MENARINI

30 September 2022

To the Medicines Classification Committee

Re: Medicines Classification Committee 69th meeting, item 5.2 Bilastine

Thank you for the opportunity to comment on the classification of bilastine. This submission provides the committee with information about bilastine to support their decision at this meeting from the sponsor of the product in New Zealand.

This submission provides the following information:

1. Brief introduction to bilastine
2. Support for the pharmacy-only classification statement to include children's formulations
3. Classification of second-generation antihistamines in New Zealand for comparative purposes
4. Classification status of bilastine elsewhere
5. Market authorisation status of bilastine in New Zealand and globally and global sales
6. Background information about antihistamines
7. Bilastine – further details
8. Information specific to New Zealand regarding bilastine and allergies
9. Benefits of the reclassification
10. Risks of the reclassification and any risk mitigation
11. A copy of the proposed packaging for children's formulations

1. Brief introduction to bilastine

Bilastine is a fast-acting non-sedating long-acting second-generation antihistamine with selective peripheral H_1 receptor antagonist affinity and no affinity for muscarinic receptors. As such, bilastine is a similar medicine to other oral second-generation antihistamines marketed in New Zealand or elsewhere, e.g. loratadine, desloratadine, cetirizine, levocetirizine, fexofenadine, ebastine and epinastine. Bilastine is administered once a day for its licensed indications of symptomatic treatment of allergic rhino-conjunctivitis (seasonal and perennial) and urticaria.

Bilastine was first authorised in most of the European countries in 2010 and has been marketed in New Zealand since 2018 as a pharmacy-only medicine in the form of 20 mg tablets for adults and adolescents. Children's formulations were subsequently authorised from 2017 in various markets.

One formulation primarily for children has been submitted to Medsafe for consent, bilastine 10 mg orodispersible tablets with a recommended minimum age of 6 years and bodyweight of 20 kg. [redacted]

2. Support for the pharmacy-only classification statement to include children's formulations

We support the classification wording for bilastine to enable non-prescription use in children from 6 years of age and adult. This would align with other non-sedating antihistamines which are available without prescription for children (Table 1).

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To allow for patient choice and convenience, and alignment with other pharmacy-only classification wording for other marketed second-generation antihistamines, possible wording for the classification could be:

> Pharmacy only: for oral use

The above classification would match the pharmacy-only entry for the other second-generation antihistamines, and minimum age and indications would be managed by the product licence and labelling. However, if it is preferred to be more specific the following is an alternative:

> Pharmacy only: for oral use containing 20 milligrams or less per dose for the treatment of the symptoms of allergic rhinoconjunctivitis (seasonal and perennial) and urticaria in adults and children aged 6 years or older and weighing at least 20 kg.

The current wording is as follows:

> Pharmacy only: in divided solid dosage forms for oral use containing 20 milligrams or less for the treatment of the symptoms of allergic rhinoconjunctivitis (seasonal and perennial) and urticaria.

3. Classification of second-generation antihistamines in New Zealand for comparative purposes

This comparison is limited to second-generation oral antihistamines currently marketed in New Zealand. The five oral antihistamines concerned are all available without prescription for children. The wording varies, but essentially solid dosage forms are available without prescription for three of the medicines as general sales (loratadine, cetirizine and fexofenadine), with a minimum age specified of 12 years for fexofenadine for general sales and no age mentioned otherwise.

Table 1 - Classification of second-generation oral antihistamines on the New Zealand market

Medicine	Pharmacy Only	General Sales
Loratadine	for oral use; **except** in divided solid dosage forms for oral use containing 10 milligrams or less per dose form for the treatment of seasonal allergic rhinitis when sold in the manufacturer's original pack containing not more than 10 days' supply	in divided solid dosage forms for oral use containing 10 milligrams or less per dose form for the treatment of seasonal allergic rhinitis when sold in the manufacturer's original pack containing not more than 10 days' supply
Desloratadine	For oral use	N/A
Cetirizine	for oral use **except** in divided solid dosage forms for oral use containing 10 milligrams or less of cetirizine hydrochloride per dose form for the treatment of seasonal allergic rhinitis when sold in the manufacturer's original pack containing not more than 5 days' supply	in divided solid dosage forms for oral use containing 10 milligrams or less of cetirizine hydrochloride per dose form for the treatment of seasonal allergic rhinitis when sold in the manufacturer's original pack containing not more than 5 days' supply
Levocetirizine	For oral use	N/A
Fexofenadine	for oral use **except** for the treatment of seasonal allergic rhinitis in adults and children 12 years of age and over	for the treatment of seasonal allergic rhinitis in adults and children 12 years of age and over when in capsules

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	when in capsules containing 60 milligrams or less of fexofenadine hydrochloride or in tablets containing 120 milligrams or less of fexofenadine hydrochloride with a maximum daily dose of 120 milligrams when sold in the manufacturer's original pack containing 10 dosage units or less and not more than 5 days' supply	containing 60 milligrams or less of fexofenadine hydrochloride or in tablets containing 120 milligrams or less of fexofenadine hydrochloride with a maximum daily dose of 120 milligrams when sold in the manufacturer's original pack containing 20 dosage units or less and not more than 10 days' supply; for the treatment of seasonal allergic rhinitis in adults and children 12 years of age and over when in tablets containing 180mg or less of fexofenadine hydrochloride with maximum daily dose of 180mg when sold in the manufacturer's original pack containing 5 dosage units or less and not more than 5 days' supply.

Source: Medsafe Classification Database, 20 September 2022

Other oral non-sedating antihistamines such as ebastine and epinastine are marketed as OTC medicines in some countries but are not available in New Zealand.

Second-generation antihistamines in adults, adolescents and children have been OTC for decades. Children's formulations have been launched as OTC before. To use cetirizine as a case study, the 4 November 1993 NZ Gazette lists cetirizine as a pharmacy only medicine, listed simply as "Cetirizine; and its salts" (reflecting the May 1992 Medicines Classification Committee recommendation to reclassify from prescription only status to pharmacy-only [a]). The Medsafe product application search shows that cetirizine was licensed in New Zealand in February 1993 as 10 mg tablets. Cetirizine oral solution and oral drops were then consented for distribution in the 25 September 1997 New Zealand Gazette with no change to the classification statement. Reconsideration by the Medicines Classification Committee at their meeting on the 15 May 1997 about safety data for cetirizine and loratadine (in light of the concerns about other second-generation antihistamines) resulted in no change to the classification. On 13 April 2000, a minor wording change made cetirizine prescription medicine except for oral use, and cetirizine pharmacy-only for oral use. A reclassification to general sales was gazetted 2 February 2012 for up to 5 days' supply with the wording that stands today (Table 1). This case study shows that cetirizine liquid was launched as a pharmacy-only medicine, as seems reasonable now with bilastine.

4. Classification status of bilastine elsewhere

Bilastine is OTC for adult use (or over 12 years) in various countries which include: Australia (pharmacist-only), Austria, Czech Republic, Germany, Poland, Lithuania, Switzerland, Russia, Moldavia Georgia, South Africa, Turkmenistan, Thailand and Malaysia and Latvia. It is a prescription medicine in Canada, it is not registered in the United States of America, and prescription only in the United Kingdom. Bilastine has not been submitted for reclassification in Canada or the United Kingdom, as decided by the market authorisation holder in these markets.

[a] The Gazette notices on line may not include the earliest reclassification but a subsequent repeat of it, owing to time limitations on gazette notices available.

New Zealand would be the first country to have OTC status of bilastine for children. To our knowledge, other countries have been slower to apply for OTC status for children.

5. Market authorisation status of bilastine in New Zealand and global and sales

Bilastine 20 mg tablets were consented for the New Zealand market on 9 February 2018, and launched on the market around May-June in 2018. Bilastine 10 mg orodispersible tablets is in the process of evaluation for consenting for distribution in New Zealand [redacted]

Sales to Wholesalers in New Zealand and Physician Sample Pack supply have equated to about [redacted]

[redacted]

[redacted]

Bilastine 20 mg tablets is licensed in 26 European countries, and 93 other countries including the United Kingdom, Canada, New Zealand, Singapore, Switzerland, Australia and Japan. [redacted] The first countries to authorise bilastine were Spain, Sweden, the United Kingdom and Portugal in 2010.

Bilastine 10 mg orodispersible tablets (for children) is licensed in over 60 countries. [redacted] The earliest authorisations occurred in 2017.

Bilastine 2.5 mg/mL oral solution (for children) is licensed in 26 European countries and 45 other countries including Canada, Switzerland and Singapore [redacted] The earliest authorisations occurred in 2017 in European countries.

[redacted]

6. Background information about antihistamines

First-generation H_1 receptor antagonists played an important role in management of allergies last century. As these agents are lipophilic and cross the blood-brain barrier, interacting with the brain H_1 receptors, they cause sedation and impaired cognition. They also lack specificity for the H_1 receptor resulting in often undesirable effects such as antimuscarinic activity[1]. First-generation antihistamines are also potentially toxic in overdose. These antihistamines were up-scheduled to pharmacist-only medicines except in combination cold remedies many years ago, in light of their adverse effects.

Second-generation antihistamines became available in the 1980s, with the advantage of minimal penetration across the blood brain barrier and increased selectivity for the H_1 receptor. Some of the initial second-generation antihistamines, e.g. terfenadine and astemizole, were found to have the potential to cause QT prolongation in overdose or with interactions with medicines that inhibit metabolism. However, this potential cardiac toxicity is not a class effect[1, 2], and those medicines affected were withdrawn decades ago with rigorous testing of all second-generation antihistamines. Changes in drug development have occurred to consider cardiac safety[2]. The second-generation antihistamines remaining on the market have been tested and found safe[1], and medicines developed since that time, including bilastine, have cardiac studies conducted to specific standards.

Second-generation antihistamines are an important non-prescription medicine used to treat allergic rhinitis and urticaria, conditions that are common worldwide, and particularly in New Zealand. They are well-known to the public and health care professionals, convenient in oral dosage forms, and are often used first-line by the public and health care professional recommendations.

7. Bilastine – further details

As noted at the start of this submission, bilastine is a fast-acting non-sedating long-acting second-generation antihistamine with selective peripheral H_1 receptor antagonist affinity and no affinity for muscarinic receptors. As such, bilastine is a similar medicine to other oral second-generation antihistamines marketed in New Zealand or elsewhere, e.g. loratadine, desloratadine, cetirizine, levocetirizine, fexofenadine, ebastine and epinastine. Bilastine is administered once a day for its licensed indications of symptomatic treatment of allergic rhino-conjunctivitis (seasonal and perennial) and urticaria. Bilastine was deliberately developed for a sustained 24-hour effect devoid of central nervous system and cardiovascular side effects, and convenient pharmacokinetics (i.e. rapid absorption, high bioavailability, prolonged half-life, and lack of hepatic metabolism).

Lyseng[3] reported that "[Bilastine] has a favourable pharmacological profile, with a rapid onset of action and sustained efficacy over the 24-h dosing interval period, as well as a lack of CNS and cardiotoxic effects and clinically relevant drug interactions. In clinical trials, the efficacy of bilastine in treating rhino-conjunctivitis and urticaria was greater than that with placebo and generally similar to that of other second-generation antihistamines, and the overall tolerability profile of bilastine was similar to that of placebo." Studies in children also show good tolerability that is not different from placebo. Serious adverse events occurred in 0.4% of those taking bilastine and 1.8% of those taking placebo but none was considered to be related to the study treatment (see the attached Clinical Overview for further details).

Bilastine reaches maximum plasma concentration in about 1.3 hours[4]. Bilastine has a mean oral bioavailability of 61%. Bilastine is not significantly metabolised in humans and has no clinically relevant drug interactions. It has linear pharmacokinetics in the dose range studied 5-220 mg with low interindividual variability. It has a mean elimination half-life of 14.5 hours with clinical effects lasting 24 hours with allergic rhino-conjunctivitis and histamine-induced wheal and flare skin reactions. The AUC and C_{max} in children administered 10 mg bilastine are highly comparable to corresponding values in adults at the therapeutic dose of 20 mg, and far below the safety thresholds established for bilastine. There is a lack of age-related tendencies of bilastine pharmacokinetics. The drug does not accumulate.

Bilastine has a large therapeutic index. Administration of 220 mg as a single dose or 200 mg daily for 7 days to healthy volunteers was not associated with serious adverse events or significant prolongation in the QTc interval[4]. The cardiological safety of bilastine was proven in a thorough

QT/QTc study performed according to ICH E142. Adverse effects were two times higher in frequency than with placebo, with dizziness, headache and nausea most frequently reported.

The orodispersible tablets are easy to use in children with solid oral dose forms having the advantage of being easy to dose correctly, no need to find or clean a measuring device, no potential for spills, and less bulky. [redacted]

The Clinical Overview of bilastine is attached as a confidential appendix. This shows the clinical development conducted, providing reassurance of safety.

The paediatric development studies are summarised in the appendix. Effectively these showed that

- the pharmacokinetics in children aged 4-11 years did not require adjustment for age or bodyweight
- Safety data for children 2-11 years supported a flat dose of 10 mg across this age range.
- Tolerability was not significantly different for bilastine from placebo in a double-blind study of 509 randomised children aged 2-11 years. Adverse reactions occurred in 5.8% and 8.0% of patients taking bilastine 10 mg and placebo, respectively.
- Bioavailability is reduced by about 21%[b] with food using paediatric formulations in children, a little less than the 30% reported with the 20 mg tablets in adults[5].

Further information is available in the appendices.

[redacted]

8. Information specific to New Zealand regarding bilastine and allergies

The New Zealand population is particularly affected by allergic rhino-conjunctivitis symptoms. For example 11% of children aged 6-7 years and 18% of children aged 13-14 years are affected[6]. This is similar to the United Kingdom and Australia, but higher than most other countries. We are unaware of any national data indicating the prevalence of allergic rhinitis in Māori specifically.

Bilastine tablets were first marketed in New Zealand in 2018, providing an additional choice for patients over existing antihistamines. It is proposed to add bilastine orodispersible 10 mg tablets [redacted] for patient convenience, particularly for children. We recommend a statement aligning with other second-generation antihistamines for pharmacy-only classification stating "for oral use" to allow for future-proofing for future possible dosage forms.

Allergy medications available without prescription in New Zealand include oral, nasal and ocular antihistamines and nasal corticosteroids. Not all of these are OTC in children.

Pharmacists and pharmacy staff are very familiar with managing symptoms of allergic rhino-conjunctivitis and urticaria, as this has been a common reason for people to present in pharmacy for decades. Pharmacy students and pharmacy staff are very competent in distinguishing a cold from allergic rhinitis, and identifying urticaria and advising patients about the appropriate medication/s for them.

[b] Paediatric formulations summary of product characteristics (UK equivalent of a data sheet in NZ) states 20% reduction in bioavailability.

New Zealand consumers are also very familiar with safely self-managing symptoms of allergic rhino-conjunctivitis and urticaria for both themselves and their children; as evident by the long history of symptom-relieving medications being OTC and in grocery stores.

Allergic rhinitis is usually a long-term condition that may come at the same time every year. Consumers are very familiar with the condition and what works for them, while being interested in trying new medicines for the condition[7]. They are keen to have choice for safe self-management for themselves[7] and this is also likely to apply to their management of their children. Urticaria is a condition commonly presenting in the pharmacy which will be familiar to many consumers who would reach for an antihistamine to manage it.

New Zealand consumers are likely to appreciate having a choice of second-generation antihistamine to use.

9. Benefits of this reclassification

The primary benefit of this reclassification is the provision of choice to New Zealand consumers suffering from a common and troubling condition which they already self-treat in themselves and their children.

Allergic rhinitis impairs quality of life, cognitive function, productivity, sleep and causes irritability and disruption[8]. In children, allergic rhinitis affects the quality of sleep, often resulting in day-time fatigue[9]. Increased distraction in class or absenteeism is increased by allergic rhinitis. A recent Australian study found that having allergic rhinitis significantly reduced ability to perform schoolwork and other activities, being significantly worse in those children who were not treating their allergic rhinitis[10].

As noted above, bilastine is a fast-acting, once daily non-sedating antihistamine with good tolerability that provides choice for the patient. For children this is important in terms of palatability and the ability to choose a syrup or an orodispersible tablet. The orodispersible tablets are easy to use in children with solid oral dose forms having the advantage of being easy to dose correctly, no need to find or clean a measuring device, no potential for spills, and less bulky. Australian Market Research has shown that people like to try different antihistamines, but want their antihistamine to be non-drowsy, fast-working, effective, without side effects, once a day, reasonable in price and accessible (without prescription)[7]. Having bilastine paediatric formulations available for children adds choice. Other research has confirmed people want efficacy, fast onset of action, safety and lack of side effects[8]. Bilastine delivers on these requirements.

Brain H_1 receptor occupancy (H_1RO) has been used to help indicate potential for sedation[11]. Correlations are evident between proportional impairment ratio, incidence rate of sedative effects and H_1RO measured by positron emission tomography. Bilastine and fexofenadine have the lowest brain H_1 receptor occupancy of the second-generation antihistamines (Figure 1 below; adapted from Kawauchi et at, 2019), and therefore should have the lowest chance of sedation and impact on cognition[11].

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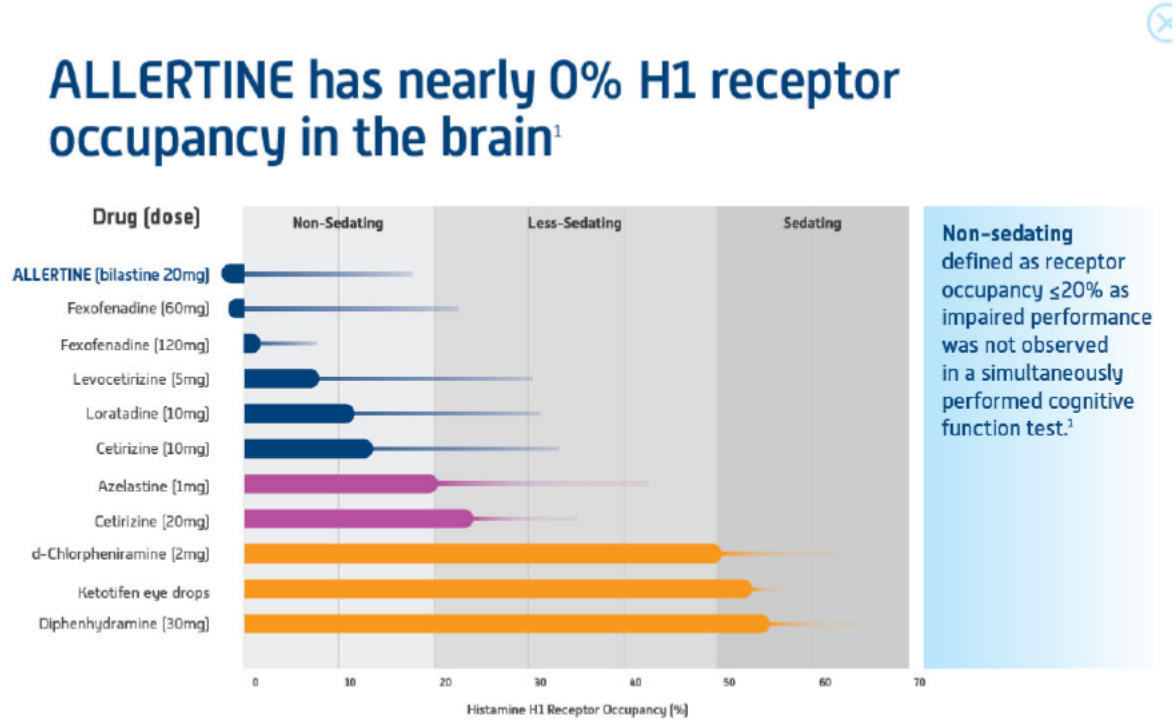
Figure 1 - Brain histamine H1 receptor occupancy of various antihistamines and sedation classifications – adapted from Kawauchi et al, 2019



n.b. – "Allertine" refers to Labixten (bilastine) in New Zealand

Bilastine does not affect CNS function, cause driving impairment, or interact with alcohol[3]. The lack of effect on CNS function is important in children for managing school and activities.

It is important for patients (and parents) to have choices to treat allergic rhinitis and urticaria.

10. Risks of the reclassification and any risk mitigation

Second-generation antihistamines are well-known and widely-used medicines frequently used for self-medication for a common condition. Bilastine has been carefully studied and has a number of safety features discussed above, including no contraindications, few precautions, no clinically significant interactions with other medicines, safety in overdose, excellent tolerability, no propensity for sedation or cognitive impairment, high bioavailability, ease of accurate dosing with the 10 mg orodispersible tablets [redacted]

Bilastine is registered in over 110 countries and has been used since 2010, with significant experience gained in that time. Bilastine paediatric formulations have been well-studied, are well-tolerated and have been available in many countries since 2017. [redacted] Other second-generation antihistamines have had paediatric formulations go directly to pharmacy-only in New Zealand (e.g. cetirizine when launched in 1997 – see case study above), reflecting the safety of these medicines.

Pharmacy only status for paediatric formulations would ensure pharmacy staff would be able to provide advice at the time of supply, with the pharmacist available if necessary.

Package labelling has clear precautions and administration instructions to minimise risk of patient error.

Misdiagnosis will be no more common than for other antihistamines already marketed, and, as a pharmacy-only medicine, assistance will be available where needed. Allergic rhinitis and urticaria are common complaints well-known to consumers.

Safety in overdose has been discussed above. Ten to 11 times the recommended adult dose has been given to healthy volunteers with no serious adverse events[4].

There could be a risk of two different antihistamines being used at once. This risk already exists with the other products on the market, adding bilastine to the market is not likely to increase the risk any further, particularly if it is a pharmacy-only medicine.

Parents are used to giving their children antihistamines for allergic rhinitis and urticaria. They will be able to follow the package instructions well and ask the pharmacist or their doctor if they have any questions.

It is recommended that bilastine is taken at least one hour before or two hours after food, grapefruit or other fruit juices. However, should it inadvertently be taken at the same time as food the effect on bioavailability is only small (a small reduction of 20% for the orodispersible tablets[5] and the oral solution[12]). The Australian product information for 20 mg tablets suggests that it is not certain if this interaction is clinically significant, particularly with low-fat food[4].

11. A copy of the proposed packaging for children's formulations

This is attached as an appendix. [redacted]

Conclusion

Bilastine is a fast-acting once daily second-generation antihistamine with an excellent safety profile, good tolerability and similar efficacy to other second-generation antihistamines. It has been available since 2010 in other countries, and since 2018 in New Zealand. Allergic rhinitis and urticaria are common conditions in New Zealand, including in children, and having a choice of effective medicines for the condition is beneficial to sufferers and their parents, [redacted] It is reasonable to allow the children's formulations to be classified as pharmacy-only medicines, in line with the other second-generation antihistamines in New Zealand.

[redacted]

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[redacted]

References

1. Simons FE and Simons KJ. H1 antihistamines: current status and future directions. *World Allergy Organ J* 2008; 1: 145-155. 2008/09/01. DOI: 10.1186/1939-4551-1-9-145.
2. Shah RR. Cardiac repolarisation and drug regulation: Assessing cardiac safety 10 years after the CPMP guidance. *Drug Safety* 2007; 30: 1093-1110. Review. DOI: 10.2165/00002018-200730120-00003.
3. Lyseng-Williamson KA. Bilastine in symptomatic allergic rhinoconjunctivitis and urticaria: a guide to its use. *Drugs and Therapy Perspectives* 2017; 33: 102-109. DOI: 10.1007/s40267-017-0381-2.
4. A. Menarini Australia Pty Ltd. Australian Product Information - Allertine (Bilastine) tablet. 2022.
5. A. Menarini Farmaceutica Internazionale SRL. Ilaxten (bilastine) 10 mg orodispersible tablets SmPC, https://www.medicines.org.uk/emc/product/11727/smpc (2021, accessed 29 Sep 2022).
6. Asher MI, Montefort S, Björkstén B, et al. Worldwide time trends in the prevalence of symptoms of asthma, allergic rhinoconjunctivitis, and eczema in childhood: ISAAC Phases One and Three repeat multicountry cross-sectional surveys. *Lancet* 2006; 368: 733-743. 2006/08/29. DOI: 10.1016/s0140-6736(06)69283-0.
7. *Market Research in Australia for Bilastine (data on file)*. 2019.
8. Canonica GW, Mullol J, Pradalier A, et al. Patient perceptions of allergic rhinitis and quality of life: findings from a survey conducted in europe and the United States. *World Allergy Organ J* 2008; 1: 138-144. 2008/09/01. DOI: 10.1097/WOX.0b013e3181865faf.
9. Mir E, Panjabi C and Shah A. Impact of allergic rhinitis in school going children. *Asia Pac Allergy* 2012; 2: 93-100. 2012/06/16. DOI: 10.5415/apallergy.2012.2.2.93.
10. Bosnic-Anticevich S, Smith P, Abramson M, et al. Impact of allergic rhinitis on the day-to-day lives of children: insights from an Australian cross-sectional study. *BMJ Open* 2020; 10: e038870. DOI: 10.1136/bmjopen-2020-038870.
11. Kawauchi H, Yanai K, Wang DY, et al. Antihistamines for allergic rhinitis treatment from the viewpoint of nonsedative properties. *International Journal of Molecular Sciences* 2019; 20. DOI: 10.3390/ijms20010213.
12. A. Menarini Farmaceutica Internazionale SRL. Ilaxten (bilastine) 2.5 mg/mL oral solution SmPC, https://www.medicines.org.uk/emc/product/11725/smpc (2021, accessed 29 Sep 2022).

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30 September 2022

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Dear Sir/Madam,

Re: Response to public consultation for the Medicines Classification Committee Agenda for 69th meeting, October 2022, Item 6.1a Methenamine hippurate

Thank you for the opportunity to comment on the agenda for the 69th meeting of the MCC. Consumer Healthcare Products Australia would like to provide some comment on agenda item 6.1a of the agenda on the proposed reclassification of methenamine hippurate to a more restrictive classification.

CHP Australia is the leading voice and industry body for manufacturers and distributors of consumer healthcare products, which includes non-prescription medicines. We strive to advance consumer health through responsible Self Care and were previously known as the Australian Self Medication Industry (ASMI). Our key priorities for the industry include improving health literacy, growing the consumer healthcare products industry and increasing access to medicines where appropriate.

Attached is CHP Australia's response, addressing some of the points made in the MCC agenda item.

CHP Australia does not support the proposal to reclassify methenamine hippurate . Evidence suggests that consumers use these products safely and responsibly and there is no new evidence of safety concerns, that would indicate that there has been any change in the existing benefit/risk balance. Any change to the classification of methenamine hippurate would significantly impact the ability of sponsors to supply harmonised products across both markets and is likely to have an impact on access and/or cost of the product in both Australia and New Zealand.

Methenamine hippurate products marketed in Australia are also marketed in New Zealand, in common packaging. The ability to market harmonised products is very important given that both Australia and New Zealand are relatively small markets individually. Some sponsors choose not to market unique Australian or New Zealand products, due to the detrimental impact on the cost of goods and the increased cost

burden on consumers. A single product harmonised across both markets is important for economic viability of the product in both countries.

Kind Regards

CHP Australia response - Medicines Classification Committee Agenda for 69th meeting – Item 6.1a Methenamine hippurate

Consumer safety is of paramount concern to CHP Australia and our members, however we do not believe that the submission put forward by the MCC and Medsafe justifies re-classification of methenamine hippurate to a more restrictive classification.

Methenamine hippurate has been the subject of classification reviews – first in 2001, when it was classified to a General Sale Medicine, and this remained unchanged in the 2012 review. There is no evidence of any shift in risk vs benefit since the last review in 2012.

Benefit/Risk

Like all medicines, methenamine Hippurate has risks and benefits. The Medsafe submission to the MCC points to the following concerns:

- Long term safety: Methenamine hippurate is a prodrug that converts to formaldehyde in an acidic environment. Formaldehyde is the active substance that exerts bactericidal activity. Information on safety of long-term exposure to formaldehyde is lacking.
- Evidence supporting efficacy is weak.
- Consultation with a healthcare professional is advisable for patients with symptoms of recurrent urinary tract infections (UTI)

We would like to address the above points below.

Methenamine hippurate has a long history of use, being available in New Zealand and Australia and the UK for approximately 50 years. Although the product is grandfathered, it has been subject to the standard conditions for post-marketing surveillance and adverse event monitoring in New Zealand, Australia and the UK. Available information from the Australian and New Zealand adverse event databases suggests that considering the duration of marketing, adverse events are low in numbers, generally non-serious, with common adverse events being gastrointestinal and dermatological. This is consistent with the information available in the UK Summary of Product Characteristics for methenamine hippurate[1] which lists nausea, vomiting, rashes and bladder irritation as the most common adverse events.

Methenamine hippurate is converted to formaldehyde in the body, and the MARC review has raised concerns about the possibility of harm. Methenamine hippurate reacts with water and converts to formaldehyde and ammonia, with the

[1] https://www.medicines.org.uk/emc/product/12707

formaldehyde being the active moiety with bactericidal effects. CHP understands that at the maximum recommended daily dose of 2g per day, the theoretical maximum amount of formaldehyde in the body that may be produced from methenamine hippurate is approximately 1.2 g per day[2]. This represents a small increment to the amount of formaldehyde produced endogenously from foods, household products, pollution, cigarette smoking[3].

The majority of the research on the carcinogenicity of formaldehyde pertains to the inhalational and dermatological routes. While there is evidence that inhaling airborne formaldehyde carries an increased risk, and that acute exposure to formaldehyde via the inhalation, dermal and oral routes can be toxic, the available data in animals does not support formaldehyde being carcinogenic by the dermal or oral routes[4].

Methenamine hippurate is indicated for suppression or elimination of urinary tract bacteria, and in clinical practice this relates to prevention of recurrent UTI. A Cochrane review in 2012 showed that short-term usage prevented recurrent UTIs in women without urinary tract abnormalities or neuropathic bladder and was well tolerated with few adverse effects[5]. There was no analysis on optimal duration of use, however two of the studies included longer durations of treatment, with one study of up to six months (Lee 2007) and one that was possibly for several months (Furness 1975).

The Royal Australian College of General Practitioners (RACGP) Clinical Guidance on Recurrent UTIs and cystitis symptoms[6] states that UTIs are an extremely common problem in women and a cause of great personal morbidity as well as cost to the health system. While occasional UTI is relatively simple to treat, recurrent UTI and cystitis with variable or negative urine cultures can be a complex diagnostic and therapeutic challenge. The RACGP Guidelines include a management pathway and refer to methenamine hippurate as a non-antibiotic prophylaxis therapy in women who have no 'red flags'. One of the points made in the guidance is that women with recurrent UTIs benefit from the use of non-antibiotic measures to prevent infection, as well as the considered use of antibiotics.

