

[REDACTED]

To whom it may concern,

The decision to class codeine combination drugs as prescription-only is wrong-headed and will not serve the interests of patients.

I occasionally use codeine (mostly in combination with paracetamol) for pain related to menstruation, severe headaches, or joint pain. I am well aware it is not a medicine of first resort and as such I use it sparingly, such as when problems arise which interfere with my day to day life and responsibilities (e.g. going to work) that cannot be addressed immediately in any other way. As a general rule, if I find myself with issues that can only be resolved through codeine, I pursue it with my GP followed by other care if necessary to tackle the root of the problem and find a more permanent solution.

I do not live or work in areas where it is possible to find a doctor that bulk-bills and is available on such short notice (to put aside the issue of whether I am physically able to go to the doctor to get a prescription, when currently I can ask someone to go to the pharmacy in my stead). I go to a non-bulk billing doctor for my general medical needs and this cost adds up. It is simply wrong that I should have to pay a non-refundable gap of around \$40 simply to get a prescription for a medication that I, like the vast majority of people in this country, use sparingly and responsibly.

Moreover, in my experience, pharmacists are judicious in discussing alternative forms of treatment with people who request a codeine combination over-the-counter, such as suggesting a visit to the GP to investigate the issue more thoroughly. There is no reason why the checks and balances that already exist for over-the-counter medication are insufficient. If it's a problem of addiction, let addiction be dealt with in a targeted fashion - not by tarring perfectly sensible and informed people who know what they are doing with their health, as the vast majority of Australians are.

I strongly advise reversing this interim decision.

[REDACTED]

Department of Health
Therapeutic Goods Administration
October 2nd, 2015

Please note: confidential details are marked in red.

Regarding the Secretary to the Department of Health's proposed amendments the Poisons Standard (commonly referred to as the *Standard for the Uniform Scheduling of Medicines and Poisons* - SUSMP) under subsection 42ZCZP the Therapeutic Goods Regulations 1990 (the Regulations).

To whom it may concern,

I was dismayed to hear a report on SA ABC radio this morning on the proposal to up-schedule Codeine.

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

I believe that adult Australians, already screened by pharmacists at the counter, are capable of managing the risks and taking responsibility for over the counter Codeine medications such as Nurofen Plus.

Please be aware that by up-scheduling Codeine you are potentially condemning responsible Australians to a life of unnecessary pain. For people who can access a doctor and pharmacy, you are creating an unnecessary waste of time and energy for clinic workers, GPs and patients, not to mention an increase in load on the Medicare system, which of course is paid for by taxpayer dollars.

Thankyou for your consideration,

[REDACTED]

[REDACTED] [REDACTED]
[REDACTED] [REDACTED]
[REDACTED] [REDACTED]
[REDACTED] [REDACTED]

Good afternoon

I rarely feel driven to contribute to public comment but in this instance I feel very strongly this committee is making the WRONG decision to remove codeine products from pharmacy over the counter supply.

You are doing the Australian community a tremendous dis-service in potentially forcing members of the public to have to go through GPs to obtain prescriptions to manage minor concerns. It will case a cost blow-out to medicare, cost ordinary people much time and inconvenience and PAIN.

Please consider this decision and fall over on the side of COMMON SENSE.

[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

From: [TGA Info](#)
To: [Medicines Scheduling](#)
Subject: FW: Heroin Use will Skyrocket of Codeine is script only [SEC=UNCLASSIFIED]
Date: Friday, 2 October 2015 2:58:25 PM

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

Regulatory Services and Improvement Branch

Phone: 1800 020 653 Fax: 02 6203 1605

Email: info@tga.gov.au

Therapeutic Goods Administration

Department of Health

PO Box 100

Woden ACT 2606 Australia

www.tga.gov.au

[REDACTED]

To: TGA Info

Subject: Heroin Use will Skyrocket of Codeine is script only

Hello.

Please see above.

I for one, will keep Heroin if the above stupidity is undertaken.

Regards.

[REDACTED]

From: [TGA Info](#)
To: [Medicines Scheduling](#)
Subject: FW: Contacting the TGA [SEC=UNCLASSIFIED]
Date: Friday, 2 October 2015 3:15:38 PM

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

Regulatory Services and Improvement Branch

Phone: 1800 020 653 Fax: 02 6203 1605

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Therapeutic Goods Administration

Department of Health

PO Box 100

Woden ACT 2606 Australia

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[REDACTED]

To: TGA Info

Subject: Contacting the TGA

Hi,

Read with interest the plan to make codeine mix painkillers prescription only. Understand the need to cut out shopping at multiple chemists but it seems ridiculous in this day and age that you would force people to pay to go to the doctor to get \$10 painkillers. Surely a much easier way would be to connect all chemists to a central db where all purchases would be logged and accessible by all pharmacists when someone makes a purchase.

Sure setup costs would be high and privacy issues would exist, but the long term benefits of being able to track usage and the possibility of doing away with written scripts if doctors were onboarded along with others benefits could be huge.

Oh well the 1960s was a great decade, seems we are still there

Regards

[REDACTED]

[REDACTED]

From: [TGA Info](#)
To: [Medicines Scheduling](#)
Subject: FW: Codeine re-classification [SEC=UNCLASSIFIED]
Date: Friday, 2 October 2015 3:26:05 PM

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

Regulatory Services and Improvement Branch

Phone: 1800 020 653 Fax: 02 6203 1605

Email: info@tga.gov.au

Therapeutic Goods Administration

Department of Health

PO Box 100

Woden ACT 2606 Australia

www.tga.gov.au

-----Original Message-----

[REDACTED]

To: TGA Info

Cc: [REDACTED]

Subject: Codeine re-classification

To whom it may concern,

After reading an article in the paper today about the TGA re-classifying codeine as a prescription only medication, I was dumbfounded.

Pregnant women are advised to use codeine as a safe alternative for pain relief during pregnancy, so should they now have to line up at the doctor (again) to get a basic essential item because a minority cant control themselves?

Should migraine sufferers also now have to sit in a waiting room as the room spins, while they suffer with nausea and horrendous pain because, again, a minority can't control themselves?

What about those after a procedure who need something that doesn't contain ibuprofen as pain relief, as it is a 'blood thinner', and Panadol just isn't enough, yet Panadine Forte is too much, are you also going to make them book back into the doctor for a 24 pack of Panadine?!

This is ludicrous! You still allow pseudoephedrine to be stocked behind the counter at a pharmacist, something that goes into making speed and other illicit drugs, but let's ban

codeine. Did 'anyone' think of doing the same procedure as pseudoephedrine and getting everyone's details and just 'limiting' the amount to codeine dispensed if you think there is an issue? There are far worse, more serious drugs dispensed over the counter than codeine.

May I ask the names of those who thought this blanket pharmacist ban was a good idea? As a government body, I think it's important for full disclosure as Australia deserves to know the names are of those who make these life changing decisions without consultation of the community.

Whoever advised such an idea without having a full understanding of the impact changing a basic drug classification to 'prescription' only will have on everyday households, needs their work to be reviewed immediately.

Hopefully this never eventuates, or God help our already stretched hospitals and medical centres who will now be filled with pregnant women and headache sufferers.

Regards,

A solid black rectangular box used to redact the signature of the sender.

From: [TGA Info](#)
To: [Medicines Scheduling](#)
Subject: FW: Contacting the TGA [SEC=UNCLASSIFIED]
Date: Friday, 2 October 2015 3:31:49 PM

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

Regulatory Services and Improvement Branch

Phone: 1800 020 653 Fax: 02 6203 1605

Email: info@tga.gov.au

Therapeutic Goods Administration

Department of Health

PO Box 100

Woden ACT 2606 Australia

www.tga.gov.au

-----Original Message-----

[REDACTED]

Sent: Friday, 2 October 2015 8:38 AM

To: TGA Info

Subject: Contacting the TGA

I was appalled to read the proposal for making codeine a prescription medication.

First it's already now too expensive to go to a doctor due to the governments scare of having to pay \$7. It would have been better if you had brought this in its \$20 less than what I would have to pay now because no doctor bulk bills anymore since this came up. And of course unless your lucky enough to fall in the bracket of a healthcare card which I am not....just....even though I pay my huge fair share of tax and what do I get for it,

[REDACTED]

If you bring in this change to this drug and I have to go to a doctor I won't be getting a mild pain killer which is what it is. I will be asking for the full hog if I have to waste my time and money just because you want to punish those who are using it correctly for a minor few who don't.

So maybe you guys should take a harder look at it and realise that just because you can't get those few who are not using it correctly, you're then going to turn around and punish the rest of us who do.

You do realise these people who abuse drugs will find something else to abuse and for those who don't and can't afford to go to a doctor all the time will just end up being in more pain and you will kill their quality of life.

Regards



From: [TGA Info](#)
To: [Medicines Scheduling](#)
Subject: FW: Contacting the TGA [SEC=UNCLASSIFIED]
Date: Friday, 2 October 2015 3:34:48 PM

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

Regulatory Services and Improvement Branch

Phone: 1800 020 653 Fax: 02 6203 1605

Email: info@tga.gov.au

Therapeutic Goods Administration

Department of Health

PO Box 100

Woden ACT 2606 Australia

www.tga.gov.au

-----Original Message-----

[REDACTED]

To: TGA Info

Subject: Contacting the TGA

Hallo my name is [REDACTED] I'm writing to you to show my support on your decision to ban codeine products from chemist and have it distributed through doctors. [REDACTED] has been addicted to this medication for the past [REDACTED] years and the access is so simple. At [REDACTED] highest state [REDACTED] was consuming 40 per day and would end up in hospital and near death. To this day it's so simple to become addicted as its access is to easy. At one stage there was talk of a national register with all chemists being linked but this never eventuated. This is a relief to tens of thousands as is a deterrent as most drug addicts are compulsive and chemists are easier to find then drug dealers. As a paramedic I saw lots of Pepole addicted to codeine and even went to a death from the drug being cut up and injected. I had a young [REDACTED] that was taking them and [REDACTED] organs shut down and [REDACTED] also died. Please this is a must, take codeine based products of the shelf.

Kind regards

[REDACTED]

[REDACTED]

From: [TGA Info](#)
To: [Medicines Scheduling](#)
Subject: FW: Just say no to the TGA re Codeine [SEC=UNCLASSIFIED]
Date: Friday, 2 October 2015 3:36:42 PM

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[Regulatory Services and Improvement Branch](#)

Phone: 1800 020 653 Fax: 02 6203 1605
Email: info@tga.gov.au

Therapeutic Goods Administration
Department of Health
PO Box 100
Woden ACT 2606 Australia
www.tga.gov.au

[REDACTED]

To: TGA Info
Subject: Just say no to the TGA re Codeine

No doubt the bureaucrats job is to bureaucratised and this is right up your alley.
I guess I have to spell it out to you because obviously there is no one there with an ounce of sense.
Pain relief means the RELIEF of pain
It does not mean ring the doctor (assuming you are on their books and won't be turned away because they are not accepting any more patients) and make an appointment for 2,3,4, days time.
It does not mean sitting in a waiting room for an hour then paying the difference between the rebate and the fee or more probably paying the fee in advance and hoping another constipated bureaucrat can organise to provide you with a rebate.
Then drive to a pharmacy hoping they are open then wait for another 15 min while they stick on a label for their cut.
I trust that one day you, like myself, will suffer from Diverticulitis and Crohns disease and try and find PAIN RELIEF via a doctor at 3.00 AM

I hope you watch the current ABC series Utopia - because it's about you.
Incredible that Alcohol & tobacco are freely available despite being responsible for the majority of hospital beds yet you sit there staring out the window wondering what to do next to make yourselves look good and come up with this dumb. dumb idea.



To:

[Medicines Scheduling](#)

Subject:

Codeine - Paracetamol Submission

Dear Sir/Madam

It is with some concern that [REDACTED] I listened to the information over television that codeine based drugs were to be made not available over the counter.

I am also disturbed that submissions and consultation finishes on the 15th of this month. Not exactly the consultative position represented by our new Prime Minister.

I would have thought that this web address would have been advertised over the media.

Removing codeine based products from the supermarket shelves appears to be somewhat very poor public relations for a medical system that is mostly distrusted by people like myself and other acquaintances.

When talking to our friends(who come from a wide spectrum), it is common to find 'another' doctor has got it wrong and has harmed rather than healed.

[REDACTED] almost died from a gradually induced negative effect from Metformin and if it was not for the information found on the internet enabling the doctor's prescription to be challenged, I would not have [REDACTED] with me today.

The doctor even had the gall to say [REDACTED] should see a Physician as he did not know that much about diabetes.

When one looks for a doctor around the suburbs, it is difficult to find one that seems anywhere near competent.

There is also a current problem where many doctors now are contracted by a multinational medical companies and all consult in large purpose built buildings. Going to these clinics is like going through a revolving door: the shortest possible consultation, a quick script and out the other door. I have been seen by some, of all colours, (I am not racially prejudiced) where I could not even understand their accent. I am sure they did not understand my problem.

[REDACTED]
[REDACTED]
We do use a small amount of Panadol Osteo for our arthritis but I am sure we do not over indulge.

I am sure I do not want to get a script every time I need a pill.

I also have a certain resentment to so called professionals and beurocrats telling me how to control my life.

If there is a problem with the drugs such as codeine being available to minors, perhaps it would be better if they were kept in separate areas where you have to be older than 18 years to enter. We have been informed that codeine is not available over the counter in several other countries. I would like to think we are not being overly pressured because of trade agreements, or that we are a trade off to the AMA.

Yours truly,

[REDACTED]
Concerned Citizen

To:

[Medicines Scheduling](#)

Subject:

Codeine medicines to be prescription only

Hi,

I'd just want to put in submission about the above subject.

I use [REDACTED] or a generic of the same type.

I buy about one pack per month or so and it helps considerably in two areas for me.

I suffer from sinus and was diagnosed with migraines about 10 years ago.

In both cases, Ive found this medication to be extremely helpful. My doctor agrees and at times, he has written scripts for me to take this.

His statement to me was that if this is working, keep taking it as its better than going to full migraine prescription medication.

I don't believe I ever abuse the medication – in fact I try to take as least of it as does the job at the time.

If this medicines goes to prescription only, the only ones that are going to benefit is the doctor as I still will get the [REDACTED] as it does a fantastic job for me, but I will be out of pocket around \$50 more for the visit.

Surely theres other ways to stop the ppl that are abusing this drug.

Please do not punish the ones that are using it responsibly.

Yours sincerely,

[REDACTED]

[REDACTED]

To:

[REDACTED]

[Medicines Scheduling](#)

Subject:

Reasons for the scheduling delegate's interim decision and invitation for further comment for the ACMS,
October 2015

[REDACTED]

[REDACTED]

I oppose this change. For many people standard otc medication does not address the mild pain concern. Pain not requiring doctors treatment, i.e. headaches. A monitoring system similar to pseudoefodrine to address addiction would be a better option rather than force consumers who do not abuse this medication to the doctors unnecessarily.

[REDACTED]

██████

To:

██████

[Medicines Scheduling](#)

Subject:

Codeine rescheduling

████████████████████

To whom it may concern

Please do not reschedule to S4

As a community pharmacist in ██████ we take our responsibilities seriously re codeine abuse in the community

Absolutely We NEED a live monitoring system like Projectstop it is the most logical step to take

As a consumer. Once a year my shoulder flares up with calcific tendinitis and bursitis. Best painkiller ?

Paracetamol and Codeine. I know my medical condition, I know what helps me, and I don't need to waste Drs time, Hosp time and valuable tax payers \$\$ once a year !!

████████████████████

██████
To:

██████████
[Medicines Scheduling](#)

Subject:

SUBMISSION
██

Hello,

Submission regarding the need to lose money from taking time off work, increase waiting times in GPs, pay for a doctor's fee/gap and the inevitable rise of codeine products is as follows:

Point One. This is an abuse of authority that only contrirbutes to the ever increasing nanny state. Or is this just greedy grab at more money?

