Public Consultation on Proposed Amendments to the Poisons Standard (codeine)

Notice under subsections 42ZCZL of the Therapeutic Goods Regulations 1990 (the Regulations)

The delegate of the Secretary to the Department of Health publishes herein all valid public submissions made in response to the invitation for public submissions on the proposed amendments to the Poisons Standard. In order to give due consideration to the submissions received in the interim decision public consultation period and to seek further advice from the Advisory Committee on Medicines Scheduling (ACMS) at its March 2016 meeting, the medicines scheduling delegate on 18 November 2015 deferred a final decision on the proposed codeine re-scheduling. The TGA then sought further advice and public comment on several options for codeine re-scheduling via an additional consultation period that was open from 10 December 2015 through 29 January 2016. These submissions were considered by the medicines scheduling delegate when making their final decision.

In accordance with the requirements of subsection 42ZCZL of the Regulations these submissions have had their confidential information removed.

Materials claimed to be commercial-in-confidence were considered against the guidelines for the use and release of confidential information set out in Chapter 6 of the Scheduling Policy Framework for Medicines and Chemicals (SPF, 2015), issued by the Australian Health Ministers' Advisory Council. The SPF is accessible at https://www.tga.gov.au/publication/ahmac-scheduling-policy-framework-medicines-and-chemicals.

[redacted]

1 February 2016

The Secretary
Scheduling Secretariat
GPO Box 9848
Canberra ACT 2601

Email: Medicines.Scheduling@tga.gov.au

Dear Sir or Madam,

Notice inviting public submissions under Reg 42ZCZK of the *Therapeutic Goods Regulations* 1990 Scheduling proposals to be considered at the ACMS Meeting, March 2016

We refer to the notice inviting public comment under Regulation 42ZCZK of the *Therapeutic Goods Regulations* and would like to provide comment on some of the scheduling proposals that will be referred to the March 2016 meeting of the ACMS.

[redacted] is [redacted] in Australia. [redacted] also represents related businesses providing support services to manufacturers, including advertising, public relations, legal, statistical and regulatory consultants.

[redacted] appreciates the opportunity to provide public comment in relation to ACMS agenda scheduling proposals. We wish to address relevant matters under section 52E of the *Therapeutic Goods Act* 1989.

Please find enclosed, under cover of this letter, [redacted] comments in relation to the following scheduling proposal that will be considered by the ACMS at the March 2016 meeting:

Codeine

Schedule 2 (Cough and cold medicine preparations)

a. *Proposal to amend the Schedule 2 entry to reduce the pack size to not more than 3 days' supply and include a label warning that codeine can cause addiction; OR*
b. *Proposal to up-schedule the Schedule 2 entry to Schedule 3 and reduce the pack size to not more than 3 days' supply and include a label warning that codeine can cause addiction; OR*
c. *Retain the interim decision to up-schedule to Schedule 4*

Schedule 3 (including, but not limited to codeine containing analgesics)

a. *Proposal to amend the Schedule 3 entry to reduce the pack size to not more than 3 days' supply and include a label warning that codeine can cause addiction; OR*
b. *Retain the interim decision to up-schedule to Schedule 4.*

[redacted]

Comment on the above proposals is presented as a separate attachment.

As an industry representative, [redacted] is a key stakeholder in scheduling matters and we are keen to provide further input as required. We look forward to the Delegate's interim decisions and greater detail on the final scheduling proposals.

Please contact me should you require any further clarification relating to this submission.

Yours sincerely,

[redacted]
Scientific and Regulatory Affairs Director

[redacted] Comment

Item 1. Background – Previous submissions

[redacted] provided a submission in relation to codeine dated May 2015, that was considered at the August 2015 meeting of the ACMS.

The [redacted] position on OTC codeine containing analgesics, as discussed in more detail in the previous submission, is:

- The majority of people who use OTC codeine containing analgesics medicines do so responsibly.
- Although there has been evidence of adverse events and morbidity reported as a result of dependence on codeine containing analgesics, [redacted] believes that the incidence is low in comparison to the volume of sales and many published reports pre-date the regulatory action taken in 2010, when a decision was made by the NDPSC to re-schedule these products to Schedule 3.
- There will be potential negative consequences to making OTC codeine containing analgesics prescription only. These include increased costs to government through Medicare and additional pressure on GPs and medical centres, many of which currently have long waiting times. Consumers may also face increased out-of-pocket costs and the possibility that they may be prescribed higher strength opiates in larger pack sizes – as these are currently PBS listed.
- [redacted] therefore does not support re-scheduling of OTC codeine containing analgesics to Schedule 4 and the current scheduling of OTC codeine containing analgesics is appropriate
- [redacted] supports other risk-mitigating measures – such as the introduction of a monitoring system for use by pharmacists, label warning statements and consideration of smaller pack sizes to reduce the risk of misuse of OTC codeine containing analgesics

In relation to OTC codeine containing cough and cold products that are currently in Schedule 2, the [redacted] position outlined in the previous submission is:

- Cold and flu products that contain codeine 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.
- There has been no evidence of abuse or misuse of the OTC codeine containing cold and flu medicines currently in Schedule 2.
- Evidence has been provided (confidentially) by an [redacted] member company that there has been no transfer of demand from OTC codeine containing analgesics to OTC S2 cold and flu products containing codeine and that these cold and flu medicines are not the subject of abuse or misuse.
- [redacted] believes that the current scheduling of these products is appropriate and does not support re-scheduling.

[redacted] did not support the Delegate's interim decision to reschedule all OTC codeine containing products to Schedule 4, and in October 2015 [redacted] provided a submission in relation to the Delegate's interim decisions consistent with that position.

[redacted] therefore welcomes the Delegate's final decision to reconsider the interim decision. The separation of Schedule 3 OTC codeine containing analgesics from Schedule 2 cold and flu medicines, together with a set of different regulatory options for consideration by the ACMS in March 2016 provides more structure and information for more informed public comment.

In this submission, [redacted] does not intend to duplicate the content of the two previous submissions:

- The submission to the ACMS dated 14th May 2015, in relation to the ACMS meeting held in August 2015
- The submission dated 15th October 2015, responding to the Delegate's interim decisions following the August 2015 meeting of the ACMS

The [redacted] position is consistent - essentially that the current scheduling of both OTC codeine containing analgesics and cold and flu medicines is appropriate, however we support some additional measures that will mitigate risk of addiction and misuse (particularly in relation to analgesics) and its resulting impact on health and morbidity, while at the same time retaining the consumer's ability to consult the pharmacist for advice and access without the need for a prescription.

In keeping with the structure of the consultation notice, the Schedule 2 cold and flu medicine preparations and the Schedule 3 OTC codeine containing medicines (including but not limited to analgesics) will be discussed below, separately.