Women who have experienced recurrent UTI will have sought the advice of their GP for treatment of initial acute infection, and advice on prevention. They will be able to recognise symptoms and given the very uncomfortable symptoms of UTIs, they will not inappropriately self-medicate. It is highly unlikely that women with recurrent UTI will be self-treating with methenamine hippurate without having received medical

[2] Information provided by iNova Australia, September 2022

[3] https://www.euro.who.int/__data/assets/pdf_file/0014/123062/AQG2ndEd_5_8Formaldehyde.pdf

[4] https://www.industrialchemicals.gov.au/sites/default/files/PEC28-Formaldehyde.pdf

[5] https://pubmed.ncbi.nlm.nih.gov/23076896/

[6] https://www1.racgp.org.au/ajgp/2021/april/recurrent-utis-and-cystitis-symptoms-in-women

advice and undergone prior assessment. The current GSL availability of methenamine hippurate does not mean that women are not seeking medical advice, or that they are not being treated appropriately. Changes to a more restrictive classification should be informed by evidence of inappropriate use or misuse, however these concerns have not been apparent with methenamine hippurate and the available clinical guidelines do not suggest that any changes to the current approach are necessary.

While methenamine hippurate is a grandfathered medicine and was not subjected to modern pre-market evaluation, there is evidence of safety and efficacy that demonstrates its favourable risk vs benefit profile for women who have recurrent UTI. Treatment with methenamine hippurate may be a good treatment option that mitigates against over-use of antibiotics and the associated risks of antibiotic resistance.

Given the lack of evidence of misuse or inappropriate use we do not believe that changing the classification from GSL to a more restrictive classification will result in any incremental benefits for women who have recurrent UTI.

Commercial considerations

CHP Australia understands that methenamine hippurate is supplied in New Zealand through pharmacy channels, where healthcare professional information is available as needed. We also understand that the majority of the products supplied are through the Pharmaceutical Schedules, and the product is fully subsidised for suppression or elimination of urinary bacteria for consumers who have a doctor's prescription.

Treatment with this medicine is generally initiated by a healthcare professional, and continuing access as a general sale medicine means that consumers can access the product for preventative therapy without the need to consult a doctor for each supply. There is no evidence that consumers are inappropriately self-selecting or self-treating acute urinary tract infections (UTIs) with this medicine. In practice therefore, there is no evidence of inappropriate prescribing or inappropriate use by consumers.

Reclassifying to a more restrictive schedule will therefore achieve minimal gain in public health outcomes, but at a significant commercial impact for sponsors in both Australia and New Zealand, with added cost imposition for consumers.

Given the availability of this product is currently largely through pharmacy and is subsidized through that Pharmaceutical Schedule, the MCC may form the view that a more restrictive classification may have little impact on the commercial supply of the product. CHP Australia urges the MCC to appreciate that reclassifying to a more restrictive classification will certainly impact the commercial supply by resulting in an

inability to supply harmonised product the GSL classification, low volumes and minimum order quantities for both Australia and New Zealand, and increased costs. Given the way that the product is supplied at present and the lack of evidence regarding misuse or inappropriate use, this represents a low overall benefit for the significant increase in costs.

Conclusion

CHP Australia does not support a more restrictive classification for methenamine hippurate. There is no evidence that the current GSL classification is encouraging inappropriate use of methenamine hippurate, or that it is resulting in inferior treatment of recurrent UTI in women. Any change to restrict the classification will result in little public health gain for women, at a cost of significant commercial impact.

Medicines Classification Committee Meeting No. 69

Public Comment - Agenda Item 6.1a - Proposal for review of the classification of medicines containing methenamine hippurate

Executive Summary

Methenamine hippurate has been classified as a general sale medicine in New Zealand for over 20 years and is harmonised with the Australian unscheduled classification. Methenamine has undergone periodic classification reviews since consent in 1969, which have resulted in either relaxation of its classification (2001) or remained unchanged (2012). MARC's current review does not alter the current benefit: risk profile. Tran-Tasman harmonisation of medicine classification should be maintained unless there is a sound public health reason to justify different schedules in New Zealand and Australia.

Methenamine usage data and incidence of adverse reactions provide no evidence to suggest it either poses a significant safety risk or that the existing classification is leading to inappropriate use or improper treatment of recurrent UTIs. To the contrary, with over 50 years of safety data available through spontaneous adverse event reporting, the long-term safety of methenamine has been established.

Methenamine has been fully funded on the Pharmaceutical Schedule since 1 December 2019 and supports an important public health objective to reduce antibiotic resistance. The increasing sales of methenamine are testament to the value of subsidised methenamine to achieving this objective. The current methenamine classification as a general sale medicine does not influence the decision to initiate therapy with methenamine but does allow continued convenient access to consumers post-diagnosis. Up scheduling methenamine will unnecessarily restrict access and may lead to an unintended increase in urinary tract infections (UTIs) requiring antibiotic treatment because cost and time are disincentives to visit a doctor to renew a methenamine prescription. Preventative therapy is intended to avoid UTIs. The methenamine classification should facilitate access and convenience to enable effective use of prophylactic treatment. The general sale classification enables achievement of that objective.

There is no evident public health benefit to reclassification and the proposal is inconsistent with good regulatory practice. Up scheduling will increase costs to consumers and sponsors without a corresponding tangible benefit.

Overall, the proposal to reclassify methenamine to a more restricted schedule is unsupported. To reclassify methenamine for administrative reasons is to deny the New Zealand public reasonable access to a well-established medicine with a long history of safe use. iNova recommends rejection of the proposal to reclassify methenamine hippurate and supports retention of the current general sale classification.

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1. Introduction

iNova Pharmaceuticals (iNova) wish to comment on agenda item 6.1 of the 69th NZ Medicines Classification Committee (MCC) meeting – the proposal to reconsider the classification of medicines containing methenamine hippurate from general sale to either Restricted Medicine or Prescription Medicine.

The MCC classification review has been prompted by a Medsafe submission made in response to a review of the benefits and risks of methenamine hippurate by the Medicines Adverse Reactions Committee (MARC) at their June 2022 meeting.

As there has been renewed interest in the use of methenamine hippurate as an alternative to low-dose daily antibiotic prophylaxis for the prevention of recurrent UTI in women, Medsafe considered it timely to review the efficacy and safety of methenamine hippurate to ensure that the benefit-risk balance of this historically approved medicine is favourable.

Medsafe (2022) summarised the MARC position as '…on balance, the benefit-risk profile for methenamine hippurate is favourable but expressed concern that the general sale classification may not be appropriate for the indication' (p.2). iNova considers that the current general sale classification for methenamine remains appropriate given its favourable benefit-risk profile and its well-established patterns of use and supply within the community. Without evidence of misuse or harm when supplied as a general sale medicine, up scheduling for essentially "administrative purposes" and no discernable benefit is unjustified.

2. Registration status

Hiprex received consent in New Zealand on 31 December 1969. Its current registered indication is "Suppression or elimination of urinary tract bacteria". Prior to 2001, the medicine classification for methenamine was Pharmacy Only Medicine (Hiprex TPDR, 1999), but was down scheduled to general sale due to Trans-Tasman harmonisation. Therefore, Hiprex has been available in New Zealand as a general sale medicine for over 20 years. Hiprex was first registered in Australia in September 1969 as an unscheduled medicine and that scheduling classification has remained unchanged for the past 53 years. (Reg Vic letter, 1969). Trans-Tasman harmonisation of the methenamine classification has enabled iNova to supply a small market such as New Zealand with a common Hiprex pack, which avoids incurring the additional costs that would be borne by the consumer if supplying a New Zealand specific presentation.

Trans-Tasman harmonisation of schedules and labelling is an important measure for providing accessible cost-effective products and reducing regulatory burden in both markets. Consequently, unless there are specific public health reasons to deviate from harmonisation then regulators should retain the harmonised status quo. The MCC at its 47th Meeting (May 2012) also considered the appropriate methenamine schedule and concluded that the existing general sale classification was appropriate, and that there was insufficient evidence to justify a more restrictive classification. It is iNova's position that this remains the case.

The scheduling status for methenamine varies internationally ranging from unscheduled in New Zealand and Australia, to pharmacy and ethical medicines in the UK and Canada respectively. Whilst in the USA it is a prescription medicine, there is inconsistency in the scheduling of methenamine salts as the methenamine sodium salicylate salt is available over the counter. Whilst there is international

variability in the controls placed upon methenamine, overall, the controls are weighted towards a non-prescription classification. Up-scheduling to a prescription only medicine is inconsistent with international practice.

3. Scheduling Criteria

The MCC uses the following principles from the Medsafe guidance *How to Change Medicine Classification* (2019) when considering a medicine for suitability for nonprescription sale:

"Medicines available without a prescription should be able to show substantial safety in use in the prevention or management of the condition or symptom under consideration and either:

a. be for conditions or symptoms that can be diagnosed and managed by a pharmacist or other specified appropriate health care professional, or
b. be easily self-diagnosed and self-managed by a consumer." (p.7)

iNova consider that methenamine satisfies these criteria, which is discussed further in the following sections. Its safety profile is well-established with side effects non-serious and infrequently reported. No new safety signals have emerged since the previous MCC review of methenamine in 2011-2012. When understood in the context of its current usage patterns and purchasing influences, such as its fully funded status on the Pharmaceutical Schedule, methenamine also meets criteria (a) and (b) above and has done so for over 50 years. No evidence has been presented in the MARC review (2022) to suggest there is inappropriate use of methenamine by consumers and nor is iNova aware of any such data.

4. Methenamine Safety

Methenamine has a long history of safe use in New Zealand and internationally. Side effects are non-serious and generally limited to gastrointestinal or dermatological reactions. The NZ Label Statements Database has no specific warnings for methenamine and nor are any listed in the corresponding *Required Advisory Statements for Medicine Labels* (RASML No. 6, 2022) (DOH, 2021) in Australia. When contrasted to the extensive list of label warnings required for some other general sale medicines, such as paracetamol and ibuprofen, then the safety profile of methenamine clearly is suitable for a general sale classification.

As Hiprex (methenamine hippurate) is classified as a general sale medicine, there is no requirement for the product to have a Data Sheet. However, [redacted] iNova has developed a Data Sheet, which has been provided to Medsafe for review. The data sheet utilises the UK Hiprex Summary of Product Characteristics (SmPC) (2019) as its reference text and its safety information including contraindications, precautions, drug interactions and adverse reactions has been adopted.

Adverse reactions reported in the UK Hiprex SmPC include:

Gastrointestinal disorders
Uncommon: gastric irritation, irritation of the bladder, nausea, vomiting
Not known: Diarrhoea, abdominal pain

Skin and subcutaneous disorders
Uncommon: Rash, pruritus

This adverse reaction profile is consistent with spontaneous reports to Medsafe, TGA, iNova and with the Australian Product Information (PI) for methenamine (not the Hiprex brand) reported Table 1 of the MARC Review (2022).

For the period 1 January 2000 to 5 September 2022, a review of Medsafe's Suspected Medicine Adverse Reaction Search (SMARS) identified 10 adverse event reports covering 15 adverse reactions **(Table 1**) as follows:

Table 1: Adverse Events reported to Medsafe 2000 - 2022

System Organ Class	MedDRA Reaction Term	Number of Reports
Gastrointestinal disorders	Cheilitis	1
	Vomiting	1
General disorders and administration site conditions	Drug ineffective	1
	Drug interaction	1
Infections and infestations	Candida infection	1
Renal and urinary disorders	Pollakiuria	1
	Urinary tract disorder	1
Respiratory, thoracic and mediastinal disorders	Haemoptysis	1
Skin and subcutaneous tissue disorders	Angioedema	1
	Pruritus	1
	Rash	1
	Rash pruritic	1
	Skin disorder	1
	Urticaria	2

The frequency of adverse event reporting is less than 1 event per annum.

In Australia, a review of the TGA's Database of Adverse Events Notification (DAEN) for the period 1 January 1971 – 31 August 2022, identified 71 reported cases of adverse events; a reporting frequency of less than 1 report per annum. Methenamine was the single suspected medicine in 45 cases. The most frequent adverse events reported were nausea (10), pruritus (6), urticaria (6), vomiting (6), diarrhoea (5) and maculopapular rash (5).

In the UK for the reporting period 1966 - 31st July 2022 (56 years), the MHRA (2022) received only 81 spontaneous suspected Adverse Drug Reactions (ADRs) reported through the Yellow Card Scheme, encompassing 148 reactions. Gastrointestinal and dermatological reactions were the most commonly reported, consistent with New Zealand and Australian experience.

A retrospective review of the iNova safety database revealed 90 reports (cases) of adverse events, mainly non-serious for Hiprex for the period 1 January 2010 to 26 August 2022 from within iNova market regions including Australia and New Zealand where this product is marketed. Out of those 90 reports, 3 were from New Zealand. Case details are limited and there is no detectable trend among the reports. Given the volume of methenamine hippurate sold in New Zealand over the 8-year period 2014-2022 of [redacted] (both 100s and 20s SKU), the 3 cases are clearly a relatively low number of adverse event reports received by the sponsor and/or directly to CARM over this period.

To date, no signs or signals of any safety concerns have emerged from reports or published literature. No new safety findings have been identified through ongoing pharmacovigilance activities, no action

on safety grounds is warranted nor required, other than continuing normal post-marketing safety surveillance and pharmacovigilance activities, as for all other medicines by health authorities in all countries.

MARC (2022) concluded, "A review of the safety data from CARM found reported adverse events to be consistent with the known adverse effects listed on the sponsors dedicated website and in the Australian product information. The most commonly reported adverse effects were dermatological /allergic reactions (urticaria, angioedema, rash, pruritis) and gastrointestinal symptoms (abdominal pain, vomiting). Adverse effects that may suggest lack of efficacy were also reported (medicine ineffective, UTI, micturition frequency). Given the volume of methenamine hippurate sold in New Zealand over the 5-year period 2017-2021, and the relatively low number of reports submitted to CARM over this period, the safety profile appears to be acceptable" (p.27).

Thus, no change to the methenamine adverse event profile is evident since the previous MCC review in 2011-2012, where it was determined that the general sale classification remained appropriate. Consequently, from a safety perspective, the adverse event profile is well-established, unchanged and there is no justification to change the general sale classification for methenamine. It also satisfies the first of the MCC's classification criteria: "Medicines available without a prescription should be able to show substantial safety in use in the prevention or management of the condition or symptom under consideration."

5. Public Health Benefit of Methenamine

Methenamine hippurate is indicated for the suppression or elimination of urinary tract bacteria. It is often used for prolonged periods because, unlike conventional antibiotics, acquired resistance does not develop. (Lee, 2012). Antibiotic resistance is a global issue, primarily driven by inappropriate and excessive use and therefore measures to minimise their use have become best practice (BPAC NZ, 2021). The PHARMAC subsidy of Hiprex is a tangible example of supporting best practice in the appropriate use of antibiotics.

Alternatives to methenamine include antibiotic treatment or cranberry juice or capsules. However, Jepson (2012) found the use of cranberry for recurrent UTIs was not supported by the evidence.

Thus, the main alternative to methenamine for the prevention of UTIs is antibiotic use, most commonly trimethoprim. In New Zealand trimethoprim tablets have an indication for long term prophylaxis of recurrent, or suppression of chronic urinary tract infections following sterilisation of the urine (Mylan, 2019) and is listed on the Pharmaceutical Schedule. In addition to concerns regarding antibiotic resistance, long term use of trimethoprim for extended periods of time may in rare cases cause bone marrow depression manifested as thrombocytopenia, leukopenia and/or megaloblastic anaemia. The adverse reaction and drug interaction profile is also more extensive than reported for methenamine. Furthermore, low dose antibiotic prophylaxis should generally be considered as a last resort with females with recurrent UTIs six times more likely to experience another UTI if they take prophylactic antibiotics (BPAC NZ, 2021).

Thus, methenamine offers an alternative treatment with a limited side effect and drug interaction profile, which also avoids issues of antibiotic resistance. A significant reason PHARMAC (2019) gave when increasing the subsidy available for prescription of methenamine hippurate was that 'prevention and control of anti-microbial resistance is a health priority in New Zealand and consider that this

funding decision will contribute to this priority. BPAC NZ (2021) guidance also supports prophylactic use of methenamine in patients with recurrent UTIs to avoid long term antibiotic use.

Reducing the availability of methenamine through up scheduling will not improve health outcomes for New Zealanders and is contrary to the goal of reducing antibiotic use. The increasing sales of methenamine are testament to the value of subsidised methenamine to achieving this objective. The current methenamine classification does not influence the decision to initiate therapy with methenamine, however it does allow continued convenient access to consumers post-diagnosis. Up scheduling methenamine will unnecessarily restrict access and may lead to an unintended increase in UTIs requiring antibiotic treatment because cost and time are disincentives to visit a doctor to renew a methenamine prescription. The objective of preventative therapy is to avoid UTIs. The methenamine schedule should facilitate access and convenience to enable preventative therapy to be effectively used. The general sale schedule facilitates achievement of that objective whilst supporting the public health policy.

6. Methenamine Hippurate and the Production of Formaldehyde

The MARC review discussed formaldehyde toxicity and raised concerns about the possibility of harm from long-term exposure.

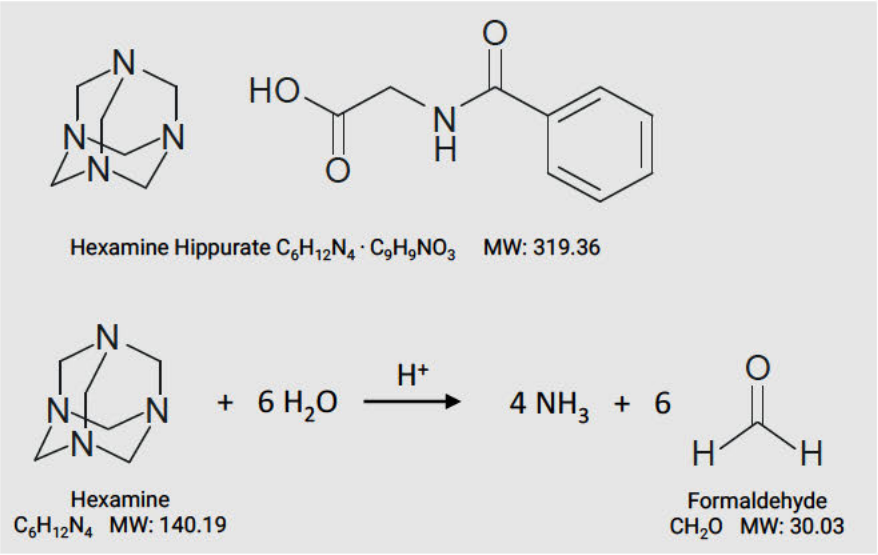
Formaldehyde is a colorless, pungent, irritant gas at room temperature. Formaldehyde is a normal byproduct of our body's metabolism and is physiologically present in all our cells (EFSA, 2014). Formaldehyde is essential for cell growth in all living cells. The biochemical pathway called the one-carbon cycle utilises endogenously formed formaldehyde to produce essential amino acids and DNA. There are two biochemical pathways for the breakdown of formaldehyde; the first is the conversion to formate (non-toxic) by the enzyme formaldehyde dehydrogenase. Folate produced in this process is then used in purines - one of the building blocks of DNA (Urgos-Barragan, 2017).

Formaldehyde is also found naturally in our diet. It is also a common indoor air pollutant due to its use in many household products, building materials and as a byproduct in tobacco smoke.

Methenamine hippurate reacts with water and releases formaldehyde and ammonia, which is accelerated in the presence of acid. This is believed to be the mechanism behind its bactericidal effects in urine.

The *in vitro* conversion of methenamine hippurate to formaldehyde and ammonia is shown in **Figure 1** below.

Figure 1: *In vitro* Conversion of Methenamine Hippurate



Theoretically, 1 mole of methenamine hippurate could convert to up to 6 moles of formaldehyde. Thus 319.36 g of methenamine hippurate could release a theoretical 180.18 g of formaldehyde (ratio: 0.564). Therefore, if the reaction goes to completion, then a 1 g Hiprex tablet could release a maximum 0.56 g of formaldehyde. At a maximum dose of 2 g/day, the theoretical maximum amount of formaldehyde that could be produced from methenamine hippurate is about 1.12 g/day.

Based on blood steady state concentrations and half-life values in humans of 1-1.5 min, formaldehyde turnover has been estimated to be approximately 0.61 – 0.91 mg/kg bodyweight per minute corresponding to a daily turnover of 878 -1310 mg/kg bodyweight per day. Thus, for a 60 kg person, endogenous rate production and processing of formaldehyde equates to approximately 50 g – 75 g/ day (EPSA, 2014).

The European Medicines Agency (EMA) has also previously estimated the average intake of formaldehyde from food of 1.4 – 1.7 mg/kg of bodyweight per day for a 60-70 kg person, giving an average intake of 108.5 mg/day from diet for a 70 kg person (cited in EFSA, 2014).

Thus, the daily production of formaldehyde from Hiprex of no more than 1.12 g/day represents a small contribution compared to its endogenous production.

To support its concerns regarding the toxicity of formaldehyde, MARC refers to a systematic review of *The Carcinogenic Effects of Formaldehyde Occupational Exposure* (Protano, 2021). Occupational exposure occurs primarily by inhaling airborne formaldehyde, but it can also be absorbed through the skin or ingested. Protano states, "Most of the studies included in this review dealt with occupational settings, characterised by a deliberate use of formaldehyde as a component of the production cycle. Those were mainly represented by chemical industries dedicated to the production of plastics, fiberglass, paints, etc.; it is reasonable to imagine that in such contexts the levels of exposure to [formaldehyde] were particularly high." The author concluded that the evidence of correlation between formaldehyde occupational exposure and the occurrence of cancer is limited. The International Agency for Research on Cancer (IARC) classification of formaldehyde as a Group I carcinogen (carcinogenic to humans) determined in 2004 was also questioned. It was noted that most

of the studies on the relationship between formaldehyde and cancer were *in vitro* experiments demonstrating the effects on culture cells and that epidemiological studies have not been able to confirm this association (Protano, 2021 p.2). Furthermore, the exposure concerns relate primarily to formaldehyde inhalation with most studies in the systematic review focusing on neoplasms of the upper airways. In contrast, Hiprex is ingested orally as methenamine hippurate and converted to formaldehyde *in vivo.* Formaldehyde inhalation from occupational exposure to potential Hiprex toxicity is of questionable relevance.

No evidence has been presented that suggests methenamine due to its *in vivo* conversion to formaldehyde is toxic, and in particular carcinogenic, with long term use. MARC (2022) also comments, "The medicine has been used by a large number of patients in New Zealand over many years with little apparent evidence of harm (based on reports to CARM), but long-term safety data is lacking." (p. 27). iNova would like to suggest that long-term safety data is available, in the form of over 50 years of international usage, the very low reporting rates of adverse events in multiple markets and the consistent adverse reaction profile over time. Thus, theoretical concerns regarding long term safety do not justify the up scheduling of methenamine on safety grounds.

7. Self-Diagnosis and Self-Management of Urinary Tract Infections

Methenamine is indicated for the "Suppression or elimination of urinary tract bacteria". In practice Hiprex is used for the prevention of recurrent urinary tract infection (UTI).

UTIs are one of the most frequent clinical bacterial infections in women. Around 50–60% of women will experience a UTI in their lifetime. The estimated average number of UTIs per person per year is 0.5 in young females. Recurrences usually occur within three months of the original infection, and 80% of recurrent UTIs are reinfections. The incidence of UTI increases with age and sexual activity. Post-menopausal women have higher rates of UTIs because of pelvic prolapse, lack of oestrogen, loss of *lactobacilli* in the vaginal flora, increased periurethral colonisation by *Escherichia coli* (*E. coli*), and a higher incidence of medical illnesses such as diabetes mellitus (Al-Badr, 2013). About 1 in 10 men will get a UTI in their lifetime (Stamos Kovas, 2021).

Symptoms of a UTI include:

- A burning feeling when urinating
- Urinary frequency and/or urgency
- Cloudy, dark, bloody, or strange-smelling urine
- Fatigue or shakiness
- Fever or chills
- Pain or pressure in the back or lower abdomen (Stamos Kovas, 2021).

These symptoms are all readily self-diagnosable by a consumer, particularly by those consumers who experience recurrent infections. As Hiprex is used a preventative treatment consumers will be self-managing their condition. Thus, the symptoms combined with the high incidence of UTIs make the presence of a UTI quite recognisable, particularly for women. Antimicrobial therapy is the core treatment for a UTI and requires a medical consultation for confirmation of infection and treatment. Hiprex is a preventative therapy option, not a treatment for UTI. Therefore, the Hiprex candidate is likely to have visited a doctor on more than one occasion for a UTI before the doctor prescribes Hiprex. Consequently, with respect to the diagnosis and management of UTIs, Hiprex users would generally

be informed consumers and capable of making subsequent purchases of Hiprex over the counter for prevention purposes without healthcare intervention. It is the treatment of a UTI that requires the doctor's visit rather than UTI prevention, which can be self-managed. The funding of Hiprex on the Pharmaceutical Schedule also provides medical oversight of the UTI prevention strategy, irrespective of its classification.

Furthermore, despite its general sale classification, a consumer is unlikely to purchase Hiprex without prior medical consultation. There is no rational reason for a consumer, who has never had a UTI to purchase this product. The label principal display panel claims: "Antibacterial: Suppression or elimination of urinary tract bacteria." Despite the antibacterial claim, a consumer is unlikely to purchase Hiprex to treat other bacterial infections, given the specificity of the claim. It is not labelled as a prophylactic medicine, hence unless the consumer has been advised to use the product for UTI prevention then purchase for this purpose is unlikely. The consumer experiencing a UTI for the first time is likely to seek medical attention as the first resort. Even if the consumer visited a pharmacy as the initial action, Hiprex is not labelled as a UTI treatment. Thus, a consumer is unlikely to purchase Hiprex unless advised by a pharmacist.

Whilst this consumer behaviour could also be argued to support up scheduling, Medsafe and MARC have not presented any evidence to demonstrate or suggest that methenamine is inappropriately purchased or used with its current classification. This includes evidence for off-label indications, or that methenamine is misused in some other way. The upsurge in sales since 2020 coincides with the change in methenamine's funding status, which should be viewed as a positive contribution to public health priorities. Given the receipt of subsidised medicine requires a doctor's prescription, it is reasonable to conclude that the increase in sales is driven largely by doctor recommendation. Thus, it is funding that is driving product use not its medicine classification.

Hence, the combination of the frequency of UTIs, their distinctive symptoms and the role methenamine plays as a UTI prevention strategy support the general sale classification of Hiprex; a classification that has served the New Zealand public well for over 50 years. It is unclear what incremental benefit a consumer will obtain by restricting access to prescription only medicine or restricted medicine.

8. Paediatric Use

The Hiprex product label provides the following directions for use:

Adults: 1 tablet twice daily

Children (6 -12 years): ½ to 1 tablet daily.

These dosage instructions have remained unchanged on the label since initial consent was provided more than 50 years ago. These are also the approved directions for use for Hiprex in Australia and for methenamine in the UK. However, iNova note there is a discrepancy between methenamine hippurate products in Australia with the Uramet (methenamine hippurate) brand indicated for adults and children 12 years and over (Aspen, 2020). It is recognised that management of UTIs in children should be appropriately overseen by a doctor. Therefore, iNova is receptive to amending the directions for use to limit use to adults and children 12 years and over.

9. Methenamine Sales Patterns

Whilst methenamine has been classified as a general sale medicine since 2001, iNova has only ever supplied Hiprex to pharmacy. Prior to 2001 the medicine was classified as Pharmacy Medicine. Consequently, there has always been healthcare professional oversight of Hiprex. Despite the anomaly of a general sale medicine only ever been sold in pharmacy, the safety profile of methenamine as reported above is consistent with the expectations for a general sale medicine.

In November 2019, PHARMAC announced a decision to fully fund Hiprex (100 tablet bottle) on the Pharmaceutical Schedule (previously it was partially funded) for people with recurrent urinary tract infections. PHARMAC (2019) noted that "prevention and control of anti-microbial resistance is a health priority and consider that this funding decision will contribute to this priority."

Patients with a doctor's prescription would be supplied the 100's presentation due to its funding, whereas the unfunded 20's pack would be over the counter purchases to consumers, who may not have visited a doctor immediately prior to purchase. However, it should not be assumed that consumers purchasing 20's or 100's pack sizes without a prescription have not had their condition diagnosed.

Whilst the cost for a standard GP consultation varies between regions and practice enrolment status, it is typically about $50 - $75, excluding eligible pensioners who receive a subsidised rate of about $18.50. Therefore, for both economic and convenience reasons, patients who have initially received Hiprex fully funded under the Pharmaceutical Schedule may elect to purchase further methenamine supplies directly from the pharmacy over the counter. These are informed consumers able to self-manage their condition. Up scheduling to prescription medicine unnecessarily restricts their access to product and increases their medical costs. Other reasons why purchase of unfunded product may occur include:

- Consumers who have run out of funded product before they have obtained a new prescription
- Consumers with a history of UTIs currently not taking methenamine who purchase as a 'stop gap' prior to obtaining a prescription. These patients recognise the symptoms of UTIs and the appropriate treatment and may not have ready access to a doctor, for example over the weekend, or are unable to quickly obtain an appointment

- Consumers whose initial consultation is with a pharmacist who recommends methenamine.

In all these scenarios consumers would be denied convenient access to methenamine for legitimate health reasons for no other reason than to satisfy an administrative need.

Obtaining a subsidised medicine requires a prescription from a medical practitioner. MARC (2022) is concerned that a general sale classification may be inappropriate because "consultation with a Healthcare Professional is advisable for patients with symptoms of recurrent urinary tract infection to ensure accurate diagnosis and appropriate treatment". The current PHARMAC funding arrangement and sales patterns strongly suggest that patients are seeking medical advice for UTIs and thus the professional oversight occurs independent of the medicine classification.

10. Sponsor Impact

The proposal to up-schedule methenamine appears inconsistent with the principles of the New Zealand government document '*Government Expectations for Good Regulatory Practice*', which outlines that the New Zealand government believes durable outcomes of real value to New Zealanders are more likely when a regulatory system: "seeks to achieve those objectives in a least cost way, and with the least adverse impact on market competition, property rights, and individual autonomy and responsibility" (NZ Govt, 2017).

This submission has demonstrated that methenamine has a safety profile suitable for a general sale medicine and that consumers are capable of self-diagnosing and self-managing their condition. There is no evidence of inappropriate use and therefore, the proposal to up schedule methenamine appears to be seeking to satisfy administrative objectives rather than improve patient health outcomes.

With up scheduling offering no discernible benefit to consumers, it also adversely impacts sponsors. Hiprex tablets in packs of 100's is fully funded on the Pharmaceutical Schedule. This arrangement provides cost and accessibility benefits to the consumer and supports an important Public Health priority in minimising antibiotic use. [redacted]

A decision to up schedule methenamine, which increases the cost to supply without a benefit offset to consumers, is inconsistent with the principles of good regulatory practice and thus is not justified.