Thanks

██████

Medicines.Scheduling@tga.gov.au

03/10/15

To whom it may concern,

RE: Response to Interim decisions & reasons for decisions by delegates of the Secretary to the Department of Health, October 2015, Notice under subsections 42ZCZP of the Therapeutic Goods Regulations 1990 (the Regulations)

I object to the rescheduling of codeine due to "morbidity, toxicity and dependence."

I suggest that the benefits of codeine in its current accessible forms far outweigh the rare chance of morbidity, toxicity or dependence.

I suggest that patients using a lot of codeine are potentially using a range of medications and treatments, with codeine being a part of the pain relief aspect. Rescheduling will potentially increase the price, which will unfairly add to the financial burden of the patient.

I support the down-scheduling of Naloxone. If there is anyway to have it more cheaply available, that would be beneficial to the people who need it the most,

Sincerely,

A black rectangular redaction box covering the signature area.

██████

To:

██████████

[Medicines Scheduling](#)

Subject:

Codeine Based Medicine

████████████████████

Dear Sir/Madam,

I wish to object to the proposed scheduling of Codeine based medications, and hence the requirement of an expensive visit to the GP wasting their and my time.

The 1000 Australians with addictive issues with Codeine, whilst sad, represents less than 0.01% of the Australian population. It is clear that the proposed scheduling is a massive over reaction. The massively vast number of responsible users should not be punished for the sins of the miniscule.

Yours sincerely,

██████████

████████████████████

[REDACTED]
To:

[REDACTED]
[Medicines Scheduling](#)

Subject:

Panadeine Scheduling
[REDACTED]

I am absolutely disgusted that you would inflict another restraint on the ordinary average law abiding citizen, because of a few people abusing the system!! Let them, it is their choice!!

The cost to the Government will be multi millions, also the already stretched GP's will be inundated with people just wanting a simple painkiller. This whole system is broke, where the average citizen suffers constantly for the fools. We already get drilled by the chemist for any and everything, even though we have already seen a doctor!!!

What next banning Panadol!

I am an poly arthritis sufferer and Panadol is next to useless, whereas I can take a couple of Panadeine when it becomes very bad, mostly I just put up with it! I cannot believe it, that now I will have to go to a doctor, pay \$70 odd, just to get a panadeine!!

You really need to have a long hard think about this, you are inflicting a completely unnecessary expense on the average person, usually retired people that may already be financially strapped! The doctors queues will be come even longer!

Concerned citizen

[REDACTED]

[REDACTED]

[REDACTED]

██████████

To:

██████████

[Medicines Scheduling](#)

Subject:

"Proposed Amendments to the Poisons Standard (Medicines)" i

Date:

Monday, 5 October 2015 12:21:31 PM

██

██████████ years ago I had a ██████████ implant inserted by ██████████, which left me with severe pain from ensuing nerve trauma / damage. After spending a fortune on trying to get a 'diagnosis', I eventually consulted a pain management specialist, and the ██████████ cases panel also sent me to a specialist to try and improve the condition of the implant. I was prescribed a gel with ketamine to use topically & eventually agreed to take ██████████. I was not keen to use these drugs, and have now worked out that by taking ½ a ██████████ as soon as the pain starts, and then maybe another ½ 30 mins later I can often prevent the build-up of the right sided neuropathic pain which use to be a daily feature of my life. I have also managed to maintain my active lifestyle, which includes Yoga and Feldenkrais. It is also cheaper, and far preferable to living with the side effects of ██████████ etc. This is a minimal drug pain management system which I've worked out for myself, and means that I do not have to rely on the stronger drugs that I was initially prescribed, and I'm able to function as a teacher without worrying about side effects from the stronger pain management drugs. Having to visit the doctor for such basic pain management would be expensive, and mean that I would have less money available for activities such as Yoga and Feldenkrais which are also part of a holistic pain management approach.

I understand why there is a need for limiting access to codeine, but surely a system such as having your driver's licence recorded, which is used for other over the counter medications, would be sufficient.

████████████████████

To: Medicines.Scheduling; Minister.Ley@health.gov.au
Subject: RE: Proposal for the re-scheduling of Codeine products

Dear Minister and Bureaucrats

OK I found the relevant part of the TGA Act 1989. You don't make it easy and I wanted to make sure I made a 'relevant' submission.

(1) In exercising a power under [subsection 52D\(2\)](#), the Secretary must take the following matters into account (where relevant):

- (a) the risks and benefits of the use of a substance;
- (b) the purposes for which a substance is to be used and the extent of use of a substance;
- (c) the toxicity of a substance;
- (d) the dosage, formulation, labelling, packaging and presentation of a substance;
- (e) the potential for abuse of a substance;
- (f) any other matters that the Secretary considers necessary to protect public health.

I could find nothing in the reasons given in the interim notice which to my way of thinking clearly supports the TGA proposals to place further restriction on sale of codeine products. Do you make this stuff up to keep busy? And I may add that I totally reject the claims made that preparations with codeine is no more effective than aspirin or paracetamol alone. Perhaps my sample size was too small.

Relatively few people die each year where codeine is 'involved' (let's face it the real cause of death is mostly other drugs legal and illicit). Now the rest of us who use legal drugs responsibly may have to line up at the doctors to get a script. Where is the proportionality in that I ask. There is none; is the answer.

Take a look around you. Lots of people die and suffer all sorts of damage both physical and mental as a result of alcohol consumption. Can we just deal with that one eh! No you lot will waste precious public and private resources to make changes which will have very little effect in terms of community benefit.

I can tell you for a fact that if we took the resources you propose to put into codeine 'safety' and applied it to restricting alcohol consumption and preventing alcohol abuse the whole country would be much better off.

Please join the rest of us in the real world and stop wasting our time and money on less than effective fixes to public health 'problems' that aren't or which are clearly of a much lower order than many others public health problems. Surely it is not beyond our system of government to take a more strategic approach to these matters. Your proposal to further regulate codeine lacks strategic intent.

Your sincerely

[Redacted Signature]

[REDACTED]

[REDACTED]

[REDACTED]

To: [Medicines Scheduling](#)
Subject: Submission to Codeine Scheduling Proposal

To the Advisory Committee on Medicines Scheduling

I hereby request that the proposed changes to the scheduling of medicines containing codeine will **not** be implemented.

Reasons:

I am suffering from chronic [REDACTED] pain following [REDACTED] years ago. During the acute stage of my illness I received intensive medical treatment, including physiotherapy, hydrotherapy and a two week admission to a clinic specialising in the management of spinal injuries. Surgical intervention was considered unsuitable in my case because the long term prognosis did not justify the associated risks.

The focus has since been on managing my pain through medication and physiotherapy as well as counselling by a clinical psychologist. While I have been able to re-train and return to full-time work, I have recurring episodes of elevated pain levels, especially at night. Under the guidance of my GP I have tried different methods to manage these episodes, including heat packs, self hypnosis and natural medicines. I have also used prescription and over the counter medication, such as Endone, Ibuprofen, Paracetamol, Voltaren and others, but have found that Mersyndol night strength is by far the most effective medicine for my condition.

I only take [REDACTED] tablets of this codeine containing medication intermittently to enable me to get sufficient sleep during the night. I never take this medication on weekends or when I do not have to go to work the following day. Making this a prescription only medication would mean that I have to spend additional time and money for GP visits, which would also burden the tax payer through the Medicare subsidies. I believe it is not justifiable to punish legitimate and responsible users of codeine, like myself, because there is a theoretical risk of people abusing these medicines.

People who deliberately ignore recommended daily intake limits will simply look for alternative, possibly even more dangerous sources of potentially addictive substances. The treatment of addictive behaviour needs to focus on education, addressing the causes of addiction and rehabilitation programs rather than trying to restrict access to effective pain relief medication.

I hope that the members of the Advisory Committee have the wisdom to recognise that legitimate users of codeine containing medicines, such as people with chronic pain, need to have access to affordable and effective pharmaceuticals in order to manage their condition. Please do not restrict current access to codeine containing pain relief medication.

Yours sincerely

[REDACTED]

I have **highlighted** my confidential personal details in order to be deleted prior to publication of my submission.

From: [REDACTED]
To: [Medicines Scheduling](#)
Subject: Proposed Amendments to the Poisons Standard (Medicines)
Date: [REDACTED]
[REDACTED]

Dear Sir or Madam

I am responding to the call for public submissions regarding restricting the availability of medicines containing codeine.

I submit that these medicines should remain available without a prescription for the following reasons.

- . It is difficult or impossible to obtain a Doctor's appointment during the winter season. This means that people suffering from sore throats etc will be delayed in obtaining their usual cough medicines.
- . Attending a doctors surgery typically involves taking time off work with all of the inconveniences and ramifications that this incurs.
- . Attending a doctors surgery involves considerable costs to the patient and exposes him or her to sick people in the waiting room with the risk of contracting further illness.
- . Pharmacists have the expert knowledge required to warn patients about the potential side-effects of codeine based medicines.
- . People who are suicidal or suffering from mental illnesses are likely to find any number of ways to harm themselves. The rights of the general public to have easy access to effective medications should not be outweighed by those unfortunate enough to be suffering from mental illness.

For your information I am a school teacher and have no conflict of interest in making this submission.

Thank you for your consideration.

Regards

[REDACTED]

Codenine shouldn't be restricted so harshly, it is punishing a those who use it for medicinal purposes just to stop a few abusers of the drug we need fair reform not something that punishes everyone just because of the mistakes of a few. Even if It was restricted It shouldn't be to the extent that is proposed.

From: [REDACTED]
To: [Medicines Scheduling](#)
Subject: please make codeine prescription only
Date: [REDACTED]

hi there

i have wtnessed too many addicts and the health problems this has caused, you are doing the right thing by making thing script only

From: [REDACTED]
To: [Medicines Scheduling](#)
Subject: codeine and naloxone
Date: [REDACTED]

To whom it may concern,

I suffer from chronic [REDACTED] pain and have exhausted all medical and alternative therapy options. [REDACTED] Doctors have prescribed me [REDACTED] [REDACTED] for my pain. None of them worked and there were awful side effects including nausea, migraines, dizziness and weight gain. Codeine is the only thing that works without side effects. I would need to be going to the doctor a lot more if these changes take effect. I will be clogging up an overloaded system for no reason.

On naloxone, I believe that this should be freely available, I do not use illicit opioids but I know naloxone to be life saving and if people had access to it there would be fewer fatalities.

Regards,

[REDACTED]

From: [TGA Info](#)
To: [Medicines Scheduling](#)
Subject: FW: Codine based medication [SEC=UNCLASSIFIED]
Date: Tuesday, 6 October 2015 11:04:53 AM

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

Regulatory Services and Improvement Branch

Phone: 1800 020 653 Fax: 02 6203 1605

Email: info@tga.gov.au

Therapeutic Goods Administration

Department of Health

PO Box 100

Woden ACT 2606 Australia

www.tga.gov.au

-----Original Message-----

From: [REDACTED]

Sent: [REDACTED]

To: TGA Info

Subject: Codine based medication

To the TGA.

I have suffered [REDACTED] all of my life among a number of other problems [REDACTED] injuries and more. now your making an issue out of people who use codeine based products such as [REDACTED].

What you will end up in doing is costing me more money and time.

I should sue you [REDACTED], for wanting to make my pain management more difficult! So tell that existentialist bloke that appeared on tv that when I'm in pain I have nothing to loose, and if he wan'ts to insult my intelligence by creating this problem I'll sue him!

The TGA are self serving free loaders, that pretend to care about the community, but I put to you, you are [REDACTED], and your motives are specious! People like you useless free loaders don't deserve to breath the same air as the rest of us!

If you want the laws to be like some other country, move over there, we don't need you here!

Oh yes If you get your way I'll have to see a doctor to get a script, but you will be paying for my visit to the doctor not me or medicare! I assure you I will fight you! Get a real job free loaders! stop leaning on the tax payer, and creating problems to justify your existence!

[REDACTED]

From: [TGA Info](#)
To: [Medicines Scheduling](#)
Subject: FW: Making over the counter medications with codeine in them prescription only medication
[SEC=UNCLASSIFIED]
Date: Tuesday, 6 October 2015 11:27:14 AM

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[Regulatory Services and Improvement Branch](#)

Phone: 1800 020 653 Fax: 02 6203 1605

Email: info@tga.gov.au

Therapeutic Goods Administration

Department of Health

PO Box 100

Woden ACT 2606 Australia

www.tga.gov.au

From: [REDACTED]
Sent: [REDACTED]
To: TGA Info
Subject: Making over the counter medications with codeine in them prescription only medication

[REDACTED]

Dear Sir/Madam,

Re: Making over the counter medications with codeine in them prescription only medication is stupid.

[REDACTED] have an [REDACTED] Injury or sometimes known as a
[REDACTED] Injury from sustaining injuries in separate motor cycle accidents.

We are not prolific users of [REDACTED], which contains codeine, but we do use it for pain relief when required for pain relief when we get very painful headaches.

A majority of the time the Pharmacist will ask what are you using the pills for and on occasions they will ask for Identification prior to selling the product. I have no problem with providing my details and offering my drivers licence for identification if the pharmacy staff ask for it.

By placing the over the counter medication in the prescription schedule I would have to agree with the Pharmacy Guild of Australia which they have said:

"The industry groups including the Pharmacy Guild of Australia will fight the decision, saying it would be "unlikely" to curb addiction, create more work for doctors and disadvantage the majority of people who use the products safely."

In addition I can see more pharmacist being be robbed by addicts, and it seems the minority mentality has duped the TGA whereby the majority like myself and my son who are on Disability Pensions and live in a rural area some 15km away from the nearest doctors surgery only take over the counter medication containing 'codeine,' as required and definitely NOT 100 a day! More like 3 when required.

I trust my letter makes the TGA takes my letter into account and does not introduce prescriptions for over the counter medications containing 'codeine,' and they remain as 'status quo.' As we use the medication safely.

Yours Sincerely

[REDACTED]

From: [TGA Info](#)
To: [Medicines Scheduling](#)
Subject: FW: codeine reschedule [SEC=UNCLASSIFIED]
Date: Tuesday, 6 October 2015 11:29:33 AM

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

Regulatory Services and Improvement Branch

Phone: 1800 020 653 Fax: 02 6203 1605

Email: info@tga.gov.au

Therapeutic Goods Administration

Department of Health

PO Box 100

Woden ACT 2606 Australia

www.tga.gov.au

From [REDACTED]

To: TGA Info

Subject: codeine reschedule

Hi,

after hearing the news story today I find it necessary to write to you to express my strong disagreement with the pending decision to make codeine a prescription only medicine. I think this is way too excessive. There is already over-regulation now and this is just too much. This would lead to collapse of Medicare in a way where most visits would be for trivial things, time pressures on working people, financial pressure etc. Further with some doctors charging \$90 per visit then add the actual cost of the panadeine, it is almost cheaper to get far more effective drug on the street. And that one is definitely addictive if you catch my drift. The regulation should be going the other way. I and many people do not need to be micromanaged at ridiculous cost to the tax payer and me. Talk about overuse of Medicare and then you come up with this nonsense. I noticed via search there was some public consultation in May. How the hell was I supposed to know about it? I could not. So had to write this now.



From: [TGA Info](#)
To: [Medicines Scheduling](#)
Subject: FW: Proposed changes to over-the-counter sale of codeine painkillers [SEC=UNCLASSIFIED]
Date: Tuesday, 6 October 2015 11:43:02 AM

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

Regulatory Services and Improvement Branch

Phone: 1800 020 653 Fax: 02 6203 1605

Email: info@tga.gov.au

Therapeutic Goods Administration

Department of Health

PO Box 100

Woden ACT 2606 Australia

www.tga.gov.au

From: [REDACTED]
Sent: [REDACTED]
To: TGA Info
Subject: Proposed changes to over-the-counter sale of codeine painkillers

Dear Sir / Madam,

I am writing to you in regard to the proposed changes to the sale of codeine products.

