APPLICATION TO WIDEN THE CLASSIFICATION FOR TOPICAL ORAL BENZOCAINE, TETRACAINE HYDROCHLORIDE, LIDOCAINE AND PRILOCAINE, AND INJECTED ARTICAINE, LIDOCAINE AND PRILOCAINE WITH OR WITHOUT FELYPRESSIN, TO ALLOW ACCESS WITHOUT PRESCRIPTION FOR DENTAL HYGIENISTS TO USE THEM IN THEIR PRACTICE

Dental Council
Te Kaunihera Tiaki Niho

Executive Summary

This application seeks to make topical local anaesthetics, injected local anaesthetics and injected felypressin (used as a vasoconstrictor with injected local anaesthetics) more accessible for dental hygienists whose scope of practice allows use of local anaesthetics.

This application follows a successful reclassification application in 2021[1] for exception from prescription to make topical oral amethocaine (tetracaine), benzocaine, lidocaine (lignocaine) and prilocaine more readily available to dental therapists and oral health therapists. It also follows on from a successful reclassification application in 2017[2] to improve access to injected articaine, lidocaine and prilocaine with or without the vasoconstrictor felypressin for oral health therapists and dental therapists. The dental hygienists affected by this application would be only those registered with the Dental Council who are not excluded from using local anaesthetics on their registration. The application is being submitted by the Dental Council New Zealand, the regulator of oral health practitioners practising in New Zealand. It follows work on scopes of practice for these professionals.

Topical and injected local anaesthetic agents are widely used in NZ and internationally by dentists and other oral health practitioners. They have clear consumer benefit in terms of comfort with dental procedures, which is important in encouraging people to receive dental care.

Oral health therapists and dental therapists can access topical and injected local anaesthetic agents (with or without vasoconstrictors) without the need for a standing order and can administer them without supervision or a dentist on-site.

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

The strong support for this change demonstrates the wide understanding that dental hygienists who administer topical and injected local anaesthetic agents have had appropriate education to do so competently, safely and independently. This education is comparable to that received by oral health therapists and dental therapists who are not required to have a dentist on site to administer local anaesthetic.

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 dental hygienists hold a practising certificate that allows them to administer topical and injected local anaesthetic agents.

A minority of dental hygienists (n = 87) registered to practise in New Zealand have an exclusion on their scope of practice which prevents 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 proposed reclassification of local anaesthetic agents for use by dental hygienists will not alter this situation – that is, those hygienists who currently have an exclusion on their scope of practice which prevents them from administering topical or injectable local anaesthetic agents, will continue to be unable to administer these agents.

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.

The local anaesthetic agents in this application are well-known in terms of use, contraindications, precautions and adverse effects. NZ spontaneous reports of adverse events have shown few concerns with the agents this application seeks to reclassify, with anaphylaxis and methaemoglobinaemia very rarely experienced.

Dental hygienists are trained, as are dentists, dental therapists and oral health therapists, to CORE Immediate resuscitation level and must have oxygen and adrenaline available.[3] They are required to renew their resuscitation training every two years and to declare in their annual practising certificate application that they hold a valid resuscitation certificate.

Dental hygienists work independently in New Zealand and internationally, for example in Australia, UK, Singapore, and some states in the USA. The medicines affected by this application would be used on-site by the dental hygienists, there is no consumer self-use.

The proposed reclassification of four topical local anaesthetic active ingredients (which are used in two marketed products) and three injected local anaesthetic active ingredients would enable dental hygienists to work more easily within their scopes of practice for the benefit of their patients and to minimise the workload of standing orders.

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

PART A

1. International Non-proprietary Name of the medicine

a. Lidocaine (INN and BAN) also known as lignocaine. Named in the classification schedule as lignocaine
b. Benzocaine
c. Tetracaine (INN) also known as amethocaine. Named in the classification schedule as amethocaine
d. Prilocaine
e. Articaine
f. Felypressin

NB: as lidocaine is the INN name and used in product data sheets, it is used throughout this application rather than lignocaine. It is noted that in the classification statement on the Medsafe website, a lidocaine search is referred to the lignocaine entry. Data sheets typically refer to lidocaine. Tetracaine is the INN name and used in the product data sheet, but it is referred to as amethocaine in the classification statement on the Medsafe website, so both names are included in this application to aid with clarity.

2. Proprietary name (s)

The two topical anaesthetic products specifically targeted for this change are Oraqix (NZ Sponsor Dentsply, containing lidocaine 25 mg/g and prilocaine 25 mg/g) and Zap gel (NZ Sponsor DE Healthcare Limited, containing 18% benzocaine and 2% tetracaine hydrochloride).

Proprietary injectables including articaine, lidocaine and prilocaine primarily used for dental reasons are presented in table 1 below.

Table 1: Proprietary injectables including articaine, lidocaine and prilocaine primarily used for dental reasons

Medicine	Brand	Sponsor
Prilocaine plus felypressin	Citanest® dental with Octapressin® solution for injection (3% prilocaine, felypressin 0.54 µg/mL)	Dentsply
Lidocaine and adrenaline	2% Xylocaine® Dental with Adrenaline 1:80,000 Solution for injection, dental cartridge	Dentsply
Lidocaine and adrenaline	Xylestesin-A® 20 mg/mL + 12.5 µg/mL solution for injection (for dentistry)	3M
Lidocaine and adrenaline	Lignospan lidocaine 2% with adrenaline 1:80,000	Ivoclar Vivadent
Lidocaine and adrenaline	Henry Schein lidocaine 2% and adrenaline 1:100,000	Henry Schein Regional

Medicine	Brand	Sponsor
Articaine and adrenaline	Articadent articaine 4% with adrenaline 1:100,000	Dentsply
Articaine and adrenaline	Ardanest articaine 4% with adrenaline 1:100,000; articaine 4% with adrenaline 1:100,000	DE Healthcare Limited
Articaine and adrenaline	Septanest articaine 4% with adrenaline 1:100,000	Ivoclar Vivadent
Articaine and adrenaline	Ubistesin Forte articaine 4% with adrenaline 1:100,000; Ubistesin articaine 4% with adrenaline 1:200,000	3M

Table 2 Examples of injectables including lidocaine and prilocaine that are not specific for dentistry

Medicine	Brand	Sponsors
Lidocaine	Lidocaine 1% and 2% injections in various generics; Xylocaine.	Baxter Healthcare, Seqirus, Pharmacy Retailing
Lidocaine with adrenaline	Xylocaine 2% with Adrenaline 1:100,000 and Xylocaine 2% with Adrenaline 1:200,000	Pharmacy Retailing
Lidocaine	Lidocaine-Claris solution for injection (1% and 2% lidocaine)	Multichem
Prilocaine	Citanest® 0.5% or 2.0%	Pharmacy Retailing

NB Formulations of the selected local anaesthetics with adrenaline will be captured by the classification change because adrenaline is general sales in medicines for injection containing 0.02% or less. 1:80,000 is equivalent to 0.00125%.

3. Name of company/organisation/individual requesting reclassification

Dental Council - New Zealand.
Level 7, 22 The Terrace
Wellington 6011
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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, dental therapists, dental hygienists and orthodontic auxiliaries, clinical dental technicians and dental technicians.

