Reclassification of a Medicine for consideration by the Medicine Classification Committee

Application for the reclassification of pseudoephedrine from Restricted Medicine to Pharmacy Only Medicine

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Submitted by:

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Executive summary

This application seeks the reclassification of pseudoephedrine in solid-dose cough or decongestant medicines containing not more than 60 mg per recommended dose and not more than 240 mg per recommended daily dose, in a pack size of 240 mg or less, for use by adults and children over 12 years of age, from a Restricted Medicine to a Pharmacy Only Medicine. Larger pack sizes containing more than 240 mg of pseudoephedrine and liquid formulations, are to remain as a Restricted Medicine and are not the subject of this application.

This application is consistent with New Zealand government initiatives to improve access to effective oral decongestants to manage the symptoms of the common cold.(1, 2) Recent regulatory actions by the United States of America (USA) FDA regarding oral phenylephrine and its pending removal from the Generally Recognized as Safe and Effective (GRASE) list due to lack of efficacy(3, 4), together with anticipated action by other comparable regulators, including Medsafe and the current class actions in New Zealand in relation to oral phenylephrine containing cold and flu medications(5), indicate that oral phenylephrine-containing cold and flu medicines may no longer be available in New Zealand in the near future. There are currently no effective oral medications that can take its place and improving access to pseudoephedrine will ensure New Zealanders have access to effective cold and flu medications for the 2027 cold and flu season.

Providing Pharmacy Only access in the absence of pharmacist intervention to a pack size that represents a single day's use has considerable public health benefits with negligible risk of reigniting the diversion of pharmacy purchased pseudoephedrine products for the production of illicit methamphetamine by clandestine laboratories in New Zealand.

This reclassification application is not predicated on the potential withdrawal of phenylephrine. There are multiple additional health benefits of having improved access to a small pack (one day's supply) of pseudoephedrine-based cold and flu preparations as a Pharmacy Only medicine including:

- Providing New Zealanders with easier access to medications that contain a more effective oral decongestant than phenylephrine with an equivalent safety profile.(6) Noting that the current Restricted Medicines classification represents a barrier to access amongst people who have a higher difficulty accessing a pharmacist, such as those in rural areas.(1)
- Given the pending decision by the FDA to remove oral phenylephrine from the GRASE list due to lack of efficacy,(3, 4) the impending decisions of other regulators including Medsafe and the class actions in New Zealand,(5) improving access to pseudoephedrine will ensure New Zealanders have effective and safe(6) over the counter cold and flu decongestant medications available for the 2027 cold and flu season.
- Providing consumers with lower cost access to pseudoephedrine-based cold medications, helping to relieve the current cost of living pressures.
- Reducing the workload for pharmacists, whose resources are already stretched.(1)

The proposed reclassification has negligible risk of influencing the illicit abuse of methamphetamine in New Zealand. This is established by the observations that:

- The long-term supply and use of methamphetamine in New Zealand was not effectively controlled when pseudoephedrine was reclassified as a Prescription Medicine, as the illicit supply and production methods adjusted to changes in pseudoephedrine precursor supply.(1)

- The supply and manufacture of methamphetamine use in New Zealand has shifted from small scale production, where pharmacy sourced pseudoephedrine was the main precursor used, to:(1, 7)
    - Large scale clandestine manufacture where bulk quantity of precursors is sourced from overseas.
    - Large scale clandestine manufacture where methamphetamine is produced from pre-precursors, such phenyl-2-propanone (P2P).
    - Bulk importation of methamphetamine.
- The changes in the sources of methamphetamine have resulted in easier and cheaper access to methamphetamine in New Zealand during the period when pseudoephedrine products were Prescription Medicines(1, 8, 9) and these sources of illicit methamphetamine are unlikely to change back to small scale clandestine laboratory manufacturing, based on the proposed increased consumer access to one day's supply of pseudoephedrine medications as a Pharmacy Only product. This is supported by the observation that, since the reintroduction of pseudoephedrine-based medications in New Zealand in 2024, no evidence has been identified to indicate diversion of these medicines for the production of methamphetamine, nor any increase in pseudoephedrine-related pharmacy crime.(9, 10)
- The proposed quantity of pseudoephedrine to be supplied as a Pharmacy Medicine is limited to a one-day supply (240 mg). This represents approximately 30% of the quantity that is currently available as a Restricted Medicine in New Zealand, 8% of the quantity that is available as a Pharmacy Medicine in Canada, and 33.3% of the quantity that is available as a Pharmacy Medicine in the UK and as a Pharmacist Only Medicine in Australia.
- Limiting access to pseudoephedrine-based products to a Restricted Medicine does not effectively control the supply and use of methamphetamine, even in countries like Australia and USA which also implemented additional measures such as Project Stop to monitor pseudoephedrine purchases.(1, 7, 11, 12)

The evidence enclosed in this submission demonstrates that oral pseudoephedrine is an effective systemic nasal decongestant(6) and that, when supplied in primary packs limited to 240 mg or less, it is suitable for reclassification to a Pharmacy Only Medicine:

- The approved indications for pseudoephedrine-based products are identical to those for phenylephrine-based products that are currently available as Pharmacy Only and General Sales medicines. It is accepted that these ailments are easily recognised, are unlikely to be confused with more serious conditions, and are appropriate for self-selection by consumers within a pharmacy setting.(1, 2, 13)
- Pseudoephedrine-based products have a well-established safety profile. Previous reclassification decisions were not based on any safety issue associated with its therapeutic use, but rather as a measure to control the illicit production and abuse of methamphetamine (evidence suggest this has not been effective).(1, 13)
- Pseudoephedrine-based products when used as directed are safe.(6) The safety profile associated with the short-term use of pseudoephedrine-based products is essentially the same as phenylephrine,(14, 15) making it suitable for Pharmacy Only classification.
- Pseudoephedrine has an acceptable therapeutic index and risk of harm from overdose (intentional or accidental) is minimal.(14, 15)
- Safety in at-risk populations is appropriately addressed through existing product labelling, which will also be applied to the proposed smaller, one-day supply Pharmacy Only products.

The current Restricted Medicines classification imposes physical and financial barriers on the legitimate therapeutic use of pseudoephedrine-based products for relief of acute, self-limiting cold and flu symptoms, and does not reduce the individual or societal harm associated with methamphetamine use.(11, 12) The proposed reclassification is expected to have negligible impact on the supply or use of methamphetamine in New Zealand, but will provide a meaningful public health benefit by improving access to an effective oral decongestant for consumers who currently rely on phenylephrine-based cold and flu medicines, particularly when a decision is ultimately made to remove these products from the Medsafe database. In addition, the proposed reclassification will make safe and effective pseudoephedrine-containing cold and flu medicines more affordable and easier access for New Zealanders.

Part A

1. International Non-proprietary Name of the medicine.

Pseudoephedrine

2. Proprietary name(s).

[redacted]

3. Name and contact details of the company / organisation / individual requesting a reclassification.

[redacted]

Reckitt Benckiser (New Zealand) Pty Limited

Postal address: Level 47 / 680 George Street Sydney NSW 2000, Australia

[redacted]

[redacted]

4. Dose form(s) and strength(s) for which a change is sought.

Pseudoephedrine tablets or capsules containing not more than 60 mg per recommended dose and not more than 240 mg per recommended daily dose.

