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Submission on the Therapeutics Products Bill

Committee Secretariat
Health Committee
Parliament Buildings
Wellington

This submission is from the Dental Council New Zealand.

The Council thanks the Health Committee for the opportunity to present our views and highlight areas of concern on the Therapeutics Products Bill.

We wish to appear before the committee to speak to our submission.

In the interim, do not hesitate to contact us if you want to discuss any aspect of our submission.

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Marie MacKay

Chief Executive

Submission

We support the intent of the Therapeutics Products Bill (the Bill) to protect the health and safety of patients and the public of Aotearoa New Zealand.

The Dental Council (the Council) is established under the Health Practitioners Competence Assurance Act 2003 (HPCA Act) to regulate oral health practitioners in Aotearoa New Zealand.

The Council regulates:

- Dentists and dental specialists
- oral health therapists
- dental hygienists and orthodontic auxiliaries
- dental therapists
- dental technicians, and
- clinical dental technicians.

We currently have around 5,300 oral health practitioners on our register across 21 scopes of practice.

The Council members, appointed by the Minister of Health, considered the Bill, and the identified areas of concern or where clarification may be required. Input was sought from some oral health practitioners on manufacturing of dental appliances. The Council hosted a session with the key professional associations representing the various professions, where the groups shared their respective views on the Bill.

This submission reflects the positions from the Dental Council.

We wish to make the following comments.

1. Subpart 3 of Part 3: Different requirements when oral health practitioners manufacture dental appliances using a device production system (e.g. ceramic milling) vs traditional manufacturing methods

Key issue

The following is not provided for in Subpart 3 of Part 3: controlled activities to be performed by health practitioners:

- manufacturing of personalised medical devices by a health practitioner **not using a device production system**, currently allowed for in their scope of practice
- manufacturing not completed at point of care.

Context

In its first submission on the Bill (April 2019), manufacturing of appliances in dental practice without the need for the health practitioner to have a manufacturing license was raised as a concern. This Bill has addressed some of our earlier concerns with recognition of patient-specific, personalised medical devices, and special provisions for controlled activities delivered by health practitioners under Subpart 3 of Part 3. However, the Council has remaining concerns.

s90 of the Bill provides for health practitioners to manufacture a medical device using a device production system at the point of care (s45), for a specific patient. This would cover the manufacturing of some dental appliances, such as a ceramic milling system to produce dental crowns – used often in private dental practices.

However, there is not a similar provision under Subpart 3 of Part 3 of the Bill for health practitioners to manufacture personalised medical devices **without** using a device production system.

s108 of the Bill allows a person to manufacture a custom-made device (not using a device production system) if—

(a) they are in a class of persons the regulations say are allowed to manufacture the device; and

(b) they manufacture it at the request of a health practitioner or veterinarian for a specific patient of that practitioner or veterinarian

(c) the device meets the product standards that apply to it; and

(d) they comply with any requirements in the rules about that manufacture.

Concerns and examples

Without a specific provision for the manufacturing of custom-made medical devices by a health practitioner not using a device production system under Subpart 3 of Part 3, these manufacturing activities would have to occur under s108.

There is no rationale provided on the need for different regulatory provisions (s90 vs s108) between a registered health practitioner manufacturing a custom-made medical device using other methods and/or materials manufacturing the same medical device, to those using a device production system.

If a health practitioner's scope of practice, supported by its education and training, allows for the design, production, repair and/or adjustment of a medical device – then why would they require different manufacturing provisions?

Regulation of registered health practitioners under the HPCA Act ensures ongoing competence and safe practice. These are ensured through various mechanisms that includes:

- accreditation to ensure academic quality of prescribed qualifications for registration (s11-14)
- issuing of annual practicing certificates (s26-33)
- ensuring ongoing competence through recertification programmes (s41)
- setting of standards (s118i)
- remediation of competence concerns (Part 3), etc.

If the manufacturing of the device falls outside of a health practitioner's scope and/or competence – then the practitioner has the professional obligation to refer the activity/patient to another appropriate health practitioner.

The Council does not see an increased risk to patient safety from existing practice, to justify different regulatory requirements. No evidence of widespread harm to patients or the public of Aotearoa by health practitioners manufacturing medical devices, has been shared to justify different legal requirements.

Examples within oral health practice where the different regulatory provisions would apply (s90 vs s108):

- Dental technicians and clinical dental technicians complete undergraduate degrees followed by postgraduate qualifications. Their scope focuses solely on the manufacture of dental appliances. They would have limited use for device production systems. Currently, most of their activities would fall under s108 requiring authorisation in the regulations to continue their practice, and other yet-to-be-defined standards.

- If a dentist produces a crown using a ceramic milling system, s90 would apply. Whereas, if the dentist decides it is clinically more appropriate to make the same crown for the same patient using gold, s108 will apply as the device production system cannot be used with this material.

- Most orthodontic appliances would not use a device production system, and these appliances would need to be manufactured under s108. In cases where a device production system is used, they would be manufactured under s90.

