PHARMACY GUILD OF NEW ZEALAND

11 February 2025

PHARMAC
PO Box 10254
The Terrace
Wellington 6143

Sent via email to: *consult@pharmac.govt.nz*

Dear Sir/Madam,

Re: Medsafe and Pharmac proposal to change the regulatory and funding restrictions for stimulant treatments for attention deficit hyperactivity disorder (ADHD)

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.

Our submission 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.

We support Medsafe and Pharmac's proposal to expand the regulatory and funding restrictions currently in place to enable a broader range of prescribers to initiate and manage stimulant treatments for people living with attention deficit hyperactivity disorder (ADHD). This proposal has the potential to significantly enhance access to these essential medicines, ensuring more timely and continuous care of patients. By reducing administration burdens, this change will also benefit both prescribers and pharmacists, streamlining workflows and minimising delays in treatment, alleviating unnecessary distress for patients and their whānau, while positively enhancing patient wellbeing, supporting continuity of care, and improving the quality of life for those living with ADHD.

However, we would like to highlight several key considerations to ensure the successful implementation of this proposal. It is essential to safeguard patient care while also supporting the long-term sustainability of community pharmacy operations, and proactive measures will be required to help mitigate potential challenges, ensuring that the proposal delivers its intended benefits effectively without unintended consequences for patients, prescribers, or pharmacists.

Increased dispensing volumes and ongoing difficulties in stock availability

- The proposal is expected to result in a substantial increase in dispensing volumes, however, this anticipated growth may not offset the additional operational costs incurred from increased administrative tasks, staff training, and the complexities of inventory management, particularly if pharmacists are required to intervene frequently due to prescription errors from inexperienced prescribers of ADHD medicines.
- ADHD medicines often require careful titration and ongoing adjustments to ensure safe and effective treatment. As prescribing expands, pharmacists may face increased demands for medicine counselling, monitoring adherence, and managing potential side effects, adding to their workload without corresponding remuneration, leading to workflow disruptions and reduced capacity for other essential pharmacy services.

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- Community pharmacies will face the challenge of managing larger volumes of ADHD stimulant medicines, further exacerbated by ongoing difficulties in the sourcing of these important medicines, which are not exclusive to New Zealand but are prevalent globally and are expected to persist. These challenges, including fluctuations in supply, increased order processing, and ensuring accurate stock levels, may cause significant disruptions in workflow, extend dispensing times, and affect overall efficiency, potentially impacting patient care.

Special Authority requirements

- Despite improvements in the renewal process for stimulant treatments following the removal of renewal criteria in November 2024, pharmacists continue to face significant administrative challenges due to the requirement for different Special Authority numbers for various presentations of ADHD medicines. This is particularly problematic for the two funded extended-release methylphenidate brands—Teva and Concerta—which, despite being similar in formulation, require separate Special Authority applications with differing criteria. Ongoing supply shortages, now extending beyond these two brands to other methylphenidate formulations, have further exacerbated this issue.
- Pharmacists are frequently required to contact prescribers to resolve discrepancies, obtain the correct Special Authority or request the prescriber apply for the alternative formulation or new ADHD stimulant, diverting valuable time and resources away from direct patient care. These administrative hurdles not only increase the workload for pharmacy staff but also contribute to unnecessary delays in treatment, impacting patients who rely on timely and consistent access to medicines to manage their chronic condition effectively, disrupting a patient's ability to function optimally in their daily lives and creating frustration and diminishing trust in the healthcare system.

Potential financial risks

- Persistent stock shortages of the current ADHD treatments present a significant challenge for community pharmacies, potentially leading to increased costs when sourcing second-line or alternative products. These additional expenses can erode profitability, placing further financial strain on pharmacies already operating within tight margins. These sourcing difficulties not only increase costs but also risk undermining the equity and access benefits the proposal aims to achieve, as patients may experience inconsistent access to essential ADHD medicines.
- Community pharmacies often have limited flexibility when it comes to sourcing high-cost medicines from alternative wholesalers. The current funding model relies heavily on Terms of Trade agreements, which dictate purchasing terms, rebates, and discounts. These agreements are critical, not only for generating profit but, in some cases, for simply allowing pharmacies to break even on dispensing these medicines. Without sufficient margin from these agreements, community pharmacies may struggle to stock these medicines, potentially leading to gaps in patient access and disruptions in continuity of care.

Security considerations

- Stimulants are commonly associated with misuse and diversion, increasing the risk of aggressive behaviour, theft, or break-ins at community pharmacies. With the increased access to ADHD medicines, pharmacies may need to implement enhanced physical security measures to mitigate these risks, such as panic buttons and increased security cameras. Staff training on de-escalation techniques, identifying and handling suspicious or aggressive behaviour, along with clear protocols for reporting attempted theft or fraudulent prescriptions, will also be essential, along with collaboration with law enforcement and regulatory agencies to further strengthen security measures, ensuring pharmacies remain

vigilant against potential threats while maintaining patient access to these necessary medicines.

