NZSMI SUBMISSION
TO THE 61st MEDICINES CLASSIFICATION COMMITTEE MEETING
REGARDING RECLASSIFICATION OF COUGH MEDICINES

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. The major manufacturers who have products registered with these ingredients are members of NZSMI.

Summary

1. The NZSMI position on the proposed reclassification of cough medicines containing dextromethorphan, opium tincture, squill oxymel and Pholcodine to restricted medicines is:

    1.1 The majority of people who use OTC cough medicines do so responsibly.

    1.2 Consumer safety is the primary concern of NZSMI and its members. This Medsafe submission does not provide a balanced view of the risks and benefits of these ingredients and does not provide sufficient explanation or evidence to warrant increased restricted access.

    1.3 The reason given for the proposal by Medsafe is that "because of the recent look at codeine containing cough and cold products, it was reasonable to look at other cough and cold products". To conflate the codeine containing cough/cold products with cough preparations containing these ingredients is confusing and potentially misleading, particularly as codeine has a strong analgesic profile (which none of these have) and defined opioid characteristics.

    1.4 The easy availability of cough relief is important to reduce personal disruption and discomfort and to reduce spread of bacterial and viral infection. The New Zealand Health Strategy has a goal, under the heading "Closer to Home" : "People have access to services, information and support as close to home as possible. These services are available when they want them, and access is as easy as possible"

    1.5 We do not agree that "Dextromethorphan has a history of abuse in New Zealand" (Page 1,Para 2) is a reasonable statement and the Medsafe paper shows only isolated cases of misuse are recorded.

    1.6 We can find no local or international research data that agrees with the statement "DXM is an opioid" as stated in the Medsafe paper under Background and find it confusing that this statement comes after the earlier statement "Dextromethorphan is a substance that does not belong to the opioid family

1.7 There will be potential negative consequences to making OTC cough medicines containing these ingredients pharmacist only. These include delay in seeking treatment due to restricted availability and potential additional pressure on GPs and medical centres, many of whom are currently experiencing long waiting times.

1.8 Changing schedules that put New Zealand out of step with Australian regulations means, in most cases, label harmonisation will no longer exist.

1.9 Products containing dextromethorphan (DXM) and Pholcodine are widely available over the counter in many other countries.

1.10 DXM abuse in the United States was a serious issue some years ago and has been mitigated by educational programmes and improved labelling – not up scheduling.

1.11 There is little evidence of an abuse problem in New Zealand apart from low numbers of isolated instances and even if there was a quantifiable problem NZSMI believes that changing the schedule is not a balanced solution in the best interests of improving primary care for New Zealanders.

1.12 There will always be a minute population of any society that will seek mind altering substances by way of abuse and excess and NZSMI contends there are better ways of reducing this than blanket barriers to access; and agrees with the comment in the Medsafe proposal paper that "…other medicines may be misused instead or purchase directed to internet outlets"

1.13 We can find no evidence of abuse of Pholcodine containing products in New Zealand.

1.14 Squill Oxymel is a traditional medicine with anti-inflammatory, anti-oxidant and anti-cholinergic effects used in the treatment of upper respiratory tract inflammation and congestion. It is widely accepted that there are unpleasant and potentially harmful side effects of excessive dosing of Squill but dose guidelines in New Zealand have ensured that this has not manifested itself as a problem, particularly as it is only widely used in combination. It is not an opium derivative and we can find no evidence of abuse or any other reason why it should be restricted to sale by a pharmacist.

1.15 NZSMI notes that Linctus Gee is currently a Pharmacy Only medicine which, in most pharmacies, is treated as a quasi-Pharmacist Only supply.

1.16 NZSMI notes the suggested link causing sensitisation to neuro muscular blocking agents and Pholcodine use. There is conflicting evidence available, over the last twenty years, regarding this hypothesis but enough to raise concern. NZSMI contends that changing the availability of Pholcodine to Pharmacist Only will do nothing to solve this problem if it does exist and the pharmaceutical industry and pharmacy need to work with anaesthetists to improve public education and pre-anaesthesia screening protocols.

1.17 This Medsafe paper highlights the issue that medicine use and abuse reporting data in New Zealand may be inadequate. NZSMI would like to work with Medsafe, CARM and the National poisons centre to change this.

2. Use of Dextromethorphan in other Countries

Dextromethorphan is widely used, and has been for decades in over-the-counter (OTC) settings. It was first approved as a prescription antitussive drug in the United States of America (USA) in 1954 and subsequently as an over-the-counter (OTC) medication in 1958.