5. Pack size, storage conditions and other qualifications.

Pack size: Primary packs of pseudoephedrine containing 240 mg or less to be reclassified as Pharmacy Only Medicine.

Qualifications: in solid-dose cough or decongestant medicines containing not more than 60 mg per recommended dose and not more than 240 mg per recommended daily dose, in a pack size of 240 mg or less, for use by adults and children over 12 years of age.

Note: This application does not propose any change to the classification of pseudoephedrine in liquid-dose cough or decongestant medicines containing not more than 60 mg per recommended dose and not more than 240 mg per recommended daily dose, supplied in pack sizes of 800 mg or less.

6. Indications for which change is sought.

The approved indication for pseudoephedrine is for the relief of nasal congestion.

As this classification is also for pseudoephedrine when combined with other ingredients such as analgesics and antihistamines the specific indications will vary slightly dependent on the specific combination. Examples of this are summarised below:

- For the temporary relief of the symptoms of colds and flu with associated congestion, including aches and pains, headaches, fever, sore throat, runny nose, blocked nose and sinuses ([redacted]).
- Temporary symptomatic relief of sinus pain and congestion and nasal congestion of allergic (seasonal) rhinitis, vasomotor (perennial) rhinitis, and the common cold in adults and children over 12 years ([redacted]).
- For fast and effective relief from sinus pain and congestion day and night [redacted].
- For temporary relief from the symptoms (runny nose, nasal congestion headache, body aches and pains, and fever) of colds and flu without drowsiness ([redacted]).

7. Present classification of the medicine.

The current classification of pseudoephedrine is summarised in Table 1. The classification of oral pseudoephedrine containing not more than 60 mg per recommended dose and not more than 240 mg per recommended daily dose, in a pack size of 720 mg or less; tablets or capsules is a Restricted Medicine.

Table 1: Current classification of pseudoephedrine

Ingredient	Conditions (if any)	Classification
Pseudoephedrine		Class C3 Controlled Drug
Pseudoephedrine	**except** when specified elsewhere in this schedule	Prescription
Pseudoephedrine	in solid-dose cough or decongestant medicines containing not more than 60 milligrams per recommended dose and not more than 240 milligrams per recommended daily dose, in a pack size of 720 milligrams or less; in liquid-dose cough or decongestant medicines containing not more than 60 milligrams per recommended dose and not more than 240 milligrams per recommended daily dose, in a pack size of 800 milligrams or less	Restricted

8. Classification sought.

The classification sought is Pharmacy Only Medicine, for solid-dose cough or decongestant medicines containing not more than 60 mg per recommended dose and not more than 240 mg per recommended daily dose, in a pack size of 240 mg or less;

If accepted the proposed classification of pseudoephedrine is summarised in Table 2.

Table 2: Proposed classification of pseudoephedrine

Ingredient	Conditions (if any)	Classification
Pseudoephedrine		Class C3 Controlled Drug
Pseudoephedrine	**except** when specified elsewhere in this schedule	Prescription
Pseudoephedrine	in solid-dose cough or decongestant medicines containing not more than 60 milligrams per recommended dose and not more than 240 milligrams per recommended daily dose, in a pack size more than 240 mg to not more than 720 milligrams; in liquid-dose cough or decongestant medicines containing not more than 60 milligrams per recommended dose and not more than 240 milligrams per recommended daily dose, in a pack size of 800 milligrams or less	Restricted
Pseudoephedrine	in solid-dose cough or decongestant medicines containing not more than 60 milligrams per recommended dose and not more than 240 milligrams per recommended daily dose, in a pack size of 240 milligrams or less.	Pharmacy only

9. Classification status in other countries (especially Australia, UK, USA, Canada).

The classification status of pseudoephedrine in comparable markets is summarised in Table 3 below. In addition to the classification, some countries require proof of identity at point of purchase as well as electronic monitoring systems such as Project Stop in Australia.(2) Please note, the effectiveness, or more specifically the lack of effectiveness, of electronic monitoring systems in addressing the illicit use of methamphetamine in these countries(11, 12) is addressed in detail in Part A, Section 11 of this application.

Table 3: Classification of oral pseudoephedrine in comparable markets

Country	Status
Australia	Pharmacist Only (Schedule 3), with electronic monitoring system (Project Stop) and proof of identity
Canada	Pharmacy medicine (behind the counter for single-ingredient pseudoephedrine)
UK	Pharmacy medicine
USA	Pharmacy medicine (behind the counter).
Bulgaria	OTC (in combination formulations)
Czech Republic	OTC (in combination formulations)
Denmark	Prescription
Finland	Prescription
France	Prescription
Germany	OTC (in combination formulations)
Greece	OTC (in combination formulations)
Hungry	OTC (in combination formulations)
Italy	OTC (in combination formulations)
Lithuania	OTC (in combination formulations)
Netherlands	Prescription
Norway	Prescription
Portugal	OTC (in combination formulations)
Romania	OTC (in combination formulations)
Slovak Republic	OTC (in combination formulations)
Slovenia	OTC (in combination formulations)
Switzerland	Prescription
Austria	OTC (in combination formulations)
Belgium	Prescription
Croatia	OTC (in combination formulations)
Estonia	OTC
Ireland	OTC
Poland	OTC
Spain	OTC
Luxembourg	OTC
Malta	OTC
Cyprus	OTC (in combination formulations)
Latvia	OTC (in combination formulations)

OTC = Over the counter

In Australia, pseudoephedrine is Schedule 3 non-Appendix H (other than preparations for stimulant, appetite suppression or weight-control purposes) when supplied in a primary pack:

a) in liquid preparations containing 800 mg or less of pseudoephedrine hydrochloride (or its equivalent); or
b) in other preparations containing 720 mg or less of pseudoephedrine hydrochloride (or its equivalent).

In addition, the sale of pseudoephedrine in Australia requires proof of identity and is supported by an electronic monitoring system, known as Project Stop which was implemented nationally in 2007.(11)

Health Canada regulates pseudoephedrine as pharmacy medicines. Pseudoephedrine as a single ingredient (or non-combination product) is restricted to behind-the-counter sale by a pharmacist, that is not available for self-selection. Pseudoephedrine in combination with other ingredients for cough, cold or allergy relief are available for open self-selection pharmacy medicines. However, a pharmacist must be available at the request of a purchaser or consumer to discuss the products prior to purchase. Pharmacist availability is technology neutral, allowing self-selection purchase online as long as a pharmacist is accessible by

telephone, video, text or other means of communication. In addition, the total quantity that can be supplied as a pharmacy medicine is limited to 3000 mg of pseudoephedrine.(16)

In the USA, pseudoephedrine is available in pharmacies as a behind-the-counter medication. The amount of pseudoephedrine that an individual can purchase each month is limited, and individuals are required to present photo identification to purchase products containing pseudoephedrine. Stores are required to keep personal information about purchasers for at least two years. In addition, some States have state-wide electronic monitoring systems to track consumer purchases.(17)

In the United Kingdom, pseudoephedrine is available as a pharmacy medicine, with a maximum quantity of 720 mg. In addition, pharmacies are prohibited from selling both a pseudoephedrine containing product and a ephedrine product in a single transaction.(18)

