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.

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