Application to widen the classification for adrenaline to allow access without prescription for oral health therapists, dental therapists and dental hygienists registered with the Dental Council to have and use them for emergency use in their practice

Dental Council
Te Kaunihera Tiaki Niho

Executive Summary

This application seeks to widen access of adrenaline for emergency use by injection to oral health therapists, dental therapists and dental hygienists who are registered with the Dental Council. The application is being submitted by the Dental Council of New Zealand, the regulator of dental professionals practising in New Zealand. It follows work on scopes of practice by the Dental Council for these professionals and other successful reclassification applications for oral health therapists and dental therapists to have access to specific injected and topical oral anaesthetics without requiring a standing order.

Oral health therapists, dental therapists and dental hygienists have a requirement to have resuscitation training and stock and, if necessary, use adrenaline, as per the attached Medical Emergencies Practice Standard from the Dental Council [1]. The Dental Council is seeking to reclassify adrenaline to facilitate such availability and avoid the need for a standing order for oral health therapists, dental therapists and dental hygienists registered with the Dental Council. Please note that this application applies to all dental hygienists, not only those endorsed to use local anaesthetics, owing to other potential allergens in their practice.

Adrenaline is well-known in terms of use, contraindications, precautions and adverse effects, and has a long-standing, well-established role in managing anaphylaxis.

Oral health therapists, dental therapists and dental hygienists are trained, as are dentists, to CORE Immediate resuscitation level and must have oxygen and adrenaline available. Oral health therapists, dental therapists and dental hygienists are working independently in New Zealand and internationally, for example in Australia, UK, Singapore, and some states in the USA. The adrenaline affected by this application would be used on-site by the oral health practitioners concerned along with referral to emergency services, there is no consumer self-use nor use outside of an emergency setting.

The proposed reclassification of adrenaline would enable all of these oral health practitioners to work more easily within their scopes of practice for the benefit of their patients without the burden for these practitioners and dentists of standing orders. There is no greater risk than the current situation of standing orders.

The benefit-risk balance of this minor change to the classification statement is reasonable.

PART A

1. **International Non-proprietary Name of the medicine**

   Adrenaline (BAN) is known also as epinephrine (INN). Adrenaline is the commonly used name in New Zealand and is the name used in gazette notices.

2. **Proprietary name (s)**

   Registered products that are 1 in 1,000 1 mL ampoules include DBL adrenaline injection and Aspen adrenaline injection.

   Epipen auto-injectors deliver a single 300 microgram (µg) intramuscular dose of adrenaline (epinephrine) from Adrenaline Injection 1:1,000 USP (0.3 mL)[a]

3. **Name of company/organisation/individual requesting reclassification**

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   Level 7, 22 The Terrace
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   The Dental Council is a responsible authority created by the Health Practitioners Competence Assurance Act 2003 to regulate the oral health professions. It ensures oral health practitioners meet and maintain its standards in order to protect the health and safety of the New Zealand public. The oral health practitioners it regulates are dentists, dental specialists, oral health therapists (OHTs), dental therapists (DTs), dental hygienists (DHs) and orthodontic auxiliaries, clinical dental technicians and dental technicians. This application applies to OHTs, DTs and DHs.

4. **Dose form(s) and strengths for which a change is sought**

   Dose form: injection.
   Strength 1 in 1,000 (0.1%).

5. **Proposed pack size, storage conditions and other qualifications**

   There are no qualifications required on pack size. Storage is the usual for injections according to manufacturer recommendations. We are proposing the following

[aa] EPIPEN JR.Auto-Injector delivers a single 0.15 mg adrenaline injection (0.3 mL, 1:2,000) – given it is a different strength, it is not covered by this application.

qualification: *for use in practice in an emergency by a dental therapist, an oral health therapist or a dental hygienist registered with the Dental Council.*

Alternatively, we propose the same qualification but without specifying "in an emergency" because that is also covered by the licensed indications and the Dental Council's Medical Emergencies Practice Standard [1]. In this case wording could be the following (or similar): *supplied to a dental therapist, an oral health therapist or a dental hygienist registered with the Dental Council.* This wording is similar to that used for fluoride.