With all due respect this can only have been hatched out by someone who does not have to deal with recurring severe pain.

Instead of tackling the problem and create barriers to obtain codeine containing medicine **in large quantities** let's just tarnish the whole community with the same brush and punish genuine people, who just wish to make their recurring pain somewhat bearable, by making them waste even more time and money.

I don't wish [REDACTED] on anybody, however the experience would certainly help understand my concern.

So how will this work? Does my GP take me at face value that I have to deal with [REDACTED]

██████ EACH month, meaning ██████ two days of relentless pain where every sound or bits of light feels like an ice pick is jammed into my left temple, even with 1 tablet of Panadeine every 3 hrs.

Or do I have to make a doctors' appointment in the middle of an episode to be able to obtain the prescription? Anyone who has ever had a serious migraine episode will understand that this scenario would be impossible!

Other more potent ██████ prescription drugs are available, one doctor suggested ██████, however I believe stronger medication would elevate my threshold and could possibly do more harm in the long run due to the medication's components.

This is only my story however I hope my view would be taken into consideration, at least hopefully it will be read.

Please invest more time and effort in monitoring the sale of codeine products to **weed out the abusers** instead of just punishing everyone, including the genuine responsible users.

If there are any queries please do not hesitate to contact me.

██████████

From: [TGA Info](#)
To: [Medicines Scheduling](#)
Subject: FW: Contacting the TGA [SEC=UNCLASSIFIED]
Date: Tuesday, 6 October 2015 11:45:10 AM

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

Regulatory Services and Improvement Branch

Phone: 1800 020 653 Fax: 02 6203 1605

Email: info@tga.gov.au

Therapeutic Goods Administration

Department of Health

PO Box 100

Woden ACT 2606 Australia

www.tga.gov.au

From: [REDACTED]

Sent: [REDACTED]

To: TGA Info

Subject: Contacting the TGA

I read recently about a proposal to make codeine based pain killers like panadiene prescription only.

Isn't this going too far? Gp appointments are already hard to get, minimum 2 day wait.

If this was to happen, black market of this would thrive.

Haven't you learnt anything from the alcohol prohibition era of the 20s and 30s?

All you are basically doing is creating a lucrative black market for people looking to make easy money.

You can't punish people who do the right thing. It seems that a small minority of people is all it takes to stuff up things for the majority.

You have no legal rights to speak and represent the idiots who abuse it. Those who abuse it gave the democratic right to do so and if they want to destroy themselves well so be it cause that is life.

[REDACTED]

From: [TGA Info](#)
To: [Medicines Scheduling](#)
Subject: FW: Re Codeine based pain killers [SEC=UNCLASSIFIED]
Date: Tuesday, 6 October 2015 11:49:09 AM

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] [Branch](#)

Phone: 1800 020 653 Fax: 02 6203 1605
Email: info@tga.gov.au

Therapeutic Goods Administration
Department of Health
PO Box 100
Woden ACT 2606 Australia
www.tga.gov.au

From: [REDACTED]
Sent: [REDACTED]
To: TGA Info
Subject: Re Codeine based pain killers

Dear Therapeutic Goods Administrator,

I am writing regarding recent news articles about codeine based pain killers and the TGAs call to restrict access to them.

For what it is worth, I just wanted to say that I have been a [REDACTED] sufferer my entire life – I have experience [REDACTED] pain regularly since a child. I have been diagnosed with chronic [REDACTED], and [REDACTED] I have been on this planet I have sought every type of treatment imaginable. I have seen GP's, chiropractors, physiotherapists, osteopaths, myotherapists, [REDACTED] specialists, used diets, acupuncturists, herbal therapists – you name it, I've tried it, and on many occasions.

Although some therapies may help for short periods of time, the [REDACTED] return eventually without fail. The ONLY thing I can rely on to give me relief is a codeine and anti-inflammatory based tablet (like [REDACTED] I use them according to the packet and I take precautions such as taking my blood pressure. Every time I go to the doctor, it costs me between \$60 and \$100 and I simply cannot afford to spend that sort of money every time I need to get relief form

[REDACTED]

I for one would appreciate it if medical science could find a cure for my [REDACTED] so I would never have to take painkillers, but in the meantime, I must rely on these. My point is that there is no cure for my condition and these tablets are the only thing that give me some relief; pain relief that is affordable and provides me with some sanity and the capacity to work and study and do something with my life other than lie in bed in pain.

I am really sorry that others may not be doing the right thing, but please do not 'punish' people with chronic pain who rely on these tablets to get by. I would like to add that whenever possible, I take [REDACTED] or something considered milder, but they do not work for me.

Please reconsider your position to make codeine and anti-inflammatory pain killers prescription only.

Regards,

[REDACTED]

[REDACTED]

[REDACTED]

From: [TGA Info](#)
To: [Medicines Scheduling](#)
Subject: FW: Codeine enquiry [SEC=UNCLASSIFIED]
Date: Tuesday, 6 October 2015 11:52:35 AM

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

Regulatory Services and Improvement Branch

Phone: 1800 020 653 Fax: 02 6203 1605

Email: info@tga.gov.au

Therapeutic Goods Administration

Department of Health

PO Box 100

Woden ACT 2606 Australia

www.tga.gov.au

From: [REDACTED]
Sent: [REDACTED]
To: TGA Info
Subject: Codeine enquiry

To whom it may concern,

Hi [REDACTED] I have been hearing a lot of the media talk on the possibility of making codeine a prescription only drug.

I take a medication called [REDACTED], it contains codeine. I do not take the medication for pain management, the medication helps control diarrhoea, as I suffer from chronic [REDACTED].

I have big concerns if they change this to prescription only, although I do get scripts for it, but I cannot afford to pay over \$55 to see my G.P every time I need a piece of paper written on for the medication.

I don't believe people like myself should pay the price for those who abuse codeine.

I have been worrying a lot over this proposal and have to say, suffering from a condition like [REDACTED], such worry does not help my condition one bit.

I was hoping you can give me some light on if it will be all codeine based medications or just pain killers that will require prescriptions?

Like I said I don't believe it is fair at all for everyone to pay the ultimate price for those who don't do the correct thing.

I look forward to any assistance you can give me on the matter.

Thank you for your time

Regards



From: [TGA Info](#)
To: [Medicines Scheduling](#)
Subject: FW: Contacting the TGA [SEC=UNCLASSIFIED]
Date: Tuesday, 6 October 2015 11:56:19 AM

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

Regulatory Services and Improvement Branch

Phone: 1800 020 653 Fax: 02 6203 1605

Email: info@tga.gov.au

Therapeutic Goods Administration

Department of Health

PO Box 100

Woden ACT 2606 Australia

www.tga.gov.au

-----Original Message-----

From: [REDACTED]

[REDACTED] Monday, 5 October 2015 6:49 PM

To: TGA Info

Subject: Contacting the TGA

RE: termination of over the shelf Panadeine.

I wish to express my extreme upset regarding this issue. I do understand the issues re addicted drug users, etc. [REDACTED] who has endured daily [REDACTED] [REDACTED] years, where NO other medication relieves my pain other than [REDACTED], it will be a huge disadvantage and distress having to obtain a prescription regularly, not to neglect mention of excess use of a Dr which in my case is not required, with the added distress of the Dr not believing me that only [REDACTED] relieves my pain. I am a nurse and have seen much suffering related to inadequate pain relief, and typically the Dr ordering [REDACTED] which is regularly ineffective for many patients!!!!!!!!!!'

Please listen to the ordinary individual!!!!!!!!!!

[REDACTED]



Scheduling delegate's interim decision regarding medications containing codeine.

Dear Sir/Madam

I have read with some concern of the TGA's proposal to make codeine containing medication prescription only. I strongly object to this proposal.

[REDACTED] suffer from [REDACTED] and am virtually in constant pain. Due to a [REDACTED], I'm unable to tolerate NSAIDs. Also as I'm taking [REDACTED], I'm not able to use [REDACTED].

This means I *have* to use analgesics such as [REDACTED] for pain relief. To have to visit my GP for a prescription for these analgesics would not only mean extra inconvenience, but additional expense I can ill afford. I only work part-time and a large proportion of my income already goes to medical and pharmaceutical expenses.

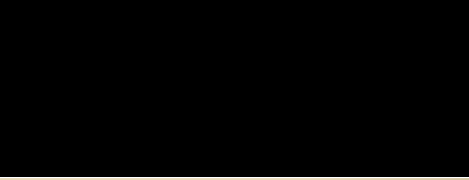
At a time when the Health Minister, Hon Susan Ley, is looking to *reduce* the cost of Medicare to the Australian taxpayer, it seems inconsistent to force more people unnecessarily (to my mind) to visit their doctors for prescriptions.

While I appreciate that some codeine based analgesics are being abused by younger folks, surely an identification and monitoring system similar to that used for pseudoephedrine containing drugs could be used quite effectively for codeine containing analgesics.

I understand there is a sizable black market in prescription and other illicit opiates. My thought is that opiate addicts, unable to obtain codeine via legal sources, will resort to stronger and potentially more dangerous alternatives.

I hope my submission will be received favourably. My contact details are above.

All the best,



[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

Concerning 1.1 Codeine - Scheduling proposal

To Whom It May Concern,

I write to you to request that Codeine be exempted from rescheduling, as it would place an unreasonable burden on people seeking therapeutic medication, and I believe the benefits of rescheduling have been exaggerated.

With reference to THERAPEUTIC GOODS ACT 1989 - SECT 52E, I present the following:

Risk vs Benefits

Codeine has two therapeutic benefits: pain relief, (and the less talked about) cough suppression. While the risk of addiction is recognized, codeine addiction figures are almost certainly padded by individuals who also deal with genuine chronic pain. Can someone show signs of addiction to the genuine relief of pain without also having a chemical dependency? Of course.

If chocolate biscuits provided relief from back-pain, large numbers of people would be 'addicted' to Tim Tams instead.

For responsible Codeine users, it's current scheduling allows for it to be included with over-the-counter cold and flu medication which may be 'stored' for when it is required. Most people avoid taking medication unnecessarily, and therefore will wait right up until it is 'needed'. This means, having the medication on hand, rather than waiting for a doctor's prescription – further burdening health services, increasing time off work, increasing risks of 'cross infection' in waiting rooms, and foisting an inconvenience upon perfectly innocent people who simply need to get back to work without a blocked nose and a headache.

Rescheduling of Codeine may force cold and flu sufferers to examine separate cough suppressants with their pain relief medication and decongestant – increasing the chances of mixing incompatible medications for reasons as simple as "I feel sick and this is all the closest pharmacy had available." which creates a significant danger of poisoning.

Codeine forms a valued bridge between mild pain relief and medical intervention especially on weekends where less health care services are available, for example coping with pain until a dental appointment can be made to fix a broken tooth, or a sporting injury until a visit to the physiotherapist can be arranged – these exact scenarios are common, and were Codeine to be rescheduled and restricted would increase hospital visits, further burdening our emergency care system.

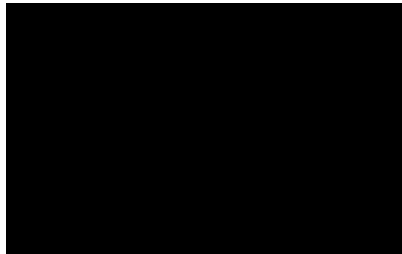
If we can speak more about the social reasons for rescheduling, let us remember when Pseudoephedrine was rescheduled and restricted in 2006, in response to methamphetamine manufacture: 8 years later, Australia finds itself in the grip of a much publicized 'Ice Epidemic', despite the restrictions – and everyone else just trying to clear a blocked nose is burdened with a photo ID requirement and is allowed to buy only 4 days worth of medication to treat the symptoms of our most common illness which lasts 7-10 days.

The outcome of the 2006 restriction has been increased medication costs to patients, increased administration costs to pharmacies, and great inconvenience to the average Australia – while accomplishing next to nothing in the war on drugs.

I hope you will apply common sense in evaluating all the issues related to this rescheduling, and understand that we can not ban, arrest, or gaol ourselves out of society's addiction problems – and to attempt to do so only harms or inconveniences the majority of stakeholders at considerable taxpayer expense.

Best Regards,

██████████



6 October 2015

Medicines Scheduling Secretariat,
Therapeutic Goods Administration,
PO Box 100,
Woden,
ACT 2606

Email: Medicines.Scheduling@tga.gov.au

Dear Sir,

I was personally pleased to read of the proposal to delete the Schedule 3 entry for codeine, and reschedule all current Schedule 3 codeine to Schedule 4 due to issues including morbidity, toxicity and dependence. I fully support this action and for personal reasons wish that it had been in place many years ago.

██████ died in ██████ from multiple organ failure (liver, kidney, pancreas), as a result of prolonged misuse of ██████ and other similar readily available OTC drugs, taking upwards of a packet a day.

While originally ██████ after periods of rehab at various clinics around ██████ including the ██████, ██████ would stay dry, but later would become dependant on ██████ which I believe are Schedule 4 and are prescribed medications. When ██████ doctors (██████ often tried "doctor shopping") refused to prescribe ██████ more, ██████ would then buy OTC codeine based pills, principally ██████, which are readily available. These can be purchased in quantity by shopping at multiple outlets and would tragically result in overdoses and ambulances being called.

I feel that I qualify as an interested party and stakeholder with regard to the nominated substances and would appreciate being advised of the Committee's considerations and the Delegates interim decision, with the opportunity for further submission, if appropriate.

Yours faithfully

████████████████████

████████████████████

From: [TGA Info](#)
To: [Medicines Scheduling](#)
Subject: FW: Objection to the proposed law to make codeine a prescription only medication [SEC=UNCLASSIFIED]
Date: Tuesday, 6 October 2015 2:09:58 PM

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]
Regulatory Services and Improvement Branch

Phone: 1800 020 653 Fax: 02 6203 1605

Email: info@tga.gov.au

Therapeutic Goods Administration

Department of Health

PO Box 100

Woden ACT 2606 Australia

www.tga.gov.au

From: [REDACTED]
Sent: [REDACTED]
To: TGA Info
Subject: Objection to the proposed law to make codeine a prescription only medication

<mailto:info@tga.gov.au>

To whom it may concern,

I feel compelled to write to have my say in light of the recent talk of making codeine a prescription only medication. I honestly believe this to be a mistake for the sufferers of genuine chronic pain.

I've read that it's being done in response to a study that showed 'codeine related deaths'.

Making codeine a prescription only drug might appear to be protecting people.

But it's only going to do so on a very surface level.

I believe this to be a sort of knee jerk reaction. A kind of band aid response to this news.

You need to act right? I imagine.

The reality of the ramifications for long term pain sufferers isnt being fully considered.

And genuine chronic pain sufferers would be forced to seek alternative 'non prescription' pain relieve which is far worse for you 'long term'.

This new 'law' might prevent people who are abusing the drug from doing so.

But what about us serious chronic pain sufferers who are trying to maintain some kind of a functional and productive life in the year 2015.

My name is [REDACTED]. I am [REDACTED] and a lifetime sufferer of rheumatoid arthritis, and a sufferer of endometriosis.

I had my left knee replaced when I was [REDACTED]. Most of my joints are fused or somewhat disfigured but I do manage to remain to live a productive life.

I have a happy [REDACTED] and I guess you could say I'm a regular busy [REDACTED].

When used according to the label. Codeine is no danger to anyone.

My understanding is that those abusing the medication must be harming themselves from overdosing on paracetamol. And most if not all codeine based over the counter medications are mixed with high doses of paracetamol.

For their pain relief properties but also to discourage their abuse. I'd imagine.

I can tell you sincerely from the bottom of my heart. That we chronic pain sufferers cannot rely solely on doctors to manage our long term pain control.