11. Conclusion

The available evidence does not support the proposition that a general sale classification for methenamine is creating inappropriate use, safety concerns or that consumers are unable to effectively self-manage their condition. Whilst it is tempting to conclude that as methenamine is effectively supplied as a prescription medicine because patients are already seeking medical advice, then the medicine classification should be aligned to match current practice. iNova strongly discourages that reasoning due to the following factors:

- No new safety signals have been detected and nor is there any increase in adverse event reporting which is inconsistent with historical sales volume trends.
- Methenamine has undergone periodic classification reviews since consent which have resulted in either relaxation of its classification (2001) or remained unchanged (2012). Data presented in the 2022 MARC review do not change the current benefit: risk profile.
- The methenamine classification is harmonised with Australia. Tran-Tasman harmonisation of medicine classification should be maintained unless there is a sound public health reason to have different schedules in Australia and New Zealand.
- A review of the available data on the usage and incidence of adverse reactions to methenamine hippurate provides no evidence to support concerns the ingredient poses a significant safety risk, nor that the existing scheduling is leading to inappropriate use of the medicine, or improper treatment of recurrent UTIs. To the contrary, with over 50 years of safety data available through spontaneous adverse event reporting, the long-term safety of methenamine has been established.
- Methenamine has been fully funded on the Pharmaceutical Schedule since 1 December 2019 and supports an important public health objective to reduce antibiotic resistance. The increasing sales of methenamine are testament to the value of subsidised methenamine to achieving this objective. The current methenamine schedule does not influence the decision to initiate therapy with methenamine but does allow continued convenient access to consumers post-diagnosis. Up scheduling methenamine will unnecessarily restrict access and may lead to an unintended increase in UTIs requiring antibiotic treatment because cost and time are disincentives to visit a doctor to renew a methenamine prescription. The objective of preventative therapy is to avoid UTIs. The methenamine schedule should facilitate access and convenience to enable prophylaxis to be effectively used. The general sale schedule enables achievement of that objective.
- There is no evident public health benefit to reclassification and the proposal is inconsistent with good regulatory practice. Up scheduling will increase costs to consumers and sponsors without a corresponding tangible benefit.
- Depending on continued funding viability, up scheduling of methenamine may result in increased antibiotic use inconsistent with NZ Public Health objectives.
- The anomalies in paediatric dosage instructions are noted. iNova is receptive to amending the directions for use to limit methenamine use to adults and children 12 years and over.

Therefore, the proposal to reschedule methenamine hippurate to a more restricted schedule is unsupported. To reclassify methenamine due to an administrative consideration is to deny the New Zealand public reasonable access to a well-established medicine with a long history of use. iNova recommends rejection of the proposal to reclassify methenamine hippurate and supports retention of the current general sale classification.

12. References

Al-Badr, A and Al-Shaikh, G. (2013). Recurrent urinary tract infections management in women. A review. Sultan Qaboos Univ Med J. 13(3): 359–367. Published online 2013 Jun 25. doi: 10.12816/0003256

Aspen (2020) Uramet Product Information.
Accessed at: https://www.aspenpharma.com.au/wp-content/uploads/PICMI/PI/PI_Uramet

BPAC NZ (2021). Urinary tract infections (UTIs) – a review of lower UTI management in adults. Accessed at: https://bpac.org.nz/2021/uti.aspx

Dept of Health (Australia) [DOH] (2021). *Required Advisory Statements for Medicine Labels* (RASML No. 6, 2022). Therapeutic Goods (Medicines Advisory Statements) Specification 2021 https://www.legislation.gov.au/Details/F2021L01888

Dept of Health (Victoria) (1969). Letter to Riker Laboratories on Hiprex scheduling status. (Available on request).

European Food Safety Authority [EFSA] (2014). Endogenous formaldehyde turnover in humans compared to exogenous contribution from food sources. *EFSA Journal* 12(2):3550.

Jepson_RG, Williams_G, Craig_JC. (2012) Cranberries for preventing urinary tract infections. *Cochrane Database of Systematic Reviews*, Issue 10. Art. No.: CD001321.
DOI: 10.1002/14651858.CD001321.pub5.

Lee, BSB, Bhuta T, Simpson JM (2012). Methenamine hippurate for preventing urinary tract infections. *Cochrane Database of Systematic Reviews*, Issue 10. Art. No.: CD003265.
DOI: 10.1002/14651858.CD003265.pub3.

MARC (2022) Methenamine benefit: risk review.
https://medsafe.govt.nz/profs/adverse/Minutes190.htm#3.2.4

MCC (2012) Minutes of the 47th meeting of the Medicines Classification Committee - 1 May 2012.
https://medsafe.govt.nz/profs/class/Minutes/2011-2015/mccMin1May2012.htm

Medsafe (2019) How to change the legal classification of a medicine in New Zealand. Guidance document. https://www.medsafe.govt.nz/downloads/How_to_change_medicine_classification.pdf

Medsafe (2022) Suspected Medicine Adverse Reaction Search (SMARS).
https://www.medsafe.govt.nz/Projects/B1/ADRSearch.asp

Mylan (2019) TMP Data Sheet.
https://medsafe.govt.nz/profs/Datasheet/t/tmptab

NZ Govt. (2017) *Government Expectations for Good Regulatory Practice.* Accessed at: https://www.treasury.govt.nz/sites/default/files/2015-09/good-reg-practice

PHARMAC (2019). Decision to increase the subsidy for methenamine (hexamine) hippurate tablets and flecainide acetate injection. Accessed at: https://pharmac.govt.nz/news-and-

resources/consultations-and-decisions/decision-to-increase-the-subsidy-for-methenamine-hexamine-hippurate-tablets-and-flecainide-acetate-injection

Protano, C et al. (2022). The carcinogenic effects of formaldehyde occupational exposure: A systematic review. *Cancers* 14, 165. https://doi.org/10.3390/cancers14010165

Stamos Kovacs, J. (2021). Urinary tract infections (UTIs). Accessed at: https://www.webmd.com/women/guide/your-guide-urinary-tract-infections

TGA (2022) Database of Adverse Event Notifications (DAEN). https://www.tga.gov.au/safety/safety/safety-monitoring-daen-database-adverse-event-notifications/database-adverse-event-notifications-daen

UK MHRA (2022) Interactive Drug Analysis Profile. Available from: https://info.mhra.gov.uk/drug-analysisprofiles/dap.html?drug=./UK_EXTERNAL/NONCOMBINED/UK_NON_001064250405.zip&agency=MHRA (Accessed 21 Sept 2022).

UK Hiprex Summary of Product Characteristics (2019) https://www.medicines.org.uk/emc/product/1530/smpc#gref

Urgos-Barragan, G., et al (2017). Mammals divert endogenous genotoxic formaldehyde into one-carbon metabolism. *Nature,* 548(7669), 549–554. doi:10.1038/nature23481

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21st September 2022

Kia ora,

Application to increase access to Maviret through exemption to prescription status for specific nurses

I am lead hepatologist at the New Zealand Liver Transplant Unit at Auckland City Hospital and Professor. I am writing in my capacity as Ministry of Health Clinical Advisor on Viral Hepatitis and as Chairman of the Ministry of Health Hepatitis C Oversight committee.

Today more than 40,000 New Zealanders are living with chronic hepatitis C with an additional 500 being infected each year, chiefly through injecting drug use. Although there is no vaccine against Hepatitis C, we do have highly effective oral antivirals which are funded without restriction. We have already cured almost 10,000 New Zealanders. Despite this, we continue to see almost 150 new cases of liver cancer or liver failure each year whilst many more will suffer chronic ill health or stigma, reflecting a very low rate of diagnosis and treatment uptake in this country. Increased treatment uptake in people who inject drugs will prevent transmission and save lives.

In July 2021, Associate Minister Verral launched the first National Hepatitis C Action Plan for Aotearoa New Zealand (Māhere Mahi mō te Ate Kakā C), outlining a public health approach which aims to improve awareness, testing and treatment uptake to achieve elimination of Hepatitis C in New Zealand by 2030.

The attention-grabbing Stick-it-hepC awareness campaign launched last month should resonate with our target audience of people who inject drugs. But to reach our most vulnerable and isolated communities, we must decentralise our models of care, adopting simplified testing and treatment pathways.

We have looked to Scotland, which will be one of the first countries in the world to achieve HepC elimination. Their success can be attributed to NHS Scotland's initiative to widen community access to treatment by enabling both nurses and pharmacists to treat HepC.

We would like to adopt the same model here, utilising a small, yet highly experienced, group of nurses who have been managing people living with hepatitis C in the community. This includes around 30-40 hospital and community-based nurses who conduct outreach clinics in high priority settings such as community alcohol and drug services, needle exchanges, prisons/PARS, and community mental health services. Outreach work with mobile vans is taking hepatitis C testing and management into remote communities where access to health care may be challenging, and with an equity focus including Māori populations and deprived communities. This community work is vital to finding people both in the transmitting population, and the aging population with hepatitis C who need to be found before complications occur. Currently only two of these nurses are currently allowed to prescribe Maviret - both are qualified nurse practitioners.

The proposed reclassification to allow nurses to treat hepatitis C in the community follows on from reclassifications for the emergency contraceptive pill (levonorgestrel) through nurses some 20 years ago. It is logical in finding a group of health care professionals with the experience and expertise to provide a medication safely to a group who need better access, an important feature of reclassification in New Zealand. I have been involved in consultation to date, including with the Nursing Council, with stakeholders seeing merit in improving access through nurses and the proposal to have micro-credentialling.

We urgently need to stop transmission in people who inject drugs. Therefore, I urge the Medicines Classification Committee and Medsafe to recommend that Maviret be available for nurse-led treatment at this upcoming meeting. This recommendation could include suggesting input from the stakeholders including the Nursing Council, the Hepatology Nurses Network, The Pharmaceutical Society, the College of GPs, Te Whatu Ora, and myself, to finalise the model and the wording that allows this to be in place to maximise the opportunity to reach this vulnerable population.

Reclassification of Maviret to allow nurses to treat patients with hepatitis C in the community should not be delayed because it will put Aotearoa back on track to achieve the WHO goals to eliminate hepatitis C as a public health threat by 2030, which will save thousands of lives. And consistent with our Treaty obligations, this improved access to treatment will advance the health aspirations of Māori, who have higher prevalence and poorer outcomes from hepatitis C.

I would be happy to address any questions that members of the Medicines Classification Committee and Medsafe may have about this initiative.

Ngā mihi nui,

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Te Whatu Ora – Health New Zealand
TeWhatuOra.govt.nz | Te Toka Tumai Auckland

NZgNC
NZNO GASTROENTEROLOGY NURSES' COLLEGE

RŌPŪ TĀPUHI HEPATOLOGY O AOTEAROA
NZ HEPATOLOGY NURSES GROUP

28 September 2022

Glecaprevir and Pibrentasvir (Maviret) – proposed change to prescription classification

Background

The New Zealand Hepatology Nurses Group (NZHNG) is a sub-group of the New Zealand Nurses Organisation Gastroenterology Nurses' College. This response represents the views of the members of the NZHNG and not those of all nurses working with patients with hepatitis C.

The NZHNG was established primarily to provide a network for nurses who often work in isolation due to the small number of hepatology nurses throughout NZ, and in response to the changing nature of our role. With treatment for hepatitis C moving more to the primary care setting, our role has evolved from working predominantly with people with hepatitis C to working with people with liver diseases of various aetiologies and stages. The need for a knowledge and skills framework to support the changing scope of practice for these nurses was seen as a key task for the group and is still in development.

Response

<u>We support Nurse Prescribing of Maviret</u>

The NZHNG has always supported the proposal that nurses working with patients with hepatitis C should be able to prescribe Maviret, and wrote a submission that saw Maviret added in 2021 to the list of medications nurses can prescribe.

<u>Prescription of Maviret not a barrier to treatment in most situations</u>

We have consulted with our members and although only a small number of responses were received, the majority do not find the inability to prescribe Maviret to be the main barrier to treatment for hepatitis C as most members have ready access to doctors or authorised prescribers. This reflects the fact that most members work in secondary care settings. We wonder if the amount of work involved in implementing this proposal for a small number of community based nurses is disproportionate to the potential return.

<u>We have concerns about how a nurse is deemed to have 'appropriate knowledge and experience'</u>

The current proposal to expand access to Maviret through 'exemption to prescription status' for specific nurses has been considered by our group. There are certainly some nurses with expert knowledge of hepatitis C and Maviret that would be more than capable to administer Maviret under the current proposal. However, we are unsure how this knowledge would be assessed and how they

would be supported i.e. what levels of physician oversight and other oversight requirements are going to be provided. While we feel there is a lack of clarity around this, we acknowledge the exact model has yet to be established. We have a responsibility to not only keep patients safe, but also our practice, so any potential training modules need to be 'of a standard' which already exists in the established post graduate courses available for pathways to Nurse Prescriber and Nurse Practitioner.

The nurses' roles in medication management cannot be over-emphasized. This is particularly true when designing a model if this proposal is to be considered. Thus far, we feel, there has been very little consultation with the members (in a timely manner).

Most Hepatology Nurses have, or are working towards, post graduate nursing qualifications

While many have completed the necessary pre-requisite post graduate study to become prescribers, namely of Maviret, they have chosen not to do so because they see it as unnecessary when access to doctors or authorised prescribers is available as above. The other consideration is they receive no financial recognition for the added responsibility and work required to maintain prescriber status. We would welcome support being provided to these nurses to become prescribers.

Conclusion

We support an equity approach to all healthcare and access to medication that seeks to eliminate hepatitis C in all healthcare.

- We do support better access and support to those educational pathways already established.
- NZHNG does not support another means of an educational nursing pathway.

NZHNG would be happy to discuss this further if you have any questions or seek further clarification.

Judith McLaughlin
Chairperson
New Zealand Hepatology Nurses Group

Te Kaunihera Tapuhi o Aotearoa
Nursing Council of New Zealand

3 October 2022

Medicines Classification Committee
Medsafe

Via email: committees@health.govt.nz

Tēnā koutou Medicines Classification Committee

Maviret reclassification

Thank you for the opportunity to contribute to the current application to reclassify Maviret. Nursing Council was approached by nurses working in the area of hepatic health when developing this submission. Overall, the Nursing Council of New Zealand supports the application to exempt Maviret through exemption to prescription status for specific Registered Nurses.

In particular, the Council supports Registered Nurses to complete a short education and training programme to qualify for the exemption, and acknowledges this programme would be developed and maintained by the group making the submission. The Council also acknowledges eligible Registered Nurses would need to be working as part of a collaborative team. The Council would then authorise Registered Nurses who have completed the short education and training programme using a process similar to Registered Nurses who supply the Emergency Contraceptive Pill (ECP). This authorisation would be visible on the Council's public register and would therefore be accessible to participating pharmacists.

Nāku noa, nā

Brittany Jenkins
Kaiwhakahaere Paerewa Ngaio | Director Professional Standards
Nursing Council of New Zealand

To whom it may concern:

I write to the Medicines Control Committee in my role as the Regional funding manager for Hepatitis C work.

The impact on Maverit on the treatment of Hepatitis C has been huge. The previous medications had considerable side effects and were only effective against certain virial genotypes. In contrast Maverit is effective for all genotypes and is a relatively simple course of treatment.

Identifying and treating people with the virus is critical if we are to have any hope of eliminating the disease within New Zealand by 2030. Currently much effort is going into identifying people with the disease through both laboratory and point-of-care testing. We need to optimise and maximise our ability to do both.

The proposition you are reviewing is that specialist nurses would be able to prescribe Maverit. It is essential that once a positive case has been identified that treatment should be initiated as soon as possible. Given the population which has a high incidence of Hepatitis C, and given the downsides of the past treatments, loosing people before they are treated is a real problem. We need to enable as many people to prescribe the medication as is clinically safe.

The parallel with another virial disease, Covid-19, is interesting. Here the antivirals being used are now a pharmacist-only medication. While I am not suggesting going this far for Maverit, enabling fast diagnosis and treatment loops is the key to the future and this change will be an enabler for this to occur.

Thank you for your consideration.

Russell Cooke

Senior System Development Manager

Strategy, Performance and Planning (SPP) | Capital, Coast and Hutt Valley

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Medicines Classification Committee Secretary
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BAY OF PLENTY
DISTRICT HEALTH BOARD
HAUORA A TOI

Submission for Medsafe Meeting re-classification of Maviret

Submitted by: Nicola Caine Msc(Hons), RN,

Dear Sir/Madam

Thankyou for the opportunity of submission to the Medicines Classification Committee.

World Health Organisation targets for the elimination of viral hepatitis are fast approaching meaning we must encourage the health delivery workforce to become smart about ways to improve diagnosis, access, and linkage to care for those most impacted by this infection and the health sequalae that follow. Recent progress in anti-viral treatments, mean that there is a highly efficacious, well tolerated, short course, all oral curative medicine now available. Maviret cures infection and reduces the burden of potential life-limiting chronic liver disease, liver failure and liver cancer. However, we know that funding of this medicine is not sufficient to address this issue.

Finding those living with an undiagnosed HCV infection, alongside linking to care those with known infections pose significant challenges that we must address to look towards the WHO targets. Much work has been undertaken around priority populations and the enablers and barriers that exist (Goutzamanis, Doyle, Higgs & Hellard, 2019). Removing as many steps as possible and simplifying the process is key to maximising engagement in care of a population often disadvantaged by traditional healthcare delivery systems.

The settings in which hepatitis C care are now delivered mean that we are maximising the nurse/patient therapeutic relationship. Reducing power imbalances in care delivery, particularly in blood-borne virus care are important when we acknowledge the significant and far-reaching effect that stigma and discrimination has. Actively seeking to provide care through an equitable and socially just lens means we must apply new ways of working and allowing the growth of the nursing role in this setting.

The benefits to patients from nurse prescribing are well reported (Gagan, Boyd, Wysocki & Williams, 2014) Indicating this method to be safe, effective, and acceptable to those receiving the care. I would envisage that the re-classification of Maviret would also meet these criteria. While acknowledging autonomous prescribing within the Nurse Practitioner setting and the recent addition of Maviret to the list of approved medicines for Nurse Prescribers, this still leaves a large untapped group of expertise that could potentially add value in this setting. The re-classification of Maviret would allow a sub-group of very experienced and knowledgeable nurses to work at the top of their professional scope for better outcomes for priority populations that carry the burden of this infection. This valuing of experience and knowledge

would allow barriers to be removed and could become another important tool to help achieve Hepatitis C elimination.

I absolutely support the re-classification of Maviret.

Yours Sincerely

Nicola Caine: Hepatology Clinical Nurse Specialist Hauora a Toi Bay of Plenty and Nurse Practitioner (intern) The Hepatitis Foundation NZ

REFERENCES

Gagan, M. J., Boyd, M., Wysocki, K., & Williams, D. J., (2014) The first decade of nurse practitioners in New Zealand: A survey of an evolving practice. *Journal of the Association of Nurse Practitioners.* 26 612-619. DOI: 10.1002/2327-6924.12166

Goutzamanis, S,. Doyle, J,. Higgs, P,. & Hellard, M,. (2019) Improving hepatitis C direct-acting antiviral access and uptake: A role for patient-reported outcomes and lived experience. *Journal of Viral Hepatitis.* 26 218-223. DOI: 10.1111/jvh.13020

2022-10/03-01

3 October 2022

NEW ZEALAND NURSES ORGANISATION
TŌPŪTANGA TAPUHI KAITIAKI O AOTEAROA

Medsafe
Secretary of the Medicines Classification Committee
By email: committees@health.govt.nz

Tēnā koe

Application to increase access to Maviret through exemption to prescription status for specific nurses (Maviret reclassification)

Tōpūtanga Tapuhi Kaitiaki o Aotearoa, New Zealand Nurses Organisation (NZNO) welcomes the opportunity to comment on an application for Maviret reclassification.

NZNO represents 55,000 nurses, midwives, students, kaimahi hauora and health workers on professional and employment matters. NZNO embraces te Tiriti o Waitangi and contributes to the improvements of the health status and outcomes for all people of Aotearoa New Zealand through influencing health, employment, and policy development.

Tiriti o Waitangi
NZNO is committed to upholding the articles of te Tiriti o Waitangi across all our work.

Equity
Māori are our priority population for all equity work. We share the intent of the Ministry of Health's definition of equity where *in Aotearoa New Zealand, people have differences in health that are not only avoidable but unfair and unjust. Equity recognises different people with different levels of advantage require different approaches and resources to get equitable health outcomes*.[1] This equally applies to NZNO's work across professional, industrial and members' activities.

Active protection
Alongside our commitment to equity, we are well informed on the extent and nature of Māori health outcomes and what is being done to achieve Māori health equity. Our research, monitoring and data analysis is undertaken in a way that upholds the mana and tikanga of whānau Māori. We actively protect tino rangatiratanga through increasing Māori participation in governance, leadership, management, and decision-making at all levels of NZNO. We ensure mātauranga Māori is given respect in any decision-making process.

Chronic Hepatitis C
NZNO supports the initiatives that have been identified in the National Hepatitis C Action Plan where they are endeavouring to address chronic Hepatitis C and its disproportionate effects on marginalised populations (e.g. people who inject drugs, people in prison, homeless). Furthermore,

[1] Ministry of Health https://www.health.govt.nz/about-ministry/what-we-do/work-programme-2019-20/achieving-equity

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help reach populations, to *turn off the tap of new infections,* prevent complications such as hepatocellular carcinoma and liver failure.

NZNO recognises that actions to increase access and treatment uptake will assist the health system to better manage its resources with fewer new infections to find and treat and fewer people with complications to be managed.

NZNO acknowledges Maviret is the preferred treatment for chronic Hepatitis C infection in New Zealand. NZNO also endorses nurse-led management and recommends it as a strategy for Medsafe to consider as part of the Maviret reclassification because it speaks to equity as Māori are likely to be disproportionately affected. Improving access with fewer stages to getting treated, including through outreach work, will increase treatment for Māori.

Additionally, nurse-led clinics are evidenced-based and supported by NZNO's research. There is a risk that if reclassification occurs, and if nurses are not supported in this practice then it may be reclassified to *Prescription unless provided by a pharmacist with appropriate training*. This is a less favourable option when nurses have an established clinical relationship with patients who they will be supporting to undertake the recommended treatment for its full duration and as per the evidenced based treatment guidelines.

NZNO strongly supports this proposal as it will enable a group of nurses with relevant knowledge and support, manage and treat people with chronic Hepatitis C, to benefit individuals themselves, the communities they work with and the health system. This action will in turn enable nurses to work to their full scope and reiterates previous submissions to the Medicines Classification Committee on applications for reclassification.

NZNO expects these nurses will self-identify and undertake the appropriate training. We also expect that wrap around support services will be made available to this group of nurses to reduce any personal or professional risk they may experience undertaking this work.

NZNO does question why there are no fully, or part funded co-payments for General Practitioners, Nurse Practitioners of Registered nurse consultations to enable patients to have the first conversation – *Do I have Hepatitis C* and if yes, what are my options. Patients without signs or symptoms are unlikely to seek medical or nursing assistance, without a reason as has been demonstrated through the breast, cervical and bowel screening programmes, Diabetes and Cardiovascular Risk Assessment, etc. Has consideration been given to funding all the treatment visits, or at the least the first appointment? Uptake may improve.

Thank you for the opportunity to contribute to your consultation process.

Nāku noa nā

Lucia Bercinskas
Senior Policy Analyst
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Medicines Classification Committee (MCC) – 69th Meeting

Comments on Agenda item 6.1b Glecaprevir and Pibrentasvir – proposed change to prescription classification statement (Health New Zealand, Long Term Conditions)

AbbVie is in broad agreement with the proposal to retain the current prescription classification for both glecaprevir and pibrentasvir with the exception made for treatment of patients aged 16 years and older with chronic hepatitis C virus infection who meet the clinical and eligibility criteria of the approved hepatitis C training programme and are under the care of registered nurses who:

- have specialized knowledge of hepatitis C, or
- are working in a community in a high-prevalence hepatitis C environment and
- have successfully completed the approved training programme and
- meet the criteria of the training programme and
- are the principal health professionals managing patients with hepatitis C

We agree that this exception to the prescription classification be applied only to registered nurses who have a specialty knowledge of hepatitis C, including hospital-based nurses working in gastroenterology, hepatology or infectious diseases and also community-based nurses in alcohol and drugs services, including opioid treatment services, corrections, homeless shelters, outreach and needle exchange.

Furthermore, there is agreement with the submission content that states:

- there is no labelling change required as the medicine would remain prescription only with an exception
- as the usage is virtually unchanged, no additional warning statements are required.

Additional Comments:

- On page 10 of the submission, we note that for patients under 30 years of age, a point-of-care PCR RNA test plus a urine pregnancy test, if indicated, will be sufficient to start a person on treatment. Whilst most New Zealand born patients in this age group are likely to have received immunisation against Hepatitis B virus (HBV), there is also an immigrant population who may not have been immunised. Therefore, the Hepatitis B status would still be required before starting treatment. This is in line with the information in the "Special warnings and precautions for use" section in the approved Datasheet, which states "All patients should be screened for HBV before initiation of treatment".

- In line with the information contained in the "Contraindications", "Special warnings and precautions for use" and the "Interaction with other medicines and other forms of interaction" sections of the approved Datasheet, in order for nurses to be able to initiate treatment without prescription, access to Patient Medical records including immunisation status, medications, medical history (including diabetes) and Hepatitis B status would need to be available.

In summary, AbbVie is in agreement with the proposal to enable registered nurses with specialist knowledge about hepatitis C, after completing an approved training programme and meeting the criteria of the programme, to initiate treatment to eligible patients without prescription.

A nurse-led model, utilizing competent and trained health professionals, will help in overcoming some of the access barriers and enable eligible patients to receive treatment for Hepatitis C in New Zealand.

28 September 2022

Te Whatu Ora
Health New Zealand

To Whom it may concern

Reclassification of Maviret

This is a letter of support for the reclassification of Maviret to enable a designated group of nurses to dispense Maviret within their community.

I am one of the four hepatitis C regional programme managers, and also a registered nurse working in the hepatitis C area for the last 7 years. Each region has implemented community hepatitis C services within their community.

We have piloted many community models using nurse-led services and partnering with other community providers, across a number of years. We are now in a position of knowing what works and what doesn't. These pilots and projects inform us that it is time for change to enable equitable services for this often-vulnerable population.

Often this population is stigmatised as the priority hepatitis C population is usually people who inject drugs, either currently or in the past. People who currently inject drugs often lead a chaotic life, and may have a distrust of, or not engaged with the health system.

One critical part of the hepatitis C clinical pathway is where a person is identified as positive with hepatitis C and then needing to get on to treatment as close as possible to the initial contact, as there is a high risk of some people "disappearing" and it could take years for them to re-engage.

The nurses working in the hepatitis C community often have years of experience looking after people with hepatitis C and build a rapport easily. One gap identified in the pathway is that the treatment or prescription is not available by the nurse at the time of consultation. Within our region our extremely experienced registered nurse offers a one-stop-shop where she can do a complete work up on the patient but then must get a doctor to sign the script, send the script to the pharmacy, the pharmacy must order the medication in (which takes a day or two) and then contact the patient to come into the pharmacy. By having the nurse able to treat the patient, and arranging for certain pharmacies to already have stock to start the patient on, we can save time. For remote areas, this could enable the nurse to provide the stock directly to the patient.

This is one of the times where the patient may disappear, untreated and may take many years to be able to engage. If the person could walk out with the medication as soon as possible, with support from the nurse and pharmacy, this could be a game changer in the hepatitis C community. This will benefit individuals, society, and the health system, as treated by experienced nurses prevent people requiring hospital admissions and being at risk of liver scarring and cancer. This change is urgently needed.

We have a mobile van that will be going to places like needle exchanges, community events and remote locations where people are not accessing health care. This nurse-led

model including treatment is vital to our mobile service and increasing our treatment numbers. It will also provide a complete sense of satisfaction for a nurse to then cure a what had previously been classed as a long-term condition. These nurses are very experienced and capable, and with micro-credentialling, e.g. short on-line course, and good links with the gastroenterology department or a doctor very experienced in hepatitis C management, will be easily capable of safe provision of Maviret. Nurse-led care has been effective in Scotland at helping eliminate hepatitis C.

What I would like to urge is that the committee makes the recommendation at this meeting to change the classification and enable nurse-led care. We do not want delay to this initiative because people who are potentially transmitting the infection or at risk of complications will be delayed in being found. A recommendation that this is approved and the way forward has had input from stakeholders will ensure a mechanism that is workable and safe, and in place in a timely manner.

Ngā mihi,

Jo de Lisle (she/her)
Programme Manager, Hepatitis C, Regional Health Integration Team

HealthShare | Te Manawa Taki

Te Whatu Ora

3 October 2022

The Secretary
Medicines Classification Committee
Medsafe
P.O. Box 5013
Wellington 6145

Submitted via email to committees@health.govt.nz

Dear Sir/Madam,

RE: Public Comment on Agenda for 69th Meeting of Medicines Classification Committee

6.1c Topical and injected local anaesthetics - proposed change to prescription classification statement

On behalf of Dentsply Sirona, we appreciate the opportunity to provide further comments on Medsafe's Agenda Item 6.1c listed above for the upcoming 69th Meeting of Medicines Classification Committee (MCC).

Dentsply Sirona supports the Dental Council's submission and proposal to reclassify the following chemical entities from '*prescription medicine*' to '*prescription except when classification'* for dental hygienists:

1. Lidocaine (lignocaine) and Prilocaine for topical use
2. Prilocaine and felypressin for injectable use
3. Articaine and adrenaline for injectable use
4. Lidocaine (lignocaine) and adrenaline for injectable use

Reclassification of these chemical entities will align their uses and restrictions with the current exemption for a prescription for dental hygienists registered with the Dental Council.

[redacted]

[redacted]

Safety and Usage of Oraqix and Citanest

The safety and usage of Oraqix and Citanest are well established. [redacted]

The information provided supports the long and extensive use of the products in dental work in New Zealand and confirms the low risk associated with the use of the products by dental healthcare professionals.

Dentsply Sirona welcomes the Committee's decision to consider and review the reclassification of topical and injected local anaesthetics for use by dental hygienists without prescription.

