29 September 2017

Medicines Classification Committee Secretary
Medsafe
Wellington

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

Dear Sir/Madam

RE: AGENDA FOR THE 59th MEETING OF THE MEDICINES CLASSIFICATION COMMITTEE

Thank you for the opportunity to provide feedback on the agenda for the 59th meeting of the Medicines Classification Committee. I would like to provide feedback on agenda item 5.3 – the proposed reclassification of codeine from pharmacy-only and restricted medicines to a more restricted classification.

I am **opposed** to a reclassification of codeine products that would reduce direct access through a pharmacist. I would however **support** the reclassification of all codeine products to pharmacist-only.

The vast majority of consumers who use over-the-counter codeine products do so safely, effectively and in a responsible manner. As a pharmacist, I am directed by my Code of Ethics to prevent the supply of unnecessary and excessive quantities of codeine products. I assure you that I take this responsibility seriously.

In our pharmacy codeine products are used effectively for short-term management of acute moderate pain. I am concerned that if codeine products are reclassified to prescription only, general practitioners will be under pressure due to an increased patient load, with the possibly that patients will seek higher strengths of codeine or more potent opioids as a result of having to see a doctor to access pain relief. Reclassification of codeine products could also increase the inappropriate use of anti-inflammatories.

Currently a lack of information sharing between pharmacies means consumers can seek codeine from multiple pharmacies. This means repeated purchases of codeine at our pharmacy are easy to detect, but we do not know if a customer has already purchased codeine from another pharmacy.

Currently Pharmacies in the Northern Region have access to Testsafe Data. This only records data that is “dispensed” as an NSS prescription. While it is policy at our pharmacy to do this, most pharmacies do not use this as a recording system.

I understand that sector organisations are looking to implement a real-time recording and monitoring system that will allow pharmacists to track codeine sales and better identify consumers with additional needs for pain management and/or addiction problems. I fully support the implementation of a real-time monitoring system and support this being mandatory for any pharmacy that wants to supply codeine products over-the-counter.

I also understand that sector organisations are working together to ensure there is adequate training and education in place for pharmacists and pharmacy support staff. As pharmacists, we are medicine experts and are well aware of the risks associated with codeine use, however dealing with patients with addiction issues can be difficult. Training around managing and communicating with patients with identified problematic use of codeine would be welcomed by pharmacists and the wider health sector.

To ensure my patients are getting the best possible care I would happily agree to an accreditation programme to supply codeine.

Pharmacists would greatly appreciate a public information campaign promoting the safe use of codeine. This would create a level of public awareness for consumers around the risk of codeine misuse and addiction, promote the appropriate use of codeine, and empower consumers with a pain management problem or codeine dependence to seek help.

I understand sector organisations have requested a two-year suspension in the rescheduling of codeine containing products to allow time to implement a real-time monitoring system and pharmacist training programme. I would like to echo this timeframe request.

Thank you for considering my feedback. If you have any questions about my feedback please contact me on hillpark@unichem.co.nz or 09 2676392

Yours sincerely,

Kathy Maxwell
Pharmacist

MAUNU PHARMACY

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I understand sector organisations have requested a two-year suspension in the rescheduling of codeine containing products to allow time to implement a real-time monitoring system and pharmacist training programme. I would like to echo this timeframe request.

I have discussed this with our Pharmacist Team, all of whom are concerned with the ramifications for our genuine patients, seeking help to treat their acute pain needs. Most of these patients present seeking advice from our Pharmacists on how best to treat their acute pain, after having already tried less effective treatments. Reclassifying Codeine to a Prescription Medicine will leave us with nothing more effective than they have already tried. These patients would be forced to either seek help from an already overburdened GP service (unlikely to get an appointment immediately) or endure their pain.

I am also concerned about the effectiveness of such a reclassification, using Pseudoephedrine as an example, this did not solve the “P” issue in New Zealand, in my opinion most of the sales of these products through our channel were to genuine patients.

I have talked to many customers regarding this, all have been dismayed that they will be unable to receive timely effective treatments that the currently can. They voiced concerns about their human rights being adversely affected by such a reclassification.

Thank you for considering my feedback. If you have any questions about my feedback please contact me on 09 4373722 or 027 524 0543.

Yours sincerely,

Shane Heswall
Director
Maunu Pharmacy

pharmacycouncil
Te Pou Whakamana Kaimatu o Aotearoa

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29 September 2017

Medicines Classification Committee
Ministry of Health
By email: committees@moh.govt.nz

To the Medicines Classification Committee

Proposed reclassification of codeine to a more restricted classification

The Pharmacy Council would like to submit the following comments with regard to the Committee's recommendations on the proposed reclassification of codeine containing products from pharmacy-only and restricted medicines to a more restricted classification.

The Pharmacy Council (Council) is a health regulatory authority established under the Health Practitioners Competence Assurance (HPCA) Act 2003. Council's primary role is to protect the health, safety and wellbeing of the public by ensuring pharmacists are competent and fit to practice.

One of Council's functions under section 118(i) of the HPCA Act 2003 is to set standards of clinical competence, cultural competence, and ethical conduct to be observed by health practitioners of the profession.

Under this function the Pharmacy Council works jointly with the sector to promote best practice when supplying products containing codeine, when sold as pharmacy only or pharmacist only medicines. Council and the Pharmaceutical Society have published a joint statement around the supply of any codeine containing product to ensure that patient safety is protected.

This statement is attached as Appendix 1. Pharmacists are expected to adhere to the protocols in the statement, be alert for patients actively seeking codeine containing products or requesting repeat purchases and to refuse supply when concerned about patient health or suspected misuse or abuse.

The statement requires pharmacists to record any pharmacist only medicines containing codeine in the dispensary patient system as an electronic record, which ensures patient medication history is checked and repeat purchases from the pharmacy can prompt discussions with patients around pain management, misuse or overuse of codeine and referral to appropriate health professionals for follow up.

Information sharing data gap
The limiting factor at present is the sharing of information between pharmacists. Privacy restrictions prevents the active sharing of information around codeine containing preparations purchased over the counter (OTC) between pharmacists.

In the Auckland region TestSafe database enables pharmacists to access dispensing data and pick up patients presenting to more than one pharmacy to purchase codeine containing products, however this is not nationally available. In the South Island Health One is a patient information sharing platform that requires patient consent before the data base can be accessed unless there is imminent concern with regard to patient safety. Patients are able to opt off at any time and when patients are misusing or abusing codeine containing products it could be expected that patients will select to opt off to avoid detection.

National database to record and track OTC codeine purchases
The Pharmacy Council is supportive of any nationally available, mandatory method of recording and sharing patient data around purchases of codeine containing products supplied as pharmacy only or pharmacist only which will improve patient safety. Council is aware of sector partners working on options for a unique database called Meds Assist, to record sales of pharmacist only medicines that contain codeine and would enable ready access to data around purchasing of codeine containing products and enable usage to be tracked nationally.

The system has already been developed and used in Australia for a similar purpose and has comprehensive privacy settings. Mandatory consent for recording of and sharing of information is a condition of purchase of codeine containing preparations. This tool could easily be used to identify patients seeking or using regular quantities of codeine containing preparations and enable pharmacists who have received additional information around management of chronic pain or codeine addiction to actively engage with patients.

Improved patient health outcomes and public safety are two such results that have potential from a robust OTC codeine recording and tracking platform.

Pharmacist obligations to prevent abuse and misuse of medicines
Under the Council Code of Ethics pharmacists are obliged to prevent the abuse, misuse or overuse of any medicine, and with their skills as medicines managers they are appropriately qualified to consult with and effectively manage patients who may require referral for pain or addiction management.

Council is supportive of any initiative that improves patient health, well-being and safety through public education around codeine safety and dangers of overdosing on other active ingredients combined with codeine, such as ibuprofen and paracetamol. With their medicines management expertise pharmacists can competently contribute to such public education initiatives.

Education and training of pharmacists
Another function of the Pharmacy Council under section 118(k) of the HPCA Act is to promote education and training in the profession. In order to safely retain access for the NZ public to non-prescription codeine containing products, Council is willing to actively distribute information to ensure pharmacists are informed of and able to contribute to medication safety campaigns, including monitoring the purchase of non-prescription codeine containing products and informing the public of risks associated with misuse and overuse of such products.

The Pharmacy Council works collaboratively with the key sector organisations and is actively engaged in promoting optimised medicines related outcomes for patients and the NZ public.

To reflect any added requirements deemed necessary by Medsafe to enhance patient safety around the use of non-prescription codeine containing preparations, Council will work with the Society to amend the joint codeine containing preparations statement, which will set out the behaviours expected of pharmacists and be enforceable both under the profession's Code of Ethics and by way of inclusion in the Council statement itself.

If you require any further information on any aspect of our submission please contact Council's Professional Standards Advisor, Pam Duncan by email, p.duncan@pharmacycouncil.org.nz.

Yours sincerely

Michael A Pead
Chief Executive

Encl.

pharmacycouncil
OF NEW ZEALAND
Te Pou Whakamana Kaimatu o Aotearoa

PHARMACEUTICAL SOCIETY
of New Zealand Incorporated

Sale of Codeine Containing Analgesics
Joint Statement

1. Pharmacist only sales of codeine containing analgesics are intended for acute use only. The features of acute conditions are described in the Council's statement, *Protocol for the Sale and Supply of Pharmacist Only Medicines for Chronic Conditions* as usually having a rapid onset and often lasting less than three weeks. They may recur from time to time, may or may not resolve on their own and may or may not require referral to a doctor.

2. Repeat sales of codeine containing analgesics within a short timeframe are likely to be inappropriate in the majority of cases. An alternative, clinically suitable non-codeine containing analgesic should be offered or the patient referred to an appropriate health professional for a full diagnostic assessment so that the optimal management can be identified.

3. Pharmacists must be vigilant about frequent purchasers and use clinical judgement about whether supply of the requested codeine containing analgesic is appropriate. Codeine seekers usually provide false details about symptoms and do not accept offered alternatives.

4. Codeine seekers are known to offer false names or addresses when attempting to purchase from the same pharmacy. It is advisable to consider requesting photo identification to confirm patient identity when recording purchaser details, particularly if there are concerns about the legitimacy of the request. Recording details of the sale in an electronic database, such as your dispensary system provides additional information regarding patient medication use particularly in areas where a shared patient record is accessible. Any concerns about frequent purchasers should be reported to Medicines Control.

5. Pharmacist Only Medicines must not be available for patient self-selection. It is the responsibility of the pharmacist to ensure that the patient receives safe, clinically appropriate assessment before a decision on management can be made.

6. To ensure that patients continue to have access to codeine containing analgesics as Pharmacist Only Medicines, it is vital that best practice principles through strong clinical and ethical decision making are adhered to at all times.

7. Due to their potential for misuse, advertisements related to codeine-containing analgesics are subject to extra restrictions in the joint *Pharmacy Council and Pharmaceutical Society Advertising Guidelines*, on the Council's and Society's websites.

Dummy boxes

8. The placement of dummy boxes of codeine containing analgesics on over the counter shelves could be viewed as a form of advertising and could in some instances, be seen as a breach of a pharmacist's obligations to prevent misuse of substances of abuse. A pharmacist must be able to refuse the sale of any product that is unsuitable for a patient or where misuse is suspected.

9. By permitting a customer to self-select a codeine containing analgesic dummy box the patient has already made a decision about the choice of analgesic and it then may be more difficult for the pharmacist to decline the sale. It is preferable for the pharmacist to make a clinical decision regarding the most appropriate choice of analgesia for the patient in response to patient symptoms and medical history.

Code of Ethics 2011

10. The Council's Code of Ethics 2011 addresses the sale of products of potential misuse in many clauses:

- *"Clause 1.2 – Take appropriate steps to prevent harm to the patient and the public.*
- *Clause 1.7 – Only supply a medicine, complementary therapy, herbal remedy or other healthcare product to a patient when you are satisfied that the patient understands how to use it safely and appropriately*
- *Clause 6.12 – Make certain the public cannot self-select medicines you know or should reasonably be expected to realise are likely to cause or have a potential for misuse, abuse or dependency.*
- *Clause 6.13 – Take appropriate steps to prevent the supply, by any means, of unnecessary or excessive quantities of any medicine or healthcare product which you know or should reasonably be expected to realise is likely to cause or have a potential for misuse, abuse or dependency."*

What is an appropriate supply?

11. Pharmacists should not engage in the sale of multiple packets of codeine containing analgesics in one transaction or repeat, frequent sales to one patient. This practice is likely to breach the Council's Code of Ethics 2011. There may be limited situations when a subsequent sale is necessary, for example when access to medical or dental care is not immediately available.

12. Treatment for a period of up to one week can be considered appropriate in certain circumstances but, medical attention is essential if a longer period of treatment is requested.

13. Pharmacists are experienced health professionals and highly qualified medicines experts capable of using clinical and ethical judgement to assess the patient and recommend the most appropriate analgesic for patient management.

14. It is essential that pharmacists adhere to the highest practice standards to ensure patient and public safety.

Effective date

15. Effective: February 2016.

NZSMI SUBMISSION
TO THE 59TH MEDICINES CLASSIFICATION COMMITTEE MEETING
REGARDING RECLASSIFICATION OF CODEINE

Introduction

NZSMI is New Zealand's premier organisation representing the importers, manufacturers and distributors of over the counter (**OTC**) medicinal products and complementary healthcare (**CHC**) products in New Zealand. Its membership accounts for over 85% of all OTC and complementary healthcare sales in New Zealand. All members submit to abide by a code of practice and it has a fully constituted board comprising the chief executives of the major pharmaceutical companies in New Zealand. It exists to promote the value of self-care in the community by encouraging health literacy and the safe use of clinically proven product. It seeks to work with the Regulator to ensure the New Zealand public has good ready access to well labelled, well marketed and well researched product manufactured to high standards. All manufacturers who distribute OTC codeine in New Zealand are members of NZSMI.