Absolutely no doctor is comfortable prescribing long term ongoing pain management.

Who could blame them. Their livelihood is at stake. There are lots of 'drug seekers' who seek drugs for the wrong reasons. People can become addicted to pain medication and it's too much of a risk for them to take based on a ten minute consultation in your average busy GP clinic.

I myself resist seeking medication for genuine extreme pain probably 80 percent of the time.

Everyone with chronic pain would do the same. I'd imagine and be prepared to bet.

As it is I have to consider the long term effects of pain relieving medications for myself.

Taking away codeine based medications would mean that I would inevitably be forced to result to much increased doses of over the counter medications of the Non Steroidal Anti Inflammatory kind.

Which I know to have far more severe long term consequences health wise.

They destroy the stomach lining and are harmful to our liver and kidneys.

Also I feel I'd be forced to take more panadol than I should to help keep my pain at bay.

This is not good for the long term health of my kidneys.

The truth very real truth is that I'm going to do more harm to myself, managing my long term pain, under the new proposed law. I have no doubt.

So if this new law was being put in place to protect me from doing such harm.

Then it's not going to serve its purpose.

It may serve a purpose for you. In the short term. The one that is looking upon you to take action in light of the studies showing codeine related deaths. But it's not in the best interests whatsoever of long term pain sufferers. We already find it difficult to manage our pain levels. In a society that is disinclined to tolerate 'invisible illnesses'. That wants us to work and contribute to society. We want to work and contribute to society.

Please don't make it harder for us, for our families, than it already is.

I know there's a push from pharmacists to make it prescription only.

Pharmacists who are not educated in management of chronic pain. Or of conditions causing chronic pain.

Please reconsider this matter. I beg you.

I have a life I love and wish to participate in.

A child I wish to be present for.

A body I wish to use and keep healthy.

A home I wish to afford to continue to live in.

This is all without then considering the long term effects of chronic pain on mental health and suicide issues relating to chronic pain.

It's not as simple and straightforward a solution as it may sound. For us to 'just seek pain control from our doctors', I promise you it's not. Please hear us.

Yours sincerely

Chronic Pain sufferer



Submission to TGA on rescheduling of Codeine to prescription only status

I am opposed to this proposal for the following reasons:

I suffer from acute on chronic pain episodes. There is a current wait of approximately 5 weeks to see my general practitioner. There are no after hours GP services in my town.

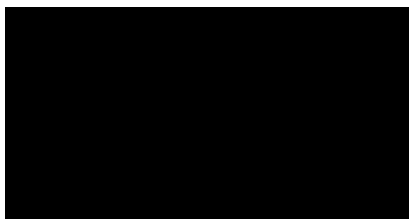
My GP is fully aware of the medication I take for pain and is happy with the level of analgesic use.

I am unable to take NSAIDs including Ibuprofen so the combined Paracetamol/Ibuprofen product is not available to me.

I understand the risks of Codeine and I believe there are methods to improve consumer safety whilst not disadvantaging those who use Codeine safely.

- Improve the real time monitoring of dispensing across pharmacies in Australia. This would have the benefit of also monitoring those who use/misuse prescription drugs such as Valium.
- Allow a doctor to write multiple repeats with the prescription having to be maintained at the pharmacy, so frequency of purchase is monitored.

Whilst my preference is for the current scheduling to remain, if it is changed, it must be for all strengths of Codeine. If lower dose combination products are excluded, there is a potential for accidental/intentional overdose of either the other analgesic in combination.



[illegible]

From: [REDACTED]
Sent: Tuesday, 6 October 2015 2:42 PM
To: TGA Info
Subject: Pain Management Clinics.....The doctor's Goldmine

Alcohol is so easy to get in unlimited amounts. No one wants to know your great grandmothers maiden or her birthdate when you buy it. I am trying to say the nanny state is now so horrific that you need your passport , birth certs, marriage license just to buy an aspirin. Hardly worth living, living like this and I will get to that a little later. But alcohol

is a million times worse than any of them. Ice is now equal to what alcohol causes. You know what I mean, the violence, the family nightmare, car accidents, murders, theft.

Drugs like alcohol and ice effect so much of society not just the user. Then of course there's the massive physical effects from alcohol. It rots your guts. It does that because as you all surely know its fermented (ie bad) grain, vegetables, fruits. Stuff that's gone off. So its chocka with poisons. Its a poison, a strong one. So now we have not just alcohol taking up all the time in the ER, we also have ice. Regardless what the hysterics are saying alcohol causes the majority of drama in the ER. The hypocrisy of it all is infuriating.

Theres always someone who is trying to have a few minutes of fame and big note themselves so we get pretty much uneducated people on patient issues calling themselves 'patient wellness outcome people' or something talking about crap they have no idea on. Take it from me, NOTHING DRIVES NURSES Madder than those who have no experience at the coalface with patients telling US, US NURSES whats going on!!!!!!!!!!!!!!!!!!!!!! Those people are totally unnecessary and have just created jobs for brainless wankers. They have no medical exp or training, at best they MAY be an absolutely maddening psychologist of which there is an over explosion and they are virtually useless btw. I ought to know, [REDACTED] They charge outrageous fees for something a good exp psychiatric nurse can do v easily. So we have been forced to endure someone like this blabbing at us through our tv screens as well.

The result of all this is people are suffering. A LOT. From pain. People are now so paranoid of taking a pill they suffer instead. Plus they HIT THE BOTTLE. Because its so much more socially acceptable which is just straight out inexplicable idiocy. The alcohol will make them sicker, rot their oesophagus, stomach, liver, kidneys, bowel. Plus its a well known carcinogenic. Wait until some of you people suffer from chronic pain. Chronic pain reduces quality of life drastically and a few people have already told me they will just kill themselves instead rather than camp at the doctors. Your quality of life goes right down and you cant be a productive member of society with constant pain. It drives you insane. For some its too expensive to keep going to the doctors. If their doctor doesn't bulk bill and a great number don't. Which brings us to the famous doctor's Goldmine. THE PAIN MANAGEMENT CLINIC. These clinics make the doctors of America v v v rich indeed. They are famous for it. You cant tell me that as doctors realize the Medicare situation is tightening that they will lose a lot of income. This will reverse that loss immensely. I know them, worked with them for decades. (Besides around 50% of doctors are addicted to pain meds at any one time, this will also make it easier for them to get it, anyone think of THAT???? That's the experience in America btw and yep its as much as 50%)

I am also angry at doctors saying you cant get the tabs in America otc and parts of Europe. BUT YOU CAN GET THEM IN CANADA, ENGLAND, IRELAND GERMANY ETC ETC.....No one said that on tv. Appalling and misleading. Back TO AMERICA. America HAS THE BIGGEST PROBLEM OF PAINKILLER ABUSE IN THE WORLD AND YOU CAN ONLY GET THEM BY SCRIPT. [REDACTED] Stupidity reigns supreme. The doctors are NOT Gods btw. Far from it. That's what will now happen here. The pain clinics will sprout and the scripts will go flying everywhere. With much stronger drugs on those scripts. Then people will drink with them and its all over. In every country where this idiocy exists, there's a big black market and its uncontrollable. You are also giving new options to black market drug suppliers. People get desperate for pain relief and these types will learn that pretty quick. So we will also get a big lift in heroin and morphine users. Illegally. People who would never have dreamt of it will go hunting it up.

But the main problem will be alcohol. Its use will shoot up. Its so easy to get. I could get a bottle of vodka a day no questions asked and I probably will. I haven't drunk for decades but for pain relief I will. I don't care any more. I have had 3 friends drink themselves to death. Who wants to live in a nanny state?? We cant do anything. Combined with the fact you have to watch what you say all the time or watch what you even think life is becoming intolerable. I don't recognize the country anymore either. Its like living in a totally alien land sometimes. Its happened so quickly too. The place is so different to even 8/10 years ago. Its so aggressive, judgmental, and idiots run everything, especially people who have no experience or knowledge seem to be in positions where they have no right to be. Making life and death decisions because they have no insight or foresight and they think they are important and have power.

There's no men either in the societies we have made. Oh, the outer shell is there, they LOOK like men (sometimes) but they ARE NOT. They are wimpy, wishy washy, always going on about ' people don't like to be spoken to like that' or something, always going on about 'feelings' and Political Correctness etc. They are humourless, cant stand firm often and sometimes brain dead. We all know whats caused that don't we??? At least [REDACTED] not like that. There's a few guys still trying to stand as men but they sometimes get attacked for it. Its madness. So that's why we see the only man in world politics and public life today is [REDACTED] He's also just shown how emasculated men like [REDACTED] [REDACTED]. He's the most popular politician in the world now, especially amongst the European countries. But the Americans love him too, the American people that is.

Like a few of my friends I don't know if I am going to camp outside my doctors. Its expensive for me and the government. It will cost the government untolds. They might as well give up trying to reduce the Medicare bill. Its amazing that the health minister as no say in this. Its appalling. I have legit pain issues, 3 actually. I have always been v independent and looked after myself as much as possible. I don't go running to the doctor all the time. I go twice a year unless I think there's something v pressing occurring. I am a dream for the government. This means I will have to be there a lot, at least twice a month. Cost, cost cost. There's a whole army like me. Millions of Australians. We are a goldmine for the doctors and their pain clinics that will spring up. I have already started bringing in alcohol for assistance with my pain now over last few months as I see the writing on the wall. As I said, I can get the alcohol very easily, as we all can. I will get sick from it, more cost.

Here I should mention of course that its not the codeine that is the poison in the tabs, its the paracetamol and ibuprofen. both synthetic chemicals. They are available EVERYWHERE. HUGE PACKETS OF THEM. I always find it amusing how pharmacists say take tab with food, but never when you buy just the plain ibuprofen on its own. BUT ITS THE IBUPROFEN THATS THE PROBLEM FOR YOUR STOMACH NOT THE CODIENE!!!!!!!!!!!!!!!!!!!!!! So why can you just buy 5 packets of them, in 50's or 100's and no one says a thing???? They are hitting your stomach the same way. See, stupidity and madness. Same with paracetamol, take a packet of them and your dead. You can buy 500 of them in 100 size pkts in one day and no one says a thing. Your liver will pack it in in 3 days after as little as 15 tabs and no one can stop it. No liver function you die quick. Plus we have recently been told paracetamol is a v poor pain reliever especially for back pain. Useless, unless its got codeine in it. I am thoroughly sick of all this insanity. People swallow this nonsense too. They cant think for themselves.

The thought of the inconvenience, the cost, the struggle with pain that I have managed for

so long (my doctor knows) by myself is too much. I have PERFECT LIVER AND KIDNEY FUNCTION BTW..after more than [REDACTED] years. If you use the tabs properly you always do. Millions of Australians use them properly. My alcohol use that I have started will reduce my liver function and probably destroy it. I don't care. I am over it. I am over living in a madhouse country. Whats next??? What will be the next nanny state nonsense???

Perhaps we will follow England with their leaving what they call 'flip flops' in pubs so that when women in high heels get drunk and try to leave they wont fall over and maybe break their legs. Also the law reducing the number of holes in salt shakers in restaurants so that people get less salt, what about THAT one???? Brought in a few years ago by the stupid [REDACTED] Government of England but still used. Dumb??? Stupid??? Well considering you can just unscrew the lid and get a heap of salt, yes v dumb and these idiocies are from PEOPLE RUNNING THE COUNTRY!!!!!!!!!!!!!! What hope do any of us have??? However England still has otc decent painkillers.

I cant bear the thought of it, ending up like America. I don't want to live like that. The pharmacists are right, the real time situation will completely solve the problem and cost us all less money, going to doctors, costing Medicare an arm and a leg, making very rich doctors. Where's the vodka, I am going to drink myself to death. Bye.

From: [TGA Info](#)
To: [Medicines Scheduling](#)
Subject: FW: Comments on codeine [SEC=UNCLASSIFIED]
Date: Wednesday, 7 October 2015 9:43:17 AM

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

Regulatory Services and Improvement Branch

Phone: 1800 020 653 Fax: 02 6203 1605
Email: info@tga.gov.au

Therapeutic Goods Administration
Department of Health
PO Box 100
Woden ACT 2606 Australia
www.tga.gov.au

From: [REDACTED]
Sent: [REDACTED]
To: TGA Info
Subject: Comments on codeine

Hello,

In relation to the recently publicised story that the TGA will make codeine painkillers (panadeine etc) only available from the doctor I provide the following comments.

The cost to see a doctor in the ACT (Canberra) for a standard adult is around \$70.00 (this is just at a general GP clinic as well) for just 15 minutes, so even if you get a repeat script the cost of a pack of Panadeine will be around \$30 when you factor in the doctors costs and cost of the pack. Not to mention the difficulties in seeing the doctor as it takes a week to book a doctor in the ACT. The move to make it prescribed is very silly.

I accept the need to minimise addiction. This is important. However, if that is the issue then bring in a similar system that you have with pseudoephedrine where you have to show a licence to the pharmacist. Even then I think it is over kill.

Codeine is the only pain killer that works for [REDACTED] for me. It is often the case that a [REDACTED] hits very quickly and you need a pain killer very quickly or say while you travel. The two need to correlate. It takes about a week to book an appointment in the ACT so how will that work? Also I find it rather silly that you will need to ring up the clinic and

say 'Hi I have ahead ache I need an appointment to get some [REDACTED] tablets... next week is the next available appointment you say...'.

This move of prescribing codeine from doctors will force people to 'hoard' the tablet as you will need it in the car, at work, in the house etc as it will take a week or so to get hold of. You will also likely get people taking double doses of ibuprofen and paracetamol as codeine will not be available.

Please look to other options to minimise addiction. Prescribing it by a doctor will perhaps minimise addiction but will have a massive negative affect on the vast majority of legitimate users like my self.

I am happy to make these comments through other channels if this email address is the wrong channel. Please let me know.

Kind regards,

[REDACTED]

From: [REDACTED]
To: [Medicines Scheduling](#)
Subject: Opposed to Codiene Products becoming prescription drugs
Date: [REDACTED]
Attachments: [REDACTED]

Hello,

I would like to voice my opposition to the proposed changes to codeine from an S3 to an S4 product. I believe that the change is excessive and will cause more issues than it will resolve. I use codeine based product when I am sick (e.g. [REDACTED]) or to manage pain on some occasions. As a [REDACTED] it's very hard and costly be forced to see a Doctor to get a script every time I have a cough that is keeping me awake at night when a pharmacist is more than equipped to discuss and advise me on the best course of action.

Aside from the inconvenient and extra costs that it will incur for my limited income resources, it also means that any people with ongoing pain conditions will also be unable to get the pain medication they require easily without extra costs. It will not be profitable for pharmaceutical companies to continue to keep the cost of these products at a reasonable price which will also impact people with ongoing debilitating pain. Or the pharmaceutical companies will just stop making these products due to extra financial burden on them by making these changes (packaging changes/insert changes etc.) It will also increase pressure, on already struggling to capacity, Medical Centres and Hospitals/Emergency Departments and overall Medicare costs will increase. It is already impossible to get a Doctor appointment on the day that you are ill or in pain.

Pharmacists hold the power to ensure that these medications are safely provided to individuals, making them a prescription medication won't stop a minority from abusing these medications. Addicts will move onto the next readily available product mixing it with other medications or alcohol to get the desired effect.

Kind Regards,

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]



[REDACTED]

Therapeutic Goods Administration
136 Narrabundah Lane,
Symonston ACT 2609, Australia

Dear Sir/Madam,

Codeine in Pharmacy Medicine

I heard on the radio that the Therapeutic Goods Administration intends to ban any&all codeine in pharmacy medicine. That is unfair, but first, here is my story which happened not too long ago.

In short I had a [REDACTED] which wouldn't go away which is highly unusual for me, so I went to the doctor. It turns out I had [REDACTED] gave me a prescription for antibiotics, and because the usual [REDACTED] wasn't enough she told me to take [REDACTED] which has added Codeine. N.B. I had never heard of it [REDACTED] prior to my doctor telling me about it at that time.