- Leading up to producing the final dental appliance (and other medical devices) other manufacturing activities occur to support the design of the final product.

  For example, the use of impressions before the manufacturing of the actual medical device. These activities would not use device production systems, and their manufacturing would fall under s108.

For the above examples, when s108 applies, it may mean the health practitioner having to meet the requirements of a manufacturer.

At this point it is unclear what the manufacturing requirements under s108 would be. For example:

- Who would be defined as "class of persons" in the regulations?
- Whether the person will need a manufacturer licence? If yes, potential downstream supply and cost implications for small volume, individualised, manufacturing processes.
- What would the required product standards be?
- What would the rules on manufacturing be?

Within dentistry, manufacturing of medical devices often occurs outside of the patient's point of care (i.e., dental practice or hospital service). For example, manufacturing of an appliance on request of a dentist occurs in dental laboratories by dental technicians or clinical dental technicians. These laboratories are off-site from the treating practitioner.

Recommendations

To enable registered health practitioners whose scope of practice allows for the manufacturing of custom-made medical devices to continue to do so without unnecessary legal barriers, and under similar regulatory frameworks regardless of whether they use a device production system or traditional manufacturing methods/materials:

A. It is proposed that s90 be expanded to include manufacturing a custom-made medical device **without using a device production system** by a health practitioner if it is relevant to the health service that forms part of the practitioner's scope of practice.

   This can be achieved by:

   - removing the specific reference to a device production system in s90, or
   - introducing a new provision under Subpart 3 of Part 3 for health practitioners manufacturing a personalised medical device without using a device production system if it is relevant to the health service that forms part of the practitioner's scope of practice.

B. To remove the requirement for a device production system to be used by the health practitioner at the point of care under s45.

   If the health practitioner is allowed to manufacture the custom-made medical device, they should be allowed to do so at any health practice. This could be at the point of care, or at another practice if the manufacturing occurs by a health practitioner on request from another health practitioner.

2. Uncertainty about the status of existing exemptions in Medicine Regulations for administration, use and/or supply of prescription medicines without a prescription or a standing order

Key issue

A number of exemptions exist in Schedule 1 of the Medicines Regulations 1984 that changes the classification status of a medicine for a group/s of health practitioners.

Over recent years Medsafe's Medicines Classification Committee has approved a number of classification changes for oral health practitioners. Exemptions to allow the administration of some prescription medicines by oral health therapists, dental therapists, and dental hygienists without a prescription or standing order, were approved based on the Council's assurance of competence and safe practice of those practitioner groups.

Specifically:

- Local anaesthetics: articaine, lignocaine, and prilocaine with or without felypressin
- Topical anaesthetics: oral benzocaine, tetracaine hydrochloride, lidocaine and prilocaine
- Adrenaline for the management of medical emergencies[1].

It appears that current exemptions in place under the Medicines Regulations allowing for oral health therapists, dental hygienists, and dental therapists to administer topical and local anaesthetics, and adrenaline without the need for a prescription or a standing order, is not provided for in the Bill.

Context

s14 of the Bill now defines a health practitioner prescriber, in relation to a medicine, as a "health practitioner whose scope of practice includes prescribing the medicine".

s85 allows a health practitioner to administer a prescription medicine if they are a health practitioner prescriber for that medicine.

- In oral health, this activity will be limited to dentists and dental specialists – as the only prescribers.

- At this point, there is no rationale to expand prescribers within the oral health professions, as the oral health professions currently exempted to administer specific prescription medicines use these medicines as part of a procedure or on-site patient management – rather than for ongoing patient use or at-home use by a patient, that would require prescribing rights.

There appears to be no provision in the Bill to update the scopes of practice of health practitioners to administer/use a prescription medicine, and non-wholesale supply of a pharmacy medicine with NZ authorisation, if their education and training allows them to do so within their scopes of practice[1].

The proposed amendments to the Health Practitioners Competence Assurance Act 2003 (HPCA Act) in s389 and s391 only relate to the prescribing of medicinal products.

At minimum, those who have existing exemptions in place should be transitioned into the new regulatory scheme. Without updated provisions, these practitioners will no longer be able to administer these prescription medicines without a prescription or a standing order. Whilst s54 of the Bill allows for a person to administer a prescription medicine under a standing order, this would change existing practice for those who are currently exempted in the Medicines Act Regulations.

[1] For example: administer LA or adrenaline, use/apply fluoride varnish, and supply fluoride toothpaste

Recommendation

C. It is proposed that the updated s11A of the HPCA Act be expanded to allow a scope of practice to include *administration and use of a prescription medicine, or supply of a pharmacy medicine*, if the practitioner's education, training and competence allows for it.

3. Import of medical devices by health practitioners

Key issue

There appears to be a potential lack of quality assurance of imported medical devices without NZ authorisation by health practitioners.

