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.

any different in the 30 different versions that we found (Appendix 1), other than whether the formulation is a standard acid or fast acting. There may well be differences in the actual formulation process, in the way the drug dissolves in the stomach, or the way it is absorbed and acts.

We know of no registry of studies or source of study results we could use to determine whether any one of these different products is better than any other, except that fast acting tends to be better than standard formulations. We just cannot know, for any product, how much analgesia is produced by it: all we have are the average values from all trials ever done, and the expectation that the average will apply to a particular product. The exception is for ibuprofen plus paracetamol combination, where all the studies used the same formulation (Appendix 1).

The postoperative pain model used in this overview is predominantly (80%) pain after third molar extraction, which is used as the industry model for everyday pain (Derry 2011). That makes the results relevant to many pain conditions for people who use non-prescription analgesics. The ideal would be to have results also available for other common pain conditions where non-prescription analgesics are used, but where the efficacy may be different. The most common pain conditions are dental caries, tension-type headache, and migraine (Vos 2012). There were few data for tension-type headache (Moore 2014b), while there were Cochrane reviews for some OTC analgesics in migraine (Derry 2013; Kirthi 2013; Rabbie 2013). A review of dysmenorrhoea did not give efficacy results according to drug, but suggested that the NNT for providing moderate or excellent pain relief for NSAIDs was around 3.2, with success rates up to 43% (Marjoribanks 2015); NSAIDs were better than paracetamol, mirroring results in this overview in acute pain.

The results do not apply to treatment of chronic musculoskeletal conditions, such as osteoarthritis.

Quality of the evidence

The quality of the evidence was good, using standard reviews examining standard clinical trials designed to measure the analgesic efficacy of drugs in sensitive assays in acute painful conditions (McQuay 2012). The overview process further removed any results likely to be the object of potential publication bias, so that only reliable results remained. This leaves a very large body of efficacy results presented by dose and formulation.

These results report a clinically useful level of pain relief over a sensible period, and with the common comparator of placebo. Though indirect comparisons are often criticised, this is one circumstance where indirect comparison can be justified because of the clinical homogeneity of trials and outcomes, and because data like these have been tested and indirect comparison found to be a reasonable approach (Song 2003).

Potential biases in the overview process

No obvious biases in the overview process existed, for the reasons given above.

Small data sets are clearly more variable than larger ones, as would be expected (Moore 1998). However, with few exceptions placebo response rates were within limited ranges, typically between 5% and 20%.

Most studies in the individual reviews will have been sponsored or conducted by manufacturers. This is not likely to be a source of any bias, since specific analyses have been conducted on some of the larger data sets to demonstrate that no industry bias exists in like-for-like comparisons (Barden 2006).

Agreements and disagreements with other studies or reviews

The only other overviews of this type known to exist for acute pain studies are non-Cochrane overviews in dental pain (Barden 2004; Derry 2011), and a review of OTC analgesics based on Cochrane reviews (Moore 2013c). The general methods used were similar and there were no major differences. Two other overviews have looked in detail at all available data on efficacy (Moore 2015a) and adverse events (Moore 2015b).

AUTHORS' CONCLUSIONS

Implications for practice

For people with acute pain

The major implication for people with acute pain is the knowledge that there is a body of reliable evidence about the efficacy of some of the most commonly available drugs and doses that are available without prescription. The proportion of people with acute pain who get good pain relief with any of them ranges from about 70% at best to less than 20% at worst. Low doses in fast acting formulations can provide good analgesia in many people. Adverse events are generally no different from placebo. Consumers can make an informed choice based on this knowledge, together with availability, and price.

Advice is often given to take analgesics with food, with the ostensible aim of reducing adverse effects in the gastrointestinal tract, and this advice needs urgent re-evaluation.

For clinicians

There is also a clear message that simple drug combinations and fast acting formulations deliver good analgesia in many people with acute pain, and at relatively low doses. Clinicians can use this knowledge to provide good evidence-based advice to people who want to self medicate. There are no drugs available with prescription that are more effective.

Advice is often given to take analgesics with food, with the ostensible aim of reducing adverse effects in the gastrointestinal tract, and this advice needs urgent re-evaluation.

For policy makers

Simple drug combinations and fast acting formulations can deliver good analgesia in many people with acute pain at relatively low doses. This can help provide potentially useful public health messages about maximising pain relief while minimising population exposure to analgesics.

Advice is often given to take analgesics with food, with the ostensible aim of reducing adverse effects in the gastrointestinal tract, and this advice needs urgent re-evaluation.

For funders

The knowledge that no better analgesics are available with a prescription than without a prescription may have implications for prescribing policy and the health economy.

Implications for research

General

It appears to be possible to provide useful evidence-based information directed at consumers concerning commonly used drugs available without prescription. That this is based on an in-depth understanding of clinical trials and systematic reviews, consistently done to high quality levels, and using a simple message about outcomes of value to people with pain, provides an exemplar for how more can be done to inform consumers.

The lack of any information on the efficacy of low dose codeine combination therapies is a major gap in knowledge. While the doses of codeine may be small in individual doses, this possibly represents substantial population consumption, and we need to know that there is some benefit in terms of analgesic efficacy in individuals as a balance to possible harm to the community.

Design

Perhaps the most important design issue relates to the outcome. The outcome used is one of value to people with pain, and results can be expressed in a simple and understandable way.

Measurement (endpoints)

Pain measurement is not an issue.

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* *Indicates the major publication for the study*

APPENDICES

Appendix 1. List of available non-prescription analgesics in the UK in May 2015, from Boots and Lloyds Pharmacy websites

Drug and dose (mg)	UK OTC product	Comments
Aspirin only products		
Aspirin 300	Disprin Direct	-
	Disprin soluble	-
	Boots Aspirin Tablets	-

(*Continued*)

	Boots Aspirin Dispersible Tablets	-
	Lloyds Pharmacy Aspirin Tablets	-
	Lloyds Pharmacy Dispersible Aspirin Tablets	-
	Aspro Clear Regular Strength	-
	Disprin Original Tablets	-
Aspirin 325	Aspirin Regular Strength Tablets	-
	Aspro Tablets	-
	Bayer Aspirin Coated Tablets	-
	Bayer aspirin Tablets	-
	CVS Regular Strength Aspirin	-
	CVS Enteric Aspirin Regular Strength	-
Aspirin 500	Aspro Clear Extra Strength	-
	Disprin Max	-
	Bayer Extra Strength Coated Caplets	-
Combination products containing aspirin		
Aspirin 500 + codeine 8	Codis	-
	Boots Aspirin & Codeine Tablets	-
Aspirin 300 + paracetamol 200 + caffeine 45	Anadin Extra	-
	Anadin Extra Soluble	-
	Anadin Extra Triple Action Tablets	-
	Boots Aspirin Extra	-
	Lloyds Pharmacy Extra Power Pain Reliever Caplets	-
Aspirin 250 + paracetamol 250 + caffeine 65	Excedrin Extra Strength	-

(*Continued*)

Aspirin 500 + caffeine 50	Beechams Powders	-
Aspirin 500 + caffeine 32.5	Bayer Back & Body Caplets	-
	CVS Extra Strength Back & Body Pain Caplets	-
Aspirin 325 + caffeine 15	Anadin Original	-
Diclofenac only products (not now available in the UK)		
Diclofenac potassium 12.5	Boots joint pain relief 12.5 mg tablets	Fast acting
	Voltarol joint pain 12.5 mg tablets	Fast acting
Diclofenac potassium 25	Voltarol pain-eze extra strength 25 mg tablets	Fast acting
	First resort double action pain relief tablets	Fast acting
Ibuprofen only products		
Ibuprofen 200	Nurofen Tablets	-
	Nurofen Caplets	-
	Value Health Ibuprofen	-
	Boots Ibuprofen Caplet	-
	Anadin Joint Pain	-
	Lloyds Pharmacy Ibuprofen Caplets	-
	Life Brand ibuprofen Tablets	-
	Advil Ibuprofen Tablets	-
	Gold Cross Ibuprofen	-
	Guardian Ibuprofen	-
	Herron Blue Ibuprofen Tapsules	-
	Value Choice Ibuprofen	-
	CVS Dye-Free Ibuprofen Tablets	-

(*Continued*)

	Nurofen Meltlet Lemon	Probably fast acting
	Nurofen Migraine Pain (as lysine)	Fast acting
	Nurofen Tension Headache (as lysine)	Fast acting
	Nurofen Express Liquid Capsule	Fast acting
	Nurofen Express Period Pain	Fast acting
	Feminax Express	Fast acting
	Nurofen Liquid capsules	Fast acting
	Boots Ibuprofen Liquid Capsules	Fast acting
	Boots Rapid Ibuprofen Lysine	Fast acting
	Nurofen Express Caplet (as sodium salt)	Fast acting
	Anadin Ultra Ibuprofen Liquid capsules	Fast acting
	Life Brand Ibuprofen Liquid Capsules	Fast acting
	Nurofen Zavance (Capsules and Tablets)	Fast acting
	Advil Liqui-Gels	Fast acting
	Advil Migraine solubilised ibuprofen	Fast acting
	Boots Ibuprofen Long Lasting	Slow release
	Lloyds Pharmacy Ibuprofen Long Lasting Capsules	Slow release
Ibuprofen 300	Nurofen Back Pain Sustained Release Capsules	Slow release
Ibuprofen 400	Boots Ibuprofen Caplets	-
	Nurofen Maximum Strength Migraine	-
	Nurofen Express Caplet	-
	Lloyds Pharmacy Ibuprofen Caplets	-
	Advil Extra Strength Caplets	-

(*Continued*)

	Advil Muscle & Joint Extra Strength Tablets	-
	Life Brand Extra Strength Ibuprofen Muscle & Joint	-
	Nurofen Express Liquid Capsule	Fast acting
Combination products containing ibuprofen		
Ibuprofen 200 + codeine 12.8	Nurofen Plus	-
	Solpadeine Migraine	-
	Boots Ibuprofen and Codeine	-
Ibuprofen 200 + paracetamol 500	Nuromol	-
Ibuprofen 200 + phenylephrine 5	Nurofen Sinus Pain PE	-
Ibuprofen 100 + caffeine 100	Not in UK	-
Ibuprofen 200 + caffeine 100	Not in UK	-
Naproxen only products		
Naproxen 250	Boots Period Pain Relief	Probably slow release
	Feminax Ultra 9 Tablets	Probably slow release
Naproxen 220	Life Brand Naproxen Sodium Tablets	-
	Aleve Liquid Gels Naproxen Capsules	-
	Aleve Naproxen Tablets	-
	Aleve All Day Strong Tablets	-
	Aleve Liquid Gels	-
	Aleve Tablets and Caplets	-
	CVS All Day Pain Relief Caplets	-
	CVS All Day Pain Relief Tablets	-
Paracetamol only products		

(*Continued*)

Paracetamol 650	Tylenol Arthritis Pain	-
	Life Brand Muscle Aches & Body Pain Acetaminophen Extended Release Tablets	-
	CVS 8 Hour Acetaminophen Extended Release	-
Paracetamol 500	Paracetamol 500 mg Tablets or Caplets	-
	Panadol Actifast	-
	Panadol Advance	-
	Panadol Rapid Soluble	-
	Panadol Rapid Caplets	-
	Value Health Paracetamol Tablets	-
	Anadin Paracetamol	-
	Lloyds Pharmacy Paracetamol Caplets	-
	Lloyds Pharmacy Paracetamol Capsules	-
	Life Brand Extra Strength Acetaminophen	-
	Tylenol Extra Strength Acetaminophen Tablets	-
	Guardian Paracetamol	-
	Herron Gold Paracetamol	-
	Value Choice Paracetamol	-
	CVS Extra Strength Pain Relief 500 mg Caplets	-
Paracetamol 325	Life Brand Regular Strength Caplets	-
	Tylenol Regular Strength	-
Combination products containing paracetamol		
Paracetamol 500 + diphenhydramine HCl 25	Panadol night pain	-

(*Continued*)

Paracetamol 500 + caffeine 65	Boots Paracetamol Extra	-
	Panadol Extra Advance	-
	CVS Tension Headache Coated caplet	-
	Excedrin Tension Headache	-
Paracetamol 500 + caffeine 60 + prilamine maleate 15	Maximum Strength Midol	-
Paracetamol 500 + pseudoephedrine HCl 60	Boots Decongestant with Pain Relief	-
Paracetamol 500 + codeine 8	Boots Paracetamol and Codeine	-
	Paracodol	-
	Lloyds Pharmacy Co-Codamol	-
	Lloyds Pharmacy Co-Codamol Effervescent Tablets	-
	Codapane	-
	Migraleve Yellow	-
Paracetamol 500 + codeine 8 + buclizine HCl 6.25	Migraleve Pink	-
Paracetamol 500 + codeine 8 + caffeine 30	Solpadeine Plus	-
	Lloyds Pharmacy Paracetamol Codeine Extra Effervescent Tablets	-
Paracetamol 500 + codeine 12.8	Panadol Ultra	-
	Solpadeine Max	-
Paracetamol 500 + dihydrocodeine tartrate 7.5	Paramol	-
Aspirin 300 + paracetamol 200 + caffeine 45	Anadin Extra	-
	Anadin Extra Soluble	-
	Anadin Extra Triple Action Tablets	-
	Boots Aspirin Extra	-

(*Continued*)

	Lloyds Pharmacy Extra Power Pain Reliever - Caplets

HCl: hydrochloride; OTC: over-the-counter.

Appendix 2. Search strategy for Cochrane reviews

1. (postoperative):ti,ab,kw or (post NEXT operative):ti,ab,kw
2. (pain):ti,ab,kw or (painful):ti,ab,kw or (analgesi*):ti,ab,kw
3. (1 AND 2) in Cochrane Database of Systematic Reviews

Appendix 3. Results for the efficacy outcome of NNT for at least 50% of maximum pain relief over four to six hours

Drug	Dose (mg)	Number of		Number with outcome/total		Percent with outcome		Risk ratio (95% CI)	NNT (95% CI)
		Studies	Participants	Active	Placebo	Active	Placebo		
Aspirin	500	2	213	45/135	20/78	34	26	1.3 (0.8 to 2.0)	Not calculated
Aspirin	600/650	60	4965	983/2496	379/2469	39	15	2.5 (2.3 to 2.8)	4.2 (3.8 to 4.6)
Aspirin	1000	6	618	138/340	40/278	41	14	2.7 (2.0 to 3.7)	4.2 (3.8 to 4.6)
Dexketoprofen	12.5	5	452	104/230	38/222	45	17	2.7 (2.0 to 3.7)	3.6 (2.8 to 5.0)
Dexketoprofen	25	6	523	129/225	38/248	47	15	3.3 (2.4 to 4.5)	3.2 (2.6 to 4.1)
Diclofenac potassium	25	4	502	140/248	37/274	56	15	3.9 (2.8 to 5.3)	2.4 (2.0 to 2.9)
Diclofenac potassium	50	7	757	253/398	60/359	64	17	3.7 (2.9 to 4.7)	2.1 (1.9 to 2.5)
Dipyrone	500	5	288	106/143	45/145	74	31	2.4 (1.8 to 3.1)	2.3 (1.9 to 3.1)

(*Continued*)

Ibuprofen acid	200	18	2103	448/1094	67/1009	41	7	6.5 (5.1 to 8.2)	2.9 (2.7 to 3.2)
Ibuprofen acid	400	51	5604	1596/3070	289/2543	52	12	4.6 (4.0 to 5.1)	2.5 (2.4 to 2.6)
Ibuprofen fast acting	200	7	828	270/478	34/350	57	10	5.7 (4.2 to 7.9)	2.1 (1.9 to 2.4)
Ibuprofen fast acting	400	13	1364	427/658	85/466	65	18	3.9 (3.2 to 4.7)	2.1 (1.9 to 2.3)
Ibuprofen + caffeine	200+100	4	334	103/174	16/160	59	10	5.5 (3.5 to 8.7)	2.1 (1.9 to 3.1)
Ibuprofen + paracetamol	200+500	3	508	240/349	10/159	69	6	10 (5.7 to 19)	1.6 (1.5 to 1.8)
Ibuprofen + paracetamol	400+1000	3	543	278/384	10/159	72	6	11 (6.2 to 20)	1.5 (1.4 to 1.7)
Naproxen	200/220	2	202	54/120	16/82	45	30	2.9 (1.6 to 5.1)	3.4 (2.4 to 5.8)
Naproxen	400/440	3	334	103/210	14/124	49	11	4.8 (2.8 to 8.4)	2.7 (2.2 to 3.5)
Naproxen	500/550	9	784	200/394	59/390	52	15	3.4 (2.6 to 4.4)	2.7 (2.3 to 3.3)
Paracetamol	500	6	561	176/290	86/271	61	32	1.9 (1.6 to 2.3)	3.5 (2.7 to 4.8)
Paracetamol	600/650	19	1886	358/954	145/932	38	16	2.4 (2.0 to 2.8)	4.6 (3.9 to 5.5)
Paracetamol	975/1000	28	3232	876/1906	241/1329	46	18	2.7 (2.4 to 3.0)	3.6 (3.2 to 4.1)

