PHARMACY GUILD OF NEW ZEALAND

09 May 2025

PHARMAC
PO Box 10254
The Terrace
Wellington 6143

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

Dear Sir/Madam,

Re: Proposal to support access to budesonide with eformoterol inhalers

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

This submission focuses on Guild members' concerns around general economic, funding, access and supply issues. Guild submissions should not be taken as any endorsement of, or any attempt to comment on, issues on medicine safety, efficacy, or appropriateness for individual patients.

We appreciate the opportunity to provide feedback on Pharmac's proposal to:

1. Allow up to three months' (stat) dispensing of selected budesonide with eformoterol inhalers at one time, and
2. List certain budesonide with eformoterol inhalers for supply under a Practitioner's Supply Order (PSO).

The Guild would like to respectfully oppose the proposal to allow up to three months dispensing of selected budesonide with eformoterol inhalers at one time and conditionally support the listing of one (1) budesonide with eformoterol inhaler for supply under a Practitioner's Supply Order (PSO).

While we support efforts to enhance asthma management and improve access to medicines, the shift to stat dispensing of selected budesonide with eformoterol inhalers under standard prescriptions raise serious concerns. Our opposition stems from the absence of a demonstrated need to alter the current supply system, particularly when New Zealand has already achieved significant uptake of 'anti-inflammatory reliever (AIR)' therapy with budesonide with eformoterol inhalers and substantial improvements in asthma outcomes through the existing community pharmacy-based supply model.

Key concerns of allowing up to three months' (stat) dispensing of selected budesonide with eformeterol inhalers

1. **Loss of monthly professional touchpoints**
   Each dispensing event at a community pharmacy represents a critical clinical touchpoint. These are not mere transactions - they are professional encounters where pharmacists undertake clinical reviews, provide patient counselling, perform safety checks, and assess inhaler technique. For inhaled therapies, these monthly professional touchpoints are vital as they offer scheduled opportunities to monitor inhaler technique, assess asthma control, track symptom trends, reinforce asthma management plans, and evaluate adherence, all of which directly impact therapeutic efficacy, asthma control, and ultimately, patient outcomes. These regular touchpoints help to prevent deterioration in asthma control, which could lead to secondary or emergency care, thereby contributing to greater system efficiency.

   Unlike fixed-dose preventers, the AIR approach requires flexible use, making frequent monitoring essential. Without regular dispensing touchpoints, opportunities to reinforce correct inhaler technique, a well-documented contributor to treatment failure, are lost. Many

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patients remain unaware of their errors, and poor technique can substantially reduce drug delivery to the lungs, undermining therapeutic benefit and worsening asthma control. Moreover, monthly pharmacist interactions allow for timely reinforcement of asthma action plans, review of symptom trends, and education tailored to the patient's recent experience. For example, increased reliever use may indicate deteriorating control, the need to escalate therapy, or address environmental triggers. Delaying such assessments by three months risks avoidable deterioration and undermines proactive asthma management.

Current asthma management guidelines highlight the importance of regular checks on inhaler technique and symptom control, emphasising that these actions improve long-term outcomes. By extending the dispensing interval to three months, however, up to two-thirds of these vital pharmacist-led touchpoints are eliminated, which reduces proactive support, creates missed opportunities for timely intervention, and undermines a model that is already proving successful in improving asthma care outcomes. Furthermore, less frequent dispensing not only eliminates these built-in touchpoints for intervention but also risks increasing inequities. Patients who are less health literate, managing multiple medicines, or living with co-morbidities are more likely to benefit from, and rely on, regular pharmacist-led support and delaying these opportunities for care could widen outcome disparities, particularly in high-needs communities where asthma burden is already disproportionately high.

2. **Reduction in monitoring of adherence**

Monthly dispensing serves as a practical and effective tool for monitoring adherence and supporting patient safety, particularly for asthma inhalers like budesonide with eformoterol, which serves a dual role as both maintenance and reliever therapy under the AIR approach. When patients return for their repeats, each dispensing event provides pharmacists with a structured opportunity to identify early warning signs of overuse, such as returning too early, or underuse, where delayed collection may indicate poor adherence or confusion about the treatment regimen. These patterns are not merely administrative observations - they are clinically significant indicators that inform proactive interventions and timely detection of these trends enable pharmacists to address issues before they lead to deterioration of asthma control, exacerbations, emergency department visits, or hospitalisation.