The problem was that I was in such persistent pain that it was difficult for me to have a full nights sleep. I would wake up early in the morning to a throbbing pain, and try to get more sleep but I couldn't. With nothing else to do I went go to eat breakfast except [REDACTED] I couldn't eat. So I take [REDACTED] to ease the pain, BUT I have an empty stomach so I vomit up whatever I managed to get in my mouth with a little stomach bile. I needed a better solution.

I went back to the doctor only to be told of Paracetamol with added Codeine, also I didn't need a prescription for it anyway. So far so good even though I am still in pain and starving after hours of waiting for the doctor. I then went to the same old local pharmacist only to be interrogated and rejected by an [REDACTED]. Don't worry, I got the Paracetamol + Codeine tablets from [REDACTED] medical kit. Relief at last, I could think clearly again and eat - in no thanks to the arbitrary compassion of a doctor or pharmacist. No, it was [REDACTED] was thoughtful enough to have a medical kit in case of medical emergencies. Thankfully I didn't need any more pain medication after that packet of Paracetamol + Codeine.

Back to the issue at hand: how [REDACTED] is anyone in severe pain supposed to function as a normal human being? They don't and I didn't. Are you now expecting everyone to wait on hand&foot for the mercy of a doctor's blessing? That is utterly unfair to people in immediate need of pain medication. Delaying access to immediate pain relief by requiring a doctor's script is effectively saying no to everyone. What happens if you shatter your leg in an accident at home? You only have paracetamol which doesn't [REDACTED]. And what if Codeine is banned from pharmacy medication? Do you offer two placebo pills and wait until your

Royal Highness Doctor grants you the pleasure of her attention? [REDACTED] you delusional bureaucrats.

I suppose I did get unlucky with the harpy at the local pharmacist. Mind you, I was trying to buy Paracetamol + Codeine at the same time I was handing in an antibiotics prescription. It should have been obvious I had a pain problem. Maybe that is the real solution after all, that you should instruct your pharmacists to use their common sense.

In summary, while writing your report on whether to ban codeine in pharmacy medicine, I urge you to hammer nails into yourselves so that you will be in the right mind to make a sensible decision on the matter. Anything less is unfair and callous.

Yours faithfully,

[REDACTED]

P.S. Thank God you don't regulate alcohol retailers.

I am writing with to make a submission about the proposed changes to the rescheduling of codeine.

Firstly I would like to say I understand why this has been proposed due to a small amount of people using codeine products incorrectly you cannot let a minority of people make it worse for the majority of people who use codeine products correctly and responsible. At the end of the day it is no different to people abusing alcohol we haven't raised our legal drinking age because other countries are 21 years old.

I think the way the system is now is fine I don't think it should be changed there is a few reasons I can think of

1- Pharmacist do make you feel like a bit of a criminal with the questions you get asked when you buy the products, they do a good job

2- If the product is monitored like cold and flu tablets I think is a bad idea I would rather see a doctor and get a scripted.

Because of this reason Let's say 1 30 packet of say [REDACTED] if you have 1 tablet a day in the morning to help you get moving you may have bad joint pain any pain etc 1 box will last a month if you have two tablets a day that's only half a month. So when you buy 1 pack or 2 packs a month the Pharmacist is going to turn around and say you're abusing.

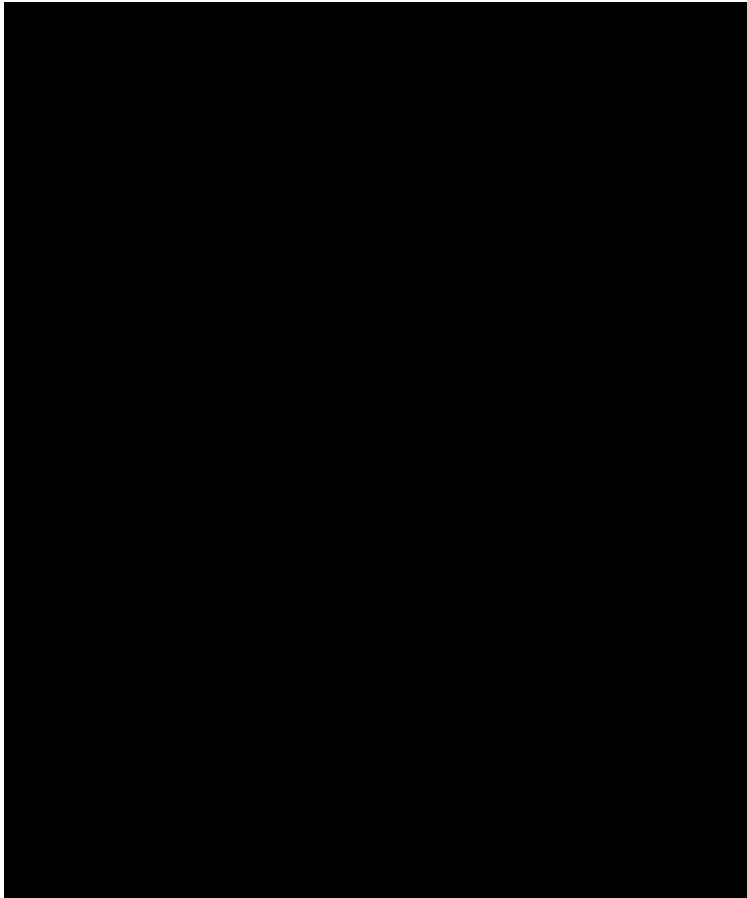
I can speak from my personal experience using codeine I have had a few operations [REDACTED] [REDACTED] from [REDACTED] injuries. I wasn't in private health at the time I had to wait over a year to get a operation I was taking [REDACTED] tablets a day for a year until a had my operation [REDACTED] tablets a day is not enough to be dependent the drug once I had the operation I stopped using it because I didn't need it, even with the [REDACTED] operations I had I had to wait a few months for them I was having either [REDACTED] tablets a day. Then stopped after the operation. My doctor would give me scripts for [REDACTED] which I never took they made me feel sick.

So I don't believe a Pharmacist can tell someone no you're not having any more you are abusing. i guess the question is how much codeine is enough to get someone hooked everyone is different everyone has difference tolerances.

I honestly think it should just be left the way it is or you see a doctor at the end of the day a doctor is more qualified than a Pharmacist. I think there would be more people who just want to see it stay the way it is then change.

Thank you for taking the time to read my opinion on this issue. [REDACTED]
[REDACTED]

Pharmacy



Medicines Scheduling Submission

Subsections 42zczp of the Therapeutic Goods
Regulations 1990



Medicine that have the potential of causing addiction must be controlled and monitored to prevent in harm and death. This should be the Government's commitment to give all Australians a Duty of Care.

I have unfortunately had years of experience with a person [REDACTED] (deceased [REDACTED] that has suffered from an addiction to chemist medication over many years. The drugs of [REDACTED] choice were:

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] started having traumatic [REDACTED] issues from childhood getting bullied and bashed at school, having an abusive and violent [REDACTED] had a culture of hiding everything from the [REDACTED] as [REDACTED] was emotionally and physically abusive and terrified the kids. With years of having to wear the traumatic burden as a kid caused [REDACTED] to suffer from [REDACTED] [REDACTED]. [REDACTED] started taking [REDACTED] to help [REDACTED] with the many [REDACTED] [REDACTED] told the MP [REDACTED] was having. Apart from the [REDACTED] was occasionally taking [REDACTED] also took the medication to make [REDACTED] sleep and calm her down. [REDACTED] illness was not diagnosed until [REDACTED] was [REDACTED]

[REDACTED] continued getting prescriptions from doctors for many years but then the quantity was given by the MP was not enough for [REDACTED] then got other prescription from other MD's without a problem. [REDACTED] was doctor shopping or hopping and got to the point that [REDACTED] one day changed the quantity on her prescription from one to two and got caught with changing the prescription and was charged and appeared in the [REDACTED] court over the incident.

[REDACTED] was very much addicted to this medicine and was taking around half a box a day which was astonishing. As the accessibility to access [REDACTED] easily [REDACTED] started to take [REDACTED] as they were easy accessed and also cheaper I think, from a pharmacy. If [REDACTED] was asked to give [REDACTED] name [REDACTED] would say the medicine was for me or [REDACTED] or someone else as long as [REDACTED] was able to get what [REDACTED] wanted. The medicine was not enough at a certain point and then [REDACTED] started drinking whiskey as well as the [REDACTED].

[REDACTED] would also go to multiple Pharmacies to stay below the radar. The years of taking these harmful and addictive medicines and alcohol finally took [REDACTED] life last year at the age of [REDACTED]

In having many years' experience with [REDACTED] issues as [REDACTED] was suffering from [REDACTED] and [REDACTED] What I was told by professionals is that when a person suffers from [REDACTED] illness there is a very big chance that they will also revert to drugs and or alcohol, the two are linked.

With the amount of people these days having depression and various other psychological issues it is important for us to have some mechanism (system) in place that would register the purchase of these medicines on a central database. This central database must be used by all registered Pharmacist's and doctors. This way would eliminate the doctor shopping or jumping and would be able to track the abuse of medicines and give the patient a better management plan. This tool would be able to be used to better support sufferers with the best professional approach and take the self-medicating option of the board.

By just taking a name or selling the medicine behind a counter is no solution it is just a smokescreen.

My suggestion would be to use our Medicare cards to scan prior to purchasing any of these medicines and then have that data used in conjunction with doctor's scripts and done electronically. There needs to be a central medical database for all authorized medical practitioners to use. This is only a thought.

This problem has been known by the pharm cuticle board as I raised these same concerns with them years ago. They agreed but said it was out of their hands. I was outraged and likened the issue to a kid buying lollies in a candy shop.

I thank you for your time and take that you will make the right choice for the safety of all Australian's

Kind Regards

[REDACTED]

From: [REDACTED]
To: [Medicines Scheduling](#)
Subject: codeine scheduling submission
Date: [REDACTED]

[REDACTED] are healthy mature adults who exercise regularly and eat a well balanced diet.

We are very proactive when managing our health status . We rarely use antibiotics or see a doctor.

A part of our own wellness management plan consists of eating probiotic foods, drinking herbal teas with eating recommended quantities of fruit and vegetables [REDACTED]

When we get sick we also like to manage our illness, unless it needs medical intervention. A part of our first aid kit contains original [REDACTED] day and night tablets. We use these perhaps 1-2 times a year if we get a head cold so we can sleep at night. The process involves showing a drivers license and we have always been consoled by our chemist when we buy them. Equally we are very physically active and sometimes use panadine forte for back sprain.

We use these responsibly and limit their use as we don't want to stay on any medication longer than necessary.

We strongly oppose any rescheduling of these drugs on these grounds:

1. We find it very disempowering and quite insulting not being able to manage minor health problems without getting the doctors approval.
2. The added cost to the health system, if we had to see a doctor for a prescription for these medicines, could not be justified.
3. Going to the doctor for a cold is embarrassing when there are others in the waiting room with real health problems.

Regards

[REDACTED]



Thursday, 8 October 2015

Re: Proposed Codeine Rescheduling

Dear TGA Advisory Committee,

In response to the current proposal to reschedule Codeine based Schedule 3 and Schedule 2 medicines I wish to object to the rescheduling.

Consumer groups such as Pain Australia, Consumers Health Forum (CHF), Australian Pain Management Association are opposed to the up-scheduling. This is not an issue that simply inconveniences pharmacists, but will put a considerable financial burden on the health care budget, overload doctors with unnecessary visits, restrict patient access to timely pain relieving medication, especially in rural communities and provide no reduction whatsoever in the inappropriate use of codeine containing substances.

As with many other prescription based products, without the real time monitoring solution that the Pharmacy Guild proposes as an alternative to rescheduling, supply of codeine based substances will be driven underground, with the burden of managing those who are attempting to misuse Codeine (either directly themselves or by on-selling to drug dealers) being simply passed from pharmacists to doctors who will be pressured to write prescription quantities for well in excess of maximum supplies currently available in pharmacy (currently 40 tablets).

A real time, real world solution exists and based on its similarity with ProjectSTOP towards significantly reducing the illicit use of pseudoephedrine, and will provide real evidence based effectiveness towards reducing the harm that can be caused by codeine to individuals seeking illicit or inappropriate use.

This is a prime example of the potential usefulness and effectiveness of community pharmacy towards minimising unwanted costs and burdens on our already overloaded and heavily burdened health care system. I urge you to withhold the interim decision and consult with the Pharmacy Guild as to how community Pharmacy may work with the TGA for better health outcomes such as I describe above.

Regards



Pharmacist / Proprietor



TGA submission Notice under subsections 42ZCZP of the Therapeutic Goods Regulations 1990 (codeine rescheduling)

Submission

I would like to state my opposition to the TGA recommendation for codeine to be reclassified resulting in a prescription from a GP will be required.

This recommendation was accompanied by headlines saying codeine overdose deaths had “doubled” in 10 years, as apparent justification for this recommendation. Without wanting to minimise any loss of life, considering the figures quoted 3.5 deaths/million to 8.7 deaths/million, this does not appear to be a significant increase over 10 years given the hundreds of thousands of people, if not millions, responsibly using codeine products across Australia in this time.

In fact, it could be argued if the abuse of codeine is so widespread, then you would expect the mortality rate to be significantly higher.

The vast majority of codeine users – including those in chronic pain who are already under the care of GPs, specialists and pharmacists – are responsible users of the drug. Those who actively abuse codeine will find ways around any regulation, but reclassifying this drug will bring unnecessary hardship for the vast majority.

Is the TGA really advocating a position that people suffering tooth ache and period pain (who may use [REDACTED] need to visit a medical professional to prescribe pain relief? This appears to be ham-fisted response essentially penalising and inconveniencing the vast majority of codeine users, who use the drug regularly and responsibly. There will also be unintended consequences of putting further strain on GP and hospital services.

Where is the suggestion for real time recording or a suitable monitoring system – this should be the very first step to gauge any patterns of behaviour/abuse before a reclassification of the drug is even considered.

Was there any community and stakeholder consultation undertaken to reach this recommendation?

Where is the re-education and community education campaign if accidental codeine overdose is such a concern? This recommendation appears to be an over-the-top response to an alleged problem that is not even consistently agreed and/or acknowledged as an issue within the medical, pharmaceutical and other relevant sectors.

Further research needs to be undertaken to justify this recommendation before it is even considered for implementation.

Kind regards

[REDACTED]

[REDACTED]

From: [REDACTED]
To: [Medicines Scheduling](#)
Subject: Codeine
Date: [REDACTED]

Please be aware that people just can not afford the time nor the money to get prescriptions for simple things like over the counter Codeine products.

For someone like me who suffers [REDACTED] products such as Codeine is a necessity at times.

If this change goes through it takes a simple task of going to the chemist and purchasing the relevant pain killers a matter of minutes to, Ringing and making an appointment, Getting said appointment when one is available, (Hours away or this could be days away at times) Travelling to Doctors Surgery, Waiting up to an hour to see Doctor, then walking Next door to have prescription filled. A total of, possibly days or at times, maybe 2-5 hours minimum before pain medication can be implemented, another half hour for the medication to work. Against the Maximum 45 Minutes needed NOW.

I would suggest that instead of passing laws that are seriously detrimental to Ordinary Australians on Ordinary wages that those that would think this a good law should think of us rather than those that are on 6 figure incomes and really have NO idea how we really suffer.

I urge a rethink of this legislation in the favour of ordinary Australians.