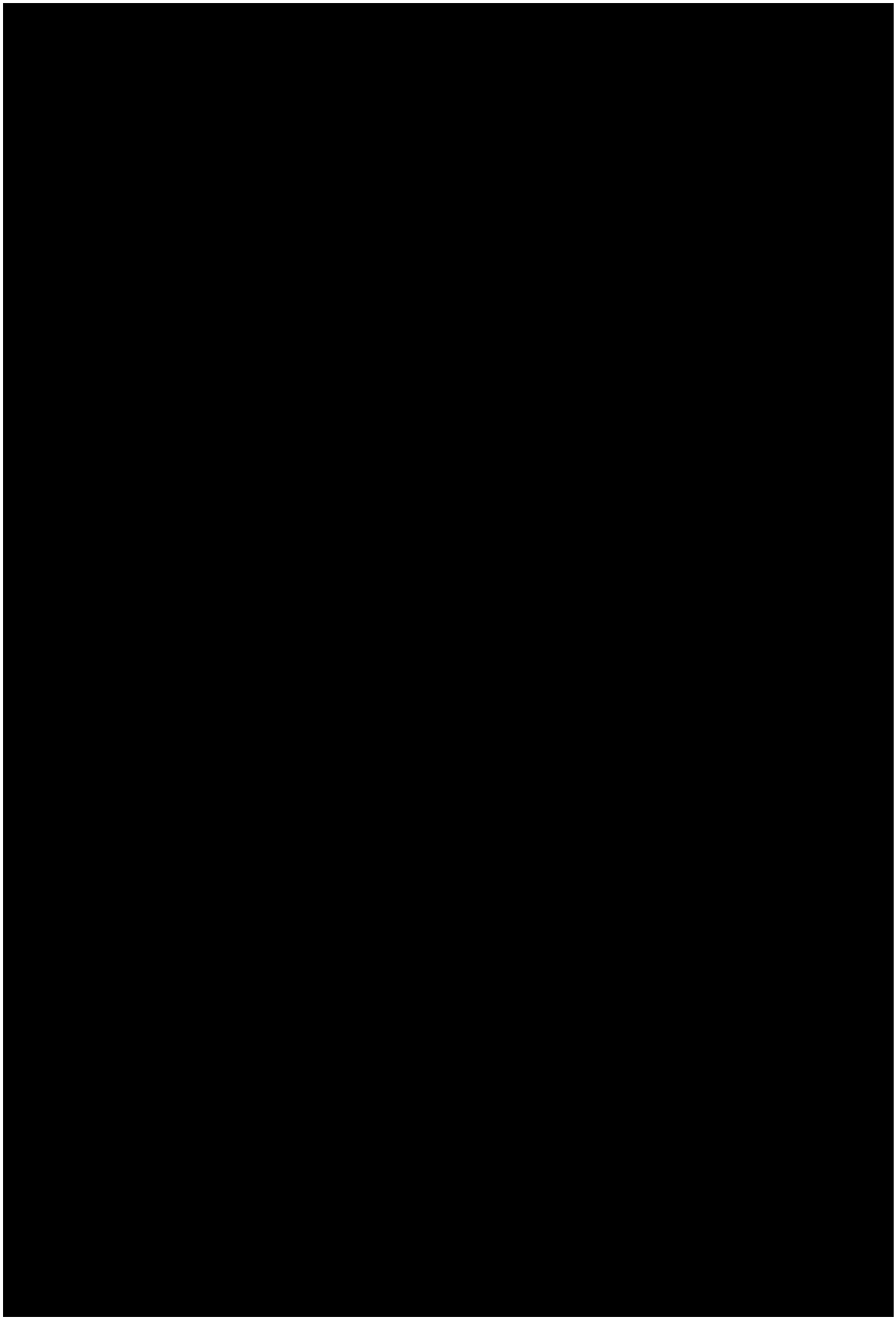
Should you have any questions regarding our consultation feedback or data, we welcome the opportunity to discuss them further.

Yours sincerely,

Anna Tang
Senior Regulatory Affairs Associate, ANZ region
Dentsply Sirona (N.Z.) Limited/Dentsply Sirona Pty Ltd (Australia)

[redacted]

[redacted]



3rd Oct 2022

Medicines Classification Committee Secretary
Medsafe
PO Box 5013
Wellington

Submission for reclassification application for injected local anaesthetics

Dear Secretary

HealthCare Essentials are suppliers of Dental products in New Zealand.

This letter is to confirm we support the reclassification of for injected local anaesthetics proposed for the Dental Hygienists registered with the Dental Council.
The proposal is consistent with the [redacted]

- [redacted]
- [redacted]

We have [redacted]
The following [redacted]

[redacted]

Yours Sincerely

HealthCare Essentials Limited

7/489 Hutt Road, Alicetown, Lower Hutt 5010, New Zealand
Telephone (64-4) 387 3874 or NZ toll-free *0508* 802 5577
E-mail *sales@**healthcare**essentials.nz* Website *www.**healthcare**essentials.nz*

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Medicines Classification Committee, Medsafe

committees@health.govt.nz

1 October 2022

To Whom It May Concern,

I am writing this submission and comments on behalf of myself (Dr Megan Corbett), Dr Ravi Sandhu, and all the doctors at CityMed –Auckland. This submission is to the Medicines Classification Committee (MMC) at Medsafe, and is **against** some of the proposed changes as outlined in item 6.1e on the Agenda of the upcoming 69th Meeting of the MCC to be held in October. It is my opinion that increasing access and availability of any medication, (including vaccines) without the provision of appropriate additional information related to their purpose is potentially dangerous.

My submission is solely against the re-classification of travel vaccines – namely - Cholera vaccines, Hepatitis A vaccines, Japanese Encephalitis vaccines, Polio vaccines, Rabies vaccines, Typhoid vaccines and Yellow Fever vaccines– being administered by pharmacists and other non-travel-medicine-trained vaccinators. This is the new proposed changed wording = "Prescription-only EXCEPT when administered by a vaccinator who has successfully completed the Vaccinator Foundation Course (or equivalent course) approved by the Ministry of Health and who is complying with the immunisation standards of the Ministry of Health, but excluding COVID-19 Vaccinators Working Under Supervision, Provisional Vaccinators, Provisional Pharmacist Vaccinators, and Vaccinating Health Workers. " I think this is unsafe with respect to travel vaccines.

My reasons behind this objection are related mainly to the safety of the travelling public, the associated costs, compliance with International Health Regulations (IHR), and the likelihood that travellers will not be provided with the appropriate information and advice. Travel vaccines are only a very small part of the usual pre-travel consult. To ensure the travellers are well informed we provide a raft of information relating not only to the few vaccine-preventable diseases but also the other non-vaccine preventable illnesses and risks of travel. It is my opinion that the public should receive this information alongside receiving any vaccination for travel. We do not want travellers assuming they are fully protected for their travel – when in fact they have only received vaccines for a limited number of tropical and other illnesses. It should also be noted that no vaccine is 100% effective, in preventing disease. Vaccines available in New Zealand certainly do not protect against malaria, dengue, zika, chikungunya or the many other diseases that exist overseas. Nor do vaccines protect against environmental and human made hazards.

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Ill-prepared travellers will risk exposing themselves unwittingly to illness and danger if they are unaware of the perils that exist at their holiday destination/s. We do not want an increase in people returning to New Zealand with ailments, and injuries acquired overseas resulting in treatment costs that far outweigh that of a pre-travel consult. There could be a significant increased cost burden on primary and secondary care services post –travel. Not to mention the associated morbidity, mortality and disability.

Obviously the administration of the Yellow Fever vaccine is currently regulated internationally (through the World Health Organisation's International Health Regulations – IHR) to only IHR approved Yellow Fever Vaccinators, and only to be administered in an IHR approved Yellow Fever Vaccinator Centre. To gain approval and certification there is a high standard of travel medicine training required and an ongoing re-certification process for both vaccinators and vaccination centres in New Zealand – see **Appendix 1** (https://www.health.govt.nz/system/files/documents/pages/policy-for-yellow-fever-authorisations-aug-2017.pdf). This training we apply to all travel medicine consults to inform the travellers of associated risks and diseases. These proposed changes do not appear to comply with the regulations as set out by the World Health Organisation in relation to administering Yellow Fever vaccine and any other vaccine or illness that in future comes under the IHR.

I agree that you don't need a medical degree to administer a vaccine – that is easy – anyone can be trained to do it. However, to provide the associated appropriate background information to ensure safe travel is far more than a needle in the arm. When it comes to travel, I believe it is essential people are provided with the correct information for their intended destination. Travel medicine specialists provide information on many aspects of travel (never just vaccines) – including: food and water safety; sexual safety; climate and environmental risks; altitude information; insect bite avoidance; other animal bite avoidance; zoonoses; issues surrounding travel insurance; personal safety; common travel ailments and afflictions such as traveller's diarrhoea and influenza etc; and much more.

Travel medicine is increasingly becoming more and more specialised as is becomes intimately associated with the health of the traveller. 'Health' infers guidelines on:

i) Disease management pre-, during, and post- travel;
ii) Safety and security of travellers that demands constant proactive surveillance of international news;
iii) Disease management when travellers are abroad wanting further advice;
iv) Assessment and management of the signs and symptoms of illness when travellers return home.

When we specialise in travel medicine, we commit to maintaining the level of knowledge that is required to achieve the standards of evidence-based care expected of a travel health professional. This academic understanding, knowledge, and experience are manifest in our consultations with our travellers. Such consultations demand time and simply cannot be dismissed with just the administration of a vaccine.

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It is my opinion - that to administer travel vaccines safely - the vaccinator requires significant and ongoing travel medicine training and must impart that knowledge to the traveller. The ongoing COVID pandemic has created a huge gap in knowledge and the application of travel medicine. I do not want to see the New Zealand public adversely affected as they are again starting to travel.

When any vaccine is administered – the facility also needs to have enough staff with knowledge and experience in how to deal with immediate adverse reactions – like anaphylaxis. The centre should also have adequate resuscitation equipment and medication – as is required by the IHR for Yellow Fever approved Vaccinating Centres (see Appendix 1). It is also essential to have knowledge and facilities to deal with delayed adverse events (as has been the case with General Practitioners and secondary care dealing with myocarditis and cardiac adverse events following COVID vaccinations).

Another concern is that New Zealand does not yet have a fully integrated National Immunisation Register – for the documentation and permanent recording of the administration of travel (and many other) vaccines. As a result, travellers are likely to inappropriately receive additional doses of some vaccines when they may already have adequate immunity. Currently that information is stored mostly by General Practitioners and Travel Medicine Clinics.

Pharmacists are internationally joining Doctors and Nurses in administering 'travel health vaccines'. I am happy for them to do so as long as they are also receiving appropriate training and qualification in Travel Medicine. This specialty is diverse and demands much more than simply being able to give a vaccine. Postgraduate training is required for a full understanding of our field, and even then, the ongoing acquisition of knowledge (Continuing Medical Education) is essential to maintain our standards in this specialisation. Again, this is a requirement of the IHR for Yellow Fever vaccinators.

It seems that the simplified MOH approved vaccinator training that occurred during COVID has created a perception that 'this is all that is required for travellers going abroad'. This is not so! It is my contention that specialisation in travel medicine is essential for providing appropriate advice to those going abroad. This simply cannot be achieved if a vaccinator is qualified in vaccinating alone. Vaccination is only a small factor in what happens in a travel health assessment.

Approximately fifty percent of travellers become unwell in some way whilst travelling. For intending travellers to go to a vaccination centre to have their vaccines, without any other travel-associated-health-advice, is an injustice to both our fellow New Zealanders and our Travel Medicine specialisation. The costs to treat illness in returning travellers ill-prepared for their travel are likely to be substantial.

It is my opinion also that a doctor, nurse, or pharmacist providing travel health advice needs to have training, understanding and experience in:

i) The diversity of the Specialisation of Travel Medicine;
ii) Global history, health and welfare;
iii) Diseases for which vaccination is required;
iv) Travel and travel health issues;

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v) Vaccinology.

In summary these are criteria that patients/travellers expect from us. They simply cannot be relinquished because of requests or pressures to 'open up' regulations to administer vaccinations under the pretext of increased access and availability. We need to practise safe medicine. As I note, vaccinations are the end products of the points i) – v) above and must be maintained as such. If such vaccinators are permitted to do travel vaccinations, then they must only be able to do them on the precondition that they complete specialised training in travel medicine, alongside having facilities with appropriate resuscitation space, equipment and trained personnel. I do not want the New Zealand public to be put at undue risk whilst travelling because they have sought vaccination but not received the associated travel destination appropriate advice.

Yours Sincerely

Dr Megan Corbett (MBChB, FRNZCGP, PG Cert Travel Medicine and Migrant Health)

Dr Ravi Sandhu, (MBChB, FRNZCGP, PG Cert Travel Medicine and Migrant Health)

And all the doctors at CityMed Auckland

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Dear Medsafe,

Thank you for the opportunity to provide feedback on the proposal to widen the classification for vaccines to allow vaccinators who have successfully completed the Vaccinator Foundation Course (or equivalent course) approved by the Ministry of Health and who comply with the immunisation standards of the Ministry of Health to both distribute and administer vaccines.

GSK is overall very supportive of the proposed reclassification and consider it critical to reduce access barriers to vaccinations in New Zealand. GSK is a leading global supplier of vaccines and supplies most of the vaccines on the National Immunisation Schedule.

GSK notes however, that the wider vaccinator workforce, that includes COVID-19 Vaccinators Working Under Supervision, Provisional Vaccinators, Provisional Pharmacist Vaccinators, and Vaccinating Health Workers, are excluded from this reclassification.

In a time when childhood immunisation rates, particularly for Māori and Pacific infants, are terrifyingly low and urgent action is needed to address the crisis and inequity (6-month immunisation rates for Maori are 45%, and less than 35% in several DHBs, including Counties Manukau, Waikato and Northland)[1], GSK sincerely hopes that the benefits and risks of extending the reclassification to include as many vaccinators as possible has been carefully evaluated.

Considering that this wider group of vaccinators, especially the Vaccinating Health Workers, often work in outreach programmes and over half identify as Māori, GSK requests that the benefits of extending reclassification to this group are carefully considered, and that all effort and support is being provided to upskill this workforce to fully authorised vaccinators.

Yours sincerely,

Dr Lindsay Ancelet

Medical Affairs Manager, Vaccines

GSK NZ

1. New Zealand National Immunisation Data. Immunisation coverage data – three-month reporting period from 1 April – 30 June 2022. https://www.health.govt.nz/our-work/preventative-health-wellness/immunisation/immunisation-coverage/national-and-dhb-immunisation-data

New Zealand Society of Travel Medicine
30 September 2022

To Medicines Classification Committee (MCC)
By email: committees@health.govt.nz

Kia ora koutou,

The New Zealand Society of Travel Medicine (NZSTM) would like to thank the MCC for the opportunity to comment on the Agenda for the 69th meeting of the MCC to be held in October 2022.

The NZSTM is an incorporated society first formed in 1996. Our current membership of 1,482 is comprised of doctors and nurses with a small number of pharmacists. Our kaupapa is to support the provision of excellence in travel medicine in New Zealand and to provide educational support to health care professionals involved with the provision of travel medicine in New Zealand.

Submission
The NZSTM wishes to comment on Agenda item 6.1e *National Immunisation Schedule – proposed change to prescription vaccine classification statements*. This submission from the Ministry of Health proposes to widen the classification of 31 vaccines to allow vaccinators who have successfully completed the Vaccinator Foundation Course (or equivalent course) approved by the Ministry of Health and who comply with the immunisation standards of the Ministry of Health to both distribute and administer these vaccines; excluding COVID-19 Vaccinators Working Under Supervision, Provisional Vaccinators, Provisional Pharmacist Vaccinators, and Vaccinating Health Workers.

General Comments
The Society wishes to confine comments to the 6 vaccines on the submitted list whose main/sole indication is for international travel, i.e. Cholera, Hepatitis A, Japanese encephalitis, Rabies, Typhoid, and Yellow fever vaccines.

Travel medicine is a dynamic and specialised field and delivery of pretravel services requires adequate time, expertise, and resources to deliver the appropriate standard of care. The Society's view is that regardless of whether a doctor, nurse practitioner, nurse, or pharmacist delivers travel vaccines, administration should be:

- Within the context of a comprehensive pretravel consultation.
- By a healthcare professional suitably trained and up to date in travel medicine.
- By a healthcare professional trained and authorised in vaccine administration.

Training
The Society acknowledges the Ministry of Health's intent to improve access to routine/funded vaccines by increasing the vaccinator pool. However, travel vaccines are not 'routine' nor funded, and recommendations for these require an individual risk assessment, which takes time and expertise. A pretravel assessment needs a dedicated consultation to determine the traveller's itinerary, risk profile and risk tolerance, and apply knowledge of the diseases and risks at the geographical destination/s to educate the individual about risk avoidance (including for the many non-vaccine preventable diseases) and recommend appropriate vaccinations and medications, for administration or supply after shared decision making. This takes a minimum of 20 minutes, with more time needed for those with long/complex itineraries or travellers recognised as high risk (i.e. pregnant women, children, those

with chronic medical conditions, immunosuppressed individuals, elderly travellers, long-term travellers, and those visiting friends and relatives).

Essential training to deliver pretravel health services, regardless of profession, should cover pretravel risk assessment, vaccine preventable diseases, non-vaccine preventable diseases, risk management advice, detailed information on travel vaccines and medications, access and use of travel medicine/health resources, and how to communicate tailored recommendations to travellers to help them make informed choices. And this training should be carried out by a trainer with a recognised qualification in travel medicine. As travel medicine is a rapidly evolving specialty with changing disease epidemiology, emerging diseases, and ongoing research, providers also need to keep up to date through appropriate continuing education activities.

The Postgraduate Certificate in Travel Medicine (PGCertTravMed) through the University of Otago, which is open to doctors, nurses, and pharmacists, provides comprehensive travel medicine training and is a nationally recognised qualification for travel health providers. Papers were first offered in 1998 and qualifications have expanded to a postgraduate certificate, diploma, and masters in travel medicine. On average one pharmacist per year has completed the PGCertTravMed over the past 12 years. Another internationally recognised qualification for travel health providers is the Certificate in Travel Health (CTH) through the International Society of Travel Medicine (ISTM). In contrast, the Vaccinator Foundation Course (VFC) was developed for vaccinators, including pharmacist vaccinators, administering vaccines from the National Immunisation Schedule (NIS) and other authorised programmes, and provides neither specific training nor information on travel medicine or travel vaccines.

Therefore, the required standards proposed by the Ministry submission for vaccinators to administer travel vaccines if these were reclassified falls well short of the training needed to deliver pretravel health services.

Comparison of Vaccine Classification/Pharmacist vaccination in Other Countries

In NZ, pharmacist vaccinators can currently supply/administer 8 vaccines (i.e. Cholera, Influenza, Tdap, Shingles, Meningococcal, MMR, HPV, and COVID-19 vaccines) with age restrictions for the Tdap, Shingles, and Meningococcal vaccines (IMAC, 2022). The Ministry submission reports on pharmacist vaccinators and the classifications status of vaccines in Australia, UK, US, and Canada to illustrate the expansion of pharmacist scope of practice in these countries. However, there is marked variation in types of vaccines, as well as procedures and oversight/support, within and among these countries.

In Australia there is considerable variation between states. Only Influenza, Tdap, MMR, and COVID-19 vaccines can be administered by a pharmacist vaccinator in all 8 states, with HPV vaccine in 2 states and Meningococcal ACWY vaccine in 4 states (NCIRS, 2022). Travel vaccines are not administered by pharmacist vaccinators, with the exception of Hepatitis A and Cholera vaccines in Queensland (and Japanese encephalitis vaccine in Victoria this year in response to the local outbreak of JE).

In the US, pharmacy practice is regulated by individual states: pharmacists in 15 jurisdictions (out of 51) can administer all routine vaccines independently and in 30 require a collaborative practice agreement (CPA) with a physician or a prescription; and pharmacists in 8 jurisdictions can administer all travel-related vaccines independently and in 36 require a CPA or prescription. Furthermore, 8 states have specific travel health training requirements, with the American Pharmacists Association reporting in 2018 that >10,000 US pharmacists had received specialised travel health training (Hurley-Kim et al, 2019).

In Canada, pharmacy practice is also regulated by individual provinces: pharmacists in 11 provinces (out of 13) can administer vaccines (authority to inject may not be inclusive of all vaccines) and are authorised to prescribe any Schedule 1 drug (including travel vaccines), with additional training, independently in Alberta and in a collaborative practice setting/agreement in 6 provinces (Canadian

Pharmacists Association, 2022). Additional training is not necessarily in travel health, but the ISTM certificate is increasingly being recognised as a requirement for prescribing authority in this area (Thidrickson & Goodyer, 2019).

In the UK, pharmacists can become independent prescribers (since 2006) or administer travel vaccines under a Patient Specific Direction (PSD) or a Patient Group Direction (PGD) (Evans, 2018). A PSD is a written instruction, signed by a prescriber, which allows the pharmacist to administer a vaccine to a named patient after the prescriber has assessed the patient on an individual basis. Whereas PGDs are written standing orders that allow the pharmacist to administer the vaccine to a pre-defined group of patients, without them seeing a prescriber. PGDs include those for NHS-funded travel vaccines (e.g. the UK Health Security Agency PGD for Typhoid vaccine[1]), online PGDs for purchase (e.g. the National Pharmacy Association has a full Travel PGD package, which includes 3.5 hours face-to-face training, and online modules, certificate and PGDs for all of the travel vaccines, except Yellow fever, plus drugs[2]), and PGDs developed by individual clinics involving a pharmacist and the prescribing doctor/nurse signing off the PGD. PGDs have greatly expanded the range of immunisation programmes in the UK but take a significant amount of time and resource to develop and implement and users need to be proficient working with them (Chiodini et al, 2020). And although UK pharmacist vaccinators do have training in travel medicine, there are inconsistencies in levels of training and training is not regulated (Evans, 2018).

In addition, the UK, US & Canada all have national travel medicine guidelines – via the National Travel Health Network and Centre (NaTHNaC) & Green Book in the UK, CDC & Yellow Book in the US, and Public Health Agency of Canada (PHAC) and Committee to Advise on Tropical Medicine and Travel (CATMAT) in Canada – plus national phone/email support for travel health providers in the UK & US. In Australia, the Australian Immunisation Handbook does cover travel vaccines and the Australasian College of Tropical Medicine (ACTM) is planning to develop travel medicine guidelines for Australian and NZ travel health providers. However, in NZ there are currently no national travel medicine guidelines – the Immunisation Handbook does not cover travel vaccines (apart from Hepatitis A) and the NZ Formulary provides only an overview of travel vaccines – nor national phone/email support for travel health providers, who rely on support from colleagues in specialised travel clinics or primary care or, if members, can post clinical queries to the ISTM mailing list.

Standards of practice

Travel health services are unregulated in most countries and provided in a range of settings including specialist travel clinics, primary care, pharmacies, and other occupational healthcare and military settings. However, in many countries inconsistencies have been noted in the standards of training, competency, and auditing by the various regulatory bodies of the different healthcare professionals involved. Increasingly it has therefore been recognised there is a need for a framework to define minimum standards of practice in this area.

In 2020, such a framework was published by the Faculty of Travel Medicine of the Royal College of Physicians and Surgeons of Glasgow (Chiodini et al, 2020). This details standards of practice and training in travel medicine and can be used to identify a travel health provider's current level of practice and further requirements to support their continuing professional development. Recently Travel Health Nurses of Australia and New Zealand (THNANZ) also developed a competency framework, adapted from Royal College of Nursing competencies, to guide the training and upskilling of nurses who wish to work in travel medicine (THNANZ, 2021). This has been endorsed by the ACTM and NZSTM.

[1] See https://www.england.nhs.uk/london/wp-content/uploads/sites/8/2022/02/NHSEI-UKHSA-Typhoid-PGD-v0300.pdf

[2] See https://www.npa.co.uk/travel-and-vaccination-pgds/

The Society believes a similar guidance/framework defining minimum standards for any provider of travel health services needs to be in place before consideration of regulatory change to the classification of travel vaccines.

Yellow fever vaccine

The proposed submission to reclassify the Yellow fever (YF) vaccine does not comply with the WHO International Health Regulations (IHR) regarding YF vaccination and certification (WHO, 2016) and the Ministry's own YF Policy under the IHR, which regulates YF vaccinators and YF vaccination centres in NZ (MoH, 2017). This policy dictates the training and experience required for YF vaccinator authorisation and conditions of YF vaccinating centres. Stipulations include:

- A YF vaccinator must be a NZ registered medical practitioner or nurse practitioner with general scope of practice, or nurse with postgraduate experience in travel health and currently working in travel health.
- Initial YF authorisation requires evidence of an approved postgraduate qualification in travel medicine.
- Renewal of YF authorisation requires evidence of a log (vaccinations and exemptions), required hours of CME (general & YF specific), and active engagement of approved international surveillance sources.
- All YF vaccinators are only able to be fully authorised if they are operating from an authorised YF vaccinating centre, and vice versa.
- Only YF vaccination centres with one or more YF vaccinators may order YF vaccine from a supplier.

Similar national requirements for YF vaccinators and YF vaccinating centres exist in Australia and the UK, and vaccinators in general practice and pharmacy are not authorised to administer YF vaccine in either country.

Other Considerations

In recent years there have been global shortages of travel vaccines, including Hepatitis A, Typhoid, Rabies and Yellow fever vaccines. And currently in NZ there is no Japanese encephalitis (JE) vaccine or oral Typhoid vaccine and no estimated dates of supply. Thus, if travel vaccines were reclassified from prescription only this is likely to lead to spread of supply, which is already often limited, across a wide range of providers and not necessarily improve access to those who most need them.

Off-label indications and/or route of administration are more commonly used with travel vaccines than routine vaccines. The Ministry submission does not address off-label use nor different routes of administration, but this particularly applies to JE and Rabies vaccines. Off-label use of these vaccines improves availability +/- reduces cost (which can be considerable) to the traveller, with use by NZ practitioners based on overseas evidence and guidelines. JE vaccine is licensed in NZ for those ≥ 18 years on a D0 & 28 schedule, but can be given off-label to children ≥ 2 months of age and for adults by accelerated schedule (D0 & 7) if travel is imminent. Similarly, the Rabies vaccine is commonly given off-label in specialised clinics and in some primary care practices by intradermal (ID) administration, which requires specific training. This significantly reduces cost to the traveller, especially families, and improves availability as multiple doses can be given from an equivalent IM dose. The current IM schedule recommended in the NZ Formulary is also an unapproved schedule and so could not be used by vaccinators in the Ministry submission if Rabies vaccine was reclassified, which is likely to create confusion among both vaccinators and travellers. Furthermore, vaccine recommendations for rabies are complex (regarding number of doses, ID or IM, and possible need for serology and/or boosters), and require a good understanding of the options, as well as thorough education of the traveller about animal avoidance and the difference and importance of pre- and post-exposure prophylaxis.

The oral travel vaccine for Cholera/ETEC (trade name Dukoral) was reclassified by the MCC in 2011. This was after a submission by Pharmacy Brands Limited for the vaccine to be reclassified as a pharmacist only medicine to increase access, particularly for foreign aid workers and others intending to visit or spend an extended period of time in areas in which cholera infection is a risk (MCC, 2019).

The Society's view is that Dukoral has specific, limited indications, as the risk of cholera in the vast majority of travellers is very low and there is evidence of poor efficacy against ETEC. Anecdotally however it is supplied inappropriately in pharmacy (and general practice) to holiday travellers on short trips, in some cases instead of the recommended advice on food and water precautions. This illustrates that without proper, ongoing controls, pecuniary interests and insufficient knowledge can override recommended use. And the further liberalisation of classification being sought for this vaccine will likely only make this situation worse.

Issues with National Immunisation Register (NIR) recording and sharing of information between pharmacist vaccinators and practices have been reported when other vaccines (such as the HPV vaccine) were reclassified, resulting in duplication or omission of vaccines. The Society understands the new Aotearoa Immunisation Register (AIR) will include travel vaccines but the rollout of this is not due to start until November. It would seem prudent to have this new system up and running well, before any consideration is given to increasing the number of vaccines to be recorded by a wider range of vaccinators.

Pharmacists solely administering travel vaccines will also further fragment travel health care. As many travellers require prescription medicines (e.g., antimalarial, antibiotic, acetazolamide, as indicated), which would necessitate seeing another provider and is therefore not actually improving access. Such doubling up of consult costs also risks travel medicine being viewed by the travelling public in a less than positive light. Other potential issues include pharmacists having difficulty maintaining competency as giving the various vaccines on an infrequent basis, and not having the knowledge to recognise when to refer high-risk travellers to more experienced providers to cover their additional health needs. Members themselves have commented that they had little idea how much they didn't know until they did specific travel medicine training.

Finally, members have raised concerns about the vaccinating standards of some pharmacists, which have been reinforced with the national COVID-19 immunisation programme. Reports have included patients frequently being allowed to leave very soon after a vaccine was administered; inability to deal with adverse reactions, including anaphylaxis (with nearby medical clinics being called upon to urgently manage); power failures with no cold chain failure policy/alternative storage in place; and the vaccination event being seen as an opportunity for 'companion sales' of unnecessary or unsubstantiated products. These instances have resulted in some loss of confidence that the pharmacy sector is adhering to the required immunisation standards expected of all vaccinators. And fears the situation will only worsen if pharmacists are allowed to administer travel vaccines without appropriate training, competency and audit processes in place.

Summary

The Society acknowledges and supports measures by the Ministry of Health to increase the vaccinator pool to improve coverage and inequities in access to scheduled vaccines (and control local outbreaks). However, there is no data to suggest that access to travel vaccines in NZ is an equity issue; these are not funded, travel for most is by choice, and a traveller's decision to get vaccines (even if indicated and available) is often influenced by their budget.

Furthermore, the Ministry submission appears to have taken the view that all vaccines are the same and can be approached in the same manner. This is simplistic and does not recognise that travel health involves much more than vaccines. Administration of these needs to be within the context of a comprehensive pretravel consultation by a healthcare professional suitably trained and current in travel medicine. Opening up administration of travel vaccines as proposed will therefore not improve travel health services, as the proposal puts emphasis purely on vaccination. And a basic 'jab and charge' service is not sufficient to meet the health needs of travellers. This proposal would also put significant pressure on nurses and pharmacists, with no/little travel medicine training or support, to administer travel vaccines in practices/pharmacies that see these vaccines solely as another source of income, especially if travel medicine training and competency are not mandated.

As the world recovers from the COVID-19 pandemic, return of travel will see the need for pretravel care return and rise. So NZ is in an ideal position to learn from the experience of providers overseas and recognise the importance of setting standards around provision of travel health services, regardless of which professional group delivers the care. For that reason, regarding travel vaccines, the Ministry submission represents a huge step backwards and we believe has significant potential for harm.

Therefore the Society is strongly opposed to the reclassification of travel vaccines proposed and considers this should not be contemplated without thorough consultation and before an adequate framework (of competencies, policies, and resources) is in place, in order to safeguard both travellers and vaccinators.