Background

1. The NZSMI position on OTC codeine containing analgesics is:

    1.1 The majority of people who use OTC codeine containing analgesic medicines do so responsibly.

    1.2 Although there has been evidence of adverse events and morbidity reported as a result of dependence on codeine containing analgesics, NZSMI believes that the incidents are low in comparison to the volume of sales and many published reports predate the regulatory action and the intensified monitoring and recording of codeine containing analgesics from 2010 to 2014.

    1.3 There will be potential negative consequences to making OTC codeine containing analgesics prescription only. These include increased costs to government through prescription subsidy and additional pressure on GPs and medical centres, many of whom are currently experiencing long waiting times.

    1.4 Consumers may also be faced with increased out of pocket expenses and the possibility that they may be prescribed higher strength opiates in larger pack sizes as these are currently subsidised by the government. It is noted that this may adversely affect those patients who use codeine products responsibly. In a recent media article a physiotherapist highlighted the challenges around the high levels of opiate prescribing for pain management and the effect of up scheduling could place further pressure on prescribers.

2. NZSMI therefore does not support the up-scheduling of OTC codeine containing analgesics to prescription only and maintains the current scheduling of OTC codeine containing analgesics is appropriate. We do support real time monitoring of OTC codeine containing analgesics to allow the sector to better support and enhance a responsible approach on the use of this analgesic class; to reduce the risk of abuse and provide a platform to educate on safe use.

3. In relation to OTC codeine containing cough and cold products that are currently pharmacy only, the NZSMI position is:

3.1 Cold and flu products typically also contain a decongestant such as phenylephrine in addition to a non-opiate analgesic such as paracetamol. The product indications include pain, however, this is always in the context of, or associated with cold and flu symptoms. These medicines should not be confused with or classed as analgesics.

3.2 There has been no evidence of abuse or misuse of OTC codeine containing cough and cold medicines currently classified as pharmacy only. It is also interesting to note that when recording processes for codeine containing analgesics were intensified there was no concurrent shift to cough and cold preparations as a source of codeine for abuse.

4. NZSMI therefore believes the current scheduling of these products is appropriate and we do not support up-scheduling to restricted medicine or prescription only.

Reasons to differentiate between Analgesics and Cough/Cold preparations

5. NZSMI supports the separation of pharmacy only OTC codeine containing cough and cold products from analgesics and cough and cold products currently restricted medicines. These two categories should rightly be viewed differently and the evidence relating to misuse and potential risk supports this distinction.

6. Pharmacy only cough and cold products have different labelling, different indications and multiple ingredients, which collectively mitigate the risk of misuse. These products should not be conflated with codeine containing analgesics.

7. There is no specific evidence to justify up-scheduling and the scheduling decision should not be made without considering the different labelling, different indications and presence of other ingredients such as decongestants.

8. Sales data on cold and flu products indicates that the product usage is largely seasonal and there has been no indication of any growth in demand since the codeine containing analgesics were part of the intensified reporting system by New Zealand pharmacists.

9. There is therefore little evidence that any change to pack sizes is needed. However, NZSMI does believe that a discussion on improved labelling may be warranted. NZSMI notes the recent research regarding children under 18, those with breathing difficulties, and those who have, for example, had tonsillectomies or similar surgery.

10. NZSMI concludes that improved statements could be added to the current list for both analgesics and cough/cold preparations which includes:

- Do not use for more than 3 days;
- Codeine is an addictive substance;
- Do not use if you are breastfeeding except on doctor's advice;
- This medicine may cause drowsiness;
- If affected, do not drive a vehicle or operate machinery.

11. NZSMI believes further discussion would be valuable around including statements like:

- Do not use in children or adolescence under the age of 18;
- Do not use following tonsillectomy, throat surgery or patients experiencing breathing difficulties.

Pack size reduction

12. There is no evidence that a change to pack size is needed for cold and flu products. Cold and flu medicines are for seasonal use and are used for a condition that is episodic in nature.

13. Limiting the pack size to 3 days may help mitigate against consumers using the product for a prolonged period once purchased for a cold or flu episode and there will be a lesser likelihood of excessive quantities of codeine containing medicine being stored, however, there is no evidence that the use of these medicines has been inappropriate, outside the recommended duration or that stockpiling of these medicines is taking place. It is for this reason that NZSMI would prefer to see increased reporting and monitoring systems established rather than reduction in pack size.

14. It is NZSMI's view that codeine containing cough and cold medicines still meet the scheduling factors for pharmacy only. The medicine is for a minor ailment or symptoms that can easily be recognised and are unlikely to be confused by the consumer with other more serious diseases or conditions. Treatment can be managed by the consumer without the need for medical intervention. However, the availability of a pharmacist at the point of sale supports the consumer in selecting and using the appropriate medicine.

15. Consumers are able to recognise the symptoms of cold and flu and manage their treatment. Cold and flu, as previously stated, are seasonal and episodic in nature and usually there is a short duration of treatment. Consumers typically consult their doctor when they experience persistent cold and flu symptoms or complications and it is well understood by consumers that cold and flu products are used for temporary relief of symptoms as per the label statements.

16. The use of the medicine is substantially safe for short term treatment and the potential harm from inappropriate use is low. The safety of these combination products is well established and there is no evidence of actual or potential misuse or use by consumers who seek codeine. The presence of additional ingredients, such as decongestants, also mitigates risk in this regard.

17. The use of the medicine at therapeutic dosage levels is unlikely to produce dependency and the medicine is unlikely to be misused, abused or illicitly used. There is no evidence of addiction or dependency occurring from codeine used as per the instructions on the label of OTC codeine containing analgesics.

18. It is the NZSMI's contention that the risk profile of these medicines is well defined and the risk factors can be identified and managed by the consumer with appropriate packaging, labelling and consultation with the pharmacist if required. There is a low and well characterised incidence of adverse effects, interactions with commonly used substances or food and contra indications. The safety of these combination products is well established and adequate warnings regarding interactions, contraindications and precautions currently appear on the labelling.

19. It is also contended that the use of the medicine at established therapeutic dosage levels is not likely to mask the symptoms or delay diagnosis of a serious condition. It is important to be reminded of what is trying to be achieved here and NZSMI believes that appropriate labelling and packaging with increased pharmacist involvement in sales and recording can manage risks.

20. It is clear from the previous comments that NZSMI's position revolves strongly around changes being made to the reporting system for codeine containing products. We believe this to be a

common-sense modern and innovative approach to improved primary healthcare. Later detail will be provided under the section of "Intensified Monitoring".

Codeine containing analgesics

21. NZSMI agrees with the current scheduling of codeine containing medicines as restricted medicines and that these are appropriately different to codeine containing cough and cold preparations which are pharmacy only. The restricted medicine codeine containing analgesics should not be considered to have the same risk profile as the OTC pharmacy only cough and cold medicines.

22. NZSMI is prepared to further discuss the net overall value of reducing the pack size of codeine containing analgesics to not more than 3 days' supply and also to include warning labels that codeine can cause addiction, however, it is our preferred position that this change on its own will not prove to be useful in reducing the abuse of codeine containing analgesics. NZSMI contends that a more comprehensive real-time reporting of sales and purchaser data is a far more effective and professionally orientated intervention rather than regulated minimum pack sizes.

23. In the event that a reclassification does take place, NZSMI would wish to work with Medsafe on an implementation plan that does not alarm the public, cause stock piling to occur, put medical practitioners at risk or under pressure and allows for an orderly run-out of existing stocks.

Intensified reporting and monitoring (IRAM) of codeine containing medicines

24. It is a known fact that New Zealand does not suffer from the same extent of codeine addiction and OTC abuse evidenced in Australia. The statement on the pack, required by Medsafe since 2011 "Caution:Codeine use can cause addiction" appears to have been effective in reducing the risk and incidence of codeine addiction in New Zealand.

25. If a real-time recording system were to be developed and compulsorily integrated into New Zealand pharmacy, the overall health benefits could be substantial.

26. NZSMI suggests that a two year moratorium on the rescheduling consideration of codeine containing analgesics to allow the development of a nationwide improved mandatory real-time sales and patient data recording system for pharmacy. The benefits of such a system are plainly obvious:

- Only pharmacists who implement the system would be allowed to sell codeine containing analgesics. Only pharmacists who have completed the mandated educational course will be allowed to sell codeine containing product. This education program will include techniques on motivational interviewing as well as handling those patients where drug seeking tendencies have been uncovered.

- Patients would be clearly informed that due to the nature of this medicine their details are required and are held for recording. This highlights the extraordinary or exclusive nature of this particular class of analgesic and lends weight to the need to carefully follow instructions and warnings.

- While not entirely fool proof, the need to produce unique photo ID, e.g. driver's licence, will make life extremely difficult for those wishing to abuse the system as multiple identities would be necessary.

- Codeine use will be simply and accurately monitored and the reporting system will flag very quickly potential abusers.

- Of more importance, the system will also highlight the over-user who is unintentionally 'abusing' codeine containing analgesics and the reporting system provides an easy opening to allow better patient counselling referral and discussion around a potential health issue that is more than a minor ailment.

- Such a reporting system will also improve the relationship between doctors and pharmacists as patients flagged with multiple purchases will activate a response from one or both health professionals.

- In time the system could also be used for other medicines or medicine classes where current reporting systems are seen as inadequate or fragile. This could lead to a greater ease of SWITCH products being accepted for over the counter sales.

- Discussions have already been held with multiple stakeholders around the development of an IRAM system. These include the Pharmacy Guild, Pharmaceutical Society, Green Cross Health and major manufacturers.

- Excellent progress has been made and all parties agree that they will need to contribute funding to make such a system possible. It is our intention that the Ministry of Health would also be involved in this ground breaking initiative as its benefits could well extend far beyond reporting of codeine sales which in the global scheme of primary healthcare is an extremely small cohort.

27. This most important benefit of the proposed real-time monitoring system is that it will be able to accurately identify consumers who visit multiple pharmacies to access products, allowing pharmacists to provide appropriate information and advice to assist consumers who may be having problems with chronic pain, dependence or misuse. There are no comparable software systems in place that record or identify *"doctor shoppers / pharmacy shoppers"* who may have problems with dependence or misuse of prescription opiates.

28. A new intervention process like this will obviously require a well-structured instructional and educational program to work in tandem.

Data collection and analysis

29. Pharmacists will be able to review any other recent codeine containing analgesic purchases to assist in assessing how to best manage the consumer's request. Information entered into the system will be linked in real-time allowing pharmacy shoppers to be identified and referred to their GP or pain clinic as appropriate.

30. This data will also be collected and reported and will provide valuable usage and metadata for better understanding analgesic use in a broad patient base in New Zealand.

31. The intensified reporting and monitoring also opens the door for better patient education by pharmacists on appropriate use of analgesics, not just codeine containing product. NZSMI would like to discuss with Medsafe, the Pharmacy Guild, the Pharmaceutical Society and major pharmacy marketing groups, along with the Self Care Alliance of New Zealand (SCANZ) on how best to develop a consumer education package around appropriate analgesic use.

Education programme

32. In parallel to the development of IRAM, NZSMI believes that an intensive education programme needs to be developed that covers medical professionals and prescribers, including specialists, pharmacists, pharmacy staff and the general public.

33. NZSMI has had discussions with major manufacturers who are willing to be involved in the construction of a comprehensive education programme and are prepared to contribute funding.

34. NZSMI also believes that an education Programme endorsed by the Pharmacy Council should be investigated for pharmacists who wish to sell OTC codeine. This programme would cover aspects of appropriate prescribing, appropriate diagnosis and questioning of patients seeking codeine based product, education and advice on the value and risks of codeine containing product, the need and reason behind seeking identification from those wishing to purchase and the notification that data will be shared or collated on these products. The training would also cover how to manage those patients who have been identified as potential drug seekers.

35. The strategic planning around this education programme has already begun and a timeframe for development and implementation is being worked on. For this reason, NZSMI seeks the moratorium on the existing scheduling of codeine to allow proper development and implementation of the recording system and education programme and suggests that Medsafe could develop reporting milestones that need to be met to maintain this moratorium.

36. This education package and intensified reporting module that is supported sector wide is a major innovation and potential substantial improvement in the delivery of focused primary healthcare.

Other initiatives

37. NZSMI believes that the model created by this initiative of intensified reporting coupled with specialist and public education is capable of being positively scaled for improved benefit at primary healthcare level. NZSMI would then encourage members to look at their current portfolio of products and suggest those which may benefit from better education and better reporting – Gees Linctus is one such product.

38. Members will also be encouraged to look internationally at modern and innovative products that are available in foreign markets that, with appropriate regulation, would sit well in the New Zealand market provided there is intensified monitoring and specialist education. These products are specific, more effective than many old remedies, are in many case technically and pharmacologically advanced, but have not been made available to the New Zealand market because of regulation and less than adequate OTC systems for safe widespread use.

39. NZSMI believes that affordable access to real-time digital innovation is at hand and should be implemented to provide wider access to the safer monitored medicine sales.

Conclusion

40. NZSMI supports an amended status quo for the classification of codeine containing analgesics – the amendment being that:

    40.1 the existing classification remains for up to two years to allow time for a nationwide comprehensive, real time reporting system be developed to monitor all sales of codeine containing product;

40.2 that the medical profession, pharmacists and the public are the target of an educational programme, funded by all major stakeholders, on the better use of analgesics including codeine containing analgesics

40.3 that regulations are implemented to require that photo ID must be produced by those wishing to purchase codeine containing product and that they agree to usage data being collated

40.4 that an education program be developed and mandated for any pharmacist wishing to supply codeine and

40.5 that all such sales must be recorded on the real time reporting platform at the time of sale.