Best regards

[REDACTED]

NOTICE

[REDACTED]

From: [REDACTED]
To: [Medicines Scheduling](#)
Subject: Having to get a script for codeine Phosphate
Date: [REDACTED]

I would like to strongly recommend that you dont make it so that people have to attend the already hard enough to get an appointment dr just to get tablets that my pharmacy already has monitors for people who dont need to use this medicine it will be an inconvenience and for those who do use it more often then there is the added cost of seeing the dr everythime you need this medicine. Please please dont do this. Thank you for taking the time to read this email. [REDACTED]

From: [REDACTED]
To: [Medicines Scheduling](#)
Subject: Submission on Proposed Amendments to the Poisons Standard (Medicines): Proposal to reschedule codeine from Schedule 3 to Schedule 4
Date: [REDACTED]

9 Oct 2015

Therapeutic Goods Administration
medicines.scheduling@tga.gov.au

I wish to bring to the attention of the TGA a drug far worse than codeine.

- It is highly addictive
- It is available over the counter
- It is used recreationally
- It causes immeasurable social harm both to self and others
- Its effects on individuals is unpredictable

It's ALCOHOL!

You should get your priorities straight before you restrict the availability of a very effective pain reliever to the vast majority of the public who take drugs responsibly.

I suffer occasionally from [REDACTED] that have no apparent cause and the only effective relief is from [REDACTED]. Getting to see a doctor at short notice these days is next to impossible. Those in the industry pushing for the change have greater empathy for the few over the many. There is nothing worse than [REDACTED]. Just thinking causes pain. You cannot push it to the back of your mind like other pain because it is [REDACTED] [REDACTED] And you want to make my life more difficult!? [REDACTED] YOU!

It doesn't take a genius to realise that it is not the codeine that is causing the damage to people that become addicted. It is the paracetamol and the ibuprofen. For these people wouldn't it be better to treat their addiction by giving them access to pure codeine in conjunction with therapy to wean them off it. But nooooo. It takes far less mental effort to ban something. Treat the disease, not the symptoms!

Please consider the good of the many over the misfortune of the few.

(I know this submission is a little late but I was not aware of the proposal until it was brought to my attention by the media.

But then you didn't want too opposing submissions until it was too late, did you? Medical professionals will not be affected by this looming fait accompli. Their access to whatever drugs they desire will remain unrestricted, while leaving the rest of us hung out to dry.)

Regards

[REDACTED]

All Codeine-containing medicines in Australia will require a prescription. Currently, things like [REDACTED] can be bought at a pharmacy without a doctor's prescription even though they contain Codeine. This has been the case for about 50 years. From June 1, 2016 everyone will require a doctor's prescription for these medicines, and all others that contain Codeine.

As you know the Federal government is trying to prune waste from public expenditure, given Australia's finances. When doctors have to see vastly more patients who want prescriptions for medicines which are now bought at pharmacies over-the-counter, the cost to Medicare will be more, not to mention the cost to patients in time and money. The Australian Self-Medication Industry estimates it will cost Medicare alone, an extra \$675 million per year in subsidised doctor consultations.

You would also know of the current Senate inquiry sponsored by the Federal government, which is aimed at reducing the erosion of our freedom by excess regulation. The decision to force vast numbers of people to obtain prescriptions for medicines which have been in common use for 50 years, will increase, not reduce, the burden of regulation on patients.

The TGA appears to have based its recommendation to make all Codeine products prescription-only, on limited studies similar to that published in the latest Medical Journal of Australia. The study was conducted at the National Drug and Alcohol Research Centre within the University of NSW, referred to just now in Pharmacy News, October 9, 2015. This study analysed drug-related deaths between 2000 and 2009. Of the total of 1437 deaths analysed, 1325 were caused primarily by drugs or causes other than Codeine. That is a proportion of 92%, almost all of them. The remaining 112 deaths, or just 8%, were caused specifically by Codeine toxicity.

However the study did not note, what proportion of that Codeine was obtained by patients having been prescribed it by their doctor, and what proportion was obtained as over-the-counter medicines like [REDACTED], from pharmacies. For all anyone knows, the bulk of the Codeine medications could have been obtained from doctor prescriptions. Doctors prescribe mostly [REDACTED] which has 30mg of Codeine per tablet. [REDACTED] average-sized pharmacy has dispensed over 700 boxes of doctor-prescribed [REDACTED] in the last 12 months. Over-the-counter pharmacy medicines can contain only between 8mg and 15mg of Codeine per tablet, which is no more than half the amount of Codeine 30mg in virtually all the tablets prescribed by doctors. Doctors have no system at their disposal like the Pharmacy Guild's Project Stop. Doctors have no means of monitoring Codeine usage by doctor shoppers who use multiple surgeries. The UNSW study went no further than to conclude, that different strategies were needed to ensure safe use of Codeine by the public. This could have meant several things besides making all Codeine prescription-only.

Some academics make the spurious argument that the amount of Codeine contained in common medicines like [REDACTED], has not been clinically proven to be effective. This flies in the face of public experience of such medicines and their effectiveness. There is a 'lack of evidence' because it costs a company, hundreds of thousands of dollars to perform effectiveness testing that meets TGA standards. No company wants to pay for this testing of Codeine. The drug is off-patent, so a company does not want to pay for testing that will also benefit its many competitors, who also manufacture Codeine-containing medicines.

The Pharmacy Guild has had a monitoring system in place to prevent misuse of medicines containing Pseudoephedrine. This system has worked well for the last ten years. During that time, the Guild has repeatedly offered to add over-the-counter Codeine-containing medicines to the system. Doing this

would control any abuse of Codeine without the need to make Codeine prescription-only. Even without having Codeine in Project Stop, pharmacists have always monitored via dispensary records, the over-the-counter purchases of Codeine-containing medicines to prevent abuse. No government has accepted any of the Guild's offers during the last ten years, to add Codeine to Project Stop to reinforce safety monitoring by pharmacists.

I would also point out that the committee which has concerns about public safety because Codeine is contained in some common over-the-counter medicines, is not consistent. At present it is possible to make unlimited purchases of [REDACTED] at any supermarket or service station. Anyone can buy these medicines in any quantity, certainly in enough quantity to do self-harm or commit suicide. The AMA and Pharmacy Guild have repeatedly called for the TGA / ACMS to remove the availability of [REDACTED], or at least restrict quantities, which are available from supermarkets and service stations. These requests have been made in the name of public safety. To date the TGA / ACMS has ignored all such requests. Reducing the maximum pack size of [REDACTED] available in supermarkets, does not prevent anyone simply buying extra boxes [REDACTED] if they wish to self-harm.

Codeine is no more than a minor contributor to drug-related deaths. It is not clear from the study what is the main source of Codeine which is abused. The study does not say whether it is mainly over-the-counter purchases from pharmacies, or Codeine which is provided on prescription by doctors. The doctors have no monitoring system which can be used to control Codeine use. Pharmacists do have such a system. Despite all this, the TGA wants to give complete control of Codeine to doctors alone. The TGA conclusion and recommendation is illogical, and excessive. Codeine-containing medicines can continue to be provided safely without prescription by pharmacies.

From: [REDACTED]
To: [Medicines Scheduling](#)
Subject: Controversial changes to Codeine products.
Date: [REDACTED]

To who this applies,

WE as the general public who does not abuse these products are very concerned at the new proposal that these products may only be available by attending our local GP to obtain a prescription thus clogging up the already busy Doctors & Clinics.

Why not still make them available Pharmacies but purchasers having to produce identification meaning that the pharmacist can therefore track them so that they cannot be abused.

Therefore legitimate users are not denied the right to purchase them at their local Pharmacies.

Hopefully the scheduling body will take these comments on board for consideration,

Yours faithfully

[REDACTED]

From: [REDACTED]
To: [Medicines Scheduling](#)
Subject: Codeine on prescription should not happen
Date: [REDACTED]

Hello there,

I am writing this to inform you that only a minority of the public abuse the use of codeine. By introducing the prescription rule you are giving drug abusers the chance to go for a stronger pain reliever such as prodeine forte and panadine. It will cause a major inconvenience for the public who are using it for proper reason. There will be people who may need it for an actual emergency such as cramps, period pain, work injuries etc. I do agree that you should use project stoop to monitor the use of codeine, it is too inconvenient to have wait for hours to see a doctor just for a box of codeine, when instead you can just get the pharmacists to monitor the activity.

Kind regards,

[REDACTED]

From: [REDACTED]
To: [Medicines Scheduling](#)
Cc: [REDACTED]
Subject: Proposal to make medications containing codeine prescription only
Date: [REDACTED]

Dear Sir/Madam

I am emailing to express my concern at the proposal to make medications containing codeine (currently available from Chemists), prescription only. For many years I have self-managed my pain on and off using these drugs, typically [REDACTED], for the treatment of [REDACTED] pain. I estimate my usage as one to two doses every two to three weeks on average. So, you can see that having to visit a doctor for the pain relief would be excessive in cost and inconvenience, as I work full time and have no concessions.

I understand the focus on trying to prevent addiction; however, I would be interested in whether there has been an estimate made of the amount of people who responsibly use the drugs, such as myself? For these many people making the drug prescription only will also result in excess sick leave from work to visit the doctor which is counterproductive.

I am outraged that my right to manage my own health will be impacted. I do not believe that I should have to "run to the doctor" with every little complaint especially since I have been managing my own health responsibly for more than 20 years. I also do not believe that forcing consumers (not patients!) to see a doctor unnecessarily is ethical in that doctors will benefit financially from this policy.

I would support having to show identification when buying these drugs. Perhaps a register would identify at risk users who may then be asked to see a doctor?

Please reconsider the proposal and keep these drugs in the Chemist where they can be safely supplied.

Yours sincerely

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

From: [REDACTED]
To: [Medicines Scheduling](#)
Subject: Objection against prescriptions for OTC pain medications
Date: [REDACTED]

I am writing this email today to express my feelings towards the proposal for making over the counter pain medication with small amounts of codeine phosphate in them require a prescription from a GP.

I take extra pain relief tablets containing codeine for [REDACTED] pain due to regular paracetamol being insufficient enough to relief my pain. Not only will making over the counter pain medication containing codeine require a prescription cost me money that I don't have, going to the doctors and paying money to get a prescription is extremely inconvenient for myself and the general public who require these types of medications.

Instead I'm supportive of the proposal for record keeping control measures and proof of ID requirements as this is a much more reasonable option and the general public and myself will not have to incur in unnecessary fees and time wasting.

The general public should not have to suffer due to the inappropriate use of these products a minority of individuals.

From: [REDACTED]
To: [Medicines Scheduling](#)
Subject: Codeine rescheduling
Date: [REDACTED]

The proposed interim decision does not consider the practicalities of obtaining a prescription from a doctor and the costs involved. At present it can take three days to get a doctor's appointment. Then there is the cost of the appointment which is usually \$75.00 (less rebate from Medicare) and the cost of the script around \$30.00. This is to buy a product that is currently around \$10.00. There is also the cost to business for the employee attending a doctor, whereas they could visit a chemist during a lunch break, for example.

There are a number of people who get headaches at work due to poor posture, or air conditioners blowing on them, etc. People also suffer pain from joint injuries, arthritis, and other conditions. These are ordinary people who need to deal with higher than average pain, in order to get on with their lives. This does not appear to be the area of concern that the TGA has.

For people with severe or chronic pain, due to accidents or injuries, they may have to visit a doctor every 7 – 14 days. Again this becomes a huge cost to Medicare, a huge cost to the person concerned, and a huge cost to the business community. This also clogs up the medical system when it is already difficult to see a doctor. Our GP is often booked up a week in advance.

Surely, it would be easier for a person with severe or chronic pain to obtain a letter from their doctor confirming this. This could be renewed every 6 – 12 months.

The pharmacy suggestion of tracking purchases of codeine products is not going to identify those people with severe or chronic pain, compared to those who do have an issue with addiction.

If a person wakes up with a headache, or develops a headache at work, or has a migraine, they may have to wait up to three days to see a doctor to obtain relief. Similarly, if a person develops a cold or flu, they may have to wait three days to see a doctor. Alternatively, they may see any doctor who is available, at any medical practice, rather than their own GP. This seems to be an impractical solution to the problem, particularly as many medical practices are not taking new patients. For parents with children who suffer from migraines it will be very distressing to have to tell a child that the doctor is booked up, and they cannot have any medication.

Similar arguments can be raised for products containing codeine such a cough medicines. Most people will take cough medicine only for a day or two.

For those people who do have an issue with addiction, there has been no mention of programs to assist them. By removing the source, this does not solve the issue. This could result in people who are addicted changing to illegal drugs.

The fact that codeine products cannot be purchased over the counter in some countries, does not make it the right decision to introduce into Australia. Ignoring, the cost, it would be a lot different if a person could immediately get an appointment to see a doctor, but this is rarely the case.

Because chemists can provide medical certificates, it also seems reasonable for them to make a decision about the appropriateness of the product for the person. This could be backed up by a register of codeine usage. For those with chronic pain they could have a letter or certificate from their doctor.

It seems that the AMA supports the proposal because it means more people will have to visit a doctor. It ignores the practicalities of actually getting to see a doctor. In cases of severe pain, when it is not possible to get a doctor's appointment, people may be forced to attend the emergency department at the closest hospital. Again, this is a poor usage of resources.

Other practical issues:

- Will doctors be able to provide repeats for a script?
- If painkillers are only available on a script, will packets of 100 be available, rather than

- packets of 40?
- Will different strengths of codeine be available, as is currently the case with 8mg, 10mg & 15mg products (before moving to the stronger medication currently available on prescription)?

This could also result in a culture whereby people stockpile medication in case they need it, rather than purchasing when required.

There was also a news headline that supported making codeine based products prescription only, as the deaths had doubled. Firstly, this appears to exaggerate the problem, as the total number of people involved will still be a very small percentage of the population. This is a bit like saying that no one should drive cars because people get killed on the roads. There must be a practical and balanced outcome that does not result in a large cost to Medicare, the large cost to the consumer, a large cost to business through lost time at work due to employees attending doctor's appointments, or inefficiencies at work where employees have pain, can't concentrate and are unable to see a doctor.

[REDACTED]

I trust that the TGA will take a more practical approach.

[REDACTED]

[REDACTED]

From: [REDACTED]
To: [Medicines Scheduling](#)
Subject: Submission on the proposed rescheduling of codeine
Date: [REDACTED]

This email forms my submission. There is no attachment.

The first part of this submission is private and must be kept confidential.

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

I will keep using codeine. No substitute over-the-counter medicine can replace it: paracetamol in a dose that would work for my pain would poison me; ibuprofen has little analgesic effect on me.

Consequently I will need to visit my GP more often, sometimes just to stock up on painkiller even if I am not in pain at the time. This will:

- Cause a road trip that is currently unnecessary, increasing traffic congestion and risk of accident.
- Waste two hours of my day in travelling to the clinic and sitting in the waiting room, where other patients might transmit their diseases to me.
- Put additional strain on the clinic to fit my appointment in, prompting some patients to consider going to a hospital emergency room instead.

I imagine that this situation is common. Multiply the above consequences accordingly.

I am responsible with my medication. You do not need to worry about me becoming dependent on codeine. You do not need to worry about me overdosing.

You do need to consider the unintended consequences of your decision. I have read the proposal and although you have raised all of the points that I made in this submission, you have not explained why they are not a problem. I don't believe that you have factored them into your decision.

Please consider a less drastic solution than requiring patients get a prescription to obtain codeine.

[REDACTED]

Official Opposition to TGA Proposal to Reschedule Codeine Products

I am 100% opposed to this proposition. I am a [REDACTED] that has had chronic [REDACTED] issues for the last [REDACTED] years. Not restricted to [REDACTED]
[REDACTED] There is no procedure that can be done to cure it other than management through flares as described below.

I mostly manage my pain through exercise and trying to keep mobile, however on the days when I do flare up (maybe I have [REDACTED], or sneezed the wrong way, or [REDACTED] [REDACTED]) going to a doctor is useless and a waste of their time and resources that could be used for someone more in need than I. However in conjunction with my health care team, we have discovered that self-management when it comes to purchasing my own [REDACTED] and Anti Inflammatory works best.