Context

s88 allows for the importing of medical devices by health practitioners without NZ authorization *for a patient to whom they are allowed to supply it*. This is compared to if a person (non-health practitioner) imports the same product, they need NZ authorisation (s67).

There is a potential patient safety risk to imported products. For example, an imported metal crown can contain toxic metals that cannot be identified easily by the practitioner from visual inspection of the end-product. At least some level of assurance to the health practitioner would provide additional protection to the public.

Given these imported, unauthorised medical devices are for individual patients rather than general population use, a risk-proportional approach is recommended rather than disallowing the activity. There continues to be a place for allowing this to continue within the new regime.

Recommendation

D. Potential quality assurance measures for unauthorised medical devices imported by health practitioners, could include:

- For the practitioner who imports the medical devices to at least know the composition of the materials used in the manufacturing of the product, and/or
- For the new Regulator to accept the import of products from comparable/reputable countries/international licensed companies without the need for NZ authorisation.

Other comments

4. Part 7: Compliance monitoring and potential regulatory overlap

It is unclear who will be monitoring non-compliance and managing remedial actions of health practitioners who are allowed under the Therapeutics Products Act to perform certain functions as part of their scopes of practice - with those powers granted under the HPCA Act.

Will compliance monitoring, enforcement and/or remediation be the responsibility of the Regulator under the Therapeutics Products Act, or the responsible authority under the HPCA Act dealing with issues related to the practising outside of their scope of practice, competence or conduct?

For example, if a practitioner prescribes outside of their scope of practice—

Would the responsible authority act in accordance with s8(2) of the HPCA Act[2], or will the Regulator responds under s239 of the Therapeutics Products Act, or could it be a joint responsibility?

Clarity on the potential areas of regulatory overlap of registered health practitioners, and functions related to the Bill, would be essential to ensure appropriate regulation.

5. Proposed amendments to the HPCA Act 2003

- Part 11, subpart 2: It is proposed to align the terminology of the HPCA Act – *medicinal products*, with the language used in the Therapeutics Products Bill, being *medicine* or *therapeutic products* (as appropriate to the section).

- s394: The requirements relating to the *form and content of the prescribing provisions* for the scopes of practice have not yet been defined, and would be essential for responsible authorities to identify required scope of practice changes.

  Responsible authorities setting these scopes, would require sufficient opportunity to comment on the proposed provisions, and time to draft the changes, consult on the proposed changes, gazette and effect these.

6. Sharing of information with regulatory entities

s343: *7(j) a professional body for health practitioners or veterinarians*.

Clarity is needed on who this is meant to include.

Health regulators set up under the HPCA is covered under s343(7)(n): *an entity with regulatory functions under an Act that the regulations say is a regulatory entity*.

Professional bodies or associations for health practitioners are not regulatory entities and in our view should not be included in this provision.

7. Wholesale supply of medical devices by health practitioners

s67 prevents the supply of medicine or a medical device without NZ authorisation, unless subpart 3 allows for it.

s89 allows for the wholesale supply of medical devices by health practitioners – with no specific reference to NZ authorisation or not.

The absence of a specific exemption for authorisation would indicate that potential NZ authorisation would be needed for a health practitioner to wholesale supply medical devices? Clarity on that would be helpful.

The Council is aware that some NZ clinicians do import and supply products that would fall under the definition of medical devices, for use in oral and maxillofacial surgery. These products are not readily available in NZ due to the small market size.

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[2] No health practitioner may perform a health service that forms part of a scope of practice of the profession in respect of which he or she is registered unless he or she—
(a) is permitted to perform that service by his or her scope of practice; and
(b) performs that service in accordance with any conditions stated in his or her scope of practice.

Without details on what “the requirements in the rules will be”, the potential impact on the supply chain is unknown.

8. Health students undertaking controlled activities

Students enrolled in one of the health sciences programmes to become a registered health practitioner may perform controlled activities as part of their education programme.

In Aotearoa New Zealand health students are not required to be registered under the HPCA Act.

Students will be undertaking controlled activities, albeit under the clinical supervision or oversight of their registered health practitioner supervisors. These activities become more independent in the advance years of their studies. Responsible authorities accredit these programmes – which provides quality assurance and protection to the public of Aotearoa New Zealand.

As it stands, because students are not registered health practitioners under the HPCA Act, health students will fall outside of the provisions allowed for health practitioners in Subpart 3 of Part 3 of the Bill.

It is recommended that the Bill:

- makes provision for students to continue to perform controlled activities during their programme under clinical supervision or oversight of registered health practitioner supervisors, or
- excludes health students while performing controlled activities,

as part of their educational programmes offered in New Zealand and accredited by a responsible authority as a prescribed qualification for health practitioner registration in Aotearoa New Zealand.

9. Materials used in 3D printing when manufacturing medical devices

It is unclear whether the regulation of materials used in 3D printing (by persons or health practitioners) would fall outside of the scope of the Bill. Given this is a developing area, with very limited materials considered safe for manufacturing of medical devices to be used on/in humans, focus on this would be beneficial.