Dextromethorphan is currently marketed without a prescription in a wide number of countries:

Non-prescription countries		Prescription countries
Austria	Lithuania	Argentina
Australia	Mexico	Bulgaria
Belgium	Netherland	Chile
Brazil	New Zealand	Denmark
Canada	Peru	France
China	Philippines	Greece
Columbia	Poland	Russia
Croatia	Portugal	South Korea
Czech Republic	Singapore	Turkey
Ecuador	Slovakia Republic	
Finland	Slovenia	
Germany	Spain	
Hungary	Switzerland	
India	Taiwan	
Indonesia	Thailand	
Ireland	United Kingdom	
Italy	USA	
Japan	Venezuela	

Source: Association of the European Self-Medication Industry (AESGP) database and outcome of an internal survey performed in July 2017.

NZSMI is aware that a small number of Health Authorities have taken local decisions regarding the supply status of dextromethorphan containing products due to recreational abuse concerns:

France
In July 2017, French Health Authorities decided a switch back of dextromethorphan products as well as products containing codeine, ethylmorphine and noscapin. This measure was taken to minimize the risk of abuse for recreational purpose in adolescents and young adults and triggered by severe cases (including 2 fatal outcomes in 2017) occurred in France with codeine products.

Czech Republic
Czech Republic Health Authority decided on 15 August 2017 the immediate switch back of all dextromethorphan single INN products in solid forms and requested for other dextromethorphan products to provide a rationale regarding supply status

Further to the assessment of all Companies' feedbacks, Czech Republic Health Authorities decided to maintain these products with a non-prescription status with reinforcing the Risk Minimisation Measures through a direct healthcare professional communication and a close monitoring of abuse cases.

United States
Dextromethorphan abuse concern was also discussed in the US for several years where a risk mitigation plan led by the US Consumer Healthcare Product Association has been effectively implemented.

In all these cases the situations are entirely different to those which exists in New Zealand. After a recent analysis of all available data, NZSMI confirms its position that dextromethorphan containing products should be available with an over-the-counter status, as it has a good efficacy and safety profile, particularly when compared with other non-prescription alternatives.

Oral dextromethorphan 30 mg is the only active substance demonstrating significant suppression of acute cough in clinical trials using objective measures (*Morice et al. 2016*).

Based on its good safety and efficacy profile, and in the absence of any data that demonstrates a prolonged or significant misuse profile in New Zealand over decades NZSMI believes that the current scheduling of dextromethorphan in New Zealand does not need to be reclassified.

3. Consultation with sister organisations Globally

NZSMI has consulted with numerous equivalent organisations in Australia, USA, South Africa, Europe and the UK. NZSMI also consulted with WSMI (World Self Medication Industry Association) with whom it is a member.

WSMI is a Non- Governmental Organization (NGO) in official relations with the World Health Organization since 1977. For these reasons, NZSMI have an interest via WSMI in the WHO Expert Committee on Drug Dependence pre-review of dextromethorphan which occurred in 2012. The Executive summary of that involvement is reproduced as follows;

Dextromethorphan is a safe, effective cough suppressant that has a long history of therapeutic use without a prescription in a wide number of countries around the world. Medicines with the ingredient are among the most widely used cough and cold medicines in the world. Its use dates back more than 50 years.
Data suggest that abuse of dextromethorphan is limited in prevalence and scope, is not trending upward, and is within an identifiable population (largely North American teens). The physical effects from abusing dextromethorphan are generally not desirable, with negative effects of exposure to high doses of dextromethorphan including dysphoria, nausea, vomiting, blurred vision, and disorientation. To the extent there is local abuse, USA survey data indicates abusers are already engaged in substance abuse behaviors. Further, we believe more targeted, effective, and less disruptive interventions than scheduling exist that can address this abuse where it is occurring.
Scientific research on the abuse or dependence potential and prevalence of abuse seen with dextromethorphan support the conclusion that this medication does not merit the types of controls mandated in the UN Convention on Psychotropic Substances. <u>There is insufficient evidence that dextromethorphan is abused on a sufficient scale so as to constitute a public health and social problem warranting the placement of dextromethorphan under international control; nor does dextromethorphan have dependence-producing capacity as is required for scheduling under the Convention on Psychotropic Substances.</u>
The international control of dextromethorphan would result in a reduction in the legitimate use of this safe and effective medication that has benefits that far outweigh its risks. This reduction would come at a great cost to citizens worldwide who benefit from this medicine used without a prescription to

treat their coughs. There is also the potential for an increased burden being transferred to health systems as individuals turn to their physicians for support and to seek a prescription. International control would also raise the potential consequence of additional codeine, dihydrocodeine, or hydrocodone use as cough suppressants, which would come with its own set of negative, unwanted effects.
WSMI encourages the WHO Expert Committee on Drug Dependence to conclude that dextromethorphan should not move forward for further action after pre-review.

