New Zealand
Medicinal Cannabis Council
Te Kaunihera Rautini
o Aotearoa

26 April 2023

The Medicines Classification Committee Secretariat
Medsafe
PO Box 5013
Wellington

Dear Sir/Madam,

Re: Comment on the Medicines Classification Committee 70th meeting agenda item 5.1a

The New Zealand Medicinal Cannabis Council appreciates the opportunity to provide a submission to the Medicines Classification Committee (MCC) 70th meeting for cannabidiol (CBD). This reconsideration follows objections to the recommendation from the MCC's 69th meeting where cannabidiol was recommended to remain prescription-only despite the reclassification to pharmacist-only in Australia.

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 objected to the recommendation from the MCC 69th meeting regarding CBD on the basis of benefits not being considered, safety concerns being over-stated and inconsistencies with other decisions. We now wish to provide a submission for the reconsideration by the MCC at their 70th meeting.

We encourage a proportionate response to a consideration of a herbal remedy that has been used for thousands of years[1], is available without prescription in many jurisdictions[2], and would be available in relatively low doses. The committee can have further assurance that the proposed classification would require products on the market to have gone through review for safety and efficacy by Medsafe, similar to other non-prescription medicines. It is very reasonable to make cannabidiol prescription except when provided by a pharmacist in a dose up to 150 mg/day to enable safe access to this herbal remedy.

We note that the MCC recommendation from 2022 varied substantially from the international trend to widen access to CBD[2, 3] which is based on lack of harm from CBD despite widespread use. We also note the lack of alignment with NZ government policy regarding Trans-Tasman Harmonisation. We also believe the decision to retain the prescription-only status without exemption for pharmacist-supply underrates the ability of pharmacists to manage CBD. The pharmacist-only model has been taken seriously by pharmacists for other medicines[4-9], and would provide considerable protection for consumers while still enabling improved access. Finally, the approach for CBD could be more aligned with the approach taken previously by Medsafe and the Medicines Classification Committee with other herbal remedies, the proportionate approach taken with other non-prescription medicines, and aligned to that taken in other countries which have used this safety-based approach. New safety data is now available to assist the decision.

We discuss these points in greater detail below.

The committee discussion in 2022 was minuted as follows:

"The Committee noted that CBD medicines did not have an established long-term safety profile, when used as medicines, which would usually be expected to support down-scheduling of a substance. They also noted that there are currently no approved products in New Zealand that have a daily dose of <150 mg, it was not clear what indications this dose would cover, and therefore there was no clear access issue for these specific medicines.

The Committee noted that there are potential safety issues pertaining to drug-drug interactions with CBD.

The Committee concluded that it was not necessary to harmonise with Australia's scheduling of low-dose CBD."

International view

Many developed countries allow non-prescription supply of CBD[2, 3], reflecting the low risk of CBD, its very long use as a herbal remedy, and the lack of safety concerns that have arisen over the years with CBD. There are recent examples where regulators and the European Court of Justice have examined CBD with respect to the need to restrict availability which are discussed below. The trend is for wider access not for limiting to prescription only status.

The Therapeutic Goods Administration (TGA) in Australia reviewed the safety of low dose CBD in 2020[10] which indicated that *"at low doses, CBD appears to have an acceptable safety and*

tolerability profile, although it was evident that there is a high potential for drug-drug interactions" noting it is unclear if these interactions existed with low-dose CBD. The review (which is attached) recommended that downscheduling of CBD up to 60 mg/day should be considered. The subsequent decision to downschedule to pharmacist-only was made by a Delegate of the Secretary of the Department of Health, a senior medical officer at the TGA following consideration by the Advisory Committee for Medicines Scheduling and extensive public consultation, and was uplifted to 150 mg/day based on evidence provided to the Delegate and consultation[11]. The Notice of Final Decision is attached, and includes the following comments by the Delegate:

"…I have resolved that a maximum daily dose of 150 mg is consistent with the expected safety profile of a Schedule 3 medicine.

In forming this view, I considered the findings of a recent systematic review of clinical trials, which concluded that CBD is well tolerated across a wide range of dosages. I note that CBD is rarely associated with severe adverse events, and that non-serious adverse events appear significantly lessened at lower dosages. The study demonstrates that, outside of the treatment of epilepsy, diarrhoea is the only adverse event that is more prominent than placebo. I note that similar margins of safety were reported in two separate systematic reviews and meta-analyses published in 2020 (Larsen and Shahinas et al., 2020 and Dos Santos et al., 2020).

I have considered the evidence presented in a submission, which outlined the findings of a confidential report on efficacy and safety of oral CBD. I find the evidence presented in this report to be credible and relevant and I have attached weight to this report on the basis that this is a current and comprehensive scientific review of the literature."

It is also of note that the Australian scheduling committee had the view that: *"restriction of the Schedule 3 entry to preparations included in the ARTG [ie registered as medicines] would ensure that such products had a defined indication appropriate for supply as a Pharmacist Only Medicine."* Note that the same situation applies in New Zealand with the proposed availability through the pharmacist – the product would need to be registered and the indication would be considered at that time and able to be referred to the committee if there was any doubt about the appropriateness of the indication for supply by the pharmacist.

In December 2021, the French government approved the sale of products containing CBD with a THC content under 0.3%, and in January 2023 this was extended to CBD flowers[12]. A ruling in November 2020 by the European Court of Justice relating to a CBD product in France noted that CBD was not a drug, was not a narcotic, and that *"… the CBD at issue in the main proceedings does not appear to have any psychotropic effect or any harmful effect on human health on the basis of available scientific data*."[13] The ruling discussed the principle of proportionality in protecting public health. It also referred to the French National Agency for Medicines and Health Products Safety stating 25 June 2015 that there were insufficient data to classify CBD as *"harmful".*

Trans-Tasman Harmonisation

Considerable work has occurred since the late 1990s to harmonise the scheduling of medicines between Australia and New Zealand[14, 15]. A previously published guidance for Trans-Tasman harmonisation from Medsafe indicated that where the scheduling differs between Australia and New Zealand for a medicine, the intent has been to harmonise to the least restrictive schedule while considering public health and safety issues and/or jurisdictional needs. This is a logical process that remains consistent with a wider still active intent to reduce unnecessary regulatory barriers between Australia and New Zealand under the Closer Economic Relationship (CER) and the Single Economic

Market (SEM) Agenda. New Zealand and Australia's economic and trading relationship is recognised as one of the closest, broadest and mutually compatible in the world[16]. CER highlights include that *"most goods that can be legally sold in one country can also be legally sold in the other".* There has been no reason given that New Zealand consumers or pharmacists are less capable than those in Australia of managing CBD, or that New Zealanders would be subject to harm as a result of harmonising CBD.

We note that the MCC did not consider all the benefits, and apologise that we did not highlight these in our previous submission. Benefits of particular note include:

1. Self-medication for reduction of symptoms from medical conditions occurs with cannabis in New Zealand[17-21]. Having a licensed CBD product available without prescription in NZ in the future would provide a benefit over the current situation where people are acting illegally in purchasing and using this product, may have challenges getting regular supply, are receiving unknown and variable doses, and potentially having adverse effects from THC (including influence on driving) an ingredient they may not seek. Barriers to access of medicinal cannabis exist[19, 21] some of which would be aided by pharmacist-supply of CBD. In a publication from a recent French study[22] in which usage was higher in people with more than one chronic medical condition, authors hypothesised that some people use CBD to reduce their cannabis consumption.

2. Despite over 14,000 CBD products being purchased in New Zealand in the first half of 2021 (compared to just over 2,000 CBD and THC products, and less than 1,000 THC products), it is still considered inaccessible and unaffordable for many[21, 23]. Reclassification to allow pharmacist-supply will improve access and affordability, aiding equity of access in the future.

3. Availability as prescription except when provided by a pharmacist provides interaction with a health care professional, a pharmacist, who would refer people who needed medical advice, as they currently do regularly for many medicines[24]. This is preferable to self-medication with illicit cannabis which will be unlikely to involve a health care professional.

4. A reclassification is likely to stimulate drug trials to aid in gaining registration of a CBD medicine suitable for non-prescription use. Anecdotal reports indicate this has happened in Australia with their downscheduling. This would be very beneficial to future knowledge.

5. The purchase of CBD products from overseas by people located in New Zealand will include some purchases which are not stopped at the border (based on anecdotal reports). These products may not meet the NZ requirements for product registration, may not meet their label claims, may have contaminants, and are unlikely to have a health professional involved in their supply. Legal supply in New Zealand of a CBD medicine through the pharmacist would remove the need to import CBD.

Inconsistency of approach

The CBD decision is inconsistent with other New Zealand classifications of long-known herbal ingredients without significant toxicity or abuse which have taken a more proportionate approach.

Unless there are known harms, other pharmacologically active plant-based ingredients tend to be classified in New Zealand as pharmacist-only, pharmacy-only or general sales, or not classified at all

with less data available than for CBD. These remedies typically do not have long-term safety data or listed indications. This is a pragmatic, proportionate and reasonable approach that has historically been taken by Medsafe and been seen in Medicines Classification Committee considerations, and one that we would recommend here. Examples are listed in Table 1 below.

Table 1. Examples of herbal ingredients classified in New Zealand as pharmacist-only or pharmacy-only medicines or unscheduled

Classification	Ingredient
Pharmacist only	Santonin, Stramonium
Pharmacy only	Aconitum spp; for oral use in packs containing 0.2 milligrams or less and more than 0.02 milligrams of total alkaloids; for dermal use in concentrations of 0.02% or less and in packs containing 0.2 milligrams or less and more than 0.02 milligrams of total alkaloids Aloes; for internal use; except when obtained solely from the mucilaginous gel of the leaf Aloin Colocynth Datura spp; for oral use in liquid form in medicines containing 0.03% or less and 0.3 milligrams or less per dose and not more than 1.2 milligrams per recommended daily dose of total solanaceous alkaloids; in solid dose form in medicines containing 0.3 milligrams or less per dose form and not more than 1.2 milligrams per recommended daily dose of total solanaceous alkaloids Delphinium staphisagria; except in medicines containing 0.2% or less Duboisia leichhardtii; for oral use in liquid form in medicines containing 0.03% or less and 0.3 milligrams or less per dose and not more than 1.2 milligrams per recommended daily dose of total solanaceous alkaloids; in solid dose form in medicines containing 0.3 milligrams or less per dose form and not more than 1.2 milligrams per recommended daily dose of total solanaceous alkaloids Gelsemium sempervirens; except in medicines containing 1 milligram or less per litre or per kilogram Ipomoea spp; except ipomoea batatas Jalap resin Lobelia inflata; except in medicines for smoking or burning Lobeline; except when in medicines for smoking or burning Papaverine; except for injection
Not scheduled	St John’s Wort

Source: Medicines Regulations 1984 Version as at 22 December 2022

Drug interactions

We consider that the MCC could usefully reconsider the drug interactions concerns. Drug interactions with CBD would easily be manageable by pharmacists who are well-trained in drug interactions. Pharmacists have been trusted to manage the drug interactions with the pharmacist-only classification of the Covid treatment, Paxlovid. These include many contraindicated interactions associated with serious or life-threatening adverse effects with commonly used medicines such as simvastatin, sildenafil, triazolam and colchicine[25]. St John’s Wort has important interactions with drugs (as notified to prescribers in Prescriber Update Issue 20 in April 2000) but this has not required greater restriction on its availability which has remained unscheduled. The interactions with CBD are known and available in common drug interactions resources that

pharmacies have access to, e.g. Stockley's Drug Interactions. Drug interactions were noted in the Australian downscheduling consideration, but did not impede the reclassification.

Safety

Safety reviews were noted to be important in the Australian down-scheduling. More recent data supports the earlier findings. A review of data from CBD studies through to 2022 concluded that: "(1) clinically relevant CBD effects tend to become more robust as dosage is increased (up to 400 mg); (2) CBD appears exceptionally safe, with very few concerns even at the highest dose range considered (>300–400 mg); and (3) further high-quality clinical trials involving lower oral doses of CBD are urgently needed to clarify therapeutic actions."[3]

Souza et al[26] updated their previous review with a paper published January 2019 to May 2022. They concluded: *"The data from the present systematic review agree with previous data on the safety of purified CBD. The most common adverse effects are mild and moderate, and serious adverse effects are rare and have been only reported in epilepsy studies, with concomitant use of CBD with antiepileptic drugs."* They also recommended additional safety data be collected with different dosages and different formulations (e.g. purified CBD versus broad-spectrum products).

In 2020, the European Parliament was informed there is no evidence of public health-related problems associated with the use of pure CBD[27].

The UK MHRA Drug Analysis Profiles (accessed 21 Apr 2023) reports 508 adverse effect reports in 172 people for CBD as a single active constituent from 2006-2023, and one fatality. The fatality listed was sudden death. The information provided is insufficient to ascertain the likely causality for the reactions and there is no dose information.

A New Zealand SMARs database search of CBD includes 43 people with 107 reactions since 2000 and no fatalities. This included 22 people taking cannabis or THC. Of the remaining 21 people who took CBD the adverse reactions did not indicate the dosage provided to the patient. These adverse reactions were not unreasonable for a non-prescription medicine.

The MCC was concerned about lack of long-term safety data. Many non-prescription medicines do not have long-term safety data, e.g. the various herbals noted above, but other medicines also. For Methenamine Hippurate, considered by the MCC at the same meeting as CBD in October 2022, the discussion noted *"there is no long-term safety data"*, yet it was considered appropriate to be a pharmacist-only medicine, an inconsistent approach at the same meeting.