CI: confidence interval; NNT: number needed to treat for an additional beneficial outcome
Note: NNT not calculated when result not significantly different from placebo

Appendix 4. Success and failure rates for at least 50% maximum pain relief

Drug	Dose (mg)	Percent with outcome		Success rate (%)	Failure rate (%)
		Active	Placebo		
Aspirin	500	34	26	11	89
Aspirin	600/650	39	15	28	72
Aspirin	1000	41	14	31	69
Dexketoprofen	12.5	45	17	34	66
Dexketoprofen	25	47	15	38	62
Diclofenac potassium	25	56	15	48	52
Diclofenac potassium	50	64	17	57	43
Dipyrone	500	74	31	62	38
Ibuprofen acid	200	41	7	37	63
Ibuprofen acid	400	52	12	45	55
Ibuprofen fast acting	200	57	10	52	48
Ibuprofen fast acting	400	65	18	57	43
Ibuprofen + caffeine	200+100	59	10	54	46
Ibuprofen + paracetamol	200+500	69	6	67	33
Ibuprofen + paracetamol	400+1000	72	6	70	30
Naproxen	200/220	45	30	21	79
Naproxen	400/440	49	11	43	57
Naproxen	500/550	52	15	44	56
Paracetamol	500	61	32	43	57

(*Continued*)

Paracetamol	600/650	38	16	26	74
Paracetamol	975/1000	46	18	34	66

Appendix 5. Results for participants with at least one adverse event

Drug	Dose (mg)	Number of		Percent with outcome		Risk ratio (95% CI)	NNH (95% CI)	NNTp (95% CI)
		Studies	Participants	Active	Placebo			
Aspirin	500	3	319	7	6	0.9 (0.4 to 1.9)	-	-
Aspirin	600/650	46	3633	11	9.5	1.2 (1.0 to 1.4)	-	-
Aspirin	1000	4	404	26	12	1.6 (1.1 to 2.3)	7.5 (4.8 to 17)	-
Dexketoprofen	12.5	3	258	9	14	0.6 (0.4 to 1.3)	-	-
Dexketoprofen	25	5	413	20	13	1.5 (0.9 to 2.3)	-	-
Diclofenac potassium	25 and 50	7	1090	8	46	1.0 (0.7 to 1.6)	-	-
Dipyrone	500	No data	-	-	-	-	-	-
Ibuprofen acid	200	14	1808	19	19	1.2 (0.7 to 2.1)	-	-
Ibuprofen acid	400	40	4867	17	16	0.9 (0.7 to 1.02)	-	-
Ibuprofen fast acting	200	No data	-	-	-	-	-	-
Ibuprofen fast acting	400	No data	-	-	-	-	-	-
Ibuprofen + caffeine	200+100	4	336	11	6	2.2 (1.03 to 4.9)	19 (8.9 to 220)	-

(*Continued*)

Ibuprofen + paracetamol	200+500	3	508	30	48	0.7 (0.6 to 0.9)	-	5.4 (3.6 to 11)
Ibuprofen + paracetamol	400+1000	3	543	29	48	0.6 (0.5 to 0.8)	-	5.1 (3.5 to 9.5)
Naproxen	200/220	No data	-	-	-	-	-	-
Naproxen	400/440	3	334	22	17	1.3 (0.8 to 2.2)	-	-
Naproxen	500/550	9	784	27	29	1.0 (0.7 to 1.2)	-	-
Paracetamol	500	3	319	7	6	0.9 (0.4 to 1.9)	-	-
Paracetamol	600/650	13	1522	16	14	1.2 (0.9 to 1.5)	-	-
Paracetamol	975/1000	19	2342	18	16	1.1 (0.9 to 1.3)	-	-

NNH: number needed to treat for an additional harmful outcome; NNTp: number needed to treat to prevent an adverse event occurring
Note: NNH and NNTp not calculated when result not significantly different from placebo

WHAT'S NEW

Last assessed as up-to-date: 21 May 2015.

Date	Event	Description
6 November 2015	Amended	PLS stated that the overview included nine Cochrane reviews. This has been corrected to read 10 Cochrane reviews

CONTRIBUTIONS OF AUTHORS

YR and LT performed an initial search for medicines available without prescription, supplemented with additional searches by RAM.

RAM and SD extracted data from Cochrane reviews relating to drug efficacy.

RAM and PW checked data extraction and assessment.

TM provided input and insight from a retail pharmacy perspective.

RAM produced the initial draft, and all authors contributed to developing the manuscript.

RAM will be responsible for updates.

DECLARATIONS OF INTEREST

RAM has no conflicts relating to this review or any similar product.

PJW has no conflicts relating to this review or any similar product.

SD has no conflicts relating to this review or any similar product.

TM has no conflicts relating to this review or any similar product.

YR has no conflicts relating to this review or any similar product.

LT has no conflicts relating to this review or any similar product.

We are funded by the NIHR for work on a series of reviews informing the unmet need of chronic pain and providing the evidence for treatments of pain but this review is not supported by that funding.

SOURCES OF SUPPORT

Internal sources

- Oxford Pain Relief Trust, UK.

Institutional support

External sources

- No sources of support supplied

[redacted]

Consultation on proposed amendments to the Poisons Standard (Codeine) – Submission for consideration by the Advisory Committee on Medicines Scheduling in March 2016

JAN
2016

Purpose

[redacted] makes this submission on proposed amendments to the Poisons Standard for codeine referred by the delegate for scheduling advice for consideration by the Advisory Committee on Medicines Scheduling (ACMS) in March 2016.

[redacted]

[redacted]

Summary of [redacted] position

Codeine: Schedule 2 (cough and cold medicine preparations)

[redacted] *supports proposal b – 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.*

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

[redacted] *supports option a – 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.*

Background

The scheduling of codeine has been the subject of consideration and discussion over many years. Key issues giving rise to the most recent proposal to reschedule codeine has included the steady increase in inappropriate use of codeine-containing prescription and over-the-counter (OTC) medicines, increase in the rates of dependence to codeine and the resulting significant adverse health outcomes due to codeine and associated ingredients.

As outlined previously through [redacted] policies and submissions, we believe that finding workable solutions to this complex topic must include the following fundamental considerations[2]:

- supporting consumers to have continued reasonable access to OTC analgesics with the advice of a pharmacist on appropriate pain management options in accordance with quality use of medicines (QUM) principles
- supporting pharmacists to provide information and solutions to consumers seeking to manage pain and addiction issues
- calling for the urgent implementation of a national real-time recording and reporting system to enable pharmacists in the recording and reporting of dispensing and supply of particular substances and medicines (including OTC analgesics containing codeine) in accordance with relevant State and Territory legislation
- regardless of jurisdictional requirements, supporting and encouraging best practice by pharmacists through the recording of all supplies of Pharmacist Only Medicines (Schedule 3 medicines) in the pharmacy's dispensing system
- continuing to advocate strongly for a partnership approach to promote QUM of all medicines and responsible self-medication.

[redacted]

[redacted]

These core principles provide the basis for [redacted] views, submitted to the ACMS previously, that rescheduling all codeine-containing medicines to Schedule 4 is not a balanced solution and not in the best interests of consumers.

With regards to the Therapeutic Goods Administration's invitation to provide further comment on the codeine proposal following the deferral of the final decision, [redacted] provides feedback below on the preferred option and rationale for each schedule (Schedule 2 and Schedule 3). Much of the context and reasons for [redacted] views have been submitted to the ACMS previously and therefore have not been replicated in full here.

Schedule 2 cough and cold preparations

When codeine-containing analgesics were rescheduled to Schedule 3 in 2010, [redacted] expressed caution that there may be an unexpected increase in demand for Schedule 2 codeine-containing cough and cold products. Although not privy to specific data, [redacted] was advised that industry sector information reportedly showed no such trends associated with the fall in supply of codeine-containing analgesics although an increase in single ingredient analgesics had apparently been observed. We were advised that the usage patterns of cough and cold products remained as before where seasonal increase in demand was observed but no other increase in demand had been recorded. Further, it was also suggested to [redacted] that feedback to industry from the community pharmacy sector and adverse drug reaction reporting figures did not raise any concerns with cough and cold products containing codeine.

Overall, [redacted] is not aware of any evidence which indicates codeine-containing cough and cold medicines are subjected to the type or level of misuse seen with codeine-containing analgesics.

Nevertheless, in view of the public health impact of the codeine misuse issue, [redacted] suggests that Schedule 3 would provide consistency in consumer expectations of pharmacist intervention and optimal use of all codeine-containing products. [redacted] therefore re-iterates its recommendation presented previously to include all codeine-containing OTC preparations in Schedule 3.

In terms of consumer access to Schedule 2 medicines, [redacted] has also noted previously that other options for cough and cold treatment (not containing codeine) would remain available.

Thus, [redacted] supports option b presented for Schedule 2:

> *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.*

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

As re-iterated above, [redacted] does not support rescheduling codeine to Schedule 4. We have highlighted our rationale that rescheduling to Schedule 4 will not fundamentally address the issues associated with the misuse of OTC codeine-containing analgesics, noting that prescription-only opioid analgesics are also associated with inappropriate use. We also alluded to the likely disproportionate and unreasonable burden placed on consumers and general practitioners (GPs) if a prescription is necessary for a medicine to be used for relatively minor health complaints (e.g. cough, cold, short-term pain). Further, there may be consumers who are directed or choose to visit a hospital emergency department instead if they cannot secure a timely

appointment with a GP. Clearly it is likely there would be a significant increase in health care expenditure.

With regards to the proposed amendments [redacted] supports option a under Schedule 3:

> *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.*

This option is consistent with [redacted] position which has been outlined in response to previous codeine rescheduling proposals. It appropriately balances and supports consumers to have reasonable access to all codeine-containing OTC products with the advice of a pharmacist.

Pack size and label warning

Both of [redacted] preferred options include the proposal to "reduce the pack size to not more than 3 days' supply" and to "include a label warning that codeine can cause addiction". These proposals are fully supported by [redacted] and mirror our initiatives from 2015, designed to alert and support consumers, including:

- Cautionary and Advisory Label 24 containing the advice "*FOR 3 DAYS USE ONLY, can cause addiction*"[3] and recommended for use by pharmacists to advise consumers of the potential for addiction with continuous use of combination analgesics containing codeine. This resource was created by [redacted] in the absence of any mandatory introduction of a product packaging warning statement (regarding possible addiction). The label also highlights the need to be vigilant about short term use, a particularly pertinent point in the absence previously of a regulatory decision to reduce the pack size of codeine-containing analgesics.

- a consumer information leaflet (*Using codeine pain relievers safely*) explaining the possible adverse effects of inappropriate use of combination analgesics containing codeine and providing consumers with a checklist of signs of codeine dependence. The tool assists pharmacists in discussing appropriate pain management solutions with consumers.

[redacted] notes the ACMS interim decision report acknowledged that "activities to reduce the use of codeine cannot occur in isolation from consideration of alternative pain management strategies". Pharmacists fully appreciate this and actively seek other practice support resources such as those produced by [redacted] and addressing issues such as pain management, difficult conversations in the pharmacy, and addiction care.

Proposed implementation timeframe

While the significance and magnitude of amendments will depend on the final decision, [redacted] would re-iterate that adequate time must be allowed for implementation and all sectors consulted appropriately. This may mean an extension to the usual implementation timeframes for scheduling decisions such as that initially proposed in relation to the interim decision for codeine.

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[3] Sansom LN, ed. Australian pharmaceutical formulary and handbook. 23rd edn. Canberra: Pharmaceutical Society of Australia; 2015. p. 12.

National real-time recording and reporting system

While considering the importance of the final scheduling decision for codeine, [redacted] firmly re-states that the implementation of a national real-time recording and reporting system to allow for real-time monitoring of prescribing and dispensing of specific medicines remains a high priority for Australia. We firmly believe that, ultimately, such a system will make significant changes to health professional practice and, more importantly, for consumer health outcomes.

The ACMS would be aware that [redacted] call for the urgent implementation of a national system for the Electronic Recording and Reporting of Controlled Drugs (ERRCD) was joined by the [redacted].

While the ERRCD is intended to capture Schedule 8 medicines, [redacted] strong view is that the system should be expanded to include all drugs of dependence, including OTC codeine-containing analgesics, as appropriate and in accordance with relevant State and Territory legislation. This would provide more holistic and comprehensive information to assist prescribers and pharmacists in their informed clinical decision-making for the benefit of the consumer.

[redacted] appreciates that some progress has been made in several jurisdictions. Nevertheless, given the ACMS has representation across all jurisdictions, we urge ACMS Members to consider the positive impact that a real-time system could have for consumers. Health professionals, consumer groups and industry are united in calling for the immediate implementation of a national system for the ERRCD.

Summary

In summary, [redacted] welcomes this further opportunity to comment on additional proposed amendments to the scheduling of codeine. [redacted] expresses support for the proposals which will result in the inclusion of all OTC codeine preparations in Schedule 3 with a reduced maximum pack size of three days' supply and inclusion of a warning label that codeine can cause addiction. [redacted] believes these scheduling-based measures will provide greater clarity and consistency for consumers and complement efforts to better recognise and assist with codeine addiction issues.

In addition, [redacted] re-iterates there should be the highest priority for the implementation of a national real-time recording and reporting system which can capture all prescribing, dispensing and supply of prescription and OTC drugs of dependence. [redacted] firmly believes this represents potential for substantial public health benefit.

Submitted by:

[redacted]

Contacts:

[redacted]

[redacted]

28 January 2016

Northern Territory Pharmacy Premises Committee

Registrar Contact Details
PO BOX 40596
Casuarina NT 0811
Telephone: 08 8922 7035
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The Delegate
Therapeutic Goods Administration
medicines.scheduling@tga.gov.au

Dear Sir/Madam,

RE: PROPOSED AMENDMENTS TO THE POISONS STANDARD FOR CODEINE

The Northern Territory (NT) Pharmacy Premises Committee (Committee) is appointed by the NT Minister for Health to administer the pharmacy premises and ownership controls of the NT *Health Practitioners Act*.

The Committee supports the Pharmaceutical Society of Australia's March 2015 position statement *"Minimising harm from the inappropriate use of over the counter analgesics"*.

The current proposal for Codeine is two-fold:

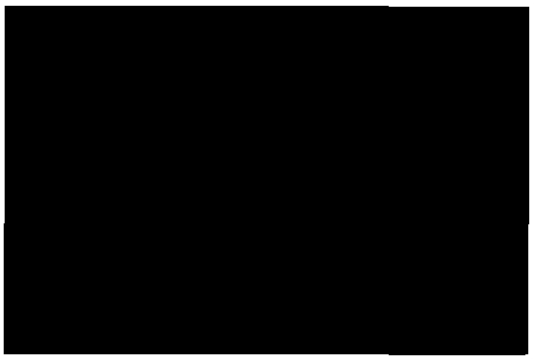
1. for Schedule 2, cough and cold medicines preparations, the Committee supports proposal (b) *"to up-schedule the Schedule 2 entry to Schedule 3 and reduce the pack size to not more than 3 days' supply and include a label warning that codeine can cause addiction"*.

2. for Schedule 3, codeine containing analgesics, the Committee supports proposal (a) *"to reduce the pack size to not more than 3 days' supply and include a warning that codeine can cause addiction"*

The Committee believes that codeine products currently available over the counter should continue to be available but with a Schedule 3 restriction such that pharmacist must personally acknowledge the sale.

The Committee accepts there have been increasing levels of addiction and misuse of over the counter codeine containing products and therefore believes that in the interests of public health and harm minimisation an appropriate real-time recording and reporting system must be implemented. This system would enable pharmacists to prevent inappropriate sales and objectively refer patients to a medical practitioner for assessment and review.

Thank you for the opportunity to comment on the proposed scheduling changes for codeine.