Nāku noa, nā

Dr Robert Bester
President
NZSTM

On behalf of the NZSTM Committee:
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References:

Immunisation Advisory Centre (IMAC). Pharmacists: community pharmacist vaccination. September 2022. Available at: https://www.immune.org.nz/pharmacists

National Centre for Immunisation Research and Surveillance (NCIRS). Vaccination from community pharmacy – at a glance. 26 July 2022. Available at: https://www.ncirs.org.au/fact-sheets-faqs/vaccines-from-community-pharmacy

Hurley-Kim K, Goad J, Seed S & Hess KM. Pharmacy-based travel health services in the United States. Pharmacy 2019;7(1): 5. https://doi.org/10.3390/pharmacy7010005

Canadian Pharmacists Association. Pharmacists' scope of practice in Canada. Feb 2022. Available at: https://www.pharmacists.ca/advocacy/scope-of-practice/

Thidrickson D & Goodyer L. Pharmacy travel health services in Canada: experience of early adopters. Pharmacy 2019, 7(2): 42. https://doi.org/10.3390/pharmacy7020042

Evans, D. Impact of pharmacy-based travel medicine with the evolution of pharmacy practice in the UK. Pharmacy 2018;6(3),64. https://doi.org/10.3390/pharmacy6030064

Chiodini JH, Taylor F, Geary K, et al. Good Practice Guidance for Providing a Travel Health Service. Faculty of Travel Medicine of the Royal College of Physicians and Surgeons of Glasgow; 2020. Available at: https://rcpsg.ac.uk/travel-medicine/good-practice-guidance-for-providing-a-travel-health-service

Travel Health Nurses of Australia and New Zealand (THNANZ). The Competency Framework for Travel Health Nurses of Australia and New Zealand. 2021
Available at: https://www.tropmed.org/wp-content/uploads/2021/12/The-Competency-Framework-for-Travel-Health-Nurses-of-Australia-and-New-Zealand.pdf

World Health Organization. International Health Regulations (2005), 3rd edition. Geneva, Switzerland: World Health Organization, 2016. Available at:
https://www.who.int/publications/i/item/9789241580496

Ministry of Health. Policy for the Authorisation of Yellow Fever Vaccinators and Vaccination Centres in New Zealand. Aug 2017. Available at:
https://www.health.govt.nz/system/files/documents/pages/policy-for-yellow-fever-authorisations-aug-2017.pdf

Medicines Classification Committee (MCC). Reclassifications of vaccines. Medsafe. 26 July 2019. Available at: https://www.medsafe.govt.nz/profs/class/ReclassificationOfVaccines.asp

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Medicines Classification Committee, Medsafe

It is with regret and some ire that I learnt the Medicines Classification Committee of Medsafe is considering relaxing rules around various vaccinations so that these can be given by anyone trained in vaccinating.

The vaccines to be added to this Reclassification are those that are used as part of a Travel Medicine consultation—> Hepatits A, Typhoid, Rabies, Japanese Encephalitis Virus, Yellow Fever

(That these vaccines MAY/MAY NOT be used at the end of the consultation is another matter.)

This is an issue that will affect all doctors and medical centres that provide Travel Medicine services.

With this idea and proposed Reclassification the Committee is proposing to reduce, and, thus decry the value of a full Travel Consultation by reducing this consultation to be nothing but Vaccinations.

(The Reclassification should also consider that these vaccines are not subsidised and each person who gets them has to pay. Thus the relaxation of such rules is not going to make any difference the Health Bill overall.)

A Travel Consultation is more than vaccines.

All doctors who offer Travel related consultations have to train in Travel and Migrant Health and be well versed in Migrant Health.

The medical centres they work in have to be fully certified Vaccination Centres maintaining ongoing Cold Chain Processes and be staffed with trained vaccinators.

And all Doctors who offer Travel Medicine in this setting must stay up-to-date with the latest developments in old and new emerging diseases/zoonoses.

They have to be aware of any Health Department notifications of any disease that may be of concern to the general medical health of the community in New Zealand and be aware of WHO directives that are issued regularly under the International Health Regulations. These regulations were signed by 96 countries, New Zealand being one of them, and are legally binding.

Under the IHR the Medical Centre and the Doctors working in these have to be certified as International Vaccinators. Each Doctor must maintain Medical Professional Standards and rectify every three years to maintain their vaccinator status. The medical centres also have to be certified.

Each medical centre that provides vaccinations must also maintain certified procedures for dealing with medical emergencies arising from any reaction to ANY vaccine that may occur. Thus each centre must also have medical staff trained to act on these emergencies with clear certified protocols and procedures.

I work as a vocationally trained General Practitioner with a sub-speciality in Travel Health.

To maintain our Travel Health certification I spend at least 5 hours per week on scouring health sites, WHO, CDC and Health Ministry sites to keep up-to-date with the latest health/disease notifications emerging overseas that may affect New Zealand through travel and returned travellers.

I have to consider giving the latest information I can on Hepatitis A, Typhoid, JEV, Rabies and Yellow fever diseases and any vaccinations that may be required.

Under the IHR I have to keep abreast of issues related with Yellow Fever—travellers going to Yellow Fever endemic countries.

Under the IHR I have to provide the latest information on Yellow Fever to anyone going to endemic countries or travelling through them.

My consultation with travellors may last 45-60 minutes and MAY end with vaccinations.

A general health check is done to ensure that any existing diseases and medications do not cause any conflict with any vaccinations that may be needed

Under the IHR the WHO can declare any disease to be a Public Health Emergency of International Concern (PHEIC) thus ensuring heightened awareness of these diseases and how they may affect New Zealand.

In 2014 the WHO declared Polio as a PHEIC and required vaccinations be given to travellors going to affected countries. This meant I had to learn of the countries that required an IHR certificate for Polio for these countries. We are now awaiting the outcome of Polio vaccine requirements in the USA and the UK and other countries.

Currently the World is under a pandemic PHEIC for SARS CoV19.

There is a PHEIC for Monkeypox.

The Polio PHEIC has not yet been lifted.

There is the underlying threat of Measles spreading again due to the poor uptake of vaccinations under Pandemic restrictions.

There is currently a vaccine resistant Ebola outbreak in northern Uganda and southern South Sudan and the Northeastern corner of the Democratic Republic of Congo.

I understand that a vaccination can be given by anyone trained in giving injections.

I also understand the need to expand childhood vaccination in the community due to poor uptake during the pandemic.

The point of my discontent is not this.

But by relaxing rules around the vaccines that may be used for travellers you are going to erase any Medical Centres and Doctors who have specialised as Travel Medicine centres for minimal gain.

Who will take time out to talk the traveller about his/her specific needs, allergies, existing conditions, immune statuses and a history of previously taken vaccinations and needs for any boosters?

This decision threatens the safety and health of the community in New Zealand.

I would beg you not to consider these travel medications in your deliberations for short term gains and long term pain.

I write this with the support of my colleague Dr Megan Corbett and also all the doctors working in CityMed medical centre in Auckland.

Sincerely on behalf of,

Dr Ravi Sandhu MBChB, PG cert in Travel Medicine an Migrant Health,

Dr Megan Corbett, MBChB, FRNZCGP, PG Cert in Travel Med and Migrant Health

.

Submission on agenda item 6.1e

National Immunisation Schedule - proposed change to prescription vaccine classification statements (Ministry of Health)

Having the schedule vaccines on here is a good idea. Including the non-schedule vaccines on this list is not a good thing at all . Whose bright idea was this? I have lived and worked in countries where pharmacies etc are able to provide travel vaccines e.g. Yellow fever, Japanese encephalitis, Rabies. It has led to indiscriminate use of vaccines that are not always indicated either through lack of knowledge or rampant profiteering where patients are commonly charged for vaccines that are not indicated.
I became a healthcare professional to try and improve outcomes for patients and it saddens my soul to see such a retrograde step

SUBMISSION on 6.1e National Immunisation Schedule

Thank you for the opportunity to provide a submission on **6.1e National Immunisation Schedule - proposed change to prescription vaccine classification statements from the Ministry of Health.**

ABOUT WORLDWISE GEOMED TRAVELLERS HEALTH CENTRES OF NEW ZEALAND

WORLDWISE is the only Travel Health Medical Assessment and Advisory Service Group in New Zealand. We have been active in our work for 27 years. We are a group of 9 either 'stand-alone' or 'General Practice related' primary health centres. The focus of our work in pre-travel advice and resultant vaccinations, intra-travel service advice and post-travel assessment of lesions contracted from travelling abroad.

I am **Professor Marc Shaw, Medical Director WORLDWISE GEOMED New Zealand**. I have 30 years' experience in Travel and its associated Tropical medicine. I have post-graduate qualifications in both Public Health and Travel Medicine.

My Co-Colleague is **Dr Robert Bester, Medical Director of WORLDWISE INVERCARGILL.** Practicing in Travel Medicine and recently graduated in Tropical Medicine, for at least 10 years.

Each of the clinicians at our clinics are either trained to a post-graduate level in Travel and/or Tropical Medicine, or receive on-site continuous training in travellers' medicine, health and vaccinations issues.

Our group would conservatively see, assessment, review, manage and then vaccinate (if appropriate) about 15-20,000 intending travellers throughout the country every year. *This would be pre-COVID.*

FEEDBACK ON THE PROPOSED CHANGES

My colleagues and I do not support the projected changes by the Ministry of Health, under the current proposal. In our opinion, this proposal has been naively developed and ill-thought through and needs significantly more development and understanding of the greater aspects of the roles 'Travel Health Practitioner' (THP) and 'Vaccinator'.

As we understand it from the Ministry of Health proposing to widen the classification for a number of vaccines to allow vaccinators who have successfully completed the Vaccinator Foundation Course (or equivalent course) approved by the Ministry of Health and who comply with the immunisation standards of the Ministry of Health to both distribute and administer vaccines.

Vaccines to be included in the submission include those Travel Medicine Practitioners' use to prevent **Cholera, Diphtheria, Japanese encephalitis, Rabies, Typhoid vaccine both oral and parental, Tuberculosis vaccine, Vaccinia virus vaccine, Yellow Fever and Hepatitis A**

That there has been a recognised inadequacy and inequity in access and administration of scheduled childhood vaccinations and thus a need to increase the vaccinator pool to increase access to these vaccines is a given. New Zealand has experienced this phenomenon during the ongoing COVID pandemic. At a time when i) there were huge numbers of persons to vaccinate in the prevention of COVID and ii) declining immunisation rates, this was an important Public Health initiative that had widespread governmental and public support.

However, the administration of travel vaccinations or immunisations during the time of the Covid pandemic was almost universally undertaken throughout New Zealand by WORLDWISE Travellers Health Centres (WORLDWISE GEOMED) as the only surviving group of travel health professionals in the country. There was indeed no evidence of inadequacy and inequity in access to travel vaccinations and their obligatory support of information on related travel health preventative measures to support a need for travel-health vaccinations to be incorporated in the proposal, viz:

6.1e National Immunisation Schedule - proposed change to prescription vaccine classification statements (Ministry of Health)
This submission from the Ministry of Health proposing to widen the classification for a number of vaccines to allow vaccinators who have successfully completed the Vaccinator Foundation Course (or equivalent course) approved by the Ministry of Health and who comply with the immunisation standards of the Ministry of Health to both distribute and administer vaccines. COVID-19 Vaccinators Working Under Supervision, Provisional Vaccinators, Provisional Pharmacist Vaccinators, and Vaccinating Health Workers are excluded from this submission.

For those working within our group, vaccinations are tool of our job not a raison d'etre. Appropriate vaccinations for travel are the end-point of a travel health checklist consultation that lasts anything from 20 to 90 minutes.

Vaccinations for travel are different from scheduled childhood vaccinations.

- They are not funded by the Ministry of Health (although Hepatitis A could be during an outbreak)
- They are not part of the immuisation schedule,
- The context in which they are given is completely different.

- They historically have side-effects that require vigilance, and maintenance in their management, by travel health professionals
- The requirement for skill and knowledge around this context is vastly different

THE CONTEXT OF A TRAVEL VACCINATION:

The act of vaccinating a traveller is the endpoint of a consultation process that requires an understanding the traveller's past medical history, prior travel experience, prior vaccinations (including routine vaccinations), duration and mode of intended travel, destinations to be visited and intended activities. As mentioned, this process in consultation time takes a minimum of 20 minutes and often anything over an hour, as questions and answers are parried. Often there are repeat consultations about vaccines and about their effects post-vaccination. Academic papers on the role of the THP indicate both the extent of the role of the THP and the value of advice of the THP.

To undertake the role of THP requires a significant understanding of the epidemiology of diseases (vaccine preventable and non-vaccine preventable), outbreak information, and usually an understanding of the some of the geography and current history for the intended destination. As vaccine preventable diseases make up only a very small part of a traveller's risk, the traveller needs to be educated about the other risks, such as food and water precautions, vector-borne disease (Dengue, Zika, Malaria), travellers' safety and security including activity based risks (e.g. mountaineering, altitude travel, cycling, waterbased activities etc), global health and air quality, and the need for medical insurance. A skilled evaluation of the traveller's risks, their risk tolerance, and the need for any vaccination (if required) together with the prioritisation of costs of vaccination needs to be made in conjunction with the traveller.

Not all travellers that attend our clinics with a list of what they feel that they need are advised to have vaccinations, if this is not indicated with evidence-based data for their need. In addition, those not vaccinated will have been educated about risks and risk reduction measures for their intended travel. To simply arrive at a centre that solely performs vaccinations without any of the pre-vaccination consultation, as outlined, would be a purely naive and unjustified approach to preserving the health of our fellow countrymen and women travelling abroad. Thus, the actual role of vaccinations in the overall risk reduction is small. Most THPs would also consider the impact of travel on host countries and communities and, with a need for eco-consideration they would give additional advice on responsible travel. Certainly, that is the brief of the WORLDWISE GEOMED Group. Indeed THAT is the point of having a group, such as ours, practising this specialisation in medicine – to preserve local and international standards of travel healthcare.

TRAVEL HEALTH EDUCATION AND RAISING STANDARDS:

In the specialisation of those who choose to do Travel and Geographical Medicine, there have been huge steps from both international and local organisations to improve and maintain the standards of delivery in Travel Medicine. These have been acknowledged by the NZ Ministry of Health (MOH).

In Australia and New Zealand there has been a concerted effort to raise standards through the :

- Academic Qualifications
    - James Cook University in Townsville, Australia. The regions oldest Travel Health institution for 30 years. Prof Shaw has a Doctorate in Public Health and Trop Med from this University
    - University of Otago with Certificates, Diplomas and Masters qualifications in Travel Medicine
    - London School of Hygiene and Tropical Medicine. Dr Bester has qualified recently from this institution.
- Professional Qualifications
    - Australasian College of Tropical Medicine (ACTM)
    - New Zealand Society of Travel Medicine (NZSTM)
- Ongoing professional education
    - WORLDWISE travel medicine courses and seminars
    - Lectures and evidence based travel medical courses run Australiasian College of Tropical Medicine, and Asia Pacific Travel Health Society.
- Writing appropriate articles in New Zealand Doctor, some of which are reprinted in Pharmacy Today
- The development of Nurse Competencies in Travel Medicine by the NZSTM, and in both Australia and New Zealand by ACTM. These measures have been taken up buy the NZ MOH.

Such focused activity has enabled NZ academics (doctors and nurses) hold prominent positions in international organisations that promote Travel Medicine as a speciality, all with the common cause of improving standards of care, e.g. the International Society of Travel Medicine.

Whilst the education that this confluence of organisations produces is aimed at doctors, nurses, nurse practitioners and pharmacists, and more latterly to paramedics, ultimately it is primed to increase public awareness that travel health is not just about 'vaccinations and malaria'.

It will be obvious from our discussion that we are trying to convey the fact that considerable efforts are going into improving the knowledge, experience and standards in travel medicine, noting that the tool of vaccination at the end of a travel health consultation is a very small part of the pre-travel health advice experience.

This proposal to open vaccination for Cholera vaccine, Diphtheria, tetanus and pertussis (acellular, component) vaccine (Tdap), Diphtheria toxoid, Diphtheria vaccine, Haemophilus influenzae vaccine, Hepatitis A vaccine, Hepatitis B vaccine, Human papillomavirus vaccine (HPV), Influenza vaccine, Japanese encephalitis vaccine, Measles vaccine, Meningococcal vaccine, Mumps vaccine, Pertussis (whooping cough) vaccine, Pneumococcal vaccine, Poliomyelitis vaccine (polio), Rabies vaccine, Recombinant varicella zoster virus glycoprotein E antigen, Rotavirus vaccine, Rubella vaccine, Staphylococcus aureus vaccine, Streptococcus beta-haemolyticus vaccine, Tetanus toxoid, Tetanus vaccine, Triple antigen vaccine, Tuberculosis vaccine, Typhoid vaccine, Vaccinia virus vaccine, Varicella vaccine and Yellow fever vaccine is incomprehensible given the discission above.

More particularly vaccinating **Cholera, Diphtheria, Japanese encephalitis, Rabies, Typhoid vaccine both oral and parental, Tuberculosis vaccine, Vaccinia virus vaccine, Yellow Fever and Hepatitis A** without any requirement for a comprehensive travel consultation by a person skilled and trained in Travel Medicine undermines would be a huge mistake given the potential for adverse risks with uncounselled administration for each of these particular vaccines.

All the previous work done to raise standards, including the Ministry's own work to set standards of accreditation for administration of Yellow Fever vacination (which ironically requires training in Travel Medicine and Health, Yellow Fever specific training, and evidence of ongoing CME in standards of yellow fever and travel health academia). This spurious proposal also feeds into the erroneous narrative that Travel Health is only about the vaccination.

NUANCES OF TRAVEL VACCINATIONS THAT REQUIRE SPECIFIC KNOWLEDGE

Travel vaccinations demand more knowledge than many other vaccines – due to their need for storage, an understanding of their adverse reactions, the fact that some are live vaccines with the urgent need to often be given together, and because many are often given over a short interval in time. This requires understanding the evidence, safety and need for informed consent and shared decision making. This is a very different scenario from routine childhood vaccinations. For example:

- **Rabies vaccination is only licensed in NZ as a 3-dose intramuscular vaccination on days 0, 7, and 21 or 28. Yet it is most often given off label with informed consent by intradermal route, and with different schedules**. This is based on changing evidence of the immunopotency of the vaccine. Rabies vaccination also needs to come with education about animal avoidance, managing bites, and accessing post exposure prophylaxis after a bite. This education is even more important for those who have chosen *not* to have the vaccination and this information can only be imparted if a consultation has taken place.
- There are **specific vaccine peculiarities for all vaccines that the Travel Health Practitioner is aware of –** e.g. Typhoid intramuscular vaccination is only 70-75% effective, does not cover paratyphoid, and become less effective with the greater number of doses given, requiring switching to an oral vaccine.
- **Yellow Fever vaccination and NZ's Yellow Fever Policy is regulated by the International Health Regulations set out by the World Health Organisation. As mentioned, the Ministry of Health requires certification for Yellow Fever Vaccinators and Vaccinating Centres and has set a bar much higher than most developed nations for Travel Health education and ongoing education, and record keeping.** This is because of the potential serious consequences of the vaccine being given inappropriately and to comply with WHO regulation. A Yellow Fever Vaccination Certificate has to be issued, in a very specific format according to World Health Organization WHO criteria, otherwise it becomes invalid and the traveller can be denied entry to the specific country.
- Travel vaccines are not always available due to supply issues. This has recently often applied to all the travel vaccines and currently to Japanese Encephalitis and Dukoral (oral Cholera). **The fact that a vaccine is unavailable should not prevent the traveller from education about the disease, risk reduction and disease recognition and magement**. A traveller attending those who vaccine, to be told of its unavailability, may infer less of a risk at an intended destination.
- **Different brands of travel vaccines for the same disease have different licensing and administration recommendations** including vaccination interval or younger age of vaccination. This applies to Japanese encephalitis, Hepatitis B, and rabies vaccination. The use of these vaccinations requires often extra-ordinary explanation and consent.
- **Rapid schedules of vaccinations are frequently given to last minute travellers.** This is unapproved but evidence based, and requires informed consent. **Examples are Rabies, yellow fever, Japanese encephalitis and combined Hepatitis A and B vaccines.**

THERE ARE A NUMBER OF CONCERNS ABOUT HOW THIS PROPOSAL WAS PUT FORWARD THAT NEED EXPLANATION:

1. *The way in which we have found out about the possibility – poor process*
    a. The Ministry could have done its own research to improve its understanding of the issue before making a proposal for a change. This whole process has been apparently unashamedly hurried. It is likely that an assumption was made that all vaccinations are the same and if access to scheduled funded vaccines should be improved, the same would apply to unfunded travel vaccinations.

b. Process could be improved by engagement and consultation with NZ based leaders and organisations in Travel Medicine such as Prof Marc Shaw (Prof James Cook University), Dr Jenny Visser (senior lecturer at University of Otago), and the New Zealand Society of Travel Medicine.

2. *The speed at which submissions are being called for consideration – poor process*
    a. A philosophy of consultation would be preferable to one of imposing policy. It appears this is being pushed through either because nobody thought to consult, a decision was made not to consult, or pressure was being exerted for a hasty decision with a predetermined outcome.
    b. It can be argued that this was notified on the Ministry/Pharmac website, however, it would be naïve to think that these websites are on everyone's routine reading lists *in case* something relevant is posted.
    c. The process has resulted in suspicion and distrust of the Ministry. This should have been done together rather than covertly, thus building bridges and collaboration. In our view, this entire process needs to be put on hold and engage with the Travel Health leaders and educators.
3. *The Recognition that travel medicine is much more than just vaccinations – knowledge deficit*
    a. Travel medicine is a speciality however many health professionals and vaccinators are unaware of this and of what the 'don't know that they do not know'. There are many General Practitioners, and Nurses or Nurse Practitioners who prescribe travel vaccinations without a thorough travel consultation. This is why education is important and why there have been strenuous efforts to increase knowledge. Interest in conferences, education and feedback on Travel Medicine related articles suggest real progress is being made.
4. *The potential to totally undermine the speciality of travellers' health advising, ministering and managing in this country. It would potentially be the end of our specialisation here in New Zealand. A specialisation that we have locally developed slowly but surely over 30 years. We now have significant trust amongst our colleagues and we have developed significant global alliances – knowledge deficit*
    a. In reviewing travel vaccinations, the Ministry is well positioned to highlight the need for travellers' vacinations to be given in the context of excellence in travel medicine understanding and experience. Alternatively, the Ministry can undermine efforts to raise the standard, and such a proposed initiative would do this, thus in the process undermine the speciality of Travel Medicine in New Zealand. It is sincerely hoped the former approach would be taken.
    b. Rather than trying to include, or exclude certain vaccinator groups in the administration of travel vaccines and create dissent amongst providers, the Ministry are urged to consider, develop and require core competencies and standards for all groups influenced in this proposal. Further the MOH is urged to negotiate appropriately to this end.

Travellers presenting to a vaccinator to have their travel health vaccinations, often come with a list of what they think they should have, what they want or what someone told them they need for their intending travel. Invariably, from our experience, these folk have little knowledge of the true risk of their travel in relation to other diseases that may be communicable or non-communicable. The vaccinator cannot be expected to display assuring knowledge to those that they vaccinate as they are not trained in this level of specialisation.

The value of the vaccinator lies in the ability to work under the tutelage of the THP. This should have been the considered process at all stages in this proposal.

We remain optimistic that a full understanding of the issues relating to both Travel health Professional (THP) and vaccinator will adequately convey the need for a differentiation of the role of vaccinator from that of THP and why there is an ongoing need to ensure travellers health vaccinations are underlined as part of an essential specialisation for New Zealanders going abroad now and well into the future.

The Ministry of Health has a responsibility to ensure appropriate standards. In order to do this, appropriate understanding and acknowledgement of the work of those in the specialisation needs to be fully understood. This has not been so in this instance.

'**It is the job of a Travel Health Professional to guide the knowledge that contributes to good judgement acquired by our traveller with respect to their travel.'.** That is why we both, in representing our Group, are doing this job that we love.

Yours sincerely

Marc Shaw *DrPH, FRNZCGP, FRGS, FISTM, FACTM, FFTM (ACTM), FFTM RCPS (Glas), DipTravMed*
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WORLDWISE EDU
Information, Education, Academic Travel Medicine Courses

GeoSentinel WORLDWISE
WORLDWISE clinics in New Zealand are 1 of 70 globally dispersed GeoSentinel sites for surveillance and monitoring of all travel related illnesses
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(Although I am also president of the NZSTM, my submission in that capacity is being lodged directly by the NZSTM Committee)
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REFERENCES:

1. Shaw MTM. Proposing continuing medical education for the Pacific. Pacific Health Dialog. *Journal of Community Health and Clinical Medicine for the Pacific* 2000, 7(2): 86-87
2. Shaw M, Leggat PA. Traveling to Australia for the Sydney 2000 Olympic and Paralympic Games. *Journal of Travel Medicine*. 2000;7:200-204.
3. Shaw MTM. Internet Feature: Travel Medicine. *New Ethicals Journal*. 2001; 4: 1 Special Feature, 33-35
4. Leggat PA, Shaw MTM. Travel health advice for backpackers. *Journal of Travel Medicine*. 2004; 10 (6): 340-345
5. *S*haw MTM, Dallimore J. The medical preparation of expeditions: the role of the Medical Officer. *Travel Medicine and Infectious Disease (2005) 3, 213–223*
6. Shaw MTM. Running a Travel Clinic. *Travel Medicine and Infectious Disease (2006) 4, 109–126*

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3 October 2022

Medicines Classification Committee (MCC)
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I wish to comment on the Agenda for 69th Meeting of the MCC, in particular to item 6.1e *National Immunisation Schedule – proposed change to prescription vaccine classification statements.* I am grateful for the opportunity to comment.

My objection to item 6.1e the above agenda item is made in my personal capacity as medical director of Bester McKay Family Doctors Ltd and Worldwise Travellers Health and Vaccination Centre (Invercargill). I wish to disclose that I have also signed a comment in my capacity as president of the New Zealand Society of Travel Medicine which represents all its members, and in conjunction with Professor Marc Shaw on behalf of Worldwise Geographic Medicine which represents its members.

Bester McKay Family Doctors Ltd is a General Practice established in 1990, since when travel medicine has been part of its practice. Having established knowledge gaps, I completed the Diploma in Travel Medicine (University of Otago) in 2006, and became a Ministry of Health Approved Yellow Fever Vaccinator and Yellow Fever Vaccinating Centre. Our team has pro tovided a specialist level travel health service the population of Southland ever since . I have continued to participate in learning, and completed the Diploma of Tropical Medicine and Hygiene (RCP, London) in 2021. I have been president of the New Zealand Society of Travel Medicine since 2019. I am an active member of the International Society of Travel Medicine.

SUBMISSION

The submission from the Ministry of Health proposes to widen the classification of 31 vaccines to allow vaccinators who have successfully completed the Vaccinator Foundation Course (or equivalent course) approved by the Ministry of Health and who comply with the immunisation standards of the Ministry of Health to both distribute and administer these vaccines; excluding COVID-19 Vaccinators Working Under Supervision, Provisional Vaccinators, Provisional Pharmacist Vaccinators, and Vaccinating Health Workers. Vaccines to be included in the submission include those to prevent Hepatitis A, Typhoid, Japanese encephalitis, Rabies, and Yellow Fever.

I wish to comment on 2 aspects of this submission:

1. Routine scheduled vaccines
2. Travel vaccines - Hepatitis A, Typhoid, Japanese encephalitis, Rabies, and Yellow Fever

1. ROUTINE SCHEDULED VACCINES

Both routine scheduled vaccines, and Covid-19 vaccines, are part of a public health strategy, which is funded by the Ministry of Health. Primary Care (General Practice) has previously been the major site of these vaccinations, where nurses have required vaccinator training, and have been closely supervised and monitored by vaccination co-ordinators to maintain standards.

COVID-19 has highlighted the inequity and inadequacy in access and administration of scheduled vaccinations and the need to increase access. Our practice appreciated the addition of vaccination capacity in pharmacies and localities set up by the Primary Health Organisations.

However, we have had ongoing concerns about the standards of vaccination in many of these locations. Our concerns have been echoed by colleagues as well as the regional Vaccination Co-ordinator, who in turn has been aware of similar concerns from other Vaccination Co-ordinators in other areas. Due to the dramatic increase in need for the co-ordinator's role and support, the co-ordinator was unable to meet the demand of support and supervision to maintain standards. Anecdotally this appears to be a widespread problem. This situation has been acceptable given the public health emergency that required the rapid training and mobilisation of vaccinators, but should not be acceptable in future planning.

While I fully support and increase in the vaccinator pool to increase access to these vaccines, all vaccinators must be provided with the same level of support, appropriate supervision, and be subject to the same safety monitoring as has previously been required of vaccinators in primary care.

2. TRAVEL VACCINES - Hepatitis A, Typhoid, Japanese encephalitis, Rabies, and Yellow Fever

These vaccines are different from vaccinations on the National Immunisation Schedule, which is why they have never been funded, or included on the Schedule. In my opinion this submission fails to acknowledge the additional assessment and consideration required in their administration and would undermine the efforts to raise the standards of Travel Medicine.

They differ from routine vaccinations in that:

- They are not funded by the Ministry of Health.
- They are not part of a public health strategy.
- New Zealand's geographic isolation, temperate climate and standard of living means that these diseases generally do not pose a risk to the public health (I acknowlege very rare occasions of Hepatitis A outbreaks from seasonal workers or imported foods).
- The context in which they are given is very different from routine vaccinations.
- They are given to individuals travelling outside of New Zealand to areas where the risk of infection exists.
- Their administration requires a higher level of knowledge and patient/traveller assessment and education than is required for routine vaccinations.

In the context of vaccinations given for international travel, it is noteworthy that infectious diseases account for 1.5-2% of deaths amongst international travellers, and of these an even smaller proportion are due to vaccine preventible diseases.[1,2,3]

Researchers have also concluded that common travel health interventions such as vaccines and antimalarial drugs would have played limited roles in terms of preserving life or preventing death in the majority of travelers' deaths abroad.[4]

Experts in Travel Medicine have also stated ".....it is essential for those providing travel health to discuss the itinerary and establish all travel health risks that need to be addressed prior to departure. Failure to do so could result in inadequate pre-travel advice, failure to appropriately vaccinate, or inappropriately vaccinate.....A failure to counsel travellers about relevant travel precautions could be considered negligent".[5]

This highlights the importance of a comprehensive travel consultation of which vaccinations are a very small part, and often the last part.

The act of vaccinating a traveller is the endpoint of a consultation process that requires an understanding of:

- the traveller's past medical history (including underlying health conditions that may be exacerbated by travel),
- prior travel experience,
- prior vaccinations (including routine vaccinations),
- details of their travel (itinerary, duration, season of travel, travel style, and mode of transport, and intended activities that increase risk).
- specific needs such as those who are pregnant, children, immunocompromised, longterm travellers, working overseas, or travellers with disabilities.
- Some destinations and activities have very specific risks such as trekking/climbing at altitude, rafting (Schistosomiasis and Leptospirosis), caving (Histoplasmosis, rabies).
- important topics include travellers' safety and security, air quality, and the need for medical insurance.
- Risk behaviours associated with injury and education around alcohol/drug use, sexual activity, water based activity, road use and
- stressing the importance of travel insurance are important.

This enables an assessment of risk, exploration of risk tolerance, and finally risk management. Many travellers decide not to be vaccinated, or to direct their budget to safety equipment to ameliorate risks greater than the vaccine preventable risks.

The very basics of a travel consultation are highlighted in many publications including Centres for Disease Control Yellow Book[6] and by organisations such as the National Travel Health Network and Centre.[7]

Travel vaccinations require a higher level of understanding of the diseases, their risks and risk prevention, vaccine interactions and variations in vaccine scheduling that is often off label and require informed consent. These requirements are substantially different from administering chilhood and scheduled vaccines.