10. Extent of usage in New Zealand and elsewhere (e.g., sales volumes) and dates of original consent to distribute.

Pseudoephedrine has been used as a nasal decongestant since the 1940s and was available in New Zealand as a Pharmacy Only Medicine up until 2004. In October 2004 pseudoephedrine was scheduled as a Class C Part III (partially exempted) controlled drug in cough/cold/flu or decongestant preparation where the package in which the preparation is sold or supplied contains not more than 1.8 grams of pseudoephedrine as a measure to reduce its diversion and use as a precursor for methamphetamine production.(13, 19)

In 2011, as part of a plan to reduce the harms associated with methamphetamine use, the Government made medicines containing pseudoephedrine prescription-only. Medical practitioners rarely prescribed pseudoephedrine products and due to low consumer demand, manufacturers allowed product approvals to lapse, so that there were no pseudoephedrine products approved or available in New Zealand at the start of 2024.(1)

In 2024, the New Zealand government acknowledged that restricting pseudoephedrine to a prescription medicine was not an effective strategy to address methamphetamine use in New Zealand and reinstated the current Restricted Medicines classification, with the first products being for sale in retail pharmacies from June 2024.(20)

Since the reintroduction of pseudoephedrine containing products in New Zealand, usage has been modest. Table 4 summarises the volume of pseudoephedrine-based products in Pharmacy for the 12 months up to 15 March 2026. Assuming that each sale was to a discrete single user, this indicates that approximately 5.4% of the New Zealand population used a pseudoephedrine-based products in a 12 month period.

Table 4: Sales volume of pseudoephedrine containing products in New Zealand for the 12 months up to 15 March 2026.

Pseudoephedrine formulation	Units	Doses
Pseudoephedrine in combination with ibuprofen	2,478	59,472
Pseudoephedrine in combination with paracetamol	144,935	3,478,440
Pseudoephedrine in combination with paracetamol and chlorphenamine	89,840	2,163,900
Pseudoephedrine (alone)	48,549	659,700
Total	**285,802**	**6,361,512**

11. Local data or special considerations relating to New Zealand (if applicable).

The primary determinant of the classification of pseudoephedrine in New Zealand and other countries has been to control access to pharmacy sourced pseudoephedrine as a precursor for the illegal production of methamphetamine.(1, 19)

Methamphetamine, known colloquially in New Zealand as “P”, is a powerful and addictive psychostimulant. Methamphetamine use emerged in New Zealand in the late-1990s, peaking at the population level in the mid-2000s before declining over subsequent years.(21) New Zealand has a comparatively high prevalence of methamphetamine use by international standards, with use being overrepresented in areas of socio-economic deprivation, among males, and among Māori.(22)

This section provides an overview of the effectiveness of measures to control access to therapeutic pseudoephedrine products in addressing the supply and use of methamphetamine.

Precursor control has been ineffective in reducing the supply and use of methamphetamine

Methamphetamine can be synthesised from a reduction of precursors ephedrine or pseudoephedrine, the active ingredients in commonly used cold medicines. Historically, the illegal methamphetamine product market was dependent on access to precursors via cold medications that could be purchased or stolen from retail pharmacies.(17) Disruption to the supply of pharmacy sourced precursors associated with restricting access through medicine classifications have been ineffective at addressing the supply and use of methamphetamine. This has been demonstrated in multiple countries including the USA,(12, 17, 23) Australia(11) and New Zealand.(1, 8, 9)

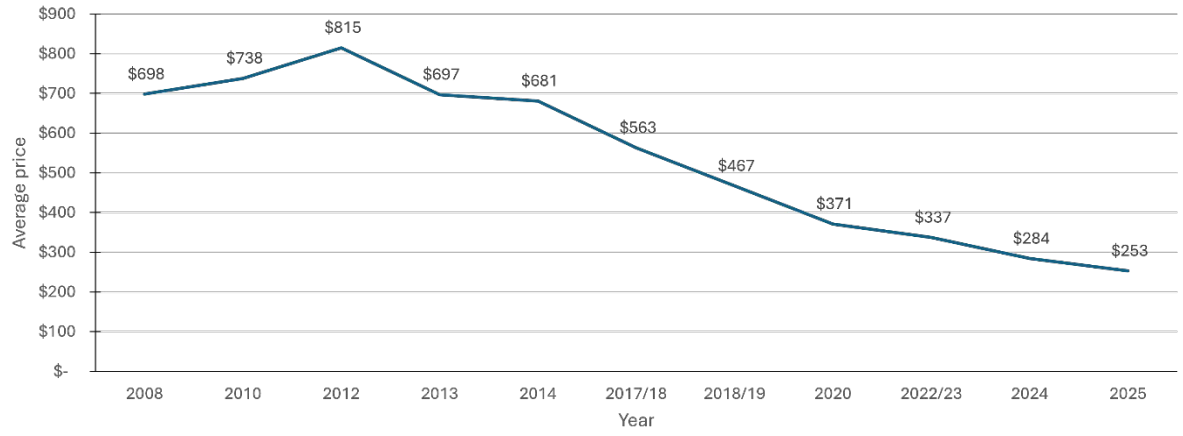
In response to the reclassification of therapeutic pseudoephedrine in cold and flu medications, and other measures such as applying sales limits and implementing sales monitoring systems, the organised crime groups that control methamphetamine production and supply quickly adapted to maintain continuity of methamphetamine supply. Adaptations include the bulk importation of precursors, such as pseudoephedrine, increased use of alternative precursors to pseudoephedrine to manufacture methamphetamine such as ephedrine and the pre-precursor phenyl-2-propanone (P2P), as well as the bulk importation of methamphetamine.(1, 7, 11, 12, 24, 25)

In addition, the scale of clandestine laboratories that manufacture methamphetamine have evolved. Since 2009, the scale of located clandestine laboratories has increased from mainly addiction-based processes (producing 1–100 grams of methamphetamine) to larger, more commercial-sized operations (producing 100–1000+ grams of methamphetamine). Before 2011, the precursor encountered was almost entirely pseudoephedrine sourced from pharmaceutical preparations sold in New Zealand and overseas preparations that were smuggled across the border. The reclassification of pseudoephedrine/ephedrine to Prescription Medicines led to overseas pharmaceutical preparations becoming the main source of pseudoephedrine, e.g., the Chinese pseudoephedrine-containing pharmaceutical preparation, ContacNT. In 2013 when restrictions were placed on the purchase of ContacNT in China, precursor importation shifted to high-purity ephedrine hydrochloride, peaking in 2016 (based on Customs seizures) and subsequently steadily declining as importation of finished methamphetamine increased. The authors of this evaluation proposed that “Increased importation of methamphetamine into New Zealand is likely to decrease the need for domestic

manufacture, and therefore, the amount of pseudoephedrine/ephedrine required to produce methamphetamine."(7)

Evidence that restricting the legitimate, therapeutic use of pseudoephedrine to consumers when it was classified as a Prescription Medicine and was effectively removed from the New Zealand market between the years of 2011 to 2024, was ineffective in addressing methamphetamine supply and use in New Zealand is reflected by the observation that the average price of methamphetamine per gram in 2025 is approximately a third of what it was in 2010, and has steadily declined year on year during this period,(8, 26) see Figure 1.

