PHARMACEUTICAL SOCIETY
of New Zealand Incorporated

17 April 2024

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 72nd MEETING AGENDA June 2024

Thank you for the opportunity to submit comments on the agenda for the 72nd 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 pharmacist's 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:

6.1 Sedating antihistamines

The Society supports the proposed inclusion of age restrictions in the classification statements for sedating antihistamines when indicated for insomnia or sedation.
The recommended reclassification statements would deliver on the Medicines Adverse Reactions Committee (MARC) suggestions and ensure there is alignment with the current approved indications.

6.2 Respiratory Syncytial Virus Vaccine adjuvanted

The Society supports the proposed reclassification of Respiratory syncytial virus vaccine, adjuvanted to "prescription except when" in accordance with all other vaccines.
We are aware that this medicine is currently progressing through the approval and funding processes. However, there is evidence that this product is beneficial for the proposed age group.[1] Increasing potential access through utilising a pharmacist would also have beneficial outcomes for those seeking vaccination.

8.1b Palovarotene

The Society does not support harmonisation of palovarotene. The medicine is approved in Australia and the United States.[2]
However, the company have advised that the European Medicines Agency Committee for Medicinal Products (CHMP) have issued a negative opinion for palovarotene to reduce the formation of heterotopic ossification associated with fibrodysplasia ossificans progressiva.[3] As a result this medicine is not approved in Europe.
Palovarotene also carries a significant risk of teratogenicity and is contraindicated in pregnancy. International evidence supports the use of a pregnancy prevention programme to mitigate this risk.[4]. We are not aware of any systems like this currently across New Zealand.

If the Committee decide it is clinically appropriate to harmonise, the Society recommends that an appropriate robust New Zealand pregnancy prevention programme is included as part of the requirement for approval.

8.1b Nirsevimab

The Society is supportive of harmonisation of nirsevimab. There is clear evidence that this medicine will benefit neonates and infants under certain conditions.[5]

8.2.1 Bisacodyl

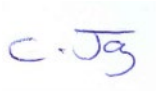
The Society is not supportive of harmonising bisacodyl under criteria in the Australian schedule.
In June 2021, MARC undertook a review of the potential abuse with stimulant laxatives.[6]
The Committee noted that the effectiveness of the recent MHRA regulation activities around stimulant laxatives had not been evaluated.
The Committee were also advised that there were guidelines and recommendations from the Pharmaceutical Society of New Zealand to assist pharmacists around the supply and storage of OTC medicines associated with misuse which included stimulant laxatives. The Committee recommended adding warning and advisory statements to the manufacturer's original pack for all stimulant laxatives through a Label Statements Database consultation. The Committee also endorsed the Pharmaceutical Society of New Zealand's practice and guidelines on the supply and storage of medicines that could be misused over the counter.
A recent review of the pharmacology and clinical evidence of bisacodyl in clinical practice has concluded that available evidence does not indicate that stimulant laxatives at recommended doses are harmful to the colon.[7]
MARC did not recommend a referral to MCC for change of classification and were comfortable with the current classification statements. There we would support the current positioning of bisacodyl in New Zealand.

8.2.2 Olopatadine

The Society has no concerns with the reclassification of olopatadine under the TGA's Schedule 2 listing.

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

Yours sincerely,



Chris Jay
Manager Practice and Policy

References

1) Walsh et al. Efficacy and Safety of a Bivalent RSV Prefusion F Vaccine in Older Adults. N *Engl J Med* 2023;**388**:1465-1477.
2) US Food and Drug Administration. FDA approves first treatment for Fibrodysplasia Ossifcians Progressiva.URL.[accessed16/4/2024]
3) National Institute for Health and Care Excellence. Palovarotene for preventing heterotopic ossification associated with fibrodysplasia ossificans progressiva [ID3739]. URL [accessed 16/4/24]
4) Palovarotene (Monograph). Drugs.com URI. [accessed 16/4/24]
5) Dawood F.S. et al. Assessing the Real-World Effectiveness of Immunizations for Respiratory Syncytial Virus. April 11, 2024. doi:10.1001/jama.2024.5859 [accessed 16/4/24]
6) Medicines Adverse Reactions Committee. Misuse of stimulant laxatives. 2021. URL [accessed 16/4/24]
7) Corsetti M et al. Bisacodyl: A review of pharmacology and clinical evidence to guide use in clinical practice in patients with constipation. Neurogastroenterol Motil. 2021 Oct; **33(10)**: e14123.