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

Dose form: topical oral gel
See point 8 below for the strengths involved for each medicine.

Dose form: Injection
Strength is not specified, consistent with the current classification entries.

Dentistry mostly uses cartridges for local anaesthetic administration, with limited other injectable forms used in practice.

5. Proposed pack size, storage conditions and other qualifications

There are no qualifications required on pack size. We propose adding the qualification that the medicine can be used in practice by a dental hygienist registered with the Dental Council, and who does not have a *Local anaesthetic* exclusion on their scope of practice. See point 8 below for exact wording. No storage conditions need to be provided for the classification statement.

6. Indications for which change is sought

Rather than specifying the indications, the change for the classification statement will specify that the medicines are to be used in practice by a dental therapist, oral health therapist or dental hygienist (without Local anaesthetic exclusion on their scope of practice). Note that the only addition here is dental hygienist, dental therapists and oral health therapists already have this access. Product licences and scopes of practice through the Dental Council will ensure appropriate usage better than the classification statement.

In this application, the following active ingredients are used for:

- topical anaesthesia - benzocaine, prilocaine, lidocaine (lignocaine), and tetracaine (amethocaine).
- injected local anaesthesia - articaine, lidocaine (lignocaine) and prilocaine

Felypressin: Localising agent (vasoconstrictor) as an adjunct to local anaesthesia.

Examples of the licensed indications for the topical products are below:
"ZAP Topical Anesthetic Gel [containing 18% benzocaine and 2% tetracaine hydrochloride] is indicated to reduce the discomfort of local anaesthetic injected into the mandibular mucobuccal fold and maxillary anterior sites, and to minimise pain in oral mucosal tissue arising from needle punctures, deep scaling procedures, prosthetic adjustments, clamp or crown placement, removal of primary teeth and suture removal. ZAP Topical Anesthetic Gel may also be used for the reduction of pharyngeal (gag) reflex associated with the placement of various dental materials into the oral cavity (impression trays, x-ray films)."[4]

Please note that the indication including primary teeth (baby teeth) shows use in children is indicated. The data sheet only excludes use in children under 6 months of age, and advises caution in paediatric patients given the risk of systemic toxicity. The Medicines

Classification Committee consideration in 2021[1] noted use was only for adults, but Zap gel is able to be used in children.

"Oraqix® [lidocaine 25 mg/g and prilocaine 25 mg/g] is indicated in adults for localised anaesthesia in periodontal pockets for probing, scaling and/or root planing."[5]

Licensed indication wording for injected local anaesthetic agents varies across the products, e.g. Citanest with octapressin[6] has the following indications:

- Infiltration anaesthesia in dentistry, where there is no need for profound ischaemia in the injected area.
- Regional nerve block anaesthesia in dentistry.

Xylocaine 2% with adrenaline[7] states the following:

Lignocaine solutions are indicated for the production of local nerve anaesthesia in routine dental procedures and oral surgery by means of infiltration and nerve block techniques. Lignocaine solutions with adrenaline are recommended for oral surgery requiring prolonged duration of anaesthesia and haemostasis.

7. Present classification of the medicines

Table 3 Current classifications of medicines

Medicine	Current Classification
Benzocaine	**Prescription: except** when specified elsewhere in this schedule; **except** in dermal preparations containing 2% or less of total anaesthetic substances; **except** in lozenges containing 30 milligrams or less of total anaesthetic substances per dosage unit **except** when containing 20% or less and used topically as a local anaesthetic in practice by a dental therapist or oral health therapist registered with the Dental Council. **Pharmacy Only:** in preparations for topical use, other than eye drops, containing 10% or less of total anaesthetic substances **except** in dermal preparations containing 2% or less of total anaesthetic substances; in divided preparations containing 200 milligrams or less of total anaesthetic substances per dosage unit **except** in lozenges containing 30 milligrams or less of total anaesthetic substances per dosage unit **General Sale:** in dermal preparations containing 2% or less of total anaesthetic substances; in lozenges containing 30 milligrams or less of total anaesthetic substances per dosage unit

Medicine	Current Classification
Prilocaine	**Prescription:** for injection **except** when used as a local anaesthetic in practice by a dental therapist or oral health therapist registered with the Dental Council; **except** when specified elsewhere in this schedule; **except** when containing 2.5% or less and used topically as a local anaesthetic in practice by a dental therapist or oral health therapist registered with the Dental Council. **Pharmacy Only**: for dermal use in medicines containing 10% or less of local anaesthetic substances
Lidocaine (lignocaine)	**Prescription:** for injection **except** when used as a local anaesthetic in practice by a nurse whose scope of practice permits the performance of general nursing functions or by a podiatrist registered with the Podiatry Board or by a dental therapist or oral health therapist registered with the Dental Council; for ophthalmic use **except** when used in practice by an optometrist registered with the Optometrists and Dispensing Opticians Board; for oral use **except** in throat lozenges in medicines containing 30 milligrams or less per dose form; for external use in medicines containing more than 10%; **except** in throat sprays in medicines containing 2% or less; **except** when specified elsewhere in this schedule; **except** when containing 2.5% or less and used topically as a local anaesthetic in practice by a dental therapist or oral health therapist registered with the Dental Council. **Pharmacy Only:** for urethral use; for external use in medicines containing 10% or less and more than 2% **General sale:** in throat lozenges in medicines containing 30 milligrams or less per dose form; for external use in medicines containing 2% or less; in throat sprays in medicines containing 2% or less
Tetracaine (Amethocaine)	**Prescription:** for internal use; for external use in medicines containing more than 10%; for ophthalmic use **except** when used in practice by an optometrist registered with the Optometrists and Dispensing Opticians Board; **except** when containing 2% or less and used topically as a local anaesthetic in practice by a dental therapist or oral health therapist registered with the Dental Council. **Pharmacy Only:** for external use in medicines containing 10% or less and more than 2% **General Sale:** for external use in medicines containing 2% or less
Articaine	Prescription **except** when used as a local anaesthetic in practice by a dental therapist or oral health therapist registered with the Dental Council

Medicine	Current Classification
Felypressin	Prescription: **except** when combined with a local anaesthetic and used in practice by a dental therapist or oral health therapist registered with the Dental Council.