6. Indications for which change is sought

The use of adrenaline in dental practice for the purposes of this application is to have it on hand for intramuscular injection in case of the medical emergency of anaphylaxis.

The change for the classification statement could specify that the medicines are to be used in practice in an emergency by a dental therapist, an oral health therapist or a dental hygienist registered with the Dental Council. Alternatively, if "in an emergency" is not specified, product licences, the Dental Council's Medical Emergencies Practice Standard[1] and scopes of practice through the Dental Council will ensure appropriate usage rather than the classification statement. We have offered two options for consideration by the Medicines Classification Committee and Medsafe (see point 8 below).

7. Present classification of the medicine

Adrenaline has the following classification:

Prescription in medicines containing more than 1%

Restricted medicine in medicines containing 1% or less except in medicines for injection containing 0.02% or less.

General sales in medicines for injection containing 0.02% or less

8. Classification sought

The below wording uses red font to indicate the proposed change for adrenaline:

Prescription in medicines containing more than 1%.

Restricted medicine in medicines containing 1% or less **except** in medicines for injection containing 0.02% or less, **except** in medicines for injection containing 0.1% for use in practice in an emergency by a dental therapist, an oral health therapist or a dental hygienist registered with the Dental Council.

Or: Restricted medicine in medicines containing 1% or less **except** in medicines for injection containing 0.02% or less, **except** in medicines for injection containing 0.1% to be supplied to a dental therapist, an oral health therapist or a dental hygienist registered with the Dental

Council. [Note: this wording is similar to the fluoride classification wording, with no mention of indication]

General sales in medicines for injection containing 0.02% or less

We appreciate that the exact wording may need to differ from the above to achieve the desired outcome.

9. **Classification status in other countries (especially Australia, UK, USA, Canada)**

In Australia, adrenaline is prescription medicines except (a) when included in Schedule 3; or (b) in preparations containing 0.02% or less of adrenaline unless packed and labelled for injection. It is Schedule 3 (pharmacist only medicine) in preparations containing 1 per cent or less of adrenaline **except** in preparations containing 0.02 per cent or less of adrenaline unless packed and labelled for injection.

Adrenaline 1:1000 injection is a prescription-only medicine in the UK.

Adrenaline is a prescription medicine in the USA.

In Canada, adrenaline in injectable form is prescription only (schedule I) except in pre-filled syringes intended for emergency administration in the event of anaphylactic reactions to allergens, in which case it is pharmacist-only (schedule II).

New Zealand varies from other countries in using the classification statement to allow different medicines to be used by various health practitioners.

In the UK, dental hygienists and dental therapists can independently administer local anaesthetics for their patients' needs under Patient Group Directions [2, 3]. However, The Resuscitation Council (UK) has directed that a PGD for adrenaline injection is not required for anyone (whether a healthcare professional or not) to administer intramuscular adrenaline for the purpose of saving a life in an emergency.

In Australia, the Australian Dental Council outlines the scopes of practice for dental hygienists, dental therapists and oral health therapists, which includes administering pharmaceutical agents. In Victoria, Australia, a dental hygienist, dental therapist or an oral health therapist are generally approved under the Health Practitioner Regulation National Law to have in their possession and use listed Prescription Medicines which are required for the provision of dental care [4]. This includes adrenaline with no specification of strength.

10. **Extent of usage in New Zealand and elsewhere (e.g. sales volumes) and dates of original consent to distribute**

The Medsafe website indicates that DBL adrenaline injection 1:1,000 was consented in 1984, but it seems likely that another brand was available earlier than that. Epipen was consented in 1997.

Sales data are not readily available. However, these products for use in anaphylaxis have been very commonly stocked as emergency equipment in dental practices, medical practices, hospitals, and other relevant places for decades.

