing the wrong organisations.

35. Clause 343 provides for the sharing of information between the RAs and the Regulator. We ask whether there should be a reciprocal responsibility placed on the Regulator to notify the RAs in circumstances where the Regulator believes a health practitioner poses a risk of harm to the public.

36. The transitional arrangements are important to the implementation and effectiveness of the new regulatory regime given the Responsible Authorities under the HPCA Act are concurrently under review. It is not possible at this stage to know how potential amendments to the HPCA Act will fit with this Bill and vice versa. This makes it difficult for RAs to plan and has several downstream effects. As a registered charity we need to plan for structural changes well in advance as we have small reserves on which to fall back on should our level of risk or functions change.

Part 11 Repeals, revocations, and amendments to other enactments

37. Medicines Act powers transferred to Responsible Authorities Clause 389
38. The Bill proposes a significant shift in responsibilities from the regulator Medsafe to the Responsible Authorities. There has been little discussion with the RAs that monitor prescribing about this proposed change.

39. The explanatory note subpart 2 of Part 11 amends the HPCA Act. It shifts the responsibility for the regulatory functions for the classes of health practitioners able to prescribe, the classes of medicines they can prescribe and under what circumstance they can prescribe out of the Medicines Act and onto the Responsible Authorities. This is a significant shift in powers, it shifts regulating of risk away from the Crown's regulator Medsafe to authorities that are established under statute but operationally are registered charities with limited reserves to manage such a major change. It also represents a major cost shift exercise by placing the risk of determining who prescribes what and when entirely with the Responsible Authorities. Health practitioners will need to carry the burden through increased regulatory fees for the additional responsibilities.

40. Dietitians NZ supports this significant shift and believe that the regulator of dietitians (the Dietitians Board) is best placed to know what medicines, medical devices and NHPs dietitians should be prescribing to enhance care, reduce inequities and improve patient outcomes. Dietitians NZ and the Dietitians Board acknowledge that the proposed change will require a strengthening of expertise, reserves, and monitoring capability to manage a more direct regulatory role and responsibilities formerly held by Medsafe under the auspices of Manatū Hauora (Ministry of Health). Currently, RAs determine the competence standards and under what conditions the prescribers may issue prescriptions, but this is within the remit of the Medicines Act. The Medicines Act imposes controls on the type of controlled drugs able to be prescribed, and the classes of practitioners able to prescribe and in what circumstances.

41. It will be difficult for smaller RAs with prescribing rights to manage these additional responsibilities without increased capacity and capability.

42. Monitoring by Medsafe of unusual prescribing is completed quarterly and issued after the fact to enable a practitioner to be traced and followed up as an educative or competence issue. The reporting is not contemporaneous. There is a delay in reviewing the trend information for unusual prescribing. Medsafe can act on reports of harm from multiple sources including CARM, from individual complaints, from other health agencies, from Medicines Classification and sponsor information, all before the quarterly reports are generated for the RAs.

43. As the RAs have Ministerially appointed Boards/Councils, the membership may or may not have an adequate representation of prescribers on the Board as there is no composition criteria for the ratios of prescribers appointed to Boards. The Dietitians Board, for example, while registering over 80% of the profession (683 dietitians) as prescribers, has only one prescriber appointed to the Board.

44. The HPCA review team only last week (February 20, 2023) asked about increasing the proportion of lay persons on RA boards as part of their review work. Potentially, this could exacerbate the prescribing skills deficit that exists now in prescribing expertise on the Board. Given this Bill recommends the RAs amend the scopes of practice to complement this Bill, it presupposes the Boards have the capacity and capability at hand to do so with [potentially] fewer appointed clinically trained members.

45. An alternative is to have expert advisory groups to the Board on medicines and scopes of practice (which may proliferate under this model as the Board works to manage risk and classes of medicine for different specialities – diabetes dietitians, metabolic or paediatric dietitians - in a similar way to how medicine operates). One possible downstream effect of specialist scopes of practice is reduced workforce flexibility adding complexity and cost to the system. This is because it is hard to move between specialist or limited scopes. This is the case for medicine which now has 30 different scopes.

46. The Dietitians Board has an expert advisory group (EAG) to advise the Board on prescribing matters and monitors Medsafe quarterly reports on unusual prescribing. There would be significant costs to the Board to increase the EAGs roles and functions and these costs will need to be borne by the dietitian prescribers through a flow-on effect to fees. Across all eight RAs with prescribing rights – medical practitioners, nurses, pharmacists, dietitians, optometrists, Chinese Medicine, midwives, occupational therapists for devices, this is likely to have a significant inflationary effect on practitioner and insurance fees due to increased risk of managing the amended and revised scopes of practice, monitoring the classes of medicines able to be prescribed and compounded, and monitoring the effects of these changes. Insurers and auditors must be advised of any major law changes that have an impact on new risks for the Boards and this is a significant one.

47. The Bill provides for a further level of reporting by RAs to the Regulator of rule breaches and harms that adds complexity for the Boards and health practitioners. Not only will dietitians be exposed to double jeopardy of reporting to the HDC, the Board and ACC but also to the Therapeutic Products Regulator (which does not reflect the principles of right-touch regulation). This new reporting line adds further system costs with increasing lines of accountability falling on RAs. The only way RAs can meet new functions to be incorporated into their operating costs is by on charging of fees to practitioners, and ultimately consumers.

48. What advice has been received on unintended consequences flowing from this proposed change in the Bill? Has analysis been done on the potential for increased risks around reported harms to ACC or the HQSC? How will monitoring be timely and support public safety? Just because the costs of prescribing errors fall elsewhere in the health system does not mean they should not be considered or inform such a major change in responsibilities from a Crown regulator to a third-tier statutory body. Have the impacts of this change been canvassed with Australia under the TTMRA?

49. We would appreciate the opportunity to discuss these issues with the Committee and to tease out options for a safe transition or add in further controls, possibly around classes of medicines or classes of prescribers.

Criminal liability

50. We also have concerns about the inclusion of severe penalties and the addition of criminal liability for practitioners who hold an import licence or manufacture products for supply. We see these penalties as substantial and a deterrent to health practitioners doing their jobs. These health practitioners will need substantial liability insurance to continue to operate and may withdraw from the workforce as dietitians if the risks and costs are perceived to be too great.

51. We are also concerned at the risk of exposure for the Board as the regulator of dietitians who may then find themselves in breach of the law and criminally liable. In addition, if the Responsible Authorities were made Crown Entities as a consequence of the HPCA Act review, would the same legal provisions be applied including enforceable undertakings, fines against Crown organisations, and attributing liability downwards including to Board members?[3] There are potentially significant new risks and insurance liabilities for the RAs if there is no carve out for criminal liability for the registration boards. It may be harder to attract Board members given the ramifications of criminal liability.

[3] https://www.health.govt.nz/system/files/documents/pages/crown_liability_under_the_therapeutic_products_bill_and_other_offence_and_penalty_matters_3_redacted.pdf

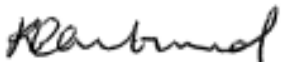
Conclusion

52. Dietitians manage risk daily as part of their practice as registered health practitioners. They support the intent of the Bill and have concerns about the gaps in detail, errant references, and the reliance on secondary legislation to resolve issues and conflicts in the primary legislation.

53. We would like to engage further on the detail in the Bill.

54. We would like the opportunity to appear before the Committee to present an oral submission and answer any questions the Committee may have. This Bill may result in new law that is around for 30+ years in the same way the Medicines Act has been. We would welcome the opportunity to engage and contribute to the Committee's advice.

Yours Sincerely



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