[redacted]

[redacted]

29 January 2016

Department of Health
Therapeutic Goods Administration
Advisory Committee on Medicines Scheduling

Email: medicines.scheduling@tga.gov.au

To whom it may concern,

The [redacted] thanks the Advisory Committee on Medicines Scheduling (ACMS) of the Therapeutic Goods Administration (TGA) for the opportunity to provide comment on the proposed amendments to the Poisons Standard (Codeine). These include:

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]

The [redacted] supports the decision to retain the interim decision to up-schedule to Schedule 4. We believe that on balance, the evidence suggests rescheduling is a necessary step to improve patient safety and reduce harm. There is increasing evidence of serious harms from over the counter (OTC) codeine combination analgesics. This harm has not been reduced by restricting medicines to pharmacy only.

The [redacted] supports the availability of safe and effective medications for consumers to self- manage minor pains. However, the evidence is clear that the 8mg and 15mg doses of codeine (in the OTC codeine combination analgesics) are “sub-therapeutic” i.e. they offer no benefit above the Panadol/Nurofen combination, to which they are added. Indeed, combinations of ibuprofen plus paracetamol provide superior analgesic efficacy to the OTC codeine combination analgesics and should be readily available and promoted as superior alternatives.

[redacted]

[redacted]

Codeine based OTC medications are "big business" and as a result, there is likely to be significant pressure to resist rescheduling of these medications. We urge the Advisory Committee on Medicines Scheduling to resist these business pressures. The case for rescheduling is clear as the evidence demonstrates ineffective therapeutic effect and a generation of significant harm.

Yours sincerely

[redacted]

[redacted]

[redacted]

[redacted]

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29 January 2016

The Secretary,
Scheduling Secretariat
GPO Box 9848
Canberra ACT 2601,

Email: Medicines.Scheduling@tga.gov.au

Dear Sir or Madam,

Notice inviting public submission under Reg 42ZCZK of the Therapeutic Goods Regulations 1990: Scheduling proposal to be considered at the ACMS Meeting, March 2016

Please find [redacted] response to the invitation for public comment under Reg 42ZCZK of the Therapeutic Goods Regulations 1990 for comment on the following proposal at the March 2016 ACMS meeting:

Substance: Codeine

Proposal:

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] Position

[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 reduce potential risk to consumers:

- Introduction of a real time monitoring system for use by pharmacists
- Collaborative approach - industry working with the [redacted] and [redacted] to assist health care professionals in facilitating appropriate use of codeine-containing analgesics and to educate consumers.

Overview

[redacted] is the manufacturer of [redacted], an ibuprofen-codeine combination. [redacted] acknowledges that there have been case reports of adverse outcomes from misuse of OTC codeine containing analgesics with excessive consumption linked to codeine dependence. OTC misuse can be defined as the use of OTC medicines for a genuine medical reason but in an incorrect manner in terms of dosage or duration.

In this submission [redacted] contends that, while recognising the genuine concern of some in the medical profession, and in the community over misuse and/or abuse of OTC codeine-combination products, the incidences are very low. We are not aware of robust evidence that shows an escalating risk to public health. The majority of case reports were published between 2010 and 2011. [redacted] notes that OTC codeine combinations were re-scheduled to Schedule 3 in 2010. At the same time pack-sizes were limited to 5 days' supply. Again, we are not aware of an increased incidence of adverse events since this time.

[redacted] acknowledges that there is a low level of misuse and abuse of codeine-combination analgesic products in the community, which is clearly unwelcome and [redacted] acknowledges that more needs to be done to reduce any misuse or abuse that does occur.

However [redacted] opposes up-scheduling to Schedule 4. We believe that careful consideration needs to be given to other specific measures to assist in reducing the incidence further whilst maintaining the current scheduling of S3.

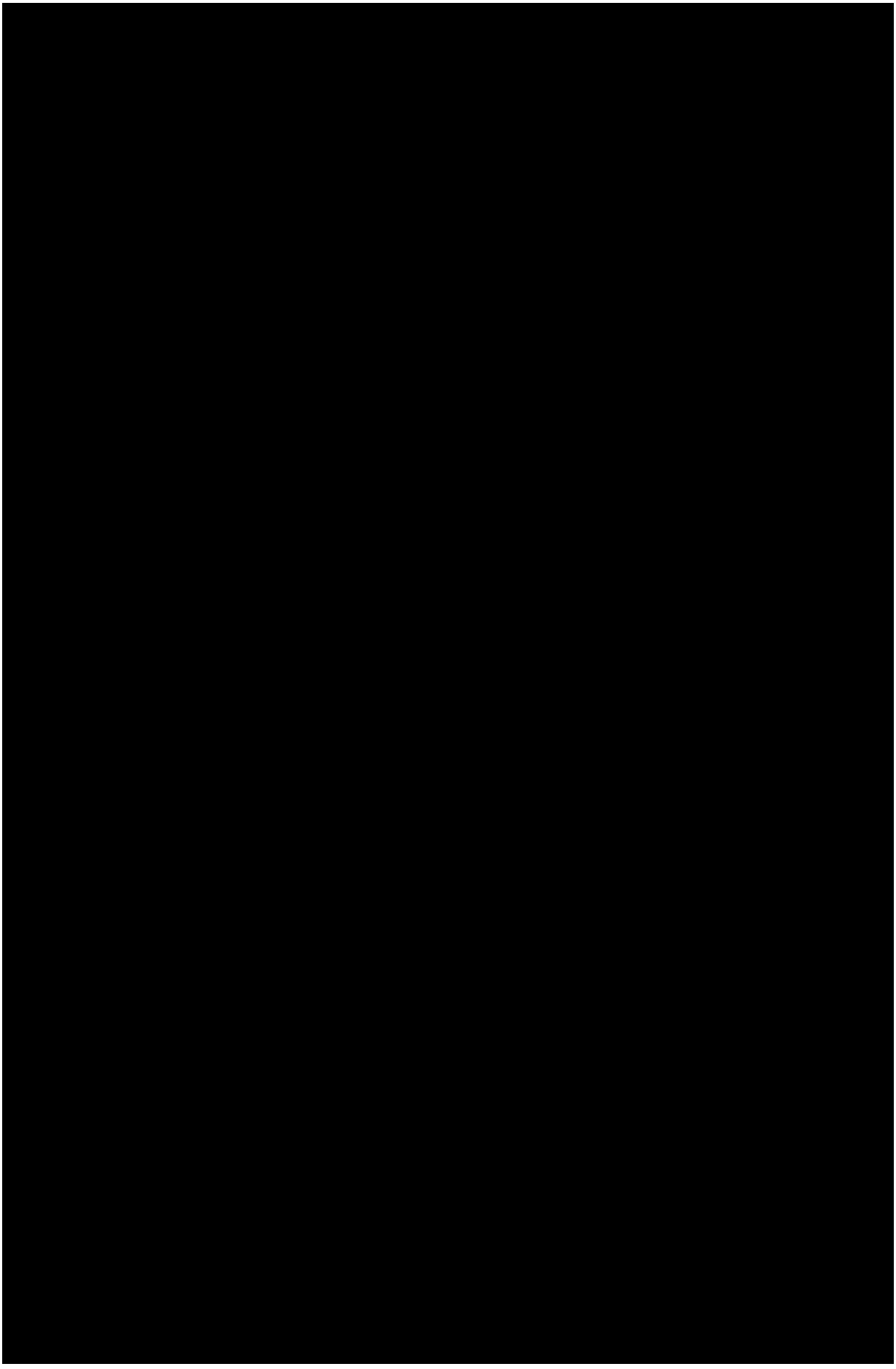
1. OTC codeine-containing analgesics – the current situation

OTC codeine-analgesic combinations, including [redacted] were developed to give thousands of people world-wide significant relief from strong pain, over and above the use of a single analgesic active alone, without a visit to the doctor. It is longstanding Australian Government and medical professional policy to have a well-educated community with the knowledge to self-select for their health needs, including pain relief, without a prescription from the doctor.

Currently OTC codeine-combination analgesics are only available behind the counter in pharmacy after mandatory consultation with a pharmacist. As a Pharmacist Only (S3) medicine, pharmacists are required to determine whether it is appropriate to supply codeine-containing analgesics. They are required to assist the consumer with appropriate product selection and recommend an alternative analgesic option where necessary. Pharmacists are highly trained professionals to assist consumers to make the appropriate choice for medicines.

It is also important to note that currently pack sizes are limited to five days' supply. This means that a single pack cannot, on its own create a physiological dependency. For dependency to occur, a consumer must interact repeatedly with a pharmacist if more pain relief is needed. The pharmacist is ideally placed to advise the consumer and refer them to a GP or pain clinic for further management.

[redacted] therefore concludes that the current scheduling of codeine analgesic combinations is appropriate. Rescheduling would not provide any tangible benefits but would result in disadvantages to consumers and increased economic burden.



[redacted]

3. Assessing relative risks

The risks associated with abuse of codeine combination medicines need to be evaluated from a risk/benefit perspective against other substances of abuse to provide a true estimate of risk to the wider community, rather than to a smaller population who already may abuse other substances.

A change in scheduling of codeine combination medicines would deny access to proven community pain relievers for the vast majority to potentially 'protect' a very small minority.

One of the impacts of rescheduling to Schedule 4 is an increase in consumers visiting doctors. Doctors' visits, apart from being costly to the community, also usually involve time away from work and loss of productivity for the individual. If pain relief is not adequate, acute pain can have a very negative impact on the life of a consumer and their family. Those using codeine-combinations appropriately will be disadvantaged and there will be unnecessary burdens on the healthcare systems.

4. Assessment of financial impact

- Preferred approach – retain current scheduling, reduce pack sizes to 3 days and include labelling warning statements

Any changes to packs will have a significant cost implication to [redacted] These costs include updating of labels, artwork revisions, printing costs and write-off and destruction of stock that can no longer be used. There are also additional costs for a global company such as [redacted] where Australian only packs may be required because additional warnings means the packs cannot be harmonized with other markets.

The set up costs and maintenance of a real time monitoring system will be considerable. [redacted] are prepared to partner with other stakeholders to support the development and implementation of such a system to assist in gathering actual data on the use and potential misuse of codeine containing analgesics.

- Upscheduling to S4

The financial burden on the healthcare system will increase with the proposed upscheduling. Financial impact on manufacturers of codeine containing analgesics will be as above.

4. Proposed actions to reduce risks

Even though [redacted] believes that the level of abuse/misuse of codeine-containing analgesics is currently very small, we acknowledge the genuine concern among a number of healthcare professionals and the wider community.

[redacted] therefore supports the following:

(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.

(b) Collaborative programs working with the [redacted] and [redacted] to assist health care professionals in facilitating appropriate use of codeine-containing analgesics and to educate consumers.

(c) Introduction of a real time monitoring system for use by pharmacists.

4.1 Pack size and label warning

[redacted] does not oppose a reduction in pack size to 3 days for OTC codeine-containing analgesics, consistent with the UK pack size and front of pack labeling statement which states a 3 day duration of use.

- For three days use only, can cause addiction.

4.2 Collaborative approach

[redacted] believes the best patient outcomes will depend on a collaborative approach rather than problem shifting. Collaborative educational programs to maintain high levels of awareness amongst pharmacists and consumers about the appropriate use of codeine-combination analgesics will reduce the risk of misuse and abuse

[redacted] therefore will work closely with pharmacists, [redacted], the [redacted] and other stakeholders to put measures in place to minimise the risk of abuse/misuse.

4.3 Real time monitoring system

[redacted] understands that the [redacted] has been working with various stakeholders to develop a software system that will provide pharmacists with a tool to identify and assist consumers who abuse/misuse codeine-combination products.

This proposed real time monitoring system will enable pharmacists to review any purchases of consumers at their pharmacy and other pharmacies. The system will allow pharmacists to identify consumers who may be purchasing large quantities of codeine-combination analgesics, and assist them in referring the consumer to a doctor for further assessment and management.

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

5. Conclusions and recommendations

In the absence of compelling validated community incidence data demonstrating an increasing risk from codeine analgesic combinations and with consideration of the risk/benefit profile to the Australian community, [redacted] supports the following:

- That the current scheduling for OTC ibuprofen-codeine combination products remain as S3;

- The proposal 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 is considered appropriate;

- A collaborative approach - industry working with the [redacted] and [redacted] to assist health care professionals in facilitating appropriate use of codeine-containing analgesics and to educate consumers; and the

- Introduction of a real time monitoring system for use by pharmacists.

Yours sincerely,

[redacted]

[redacted]

[redacted]

29 January 2016

Advisory Committee on Medicines Scheduling
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606
Email: medicines.scheduling@tga.gov.au

Dear Sir/Madam,

Re: Consultation: Proposed Amendments to the Poisons Standard (Codeine)

[redacted] refers to the notice inviting public comment under subsection 42ZCZK/42ZCZL of the Therapeutic Goods Regulations 1990 (the Regulations). [redacted] provides the following submission in relation to the proposed amendments to the scheduling of codeine that will be referred to the March 2016 meeting of the Advisory Committee on Medicines Scheduling (ACMS).

Prior consultations on the scheduling of codeine undertaken in 2015 had resulted in an interim recommendation to delete all current Schedule 2 and 3 entries for codeine. However, the delegate's final decision on this matter (November 2015) was to defer making a final decision on the possible rescheduling of codeine to allow sufficient consideration of the large number of public submissions received regarding the interim decision (127; 113 against the proposals and 14 in their support).

Proposal under consideration

[redacted] currently markets [redacted] codeine-containing analgesic combination products in Australia ([redacted]), all of which are indicated for temporary relief of pain and discomfort associated with various moderate to severe acute pain conditions. This submission therefore comments on only the proposed amendments to the scheduling of Schedule 3 codeine-containing analgesic combination products.

Two proposals have been suggested for Schedule 3 codeine-containing products. [redacted] supports proposal "a" – 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.

Review the effects of current regulatory changes

Since 2010, all codeine-containing analgesic combination products in Australia have been Schedule 3, non-advertisable. The pharmacist is therefore in a position to manage and supervise supply and to ensure that the product is appropriate for the consumer and their pain condition based on a direct product request.

A recent publication by Roxburgh et al,[1] which examined codeine-related mortality trends in Australia, reported a significant increase in accidental fatal codeine overdoses between 2000 and

[redacted]

2009. Data on the source of the codeine was available for less than half of the cases, but where it was available 59.9% of cases had involved prescription codeine products. Although data for the period 2010-2013 were collected, at the time of writing the authors commented that this data was incomplete and trends could not be reliably determined. It follows that while mortality data post the up-scheduling of all codeine products to Schedule 3 are available, they have not yet been adequately analysed or published. Such data may provide additional insight into the current consultation.

Risk:benefit assessment

The ACMS #15 interim decision stated that there is no evidence that low dose codeine combination analgesics provide any additional analgesia over optimal dosing of paracetamol, aspirin or ibuprofen. Should that discussion point arise on the forthcoming meeting we would direct the ACMS and the TGA Delegate to consider [redacted] submission dated 15 October 2015.

Reduce the pack size to 3 day's supply

In prior submissions on this matter, [redacted] provided a review of adverse event data based on data from the company's global safety database.

[1] In summary:

[redacted]

It is evident from this data that the number of reported cases of drug abuse and dependency remain very small when considered in the context of the volume of use of these products. Moreover, the data within Frie 2010[2] suggest that issues of dependence arise after prolonged use of supratherapeutic doses of these products.

Include a label warning regarding addiction

[redacted] supports the TGA proposal to include a mandated label warning that codeine can cause addiction. As noted in our prior submissions on this matter, a voluntary front of pack warning statement "***Can cause addiction. Use for 3 days only"*** was implemented across all [redacted] OTC codeine-containing analgesic combination products in early 2015. [redacted] is currently in the process of refining the product artwork to ensure it has further prominence.

[redacted]

Monitor consumer purchase transactions

[redacted] is supportive of the development of further means for Pharmacists to track real-time purchase of products. Implementation of a system, such as that employed for pseudoephedrine (Project STOP), may help to reduce the risk of misuse of OTC codeine-containing analgesic combination products.[5] Industry will assist such a program, to be implemented by the [redacted], with funding and ancillary support to help further educate consumers about its use.

The Roxburgh et al[1] analysis reported that a large proportion of deaths were related to the use of prescription codeine products. Investigation of trends in sales of OTC codeine and of prescription codeine patterns is warranted to better understand codeine-related harms in these two different settings. This could be facilitated by analysis of data from the above-mentioned real-time monitoring system for OTC codeine-containing analgesic combination products. The proposed system is such that OTC codeine use would be monitored at a higher level than prescription codeine use.