In contrast, shifting to three-month dispensing intervals significantly reduces visibility in patient behaviour and removes key opportunities for clinical engagement. By introducing a 90-day gap between pharmacist encounters, the system risks allowing critical warning signs, such as over-reliance on reliever therapy, incorrect dosing patterns, or declining technique, to go unnoticed. This is particularly problematic for budesonide with eformoterol inhalers, where usage can vary widely based on symptom severity and patient interpretation of the AIR model, in comparison to fixed-dose maintenance inhalers with predictable refill patterns, where the variable-use nature of AIR therapy demands more frequent monitoring to ensure safe and effective use.

Multiple studies have shown that monthly dispensing improves medicine adherence and patient outcomes. A 2013 study in the *Journal of Clinical Pharmacy and Therapeutics* found that regular pharmacist interactions, particularly through frequent dispensing and counselling, significantly enhanced adherence and asthma control in patients with chronic conditions. Similarly, a 2018 systematic review and meta-analysis in the *European Respiratory Journal* concluded that pharmacist-led interventions, including frequent dispensing, effectively improve adherence in asthma patients.

The benefits of monthly dispensing on adherence are evident in the Long Term Conditions (LTC) service, which supports patients with chronic conditions like asthma by improving adherence, optimising medicine use, and enhancing health outcomes. Research at its inception showed that monthly dispensing was far more effective than longer intervals in promoting patient safety, reducing preventable harm, supporting self-management, and reinforcing health literacy. The LTC service has become one of New Zealand's most successful pharmacist-led models for chronic disease management, and by reducing pharmacist contact through longer dispensing intervals risks undermining this proven approach and the ongoing asthma education and

clinical oversight that pharmacists provide, which has significantly improved asthma outcomes nationwide.

3. **Increased risk of waste**
   Asthma is a dynamic condition that frequently requires adjustments to treatment, particularly in the early stages of initiating a new regimen. Changes to inhaler dose, frequency, or even the type of inhaler are common within the first few weeks as clinicians and patients work to stabilise control and tailor therapy. Dispensing a three-month supply of budesonide with eformoterol inhalers at once limits the ability to respond quickly to these changes and increases the likelihood of patients being left with surplus inhalers that are no longer appropriate, which not only presents safety risks, such as patients continuing outdated treatment or self-adjusting doses without clinical input, but also contributes to medicine waste.

   A *New Zealand study* on returned medicines, including inhalers, found that treatment changes and over-supply were key reasons for unused medicines being returned to pharmacies. The research highlighted that frequent dispensing reduces the risk of medicine accumulation, which is more common with longer dispensing intervals like three-month supplies, and concluded that more frequent dispensing better aligns supply with evolving treatment needs. Additionally, a 2023 *He Ako Hiringa report* referenced a 2009 survey of 452 New Zealanders, revealing that over 60% had leftover or unwanted prescription medicines at home, with fewer than one in four returning them to pharmacies. Given the growing emphasis on sustainable healthcare, we encourage Pharmac to consider the environmental implications of excess inhaler supply, especially as the health sector works to reduce its carbon footprint in alignment with broader climate goals and the principles of environmental stewardship in the healthcare system.

Key concerns and rationale of listing certain budesonide with eformoterol inhalers for supply under a Practitioner's Supply Order (PSO)
The Guild conditionally supports this proposal, provided that the quantity restriction of one (1) inhaler per PSO is maintained, for the following reasons:

1. **Loss of professional touchpoints and potential impact on patient outcomes**
   Pharmacists play a critical role in healthcare as they are often the only health professionals with a comprehensive, or at least expanded, view of a patient's complete medicine profile. General practitioners and other prescribers may not have visibility of all the medicines a patient is using, which should not be considered in isolation. Without pharmacist oversight, important drug interactions, whether with prescribed, over the counter, herbal, or supplementary medicines, may be missed, which is particularly concerning in the management of chronic conditions like asthma, where inhaled corticosteroid/long-acting beta-agonist combinations must be used safely in the context of a patient's overall medicine history.

