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,

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