Established pharmacy protocols are such that Schedule 3 products can be dispensed either after assessment of a direct request from the consumer or as the result of a symptom-based consultation. There are no available data on the relative proportion of OTC sales of codeine-containing analgesic combination products that arise from direct requests versus symptoms-based requests. Real-time monitoring may also be able to provide important data to help answer this question.

Conclusion

As noted earlier, [redacted] supports proposal "a" – 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. These changes to pack sizes and labelling are feasible within the suggested implementation date of "not before 2017".

[redacted] also supports implementing in-Pharmacy real-time monitoring. Such a monitoring system may also help provide important data to better understand codeine-related harms in the OTC setting.

[redacted]

[redacted]

References:

1. Roxburgh A, Hall WD, Burns L, et al. Trends and characteristics of accidental and intentional codeine overdose deaths in Australia. *Med J Aust*. 2015;203:299.
2. Frei MY, Nielsen S, Dobbin MD, Tobin CL. Serious morbidity associated with misuse of over-the-counter codeine-ibuprofen analgesics: a series of 27 cases. *Med J Aust*. 2010;193:294-6.
3. McDonough MA. Misuse of codeine-containing combination analgesics. *Med J Aust*. 2011;194:486.
4. Thomson AD, Weltman MD. Electronic images of the month. Severe duodenitis after massive chronic Ibuprofen overdose. *Clin Gastroenterol Hepatol*. 2010;8:e114.
5. Arora S, Roxburgh A, Bruno R, Nielsen S, Burns L. A cross-sectional analysis of over-the-counter codeine use among an Australian sample of people who regularly inject drugs. *Drug Alcohol Rev*. 2013;32:574-81.

[redacted]

Wednesday 27th January 2016

Medicines Scheduling Secretariat
Therapeutic Goods Administration
136 Narrabundah Lane
Symonston ACT 2606
Australia

Dear Sir/Madam,

Re: Public Submission – under Reg. 42ZCZK of the Therapeutic Goods Regulations 1990. Proposed amendments referred by the delegate for scheduling advice on Codeine for consideration by the Advisory Committee on Medicines Scheduling (ACMS), March 2016

[redacted] is pleased to be invited to provide comment on the scheduling proposals for codeine to be considered by the ACMS during the March 2016 meeting.

[redacted] is the sponsor of both Pharmacist Medicines (S3) and Pharmacy Only Medicines (S2) that contain codeine, in combination with paracetamol and either pseudoephedrine (PSE) or phenylephrine (PE). These products are indicated for the relief of symptoms associated with colds and flu under the brand name of [redacted] a local brand that can only be found in Australia and New Zealand.

[redacted] is not a sponsor of analgesics and do not supply either single component or multi-component analgesics in Australia or New Zealand.

Information provided to the ACMS and delegate in May 2015 and in October 2015 remain relevant. For ease of review, these have been provided as Attachments 1 and 2.

Scheduling Proposals for 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] Position

[redacted] is pleased to see that the scheduling of codeine is now being considered more appropriately in the context in which it is used. Below summarises [redacted] position:

- [redacted] would like to recommend that the reference in the scheduling proposal of "cough and cold medicine preparations" is changed to "cold and flu medicine preparations". As "cough" is not an OTC indication for codeine
- [redacted] maintain the position that the evidence shows that there is no abuse or misuse of codeine containing cold and flu products and will continue to actively monitor the situation
- [redacted] supports the proposal for maintaining the S2 scheduling of codeine containing cold and flu products when supplied with new label warnings as proposed. Whilst questioning the impact, [redacted] does not oppose limiting the pack size to no more than 3 days supply.
- [redacted] strongly opposes other scheduling proposals for codeine containing cold and flu products.
- [redacted] supports the proposal to maintain the S3 scheduling of codeine containing analgesics limited to 3 days' supply with the additional label warnings as proposed.
- [redacted] support of the S3 scheduling proposal for codeine containing analgesics is contingent on the introduction of a real time monitoring systems that has been proposed by [redacted]
- [redacted] recommends that a well-designed, scientifically robust, Australia wide study on mortality rates associated with codeine misuse/abuse in OTC products, pre and post all codeine related scheduling decisions and other implemented measures (such as a real time monitoring system) be undertaken to determine the success of these measures in a systematic and accurate manner.

Details supporting [redacted] positions are provided below.

Changing *"cough and cold medicine preparations"* to *"cold and flu medicine preparations"*

Historically codeine containing cold and flu products have been referred to as codeine containing *cough* and cold products. We would like to highlight the fact that "cough" is not a TGA approved OTC indication for codeine containing medicinal products intended to provide temporary relief from the symptoms of cold and flu.

We believe that it would be confusing and inappropriate to continue to refer to these products as "*cough and cold medicine preparations*". Similarly as these products are indicated for the temporary relief of the symptoms of cold and flu, it is equally confusing and inappropriate to refer to treatment

Therefore we recommend that any entry in the SUSMP referring to Codeine is changed from:

CODEINE *in preparations for the treatment of coughs and colds when:*

To

CODEINE *in preparations for the symptomatic relief of colds and flus when:*

Evidence of No Abuse or Misuse of Codeine Containing Cold and Flu Products

In the 2009 foreshadowing of up-scheduling and pack size reduction of OTC pain tablets containing codeine to be implemented in May 2010, the NDPSC made the considered decision not to up-schedule cold treatments containing codeine. This decision was based on their finding that there is no evidence to support the notion that cold treatments containing codeine were being misused. It should be noted that this decision was taken after a 12 month review by the Committee.

At the time, the NDPSC raised the question "by restricting access to pain tablets containing codeine through up-scheduling to S3, would there be a corresponding shift in demand towards cold tablets with codeine, as theoretically these would be easier to access by remaining S2?"

It is important to emphasise that the NDPSC was only concerned about the potential for an upsurge in demand for cold and flu treatments containing codeine as a consequence of pain treatment up-scheduling. Their concern was **not** about current misuse or abuse of these products. Since then, there has been no change in the pattern of demand for codeine containing cold and flu treatments. The NDPSC clearly made the correct decision, and knowing their concerns allowed [redacted] to monitor the situation. Unfortunately there was no opportunity for sharing this data with the currently advisory committee.

Evidence supporting the reduction in demand of codeine containing analgesics has not affected cold treatments containing codeine is provided in the follow pages. This evidence is from substantial data bases (IMS, AZTEC) and data presented here is limited to supporting the above point.

In the Delegate's interim decision relating to Codeine, it is stated that the ACMS' recommendation was based on numerous points, including that the OTC sales data are incomplete. We respectfully invite the Delegate to approach [redacted] should there be further specific questions relating to the data.

Data Sources and History

- **IMS Health – Product supplied to all pharmacies across Australia:** data obtained from all Pharmaceutical Wholesalers and most of the direct supply by manufacturers to pharmacy (feedback from IMS). This represents supply of c. 95% of all pharmaceutical products to pharmacy in Australia. Data includes special offers, discount deals etc.
- **AZTEC** – Scan data supplied by all major grocery outlets to AZTEC.
- [redacted] holds historic IMS and AZTEC data for the Cold Treatment market, from 2007 to 2015.
- Data for the Pain Treatment sector is only available from 2009 and is limited to Pharmacy Only. This is because [redacted] is not active in the OTC Pain sector and has had no reason to monitor IMS prior to 2009, nor purchase grocery data. As a subscriber to IMS, 5 year historic data is available for all therapeutic categories.

Data Analysis

- The analysis has been limited to solid dose formats e.g. tablets, capsules, gel-caps etc. This is because the issue facing the Scheduling Committee and Delegate is fundamentally an issue pertaining to the reporting of inappropriate supply of solid dose products containing codeine.
- Pack sizes vary widely across different brands and treatment categories. The data is represented as the equivalent number of packs of 24 i.e. a pack of 48 tablets is equivalent to 2 packs of 24.
- In order to create an analysis that is comparable and to provide a true perspective of the volume of product supplied across all brands and pack sizes, this "Like for Like" analysis has been performed. All brands across all Sponsors are represented and not limited to [redacted]

Legend & Abbreviations

The following pages include data relating to the sales of codeine containing cold and flu products and codeine containing analgesics. The terms used within the graphical representations are provided in Table 1.

Table 1: Terms used within graphical representation of sales data for codeine containing products.

Abbreviation	Definition
Px	Pharmacy
CT	Cold Treatments
Gr	Grocery
Cod	Codeine
w	with
w/o	without
vs	versus
Pain	Analgesics - pharmacy supply (tablets)
Pain w/o Cod	Single ingredient ibuprofen, paracetamol and asprin tablets, and multi-ingredient non-codeine analgesics
Asp/Cod	Aspirin with codeine
Par/Cod	Paracetamol with codeine
Ibu/C	Ibuprofen with codeine
Tens	Multi ingredient analgesic with codeine usually indicated for 'tension pain' (e.g. Mersyndol)

Sales Trends for Cold and Flu Products 2007 – 2015 (IMS, AZTEC, MAT 2007 to 2015 inclusive)

Since 2009 there has been a general trend for pharmacy to supply cold treatments containing codeine above those without codeine (Figure 1 and Figure 2). It is apparent that this trend started in 2009 at the same time as non-pharmacy retailers began competing with pharmacy with the introduction of the unscheduled solid dose phenylephrine range of products. The volume of loss of cold and flu products without codeine from pharmacy is directly proportion to the gain in grocery (Figure 3).

When the total sales of codeine-free cold and flu treatments in both pharmacy and grocery are compared with pharmacy and the sales of codeine containing cold and flu products, the combined supply trend for each product group is close to equivalent. There is no sudden or unexplained surge or separation in demand in favour of cold treatments with codeine through pharmacy (Figure 4).

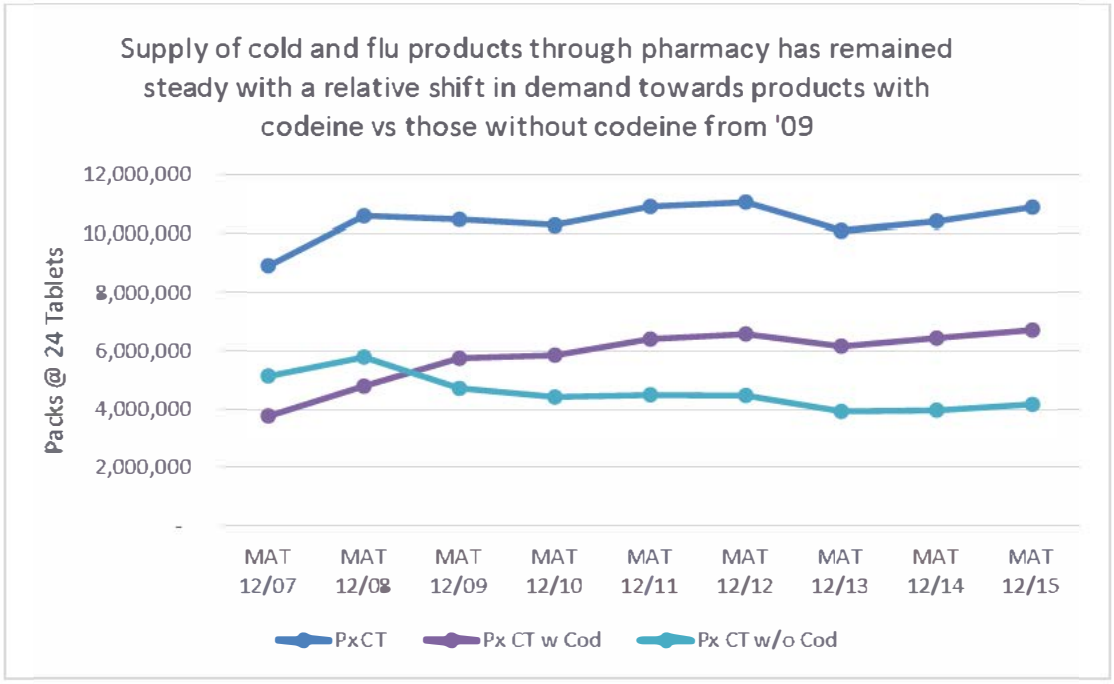


Figure 1 There is a general trend for pharmacy to supply cold and flu products containing codeine above those without codeine. This graph represents the supply of total cold and flu products through pharmacy for each 12 months from 2007 to 2015 (Px CT). This trend is evident from 2009 onwards. This trend started in 2009 as non-pharmacy retailers began competing with pharmacy with the introduction of the unscheduled solid dose phenylephrine range of products.

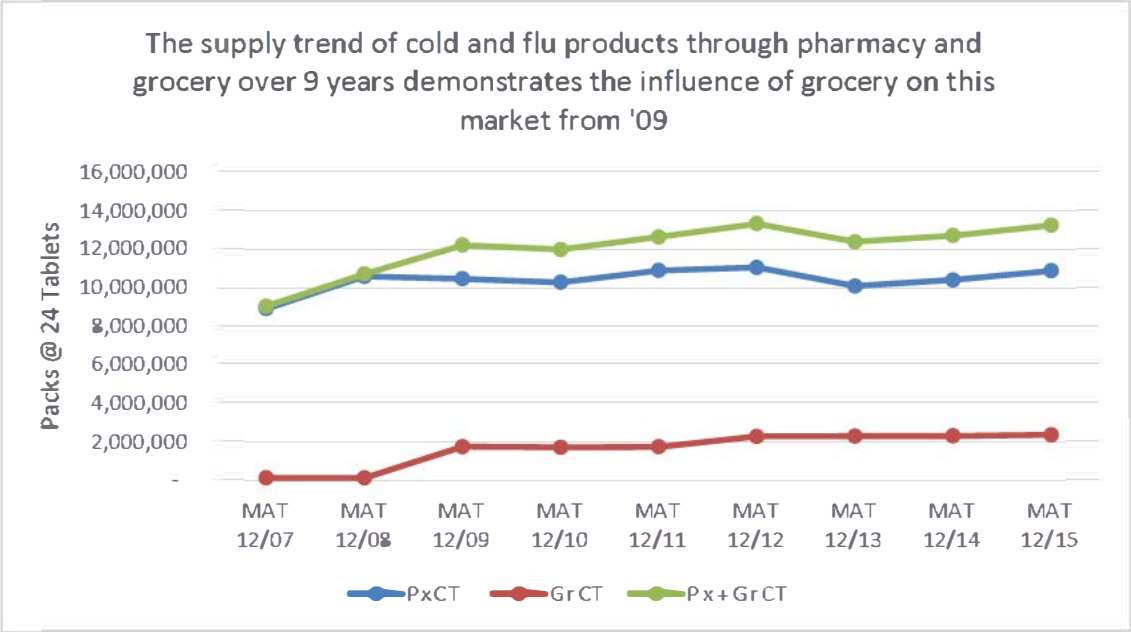


Figure 2 represents the total volume of cold and flu products supplied through pharmacy, and introduces cold and flu products supplied through grocery (Gr CT). Prior to 2009, the supply of cold and flu products through grocery was minor but with the introduction of the general sale solid dose phenylephrine range of products, grocery started actively competing for this market with pharmacy. Pharmacy cold and flu products (Px CT) has since stabilised and growth of the total sector (Px + Gr CT) is purely due to expansion in grocery.

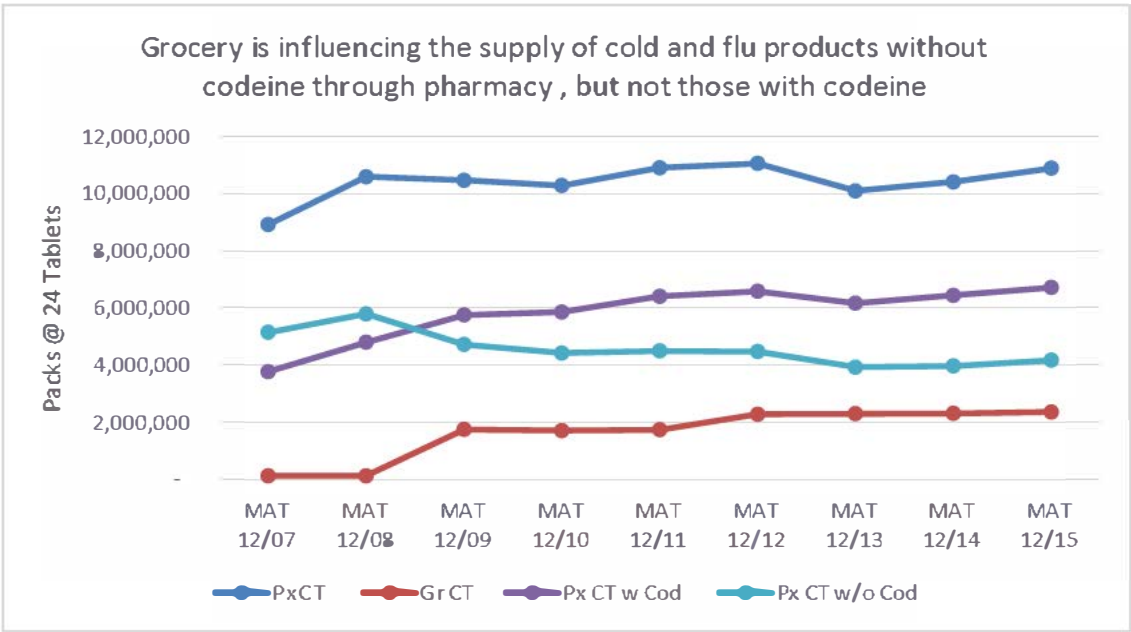


Figure 3 Graphic representation showing how the growth of the grocery cold and flu sector (Gr CT) has had a direct negative impact on supply of cold and flu products without codeine (Px CT w/o Cod) in pharmacy. The volume of loss of cold and flu products without codeine from pharmacy is about in direct proportion to the gain in grocery.