Examples of these differences have been highlighted in other submissions, but a few examples include:

1. <u>Rabies vaccine</u>
    a. Should never be given without education about risk reduction, wound management and post exposure prophylaxis
    b. frequently given in an unlicensed but evidence based schedule that requires consent
    c. often given intradermally which requires additional skill (and numerous evidence based but unlicensed protocols such as 2-site and 2-dose)
    d. changes from 3 dose to 2 dose but needing to know the role of boosters,
    e. if/when boosters are required
    f. some anti-malarials reducing efficacy of intradermal vaccination

2. <u>Yellow fever vaccination requires</u>
    a. Authorisation from NZ Ministry of Health as a Yellow Vacinator and Yellow Fever Vaccinating Centre[8]
    b. Understanding of the correct completion of International Certificate of Vaccination or Prophylaxis (as required by World Health International Health Regulations) and the serious consequences to the traveller if this is not completely correctly
    c. Understanding of important vaccination interactions, vaccination contraindications and precautions

d. Understanding of differences between vaccination recommendation and vaccination requirements, failure of which can result in travellers being denied country access
e. Understanding disease epidemiology and distrubution and vector avoidance
f. If/when boosters are required

3. Vaccine scheduling and availability
    a. Rapid or interrupted schedules (e.g. Twinrix, Hepatitis B and Japanese encephalitis)
    b. Variation in schedules (e.g. rabies and Hepatitis B, and Dukoral/cholera scheduling with antibiotics
    c. Switching brands/schedules/routes (e.g. Hepatitis B, rabies, and changing from intradermal to intramuscular)
    d. Vaccine unavailability to complete courses and arranging overseas completion of schedules, or arranging vaccines in host country when no longer available in NZ (e.g. Japanese encephalitis)

4. Vaccine efficacy can be reduced in some circumstances, and poor to start in others
    a. Several vaccines have reduced efficacy due to smoking, obesity, recent steroids or antibiotics, immunosuppression and require serology, additional doses, or eduaitng the traveller on increased risks
    b. Typhoid (intramuscular) has only 70-75% efficacy and drops off rapidly and with repeated administration, does not reduce paratyphoid, and Typhoid (oral) has more interactions

IMPACT OF THIS SUBMISSION ON TRAVEL MEDICINE STANDARDS, KNOWLEDGE, SKILL

New Zealand has been part of the international efforts to improve the standards of travel medicine through education, qualifications, interprofessional collaboration of doctors, nurses, and pharmacists, publications on-line resources and national and international organisations (like New Zealand Society of Travel Medicine and International Society of Travel Medicine).

This submission to open vaccination for Hepatitis A, Typhoid, Japanese encephalitis, Rabies, and Yellow Fever :

- is well intentioned in the context of routine scheduled vaccinations on the National Immunisation Schedule but does not acknowledge the different reason and circumstances for administering these vaccinations.
- Does not acknowledge the context and need of a comprehensive travel consultation prior to giving these vaccines
- Undermines the strenuous efforts to raise the standards of travel medicine.
- Does not acknowledge the education and skill required in considering and given these vaccinations.
- Fuels the public and poorly informed practitioner's understanding that travel medicine is only about vaccination.
- Undermines the exisiting New Zealand Yellow Fever Policy and the International Health Regulations

CONCLUSION

Travel medicine was the preserve of doctors and some of these have followed the *vaccination only* approach to travel medicine. There is now and increased awareness of the complexity involved in travel medicine, and more doctors are now referring to doctors and nurses with travel health expertise, or increasing their own expertise. Nurses have fought hard to get acknowledgement of their role and skill in the field, and it is pleasing to see their role evolving. Internationally pharmacists play a significant role in

travel medicine, and alongside doctors and nurses contribute a wealth of knowledge and expertise. Personaly I would welcome pharmacists into the field, but would sincerely hope that this discourse recognises the opportunity to raise the standard of travel medicine and increase collaboration between doctors, nurses, nurse practitioners and pharmacists in the delivery of travel medicine, rather than undermining expertise and practice of travel medicine through merely widening access to vaccination.

Yours sincerely

Dr Robert Bester
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REFERENCES:

1. Christopher A. Redman, PhD, Alice MacLennan, RGN, Eric Walker, MB, DSc (Hon), FRCP, Causes of Death Abroad: Analysis of Data on Bodies Returned for Cremation to Scotland, *Journal of Travel Medicine*, Volume 18, Issue 2, 1 March 2011, Pages 96–101, https://doi.org/10.1111/j.1708-8305.2010.00486

2. Benjamin A Wyler, MD, MPH, DTM&H, Hannah M Young, MD, MPH, Stephen W Hargarten, MD, MPH, John D Cahill, MD, DTM&H, Risk of deaths due to injuries in travellers: a systematic review, *Journal of Travel Medicine*, Volume 29, Issue 5, July 2022, taac074, https://doi.org/10.1093/jtm/taac074

3. Ruairi Connolly, MB, Richard Prendiville, Denis Cusack, FRCPI, Gerard Flaherty, MD, Repatriation of human remains following death in international travellers, *Journal of Travel Medicine*, Volume 24, Issue 2, March/April 2017, taw082, https://doi.org/10.1093/jtm/taw082

4. Douglas W. MacPherson, MD, MSc(CTM), FRCPC, Brian D. Gushulak, MD, James Sandhu, BSc, Death and International Travel—The Canadian Experience: 1996 to 2004, *Journal of Travel Medicine*, Volume 14, Issue 2, 1 March 2007, Pages 77–84, https://doi.org/10.1111/j.1708-8305.2007.00107

5. Kennedy, Kieran M., and Gerard T. Flaherty. "Medico-legal risk, clinical negligence and the practice of travel medicine." *Journal of travel medicine* 23.5 (2016)

6. https://wwwnc.cdc.gov/travel/yellowbook/2020/preparing-international-travelers/the-pretravel-consultation

7. https://travelhealthpro.org.uk

8. https://www.health.govt.nz/our-work/diseases-and-conditions/yellow-fever

GREEN CROSS HEALTH

The Secretariat
Medicines Classification Committee
Medsafe
PO Box 5013
Wellington 6140
By e mail: committees@health.govt.nz

27 September 2022

Re: Submission for the 69th meeting of the Medicines Classification Committee

We are pleased to provide the following submission for the 69th meeting of the Medicines Classification Committee in response to the agenda items.

6.1e National Immunisation Schedule - proposed change to prescription vaccine classification statements (Ministry of Health)

We strongly support the submission made by the Ministry of Health to widen the classification of a number of vaccines to allow vaccinators who have successfully completed the Vaccinator Foundation Course (or equivalent course) approved by the Ministry of Health and who comply with the immunisation standards of the Ministry of Health to both distribute and administer vaccines.

We believe that widening the vaccine classification will further support consumer choice and reduce barriers to access created due to current limitations resulting in inconsistencies across different vaccine providers. Community Pharmacists are highly regarded by their community and as a trusted healthcare professional have been providing vaccinations since 2012. The recent pandemic response has shown that by increasing access to the Covid-19 vaccine through Community Pharmacists not only increased uptake but also allowed us to move at pace to facilitate and mobilise collaborative community focussed campaigns.

The importance of Community Pharmacists being enabled not only to have health discussions with their communities but being able to vaccinate all people of all ages at the same time has significant health benefits. We believe that widening the classification of vaccines and increasing the number of vaccines a pharmacist can administer aligns with the immunisation strategy and supports the increased role we see Community Pharmacists taking in the health of our communities. This also increases the number of vaccinators available to administer all vaccines at the frontline.

Pharmacies are open extended hours and weekends, and this again supports convenient access for our communities to be vaccinated. Pharmacies are often also located close to where people live and this further reduces barriers to accessing vaccinations. Community Pharmacists will welcome the widening of the classification and the ability to be fully engaged in public health campaigns with the ability to offer the vaccine at the same time rather than missing the opportunity to administer the vaccine if the consumer has decided to have it.

We hope you will favourably consider this submission when making your classification decision

Please do not hesitate to contact me should you require any further information or clarification.

Yours sincerely,

Alison Van Wyk

ALISON VAN WYK
Group Chief Operating Officer
Green Cross Health

Unichem Life Pharmacy

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Submission on proposed changes to vaccine classification

3 October 2022

Submission for: 69th meeting of the Medicines Classification Committee, item 6.1e

Main contact: Bernadette Heaphy, Programme Manager, IMAC, b.heaphy@auckland.ac.nz

Kia ora koutou and thank you for the opportunity to comment on Manatū Hauora's submission on the classification of vaccines.

In general, IMAC supports all work to improve and expand access to vaccination to protect New Zealanders from vaccine preventable diseases. The submission covers both vaccine and workforce issues, so we have commented on both.

IMAC is supportive of National Immunisation Schedule vaccines (excluding BCG) being reclassified as:

> *Prescription-only EXCEPT when administered by a vaccinator who has successfully completed the Vaccinator Foundation Course (or equivalent course) approved by the Ministry of Health and who is complying with the immunisation standards of the Ministry of Health, but excluding COVID-19 Vaccinators Working Under Supervision, Provisional Vaccinators, Provisional Pharmacist Vaccinators, and Vaccinating Health Workers.*

We are supportive of this for a number of reasons:

- It provides nationwide, consistency. New Zealand currently lacks a national authorisation process. This leads to local variations and inconsistencies. Vaccinators who complete the same education should have the same options around the country.
- It provides clarity. The current process is confusing as there are multiple pathways for vaccinators with the same education requirements. The current process means that vaccinators with the same education are unable to give the same range of vaccines. This creates confusion and inequities.
- It will allow for greater development of a vaccinator workforce across health professional groups.
- It should improve access to vaccination by not requiring prescriptions or standing orders when appropriate health professionals are vaccinating.

Note: that to be a vaccinator you must meet the requirements outlined in Appendix 4 of the Immunisation Handbook 2020. At this time only Registered and Enrolled Nurses and Pharmacists are consistently either being authorised or meeting the Pharmacist Vaccinator criteria. However, there are some Paramedics who have also been authorised in specific geographical areas.

IMAC supports the related workforce issues being addressed:

We ask Manatū Hauora to clarify which health care professional groups are able to become vaccinators (authorised). There are a number of allied health professionals who were able to vaccinate as part of the COVID-19 pandemic response as Provisionally Authorised Vaccinators, however at this time, they are not able to routinely become fully authorised vaccinators. This would also improve access to vaccination by expanding the vaccination workforce.

IMAC is supportive of the removal of age limits from existing classifications for vaccines:

This would allow vaccinators (who have completed an appropriate clinical assessment) to give vaccinations across the age groups to those who are eligible for the vaccine as per datasheet and/or national

immunisation schedule eg Tdap – this would reduce the complication associated with who can give which vaccines to which age group.

Workforce

Having a cohesive workforce plan to support immunisation is key to improving access to immunisation services. This may include a range of health professionals and healthcare workers. Allowing nurses, pharmacists and other vaccinators to give vaccines without the need for prescription, standing order or authorisation will increase the numbers of vaccinators who can give a range of vaccines, improving access for those who need vaccination.

At the MCC meeting on 9 July 2020 the Immunisation Team from the then Ministry of Health noted that *Classification is only part of the vaccination landscape and that they would like to move to a consistent, robust, and accessible system.* The MCC in response agreed to invite the Immunisation Team and Primary Care Team of the Ministry of Health to meet with the Committee to discuss how classification can help achieve the goals of wider access to immunisations within a clearer, more person-centric system, either at the next meeting or in an extraordinary meeting as needed to support this work. This has not occurred.

Manatū Hauora Immunisation Standards note that:

- Immunisation is not delivered in isolation, but as an integrated part of primary healthcare services, including Well Child Tamariki Ora for children.
- If possible, at the time of immunisation, the organisation undertakes other health promotion and/or disease prevention activities as applicable, such as the Well Child National Schedule or Care Plus.
- Immunisation events, childhood, and adult are well communicated to other health services linked to the individual (eg, primary health care, outreach immunisation services, pharmacies, occupational health). (A3.4 Appendix 3 of the Immunisation Handbook).

IMAC is supportive of broadening the workforce as part of an integrated plan:

Broadening the workforce in the NIS space would reduce barriers to access for the community but we believe that this needs to come as part of integrated plan.

This change of classification for a range of vaccines is not required to allow pharmacists to take a wider role in administering NIS vaccines. Currently pharmacists can apply for authorisation so they can give vaccines outside the Pharmacist Vaccinator range eg pharmacist working in outreach in Auckland are doing this with authorisation. However, this is an inconsistent approach.

The primary barrier to pharmacists giving a boarder range of vaccines, including childhood and older adult vaccines, through community pharmacy is the PHARMAC funding model.

Vaccinator Education and Clinical requirements

All vaccinator receive the same vaccinator foundation education, to become either an authorised or pharmacist vaccinator, and must meet the immunisation standards, however we have concerns about the ability of non-primary care vaccinators being able to access opportunities to gain skills and experience for vaccinating the younger age group, prior to clinical assessment. Currently for most pharmacists and non-primary care vaccinators, the first vaccines they give are given during their assessment. While less than ideal, those being vaccinated are adults and usually friends or colleagues of the vaccinator making it possible to do this. This is not, in our opinion, appropriate when it comes to vaccination of children or infants. Providing access to a clinic where a non-employee can undertake vaccination work experience is not simple and there are limited providers willing to do this or to supervise this.

We believe that where pharmacists are working with other providers (PHC, OIS or DHB) the process of support and experience is more likely to be in place. Having to then apply for authorisation should not be considered a significant issue.

IMAC supports Pharmacist Vaccinators taking on a larger role, supported by PHARMAC funding model adjustment

Having pharmacist vaccinators take a large role in offering adult NIS vaccines eg funded Tdap, funded Shingrix, funded meningococcal vaccines, funded Influenza and funded HPV would potentially help free up primary care services to deliver childhood and infant vaccines. None of these vaccines require classification change for this to occur, but they need to be included in PHARMAC's funding criteria for contractors if they are to be given in Community Pharmacy.

The vaccines

There are several vaccines in the submission which are not on the National Immunisation Schedule, that have specific requirements related to their use or are not even used in Aotearoa/New Zealand – we would recommend the following are removed and not included in the reclassification:

Vaccine	Rationale for exclusion
Diphtheria toxoid, Diphtheria vaccine, Measles vaccine, Mumps vaccine, Pertussis (whooping cough), Tetanus toxoid.	Single antigen vaccine not available in NZ.
Triple antigen vaccine.	Vaccine not available in NZ.
Vaccinia virus vaccine, Streptococcus beta-haemolytics vaccine, Staphylococcus aureus vaccine.	Not licensed or available in NZ.
Cholera vaccine, Japanese Encephalitis vaccine, Rabies, Typhoid vaccine.	Travel vaccine.
Yellow Fever.	Travel vaccine and has international regulations around who can administer.
Tuberculosis vaccine.	Has specific requirements re endorsement to give.

Having these vaccines in the list is a distraction from the equity issue we face with the childhood immunisation schedule.

IMAC supports the removal of travel vaccinations from the list for reclassification:

Travel vaccinations should be provided following a consultation that also reviews other aspects of the intended travel - health, safety and wellbeing. At this time there is not the education programme in place for vaccinators to be supported with this wider scope of vaccines. This is not to say that it can't occur in the future.

IMAC supports adding these NIS vaccines:

- Combined diphtheria-tetanus-acellular pertussis, hepatitis B, enhanced inactivated polio vaccine and Haemophilus influenzae type b powder and suspension vaccine (DTaP-IPV-HepB/Hib).

- Combined diphtheria-tetanus-acellular pertussis (DTPa) and enhanced inactivated polio vaccine (DTaP-IPV).

IMAC supports removal of age limits:

We would support the removal of age limits from existing classifications for vaccines, so that vaccinators can give across the age groups to those who are eligible for the vaccine as per datasheet and/or national immunisation schedule eg Tdap – this would reduce the complication associated with who can give what.

Other related issues

The Aotearoa Immunisation Register (referred to in the submission document as the National Immunisation Solution), is not yet functional, so providers without a National Immunisation Register linked practice management system do not have full electronic access to the immunisation records held. This will make it challenging for all non-PHC providers. It is important that immunisation practice sits within universal health care and is not separated off. Ensuring full access and read/write for all immunisation providers to AIR is key to ensuring that vaccination is linked back into primary health care.

Linking infants into primary health care must remain a focus for all immunisation providers to ensure effective health care and equitable outcomes for all.

All pharmacist vaccinators who wish to give infant/child vaccines will require a further clinical assessment vaccinating a child under the age of 2 years. Prior to this they will need an opportunity to vaccinate and work with infants/children and their families to gain confidence prior to clinical assessments. There will also need to be sufficient clinical assessors available.

There needs to be a national register of all vaccinators, so that workforce planning and information dissemination can occur systemically. If the authorisation process for RNs and ENs is removed this will become more critical as there will be no local data available from Medical Officers of Health.

Submission on behalf of Clinical Directorate Comprehensive Care PHO, Waitematā Auckland
In relation to the Ministry of Health's (MoH) proposal to widen the classification for a number of vaccines

3 October 2022

Thank you for the opportunity to provide feedback on this important change in classification. As a PHO we are in favour of the proposal, if due diligence has been undertaken and there is a commitment to an effective project roll out for which we believe will be integral to making this reclassification a success.

The PHO concurs with

- The sentiments of increasing access and equity with enhancing and increasing workforce autonomy
- One centralised system to record, and ideally remind practitioners of their authority and renewal requirements.
- Vaccinators ability to immunise cross district borders
- All national schedule vaccines, including special schedule, in the future will be given same classification.

Areas for Review

Circulation

CCPHO would like to express concern that the proposal has not been widely circulated nor has it included hui which would enable the primary care and community sector to engage more importantly it would have been an opportunity for the contribution of General Practitioners / RNZCGP /GPNZ and occupational and travel health specialists to be heard .

Background / Diligence

- There is no preceding policy document relating to why the MoH is now proposing this or what the overall intended benefit of this classification change is.
- Are the proposed changes for all age groups (whole of life) or only for administration to tamariki/rangatahi?
- Noting that the risks and benefits analysis, to both nurse and pharmacist vaccinators, has not been included in the appendix
- The consultation documents with both Nursing and Pharmacist legislative bodies has not been included in the appendix
- Details of what the implications on scopes of practices, indemnity, pay terms and conditions have not been defined.
- There is no timeframe for adoption nor implementation plan/planning
- Vaccines given at non general practice sites will be entered on AIRS which is not visible to NIR so Practices will not know if vaccine given or not. Practices not scheduled for AIRS access until April 2023.

Scope

- Is the intention that all RNs whom have completed their VTC and currently authorised will transition to the new authority or will there be an extension to their scope of practice?

- When would this change come into effect?
- Would this change mean nurses will effectively operate like they have a local immunisation programme for “private vaccines”?
- Will pharmacists and RNs not yet authorised will still require prescription or standing orders to deliver immunisations?
- Will new authorised immunisers be able to delegate their authority ie me training or assessing a new RN?
- What does this mean for indemnity insurance, both personal and employer?
- Role scope of non regulated health workforce vaccinators stated they would be supervised but no definition had been agreed with nursing council (sector zoom meeting July 2022) . Has the supervision definition been agreed to and if so, who is responsible and what is the definition?
- With increasing scope will there be additional up-skilling of well child tamariki ora principles (WCTOP) as the immunisation event at the GP is not solely for the administration of vaccines. How will issues identified at Pharmacy vaccination sites be communicated to GP?

Education

- Currently whilst the training is the same for all full vaccinators those immunisers like pharmacists, age restricted vaccinators, whom haven’t been responsible for tamariki immunisations have not necessarily taken on board information about tamariki immunisations (as previously outside of scope). There would be a significant concern a blanket widening without a programme of upskilling our current restricted workforce.
- Additionally what training would be provided to pharmacists relating to special immunisation schedule?
- What does this mean for unregulated workforce are their supervisors required to be new authorised workforce?
- Recommend a mandated module to complete relating to understanding their new responsibilities
- Clarity on pharmacy competence and upskilling of WCTO Principles

Equity

- Equity is at the heart of our practitioner network; whilst we concur access is a major issue for immunisation up-take, engagement with carers, whanau ora care and integrated services are also vital to ensure good quality outcomes for the sector. We are concerned that the focus on task based care, increased instead of reduces inequity in healthcare.
- GP recognition, appropriate funding, IT infrastructure and quality education should be additional levers added to this proposal to strengthen it. We would argue that the success of the Covid roll out was all of these and not just access acting in isolation.

Standards / Framework

- If vaccinators are effectively Providers, would they not require a GP/ prescriber to “underwrite” their access to contracts and payment for immunisations given?
- Would the change also allow for all providers to have access to funded vaccine stock for provision? i.e. occupational health

- How will providers be audited to ensure they are maintaining standards across all immunisations if only giving some irregularly? i.e There is significant room for error with vaccines with similar names, i.e. Infanrix Hexa / Infanrix IPV
- It is noted the submission aims to remove the need for authorisation by their local Medical Officer of Health. However there is not much clarity on how vaccinators are to be authorised moving forward, save for noting Te Whatu Ora is exploring development of a national register.
    - Would this be in place before the submission is accepted?
    - Do we have a timeline on this?
    - Will renewal of "authority" continue to be biennially (every 2 years)?
    - Complaints/concerns re vaccinators / competence – would this also be handled by the new National authority or local Med Officer of Health?

- Clinical assessments
    - What will be the process for vaccinator clinical assessments?
    - Will you require current age restricted vaccinators to be re-assessed (In our experience this would be strongly recommended but will have flow on effect for immunisation assessors)
    - Will the assessor need national assessor authority?
- Is the expectation that all undergrad programmes going forward for nurses will include immunisation to again increase workforce and reduce barriers?
- In the document there is no commentary about obligation to document any immunisations in WCTO book, advise GP or NIR/AIR – think this should be fundamentally included to mitigate any risk of duplication of doses
- How will this role work within Hospital settings?
- Currently there is no National Immunisation /Cold Chain Staff Provision, with each District employing their own contracts for service provision. Without one funded equitable service provision framework, there could be significant pressures on the "Oversight" workforce – Cold Chain and Immunisation Coordinators (See Below)
- As proposal does not identify specific sector responsible for immunisation programme,
    - does AIR take on role of recall / follow up of will this remain GP role? If this is GP role how will they be funded for this activity as currently on needle-in-arm is funded
    - How do we ensure there is not duplication as GP wont have access to AIR till middle 2023
- If person does not use internet for booking appts, how would they access booking schedules/availability?

Travel Vaccines

- The inclusion of travel vaccines, and especially higher risk ones like yellow fever, rabies, Japanese encephalitis. Travel medicine is not just the "administration" of vaccines, but more holistic pre trip counselling and planning and needs a practitioner (GP/NP) skilled in these areas. The average GP would not consult or administer these and instead defer to Occupational and Travel medicine specialists who have a valuable role to play in medical support during travel (when traveller gets ill and critical accurate advice can save lives) and well as after travel or for repatriation. This essential service would be lost and cannot be replaced easily with very immunisation focused training
- If travel vaccinations are to be given without GP/Travel specialist interaction/prescription (i.e. pharmacist who can supply and administer) then the concern would be that we see a corresponding rise in travel related morbidity/mortality.

- Current vaccinator training doesn't include Travel vaccines, will these modules be provided by Te Whatu Ora or IMAC going forward or up to the individual to upskill?
    - Who would assess that training as acceptable or is this not required?
    - There is concern brief vaccine related modules couldn't replicate holistic care adequately.

Impact on AIR (Aorteroa Imms Register)

- Currently in planning with current scope limitations – will this cause disruption.
- General practice will not have access to AIR until April 2023- potential confusion of who is due for the vaccine

Sectional Feedback

Under section 3 Consumer benefits the report does not acknowledge any benefits to nurses? i.e. the increased mana to the nursing workforce or the opportunity for them to work more independently of a GP and in more locations increasing access in a number of areas and locations and opportunistic immunisations.

There was also no acknowledgement of the two sided coin

1) Patients would be more aware of and have greater access to immunisations i.e. if high risk PCV/PPV however
2) This will have impacts on programme funding and stock – which needs to be accounted for.
3) When stock runs out or is low, how is priority allocated for which groups receive stock?

Follow-on effects of reclassification

- Cold Chain
    - No mention of limited Cold chain storage in many pharmacies or occupational health workforce
    - The CC National Standards need reviewing in relation to oversite – recommendation would be to re-instate overview annually of all vaccine providers, to ensure quality and standards and stock management
    - Would Pharmacies CC still sit under Medicines Control or revert back to Immunisations Coordinators (It is our recommendation it returns to local coordinators whom understand immunisation is larger than the cold chain alone but CC is often the canary in the site)
- Ability to provide adequate privacy and facilities for permanent immunisation service
- There is significant room for error with the roll out of additional vaccines with similar names, i.e. Infanrix Hexa / Infanrix IPV (*see standards)
- Changes will have significant flow on to Cold Chain & Immunisation Coordination role; particularly in the initial stages of setting up sites but also ongoing to ensure providers are maintaining their knowledge, supporting decision making and capability around paediatric immunisation – what are the workforce plans for this role?
- How will pharmacist vaccinators support special immunisation schedule delivery? I.e those on transplant lists or post chemotherapy?
- How will the roll out of the new workforce be implemented,
    - with workforce and
    - the community

  to optimise this new strategy.
- As immunisations are proposed to be done outside of general practices, will the immunisation target no longer be a PHO / general practice responsibility?

- The proposal separates immunisation from normal business where practices are making each contact count. Since covid more impetus has been given to making each contact count in primary care. e.g recording blood pressure or smoking status at immunisation event or reminding upcoming recall for diabetes annual review. The proposal creates repeated missed opportunities to make each patient/client count and will increase burden on the individual and whanau. In that respect the proposal is tinkering with a service aspect and disregarding the service USERS –the client , whanau and community to develop and maintain pae ora.

8. Communal harm and/or benefit

- There was no statement on the effect on public confidence if there were delivery errors or mishandling of AEFI. I appreciate Covid has seen the workforce make significant leaps forward however the public were prepared to accept a certain degree of "error" in an pandemic, I do not believe the public would feel the same in relation to core tamariki immunisations.

9. Impact on family/whanau

- Separating the immunisation from well-child check at GP clinic necessitates MORE visits by whanau with greater disruption to them. Well-child checks and immunisation events were originally combined, in part, to reduce the number of clinic visits required.
- Separating immunisation from GP practice well child checks at 6 wks, into non GP clinics will create more gaps in continuity of care so issues of concern will be missed. WCTO providers are currently not engaging with whanau until after 6 weeks and do not complete some of the checks done by GP.
- Whanau who do not engage with WCTO are picked up for well child checks at the general practice at time of immunisation. If immunisation done at non GP clinics, is a missed opportunity to identify issues.
- The last 4 years has seen repeated shortages of vaccines- influenza (each year), MMR, Gardasil. Which service would be given priority for supply? How will this be communicated to maintain whanau confidence in the system?
- If vaccine shortages and clinics are cancelled will people be notified electronically by the system they book on(AIR)?

CCPHO look forward to participating in further korero to support this mahi.

Ngā mihi

Sian Gilhooley
On Behalf of the Clincial Directorate
Comprehensive Care PHO
Waitematā

Tuesday 11th October 2022,

Medsafe
New Zealand Medicines and Medical Devices
Safety Authority.

Tēnā koe,

RE: Proposed Change to prescription vaccine classification.

I am writing in support of the proposed changes to widen the classification for vaccines to allow for vaccinators who have successfully completed the Vaccinator Foundation Course or an equivalent approved Ministry of Health Course and who comply with the immunisation's standards of the Ministry of Health to distribute and administer vaccines.

The proposed change is important as it enables registered nurses to work to their full scope of practice and improve access of service provision to high needs populations. This in turn supports improving equity particularly for Māori, Pacific and those residing in rural remote regions that may have limited access to vaccinations.

Please feel free to contact me directly if you require any further information to support our recommendation,

Ngā mihi,

Lorraine Hetaraka
Ngāti Kahu, Tapuika, Ngāti Pikiao, Ngāti Ranginui, Ngāi Te Rangi

Tapuhi Rangatira | Chief Nursing Officer
Ngā Āpiha Hauora | Manatū Hauora

I, as a community pharmacist am extremely excited by this proposal to reclassify travel vaccines. It opens the door even further for vaccinating community pharmacists to become even more involved with vaccine uptake in our local communities. Vaccines are a key component of primary care and now with our borders opening to travel, we would be able to offer this service without referring to GP practice and expensive travel clinics and make the prices more competive and affordable for unfunded travel vaccines. This will ensure better, easier uptake for overseas travel vaccines and reduce the likes of hepattis A and typhoid for our returning travellers, thus reducing the burden on GP care and hospital ED. I, personally see this as a huge oppurtunity to be involved with travel vaccines together with our normal vaccine rollout to the NZ population, for vaccine prevention and control of infectious disease. I am in full support if this reclassification goes through and many of my vaccinating pharmacist colleagues would be as well. Thank for reading my small contribution. Nga mihi [redacted]

21 October 2022

Te Whatu Ora
Health New Zealand

Medicines Classification Committee Secretariat
Via email: committees@health.govt.nz

Reclassification of vaccines

The National Immunisation Programme (the Programme) supports the reclassification of vaccines. This will enable a wider range of vaccinators to administer vaccines in a wider range of settings as well as to all ages.

The Programme is part of the Prevention Unit, in the National Public Health Service and has the overarching responsibility of providing immunisation across the motu, by partnering with Te Aka Whai Ora, Health Districts, local providers, and the wider health and wellbeing system.

Childhood immunisation coverage in Aotearoa has fluctuated since 2017 and began trending downwards in 2020. Coverage shows that an equity gap persists and there is lower coverage for tamariki Māori at all milestone ages compared to the total coverage.

Reclassifying vaccines will support strengthening the workforce capability and capacity. Both of which are key priorities for the Immunisation Taskforce, which was established to set priorities and progress actions to lift immunisation rates for tamariki 0 to 3 years of age.

The Programme is committed to the quality and safety of the vaccinating workforce. This is managed through approved training courses and potential vaccinators being clinically assessed. The Programme is now in the discovery phase of considering a central "registration" process for all vaccinators. The benefit of this will be a national repository of vaccinators.

