PHARMACY GUILD OF NEW ZEALAND

26 July 2024

Medicines Classification Committee Secretary
Medsafe
Wellington

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

Dear Committee Members,

Re: Objection to the decisions from the 72nd meeting of the Medicines Classification Committee held on 12 June 2024

Thank you for the opportunity to submit an objection to the decisions from the 72nd meeting of the Medicines Classification Committee held on 12 June 2024.

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

We would like to raise objections to the decisions on the following items:

- 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)

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

We respectfully request that the MCC re-evaluate its decision to impose broad age restrictions on sedating antihistamines. We recommend reverting to the original proposal or engaging via the appropriate consultation process with the sector before making such significant changes.

The original submission proposed classification changes to restrict the use of sedating antihistamines in children *when indicated* for sedation and insomnia. The committee's decision to extend this restriction to all indications for both children and adults over 6 years old significantly broadens the scope of change beyond what was initially proposed. This decision impacts a wider range of therapeutic uses for these medicines and should have been subjected to comprehensive sector consultation.

The decision made at the MCC meeting appears to have bypassed the necessary consultation with the sector regarding the wider classification change. It is essential that all stakeholders, including healthcare professionals and industry representatives, are given the opportunity to provide input on such significant amendments. The lack of consultation may result in unintended consequences and limit the ability of healthcare providers to effectively treat patients. Ensuring that all stakeholders have the opportunity to provide input will lead to more balanced and effective regulatory outcomes.

The decision also differs from the approaches adopted in other jurisdictions. Many countries have specific guidelines and restrictions based on the indications and age groups for the use of sedating antihistamines. The MCC's broader restriction may not align with international best practices and could place New Zealand out of step with global standards.

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Sedating antihistamines have established therapeutic roles for various indications beyond insomnia and sedation, such as managing allergic reactions and motion sickness. Restricting their use without appropriate justification and consultation could negatively impact clinical practice and patient outcomes. Healthcare professionals need the flexibility to use these medicines where clinically appropriate.

Implementing such a wide restriction without adequate sector consultation sets a concerning precedent for future classification decisions. The sector relies on a transparent and consultative process to ensure that regulatory changes are well-informed and balanced. The MCC's decision deviates from this principle and risks undermining confidence in the regulatory process.

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

We urge the MCC to reconsider its decision that the RSV vaccine should remain as a prescription only medicine as reasonably, scientifically and eloquently requested in the original submission for reclassification. Reclassifying the RSV vaccine to allow pharmacist vaccinators to apply their clinical knowledge and administration of vaccines within pharmacy settings will enhance public health outcomes, improve access and equity, and align with the current healthcare direction both in New Zealand and globally. The decision should be based on sound scientific evidence and patient-centric principles, rather than maintaining outdated and, what could be perceived as, protectionist practices.

We would like to present the following counterarguments to the concerns and reasons cited by the MCC in the minutes of the meeting as the basis for the decision not to reclassify the RSV vaccine:

Novelty of the RSV vaccine: The argument that the RSV vaccine's novelty justifies its prescription only status is inconsistent with precedent. The Covid-19 vaccine was also novel, yet pharmacist vaccinators were deemed clinically capable to assess whether the vaccine should be administered to a health consumer and to administer it effectively and safely. This demonstrates that pharmacist vaccinators are fully competent to handle new vaccines, and the same rationale should apply to the RSV vaccine. In addition, the RSV vaccine was evaluated by Medsafe, who confirmed its safety and effectiveness for use without any further monitoring requirements in April 2024.

Recording the vaccine uptake in the Aotearoa Immunisation Register (AIR): Pharmacist vaccinators have been enabled to record vaccinations in the AIR for some time and are currently recording both funded and non-funded vaccines so that a health consumer's vaccination history is available for healthcare professionals to view. There is no reason to doubt that pharmacist vaccinators will ensure RSV vaccine uptake is recorded accurately in the AIR and that pharmacist vaccinators will consult the patient's vaccination history in the AIR prior to the administration of any vaccine, including the RSV vaccine, to ensure that the patient is not administered multiple doses.

Accessibility and uptake: The MCC acknowledged the potential benefits of greater accessibility to the RSV vaccine, especially in rest homes and rural areas. However, maintaining its prescription only status undermines this potential. General practitioners do not typically visit rest homes, pharmacists and nurses do. Allowing pharmacist vaccinators to administer the RSV vaccine to vulnerable people who will benefit from its protection will enhance accessibility and assist in reducing health inequities, 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 rates and outcomes and ensure more widespread uptake, as well as assist in reducing the burden on busy general practice which is experiencing heavy workforce shortages.

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Regional vs. national RSV outbreaks: The argument that the regional nature of RSV outbreaks diminishes the vaccine's public health importance does not hold up when considering the broader epidemiological and statistical context. A vaccine can still be crucial for public health by reducing the overall burden of disease, regardless of regional variations in outbreaks. This reasoning fails to recognise the value of preventing outbreaks regardless of their geographic scope.

Generating efficacy and performance data: Restricting the RSV vaccine's availability hampers the ability to gather comprehensive efficacy data. Wider use and availability are necessary to collect real-world evidence on the vaccine's performance. Limiting access based on this argument is counterproductive to understanding the RSV vaccine's full benefits and potential.

Evolving safety profile: The safety profile of all vaccines evolves over time. Some vaccines have been in use for decades, and we continue to learn about their long-term effects and benefits. Waiting for an extensively matured safety profile before reclassification is impractical and delays potential public health benefits. Pharmacist vaccinators are well-equipped to handle the safety monitoring and adverse event reporting required for new vaccines.

Affordability and funding: The MCC's focus should be on safety and accessibility rather than affordability. Separating the responsibilities of safety and efficacy from affordability ensures that medicines are classified purely on scientific and medical grounds and helps maintain a clear focus on patient safety and access, without the complications that financial considerations might introduce. Affordability concerns should be addressed by other relevant bodies, ensuring that access to medicines is not unduly restricted based on cost considerations. This separation allows for a more balanced and effective approach to public health and safety.

In addition to the concerns that influenced the MCC's decision, we would like to present the following points as reasons to reconsider the decision:

Consultation with public health agencies: We seek clarification on the evidence or concerns that were presented to the committee leading to this decision and whether any public health agencies were consulted. We would recommend consulting with the Public Health Team or Immunisation Team at Health New Zealand or the Public Health Agency in the Ministry of Health to ensure a consistent agreement on the delivery of RSV vaccinations in New Zealand.

Global precedents: The RSV vaccine, Arexvy, is authorised for administration primarily through pharmacies in the United States and the United Kingdom. In Canada, most provinces permit pharmacists to administer the Arexvy vaccine. In Australia, the Arexvy vaccine is undergoing evaluation for potential inclusion in the National Immunisation Programme (NIP), which would authorise pharmacist vaccinators to administer it. Guidance from the UK Health Security Agency for RSV vaccination among older adults emphasises the involvement of pharmacists to mitigate the impact of RSV disease in terms of both frequency and severity.

Training and competence of pharmacist vaccinators:
Pharmacist vaccinators have undergone the same extensive training, both clinically and in the administration, as required of other vaccinators in New Zealand and are expected to maintain their competency as detailed in the Immunisation Handbook. With their specialised training, pharmacist vaccinators are competent to conduct thorough assessments, provide education, and address concerns before and after vaccination to support patients and caregivers in making informed choices, as well as monitoring for adverse effects and providing appropriate support management for all vaccines. In addition, pharmacies that deliver vaccination services are required to meet the same standards than other providers in terms of emergency equipment, vaccine storage and documentation.

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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