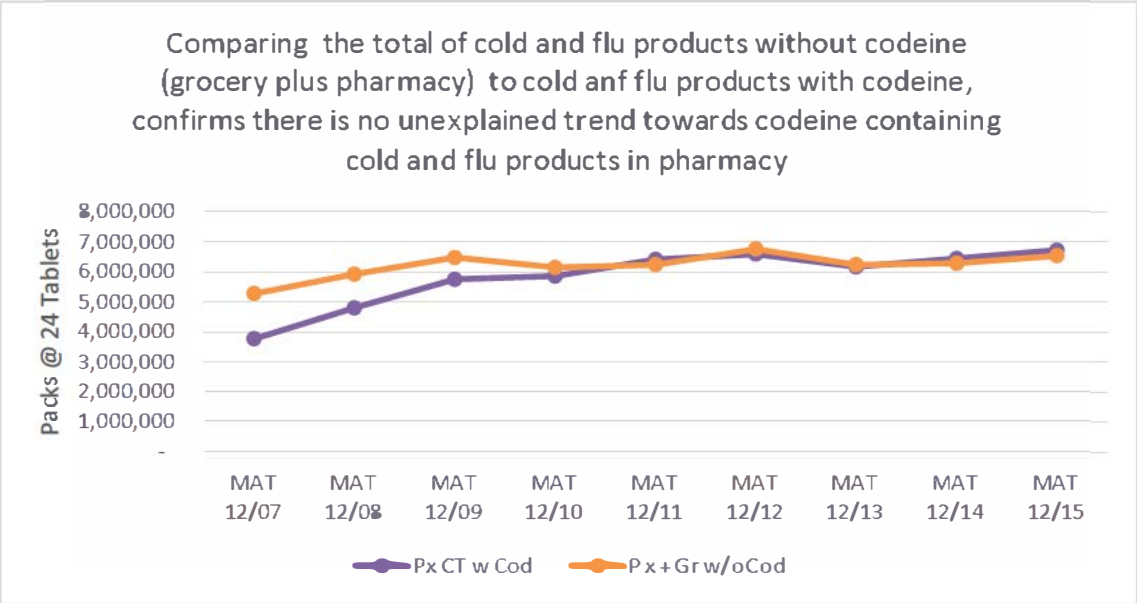


Figure 4 demonstrates that when combining the sales of pharmacy and grocery cold treatments without codeine (Px + Gr w/o Cod), and compare this with the sales of codeine containing cold treatments (Px CT w Cod), the combined supply trend for each product group is close to equivalent. There is no sudden, or unexplained surge or separation in demand in favour of cold treatments with codeine through pharmacy (Px CT w Cod).

Sales Trends of Analgesics 2009 – 2015 (IMS, MAT 2009 to 2015 inclusive)

There has been a sharp decline in codeine containing analgesics with a decrease of approximately 5 million packs in annual demand between 2009 and 2010. This fall in volume has been sustained through to 2015 (Figure 5). Interestingly, the decrease in demand of codeine containing analgesics has seen a strong increase in demand for codeine free analgesics (Aspirin, Ibuprofen, Paracetamol or non-codeine combination analgesics. All other single active analgesics {e.g. naproxen or mefenamic acid} have been excluded).

Ibuprofen with codeine is the only codeine containing analgesic product that continues to experience a strong decline in sales. Paracetamol with codeine has started to increase slightly, but this is likely to be gaining from this decline. Demand for any of codeine containing analgesics remains well below the levels of demand seen in 2009.

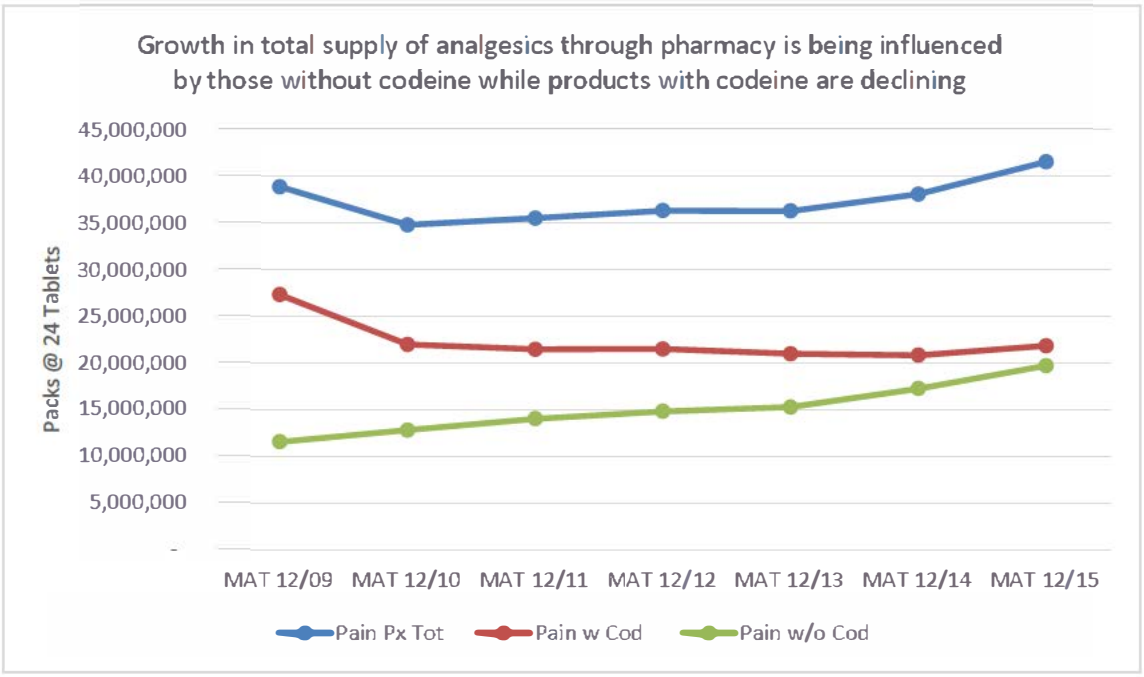


Figure 5 graphically represents the total pain treatment solid dose sector through pharmacy (Pain Px Tot). There has been a sharp decline in pain treatment with codeine (Pain w Cod) – approximately 5 million packs between 2009 and 2010. This fall in volume has been sustained through to 2015. However the sector has been supported by a strong increase in demand for pain products without codeine (Pain w/o Cod) resulting in overall growth of the pain treatment sector in pharmacy. Pain without codeine include single ingredient paracetamol, ibuprofen, aspirin, and non-codeine combination analgesics.

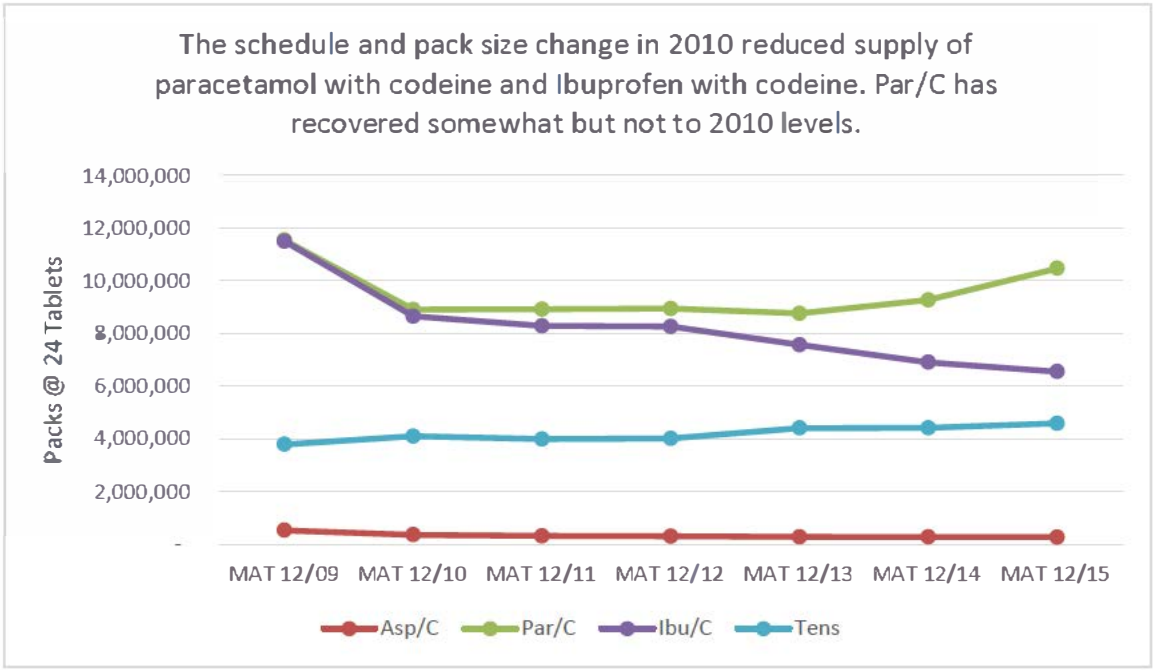


Figure 6 graphically represents the performance trends of the individual codeine containing analgesics (aspirin with codeine –Asp/Cod; paracetamol with codeine – Par/Cod; ibuprofen with codeine – Ibu/Cod; Tens – multi-ingredient pain product with codeine plus doxylamine – usually indicated for 'tension pain', e.g. Mersyndol). Ibuprofen with codeine is the only product that continues to decline strongly. Paracetamol with codeine is likely to be gaining from this decline, however has not reached 2009 levels. Figure 5 shows that in 2015 total analgesics with codeine remain below 2010 levels.

Comparison of Sales Trends of Codeine Containing Cold & Flu products and Codeine Containing Analgesics in Pharmacy (IMS, MAT 2007 to 2015 inclusive)

Between 2009 and 2010 there was a decline of approximately 5 million packs of analgesics with codeine. The trend from 2007 to 2015 for codeine containing cold and flu products has remained relatively flat, with no increase in demand at the time of or after the up-scheduling of codeine containing analgesics (Figure 7). There is no cross-over in supply between the pain and cold categories further confirming that these market sectors behave independently of each other.

Potential for cross-over in demand between pain with codeine and cold treatments with codeine: Conclusion

The NDPSC expressed some concern about a potential for an increase in demand for cold treatments with codeine as a result of scheduling and pack size change to codeine containing analgesics. Through sales date trend analysis it is clear that there has been no change in demand for codeine contain cold and flu products. This clearly shows that the concern of a transference of abuse or misuse of codeine did not occur and there is no cross-over in demand between these two sectors.

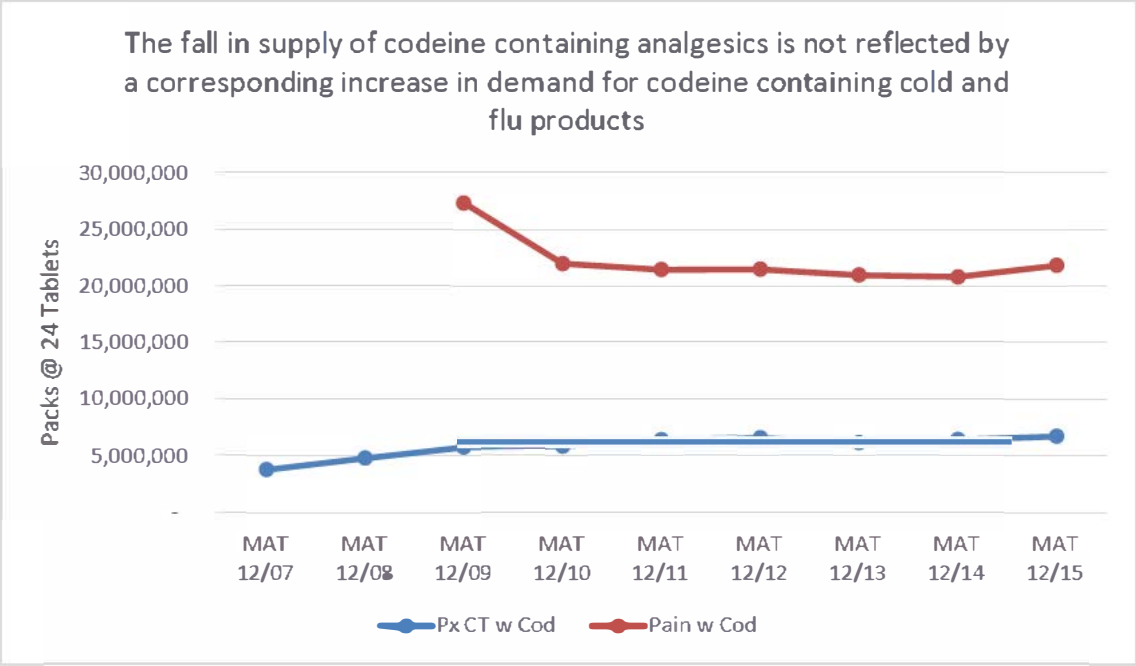


Figure 7 shows the loss between 2009 and 2010 of about 5 million packs of analgesics with codeine (Pain w Cod) from pharmacy, and the trend from 2007 to 2015 for codeine containing cold and flu products (CT w Cod). There is no increase in demand of codeine containing cold and flu products at the time of or after the up-scheduling of codeine containing analgesics. The graph demonstrates that there is no cross-over in supply between the pain with codeine and cold treatment with codeine sectors. It clearly demonstrates that these market sectors behave independently of each other. (Note that IMS data pertaining to the pain sector is not available prior to 2009).

Adverse Event Data
As previously highlighted in the submission of May 2015, Approximately 21 million packs of [redacted] (24 dosage units) were sold the period between January 2010 and April 2015 (equating to approximately 500 million individual dosage units and an average of 3.8 million packs per year).

During this same period [redacted] has recorded a total of 3 ***suspected*** cases of abuse (not confirmed). What cannot be concluded from the information held by [redacted] is whether the abuse is directly related to the codeine content, as the verbatim does not indicate this in two out of the three cases.

- **Case One**: An individual, reported to be an ex-smoker who excessively used cold and flu medication (not only [redacted] including non-codeine containing products. The role of codeine in this instance has not been determined.
- **Case Two:** An individual felt that when they stopped taking [redacted] their cold and flu symptoms retuned. The role of codeine in this instance has not been determined.
- **Case Three:** Reported via social media, a consumer stated that "I abuse your product" - no further details (including actual product) were reported and no further contact with the consumer could be made. The role of codeine in this instance has not been determined.

Conclusion
There is evidence that there has been no transference of abuse or misuse from codeine containing analgesics to codeine containing cold and flu products. Sales trends for codeine containing cold and flu products remain unchanged when compared to the demand prior to the up scheduling of codeine containing analgesics in 2009.

In the public submissions made in response to the call for public comment for the scheduling of codeine, there was no cold and flu products containing codeine implicated in any of the medicine misadventures reported, therefore there is no evidence to warrant a change to the scheduling of these products.

This is further supported by the fact that, significant volumes of codeine containing cold and flu products are distributed annually by [redacted] During the last 5 years, [redacted] have received a total of three, unconfirmed cases of abuse or misuse.

Consumers are using the codeine containing cold and flu product responsibly and as directed. There is evidence of no abuse and as such, the current scheduling remains appropriate.

[redacted] **Position**: There is evidence of no abuse or misuse of codeine containing cold and flu products, which justifies the recommendation to maintain the current scheduling (S2) for codeine containing cold and flu products.