Item 2. Codeine containing cough and cold medicine preparations, currently in Schedule 2:

Schedule 2 (Cough and cold medicine preparations)

a. Proposal to amend the Schedule 2 entry to reduce the pack size to not more than 3 days' supply and include a label warning that codeine can cause addiction; OR

b. Proposal to up-schedule the Schedule 2 entry to Schedule 3 and reduce the pack size to not more than 3 days' supply and include a label warning that codeine can cause addiction; OR

c. Retain the interim decision to up-schedule to Schedule 4

[redacted] supports the separation of Schedule 2 OTC codeine containing cough and cold products from analgesics and cough and cold products currently in Schedule 3. These two categories should rightly be viewed differently and the evidence relating to misuse and potential risk supports this distinction.

By way of clarification – currently, the Schedule 2 products contain codeine compounded with one or more therapeutically active substances, of which at least one is phenylephrine and not more than one is an analgesic substance. These products do not include cough suppression as a registered indication, unless compounded with a cough suppressant and the ARTG does not contain any Schedule 2 codeine products that include a codeine as a cough suppressant. The registered indications are confined to symptoms of cold and flu and not cough suppression.

The Schedule 3 codeine containing cold and flu products typically contain pseudoephedrine as a decongestant together with an additional non-opiate analgesic and these products also do not include cough suppression as an indication.

Of the options presented, [redacted] supports Proposal (a) above – *to amend the Schedule 2 entry to reduce the pack size to not more than 3 days' supply and include a label warning that codeine can cause addiction.*

Schedule 2 cold and flu 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.

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

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 re-scheduled to Schedule 3 in 2010.

There is therefore little evidence that any change to pack sizes is needed, however of the three options provided, this approach has the least regulatory impact and is therefore preferred by [redacted] members.

Label statements

[redacted] supports the inclusion of a label warning statement for all OTC medicines containing codeine. Label warning statements are an accepted way of mitigating risk by providing consumers with important advice that facilitates the appropriate use of the medicine and addressing specific risks.

Other comparable jurisdictions require OTC codeine containing medicines to contain labelling warning statements.

In New Zealand, Medsafe requires all OTC codeine containing products to include the following statements:

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.

[redacted] supports the inclusion of label warning statements, and believes that consistency with New Zealand in this regard is appropriate.

Some cold and flu medicines marketed in Australia with harmonised labelling with New Zealand already include these labelling statements as required by Medsafe.

The UK MHRA requires Pharmacy Only cough products (codeine linctus is available in the UK) to include the following warning statements:

Breastfeeding warning statement
Drowsiness warning statements – if affected do not drive or operate machinery
Do not exceed the stated dose
Do not use in children or adolescents under the age of 18

Codeine containing analgesics also require the following additional statements:

For three days use only
Can cause addiction

Pack size reduction

There is no evidence that a change to pack sizes is needed for cold and flu products, however of the options provided [redacted] supports the reduction of pack sizes for Schedule 2 cold and flu medicines to 3 days. Cold and flu medicines are for seasonal use and are used for a condition that is episodic in nature. Limiting the pack size to three 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 a codeine containing medicine being stored, however there is no evidence that use of these medicines has been inappropriate, outside the recommended duration or that stockpiling of these medicines is taking place. It will also mean that consumers who require repeated supply will be visiting the pharmacy more frequently, providing an opportunity for them to discuss symptoms with their pharmacist and referral for medical advice if needed.

Scheduling Policy Framework – Scheduling Factors - Schedule 2 medicines

In [redacted] view, codeine containing cold and flu medicines meet the scheduling factors for Schedule 2.

1. *The quality use of the medicine can be achieved by labelling, packaging, and/or provision of other information; however access to advice from a pharmacist is available to maximise the safe use of the medicine.*

The medicine is for minor ailments 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.

- Consumers are able to recognise the symptoms of cold and flu and manage their treatment. Cold and flu 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.

2. *The use of the medicine is substantially safe for short term treatment and the potential for harm from inappropriate use is low.*

Suitable for diagnosis and treatment by the consumer in the management of minor ailments.

- The safety of these combinations 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.

3. *The use of the medicine at established therapeutic dosage levels is unlikely to produce dependency and the medicine is unlikely to be misused, abused or illicitly used.*

Medicines which do not meet this factor, are not suitable to be classified as Schedule 2 Pharmacy Medicines, irrespective of any other applicable factors.

- There is no evidence of actual or potential misuse or dependence. There is no evidence of illicit use.

4. *The risk profile of the medicine is well defined and the risk factors can be identified and managed by a consumer through appropriate packaging and labelling and consultation with a medical practitioner 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.

5. *The use of the medicine at established therapeutic dosage levels is not likely to mask the symptoms or delay diagnosis of a serious condition.*

Appropriate labelling and packaging can manage risks.

- These combination products are for short-term, symptomatic relief of self-limiting conditions. [redacted] supports reduction in pack size and additional labelling warning statements as further risk management options.

Item 3. Schedule 3 (including, but not limited to codeine containing analgesics)

a. Proposal to amend the Schedule 3 entry to reduce the pack size to not more than 3 days' supply and include a label warning that codeine can cause addiction; OR
b. Retain the interim decision to up-schedule to Schedule 4.

[redacted] agrees with the separation of the Schedule 3 codeine containing medicines from those that are in Schedule 2. The Schedule 3 codeine containing analgesics should not be considered to have the same risk profile as the Schedule 2 cold and flu medicines.

The Schedule 3 cold and flu medicines contain pseudoephedrine together with an additional analgesic such as paracetamol, and it is the presence of pseudoephedrine in these medicines that is the main factor resulting in these medicines being in Schedule 3. Cough is not a registered indication for these Schedule 3 cold and flu medicines.

[redacted] supports proposal (a) – to amend the Schedule 3 entry to reduce the pack size to not more than 3 days' supply and to also include a label warning that codeine can cause addiction.

In addition, [redacted] supports the following initiatives to further mitigate risk to consumers:

- Introduction of a real time monitoring system for use by pharmacists
- Roll-out of resources to assist health care professionals and to educate consumers

The current scheduling of OTC codeine containing analgesics is appropriate. Although this submission does not intend to re-iterate the points that have been raised already, [redacted] opposes up-scheduling to Schedule 4 for the following reasons:

- The majority of consumers use OTC codeine containing analgesics appropriately. Misuse and addiction are serious problems, however [redacted] believes that these concerns can be addressed by additional measures, such as a real-time monitoring system, labelling and limiting pack-sizes.
- Limiting access to medicines for self-management of acute pain will create a significant burden on the healthcare system. The availability of a range of pain management options that are readily accessible without the need for a prescription addresses an important medical need. Limiting access will result in inconvenience and additional expense for consumers and a burden on over-stretched GPs.
- Following the publication of the Delegate's final decisions, there have also been changes to the Pharmaceutical Benefits Scheme that have resulted in the de-listing of the OTC codeine containing analgesics (other than for specific population groups). The PBS listed options available to prescribers are now largely the higher strength codeine preparations and other opiates. Many prescribers may choose to prescribe these, particularly for consumers who hold a PBS Healthcare Card and are eligible for PBS concessions. These consumers who are least able to afford increased healthcare costs, would face greater out-of-pocket costs from rescheduling by requiring a prescription for the lower strength (currently OTC) combination products and for this prescription to be dispensed as a private prescription, that includes a dispensing fee. Up-scheduling of these medicines to Schedule 4 may inadvertently shift prescribing towards higher dose opiates on the PBS and increase exposure to higher dose opiates.
- Pharmacists are accessible and suitably qualified to implement an effective risk-mitigation strategy to address concerns of misuse and abuse. The Pharmaceutical Society rolled out an educational program and additional pharmacist resources in 2015.