41. NZSMI does not support any change to the classification of codeine containing cough and cold preparations, but does support continued education of the medical profession, pharmacists and the public around the responsible and appropriate use of these products.

41.1 NZSMI supports the re-evaluation of this position at the end of the two year moratorium on codeine containing analgesics

42. NZSMI believes that reclassification will **not** lead to a better, safer, more informed primary healthcare sector and that far better long-term solutions have been and are being developed. The reclassification will disadvantage those people who do use codeine based preparations responsibly and potentially shift the drug seeking tendency to our medical colleagues. The real time monitoring coupled with education, both mandated, will provide a more evidence based approach and could be included as part of the Pharmacy audit process.

September 29th 2017

29th September 2017

Attention: Medicines Classification Committee (MCC) Secretary

Comments for 59th Meeting of the Medicines Classification Committee (Tuesday 7th November 2017)

Subject: Codeine – proposed reclassification from pharmacy-only and restricted medicines to a more restricted classification

With regard to the agenda items to be discussed at the 59th meeting of the Medicines Classification Committee regarding the classification of codeine, we wish to make the following comments:

1. What education and continuing professional development would be provided to health professionals regarding the sale and prescription of codeine to minimise the risk of misuse and addiction in consumers?

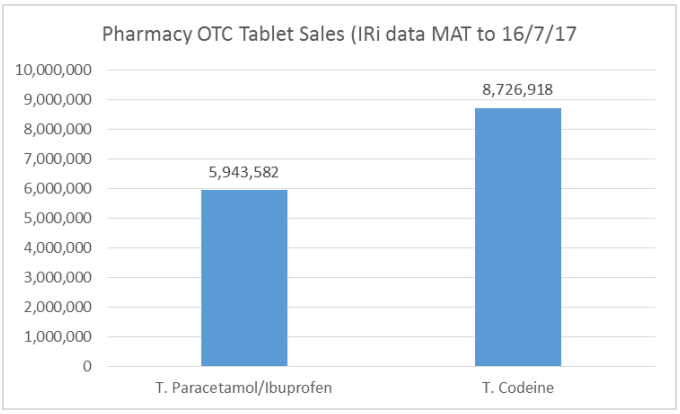
We believe that the most appropriate course of action is to change the classification for OTC codeine products to prescription-only, and then restrict the criteria for PHARMAC funding as it is too readily available given the poor risk/benefit ratio for patients [minimal increase in efficacy versus risks of abuse and misuse].

The risks regarding misuse and potential addiction are well known throughout the pharmacy industry and have been for some time. Further education and professional development would have a limited effect in mitigating the risks of abuse and misuse with at-risk consumers, and a more restrictive classification is a necessary first step in properly addressing this issue.

2. How will the sector fill the data gap with respect to over-the-counter codeine use?

Currently there is only data available for tracking total sales of OTC codeine in Pharmacy (through IRi), however there is currently no coordinated way of tracking individual purchase and use of codeine products to identify at-risk individuals beyond any efforts made by individual pharmacies to do so.

Suitable alternative OTC analgesics to codeine are available and have been for some time (i.e. Paracetamol + Caffeine or Paracetamol + Ibuprofen). While the gap in overall sales between codeine analgesics and these alternative products is slowly closing, the tablet sales of OTC codeine analgesics were still 47% more than Paracetamol/Ibuprofen combinations in the 12 month period ending 16/7/17.



A significant base of codeine analgesic use therefore still remains, and although local data on misuse and abuse is limited, the international experience suggests that many consumers are at-risk through the continued availability of codeine over-the-counter.

3. How will the sector track the sale of codeine in pharmacy in order to better identify consumers with additional needs for pain management and/or addiction problems?

Various possibilities, such as 'real time monitoring', have been suggested to assist in tracking and identifying at-risk individuals. However these measures are largely reliant upon suitable ID, which currently is almost always a Driver's License. It should be noted that it is relatively easy to obtain a falsified driving license, and this is a common practice in order for under-age drinkers to get into bars and pubs. If there is a motivating factor such as codeine addiction at play then the same opportunities exist for these at-risk individuals to circumvent a real time monitoring system.

Findings published in The Lancet in early 2016 highlighted that New Zealand had quadrupled its use of over-the-counter and prescription opioid painkillers such as codeine and morphine in a little over a decade. Furthermore a paper by Brian McAvoy, Malcolm Dobbin and Claire Tobin published in the New Zealand Medical Journal in 2011 (Over-the-counter codeine analgesic misuse and harm: characteristics of cases in Australia and New Zealand) also identified that controls on OTC codeine analgesics in both countries were not sufficient to limit non-medical use of these products. As a result, cases identified in these two countries escalated the number of self-administered tablets taken daily for misuse, resulting in codeine dependence and serious NSAID toxicity secondary to this dependence. The results from the two New Zealand studies used in this report were consistent with the published literature and with the Australian study also used in the report.

In July this year France announced that opioid-derivatives, including codeine, would be placed on their list of prescription-only medicines with immediate effect, and in recent weeks Canada has also followed suit joining the growing number of developed nations that classify codeine in this way. A Toronto Star investigation in 2015 found frequent abuse of codeine in Canada, despite warnings from medical experts for decades about the potential for harm. If New Zealand maintains the status quo with regard to codeine it literally would be out of step with almost all comparable markets.

Recent Australian data further validates the decision to upschedule codeine there from February 2018. Research by NPS MedicineWise found that more than a million Australian's (6%) had taken nine or more paracetamol/codeine tablets in a day at least once, while another 1.2 million (9%) had at least once taken seven or more ibuprofen/codeine tablets in a day. The data showed that 1% of people had taken 16 or more paracetamol/codeine tablets in one day at some point in their lives, and another 2% had taken 13 to 15 tablets.

The National Drug Strategy Household Survey 2016 has also recently been released in Australia with some startling information about the misuse of pharmaceuticals:

- Pain killers/opioids were the most commonly misused pharmaceutical (3.6% of people)
- 3 in 4 (75%) of recent pain-killer/opioid misusers had misused an over-the-counter codeine product in the past 12 months
- 29% used painkillers/opioids weekly or more
- 1 in 10 misusers could not stop using or cut down even though they wanted to

We believe that upscheduling codeine to prescription-only to bring New Zealand into line with other developed nations is the most appropriate course of action, and encourage the MCC to proceed with this recommendation. It may be appropriate to introduce initiatives to further monitor prescription use of codeine and help mitigate misuse, but at the very least the suitability of codeine for individual patient use should be assessed by a doctor and prescribed at their discretion. We reiterate that tightening of funding criteria for codeine seems to be a suitable further action to consider.

Yours sincerely,

Medicines Classification Committee

C/- Medsafe

Ministry of Health

Wellington

29 September 2017

Dear Sirs/Madams

RE: Consideration of codeine for reclassification

I write to thank the MCC for giving consideration to the problem of over-the counter codeine misuse and dependence in New Zealand, and to offer a submission on the options being considered by the committee. I commend the committee's request that the pharmacy sector provide information on how it may be able to mitigate the harms associated with codeine misuse.

My background is as a pharmacist working within Australasia's largest addiction service (Community Alcohol & Drug Services, Auckland) for over 15 years. I have also completed a specialist Masters in addiction studies and am currently undertaking a Doctorate with the University of Auckland, investigating pharmaceutical opioid dependence. I continue to have professional relationships with opioid dependence treatment providers throughout New Zealand since leaving the treatment sector.

It is my view that an effective real-time monitoring package which was mandated to be used with the sale of codeine would greatly diminish the harms associated with its use. A study of OTC codeine dependent cases in Australasia found that an average of 49-65 tablets per day were being consumed by those who presented for treatment for codeine dependence[1].

With a real-time monitoring system, these individuals would not have been able to access such large volumes of medicines and their dependence may either have not developed or would have been much more likely to have been picked up by a health professional in its early stages. The people in this case series had all suffered serious health consequences of their codeine misuse due to the regular ingestion of significant doses of ibuprofen and paracetamol.

To be successful, the real-time monitoring system must be mandated. When implemented, it should be accompanied by education of pharmacists and GPs, and include collaboration with addiction services, as there may be a significant number of people needing referral, advice and treatment because of their current access to OTC codeine being suddenly restricted. A small French study found around one sixth of people purchasing OTC codeine met clinical criteria for dependence [2]. The generalisability of this finding to the NZ context may be limited due to cultural differences around OTC medicine use and the population being sampled, however it highlights the point that we currently have no knowledge of the potential size of the problem in this country.

It is my view that pharmacists are well placed to identify and provide assistance to people who develop pharmaceutical opioid dependence, provided they are given support to further develop their competence and confidence in managing this problem. I would strongly support tying pharmacist education to the ability to sell codeine. (In the interests of transparency, I

have been approached to provide assistance to the development of any required education for pharmacists, and am happy to do so). Consumer information, perhaps in the form of a leaflet, and information for GPs disseminated by an agency such as BPAC would also be necessary to have in place at the same time as a monitoring system is implemented,

I would further urge the committee to consider that there may be an increase in the misuse of OTC Gees linctus in response to the restrictions placed on OTC codeine sales. I have spoken to people in the course of my research who access Gees linctus when other opioids become unavailable to them, and addiction services commonly see people who supplement their opioid consumption with this product.

It is therefore my view that a real time monitoring system should also monitor the sales of Gees linctus, and need not be restricted to opioid products but could also include other misused OTC medicines such as cyclizine.

If the committee would like any further information, I am happy to provide this.

Yours faithfully

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2 Roussin A, Bouyssi A, Pouche L et al. Misuse and dependence on non-prescription codeine analgesics or sedative H1 antihistamines by adults: a cross-sectional investigation in France. PloS one. 2013;8(10):e76499. doi: 10.1371/journal.pone.0076499

26 September 2017
Secretary Medicines Classification Committee
Medsafe
Wellington

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

Dear Sir/Madam
Re: Agenda for the 59th Meeting of the Medicines Classification Committee

Thank you for the opportunity to provide feedback on the agenda for this meeting. This feedback concerns **item 5.3 Codeine** – the proposed reclassification from pharmacy-only and restricted medicines to a more restricted classification.

I am opposed to a reclassification of codeine-containing products that would reduce direct access through a pharmacist. I would, however, support the reclassification of all codeine-containing products to pharmacist-only.

As a proprietor of a community pharmacy in Greymouth, I see on a day-to-day basis the trouble our patients have accessing appointments in general practices. Due to the shortage of GPs in areas such as ours, waiting times for appointments can range from days to weeks. Dental appointments are also difficult to obtain at short notice. Restriction beyond pharmacist supply would impose additional workload on these practices and, due to the high reliance on locum GPs, could lead to prescription of higher strength codeine or more potent opioids for those with acute pain. Health services in this community are stretched without this additional burden.

Our pharmacy has, for a number of years, treated all codeine-containing products as pharmacist-only medicines, requiring supplies to be recorded in the point of sale system against customers' details. This provides pharmacists the opportunity to track sales to individuals, intervene to prevent supply or suggest an alternative course of action. This responsibility is taken very seriously, in accordance with the profession's Code of Ethics. As an increasingly elderly population with multiple morbidities seeks pain relief, inappropriate use of non-steroidal anti-inflammatory agents could result from more restricted access to codeine-containing products.

While health professionals in smaller centres may work closely together, the lack of information sharing across New Zealand means customers can seek codeine products from multiple pharmacies and practices. Repeated purchases from our pharmacy are easy to detect but we do not know if a customer has made a purchase, or indeed filled a prescription, elsewhere.

The implementation of a real-time recording and monitoring system developed by sector organisations has my support. Allowing pharmacists to track sales of codeine-containing products would better identify consumers with additional pain management needs or addiction problems. I would support use of such a system being a mandatory requirement for any pharmacy wanting to supply codeine-

containing products. Such a system could also be used to monitor opioid prescribing and dispensing.

I also understand that sector organisations are working together to ensure there is adequate training and education in place for pharmacists and their support staff. Pharmacists, as medicines experts, are well aware of the risks associated with codeine use. Dealing with patients with addiction issues, however, can be difficult. Training in the management of and communication with patients identified as problematic users of codeine would be welcomed by pharmacists and other health professionals alike. I would agree to an accreditation programme in order to supply codeine-containing products to ensure our customers could receive appropriate and timely care. This would sit well with opioid substitution services currently provided by pharmacies.

I would encourage and appreciate a public information campaign promoting the safe use of codeine – from any source. This would create a level of public awareness for consumers around the risk of codeine misuse and addiction, promote the appropriate use of codeine and empower consumers with a pain management problem or codeine dependence to seek help.

I understand sector organisations have requested a two-year suspension in the rescheduling of codeine-containing products to allow time to implement a real-time monitoring system and pharmacist training programme. I support to this time-frame request.

Thank you for considering my feedback

If you have any questions about my feedback, please contact me on 03 768 4075 (work) or 021 162 3817 (cellphone).

Yours sincerely

Julie Kilkelly
Pharmacist/Co-owner
Unichem Olsens Pharmacy

PHARMACEUTICAL SOCIETY
of New Zealand Incorporated

29 September 2017

The Secretary
Medicines Classification Committee
via email: committees@moh.govt.nz

Dear Secretary

Re: Agenda for the 59th Meeting of the Medicines Classification Committee

Thank you for the opportunity to submit comments to the 59th MCC Meeting agenda.

The Pharmaceutical Society of New Zealand Inc. (the Society) is the professional association representing over 3,000 pharmacists, from all sectors of pharmacy practice. We provide to pharmacists professional support and representation, training for continuing professional development, and assistance to enable them to deliver to all New Zealanders the best pharmaceutical practice and professional services in relation to medicines. The Society focuses on the important role pharmacists have in medicines management and in the safe and quality use of medicines.