   Permitting a larger quantity than the proposed single inhaler per PSO under the proposed shift to clinic-based PSO supply would disrupt a well-established and evidence-backed model and risk excluding pharmacists from a crucial stage in the patient's asthma care journey, undermining both patient education and safety. While the proposal states "*This is so people initiating AIR therapy or requiring emergency treatment and needing to learn how to use budesonide with eformoterol inhalers can do so during their healthcare appointments*", this rationale does not justify bypassing the pharmacist, unless the initiation of treatment is considered medically urgent and immediate access to a community pharmacy unavailable.

2. **Reduced patient safety and traceability**
   Supplying budesonide with eformoterol inhalers via the PSO mechanism, without linking supply to an individual through a centralised patient record, poses risks to patient safety and care continuity. These inhalers are used as both maintenance and reliever therapy under the AIR model, which requires clear tracking of patient use, especially during treatment initiation or following an acute episode. When supplied under a PSO, the inhaler is not recorded in digital medical systems such as Conporto, TestSafe, or HealthOne, meaning the dispensing event may

not be visible to other members of a patient's care team, obscuring who received the medicine, when it was supplied, and by whom, weakening clinical oversight and pharmacovigilance efforts.

The current electronic ecosystem supporting the NZePS does not allow for electronic recording of PSO-based supply into a patient's Electronic Medical Record. This limitation poses a significant risk of gaps and inaccuracies in treatment history, particularly as the digital health systems evolve. The concern becomes even more critical with the introduction of the proposed My Health Record, where patients will have direct access to their health information as incomplete or inconsistent records could lead to confusion, undermine trust in the system, and potentially impact clinical decision-making.

Accurate, timely, patient-specific documentation is particularly important for budesonide with eformoterol inhalers due to their dual role in both maintenance and reliever therapy and the need for clinicians to monitor frequency of use, evaluate treatment response, and ensure alignment with asthma management plans. The Health Quality & Safety Commission's 2020 *Contraceptive Use Methodology Report* explicitly warns of the equity and visibility issues introduced by PSO supply models. The report found that "*High PSO use obscures patient-level data… [and] under-reports uptake because medicines are not linked to an individual's NHI*." Although the focus was on contraceptives, the same risks apply to inhalers. Supplying these medicines outside of integrated health records increases the chance of missed interactions, duplicated therapy, and poor traceability, particularly for mobile or high-needs populations. In cases of adverse effects, treatment failure, or recalls, the absence of traceable dispensing records undermines effective follow-up.

3. **No perceived clinical justification for bypassing community pharmacy**
   Budesonide with eformoterol inhalers are self-administered and do not require specialist intervention or procedural administration. Unlike injectable medicines, where the act of administration justifies in-clinic supply, these inhalers are designed for independent use, with education and support available outside the clinic setting. The suggestion that PSO access is needed to allow for training during a health care appointment bypasses a critical existing resource - community pharmacists.

   Since the introduction of updated asthma guidelines in 2020 recommending AIR therapy, national uptake of budesonide with eformoterol inhalers has more than doubled across the motu, entirely within the existing community pharmacy dispensing framework. This demonstrates that current access pathways are functional, and the current community pharmacy-based model is effectively addressing these challenges, suggesting that better treatment uptake and inhaler technique support, facilitated by pharmacists, are contributing to improved outcomes.

For a condition as variable and potentially life-threatening as asthma, regular engagement with trained health professionals is not a luxury - it is a necessity. Any changes that reduce these opportunities must be carefully scrutinised for its impact on patient outcomes and risks reversing recent gains in asthma outcomes at a population level. Furthermore, the risk of over-supplying inhalers via PSO without proper patient traceability raises safety concerns and may disrupt the patient care continuum.

If you have any questions about our feedback or would like further information and/or references to support our concerns, please do not hesitate to contact us.

Kind regards,

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