

Newsletter: May 2019

Dental Council - May 2019

From the Chief Executive

From the Chief Executive

Greetings from the Chief Executive



This newsletter sets out information about two legislative matters relevant to oral health practitioners.

Firstly you may be aware that the **Health Practitioners Competence Assurance Amendment Act 2019** came into force on 11 April 2019. This Amendment Act reflects the Government's greater focus on regulators and regulated health professionals to increase public confidence and safety in health services they receive in New Zealand. Our article summarises the key changes practitioners should be aware of.

Secondly we cover the submissions made by the Council on the draft **Therapeutics Products Bill**. Although still in draft form, this Bill proposes a new regulatory scheme for therapeutic products in New Zealand to replace the the Medicines Act 1981. As drafted, it appears many dental appliances commonly used by oral health practitioners may become regulated as "medical devices". We focussed our submissions on the impact of having dental products regulated under the proposed scheme and what this may mean for practitioners and patients. We will continue to monitor this Bill and provide further updates as it progresses through the legislative process.

In this issue...

Changes to the HPCA Act

The Health Practitioners Competence Assurance Amendment Act 2019 (the Amendment Act) came into force on 11 April 2019 introducing some changes for both the Dental Council and oral health professionals in New Zealand.

The Minister of Health described the Amendment Act in Parliament as “an incredibly important piece of legislation for public safety and for public confidence in the services that our health practitioners present”.

What are the main changes introduced by the Amendment Act?

Although the changes made in the Amendment Act apply to all health regulatory authorities and health practitioners, our summary and comments focus specifically on the implications for the Dental Council and oral health practitioners.

With one exception, the amendments came into effect on 11 April 2019.

Greater accountability for the Dental Council

The Amendment Act introduces five-yearly independent performance reviews for the Dental Council to ensure we are carrying out our functions as intended by the HPCA Act. We expect our first review within the next 3 years. The results of the performance review must be posted on our website.

Greater scope for Council to receive information about practitioners

The Dental Council can now receive and act on information from any person about a practitioner’s competence, health or practice. Before the Amendment Act we were restricted to acting on information about practitioner competence received from a practitioner, an employer or the Health and Disability Commissioner.

Disclosure to notifiers

In the past, Council did not disclose the outcome of Council investigations or any actions taken to the person making a notification. Confidentiality was maintained to preserve a practitioner’s right to privacy.

The Amendment Act now obliges us to provide information about the orders it makes to notifiers of concerns about a practitioner’s competence or health. However, it does limit the extent of information sharing to avoid

disclosing too much detail about an individual practitioner. In addition, copies of any orders made by Council must be given to the employers and those who work in association with the practitioner concerned.

Naming policy

The Amendment Act requires the Dental Council to develop and put in place a “naming policy” within one year. This policy will determine situations where the Council will publish orders and directions made about individual practitioners under a new section 157A of the HPCA Act. This reflects the trend for greater transparency – ensuring the public can see regulation is happening.

Increased Council powers where there is a risk of serious harm

The Amendment Act gives the Dental Council new powers to act immediately and without notice to suspend a practitioner's practising certificate. This power can be used in cases where there is significant concern about the risk to public health and safety due to the conduct of an individual practitioner pending a prosecution or investigation.

Conviction cases

The Council now has discretion to decide whether to refer practitioners with certain Court convictions to a professional conduct committee (PCC) or to a health process, provided the practitioner consents. Once the Council receives a report on the practitioner's health, it can then decide to take no further action, or order conditions, or refer the practitioner to a PCC.

This means that in appropriate cases and where the practitioner agrees, the Council has an alternative process available to manage these practitioners; and identify and address health issues.

Cultural competence

Council is required to focus more on cultural competencies that will enable effective and respectful interaction with Māori. Council has already planned for a review of its cultural competence standards to take place.

Electronic communications

The Amendment Act brings communication with practitioners into the 21st century. Practitioners must now provide us with an email address as well as a postal address.

Collecting workforce data

We already invite practitioners to complete a workforce survey when they apply for their practising certificate each year. The Amendment Act gives the Council a legal mandate to collect workforce data so the Ministry can better forecast and match health needs and skills around New Zealand in the future.

Accreditation

The Amendment Act gives the Council specific power to revoke the accreditation of an education institution's qualification if necessary.