Minutes of the 58th Meeting of the Medicines Classification Committee

Before we offer our comments to the agenda items for the 59th MCC meeting in November, we would like to comment on the minutes of the 58th MCC meeting held in May of this year, as published on the Medsafe website.

6.5 Change in classification wording of lansoprazole, promethazine, sumatriptan, ibuprofen, omeprazole, pantoprazole, opium, phlocodine and ranitidine – proposed change in classification wording (Pharmaceutical Society of New Zealand)

We would like to note our disappointment and objection to the minutes which state that "Further information from the Pharmaceutical Society of New Zealand had not been received". In addition to this statement in the minutes, a letter had been received from the Acting Chair regarding this item in follow up from the May meeting.

The Society had indeed submitted further information to MCC in our letter dated 31 January 2017. However, we understand this submission was rejected by the Chair without being tabled for the Committee's consideration. As a matter of record, we include a copy of this submission. We reiterate the points made in this letter and note our frustration that the Committee's perceived safety benefits from original pack labelling are overstated, and in some respects incorrect. As has been outlined in previous submissions to the Committee, there are patient and public benefits from being able to supply smaller quantities of these medicines. This is also managed very appropriately by pharmacists, who are already utilising this regulatory permission for a number of other medicines.

We therefore withdraw the application for the proposed change in classification wording, and will seek to resolve our concerns outside of the prolonged time-course between MCC meetings.

6.1 Codeine – proposed reclassification of the pharmacy-only medicine entry to a more restricted medicine classification (Medsafe)

The Society would like to comment on some statements made in the minutes of this item from the 58th meeting:

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1. *"Codeine is also a controlled drug regulated under the Misuse of Drugs Act 1975 and the Committee questioned whether it should be available in an over-the-counter category at all."*

The statement about being "regulated under the Misuse of Drugs Act 1975" is technically correct. However, the context of this statement used in the remaining sentence is perhaps spurious, as codeine is classified as an "*exempted* drug" under the Misuse of Drugs Regulations 1975, when in combination with another active substance. We note pholcodine, diphenoxylate (antidiarrhoeal) and low strength opium (eg. Gees Linctus) also fall under this status as an "exempted drug" under Part 6 of Schedule 3 of the Act.

2. *"Other opioids were the most tracked medicines in New Zealand yet there was no existing tracking system for codeine."*

As mentioned above, codeine is classified as an "exempted drug" when combined with another pharmacologically active ingredient, and it is not the only opioid falling under this classification. Outside of its "exempted drug" status, codeine is classified as a Class C controlled drug in Part 2 of Schedule 3 of the Misuse of Drugs Act 1975.

Class C controlled drugs are granted certain regulatory exemptions for their prescribing, supply, handling and storage compared to Class B controlled drugs such as morphine, pethidine, oxycodone etc. However, the minuted statement above is again somewhat spurious in comparing over the counter codeine (as an "exempted drug") with codeine itself (as a Class C controlled drug) with the more restricted (and "tracked") opioids which are Class B controlled drugs. In comparison, benzodiazepines (Class C controlled drugs) are not "tracked", nor is tramadol or zopiclone; however we understand the Expert Advisory Committee on Drugs (EACD) is reconsidering the classification of the latter two.

3. *"Reclassifying codeine to prescription would send a message to prescribers. General practitioners could reconsider their current approaches to prescribing codeine and aim to reduce the prescription rates of codeine given its limited effectiveness in the majority of the population compared with other analgesics."*

What is not clear from the minutes is whether this statement is referring to the prescribing of codeine or codeine combination products. Anecdotal and published studies demonstrate considerable challenges in managing pain and prescription drug misuse in primary care[1,2,3], as expressed by GPs themselves. We question the use of a medicine classification for "sending messages", and would suggest this to be an ineffectual method for forcing practice change in the complex area of pain management; particularly considering recent experiences with inappropriate prescribing and management of oxycodone use in New Zealand.[4]

The poor understanding to how pain management is approached can be illustrated by the recent profile of oxycodone prescribing in New Zealand. On the background of dramatically increasing numbers of patients being prescribed oxycodone, PhamHouse data published in 2011 showed 30% of prescriptions were initiated in general practice, 70% initiated outside general practice, with 17% of that continued by GPs.[5] Concerns with the appropriateness of oxycodone prescribing in primary and secondary care led to major campaigns to raise awareness that it is not appropriate to use first-line.[4] The campaign highlighted how a multidisciplinary education and awareness campaign across primary and secondary care can be used to address actual or perceived issues with rationalisation of responsibilities including who initiates or continues analgesic treatment.[4] The campaign focussed on oxycodone use demonstrated benefits in reducing prescribing rates.

Aside from the present consideration being given to combination codeine products, the Society contends that an overall "message" to all prescribers, pharmacists, nurses, and all health professionals, should be a focus on the appropriate management of pain in the context of that professional's scope of practice. This would include a low threshold for referring patients or seeking advice for more complex care, assessment or diagnosis. Patients with chronic pain

are reported to have poorer quality of life and are five times more likely to visit emergency departments.[6] A UK editorial highlighted the need to undertake a strategic multi-level promotion of the role of pharmacists in chronic pain management, that extends to GPs, physiotherapists, nurses and patients.[6]

Minutes of the 59th Meeting of the Medicines Classification Committee

Regarding the agenda for the 59th Meeting of the Medicines Classification Committee, the Pharmaceutical Society of New Zealand would like to make the following comments:

5.3 Codeine – proposed reclassification from pharmacy-only and restricted medicines to a more restricted classification

At the 58th meeting, the Committee recommended that the sector would need to answer the following questions to allow codeine to continue to be available without prescription:

1. *what education and continuing professional development would be provided to health professionals regarding the sale and prescription of codeine to minimise the risk of misuse and addiction in consumers?*
2. *how will the sector fill the data gap with respect to over-the-counter codeine use?*
3. *how will the sector track the sale of codeine in pharmacy in order to better identify consumers with additional needs for pain management and / or addiction problems?*

The Committee will consider any information received from the sector before making a recommendation on the reclassification of codeine.

The Pharmaceutical Society acknowledges the potential of harm arising from misuse of, and dependence on, combination codeine products. For those affected, there is a significant potential for risk. However, the risk must be considered in the broader context of appropriate use of these products, the factors determining why patients seek their use or commence on them, and how this may lead to misuse and abuse.

The Society considers the current concerns expressed internationally with respect to inappropriate use of codeine-combination products is not specifically a "pharmacy problem", nor a 'problem' from the medicine classification, nor is it an issue specifically related to codeine-combination products. The Society contends the targeted focus on the supply of combination-codeine products through pharmacies does not address the primary problem of poor pain management.

In response to the questions raised by the Committee:

1. *What education and continuing professional development would be provided to health professionals regarding the sale and prescription of codeine to minimise the risk of misuse and addiction in consumers?*
2. *How will the sector fill the data gap with respect to over-the-counter codeine use?*
3. *How will the sector track the sale of codeine in pharmacy in order to better identify consumers with additional needs for pain management and / or addiction problems?*

The Pharmaceutical Society has a long-standing role in developing and delivering education and continuing professional development (CPD) to the pharmacy profession. Over recent years, this has included sessions covering pain management, drug dependence, and managing "drug seekers', among others.

The Society recognises our specific role in developing further targeted education and practice support resources for the profession in the appropriate assessment and management of pain, in the context of pharmacy practice. Including, but not limited to determining the expected cause of pain, the pharmacological and non-pharmacological options for managing pain, and developing a management plan with the patient that outlines expectations of treatment and strictly observed criteria for referring to the GP.

Considering the wider problematic issues with the management of pain in New Zealand, education and continuing professional development must be available for the entire health sector AND public, as part of an awareness campaign. This should involve the professional organisations, Ministry of Health, ACC, and Health Quality Safety Commission in the very least. Further to education and CPD on pain, the same is also required for the prevention, assessment and management of dependence and prescription medicine misuse. Similar to public health messages highlighting the inappropriate use of antibiotics for coughs and colds, a similar campaign is required around managing pain.

The Society believes that reclassifying codeine combination products to a prescription medicine status would just shift the management of these patients to general practice, which is already stretched. Or, patients would seek to use or borrow unused supplies prescribed for friends or family members.

Sharing of prescription and OTC medicines, including analgesics is highly common[7,8,] with one study noting 76% of people in studied focus groups admitting to sharing of prescription analgesics.[9] A further study of 254 Australians with arthritis noted many self-manage their pain with prescription and/or OTC analgesics, and almost 30% indicating that they had or intended to borrow or share their OTC analgesics.[8]

The reasons for sharing medications in New Zealand was recently explored by a group from the School of Pharmacy at the University of Auckland.[10] The study found the perceived benefits and factors that influenced sharing medicines included:

- Saving time and money by avoiding doctors' fees and prescription charges, and the burden associated with medical visits such as appointments and transport.
- Some saw it as preventing waste of resources.
- Sharing as a form of social support.
- Altruism – the desire to help others, particularly influenced by past experience.
- Sociocultural factors – where getting medicines was difficult through communication or cultural differences, or through embarrassment.
- Having leftover/unused medicines was noted by many, some criticising their doctors for prescribing surplus to need, including the very telling quote:

"Sometimes I have a really bad back problem and so for a little while I went to a back person [doctor] and I think they're very negligent. He gave me a million tramadol, you know, it was like so much and they just give you these giant prescriptions…"[10]

Pharmacists often recognise the inappropriate use of combination codeine products requested over the counter (OTC), as well as OTC and prescribed analgesics in general. Pharmacists are also often aware of some individuals who are "pharmacy shopping" or "doctor shopping", and while they have certain permissions to raise awareness in some cases, there are no nationally coordinated mechanisms for tracking sales or requests.

Pharmacists are not currently required to document OTC supply of medicines to existing electronic shared care records such as Testsafe or HealthOne, however some do. With respect to prescribing, the NZ Electronic Prescribing Service (NZePS), where used, *should in theory* be able to provide data about the prescribing of medicines. The Society would support the Ministry of Health actioning this, and appropriately utilising this data.

The Pharmaceutical Society supports real-time monitoring of prescribing, dispensing and over-the-counter supply of medicines. The use of a real-time monitoring system would allow for tracking of excessive use or supply of at-risk medicines, and support education to improve practice.

The recording requirements for Restricted Medicines are mandated by regulation, and has been electronic since computer-based dispensing systems became standard in pharmacies.

In many respects, the supply of codeine-based products (classified as Restricted Medicines), is already captured electronically. What is missing is the connectivity of these systems so that supply is visible in real-time, between different sites.

The Society has seen a tool in Australia used to record and monitor the supply of OTC codeine-containing products called MedsASSIST. The system is able to provide prompts to question the therapeutic need for treatment, and provides decision support for pain management options and triggers for medical referral. Requiring photo-ID is a common process for managing drug-seeking in community pharmacy. Identifying information and consent to record can be made a mandatory requirement for supply of these products through the MedsASSIST system (details required for the supply of Restricted Medicines anyway). When ID and supplies are captured as part of a real-time networked system, this will immediately highlight drug-seeking behaviour. Or equally, with legitimate clinical use, if the short-term supply has provided inadequate treatment or pain is on-going, the system can prompt further questions and/or a recommendation for medical referral. This supports good clinical decision making, while minimising the risks associated with poor pain management and the potential for misuse or the development of dependence.

In the absence of a Ministry-introduced real-time monitoring system, The Society would support the use of tools such as MedsASSIST. But would advocate the cost of purchasing and implementing such systems should be supported by the Ministry and/or DHBs. Ideally these systems should be integrated with existing dispensing (and prescribing!) systems, to enable the real-time monitoring of prescribing, dispensing AND OTC supply of not only combination-codeine products, but at-risk prescription medicines such as tramadol, oxycodone, benzodiazepines etc - which may already exist within the NZePS.

As noted above, pharmacists commonly identify people they are concerned are dependent or potentially misusing medicines, including codeine-combination products. While a large-scale, sector wide education and awareness campaign could enable these people to be identified and referred to their GP, such a programme would require an integrated care approach to define the roles and activities of all involved.

The Society strongly supports the development of an interprofessional pain management programme, that utilises the skills and scopes of practice of all applicable health professionals. We see this potential programme being developed using the Integrated Health Care Framework for Pharmacists and Doctors, co-developed by the Pharmaceutical Society and NZ Medical Association.[11] Due to the large-scale requirements needed by this programme, it should be developed with the support of the Ministry of Health, ACC, HQSC, professional bodies and colleges, and consumers for it to be a patient/whānau-centred model of care. For such a programme to be effective, and meet the overall needs for a pain management programme, it would require the input and participation across the primary and secondary care interface. This is the approach needed to address the problem of inadequate pain management, inappropriate prescribing of opiates, and inappropriate OTC supply of analgesics, including codeine-containing products.

The Society notes the patient-centred interventions identified in a Canadian study[12] looking to improve the management of chronic non-cancer pain in primary care, that:

- Awareness and education are keys
- Patient empowerment is the overarching priority
- Interdisciplinary collaboration is necessary for better care: noted examples included pharmacist-nurse collaboration, pharmacist-led interventions such as medication reviews, and greater collaboration between the medical profession and enhanced utilisation of non-medical professions.
- Partnerships are essential to ensure access to care

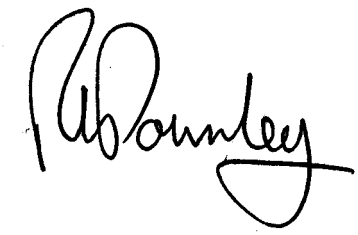
Similar sentiments have been raised in other studies, which also highlight that the vast majority of patients with chronic pain are managed in primary care.[13] There is therefore a considerable opportunity for an active and meaningful contribution of the pharmacist in an integrated care approach to supporting the management of patients with pain.