- Real-time monitoring is an effective approach for mitigating risk. This will enable quick and easy identification of pharmacy-shopping, misuse and abuse and enable appropriate referral. There is currently no real-time monitoring for prescription medicines that can provide the same level of oversight.
- Additional labelling warning statements are an appropriate way of assisting consumers by providing information on appropriate use.

Three day pack size

[redacted] supports limiting packs of OTC codeine containing analgesics to three days' supply. Three days' supply is sufficient to meet the needs of a consumer using the product for relief of acute pain, while also ensuring more frequent contact with a health care professional if further supply is needed.

Together with the implementation of the real-time monitoring system, the three day pack size is an appropriate way by which risk is minimised, vulnerable people are more easily detected and provided assistance and consumers who use the products appropriately are not disadvantaged.

Dependence and misuse are not expected to occur with three days duration of treatment at recommended doses.

A three day pack size would also be consistent with any labelling warnings limiting duration of use to three days, as per the [redacted] Cautionary & Advisory No. 24, and New Zealand Medsafe and MHRA labelling requirements. [redacted] would have no objections to wording along the lines of "For three days use only" being a requirement on labelling of OTC codeine containing analgesics.

Labelling

The label of a medicine provides all of the important information required by a consumer as it provides information on the use of the medicine, the dose, the recommended duration of treatment and cautionary and advisory statements to assist with safe and appropriate use.

The [redacted] has, in the 23rd edition of the Australian Pharmaceutical Formulary and Handbook, provided guidance to pharmacists on codeine as part of the Clinical Monographs (Section D) and recommended use of Cautionary & Advisory labels:

- For three days use only, can cause addiction (label 24)
- This medicine may cause drowsiness and may increase the effects of alcohol. If affected do not drive or operate machinery (label 1, for doses of 20 mg or over).

As stated above, Medsafe requires the following labelling statements:

- 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.

The MHRA has the following additional specific labelling requirements for OTC codeine containing analgesics:

- For three days use only
- Can cause addiction

[redacted] supports the introduction of specific labelling statements limiting use to three days and warning against addiction.

Introduction of labelling warning statements should follow the TGA processes of public consultation prior to inclusion in RASML and the Medicines Advisory Statements Specification.

Real time monitoring system

[redacted] supports the introduction of a real time monitoring system to be used by pharmacists.

[redacted] has been working with other stakeholders, notably the Pharmacy Guild, which has been developing and refining a prototype software system that will provide pharmacists with a clinical and decision making support tool. It is intended to be used in conjunction with the [redacted] "Guidance for provision of a Pharmacist Only medicine – Combination analgesics containing codeine" guidance document that provides a series of recommended steps for pharmacists to follow when deciding whether to supply OTC codeine containing analgesics for temporary relief of moderate to severe pain.

The system will be capable of real time recording and monitoring of Schedule 3 codeine containing analgesics. It will record the details of customers and record information such as whether product was supplied or not, details of the product supplied and indications for supply or refusal.

Pharmacists will be able to review any other recent 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. It will also enable usage data to be collected and reported.

[redacted] understands that the real time monitoring system will be pilot-tested from early February onwards.

This is a separate initiative to Project Stop and the two systems are independent; The Schedule 3 codeine real time monitoring system is a clinical support and decision making software platform whereas Project STOP is also utilised by the relevant law enforcement agencies to access data, identify persons of interest and link identification used.

The 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" who may have problems with dependence or misuse of prescription opiates.

Scheduling Policy Framework – Scheduling Factors – Schedule 3 medicines

1. *The medicine is substantially safe with pharmacist intervention to ensure the quality use of the medicine. There may be potential for harm if used inappropriately.*

The consumer can identify the ailments or symptoms that may be treated by the medicine but counselling and verification by a pharmacist is required before use. Pharmacist-consumer dialogue is necessary to reinforce and/or expand on aspects of the safe use of the medicine.

- Consumers are able to recognise pain and manage short-term treatment.
- Pharmacist intervention and monitoring can ensure appropriate quality use of the medicine and refusal of supply and referral if needed
- Pharmacist counselling and labelling warning statements will reinforce the need to use the medicine for the shortest possible duration at the recommended dose

2. *The use of the medicine at established therapeutic dosages is not expected to produce dependency. Where there is a risk of misuse, abuse or illicit use identified, the risk can be minimised through monitoring by a pharmacist.*

- At established therapeutic doses, and for short-term use, dependency is not expected.

3. *The risk profile of the medicine is well defined and the risk factors for adverse effects and interactions are known, identifiable and manageable by a pharmacist.*

- The risks are known and can be managed by a pharmacist.

4. *Where the medicine is intended for recurrent or subsequent treatment of a chronic condition, pharmacist intervention is required to monitor safe use of the medicine following recommendation by a medical practitioner or a pharmacist.*

The consumer may not be able to self-monitor the safe ongoing use of the medicine. The condition does not require medical diagnosis or only requires initial medical diagnosis, and the consumer does not require close medical management.

- OTC codeine containing analgesics are intended for short-term pain relief. Implementation of real time monitoring by pharmacists will enable detection of consumers who use the product for longer durations or try to purchase the product frequently, and these consumers can be referred to their doctor or a pain clinic.

5. *The use of the medicine at established therapeutic dosage levels may mask the symptoms or delay diagnosis of a serious condition.*

Pharmacist-consumer dialogue is required to detect the risk of masking a serious disease or compromising medical management of a disease, and to deal with it appropriately.

- The products are intended for short-term pain relief. Pharmacist counselling and monitoring can protect consumers and mitigate against inappropriate use.

Item 4. Assessment of financial impact of scheduling proposals

The invitation for public submissions has requested that stakeholders provide an assessment of how the proposed change will impact, by looking at likely benefits and costs, both financial and non-financial.

The impact of rescheduling to Schedule 4 has been briefly addressed in the bullet points on pages 9 and 10 of this submission and has been covered in greater detail in previous submissions. Potential impact of rescheduling includes a narrowing of OTC pain relief options for consumers, increases in direct healthcare costs for consumers, increased burden on GPs and medical centres and increased Medicare and government healthcare costs. An estimate of the financial implications has been included in the previous [redacted] submissions and the submissions of other stakeholders.