Next steps

We are now reviewing and updating our internal processes, documents and templates to ensure they reflect the changes made by the Amendment Act.

We have already started implementing the updated HPCA Act and orders made by Council at its most recent meeting have been shared with the employers of the affected practitioners. In other cases, we have been able to give feedback to notifiers on the decisions made by Council on their notification.

You can read the updated HPCA Act (<http://www.legislation.govt.nz/act/public/2003/0048/latest/DLM203312.html>) online. Please contact us (<mailto:inquiries@dcnz.org.nz>) if you have any queries or concerns.

Council's submissions on the Therapeutics Products Bill

The Government wishes to protect the public's health by ensuring that therapeutic products in New Zealand are safe and effective, and meet quality and performance standards. To this end, the Ministry of Health recently invited submissions on a draft Therapeutics Products Bill.

The Council made extensive submissions on the draft Bill as its proposals will potentially impact on oral health practitioners, their practice and regulation. Prior to making our submissions we discussed key areas of concern with our colleagues at the Pharmacy Council and sought legal advice to confirm our understanding on the various provisions.

What is proposed by the Therapeutics Products Bill?

The Bill proposes a modern and cost-effective regulatory scheme for therapeutic products in New Zealand. Once enacted the draft Bill will replace the the Medicines Act 1981.

The new scheme will cover a broader range of therapeutic products used in health care in New Zealand. It will cover medicines, active ingredients of medicines, medical devices and type 4 products—a new category established for future innovative therapeutic products.

Council's submissions

Our submission ([assets/Uploads/Publications/Submissions/Therapeutic-products-consultation-submitter-profile-dec18-final.pdf](#)) focused on the areas that impact oral health practitioners most directly and is summarised below.

Medical devices

The most significant impact of the proposed Bill for oral health practitioners will be the regulation of medical devices. Therapeutic product regulation in New Zealand has not included medical devices previously.

Our primary concern is that dental appliances commonly designed, made, used and imported by oral health practitioners may become regulated as “medical devices” under the new regulatory scheme proposed by the Bill.

Access and costs for patients

We are concerned that the new proposed regulatory scheme for medical devices may compromise patient access if the products become more expensive due to increased regulatory compliance.

Product approval processes for such a vast number of devices will take time and require specialised expertise, availability of which may be limited in New Zealand. This could adversely impact the availability of these devices that could compromise patient care.

We have no evidence of systemic risk to patient safety or harm resulting from the use of dental appliances or equipment under the current regulatory framework. We rely on the practitioner's ethical and professional obligations to ensure patients receive the appropriate quality of treatment and to ensure patient safety is central to the practitioner's treatment plan.

We strongly encouraged a pragmatic and staggered approach using a robust risk framework to clearly identify and prioritise those medical devices that require immediate regulatory intervention.

Dental appliances and obligations for practitioners

Dental appliances (both fixed and removable) are likely to fall within the Bill's definition of therapeutic products and there appear to be various provisions which could direct the regulatory requirements for them. Each of these options have different compliance obligations and would change the current approach by oral health practitioners who prescribe, use, supply, design, manufacture, repair or import dental appliances.

The various activities involved in creating, sourcing and fitting the dental appliance for each patient occur in premises that are diverse in nature and scale, such as dental laboratories, private dental practices, hospitals, and often overseas and involve both registered and unregistered people.

We requested further discussions with the Ministry staff on the proposed legal and regulatory framework envisaged for dental appliances, to better understand the potential obligations for oral health practitioners.

What medical devices will be regulated and what will be exempt?

With the broad definition proposed for medical devices and in the absence of the supporting regulations and details about the risk-proportionate approach that will be used, we are concerned about the potentially large number of medical devices that could be caught in the new regulatory scheme.

For this reason, we have asked the Ministry to clarify whether they anticipate that dental devices, equipment, materials and software used by oral health practitioners would fall under the new regulatory scheme. And if so, which products.

We highlighted the broad range of dental equipment, all with different risk profiles that might be subject to the proposed scheme including dental chairs and lights, instrument trays, mouth rinse, examination mirrors, retractors, cameras, protective equipment, blow torches, and more invasive or higher risk instruments such as x-ray machines, pluggers, scalers, lasers, burs, curets, forceps, files, and scalpels.