11. Local data or special considerations relating to New Zealand (if applicable)

See information in part B. These oral health practitioners already have access to and are ready to use adrenaline for medical emergencies. They have appropriate training to do this. The current mechanism used to ensure this in New Zealand is by standing order. Standing orders are cumbersome to develop and administer, need to be reviewed annually and audited. OHTs, DTs and DHs all must be trained in resuscitation, including the use of adrenaline for anaphylaxis. They will be passing anyone needing emergency administration of adrenaline onto ambulance services, so there is no need for dentists to have oversight. Standing orders are time-consuming. In the public system there is a backlog of dental work and reducing unnecessary administrative time will increase time for patient services which will be beneficial.

There has been a backlog for dental services partly resulting from Covid-19 lockdowns,[5, 6] therefore it is important to provide efficiencies where possible for these oral health practitioners and dentists.

12. Labelling or draft labelling for the proposed new presentation(s)

Not applicable. The labelling would not need any change because this is an "except when" addition, usage is unchanged and the medicine will not be self-used by consumers.

13. Proposed warning statements (if applicable)

There would be no need for any additional warning statements as usage is effectively unchanged.

14. Other products containing the same ingredient(s) and which would be affected by the proposed change

The affected products are mentioned above.

PART B

Reasons for requesting classification change including benefit-risk analysis

This reclassification application follows the positive Medicines Classification Committee's consideration of a reclassification of injected local anaesthetics for OHTs and DTs in 2017 [7], and of topical oral local anaesthetics for OHTs and DTs in 2021 [8]. Concurrent with this application we have submitted applications for topical and injected oral local anaesthetics for DHs endorsed by the Dental Council for administration of LAs. These reclassifications recognise the scopes of practice for these oral health practitioners and the reduction of unnecessary burden by removing the need for standing orders.

Adrenaline is a medicine that needs to be held by registered OHTs, DTs and DHs (regardless of whether they are endorsed for LA administration or not), as per the Dental Council's Medical Emergencies Practice Standard, and therefore should also have a classification that is appropriate to facilitate such supply.

This proposal will aid OHTs, DTs and DHs to work to their competencies without needing standing orders. A reclassification will be as safe as standing orders, given the Dental Council requirements for training, but such a reclassification will reduce administrative burden. A reclassification will mean that they can continue to practise within their full scope. It will also mean OHTs, DTs and DHs can purchase the adrenaline injection for use in an emergency directly from distributors or wholesalers. These practitioners can own their own dental practices or provide domiciliary care – reduced burdens to access and administer adrenaline would recognise their professional capabilities and allow more time to focus on patient care.

Patient safety requires adrenaline to be readily available for administration in an emergency and this reclassification reduces barriers for the aforementioned oral health practitioners to this vital emergency drug.

The risks have been managed through appropriate training; requiring these oral health practitioners to undertake resuscitation training every two years; and the attached Dental Council's Medical Emergencies Practice Standard.[1] ODTs, DTs and DHs have had access to adrenaline for emergency use for many years, but through the more cumbersome mechanism of standing orders or within a practice that has a dentist. ODTs, DTs and DHs are already able to work without a dentist on-site, and already need to call an ambulance for anyone with symptoms and signs suggesting anaphylaxis, following IM administration of adrenaline (see the Medical Emergencies Practice Standard, Appendix 1), so there is no additional risk of this reclassification.

Below we provide background information on OHTs, DTs and DHs and their use of local anaesthetics and holding of adrenaline for emergency use. Then we provide further information about the benefit-risk analysis.

BACKGROUND ON DEVELOPMENT OF ORAL HEALTH THERAPY SCOPE OF PRACTICE

This application refers to oral health therapists, dental therapists and dental hygienists.

Dental therapists

Internationally leading, New Zealand introduced school 'dental nurses' in 1923 [9]. Now called dental therapists, their work includes an extensive range of preventive and restorative services, and thus they frequently use local anaesthetics by injection and orally.

Dental hygienists

Dental hygienists primarily focus on the prevention and non-surgical management of periodontal disease which affects the gums and supporting tissues of the teeth. Dental hygienists may treat patients of all ages, however typically most of their patients are adults. Some of their patients are adolescents (for example, when working in orthodontic practice), and very few (if any) of their patients are children.