8. Classification sought

Table 4 Proposed classifications of medicines (red shows the proposed changes)

Medicine	Current Classification
Benzocaine	**Prescription: except** when specified elsewhere in this schedule; **except** in dermal preparations containing 2% or less of total anaesthetic substances; **except** in lozenges containing 30 milligrams or less of total anaesthetic substances per dosage unit; **except** when containing 20% or less and used topically as a local anaesthetic in practice by a dental therapist, ~~or~~ oral health therapist or dental hygienist (without local anaesthetic exclusion on their scope of practice) registered with the Dental Council **Pharmacy Only:** in preparations for topical use, other than eye drops, containing 10% or less of total anaesthetic substances **except** in dermal preparations containing 2% or less of total anaesthetic substances; in divided preparations containing 200 milligrams or less of total anaesthetic substances per dosage unit **except** in lozenges containing 30 milligrams or less of total anaesthetic substances per dosage unit **General Sale:** in dermal preparations containing 2% or less of total anaesthetic substances; in lozenges containing 30 milligrams or less of total anaesthetic substances per dosage unit
Prilocaine	**Prescription:** for injection **except** when used as a local anaesthetic in practice by a dental therapist, ~~or~~ oral health therapist or dental hygienist (without local anaesthetic exclusion on their scope of practice) registered with the Dental Council; **except** when specified elsewhere in this schedule **except** when containing 2.5% or less and used topically as a local anaesthetic in practice by a dental therapist, ~~or~~ oral health therapist or dental hygienist (without local anaesthetic exclusion on their scope of practice) registered with the Dental Council. **Pharmacy Only:** for dermal use in medicines containing 10% or less of local anaesthetic substances

Medicine	Current Classification
Lidocaine (lignocaine)	**Prescription:** for injection **except** when used as a local anaesthetic in practice by a nurse whose scope of practice permits the performance of general nursing functions or by a podiatrist registered with the Podiatry Board or by a dental therapist, ~~or~~ oral health therapist or dental hygienist registered with the Dental Council; **except** when containing 2.5% or less and used topically as a local anaesthetic in practice by a dental therapist, oral health therapist or dental hygienist (without local anaesthetic exclusion on their scope of practice) registered with the Dental Council. for ophthalmic use **except** when used in practice by an optometrist registered with the Optometrists and Dispensing Opticians Board; for oral use **except** in throat lozenges in medicines containing 30 milligrams or less per dose form; for external use in medicines containing more than 10%; **except** in throat sprays in medicines containing 2% or less; **except** when specified elsewhere in this schedule **Pharmacy Only:** for urethral use; for external use in medicines containing 10% or less and more than 2% **General sale:** in throat lozenges in medicines containing 30 milligrams or less per dose form; for external use in medicines containing 2% or less; in throat sprays in medicines containing 2% or less
Tetracaine (Amethocaine)	**Prescription:** for internal use; for external use in medicines containing more than 10%; for ophthalmic use **except** when used in practice by an optometrist registered with the Optometrists and Dispensing Opticians Board **except** when containing 2% or less and used topically as a local anaesthetic in practice by a dental therapist, ~~or~~ oral health therapist or dental hygienist (without local anaesthetic exclusion on their scope of practice) registered with the Dental Council **Pharmacy Only**: for external use in medicines containing 10% or less and more than 2% **General Sale:** for external use* in medicines containing 2% or less
Articaine	Prescription **except** when used as a local anaesthetic in practice by a dental therapist, ~~or~~ oral health therapist or dental hygienist (without local anaesthetic exclusion on their scope of practice) registered with the Dental Council
Felypressin	Prescription: except when combined with a local anaesthetic and used in practice by a dental therapist, ~~or~~ oral health therapist or dental hygienist (without local anaesthetic exclusion on their scope of practice) registered with the Dental Council.

*External use has been defined in the Medicines Regulations which states:

"…for external use, in relation to any medicine or related product, means for application to the anal canal, ear, eye, mucosa of the mouth, nose, skin, teeth, throat, or vagina, where local action only is required and where extensive systemic absorption will not occur; but nothing in these regulations relating to medicines or related products intended for external use shall apply to nasal drops, nasal inhalations, nasal sprays, teething applications, throat lozenges, throat pastilles, throat sprays, or throat tablets …"

External use was noted to include topical use within the mouth when discussed previously for local anaesthetics by the Medicines Classification Committee. [8] This was acceptable when these same medicines were reclassified for dental therapists and oral health therapists in 2021.[1]

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

Topical anaesthetics

The Australian schedules for topical anaesthetics are somewhat aligned with New Zealand because of Trans-Tasman Harmonisation, although a small difference occurs in that Australia has a maximum of total local anaesthetic substances, while NZ does not specify that, and Australia sometimes uses the term "topical" while NZ has not used this for the medicines in this application. Dermal local anaesthetic preparations in Australia are frequently unscheduled for low doses. Tetracaine (amethocaine) is Schedule 2 (S2; pharmacy only) in preparations for topical use other than eye drops, containing 10% or less of total local anaesthetic substances, and unscheduled in dermal preparations containing 2% or less of total local anaesthetic substances. Benzocaine is Schedule 2 in preparations for topical use other than eye drops, containing 10% or less of total local anaesthetic substances, or in divided preparations containing 200 mg or less of total local anaesthetic substances per dosage unit. Benzocaine is unscheduled (general sales) in dermal preparations containing 2% or less of total local anaesthetic substances; or in lozenges containing 30 mg or less of total local anaesthetic substances per dosage unit. Otherwise, benzocaine is a prescription medicine. This would make Zap gel a prescription medicine given it contains benzocaine 18% and tetracaine hydrochloride 2%.

In Australia, prilocaine is Schedule 2 in preparations for dermal use containing 10% or less of total local anaesthetic substances, and otherwise prescription. Lidocaine is Schedule 2 for topical use other than eye drops containing 10% or less of total local anaesthetic substances, and unscheduled in dermal preparations containing 2% or less of total local anaesthetic substances, in lozenges containing 30 mg or less of total anaesthetic substances per dosage unit, or in aqueous sprays for oromucosal use containing 0.6% of less of total local anaesthetic substances. Therefore, Oraqix, with 2.5% of prilocaine and 2.5% of lidocaine used topically (not dermally) would be a prescription medicine.

In Canada, tetracaine is schedule III (Pharmacy only equivalent) for "topical use on mucous membranes, except lozenges". Lidocaine is schedule II (Pharmacist only equivalent) "for ophthalmic or parenteral use, or topical use on mucous membranes, except lozenges". Prilocaine and its salts are schedule III (Pharmacy only equivalent) "for topical use on mucous membranes, except lozenges" or for lidocaine and prilocaine together.

Benzocaine and its salts are schedule II (Pharmacist only) "for parenteral or ophthalmic use."

Oraqix is a prescription medicine in the UK. Zap gel does not appear to be available there.

Oraqix is available in the US where it is a prescription medicine. Zap gel is available in the US where it is a prescription medicine.

Injected local anaesthetics

The classification status for these injectable agents is provided in Table 5. New Zealand varies from other countries in using the classification statement to allow different medicines to be used by various health practitioners. Hence, other countries typically have prescription-only status for these medicines. However, the UK and Australia both allow use of local anaesthetics by dental therapists and dental hygienists without direct supervision by a dentist, similar to what we are proposing to enable through this classification change. In Australia an oral health therapist can also do this without direct supervision, but the UK does not have this category of practitioner.

Table 5 Classification Status in Australia, UK, Canada and USA

Medicine	Australia	UK	Canada	USA
Lidocaine injection	Prescription	Prescription	Schedule 2 (pharmacist-only) for parenteral use	Prescription
Articaine injection	Prescription	Prescription	No listing in the schedule	Prescription
Prilocaine injection	Prescription	Prescription	Schedule 2 (pharmacist-only) for parenteral use	Prescription
Felypressin injection	Prescription	Prescription	No listing in the schedule	Not found

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 [9, 10].

In Australia, the Dental Board of Australia outlines the scopes of practice for dental hygienists, dental therapists and oral health therapists, which includes administering pharmaceutical agents. In Victoria, Australia, dental hygienists, dental therapists and oral health therapists 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 [11]. These listed medicines include articaine, lignocaine, mepivacaine, and prilocaine.

