PHARMACY GUILD OF NEW ZEALAND

19 October 2023

Medicines Classification Committee Secretary
Medsafe
Wellington

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

Dear Committee Members,

Re: Agenda for the 71st meeting of the Medicines Classification Committee (MCC)

Thank you for the opportunity to provide feedback on the upcoming MCC 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 covers the following agenda items:

- 6. Submissions for reclassification:
  - 6.1 Phenol – proposed change to prescription classification statement to include provision by podiatrists under certain conditions
- 8. Harmonisation of the New Zealand and Australian Schedules:
  - 8.2.1 Paracetamol
  - 8.2.2 Brimonidine
  - 8.2.3 Fexofenadine
  - 8.2.4 Melatonin
  - 8.2.5 Cetirizine

6.1: Phenol – proposed change to prescription classification statement to include provision by podiatrists under certain conditions (Podiatrist Board of New Zealand and Podiatry New Zealand)

The Guild does not endorse the proposed change to the prescription classification of phenol to include provision by podiatrists under certain conditions for chemical matrixectomy as proposed by the Podiatrist Board of New Zealand (PBNZ) and Podiatry New Zealand. Although the proposed change to prescription classification could potentially simplify access to treatment for patients by podiatrists, their application does not provide any detail and assurance on the controlled provision, storage and custody of a toxic and potentially harmful chemical.

Currently there are no approved products available in New Zealand that would be suitable for a podiatrist to use, including the example that the PBNZ has mentioned in their application, that is, Podopro Swab-It (each ampoule contains between 0.15 – 0.2 ml USP Phenol, which is applied using a swab; ampoules are individually wrapped, pack size of up to 30 units). Therefore, we do not understand how the PBNZ propose to oversee the logistics surrounding such a change and ensuring safe conditions for both the podiatrist and their patients of a toxic and potentially harmful chemical in an enclosed environment.

Keeping in mind the stringent storage and access control requirements that pharmacies must adhere to, we would expect that any podiatrist planning to store phenol for use in chemical matrixectomy would have to adhere to the same requirements and audit processes that pharmacies are currently subject to.

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8.2.1: Harmonisation of the New Zealand and Australian Schedules -Paracetamol

The Guild does not believe that harmonisation of New Zealand with the Australian TGA decision to limit paracetamol pack sizes available for retail sale will result in harm minimisation by reducing the quantity of paracetamol in the home. This is because without a real-time monitoring system, consumers can continue to stockpile paracetamol by visiting multiple stockists.

Paracetamol provides a valuable means for self-management of minor painful ailments and is an effective antipyretic. Even though paracetamol is a commonly used medicine, it has been associated with misuse, self-harm, and suicide attempts due to its ability to cause severe liver toxicity and death, especially in late presentations and high doses. However, a balance needs to be found between meeting a consumer's need for timely and appropriate self-management of pain or fever whilst helping minimise stockpiling in New Zealand households. It is also important that any measures being currently considered for paracetamol do not inadvertently create misinformation pertaining to its well-established safety profile when used as directed on the label.

Given the potential for abuse and the history of harm resulting from paracetamol overuse, the Guild ideally advocates for all sales of paracetamol to be restricted to pharmacies. Pharmacy staff can assess the suitability of paracetamol for individual consumers, provide proper dosing instructions, and monitor usage to ensure it is both safe and effective. This approach not only promotes responsible use but also mitigates the risk of excessive paracetamol consumption, which is of paramount importance in safeguarding public health.

The Guild acknowledges that there might be concerns regarding the potential inaccessibility of paracetamol if it were to be removed from general sales. However, it is important to note that community pharmacies have demonstrated their high accessibility, remaining open seven days a week, often for extended hours.

We believe that, practically speaking, for pack size restrictions in general sales outlets to have the desired outcome of restricting means, it would need to be implemented in conjunction with other purchasing restrictions, otherwise, there is nothing prohibiting multiple packs being purchased. This is particularly the case in supermarkets with the proliferation of 'self-service' checkouts that allow an individual to purchase multiple packs of a medicine without any oversight or involvement of a staff member. Additionally, general retail outlets may offer specials to make it more enticing for consumers to buy multiple packs. It is also not clear if there is the ability to enforce restrictions on the purchase of multiple packs of general sale packs through various retailers and providers, or who will hold responsibility for enforcement and monitoring of non-compliance.