Yours sincerely

Astrid Koornneef
Interim Director, Prevention
Te Whatu Ora
Health New Zealand

29th September 2022

Te Whatu Ora
Health New Zealand

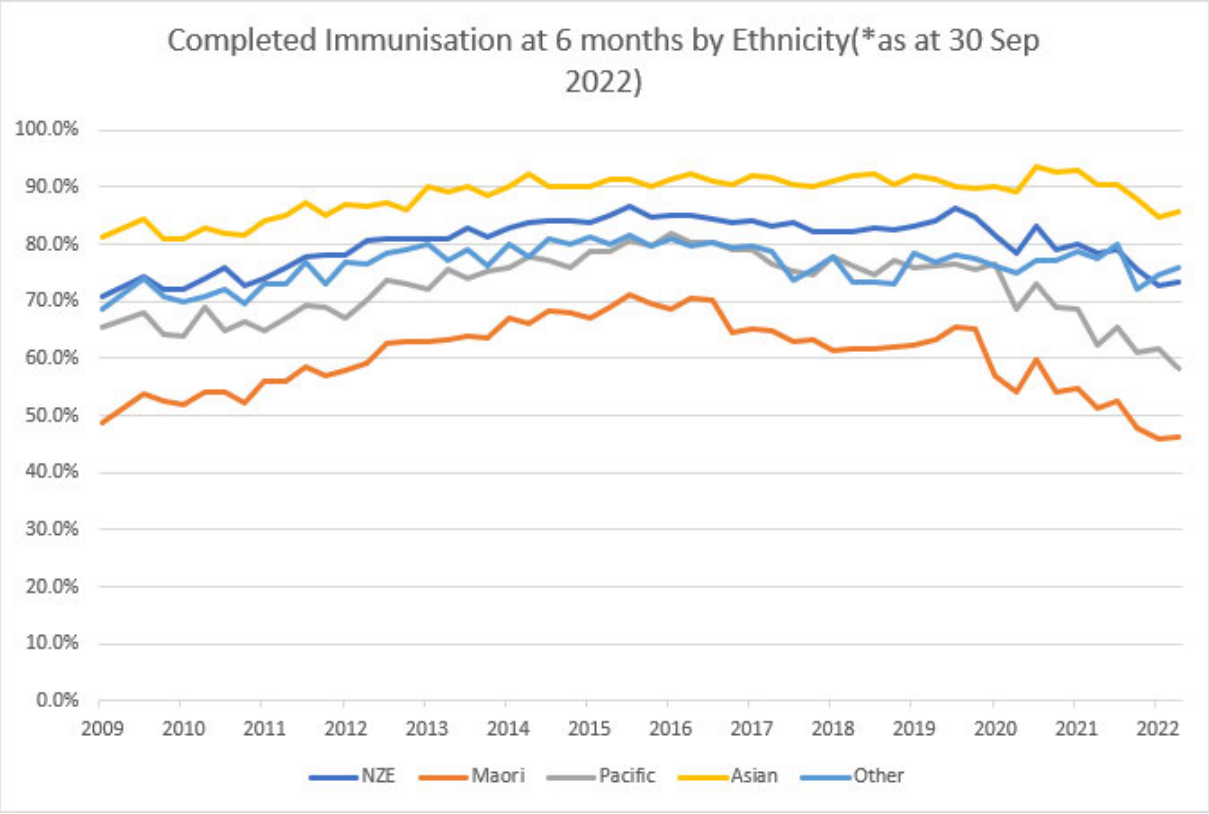
Immunisation Taskforce

Attn: Medicines Classification Committee

Tēnā koutou katoa,

I am writing to you as the co-chair of the National Immunisation Task force regarding the proposal to re-classify all immunisations currently under review with the Medicines Classifications committee. Our Taskforce strongly supports this initiative.

This Taskforce was formed due to our failing Aotearoa New Zealand (NZ) immunisation system and the crisis in immunisation coverage affecting tamariki and rangitahi. Improving immunisation access in Aotearoa needs an urgent whole system approach.



In Aotearoa NZ there has been persistent and significant ethnic inequity in immunisation coverage through the lifespan. The graph above shows completed immunisations at 6 months by ethnicity. Whilst the 8-month milestone is used in national reporting, 6-month reporting is better at indicating the proportion of infants who receive their first three scheduled immunisation events on time and are therefore provided with maximal vaccine preventable disease protection at the earliest possible age. It reveals a number of concerning issues about receiving immunisations in NZ:

- That at age 6 months the best predictor of a child's immunisation status is their ethnicity.
- The percentage of tamariki in Aotearoa NZ aged 6 months who have completed immunisations is at its lowest level since data has been recorded.
- The Aotearoa NZ immunisation system has never achieved targeted levels of immunisation coverage (95%) needed to adequately protect tamariki. This is particularly true for Māori and Pacific.

We support the approach of standardising the certification of all vaccines. We also support this process that will allow pharmacies to be a place childhood vaccine can be given. Pharmacists have been vaccinating since 2012 in NZ. Recent experience with the COVID vaccine programme has highlighted the importance of pharmacist vaccinators who are estimated to have delivered 30% of COVID vaccines. The acceptability of pharmacy vaccination, particularly for Māori, has also been demonstrated in Aotearoa NZ [1,2]. A pharmacist vaccinator currently delivers a range of adult vaccines (pertussis/tetanus, influenza, HPV, meningococcal, shingles and MMR) for whānau including hapū māmā. Addition of childhood vaccinations which are safe, essential, and laid out in a clear sequential National Immunisation schedule will be relatively simple compared with the complex delivery of COVID vaccines which required multidose vials, different vaccine formulations and complex, changing booster scheduling. We feel pharmacist vaccinators will be an invaluable benefit to streamline vaccination delivery across the lifespan.

Equity and Te Tiriti

Addressing inequities and incorporating Te Tiriti o Waitangi in all aspects of the health service underly every consideration. Reviews into other similar entities like PHARMAC showed isolated technical decisions resulted in significant inequities. Isolated technical approach is evident throughout the vaccination system.[3] We would ask that the Medicine classification committee considers how any decision they make on vaccines affects equity.

Immunisation success

Reversing the failure of healthcare and immunisation in Aotearoa NZ will require all parts of the health care system to change. The reclassification of vaccines reflects immunisations are safe and essential and will demonstrate confidence in the NIP to providers and communities. It will allow the immunisation taskforce to develop improved systems for expanding workforces and then provide greater appropriate immunisation solutions to those most vulnerable in Aotearoa.

Again, I iterate our support for this initiative.

Our children deserve this.

Ngā mihi

Dr Owen Sinclair *Tane | He | Him*

Te Rarawa

Rata Hauora Tamariki/Paediatrician | Acute lead Paediatrics
Waitematā
Co-Chair National Immunisation Taskforce
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Te Whatu Ora
Health New Zealand

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Te Whatu Ora
Health New Zealand

Te Whatu Ora – Health New Zealand

TeWhatuOra.govt.nz

References

1. Howe A et al. Increasing Uptake of Maternal Pertussis Vaccinations through Funded Administration in Community Pharmacies. Vaccines (Basel) . 2022 Jan 20;10(2):150.doi: 10.3390/vaccines10020150.

2. Gauld N et al. A Qualitative Study of Views and Experiences of Women and Health Care Professionals about Free Maternal Vaccinations Administered at Community Pharmacies. Vaccines (Basel). 2020 Mar 29;8(2):152. doi: 10.3390/vaccines8020152.

3. Pharmac Te Pātaka Whaioranga. Interim response to outcomes of the Pharmac review 2022 https://pharmac.govt.nz/about/pharmacreview/interim-response-to-outcomes-of-the-pharmac-review/.

RUA BIOSCIENCE

Attention: Secretary Medicines Classification Committee (MCC)

Submission on Agenda Item 8.2a of the 69th Meeting of the MCC Low Dose Cannabidiol

Rua is pleased the MCC is to consider re-classifying low-dose cannabidiol in the trans-Tasman harmonisation segment of its agenda.

Rua strongly supports aligning the New Zealand classification requirements for low dose cannabidiol (CBD) with the changes implemented in Australia on 1 February 2021 through updates to Schedule 3 and Appendix F of their Poisons Standard.

Rua considers consumers would gain significant benefit from improved access to non-prescription CBD products with demonstrated efficacy. It is clear from published studies that CBD is well tolerated across a wide range of dosages, rarely associated with severe adverse events, and that non-serious adverse events appear significantly lessened at lower dosages.

Rua also considers that a Restricted Medicine classification is appropriate at this time and that New Zealand pharmacists have the necessary competencies to assess whether a low-dose CBD product, for an approved indication, is appropriate for a consumer who has sought their advice or requested a product.

The Australian re-scheduling process and decision

The Australian decision to reschedule low-dose cannabidiol from Schedule 4 (Prescription only) to Schedule 3 (Supply by a pharmacist) was announced in December 2020. It was made after a lengthy and robust process that included the review of published clinical trial data and safety reviews and analysis of submissions from interested parties.

The Therapeutic Goods Administration (TGA) has published a detailed explanation of the information that was considered and the evidence-based reasons for its decision, including findings on material questions of fact. Links to this material have been republished by Medsafe in the context of this agenda item:
https://www.tga.gov.au/sites/default/files/review-safety-low-dose-cannabidiol.pdf .

Rua has reviewed this information and agrees with the TGA assessment that the safety profile and characteristics of low-dose CBD are such that a classification level that allows supply by a pharmacist is appropriate.

The re-scheduling decision was given effect in Australia from 1 February 2021 through the Poisons Standard; by creating a new Schedule 3 entry for CBD and by amending Appendix F to the standard to apply labelling requirements.

The Schedule 3 entry for cannabidiol in the Australian Poisons Standard now reads:

CANNABIDIOL in oral, oromucosal and sublingual preparations included in the Australian Register of Therapeutic Goods when:

a) the cannabidiol is either plant derived or, when synthetic, only contains the (-)-CBD enantiomer; and

b) the cannabidiol comprises 98 per cent or more of the total cannabinoid content of the preparation; and

c) any cannabinoids, other than cannabidiol, must be only those naturally found in cannabis and comprise 2 per cent or less of the total cannabinoid content of the preparation and of which tetrahydrocannabinol (THC) can only comprise 1 per cent of the total cannabinoid content; and

d) the maximum recommended daily dose is 150 mg or less of cannabidiol; and

e) packed in blister or strip packaging or in a container fitted with a child-resistant closure; and

f) in packs containing not more than 30 days' supply; and

g) for persons aged 18 years and over.

Rua's position on the classification caveats that should apply in New Zealand

Rua has considered each aspect of the Australian decision. Its view on whether they would be appropriate for a CBD product supplied as a Restricted Medicine in the New Zealand setting is set out in Table 1 below.

Table 1: Rua's Position on the Caveats that Should Apply in NZ to a Low-Dose CBD Product

Australian Poisons Schedule Entries for Low-Dose CBD (Schedule 3 and Appendices F and H)	RUA's Position
CANNABIDIOL in oral, oromucosal and sublingual preparations included in the Australian Register of Therapeutic Goods when:	• Rua supports limiting the dose forms that may be provided as Restricted Medicines to those set out in the Schedule 3 entry. It also believes consideration could be given to including topical preparations as the evidence base for those increases. • The reference in the Australian entry to products needing to be included in the Australian Register of Therapeutic Goods maps to products needing to be an "approved medicine" in NZ. **Rua strongly supports imposing a caveat that Restricted Medicine CBD products must have been granted Ministerial consent in NZ under section 20 of the Medicines Act 1981 or have been approved by the Director-General of Health under section 24 of the Act (or words of similar meaning).**

	It believes this is a necessary safeguard to ensure that the efficacy of a non-prescription product for its intended use has been independently assessed by the regulator, and that its benefits outweigh its risks. We think this is important for the integrity of the regulatory system and for consumer confidence in the products. Rua also considers it important to reclassify low-dose CBD ahead of there being a consented non-prescription product. The classification change would be an important positive signal to industry to prompt and accelerate product development research, and the compilation of data to support an application for Ministerial consent.
a) the cannabidiol is either plant derived or, when synthetic, only contains the (-)-CBD enantiomer; and	Rua supports this caveat being included in the New Zealand classification entry given that the (+) CBD enantiomer is likely to be psychoactive and present in different pharmacological activity from the (-) CBD enantiomer found in cannabis plants
b) the cannabidiol comprises 98 per cent or more of the total cannabinoid content of the preparation; and	Rua supports this caveat being included in the New Zealand classification entry.
c) any cannabinoids, other than cannabidiol, must be only those naturally found in cannabis and comprise 2 per cent or less of the total cannabinoid content of the preparation and of which tetrahydrocannabinol (THC) can only comprise 1 per cent of the total cannabinoid content; and	Rua supports this caveat being included in the New Zealand classification entry.
d) the maximum recommended daily dose is 150 mg or less of cannabidiol; and	Rua supports this caveat being included in the New Zealand classification entry.
e) packed in blister or strip packaging or in a container fitted with a child-resistant closure; and	Rua supports this caveat being included in the New Zealand classification entry.
f) in packs containing not more than 30 days' supply; and	Rua supports this caveat being included in the New Zealand classification entry.
g) for persons aged 18 years and over.	Rua supports this caveat being included in the New Zealand classification entry.

Appendix F of the Poisons Standard requires the product to be labelled with the warning statements: • Do not use if pregnant or likely to become pregnant. • Do not use if breastfeeding or planning to breastfeed.	Rua supports these labelling requirements but considers they should be applied through the medicine assessment process rather than being specified in the New Zealand classification entry.
Appendix H of the Poisons Standard does not list Schedule 3 cannabidiol (as a medicine that may be advertised)	When making its decision to move low-dose CBD to Schedule 3, the TGA explicitly stated it would prohibit advertising of the S3 product. • **Rua strongly believes that a similar prohibition on advertising is unnecessary and would not be appropriate for New Zealand.** The two countries have quite different policy and regulatory settings for advertising medicines. Under the Australian system, no S3 medicine may be advertised to consumers unless it is listed in Schedule H of the Poisons Standard. Such listings have been the exception rather than the norm. In contrast, New Zealand has permitted responsible advertising of all Restricted Medicines. The self-regulatory mechanisms administered by the Advertising Standards Authority (ASA) and Association of New Zealand Advertisers (ANZA) have together played important roles in setting requirements for accurate and socially responsible advertising of medicines, pre-vetting of advertisements, adjudicating on complaints and preventing further publication of non-compliant advertising in mainstream media. The ability to inform the public about the availability of a non-prescription CBD product from their pharmacist, if the pharmacist considers that is an appropriate medicine for that consumer, is an important element of improving access for consumers.

Thank you for the opportunity to provide this submission. Please do not hesitate to contact me if you would like me to provide further information or input that might aid the committee's deliberations.

Yours sincerely

Dr Susan Martindale
Head of Regulatory Affairs

3 October 2022

MCC Secretary,
Medicines Classification Committee
By email: committees@health.govt.nz

Cannabidiol (CBD) scheduling, 69th Meeting of the MCC

Tēnā koutou, thank you for this opportunity to provide guidance to committee members regarding the proposed re-scheduling of low-dose cannabidiol (CBD) medicines.

About us

Zeacann was founded in 2017 and currently holds a Medicinal Cannabis License for one site (at CompoundLabs in Auckland), with a Nursery activity. Zeacann has an interest in both importing and locally manufacturing CBD products.

The problem

Cannabidiol (CBD) is a naturally occurring cannabinoid that is often extracted from hemp, or high-THC cannabis. CBD can also be manufactured synthetically. Notwithstanding the progress to date, we are regularly contacted by patients and medical professionals enquiring about the availability of CBD products. It is commonly expressed that existing products are too expensive and limited in options (such as dosage format, strength, formulation). No medicinal cannabis products, including CBD products, are subsidised by Pharmac. This means cost and affordability are big issues for many patients.

From an industry perspective, the product approvals process remains very difficult to meet. It is unlikely that many – if any – products will go through the full consenting process. In fact, that assumption is the reason we have a Medicinal Cannabis Scheme separate from the regular consenting process.

Proposed changes

The proposed changes would allow over-the-counter Pharmacy Only sales of low-dose cannabidiol products (up to 150mg/day, in packs of up to 30 days). It is proposed that these changes would apply only to products that have gone through the full medicines classification process (i.e. not products available under NZ's Medicinal Cannabis Scheme). This would in turn mean such consented products could be marketed, with therapeutic claims for which evidence has been met, and could be provided by a Pharmacist with or without a prescription.

Zeacann supports the proposed change as a first step. However, it would currently apply to no products, as none have Ministerial consent. In theory it could benefit *Epidiolex* (manufactured by GW Pharmaceuticals in the UK) which is approved by the FDA although it has not yet received consent in New Zealand. However, *Epidiolex* is a high dose product and unlikely to qualify.

The proposed change may assist some industry players in that it may attract new investors or provide an incentive to manufacturers with very deep pockets, or who have the backing of billionaires. But the consenting process remains slow and expensive, Medicines often take years or decades to reach the market via the regular consenting process, at a cost that can run to hundreds of millions of dollars.

We are mindful the Medicinal Cannabis Scheme was created expressly because the standard consenting process is recognised as too onerous and slow to meet the immediate needs of patients. In addition, the regular consenting process is not seen as viable for herbal medicinal cannabis production, including CBD products.

Looking to Australia, the change appears to have made no difference so far. We have not found any Pharmacy-Only CBD products there and have not seen any significant industry player announce new investment or strategy in this area.

While further changes are deemed by Medsafe as outside the scope of the Committee, we encourage members to make recommendations for further reform, especially given the scheme has been going 2.5 years with an estimated uptake by patients of only 6%, and a long-promised review of the scheme still not in the public domain.

New Zealand authorities should look to North America and Europe – not just Australia. It is common overseas that hemp-derived CBD products are not included in medicines regulations or schemes and are available on general sale in addition to having consented products available under prescription or, as in this proposal, available from Pharmacies. The CEO of Zeacann and author of this submission, Chris Fowlie, recently returned from Europe where he found CBD products on general sale in every country he visited. CBD products were also available from doctors and pharmacies. He reports it was difficult to find any problem with this approach.

Recommendations

Zeacann Ltd supports the proposed changes for cannabidiol. However, we believe the proposal does not go far enough to make a meaningful and timely difference for patients.

We recommend *all* hemp-derived CBD products be available over-the-counter on general sale (*in addition* to the current proposal, and noting that any product assessed as meeting the NZ Minimum Quality Standard would *also* be available by prescription).

Ngā mihi,

Chris Fowlie
CEO, Zeacann Ltd

the hemp store

253 Karanghape Road, Auckland, Aotearoa | hempstore.co.nz | 0800-HEMPSTORE

4 October 2022

MCC Secretary
Medicines Classification Committee
Ministry of Health
Wellington
By email to: committees@health.govt.nz

Re: CBD scheduling – 69th meeting of the Medicines Classification Committee

About us and our experience

The Hempstore is an Auckland-based retailer of hemp and cannabis-related items, founded in 1997. We write to offer our experience in this area. We are grateful for this opportunity to correspond with you on a matter that is very important to us.

Customers regularly enquire about the availability of CBD. They expect that we can provide it to them. We receive enquires every day – sometimes many times per day.

We explain the law and how they can access it legally through a doctor. Many customers are surprised and shocked to discover accessing CBD legally requires a prescription. Very few give any indication they will seek it through a doctor; they are concerned about onerous processes and unaffordable products.

Visiting tourists inform us they can buy CBD over the counter in North America and Europe, with few restrictions on pack size, strength, dose or format. They must go without their medication while visiting New Zealand. Tourists often seem taken aback that New Zealand operates so conservatively, while some have noted to us that no one has died from taking CBD and there is no controversy around this.

In fact, in many places a store like ours is exactly where people expect to find CBD products, and are capable of doing this. Our staff have the experience and expertise to safely provide CBD products to customers for their health and wellness purposes.

We believe that this international experience of CBD as a common health and wellbeing product was the intention of the United Nations in calling for provisions for it's use. We note that despite changes in NZ law in response to this, the outcomes of our Medical Cannabis Scheme has not matched it's intended spirit. As a result, New Zealand is considered somewhat backward in this arena.

The proposal is weak but a step in the right direction

The proposed changes, as we understand them, will bring New Zealand rules in line with Australia, allowing over-the-counter sales of qualifying low-dose CBD products in pharmacies.

That does not go far enough. The Australian approach has not made any material difference to patients there, or to the viability of their local industry, because it only applies to products that have gone through the full medicines approval process. Currently, that is none.

We might hope that Epidiolex would qualify if they applied, but note it is apparently the world's most expensive CBD product and is not actually available in Australia or New Zealand.

The wider framework for this issue is the unnecessary medicalisation of CBD. The international experience of our customers is that low dose CBD is a hemp product : a herbal supplement, or an over-the-counter painkiller at most.. But while the legislative framework adopted here in New Zealand correctly excludes CBD from the Misuse of Drugs Act, by shunting its regulation entirely into The Medicines Act, it has effectively scuppered the intention of making products widely available to Kiwis. The expensively high standards required for pharmaceutical grade products have shut small local producers entirely out of the market and forced consumers into an unnecessary prescription process over a medicine that functions on about the same level as paracetamol.

Low dose CBD products should never have been treated like prescription level medicines, but instead belong under ordinary hemp regulations, like most other juristictions. This would still provide consumers with full assurance that products are not contaminated by agricultural chemicals, disease, or mishandling; which is all that should be required for a herbal medicine of mild strength and very low risk. Medical grade, prescription-only CBD products would remain available under The Medical Cannabis Scheme, for those who require this level of medication.

Bolder change is required

Notwithstanding Medsafe's guidance to only consider what could happen within current regulations, we encourage the committee to send a message and recommend bolder steps, even if Medsafe's constraint is adhered to now.

We encourage you to recommend further steps to provide more equitable, and risk-proportionate, access to CBD Products, by recommending that cannabis regulations should be changed, and the Medicinal Cannabis Scheme updated to facilitate access that is more broadly aligned with Europe and North America.

The bottom line

We recommend:

1. MCC support the current proposal (as a minimum first step)
2. MCC encourage further changes to allow:
    a. Pharmacy-only provision of *any* CBD Product approved under the Medicinal Cannabis Scheme (i.e. assessed as meeting the NZ Minimum Quality Standard)
    b. In addition, general sale of low-dose CBD Products as described by the current proposal (i.e. up to 150mg per day x 30 days)

c. Idealy, b. would be achieved by the complete removal of all low-dose CBD products from the Medical Cannabis Scheme, and they would be regulated on par with hemp foods

Thank you for considering our submission.

Ngā mihi,

Jonathan Rennie
Harm Reduction Officer
The Hempstore Aotearoa

New Zealand
Medicinal Cannabis Council
Te Kaunihera Rautini
o Aotearoa

3 October 2022

Re: Medicines Classification Committee 69th meeting, Item 8.2a Low dose cannabidiol

Thank you for the opportunity to comment on the possible reclassification of low dose cannabidiol (CBD) to harmonise with the Australian scheduling of schedule 3 or pharmacist-only medicine.

Te Kaunihera Rautini o Aotearoa, the New Zealand Medicinal Cannabis Council, (NZMCC) is the peak body for the New Zealand medicinal cannabis sector to coordinate and represent organisations involved in all aspects of the industry in New Zealand.

More than 20 member companies are represented by the Council, including ancillary services such as testing labs, "cultivation only" (biomass) suppliers, vertical (seed to sale) producers of finished products and regulatory consultants.
The objectives of NZMCC are to:

1. Provide a vehicle for the medicinal cannabis sector to organise itself and communicate key priorities.

2. Contribute to the establishment of a successful, professional and respected medicinal cannabis industry based on world-leading regulations and the best science.

3. Ensure the integrity of the New Zealand industry provides the best opportunities for patients to access safe and effective products.

4. Promote collaboration and cooperation within the sector to enhance the reputation of medicinal cannabis products and services developed in New Zealand.

The Council is determined that the New Zealand industry and its products will be built on sound science and underpinned by industry processes and standards that ensure patients, prescribers and our export markets have confidence in our sector and its products.

The NZMCC agrees that low dose CBD (e.g. up to 150 mg/day as in Australia) does not need prescription medicine status, owing to its safety and in line with a number of other jurisdictions [1]. Academics and organisations in New Zealand have recommended non-prescription CBD availability [2, 3 4], for example to help address an inequity of medicinal cannabis availability [3, 4] caused by the high monthly cost [3].

However, we recommend using the "prescription except when" wording rather than pharmacist-only medicine. This will ensure that product can still be stopped at the border and not be released without a doctor's prescription to safeguard the public from products which do not meet the quality requirements for manufacture and licensing that New Zealand sets. This will provide greater safety for the New Zealand consumer.

If CBD became a pharmacist-only medicine, people would be able to personally import the product without requiring a doctor's prescription, exposing them to risk of incorrect strength, undeclared ingredients (such as THC), contaminants [5], and not consulting a health care professional about the medicine or the condition they are intending to use it for. Interactions might not be identified with medicines being taken. The intent of having a Medicinal Cannabis Scheme in New Zealand is to improve access to quality medicinal cannabis products for patients [6]. Enabling personal importation, particularly if no CBD product is available without prescription in New Zealand would not improve access to quality medicinal cannabis products for patients, but rather enable access to products of dubious quality.

We note that Medsafe's document about CBD Harmonisation stated: *"If CBD were to be down-scheduled, and therefore available as pharmacist only in New Zealand, this would only impact products that have ministerial consent."* As discussed above, we think that a pharmacist-only classification will have an impact on products without ministerial consent (brought in from overseas for personal use), unless done as "prescription except when".

The Australian Schedule 3 entry states the following:

CANNABIDIOL in oral, oromucosal and sublingual preparations included in the Australian Register of Therapeutic Goods when:

> *a) the cannabidiol is either plant derived or, when synthetic, only contains the (-)-CBD enantiomer; and*
>
> *b) the cannabidiol comprises 98 per cent or more of the total cannabinoid content of the preparation; and*
>
> *c) any cannabinoids, other than cannabidiol, must be only those naturally found in cannabis and comprise 2 per cent or less of the total cannabinoid content of the preparation and of which tetrahydrocannabinol (THC) can only comprise 1 per cent of the total cannabinoid content; and*
>
> *d) the maximum recommended daily dose is 150 mg or less of cannabidiol; and*
>
> *e) packed in blister or strip packaging or in a container fitted with a child-resistant closure; and*
>
> *f) in packs containing not more than 30 days' supply; and*
>
> *g) for persons aged 18 years and over.*

The NZ Medicinal Cannabis Council has no concerns about using the above statements relating to the scheduling in Australia within New Zealand

Trans-Tasman Harmonisation has seen many medicines harmonised in scheduling between Australia and New Zealand. The intent has been to harmonise to the least restrictive schedule while considering public health and safety issues and/or jurisdictional needs [7]. Jurisdictional needs in New Zealand provides a reason to use "prescription except when" rather than pharmacist-only, for reasons outlined above, and this wording would essentially allow harmonisation between Australia and New Zealand in terms of how the product would be available at the pharmacy. However, we do not see any public health, safety or other jurisdictional needs in New Zealand that should require a more restrictive classification than Australia.

Non-prescription use through the “prescription except when” wording, is supported through the non-prescription availability in many other countries[1], the safety and tolerability of low-dose CBD [8-10], and the need to improve accessibility of medicinal cannabis in New Zealand [2, 3 4].

CBD has been used for thousands of years and is readily available without prescription in a number of jurisdictions [1]. CBD is not intoxicating and, outside of the high doses used in childhood epilepsy, is well tolerated with few serious adverse effects [8-10].

We propose that the classification wording would include the phrase: “prescription except when provided by a registered pharmacist”. Having a pharmacist involved in the supply would help manage the drug interactions that can be seen with CBD [10], or the potential for drowsiness, and will provide an opportunity to refer to a medical practitioner where any concerns arise, e.g. about the condition for which it is being used.

We note that any rescheduling would still require product registration. While this is not within the scope of the Medicines Classification Committee, we note that the likelihood of registration and a product being marketed would be aided by a proportionate regulatory response to registration. This would help meet the aims of reducing barriers to access for consumers to quality product.

In conclusion, harmonising with Australia to enable CBD access through pharmacists up to 150 mg per day is supported by the New Zealand Medicinal Cannabis Council, given the tolerability and safety of CBD and to improve access.

We recommend the use of “prescription except when provided by a pharmacist” to minimise the potential for personal importation of product without input from a health care professional and without the quality safeguards that would be in place with a NZ registered product.

Thank you for the opportunity to provide comment on this agenda item.

References

1. McGregor IS, Cairns EA, Abelev S, et al. Access to cannabidiol without a prescription: A cross-country comparison and analysis. *International Journal of Drug Policy* 2020; 85: 102935. DOI: https://doi.org/10.1016/j.drugpo.2020.102935.
2. New Zealand Drug Foundation. Medicinal Cannabis, https://www.drugfoundation.org.nz/policy-and-advocacy/medicinal-cannabis/ (accessed 3 Oct 2022).
3. Hutton F. Why medical cannabis is still so hard to get in NZ. In: Mulligan J, (ed.). *Afternoons with Jesse Muilligan*. Wellington: Radio New Zealand, 2022.
4. Rychert M, Parker K, Wilkins C, et al. Predictors of medicinal cannabis users' willingness to utilise a new prescription Medicinal Cannabis Scheme in New Zealand. *N Z Med J* 2021; 134: 66-75. 2021/05/01.

5. Montoya Z, Conroy M, Vanden Heuvel BD, et al. Cannabis Contaminants Limit Pharmacological Use of Cannabidiol. *Frontiers in Pharmacology* 2020; 11. Review. DOI: 10.3389/fphar.2020.571832.
6. Ministry of Health. About the Medicinal Cannabis Scheme, https://www.health.govt.nz/our-work/regulation-health-and-disability-system/medicinal-cannabis-agency/about-medicinal-cannabis-scheme (2020, accessed 3 Oct 2022).
7. Gauld NJ, Kelly FS, Emmerton LM, et al. Widening consumer access to medicines: A comparison of prescription to non-prescription medicine switch in Australia and New Zealand. *PLoS ONE* 2015; 10: e0119011. 18 Mar 2015. DOI: 10.1371/journal.pone.0119011.
8. Chesney E, Oliver D, Green A, et al. Adverse effects of cannabidiol: a systematic review and meta-analysis of randomized clinical trials. *Neuropsychopharmacology* 2020; 45: 1799-1806. 2020/04/09. DOI: 10.1038/s41386-020-0667-2.
9. Gulbransen G, Xu W and Arroll B. Cannabidiol prescription in clinical practice: an audit on the first 400 patients in New Zealand. *BJGP Open* 2020: bjgpopen20X101010. DOI: 10.3399/bjgpopen20X101010.
10. Therapeutic Goods Administration. Safety of Low Dose Cannabidiol. In: Department of Health TGA, (ed.). Canberra: Therapeutics Good Administration, 2020.

PHARMACEUTICAL SOCIETY
of New Zealand Incorporated

23 September 2022

Medicines Classification Committee Secretary
Medsafe
PO Box 5013
Wellington 6145
via email: committees@moh.govt.nz

Dear Jessica,

MEDICINES CLASSIFICATION COMMITTEE (MCC)
COMMENTS TO THE 69th MEETING AGENDA October 2022

Thank you for the opportunity to submit comments on the agenda for the 69th meeting of the Medicines Classification Committee.

The Pharmaceutical Society of New Zealand Inc. (the Society) is the professional association representing over 2,500 pharmacists, from all sectors of pharmacy practice. We provide to pharmacists professional support and representation, training for continuing professional development, and assistance to enable them to deliver to all New Zealanders the best pharmaceutical practice and professional services in relation to medicines. The Society focuses on the important role pharmacists have in medicines management and in the safe and quality use of medicines.