[redacted] supports retaining existing scheduling but mitigating risk by pack size reduction and updated labelling warning statements. Obtaining quantitative information on costs of implementation of this option to industry is difficult to do within the timeframe for consultation, however [redacted] can provide the following "top-line" information, based on member feedback:

[redacted] preferred approach – retain current schedules but reduce pack size to three days and include labelling warning statements

Likely costs include:

- Updating labelling for affected products. There are costs associated with labelling changes that include artwork costs, printing costs and write-off of superseded labels. However, implementation of the Labelling Order TGO 92 is imminent and the International Harmonisation of Ingredient Names (IHIN) project is underway within the TGA, possibly providing the opportunity for labelling changes associated with a scheduling change to be implemented simultaneously given appropriate transition times.
- Changing pack sizes. Depending on timeframes for implementation and transition, there will be costs associated with discontinuation or obsolescence of larger pack sizes and associated write-off and destruction of product in larger pack sizes. Implementation and maintenance of the OTC codeine containing analgesics real time monitoring system. According to current information, sponsors of OTC codeine containing analgesics have indicated that they are willing to contribute financially to the development of a real time monitoring system. Pharmacists will also incur costs in implementing and maintaining the system.
- Costs of resources for healthcare professionals and consumers. Pharmacy professional bodies, such as the Pharmaceutical Society of Australia and the Pharmacy Guild, will be likely to incur costs for developing and maintaining the currency of educational and practice resources for pharmacists and any associated consumer materials. Industry is also likely to incur costs and assist with development of healthcare professional resource materials (due to advertising regulations, industry cannot provide materials direct to consumers). Smaller pack sizes are proportionately more costly and consumers will more than likely incur higher costs.

Item 5. 52E Factors in summary

For completeness, the following information is provided in relation to the scheduling factors outlined in section 52E of the *Therapeutic Goods Act.* To avoid repetition, both OTC codeine containing cold and flu products as well as analgesics are addressed in the table below, to support maintaining the existing scheduling and mitigating risk by reducing pack sizes to three days' supply and including additional labelling warning statements regarding addiction.

Section 52E(1)(a) - Risks and benefits

- Benefits:
    - OTC Codeine containing analgesics offer an option for consumers to treat short term moderate pain particularly when single ingredient analgesics do not provide adequate relief. Clinical studies have shown that OTC codeine containing combination analgesics are more efficacious than placebo and single ingredient analgesics.[1,2]
    - OTC codeine containing cold and flu medicines offer an option for consumers who wish to use a combination product offering codeine together with an additional non-opiate analgesic and a decongestant, for symptomatic relief of cold and flu episodes.
    - A three day pack (as proposed and supported by [redacted] does not on its own cause dependence or abuse. When used as directed for a short duration, these products have a good safety profile.
    - Availability from pharmacists ensures advice and availability when needed, without the need for an appointment and associated Medicare and additional out-of-pocket costs.
    - For OTC codeine containing analgesics, pharmacists have a Protocol for supply as well as consumer educational material and cautionary & advisory labels to allow them to more easily raise the subject of inappropriate use with consumers. Pharmacists can refer when needed. The proposed real time monitoring system will be of benefit in identifying inappropriate or excessive use and offering additional counselling and referral to these consumers.
- Risks:
    - The reported risks of dependence and abuse particularly with excessive use over a prolonged period of time. Prolonged use at supra-therapeutic doses can lead to harm.
    - For some people, differences in drug metabolism mean that there can be variability in response, which alters efficacy and tolerability.
    - There has been no demonstrated issue of dependence or abuse with OTC codeine containing cold and flu medicines.

Section 52E(1)(b) – Purposes for use and extent of use

- Analgesics are indicated for short term use for moderate to severe pain associated with headache, dental pain and other types of pain.
- Cold & flu medicines are indicated for relief of symptoms associated with cold and flu and contain multiple ingredients.

[1] Toms L, Derry S, Moore RA, McQuay HJ. Single dose oral paracetamol (acetaminophen) with codeine for postoperative pain in adults. Cochrane Database Syst Rev 2009; (1):CD001547

[2] Derry S, Karlin SM, Moore RA. Single dose oral ibuprofen plus codeine for acute postoperative pain in adults. Cochrane Database Syst Rev 2013;(3):CD010107

- Proposed additional labelling statements and a smaller pack size, as proposed, will provide additional information for consumers - that the products are for three days use only and that codeine can be addictive.

Section 52E(1)(c) – Toxicity

- Toxicity typically occurs with longer term use at higher than recommended doses, following dependence or misuse.
- The type of harm seen is usually dependent on the non-opiate analgesic that forms part of the respective combination (ibuprofen, paracetamol, decongestant etc.)
- There has been no demonstrated concern with toxicity with the cold and flu medicines
- Limiting the pack size to three days will further mitigate against risk as it will lead to more frequent contact with a healthcare professional.

Section 52E(1)(d) - Dosage, formulation, labelling, packaging and presentation

- Currently, supply of OTC codeine is currently limited to 5 days use, however [redacted] supports further reduction to 3 days. (Note that some products that also contain pseudoephedrine have additional pack size restrictions based on the pseudoephedrine schedule entry). All OTC codeine containing medicines are intended for short term use irrespective of indications.
- Labelling of many branded products will include warning statements consistent with those used in the UK, such as "Can cause addiction. Do not use for more than 3 days" following voluntary implementation by some [redacted] member companies. This is already being phased in and should be mandated.
- Pharmacists have updated their supply protocol, undertaken educational activities and now are required to use a Cautionary and Advisory Label following the inclusion of OTC codeine containing analgesic warning statements in the APF 23. Consumer education leaflets are also provided as part of these measures.

Section 52E(1)(e) - Potential for abuse

- Although existing pack sizes are not, on their own, an instigator of addiction, [redacted] supports reduction of pack sizes to three days to further mitigate risk and ensure more frequent monitoring of use by pharmacists.
- The risk of dependence and abuse increases if the products are taken for prolonged periods at higher doses than recommended.
- A real-time reporting system is likely to be a very effective way to mitigate risk, by identifying pharmacy shoppers and targeting those who require referral for specialised care.

Section 52E(1)(f) - Other matters

- In relation to analgesics, the recently implemented [redacted] initiatives enable more effective pharmacist interaction with customers, provide an avenue to educate and counsel them and thereby further mitigate risks. The need to educate consumers will be the same regardless of the scheduling.
- These measures, coupled with universal adoption of label warnings and a real time reporting system for analgesics will be the most effective way of targeting the individuals most at risk while not inconveniencing or increasing costs for people who use the products appropriately.

