**Oral Submission to the Health Committee**

To Tracey McLellan, Chair of the Health Committee and Members of the Committee

<https://www.parliament.nz/en/pb/sc/scl/health/tab/mp>

From: NZ Dietitians Board (Responsible Authority under the HPCA Act 2003) <https://dietitiansboard.org.nz/>

And: Dietitians NZ (Professional Association of NZ Registered dietitians, dietetic students and associated nutrition professionals. ) <https://dietitians.org.nz/>

**Introduction**

Thank you for inviting us to speak to the Committee on the Therapeutic Products Bill.

My name is Philippa Bascand Registrar for Te Mana Matanga Matai Kai NZ Dietitians Board (a lay person)

On zoom Kath Eastwood General Manager for Dietitians NZ (NZ Registered Dietitian)

and Laila Cooper Chair of the Dietitians Board (a registered dietitian and CEO of Christchurch PHO)

Opening Comment:

Thank you for inviting us to speak to the Committee. I/we understand you have read our submission. We are happy to answer any questions the Committee may have on that.

We welcome this Bill and support the need for a strengthened and modernised regulatory regime that safeguards the public and incorporates medicines, medical devices, natural health products where these meet the threshold or include approved ingredients for a therapeutic purpose.

We also have some other matters we wish to bring to the Committee’s attention and would like to raise these as they are of a practical nature and affect the operation of the Bill and the responsibilities of the Board to manage risks associated with prescribing and Restricted Activities.

Kath Eastwood the General Manager for the Professional Association will open our submission and be followed by the Registrar and Chair of the Responsible Authority.

Dietitians NZ has **three main points** they would like to raise today which are outlined in our submission:

1. The first one relates to ***differentiating between NHPs for medical purposes and those for general public use***. The example we provided is following bariatric surgery. Bariatric surgeries result in varying degrees of restriction and malabsorption and so life-long supplementation is required by patients following surgery. In some cases, the recommended daily intake for micronutrients exceeds the Safe Upper Limit of that nutrient for the general population. If the regulations put in place do not allow for this differentiation, this is likely to result in patients requiring to take a far greater number of supplements in order to meet their requirements, increasing the burden and cost to them and decreasing compliance, leading to significant nutritional deficiencies and ill health. We note that this differentiation was not made in the TGA in Australia and has been somewhat problematic for the manufacturers there.
2. We would like more ***clarity regarding how this Bill will align with the Food Standards Code and the NZ Supplemented Food Standard 2016***. Currently the prescription of enteral and parenteral nutrition is a restricted activity under the HPCA Act and 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. We understand these Foods for Medical purposes would remain as part of the Food Standards Code and not part of this legislation. However, it appears that foods with added vitamins and minerals that are not currently covered in the Food Standards Code, and instead as part of the Supplemented Food Standard 2016 would be? We note this is the case in Australia. We find this somewhat unusual given the prescription of the former is a restricted activity, has a clear therapeutic purpose and carries a risk of harm from administration.
3. Our final point relates to the ***shifting of powers from Medsafe to Responsible Authorities 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. Dietitians NZ supports this significant shift and believes the regulator of dietitians is best placed to know what medicines, medical devices and NHPs dietitians should be prescribing to enhance care, reduce inequities and improve patient outcomes. However, we do acknowledge that this shift comes with some significant challenges, particularly for smaller regulatory authorities and the Dietitians Board will discuss these.

**Definitional Issues – Drafting in the Bill**

1. We are concerned that ***definitions in the Bill may cause confusion for the public and health practitioners.*** For example, health professions as described in the Bill is not compatible with the definition in the HPCA Act. While we regulate the profession of dietetics, we are not a professional body. We are described as a Responsible Authority that regulates the practise of Registered Dietitians.

The use of the ***terms Controlled Activities and Restricted Activities*** could be easily misconstrued by consumers and health practitioners alike when both are referenced in scopes of practice. This may cause confusion even though the terms have different application and coverage under this Bill and the respective HPCA Act. The distinction needs to be made clearer.

We suggest there is room for an educative approach here. We ask that a clause is added to explain the difference that restricted activities apply to high-risk procedures (activities) and are limited to classes of health practitioners and excludes others from the performance of those activities. Consumers may be confused by the use of similar language but with meaningful differences between controlled and restricted activities.

We would be ***concerned if the Bill had the unintended consequence*** of licensing people for a fee (at lower cost than a registration fee) to perform a controlled activity that is unregulated. The Bill may drive the behaviour of some practitioners to decline/reject registration and to operate under a licensing regime. This risk may be amplified for Dietitians who choose to work as nutritionists and provide controlled activities for NHPs but not dietetic advice per se. It will create a two-tier system with different pricing and costs associated with each pathway and may lead to a more segmented workforce.