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

Topical anaesthetics

Topical oral local anaesthetics have extensive and long-time use in dental practice, although they have changed over time.

The Medsafe website indicates that Zap gel was consented 21 Oct 2010 and Oraqix 24 April 2008. Sultan Topex gel containing 20% benzocaine was available from 2000-2020.

Sales data is not readily available, but some companies may choose to confidentially make this information available to the Medicines Classification Committee. However, these products have been very commonly used in everyday dental practice in New Zealand and elsewhere.

Injected local anaesthetics

These medicines have extensive use in the dental industry and in non-dental surgical procedures. Registration of some of local anaesthetic injections for dental use date back to 1969 (e.g. Xylocaine dental with adrenaline).

Sales data is not readily available, but some companies may choose to confidentially make this information available to the Medicines Classification Committee. Based on information from a survey we estimate that over 4 million LA injections are given per year for dental use in NZ.[12]

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

See information in part B.

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

Not applicable. The labelling would not need any update. The existing labelling is attached for the topical products, given their administration differs. Labelling for the injectables is not attached but can be provided if required, simply contact the applicant.

13. Proposed warning statements (if applicable)

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

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

The products listed in Table 6 (below) containing the above active ingredients for topical use in dental procedures have Medsafe datasheets available.

Sultan Topex (20% benzocaine) oral topical gel was marketed 2000 to 2020 with the approval lapsed and product no longer marketed.

Table 6. Topical products affected by the proposed changes

Medicine	Brand	Sponsor
Benzocaine plus tetracaine hydrochloride	Zap Topical Anaesthetic Gel (benzocaine 18% w/w and tetracaine hydrochloride 2% w/w)	HealthCare Essentials Limited
Lidocaine plus prilocaine	Oraqix Periodontal Gel (lidocaine 25 mg/g and prilocaine 25 mg/g)	Dentsply Sirona (NZ) Limited
Lidocaine	Xylocaine® Viscous solution* (lidocaine hydrochloride monohydrate 21.4 mg/mL equivalent to lidocaine hydrochloride 20 mg/mL)	Pharmacy Retailing

*NB Xylocaine Viscous Solution is currently a pharmacy-only medicine according to the data sheet

Table 7. Injected products affected by the proposed changes

Medicine	Brand	Company
Prilocaine plus felypressin	Citanest® dental with Octapressin® solution for injection (3% prilocaine, felypressin 0.54 µg/mL)	Dentsply
Lidocaine and adrenaline	2% Xylocaine® Dental with Adrenaline 1:80,000 Solution for injection, dental cartridge	Dentsply
Lidocaine and adrenaline	Xylestesin-A® 20 mg/mL + 12.5 µg/mL solution for injection (for dentistry)	3M
Articaine and adrenaline	Ardanest articaine 4% with adrenaline 1:100,000; Ardanest articaine 4% with adrenaline 1:200,000	HealthCare Essentials Ltd
Articaine and adrenaline	4% Articadent DENDAL with adrenaline 1:100,000 solution for injection	Dentsply
Articaine and adrenaline	Septanest articaine 4% with adrenaline 1:100,000; Septanest 1:200,000 solution for injection	Ivoclar Vivadent
Articaine and adrenaline	Ubistesin Forte articaine 4% with adrenaline 1:100,000; Ubistesin articaine 4% with adrenaline 1:200,000	3M
Non Dental		
Lidocaine	Xylocaine 1%, and Xylocaine 2%	Pharmacy Retailing
Lidocaine with adrenaline	Xylocaine 2% with Adrenaline 1:100,000 and Xylocaine 2% with Adrenaline 1:200,000	Pharmacy Retailing
Lidocaine	Lidocaine-Claris solution for injection (1% and 2% lidocaine)	Multichem
Prilocaine	Citanest® 0.5% or 2.0%	Pharmacy Retailing

PART B

Reasons for requesting classification change including benefit-risk analysis

This reclassification application requests changes in classification for topical and injected local anaesthetics and a vasoconstrictor for dental hygienists whose scope of practice allows local anaesthetic use. It has no greater risk than the changes that followed the successful applications for reclassification of injected and then topical local anaesthetics for use by oral health therapists and dental therapists without prescription (occurring in 2017[2] and 2021,[1] respectively).

Dental hygienists whose scope of practice allows local anaesthetic use are already using topical and injected local anaesthetics without a dentist on-site, therefore no additional risks are perceived. These dental hygienists have received appropriate training in administration of local anaesthetics, including education on contraindications, precautions and managing adverse events.

This proposal will aid dental hygienists whose scope of practice allows local anaesthetic use to work to their competencies without needing standing orders. A reclassification will be as safe as standing orders but reduce administrative burden. When attending patients at residential care or other facilities, they will be able to treat the patient as appropriate for their scope of practice. It will also mean dental hygienists can purchase products from distributors or wholesalers legally directly instead of needing to go through a dentist.

The risks have been managed through appropriate training; registration of the health care professional; requiring practitioners to undertake resuscitation training every two years; and use of well-known and well-tolerated medicines commonly used in dental work. Oral health therapists, dental therapists, and more recently, dental hygienists whose scope of practice allows local anaesthetic use (2021 onwards), can administer topical and injected local anaesthetics in their work without needing a dentist's supervision, and without a dentist being on-site, according to their Dental Council Scopes of Practice. The education dental hygienists receive in this practice area is known to be comparable to that completed by oral health therapists and dental therapists. The key difference is that dental hygienists whose scope of practice allows local anaesthetic administration currently need a standing order, while oral health therapists and dental therapists do not.

Mapping of the competency standards and performance measures for dental hygiene, dental therapy and dentistry by the Dental Council against the curricula of the oral health and dental programmes at the University of Otago and the Auckland University of Technology Oral Health programme, illustrated that the same competencies are achieved for the administration of local anaesthetics.

The above information gives confidence in this expansion to local anaesthetics being used topically and by injection by dental hygienists without the need for a standing order.

Dental hygienists are educated in the restrictions[1], contraindications, potential interactions with medications, and potential complications associated with the administration of local anaesthetics, and the management of the patient in the unfortunate event of a medical emergency caused by potential but rare side effects.

For patients with a history of adverse reaction to medications, complex medical conditions or who are medically compromised, dental hygienists are expected to discuss a treatment plan with a dentist or dental specialist before commencement of treatment, irrespective of the need, or not, for local anaesthetic. A written professional relationship between a dentist/dental specialist and other oral health practitioners is no longer a scope of practice requirement, including for dental hygiene. However, the Council expects that oral health practitioners will maintain their professional relationships within the oral health team, working collaboratively for the benefit of patients' health – as required under the Standards Framework for Oral Health Practitioners.

DENTAL HYGIENISTS VERSUS DENTAL THERAPISTS AND ORAL HEALTH THERAPISTS

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 therapists were formerly known as dental nurses. Their work includes an extensive range of preventive and restorative services, and thus they frequently use local anaesthetics by injection and topically.

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.

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.

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

TYPE OF DENTAL HYGIENE SCOPE OF PRACTICE ACTIVITIES WHERE TOPICAL AND/OR INJECTED LOCAL ANAESTHETICS COULD BE ADMINISTERED

***Removing hard and soft deposits from all tooth surfaces*:** use in selected cases for the removal of hard deposits, where appropriate. For example, deep scaling of root surfaces, sensitive teeth and/or inflamed gum tissue.