- With the potential increase in prescriptions for ADHD medicines, community pharmacies may need to invest in larger controlled drug safes that comply with strict regulatory requirements, which will come with a financial cost. These safes will be essential for securely storing stimulant medicines, both before dispensing and while awaiting patient collection, ensuring restricted access to the public and reducing the risk of diversion. In addition to these storage regulations, all controlled drugs, including ADHD stimulants, must be meticulously recorded in a controlled drug register. Currently, this remains a manual process, as Medsafe has not yet approved any electronic controlled drug registers. This requirement adds significant time to the dispensing process, increasing workload for pharmacy staff and potentially leading to longer wait times for patients, which can further frustrate patients and disrupt pharmacy workflow.

Patient safety considerations

- Pharmacists will play a crucial role in ensuring the safe and appropriate use of ADHD stimulant medicines, particularly as the prescribing authority expands to include less experienced prescribers. This increases the need for vigilant monitoring of potential inappropriate or off-label use, as well as the detection of concerning patient behaviours such as “prescription shopping” or “prescriber hopping,” where individuals attempt to obtain multiple prescriptions from different providers and early refill requests.
- As more healthcare professionals gain prescribing authority for ADHD medicines, ensuring they have the necessary knowledge and safeguards in place is critical to maintaining patient safety and preventing misuse, as well as the risk of overprescribing, misdiagnosis, or inappropriate use. Comprehensive training should be made mandatory before a clinician can prescribe stimulants to treat ADHD, covering ADHD medicine guidelines, risk management strategies, and the potential for misuse, dependency, and diversion, and emphasise appropriate diagnostic criteria, titration schedules, ongoing patient monitoring, and deprescribing considerations where necessary.
- While expanding prescribing authority for ADHD medicines can enhance access and convenience, it also carries the risk of reducing specialist involvement, particularly for patients with complex or coexisting conditions. ADHD often presents alongside comorbidities such as anxiety, depression, autism spectrum disorder, or substance use disorders, which require a comprehensive, multidisciplinary approach rather than just medicine management. If more prescriptions are issued by non-specialists without referrals to ADHD specialists, some patients may miss out on detailed diagnostic assessments, tailored treatment plans, or access to essential non-pharmacological interventions such as cognitive behavioural therapy (CBT), coaching, or behavioural support strategies.
- ADHD treatment requires ongoing monitoring and potential medicine adjustments to ensure optimal outcomes and minimise side effects. Specialists, such as psychiatrists and paediatricians, often have greater experience in managing complex cases, particularly in fine-tuning ADHD stimulant dosages, identifying treatment-resistant ADHD, or recognising when alternative medicines or therapies are needed. A reduction in specialist oversight may result in delayed intervention for these patients, leading to suboptimal treatment outcomes or increased risk of medicine misuse or dependency.
- Easier access to ADHD medicines, while beneficial for those with legitimate needs, could also lead to an increase in non-medical use, particularly among students and young adults seeking stimulants for cognitive enhancement or improved academic performance or those with drug addictions. This growing demand may fuel illicit drug market activity, with individuals attempting to sell or trade prescribed stimulants to those who do not have a valid prescription.

As a result, there is a significant risk of stimulant misuse in the broader community, which could have detrimental consequences for public health.

Recommendations to consider

- Ongoing procurement and dispensing challenges for ADHD medicines will place significant strain on an already overburdened pharmacist workforce. As the demand for ADHD medicines increases, community pharmacies may struggle with the ongoing supply chain disruptions and delays in product availability, leading to inventory shortages and the potential for treatment interruptions. To ensure consistent access, it is crucial that financial support is provided to pharmacies, particularly those facing operational challenges due to supply chain disruptions and time-consuming interventions from prescription errors from inexperienced prescribers, to help community pharmacies maintain their ability to meet patient needs without compromising the quality of care and ensure access to essential ADHD treatments remain equitable.
- We strongly recommend that Pharmac streamline the Special Authority application process by standardising the approval criteria across all methylphenidate formulations, enabling pharmacists to dispense the available brand without requiring additional interventions from prescribers. Such a change would improve efficiency, minimise unnecessary treatment delays, and significantly ease the administrative burden on both community pharmacies and prescribers. By simplifying these procedures, pharmacists would have more time to focus on direct patient care, rather than being overwhelmed by unnecessary paperwork and frequent prescription adjustments.
- To address ongoing challenges with the Special Authority process, we recommend implementing integrated digital solutions that automate and streamline the application and validation of Special Authority approvals. This could include a digital platform for tracking and verifying Special Authority applications that is accessible to pharmacists to quickly access and submit correct details, minimising communication with prescribers. Additionally, real-time validation within prescriber practice management systems could proactively identify and flag errors before prescriptions are sent to pharmacies. These solutions would improve prescription accuracy, reduce administrative burdens, and enhance workflow efficiency, ensuring patients receive timely access to their ADHD medicines without unnecessary delays or errors.
- Implementing a real-time inventory management system, subsidised by Pharmac, would provide community pharmacies with accurate, up-to-date stock information, allowing them to identify potential shortages early and take proactive measures for stock redistribution of ADHD medicines. Encouraging regional collaboration among pharmacies to share stock in short supply would improve access to these essential medicines while minimising financial risks and alleviating supply pressures. A structured framework, with clear guidelines on logistics, reimbursement, and regulatory requirements, would ensure smooth stock transfers while maintaining patient safety and ensuring regulatory compliance.
- We encourage Pharmac to support our efforts to establish minimum standards for prescriber practice management systems, ensuring they are kept up to date to improve overall efficiency across the supply chain. Clear and consistent guidelines, along with regular updates for prescribers, especially those new to prescribing ADHD medicines, are crucial for reducing claim rejections and administrative inefficiencies. This can be achieved by providing funding for prescriber practice management system updates, interactive training modules, quick reference tools, and direct support channels for Special Authority requirements, resulting in minimising disruptions to both prescriber and pharmacy operations and ensuring patients have timely access to their required treatment and receive high-quality care.