Overseas Regulatory Status

- Concerns about harms associated with dependence, abuse and misuse are not limited to Australia.
- Other comparable regulatory authorities have assessed these matters in reviews of safety and classification
- Low dose codeine containing analgesics and cold and flu medicines are classified as Pharmacy Medicines in some key markets:

    - UK: Pharmacy Medicines with the mandatory labelling warning statements described above. Pack size limited to three days.
    - New Zealand – analgesics are Pharmacist Only (Restricted) medicines and cold and flu products are Pharmacy Medicines
    - Canada – Pharmacy Medicines
    - Denmark
    - France
    - Ireland
    - South Africa, which also has a real time monitoring system

Conclusion

OTC codeine containing analgesics

[redacted] believes that the current scheduling of OTC codeine containing analgesics is appropriate. The majority of consumers use these products responsibly for the short term relief of moderate to severe pain for self-limiting conditions. In relation to the overall sales of the products, the number of cases of harm from addiction is low in comparison – indicating that while the harms are significant for those affected and those who treat them, the problem is not widespread so more specific and targeted interventions are needed to address those at most risk.

[redacted] does not believe that a move to Schedule 4 provides a simple solution which will solve the problems that can arise as a result of misuse or addiction. [redacted] takes the issue of harm very seriously and supports the new education and counselling initiatives undertaken by pharmacists, the new Cautionary & Advisory labelling of the APF 23. Many [redacted] members have voluntarily implemented prominent front of pack warning statements on the risk of addiction and a treatment duration of 3 days use.

The real-time monitoring system that has been developed and is currently being trialled by some pharmacists promises to be an effective risk-mitigating approach to OTC codeine containing analgesic use. This would enable better detection and referral of vulnerable people while not inconveniencing those who use the products correctly. This type of monitoring system software does not extend to prescription monitoring and doctor shopping, which is also a documented concern.

As part of Schedule 3 supply requirements, pharmacists must provide consumers with counselling and advice on use of these products and ensure that supply is in accordance with the protocol for supply. Should these products be up-scheduled, then the legitimate users of these products will require a prescription – which will be costly, inconvenient and most likely result in purchase of a larger quantity on prescription (e.g. 30 or 50 tablets), and this in itself may predispose to use for longer than needed.

OTC Cold and Flu products containing codeine

[redacted] believes that the current scheduling of cold and flu products is appropriate. These products are not labelled or marketed as analgesics. No evidence has been provided that these products are being misused.

[redacted] assumes that proposals to re-schedule OTC cold and flu products containing codeine is based on a hypothetical risk that misuse may occur by those who are misusing or seeking codeine. There is no evidence to support this position and sales data indicates that the product usage is predominantly seasonal and there has been no indication of a growth in demand since the codeine containing analgesics were rescheduled to Schedule 3 in 2010.

Recommendations

For the reasons outlined in the submission, [redacted] recommends the following options as being appropriate approaches to the scheduling of codeine:

- *The scheduling of Schedule 2 (Cough and cold medicine preparations) containing codeine should remain unchanged.*

- *The scheduling of Schedule 3 (codeine containing analgesics, as well as cold & flu products containing pseudoephedrine) should remain unchanged.*
- *The pack size should be reduced to three days' supply for all OTC codeine containing analgesics*
- *The pack size of cold and flu medicines is appropriate at present however [redacted] is prepared to accept a pack size reduction, despite this appearing to be a disproportionate requirement relative to risk.*
- *The labelling of all OTC codeine containing medicines should include warning statements regarding addiction and duration of use (consistent with Medsafe requirements). A RASML consultation on additional labelling statements (breastfeeding, drowsiness) may also be appropriate.*

As an industry representative, [redacted] is a key stakeholder in scheduling matters and we are keen to provide further input as required. We look forward to a final decision which appropriately reflects the risks and benefits of codeine containing products.

[redacted]

PROPOSED AMENDMENTS TO THE POISONS STANDARD (CODEINE)

Comments by the [redacted] to the proposed amendments referred by the delegate for scheduling advice for consideration by the ACMS - March 2016

Codeine

February 2016

[redacted]

1. OVERVIEW

The [redacted] welcomes the opportunity to provide further comment on the proposed amendments regarding codeine referred by the delegate for scheduling advice.

[redacted] provided a submission in October 2015 opposing the delegate's interim decision to delete the Schedule 2 and Schedule 3 entries for codeine. This opposition was based on a range of factors which included:

- The impact this would have on the vast majority of people who use these products safely and effectively. When the scheduling of codeine has been examined in the past, expert advisory committees in Australia, New Zealand and the United Kingdom have defined the policy problem of OTC codeine misuse and harm as small, relative to total use.[1] This is an important consideration in determining the most appropriate policy response.

- The likely cost implications to the Medicare Benefits Schedule and Pharmaceutical Benefits Scheme.

- Merely rescheduling codeine will not address issues of misuse and abuse.

- There are more cost effective and more reliable methods of identifying consumers who are at risk of codeine dependence without restricting access to the majority of Australians who use these products appropriately.

[redacted] refers to its response to the interim decision dated October 2015 included in ATTACHMENT 1 for your reference.

1.1 Summary of [redacted] position and recommendations outlined in the previous submission

1. Any decisions regarding the removal of codeine from Schedule 2 and Schedule 3 categories should be deferred so pharmacies have a sufficient time period to implement the Real Time Monitoring (RTM) system. Specifically, [redacted] recommends a decision relating to scheduling changes to Schedule 4 should not be made until at least June 2017, pending an analysis of the cost effectiveness of the RTM system from a full 12 months of data.

2. In order to maximise the effectiveness of the RTM system, State/Territory legislators must amend their medicines and poisons regulations to mandate the real-time online recording of OTC codeine products. This will ensure universal coverage of the system in pharmacies across the country.

3. [redacted] believes there is an opportunity to create a new Appendix in the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP) that lists medicines that are subject to mandatory recording. This would promote national consistency and encourage the use of real-time monitoring systems to assist health professionals in making clinical decisions.

4. In addition to the introduction of the real-time monitoring system and legislative amendments, the following measures should also be considered:

    a. Mandatory warning labels advising consumers of the potential for dependence from prolonged use of codeine products (greater than 3 days);

[1] Tobin, C. L., Dobbin, M., & McAvoy, B. (2013). Regulatory responses to over-the-counter codeine analgesic misuse in Australia, New Zealand and the United Kingdom. *Australian and New Zealand journal of public health*, *37*(5), 483-488.

b. Consideration of reducing pack sizes for codeine (particularly Schedule 3 products) to a maximum of 3 days' supply;

c. Ongoing education for pharmacists, and

d. A consumer awareness campaign.

5. It is critical that a comprehensive Regulatory Impact Statement is developed based on a thorough cost benefit analysis prior to any final decision being reached. This is particularly important given there are more cost effective and arguably more effective methods of preventing codeine dependence such as the RTM system. This is especially relevant given pressures on health expenditure.