Making me go to the doctor would just be a punishment, and increase the cost, not only to myself, but the government too. Especially as I would have to go to a Bulk Billing doctor for the 3 minutes it would take for them to tell me to go get some [REDACTED].

Please don't add more stress and anxiety to my life by making me waste the time of the Health Professionals that keep our society healthy. Don't punish the 98% of people doing the right thing, for the 2% of people that decide codeine is the best way to off themselves, they would do it another way if they weren't able to get a hold of it.

By the logic of someone may take too many, well we should make some supplements and things like alcohol, and water prescription only. Did the TGA know you can die from too much water? It's freely available from a tap! THE HORROR!

Anyway I know this is disjointed [REDACTED]. But the message is all the same. Please don't punish the many for the mistakes and stupidity of the few.

Sincerely,

[REDACTED]

Comments on Interim Decision by the Scheduling Delegate to Reschedule Codeine for the ACMS, October 2015

Good day,

I would like to offer thoughts and suggestions on regarding the recent scheduling delegate's decision to remove codeine from Schedule 3 which enables consumers to buy some codeine products over the counter.

I believe some of your conclusions regarding the use of low dose codeine such as in Panadeine are not completely accurate:

1. You state in your reasons that use of OTC codeine products is not *efficacious*. Ie "While agreeing that efficacy remains important to any case justifying OTC supply of codeine, the Committee noted the Codeine Working Party advice that there was not sufficient information available to the Members at this time to resolve the question of codeine efficacy at $\leq 30\text{mg}$."

I have used low dose Panadeine for years and when I have had the need mainly for a headache or similar I have found [REDACTED] tablets works wonders quickly and enables me to be functioning again. ***I have to be blunt and state that it is very efficacious for me.***

2. It is stated in the reasons "Potential unintended consequences and disadvantages of a decision to reschedule CCAs to S4 need to be considered. One would be a reduction in the availability of analgesics for moderate to severe pain, although the evidence suggests that the addition of codeine adds only a minor additional analgesic effect over and above that of the ibuprofen or paracetamol in the combination product." Also it was stated "Potential unintended consequences and disadvantages of a decision to reschedule CCAs to S4 need to be considered. One would be a reduction in the availability of analgesics for moderate to severe pain, although the evidence suggests that the addition of codeine adds only a minor additional analgesic effect over and above that of the ibuprofen or paracetamol in the combination product." These clearly suggest codeine adds little to paracetamol in relieving minor pain. ***I have clearly found that using paracetamol by itself does little for me, but adding small amounts of codeine is very effective.***
3. I note in the reasons for the decision that it is stated "In February 2009 NDPSC decided that Based on the currently available information from Australia, the evaluator concluded that there was potential for significant harm from OTC

combination analgesics containing codeine (CACC) and even death, and it was not possible to accurately estimate the associated risk, although the following were reasonably assumed:

- the proportion of all users that abuse OTC CACC is low.
- the risk of harm among all users of OTC CACC is low.
- the risk of harm among abusers of OTC CACC is high.”

I would contend that this analysis is probably still valid and the proportion of users abusing OTC CACC is low.

I contend the majority, like me are sensible and do not abuse the products. Yes there are undoubtedly some stupid people who abuse the products.

4. I note in this reason “Concurrently the Advisory Committee on the Safety of Medicines (ACSOM) has recently considered the risks of codeine use in children, and codeine use in persons who are ultra-rapid metabolisers of codeine..... The committee noted that the OTC availability of codeine-containing medicines supported a general perception in the community that codeine is safe....”

I am not sure that it is correct that the public as a whole thinks this. However it would be wise to better and more clearly label such products should not be used regularly or in high doses. There is enough information out there for the public to become aware that too much codeine is a NO NO as it is a derivative of poppies and also that too much Panadol is not good for the liver. I personally have always treated any codeine products with care and never abuse them.

Why it's Important for Me

I [REDACTED] as a retiree. Especially on long backpack journeys I have found it important to carry various medicines for food poisoning, diarrhoea and pressure headaches. In Australia many bushwalkers drink the water straight from the streams and it usually safe and Namadgi and Kosciuszko areas near Canberra fit that criteria. However you have to be prepared.

I have found that coming out of a few weeks of non-walking and then undertaking a long hard backpack causes extreme stress and pressure on one's body. A heavy pack does also seem to constrict blood flow to the neck on occasions. I have found that especially on the first day out I am more susceptible to getting a severe headache in mid-afternoon which would make it hard to function. I have found that taking [REDACTED] Panadeine or equivalents stops the headache and make me more functional. Usually I dont seem to find the 2nd or later days much of an issue unless I get placed under severe stress, which can occur if I got lost or the weather for example turns bad.

Either way I rarely take more than [REDACTED] Panadeine tablets and probably use around [REDACTED] a month overall. I have done this for years and never ever felt the need to take more. I firmly believe in these low doses the product is quite safe.

Because I do some backpacking and day walking I tend to carry various medicines in several bags: ie kit inside the pack and then ready access pouch around the waist. I also would have separate pouch for biking. So combined with keeping some tablets in my car I probably buy a lot more Panadeine or equivalents than I need or use. Of course I have found over time that I have to regularly replace items as they go out of their use by date.

So the result of your rescheduling, ie the need to get a prescription will cause me much angst and time and money having to visit my GP more regularly. I clearly do not over use low dose codeine products but use them wisely and effectively.

Time to use the Technology we have

I note in submissions received some people suggested pharmacies should monitor usage against individual using on line databases.

Surely it is time to use the technology we now have and force chemists to use a Medicare card or similar to quickly check the amount of product any person was buying. I think the same sort of solution should be forced on GPs who would find it useful in the long term.

I guess this is not the responsibility of the TGA itself but I am sure you must be able to see the long term benefit in such solutions and your Minister would have to be pivotal in driving such an outcome. It would be extremely beneficial for tracking all drug use.

Regards

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

From: [REDACTED]
To: [Medicines Scheduling](#)
Subject: Concerned about the Re-Scheduling of Codine products.
Date: [REDACTED]

To whom it may concern,

I would like to voice my Disappointment at the TGA, wanting to change the regulations on being able to buy Codine products over the counter,, I STRONGLY DISAGREE, with this, not only as it will cost more money to have to go see your doctor to get a prescription, the time and energy that it will take away from the doctors to do so,,, But also as it will cost the Medicare system as well..

If there is a concern of Misuse of these products, Why not implement a monitoring system like there is on such products like " [REDACTED] " so the persons abusing them can be monitored and limited.

As a casual user of this product ([REDACTED]), i find this new regulation as an Infringement of my rights, and should not be penalized for using this product correctly..

Yours sincerely [REDACTED]

Individual Submission regarding Proposed Amendments to the Poisons Standard (Medicines), Low Dose OTC tablets containing Codeine.

Introduction

This is an individual consumer submission, and relates only to our tablet experience, not to cough mixtures. We did not make a submission in response to the TGA's original invitation of 2 April 2015, because the invitation received limited or no publicity to the general public or to us. The Interim Report says that because we made no submission to the original invitation, this submission may not be considered. The original submission's required Cover Sheet provides 21 Stakeholder classifications, of which only the last, "other", is appropriate for individual consumer input from the general public. We request that this submission is considered, as part of a reasonable consultation process which should allow individual submissions from the general public, who are the Stakeholders most likely to be affected personally.

The quality of life for millions of people has been greatly improved by effective, cheap, readily available pain killers. Personal self-management of pain may be a more sensible option than joining the queue at the doctor's surgery. It is quicker, and less likely to lead to inappropriate interventions with poor side effects. It is cheaper for the individual and the community. Before changes are made to the availability of medications, there should be more adequate research than appears to exist.

Summary:

This submission is from us as individual members of the public. It relates only to our tablet experience, not to cough mixtures. In summary, the Interim Report is wrong in the following ways:

- 1. Low-dose codeine tablets are genuinely effective for many people.**
- 2. The proposed 'gap-filling' alternatives are neither effective nor safe for many people.**
- 3. The Interim Report repeatedly refers to a lack of evidence and data on many issues, but nevertheless makes its statements and conclusions without the evidentiary backing.**
- 4. It emphasises risks related to abusers, who have adverse health effects from any drug of abuse, without an adequate balance of the benefits in normal proper use.**
- 5. It emphasises risks related to uncommon medical side effects, and does not deal with alternatives to control 'side effect' problems.**
- 6. It provides no cost for implementing its recommendations, for individuals or for the public health budget. This is not an acceptable approach to public health measures.**
- 7. It does not acknowledge or respect the ability of many thousands of people to self-manage their own pain control.**

The submission is provided under the following headings:

- **Alternative pain management options:**
- **Adverse effects related to abuse:**
- **Medical side effects:**
- **Cost:**
- **Personal information:** (to explain why this TGA proposal has been such a concern to me and my husband).

My take on the Interim TGA Report is that it makes a lot of guesses that are not backed up by solid research, to solve problems that don't apply to most people. Please think again!

Alternative pain management options:

1. You say “A recently released combination of two non-opioid analgesics (ibuprofen plus paracetamol) appears to be more effective than the CCAs, with a number needed to treat (NNT) of 1.5. This combination would fill any gap left by the unavailability of CCAs over the counter.”

This stated combination does not fill the gap for many people and some types of pain.

- a) Ibuprofen is an anti-inflammatory. My GP tells me that in 10% of the population, anti-inflammatory drugs can cause pain and adverse effects in the digestive tract. With additional pantoprazole, ibuprofen is tolerated by another 5%. I am in the remaining 5%. I must never take ibuprofen or aspirin.
 - b) Recent health reports have questioned the effectiveness of paracetamol for some types of pain, particularly back pain. Paracetamol has no impact at all on my thoracic back pain.
 - c) What is the data on efficacy and safety of this 'gap-filling' combination at raised user levels, as opposed to the fact that the recommended dose is lower?
 - d) How is the safety of this combination compatible with the adverse effects associated with anti-inflammatories for very large numbers of people, in Australia and generally?
2. You say “There is no evidence that low dose codeine combination analgesics provide any additional analgesia over optimal dosing of paracetamol, aspirin or ibuprofen.”
 - a) Our 'Personal Information' explains that this is directly counter to our experience.
 - b) Why is there “no evidence”? Who has looked for it? As codeine is out of patent protection (cf ibuprofen), perhaps there is no incentive for research?
 - c) If there is “insufficient data on efficacy”, why not focus first on obtaining the data, before making pain management more difficult for many people?
 3. You suggest that codeine phosphate in any dose is inappropriate for chronic pain.
 - a) Why is it inappropriate (apart from the regulation classifications)? What is the evidence for this statement?
 - b) Even if inappropriate for chronic pain (and my husband's experience is most definitely that this is not true), there are many situations in which a chronic problem is punctuated with acute episodes. People in this situation normally have long term experience in self management. Both [REDACTED] are in this category. Our GP is well aware of it and monitors it (eg regular [REDACTED] checks for [REDACTED]). We should not be forced back to the doctor for regular prescriptions. It wastes his time, and undervalues our own self-management experience.

Adverse effects related to abuse:

1. You say “Codeine is emerging as an increasingly commonly used drug of abuse internationally and in Australia,” and is an “opioid drug of dependence”. My professional experience in reviewing [REDACTED] in [REDACTED], where many residents have substance abuse issues allied to mental health issues, is that at least in the longer term, substance abuse can be a choice. If one substance of abuse becomes more difficult to access, it is replaced with another substance. Abusers in SRFs swap tablets and prescriptions, know how and where to doctor shop, and access illegal drugs if available on their limited incomes.

2. It is not surprising that a “recently published study of 902 people who inject illicit drugs found that about one third had misused OTC codeine during the preceding six months”. They may well have used several other licit and illicit drugs as well. Equally, it is not surprising to hear an anecdote that “some abusers of OTC codeine products are consuming 30 to 70 tablets/capsules per day”, with “severe adverse outcomes associated with over dosage of the paracetamol or ibuprofen component”. It is difficult or impossible to protect serious drug abusers from damaging themselves. Removing the paracetamol or ibuprofen component might actually be a more reliable method.
3. As OTC codeine products have been available for many years, it is difficult to see the reason for its abuse becoming 'increasingly common'.
 - a) What research shows if and **why** codeine “is emerging as an increasingly commonly used drug of abuse”, in view of its long term availability?
 - b) What (non-anecdotal) research indicates the scale of abuse of high volumes of low-dose OTC tablets, by people who abuse codeine but do not abuse other drugs? There may be very few. Please provide details of this research this before penalising people who use codeine for pain management, not as a drug of abuse.
4. The management of drugs of abuse is itself quite controversial. Codeine may be a drug of addiction for some people, while doing very little damage to society. No-one needs to rob, steal, or break and enter a pharmacy to obtain Chemist's Own Pain Tablets at \$8 a packet. Low dose codeine will not lead to domestic violence, dangerous driving, or meth rage. It will not tip the balance for schizophrenia. Compared with the availability for adults of legal though addictive cigarettes and alcohol, only a small percentage of low-dose codeine users will have serious adverse health effects.

Addiction without damage raises special control issues. As a comparison, very high caffeine intake could quite realistically be classified as “an increasingly commonly used drug of abuse internationally and in Australia”, but we don't propose to outlaw coffee shops because we expect coffee drinkers to cope with the side effects themselves.

- a) What assessment has been made of the social damage caused by the abuse of low-dose OTC Pain Tablets, compared with the social damage of other substances of abuse?
- b) What advice has been sought from the health professionals who work with abusers, and what research has been done, as to the appropriate management of 'substance abuse' related to low-dose OTC Pain Tablets?
- c) What thought has been given to the next substance likely to be abused, if codeine availability is restricted and abusers look for an alternative? Meth/s is no improvement.
- d) The TGA's reduction in 2010 in CCA packet size to five days' supply did not work (ie “has not achieved the required reduction in harm to affected individuals”) because abusers simply chemist-shopped for more packets. Abusers also doctor-shop, and swap prescriptions. The TGA needs good knowledge of abuse and abusers before making restrictions intended to limit abuse.
- e) What awareness do TGA members have of substance abuse minimisation strategies generally, and in particular with the argument that more harm is done by regulation than by the drugs themselves?

Medical side effects:

1. You say “The major impact on public health of the proposed amendment would be a reduction in the risk to those individuals who, unbeknownst to themselves, have a rapid metaboliser phenotype of CYP4502D6 and are therefore at significant risk of excessive

morphine concentrations following ingestion of usually recommended doses of codeine for any indication.”

- a) What is the incidence of adverse codeine effects for people with a rapid metaboliser phenotype genotype? (The Report actually suggests genotype, not phenotype.)
- b) What percentage (and actual number) of adverse metaboliser incidents stems from high codeine intake as compared with low codeine intake? What percentage stems from low-dose OTC codeine tablets? What proportion of these last are a substance abuse problem related to high volume abuse of low-dose tablets? Finally, to what extent are these side effects actually related to normal occasional use of low-dosage tablets?
- c) If 4% to 10% of the public has rapid this metaboliser status, and is affected by low dose OTC use, surely the problem would be better known? If not, why not?

2. You say that “Individuals rarely know their metaboliser status, and testing is not readily available”.

a) Are people who obtain a GP prescription for paracetamol/codeine phosphate at 100mg/30mg high strength ('Forte') routinely checked for rapid metaboliser phenotype? (Answer: no) Why not, if this problem has a “major impact on public health”?

b) How will the problem be solved by a requirement for a GP prescription, if the GP does not know the metaboliser status of the patient?

c) Our experience is that a GP visit does not ensure that “consumers can be warned about the potential risks and adverse effects can be more closely monitored”. Beyond “*come back and see me if you have any problems*”, we can only remember one doctor's warning in several decades about possible medication side effects, and that was from a specialist [REDACTED] about [REDACTED] medication.

d) Is a check for “rapid metaboliser phenotype” made in hospitals where high-dose opioid painkillers are used or (more likely) provided on discharge? (Answer: no) Why not, if this problem has a “major impact on public health”? What steps are being taken to deal this risk?

e) If people who are prescribed high-dose codeine tablets are rarely or never analysed for this phenotype, why focus on low-dose OTC tablets?