Maintain S2 entry of codeine containing cold and flu products when limited to 3 days' supply.

There is no valid or scientifically robust reason or argument that would justify the re-scheduling of codeine containing cold and flu products.

There is evidence that demonstrates that there is no harm, abuse or dependency associated with codeine containing cold and flu preparations. The risk/benefit profile of codeine containing cold and flu preparations has not changed since the NDPSC decision in 2009 which deemed the currently scheduling as being appropriate.

The NDPSC previously determined that the S2 entry for codeine-containing cold and flu products was appropriate for the following reasons:

1. Symptoms of pain can be acute and or chronic, potentially leading to long-term use of OTC analgesic products. Conversely, symptoms associated with colds and flus are episodic and self-limiting, therefore unlikely to lead to inadvertent codeine addiction. Consumers are less likely to dose escalate or self-treat with cold and flu products for extended periods of time, mitigating any potential for misuse as is reported with codeine-containing analgesic products.
2. Cold and flu products containing codeine often have multiple therapeutically-active ingredients and these, together, might diminish abuse/misuse.
3. Reported misuse of cold and flu products containing codeine is extremely rare and no submissions asserted that there was evidence indicating a problem.
4. Evidence was provided suggesting that when PE codeine combinations are not available (due to an out of stock situation), pharmacy sales of PSE products escalated. The continued availability of PE/codeine-combination products as S2 was considered appropriate given the major concerns relating to the illicit diversion of pharmacy-originated PSE. The concern of PSE diversion into methamphetamine remains current.

This decision was affirmed by a Delegate in September 2011 where scheduling of codeine was considered as part of the cold and cough preparation review and, on the recommendations of the Advisory Committee on Medicines Scheduling **(ACMS),** the Delegate decided there should be no change to the scheduling of codeine in cold and cough preparations.

There has been no additional studies, nor increased demand or change in patterns of use of codeine containing cold and flu products since the up-scheduling of codeine containing analgesics in 2010. Any concern that may have been held in relation to transference of abuse or dependency from analgesics was addressed in the [redacted] submission of 7th May 2015 and updated in the above section.

Maintaining the S2 Standard for Phenylephrine-based Cold Treatment Products with Codeine - Phenylephrine as a Pseudoephedrine Management Strategy

Pseudoephedrine, obtained through pharmacy for the illicit purpose of the manufacture of methyl amphetamine (ice, crystal meth, etc), became a substantial law enforcement and social issue prior to 2006. Solid dose phenylephrine was registered for use in Australia in part as a strategy to reduce the quantity of pseudoephedrine stocked and supplied through pharmacy.

The effectiveness of this strategy can be demonstrated through the data presented in Figure 8. A limited range of solid dose phenylephrine products were introduced onto the Australian market in late 2005, while the full range of pseudoephedrine alternatives, including phenylephrine with codeine, were introduced in 2006.

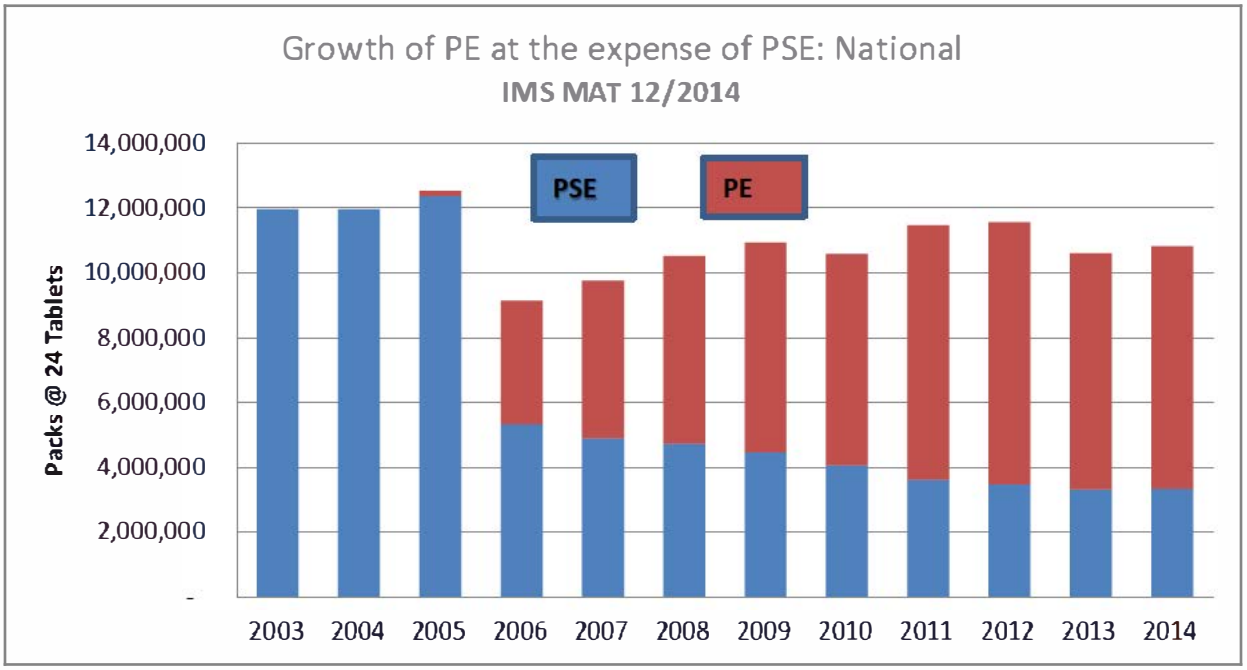


Figure 8 represents pack size equivalent of pseudoephedrine and phenylephrine based cold treatment products. After the launch in 2005/2006 of phenylephrine, followed by a schedule change to S3 for pseudoephedrine based products, the decline in volume of pseudoephedrine in pharmacy is strongly evident.

Table 2 shows that in 2015, 62% of all solid dose phenylephrine based cold treatment products contained codeine. This preference by pharmacy and consumers towards for phenylephrine products with codeine has been sustained for many years.

	2011	2012	2013	2014	2015
Proportion of phenylephrine based products containing codeine to total phenylephrine	60%	61%	62%	62%	62%

Table 2 The proportion of codeine containing phenylephrine products sold when compared with codeine free-phenylephrine combinations in pharmacy. Codeine containing phenylephrine combination products account for 60% or more of all sales of phenylephrine combination products in pharmacy.

All pseudoephedrine based products are schedule 3 Pharmacist Medicines. Pseudoephedrine is acknowledged to be the most efficacious of the systemic nasal decongestants.

Should codeine-phenylephrine cold and flu products be up-scheduled to S3, they will fall into the same restrictions and regulatory framework as the pseudoephedrine based products. The pharmacist

will therefore most likely lean towards recommending the more efficacious product range, i.e. pseudoephedrine, negating the effectiveness of the phenylephrine launch strategy described above. The result will be an increase in the volume of pseudoephedrine products in the supply chain as well as the quantities stored and recommended in pharmacy, increasing risk of illicit access.

Impact of limiting pack sizes to three days' supply

Limiting pack size to three days treatment will have a substantial impact on supply patterns to codeine containing OTC products, as the majority of packs supplied to consumers are from pack sizes above 24 tablets. Maximum daily dose for the majority of these tablets is 8 tablets per day (2 tablets 4 x per day).

Table 3 and Table 4 show the proportion of products with and without codeine based that are sold in pack sizes greater than 24.

These tables further cement the view that cold and flu products are very different to analgesics. Irrespective of the presence or absence of codeine in cold and flu products, packs sizes of greater than 24 dosage units account for 40% or less of all sales between 2011 and 2015.

Analgesics are very different to cold and flu products with the larger pack sizes counting for the vast majority of sales (irrespective of the presence/absence of codeine).

Table 3 Proportion of tablets with codeine provided in packs greater than 24 tablets. Packs sizes greater than 24 for Cold and flu treatments containing codeine account for less than half of all sales, where for analgesics, packs sizes greater than 24 account for the vast majority of sales.

Proportion of tablets with codeine provided in pack sizes greater than 24	2011	2012	2013	2014	2015
Aspirin/Codeine tablets in packs > 24	31%	36%	38%	42%	45%
Paracetamol/Codeine tablets in packs > 24	52%	57%	65%	75%	80%
Ibuprofen/Codeine in packs > 24	82%	88%	91%	93%	94%
Tension Pain tablets in packs > 24	15%	27%	56%	71%	77%
Cold Treatment tablets with codeine in packs > 24	26%	31%	34%	38%	40%

Table 4 Proportion of tablets without codeine provided in packs greater than 24 tablets. Packs sizes greater than 24 for Cold and flu treatments containing codeine account for less than half of all sales, where for analgesics, packs sizes greater than 24 account for the vast majority of sales.

Proportion of tablets without codeine provided in pack sizes greater than 24	2011	2012	2013	2014	2015
Aspirin Tablets in packs > 24	40%	41%	42%	42%	44%
Paracetamol Tablets in packs > 24	51%	51%	57%	63%	66%
Ibuprofen Tablets in packs > 24	64%	65%	68%	69%	70%
Cold Treatment tablets without codeine in packs > 24	24%	25%	27%	31%	32%

Limiting codeine containing products pack sizes to no more than 3 days' supply is likely to have the following consequences:

- An increase in total volume of smaller packs in pharmacy
- An increased frequency of exposure to the pharmacist for S3 products as a result of the smaller number of tablets per pack, as the customer will need to return more frequently. Additional exposure to the pharmacist for S2 products is unlikely.
- An increase in opportunity to council pain product consumers towards more appropriate treatment
- The unintended consequences of the loss of family pack sizes of cold treatments. Pack sizes of 48 tablets for cold treatments are there to provide a convenience and cost saving for families purchasing these products.

Overall, restricting packs sizes to 24 for codeine containing cold and flu products will have little benefit to the public health in Australia.

[redacted] **Position**: [redacted] supports the recommendation to maintain the current scheduling (S2) for codeine containing cold and flu products. [redacted] has no objections to limiting pack sizes to 3 day supply.

Opposition to other scheduling proposals for codeine containing cold and flu products.

[redacted] opposes any changes to the scheduling of codeine containing cold and flu products, with the exception of limiting supply to a maximum of 3 days supply.

In our previous submissions [redacted], we highlighted the impact on the public health system should codeine containing cold and flu products be re-scheduled to Prescription only. This argument will not be repeated here, but we do request that the information provided previously be considered in the context of this decision. The environment has not changed and the data provided previously is still valid.

We would like to highlight that in the [redacted] response to the interim decision, the Macquarie University Fact book estimated that the up-scheduling codeine-containing cold and flu medicines would cost the Australian economy $257 million annually. With costs borne by government due to increased doctor visits, Medicare and dispensing costs at $53 million and a further $174 million due to productivity losses caused by the restricted access. The balance of costs would be borne by consumers.

[redacted] **Position**: There is evidence of no abuse or misuse of codeine containing cold and flu products and therefore there is no justifiable reason to implement more restrictive scheduling for these products especially given the risk/benefit ratio will not improve if this was to occur.

Supporting the proposal to maintain the S3 scheduling of codeine containing analgesics limited to 3 days' supply with the additional label warnings as proposed.

[redacted] does not market any single active or combination primary analgesics in either Australia or New Zealand.

We are aware there have been some case reports of adverse outcomes in some patients when excessive amounts of OTC codeine containing analgesics have been consumed as a result of codeine dependence. Codeine containing analgesics have a role to play in the self-management of acute episodes of pain and the vast majority of consumers use these products appropriately.

In no way does [redacted] trivialise or down-play the serious nature of the reports of medicine misadventure that might be associated with the codeine containing analgesics, however we believe that alternative measures for addressing the issue of misuse should be explored.

As members of [redacted] fully support and endorse the position that has been put forward by [redacted] in relation to the scheduling proposals for codeine containing analgesics. This is supporting proposal (a) for analgesics – 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.

[redacted] **Position**: [redacted] supports the recommendation to amend the schedule 3 entry for codeine for analgesics to restrict the pack size to not more than 3 days' supply. [redacted] does not support the proposal to adopt the recommendation of the interim decision to make all codeine containing products Schedule 4.

Support of the S3 scheduling proposal for codeine containing analgesics is contingent on the introduction of a real time monitoring systems that has been proposed by [redacted] and the guild

As a member of [redacted] supports and recommendation by [redacted] in relation to the introduction of a real time monitoring system for the sales of codeine containing analgesics only.

[redacted] and the [redacted] have developed software that will provide pharmacists with a clinical and decision-making support tool. The software is to be used in together with the [redacted] document "Guidance for provision of a Pharmacist Only medicine – Combination analgesics containing codeine." The document provides instructions for pharmacists to follow when deciding whether to supply OTC codeine containing analgesics for temporary relief of moderate to severe pain.

The system has been designed record and monitor sales of OTC codeine containing analgesics. Details that will be recorded include, but are not limited to:

- Customer Details
- Product supply or not
- Details of the product supplied
- Indications for supply or refusal.

This system will allow pharmacists to be able to review any other recent purchases to assist in assessing how to best manage the consumer's request. This software will identify "pharmacy shoppers" to be quickly identified and allow for the referral to an appropriate healthcare professional.

For the purposes of clarity, this is a separate initiative to Project Stop and the two systems are independent. This software is about ensuring consumers that are at high risk of medicine misadventure are identified and helped in a timely manner. Project stop is a non-mandatory tool that is utilised by relevant law enforcement agencies for identification of individuals that might be involved in criminal activity.

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. If this software proves successful, it could lay the foundations for software to address this issue.

The concept of real time recording has been proposed to help identify those consumers accessing and consuming inappropriate amounts of Schedule 3 codeine containing pain products. Recording may be appropriate for products at risk of misuse, however, including products that are not at risk of misuse will increase the complexity and administration burden of the process. Also it would be reasonable to expect a proportion of consumers to purchase more than one pack of cold treatment products – a process that would not easily fit into the recordable system.

[redacted] **Position**: [redacted] supports the mandatory implementation of a real time monitoring system for the sale of codeine containing analgesics only.

Measuring Outcomes: Additional Scientifically Robust Studies

There have been some recent publications where conclusions of have been drawn about the abuse and mortality rates associated with codeine, including that "*Codeine-related deaths (with and without other drug toxicity) are increasing as the consumption of codeine-based products increases*". [1] Evidence (IMS Data) presented above categorically demonstrates that since the up scheduling of codeine containing analgesics in 2010, there has been a significant decrease in overall sales of codeine containing products, being driven by the analgesic category , and therefore there is no likelihood of increased consumption.

The studies undertaken by Pilgrim[2] and Roxborough[3] not without limitation, and a more rigorous and robust approach needs to be taken to draw any valid conclusions relating to the mortality rates associated with OTC codeine use. The publications referenced above actually open up more questions, than answers. Some of the limitations include that fact that the authors did not consider the mortality rates pre- and post- the up-scheduling of codeine containing analgesics. The studies were also limited to a small geography and are unlikely to represent the situation from a national perspective.

[1] Roxburgh *et al* - Trends and characteristics of accidental and intentional codeine overdose deaths in Australia Med J Aust 2015; 203 (7): 299.

[2] Pilgrim, Dobbin & Drummer (2013) Fatal misuse of codeine–ibuprofen analgesics in Victoria, Australia. MJA 199(5) 329

[3] Roxburgh *et al* - Trends and characteristics of accidental and intentional codeine overdose deaths in Australia Med J Aust 2015; 203 (7): 299.

[redacted] recommends that a well-designed, scientifically robust, Australia-wide study on mortality rates associated with codeine misuse/abuse in OTC products, pre- and post all codeine related scheduling decisions (including previous scheduling decisions) along with the implementations of other measures (such as a real time monitoring system for codeine containing analgesics) be undertaken to determine the success of these measures in a systematic and accurate manner. This research should be independently conducted and undertaken with the utmost rigour and without bias. This research should look at all categories of codeine containing products – inclusive of cold and flu products, non-prescription codeine containing analgesics and also prescription only codeine containing medicines.

[redacted] **Position**: [redacted] recommends a scientifically robust and independent study be undertaken to measure the success of the previous scheduling decisions for codeine products and any measures that are implemented as part of the current scheduling proposal relating to codeine to ensure all decisions evidence based.

Appropriate timeframes for Implementation

Irrespective of the scheduling decision for codeine containing cold and flu products or codeine containing analgesics, [redacted] requests that the delegate allow a sufficient implementation time for the changes to be effective. Due to supply chain and production complexities, [redacted] requests that if the delegate decides to make changes to the scheduling despite the data provided above, a minimum of 2 years is provided to make the transition, with an effect date following a cold and flu season (i.e. towards the end of a calendar year).