Pharmacists are readily available to patients to provide high-quality advice on over-the-counter analgesia, and are effective in identifying at-risk patients and providing appropriate management. A recent Australian study sent mystery shoppers posing as patients taking warfarin into 170 pharmacies.[14] All pharmacies recommended OTC analgesics that were less likely to cause harm when taken with warfarin (i.e. containing an NSAID), and the quality of communication was high. This study demonstrates the appropriate role and responsibility for pharmacists to manage simple pain concerns.[14]

In summary, The Society considers that the present consideration being given to up-scheduling combination-codeine products to 'prescription medicine' is not going to address the concerns related to the development or "maintenance" of dependence or NSAID toxicity. The underlying cause of the inadequate management and support for people with pain, from short-term acute to chronic pain, requires a system-wide, collaborative approach. Education and guidance for all health care professions, particularly prescribers, pharmacists, nurses, physiotherapists and dentists. Individualised pain management plans describing expectations and a pathway of care need to become standard care. The plans would define expectations of resolution or improvement in symptoms, monitoring and criteria for referring to other providers. The system-wide, collaborative approach to the management of New Zealanders with pain can be supported by better use of our existing electronic shared care and medication record systems, as well as the use of real-time monitoring systems such as MedsASSIST. The Society is supportive of standardising all codeine-combination products to a 'Restricted Medicine' classification, as described in our submission to the 58th MCC Meeting in May.

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

Yours sincerely



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Patent Blue is an approved food colouring substance. It is used in foodstuffs, so it is already being consumed in unknown quantities, depending on how much of a foodstuff that contains the colour is eaten.

It is a food colouring substance approved by the Food and Agriculture Organisation (FAO).
See FAO JECFA monograph: http://www.fao.org/ag/agn/jecfa-additives/specs/monograph5/additive-304-m5.pdf

It is an approved colouring substance for oral and external use on Medsafe's list of approved colours for medicines, and on the TGA's list of approved colouring substances for oral and external use.

It is a proposed permitted substance on the Ministry of Health's draft Permitted Substances List for the Natural Health Products regulatory scheme. This is a list of substances considered to be safe for use in natural health products, under the proposed Natural Health Products regulatory scheme.

There are three substances on the Permitted Substances List that would be affected. These are:
Patent Blue V
Patent Blue V aluminium lake (there may be other lakes possible)
Patent Blue V sodium salt

The draft Permitted Substances List can be accessed at:
http://www.medsafe.govt.nz/regulatory/PILSearch.asp

The Natural Health Products Bill can be accessed at:
http://www.legislation.govt.nz/bill/government/2011/0324/latest/DLM3984610.html?search=ts_bill_natural+health_resel_25_a&p=1

If Patent Blue V becomes scheduled as a Prescription Medicine, it will also not be available for use in cosmetic products or for industrial use. This is because a prescription would be necessary in order to obtain a prescription medicine.

Making Patent Blue V a prescription medicine will affect its availability for use as an approved colouring substance for use in foods, medicines, related products, cosmetic products, natural health products, and other possible industrial products.

28 September 2017

The Medicines Classification Committee
Medsafe
PO Box 5013
Wellington 6140

Dear Committee Members,

Re: MCC meeting number 59, codeine and meningococcal vaccine

Item 5.3, Codeine

We wish to congratulate the Medicines Classification Committee on their ideas of education and monitoring with codeine. The agenda item read that:

> *At the 58th meeting, the Committee recommended that the sector would need to answer the following questions to allow codeine to continue to be available without prescription:*
>
> 1. *what education and continuing professional development would be provided to health professionals regarding the sale and prescription of codeine to minimise the risk of misuse and addiction in consumers?*
> 2. *how will the sector fill the data gap with respect to over-the-counter codeine use?*
> 3. *how will the sector track the sale of codeine in pharmacy in order to better identify consumers with additional needs for pain management and / or addiction problems?*
>
> *The Committee will consider any information received from the sector before making a recommendation on the reclassification of codeine.*

We have therefore focused only on the items above in this submission.

At Green Cross Health, we believe that the implementation of both real-time monitoring and education will resolve the concern about overuse of non-prescription codeine-containing analgesics. Real-time monitoring addresses the challenges the health sector has of IT systems that do not interface resulting in the difficulty pharmacists experience in needing to make a judgement call on a particular person usually with very limited knowledge of whether or not they are making purchases elsewhere in excess quantities. Education will maximise the ability of pharmacists to screen for and identify dependence using the real-time monitoring system, and manage it as well as possible if found, to ensure patients get the help they need.

A report by Turning Point in Australia in 2010[1] stated that there was a need to enable pharmacists to respond effectively to the problem of OTC codeine. Pharmacists were considered to be able to *"play an*

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important role in raising general awareness regarding potential OTC codeine dependence and harms." However, it was recognised that legislative change and education were required.

1. Education

We agree with the Medicines Classification Committee that education is vital. Education of pharmacists will help to limit codeine dependence, identify dependence, counsel patients to avoid dependence, and manage likely cases of dependence in a way that is most likely to see the person take up a referral to a GP or addiction service. In particular, there is a risk that patients who are turned away without advice could try to purchase outside of pharmacy, including illicit purchase, and/or go to doctors for codeine. Pharmacists need to be approachable and deal with anyone in whom they suspect addiction in a way that is supportive and with messages that are right for the individual requesting the medication.

One pharmacist spoken to regarding this submission noted that he had persuaded two people with likely dependence to seek help, with opioid substitution therapy started as a consequence. The rural pharmacy he worked in was key to identifying dependence, as patients were more limited in their ability to shop around. His approach also worked well given that one patient was in denial and angry when it was first raised, but returned three weeks later for further advice from the pharmacist, which he followed. However, these interactions can sometimes be challenging, particularly if the patient is not well known to the pharmacist or in denial. The pharmacists spoken to acknowledged that education on this would be helpful, particularly for less experienced pharmacists.

> *"Education would be really great. I'm not always comfortable with these conversations, so that would really help."* Pharmacy Manager, Auckland

> *"It is difficult for younger pharmacists to handle. Education is a great idea. How to deal with it, where to refer people."* Pharmacy Manager, North Island small town pharmacy

The Australian research and report by Turning Point in 2010[1] highlights that the pharmacist interaction was key for some people in highlighting that they had a dependence and getting them to seek treatment for this dependence. It also recommended upskilling the workforce, both pharmacists and doctors for earlier identification of dependence and how to manage it.

An education session for pharmacists on OTC codeine was held in early 2017 by the Auckland branch of the Pharmaceutical Society, with Carina Walters as the speaker. This session was well attended, with positive feedback by pharmacists who attended. The education we propose is outlined below.

Changes in availability through the monitoring needs to be supported through education for health care providers in general practice (e.g. through a BPAC update) available shortly before the change so that general practice can identify and manage codeine dependency as well as possible. GPs and nurses would benefit from being informed of the change in advance through multiple communications (e.g. medical organisations, NZ Doctor, BPAC). Information to emergency departments and after hours medical clinics would also be useful at the time of the change. Australian researchers identified the need to educate doctors about codeine dependence.[1]

Patient education is also useful. Having a patient handout available to explain the new system, the potential for dependence and what to do if they think they or someone they know may be dependent. This could be developed and available on-line for pharmacists to print.

Green Cross Health has an NZQA accredited on-line training platform that could be available to all Community Pharmacists (even those outside the Green Cross Health network) and extended teams

where appropriate. We intend to use it to provide education to pharmacists that would meet the requirements of the Pharmacy Council's medicines reclassification framework criteria. We would use experts in the area, including Carina Walters, who is a pharmacist with extensive experience in addiction services and a PhD candidate examining pharmaceutical opioid dependence. We would expect to include the following information:

- Typical patterns of codeine dependence
- Identifying dependence (e.g. what usage suggests dependence has occurred or may be developing)
- Screening for dependence
- Harms associated with codeine dependence including clinical effects of overuse of combination products
- Opioid withdrawal and dependence support
- Referral pathways
- Stages of change
- Motivational interviewing/having difficult conversations
- Preventing addiction to codeine

While the training could be expanded to include pain relief generally, we do not recommend this. We want to ensure that the key messages on codeine and identification and management of dependence are not overwhelmed by other information.

We recommend that the training is mandated, i.e. that all pharmacists supplying this medicine have completed training that meets the requirements of the Pharmacy Council's medicine reclassification framework criteria.

2. Data gap

It is proposed that the data gap be filled through reporting to the MCC from the monitoring system (see below).

3. Monitoring

A nationwide on-line monitoring system could be mandated in the gazette notice. Such a system would use specified photograph ID, e.g. Drivers Licence, Passport or 18+ ID, making purchase under fake names very difficult. The system would likely work in "real-time" – that purchases are immediately available when entering a person's name and identification, from anywhere in the country, and even if it occurred in the last five minutes.

Monitoring that is mandated will mean that only pharmacies signing up to the system will be able to supply the medicines, and that recording will have to occur for all non-prescription purchases of codeine-containing medicines (and possibly Gee's linctus, see below).

Possible monitoring options include the MedsASSIST program from the Pharmacy Guild of Australia. We have viewed this program and consider it to be workable for NZ. Another possibility might be the electronic prescribing service.

Having nationwide monitoring of supplies would provide pharmacists with an indication of overall usage a person has, providing exactly the information that the pharmacist is currently missing. It would very quickly indicate usage above the recommended daily dose, regular usage within the recommended daily

dose (with a potential therapeutic dependence), or escalating usage which could be addressed as soon as it is identified. Such early detection, and the knowledge of the monitoring will prevent new addictions. It will indicate anyone with a current dependence very quickly after the system is implemented. Alternatively, it will encourage someone with a dependence to seek help rather than be identified on the system. Many people with an OTC codeine dependence are thought to be unaware that they are dependent.[1] There is a difficulty for some patients who are dependent with daily use where they can think they are medicating pain but it is actually opioid addiction.[1] For example, the headache is not recognised as medication overuse headache or opioid withdrawal. These people will be identifiable with this monitoring system and pharmacist education.

Towns and cities typically have multiple pharmacies so health care consumers can visit many different pharmacies for their OTC codeine needs. Where pharmacies are open extended hours, staff changes may add to the difficulty of identifying potential misusers. A mandatory nationwide system would immediately overcome these challenges.

The vast majority of people who take codeine-combination analgesics have occasional use without dependency on opioids. Pharmacists have to decide on the appropriateness of supply for these people without the evidence they need. This leads to people with a genuine reason for purchase feeling sometimes that they are being interrogated, and being turned down for supply inappropriately, with considerable potential for offence. It also will lead to people who appear genuine (and many do genuinely have pain conditions)[1] having an unidentified dependency and continuing to be supplied for some time.

Some pharmacies have only sold codeine-containing products with the provision of patient ID. This helps to track within store sales to an individual, avoiding the provision of false details, and has been off-putting for people who are not using the products as intended. However, it has created some patient complaints. One pharmacist working in a pharmacy where ID has been required for supply of OTC codeine-containing products reported that the Pharmacy Council had received a complaint from a patient expressing privacy concerns. A mandatory system would overcome such concerns. Patient handouts to explain it will be vital to aid the implementation.

The monitoring system can also be a trigger for counselling by the pharmacist for all patients in the fact that dependence can occur and therefore not to take on an ongoing basis.

Australian evidence

A nationwide real-time monitoring system for codeine-containing OTC medicines was started in Australia by the Pharmacy Guild of Australia in March 2016. The use of MedsASSIST is voluntary for pharmacies, and the pharmacist can enter a patient name and identification and then check the patient history in real-time and see other OTC codeine purchases. The Guild reports that 72% of pharmacies are voluntarily using MedsASSIST.[2] An independent analysis of 49 pharmacies in Western Australia found a 31% reduction in OTC codeine products in the July to December 2016 period versus the matching time period one year earlier.[2] From the 9 million transactions in MedsASSIST, pharmacists identified potential dependence issues (purchase more than once a month) in 168,000 instances, and counselled the patient. There were around 180,000 cases of no supply. The reduction in supply reported by the Pharmacy Guild has been confirmed separately by QuintilesIMS who track pharmacy sales data. They reported in May 2017 a decline of 20% in codeine containing OTC products.[3] Their smaller decline than the Guild data could arise for several reasons. The QuintilesIMS data may have included some data from pre-MedsASSIST or in the early days of MedsASSIST, it may include prescribed supplies of codeine-combination analgesics (and the Guild data would not), and/or not all pharmacies have been

using MedsASSIST. It is a shame that Australia was not able to mandate this system to resolve the issue.

A survey of 585 codeine analgesic purchasers in pharmacies in Australia found that 93% would support pharmacists supplying codeine without a prescription under strict requirements including real-time monitoring.[2] This is consistent with the Turning Point research in 2010.[1] We would expect a high level of support from consumers in NZ also.

Pharmacist feedback

We have spoken to a number of our pharmacists in in-depth 20 minute discussions, and found very strong support for the use of real-time monitoring. Quotes include:

> *"The real time thing – it will stop it."* Auckland city pharmacy employee
>
> *"That would be fantastic…. It would give you confidence you are not being spun a load of nonsense. We always suspect is this story truthful?"* [redacted] pharmacy owner, [redacted]
>
> *"I'd be very happy to do that in fact I'd like it. I can't see a downside, it would help us."* [redacted] suburban pharmacy owner, Auckland
>
> *"That is a good step to be honest."* [redacted] employee in a small town pharmacy.
>
> *"That's definitely the way to go."* Rural pharmacy owner.
>
> *"Young pharmacists can be so paranoid it becomes almost a gestapo interrogation."* Pharmacist in a mall pharmacy.

These pharmacists were strongly supportive because they really appreciate this solution as helping their staff identify potential overuse and assist clients in terms of identification of potential overuse at an early stage, and prevention of opioid addiction. They also appreciate how the system will help them and other pharmacists in easier management of the many purchasers for whom it will be clear there is no overuse. Pharmacists have generally had to be suspicious of many purchasers, which has clearly caused some offence to patients and a real challenge for pharmacists.