There is new long-term data available for CBD for up to four years for treatment resistant epilepsies in 892 patients.[28] Doses were typically considerably higher levels than what is being discussed for non-prescription use, e.g. some getting 25-50 mg/kg/day. This study found adverse events were responsible for permanent discontinuation of CBD in 7% of patients, but noted *"overall, CBD was generally well tolerated, and treatment-emergent adverse events were consistent with those reported previously."* The most common serious adverse effects were seizure, status epilepticus and pneumonia. The 20 deaths during the study were all deemed unrelated to treatment by the investigator. Patients were on a median of three concomitant anti-seizure medications. No patient met the standard criteria for drug-induced liver injury with CBD despite the long usage and high doses.

A study from the UK Medical Cannabis Registry included 2833 patients in the analysis with a mean follow-up of 226 days[29]. Few patients did not have THC in their preparation (n=86) so this limits the ability to ascertain adverse events for CBD alone. Adverse events were reported by 17% of patients, who typically reported multiple reactions. Adverse reactions were mild or moderate in most cases,

although there were a reasonable number of severe adverse events. Women were more likely to report adverse events and cannabis users less likely to. The study could not assess whether adverse reactions were treatment-related. Notably, health-related quality of life improved, as did sleep and anxiety symptoms.

A systematic review and meta-analysis of cannabidiol-associated hepatotoxicity found that no cases of drug-induced liver injury were reported in adults using CBD <300 mg/day[30]. Studies were included if they initiated daily CBD and had serial liver enzyme measures. Thus many studies were of relatively high CBD doses in patients with epilepsy. High doses of CBD (>1000 mg/day) and concomitant anti-epileptic drugs were risk factors for elevated liver enzymes and drug-induced liver injury. One study included in the review was of low dose 50-250mg/day CBD in inflammatory bowel disease, and it found no liver enzyme elevation in the 29 patients.

Given that many jurisdictions allow supply of CBD not even restricted to a pharmacy[2, 12], that the TGA in Australia and the Delegate of the Secretary of Health have looked carefully at CBD and considered pharmacist-only would be appropriate for up to 150 mg/day[11], the recent French review and decision to make CBD readily available[12], and that cannabis has been used since ancient times[3], it seems reasonable to take reassurance from decisions made in other trusted environments. This has happened before, e.g. with chloramphenicol eye drops taking confidence from the UK's review when considered by the MCC in 2009. Furthermore, the registration process will consider the appropriate safety information for CBD products.

Indications

Indications are not normally specified for herbal remedies where classification is considered, rather, safety is the focus (Table 1). Many medicines do not include indications in their classification statement, because this is typically decided at the product licence stage. Should a product be submitted for a licence and Medsafe have any concerns about the appropriateness of the indication for OTC use, it can be sent to the classification committee before the registration is complete. We suggest that the same process is involved as for other herbal remedies with classifications based on a lack of safety concerns, long-time usage, and aligned with international considerations. As noted above, the lack of indications did not prevent the reclassification in Australia as product registration was noted to be required, as it would be in New Zealand.

History of CBD

Cannabis has been used medicinally since before 2800 BC when it was listed in the Pharmacopoeia of Emperor Shen Nung (the father of Chinese Medicine)[1]. It was also mentioned in the texts of Greeks, Romans and Indian Hindus for treating health problems including arthritis, depression, inflammation and pain. In 1937, cannabis was demonised as a highly addictive drug that caused mental disorder and violence, a belief that was not evidence-based. Had there been no or minimal THC in cannabis we believe it never would have been made illegal and would likely be available as other herbal ingredients such as St John's Wort are.

Classification wording

We propose that the classification wording 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. The alternative, which we do not recommend for safety reasons, is

pharmacist-only medicine classification. This would allow 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. Given problems with products elsewhere meeting their label claims, with higher THC amount, and variable CBD strength versus the label[31, 32], plus the potential for contaminants, using *"prescription except when provided by a registered pharmacist"* as was used for sildenafil would take a safe approach while aiding access in the future.

Summary

Thank you for considering this submission. CBD is a long-used herbal remedy with good tolerability. It is reasonable to follow the proportionate approach of the many other jurisdictions that allow non-prescription sales of CBD. We note CBD is not particularly different in some respects to herbal remedies which have not been restricted to prescription. St John's Wort is also a herbal remedy with long-time use, it also has drug interactions, it has less long-term safety data than CBD, and it does not have any specific indications, for example.

We consider that CBD through pharmacist-supply holds little safety concern and has the potential to provide multiple benefits, which is why other jurisdictions, including Australia and France, have removed the need for a prescription. We hope to see CBD made available, as is appropriate, through pharmacist-supply via an exemption to prescription status to ensure a health care professional is involved in supply and protect consumers from importing unregistered products without health professional involvement.

Thank you once again for the opportunity to submit to the Medicines Classification Committee on the classification of CBD. Please contact us should you require any further information.

Yours sincerely

Sally King

Executive Director, NZMCC

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20 January 2023

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

Objection to recommendation at the MCC's 69th Meeting on Low-Dose Cannabidiol (CBD) re-scheduling

Tēnā koutou, thank you for considering this objection from Zeacann Ltd to the Medicines Classification Committee's recommendation to not re-schedule low-dose cannabidiol (CBD) medicines, and the grounds for this objection. We believe the MCC has erred in process and judgement, and we urge Medsafe to proceed with re-scheduling low-dose CBD.

The MCC was tasked with reviewing the scheduling of low-dose CBD following a decision by Australia's Therapeutic Goods Administration to make such products available over the counter in pharmacies if they have demonstrated efficacy. Specifically, the Committee was asked to harmonise with Australia.

This 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 was proposed that these changes would apply only to products that have gone through the full medicines classification process.

Instead, the Committee:

- excluded the member with the most experience in this field;
- failed to properly review the evidence given to it, including by Medsafe, such as the TGA's review of the safety of low dose cannabidiol, and does not appear to have sought out any additional information;;
- claimed New Zealand patients would face health risks with CBD interfering with other medicines, even though regulators in other countries including Australia have accepted these as minor, manageable and commensurate with other foods and herbs (and we do not require a prescription to eat grapefruit or liquorice, which carry similar "risks");
- concluded that it was not necessary to harmonise with Australia, despite the same meeting approving the scheduling of 12 other medicines under the heading "HARMONISATION OF THE NEW ZEALAND AND AUSTRALIAN SCHEDULES"; and
- failed to recommend any change.

If accepted, the recommendation for no change will mean people in Aotearoa New Zealand will have less access than those in Australia. Likewise, New Zealand medicinal cannabis companies will have less opportunities and smaller markets than Australian companies.

Yet it is normal overseas to purchase CBD products over the counter. I recently travelled across Europe and found CBD products on sale in most pharmacies, many supermarkets, and some cafes had CBD drinks or sweets. There didn't seem to be any problem and it wasn't controversial.

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In Europe and North America hemp-derived CBD products are not included in medicines regulations and may be available on general sale in addition to having consented products available under prescription or available from Pharmacies.

It is therefore puzzling why New Zealand has been so slow to allow safe, legal, and equitable access to CBD products, when all the available research and overseas experience confirms it is well tolerated at higher doses than what is proposed and has a safety profile that is superior to most approved medicines.

The Committee has made an error in stating it was “not necessary to harmonise with Australia”. This was, in fact, the reason for the item being on their agenda. New Zealand and Australia enjoy free trade, free travel, and subsidised healthcare in each country. Medsafe had provided regulatory guidance stating that “New Zealand and Australia have been working towards harmonisation of classification decisions in both countries.” The Committee clearly failed to understand why they were asked to consider this matter and are wrong to discount the importance of harmonisation.

Recommendations

Reject the recommendation of the MCC and proceed with re-scheduling low-dose cannabidiol to harmonise with Australia.

In addition, we urge non-therapeutic CBD products derived from hemp be available on general sale and regulated as foods or natural health products,

Ngā mihi,

Chris Fowlie
CEO, Zeacann Ltd

I'm writing this submission as an individual who wants to buy over-the-counter Cannabidiol and also cultivate and produce therapeutic CBD products in NZ. I think I speak on behalf of many Kiwis who want the same opportunities and desire to make our own decisions about what we can and cannot put in our bodies. Cannabis and CBD-only products have helped me a lot and I know of many other people who also report that cannabis has changed their lives for the better.

Even if we are granted the right to buy CBD OTC, Medsafe has made it clear that it will be virtually impossible for most of us to enter the industry to be able to manufacture organic, full spectrum CBD-only rongoa. They state it will be even harder than following the current medicinal standards.

"It should be noted, however, that data required to support an approved medicine, even an over-the-counter product, remains far greater than that required to demonstrate a product meets the minimum quality standard under New Zealand's Medicinal Cannabis Scheme. A large factor of cost for medicine applications is manufacturing to the standard required and running clinical trials."

It is unlikely that a small business would be able to fund and run clinical trials but even if they managed to, it would be unachievable to meet the requirement that 'the products intended to be administered must be manufactured in a GMP facility that is licenced to manufacture medicines'.

I believe that the requirement from Medsafe to make the approval of low-dose CBD products dependent on presenting data from clinical trials is too extreme, yet it seems to favour those who are licenced to manufacture under Medicinal Regs as they will be able to do so under their GMP certification. The cost to achieve those standards is out of reach for most of us.

We have all travelled or seen online the plethora of hemp-derived CBD products that can be purchased in health food shops, supermarkets and gas stations globally. Since 2016 in the UK most CBD products are sold as food supplements and there are hundreds of brands to choose from.

Data shows that millions of people have been using them for many years without any issues, so I ask that we are not intentionally held back from experiencing the same opportunities due to potential risks that have not been proven to be associated with low-dose CBD. Read US statistics

My studies have noted the presence of a worldwide clinical acceptance that hemp-derived CBD is harmless, and, accordingly, should be regulated under the Dietary Supplements Act like all other herbal supplements with the addition of providing cannabinoid and terpene test results. It should be made readily available then studied using real-world data, surveys and reports from doctors if they see any changes in patients.

I ask you to be more realistic and progressive when considering changes to the regulations for the sale and production of CBD. Please reconsider the need for pharmaceutical restrictions over a safe therapeutic supplement that is proven to be of no harm to the great majority of people. The claim of a minimal risk of side effects in a very small group is with regards to consumption of high doses of CBD. These patients can be monitored by their GPs in the medical system and advised not to use cannabis.

Medsafe refer to claims that CBD may result in increased serum levels and toxicity of mTOR and calcineurin inhibitors, of which fewer than 6000 people in NZ use. The studies that have been presented indicate that one very high CBD product administered to patients in the US at high doses may have caused an adverse reaction however it would be contrary to scientific methodology for that to be used to determine a decision on low-dose CBD.

I assert that there are plenty of herbal and pharmaceutical remedies that are readily available to everyone that contain herbs or chemicals that may interact with certain medications or conditions but it is up to the patient and their doctor to determine if there is a problem.

Having reviewed a paper submitted by Medsafe and sponsored by RuaBio, Helius, Cannasouth, and 7 pharmaceutical companies, I can see that much of that paper is inconclusive or not relevant and have provided examples below. Read the paper here

The first reference is to a study where the CBD dose was 750mg twice daily or 20mg/kg/day. This is much higher than a low-dose product. The comment from the NZ author explains that it is irrelevant:

"This article highlights that CBD may not have clinically significant DDIs with drugs that are commonly linked with pharmacokinetic DDIs. However, the relevance of these findings when CBD is co-administered with an mTOR or calcineurin inhibitor remains unknown."

One study is using a drug Epidiolex which is 100% CBD, again very different to a low-dose CBD product.This study seems irrelevant with regards to proving there is a risk as the final comment states:

"There were no significant changes in drug levels with CBD dose titration in the other AEDs analysed (valproate, levetiracetam, phenobarbital, clonazepam, phenytoin, carbamazepine, lamotrigine, oxcarbazepine, ethosuximide, vigabatrin, ezogabine, pregabalin, perampanel, and lacosamide)."

The reference to Stockley's Drug Interaction Checker states:

"There were no interactions listed for CBD and systemic mTOR/calcineurin inhibitors. Generally, listed interactions were mild to moderate in severity and are based on theoretical evidence. Only interactions with Rimimazolam, Valproate, Difelikefalin, and Ganaxolone are considered severe."

Are the interactions with these 4 drugs sufficiently significant to warrant being described as contraindications? The Stockley's website does not show the details and state they 'are based on theoretical' evidence anyway so cannot be used as valid data. See report for May 10, 2022

Two more studies do not say what CBD product was being administered, but as it was for epilepsy can we assume it may have been Epidiolex? Without having that information the studies should not be used in any decision-making. The dosages were also very high, ranging from 5-20mg per kg.

"Although this study has a small participant group, the findings do show a clinically significant increase in mTOR inhibitor levels associated with CBD use. Additional large prospective studies of CBD and mTOR inhibitors that assess the optimal dose reduction (of either medicine) to reduce the risk of toxicity would be helpful."

Three case study reports concluded the following so should therefore also be disregarded:

"The authors were unable to obtain the patients CBD levels during the study period and therefore could not assess the degree of CBD exposure that resulted in the change in tacrolimus level. Additional long-term follow up information was not available."

"As only the abstract is available, the information provided in the article is limited. Potential confounders were not discussed."

"Without THC and CBD levels being recorded the quality and dose administered in this patient is unable to be assessed."

Medsafe claimed that CBD-only 'did not have an established long-term safety profile' so can they explain how, after many years of use across the US, UK and EU, there have been no major warnings on it's safety? It would be very apparent by now if CBD products were causing any questionable health issues in the general public. Recently a novel mRNA vaccine was approved and although there was no long-term data and a list of potential side effects, it was declared safe and effective.