Conclusions

Data has been provided demonstrating that there is evidence of no abuse or misuse of codeine containing cold and flu products. Therefore [redacted] request that the delegate consider the following:

- The current scheduling for codeine containing cold and flu products remains appropriate, as there is evidence of no abuse or misuse in this category
- The schedule 2 entry of codeine is altered from “cough and cold medicine preparations” to “cold and flu medicine preparations.
- [redacted] believes the reduction of pack sizes to no more than 3 days supply is of limited benefit for this category however there are no objections to this request, providing sufficient time is permitted to allow transition without stock write offs.
- The proposal to maintain the S3 scheduling of codeine containing analgesics limited to 3 days’ supply with the additional label warnings as proposed and implementation of a real time is appropriate but the success of these measure must be measured
- A well-designed, scientifically robust, Australia wide study on mortality rates associated with codeine misuse/abuse in OTC products, pre and post all codeine related scheduling decisions and other implemented measures (such as a real time monitoring system) be undertaken to determine the success of these measures in a systematic and accurate manner

Thank-you for this opportunity to provide comment on the scheduling proposals for Codeine. Please feel free to contact me should you need provide further data or information.

[redacted]

Appendix 1
[redacted] submission to the ACMS on the scheduling of Codeine
May 2015

[redacted]

[redacted]

Thursday 7th May 2015

Medicines Scheduling Secretariat
Therapeutic Goods Administration
136 Narrabundah Lane
Symonston ACT 2606
Australia

Dear Sir/Madam,

Re: Public Submission – under Reg. 42ZCZK of the Therapeutic Goods Regulations 1990. ACMS meeting, July 2015

Proposal to delete the Schedule 3 entry for codeine and reschedule the current Schedule 3 codeine entry to Schedule 4 due to potential issues of morbidity, toxicity and dependence. In addition to considering the appropriateness of Schedule 2 entry of codeine

[redacted] recognises the challenge of addiction to society; we are strongly opposed to the proposal to review the scheduling of codeine in cold and flu products for the following reasons:

1. The NDPSC determined in 2009/2010 that Schedule 2 for codeine containing cold and flu products was appropriate due to the differences in risks associated with cold and flu products versus analgesics. No evidence has emerged to suggest that the risk-benefit/Abuse/Misuse profiles have changed since this decision was made.
2. Cold and flu medicines containing codeine are responsibly used by millions of Australians appropriately opting for self-care of what are short-term, episodic and self-limiting conditions. The appropriate care setting for these treatments to be administered is community pharmacy;
3. There is no current or historical evidence of widespread abuse of cold and flu products containing codeine;
4. Retaining S2 codeine/phenylephrine combinations was a successful strategy for reducing the amount of pseudoephedrine in trade. Further restrictions on the availability of S2 codeine/phenylephrine combinations will negate this.
5. Restricted access to safe and effective codeine containing cold and flu products could drive people with colds and flus into general practice and emergency departments for access to care, will have the perverse consequences of a negative impact on the health budget at a time when over-utilization of medical services is very difficult to control and inappropriate use of antibiotics;
6. The potential for a significant consumer backlash given these products are widely used and the new care settings proposed (GP or ED) often involve a significant co-payment or waiting times.

[redacted] is the sponsor of both Pharmacist Medicines (S3) and Pharmacy Only Medicines (S2) that contain codeine, in combination with paracetamol and either pseudoephedrine (PSE) or phenylephrine (PE). These products are indicated for the relief of symptoms associated with colds and flu under the brand name of [redacted] a local brand that can only be found in Australia and New Zealand.

[redacted] is not a sponsor of analgesics and do not supply either single component or multi-component analgesics in Australia or New Zealand.

Executive Summary

In 2009, the now defunct National Drugs and Poisons Schedule Committee (NDPSC), voted to amend the scheduling of codeine containing analgesics from S2 to S3 based on evidence of inappropriate use. At its June and October 2009 meetings, the NDPSC confirmed that the Schedule 2 codeine entry pertaining to cold and flu products remained appropriate given there were no reports that use of these products was leading to misuse or abuse. A decision was reached maintain packs sizes equivalent to 6 days' supply and to review the scheduling cold and flu could medicines in 12 months, should evidence of misuse or abuse emerge. To date there has been no evidence of misuse or abuse in this category.

In a separate decision, all pseudoephedrine (PSE) products (including combination products) were scheduled to S3 for the distinct purpose of limiting access to PSE for illicit drug trade and conversion into methamphetamine.

Since these changes came into effect, data relating to the volume of individual packs of non-prescription analgesics and cold and flu products supplied through pharmacy clearly demonstrate that there has been no transfer of demand from non-prescription analgesics containing codeine to cold and flu products containing codeine. The now defunct NDPSC previously expressed a concern that this may occur when codeine containing analgesics were up-scheduled from S2 to S3; however, as noted, there has been no evidence that this has occurred.

[redacted] wishes to raise concerns regarding the unintended consequences of scheduling changes to cold and flu products with codeine should the NDPSC's previous decision be overturned. Importantly, these changes are likely to have negative economic impacts to the patient and the public health system by unnecessarily driving cold and flu sufferers into GP clinics (or emergency rooms) for symptomatic relief. This, in turn will increase the cost to the consumer of accessing cold and flu medicines and place undue pressure on the GP with extra patient load and potential for inappropriate antibiotic prescribing.

Furthermore, the up-scheduling of codeine-containing cold and flu medicines to S4 respectively, is likely to increase demand for the PSE formulated cold and flu products still available in Pharmacy. The result would be greater volumes of PSE in the market than we see today and greater pressures on both pharmacy and law enforcement to track sales.

Evidence provided in this submission clearly supports the notion that the current scheduling of cold and flu products with codeine is appropriate and that no new evidence has emerged since the scheduling decisions in 2009 and 2010. The evidence demonstrates that this is no case for the up-scheduling for codeine containing cold and flu products.

Cold and flu products containing codeine should be excluded from any consideration of measures aimed at addressing analgesic codeine combinations. No new evidence of inappropriate use has been identified in relation to these products. The concerns that the problem of abuse/misuse may have shifted to cold and flu preparations that contain codeine have been dispelled with the data provided within.

Inability to Assess the Evidence Provided in Support of a Schedule Change

[redacted] would like to highlight that parties with a vested interest in the scheduling of codeine have not been given an opportunity to review any evidence to suggest that there is an issue that warrants the up-scheduling of codeine, especially in relation to cold and flu products containing codeine. The proposal for a review of the scheduling provides the general public with no information in relation to the issue apart from a motherhood statement of ….. **"***due to potential issues of morbidity, toxicity and dependence*".

[redacted] would argue that this statement in and of itself reflects no new developments in patient safety data and that the scheduling of codeine containing medicines has always been based on the ingredient's known risk-benefit profile.

In the interest of procedural fairness, [redacted] believes that any evidence submitted in support of the up-scheduling proposal should be made publically available for consideration by interested parties. Comments to this effect were included in the [redacted] submission to the expert panel's review of the current medicine and medical device legislation.

[redacted] would like to request that the ACMS consider deferring any recommendation in relation to the scheduling of codeine and requests that all evidence relating to "*the potential issues of morbidity, toxicity and dependence*" are published in the public domain for critical analysis by those with a vested interest in codeine.

Interested parties cannot be reasonably expected to provide a considered and complete submission addressing any issues raised in the original proposal, without being given the opportunity to review the evidence.

Furthermore, given the impact on the consumer of up-scheduling a commonly used product i.e. driving them into a new care setting where a waiting time and a co-payment is possible, this change should be subject to a period of broad public consultation to avoid a justifiable consumer backlash. In addition,

the Department of Health and Aging has a public obligation to model the impact on the health budget as a result of driving people who currently self-care into General Practice and Emergency Departments.

[redacted] urges the ACMS to consider these additional obligations before making any changes to the current scheduling arrangements for codeine.

Primary Issue is Limited to OTC Codeine-Containing Analgesics

[redacted] has been led to (anecdotally) understand that the primary issue motivating the inclusion of a change to the schedules containing codeine on the ACMS agenda is the small number of reported cases of misuse of S3 analgesics that contain codeine. This misuse might result in severe adverse events (AEs), mostly gastrointestinal, renal or hepatic injury. These AEs are believed to be the result of excessively high doses of ibuprofen or paracetamol consumed as a result of drug seeking behaviour for the codeine content of these products.

Media reports on the 25th and 26th April 2015 stated that researchers at Monash University have reported an increase in codeine abuse. This was based on a letter to the editor of the Medical Journal of Australia authored by Pilgrim *et al* 2013[1] (Appendix 1). The work conducted by Pilgrim *et al*, looked at post-mortem results from the period of 1 January 2001 to 31 December 2011. The decision to up-schedule codeine containing analgesics became on the 1st May 2010, at which time there was a significant drop in sales/demand/supply of codeine containing analgesics. **This means that in the Pilgrim *et al* study, only 19 of the 132 months in the study period (14%) were covering the period in which the access to codeine containing analgesics were more restricted, raising questions over the validity of the recommendations in the letter.**

Further, the references cited by Pilgrim *et al* in support of the apparent increased abuse of OTC were published in 2010 and 2012, and these too would have been largely based on data collated prior to the enforced restricted access was in place with the up-scheduling of codeine containing analgesics.

To determine whether the up-scheduling of codeine containing analgesics has had a real impact, the work conducted by Pilgrim *et al* should be conducted again, on a national scale looking at data both pre- and post- the up-scheduling of codeine containing analgesics. This would give a true indication as to whether there is a trend of increased codeine abuse in Australia and whether the up-scheduling of codeine containing analgesics has been successful at addressing the issue.

Given the ramifications of further restrictions (discussed later), any recommendation should be based on real, evidence submitted in a peer-reviewed publication of the current situation and not data collected prior to the effective date of the former NDPSC's re-scheduling decision. It is bad policy to base a change of this potential magnitude on anecdotal evidence submitted around a small number of difficult cases.

[1] Pilgrim, Dobbin & Drummer (2013) Fatal misuse of codeine–ibuprofen analgesics in Victoria, Australia. MJA 199(5) 329

Again, [redacted] wishes to emphasise that excessive consumption behaviour towards cold and flu products containing codeine has not been reported, nor previously considered as a consumer risk issue, when the past NDPSC reviewed and deliberated on the appropriate scheduling of OTC codeine containing products in 2009/10.

2009/10 NDPSC Scheduling Decision of Cold and Flu Products

In 2009, the NDPSC confirmed that the S2 scheduling of codeine-containing cold and flu products was appropriate. For reasons previously stated regarding the S3 scheduling of PSE products, this decision was made on the proviso that phenylephrine (PE) was always included in the formulation.

Pack sizes were maintained at no more than 6-days' supply based on status quo at the maximum dose recommended on the label allowing for a family pack size of 48 tablets. This pack size was deemed to be appropriate by the panel members as it was recognised that colds and flu are easily transmitted among household members.

Main reasons why the continued S2 listing of codeine-containing cold and flu products was deemed appropriate by the NDPSC:

1. Symptoms of pain can be acute and or chronic, potentially leading to long-term use of OTC analgesic products. Conversely, symptoms associated with colds and flus are episodic and self-limiting, therefore unlikely to lead to inadvertent codeine addiction. Consumers are less likely to dose escalate or self-treat with cold and flu products for extended periods of time, mitigating any potential for misuse as is reported with codeine-containing analgesic products.
2. Cold and flu products containing codeine often have multiple therapeutically-active ingredients and these, together, might diminish abuse/misuse.
3. Reported misuse of cold and flu products containing codeine is extremely rare and no submissions asserted that there was evidence indicating a problem.
4. Evidence was provided suggesting that when PE codeine combinations are not available (due to an out of stock situation, for instance), pharmacy sales of PSE products escalated. The continued availability of PE/codeine-combination products as S2 was considered appropriate given the major concerns relating to the illicit diversion of pharmacy-originated PSE.

The concern of PSE diversion into methamphetamine remains current.

[redacted]

[redacted]

[redacted]

Monitoring of S2 Codeine-Containing Cold and Flu Products

When the former NDPSC confirmed the S3 scheduling of codeine-containing analgesics, questions were raised over whether this would potentially lead to a surge in demand for S2 codeine-containing cold and flu products. It was noted by the NDPSC that this should be monitored.

The NDPSC was disbanded after the scheduling decisions were made for codeine and as a result, no formal requests were ever made to revisit the issue.

However, acknowledging its role as a major supplier in the cold and flu category, [redacted] decided to proactively monitor for any resulting changes to the demand of codeine containing cold and flu products in both Australia and New Zealand. In both 2014 and 2015, the Australian data was voluntarily shared with the TGA and with the Chief Pharmacist of the NSW State Department of Health. Data specific to New Zealand will similarly be shared with Medsafe and other key stakeholders (June 2015). There are plans for [redacted] to share its data more widely with other key stakeholders.

Both the national and state data conclusively demonstrates that there is **no relationship between the fall in supply/demand of non-prescription codeine-containing analgesics and the demand for cold and flu products containing codeine**. There has been no unexplained increase in demand for these products. In fact, demand has remained relatively flat, with slight seasonal variances which is dependent on the severity of the cold/flu season. The data for New Zealand also shows similar trends in the demand for codeine-containing cold and flu products (New Zealand re-classified codeine containing analgesics at a similar time to Australia).

This clearly shows that the NDPSC decision to differentiate and exclude the S2 cold and flu products with codeine from up-scheduling in 2009 was appropriate, and currently remains appropriate.

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

Table 1 represents the supply to pharmacy (Px) of S2 PE cold products with codeine (PE w Cod), S3 PSE products with codeine (PSE w Cod), and all PE cold products without codeine (Grocery (Gr) + Px no Cod). Supply of PSE w Cod remains steady. PE w Cod and Gr+Px no Cod demonstrate a similar demand pattern, likely based on seasonality.

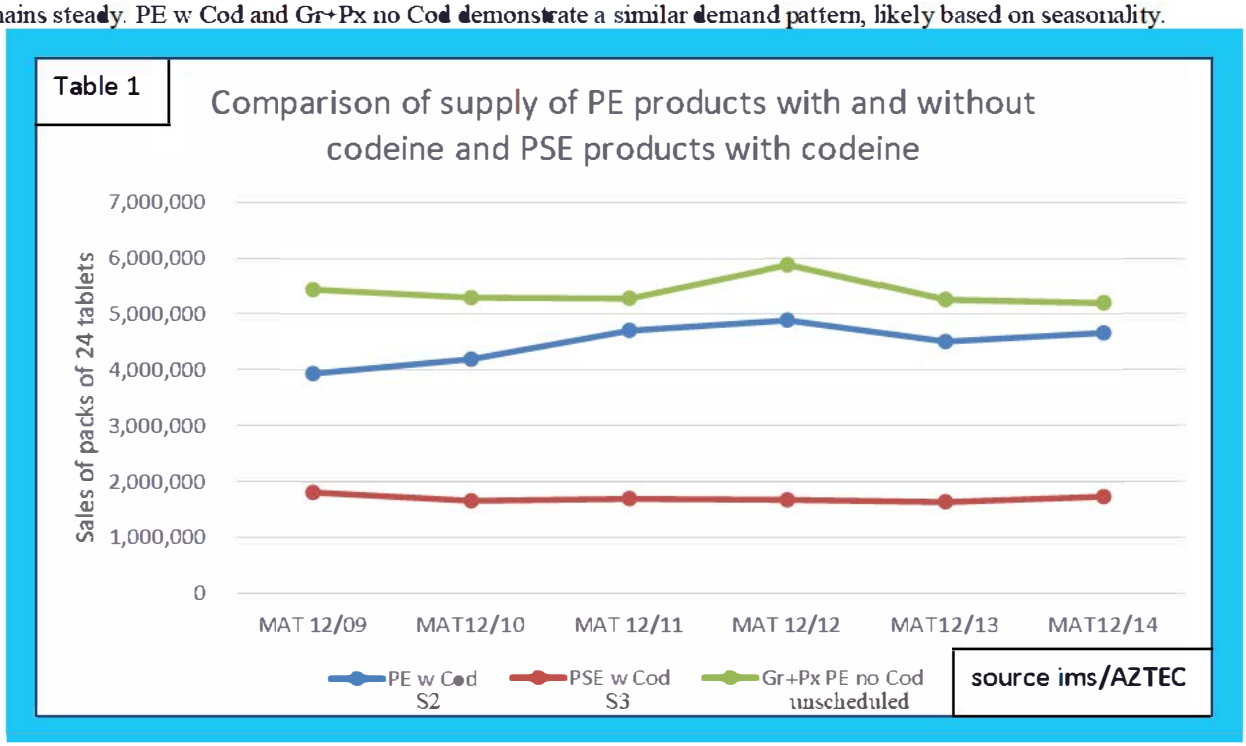


Table 2 compares the total supply of S3 analgesic containing codeine products (Pain/Cod all) to the supply of products containing only paracetamol with codeine & ibuprofen with codeine (ParC + IbuC). The products most affected by the May 2010 change in scheduling of OTC analgesics with codeine have been paracetamol with codeine and ibuprofen with codeine. The reduction in supply of ParC+IbuC is 6.9 million packs when comparing supply in 2009 to 2014.