Figure 1: Average price of methamphetamine per gram



Adapted from (8, 26-28)

Additional surveillance of pharmacy purchases of pseudoephedrine is ineffective in reducing the supply and use of methamphetamine

New Zealand has not mandated proof of identity or established online monitoring systems to deter the diversion of pseudoephedrine products from pharmacy to the clandestine manufacture of methamphetamine. The absence of these measures is not relevant to the proposed reclassification application as detailed analysis of such measures implemented overseas have confirmed that these measures are ineffective in reducing the supply and use of methamphetamine, but pose significant demands and compliance costs on the pharmacy workforce, as well as significant patient inconveniences.(11, 12)

Project Stop is a real-time monitoring program for pseudoephedrine containing medicines, that was initiated in 2005 by the Pharmacy Guild of Australia in collaboration with the Queensland Police Service, before it was rolled out nationally in 2007 across Australia. The program implemented an online database to record pseudoephedrine purchases (and attempted purchases) to prevent large-scale diversion to methamphetamine production. A comprehensive assessment of Project Stop found that:(11)

- It successfully prevented some pseudoephedrine from being diverted from pharmacies to methamphetamine production.
- Despite reducing diversion from pharmacies, Project Stop had no appreciable effect on methamphetamine production or its harmful use.
- Since Project Stop implementation there has been a significant increase in methamphetamine sales and distribution in Australia.
- The ongoing high rate of methamphetamine treatment presentations indicate that Australians continue to have ready access to methamphetamine.

The authors of the most comprehensive review of Project Stop noted that Australia's current national drug strategy, The National Drug Strategy 2017–2026, refers to the need for precursor control in a general manner, without specifying Project Stop as an example. The authors stated, *"Therefore, Project Stop appears no longer to be considered a key intervention for controlling methamphetamine production and supply, perhaps due to movement to non-pseudoephedrine sources, or sourcing pseudoephedrine outside of the pharmacy supply line."*(11)

Similar evaluations of pharmaceutical precursor control measures applied in the USA reached equivalent conclusions to Project Stop. While precursor control was initially cost-effective at reducing methamphetamine production and consumption, over time, methamphetamine producers adapted to importing pseudoephedrine and using alternative unregulated pre-precursors. These adaptations have resulted in declines in the price of methamphetamine, increased consumption and a rise in methamphetamine-related harm (hospitalisations and treatment admissions).(12, 17)

Blemings et al,(12) noted that "Another lesson is that regulations of the consumer markets for cold medications are not justified unless reductions in methamphetamine use are large." This has clearly not been achieved in any country that has introduced such measures hence the modest relaxation of these restrictions as proposed by this reclassification application is appropriate and consistent with the available evidence.

There have been no concerning signals associated with the reintroduction of pseudoephedrine-based products in New Zealand.

Since pseudoephedrine-based medications were reintroduced in New Zealand as Restricted Medicines in July 2024, there have been no signals to indicate that this has resulted in any adverse consequences or seen a return of the diversion of these therapeutic products for the production of methamphetamine in New Zealand.

This is evident by the Pharmacy Guild and New Zealand Police reporting only a small number of isolated incidents of pseudoephedrine related thefts in pharmacy since the return of these products.(10) It is important to acknowledge that New Zealand law enforcement have been proactively monitoring pharmacy crime since pseudoephedrine-based products have returned to market, hence this lack of criminal activity is real and not due to a lack of surveillance.

In addition, the most recent report on methamphetamine use in New Zealand indicates that the small increase in methamphetamine use in 2025 over 2024 was driven by increased consumption amongst existing users in response to price declines, rather than an increase in the number of users. Importantly, this report made no reference to any potential role of the return of pseudoephedrine-based products in pharmacies to methamphetamine supply or usage.(9)

Despite the best intentions and efforts of governments in New Zealand and other countries, restricting access to pseudoephedrine-based cold and flu preparations has been ineffective at addressing the methamphetamine societal issue but has inconvenienced and placed unnecessary time and financial burdens on consumers and pharmacists.

12. Labelling or draft labelling for the proposed new presentation(s).

If this application is successful, the only proposed amendments to the existing Restricted Medicine label are a change in classification to Pharmacy Medicine and to adjust quantity of tablets to 6 tablets, see Figure 2 below. Therefore, all current warnings and precaution

statements that are considered to be suitable for the self-management of cold and flu symptoms with a product containing pseudoephedrine have been retained.

Figure 2: Proposed label [redacted]

13. Proposed warning statements (if applicable).

All of the scheduling changes related to pseudoephedrine since 2004 have related to issue regarding methamphetamine precursor control and have not been due to any issues regarding the efficacy or safety of pseudoephedrine as an oral decongestant. Hence the existing warning statements remain appropriate, with no need for modification.

14. Other products containing the same active ingredient(s) and which would be affected by the proposed change.

The proposed changes will only apply to any pseudoephedrine containing product with limited pack sizes, maximum 240 mg pseudoephedrine. Currently there are no such products available for sale in New Zealand. Current cold and flu products that contain pseudoephedrine are listed in Table 5, noting that this list is not exhaustive. Smaller pack sizes of these products, representing a one-day supply, could be introduced if this application is successful.

Table 5: Other products that contain pseudoephedrine that could develop new pack sizes and be reclassified by the proposed change

Product	Number of tablets per pack	Current classification
Sudafed Sinus & Nasal Decongestant PSE	12 tablets	Restricted
Sudafed Sinus & Pain Relief Day & Night PSE	24 tablets	Restricted
Codral Cold & Flu Original Day & Night PSE	24 tablets	Restricted
Codral Original Cold & Flu PSE	24 tablets	Restricted

Part B

1. Indications and dose

− What is the medicine indicated for, and for which indication(s) is the reclassification application for?
− What is the evidence that the proposed indication is an OTC indication i.e., that the diagnosis and treatment can be understood by the consumer; that the risks of inappropriate treatment can be minimised?
− What is the treatment population for the indication (age; gender etc.)?
− What is the dose and dose frequency of the medicine for this indication?

The approved indication for oral pseudoephedrine is for the relief of nasal congestion.

As this classification includes pseudoephedrine combined with other ingredients such as analgesics and antihistamines the specific indications will vary slightly dependent on the specific combination. Examples of this are summarised below:

- For the temporary relief of the symptoms of colds and flu with associated congestion, including aches and pains, headaches, fever, sore throat, runny nose, blocked nose and sinuses ([redacted])
- Temporary symptomatic relief of sinus pain and congestion and nasal congestion of allergic (seasonal) rhinitis, vasomotor (perennial) rhinitis, and the common cold in adults and children over 12 years ([redacted])
- For fast and effective relief from sinus pain and congestion day and night ([redacted])
- For temporary relief from the symptoms (runny nose, nasal congestion headache, body aches and pains, and fever) of colds and flu without drowsiness ([redacted])

A single dose of oral pseudoephedrine as an oral decongestant is typically 60 mg, with a maximum daily of 180 to 240 mg, depending on the specific combination formulation.

The proposed reclassification only applies to use by adults (less than 65 years) and children aged 12 years or older.

The use of these medications for the symptomatic relief of acute self-limiting cold and flu and nasal congestion is well established and not disputed.(6, 13) This was acknowledged by the New Zealand government when rescheduling pseudoephedrine from a Prescription Medicine to a Restricted Medicine:(20)

"This accessibility will be a real relief to New Zealanders suffering from colds and flu this winter. They will be able to access the same effective cold and flu medicines that are available in Australia, Canada, the United Kingdom and the United States."