The Guild does not support restriction on purchasing multiple packs of paracetamol through community pharmacy. Pharmacists' ethical responsibilities require them to ensure the safe use of medicines, including paracetamol, purchased from pharmacies. We also believe that it is more difficult for individuals to make multiple purchases or purchases on consecutive days at a community pharmacy due to a more regular workforce that are likely to recognise repeat customers. To support harm minimisation efforts and promote the quality use of medicines, consideration could be given to implementing a requirement for multiple pack purchases in a pharmacy to be reviewed and authorised by a pharmacist.

8.2.2: Harmonisation of the New Zealand and Australian Schedules - Brimonidine

The Guild supports the change in scheduling status for low dose brimonidine (0.025%) to harmonise with the TGA decision in Australia and feel it is a prudent step in ensuring efficient and safe expansion of access to this medicine in New Zealand. This change will allow access to low dose brimonidine (0.025%) for the relief of red eye, itching or irritation, which is easily diagnosed and generally well tolerated with no observed potential of misuse or abuse, which does not cause the same issues of rebound redness and loss of effectiveness seen with the ophthalmic decongestants currently available in New Zealand.

In alignment with the TGA's decision, classifying brimonidine in New Zealand as "*prescription only except when provided by a pharmacist to relieve redness of the eye due to minor eye irritations in ophthalmic preparations for adult use containing not more than 0.025% brimonidine*" acknowledges the specialised knowledge and expertise that pharmacists possess in determining the suitability of this medicine for patients under the supervision of a qualified healthcare provider, ultimately enhancing patient care and ensuring that brimonidine is used safely and effectively for its intended purposes.

As pharmacists are highly trained professionals capable of providing expert guidance on the safe and effective use of medicines for specific indications there should be no requirement for additional training.

8.2.3: Harmonisation of the New Zealand and Australian Schedules - Fexofenadine

The Guild does not believe that harmonising the New Zealand's pack size regulations for fexofenadine with the TGA's recent change in Australia will benefit patient safety.

While the TGA's alteration may reflect their own regulatory approach, we believe the unique healthcare landscape in New Zealand deserves due consideration. The MCC's recommendation, following a comprehensive assessment in October 2020, was made with the paramount aim of patient safety, and proposed that fexofenadine with certain conditions, including a pack size of five dosage units or less, should remain available for general sale in New Zealand.

With fexofenadine being a pregnancy category B2 medicine and having significant adverse effects like torsades de pointes, the potential decision to increase the pack size to 10 dosage units in alignment with the TGA decision may inadvertently encourage individuals to self-administer larger quantities without professional guidance, potentially leading to misuse and safety concerns and should only be available from places where consumers will be able to seek advice from a health professional. New Zealand's current regulations and the MCC's decisions in the past prioritise patient safety and promote safe use of medicines, and any change in this regard should be approached with the same measure of caution.

We would propose the current status quo be preserved, limiting the pack size for fexofenadine for the treatment of seasonal allergic rhinitis in adults and children 12 years of age and over when in tablets containing 180 mg or less of fexofenadine hydrochloride with a maximum daily dose of 180 mg when sold in the manufacturer's original pack available general sale to five dosage units or less and not more than five days' supply via general sale.

8.2.4: Harmonisation of the New Zealand and Australian Schedules - Melatonin

The Guild fully supports the alignment with the TGA's decision in Australia to allow pharmacists to provide melatonin to adults for jet lag and feel this is a crucial step in safeguarding patient safety and ensuring responsible access to this sleep aid. This change would enable professional guidance and support for individuals seeking melatonin for jet lag, thus reducing the risk associated with buying this medicine online from non-regulated sources without oversight or information on safe usage or other alternatives that may be addictive.