Dental hygienists who are educated and trained in this practice area have long used topical and injected local anaesthetic agents to enable them to provide comfortable dental hygiene care for their patients. Currently, 174 DHs hold a practising certificate that allows them to administer topical and injected local anaesthetic agents. A further 87 registered DHs have an exclusion on their scope of practice preventing them from administering topical or injectable local anaesthetic agents. This is because they have not received the education and training in this practice area, either as part of their initial programme of study, or by completing additional training considered comparable by the Dental Council.

The Dental Council consulted widely in 2020 on proposed changes to the scope of practice for dental hygiene. In 2021, the Council removed the requirement for a dentist to be on-site at the time a DH administered local anaesthetic from the dental hygiene scope of practice following overwhelming support for this proposal, including from dentists.

There are no longer any standalone educational programmes for dental hygiene or dental therapy offered in New Zealand, thus the number of dental hygienists and dental therapists is declining over time.

Oral health therapists

In New Zealand, a three-year, tertiary level oral health degree, combining the previous dental hygiene and dental therapy programmes, has marked a significant shift in the oral health workforce. Auckland University of Technology (AUT) introduced the new oral health programme in 2006, followed by the University of Otago in 2007. Graduates from these programmes are registered as oral health therapists.

Oral health practitioners in relation to this application

As all DHs (including those not endorsed for local anaesthetic use), OHTs and DTs need to have adrenaline available for emergency use, have appropriate training for its provision, and may practise without a dentist on-site, there is a need for them to have ready access to adrenaline for emergency use. A reclassification will remove the barrier to direct access to adrenaline, and the need for a standing order, also reducing administrative work for those signing and administering the standing order.

In the 2021 Annual Report, the Dental Council reported 723 oral health therapists, 459 dental hygienists and 388 dental therapists on its register.

OHTs, DTs and DHs receive ongoing resuscitation training at the same level as other oral health practitioners (excluding dental technicians, and dentists/dental specialists providing sedation) to manage a medical emergency. That is, NZRC CORE Immediate training (previously named CORE Level 4), or equivalent. A current certificate of NZRC CORE Immediate training is required for all three groups that are the subject of this application.

COMPETENCE NOTIFICATIONS RELATED TO THE HOLDING AND ADMINISTRATION OF ADRENALINE

A review of the Dental Council competence notifications for oral health therapists, dental therapists and dental hygienists, shows few notifications for these professions, and nothing that would indicate that the proposed change to the classification statement would lead to increased harm.

Nash et al [9] reported that studies of dental therapists in Canada and Australia have shown good quality of work, and for Canada "there have been no reports of serious injuries or record of litigation or malpractice claims against dental nurses over the 50 years of their existence".

THE MEDICINES AND BENEFIT-RISK OF THE RECLASSIFICATION

1. **Indications and dose**

   For the purposes of this application, adrenaline is for emergency administration in case of anaphylaxis.

   The Medical Emergency Practice Standard from the Dental Council (updated August 2021)[1] states the following dosage:

   Administer adrenaline via intramuscular (IM) injection (1:1,000), preferably into lateral thigh:

   - Adults – 0.5mg (0.5mL)
   - Children (if weight is known) – 10mcg/kg (0.01mL/kg) (min dose 0.1mL, max dose 0.5mL)
   - Children if weight is unknown (1:1,000):
     - ➢ Infants less than 2 years – 0.1 mL
     - ➢ Child 2-4 years – 0.2 mL
     - ➢ Child 5 – 11 years – 0.3 mL
     - ➢ 12 years and over – 0.5 mL

   This dosage is consistent with the ANZCOR guidelines Dosage of IM Adrenaline for Anaphylaxis and Anaphylaxis Flowchart 2019 (see appendices).

2. Presentation

Adrenaline 1:1,000 is available as 1 mL ampoules for draw up of the appropriate dose and injection, or as ready-to-use pen injections containing 0.3 mg of adrenaline for easy consumer administration. It is likely that only the 1 mL ampoules will be stocked owing to ability to vary dosage, lower cost and better expiry. The Medical Emergency Practice Standard requires OHT, DH and DT to carry syringes and needles for use with adrenaline.

3. Consumer benefits

Adrenaline is held for emergency use as a usual part of dental care in New Zealand and internationally. The exact number of countries and number of users is unknown as this application is not being submitted by the manufacturers of these medicines.