There are multiple cold and flu products available for self-selection as General Sale and Pharmacy Medicines, confirming that these conditions can be self-diagnosed and treated by consumers, and any risks mitigated by labelling directions. The primary reason for the current Restricted Medicine classification is to limit access to one source of precursor for the illegal manufacture and supply of methamphetamine and not any inherent risks associated with the therapeutic use of oral pseudoephedrine or whether these medications are appropriate for self-selection use.(1, 13)

The dosing instructions for [redacted] are; adults and children from 12 years: 2 tablets, then 1 or 2 tablets every 4 - 6 hours as necessary (maximum 6 tablets in 24 hours). Do not give [redacted] to children under 12 years.

The maximum daily dose of pseudoephedrine in [redacted] tablets is 180 mg and the maximum daily dose of pseudoephedrine in paracetamol-based formulations is 240 mg.

2. Presentation

− What is the proposed dose form and strength of the medicine to be reclassified? Is this the same for all indications?
− What disposal considerations need to be made for the medicine?
− How practical and easy to use is the proposed presentation?

The dosage form and strength subject to this reclassification is in solid-dose cough or decongestant medicines containing pseudoephedrine not more than 60 mg per recommended dose and not more than 240 mg per recommended daily dose, in a pack size of 240 mg or less.

This is the same dosage form and strength for all indications.

In terms of disposal consideration, the usual process for disposal of medicines would be followed. The proposed Pharmacy Only pack size of up to 240 mg pseudoephedrine, representing up to 8 dose units does not require any special disposal considerations.

In terms of how practical and easy it is to use the proposed formulations; it is very easy for consumers to use one or two tablet per dose.

3. Consumer benefits

− What is the history of this medicine's use for the proposed indication(s) i.e., number of; number of countries used in?
− To what extent is this medicine used for the proposed indication(s) i.e., duration of use; frequency of use?
− What is the evidence that improved access is beneficial for the individual?
− What is the evidence of improved consumer involvement in their health?
− What are the benefits from a consumer viewpoint?

Pseudoephedrine has been used as a nasal decongestant since the 1940s and was available in New Zealand as a Pharmacy Only medicine up until 2004.(13) Products containing oral pseudoephedrine as a decongestant were reintroduced in New Zealand from July 2024 when they were reclassified from Prescription Medicines to Restricted Medicines. Between 2011 and 2024, these products were classified as Prescription Medicines as a measure to reduce the harms associated with methamphetamine use. As these products were rarely prescribed by doctors, manufacturers allowed product approvals to lapse, so that there were no pseudoephedrine products approved or available in New Zealand at the start of 2024.(1)

Pseudoephedrine in combination with ibuprofen, [redacted] was approved for use in New Zealand in April 2024. Globally pseudoephedrine in combination with ibuprofen marketed by Reckitt Benckiser is available in 35 countries of which the majority are available without a prescription.

[redacted] are indicated for the temporary relief of the symptoms of colds and flu with associated congestion and this use is limited to a maximum of 3 days except on medical advice.(29) The maximum quantity of pseudoephedrine that is the subject of this reclassification application is limited to 240 mg. As pseudoephedrine formulations are often used in combination with analgesics, the dosing regimen and maximum daily pseudoephedrine dose is determined by the analgesic component. Pseudoephedrine combined with paracetamol is dosed up to four times daily and the maximum pseudoephedrine content (240 mg) represents one day's supply. Pseudoephedrine combined with ibuprofen is dosed three times daily and the maximum pseudoephedrine content (240 mg) represents 1.3 days' supply. However, from a practicality perspective the proposed pack size for [redacted] is limited to 6 tablets also representing one day's supply, see Figure 2 in Part A Section 12.

As previously stated, the primary consumer benefit of this reclassification application relates to the public health benefit of continued availability of effective oral therapies(6) to relieve the symptoms of colds and flus that can replace phenylephrine formulations if they are withdrawn from the New Zealand market. The actions being taken by the FDA and its pending removal of oral phenylephrine from the GRASE list (3, 4) and the impending actions from comparable regulators including Medsafe and the current class actions in New Zealand in relation to oral phenylephrine containing cold and flu medications(5) indicate that oral phenylephrine may no longer be available in cold and flu oral medications in New Zealand. If this was to occur, consumers will need alternative therapies available to treat the common cold and relying on medicines that are limited to Restricted Medicine classification is associated with significant consumer and pharmacy burden.

Consumer burden:

As Restricted Medicines require the pharmacist to be directly involved in the sale, access to these medications comes at a premium price to consumers. There is a direct financial impost of higher medication costs that will directly add to the current cost of living pressures with consumers paying a 41% to 59% premium for the cold and flu medications that are Restricted Medicines compared to the equivalent Pharmacy Only products,(30) see Table 6. During the 12 months up to 15 March 2026, the sales value of phenylephrine-based solid dose products was just over $9 million. If phenylephrine was discontinued and the only alternative is Restricted Medicine pseudoephedrine-based products, the additional cost to New Zealand consumers is estimated to be $3.7 million per year, assuming the lower 41% price premium as highlighted in Table 6.

Table 6: Higher retail price of Cold and Flu medications that are Restricted Medicines(30)

Pharmacy Only product	Price per pack (Price per dosing unit)	Restricted Medicine product	Price per pack (Price per dosing unit)	Price premium per dosing unit
Codral PE Day & Night 24 tablets	$16.99 ($0.708 / tablet)	Codral Cold & Flu Original (PSE) Day & Night 24 tablets	$23.99 ($1.00 / tablet)	41%
Codral Cold & Flu 24 tablets	$14.99 ($0.625 / tablet)	Codral Original Cold & Flu (PSE) 24 tablets	$21.99 ($0.916 / tablet)	47%
Sudafed PE Day & Night Relief 24 tablets	$15.09 ($0.629 / tablet)	Sudafed Sinus & Pain Relief Day & Night 24 tablets	$23.99 ($1.00 / tablet)	59%

In addition to the direct financial impost, the sale of Restricted Medicines takes longer than self-selected medicines and this inconvenience also has a value to consumers. The consumer welfare cost associated with the purchase of a Restricted Medicines classification has been investigated in a USA contingent choice study by Finlay et al.(31) This study found that consumer compensation required to accept purchasing a medication from behind the counter versus self-selection was $9.68/packet.

It is also noteworthy that the New Zealand government has acknowledged that the current Restricted Medicines classification represents a barrier to access amongst people who have a higher difficulty accessing a pharmacist, such as those in rural areas,(1) and this would be reduced if this application was successful.

Pharmacist burden:

The New Zealand Government when deciding to make pseudoephedrine-based products available as Restricted Medicines in 2024 acknowledged that this initiative would place additional demands on the pharmacist workforce at a time when there is a shortage of pharmacists.(1) If phenylephrine products were no longer available in New Zealand and the only option for consumers was the purchase a pseudoephedrine-based medication that is only available as a Restricted Medicine, then the additional demands placed on the pharmacist workforce would be significantly increased, potentially compromising the other services provided by pharmacists. Based on the sales data for the 12 months up to 15 March 2026,

this would require pharmacists to engage in an additional five hundred thousand interventions per year.

Therefore, easing access to an effective therapy to manage a very common, self-diagnosable and self-manageable ailment would benefit both consumers and the pharmacists, without contributing to the societal problems associated with the abuse of methamphetamine.