In comparison, I think Medsafe and the MoH should be able to establish that, based on the wide and longstanding consumption of CBD-only products abroad, there is a clear indication that there are no serious concerns in relation to its use. This should provide more than enough evidence for them to be comfortable with allowing therapeutic products to market without having to provide clinical trial data or pass GMP pharmaceutical testing standards.

Our endocannabinoid systems (ECS) are all different and are often unbalanced or depleted, the cannabinoids in cannabis are designed to enhance and support homeostasis as they connect with our ECS like a lock and key. Many find CBD and other cannabis treatments helpful in managing a variety of conditions and they find a dose that suits them, they know what their body needs.

The efficacy or benefits provided by consuming low-dose CBD are sometimes considered negligible and I would suggest that if the dosage is so low that it is not having any effect then it is comparable to taking a hemp supplement. Therapeutic hemp oils may even contain other, lesser-known, cannabinoids that are considered to be safe and remain unregulated. This standard should apply to CBD which is also a very safe and well-tolerated cannabinoid.

This Australian cannabis research agency supports the belief that CBD at such low doses is ineffective so this begs the question of how it could possibly be risky when it is potentially having no effect whatsoever. Visit the ACR page

"The few existing placebo-controlled studies using doses ≤150mg of CBD alone have not shown any significant effect over placebo in a range of indications including insomnia, anxiety and inflammatory bowel disease (IBD)."

"The safety profile of CBD has been explored explicitly in a number of Phase I clinical trials, as well as being a primary outcome of a number of pilot randomised controlled trials (RCTs) and observational open-label studies. Existing evidence has shown that doses of up to 6000mg of CBD taken orally are safe and generally well tolerated in adult subjects".

CBD is being used in trials to show how high dosages can be useful in the treatment of meth addiction. With that being such a big problem in NZ, it should be a priority to produce it on a large scale rather than making it extremely difficult to even get a low-dose product to market. Read the study here

I would advocate for the public to have access to stronger CBD products but we have to start somewhere. A demand for higher dosages will occur over time and hopefully, by that stage, all CBD decisions will be managed within the natural health products domain, as was always intended.

In this 2018 Bill CBD-only was removed from the Misuse of Drugs Act and was not to be considered a controlled drug. It was agreed to be descheduled and also refers to removing the need for a prescription. See the 2018 Amendment Bill

"Regulations were amended last year to remove a number of controlled drug restrictions for the import and prescribing of CBD products, but it was not possible to remove all controlled drug restrictions for

CBD by regulations. This bill will declassify CBD and CBD products with less than 2 percent of other cannabinoids."

You may recently have read and heard many of the submissions from New Zealanders on their objections to rongoa and Natural Health Products being included in the Therapeutics Bill. They are the voices of many who want to have the freedom to treat themselves with plant medicines rather than pharmaceutical drugs and many see cannabis as an herbal remedy.

The NZ Drug Foundation statistics reveal that 94% of medicinal cannabis users are accessing their products through 'green fairies'. The public are speaking through their actions and they will continue to do so until the regulations and product approval processes allow a fair and equitable market for production and access for all Kiwis to use locally grown and affordable cannabis products. Afterall, the 2018 Bill specifies the policy intent must be an *"approach based on the principles of fairness, quality and safety, and compassion."* Perhaps they were referring to fairness in the marketplace too.

I would like to see the Ministry of Health and Medsafe listen to us and act in our best interests by revising the current regulations over this safe and wholesome natural health product so that they achieve more balanced and equanimous rules of engagement, that will in turn give the public easier access to a more affordable (and potentially more effective) range of products.

Low-dose hemp-derived CBD should be cultivated under a Hemp Licence with extraction and production regulated under the Dietary Supplements Regulations 1985, which fall under the Food Act 2014. Considering it's availability and use globally, many of us believe that listing low-dose CBD as a pharmacist-only medicine (that requires a datasheet) is unwarranted and we would like to see that decision revised.

This statement from Medsafe illustrates how a low-dose CBD-only product would require ministerial consent to be approved for pharmacy shelves; however, if the same product is manufactured via the Medicinal Cannabis Regulations it is allowed to be sold, with a prescription, as an unapproved medicine. It seems like an obstacle and deterrent to the production of any CBD products outside of the current medicinal scheme.

"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. It would not impact products that have been verified through the medicinal cannabis agency. These would remain unapproved medicines for the purposes of the Medicines Act 1981 and would remain prescription medicines that may be supplied in accordance with section 25 and 29 of the Act."

Recently the change of structure for Industrial Hemp Licences to be administered by the Regulatory Practice and Analysis (RPA) branch of Medsafe, which also administers the Medicinal Cannabis Scheme, indicates that there is a shift and consolidation occurring. This suggests that now would be a good time to make positive changes for more inclusive regulations.

I would like to see all cannabis cultivation and production have less regulatory controls as the people of NZ and it's economy will prosper from Kiwis producing outstanding brands, just as they do in our food and wine industries. I hope we will get there eventually and your decision can help us by initially opening up the CBD-only market and allowing us all to benefit from a plant that so many of us love and appreciate. I am guessing you also want what's best for our communities and GDP and can understand that CBD does not need to be controlled like a pharmaceutical drug. Infact in the 2018 Amendment Bill, it was stated:

"The overall standard for medicinal cannabis products is not expected to match that of pharmaceutical grade products, e.g. manufacturers will not be required to provide clinical trial data. Standards will

however cover the manufacturing process and end product quality, and will apply to all products manufactured domestically and imported."

This recommendation was disregarded by the MoH and Medsafe at the time but perhaps it can now be honoured with regards to CBD-only.

Medicines Classification Committee
Medsafe
PO Box 5013
Wellington 6145
New Zealand

19 April 2023

Dear Sir/Madam,

RE: Comments on Agenda Item 5.6 for the Medicines Classification Committee 70th Meeting Hold on 25 May 2023

Aspen New Zealand is pleased to have the opportunity to respond to the agenda item *5.6 Paracetamol (liquid formulations) - referred from Medicines Classification Committee 66th meeting* for the 70th MCC meeting, which proposes to set a maximum limit of 5 g of paracetamol per container in liquid preparations for oral use as a Pharmacy Only Medicine.

Aspen New Zealand markets the Pamol brand of paracetamol oral suspension 250mg/5mL strength and this is available as:

* Pamol, 100 mL or 200 mL (contains 5 g or 10 g paracetamol per container), TT50-2756/4
* Pamol (Strawberry flavour), 100 mL or 200 mL (contains 5 g or 10 g paracetamol per container), TT50-2756/4a
* Pamol Infant Drops, 60 mL (contains 3 g paracetamol per container), TT50-2756/2

Aspen New Zealand provides the following reasons to support the **existing** classification for paracetamol liquid 250mg/5mL to a maximum of 10 g per paracetamol container as 'Pharmacy Only Medicine' classification.

Aspen New Zealand recently updated the packaging to reflect the rigorous safety requirements with Over The Counter (OTC) sale of paracetamol liquid. All Pamol OTC packaging complies with the latest Paracetamol warning and advisory statements Medsafe Consultation, dated 18th March 2020. This consultation was aimed to improve the safety of paracetamol use in NZ with updated dosage guidelines and clear safety statements as outlined below:

- *Dose: every four to six hours when required, no more than four doses in 24 hours.*
- *Keep to the recommended dose.*
- *Use the dose for your child's weight. Only use the dose for age if you do not know your child's weight.*
- *If you think you may have given/taken too much paracetamol, or an overdose ring the Poisons Information Centre on 0800 764 766 or go to a hospital straightaway even if you feel well. The damaging effect on the liver can take time for your body to notice.*
- *Do not give or take with other products containing paracetamol.*
- *Keep out of reach and sight of children.*
- *Do not give/take this medicine for longer than 48 hours at a time unless advised by a healthcare professional.*
- *Keep this packet for future doses of paracetamol.*
- *Always make sure the cap is on this bottle correctly.*
- *CONTAINS PARACETAMOL*

Each Pamol OTC pack is supplied with an oral dosing syringe for accurate dosing, and the Pamol bottle has a child resistant cap. The 'required by' date for all the updated packaging was needed to be

[redacted]

implemented by 1st April 2023. These significant safety updates as listed above have only been implemented for a short duration of time.

All paracetamol liquid preparations are currently classified as *Pharmacy-only* in New Zealand. Paracetamol liquid is a necessary medicine and generally given as the first-line treatment for pain and fever relief in infants and children.

Given that there is a range of Pamol pack sizes for the parent/caregiver to choose from depending on their needs such as infants, younger/older children or multiple children in the family. They may choose the 200 mL pack if there are multiple children in one household, and if the children are all acutely unwell then a 200 mL quantity would seem acceptable. For example, for a child who weighs 20 kg will require a dosage of 5.6 mL every 4 to 6 hours as needed, for perhaps 2 days. This equates to around 45 mL for this child. If there is another child in the household who may also require a higher dosage then this remaining quantity would still seem acceptable. Further, as paracetamol dosing is based on body weight rather than age, as the child grows the dosage will need to be increased accordingly.

In New Zealand, there is currently a shortage of pharmacists, and to reclassify a container with greater than 5 g of paracetamol liquid to a 'Restricted Medicine' then a pharmacist will need to be involved with the sale. This may create extra work for pharmacists, in addition to their current workload. However, if the pharmacist is not readily available and the parent/caregiver requires 200 mL then they could purchase 2 bottles of Pamol OTC 100 mL (which may not be a cost-effective option for the family).

Further, a reclassification of a container with greater than 5 g of paracetamol may potentially cause supply challenges with the complexities of different labelling of a Pamol 200 mL pack (as this would be a different classification to the Pamol 100 mL pack).

The Pamol OTC range and pack sizes have been sold in the New Zealand market for over 50 years. The Pamol brand is colour free, sugar free, alcohol free and gluten free. The safety statements are clearly stated on each pack of Pamol (including to keep out of reach and sight of children) and each pack contains an oral dosing syringe for accurate dosing.

Furthermore, Paracetamol liquid formulations was considered as a harmonisation item with Australia at the MCC 66th meeting on the 11th May 2021. On 1st June 2020, the TGA changed the scheduling for paracetamol in liquid preparations to be:

- *Schedule 3 (restricted): liquid preparations for oral use except when in schedule 2 (pharmacy-only).*
- *Schedule 2 (pharmacy-only): liquid preparations for oral use containing a maximum of 10 g of paracetamol per container.*

For these reasons, Aspen New Zealand does not support the proposed maximum limit of 5 g per paracetamol container in liquid preparations for oral use as a Pharmacy Only Medicine.

Yours sincerely,

PO Box 11183
Ellerslie
Auckland 1542
New Zealand

13 April 2023

Medicines Classification Committee (MCC) Secretary
Medsafe
PO BOX 5013
Wellington, 6145

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

Response to trimethoprim- proposed classification change to prescription with no exceptions- 70th meeting of the Medicines Classification Committee

Dear Committee Members,

Thank you for the opportunity to submit comments on the agenda for the 70th meeting of the Medicines Classification Committee, to be held in Wellington on 25 May 2023.

Our submission addresses Agenda item 6.1b. Trimethoprim- proposed classification change to prescription with no exceptions and details why Trimethoprim as a pharmacist-only choice is still needed as a treatment option for patients.

Antimicrobial resistance (AMR) is a topic of global concern, and ensuring appropriate use of antimicrobials is critical to continued patient and population health. Equally important is ensuring the broad availability of many antimicrobial options to enable the selection of the most appropriate regimen for a given patient. Specially trained pharmacists may currently dispense certain antibiotics without the need for a prescription, including nitrofurantoin and trimethoprim. Maintaining the ability of pharmacists to dispense these medications without a prescription is well supported by the existing treatment algorithms and is critical to continue enabling patient access to the most appropriate regimen for their unique circumstances.

The selection of an antimicrobial regimen for acute simple cystitis depends on the risk of infection with multidrug-resistant (MDR) negative organism.[1] Expected susceptibility patterns of *E. coli* should inform the empiric antimicrobial selection for cystitis. Considering the risk factors for urinary tract infection (UTI) with resistant organisms and urinalysis are a couple of ways of ensuring appropriate antimicrobial selection. Since urinalysis is not available to inform an empiric treatment by the pharmacist for such cases, the choice is individualised based on the patient circumstances. Trimethoprim as a pharmacist-only choice is still needed as a treatment option for patients for the following reasons and in accordance with the treatment algorithm:

- Where nitrofurantoin is contraindicated[2]

- a previous history of cholestatic jaundice/hepatic dysfunction associated with nitrofurantoin[2]
- Allergy/hypersensitivity to nitrofurantoin[2]

- tolerability and/or history adverse reactions to nitrofurantoin[2]
  - acute or sub-acute pulmonary reactions[2]
  - G6PD: Patients with glucose-6-phosphate dehydrogenase (G6PD) deficiency since nitrofurantoin can cause haemolytic anaemia in those individuals.
  - Breastfeeding: Nitrofurantoin has been detected in human breast milk in trace amounts with potential for serious adverse reactions from nitrofurantoin in nursing infants under one month of age.
- Medicine-Medicine interactions- if the patient is on an avoidable interacting medicine with nitrofurantoin such as clozapine, probenecid or a quinolone antibiotic[2,3]
- If there are patient concerns regarding expected adherence and dosing regimen for nitrofurantoin[1]
  - trimethoprim dosage is 1 tablet of 300 mg once a day for three days (3 doses) versus 100 mg MR twice daily for 5 days (10 doses)[2,4]
- Where there are concerns for potential for the misuse (inappropriate use) of nitrofurantoin
  - Nitrofurantoin has a greater opportunity for keeping left-over medicine for a further occurrence due to the number of doses supplied.