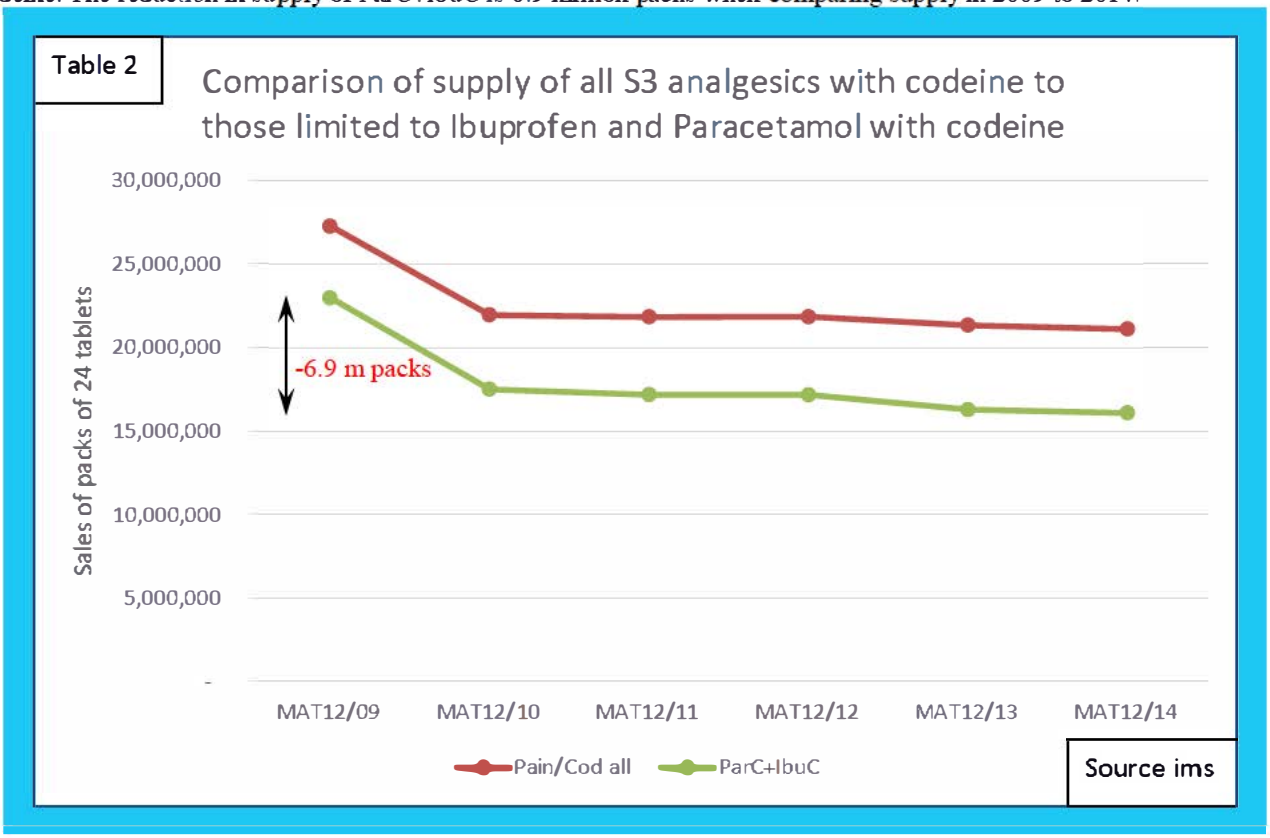


Table 3 demonstrates clearly that the fall in supply of ParC/IbuC by -5.5 million packs between 2009 and 2010 did not influence supply of PE w Cod or PSE w Cod over that period. The progressive decline by a further 1.4 million packs between 2010 and 2014 also appears to have had no influence on supply of PE w Cod nor PSE w Cod. This data clearly negates the concern expressed by the former NDPSC about the potential for a transfer of demand from S3 analgesics with codeine to S2 PE with codeine. Thus there is no requirement that consideration be given as to whether the Schedule 2 entry for codeine should also be amended.

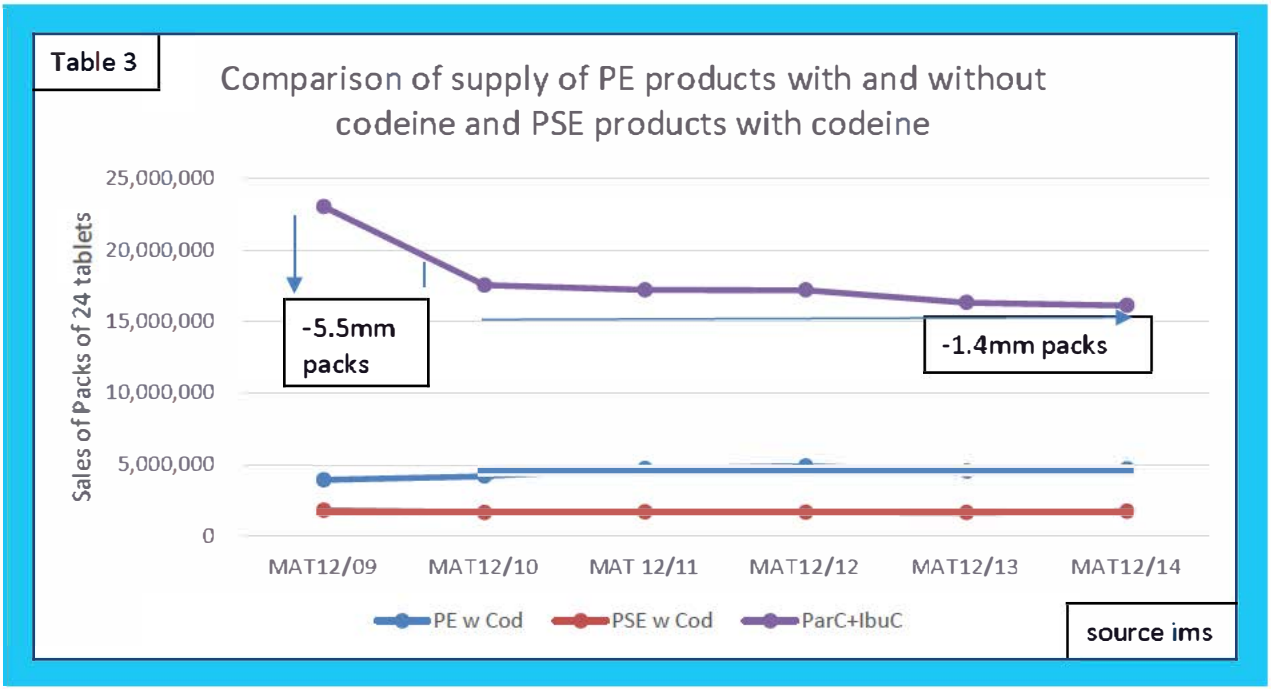
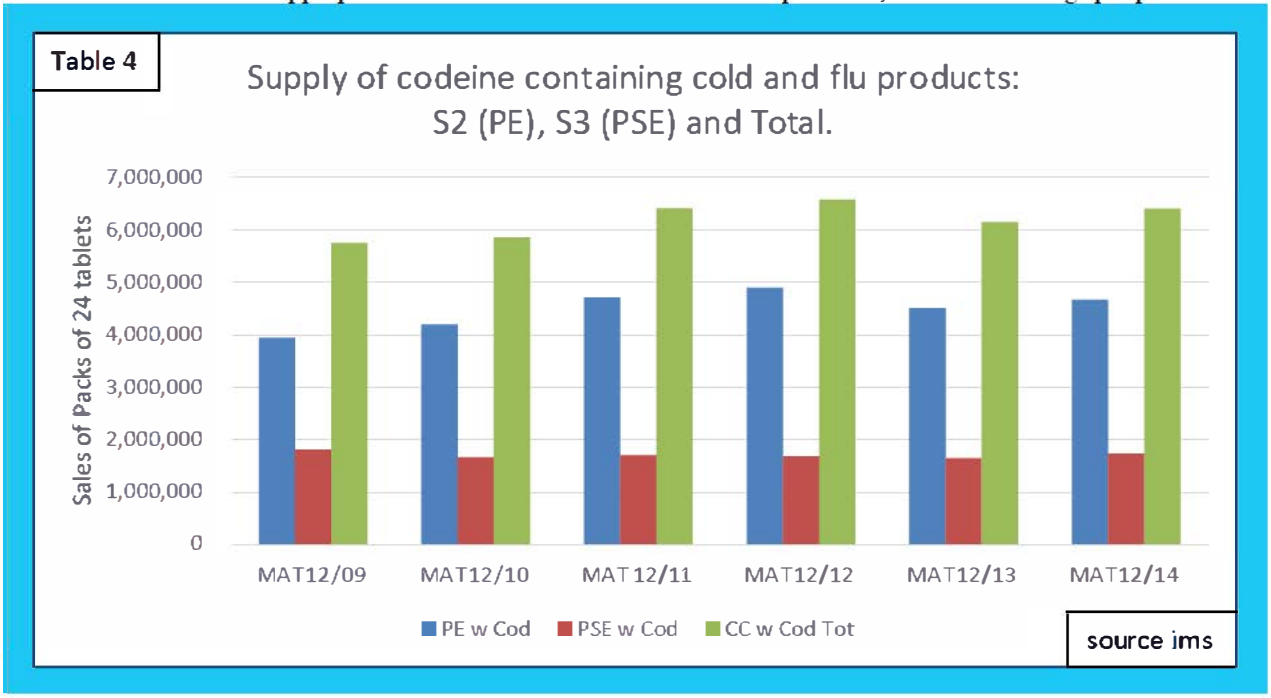


Table 4 represents the comparison of supply of PE w Cod and PSE w Cod. Supply of PSE w Cod has remained stable for the past 6 years and there is no data, from a supply perspective, that supports the notion that these preparations should be rescheduled to S4. S3 is the appropriate schedule for PSE w Cod in current pack size, limited to 720mgs per pack.



Unintended Consequences Relating to Rescheduling of Cold and Flu Products with Codeine

Increase of Pseudoephedrine in Pharmacy & Supply Chain

In the situation where PE products with codeine are rescheduled to S3, both PE and PSE products would be required to be stored behind the dispensary and supplied only upon consultation with the pharmacist. This would have the effect of a three-fold increase in the volume of product stored behind the counter - based on 2014 figures, an additional 4.7 million packs (all brands, not just JJP brands).

With both PE and PSE scheduled as S3, pharmacists will be more likely to choose or prefer the recommendation of PSE for effective relief of cold symptoms, given its superior efficacy when compared with phenylephrine.

This has been the pharmacists approach since 2006 with the rescheduling of PSE based products to S3. If S2 codeine containing cold and flu products were to be up-scheduled it would exponentially increase the volume of PSE products in pharmacy, and the associated risks related to illicit access for methamphetamine manufacture. JJP can confidently make this claim as we saw a significant increase in the demand of PSE-containing Codral when there were supply issues with PE-containing Codral. The original and **successful strategy** that was supported by the NDPSC to help reduce the volume of PSE supplied through pharmacy by maintaining the S2 scheduling of PE with codeine combinations.

To make a decision that would drive the growth of pseudoephedrine is not in the interest of public health.

If an additional move was made to make the Codeine PSE combinations S4, based on the research conducted at Macquarie University (see below), it will drive consumers to their GPs (as noted above) for prescriptions of pseudoephedrine with codeine, but it may well encourage criminals to go doctor shopping for PSE prescriptions as a means of obtaining precursor material for the manufacture of methamphetamine and the associated harm to the community. The ability to track PSE doctor shopping behaviour is limited as it would be private prescription, and will not get captured in project STOP.

Increased Burden on the Public Health System

Recent Macquarie University research has revealed that 62% of people would visit a doctor if the medication for their condition became unavailable over the counter[2] (Appendix 2). Rescheduling S3 cold and flu products with codeine means that a major proportion cold and flu products containing PSE will become S4 prescription medicines

If those people were to attend a general practice for a standard level B consultation to get access to effective symptomatic relief for cold and flu, the potential cost to the taxpayer is an additional $87 million per annum. This is not to mention the cost to the consumer if the GP does not bulk-bill, and the potential for inappropriate antibiotics to be prescribed in this care setting (supported further below).

Further, there is a current campaign that is run by the South Eastern Sydney local health district (NSW department of health) about "*Saving our emergency departments for emergencies*". Within this campaign coughs, cold and flus are called out as conditions that could adequately be managed by other healthcare service providers, such as pharmacists. Clearly this campaign is being run as people with these conditions are currently and inappropriately presenting themselves at emergency departments for what are minor and self-limiting ailments. If access to effective and safe medication for these episodic, self-limiting conditions is further restricted, it could lead to an increase in the inappropriate presentation of patients to emergency departments.

At a time when the Federal Government has been desperate to control unsustainable growth in utilisation of GP services to balance the Federal Budget, the idea of driving people with colds and flus into see a doctor at the taxpayer's expense is both contradictory and bad policy.

Increase to Inappropriate Prescribing of Antibiotics

It is widely accepted that General Practitioners have not yet managed to reign in the magnitude of antibiotics prescribed for colds and flus. Australia has one of the highest prescribing rates of antibiotics for acute viral upper respiratory tract infections. If access to codeine containing cold and flu products was further restricted by up-scheduling, it is highly likely that there would be an increased number of patients presenting to GPs with colds and flus. It is also highly likely that there would be

[2] Macquarie University. The Value of OTC Medicines in Australia. March 2015

an increased number of antibiotics prescribed, as a result of driving people into this setting of care. The inappropriate use of antibiotics for the treatment of colds and flus is an area NPS Medicinewise (the National Prescribing Service) is actively trying to address; due to the detrimental impact antibiotic resistance has on public health.

Shifting the Problem from Pharmacists to General Practice

[redacted] takes the issue of addiction very seriously - as mentioned previously we actively monitor this through adverse events reporting and analysis of market data. Moving a product from S3 to S4 will not however, solve the problem of misuse or abuse. There are medicines only available through prescription which are still abused. These include growth hormones and anabolic steroids, opioids and benzodiazepines. Oxycontin and alprazolam are currently the most abused drugs in Australia and the only means by which to obtain them is through a doctor's prescription. This is largely a result of unmonitored of doctor-shopping, and the lack of shared health records in Australia.

There is a significant risk that the desired outcome of reduced misuse will do nothing more that shift the issue from one healthcare domain to another (pharmacy to general practice) or move the issue to different substances e.g. codeine to oxycontin.

In contrast, monitoring of potential misuse has been successfully achieved in the community pharmacy care setting through the pseudoephedrine-monitoring 'Project STOP' program which has greatly reduced the diversion of PSE-containing products into the criminal supply chain in most states.

Conclusions

Rescheduling is a blunt instrument being considered to limit consumer access to the cold and flu treatment category, as a consequence of anecdotal reports of misuse of a combination in another treatment area (analgesia).

[redacted] is aware of no new evidence emerging since the 2009/10 NDPSC decisions to suggest the population is inappropriately using codeine containing cold and flu products. Evidence provided in this submission clearly supports the notion that the current scheduling of cold and flu products with codeine is appropriate and that the absolute pack sales of codeine-combination analgesic products has decreased dramatically since rescheduling to S3 in 2009.

The current scheduling arrangements for cold and flu products with codeine have remained appropriate. Consumers appear to have a preference or requirement for different levels of treatment to appropriately self-manage their symptoms of cold and flu. This ranges from simple unscheduled treatments available in grocery, to products available as S2 in pharmacy, and then S3 available behind the counter because of the PSE content.

Codeine-containing cold and flu products are different to codeine-containing analgesics; Colds and flus are self-limiting and episodic. Patients treat their symptoms until such time as those symptoms