In addition to the direct consumer benefits described above, the proposed reclassification provides broader system-level benefits within community pharmacy. Reclassifying limited-pack pseudoephedrine products to Pharmacy-Only Medicine will reduce the need for routine pharmacist intervention for a common, self-limiting condition, allowing pharmacists to focus their time on consumers with more complex therapeutic needs, higher-risk medicines, or requiring healthcare professional advice.

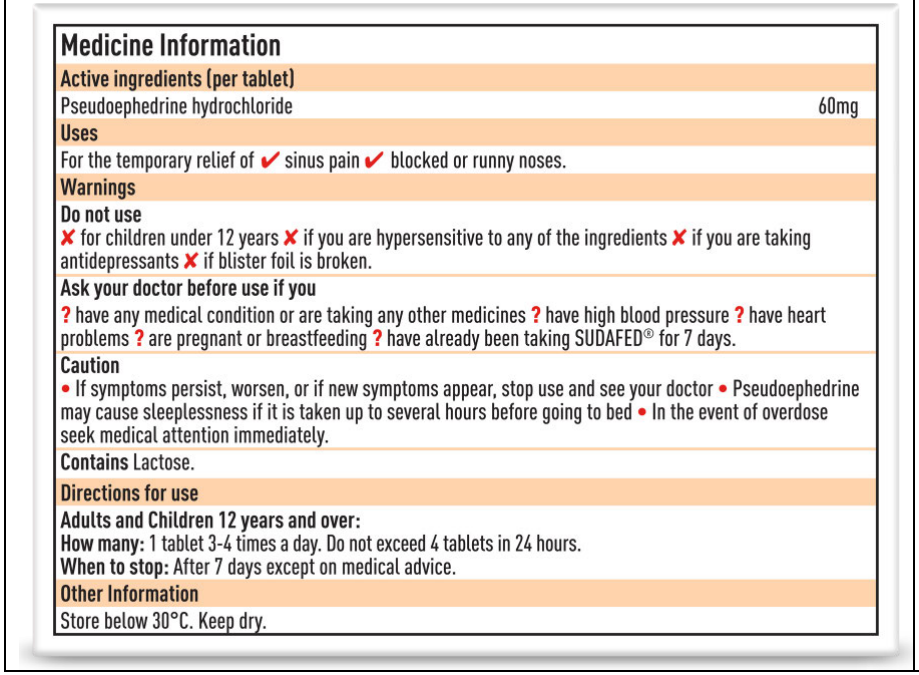
During peak cold and flu season, enabling self-selection of small, one-day-supply packs is also expected to improve pharmacy workflow efficiency and reduce congestion at the pharmacy counter, benefiting both consumers and pharmacy staff without compromising safety.

4. Contraindications and precautions

− What are the contraindications for the medicine and how easy are they to identify and prevent?
− What are the precautions for this medicine and how easy are these to understand?
− Does the medicine have a low therapeutic index?
− What class effects need to be considered and what are the risks?
− What are the risks of the medicine being used in an OTC environment?
− What other drug interactions need to be considered?
− What food and/or drink interactions need to be considered?
− Are there any other restrictions when taking the medicine i.e., driving restrictions or operating machinery?
− Are there any special populations where exposure to the medicine needs to be restricted?

As previously stated, the original restrictions applied to the use of pseudoephedrine-based products were unrelated to its therapeutic use or the risk of accidental therapeutic misadventure. More restrictive medicine classifications were implemented to limit the illegal use of pseudoephedrine in the clandestine manufacture of methamphetamine.(1) As such the safety associated with the therapeutic use of over-the-counter pseudoephedrine is already established and it remains appropriate for self-selection use. In addition, the risks associated with the use of pseudoephedrine are managed with information provided on the product label. This is reinforced by the fact that the warnings provided to consumers for pseudoephedrine-based products (e.g., Sudafed Sinus & Nasal Decongestant Tablets 12 Pack PSE) are equivalent to those associated with General Sales phenylephrine-based products (e.g. Sudafed PE Nasal Decongestant), see Figure 3. Note, these examples were selected as they list the warnings related to the decongestants alone, and do not include warnings related to other ingredients such as paracetamol, ibuprofen or antihistamines.

Figure 3: New Zealand product labels for Sudafed pseudoephedrine and phenylephrine products

Label for Sudafed Sinus & Nasal Decongestant (pseudoephedrine 60 mg) – Restricted Medicine	Label for Sudafed PE Nasal Decongestant (Phenylephrine 10 mg) – General Sales
	

Contraindications:

The contraindications for these pseudoephedrine-based medications comprises of those associated with pseudoephedrine and the other medications that it is combined with.

The contraindications for pseudoephedrine alone are:(32)

- Known hypersensitivity or idiosyncratic reaction to pseudoephedrine
- Uncontrolled or severe hypertension or severe coronary artery disease
- Taking monoamine oxidase inhibitors (MAOIs) or who have taken MAOIs within the previous 14 days
- Severe acute or chronic kidney disease/renal failure.

Precautions:

Pseudoephedrine should be used with caution amongst people who have the following:(32)

- Hepatic impairment or severe hepatic dysfunction
- Renal impairment or severe renal dysfunction
- Hypertension
- Hyperthyroidism
- Diabetes mellitus
- Coronary heart disease
- Ischaemic heart disease
- Glaucoma
- Prostatic hypertrophy.

Pseudoephedrine may cause sleeplessness if taken up to several hours before going to bed.

Therapeutic index:

The main safety concern regarding the use of pseudoephedrine is its use amongst patients with hypertension or heart disease.

To the best of our knowledge there is no evidence that pseudoephedrine effects the cardiovascular system in normotensive patients and is reported to be safe amongst patients with controlled hypertension.(6, 33)

Amongst patients with hypertension a meta-analysis determined the pseudoephedrine showed a small increase in systolic blood pressure of 1.2 mm Hg and heart rate by 3 bpm but no significant changes in diastolic blood pressure.(33) These small increases in systolic blood pressure and heart rate are below the minimal clinically important difference of 2 mm Hg(34) and 5-10 bpm(35) hence for the majority of people these are not clinically relevant. This is further supported by the meta-analysis not identifying any significant adverse events associated with pseudoephedrine use.(33)

The relative suitability of pseudoephedrine to phenylephrine is also supported by the observation that there have been similar levels of cardiovascular related adverse events reported with pseudoephedrine than phenylephrine in both New Zealand, reported in the SMARS database,(14) see Table 7 and in Australia, reported in the DAENS database,(15) see Table 8. Note the Australian data is likely to be more representative of the relative safety as there has been no discontinuation of pseudoephedrine-based products and given that this database proceeds the introduction of oral phenylephrine, as well as its rescheduling to Schedule 3 the consumer exposure to pseudoephedrine is expected to be significantly higher than phenylephrine.

In addition, an analysis of the DAENS database of adverse events reported for pseudoephedrine based products when they were Pharmacy Only (Schedule 2) medicines in Australia to a comparable length of time when they were only available as Pharmacist Only Medicine (Schedule 3) demonstrates comparable cardiovascular safety indicating that pharmacist involvement in the sales of these medications does not significantly improve the safe use of these medicines, reflecting their good safety profile and the adequacy of labelling to support their use as Pharmacy Only medicines,(15) see Table 9.