[1] Restricted to administering injected local anaesthetic using dentoalveolar infiltration and inferior dental nerve block techniques.

Prior to the procedures an injectable local anaesthetic may be provided. Use of a topical local anaesthetic prior to use of the injection can decrease the discomfort of the procedure and significantly reduce needle phobia and discomfort.

COMPETENCE NOTIFICATIONS RELATED TO THE ADMINISTRATION OF LOCAL ANAESTHETICS

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

THE MEDICINES AND BENEFIT-RISK OF THE RECLASSIFICATION

A brief note about the differences between the local anaesthetics

Articaine, lidocaine and prilocaine are amide-type local anaesthetics, while benzocaine and tetracaine are esters of para-aminobenzoic acid.

Local anaesthetics vary in potency, and their onset and duration of action. For example, an update on dental topical anaesthesia [13] reported benzocaine has an onset of 30 seconds and duration of action of 5-15 minutes, and lidocaine 2% typically has an onset of 3-5 minutes and duration of 15 minutes. The eutectic mixture of lidocaine 2.5% and prilocaine 2.5% (Oraqix) has an onset of 30 seconds and duration of 20 minutes[13]. Hypersensitivity and metabolism also vary (more details below).

Articaine may be less familiar to non-dental health practitioners. It is also known as carticaine and is an amide-type local anaesthetic. It has a rapid onset (1-6 minutes) and short duration of action (about one hour),[14] making it very commonly used in dentistry in New Zealand and internationally.

1. **Indications and dose**

   The indications are appropriate to the proposed classification statements. The dental hygienist scope of practice already covers these areas and therefore there is minimal risk of inappropriate treatment. The consumer does not need to understand indications or dosing as they are not self-treating, these medicines are only administered during dental practice.

   Topical anaesthetics

   Oraqix indications [5]:

   Oraqix® is indicated in adults for localised anaesthesia in periodontal pockets for probing, scaling and/or root planing.

   Zap licensed indications [4]:

   Zap Topical Anesthetic Gel is indicated to reduce the discomfort of local anaesthetic injected into the mandibular mucobuccal fold and maxillary anterior sites, and to minimise

pain in oral mucosal tissue arising from needle punctures, deep scaling procedures, prosthetic adjustments, clamp or crown placement, removal of primary teeth and suture removal. Zap Topical Anesthetic Gel may also be used for the reduction of pharyngeal (gag) reflex associated with the placement of various dental materials into the oral cavity (impression trays, x-ray films).

Please note that dental hygienists will not be doing crown replacement or removal of primary teeth.

Oraqix dose [5]:

Adults

On average, one cartridge (1.7 g) or less of Oraqix® will be sufficient for one quadrant of the dentition. The maximum recommended dose of Oraqix® at one treatment session is five cartridges, i.e. 8.5 g gel containing 212.5 mg lidocaine (lignocaine) base and 212.5 mg prilocaine base.

The duration of anaesthesia, as assessed by probing of pocket depths, is about 20 minutes. If the anaesthesia starts to wear off, re-apply Oraqix® as needed.

See the attached data sheet for further details.

Zapgel dose [4]:

Apply approximately 0.2 - 0.3 mL of gel to the desired area using a cotton swab or fingertip. The exact dosage depends on the area to be anaesthetised, the vascularity of the tissues at the application site, and the patient's tolerance. Do not exceed the recommended dosage or apply more than one application per procedure.

An appropriate paediatric dosage has not been established. Dosages should be reduced in the elderly, acutely ill, and very young patients.

2. Presentation

Oraqix is available as a periodontal gel containing lidocaine 25 mg/g and prilocaine 25 mg/g and is supplied in dental cartridges containing 1.7 g of gel with a sterile blunt-tipped applicator for each cartridge.

Zap gel is available as a gel containing benzocaine 18% w/w and tetracaine HCl 2% w/w. It is presented in a "magic" jar containing 30 g and 50 g – see the data sheet for more information.

These presentations are appropriate for the proposed classification statements, there is no consumer self-treatment. Both products are practical in their presentation.

Disposal will be as is usual for dental hygienists, there is no special consideration required here.

Indications for injected local anaesthetics has been covered earlier in Part A, under point 6 'Indications for which change is sought'.

3. Consumer benefits

These medicines are used in many countries around the world as a usual part of dental care. The exact number of countries and number of users is unknown as this application is not being submitted by the manufacturers of these medicines.

Regular dental checks are needed to maintain health of teeth and gums. The New Zealand annual health survey 2014/2015 [15] found that 48% of all adults with natural teeth had visited a dental health care worker in the past 12 months. People in more deprived areas, or people of Māori, Asian or Pacific ethnicity have lower attendance than others. Most Pacific, Māori and Asian adults only visit for dental problems, not regular check-ups. Dental extraction for tooth decay, abscess, infection or gum disease was reported to have occurred in the last 12 months by at least 10% of Pacific and Māori adults. Dental extraction affects quality of life, and usually results from not seeking dental care (prevention or treatment) early.

Local anaesthetics (injected or topical) are widely used by dentists, dental specialists, oral health therapists, dental therapists and dental hygienists. They are very effective in reducing pain during dental procedures [16]. As dental anxiety reduces the likelihood of routine attendance at the dentist [17], it is important to ensure patient comfort, including in people who are needle phobic. Topical and injected local anaesthetics can be used by oral health therapists and dental therapists without a dentist on the premises and without the need for a standing order to be in place.

In 2021, the dental hygiene scope of practice was changed, following wide consultation, so a dentist is no longer required to be on-site when a dental hygienist administers local anaesthetic. It would be appropriate to now extend the classification statements so that a dental hygienist can administer topical and injected local anaesthetic without the need for a standing order.

This extension would minimise the chances of treatment disruption or painful treatment. It will provide time savings for dentists, many of whom report time pressure stress [18]. It will be more efficient than standing orders which would not add any safety as they would allow product administration without a dentist on-site, and administration recorded in retrospect. Standing orders are cumbersome and time-consuming, and secondary dental services are over-burdened [19], so a reclassification is a better option.

It is also helpful for the dental hygienist for managing patients efficiently. A patient who needs a local anaesthetic and is rebooked may not return for the remainder of their treatment, so risk poorer care, in addition to inconvenience. The alternative approach of having a standing order in place would provide no greater safety than currently exists and is more burdensome on dentists and dental hygienists. In reality, the use of standing orders is not common in private dental practices.

The proposed change provides flexibility, aids quality care and patient convenience and has no greater risk than that which exists with administering topical and injected local anaesthetics which dental hygienists already do without a dentist present, through use of a standing order.