**Reporting**

1. The Bill places ***additional reporting requirements on Responsibility Authorities and introduces new licence fees.*** The lack of detail on fees makes it difficult for the Board to assess the impact or budget for new costs. There is an added layer of bureaucracy with reporting harms to the Regulator and managing all aspects of prescribing within scopes of practice. These are new functions and costs previously delivered by Medsafe. What this means for the health practitioners we regulate is that we will need to pass these costs on to them and in turn they will pass them on to Te Whatu Ora or to consumers directly. It will have an inflationary effect by increasing and passing on the costs of prescribing and of administering the broader therapeutic product regime.
2. We are concerned that the ***checks and balances in the Bill are insufficient*** when granting the new powers to Responsible Authorities (RAs) to manage all classes and aspects of prescribing and to report harms. Harms should be reported contemporaneously but this is not possible by the Board as the information on unusual prescribing or errant prescribing will not be available to the Board immediately.

**Cost shifting**

1. The new provisions in the Bill placing the responsibility for all aspects of prescribing with the Responsible Authorities in our view, are made without the safeguards and expertise provided by Medsafe and the Medicines Classification Committee. ***Costs*** that were formally borne by Government to administer and protect the public and ensure prescribers are ***will now be passed to the Dietitians Board with limited ability to raise further revenue from a small workforce base.*** The Board is a registered charity. Moves to increase its reporting and statutory powers do not sit comfortably with the purpose and functions of a registered charity. We ask if this is the right model going forward to meet increasing expectations of the Crown?
2. We are concerned about the ***capability and capacity of smaller RAs*** like our Board to manage the new responsibilities for classes of prescribers and the products prescribed. As we noted in our submission, our Board has only one dietetic prescriber member appointed to a governance role which is not representative of the dietetic workforce. We rely on expert advice from a prescribing sub-committee but our resources are limited and members have clinical day jobs. Monitoring of prescribing behaviour is part of the Board’s/expert committee’s role but is not contemporaneous and reporting of harms to the Regulator is a new function. How this would work in practice and in a timely manner is unclear. We are unsure of how the new reporting requirement interfaces with existing reporting, such as ACC or HDC.

**Direct Lobbying**

1. We believe there are good grounds for ***including additional checks and balances on new Ministerial powers*** to approve changes to scopes of practice under Part 11, 11 A, 14 A and 14 B. ***There is a risk these new powers enable the direct lobbying of the Minister*** to extend or amend prescribing rights within a scope of practice. Powers for decisions on high costs medicines and high costs treatments sit with Pharmac and Te Whatu Ora to avoid direct Ministerial decision-making and the risk of political or public interference. Any defence of a challenge to a scope of practice change would be via the Regulations Review Committee and would have to be funded by an RA through levies on the profession, as has recently been the case between the Optometrists and Dispensing Opticians Board and the RANZCO[[1]](#footnote-1).

**Complaints**

1. We are concerned that ***without further in-depth discussion around the proposed regulations, that parties will be required to take complaints to the Regulations Review Committee*** for resolution in much the same way as they did following the passage of the HPCA Act 2003.as happened in 2007/08 with the Nursing Council Enrolled Nurse Scope.[[2]](#footnote-2) This is both costly and time consuming and can negatively affect working relationships within the sector at a time when the health sector is already experiencing strain and cost and capacity issues.

**Scope of Practice**

1. The Minister also has powers to amend scope of practice prescribing rights following reports of harms, but this will be to consumers’ health disadvantage as it is following the injury occurring, takes time for harms to be reported and for evidence to build that harms are of such significance or frequent occurrence that the scope of practice needs amending. While the Minister may delegate this power to the Regulator to approve/amend scopes of practice, the power rests solely with the Minister in the Bill. We think this power in Part 11 of the Act lacks sufficient checks and balances on that Ministerial decision-making and exposes the Minister to advocacy from the sector and the risk of judicial review. ***We suggest ACC, the HDC, and HQSC be consulted on this aspect of the Bill*** given the incidence of adverse drug events was reported to be 15% in 2003.[[3]](#footnote-3)

**Legislative Review**

1. We suggest there is a strong need to ***include a legislative review clause*** in the Bill once it is passed to come into effect after say 3-5 years, to report on its workability and effectiveness, to ensure the Bill knits together with other relevant legislation and is compatible with other Acts. Given so much detail is to be relegated to Regulations and Rules we are unsure how some parts will operate. This makes it difficult to assess how the Bill will be enacted and how the regulations will be applied and if they are practical and workable for health practitioners, suppliers, industry, manufacturers, license holders. We suggest the fit and alignment with relevant legislation such as the HPCA Act, Food Standards Code and Supplemented Foods Standard, Accident Compensation Act, among others, is tested for compatibility and application.

Thank you for your time today. We welcome any questions the Committee may have.

1. <https://www.parliament.nz/resource/en-NZ/53SCRR_EVI_125648_RR2219/4f07667715b370d4b3a0cb5c4cfccb400f58d131> [↑](#footnote-ref-1)
2. 2. Regulations Review Committee “Complaint regarding Notice of Scopes of Practice and Related Qualifications Prescribed by the Nursing Council of New Zealand” [2007] [↑](#footnote-ref-2)
3. Davis P, Lay-Yee R, Briant R, et al. Adverse events in New Zealand public hospitals II: preventability and clinical context, NZ Med J, 2003, vol.116, p. U624 [↑](#footnote-ref-3)