Table 7. Cardiovascular and vascular adverse events reported in New Zealand for pseudoephedrine and phenylephrine from 1/1/2000 to 14/4/2026(14)

Adverse event	Pseudoephedrine	Phenylephrine
Arrhythmia	1	0
Atrial fibrillation	1	1
Bradycardia	1	0
Palpitations	1	4
Tachycardia	1	4
Cardiac arrest	0	1
Ventricular fibrillation	0	1
Hypertension	1	1
Vasoconstriction	1	0

Table 8. Cardiovascular and vascular adverse events reported in Australia for pseudoephedrine and phenylephrine from 1/1/1971 to 1/4/2026(15)

Adverse event	Pseudoephedrine		Phenylephrine	
	All cases	Cases with a single suspected medicine	All cases	Cases with a single suspected medicine
Blood pressure fluctuation	1	1	1	1
Circulatory collapse	1	1	2	2
Cyanosis	1	1	1	1
Hypertension	15	10	14	11
Hypertensive crisis	0	0	3	3
Hypotension	4	2	10	3
Orthostatic hypotension	1	1	0	0
Peripheral ischaemia	2	1	0	0
Vasculitis	2	1	0	0
Visceral congestion	1	0	0	0
Thrombosis	0	0	1	1
Vasospasm	0	0	1	1
Angina pectoris	1	1	1	1
Arrhythmia	4	2	3	3
Atrial fibrillation	3	2	2	1
Bradycardia	1	1	4	2
Cardiac arrest	1	0	0	0
Cardiomegaly	1	1	0	0
Coronary artery disease	1	0	0	0
Myocardial infarction	2	2	1	1
Palpitations	49	33	16	13
Sinus tachycardia	1	0	0	0
Supraventricular tachycardia	2	2	2	0
Tachycardia	23	15	6	4
Stress cardiomyopathy	0	0	1	0
Ventricular tachycardia	0	0	1	0
Blue toe syndrome	0	0	1	1

Table 9. Cardiovascular and vascular adverse events reported in Australia for pseudoephedrine as a Schedule 2 medicine and as a Schedule 3 medicine(15)

Adverse event	Pseudoephedrine as Schedule 2 (from 1/2/1983 to 31/12/2003)		Pseudoephedrine as Schedule 3 (from 1/6/2005 to 31/12/2025)	
	All cases	Cases with a single suspected medicine	All cases	Cases with a single suspected medicine
Blood pressure fluctuation	1	1	0	0
Circulatory collapse	0	0	1	1
Hypertension	10	6	4	1
Hypotension	3	2	1	0
Orthostatic hypotension	1	1	0	0
Peripheral ischaemia	2	1	0	0
Vasculitis	1	0	0	0
Visceral congestion	0	0	1	0
Angina pectoris	1	1	0	0
Arrhythmia	1	1	1	0
Atrial fibrillation	2	1	1	1
Bradycardia	1	1	0	0
Cardiomegaly	0	0	1	1
Coronary artery disease	0	0	1	0
Cardiac arrest	1	0	0	0
Myocardial infarction	1	1	1	1
Palpitations	31	16	11	11
Supraventricular tachycardia	2	2	0	0
Tachycardia	15	9	5	4
Sinus tachycardia	0	0	1	0

Overall the evidence supports pseudoephedrine is safe when taken as directed,(6) has an acceptable therapeutic index equivalent to phenylephrine(14, 15) which is available as a General Sales as well as a Pharmacy Only medicine.

Class effects

Pseudoephedrine and phenylephrine are sympathomimetic vasoconstrictors. The main class effect associated with their use is their potential impact on blood pressure and cardiovascular safety(6, 33) which has been addressed above under Therapeutic Index.

Drug interactions

There is minimal risk of drug interactions with pseudoephedrine and this is reflected in only 3 events being reported in New Zealand(14) and 6 events reported in Australia.(15)

Potential drug interactions with pseudoephedrine are:(32)

- Antidepressant medication e.g., tricyclic antidepressants and monoamine oxidase inhibitors (MAOIs); may cause a serious increase in blood pressure or hypertensive crisis.

- Other sympathomimetic agents, such as decongestants, appetite suppressants and amphetamine-like psychostimulants; may cause an increase in blood pressure and additive effects.
- Antihypertensives e.g. beta-blockers, methyldopa; pseudoephedrine may antagonize the effect of certain classes of antihypertensives and cause an increase in blood pressure.
- Urinary acidifiers enhance the elimination of pseudoephedrine.
- Urinary alkalinisers decrease the elimination of pseudoephedrine.

Food/drink interactions

There are no relevant food or drink interactions.

Other restrictions

Pseudoephedrine is not indicated for use in children under 12 years of age.

Special populations where exposure to the medicine needs to be restricted

Please refer to “Contraindications” above, noting that this risk is effectively addressed by the current product labels.

5. Undesirable effects

− What are the known undesirable effects and the frequencies of these? Do these vary for special populations?
− What are the risks and consequences of known undesirable effects?
− Are there any significant safety concerns for the medicine under review?
− Have there ever been any withdrawals of the medicine or other regulatory actions taken for safety reasons (during a time period or in a specific jurisdiction)?
− Are there any withdrawal effects following cessation of use of the medicine?

As previously stated, the original reclassification of pseudoephedrine-based medicines to Restricted Medicines or Prescription medicines were unrelated to its therapeutic use or any safety issues associated with pseudoephedrine per se, but was a measure to control the illegal use of pseudoephedrine as a precursor in the clandestine manufacture of methamphetamine.(1) As such, the safety associated with the therapeutic use of over-the-counter pseudoephedrine is already established and it remains appropriate for self-selection use.(6) This is further supported by the analysis that demonstrates comparable cardiovascular safety when pseudoephedrine was available as a Pharmacy Only medicine in Australia versus its current availability as a Pharmacist Only Medicine (Schedule 3).(15)

The issue of precursor control and the use of pseudoephedrine in the clandestine manufacture of methamphetamine is addressed in Part 1, Section 11. It is important to recognise that these measures only had transient benefits and have not resulted in reduced supply or use of methamphetamine in New Zealand or other comparable markets.(1, 8, 9, 11, 12) These restrictions have only impacted the legitimate, therapeutic use of an effective oral decongestant.(11, 12)

7. Medication errors and abuse/misuse potential

− Would reclassification affect the risk of unnecessary use?
− Is the medicine be provided with necessary tools to allow correct dosing e.g., liquids supplied with a measuring device?
− What are the reported medication errors post-market?

− What are the reported cases of abuse/misuse/accidental overdose?
− How would reclassification affect import considerations?
− What is the addiction potential of the medicine?

As addressed in Part 1, Section 11, the criminal element that control the manufacture and supply of methamphetamine no longer use pseudoephedrine sourced from pharmacy as a precursor. They have adapted to large scale production, reliant on imported precursors, pre-precursors and the importation of finished methamphetamine.(7) There is negligible risk that the proposed reclassification of pseudoephedrine limited to 240 mg per Pharmacy Only pack would result in any change in the manufacture and supply of methamphetamine in New Zealand.

This reclassification application is only related to solid dosage forms, thus the need for tools to support correct dosing is not applicable.