Some pharmacists volunteered that they thought the problem had reduced in their area over recent years, because of the questioning in the pharmacy and times when it has not been supplied to a requester. However, these pharmacists still wanted the monitoring system to help ensure they were picking up any dependence early. This is particularly relevant when considering that people with OTC codeine dependence know that when they put in an effort to look respectable (e.g. wearing a suit and tie) and answer the questions right they will be more likely to be sold the product as they appear legitimate.[1]

Some different reasons for people taking excessive OTC codeine identified in Australia were:[1]

- initiating use for pain then transitioning to high dose use after identifying euphoric effects, or finding their anxiety or stress decreased
- initiating for pain and having to increase dosing when the pain was no longer responding
- Initiating use for recreational purposes and developing a high dose dependence
- Transitioning from prescription opioids (under medical supervision) to OTC codeine.

In all three cases the monitoring system would pick up the problem use early.

The system will also aid pharmacists to be always vigilant. Additional to the following of the consumer, the pharmacy sales will also be recorded, allowing a pharmacy with outlying sales to be identified. Furthermore, if any concern existed, the monitoring records could be matched by Medicines Control with wholesaler purchase records for that pharmacy to ensure all sales are recorded.

Medicines covered

We suggest that all non-prescription codeine-containing medicines have mandated real-time monitoring. While cough-cold codeine-containing medicines do not currently have concerns around overuse, monitoring the codeine-containing analgesics could see a move to the cough cold medicines if they were not also put in the same category.

We also suggest that Gee's Linctus also has mandatory monitoring in the same way. Information from pharmacists is that Gee's Linctus has had increasing requests with the pharmacy-only pack becoming available, and there is the potential for someone to move from codeine-containing medicines to Gee's linctus.

Prescribed opioids also lead to dependence, sometimes even starting the dependence that is continued with OTC codeine, or being used in conjunction with OTC codeine containing medicines.[1] Codeine and paracetamol combined with codeine are funded prescription medicines and can be prescribed in much larger quantities in a single dispensing than pharmacy can supply at a single visit. While this monitoring system could in the future if necessary also include prescribed medicines, we suggest that it is only used for non-prescription medicine supplies at this time.

Time for implementation

There needs to be sufficient time allowed to put this program in place (e.g. 12 – 18 months, with the intention of getting it in place sooner if possible), and then sufficient time post-implementation to measure the success of it. This time would also allow education to be developed and delivered. We have noted above the data available from the Pharmacy Guild of Australia indicating the reduction in codeine sales since the introduction of the real-time monitoring system in March 2016.

Information from real-time monitoring systems

We would ensure that information from the monitoring would be provided to the Medicines Classification Committee. This information will indicate the number of sales, frequency of sales by the same person, and number of sales per pharmacy. As reported above for Australia, it could provide an indication of number of rejected supplies.

Need for codeine

All pharmacists we spoke to discussed the legitimate purchasers from whom they saw it as appropriate to have it available without prescription. Even pharmacists who noted supplying very few packs of codeine-containing analgesics wanted it to remain a treatment option that they and patients found useful. One pharmacist working in a busy mall pharmacy in Hamilton noted the cost for a patient of attending after hours services for acute pain (eg for dental pain at night or at the weekend) if codeine combination products were unavailable. Pharmacists also noted that there were patients who were at elevated risk of adverse effects with anti-inflammatories because of other medication being taken, advanced age, or

medical conditions, where they would recommend a paracetamol-codeine combination if paracetamol was insufficient.

Classification statement

We would appreciate it if any classification statement implementing these changes is discussed with key members of the sector to ensure it will work as well as possible to facilitate implementation of any changes.

Summary for codeine

We support a mandatory monitoring system that only allows supply by pharmacies which have agreed to use the system for all supplies of OTC codeine products. We support including all codeine containing OTC products and Gee's linctus in this system. The system needs to be confirmed and sufficient time allowed to put it into place. A condition we would place on any system we agreed to use is that it will have appropriate information to feedback to the committee.

We also would support education and have already outlined topics that could be included. We suggest it is mandated to ensure all pharmacists who supply the medicine have the knowledge required to best prevent dependence and manage potential or obvious dependence. We suggest educational handouts for patients, and educational material being available for GPs ready for monitoring to be implemented.

Item 8.1.8 Meningococcal B vaccine

Meningococcal B vaccine has arisen under Trans-Tasman Harmonisation. This vaccine is already captured under the existing entry for meningococcal vaccine (since 2014) as follows:

> Meningococcal vaccine; except when administered to a person 16 years of age or over by a registered pharmacist who has successfully completed a vaccinator training course approved by the Ministry of Health and who is complying with the immunisation standards of the Ministry of Health

Capturing meningococcal B vaccine within this statement is appropriate, given its safety and efficacy, and likelihood to better match to the serotype most prevalent in NZ than currently available vaccines.

For the convenience of the committee, we have provided relevant information. In particular, this submission provides information on the benefit in New Zealand (NZ) for a meningococcal B vaccine to be available from pharmacists, and information about efficacy, safety, dosage and administration.

Background

Meningococcal invasive disease is a devastating illness. Caused by a gram-negative bacterium, *Neisseria meningitidis*, meningococcal disease causes sepsis and meningitis, which can be fatal or result in permanent disability. It is spread by respiratory droplets or direct contact with nasopharyngeal secretions. The peak incidence is in the very young, with a secondary peak in adolescents and young adults.[4] About 10% of the population are nasopharyngeal carriers of *N. meningitidis*, peaking at 24-32% of people aged 15 to 24 years.[5] In the UK, following the Meningococcal C conjugate vaccine addition to the routine immunisation programme and catch up for people up to 18 years in 1999, confirmed group C cases fell by

over 90% in all age groups immediately.[6] The reduced carriage rates and reduced risk of exposure protected people in groups not vaccinated, with a reduction by two thirds in cases in these groups.

Meningococcal vaccine was reclassified in NZ to be available through vaccinator pharmacists, effective February 2014. The primary intention of this reclassification was to improve vaccination rates of people 16 years or over at higher risk of meningitis by increasing the availability and awareness of the vaccine through pharmacy. Pharmacists have been supplying meningococcal C vaccine, or the quadrivalent meningococcal A, C, Y, W135. The classification wording allows pharmacists to supply other meningococcal vaccines following approval of the medicine for distribution in New Zealand by Medsafe.

Development of meningococcal vaccine for serotype B was slower than the other serotypes, owing to poor immunogenicity from the poplysaccharide capsule of the serogroup B bacteria and similarity of this polysaccharide to human glycoproteins.[7] However, suitable vaccines have been developed using nonpolysaccharide antigens, and the first meningococcal B vaccines have been registered and marketed overseas for a few years. It is likely that one or more will enter the NZ market soon, e.g. Bexsero®. Bexsero was licensed in Europe in 2013 and the UK funded a three-dose schedule for infants from 2015.[8]

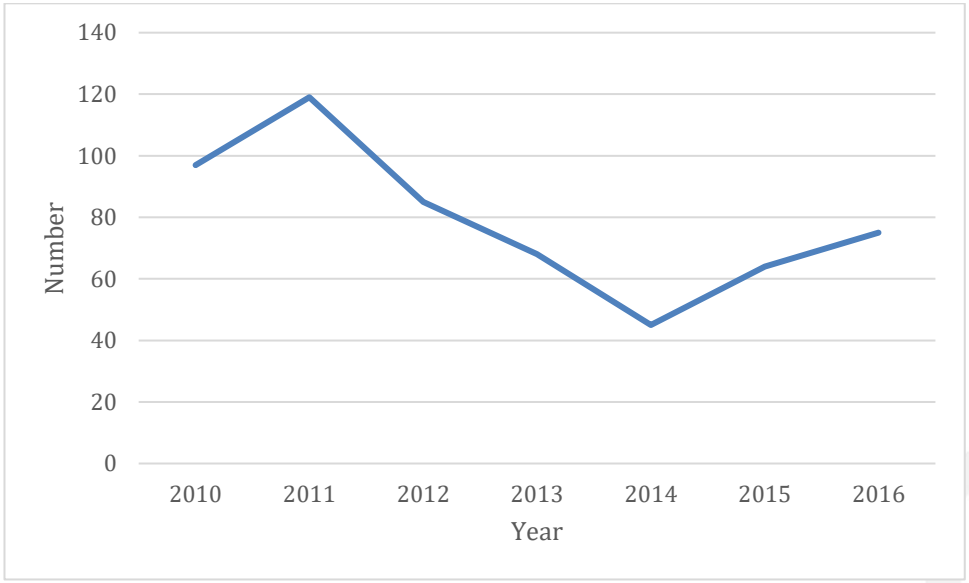
When a meningococcal B vaccine does arrive in NZ, maximising uptake in adolescents will help to reduce the incidence of and harms from invasive meningococcal disease.

Need for meningococcal vaccines

The latest NZ report of notifiable diseases available is for 2015.[9] This report shows that in 2014 there were 45 notifications for meningococcal disease in NZ, increasing to 64 in 2015, representing 1.4 cases for every 100,000 people in NZ. This is nearly 10 times the incidence in the US (0.18/100,000).[7] Data for 2016 shows a further increase to 75 reported cases, with two deaths.[4]

At the peak of the meningococcal epidemic in New Zealand, there were about 10 times as many notifications as in 2015 (16.7 per 100,000 in 2001).[9] NZ98/254 (*N. meningitidis* B:4:P1.7b,4) was the serotype responsible for the epidemic.

Figure 1 Cases reported of invasive meningococcal disease 2010-2016 in New Zealand



As for some European countries,[10] in NZ, meningococcal B is the leading serogroup causing invasive meningococcal disease.[9] In 2015, it was responsible for more than two-thirds of the cases in which the serogroup was determined, up from 53% in 2013.[11] In 2016, 70% of cases in which the serogroup was determined were meningococcal group B, about half of which were B:P1.7-2.4[12] (NZ98/254).

While children under 5 years are most commonly affected, a secondary peak incidence occurs in adolescents and early adults. For example in 2016 in NZ, 28% of cases (n=21) were in people aged 15-29 years, the second highest group after the under 5 year olds (n=28; 37%).[4]

Young adults in hostel-type accommodation (for example at university or in the military) are at greater risk,[13-16] and the Ministry of Health recommends meningococcal vaccination to these people, although it is not funded.[5]

Adolescents are a difficult group to access with vaccination, partly because of infrequent healthcare visits.[10] In New Zealand, a meningococcal C epidemic in Northland stimulated vaccinations in children and adolescents, but the adolescents proved difficult to reach and walk-in clinics were eventually set up.[17] Pharmacies are readily accessible in high foot-traffic areas where adolescents would be, are open extended hours, and usually would not require an appointment for a vaccination, making them the logical "walk-in" location for meningococcal vaccine. Thus, availability through pharmacists should increase the uptake of the vaccine in this difficult to reach group. In an epidemic, for fast reach of populations, the existing classification would enable fast access to any meningococcal vaccine through pharmacy (in addition to other appropriate providers) in an epidemic if necessary, including meningococcal B. This would benefit public health. Pharmacists have had access to the ImmuniseNow web portal that allows them to add information on specific vaccines administered and was originally set up for the 2017 Influenza season with Pertussis vaccines now added. Pharmacists will be using the National Immunisation Record (NIR) aids the consolidation of information and separately making the information accessible to the doctor of the supply with patient permission to avoid fragmentation of care. Meningococcal B vaccine could be added to this system.

We contacted [redacted], a Public Health Medicine Specialist [redacted] regarding the availability through pharmacists of meningococcal B vaccine. [redacted] responded: "I am very supportive re increasing access and availability through pharmacists makes sense to me." [redacted] was happy for us to quote [redacted] in our submission.

Reclassification of meningococcal vaccine to allow supply by qualified vaccinator pharmacists was particularly intended to help vaccination uptake in the adolescent age group, reducing the incidence of disease. This rationale for pharmacist-supply is even more relevant with serotype B vaccines.

Efficacy

Efficacy information is provided in the attached SPC documents for Bexsero and Trumenba.

The UK's Green Book[6] (primary nationwide vaccination reference book) states the following:

> *"The 4CMenB vaccine is immunogenic in young infants (Findlow et al., 2010) and adolescents (Santolaya et al., 2012) and is licensed for use from two months of age. Laboratory-based studies suggest that 4CMenB may protect against up to 88% of circulating meningogoccal B strains in England and Wales (Frosi et al., 2013), but its effectiveness in preventing disease in a population has yet to be established. 4CMenB may also protect against infection by capsular groups other than group B."*

The four component meningococcal B vaccine, 4CMenB (Bexsero), is a protein-based vaccine which provides broad protection against meningococcal B. Its four major antigenic components are: factor H-binding protein (fHbp)fused with GNA2091, Neisseria adhesin A (NadA), Neisserial Heparin Binding Antigen (NHBA) fused with GNA1030, and OMV from the New Zealand outbreak strain NZ98/254 (NZ OMV). Nolan et al[10] noted that:

> *"These components are relevant to the organism's function, virulence, and/or survival and were selected to provide broad coverage against circulating strains of MenB. Interestingly, the vaccine components are also present in meningococcal isolates of other serogroups allowing potential use against meningococcal isolates belonging to non-B serogroups, although this was not the initial intention for this vaccine. Clinical trials have shown 4CMenB to induce bactericidal antibody responses against meningococcal antigens in a high proportion of infants, adolescents, and adults, with an acceptable tolerability profile."*

Observational data from the UK funded availability and laboratory-confirmed meningococcal disease suggests 83% effectiveness of this 4CMenB vaccine (Bexsero) against meningococcal B disease for infants in their first year of life.[8]

Emergency vaccinations with 4CMenB vaccine at universities in the US has appeared successful in controlling meningococcal B outbreaks.[10]

Trumenba is also a meningococcal B vaccine. It contains 2 recombinant lapidated factor H binding protein (fHbp) variants). fHbp is found on the surface of meningococcal bacteria. The UK SPC for Trumenba notes that:

> *"A survey of over 2,150 different invasive meningococcal serogroup B isolates collected from 2000-2014 in 7 European countries, the US and Canada demonstrated that over 91% of all meningococcal serogroup B isolates expressed sufficient levels of fHbp to be susceptible to bactericidal killing by vaccine-induced antibodies."*

Usage by pharmacists in NZ will be guided by the product that is available and recommended by experts such as IMAC. The screening tool will be adapted as appropriate.