4. Contraindications and precautions

Table 8 Contraindications for the medicines

	Oraqix (lidocaine + prilocaine)	**Zap topical anaesthetic gel**	**Injected articaine, lidocaine or prilocaine with or without vasoconstrictor**
Hypersensitivity	Known history of hypersensitivity to local anaesthetics of the amide type or other component of the product	Known hypersensitivity to any ingredient in the product or local anaesthetics of the ester type	Hypersensitivity to any ingredient is a contraindication for use, in some cases this will include sodium metabisulphite.
Other	Nil	Use outside the oral cavity. Tetracaine is hydrolysed in vivo to p-amino-benzoic acid (PABA) so should not be used in people taking sulphonamides	Nil

Table 9 Warnings and precautions (see full details in data sheets, attached)

Oraqix (lidocaine + prilocaine)	**Zap topical anaesthetic gel (benzocaine + tetracaine)**	**Injected articaine, lidocaine or prilocaine with or without vasoconstrictor**
Glucose-6-phosphate dehydrogenase deficiency or congenital or idiopathic methaemoglobinaemia	Do not apply to traumatised, inflamed or infected or highly vascular surfaces	Vasoconstrictors have a caution for use in hyperthyroidism and pregnancy[20]
Avoid contact with eyes	Risk of systemic toxicity is greatest in small children and patients with pre-existing heart disease. Time and surface area increase systemic exposure	Dental care should be delayed in cases of very high blood pressure (e.g. 180/100).[20]
Do not inject	Caution in paediatric, geriatric, acutely ill or	Hepatic cytochromes degrade amide type local

Oraqix (lidocaine + prilocaine)	Zap topical anaesthetic gel (benzocaine + tetracaine)	Injected articaine, lidocaine or prilocaine with or without vasoconstrictor
	debilitated patients. Do not use on children under 6 months or older patients with cardiac or anaemia problems	anaesthetics, so severe hepatic disease requires caution with extensive use of these agents.[14] Reduced cardiac output slows delivery of amide type local anaesthetics to the liver, reducing their metabolism and prolonging the half-life.
Reduced sensation where used, care with inadvertent trauma or extreme hot or cold temperatures	Do not exceed the maximum recommended dosage	For prilocaine, congenital or idiopathic methaemoglobinaemia is a contraindication.[6] This is noted to be rare.[21]
Avoid contact to prevent allergy developing	Repeated and prolonged application may potentiate hypersensitivity.	Concurrent sedation and opioids can increase risk.[21]
Hepatic impairment can cause increased half-life of ingredients	Tetracaine is associated with a higher incidence of allergic reactions than other anaesthetics.	Datasheets note that caution is needed in patients with heart block; elderly; patients in poor general condition; severe or untreated hypertension; severe heart disease; severe anaemia or circulatory failure.[6, 7]
Renal impairment can cause metabolites to accumulate	People sensitive to PABA, parabens or paraphenylenediamine may also be sensitive to benzocaine and tetracaine	Intravascular injection must be avoided. Dental practitioners aspirate before administration to ensure a blood vessel has not been entered.
	Do not eat for one hour after use because swallowing may be impaired	
	Do not use under dentures or cotton rolls	

Benzocaine at the recommended dose for Zap gel would provide up to 56 mg of benzocaine, when toxicity has been reported at 100 mg [22]. However, it is important to note that the doses are not repeated nor reliant on consumer compliance, minimising risk. Tetracaine (amethocaine) is provided at a low strength because it is considered more potent.

For pregnancy, lidocaine and prilocaine are Category A with use by a large number of pregnant women without harm being observed [5]. Use of these agents in lactation is also expected to be reasonable owing to small exposure. The safety of benzocaine and tetracaine in pregnancy and lactation has not been fully established [4].

These contraindications and precautions are taught in under-graduate training or in additional local anaesthetic training courses. Dental hygienists who do not have this training have an exclusion of local anaesthetic use on their registration.

Dental hygienists will take a comprehensive medical history and consult with a dentist or refer patients to a dentist if concerned that the patient could have contraindications and precautions for the use of local anaesthetic.

The Oraqix product includes the prescribing information inside (see appendices). Zap gel packaging has application instructions (see appendices). Dental hygienists will be asking about hypersensitivity and other medical conditions and referring if unsure about the appropriateness of a topical local anaesthetic for an individual.

These medicines will be administered by dental hygienists, not consumers, and therefore contraindications and precautions are likely to be better managed than a person using a local anaesthetic themselves that has been purchased as a general sales medicine.

No effect on driving or operating machinery is expected. The only concern with food and drinks is that they are not too hot, but the numbness wears off quickly.

Few drug interactions are of concern and are likely to be very limited by the nature of the relatively local use and short half-life of the agents chosen.

Stockley's Drug Interactions[23] reports that there are no specific interactions for articaine (listed as carticaine in the database). Possible interactions with local anaesthetic use relevant to dental use are minimal. Nadalol 80 mg orally increases the mean duration of lidocaine 2% with 1:100,000 adrenaline by 17 minutes but not lidocaine alone. This is thought to result from increased local vasoconstriction. Prilocaine and lidocaine applied as Emla cream to a 12 week-old child also taking co-trimoxazole may have contributed to elevated methaemoglobin. It has therefore been suggested that this topical product not be used on infants under the age of 12 months who are receiving treatment with methaemoglobin-inducing drugs, including sulfonamides. There are no mentions in Stockleys of such an interaction with injectable local anaesthetics. The Citanest with Octapressin data sheet[6] suggests that "medicines which may predispose to methaemoglobin formation, e.g. sulphonamides, antimalarials and certain nitric compounds, could potentiate this adverse effect of prilocaine".

There is a caution in Stockley's about use of vasoconstrictors in local anaesthetics with tricyclic antidepressants, but they suggest that the interaction is only rarely clinically important, and aspiration would avoid inadvertent intravenous administration. Becker and Reed[21] also mention a potential interaction with vasoconstrictors with use of tricyclic antidepressants, monoamine oxidase inhibitors, digoxin, thyroxine or sympathomimetics for weight control or attention deficit disorders, and non-selective beta blockers. This is

mentioned to be a caution rather than a contraindication. Felypressin is considered a safe alternative to adrenaline used in this way. Adrenaline at the concentrations used in dental local anaesthesia is classified as general sales.

Dental hygienists will not be using a large number of injections (more than 3-5 ml of 2% lignocaine with adrenaline) in a single sitting for a patient. Extensive work is likely to be carried out either over multiple visits or is referred to a specialist periodontist instead. Furthermore, the SMARs data suggests minimal difficulties arising from drug interactions.

5. Undesirable effects

Adverse effects of local anaesthetics are well-known. Local numbness could result in inadvertent burning of the mouth with a hot drink. Sensitivity reactions include local effects through to systemic effects, including anaphylaxis, which is rare. Serious effects are sufficiently rare to allow some forms of local anaesthetics to be general sales, and some to be pharmacy-only medicines.

The Oraqix data sheet[5] reports that there were "no major differences in adverse events between Oraqix and placebo in clinical trials", with most reports being local reactions. See the data sheets for further information on adverse reaction frequencies.

Greenwood and Meechan in 2014 reported that anaphylaxis in dental practice was more likely to occur with latex or penicillin than with local anaesthetic use. [24] Hypersensitivity is rare and tends to affect the ester than amide-type local anaesthetics, [14, 25, 26] although SMARs data, below, shows reports with both the ester and amide type of local anaesthetics in this proposal. Preservatives such as parabens or added sulphite for local anaesthetics combined with a vasoconstrictor, could cause allergy.

Topical use of local anaesthetic agents can cause sensitivity which could result in hypersensitivity with later administration e.g. by injection.[25] However, dermal local anaesthetic agents are available without prescription.