The risk of medication error is small and equivalent to the use of any other over-the-counter medication. This is reflected by the observations that no medication errors have been reported in the SMARS database and only 2 listed in the DAENS database with pseudoephedrine since 1971.(14, 15)

The risk of accidental overdose is small and equivalent to the use of any other over-the-counter medication. This is reflected in the observations of no overdoses reported in the SMARS database and only 4 accidental overdoses and 4 other overdoses listed in the DAENS database with pseudoephedrine.(14, 15)

Pseudoephedrine has stimulant effects including euphoria and with chronic use has the potential to develop dependence.(36) However, the proposed reclassification which is limited to one day's supply poses negligible incremental risk to that posed by larger quantities available as Restricted Medicines.

8. Communal harm and / or benefit

− What are the possibilities of community harm resulting from wider use of the medicine in question (ego, the development of antibiotic resistance in bacteria or increased immunisation rates)?
− What are the possibilities of community benefit resulting from wider use of the medicine in question (e.g., greater herd immunity as a result of improved access to a communicable disease vaccine)?

As addressed in Part 1, Section 11, the criminal element that control the manufacture and supply of methamphetamine no longer use pseudoephedrine sourced from pharmacy as a precursor. They have adapted to large scale production, reliant on imported precursors, pre-precursors and the importation of finished methamphetamine.(7) There is negligible risk that the reclassification of pseudoephedrine limited to 240 mg per Pharmacy Only pack would result in any change in the manufacture and supply of methamphetamine in New Zealand.

The primary communal benefit of this reclassification is that it will ensure that New Zealand consumers have self-selection access to an effective oral decongestant for the relief of cold and flu symptoms. This is critical given the FDA's proposed removal of oral phenylephrine from the GRASE list(3, 4) and potential Medsafe actions, alongside current New Zealand class actions,(5) which place the future availability of phenylephrine-based medications in doubt. Should these phenylephrine products be withdrawn, this proposed reclassification guarantees alternative decongestants are available.

This reclassification application is not predicated on the potential withdrawal of phenylephrine. If phenylephrine-based medications remain available in New Zealand the proposed reclassification will give consumers self-selection access to a more efficacious oral decongestant with an equivalent safety profile to phenylephrine(6) whilst reducing the consumer and pharmacist burden associated with a Restricted Medicine classification.(1, 30, 31)

9. Integrated benefit-risk statement

− A summary of the reclassification benefits
− A summary of the reclassification risk of harm
− A summary of the need for the medicine at the classification proposed
− Precedent – how are other medicines in the same class classified?

From the information provided in this submission it is clear that restricting consumer access to pseudoephedrine-based medicines in New Zealand and comparable markets, including Australia and the USA, has not been an effective long-term strategy to address the manufacture, supply and abuse of methamphetamine.(1, 8, 9, 11, 12)

The New Zealand government has recognised the therapeutic need and consumer benefits of pseudoephedrine-based medications for the symptomatic relief of nasal congestion associated with colds and flus when it implement measures to return these medications to the New Zealand market in 2024.(1, 2, 20)

The proposed reclassification to allow Pharmacy Only access to pseudoephedrine-based medications that is limited to 240 mg representing one day's supply will:

- Improve access to these effective and safe oral decongestants.(6)
- Improve access for consumers living in rural areas where pharmacist access is more difficult.(1)
- Help reduce the financial burden and cost of living pressures associated with the treatment of colds and flus as Pharmacy Only medicines are typically cheaper than Restricted Medicines.(30)
- Reduce pharmacist workload at a time where there is a shortage in the pharmacists workforce.(1)
- Allow pharmacists to prioritise patients with more serious or complex health needs by reducing mandatory intervention for a short-term, self-limiting condition.
- Improve pharmacy workflow efficiency, particularly during peak cold and flu season, without increasing therapeutic risk.

The ability for consumers to safely and appropriately use pseudoephedrine-based medications as Pharmacy Only medicines is evident by decades of in market experience.(6, 15) There were no issues surrounding pseudoephedrine's therapeutic use that resulted in their reclassification to Prescription or Restricted Medicines, but these were motivated by methamphetamine precursor control measures.(1) The use of pseudoephedrine sourced from pharmacy for the production of methamphetamine has been replaced by larger scale importation of precursors and methamphetamine.(7) There is no evidence to indicate that the return of pseudoephedrine-based products as Restricted Medicines has altered the source of methamphetamine precursors in New Zealand(9, 10) and there is negligible risk that the proposed reclassification would alter this.

10. Risk mitigating strategies

− Are there any risk mitigation strategies required? If so, what risk mitigation strategies are required e.g., healthcare professional education; integration of care; consumer information to be provided etc?

- *What is the evidence that these proposed risk mitigation strategies would be effective?*
- *What post-market surveillance activities would be carried out?*
- *Is the proposed reclassification supported by professional bodies?*

The proposed reclassification poses negligible change in risk to consumers as pseudoephedrine-based products have been safely used for decades as self-selected medicines within pharmacy(6, 13, 15) and issues that led to higher medicine classifications were unrelated to their therapeutic use.

The current labels adequately address the therapeutic risks associated with the medication use and support the quality use of these medicines.

Limiting the proposed Pharmacy Only pseudoephedrine formulations to packs containing up to 240 mg, representing one day's supply mitigates the risk of therapeutic misadventure and diversion for use as a methamphetamine precursor.

Enhanced surveillance of the sale of pseudoephedrine-based products, as implemented in Australia with Project Stop has avoided some diversion of pseudoephedrine for the manufacture of methamphetamine, but overall has not reduced access or abuse of methamphetamine in the community(7) and is not considered to be a cost-effective strategy.(12) Thus, the evidence does not support the implementation of equivalent risk management programs in New Zealand.

Based on the above Reckitt Benckiser does not believe that additional post-marketing surveillance activities are required.

Conclusion

The evidence supports pseudoephedrine being an effective oral decongestant that is safe and appropriate for self-selection use.(6) Pseudoephedrine has an acceptable therapeutic index equivalent to phenylephrine(14, 15) which is available as a General Sales as well as a Pharmacy Only medicine. Pseudoephedrine has been safely used as a self-selection medication for decades and the risk/benefit profile continues to support its suitability for a Pharmacy Only classification.(13)

The current Restricted Medicine classification is in place as a measure to minimise the risk of pseudoephedrine from pharmacy being a precursor source for the clandestine manufacture and supply of methamphetamine. However, these measures have only had a transient benefit as the criminal element that manufacture and supply methamphetamine no longer use pseudoephedrine sourced from pharmacy as a precursor but have transitioned to large scale production reliant on imported precursors, pre-precursors and the importation of finished methamphetamine.(7) As such, there is negligible risk that the reclassification of pseudoephedrine limited to 240 mg per Pharmacy Only pack would result in any change in the current manufacture and supply of methamphetamine in New Zealand.

Given the pending decision by the FDA to remove oral phenylephrine from the GRASE list due to lack of efficacy,(3, 4) the impending decisions of other regulators including Medsafe and the class actions in New Zealand,(5) improving self-selection access to pseudoephedrine-based products limited to one day's supply will ensure New Zealanders have effective and safe(6) over the counter cold and flu decongestant medications available for the 2027 cold and flu season. In addition, it would avoid a significant escalation in the workload required for pharmacists, not having to be directly involved in every sale.

Irrespective of the future availability of phenylephrine-based medications in New Zealand the proposed reclassification has consumer and societal benefits as it will give consumers self-selection access to a more efficacious oral decongestant(6) whilst reducing the consumer and pharmacist burdens associated Restricted Medicine classification.(1, 30, 31)

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