By allowing pharmacists to provide melatonin containing 5 mg or less for the treatment of jet lag to adults aged 18 and over, within specific pack size limitations, we can ensure that consumers receive appropriate advice and guidance on its proper use. This pragmatic approach to harmonisation with Australia's regulations considers the best interests of patient safety and well-informed healthcare choices. Pharmacists are well placed to provide consumers with travel advice and solutions before departure and as medicine experts, have a good understanding of the role of melatonin for sleep issues and jet lag, it's potential adverse effects and interactions, and can counsel confidently on this and suitable non-pharmacological strategies for the individual person.

Previous applications for the rescheduling of melatonin have established that this medicine has a good safety profile and noted that the risk of toxicity in acute use of the substance is low. As symptoms of jet lag are transient, e.g., 4-6 days, the treatment of melatonin would therefore be short-term and thus jet lag is a condition suitable for self-management and treatment with melatonin.

Therefore, we suggest the current classification statement in New Zealand is changed to:
Prescription except when supplied in medicines for oral use containing 3mg or less per immediate release dose unit, or 2mg or less per modified release dose unit, when sold in the manufacturers original pack that has received consent from the Minister of Health or the Director General for the treatment of primary insomnia for adults aged 55 years or older for up to 13 weeks, or 5mg immediate release dose unit when sold in quantities up to a maximum of 10 doses in the manufacturers original pack that has received consent from the Minister of Health or the Director General for the treatment of jetlag for adults aged 18 or older by a registered pharmacist.

We also strongly believe that pharmacists are expertly and thoroughly trained and adherent to competency standards as prescribed by the Pharmacy Council of New Zealand to be able to provide melatonin for the treatment of jet lag and would not need to complete any additional qualifications or training to be able to perform the safe and effective provision of this medicine.

8.2.5: Harmonisation of the New Zealand and Australian Schedules - Cetirizine
The Guild does not support the harmonisation of New Zealand's pack size regulations for cetirizine with the TGA's recent decisions in Australia as it does not align with the best interests of patient safety.

While the TGA's rescheduling may reflect their regulatory approach, the context and healthcare landscape in New Zealand should be considered. The recommendation to maintain a five-day supply pack size by the MCC in 2020 was made after thorough evaluation, with patient safety as a paramount concern and should be adequate in providing for the general goals of allergic rhinitis treatment.

The use of cetirizine in pregnancy and breastfeeding is not recommended and consumers need to be able to discuss with a healthcare professional the benefits and potential risks with taking cetirizine in managing allergic rhinitis where medicines, information, advice, and verbal reinforcement can also be provided. While allergic rhinitis is often a self-diagnosed condition it can be commonly confused with a range of other diagnoses, such as a simple cold, a sinus infection, conjunctivitis and serious eye conditions, and thus increasing the general sales level pack size may delay a person seeking advice in a pharmacy and may mean that best practice treatment is similarly delayed, which is not in the best interest of promoting public health. A smaller pack will encourage consumers to seek advice from a pharmacist more regularly than would be the case for a larger pack size.

Amongst other things, the management of allergic rhinitis is varied and the optimal therapeutic choice for an individual patient should be made in consultation with a health professional and provision of other information, such as alternative or additional treatment options, non-pharmacological and/or self-management advice such as avoidance of allergens, use of saline nasal sprays and direct steam inhalation, which play an important role in managing the symptoms.

Cetirizine is more likely to result in sedation and impairment than other non-sedating, similarly effective, antihistamines. Sedation is noted as an adverse effect in most datasheets for cetirizine and consumers need to be advised that there is even a potential low risk with the second-generation antihistamines, which can only be done in consultation with a healthcare professional. Although its sedation effects are dose-related and risks can increase when taken in combination with alcohol and any other medicine that can cause memory impairment and affect psychomotor skills, there is still a higher risk of an adverse outcome in comparison to other antihistamines.

Adherence to the five-day supply in New Zealand serves to ensure that consumers are guided by appropriate dosing instructions and professional guidance, reducing the potential for misuse or unintentional overconsumption. The principle of prioritising patient safety should continue to guide New Zealand's decision-making independently of external harmonisation in this specific case.

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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