Thank you for your consideration of our response. If you have any questions about our feedback, please contact Medical Affairs at medinfo_anz@viatris.com

Yours sincerely,
Medical Affairs ANZ

REFERENCES:

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3. Baxter K, Preston CL (Eds), Stockley's Drug Interactions. [online] London: Pharmaceutical Press http://www.medicinescomplete.com/ (accessed on 21 March 2023)
4. TMP Data Sheet. (30 November 2022). Accessed 20th of March 2023. Retrieved from https://www.medsafe.govt.nz

Medicines Classification Committee (MCC) Secretary
Medsafe
POBox5013
Wellington, 6140

26 April 2023

Via email – committees@health.govt.nz

Re: Agenda of the 70th Meeting of the Medicines Classification Committee

Thank you for the opportunity to comment on the agenda for the 70th meeting of the Medicines Classification Committee.
Green Cross Health represents over 300 Unichem and Life pharmacies across the motu. We continue to be extremely supportive of increasing services that are available through community pharmacists for our communities. Community pharmacies are open extended hours and weekends and for a number of our communities, community pharmacy is the first port of call for care, advice and treatment.

On behalf of Green Cross Health, I would like to comment on **agenda item 6- Submission for reclassification-** with specific reference to **item 6.1b- Trimethoprim,** where a classification change to prescription with no exception has been proposed.

Green Cross Health does not support the proposed classification change of Trimethoprim from the current classification of: *Prescription 'except in medicines for oral use containing 300 milligrams or less per dose unit when sold in a pack of 3 solid dosage units to a woman aged 16-65 years for the treatment of an uncomplicated urinary tract infection by a registered pharmacist who has successfully completed the New Zealand College of Pharmacists' training in the treatment of urinary tract infections.'*

In July 2012, Trimethoprim was reclassified to enable pharmacists to supply it without a prescription. All pharmacists are required to complete the NZ College of Pharmacists' training in the treatment of urinary tract infections before providing this service. This training covers antibiotic stewardship and includes a consultation record the pharmacist discusses with women, to ensure the treatment is right for them.
The consultation record is very specific about when to refer and not supply Trimethoprim. The training covers both Nitrofurantoin and Trimethoprim with each product having a separate consultation record with specific requirements for supply.

There are times when Nitrofurantoin cannot be provided to a woman and at this point Trimethoprim maybe an option. To remove access for women to Trimethoprim provided without a prescription by a trained pharmacist does not support ongoing ease of convenient access.

The observational study conducted by Natalie J. Gauld et al in 2017, "Antibiotic treatment of women with uncomplicated cystitis before and after allowing pharmacist-supply of trimethoprim" clearly supports and highlights that pharmacists take the safe supply of Trimethoprim seriously for the treatment of uncomplicated urinary tract infections.

Pharmacists over time have provided a number of new health services and treatments to support their Communities. They continue to do this safely, following clinical guidelines and protocols. The supply of Trimethoprim is no different.

Pharmacists continue to take a very considered and safe approach to care, advice and treatment.

I trust that the above information supports the continuity of the current classification status of Trimethoprim for uncomplicated urinary tract infections supplied by a pharmacist without a prescription.

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

Your Sincerely,

ALISON VAN WYK
Group Chief Operating Officer
Green Cross Health

Reference: **https://pubmed.ncbi.nlm.nih.gov/28012119/** Antibiotic treatment of women with uncomplicated cystitis before and after allowing pharmacist-supply of trimethoprim

pharmacycouncil
Te Pou Whakamana Kaimatū o Aotearoa

26 April 2023

Medicines Classification Committee Secretary
Medsafe
PO Box 5013
Wellington 6145

By email only: committees@moh.govt.nz

Pharmacy Council submission on item 6.1d. Glecaprevir and Pibrentasvir
70th meeting of the Medicines Classification Committee 25 May 2023

Council View

Te Pou Whakamana Kaimatū o Aotearoa / Pharmacy Council (Council) supports initiatives that leverage the complementary competencies of health professionals to improve access to care and, ultimately, health outcomes for New Zealanders provided there are robust mechanisms in place to safeguard the public. Preparation for this submission has included meetings with stakeholders including Te Kaunihera Tapuhi o Aotearoa / Nursing Council of New Zealand.

This reclassification proposes an innovative interdisciplinary model to access medicines where two parties use their specific resources, differing from recent reclassification applications for which we have provided submissions[1] to Medicines Classification Committee (MCC). These typically have proposed reclassification from prescription medicine to alternative classification that that permits a pharmacist (pending certain criteria) to supply the medicine autonomously.

We consider pharmacists possess the competencies to appropriately supply the glecaprevir and pibrentasvir combination (Maviret) as per the proposal in the application. However, we recommend that pharmacists be required to complete a formal training programme that provides more in-depth and specific knowledge on:

- the medicines subject to proposal (glecaprevir and pibrentasvir),
- the condition being treated (chronic hepatitis C),
- how to respectfully engage populations most affected by chronic hepatitis C,
- the responsibilities and accountabilities of respective practitioners under the collaborative process, and
- infection control measures.

In addition, the training should minimise the potential for fragmentation of care and the training should ideally include a country-wide process to support the collaboration. This ensures that each practitioner understands their responsibilities and accountabilities, and that mechanisms for communication and documentation facilitate a safe, cohesive and unambiguous process. We recommend that the respective responsibilities and accountabilities are included as part of training.

Background

We are a Responsible Authority established by the Health Practitioners Competence Assurance Act (HPCA Act) 2003. Our purpose is to protect the public by ensuring that pharmacists are competent and fit to practise. Some of our core functions are summarised below, though a more comprehensive list is mandated within section 118 of the HPCA Act.

[1] As per Appendix 2 of Medsafe guidelines.

- Specifying scopes of practice
- Setting professional competence and ethical standards
- Prescribing and accrediting qualifications required to register in a scope of practice
- Setting requirements and processing applications for registration and recertification
- Maintaining a public register
- Investigating complaints or notifications where a pharmacist may be practising at a level below the expected standard

While it is our role to promote education and training (HPCAA s118 (k)), we are not legislated to provide education or practice support to practitioners. Instead, education provision is undertaken by providers able to provide training that meets the required criteria. This submission is therefore framed within the basis of this mandate. We believe that we are well placed to offer the Medicines Classification Committee (MCC) an independent opinion of pharmacists' competence, necessary for MCC to make an informed recommendation in the public interest.

Application to MCC for reclassifications of glecaprevir and pibrentasvir

Our view is based on our responsibilities under the HPCA Act, pharmacists' involvement in the AbbVie Care Pharmacy Programme and the Hepatitis C Pharmacy Test and Treat programme, stakeholder meetings facilitated by Te Whatu Ora, and application of the joint Medicine Reclassification framework developed by the Pharmaceutical Society of New Zealand (the Society) and Council.[2] We also note the existing MAVIRET® Quality Use of Medicines training programme that pharmacists are required to complete prior to dispensing the glecaprevir and pibrentasvir combination.

The Medicines Reclassification Framework is recognised and utilised by the MCC.[3] It provides a structure that facilities a robust analysis that informs Council's opinion of whether pharmacists may be competent to supply a medicine without prior assessment by a prescriber. If it is determined that pharmacists do possess required competencies, the framework will help determine whether a formal training programme, self-directed up-skilling, or no up-skilling is required. The framework and this submission are not intended to provide specific details of a potential training programme or practical implementation of the proposal.

The Society and Council applied the framework independently but collaborated to ensure that cohesive submissions and advice are produced for MCC. The framework breaks the analysis down into four broad elements. These are: the consultation, the medicine, documentation, and professionalism. For the purposes of this application, which proposes an innovative model to access medicines, we have also included a section on additional competencies and considerations.

We are satisfied that pharmacists possess competencies appropriate under each category to the required level, but we note that some knowledge training is likely required. Our final opinion to MCC is informed by a holistic review against the Competence Standards for the Pharmacy Profession 2015 in their full form; however, a short commentary of each category follows with particularly pertinent competence standards highlighted.[4]

[2] Pharmacy Council of New Zealand / Pharmaceutical Society of New Zealand. Pharmacy Council and Pharmaceutical Society Medicine Reclassification Framework. 2019. https://pharmacycouncil.org.nz/wp-content/uploads/2021/03/Council-and-Society-Medicine-Reclassification-Framework.pdf.
[3] Medsafe. How to change the legal classification of a medicine in New Zealand. 2019. https://www.medsafe.govt.nz/downloads/How_to_change_medicine_classification.pdf.
[4] Pharmacy Council of New Zealand. Competence Standards for the Pharmacy Profession. 2015. https://www.medsafe.govt.nz/downloads/How_to_change_medicine_classification.pdf.

Consultation Elements

The consultation includes pharmacist activities to gather relevant information from the person; form an appropriate treatment plan via shared decision-making; and convey information regarding safe use of the medicine, and recovery from and prevention of disease. In this case shared decision-making includes the person (and as appropriate whānau or other support), a pharmacist, and a nurse (and any other relevant party). These activities are described by the following competencies within the Competence Standards.

- M2.1: Communicate effectively
- M1.6: Make effective decisions
- O1.1: Consult with the patient
- O1.2: Provide healthcare
- O1.3: Review and manage patient's medicine therapy
- O2.1: Contribute to community health
- O2.2: Health promotion
- O3.5: Provide patient counselling

Under the proposed pharmacist-led model, pharmacists will be responsible for providing an initial antibody screening test via capillary blood (finger prick) sampling. They will not be responsible for the diagnosis of hepatitis C. Pharmacists must understand the theory, mechanics, and limitations of the screening test.

Based on the profiles of populations most affected by hepatitis C, people seeking treatment may have complex comorbidities that may or may not be diagnosed and / or treated. A complete medical and medicine record may also not be available. Training should ensure that pharmacists are aware of these challenges and can provide guidance on how to appropriately manage them. In addition, pharmacists require knowledge of the risks and benefits of hepatitis C treatment and non-treatment to assist the person in making an informed decision on whether to engage with treatment or seek alternatives.

The collaborative nurse-pharmacist team should also ensure that the person is familiar with lifestyle factors / public health measures regarding "infective behaviours" to reduce risk of transmission and reinfection. To ensure a cohesive experience for the person, process or communication between practitioners should, as much as practicable, preclude unnecessary duplication of information provision.

Medicine Elements

To determine whether a medicine is a viable option, a health professional must possess the competencies to access appropriate medicine information, and patient-specific medical and medicine history. They must also be able to integrate the information via a rational and evidence-based decision-making process. The competence standards that relate to these activities are below.

- O1.1: Consult with the patient
- O1.2: Provide healthcare
- O1.3: Review and manage patient's medicine therapy
- O1.5: Access, evaluate and provide medicines information
- O3.4: Administer medicines

Pharmacists may not have existing, in-depth knowledge of glecaprevir and pibrentasvir, but all pharmacists have base competencies to assess and apply medicines information appropriately. We note and accept expert opinion that the medicines are extremely effective while possessing a generally favourable risk profile. Despite this, pharmacists must be aware of mechanisms of action, cautions and contraindications, dosing regimes, drug-drug

and drug-condition interactions, and both common and serious adverse drug reactions and their management.

Pharmacists may be asked to facilitate administration or self-administration of the glecaprevir and pibrentasvir combination. In our view, no additional training, above and beyond what has already been recommended in this submission, is required.

Given that efficacy of treatment is contingent on completion of course at the appropriate dose and that the costs of the medicines and failed treatment are substantial, we would encourage a prescribed process should non-adherence be suspected. Pharmacists have broad obligations to ensure optimal use of medicines and benefits to the person.

Documentation Elements

Competence standard O1.4: Deliver quality and safe services, includes behaviours which describe professional requirements to maintain effective documentation for the purposes of continuous quality improvement, continuity of care, and pharmacovigilance.

With multiple independent (yet collaborative) parties involved, ineffective communication and lack of clarity regarding professional responsibilities and accountabilities increase opportunities for avoidable risk. A detailed process where, at each step, the responsibilities of each party are unambiguous will contribute to both efficiency and safety of the process. We support standardised communications that are embedded within the broader process and are included as part of training. Standardised communications (both in form and content) will reduce risk of misinterpretation between nurse and pharmacist and allow any trained practitioner to participate in the process without prerequisite tacit knowledge of *ad hoc* process.

Timely and accurate update of the patient record is essential for maintaining safe and continuous person-centred care. Ideally all clinical decisions and events would be recorded within a centralised cloud-based clinical information sharing service accessible to all relevant care providers. We acknowledge that national health information technology infrastructure may not be mature enough to facilitate this. Fundamentally, it is imperative that mechanisms are in place that enable pharmacists to meet their professional obligations to facilitate continuity of care across relevant care providers.

Documentation is also required for review of practice and continuous quality improvement purposes. These general principles are already embedded within current expectations, and no additional specific training is required.

Professionalism Elements

Across all medicines, safe supply must meet legal, professional, and ethical requirements, while also seeking to deliver services that contribute to optimum clinical, cultural safety, access, and equity goals. These aspects of practice and the application were considered with reference to the competence standards below:

- M1.2: Comply with ethical and legal requirements
- M1.4: Practise pharmacy within New Zealand's culturally diverse environment
- M1.5: Understand Hauora Māori
- M1.6: Make effective decisions
- M2.2: Establish and maintain collaborative working relationships
- O1.5: Access, evaluate and provide medicines information

As an innovative and collaborative model, it is important that pharmacists are clear on the permissions and limitations of the finally gazetted reclassification. A new model also means that new awareness and relationships may need to be forged. Opportunities for nurses,

pharmacists, and other stakeholders who may be collaborating to engage in whakawhānaungatanga (establishing relationship) may be facilitated by relevant organisations.