Becker and Reed report that lidocaine toxicity is seen at plasma concentrations of 5 micrograms/mL, with convulsive seizures occurring above 10 micrograms/mL.[21] A 2% lidocaine injection in 2mL in a cartridge will contain 40 mg of lidocaine. Becker and Reed suggested that lidocaine systemic absorption from dental injections would be likely to be similar to that of a study using vaginal application in which 400 mg (equivalent to 10 cartridges, far greater quantity than would be used in practice) provided close to 5 micrograms/mL plasma concentrations, and about half of that dose if used with adrenaline. A further study mentioned by Becker and Reed found 480 mg of articaine with adrenaline saw a 2 microgram/mL plasma concentration. These authors stated that "one can reasonably conclude that adhering to published maximum recommended dosages for local anesthetics will not result in systemic serum levels that approach those associated with toxicity."

Paraesthesias can occur rarely with local anaesthetics, with 95% occurring with mandibular nerve blocks.[21]

Vasoconstrictors can delay wound healing, cause tissue oedema, and tissue necrosis, and therefore are not recommended for use with local anaesthetics in areas with limited collateral circulation.[14] Dental use occurs in areas of sufficient circulation. In overdose, felypressin can increase blood pressure or cause coronary constriction.[6] Dental use of adrenaline in doses of 1:100,000 increases cardiac output, heart rate and stroke volume.[21] However, adrenaline is quickly metabolised, so the effects are short-lived.

There are no withdrawal effects after using these medicines.

See below for regulatory action with regard to benzocaine and methaemoglobinaemia. Note also the Prescriber Update in NZ with methaemoglobinaemia and local anaesthetics (attached).

Methaemoglobinaemia

Local anaesthetics, along with nitrates, amyl nitrite, sulphonamides, infections, anaemia and certain foods are risk factors for methaemoglobinaemia [27-29]. Methaemaglobinaemia can occur with prilocaine at high doses (usually greater than 8 mg/kg) [14], but Becker and Reed [21] note that this effect is "unlikely to follow the administration of recommended doses".

Infants under 3 months, and people with haemoglobinopathies, and G6PD deficiency may be at greater risk of harm [25]. In methaemaglobinaemia, the iron in haemoglobin is oxidised to its ferric state, reducing the oxygen carrying capacity of the haemoglobin. Symptoms include headache, fatigue, cyanosis, shortness of breath, tachycardia, confusion, and reduced consciousness, with serious outcomes including death possible. These can appear within minutes to 1-2 hours after use of an agent[30]. People with breathing problems or heart disease, or people who are elderly are at greater risk if experiencing methaemaglobinaemia.

The Food and Drug Administration (FDA) in 2018 stated that infants and children under two years of age should not have products containing benzocaine because of the risk of methaemaglobinaemia, and requested manufacturers stop manufacturing benzocaine-containing products for teething in this age group [30]. The FDA required a standardised methaemaglobinaemia warning to be used on labelling of benzocaine products, and noted that benzocaine was more problematic than other local anaesthetics, with more than 400 cases reported to the FDA or published in the literature since 1971. In contrast, Martindale's Complete Drug Reference suggests prilocaine has a greater incidence [25]. The FDA recommends "Health care professionals should warn patients of the possibility of methemoglobinemia and advise them of the signs and symptoms when recommending or prescribing local anesthetic products" [30]. The FDA also recommends health care professionals try to minimise the risk, including monitoring patients for signs and symptoms of methaemaglobinaemia, and having resuscitation equipment and medications readily available, including methylene blue. Note, many of the OTC benzocaine products

used in the US were items for use by a consumer multiple times a day e.g. for teething or a sore throat spray (200 mg/mL[22]), as opposed to typically one-off usage by a dental professional with dental work.

In 2009, Prescriber Update in New Zealand warned of methaemoglobinaemia with various medicines including local anaesthetics, nitrates and sulphonamides[28], but did not provide advice on needing to keep methylene blue available where these medicines are used.

NZ SMARs data 1 Jan 2000-9 May 2022

In New Zealand, SMARs data reports five reactions for benzocaine, an 8 year old in 2007 with methaemaglobinaemia with benzocaine oral, a 7 year old with application site pain with benzocaine oral topical, a 4 year old with erythema, face oedema rash and somnolence in 2017 with Mepivacaine injection plus Zap gel topical, a 51 year old in 2018 with agitation, flushing, tachycardia and tremor in 2018 with Zap gel topical and a 55 year old woman in 2021 with methaemaglobinaemia with topical benzocaine as the suspected agent.

SMARs data reports 30 reports for tetracaine (amethocaine), 26 of which are for Ametop, a dermal anaesthetic applied before a needle is inserted into a vein, and one for ophthalmic use. Most of these were local reactions, but four were systemic, including one case of anaphylaxis and another with bronchospasm. Two reports were for topical oral use (Zap gel), as outlined above for benzocaine.

Lidocaine reports were 143 in total, including 34 cases of anaphylaxis or anaphylactoid reactions. Most reaction reports arose from injections, but over 30 cases involved topical lidocaine without anaesthetic injections, and these topical cases included anaphylaxis also or dyspnoea, with several such reports naming commonly sold non-prescription products as suspect medicines.

Prilocaine had 19 reports, including two cases of anaphylaxis, one bronchospasm, one tongue oedema, one laryngospasm and vocal cord paralysis and one methaemaglobinaemia (all injections). Seven adverse reaction reports related to topical application, all application site reactions, e.g. urticaria or application site reaction.

None of the four medicinal ingredients had deaths reported in the SMARs data. With local anaesthetics used very frequently in general practice, secondary care, and with oral health practitioners, the small number of SMARs reports is reassuring, and oral health practitioners will be resuscitation trained and equipped. Additionally, children under 3 months (at particular risk)[25] will not be treated by dental hygienists.

Some of the products contain sulphites as an antioxidant where adrenaline is included, e.g. Ubistesin® (articaine with adrenaline),[31] and Xylocaine dental with adrenaline 1:80,000.[7] This excipient can cause allergy in its own right. Asthmatics and atopic patients are more likely to be allergic to sulphites.[21]

Oral health practitioners are taught to inject the local anaesthetic slowly after negative aspiration to minimise adverse events.

6. Overdose

Systemic toxicity of local anaesthetic from excessive dose or inadvertent intravascular administration provides excitation of the CNS which can be followed by depression [25]. Overdose with the local anaesthetic agent can cause headaches, light-headedness, dizziness, blurred vision, tinnitus, numb mouth, drowsiness, disorientation and loss of consciousness [20]. Adverse effects on the cardiovascular system are uncommon [14] but high systemic exposure can cause seizures and cardiac arrhythmias [4].

Martindale reports ready absorption of most local anaesthetics through mucous membranes, although the Zap gel data sheet reports minimal systemic absorption of benzocaine and higher systemic absorption of tetracaine [4, 25]. Anaesthetics of the ester type are hydrolysed by esterases in the plasma, while amides are metabolised in the liver. Oraqix reports 20-40% systemic absorption but minimal if swallowed due to first-pass effects, and a half-life of 3.6 hours for lidocaine and 2.8 hours for prilocaine after administration to mucosal surfaces[5].