OHTs, DTs and DHs may practise without a dentist on the premises, therefore it is appropriate for the classification of adrenaline to permit accessibility for this medicine for these oral health practitioners to ensure it is readily available should anaphylaxis arise.

This reclassification will provide time savings for dentists, many of whom report time pressure stress [10]. It will be more efficient than standing orders with no greater risk as standing orders allow product administration without a dentist on-site. It will also facilitate easier access to stock adrenaline – as these practitioners can then order adrenaline directly from suppliers. Standing orders are cumbersome and time-consuming, and secondary dental services are over-burdened [11], so a reclassification is a better option for consumer benefit.

Approximately 500,000 children are cared for under the community oral health services, and DHs, ODTs and DHs manage many adults. The proposed change provides flexibility and aids quality care and has no greater risk than that which exists with the current environment in which adrenaline is kept under standing orders for use by these oral health practitioners.

4. Contraindications and precautions

Please see the data sheet attached for contraindications and precautions. Note that anaphylaxis is the most severe form of allergic reaction and is potentially life-threatening, and in a medical emergency if adrenaline is required it needs to be used.

These medicines will be administered by oral health practitioners with appropriate resuscitation training and practice standards, not consumers.

The adrenaline data sheet notes there are no data available regarding the effect on driving or operating machinery. In the very rare occurrence of usage an ambulance would be called and the person will be monitored. Drug interactions are not a reason for avoiding use in a medical emergency, and again, an ambulance will be called and the person will be monitored.

5. Undesirable effects

Adverse effects of adrenaline are well-known. See below for the datasheet extract. Adrenaline has a clear benefit that outweighs risk when it is needed for use in a suspected case of anaphylaxis. The oral health practitioners concerned are required to have current appropriate resuscitation certificates. The Medical Emergencies Practice Standard[1] specifies that in case of anaphylaxis, adrenaline will be administered and an ambulance called immediately.

SMARS from 1 Jan 2000 to May 2022 records 68 reports of adverse events with adrenaline, one of which involved a death.

The data sheet for DBL adrenaline reports the following adverse events:

Metabolism and nutrition disorders

Anorexia, hypokalaemia, hyperglycaemia. Prolonged use or overdosage of adrenaline can result in severe metabolic acidosis.

Nervous system disorders

Headache, tremor, dizziness, impaired memory, psychomotor agitation. Syncopal episodes have been reported in children. Cerebrovascular or other haemorrhage and haemiplegia may result, especially in elderly patients.

Musculoskeletal and connective tissue disorders

In patients with Parkinsonian Syndrome, adrenaline increases rigidity and tremor.

Psychiatric disorders

Anxiety, fear, tenseness, restlessness, confusion, disorientation, hallucinations, irritability, insomnia, psychosis may occur, psychiatric disorders may be exacerbated.

Cardiac disorders

Palpitations, tachycardia (sometimes with anginal pain) and cardiac arrhythmias may also occur along with hypertension which in some instances may induce reflex bradycardia as can vasodilation with flushing and hypotension. Ventricular fibrillation may occur and severe hypertension may lead to cerebral haemorrhage and pulmonary oedema. High doses may result in ventricular arrhythmia.

Respiratory, thoracic and mediastinal disorders

Dyspnoea, pulmonary oedema may occur after excessive doses and following aerosol application or in extreme sensitivity.

Gastrointestinal disorders

Nausea, vomiting, hypersalivation. Vascular disorders: Peripheral coldness.

Skin and subcutaneous tissue disorders

Flushing or redness of face and skin, sweating.

Renal and urinary disorders

Difficulty in micturition, urinary retention.

General disorders and administrative site conditions

Weakness, pallor.