Under the proposed pharmacist-led model, pharmacists will receive initial enquires from people who may have been referred from another service provider (e.g., an outlet participating in the New Zealand Needle Exchange Programme) or who have been informed by hepatitis C public health messaging. Training should prepare pharmacists to understand and, as far as reasonable, accommodate the circumstances and needs of particular populations via adapted or different approaches. This applies to both how the practitioner interacts with people and the environment in which interactions occur (e.g., privacy and nature of premises). This aligns with principles of person-centred care and culturally safe practice.

The application notes that "Māori are likely to be disproportionately affected by hepatitis C", as such, training should address relevant aspects of te ao Māori and hauora Māori to enable "effective and respectful interaction with Māori".[5] More broadly, populations disproportionately affected by hepatitis C may have reservations about engaging with the health and disability system, they may suffer from shame or stigma due to history of illegal activity (e.g., illicit drug use), or as mentioned above they may be affected by complex comorbidities. Person-centred care should be non-judgemental and agnostic to current or historical circumstances not relevant to care.

Other relevant competencies and considerations

The Medicines Reclassification Framework was formulated primarily to assess proposals for a prescription medicine to reclassified to permit supply by a pharmacist pursuant to pharmacist assessment. This application proposes a different model. Because of this, we have identified some additional competencies and considerations.

O3.1 Assess prescriptions

Although this competence standard is framed with the context of the supply of a medicine pursuant to a prescription as defined by Medicines Act 1981; pharmacists have an obligation to only provide products or services, "…when satisfied that it is appropriate, and the person understands how to use it correctly and safely".[6] The competencies and behaviours within O3.1: Assess prescriptions are relevant. In particular, a pharmacist must undertake a clinical assessment and if the pharmacist has concerns that the medicines may not be appropriate, they are obligated to raise concerns and work to address issues via shared decision-making processes.[7,8] In these circumstances, the pharmacist would likely consult with the patient/carer and/or the nurse in the first instance.

The clinical assessment should review the use of glecaprevir and pibrentasvir against concomitant pharmacological treatments and any other known health conditions. This includes, but is not limited to, rongoā Māori, traditional medicines, natural health products, and other pharmacological agents (including recreational drugs). Pharmacists will require access to relevant and accurate records to meet their professional obligations.

[5] Health Practitioners Competence Assurance Act 2003, section 118 (1)(i)
[6] Pharmacy Council of New Zealand. Code of Ethics, Principle 1, Clause H. 2018. https://pharmacycouncil.org.nz/wp-content/uploads/2021/03/Council-and-Society-Medicine-Reclassification-Framework.pdf.
[7] Competence Standard Behaviour O3.1.3: Applies knowledge in undertaking a clinical assessment of the prescription to ensure pharmaceutical and therapeutic appropriateness of the treatment and to determine whether any changes in prescribed medicines are warranted
[8] Competence Standard Behaviour O3.1.4: Initiates action, in consultation with patient/carer and/or prescriber to address identified issues

Ultimately, in their professional opinions, both the nurse and pharmacist must be satisfied that the glecaprevir and pibrentasvir combination treatment is appropriate for the person. Each practitioner will use their profession-specific expertise to assess particular aspects of treatment appropriateness. The process must be clear on which aspects each practitioner is responsible for assessing.

O4.4 Provide safe working environment

Pharmacists have competencies with respect to the handling of biologics. Capillary blood (finger prick) sampling is a procedure familiar to pharmacists. However, this proposal would involve handling of samples from individuals suspected to carry hepatitis C infection. Training should reinforce practices to prevent risk of infection and the processes to follow should inadvertent exposure occur.

Training

Although our view is that pharmacists possess the competencies to participate in the proposed collaborative models for supply of the glecaprevir and pibrentasvir combination, we believe that additional knowledge training is required. The level of additional knowledge required is beyond what could be expected via self-directed upskilling, and so Council is recommending that a formal training programme be required. Broad areas where we believe additional knowledge would be beneficial are listed below.

- Relevant information of glecaprevir and pibrentasvir including, but not limited to,
  - pharmacokinetic and pharmacodynamic considerations,
  - contraindications and precautions,
  - drug-drug and drug-condition interactions, and
  - adverse drug reactions and their management.
- Overview of hepatitis C:
  - aetiology, pathophysiology, and
  - public health campaigns and measures.
- Information on the populations most affected by chronic hepatitis C and how to practise in a culturally safe manner.
- Detailed review of the process including, but not limited to,
  - theory, mechanics, and limitations of the screening test,
  - responsibilities and accountabilities of each practitioner at each step, and
  - standardised communications and documentation processes.
- Safe handling of biologics and infection control.

Nā māua noa, nā

Owain George
Manager Strategy, Policy and Practice

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26 April 2023

The Secretary, Medicines Classification Committee
Medsafe
PO Box 5013
Wellington 6145
New Zealand

Sent by email: committees@moh.govt.nz

Dear Sir/Madam,

Re: Response to public consultation for the Medicines Classification Committee Agenda for 70th meeting, May 2023

Thank you for the opportunity to comment on the agenda for the 70th meeting of the MCC. Consumer Healthcare Products Australia would like to provide some comment on the following agenda items:

Item 5.1a – Low dose cannabidiol

Item 5.7 – Zinc

Item 6.1a – Ibuprofen 400 mg

Item 6.1c - Flurbiprofen

Item 6.1e - Naproxen

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. We work together with our colleagues at the New Zealand Self Medication Industry (NZSMI), especially on matters of common interest between Australia and New Zealand.

Please see attached CHP Australia's response. We would like to thank the MCC for considering our submission.

Kind Regards

CHP Australia

Item 5.1a – Low Dose Cannabidiol (CBD)

CHP Australia supports the additional information provided to the MCC for context. As stated in this paper, low dose CBD is scheduled in Australia as a Schedule 3 medicine, with the following Poisons Standard entry and conditions:

CANNABIDIOL in oral, oromucosal and sublingual preparations included in the Register when:

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

(b) the cannabidiol comprises 98% 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% or less of the total cannabinoid content of the preparation and of which tetrahydrocannabinol (THC) can only comprise 1% 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.

(see https://www.legislation.gov.au/Details/F2023L00067)

The Australian entry has strict conditions, which mean that for a low dose CBD product to be legally available for supply in Australia, the product must:

- Be registered in the Australian Register of Therapeutic Goods. Note that Schedule 3 products require evaluation by the TGA and must meet quality, safety and efficacy requirements. Compounding pharmacies cannot legally supply low dose CBD to consumers, as the compounded products supplied by these premises are not entered in the ARTG.
- Meet the compositional standards in the entry, which place strict limits on tetrahydrocannabinol (THC) and other cannabinoids.
- Meet the maximum daily dose stipulated in the entry.
- Meet the packaging, pack size and labelling requirements in the entry.

All low dose CBD products will be evaluated by the TGA before approval, and sponsors of these products will be required to submit evidence of quality, safety and efficacy to the TGA for evaluation as per the applicable regulatory standards and evidence requirements. Products must also be manufactured in a manufacturing site that meets the appropriate standards of GMP. CBD is not entered in Appendix H of the Poisons Standard so it cannot be advertised to consumers after it is registered.

There are currently no low dose CBD products entered in the ARTG, therefore there are no registered products currently available for supply.

We are aware that clinical trials and development programs are underway for low dose CBD in Australia, and there is interest in this market.

CHP Australia encourages the MCC to consider harmonising the classification of low dose CBD with the Australian scheduling. The Pharmacist Only schedule provides an appropriate level of TGA and Medsafe oversight, such that products that enter the market will have demonstrated safety and efficacy, and meet the required quality standards. Medsafe would also similarly be evaluating and approving any low dose CBD products if the Pharmacist Only Classification were to be harmonised across both markets.

This would provide consumers with confidence in these products and ensure that unregistered products with questionable or non-evidence based claims do not enter the market.

Item 5.7 – Zinc

CHP Australia supports Medsafe's proposal to correct the classification statements for zinc, and we are also concerned with the current unintentional capture of products for external use that contain more than 5% zinc.

The agenda paper requests the MCC to recommend that the classification statements for zinc be amended so that *barrier creams* containing more than 5% zinc are clearly unscheduled and so that *zinc chloride* clearly remains pharmacy only for dermal use in medicines containing more than 5%.

We note the wording of the Zinc entry in the NZ Medicines Regulations:

Prescription Medicine: Zinc; except for internal use in medicines containing 25 milligrams or less per recommended daily dose; except for internal use in medicines containing 50 milligrams or less and more than 25 milligrams per recommended daily dose in packs that have received the consent of the Minister or the Director-General to their distribution as general sale medicines, when sold in the manufacturer's original pack and when labelled with a statement that the product may be dangerous if taken in large amounts or for long periods; except for external use when in medicines containing 5% or less; except in parenteral nutrition replacement preparations

CHP Australia agrees that the wording requires amendment to address the unintentional capture as prescription medicines of products for external use that contain more than 5% zinc.

We also note the relevant wording in the Medsafe Classification Database, database (see https://www.medsafe.govt.nz/profs/class/classintro.asp)

Zinc	for external use **except** zinc chloride in medicines containing more than 5%; - General Sale

The Classification Database appears to show the correct, intended wording of the entry.

In reviewing the proposal as written in the agenda papers, we would like to bring to the MCC's attention, that barrier creams are not the only dosage forms that contain more than 5% zinc, that would be affected by the wording of the zinc entry. At present, there are dusting powders that are currently available in Australia and New Zealand that contain more than 5% zinc. These include:

- Curash Baby Powder (zinc oxide 20%)
- Curash Family Powder (zinc oxide 20%)

In Australia, there are also spray formulations of zinc oxide lotion that contain 10% zinc oxide, and sunscreens which contain zinc oxide as an inorganic or mineral physical sunscreen agent.

We therefore kindly request that any re-worded classification statement refers to ***medicines for external use*** or ***products for external use*** rather than to specific dosage forms such as creams, so that products such as dusting powders currently being supplied in New Zealand as harmonised products are not adversely (and unintentionally) impacted by any changes to the wording of the classification statement.

Item 6.1a – Ibuprofen 400 mg

CHP Australia supports the proposed reclassification change from Pharmacist Only Medicine to Pharmacy Medicine, for ibuprofen 400 mg, with the following qualifications:

- Ibuprofen 400 mg oral tablets or capsules
- Recommended daily dose of not more than 1200 mg
- Packs containing no more than 12 dosage units, when sold in the manufacturer's original pack
- Labelled for use by adults and children over 12 years of age.

Ibuprofen has been available in Australia as an OTC medicine for more than 30 years. Ibuprofen 400 mg in divided immediate release preparations has been registered as a Pharmacist Only Medicine in New Zealand since February 2006.

In February 2021 the Australian scheduling was changed to allow immediate release preparations of ibuprofen 400 mg in packs containing no more than 12 dosage units, when labelled with a maximum daily dose of not more than 1200 mg, for use in adults and children over 12 years of age, to be supplied as a Pharmacy Medicine. This is reflective of classification status in many other countries, including the UK, where the ibuprofen 400 mg is available for self-selection as a Pharmacy Medicine.

In the two years that ibuprofen 400 mg has been available as a Pharmacy Medicine in Australia, there has been substantial consumer experience with the medicine. There has been no evidence of any increased risk of adverse events, based on reports to the TGA Database of Adverse Event Notifications (DAEN), and there do not appear to be any increased risks associated with self-selection of this medicine.

Benefits

Ibuprofen is a non-steroidal anti-inflammatory drug (NSAID) used as an analgesic, antipyretic, and anti-inflammatory.

Over-the-counter (OTC) ibuprofen is indicated for relief of pain and discomfort associated with headache, back pain, muscle pain, period pain, dental pain, cold & flu and fever. These products are intended for short term use. When used according to the label instructions, ibuprofen has an excellent safety profile.

The approved indications for ibuprofen 400mg are the same as those for ibuprofen 200mg which are available as unscheduled (general sale) and S2 (Pharmacy Only) medicines. These indications are easily recognised by consumers, are unlikely to be confused with more serious conditions and are appropriate for self-selection within pharmacy.

The 400mg product offers the following benefits over the 200mg product:

- A 400mg dose is more effective and provides longer lasting pain relief than a 200mg dose
- The 400mg product offers the convenience of a single unit dose (especially important for those patients who have difficulty swallowing)

The proposed pack size of 12 dosage units, represents 4 days' therapy for patients taking the maximum dose (3 dosage units per day) which is appropriate for short-term use.

The maximum daily dose of the 400mg product is no different to that for the 200mg product, i.e. 1200 mg / day. The TGA approved labelling for both the 200 mg strength and the 400 mg strength clearly distinguishes between the two products and thereby addresses any risks posed by consumer confusion between the two products.

Like all other NSAIDs, ibuprofen is not known to have the potential for abuse, and the potential for misuse is negligible.

Risks

The Australian experience with the Pharmacy Medicine scheduling of ibuprofen 400 mg in packs of not more than 12 tablets / capsules indicates that these risks have not been evident with consumer use, and the TGA DAEN has not shown any increased trend in safety concerns following the down-scheduling.

The MCC (at the 65th meeting in October 2020) did not approve an application to amend the classification of ibuprofen 400 mg, raising risks of safety, especially among the elderly; limited consumer familiarity; and potential for consumer harm by accidentally taking twice the recommended daily dose. We would like to address some of these issues:

All ibuprofen products are clearly labelled with the relevant precautions and contraindications, e.g. stomach ulcers, other stomach disorders, kidney problems, and include warnings regarding exceeding the recommended dose, use in pregnancy, and risk of heart attack, stroke or liver damage. There is no evidence that the elderly misuse ibuprofen or that they do not follow medical advice or labelling instructions. The labelling contains clear warning statements advising elderly consumers not to use ibuprofen unless their doctor has advised them to do so.