2. ACMS PROPOSED AMENDMENTS

Schedule 2 Codeine (cough and cold medicine preparations):

a. Proposal to amend the Schedule 2 entry to reduce the pack size to not more than 3 days' supply and include a label warning that codeine can cause addiction; OR

b. Proposal to up-schedule the Schedule 2 entry to Schedule 3 and reduce the pack size to not more than 3 days' supply and include a label warning that codeine can cause addiction; OR

c. Retain the interim decision to up-schedule to Schedule 4

Schedule 3 Codeine (including, but not limited to codeine containing analgesics):

d. Proposal to amend the Schedule 3 entry to reduce the pack size to not more than 3 days' supply and include a label warning that codeine can cause addiction; OR

e. Retain the interim decision to up-schedule to Schedule 4

[redacted] welcomes the Delegate's final decision to defer the proposed re-scheduling of medicines containing codeine, subject to further consideration of the interim decision. [redacted] provides comments on specific proposals put forward by the TGA in the section below. [redacted] prefaces these comments in the context of our comments raised regarding the implementation of a RTM system and our previous submission to the delegate's interim decision in October 2015.

2.1 Schedule 2 codeine entry (cough and cold medicine preparations):

Schedule 2 Codeine (cough and cold medicine preparations):

a. Proposal to amend the Schedule 2 entry to reduce the pack size to not more than 3 days' supply and include a label warning that codeine can cause addiction; OR

b. Proposal to up-schedule the Schedule 2 entry to Schedule 3 and reduce the pack size to not more than 3 days' supply and include a label warning that codeine can cause addiction; OR

c. Retain the interim decision to up-schedule to Schedule 4

General Comments

As noted in the delegates' interim Decision, the scheduling of codeine for cough and cold preparations was reviewed by the National Drug and Poisons Scheduling Committee (NDPSC) in 2009 and the Scheduling delegate in 2011 as part of the cold and cold preparation review. On both occasions the Schedule 2 entry for codeine was deemed as appropriate.[2]

[redacted] is not aware of any official evidence after 2011 that indicates Schedule 2 phenylephrine/codeine products are subject to abuse/misuse. It is important when investigating dependence as well as abuse/misuse that data is available for specific codeine products as cold and flu preparations are different from combination analgesics containing codeine (CACCs). [redacted] believes claims of abuse/misuse are predominantly attributed to CACCs rather than cold and flu preparations. As noted in our response to the interim decision dated October 2015, the interim decision to reschedule Schedule 2 codeine products appears to be based primarily on a purported unfavourable risk/benefit

[2] Interim decisions & reasons for decisions by delegates of the Secretary to the Department of Health – October 2015, 10

profile. [redacted] maintains that concerns regarding the risk/benefit profile of medicines should be addressed through a separate TGA review to determine whether such products should remain on the Australian Register of Therapeutic Goods (ARTG). This occurred previously with dextropropoxyphene in 2011. This eventually led to more stringent oversight regarding the supply of this medicine.[3] Simply rescheduling these products to prescription medicines is inappropriate in this context.

Consequently, the current scheduling remains appropriate until robust evidence is presented that specifically attributes a risk of dependence or misuse to phenylephrine/codeine cough and cold preparations.

Nevertheless, it is [redacted] intention to include phenylephrine/codeine products in the RTM system. If the TGA and ACMS believe this is best achieved if such products are Schedule 3, then this can be accommodated.

a. Proposal to amend the Schedule 2 entry to reduce the pack size to not more than 3 days' supply and include a label warning that codeine can cause addiction

[redacted] has no objection to this proposal. We have consistently advocated for mandatory warning labels on codeine products advising of the risk of addiction for codeine products to complement the advice provided by pharmacy staff at the point of sale.

[redacted] also has no objection to restricting pack sizes to not more than 3 days' supply, though we note that this is probably more applicable to CACCs than for cold and flu preparations.

b. Proposal to up-schedule the Schedule 2 entry to Schedule 3 and reduce the pack size to not more than 3 days' supply and include a label warning that codeine can cause addiction.

We believe in the absence of conclusive evidence regarding misuse/abuse of phenylephrine cold and flu products containing codeine the current scheduling remains appropriate. However the RTM system will have the capacity to record all types of codeine including Schedule 2 cold and flu preparations. If the TGA and ACMS believe this is best achieved if such products are Schedule 3, then [redacted] has no objection.

If the maximum pack size were to be reduced and/or new labelling requirements mandated, a sufficient lead time (to be determined in consultation with stakeholders) would be required.

c. Retain the interim decision to up-schedule to Schedule 4

Per our previous comments, [redacted] opposes the interim decision to up-schedule to Schedule 4. [redacted] is not aware of any evidence after 2011 that indicates Schedule 2 phenylephrine/codeine products are subject to abuse/misuse. Concerns regarding an unfavourable risk/benefit profile should be considered as part of a separate review to determine whether such products should remain on the ARTG. Rescheduling products to prescription medicines in this context is not the appropriate mechanism as the general risk/benefit profile of the medicine is not relevant in relation to scheduling.

[3] https://www.tga.gov.au/media-release/update-tga-decision-cancel-prescription-pain-killers-19-september-2013

2.2 Schedule 3 codeine entry (including, but not limited to codeine containing analgesics):

Schedule 3 Codeine (including, but not limited to codeine containing analgesics):

a. *Proposal to amend the Schedule 3 entry to reduce the pack size to not more than 3 days' supply and include a label warning that codeine can cause addiction; OR*
b. *Retain the interim decision to up-schedule to Schedule 4*

General Comments

[redacted] acknowledges the concerns relating to patient safety due to misuse of combination codeine analgesics (CCA) and agrees some action needs to be taken. However, the proposed rescheduling changes are a blunt instrument to address misuse and abuse of these medicines as it also restricts access to patients who are using these products safely and effectively as OTC medicines. [redacted] believes that the proposal would not only be ineffective at addressing concerns of abuse, but could also have unintended consequences which are outlined in our previous submission (ATTACHMENT 1) and are reiterated in the section below.

[redacted] contends that the implementation of a mandatory real-time monitoring system in community pharmacy would be more effective and economical to assist in identifying at-risk consumers, facilitate access to education materials and support appropriate referral when required. This is explained in further detail under the *Real Time Monitoring* section.

a. Proposal to amend the Schedule 3 entry to reduce the pack size to not more than 3 days' supply and include a label warning that codeine can cause addiction

As mentioned in our submission to the delegate's interim decision, in addition to the introduction of a nationwide RTM system, [redacted] supports mandatory warning labels that codeine can cause addiction. Similar measures were introduced in the United Kingdom in 2009.[4]

Reducing the maximum pack size to 3 days' supply would be consistent with clinical guidelines that stipulate OTC codeine should not be used for than for more than 3 days at a time except with doctor's advice.[5] In addition, reducing the maximum pack size would require consumers who are using codeine products regularly to have more frequent interaction with the health system in order to obtain these products. In combination with the introduction of the RTM system, this increases the likelihood that inappropriate use will be detected, more pharmacist intervention and advice provided and appropriate referrals made to doctors and pain specialists for pain management reviews.