7. Medication errors and abuse/misuse potential

Used by oral health practitioners, there is no potential for abuse, misuse or unnecessary use. Errors would be unlikely given the limited area in which they are used and application aids. Errors may be more likely with injected local anaesthetics which could inadvertently be injected intravascularly, or by injection be administered too rapidly. If large amounts were used in error, systemic toxicity is possible. However, the application by oral health practitioners trained in their use, and dose aids for administration would help limit this potential.

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.

We are unaware of any potential for addiction with these medicines.

8. Communal harm and/or benefit

Communal benefit could arise from efficiency for dental hygienists 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 dental hygienists.

Communal harm seems unlikely.

9. Integrated benefit-risk statement

This reclassification supports the appropriate use of topical and injected local anaesthetics by dental hygienists in line with their scope of practice. It will ensure good access for patients to appropriate pain relief when attending these practitioners, improving the acceptability of hygiene care and reducing the need for referral and potential for the person not to follow through with that referral (e.g. for financial or time reasons), creating a worse problem. Topical and injected anaesthetic agents are already available for oral health therapists and dental therapists with a similar classification to that proposed here for dental hygienists, therefore it is very logical to extend this to topical and injected local anaesthetics for dental hygienists.

10. Risk mitigating strategies

The risk mitigating strategies are the same for dental hygienists as for dental therapists and oral health therapists, who already have access to topical and injected local anaesthetics without the need for a standing order - as requested for dental hygienists in this application.

Dental hygienists who are educated in their use are very familiar with using injected and topical oral local anaesthetics. This is within their scope, and when used under standing orders, dental hygienists are already working with no dentist on-site, using these medicines in their everyday practice. Therefore we foresee no greater risk than in the current situation.

The most serious risks are anaphylaxis, methaemaglobinaemia, and potential for overdose (e.g. using topical and injected local anaesthetics). Dental hygienists are trained to avoid these risks. They are aware of them, and ready to manage an emergency should it arise.

Dental hygienists will have received training on indications, contraindications and precautions for topical oral and injected local anaesthetics. They will be asking patients about relevant medical history, and in the case of a higher patient risk, they will consult with the dentist/dental specialist before proceeding with the treatment, or refer if required. Similar professional judgment is required in all other areas of dental hygiene practice.

In the event of a medical emergency related to the administration of local anaesthesia, dental hygienists receive resuscitation training at the same level as other oral health practitioners, that is, NZRC CORE Immediate training (previously named CORE Level 4), or equivalent. The Dental Council require resuscitation refresher training every two years. Oral health practitioners declare compliance with this obligation as part of their annual practising renewal. Some first aid providers cater courses to dental practitioners with all of the dental practitioners doing these courses together.

Like dentists, dental therapists and oral health therapists, dental hygienists need to have oxygen and adrenaline available when treating patients.[3] Note that Oraqix is indicated only in adults, but Zap gel is not limited to adults.

Research (published December 2017) provides useful insights into medical emergencies in dentistry in New Zealand.[12] This survey of dentists, dental specialists, dental therapists, dental hygienists 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 dental specialists 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 were reported by dentists over the previous 10-year period, with three attributed to local anaesthetics[32]. All patients made rapid and full recoveries, following emergency management. Fourteen patients received overdoses of anaesthetic agents during the same period. Details were provided for six of these events, of which three were due to excessive local anaesthetics administered.

To minimise risk, for Zap gel, approximately 0.2-0.3 mL of gel is applied, aided by a special pressure valve (see data sheet) [4]. The data sheet warns not to use more than one application per procedure. Containing 18% of benzocaine, this would be equivalent to about 36-54 mg of benzocaine. Toxicity is not seen until at least 100 mg [22].

Extensive work is likely to be carried out either over multiple visits or be referred to a specialist periodontist instead, so multiple applications of local anaesthetics are unlikely. However, topical anaesthetics are likely to be used prior to injecting a local anaesthetic, and this is the most common use of the topical anaesthetic. The injectable would then be lignocaine, articaine or prilocaine.

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

The proposed change is in line with the education and expertise of dental hygienists who have either received education and training in the administration of local anaesthetic in their initial programme of study or have completed additional education and training in this practice area.

The main risks of harm of importance are anaphylaxis and methaemaglobinaemia. These are extremely rare, as noted above, and would be managed by the oral health practitioner. These risks already exist with both topical and injected local anaesthetics which are used regularly by dental hygienists. Such risks also exist with use of various non-prescription medicines. For the considerable benefits of these agents, rarity of these reactions and ability to manage these reactions, the overall benefit-risk equation is very clearly favourable.

The Dental Council has a practice standard for medical emergencies in dental practice (see Appendix 1)[3]. This document requires dental hygienists 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. Dental hygienists are required to have an oxygen cylinder, bag mask device, basic airway device and adrenaline 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. It does not include signs, symptoms and management of methaemaglobinaemia, however, this will be considered for inclusion in the next major update, with the latest update in 2021 being minor changes only. We do not believe there is any need for methylene blue to be kept in a first aid kit, owing to the rarity of the reaction, having oxygen readily available, and being able to call immediately for an ambulance to get appropriate emergency care. No oral health practitioner, including dentists, needs to stock this item.

There are no planned post-marketing surveillance activities. However, it would be noticed if there was an increase in reports of incorrect use by dental hygienists, and any such increase would be investigated. Given this is within their scopes and they are very familiar with these medicines, we do not expect any concerns to arise.

This application is from the Dental Council. Supportive letters are attached for the committee.

SUMMARY

This reclassification application seeks to use an exception from prescription availability to make topically applied tetracaine (amethocaine), benzocaine, lidocaine (lignocaine) and prilocaine, injected articaine, lidocaine and prilocaine, and injected felypressin more readily available to dental hygienists who do not have a local anaesthetic exclusion on their scope of practice.

Local anaesthetic agents are widely used in NZ and internationally by dentists and other dental professionals. NZ has a long history of these agents being used topically and by injection by dental therapists for children up to 18 years of age, and by dental hygienists who do not have a local anaesthetic exclusion on their scope of practice on all patients with a dentist on-site until 2021. In 2021, the requirement for a dentist to be on-site for a dental hygienist to administer local anaesthetics was removed, with the overwhelming support from oral health practitioners, including dentists and dental specialists; demonstrated through the Dental Council's consultation process.

The reclassification in 2021 enabled dental therapists and oral health therapists to use the topical local anaesthetics listed above without requiring standing orders as had been usual practice previously. Oral health therapists and dental therapists have been able to administer by injection local anaesthetics without needing standing orders since 2017. NZ spontaneous reports of adverse events have shown few concerns. It is reasonable given the levels of training and scopes of dental

hygienists to also enable them to use these topical and injected local anaesthetics, without the need for a standing order, as previously approved for oral health therapists and dental therapists.

Dental hygienists who use local anaesthesia have had appropriate education in use of injected and topical local anaesthetics. They are trained, as are dentists, dental therapists and oral health therapists, to CORE Immediate resuscitation level and have oxygen and adrenaline available. Dental hygienists work independently, including in Australia, UK, Singapore, and some states in the USA. The proposed reclassification of four topical local anaesthetics (two marketed products), three injected local anaesthetics and felypressin enables dental hygienists to work more easily within their scope of practice for the benefit of their patients.

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