Regarding the issue of consumer familiarity, consumers are familiar with 'Double Strength' products, and there are many examples of these products, e.g. aspirin, antacids. In the case of ibuprofen 400 mg, the labelling also assists consumers by using bold 'Double Strength' on the labelling, as well as clear instructions and graphic representation that each dose is one tablet (compared for two tablets of 200 mg).

Sponsors clearly differentiate the double strength tablets from the regular strength by use of different colours, illustrations and visual cues as well as directions on the pack. Product labels are subjected to consumer testing to minimise confusion. Clear labelling differentiation mitigates against risks of dosing errors.

The MCC should also note that the small pack size (not more than 12 tablets) protects consumers by providing only 4 days' supply, and this mitigates against risks of chronic or long-term use.

In our view, the proposal for reclassification of ibuprofen 400 mg together with the qualifying requirements meets the criteria for a Pharmacy Medicine:

- The quality use of the medicine can be achieved by labelling, packaging, and/or provision of other information; however access to advice from a pharmacist is available to maximise the safe use of the medicine.

- The use of the medicine is substantially safe for short term treatment and the potential for harm from inappropriate use is low.

- The use of the medicine is very unlikely to produce dependency (at either the established therapeutic dose or supratherapeutic doses) and the medicine is very unlikely to be misused, abused or illicitly used.

- The risk profile of the medicine is well defined and the risks can be identified and managed by a consumer through appropriate packaging and labelling, including consultation with a health professional if directed by labelling.

- The use of the medicine at established therapeutic dosage levels and duration of use is not likely to mask the symptoms or delay diagnosis of a serious condition.

CHP Australia therefore supports the proposal to reclassify ibuprofen 400 mg, to allow packs of 12 tablets or less to be supplied as Pharmacy Medicines.

Item 6.1c – Flurbiprofen

CHP Australia supports the application for reclassification of flurbiprofen in locally acting oromucosal preparations containing 10 mg or less per dosage unit, when sold in the manufacturer's original pack containing not more than 16 dosage units and when labelled only for the treatment of adults and children over 12 years, from Pharmacy Medicine to General Sale (GSL).

Flurbiprofen lozenges are a low dose topical analgesic and anti-inflammatory preparation, used for the relief of pain, swelling and inflammation associated with sore throats. Systemic exposure is minimal, since the active ingredient exerts its effect locally on the painful and inflamed areas of the throat.

Flurbiprofen lozenges have been available in New Zealand since 1999, first as a Pharmacist Only Medicine, and subsequently reclassified as a Pharmacy Medicine in 2002. In Australia, flurbiprofen lozenges were registered in 2001 (as Schedule 3) and since 2003 they have been available as a Schedule 2 Pharmacy Medicine and since October 2020 as a GSL medicine in packs containing not more than 16 dosage units.

The MCC considered an application to reclassify packs containing not more than 16 lozenges to general sale medicine in 2020, declining the application on the basis that it did not reflect specific concerns regarding acute rheumatic fever, that apply particularly to Māori and Pacific Islander children.

Based on information provided with the agenda paper, the applicant has accepted that acute rheumatic fever is a significant health issue and clinical priority in New Zealand and has undertaken research addressing these concerns, as evidenced by the information contained in the application. The applicant believes that the research undertaken addresses the MCC's concerns.

In Australia, flurbiprofen lozenges have been available as general sale medicines in packs of not more than 16 dosage units, for adults and children over 12 since October 2020. The Australian experience with GSL availability of flurbiprofen lozenges has not indicated that there have been any additional risks or safety issues following re-scheduling.

Risks

The systemic exposure to flurbiprofen from a lozenge format is minimal and significantly lower than alternative oral analgesics.

The potential risk of rare idiosyncratic allergic reactions is addressed by the mandatory label warning statements that apply to all NSAIDs, with the following warnings already required to be included on the labelling of flurbiprofen lozenges:

"*Do not use if you are allergic to [name of substance] or other anti-inflammatory medicines.*", and

"*If you get an allergic reaction, stop taking and see your doctor immediately.*"

Flurbiprofen lozenges have an excellent safety profile, with a very low reporting rate of adverse events and no new safety concerns/signals emerging since the medicine was down-scheduled to a GSL medicine in Australia in October 2020.

Benefits / Purpose

Sore throat is a common condition, generally self-limiting, which develops quickly. It can be easily identified and self-managed by consumers. Clinical trials have confirmed that the pain relief provided by flurbiprofen lozenges is clinically meaningful.

Lozenges are the most commonly used dosage form for the management of sore throats and most people who experience sore throats will self-manage their condition, nevertheless sore throat remains one of the top 10 reasons for visiting a GP.

Providing the public with wider access to a lozenge with both analgesic and anti-inflammatory activity therefore has the potential to improve the self-management of sore throats, to reduce the burden on healthcare professionals and to improve health-related quality of life.

Dosage, formulation, labelling, packaging and presentation

The proposed limited pack size of 16 dosage units, represents 2 days' therapy for patients taking the maximum dose (8 lozenges per day), which is not excessive. Long term use is unlikely.

Potential for abuse of a substance

Like all other NSAIDs, flurbiprofen is not known to have the potential for abuse. The potential for overdose is negligible. There has been no evidence of misuse, abuse or illicit use to date and no reports of such in the TGA's Database on Adverse Event Notifications.

CHP Australia supports the proposed exemption from scheduling based on:

- The minimal systemic absorption of flurbiprofen lozenges
- The pack size being limited to 16 dosage units (i.e. 2 days therapy for patients taking the maximum dose of 8 lozenges per day)
- The established efficacy of topical flurbiprofen
- The favourable safety profile of flurbiprofen lozenges, and
- The likely benefits of providing the public with wider access to the lozenges

In our view, the proposed exemption from classification for flurbiprofen clearly meets the requirement of being able to be supplied without supervision of a pharmacist / pharmacy assistant with reasonable safety.

Item 6.1e – Naproxen

CHP Australia acknowledges the concerns expressed by Medsafe regarding some of the indications for naproxen and supports efforts to ensure that the labelling and presentation of naproxen products allows consumers to use medicines safely and effectively. We believe that this can be achieved by the product registration process; that amendment to the classification of naproxen is not necessary to achieve the desired outcome; and that any amendment may adversely impact the potential to supply harmonised products across both markets.

The Australian Poisons Standard entries for naproxen are:

Schedule 3
NAPROXEN in a modified release dosage form of 600 mg or less of naproxen per dosage unit in packs of 16 or less dosage units when labelled not for the treatment of children under 12 years of age.

Schedule 2
NAPROXEN in divided preparations containing 250 mg or less of naproxen per dosage unit in packs of 30 or less dosage units.

According to the Medsafe Classification database, naproxen is a Pharmacy Medicine when in a solid dose form containing 250 mg or less per dose form in packs of not more than 30 tablets or capsules.

Therefore, the classifications are essentially similar in Australia and New Zealand, and for Pharmacy Medicines there is currently no misalignment in classification. We believe that changes to improve the presentation of OTC naproxen products in New Zealand can easily be made without amending the classification statements.

We agree that some products marketed in New Zealand are for indications that are not consistent with self-care use or for self-selection, because consumers may not be able to recognise or treat conditions such as gout, post-operative pain and unspecified musculoskeletal disorders without having received diagnosis and/or advice from their doctor.

In Australia, the TGA evaluates all non-steroidal anti-inflammatory products, including the dose and any indications / claims that are on pack. To our knowledge, there are no Australian OTC naproxen products that are indicated for gout, or post-operative pain. The indications for naproxen in Australia are consistent with the indications for other NSAIDs such as ibuprofen, and consistent with requirements in the Australian Regulatory Guidelines for OTC medicines. We believe that the concerns outlined by Medsafe are issues that can be better addressed at the point of medicines evaluation, and do not require any changes to classification.

In response to the discussion points in the agenda papers, we would like to make the following comments:

1. *Whether the indication for treatment of acute gout is appropriate for a pharmacy medicine*

CHP Comment: We do not agree that treatment of acute gout is a condition that can be self-diagnosed by the consumer, nor can consumers self-select treatment for acute gout. Consumers should obtain medical advice for treatment of acute gout. Therefore, an unqualified 'treatment of acute gout' indication may not be appropriate for a Pharmacy Medicine.

2. *Whether the indication for treatment of musculoskeletal disorders is appropriate for a pharmacy medicine.*

CHP Comment: We are of the view that consumers should be able to easily recognise and understand the uses that are stated on OTC medicine labels. Generally, the wording should be specific enough to provide the consumer with a good understanding as to the appropriateness of using the product. For this reason, more specific and qualified indication statements such as 'backache', 'muscular aches and pains', 'arthritis', 'osteoarthritis', 'rheumatic pain' are more appropriate for consumers. In addition, for OTC NSAIDs the context should always be for short term use.

3. *Whether the indication for treatment of post-operative pain is appropriate for a pharmacy medicine.*

CHP Comment: We are of the view that an unqualified indication for treatment of post operative pain is not appropriate for a pharmacy medicine. The treating doctor should advise the patient on appropriate post-operative pain relief.

4. *Whether the doses of naproxen in pharmacy-only products is appropriate for a pharmacy medicine.*

CHP Comment: Current dosing of naproxen products in Australia is appropriate and there is no indication of safety concerns or issues in the Australian context. Higher doses of naproxen appear to be allowed for one product indicated exclusively for period pain, which is of short-term duration and there is no suggestion of inappropriate use of this product for other indications. We believe that the TGA and Medsafe are best placed to review the dosing for the different naproxen products; this is a product registration issue, not a classification issue.

5. *Whether multiple dosing instructions for different conditions is appropriate for a pharmacy medicine.*

CHP Comment: Dosing instructions for OTC medicines should be easy for consumers to understand and be able to use the product safely and effectively. The TGA and Medsafe should assess the dosing instructions for each medicine on a case-by-case basis. The issue of dosing instructions is one that pertains to product evaluation rather than to classification or scheduling.

CHPNZ | CONSUMER HEALTHCARE PRODUCTS ASSOCIATION NZ

26th April 2023

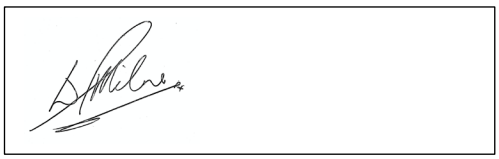
The Secretary
Medicines Classification Committee
P O Box 5013
Wellington
New Zealand 6145

Dear Sir/Madam

The Consumer Healthcare Products Association of New Zealand Incorporated (**CHPNZ**) is the pre-eminent industry body representing the importers, manufacturers and distributors in New Zealand of Over-the-Counter (OTC) products and vitamin and mineral health supplements.

We appreciate the opportunity to comment on the Agenda for the 70th meeting of the MCC particularly on the items that relate to our goal of improving the quality, access, efficacy, safety and education of the SelfCare component of primary healthcare.

In appreciation,



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Common Themes

Both Medsafe and the TGA regularly comment on the desire, practicality and merit of harmonization and equivalence between the two major regulators. CHPNZ is concerned that a number items on this agenda appear to not be aligned, with little explanation of the benefit of non-alignment.

Accordingly, CHPNZ would request that the MCC keep in mind the benefits of harmonization, particularly as it relates to General Sale and OTC medicines.

Item 5.1a – Low dose CBD

CHPNZ suggests the MCC should align its classification suggestions with the Australian scheduling. This is an emerging market category and there is an understandable and appropriate conservative approach that demands detailed evaluation. We believe the two markets and regulators should work closely together to improve consistency, availability and accuracy of evaluation in this space.

Item 5.7 Zinc

CHPNZ applauds the proposal to improve clarity in the classification statement for zinc. There are, we believe, unintended consequences in the current classification statement and we do not believe that it is the intention to confuse the regulation of the many products currently on the market that contain zinc in any of its salts at levels greater than 5%.

We suggest that a new classification statement is required and suggest it should refer to **Medicines or Products for External Use** rather than using the percentage dosage levels we currently see.

This will ensure that harmonization between Australia and New Zealand is possible and not unintentionally impacted.

Item 6.1a – Ibuprofen 400mg

Again, in the desire to promote harmonization, safety and access to improved primary healthcare CHPNZ supports the proposed reclassification change from Pharmacist Only to Pharmacy Medicine.

We are aware that this item has been discussed in earlier MCC meetings where concern was expressed that there could be consumer risk and confusion over a higher dose medicine being available alongside a standard or lower dose.

CHPNZ has not seen any evidence of consumers being confused in other instances where multiple doses are available. Likewise, we are not aware of any evidence that these products are being misused or abused.

We continue to advocate for all products to be clearly labelled with precautions, indications, dosage instructions, risks and contra indications. We also believe all of these can be accommodated in a 400mg Ibuprofen product and that the benefits of having this option available to consumers outweighs the risks.

Item 6.1b – Trimethoprim

CHPNZ believes the current classification for Trimethoprim is correct and should be maintained. It is well tolerated, utilizes a useful practitioner process that improves appropriateness and safety in supply and is a cost-effective primary healthcare solution that reduces GP pressure.

CHPNZ also suggests that the request for an up-scheduling of TMP is, primarily, a commercial ploy by the supplier of a competitive product (Nitrofurantoin) to gain a monopsonist supplier position by removing a competitor from the "OTC Prescription except when" category.

The community benefits from having more than one option when requiring treatment for acute urinary tract infections. Some may have a contra-indication to Nitrofurantoin. Choice also reduces the risk of anti-microbial resistance.