PHARMACY GUILD OF NEW ZEALAND

8 May 2024

Medicines Classification Committee Secretary
Medsafe
Wellington

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

Dear Committee Members,

Re: Agenda for the 72nd 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 Sedating antihistamines – proposed inclusion of age restrictions in classification statements of sedating antihistamines when indicated for insomnia or sedation (Medsafe)
    - 6.2 Respiratory Syncytial Virus vaccine, adjuvanted – proposed classification to allow administration without prescription (GlaxoSmithKline Australia Pty Ltd)
- 8. Harmonisation of the New Zealand and Australian Schedules:
    - 8.2.1 Bisacodyl
    - 8.2.2 Olopatadine

6.1 Sedating antihistamines – proposed inclusion of age restrictions in classification statements of sedating antihistamines when indicated for insomnia or sedation (Medsafe)

The Guild supports the proposal by Medsafe to update the classification statements of oral sedating antihistamines to align with the MARC recommendations made in 2020, that will restrict OTC products of oral sedating antihistamines for sedation to adults only and those for insomnia to adults and children over 12 years old. We also support for these medicines to continue to be classified as pharmacist-only medicines, where, after a consultation, a pharmacist will determine if the benefits outweigh the risks for each consumer.

In addition, we advocate for the provision of free training and resources for pharmacists and pharmacy staff on the differences between insomnia and sedation and on the adverse and detrimental effects of sedating antihistamines when used in children under 12 years, along with information on alternative therapies. The training and resources would assist in the discussions with consumers to ensure that they are not using these medicines incorrectly and to ensure the safer use of sedating antihistamines among vulnerable populations.

6.2 Respiratory Syncytial Virus vaccine, adjuvanted – proposed classification to allow administration without prescription (GlaxoSmithKline Australia Pty Ltd)

The Guild supports the proposal by GlaxoSmithKline for respiratory syncytial virus (RSV) vaccines to be reclassified to be:

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

Pharmacists play a vital role in preventing and managing vaccine-preventable infections, and positively assist as vaccinators and advocators in immunisation programmes, such as influenza, and during disease outbreaks and pandemics, as shown with Covid-19. With their specialised training, pharmacist vaccinators conduct thorough assessments, provide education, and address concerns before and after vaccination to support patients and caregivers in making informed choices. Pharmacist vaccinators are uniquely positioned to identify patients who need vaccinations and ensure comprehensive healthcare through referrals if necessary. Utilising advanced IT systems and the Aotearoa Immunisation Register, pharmacist vaccinators also facilitate timely vaccination schedules and recalls.

The reclassification of RSV vaccines to allow pharmacist vaccinators to administer these to eligible people would enhance patient access, allowing people to choose where and when they feel comfortable and is convenient to receive their vaccinations. Enabling pharmacist vaccinators to administer RSV vaccines through the large geographical footprint of community pharmacies will positively impact vaccination site accessibility and vaccination rates and outcomes throughout the motu for the public, independent of ethnicity or disability, as well as assist in reducing the burden on already busy general practice.

We request that free training and resources are accessible for pharmacist vaccinators on the various RSV vaccines and comprehensive media campaigns from the suppliers are available to explain and promote the accessibility and benefits of the RSV vaccines to the public.

We further believe it is important for the MCC to consider recommending the eligibility of a co-administration fee for the RSV vaccine alongside the influenza vaccine in eligible populations once the RSV vaccine is considered for funding. This would mirror the current practice with the shingles vaccine, aligning the future funding eligibility criteria for both vaccines, as they target similar patient demographics.

8.2.1 Harmonisation of the New Zealand and Australian Schedules - Bisacodyl

The Guild does not support the change in classification of bisacodyl in New Zealand to align with the recent scheduling changes of bisacodyl by the TGA in Australia as it does not align with the best interests of patient safety. We interpret that if harmonisation was to occur, the following dosage units of bisacodyl in New Zealand would be classified as a general medicine and thus available for sale in supermarkets and convenience stores:

- in divided preparations for oral use in a primary pack containing 20 dosage units or less containing 5 g or less bisacodyl per dosage unit; or
- in a primary pack containing 12 dosage units or less suppositories containing 10 mg or less of bisacodyl per dosage unit; or
- in a primary pack containing 25 dosage units or less enemas containing 10 mg or less of bisacodyl per dosage unit.

In addition, we also request that consideration is undertaken by the MCC to the upscheduling of larger pack sizes greater than 30 dosage units of oral bisacodyl to a pharmacist-only medicine classification to ensure the provision of professional advice by a pharmacist for safe use and minimisation of abuse, intentionally or unintentionally.

Currently all forms of bisacodyl are classified in New Zealand as a pharmacy only medicine. Bisacodyl is available in a 5 mg enteric coated tablet form or 10 mg suppository form in a wide range of pack sizes and under various

brands, including Dulcolax, Bisacodyl Viatris, Pharmacy Health Bisacodyl and Bisacodyl Lax-Suppositories. Currently there are no bisacodyl enemas available in New Zealand. Bisacodyl Viatris 5 mg EC tablets (pack size of 200) by Viatris and Bisacodyl Lax-Suppositories (pack size of 10) by AFT are funded on prescription.