Other

Inadvertent intravenous injection of adrenaline has also been reported to have caused convulsions, metabolic acidosis and renal failure with anuria. Overdosage or inadvertent

intravenous injection of usual subcutaneous doses of adrenaline may cause hypertension. Repeated injections of adrenaline can cause necrosis as a result of vascular constriction at the injection site. Prolonged use or overdosage of adrenaline can result in severe metabolic acidosis. Gas gangrene, which can be fatal, has been reported following intramuscular injection of adrenaline into the buttock or thigh. This appears to have been due to Clostridium organisms on the skin being deposited into muscle tissue during injection, with the vasoconstrictor properties of adrenaline enhancing the effects of the infection.

Withdrawal after use for an emergency is not a concern.

6. Overdose

The reclassification is regarding adrenaline that is for use in emergency situations. It will typically be supplied as 1 mL 1:1,000 strength ampoules. It could also be provided as anaphylaxis pens designed primarily for use by lay persons without training, with the correct dosage ready to use. Given the cost and short expiry on the anaphylaxis pens, and the dose recommendations from the Dental Council, 1 mL 1:1,000 ampoules will be stocked in most cases.

Note that ODTs, DTs and DHs currently have adrenaline on-hand (see the Medical Emergencies document attached), provided under standing orders and thus the risk of overdose already exists.

The usual dose for anaphylaxis is 0.5 mg for an adult and less for a child as noted above, based on weight or age. In neither case is a full 1 mL required from a 1:1,000 strength 1 mL ampoule. Therefore, there is a risk for excess to be drawn up and injected in error. The oral health practitioners that would be storing and (rarely) using it for an emergency will have received resuscitation training including regular refresher training, and have the Medical Emergencies Practice Standard[1] to follow. Thus, the risk of overdose is minimised and will be no greater than under standing orders.

The datasheet notes the following:
Overdosage with adrenaline produces a rapid rise in blood pressure resulting in cerebral haemorrhage, cardiac arrhythmias leading to ventricular fibrillation and death, severe hypertension leading to pulmonary oedema, which may also lead to death because of the peripheral constriction and cardiac stimulation produced.

Overdosage of adrenaline can result in severe metabolic acidosis because of elevated blood concentration of lactic acid.

7. Medication errors and abuse/misuse potential

Used by oral health professionals, there is limited potential for abuse, misuse or unnecessary use. Errors would be unlikely given the training, Medical Emergencies Practice Standard and anaphylaxis flowchart. Resuscitation training clearly differentiates

anaphylaxis from syncope (fainting), as for other practitioners who may have cause to administer adrenaline for anaphylaxis, for example vaccinators. The Dental Council has not received any complaints about DTs, DHs, or ODTs regarding management of an emergency situation or specifically adrenaline use.

We are specifying only the adrenaline 1:1,000 strength for the wording in this application as that is the one in the practice standard, and it is best to minimise risk of inappropriate strength being used.

We do not have access to manufacturer data regarding errors reported with these medicines post-marketing.

Import considerations are irrelevant for these medicines, as they would remain prescription medicines simply with an exemption.

Addiction is not a concern with adrenaline for emergency use.

8. Communal harm and/or benefit

Communal benefit is expected to arise from efficiency for these practitioners and the dentists responsible for standing orders because standing orders for these medicines would no longer be needed, and there would be easier arrangements for ordering by DHs, DTs and ODTs. Adrenaline is an important part of an emergency kit, and its use within the scopes of practice of these practitioners, therefore it is important to minimise barriers to its availability for this use.

No communal harm is expected from this reclassification.

9. Integrated benefit-risk statement

This reclassification supports the ability for DHs, DTs and ODTs to be able to purchase adrenaline from their wholesaler without having a standing order, and have it available should it be required, in line with their scopes of practice. Making it easier for these groups to purchase, hold and administer (if necessary) provides safety should a patient in their care experience signs and symptoms of anaphylaxis. An important further benefit is on the inefficiency of managing standing orders for those needing to work under them, those needing to develop and review them annually, and those signing them off needing to audit them.

The Dental Council confirms that it is within their scopes of practice for DTs, OHTs and DHs to hold and administer adrenaline in an emergency in their dental practice, and that these practitioners have appropriate training and regulatory controls to ensure good practice, with no complaints received regarding these oral health professionals and their management of emergencies.