Item 6.1e – Naproxen

In line with our opening statement, CHPNZ does not support an amendment to the classification of Naproxen as a response to concerns expressed by Medsafe regarding some additional indications for which Naproxen may have been prescribed.

A reclassification will likely make harmonization unrealistic, for no added benefit. Naproxen is currently available OTC for Period Pain. The Medsafe concerns for sponsors wishing to promote its use for other indications can be addressed during the product registration process.

CHPNZ is appreciative of the opportunity to contribute to the discussions on the Agenda of the 70th Meeting of the Medicines Classification Committee to take place in May.

Thank you.

PHARMACY GUILD OF NEW ZEALAND

26 April 2023

Medicines Classification Committee Secretary
Medsafe
Wellington

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

Dear Committee Members,

Re: Agenda for the 70th meeting of the Medicines Classification Committee

Thank you for the opportunity to provide feedback on the agenda items.

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 and advocate for the business and professional interests of community pharmacy.

Our feedback on this consultation focuses on Guild members' concerns around general economic, funding and supply issues. Guild submissions should not be taken as any endorsement of, or any attempt to comment on, issues of safety, efficacy or individual patient utility.

Our feedback covers the following agenda items:

- 5.1: Objections to the recommendations made at the 69th meeting:
  - 5.1a: Low-dose cannabidiol
- 5.6: Paracetamol (liquid formulations)
- 5.7: Zinc
- 5.9: National Immunisation Schedule
- 6: Submissions for reclassification:
  - 6.1a: Ibuprofen 400 mg
  - 6.1b: Trimethoprim
  - 6.1c: Flurbiprofen
  - 6.1d: Glecaprevir and Pibrentasvir (Maviret)
  - 6.1e: Naproxen
  - 6.1f: Bilastine

5.1a: Low-dose cannabidiol (CBD)

The Guild welcomes and supports the proposed down scheduling of low-dose CBD products with Ministerial consent to pharmacist-only medicines.

We believe that providing low-dose 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 understand the myriad of products available, the classification of these products and the requirements for storage and safe dispensing and are trained to transfer this knowledge to the patients in a way that ensures safe and effective use.

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There are currently no CBD-only products approved under the Medicines Act 1981 that would meet the definition of a low-dose CBD medicine, but we believe that this change would provide an excellent opportunity for new clinical research to be undertaken with low-dose CBD products that addresses the question of efficacy in a range of indications, including in secondary symptom control. This is beneficial as it will stimulate greater research interest and further our understanding of CBD and its utility as a medicine more broadly, which would reduce the cost barrier to the development of new products and incentivise development and subsequent new medicine applications.

Looking at recent international trends and studies published, current safety data regarding pharmacist-only supply of low-dose CBD products can be taken into consideration. In various other jurisdictions, non-prescription low-dose CBD supply (e.g., via the pharmacist-only route in New Zealand) has been deemed to hold little risk to patients, hence the increased international trend to reclassify as such.

Recently, pharmacists have proven to be able to successfully handle the initiation of therapies that are more complex and inherently carry more risk, such as the pharmacist-supply and pharmacist-initiated supply of Covid-19 oral antiviral medicines.

It is also important to keep in mind that increased access to low-dose CBD products does not mean less stringent patient safety measures but instead utilises the easy access to community pharmacy for more frequent follow-up for patients and better continuity of care.

We are convinced that this down scheduling poses numerous benefits to patients, such as:

- The reclassification of low-dose CBD products to pharmacist-only medicines has the potential to allow more products within this classification to come to the market in a controlled and structured manner, under expert control.
- Increased access: Making low-dose medicinal cannabis available via pharmacist-only supply without a prescription would make it more accessible to patients who may benefit from its use. This is particularly important for patients who live in rural or remote areas, who may not have easy access to a doctor who is able to prescribe medicinal cannabis, or do not have the facilities to access telehealth consultations.
- Reduced treatment barriers: Removing the requirement for a prescription could reduce barriers for patients who may not have a regular doctor or who have difficulty obtaining a prescription. This includes patients who have mobility issues, lack of transportation, and financial difficulties.
- Increased affordability: If medicinal cannabis is made available without a prescription, it may reduce costs for patients, as they would not need to pay for a doctor's visit or prescription. This is particularly important for low-income patients or patients with multiple medical conditions with high medical costs. Pharmacists are now also able to feedback supply or non-supply to prescribers via various communications tools, such as reCare, CCCM and Conporto to ensure patient safety if needed.
- Reduced discrimination and improved equitable access: Removing the prescription requirement of medicinal cannabis may also reduce discrimination against disadvantaged minority populations, who may be less likely to have access to a doctor who is able to prescribe low-dose CBD products, or who may face discrimination from doctors who are unwilling to prescribe it.
- Greater awareness and education: Making medicinal cannabis more easily available may increase awareness and understanding of the potential medical benefits of low-dose CBD products, which could lead to more patients seeking it as a treatment option.

We understand the MCC has a desire to meet their Trans-Tasman harmonisation policy, however the current classification of low-dose CBD products is inconsistent with this policy. The goal of this process is to ensure that medicines are classified in the same way in both countries, which can help to reduce confusion and improve safety for patients. Both agencies work together to classify medicines according to their level of risk, and to ensure that the same classifications are used in both countries. MCC and New Zealand appear to have fallen behind the rest of the world (specifically Australia).

The World Health Organization's (WHO) Anatomical Therapeutic Chemical (ATC) classification system classifies medicinal cannabis products under the code N02BA01. This code is for "Analgesics", and specifically for "Other non-narcotic analgesics and antipyretics". It is important to note that low-dose medicinal cannabis products such as CBD oil and other CBD-based products are not classified under the same code since they do not have the same level of psychoactivity and potential for abuse as high-dose THC products. All considered, this would seem to indicate that reclassification and harmonisation would be appropriate.

5.6: Paracetamol (liquid formulations)

The Guild will be interested to see how this consultation evolves. If the goal is to limit the pharmacy-only sale of paracetamol liquid formulations to a total of 5g per container per sale, there would also have to be a change in the classification of larger pack sizes to pharmacist-only, ensuring there will be health professional interaction for larger pack sizes and/or quantities.

This would also have to be reflected in the solid-dose formulations, with general sale packs of paracetamol being limited to 5g per customer as well, and larger quantities of solid-dose formulations being rescheduled as pharmacist-only medicines.

5.7: Zinc

The Guild supports the amendment of the classification statement of zinc, and we would like to know if this would be salt-specific or just a general zinc reclassification? It might be prudent to delve deeper into the clinical use of each salt and determine how appropriate a broad stroke reclassification would be.

5.9: National Immunisation Schedule

We are curious as to the meaning of "*should they be accepted as appropriate*" and would like to understand who stands to benefit from the "appropriateness". A patient-centric approach in the interest of equity and accessibility would dictate that all vaccinations should be easily accessible to all New Zealanders.

We would like to propose all vaccinations (including travel vaccines) be reclassified as pharmacist-only medicines, and support further steps and recommendations to fund all vaccinations being administered via community pharmacies.

We believe the submissions opposing the reclassifications of travel vaccines are purely 'patch-protective' and financially driven. Training can easily be achieved via micro credentialling, and all pharmacists can provide these vaccines after appropriate training. Qualified pharmacist vaccinators are already fully capable of providing vaccinations to adults and children 3 years and above, and expertly trained in all aspects of vaccination including cold chain management and storage.

We would further propose that pathways are found to enable pharmacists to provide all travel medications, including, for example, doxycycline and malarone for use by New Zealand residents when traveling abroad to malaria-endemic regions. Countries like South Africa already have these medicines classified as "prescription-only unless supplied by a pharmacist to a person traveling to a malaria endemic region" (Government Gazette [(accessed on 13 February 2018)]; 2016 Mar 15; Volume 609, No. 39815. Available online: www.gpwonline.co.za).

6: Submissions for reclassification:

6.1a: Ibuprofen 400 mg proposed classification change from restricted (pharmacist only) medicine to pharmacy-only medicine under specified conditions (Reckitt Benckiser (New Zealand) Pty Limited)

The Guild does not support the proposed reclassification of an ibuprofen 400mg dose form from restricted medicine to pharmacy-only medicine, even under specific conditions. We have general concerns over the potential confusion that patients may have with the existing 200mg dose forms of ibuprofen, leading to the potential for unintentional overdosing of ibuprofen.

In New Zealand, ibuprofen has generally only been available as a 200mg dose form, and it is only in recent years that the 400mg dose form (as a tablet) has been available for sale over the counter as a restricted medicine. In addition, only the 200mg tablet form is funded on the Pharmac Schedule, and we believe that patients will be most familiar with the 200mg dosage form and are comfortable taking the appropriate dose based on their age and requirements, i.e., one or two doses of an ibuprofen 200mg dose form.

In February 2019, modified-release paracetamol (in a formulation containing 665mg of paracetamol) was reclassified from a pharmacy-only medicine to a restricted medicine due to concerns from Medsafe over unintentional overdose of the modified-release paracetamol presentation, caused by confusion over the similar dose forms of paracetamol. The MCC noted the importance of patient interaction with a pharmacist so that appropriate advice can be given to patients to ensure the correct dosing of the modified-release paracetamol and to advise the patient not taking other paracetamol-containing products at the same time.

We believe that due to the decision made by the MCC around modified-release paracetamol to protect patient safety, the same approach should be taken with the ibuprofen 400mg dose form to mitigate any risk of patients accidentally taking the incorrect dose of the ibuprofen 400mg dose form and/or taking other ibuprofen-containing products at the same time. This also provides consistency for health professionals when considering the rationale for the different classifications of medicines.

Non-steroidal anti-inflammatory drugs (NSAIDS) are among the most commonly used pharmacological agents worldwide due to their efficacy as non-addictive analgesics and their anti-inflammatory proprieties, hence even a small risk of cardiovascular events, gastrointestinal complications, renal failure and hypersensitivity reactions associated with these medicines could produce a significant health burden in a given population.

We believe the risks associated with having an ibuprofen 400mg dose form available over the counter as a pharmacy-only medicine far outweigh the patient benefit, when the usual prescribed adult dose of ibuprofen is two of an ibuprofen 200mg dose form and this is well known by patients, and in some cases a dose of ibuprofen 400mg may not be clinically appropriate. The patient benefit

is minimal when compared to the significant potential for harm if a patient accidentally takes twice the recommended dose of an ibuprofen 400mg dose form.

Low levels of patient health literacy regarding the safe maximum daily dose of ibuprofen warrants tighter controls and providing patient access to information via handouts or labelling is not sufficient to address the concerns raised. Facilitating access to professional advice for the prescribing and supply of medicines is the best way to maintain safe and cost-effective access to medicines and patients need advice on the correct and proper way to use medicines, especially in the elderly and patients taking other medicines. If it is determined that there is a clinical need for an individual patient to be recommended the ibuprofen 400mg dose form, then the supply should always be accompanied by the oversight and advice of a pharmacist, and when necessary, referral to a general practitioner or other appropriate healthcare professional.

6.1b: Trimethoprim proposed classification change to prescription with no exceptions (Te Arai BioFarma Limited, Auckland New Zealand)

The Guild does not support this classification change. We believe the proposal to remove the exceptions from the classification statement of trimethoprim is purely commercial as Te Arai BioPharma is the supplier of Macrobid (nitrofurantoin MR 100mg capsules). Although nitrofurantoin is the first-line agent for the treatment of an uncomplicated urinary tract infection in women in New Zealand, and can now be prescribed by an accredited pharmacist, there are some circumstances where it cannot be used and therefore having another treatment option from an accredited pharmacist is beneficial for the New Zealand public.

The Guild would like to strongly advocate for the continued access to both treatment options from accredited pharmacists.

There have been no studies to indicate that the supply of trimethoprim by accredited pharmacists has compounded the growing resistance of trimethoprim or is the cause. Trimethoprim is still regularly prescribed by general practitioners, due to either best practice not being followed or as an alternative to nitrofurantoin because of contraindications, and it is recommended that either trimethoprim 300mg daily for 3 days or cefalexin 500mg twice daily for 3 days are used instead (*Urinary tract infections (UTIs) – an overview of lower UTI management in adults, bpacnz*).

Allowing patients to have timely and convenient access to two treatment options for an uncomplicated urinary tract infection from an accredited pharmacist is not only be beneficial to the public, as a urinary tract infection can start at any time, causing discomfort and distress and may result in time away from work or non-work activities, but also for our general practice colleagues who are already under system pressure due to population growth, an aging population and an increasing demand for health services in a constrained fiscal environment.

6.1c: Flurbiprofen proposed classification change from pharmacy-only to general sales under specified conditions (Reckitt Benckiser (New Zealand) Pty Limited)

The Guild does not support the proposed reclassification of Fluribiprofen from pharmacy-only medicine to general sale medicine, even under specified conditions. We have significant concerns around the implications of reclassifying flurbiprofen to general sale where it may lead to delayed detection and diagnosis of streptococcal throat infections, in particular group A streptococcal (GAS) positive sore throats, the use of flurbiprofen in pregnancy, and may lead to patients unintentionally doubling up on anti-inflammatory medicines.

Community pharmacies provide several functions in primary care regarding the management of sore throats in their communities, in some situations up to 7 days a week and in the evenings where no appointment is required. This ranges from providing a basic triage function in identifying and providing symptomatic relief for uncomplicated cases of sore throat, referring potential cases of streptococcal throat infections to general practice for follow up testing, providing screening of streptococcal throat infections through rapid point of care testing instore, to some community pharmacies being contracted by their District to provide streptococcal throat swabbing services and treatment via a standing order.