It is important to note that WHO agreed with this position and DXM was not recommended for further international supply controls.

The US industry was already responding by this time with a program to raise awareness of the teen abuse issues around DXM with an education program as mentioned in the Medsafe proposal that is credited with 35% reduction by 2015 of abuse by 12 to 17 year olds.

4. Harmonisation of Labelling.

While it is accepted that the MCC has no specific concern about the commercial effects of its' regulatory recommendations, NZSMI believes it is important to be aware of the impact on access to primary care of changing the scheduling of certain classes of products.

Linctus Gee is not marketed in Australia but Pholcodine and Dextromethorphan are available as Pharmacy Only medicines in several different dosage forms. Most these lines have harmonised labels, allowing the same product in the same box to be marketed in both countries thus achieving an economy of scale. If these items are up scheduled in New Zealand to Pharmacist Only this harmonisation will no longer exist and separate packaging and labelling for the New Zealand product will be required.

Commercially, this will seriously threaten the viability of these products as the New Zealand market is small and the costs of regulation, marketing and distribution are high in a very competitive market. The upshot could well be that the Pharmacist has NO Pharmacist Only product to supply or that prices to the consumer rise to such an extent to cover cost that many are disadvantaged.

Many scoff at this suggestion citing global pharma profits seem universally high. This is dangerous thinking as large multi-nationals are in ever increasing fierce competition that is driving margins down and many are beginning to think that even a combined Australia/New Zealand market is not substantial enough to warrant sustained investment.

NZSMI stands by its warrant to promote the appropriate availability of safe, proven, quality OTC medicines and believes a global perspective is necessary, alongside cognizance of local nuances like the very low level of abuse of cough control preparations containing DXM and Pholcodine, when considering scheduling changes.

5. Current practices around the sale of Linctus Gee

We can find no formal data that an abuse problem exists in New Zealand with this product and pharmacists regard it as a useful tool in the control of acute common cold, mucous and respiratory distress.

However, New Zealand pharmacists are acutely aware of the potential risks surrounding the sale of an opiate derivative containing medicine.

While linctus Gee is currently scheduled as Pharmacy Only most retail outlets display this product with empty boxes on shelf. This is a time proven “half-way house of self-regulation versus formal regulation”. It requires the customer to seek help from pharmacy staff to retrieve stock from behind the counter. It gives pharmacy counter staff the opportunity to evaluate the appropriateness of the sale via questioning and observation and refer to a pharmacist if required.

6. General Sale and Pharmacy Only Supply

NZSMI supports the current scheduling of DXM in New Zealand as there is no evidence to support a change in classification is warranted.

NZSMI also wishes to highlight the difference between GSL and Pharmacy Only from a practical point of view. Pharmacy Only Medicines are almost always presented for sale close to the dispensary in New Zealand pharmacies. Most New Zealand pharmacies have staff with specific training in OTC medicinals and many larger pharmacies have specialized staff dealing only in OTC medicinals and complimentary health care. This training is provided by the Pharmaceutical Society, the Pharmacy Guild, Green Cross Health and other pharmacy groups, NZSMI supplier members and is also available in continuing education on-line courses.

Pharmacy staff monitor patient requests for medication and use their training to recommend appropriate treatment to add value to the sale and relationship that is “Pharmacy”. They are also aware of the health risks and industry reputational risk of excessive supply. As such, staff will regularly check with management (often, but not always, a pharmacist) or the duty pharmacist if there are concerns. NZSMI acknowledges that these comments are anecdotal and have no research supporting them. It is currently investigating how formal research might be conducted to quantify the level of support and intervention provided by pharmacists and pharmacy staff.

NZSMI maintains informal intervention exists at “Pharmacy Only” supply level to help prevent excessive sale, misuse and abuse and that Pharmacist Only restrictions are not indicated and amount to over-regulation for the group of ingredients under discussion.