In the interests of consistency, these measures could also apply to Schedule 3 cold and flu preparations though as we elaborate below, these products should be assessed separately from CACCs.

As mentioned previously, if the maximum pack size were to be reduced and/or new labelling requirements mandated, a sufficient lead time (to be determined in consultation with stakeholders) would be required.

b. Retain the interim decision to up-schedule to Schedule 4.

[redacted] reiterates our opposition to the Interim Decision. It is the view of [redacted] that the proposed rescheduling changes to Schedule 4 are a blunt instrument to address misuse and abuse. We believe that the proposal would not only be ineffective at addressing concerns of abuse, but could also have unintended consequences such as:

[4] https://www.gov.uk/drug-safety-update/over-the-counter-painkillers-containing-codeine-or-dihydrocodeine
[5] http://atdc.org.au/wp-content/uploads/2011/02/OTC_CODEINE_REPORT.pdf , http://www.aci.health.nsw.gov.au/__data/assets/pdf_file/0020/212771/Safe_OTC_Pain_Medication_-_Pharmacy.pdf

- For the majority of people who use these products safely and effectively, rescheduling will make pain relief medicines more expensive and more difficult to obtain.
- Rescheduling codeine will result in substantial costs to the Medicare Benefits Schedule (MBS) through an increase in medical practitioner visits. There will be an increase in the workload of medical practitioners and increased waiting times for patients, especially as many medical practices have limited capacity to accept new patients.
- Patients who reside in regional, rural and remote areas would be most impacted, given the time and cost to visit a medical practitioner is substantially greater compared to metropolitan areas.[6]
- The decision is likely to have cost implications for the Pharmaceutical Benefits Scheme (PBS), particularly if medical practitioners elect to prescribe consumers higher strength codeine products or other analgesics and/or NSAIDS listed on the PBS.
- For patients who do not have ready or affordable access to a medical practitioner, their pain management may go untreated and/or lead to an increase in presentations at hospitals.

Schedule 3 cold and flu preparations

Other than diversion for use as a precursor in illegal substances, there is no evidence to suggest that pseudoephedrine/codeine products are subject to misuse/abuse and overall usage of these products is considerably lower than CACCs. The likelihood of a consumer inadvertently becoming addicted to codeine via these products is lower; given colds and flu are temporary conditions with symptoms generally dissipating within a few days.

The TGA's Database of Adverse Event Notifications (DAEN) records show that there have only been five adverse events recorded for these products over the past 5 years with no events recorded related to abuse or dependency.

In addition, products containing pseudoephedrine are currently monitored by the Project STOP RTM system. Therefore any inappropriate or excessive use of these products by people who are codeine dependent are brought to the attention of pharmacies for intervention.

[redacted] believes concerns regarding codeine dependence are almost entirely attributable to CACCs as opposed to cold and flu preparations.

Regulatory Impact Statement and Cost/Benefit Analysis

As mentioned in the response to the interim decision, given the sheer magnitude of the impact the proposed scheduling amendment will cause to a wide range of stakeholders, [redacted] believes it is imperative that a comprehensive Regulatory Impact Statement (RIS) be developed based on a thorough cost benefit analysis prior to any final decision on rescheduling.

On behalf of [redacted], Cadence Economics undertook and an analysis of the fiscal impacts (and related issues) of all medicines containing codeine to require a prescription per the proposed interim decision.

The report (attached)[7] estimated the change would result in an additional 8.7 million GP visits per year, with the resulting additional cost to Medicare Benefits Schedule estimated at over $300 million per year.

The figures do not take into account patients seeking a script for the 5.2 million codeine-based cold and flu symptom relief medications - the conservative assumption is that most will instead purchase an alternative remedy at the pharmacy - and nor does it take into account losses in time and productivity for patients.

[6] National Health Performance Authority Media Release 01 October 2015 – People 2 to 3 times more likely to avoid seeing a GP due to cost in some areas

[7] [redacted]

Costs to the PBS are also not included as these medications would not be subsidised, although there is the potential that higher strength, PBS-subsidised alternatives such as Panadeine Forte might be prescribed more often.

Given the estimated cost associated with the proposal to removal codeine from Schedule 2 and Schedule 3, [redacted] recommends that a comprehensive Regulatory Impact Statement be developed based on a thorough cost benefit analysis. This is particularly important given there are more cost effective and effective methods of preventing codeine dependence such as the RTM system.

Real-time monitoring

[redacted] has developed and is in the process of implementing a national RTM system for the sale of codeine products in community pharmacies. This system will provide a data-driven clinical decision support tool for pharmacists that would be more effective for assisting in identifying at-risk patients, facilitate access to education materials and support appropriate referral when required.

[redacted] has consistently argued that the implementation of a Real Time Monitoring (RTM) system in community pharmacy would be more effective, targeted and economical to assist in identifying at-risk consumers and enabling them to access appropriate support..

This is why [redacted], in partnership with the [redacted], has taken the initiative and developed a real-time monitoring system specifically designed to record pharmacy provision of over-the-counter (OTC) products containing codeine.

Unlike the current Project STOP system, which is primarily a law enforcement tool to prevent diversion of pseudoephedrine, the new system is a clinical decision support system, assisting pharmacists in identifying patients who are risk of codeine dependence. The system will also have the capacity for pharmacists to record clinical information and provide guidance regarding suitable referral pathways to support patients to better manage their pain and enhance health outcomes.

A preliminary user testing of the prototype took place in December 2015 involving approximately 30 pharmacies, mainly located in the Newcastle NSW region. The pharmacies were requested to integrate the RTM codeine prototype system as part of their existing clinical practice when determining a genuine therapeutic need for a CACC. Pharmacies were encouraged to use the prototype for every codeine product transaction during the user testing period and provide feedback on areas they believed the system could be improved.

Overall, the feedback received from pharmacies was positive. Most pharmacists were satisfied with the system's ease of use and the time required to use it was not considered burdensome. The majority of patients had no objection to their details being recorded with several pharmacists mentioning consumer acceptance increased once pharmacy staff explained to them the purpose and need for the system.

The system is currently being modified and updated to incorporate the feedback provided during the user testing period.

A pilot testing of the full functionality of the system, titled *MedsASSIST*, is due to commence in February 2016. Pilot testing will be conducted with an expanded cohort of pharmacies in the Newcastle NSW and North Queensland areas. The national rollout of the system is expected to commence in March 2016.

As in our response to the interim decision from October 2015, in order to allow time for a new real-time monitoring system to be developed and deployed as well as collection and analysis of data from the system, [redacted] requests the scheduling delegate defer the final decision on changes to the Schedule 2 and Schedule 3 entries for codeine until the RTM system has been rolled out and its cost effectiveness analysed based on a full 12 months of data.