Safety

Bexsero was first approved in 2013 in Europe. It is approved in over 35 countries worldwide, and over 15 million doses of Bexsero have been distributed up to January 2017 (data from GSK, September 2017). The UK SPC for Bexsero[18] reports that the most common adverse reactions were pain at the injection site, malaise and headache. Subsequent doses do not see increased adverse reaction frequency. Allergy including anaphylaxis, and significant injection site reactions can occur but the frequency is unknown.

The most common adverse events with Trumenba are injection site pain, redness and swelling at the vaccination site, headache, fatigue, chills, diarrhoea, muscle pain, joint pain and nausea.[19] As with all vaccines, allergic reactions can occur.

A search in September 2017 on the CDC VAERs site under meningococcal B vaccine selecting all possibly relevant allergy reactions and anaphylaxis or anaphylactoid reactions listed found two cases of anaphylaxis, one in a 13 year old, and another in a 17 year old reported following administration of Bexsero®. Two reports of fever, throat closing up, difficulty breathing occurred in two 18 year olds following administration of Trumenba®. The UK's drug analysis profiles which reports adverse reactions

with medicines does not include vaccines. However, the UK's Green Book reports that surveillance in the UK *"has not identified any serious or unexpected health problems associated with use of the vaccine".* It is a black triangle medicine there, and therefore subject to additional monitoring.

For Bexsero, the US FDA authorised vaccination campaigns in response to college campus outbreaks of meningococcal B.[20] Of 15,236 people vaccinated (most twice), serious adverse events were reported in 3.3 per 1000, of which two cases were suspected to be possibly (rhabdomyolysis) related, or related (anaphylaxis) to Bexsero. An observational study in Quebec saw over 43,000 people vaccinated (aged 2 months to 20 years). There were no new safety concerns.

Dosage and administration

When a meningococcal B vaccine enters the NZ market, the screening tool for meningococcal vaccine will be updated for the relevant dosage and administration details and any other changes that might be required. Green Cross Health Ltd would undertake to update this screening tool and patient information leaflet which would be reviewed by IMAC before being made available for all pharmacists.

For people aged 11 years and over, the Bexsero® summary of product characteristics for the UK,[18] has a two-dose schedule given not less than one month apart. The vaccine is administered by deep intramuscular injection in the deltoid muscle region of the upper arm. Pharmacists are used to administering meningococcal vaccines IM, but usually use a single dose rather than two doses. As pharmacists use the screening tools for vaccination administration they will not be relying on memory for the key safety and administration information, providing excellent safety and a comprehensive record of supply. For Bexsero, while there is a recommendation to provide antipyretics in children under two years, this is not required as a matter of course in adolescents.

According to the summary of product characteristics for the UK,[19] Trumenba is licensed for delivery in 10 years and over. It can be used in a two-dose primary series at a six month interval or three doses with the first two doses at least a month apart and the third dose at least 4 months later. Three doses is recommended in high risk groups.[7]

Other considerations

Registration status

There is no meningococcal B vaccine registered in NZ as yet.

Overseas availability

In Canada, meningococcal vaccine is a pharmacist-only medicine, and can be provided by pharmacists. This includes the multi-component meningococcal B vaccine (4CMedB or Bexsero) which is funded in at least one province (Ontario) in people aged 2 months to 17 years with specific risk factors, since late 2014.

Meningococcal B vaccine is available in the UK through pharmacists who have been trained in vaccination. For example, Boots pharmacies have offered unfunded meningococcal B vaccination services in children aged two to 21 years of age since 2015.[21]

Trumenba was registered in the US in 2014, and Bexsera in 2015.[7] Meningococcal B vaccine has been available through pharmacists in the US since 2014, although there may be some variation between states.[22] The US has very low prevalence of meningococcal B with fewer than 60 cases in people aged

11 to 21 per year. However, it has occurred in a couple of college outbreaks where the incidence increased 200 fold compared to the normal population and the vaccine was used.[7] CDC recommends usage as follows:

> *"Two serogroup B meningococcal vaccines — Bexsero® and Trumenba® — have been licensed by the Food and Drug Administration (FDA).*
>
> *These vaccines are recommended routinely for people 10 years or older who are at increased risk for serogroup B meningococcal infections, including:*
>
> - *People at risk because of a serogroup B meningococcal disease outbreak*
> - *Anyone whose spleen is damaged or has been removed*
> - *Anyone with a rare immune system condition called "persistent complement component deficiency"*
> - *Anyone taking a drug called eculizumab (also called Soliris®)*
> - *Microbiologists who routinely work with isolates of N. meningitidis*
>
> *These vaccines may also be given to anyone 16 through 23 years old to provide short term protection against most strains of serogroup B meningococcal disease; 16 through 18 years are the preferred ages for vaccination.*
>
> *For best protection, more than 1 dose of a serogroup B meningococcal vaccine is needed. The same vaccine must be used for all doses. Ask your health care provider about the number and timing of doses."*

Australia has been slower than NZ and North America in taking up the vaccination opportunity through pharmacists, and does not yet have meningococcal vaccine through pharmacists.

Funding

Funding is a separate discussion to classification. Where the vaccination is not funded in pharmacy but is funded elsewhere, (similar to the introduction of Influenza vaccine and Pertussis vaccine) the screening tool reflects this, prompting a referral to the general practice for the funded vaccine (e.g. for the pertussis vaccine at 28-38 weeks pregnant). The meningococcal vaccine screening tool would be updated to reflect this should this occur.

Stock shortages

Should stock shortages be of concern (e.g. with a worldwide shortage of the vaccine, or sudden demand from a local epidemic), the distributor would be able to prioritise delivery, instantly restricting distribution to authorised pharmacies if necessary to preserve stock.

Can meningococcal B vaccines be given with other serotypes?

Meningococcal B can be given at the same time as a meningococcal conjugate vaccine (meningococcal C or the quadrivalent A,C,Y,W135). They should be given in different arms.

Further reading if required:

Immunisation Handbook 2017, available at: http://www.health.govt.nz/system/files/documents/publications/immunisation-handbook-2017-may17-v3.pdf

Nolan T, O'Ryan M, Wassil J, Abitbol V, Dull P. Vaccination with a multicomponent meningococcal B vaccine in prevention of disease in adolescents and young adults. Vaccine. 2015;33(36):4437-45. doi:https://dx.doi.org/10.1016/j.vaccine.2015.06.011.

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Summary meningococcal vaccine classification statement

The current classification statement remains appropriate as it would encompass meningococcal B vaccine, aiding appropriate uptake by adolescents of a vaccine with the greatest chance to protect these individuals.

Please contact us should you require any further information or want copies of references.

Thank you for considering this submission.

Yours Sincerely,

ALISON VAN WYK

Executive – Professional Services

Green Cross Health

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18. *Bexsero Meningococcal Group B vaccine for injection*: GSK; 13 Jul 2017 2017.

19. *Trumenba Summary of Product Characteristics*: Pfizer Limited; 01 Jun 2017 2017.

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PHARMACY GUILD OF NEW ZEALAND

29 September 2017

Medicines Classification Committee Secretary
Medsafe
Wellington

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

Dear Sir/Madam

RE: AGENDA FOR THE 59th MEETING OF THE MEDICINES CLASSIFICATION COMMITTEE

Thank you for the opportunity to provide feedback on the agenda for the 59th meeting of the Medicines Classification Committee (MCC), to be held on Tuesday 7 November 2017.

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

Our feedback covers six agenda items. These are:

- Agenda item 5.3: Codeine – proposed reclassification from pharmacy-only and restricted medicines to a more restricted classification.
- Agenda item 5.4: Principles of harmonisation.
- Agenda item 6.1: Hydrocortisone – proposed reclassification from prescription medicine to restricted medicine.
- Agenda item 6.2: Penciclovir – proposed reclassification from pharmacy-only medicine to general sale medicine.
- Agenda item 8.1.8: Meningococcal Group B Vaccine.
- Agenda 8.2.1 (a): Cetirizine.

Each of these agenda items are discussed below.

Agenda item 5.3: Codeine – proposed reclassification from pharmacy-only and restricted medicines to a more restricted classification

The Guild's position on the reclassification of codeine remains unchanged. While we **support** the reclassification of the Pharmacy Only medicine entry for codeine to a Pharmacist Only (restricted) medicine classification, we are **opposed** to a reclassification of codeine products that would reduce direct access through a pharmacist.

Following the 58th meeting, the Committee put the following questions to the sector to allow codeine to continue to be available without a prescription:

1) What education and continuing professional development would be provided to health professionals regarding the sale and prescription of codeine to minimise the risk of misuse and addiction in consumers?

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2) How will the sector fill the data gap with respect to over-the-counter codeine use?

3) How will the sector track the sale of codeine in pharmacy in order to better identify consumers with additional needs for pain management and/or addiction problems?

We have taken these questions into consideration and our feedback is outlined below. Our submission is not just about codeine, but about better primary health care.

The vast majority of consumers who use codeine containing products do so safely, effectively and in a responsible manner. It is our understanding that a very small number of consumers use these products inappropriately. In New Zealand, there is published evidence of people seeking supply of codeine from multiple doctors.[i] We do not see how shifting the classification of codeine containing products to Prescription Only will address the issue. We would like to see the pharmacovigilance on codeine sales increased to help pharmacists identify consumers who are using codeine inappropriately.

We are satisfied there is sufficient clinical evidence to keep combination codeine products available from a pharmacy. In a community pharmacy setting combination paracetamol/codeine or ibuprofen/codeine products are used for short-term over-the-counter management of acute moderate pain. These products can be recommended by the pharmacist or another health professional (eg, a dentist) or requested by the patient, and are clinically appropriate for managing acute moderate pain in patients:

- Who have had an inadequate analgesic response to an initial trial of paracetamol and/or a non-steroidal anti-inflammatory (NSAID).
- Where a NSAID is clinically contraindicated and paracetamol alone is insufficient.

The analgesic effect of codeine is predominately derived from metabolism to the active metabolite morphine, via the cytochrome P450 enzyme CYP2D6.[ii] Genetic variation to the 2D6 genes means that people metabolise codeine at different rates. This means while the majority of the population obtain adequate pain relief from codeine a small portion (5-10%) do not. In our opinion, this can have an impact on research illustrating the clinical efficacy of over-the-counter codeine.

In other jurisdictions where codeine is not available over-the-counter there is evidence showing high levels of problematic use of more potent opioids, which is significantly greater to that in New Zealand.[iii] We are concerned if codeine containing products are reclassified to Prescription Only general practitioners will be put under pressure by 'doctor shoppers' to prescribe higher strengths of codeine or more potent opioids, such as oxycodone. Concerns have already been raised about the quantities of strong pain relievers that general practitioners are prescribing,[iv] and without a compulsory real-time monitoring system to track the use of prescribed opioids we believe the reclassification of codeine will increase the misuse of more potent opioids in New Zealand. We also have concerns that reclassification of codeine products would increase the inappropriate use of anti-inflammatories.

Pharmacists are directed by their Code of Ethics to prevent the supply of unnecessary and excessive quantities of codeine products. We have included a copy of the joint Pharmacy Council and Pharmaceutical Society statement on the sale of codeine containing analgesics at the end of this submission for your reference.

Currently a lack of information sharing between pharmacies means consumers can seek supply of codeine from multiple pharmacies. This means repeated purchases of codeine at an individual pharmacy are easy to detect, but not so easy when a customer uses multiple pharmacies. We are working with other sector organisations to implement a real-time recording and monitoring system, similar to the Australian software package known as MedsASSIST. To ensure patient and public safety it is the sectors expectation that only pharmacies using a MedsASSIST type system will be able to continue to supply codeine without a prescription.

MedsASSIST is a clinical decision support tool that enables a responsible supply of codeine through community pharmacy. It has a focus on patient care and is designed to help pharmacists identify patients who are at risk of problematic codeine use. When using this system pharmacists will be able to track the sale of codeine from other pharmacies, which allows them to better identify patients with additional needs for pain management and/or addiction problems.

MedsASSIST works by logging each transaction against a valid form of photographic identification, such as a New Zealand drivers licence, an 18+ card or a passport. Once a transaction has been logged in the system other pharmacies using the system will be able to view all the transactions logged against a particular identification number. This will assist pharmacists to identify patients who appear to be purchasing excessive quantities of codeine containing products.

When using the system pharmacists are also required to record the clinical indication and any recommended follow up actions. Once the pharmacist has identified a patient with additional needs for pain management and/or addiction problems they can refuse the sale and offer a referral to a doctor or a community addiction team. We do not have any patient privacy concerns as pharmacists must obtain patient consent prior to recording any patient information in the system. If a patient does not wish to provide these details they will not be able to purchase a codeine containing product.

To gain a further understanding of how MedsASSIST works please refer to the below example about Mr Smith.

> *If Mr Smith uses his driver's license to purchase Panadeine from pharmacy A for a migraine, when he tries to purchase Nurofen Plus from pharmacy B for a toothache, pharmacy B will be able to see he recently purchased Panadeine for a migraine from pharmacy A. Depending on the length of time between these transactions the pharmacist will be able to engage with Mr Smith about potential problematic codeine use and help him access the services he needs to address his problem. If pharmacy B decides to deny the sale of Nurofen Plus to Mr Smith this will be logged against his driver's licence*.