Prescribing, supplying and administering medicines

Authority to prescribe is removed from the Medicines Act by the draft Bill and will sit within the respective scopes of practice—set by the health regulators. As with any scope changes, the health regulator must consult on the proposed changes with its stakeholders, and prescribing provisions within a scope must be approved by the Minister of Health. No consultation will be needed to make the necessary scope changes for those who are already authorised under the Medicines Act to prescribe medicines.

This change will not alter dentists and dental specialists' rights of prescribing, or which medicines and quantity they can prescribe, within their scope of practice.

The permission for oral health therapists and dental therapists to administer certain medicines, with or without a standing order, will also remain unchanged. However, the authorisation of this will likely be removed from the medicine classification's schedule and sit in another legislative instrument.

Provision for standing orders remain—the detailed requirements will be developed later, as regulations or rules.

The draft Bill proposes that health practitioner prescribers can supply the medicine they prescribe to their patients, within their scope of practice, without requiring a pharmacy licence or other dispensing obligations.

The Bill further proposes staff working under health practitioner prescribers can supply category 3 medicines to patients, subject to the health practitioner's scope of practice and under general supervision (not yet defined). We do not consider non-trained and non-registered staff should supply or dispense category 3 medicines to patients.

Although we support increasing access to medicines, the Council believes the same professional and ethical standards across all health practitioners who supply and dispense medicines should be applied.

Regulatory overlap

We expressed concern about potential regulatory overlap between the regulator established under the Bill and other existing health regulators. This overlap is of concern on assuring and managing issues of professional competence and conduct of registered health practitioners as it relates to prescribing, supply and dispensing related activities.

We believe clearly differentiating regulatory powers is essential to protecting public safety and avoiding regulatory overlap or gaps.

Next steps

Consultation on the draft Bill has now closed. The Ministry of Health will analyse the feedback and provide advice to the government based on the consultation outcomes. The draft Bill will be amended as required before it is submitted to parliament.

We will continue to monitor the progress of the Bill and engage with the Ministry further on the issues we have raised. If required, Council will make further submissions to the select committee during the parliamentary process.

We encourage all practitioners to review our submission ([assets/Uploads/Publications/Submissions/Therapeutic-products-consultation-submitter-profile-dec18-final.pdf](#)) and the information available on the Ministry's website (<https://www.health.govt.nz/publication/therapeutic-products-regulatory-scheme-consultation>). You may have already made submissions to the Ministry of Health on the Bill during the consultation period.

Please contact us (<mailto:consultations@dcnz.org.nz>) if you have any comments or areas of concern about this proposed legislative change.

Updates

Consultation on OHT age limit for restorative activities re-opens for one week

We have re-opened the consultation on the age limit for restorative activities in the oral health therapy scope of practice until **Tuesday 14 May 2019** as it appears we may not have received all the submissions made.

The consultation was originally issued on 21 February 2019 but the online survey link in the email was incorrect. An updated link (<https://www.surveymonkey.com/r/X6FVH6B>) was shared the next day. For those who used the first link, we will not have received your submission.

Please check on our website (<https://dcnz.org.nz/resources-and-publications/publications/closed-consultations/consultation-submissions-on-the-age-limit-for-restorative-activities-in-the-oral-health-therapy-scope-of-practice/>) to confirm whether we have received and uploaded your submission.

If your submission is not listed, please complete the online survey (<https://www.surveymonkey.com/r/X6FVH6B>) and resubmit your feedback by **Tuesday 14 May**.

We apologise for any inconvenience caused however we do want to be sure everyone has the opportunity to have their say.

The consultation document (<https://dcnz.org.nz/assets/Uploads/Consultations/2019/Consultation-age-limit-restorative-treatment-OHT.pdf>) is available for you to review if necessary.

Ministry of Health - voluntary bonding scheme 2019

New graduate dentists may be eligible to register for the 2019 intake of the Ministry's voluntary bonding scheme.

You may be eligible if your final year of undergraduate study was 2018, and you intend to work for listed hard-to-staff providers or practices for between three to five years. If successful, you will be eligible for bond payments of \$10,000 (after tax) per year for up to five years.

More information is available here (</assets/Uploads/Newsletter-misc-files/Voluntary-Bonding-Scheme-2019-Intake-Information-Dentists.pdf>) and on the Ministry website (<http://www.health.govt.nz/our-work/health-workforce/voluntary-bonding-scheme/voluntary-bonding-scheme-2019-intake-information>).