- To support pharmacists in their essential role of pharmacovigilance, it is crucial to provide funding and access to real-time prescription monitoring systems for all community pharmacies, such as the Conporto platform. These tools will allow pharmacists to verify a patient's dispensing history across multiple providers nationwide, helping to detect patterns of misuse, prevent overprescribing, and improve patient safety. Integrating such systems into pharmacy workflows, along with establishing clear protocols for addressing concerns with prescribers, will bolster safeguards against medicine diversion while ensuring that patients with legitimate needs continue to receive appropriate care.
- With the increased demand for medicine counselling, monitoring adherence, managing side effects, and handling stock shortages of ADHD medicines, it is crucial to address the increasing workload pressures on pharmacists. To prevent professional burnout and ensure high-quality patient care, remuneration for these additional responsibilities should be reviewed and adjusted accordingly. Pharmacists should be fairly compensated for their expertise in managing complex cases, including facilitating smooth transitions between different formulations or brands, and educating patients on alternative options or the possibility of adjusting their treatment regimen. A revised pay structure that reflects their expanded role in the treatment of ADHD will help ensure continuity of care, minimise treatment disruptions, and support pharmacists in delivering safe and effective patient outcomes.
- To support responsible prescribing of ADHD medicines, it is crucial to establish best practice prescribing guidelines for the treatment of ADHD based on clinical evidence and aligned with national and international standards. Oversight from experienced clinicians, such as psychiatrists, paediatricians, and other specialist ADHD providers, will help ensure accuracy and consistency in prescribing, reducing the risk of dispensing errors and inappropriate use, enhancing the efficiency of both prescribers and pharmacists. Implementing peer reviews, prescribing audits, and mentorship programs would provide guidance and accountability, particularly for new prescribers, fostering confidence in prescribing decisions while supporting patient safety and optimal treatment outcomes.
- Establishing clear referral pathways is essential to ensure that patients with complex ADHD cases receive appropriate specialist care with needed. A collaborative care model, where prescribers work closely with ADHD specialists, psychologists, and pharmacists, can help maintain a balanced approach, allowing straightforward cases to be managed effectively in primary care, while ensuring that complex cases receive timely specialist intervention. Enhancing prescriber education on when to escalate care for specialist assessment, along with integrating multidisciplinary decision-making, will help safeguard patient outcomes while preserving broader access to ADHD treatment.
- To address the frequent need for pharmacists to contact prescribers regarding prescribing discrepancies, incorrect Special Authority applications, and early detection of concerning prescribing patterns, there should be an emphasis on strengthening communication channels between pharmacists and prescribers. Clearer guidance should be provided to prescribers on the correct application process for different ADHD medicine formulations, ensuring that both prescribers and pharmacists are aligned on the expectations and requirements. Additionally, the development of direct and efficient communication channels and coordinated care pathways will enable quicker resolution of issues, improve medicine adherence, and facilitate timely interventions when potential risks arise, minimising extensive back-and-forth communication to ensure that ADHD medicines are used safely and appropriately, while maintaining uninterrupted patient access to essential treatment.
- Strengthening collaboration between community pharmacies, law enforcement, and regulatory agencies is essential in addressing security risks related to ADHD stimulant medicines. Regular communication and information-sharing can enhance incident response

times and ensure pharmacies follow best practices to prevent diversion and misuse. A balanced approach is necessary to maintain patient access to essential ADHD treatments while implementing strong safeguards against misuse. This can be achieved through robust prescription monitoring systems and data collection, including tracking prescription trends, patient outcomes and potential misuse, clear and consistent prescribing and dispensing regulations, and educational initiatives to raise awareness of stimulant misuse risks, ensuring individuals with ADHD receive the treatment they need while minimising public health risks associated with stimulant abuse.

Community pharmacies play a vital role in ensuring equitable access to ADHD medicines while upholding the highest standards of patient care, safety, and medicine stewardship. As the landscape of ADHD treatment evolves, pharmacies remain committed to supporting patients, optimising treatment outcomes, and safeguarding against misuse or diversion. However, the proposed changes bring significant operational, financial, and security challenges that must be carefully addressed to ensure long-term sustainability.

If you have any questions about our response, 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
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