Project STOP is another real-time monitoring system used in Australia to record sales of pseudoephedrine. When first implemented Project STOP was made mandatory in Queensland and assisted the State Drug Investigation Unit of the Queensland Police to make a number of arrests of suspects involved in the purchase and diversion of pseudoephedrine based products for use in the illicit drug trade.[v] While we do not intend

for a MedsASSIST type system to be used as a policing tool, this demonstrates how powerful real-time monitoring can be in ensuring patient and public safety.

It is our understanding there are currently no comparable software systems in place that record or identify patients who may have problems with dependence or misuse of prescription opiates. We strongly believe without real-time monitoring any impact of scheduling alone will not minimise harm, and may potentially increase it due to increased prescribing and dose escalation. We believe under our proposed Pharmacist Only scheduling with mandatory real-time monitoring it is more likely that a person overusing codeine would be detected, counselled and either referred to their general practitioner or to drug addiction and pain management support. We believe our proposal offers a more effective and professionally orientated intervention than a prescription only classification.

There will be a cost to the sector for the implementation of a real-time monitoring system, as well as ongoing costs. It is our expectation that either community pharmacies will have to pay a small fee in order to use the system, or a small fee may be added by drug companies to codeine containing products to cover the ongoing costs of the system. To ensure people in rural communities have the same access to codeine containing products as those in urban centres we believe any cost to pharmacy should be based on the number of transactions for codeine containing products.

We are currently working on developing a business case with other sector stakeholders to establish an affordable implementation plan that supports the appropriate use of codeine through real-time monitoring and training. We expect to have this completed and endorsed by March 2018.

There is a data gap with respect to over-the-counter codeine use in New Zealand. We strongly believe implementing a real-time monitoring and recording system will fill this data gap. Independent researchers will be able to use the data obtained through real-time monitoring to give us a better understanding and management of any problem that may exist in a New Zealand context. This will assist in identifying risk profiles for those patients who develop problematic codeine use to better inform policy makers.

As well as having a mandatory real-time monitoring system we believe additional training should be made available for pharmacists supplying codeine containing products over-the-counter. We are working with other sector agents to ensure there is adequate training in place for pharmacists and pharmacy support staff. While pharmacists are medicine experts and are already well aware of the risks associated with codeine use, dealing with patients with addiction issues can be difficult for any health professional. We feel it is important pharmacists receive adequate training around managing and communicating with patients with an identified pain management and/or addiction problem. This will ensure those patients with inadequate pain management or who have a physical dependence to codeine are referred to the appropriate health care services. We feel it is up to the Pharmacy Council to decide whether any mandatory training is required for pharmacists and if it is required we would support this decision.

Other health professionals such as doctors, nurses and dentists also play an important role in the management of patients who use codeine. We would like to engage with the

wider health sector to ensure the correct referral pathways are established for patients with identified problematic use of codeine.

It is our expectation that the real-time monitoring and recording system will be implemented alongside an information campaign promoting the safe use of codeine. This will create a level of public awareness and engagement for consumers around the risk of codeine misuse and addiction. We expect this will promote the appropriate use of codeine and empower consumers with a pain management problem or codeine dependence to seek help.

When implemented we also believe other over-the-counter products of potential misuse, such as Gee's linctus, should be included in the real-time monitoring system.

We would like to request a two-year suspension in the rescheduling of codeine containing products. This would provide the sector the required timeframe to implement a real-time monitoring system and adequate pharmacist training. We also suggest the sector reports back to the MCC annually to show what has been done.

Agenda item 5.4: Principles of harmonisation

The Guild is **supportive** of harmonisation of labelling and packaging harmonisation of safety directions, warning statements and first-aid instructions, and common nomenclature of drugs and poisons. We are however **opposed** to the harmonisation of equivalent scheduling for drugs and poisons. We believe New Zealand drugs and poisons should be scheduled to meet the needs of New Zealanders, not Australians.

Agenda item 6.1: Hydrocortisone – proposed reclassification from prescription medicine to restricted medicine

The Guild **supports** the proposal to amend the current classification of hydrocortisone 1 per cent (1% w/w) from 'Prescription medicine' to 'Restricted medicine' when compounded with aciclovir 5% w/w in primary packs of not more than 2 g for dermal use in adults and adolescents (12 years of age and older).

We are confident that a 'Restricted medicine' classification is suitable for a hydrocortisone/aciclovir combination product. In New Zealand both aciclovir and hydrocortisone are already available without the need for a prescription, with a well-established safety record. Internationally the combination product is already available over-the-counter in over 22 jurisdictions.

Recurrent herpes labialis is a common skin infection that people often seek advice from a pharmacy on. Having a hydrocortisone/aciclovir combination product available over-the-counter offers consumers an additional choice to treat recurrent herpes labialis without having to pay for a prescription. We believe, for some patients, this combination product will offer improved outcomes over existing treatment options.

Agenda item 6.2: Penciclovir – proposed reclassification from pharmacy-only medicine to general sale medicine

The Guild **opposes** the proposal to reclassify penciclovir from pharmacy-only medicine to general sale medicine when sold for external use for the treatment of herpes labialis.

We feel that the current 'pharmacy-only medicine' classification of penciclovir is a more suitable classification. Recurrent herps labialis is a common skin infection. However, consumers often confuse other conditions affecting the lips with herpes labialis. When a person purchases herpes labialis treatment from a pharmacy they receive advice on how best to use the product, a differential diagnosis and a referral to a doctor when necessary.

Having penciclovir, or any other medicine used to treat recurrent herpes labialis, available through pharmacy only, ensures the consumer receives usage information and is assessed for any risks. For these reasons, we are opposed to penciclovir being easily accessible without verbal advice or counselling from a health care professional.

Agenda item 8.1.8: Meningococcal Group B Vaccine

The Guild **supports** the classification of meningococcal Group B vaccine as a new chemical entity. It is our expectation that the same conditions to the meningococcal vaccine will apply to this vaccine.

> *'Prescription only except when administered to a person 16 years of age or over by a registered pharmacist who has successfully completed a vaccinator training course approved by the Ministry of Health and who is complying with the immunisations standards of the Ministry of Health'*

The meningococcal group B vaccine is indicated for individuals aged 10 or older. Adolescents and young adults aged 16 to 23 years have an increased risk of developing meningococcal disease. The meningococcal group B vaccine can provide short-term protection against most strains of serogroup B meningococcal disease, and is recommended for this age group. We believe having access to this vaccine through community pharmacy will help improve immunisation rates for this vaccine.

Agenda 8.2.1 (a): Cetirizine

The Guild **opposes** the proposal to reclassify cetirizine hydrochloride from pharmacy-only medicine to general sale medicine when in preparations for the treatment of seasonal allergic rhinitis in adults and children 12 years of age and over, when in a maximum pack size of 10 days' supply labelled with a recommended daily dose not exceeding 10 days' supply labelled with a recommended daily dose not exceeding 10 mg of cetirizine hydrochloride.

We believe that increasing the available pack size of cetirizine by general sale poses several risks to the consumer. Increasing the available pack size of cetirizine from five tablets to 10 tablets would provide consumers with 10 days' supply of the medicine. Paracetamol and ibuprofen are examples of other medicines that are available through general sale. We would like to point out that the quantities of these medicines are only

sufficient to provide therapeutic dosing for less than five days. We believe that 10 days' supply of any medicine is excessive in the absence of advice from a health care professional, and increases the risk of the consumer's health deteriorating further, potential side effects, drug interactions and unintended overdoses.

We are concerned that in the absence of professional health care advice consumers will be unable to make an informed choice about the treatment options best suited to treat their seasonal allergic rhinitis. Cetirizine is also used to treat a range of allergic disorders.[vi] We are concerned that the general consumer is unable to differentiate between seasonal allergic rhinitis and other allergic disorders that require advice from a health professional, and that infections can sometimes be incorrectly self-diagnosed as an allergy.

We are concerned that with general sales, consumers will not be made fully aware of any potential side effects from cetirizine. Like other medicines cetirizine has side effects, and it is important that consumers are aware of these side effects so they know when to seek help. Drowsiness, headache, psychomotor impairment, blurred vision and dry mouth are commonly reported side effects of cetirizine.[vi] Rare but more severe side effects such as liver dysfunction, hypotension, palpitation, arrhythmia, extrapyramidal effects, dizziness, confusion, depression, sleep disturbances, tremor, convulsions, blood disorders, angle-closure glaucoma, hypersensitivity and photosensitivity have also been reported.[vi]

Cetirizine should be used with caution in people with epilepsy, renal impairment, children and the elderly,[vi] and has the potential to interact with other medicines.[vii] We believe, in the absence of health professional oversight larger packs sizes put people at a greater risk.

We are concerned that increasing the available pack size of cetirizine through general sale would increase the number of unintended cetirizine overdoses. Health professionals play an important role in preventing medicine overdoses, as they are able to verbally advise and reinforce the recommended doses to consumers.

Consumers are already able to purchase five days' supply of cetirizine without any health care advice. For the reasons highlighted above this is a more than sufficient quantity. We believe that increasing the pack size of cetirizine available through general sale has the potential to be a risk to public safety, and result in poor patient outcomes.

Thank you for considering our feedback. If you have any questions about our feedback, please contact Guild Pharmacist, Sarah Bannerman at s.bannerman@pgnz.org.nz or 04 802 8209.

Yours sincerely,

Nicole Rickman
General Manager – Membership and Professional Services

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PHARMACEUTICAL SOCIETY
of New Zealand Incorporated

pharmacycouncil
OF NEW ZEALAND
Te Pou Whakamana Kaimatu o Aotearoa

Sale of Codeine Containing Analgesics
Joint PCNZ and PSNZ Statement

1. Pharmacist only sales of codeine containing analgesics are intended for acute use only. The features of acute conditions are described in the Council's statement, *Protocol for the Sale and Supply of Pharmacist Only Medicines for Chronic Conditions* as usually having a rapid onset and often lasting less than three weeks. They may recur from time to time, may or may not resolve on their own and may or may not require referral to a doctor.

2. Repeat sales of codeine containing analgesics within a short timeframe are likely to be inappropriate in the majority of cases. An alternative, clinically suitable non-codeine containing analgesic should be offered or the patient referred to an appropriate health professional for a full diagnostic assessment so that the optimal management can be identified.

3. Pharmacists must be vigilant about frequent purchasers and use clinical judgement about whether supply of the requested codeine containing analgesic is appropriate. Codeine seekers usually provide false details about symptoms and do not accept offered alternatives.

4. Codeine seekers are known to offer false names or addresses when attempting to purchase from the same pharmacy. It is advisable to consider requesting photo identification to confirm patient identity when recording purchaser details, particularly if there are concerns about the legitimacy of the request. Recording details of the sale in an electronic database, such as your dispensary system provides additional information regarding patient medication use particularly in areas where a shared patient record is accessible. Any concerns about frequent purchasers should be reported to Medicines Control.

5. Pharmacist Only Medicines must not be available for patient self-selection. It is the responsibility of the pharmacist to ensure that the patient receives safe, clinically appropriate assessment before a decision on management can be made.

6. To ensure that patients continue to have access to codeine containing analgesics as Pharmacist Only Medicines, it is vital that best practice principles through strong clinical and ethical decision making are adhered to at all times.

7. Due to their potential for misuse, advertisements related to codeine-containing analgesics are subject to extra restrictions in the joint *Pharmacy Council and Pharmaceutical Society Advertising Guidelines*, on the Council's and Society's websites.

Dummy boxes

8. The placement of dummy boxes of codeine containing analgesics on over the counter shelves could be viewed as a form of advertising and could in some instances, be seen as a breach of a pharmacist's obligations to prevent misuse of substances of abuse. A pharmacist must be able to refuse the sale of any product that is unsuitable for a patient or where mis-use is suspected.

9. By permitting a customer to self-select a codeine containing analgesic dummy box the patient has already made a decision about the choice of analgesic and it then may be more difficult for the pharmacist to decline the sale. It is preferable for the pharmacist to make a clinical decision regarding the most appropriate choice of analgesia for the patient in response to patient symptoms and medical history.

Code of Ethics 2011

10. The Council's Code of Ethics 2011 addresses the sale of products of potential misuse in many clauses:

    - *"Clause 1.2 – Take appropriate steps to prevent harm to the patient and the public.*
    - *Clause 1.7 – Only supply a medicine, complementary therapy, herbal remedy or other healthcare product to a patient when you are satisfied that the patient understands how to use it safely and appropriately*
    - *Clause 6.12 – Make certain the public cannot self-select medicines you know or should reasonably be expected to realise are likely to cause or have a potential for misuse, abuse or dependency.*
    - *Clause 6.13 – Take appropriate steps to prevent the supply, by any means, of unnecessary or excessive quantities of any medicine or healthcare product which you know or should reasonably be expected to realise is likely to cause or have a potential for misuse, abuse or dependency."*

What is an appropriate supply?

11. Pharmacists should not engage in the sale of multiple packets of codeine containing analgesics in one transaction or repeat, frequent sales to one patient. This practice is likely to breach the Council's Code of Ethics 2011. There may be limited situations when a subsequent sale is necessary, for example when access to medical or dental care is not immediately available.

12. Treatment for a period of up to one week can be considered appropriate in certain circumstances but, medical attention is essential if a longer period of treatment is requested.

13. Pharmacists are experienced health professionals and highly qualified medicines experts capable of using clinical and ethical judgement to assess the patient and recommend the most appropriate analgesic for patient management.

14. It is essential that pharmacists adhere to the highest practice standards to ensure patient and public safety.

Effective date

15. Effective: February 2016.