Bisacodyl is classified as a stimulant laxative and acts by direct stimulation of nerve endings in colonic mucosa to increase intestinal motility. It is intended for short-term constipation relief or in bowel preparations, not exceeding a treatment duration of 7-10 days without medical supervision. The adult oral dosage ranges from 5 mg to 10 mg at night, with rectal dosage of 10 mg in the morning. Oral bisacodyl is taken at night for evacuation the next morning (onset in 10-12 hours), while suppositories typically work in 10 to 30 minutes. Bisacodyl may cause abdominal pain, cramping, and nausea, with high doses or long-term use producing diarrhoea, excessive loss of water and electrolyte imbalances, leading to hypokalaemia, renal tubular damage, metabolic alkalosis, and negatively impacting the cardiovascular system. It may also involve loss of normal colonic peristalsis and cause innocuous reflex constipation. Bisacodyl is contraindicated in patients with IBD and acute bowel conditions and should be used with caution in patients with frailty, immobility or at risk of falls. It should be taken with caution in patients taking other potassium-lowering medicines, medicines where their toxic effect increases if the body is lacking in potassium, and concomitant use with other laxatives.

Constipation is complex, requiring consideration of its root cause for effective treatment. The involvement of a health professional is required, who may recommend behaviour modification, dietary changes, and laxative therapy based on individual needs. Stimulant laxatives are typically not the first-line treatment of constipation, dietary and lifestyle adjustments are usually tried first, following by bulk-forming or osmotic laxatives, depending on the cause of the constipation, before considering stimulant laxatives. There is also a risk of misuse with stimulant laxatives, particularly in vulnerable populations, including the elderly and people with mental health conditions, which can mask more serious underlying conditions. While stimulant laxatives like bisacodyl do not aid in weight loss, they are still the most commonly class of laxatives abused, posing serious health risks.

We believe all sales of bisacodyl should remain restricted to pharmacies due to abuse potential. Downscheduling smaller pack sizes to general sale in supermarkets and convenience stores, as in Australia, will require strict purchasing restrictions to prevent multiple purchases without oversight. Maintaining pharmacy only classification status for bisacodyl for rectal use and for oral use up to a maximum of 30 dosage units as a single purchase will provide consumers with up to 15 days of supply at a maximum daily dose of 10 mg, which is sufficient for the treatment of short-term constipation, and will allow trained pharmacy staff, with oversight by a pharmacist, to assess the suitability of bisacodyl for individual consumers, provide proper dosing instructions, and monitor usage to ensure it is both safe and effective.

Consumers needing larger quantities of bisacodyl can consult with a pharmacist to address the cause of the ongoing constipation, promoting responsible use and minimising excessive consumption risks, which is of paramount importance in safeguarding public health. Those with chronic constipation associated with serious diseases and conditions are typically managed by health professionals and would normally access larger quantities of bisacodyl via prescription.

We recognise that the proposed changes may lead consumers misusing bisacodyl to turn to senna and other stimulant laxatives, also available as pharmacy only medicines, both in small and large pack sizes, for similar reasons. We believe larger pack sizes of other stimulant laxatives should also be considered for upscheduling in the future.

8.2.2 Harmonisation of the New Zealand and Australian Schedules - Olopatadine

The Guild supports the change in scheduling status for olopatadine in preparations for nasal use delivering 600 micrograms or less of olopatadine per dose when the maximum recommended daily dose is no greater than 4,800 micrograms for the treatment of allergic rhinitis or rhinoconjunctivitis for up to 6 months in adults and children 12 years of age and over, to harmonise with the TGA decision in Australia.

Although there are currently only medicines containing olopatadine in ophthalmic dosage forms available in New Zealand, the alignment with the TGA decision would allow suppliers of intranasal olopatadine preparations to apply to Medsafe for approval and would be a prudent step in ensuring efficient and safe expansion of access to this medicine and greater choice of treatment of allergic rhinitis for the public.

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, with provision of other information, such as alternative or additional treatment options and self-management advice playing an important role in managing the symptoms. Pharmacists are highly trained professionals capable of delivering expert guidance on the safe and effective use of medicines for specific indications and providing appropriate supervision of the sale of pharmacy only medicines by trained retail pharmacy assistants to the public.

Olopatadine is a selective histamine H1 antagonist, and it is noted that there is currently another nasal spray containing a selective histamine H1 antagonist with a low dose steroid, Azelastine hydrochloride / fluticasone propionate nasal spray suspension 137 mcg per spray / 50 mcg per spray (Dymista), available as a pharmacy only medicine.

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

8 May 2024

The Medicines Classification Committee Secretariat
Medsafe
PO Box 5013
Wellington 6140

Dear Sir/Madam,

RE: Comments on the Medicines Classification Committee 72nd meeting agenda item 8.2.1 Bisacodyl

Reckitt supports a change in the current New Zealand classification of bisacodyl to harmonise with the recent changed classification of bisacodyl with Australia.
Whilst we understand and acknowledge the concerns regarding the misuse of stimulant laxatives, the recent Australian scheduling has considered this. It can also be noted in the 2021 MARC consideration on the misuse of stimulant laxatives, that no risks specific to New Zealand were identified, indicating that alignment with the Scheduling decision recently made in Australia is appropriate. It can also be noted that the change in access controls in Australia also align with that of the UK.

Yours Sincerely

[redacted]

[redacted]