New Zealand continues to be an outlier in the incidence of acute rheumatic fever, which is typically an illness more prevalent in developing countries. In New Zealand, high risk groups for rheumatic fever include Māori and Pacific children aged between 4 to 19 years. By reclassifying flurbiprofen to general sale, this will increase the availability of a medicine which can potentially mask the symptoms of sore throats, and without the advice of a health professional, this may significantly impact our current incidence of untreated group A streptococcal (GAS) positive throat infections or other serious conditions, through delayed detection and diagnosis, especially for at-risk populations.

Flurbiprofen is indicated for the relief of sore throat from the age of 12 years, which falls within the age range where children are at the greatest risk of developing rheumatic fever. As stated in the New Zealand Guidelines for Rheumatic Fever "*Non-steroidal anti-inflammatory drugs (NSAIDs) are useful for the symptomatic treatment of pharyngitis. If a diagnosis of rheumatic fever is being considered, NSAIDs should be avoided until a diagnosis is secure as NSAIDs can mask symptoms and test results*" (gas-sore-throat-rheumatic-fever-guideline.pdf, heartfoundation.org.nz).

Although there are other products available for general sale for symptoms relief of sore throats, we believe that a discussion with trained pharmacy staff on the appropriate course of treatment for their sore throat, whether that is appropriate symptom relief or referral to a pharmacist or doctor, is best practice and provides an opportunity to help relieve the burden on general practice.

We also have concerns around the use of flurbiprofen in pregnant women. There is limited evidence available to demonstrate whether flurbiprofen is harmful or not. However, the general advice regarding non-steroidal anti-inflammatory drugs (NSAIDS) is to avoid use during the third trimester to minimise the risk of the premature closure of the fetal ductus arteriosus in utero and persistent hypertension of the newborn. We believe that it is insufficient to rely solely on medicine labelling to ensure that pregnant women do not take NSAIDS available in the general sale environment. Pregnancy and breastfeeding checks form part of the routine assessment of all patients who come into a community pharmacy seeking treatment and advice. If a woman is identified as being pregnant, pharmacist clinical knowledge and checks against clinical references are conducted to ensure that all medicines are appropriate for the woman to take during her pregnancy.

We have further concerns around patients purchasing and using flurbiprofen-containing products from a general sale environment where they may also be taking cold and flu preparations and other forms of pain relief that contain other anti-inflammatory medication, e.g., Nurofen Cold and Flu PE and other Nurofen products that are available as general sale. A significant proportion of sore throat lozenges contain antiseptic agents without pain relief and provide symptomatic relief of a sore throat by providing a soothing effect by coating the affected areas of the throat. We have concerns that patients will be unaware that flurbiprofen-containing throat lozenges contain an anti-inflammatory medicine and therefore may be unintentionally doubling up on anti-inflammatories

medicines. This applies particularly to outlets where there are no restrictions on the number of packs that can be purchased by patients and no access to professional advice or administration under professional healthcare supervision and guidance.

In the community pharmacy setting, pharmacy staff act as a safeguard as they are trained to advise patients at the point of sale that flurbiprofen is an anti-inflammatory medicine and to avoid the concomitant use of other products that contain anti-inflammatories medicines. Providing patient access to information via handouts or labelling is not sufficient to address the concerns raised and facilitating access to professional advice for the prescribing and supply of medicines is the best way to maintain safe and cost-effective access to medicines. Patients need advice on the correct and proper way to use medicines and this is best achieved with supply from trained staff through a community pharmacy and when necessary, referral to a pharmacist, general practitioner or other appropriate healthcare professional.

6.1d: Glecaprevir and Pibrentasvir (Maviret) – proposed change to prescription classification statement to include provision by pharmacists under certain circumstances (Te Whatu Ora)
The Guild strongly reiterates our support for this proposal and its alignment with the goal to eliminate hepatitis C as a major public threat by 2030.

This reclassification has multiple benefits for people with hepatitis C, for their community, and for the health system in the potential savings from preventing complications associated with chronic hepatitis C infection. Risks are minimal and enabling a new care model is needed urgently to help achieve the government goal of elimination by 2030 and maximise the potential gains from such care.

Adopting this exception to prescription status for the pharmacist-supply of Glecaprevir and Pibrentasvir (Maviret) will reduce many barriers to access while retaining patient safety. This model will also support the pharmacy test and treat programme that is currently funded in the Northern regions of New Zealand. The ability to treat hepatitis C without waiting for a doctor's prescription should increase treatment uptake and cure in our most vulnerable populations. We would also like to see Glecaprevir and Pibrentasvir (Maviret) added to the list of medicines that pharmacist prescribers can prescribe.

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 Glecaprevir and Pibrentasvir (Maviret). Hepatitis C is straightforward to diagnose, with clear referral criteria and 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 pharmacists for other health needs. With equity and access being the main goal, the inclusion of pharmacists 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. Based on our proposal to the Medicines Classification Committee 69th meeting, the following model could be utilised with immediate effect, based on existing infrastructure and a nurse referral system:

- 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 (CCiC) agreements, where a funding stream is already in place and functioning and there is access to CCCM and patient-information portals.
2. Secondly, pharmacies who wish to opt-in or are identified by their local districts as key locations to provide the service. They will complete the training and be set up with access to the required systems.

- Eligibility screening will take place, including funding eligibility before the pharmacist will prescribe and dispense the medicine.
- Once dispensed, the medicine can be provided to the patient by the pharmacist with the appropriate counselling and consultation.
- An appropriate follow-up consultation will be arranged.
- The medicine remains an Xpharm-funded product and the pharmacist is remunerated for the consultation, prescribing, dispensing, counselling, and follow-up counselling functions as per the COVID-19 Care in the Community (CCiC) guidelines.
- Both the initial and/or follow up counselling can be performed via a telehealth or CCCM-integrated/triggered interaction between the patient 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 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 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.

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

- As per current CCiC model: $75 per 30 minutes of consultation time, i.e., time spent prescribing and counselling the patient.
- Appropriate training: This can integrate with current training for pharmacists to dispense Glecaprevir and Pibrentasvir (Maviret). The current fee for dispensing Glecaprevir and Pibrentasvir (Maviret) and counselling will remain in place for pharmacists.
- As per existing Xpharm guidelines currently in place for Glecaprevir and Pibrentasvir (Maviret) dispensing with an added fee for prescribing.

6.1e: Naproxen – proposed up-scheduling change to classification (Medsafe)

The Guild supports the proposed changes in the classification statements for naproxen-containing products and agree that the indications should be appropriately changed to better reflect safe and effective patient guidelines.

6.1f: Bilastine proposed change to pharmacy-only classification statement (Menarini New Zealand Pty Ltd)

The Guild supports the proposed change to the pharmacy-only classification statement of bilastine as there is no additional risk from this classification because it does not change who is eligible for pharmacy-only access. However, it offers the benefit of choice for the patient who may desire a liquid formulation. It also has the benefit of alignment across all marketed non-sedating antihistamines for the pharmacy-only category, which is logical.

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 Cathy Martin (cathy@pgnz.org.nz, 04 802 8214).

Yours sincerely,

Nicole Rickman
General Manager – Membership and Professional Services

PHARMACEUTICAL SOCIETY
of New Zealand Incorporated

21 April 2023

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 70th MEETING AGENDA May 2023

Thank you for the opportunity to submit comments on the agenda for the 70th 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 Ibuprofen 400mg – proposed down scheduling change to classification.

The Society supports the harmonisation of medicines between Australia and New Zealand, where it is appropriate. As mentioned in our submission to the 65th MCC meeting, the literature does indicate that 400mg dosing of ibuprofen may be clinically appropriate for certain conditions.[1] However, ibuprofen 200mg is already available as a single agent for self-selection in packaging of up to 100 dose units and patients can choose to take one or two tablets depending on their requirements. The difficulty for patients swallowing tablets is not necessarily dependant on the number of tablets. The study provided by the applicant to explain the challenges patients face with swallowing medicines relates to altering the formulation rather than specifically the number of tablets being consumed.[2] Pharmacists can assist patients with challenges around swallowing and an alternative formulation may be more appropriate than the self-selection of ibuprofen 400mg tablet. Unfortunately, if the medicine becomes self-selection there is nothing to prevent the product being used long term, where clinical oversight and therapeutic intervention may be required, to reduce the risks of taking high dose ibuprofen.

The key design features mentioned by the applicant to potentially mitigate risk were requested by the TGA during their reclassification.[3] These alerts may be useful if this product becomes available in New Zealand.

The applicant mentioned that there no evidence of a change in the safety profile or any signals of a change in the risk-benefit profile of ibuprofen. However, we would recommend that committee ask the applicant to provide copies of the reference mentioned, as they are not in the public domain, and this would be useful to help the committee with their discussions around any potential risk.

6.1b Trimethoprim- proposed up-scheduling change to classification

The Society does not support the proposed reclassification for trimethoprim from "prescription except when" to "prescription only". The Society believes that it is important to have available a second- line option from an appropriately trained pharmacist. i.e. trimethoprim for empiric treatment of uncomplicated UTIs available for those individuals where nitrofurantoin is contraindicated.

All healthcare settings are currently experiencing workforce shortages and moving trimethoprim to prescription only will create additional barriers to accessible and equitable care, as it will require access to a prescriber.

Treatment of uncomplicated UTIs with timely empiric treatment avoids the risk of the infection spreading to the kidneys and causing more serious systemic infection. Timely empiric treatment is best practice.

Community pharmacists are an integral component of primary care in New Zealand. Community pharmacists are located all over the country throughout urban and rural areas and are currently one of the most accessible health professionals. They are medicine experts and those providing treatment for uncomplicated UTIs are trained specifically in the treatment of this condition.

The current training UTI training course is presented by Dr Juliet Elvey (Clinical Microbiologist Southern Community Laboratories) and includes:

- International best practice guidelines for the treatment of uncomplicated UTIs.
- Clearly defined patient treatment group - females aged from 16 to 65 years.
- Training to distinguish uncomplicated from complicated UTIs.
- Clinical symptoms of an uncomplicated UTI and how to distinguish this from other causes.
- Symptoms or factors that warrant referral to the GP for further investigation (Red flags).
- The place of empiric antibiotic provision.
- Self-care strategies for patients to adopt during infection and to prevent recurrence of infection.
- A Pharmacist supply algorithm and checklist for nitrofurantoin and for trimethoprim that has been peer reviewed by Juliet and Sharon Gardiner, antimicrobial stewardship specialist pharmacist and co-founder and co-chair of the New Zealand Antimicrobial Stewardship and Infection Pharmacist Expert Group (NAMSIPEG).

The course specifically informs learners about the antibiotic resistance situation and covers first line treatment and second (or third line treatment). Juliet also presented the UTI training course previously at a time when trimethoprim was considered appropriate for first line treatment of uncomplicated UTIs. She acknowledges the change in practice and fully covers the reasons for this in the current course.

Pharmacists understand the resistance issues with trimethoprim and do not supply it as a first line option for uncomplicated UTIs. They can be trusted as antimicrobial stewards to ensure their practice is aligned with international best practice guidelines and to use trimethoprim appropriately and sparingly where indicated. Trimethoprim has not been deregistered as an approved medicine in New Zealand and elsewhere. It still has a place in practice as an alternative antibiotic when other options are contraindicated. This applies regardless of its classification as prescription medicine or supplied by pharmacist under the conditions of the current classification.

If the Committee is considering reclassifying, we would suggest an amended classification statement to help position the medicine as a second line option. We would like the committee to consider, either at their current or at a future meeting, if the Terms of Reference do not allow this to occur, the following changes to the classification statement:

Prescription except when in medicines for oral use containing 300 milligrams or less per dose unit when sold in a pack of 3 solid dosage units to a woman aged 16-65 years for the **second-line empiric treatment** of an uncomplicated urinary tract infection by a registered pharmacist who has successfully completed the Pharmaceutical Society of New Zealand training in the treatment of urinary tract infections.

6.1c Flurbiprofen – proposed down scheduling change to classification

The Society does not support the proposed reclassification for Flurbiprofen from pharmacy only to general sale medicine, based on the information provided. Topical oral products such as flurbiprofen are indicated for relief of pain, swelling and inflammation associated with severe sore throat. When a person has severe, sore throat, it is important that they have access to a health professional to assess whether it could be a more serious condition such as glandular fever or streptococcal infection. The latter is a significant issue for certain population groups in New Zealand.

Although pharmacists and their support teams are not able to diagnose these conditions, they are well placed to provide an effective triage and refer at-risk patients to the GP for diagnosis and appropriate treatment. This approach also aligns with the Heart Foundation and Te Whatu Ora guidance for the management of sore throats.[4,5]

The applicant has mentioned New Zealand specific consumer research has demonstrated some positive outcomes when balancing sore throat and diagnosis of Strep A. However, this study has not been published and is referenced as confidential data on file. We would like to suggest that the Committee have access to this information to help support their discussions, especially around any potential reclassification.

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

The Society supports this application and the potential opportunity through the reclassification to increased access to Maviret for those New Zealanders requiring diagnostic services and treatment for hepatitis C.

The applicant's suggested collaborative approach is a novel and the intended outcomes to improve the health of New Zealanders are clear.

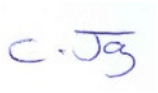
We are of the opinion that some additional thinking may be required around the governance requirements for the potential cohort of nurses delivering the proposed service and how they will collaborate with the pharmacists providing the required treatment.

6.1e Naproxen- proposed up-scheduling change to classification

The Society supports Medsafe's requests for the committee to apply a consistent approach to the current variety of clinical indications and the classification of naproxen, under the pharmacy medicine category.

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

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