While [redacted] welcomed the deferral of the final decision until at least June 2016 with any implementation date (if applicable) to be not before 2017, there is still much uncertainty regarding if and when a final decision will be announced and implemented. [redacted] reiterates its recommendation that any decisions regarding the removal of codeine from Schedule 2 and Schedule 3 categories should be deferred so pharmacies can implement the RTM system with some degree of certainty. Specifically [redacted] recommends any decision relating to scheduling changes should not be made until at least June 2017, pending an analysis of the effectiveness of the RTM system based on a full 12 months of data. [redacted] will consider engaging independent researchers to assess the impact as part of the evaluation.

Detailed screenshots of the system can found in ATTACHMENT 3.

Legislative Amendments

Notwithstanding the points raised above, in order to maximise the effectiveness of the RTM system, State/Territory legislators must amend their medicines and poisons regulations to mandate the real-time online recording of OTC codeine products. This will ensure universal coverage of the system in pharmacies throughout the country.

While this is a change that can be made straight away, from a longer term perspective [redacted] considers the recording of medicines to be a national health issue, hence laws regarding the recording of medicines should be considered at a national level. Consequently, changes should be made to the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP).

Currently, the SUSMP does not stipulate requirements for mandatory recording of medicines that may be subject to misuse/abuse (such as combination analgesics containing codeine (CACCs)) or diversion (such as pseudoephedrine). Thus the mandatory recording of medicines must occur via changes to each State/Territory Poisons legislation. This invariably causes delay and inconsistency between jurisdictions. [redacted] believes there is an opportunity to create a new Appendix in the SUSMP that lists medicines that should be subject to mandatory recording. This would promote national consistency to encourage the use of real-time monitoring systems to assist health professionals in making clinical decisions.

Government of **Western Australia**
Mental Health Commission

Our ref : MHC16/02106
[redacted]

Therapeutic Goods Administration
PO Box 100
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To Whom it May Concern

PROPOSED AMENDMENTS TO THE POISONS STANDARD (MEDICINES)

The Mental Health Commission (MHC) is responsible for planning and purchasing mental health and alcohol and other drug (AOD) services in Western Australia. The MHC has responsibility for the network of AOD treatment services that exist in Western Australia and provides services through Next Step Drug and Alcohol Services.

Over the counter codeine analgesics in combination with ibuprofen, paracetamol or aspirin are widely available, with approximately one in three Australian adults using these medications each year. Medications that are available over the counter are able to be taken in excessive doses by people who have become codeine addicted.

There are a number of people presenting to AOD treatment services in Western Australia with problems arising from codeine dependence. Treatment data for Western Australia shows that codeine was the primary drug of concern for 1.1 per cent of all treatment episodes (311) in 2014/2015. By comparison, other restricted substances such as oxycodone and benzodiazepines were the primary drug of concern for 0.7 per cent (211) and 0.6 per cent (183) of all treatment episodes in the same time period.

Many people who are experiencing codeine addiction require opioid substitution treatment with buprenorphine or methadone. Given the availability of and ease of access to medications containing codeine, this cohort of patients can be difficult to treat and relapse is common.

Furthermore, there are fundamental health concerns that result from any medication that contains an addictive drug in combination with another drug that can cause harm when taken in excessive dose (for example medications that contain codeine in combination with ibuprofen, paracetamol or aspirin).

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There is research to demonstrate that codeine adds little additional benefit when combined with non-opioid analgesics such as paracetamol and ibuprofen. However, the availability of these medications in the community increases the risk of problems relating to addiction and secondary toxicity such as gastrointestinal, renal and liver toxicity. There are a number of published medical cases of patients experiencing secondary harm from opioid addiction to Schedule 3 codeine combination medications.

Based on the available information and in order to reduce the health problems resulting from codeine dependence, the MHC supports the interim decision to make medications containing codeine Schedule 4 medications.

Yours sincerely

[redacted]

28 January 2016

Enc. Consultation submission cover sheet

[redacted] Submission to the Therapeutic Goods Administration in Response To The Proposed Changes To The Poisons Standard (Codeine).

February 2016

developing and promoting best practice standards

[redacted]

[redacted] submission

The [redacted] welcomes the opportunity to comment on the proposed amendments to the Poisons Standard (Codeine).

The [redacted] notes that the Therapeutic Goods Administration (TGA) released an interim decision in October 2015, which recommended changing approximately 150 Schedule 2 and Schedule 3 codeine containing medications to Schedule 4. This change would mean that Schedule 2 and Schedule 3 codeine products – that are currently available for purchase 'over-the-counter' (OTC) in pharmacies - will become available via prescription only.

However, following submissions from stakeholders, the TGA has decided to defer the interim decision to up-schedule products containing codeine and is seeking further submissions from interested parties.

The [redacted] endorses the TGA's original interim proposal to up-schedule products containing codeine as follows:

- Schedule 2 (cough and cold medicine preparations) codeine products to become Schedule 4 products.
- Schedule 3 codeine products (including but not limited to codeine containing analgesics) to Schedule 4 products.

The [redacted] supports this change because:

- codeine related deaths – alone and in combination with other drugs such as ibuprofen or paracetamol – are a major and increasing problem in Australia. This is highlighted by recent research, which shows that codeine related deaths in Australia increased from 3.5 deaths per million in 2000 to 8.7 per million in 2009. Most of these deaths were attributed to multiple drug toxicity (Roxburgh et al., 2015)
- we are particularly concerned that – in more than half (53.6%) of the cases of codeine-related deaths – the person concerned had a history of mental health problems (Roxburgh et al., 2015)
- to enhance patient safety and prevent abuse of codeine products, it is important that an appropriately qualified medical practitioner assesses the risk and benefits of prescribing codeine relevant to each individual patient situation.

To support this initiative, the [redacted] also recommends that the TGA undertake an education campaign to advise Australians about more appropriate and effective analgesics other than codeine. Feedback provided by [redacted] members suggests that such a campaign would also be important to highlight the deceptive nature of codeine related products. This is because the metabolism of codeine makes it a much more dangerous drug than is widely realised or understood. In particular, what might be seen as initially harmless OTC use of codeine is often seen in clinical settings - in retrospect - as an increasingly common significant step towards opioid addiction.

More broadly, the [redacted] supports the ongoing development of a real-time electronic prescription monitoring system. The [redacted] has previously called for the urgent, national implementation of the Electronic Recording and Reporting of Controlled Drugs (ERRCD) for the management of prescription drugs, which is currently only operational in Tasmania.

We consider that the national rollout of the ERRCD system will provide medical professionals with valuable, real-time information of the prescription and dispensing of restricted prescription medications,

which enable them to best monitor and assess a patient's medication history, prevent and reduce the abuse of prescription drugs and help improve the health and wellbeing of Australians. Although the ERRCD currently only permits viewing of Schedule 8 drug dispensing information, the [redacted] also supports expanding the ERRCD system to include other drugs of dependence.

Reference

Roxburgh A et al. (2015) Trends and characteristics of accidental and intentional codeine overdose deaths in Australia. Medical Journal of Australia. 203(7): 299.

[redacted]