10. Risk mitigating strategies

DTs, DHs and ODTs are well-trained in resuscitation and require current certification so have regular refreshers. They work under the Dental Council's Medical Emergencies Practice Standard. This standard requires that they have "written procedures managing medical emergencies where the role of each staff member is clearly defined, and review these regularly as a team to ensure staff members know and understand their role".

This work is within the scopes for DHs, OHT and DTs, and when used under standing orders, these oral health practitioners will already be working with no dentist on-site, holding adrenaline for the possibility of a rare case of anaphylaxis in their everyday practice.

The most serious risks are a possible use for syncope (fainting) misdiagnosed as anaphylaxis or medication dosage error. Training repeated every two years minimises these risks and clear dosing information in the Medical Emergencies Practice Standard[1] and written procedures the practitioner has will minimise the potential for a medication dosage error. Neither risk is any greater with a reclassification than the existing situation with a standing order.

DH, ODT and DTs have received resuscitation training at the same level as other oral health practitioners, that is, NZRC CORE Immediate training (previously named CORE Level 4), or equivalent. This is required to be maintained following graduation, with the Dental Council requiring resuscitation training to the same level, every two years. These practitioners declare compliance with this obligation as part of their annual practising renewal. Some resuscitation training providers cater courses to oral health practitioners with all oral health practitioners doing these courses together.

Research provides useful insights into medical emergencies in dentistry in New Zealand.[12] This survey of dentists, dental specialists, DTs, DHs and clinical dental technicians found a low incidence of medical emergencies in dental practice in NZ, with an average of 2.9 per practitioner reported to have occurred in the last 10 years. Nine dentists (4.6% of dentists responding) and four dental specialists (14.8% of dentists responding) reported one or more cases of anaphylaxis occurring in the last 10 years None of the other dental practitioners responding (n=121) reported anaphylaxis occurring in the last 10 years. In a 2000/2001 study of the readiness of New Zealand dentists for medical emergencies Broadbent and Thomson reported that seven anaphylaxis events from local anaesthetics were reported by dentists over the previous 10-year period [13]. All patients made rapid and full recoveries, following emergency management. Thus, the incidence of anaphylaxis is small, but oral health practitioners need to be prepared for it and have adrenaline readily available.

11. Potential risk of harm to the consumer as a result of the proposed change, and factors to mitigate this risk

The Dental Council has a practice standard for medical emergencies in dental practice (see appendix 1)[1]. This document requires DHs, ODTs and DTs to have CORE (Certificate of Resuscitation and Emergency Care) Immediate or equivalent resuscitation training,

revalidated every two years. The standard requires them to have written protocols for managing medical emergencies. It includes anaphylaxis management. DTs, DHs and ODTs are required to have an oxygen cylinder, bag mask device, basic airway device and adrenaline 1:1,000 available. Medical history must be taken and recorded for all clients. The Standards document includes information about management of conditions that may occur in an emergency in dental care.

There are no planned post-marketing surveillance activities. However, any reports to the Dental Council of incorrect use by DHs, ODTs or DTs would be investigated. Given this is within their scopes and they are very familiar with these medicines, well trained and have written information for managing emergencies, including with adrenaline, we do not expect any concerns to arise.

This application is from the Dental Council. Please see attachments for letters of support.

SUMMARY

This reclassification application seeks to use an exception from restricted medicine availability to make adrenaline 1:1,000 for emergency use more readily available to dental hygienists, dental therapists and oral dental therapists.

Adrenaline is a well-recognised essential emergency medicine for anaphylaxis. The dental professionals discussed in this application are trained to use it and currently do so under standing orders which are cumbersome and burdensome. The Dental Council is requesting easier availability in line with the scopes of practice and training of these oral health practitioners. This will reduce barriers to access of a vital medicine they need to have on hand and free up those involved in providing standing orders and auditing supplies against those standing orders for more time managing patients.

Oral health therapists, dental hygienists and dental therapists are working independently, including in Australia, UK, Singapore, and some states in the USA. The proposed reclassification of adrenaline injection enables dental therapists, dental hygienists and oral health therapists to work more easily within their scopes of practice without the inefficiencies of standing orders for the benefit of their patients. Letters of support have been provided with this application.

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