Regarding the agenda items for the above meeting of the Medicines Classification Committee, the Pharmaceutical Society would like to note the following comments for consideration:

6.1a Methenamine hippurate – proposed up-scheduling change to classification

Methenamine is currently considered an alternative form of antimicrobial prophylaxis for those with a history of recurrent UTIs, to avoid long-term antibiotic use.
It appears that the product is well used in New Zealand and prescription volumes have increased significantly since 2020. Before a decision is made regarding a potential up-scheduling, it would be good to understand the total volumes of product being used across the country. If the majority continues to be on prescription, there may be no requirement for an up-scheduling.
Any up-scheduling to the restricted category may result in additional cost and perhaps reduced access for patients. Resources and training for pharmacists to provide appropriate treatment under a change in category would also need to be developed and potentially funded. These areas will need to be considered by the committee before in any change in classification occurs, to ensure patients continue to access appropriate treatment.

6.1b Glecaprevir and Pibrentasvir – proposed change to prescription classification statement

The Society supports increased access to Maviret for those New Zealanders requiring diagnostic services and treatment for hepatitis C. The applicant's suggested approach is a novel one and the intended outcomes to improve the health of New Zealanders is clear. We would like to suggest that other appropriately trained health professionals, including the pharmacist workforce are considered as part of this proposed reclassification. This would increase the number of "touch points" for patients diagnosed with this condition and ultimately timely access to treatment and care.

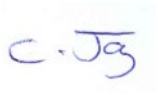
We are of the opinion that some additional thinking may be required around the governance requirements for the potential cohort of nurses (or others) delivering the proposed service. Further exploration around the bespoke training and its link to current health professionals' scopes of practice is also required to ensure safe and effective service delivery, as the proposed approach does not currently fit under the nursing scopes.
We are also concerned that the current proposal cannot be achieved using the "prescription except when" category to generate a "nurse initiated" request to a pharmacist for supply. In principle this request to provide would be classified as a prescription. It is not currently possible for this cohort of health professionals (nurses working outside the prescribing scopes) to utilise this approach under the Medicines Act and Regulations.
Utilising the pharmacist workforce to "see and treat" through the proposed "prescription except when" approach may be easier and increase access to a larger workforce to provide care and support. However, we would be more than happy to work with the applicant and other key stakeholders to progress their thinking and hopefully address some of these challenges and any other issues raised for consideration at a future MCC meeting.

6.1e National Immunisation Schedule - proposed change to prescription vaccine classification statements

The Society supports Ministry of Health's proposal to widen the classification for a number of vaccines to allow vaccinators who have successfully completed the Vaccinator Foundation Course (or equivalent course) approved by the Ministry of Health and who comply with the immunisation standards of the Ministry of Health to administer the proposed vaccines.

Thank you for consideration of this submission. I would be happy to discuss any aspect of this submission further, if required.

Yours sincerely,



Chris Jay
Manager Practice and Policy
p: 04 802 0036

PHARMACY GUILD OF NEW ZEALAND

03 October 2022

Medicines Classification Committee Secretary
Medsafe
Wellington

Sent via email to: committees@health.govt.nz

Dear Committee Members,

RE: Agenda for the 69th meeting of the Medicines Classification Committee

Thank you for the opportunity to provide feedback on the agenda for the 69th meeting of the Medicines Classification Committee (MCC), to be held by videoconference.

The Pharmacy Guild of New Zealand (Inc.) (the Guild) is a national membership organisation representing the majority of community pharmacy owners. We provide leadership on all issues affecting the sector.

Our feedback covers 4 agenda items. These are:

- **Agenda item 6.1a:** Methenamine hippurate – proposed up-scheduling change to classification
- **Agenda Item 6.1b:** Glecaprevir and Pibrentasvir – proposed change to prescription classification statement
- **Agenda item 6.1e:** National Immunisation Schedule – proposed change to prescription vaccine classification statements
- **Agenda item 8.2a:** Low dose cannabidiol

Each of these agenda items are discussed in detail below.

6. Submissions for reclassification

6.1a Methenamine hippurate – proposed up-scheduling change to classification (Medsafe).

The Guild supports the reclassification of Methenamine hippurate from a general sale medicine to pharmacist-only. The Guild feels that providing this service falls within pharmacists' core competencies and that they are in an excellent position to assess the severity and acuity of patients' condition and can appropriately escalate treatment, if/when appropriate.

We agree with the comments put forward that up scheduling means patients can access treatment with the added expert direction and support of pharmacists at each occurrence of supply. We are very confident that pharmacists are well located and well equipped to provide equitable access to safe and effective treatment.

Methenamine hippurate provides an alternative to antibiotics in the treatment of urinary tract infections, enhancing pharmacists' role in antimicrobial stewardship. It would also

help patients avoid costly GP consultations and hospitalisations and reduce inappropriate customer spending on potentially unsuitable general sale products.

The Guild does not think that the reclassification will have any pronounced effect on pharmacies financially. We are mindful of the reasons for up scheduling the preparation, as we consider pharmacists' time an extremely valuable commodity. We would want pharmacists to be remunerated appropriately for their time and expertise when performing this (and any) service and would appreciate this committee's endorsement thereof. The provision of a data sheet and consumer medicines information sheet from the sponsor of Hiprex (methanamine hippurate) will be welcome to further supplement the service provided to patients.

6.1b Glecaprevir and Pibrentasvir – proposed change to prescription classification statement (Health New Zealand, Long Term Conditions)

The Guild commends this submission from Health New Zealand in its alignment with the goal to eliminate Hepatitis C as a major public threat by 2030. Concerted efforts across all sectors to improve patient access to hepatitis C treatment has potential to vastly improve the lives of patients, reduce new infections, prevent disease-related complications and save health system resources.

Several barriers to treatment access exist and this current submission focuses heavily on the potential benefits of nurse-led clinics as a working solution to widen prescribing scope of glecaprevir and pibrentasvir (Maviret)and increase treatment access. Previous workarounds such as the utilisation of standing orders in a test-to-treat function were deemed 'not useful' as it did not allow nurses to prescribe treatment, being further limited to Hepatitis C not being classed as a 'long-term condition so treatment not being appropriately included in current nurse prescribers' prescribing schedule.

While the Guild supports the widening of access and the increased accessibility of hepatitis C testing and treatment, we feel that the inclusion of pharmacists and pharmacist prescribers would be a more efficient and safer pathway. We instead support changing the classification statement to the following:

"*Pibrentasvir - prescription except when prescribed in combination with Glecaprevir for treatment of chronic hepatitis C virus infection to people aged 16 years or over who meet the clinical and eligibility criteria on hepatitis C provision by pharmacists who have completed the approved training programme, when treatment is initiated by a pharmacist or recommended by a registered nurse who has specialty knowledge of hepatitis C*, or a nurse working in the community in a high-prevalence hepatitis C environment, who has successfully completed the approved training programme, and who meet the criteria of the training programme*."

We would also like to see Maviret added to the list of medicines that pharmacist prescribers can prescribe.

Pharmacists are perfectly positioned to provide cost-effective specialised services that can alleviate pressure on already strained healthcare sectors, for example rural outpatient clinics. The addition of Glecaprevir and Pibrentasvir (Maviret) to pharmacist

prescribers' prescribing schedule will further utilise their skills and relationships, complementing their nurse prescriber counterparts.

Community pharmacy has proven its worth during the COVID-19 pandemic not only as an invaluable health resource, but as a patient "first point of contact" who are adequately placed to meet patients' prescribing, testing and treatment requirements. Thanks to the efforts during COVID-19, pharmacies now have access to patient information portals, such as Conporto/reCare and CCCM and further access could be set up as required to ensure patient safety and continued care. These options should be more cost effective than setting up mobile outreach programmes and/or access to information for such services. Despite this, community pharmacy has been identified in the National Hepatitis C Action Plan as involved in mostly a 'early detection and screening' and dispensing function.

The Guild would suggest that pharmacists, who have dispensed over 5,000 courses of the medicine to date, are the logical choice to also be performing safe and results-based risk-assessments for patients and prescribing Maviret. As the submission outlines, Hepatitis C is straightforward to diagnose, with clear referral criteria, with treatment that is well-tolerated and easy to adhere to. The benefit to patients would be more pronounced in a campaign where a large portion of the target population are already being looked after by pharmacies.

It should be noted that while this submission has outlined the use of nurse-led clinics as a solution for hepatitis C patients, it has not provided the number of nurses currently working with hepatitis patients, their geographical spread and has also failed to quantify the number of patients that stand to benefit from this change. Having this information would give us a better indication of whether the current relevant nurse workforce is adequately staffed – numerically and geographically – to equitably optimise their current services. Despite the government's aim to reduce the 'postcode lottery' in its implementation of current health reforms, the 'how' of the changes remains a largely theoretical matter. If equity and access is the main goal, the inclusion of pharmacy will only bolster this and encourage interprofessional cooperation towards the shared goal of eliminating hepatitis C by 2030.

This submission also makes several references to 'barriers to access' yet it does not provide any further details regarding any other barriers that exist for patients.
The Guild also opposes the "one-stop-shop" model where nurses can prescribe and provide Maviret because:

- The risks involved in such a model and the precedent it creates would not benefit healthcare or public trust in the long term. Medicine provision has traditionally fallen under pharmacists' scope, being well-versed at providing patient advice. Thorough and intensive Maviret-specific training for pharmacists is well-established and has good uptake.
- There are currently no provisions or legal precedence for nurses to be able to prescribe any medicine where continued patient care or due diligence is required.
- There are currently no supply lines and/or logistics in place for nurses to be able to order, store and supply medicine.

- Access to patient clinical records/data are not available to nurses in rural/remote areas. This might extend to lack of infrastructure to perform telehealth consults, order labs and/or consult other clinicians.

The Guild would like instead to propose the following model, based on existing infrastructure and a nurse referral system:

- That the 57000-strong nurse workforce be encouraged to complete bespoke training for the programme and then be utilised to identify, promote and pre-counsel potential patients that would benefit from the therapy.
- Once identified the patient is **referred** to a pharmacist authorised (by the change in the classification statement) to prescribe and dispense the medicine.
- Nurses will perform an initial eligibility screening before referral.
- Pharmacists opt-in to provide the service via a two phased rollout, after completing the **appropriate training:**
    1. Firstly, pharmacies who have existing COVID-19 Care in the Community (CCinC) agreements; where a funding stream is already in place and functioning and have current **access to CCCM and patient-information portals**.
    2. Secondly pharmacies who wish to opt-in or are identified by their local health districts as key locations to provide the service. They will complete the training and be set up with access to the required information systems.
- Once a pharmacist receives a referral from a nurse, a further eligibility screening will take place, including funding eligibility before the pharmacist will proceed to prescribe and dispense the medicine.
- Once dispensed, the medicine can be provided to the patient by the pharmacist or the nurse with the appropriate counselling and consultation.
- An appropriate follow-up consultation will be arranged by whoever initiated the supply, if possible.
- The medicine remains an Xpharm funded product and the nurse and pharmacist are remunerated for the consultation, prescribing, dispensing, counselling, and follow-up counselling functions as per the COVID-19 Care in the community guidelines.
- Both the referral step and the counselling steps can be done via a Telehealth or CCCM-integrated/triggered interaction between nurse and pharmacist, which will improve accessibility to the service in remote areas.
- The delivery of the medicine in rural/remote areas is also provided for by the CCiC agreements.

This model provides an excellent opportunity for pharmacists and nurses to work in synergistic cooperation, preventing costly hospitalisations and, in this case provide a refined futureproof pathway to an elimination strategy.

- It also ensures a lower-risk model for a specialised product that requires specialised knowledge and access to patient records and history.
- It also does not try and re-invent the wheel and utilises existing systems hard-fought for and established during the COVID-19 pandemic, and existing funding streams that can easily be re-utilised.

- It uses existing pathways and systems. The implementation process can be extremely quick (as we saw during COVID) and effectively bring the elimination strategy and timeframe back on track with the WHO ideals.
- This pathway can then further be used to implement further "game-changing" health initiatives to areas of high need.

Funding:
We would be interested to know how nurses would be funded for the proposed prescribing function, and if that funding would encompass dispensing and associated counselling, which is not currently within their scope of practice.

Pharmacists could be funded via different models, that can be existing or bespoke:

- As per current CCinC model: $75 per 30minute per prescribing and counselling service delivered
- Appropriate training: This can integrate with current training for pharmacists to dispense Maviret. The current fee for dispensing Maviret and counselling will remain in place for pharmacists.
- As per existing Xpharm guidelines currently in place for Maviret dispensing with an added fee for prescribing.

6.1e National Immunisation Schedule - proposed change to prescription vaccine classification statements (Ministry of Health)

The Guild welcomes the proposed changes to the classification statements of the vaccines listed.

Pharmacy has the competent workforce (pharmacist vaccinators) and infrastructure (cold chain management) and are geographically well placed to be able to perform all vaccination services. We believe this will not only widen equitable access to vaccination services, but it will also improve the ease of access for patients. The successful uptake of COVID-19 vaccinations in community pharmacy during the Delta and Omicron waves is a testament of this. Pharmacist vaccinators are familiar with navigating their way around relevant training and information resources available through the Immunisation Advisory Centre (IMAC) and escalating any clinical queries accordingly.

The Guild is keen to confirm that all these vaccines will be funded via the XPharm route as is currently the case for Boostrix vaccinations, etc. This will ensure pharmacies do not have unnecessary stock outlay but be able to provide walk-in or opportunistic vaccinations.

We understand that this committee is not responsible for funding decisions but would welcome a recommendation to Pharmac and Te Whatu Ora in this regard. The recent reclassification of the shingles vaccine (Shingrix) is case in point: the vaccine was reclassified for pharmacist vaccinators to administer, but no funding structure has been implemented making the reclassification rollout less effective and administratively cumbersome and confusing to consumers. From an operational level, the Guild would also appreciate the Government's support in the communication and marketing of the resulting changes to the general public as this would ensure standardisation of marketing material and vaccination messaging.

8.2a Low dose cannabidiol

The Guild welcomes the proposed down-scheduling of CBD products with ministerial consent as pharmacist-only medicines.

We believe that providing CBD products adhering to the same conditions as the Australian Poisons Standard Schedule 3 (Pharmacist Only Medicine) would fall within the scope of practice and competence standards of New Zealand pharmacists.

Pharmacists are already providing CBD products on prescription and are coming to grips with the myriad of products available, the classification of these products and the requirements for storage and safe dispensing.

Thank you for your consideration of our response. If you have any questions about our feedback, please contact our Senior Advisory Pharmacists, Martin Lowis (martin@pgnz.org.nz, 04 802 8218) or Isabel Cala (isabel@pgnz.org.nz, 04 802 8209).

Yours sincerely,

Nicole Rickman
General Manager – Membership and Professional Services

The Royal New Zealand
College of General Practitioners
Te Whare Tohu Rata o Aotearoa

3 October 2022

Jessica Crockett
Medsafe
Ministry of Health
PO Box 5013
WELLINGTON

via email: committees@health.govt.nz

Tēnā koe Jessica

Agenda of 69th Meeting of the Medicines Classification Committee (MCC)

Thank you for the opportunity to provide comment on the agenda items for the 69th meeting of the MCC.

The Royal New Zealand College of General Practitioners (the College) is the largest medical college in New Zealand. Our membership of 5,748 general practitioners comprises almost 40 percent of New Zealand's specialist medical workforce. The Division of Rural Hospital Medicine also sits within the College's academic remit of vocational training of doctors working in rural hospitals. Our members cover both urban and rural settings, and work in a variety of business structures. The College kāupapa is to set and maintain education and quality standards for general practice, and to support our members to provide competent and equitable patient care.

Our submission

The College has commented on the following agenda items

- 6.1b Glecaprevir and Pibrentasvir (Maviret) – proposed change to prescription classification statement (Manatū Hauora/Ministry of Health, Long Term Conditions)
- 6.1e National Immunisation Schedule - proposed change to prescription vaccine classification statements (Manatū Hauora/Ministry of Health)

Agenda item 6.1b Glecaprevir and Pibrentasvir (Maviret)

Agenda item 6.1 is an application to the MCC from Te Whatu Ora/Health New Zealand, seeking to widen access to glecaprevir and pibrentasvir (Maviret), a treatment for chronic hepatitis C infection, by allowing nurses with appropriate knowledge and experience to administer Maviret without a prescription.

Summary of RNZCGP position

The College supports the proposed reclassification of Maviret which will improve access for a particularly marginalised population. The reclassification will apply to only a small group of experienced nurses specialising in Hepatitis C with close links to secondary care gastroenterology services. The College notes that existing mechanisms enabling nurse prescribing, are not being utilised.

The College supports improving equity of access to Maviret

Chronic hepatitis C disproportionately affects marginalised populations, who access health services infrequently. Fifty to eighty percent of people who inject drugs (PWID) are infected with Hepatitis C compared to only on in every 100-200 individuals in the general population. The distribution of Hepatitis C by ethnicity in New Zealand is not known however Māori are overrepresented among patients with advanced liver cancer due to Hepatitis C and emerging data suggests that Māori have a higher prevalence Hepatitis C and are likely to have higher rates of long-term complications than non-Māori.[1] The College's Foundation Standard requires general practices to have a commitment to the principles of the Treaty of Waitangi (Indicator 3.1). Practices are required to identify and understand the health needs of Māori and partner with local Māori organisations, provider groups and whānau to deliver on these needs.[2]

The College supports taking services to places frequented by people with a high incidence of Hep C to remove access barriers and improve uptake of diagnostic tests and treatment. These include shelters for the homeless, the locations of services for drug users, and prisons. Allowing suitably trained nurses to prescribe Maviret is an important enabler of such outreach. Nurse led management is one of the recommendations of the National Hepatitis C Action Plan for Aotearoa New Zealand, which provides a framework for working towards the World Health Organization's (WHO's) goal to eliminate viral hepatitis by 2030.[3]

Nurse led treatment for hepatitis C must be integrated with both secondary and primary care

We consider that integration with general practice is a key requirement for outreach programmes. We note the requirement for nurses prescribing Maviret to have ready access to their secondary care team is mentioned in the application (p16). but integration with primary care is not mentioned. Engagement with general practice facilitates patient follow up after treatment with Maviret but also enables other comorbidities to be identified and manged. Members of marginalised population groups such as PWID often have multiple chronic conditions including metal health conditions. The comprehensive holistic care provided in general practice is essential for patients with comorbidities.

The submission acknowledges that patients may have health concerns other than Hepatitis C and suggests that nurses would be advised to always recommend that the patient sees a general practitioner regularly for their wider health needs (p16). We consider that in this patient population assistance to enrol with a general practitioner should be provided. Facilitating enrolment could potentially be an additional advantage of this reclassification. Enrolment with a general practice provides access to comprehensive health care and significantly decreases the financial costs of appointments

Current programmes to enable nurse prescribing are less appropriate for single medication prescribing.

The reclassification proposal is essentially a workaround resulting from a lack of uptake of the established pathways to enable nurse prescribing namely Nurse Prescribing in Specialist and Community Teams[4] and Registered Nurse Prescribing in Community Health.[5] These programmes equip registered nurses to prescribe a range of medications however the proposal states that nurses involved in hepatitis C management consider that the time involved is a deterrent to taking up the prescribing pathway. (P 4)

Agenda item 6.1e National Immunisation Schedule

Agenda item 6.1e is an application to the MCC from Manatū Hauora/Ministry of Health. It proposes to widen the classification for a number of vaccines to allow vaccinators who have successfully completed the Vaccinator Foundation Course (or equivalent course) approved by the Ministry of Health and who comply with the immunisation standards of the Ministry of Health to both distribute and administer vaccines.

Summary of RNZCGP position

The College considers that improving the current process to enable authorised vaccinators to deliver a wider range of vaccinations should be explored, prior to consideration of reclassification. Moving from local to national authorisation of vaccinators and national approved vaccination programmes would remove the current geographic barriers for trained vaccinators wishing to administer the unfunded vaccines referred to in the application.

Should reclassification be considered necessary, a revised proposal which separately addresses childhood vaccines, unfunded adult vaccines and travel vaccines should be submitted. In this application the proprietary names of the vaccines under consideration should be included in the proposal. The College would likely support such a reclassification of adult vaccines, would likely support the role of pharmacists and other authorised vaccinators in providing childhood vaccines as part of an Outreach Immunisation Service (OIS), but would likely not support the reclassification of travel vaccines or BCG.

General practices play a key role in delivering vaccinations especially childhood vaccinations

General practices provide routine childhood vaccinations as part of providing comprehensive patient care. Whanau are contacted before immunisations are due (pre-call) via phone, letter, email or SMS. If vaccinations become overdue further contact is made on 2-3 occasions before a referral is made to the Outreach Immunisation Service (OIS). Immunisations are provided by practice nurses who are authorised vaccinators.

Indicator 7 of the Colleges Foundation Standards describes the expectations for general practices around Immunisations. These include an expectation that the practice will have a documented process for immunisation recalls and a team member (or members) responsible for overseeing the management of recalls. The practice is expected to have recent data on immunisations by age and ethnicity to identify need for improvement initiatives and benchmark progress.[6] Immunisation has a key role in addressing health inequities.[7]

The College considers that general practice should retain the key role of coordinating childhood vaccinations for their enrolled patient population.

Vaccination rates among unenrolled children are a particular concern. Dr Nikki Turner stated in her presentation to the 2022 RNZCGP conference that immunisation rates for eight-month-old enrolled babies, including Māori, were at 90 per cent or above but fell to just over 50 per cent for unenrolled eight-month-old Māori babies in February this year.[8] The College considers that Pharmacists and other authorised vaccinators have a valuable role in providing childhood vaccinations as part of outreach programmes, in particular for unenrolled children. Services to facilitating enrolment to enable the whanau to receive comprehensive health care must also be provided at the time of vaccination.

The College recommends moving from local to national authorisation and approved vaccination programmes.

Local approved immunisation programmes[9] allow authorised vaccinators to administer unfunded vaccinations. Influenza vaccination is one such programme. Under the National Immunisation Schedule (NIS) influenza vaccination is funded for people with certain health conditions or over certain age limits. However, influenza vaccination is provided to people who fund this themselves via a 'local approved immunisation programme.' Authorised vaccinators are approved by their local medical officer of health, and consequently are required to reapply for authorisation if they wish to work in a different area. Authorised vaccinators can administer a vaccine that is a prescription medicine 'otherwise than pursuant to a prescription" so long as it is part of an approved vaccination programme.
The College considers that both authorisation of vaccinators and unfunded vaccination programmes should be nationally rather than locally organised. The legal ability to do this exists already in that the Medicines Regulations 1984 state that authorisation can be from the Director-General or a Medical Officer of Health according to Clause 44A (1).[10]

> Any medical practitioner or other person who is authorised by the Director-General or a Medical Officer of Health in accordance with this regulation to administer, for the purposes of an approved immunisation programme, a vaccine that is a prescription medicine, may, in carrying out that immunisation programme, administer that prescription medicine otherwise than pursuant to a prescription.

The College considers that authorisation should be granted by the Director-General of Health, rather than the local Medical Officer removing the problem of geographical limitations on authorisation, and that influenza vaccination and other vaccinations such as MMR should be part of national rather than local programmes. We understand that influenza immunisation, moved from a local to a national programme for both funded and unfunded immunisations in 2022.[i] This will have resolved the problem identified on p 15 of the application namely that people without a qualifying health condition and under the age of 65 are unable to legally receive the flu vaccine from an authorised vaccinator without a prescription, unless there is a local vaccination program authorised by the medical officer of health.

Childhood immunisation provision should be part of a holistic service

Routine childhood immunisations provide a valuable opportunity to identify whanau requiring interventions. Providing childhood vaccinations in general practice extends beyond gaining informed consent and administering the vaccine. This opportunity is used to enquire after whanau wellbeing, with particular emphasis on mental health, safety, and infant health. Concerns can be followed up with the involvement of appropriate members of the general practice team, including, when necessary, Health Improvement

[i] Personal communication 3/10/22 Bernadette Heaphy, Immunisation Advisory Centre Programme Manager – Education

Practitioners. ‘Safety netting’ is also provided with whanau encouraged to be contact the practice should particular symptoms occur, or minor concerns persist or worsen.

Mental health issues are common in the perinatal period, with up to 18 percent of mothers and up to 10 percent of fathers developing depression, anxiety, or other mental health issues. These rates are higher among Māori and Pacific and Asian peoples. Evidence reveals that children with a parent with postnatal depression have poorer long-term health and developmental outcomes. Early identification and intervention as soon as issues begin to present is critical to achieving the best outcomes for mothers, babies and the wider whānau.[11]

Feedback from Māori Māmā shows that whānau want more than just immunisation services, they want a holistic service[12] This is consistent with the immunisation standards which state that organisations who offer immunisation services should not do so in isolation from other services Appendix 3 A3.4 (p 600).[3] General practices hold comprehensive and current lists of patients' medicines and adverse reactions. This information helps determine whether the vaccine is safe to administer. General practice offers a holistic service in a way that community pharmacy cannot.

Initial experiences of immunisation must be positive as this will influence future uptake

The immunisation status of a child at two years is influenced by the mother’s experience of her child’s early vaccinations with negative experiences decreasing the update of future vaccinations.[13]

Travel vaccinations and BCG should not be reclassified

The College considers that travel vaccinations should not be reclassified as there is currently no training available to vaccinators to support the consultation that is necessary when selecting appropriate travel vaccines and obtaining informed consent.

BCG Vaccinations currently require additional authorisation to administer BCG vaccination in the light of specific requirements of this vaccine. BCG is the only vaccine given intradermally, and it is supplied in a multidose vial.

Introduction of the Aotearoa Immunisation Register (AIR) is necessary before changes are made

The existence of multiple providers of childhood immunisation will introduce uncertainty around whether the child has already been vaccinated elsewhere and around who has responsibility for pre-call, re-call, and referral to outreach services, if required, and this uncertainty may have a detrimental effect on follow up of unvaccinated children. In future all vaccinations will be entered on the new Aotearoa Immunisation Register (AIR) unless the parents decline this. The College recommends that reclassification does not take effect until the AIR is operational.

Vaccines should be listed by proprietary names

The College recommends that the list of vaccines for reclassification reflects the vaccine formulations used in New Zealand. The current application does not include the proprietary names of the vaccines as per the guidance in the document ‘How to change the legal classification of a medicine in New Zealand’.[14] With the exception of Tdap, all vaccines are listed by the name of the disease, bacteria, or virus that they provide protection against. It is not clear why Tdap is treated differently to other vaccines.

The College considers that each vaccine formulation, should be considered individually for reclassification rather than a more generic reclassification naming a vaccine for a particular disease as vaccines protecting against the same disease can have different safety profiles.

Conclusion

Thank you for the opportunity to provide comment on the agenda items. The College supports the reclassification of Maviret. We support the widening of the vaccinator workforce but recommend that other avenues be explored to do this. If reclassification is determined to be the best option, then we recommend that a further application more accurately specifying the vaccines used in New Zealand is made. In this case we would likely support a reclassification of adult vaccines, would likely support the role of pharmacists and other authorised vaccinators in providing childhood vaccines as part of an Outreach Immunisation Service (OIS), but would not support the reclassification of travel vaccines or BCG.

If you require further clarification, please contact Maureen Gillon, Manager Policy, Advocacy, Insights - maureen.gillon@rnzcgp.org.nz

Nāku noa, nā

Dr Bryan Betty
ONZM, FRNZCGP (Dist.), FACRRM, MBChB
Medical Director | Mātanga Hauora

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[1] Ministry of Health NZ. National Hepatitis C Action Plan for Aotearoa New Zealand - Māhere Mahi mō te Ate Kakā C [Internet]. 2021 Jul [cited 2022 Sep 28]. Available from: https://www.health.govt.nz/publication/national-hepatitis-c-action-plan-aotearoa-new-zealand-mahere-mahi-mo-te-ate-kaka-c

[2] RNZCGP Foundation standard Available from https://www.rnzcgp.org.nz/Quality/Foundation/Quality/Foundation_pages/Foundation_home.aspx?hkey=f347fda1-a65f-4928-b251-fd6e03b59af0 accessed 30/9/22

[3] National Hepatitis C Action Plan for Aotearoa New Zealand - Māhere Mahi mō te Ate Kakā C [Internet]. Ministry of Health NZ. [cited 2022 Sep 28]. Available from: https://www.health.govt.nz/publication/national-hepatitis-c-action-plan-aotearoa-new-zealand-mahere-mahi-mo-te-ate-kaka-c

[4] https://www.nursingcouncil.org.nz/Public/Nursing/Nurse_prescribing/RN_prescribing_in_primary_health_and_specialty/NCNZ/nursing-section/Registered_nurse_prescribing_in_primary_health_and_specialty_teams.aspx?hkey=e0dcf5e0-b496-4f84-9dd3-24b6fc55f766 Accessed 30/9/22

[5] https://www.nursingcouncil.org.nz/Public/Nursing/Nurse_prescribing/Registered_nurse_prescribing_in_community_health/NCNZ/nursing-section/Registered_nurse_prescribing_in_community_health.aspx?hkey=6f9b0230-0753-4271-9a81-0ee990032959 Accessed 30/9/22

[6] RNZCGP Foundation standard Available from https://www.rnzcgp.org.nz/Quality/Foundation/Quality/Foundation_pages/Foundation_home.aspx?hkey=f347fda1-a65f-4928-b251-fd6e03b59af0 accessed 30/9/22

[7] ia2030-document-en.pdf [Internet]. [cited 2022 Oct 2]. Available from: https://www.who.int/docs/default-source/immunization/strategy/ia2030/ia2030-document-en.pdf

[8] Practices important players in vaccination: Don't forget the unenrolled [Internet]. New Zealand Doctor. 2022 [cited 2022 Sep 6]. Available from: https://www.nzdoctor.co.nz/article/practices-important-players-vaccination-dont-forget-unenrolled

[9] https://www.health.govt.nz/system/files/documents/pages/definition-of-an-approved-immunisation-programme-oct16.docx accessed 30/9/22

[10] https://www.legislation.govt.nz/regulation/public/1984/0143/latest/whole.html

[11] Maternal Mental Health Service Provision in New Zealand: Stocktake of district health board services [Internet]. Ministry of Health NZ. [cited 2022 Sep 28]. Available from: https://www.health.govt.nz/publication/maternal-mental-health-service-provision-new-zealand-stocktake-district-health-board-services

[12] Brown S, Toki L, Clark T. Māori Māmā views and experiences of vaccinating their pēpi and tamariki: [Internet]. Health Promotion Agency; 2021 p. 39. Available from: https://workresearch.aut.ac.nz/__data/assets/pdf_file/0019/613621/HPA_Report_2021.pdf

[13] LitRev_Influences and policies that affect immunisation coverage_final.pdf [Internet]. [cited 2022 Sep 20]. Available from: https://www.immune.org.nz/sites/default/files/publications/LitRev_Influences%20and%20policies%20that%20affect%20immunisation%20coverage_final.pdf

[14] How_to_change_medicine_classification.pdf [Internet]. [cited 2022 Sep 21]. Available from: https://www.medsafe.govt.nz/downloads/How_to_change_medicine_classification.pdf