2. What other ways have been considered to cope with uncommon side effects? As you say, “Individuals rarely know their metaboliser status, and testing is not readily available”.

a) Many, if not most, medications have side effects, and a small percentage of users suffer disproportionately severe problems. Most people and their doctors cannot anticipate these severe problems. Packet information for most drugs usually provides information about common side effects, as well as warnings such as '*seek immediate medical advice if you experience ...*'. Why do you not require packet information about codeine risks for rapid metabolisers? If the GP cannot only provide a general warning, surely this should go on the packet?

b) Why not require adverse symptom information for low codeine doses, to put rapid metabolisers on notice before they move to higher doses? Consumer products from hair dye onwards often come with advice to try a low exposure first, and then check for adverse effects.

c) What other options for reduction of the risk to people with a rapid metaboliser phenotype have been considered, researched and publicised (including to GPs)?

d) Why single out the disproportionately severe side effects of codeine, compared with the disproportionately severe side effects of other drugs, both prescription and OTC. [Obvious examples are aspirin and ibuprofen, which have no packet information. Ibuprofen is even marketed on television as 'Nurofen® for babies', 10% of whom will be adversely affected but unable to tell]

3. You refer to the [REDACTED] brand, and to no other brands of low-dose OTC codeine product. Why? [REDACTED] containing codeine 15mg provide the highest tablet OTC codeine dose of any brand of which I am aware.
 - a) Why not limit the OTC dose to 10mg, which is more usual?
 - b) If as you say, the [REDACTED] instructions “suggest or imply that before taking codeine a person should know their CYP4502D6 status”, this knowledge will not be provided by restrictions requiring medical supervision because the doctor does not know either. My experience is that it is rarely possible to buy OTC low-dose codeine without a stern lecture from a bright young pharmacist relating to “the risks of excessive opiate effect”, but never have [REDACTED] had a recommendation to learn my CYP4502D6 status from a pharmacist or from a GP.

Cost:

1. There is a high dollar cost to people with pain, and to the tax-payer, in making low-dose codeine combinations prescription-only. [REDACTED] once asked our GP for a script, to avoid having to justify himself to pharmacists. Our GP said 'sure, but it will cost you three times as much for the pharmacist's dispensing fee as it would cost to buy off the shelf'. This does not include the cost to Medicare of the doctor's visit, the gap fee to us, or any subsidy to the pharmacist. Any limit on the duration of the script, the number of repeats, or the quantity per packet, would make this even more expensive and more annoying.
2. The Minister of Health has just released a paper regarding a review of Medical Benefit items to restrict unjustified costs. The ABC's 4Corners “Wasted” program provided shocking information about the item-based incentive for GPs to refer patients for high cost tests, followed by over-diagnosis and undesirable follow-up medical interventions, with ever-greater costs to individuals, hospitals, Medicare and private insurers. Sending large numbers of pain sufferers to their GP for pain that they can manage themselves, is likely to increase this problem quite substantially. Why go down this path right now?
3. This paper provides no costing information regarding the cost of implementing these proposals, either to the public health care system or to individuals. As stated above, this includes the costs of a GP visit (Medicare and gap fee) and costs for the pharmacist (dispensing fee and subsidy). Any proposal should be adequately costed, when it is clear that the proposed changes may affect hundreds of thousands of people, and will potentially have a substantial cost impact for society generally.
4. The paper says that the reduction in 2010 in packet size to five days' supply “has not achieved the required reduction in harm to affected individuals... there hasn't been the reduction in risk that might have occurred”:
 - a) Surely the shortcomings of the TGA's previous interventions should be analysed before additional controls are imposed?
 - b) What has been the cost to users of the last limitation of availability, and to the pharmaceutical industry of the restrictions and re-tooling of packet size?
 - c) What has been the impact on those who cannot access a pharmacy each five days?
 - d) If CCA tablets are to be prescribed, presumably the packet size will increase. What arrangements have been made?
5. If this proposal is implemented, the unsubsidised cost of low-dose codeine tablets will more

than treble to people whose needs are not met by the proposed 'gap filler' paracetamol/ibuprofen combination. Unless the Pharmaceutical Benefits Scheme (PBS) lists low-dose codeine tablets before any changes are made, this trebling will include low income people on Health Care cards who normally pay \$6 for prescriptions.

- a) What arrangements have been made to get PBS listing before the proposed implementation date?
6. The last reduction in packet size was quite a nuisance for us, and achieved nothing. We live on a farm, the closest chemist is about 25 kms away, and he charges nearly double city prices. I go to the city about once a month, and then visit several chemists in a row to make sure we don't run out. I don't approve of chemist-shopping, and the whole thing is an embarrassing nuisance.

Conclusion:

In summary, this submission suggests that the Interim Report is wrong in the following ways:

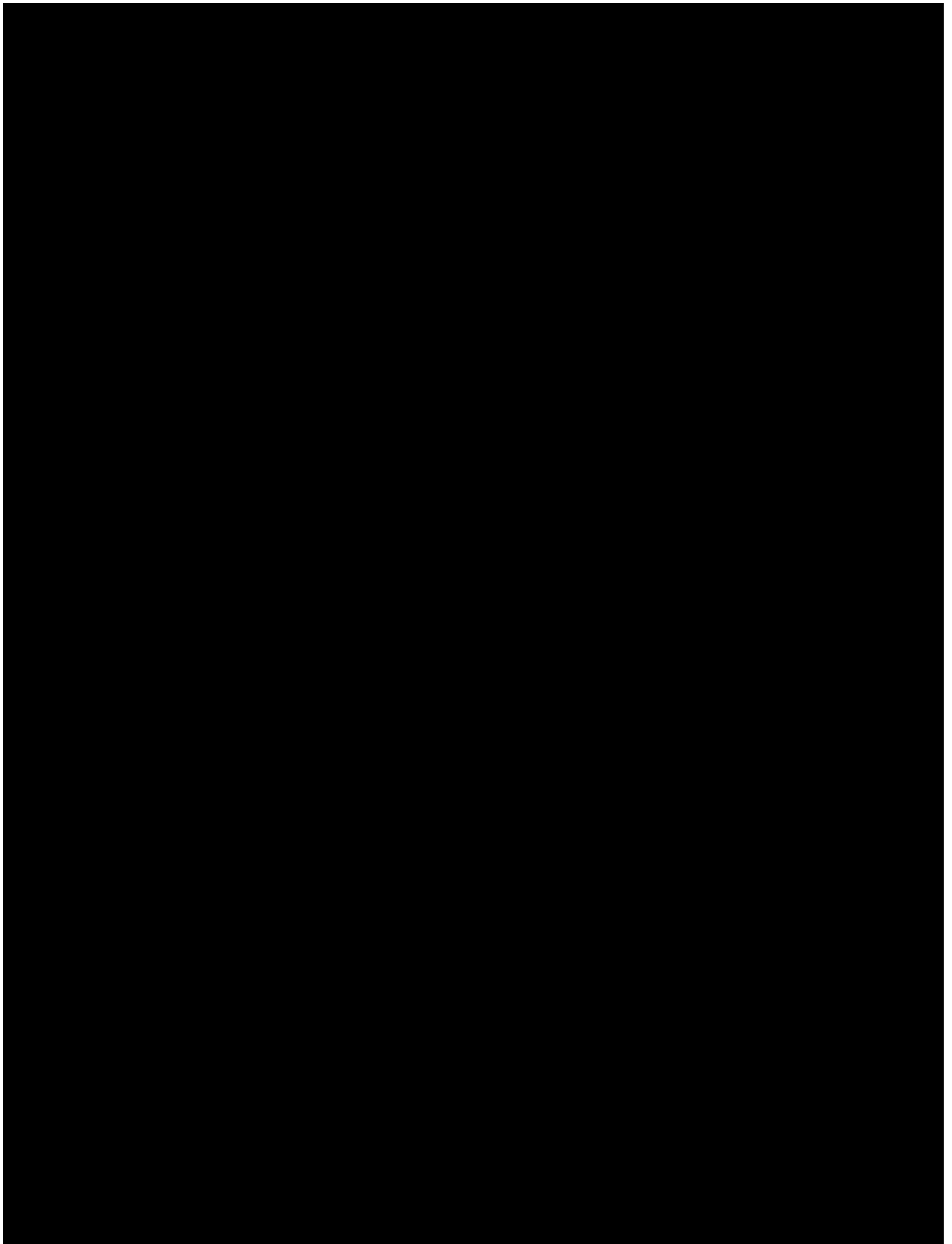
- 1. Low-dose codeine tablets are genuinely effective for many people.**
- 2. The proposed 'gap-filling' alternatives are neither effective nor safe for many people.**
- 3. The Interim Report repeatedly refers to a lack of evidence and data on many issues, but nevertheless makes its statements and conclusions without the evidential backing.**
- 4. It emphasises risks related to abusers, who have adverse health effects from any drug of abuse, without an adequate balance of the benefits in normal proper use.**
- 5. It emphasises risks related to uncommon side effects, and does not deal with alternatives to control 'side effect' problems.**
- 6. It provides no cost for implementing its recommendations, for individuals or for the public health budget. This is not an acceptable approach to public health measures.**
- 7. It does not acknowledge or respect the ability of many thousands of people to self-manage their own pain control.**

My take on the Interim TGA Report is it makes a lot of guesses that are not backed up by solid research, to solve problems that don't apply to most people. Please think again!

[REDACTED]

[REDACTED] :

[REDACTED]



Once again, we believe that this Interim Report shows insufficient respect for people's ability to self-manage their own health needs. Please think again!

Medicines.Scheduling@tga.gov.au

13 October 2015

Re: Scheduling proposals referred to the August 2015 meeting of the Advisory Committee on Medicines Scheduling (ACMS #15)

I am writing as a concerned Australian citizen and consumer regarding the proposal to re-schedule codeine products.

I oppose the proposal to classify all codeine products as S4.

Research suggests codeine is effective for acute pain which meets the claim of short term relief. A classification to S4 punishes legitimate users with acute conditions who use codeine responsibly. Consumers have already been punished by the TGA's regulation on codeine packaging reducing the size of non-prescription packages and therefore increasing the price per use of codeine. Legitimate consumers with large households are unduly affected already by the small pack size restrictions on codeine purchases, and will be further punished with the new S4 classification.

The administration costs and ongoing medicare payments that would result from the proposed rescheduling pose a poor use of tax-payer funds. It would also not achieve the stated goal of preventing codeine abuse as a mandatory real-time monitoring system across gp clinics is not yet in place.

It should not be the role of government to attempt to protect citizens from every possible substance vulnerable to abuse. For example, harmful alcohol and tobacco products are available over the counter to any adult in any dosage, and have arguably less therapeutic benefits than codeine.

Medical and pharmaceutical staff already treat any request for codeine as dependent drug-seeking behaviour, which needlessly prejudices the majority of consumers who are responsible, well-informed custodians of their own health. The rescheduling further stigmatises legitimate codeine consumers who consume responsibly and with attention to drug contraindications and safety information.

Permission is granted to repost this submission publicly provided that all identifying information (name, email address and address) are removed.

Yours sincerely

[Redacted signature block]

Introduction

The Problem

Proposals

I have observed over time the change of community attitude and improved control over the sale of pseudoephedrine products with the change in pack size and the entering of a consumer's drivers licence details into Project STOP. I support a similar system for codeine containing analgesics, as this will alert pharmacists to those consumers who are shopping around to support a dependency compared to those who have a short-term ailment.

We have to distinguish and identify the short-term users from the chronic users. By using a Project STOP type of system, the pharmacist can counsel the consumer who appears to be going to a number of different pharmacies for codeine, and refer them, in a non-judgemental way to a pain treatment centre or appropriately trained medical practitioner.

I feel that placing all codeine analgesics into schedule four will increase the burden on medical practitioners, as well as depriving those in the community who use codeine analgesics for short-term use only.

Consider reducing the pack size to 24 tablets or capsules and make it mandatory for pharmacies to use Project STOP to record codeine containing analgesics, as the system is capable of doing now. People accept the inconvenience of handing over their licence, so they can obtain a short term supply of medication to help their migraine or headache.

I request this system be implemented and reviewed in say, 18 months. If there has not been an improvement, then look to changing the scheduling of codeine containing products to schedule four.

This is an opportunity for pharmacists and medical practitioners and government to attack this problem head on. It will work if there are adequate resources available.

problem head on. It will work if there are adequate resources available.

Therapeutic Goods Administration

12 October, 2015

Dear Sir/Madam,

Re: Placing Codral Cold & Flu tablets on a Script-only list

May I please make an objection to this possible action. I don't believe that this is the most logical step to prevent drug abuse, and a step that will cause a huge number of flow-on problems for a great number of people.

. A large number of people like myself simply have respiratory issues. We rely on the Codral products to be able to breathe, function normally, and sleep.

. I work with the public and am very susceptible to colds. Each time I get a cold I require a minimum of two packs of [REDACTED] to get back to normal breathing, speaking without coughing, and sleeping, which can take up to two weeks to get back to normal.

. It can take up to a week to obtain a doctor's appointment in the country. I couldn't go for a week without sleep or normal breathing.

. I have friends in [REDACTED] who are still on the waiting list *to get a GP at all*.

. To take up scarce GP resources for simple headcolds is outrageous.

. If I had to go to a GP's surgery each time I had a cold, I would then pass the cold to a number of people in the waiting room, thus spreading the problem.

. Some years ago, customers had to sign to receive these products. Why can this system not be reinstated? The person's name could be on a data-base at the chemist exactly like it would be from a GP, requiring photo i.d.

Yours faithfully,

[REDACTED]

From: [REDACTED]
To: [Medicines Scheduling](#)
Subject: products with codeine
Date: [REDACTED]

I don't think there should be the need for a prescription on codeine products because of a few misusing the product , a prescription will not change that

[REDACTED] [REDACTED]
[REDACTED]

[REDACTED]
[REDACTED]
[REDACTED] [REDACTED]
[REDACTED] [REDACTED]

[REDACTED]
[REDACTED] [REDACTED]
[REDACTED] [REDACTED]
[REDACTED] [REDACTED]
[REDACTED] [REDACTED]
[REDACTED] [REDACTED]

The TGA is changing regulations to the availability of Codeine-containing products in Australia. From June 1, 2016, a doctor's prescription will be required for a patient to get codeine-containing medicines. I am emailing to voice my concerns about this change as a pharmacist and consumer.

The TGA is changing the regulations in the name of patient safety, based on a study analysing drug-related deaths between the years 2000 and 2009. This study found that only 8% of deaths analysed were due to codeine toxicity. However, this study has not specified which medicines were the cause and if they were prescription medicines. This means that these deaths may be due to S4 and S8 codeine based medicines, such as [REDACTED]. This study only concluded that strategies need to be implemented to ensure safe use of codeine. This study did not conclude that these deaths were due to over-the-counter codeine products. Thus, it is unwarranted that the TGA is targeting over-the-counter codeine products.

In addition, this change in regulation appears to be contradictory with the down regulation of paracetamol and ibuprofen based products. [REDACTED] can be purchased in supermarkets and other stores in unlimited quantity. There is no ethics or rules that restrict patients from purchasing several small boxes of these items. [REDACTED] is the cause of 150 hospitalizations per week in Australia. The Pharmacy Guild has repeatedly urged the TGA to remove paracetamol/ibuprofen from supermarkets for patient safety (reduce the risk of overdose and toxicity). The TGA has ignored all requests. Thus, in the name of patient safety, the TGA should be allowing pharmacists to regulate the usage of medicines, including paracetamol, ibuprofen and codeine products.

Pharmacists have a great avenue to identify patients who are over using pseudoephedrine – Project Stop. Project Stop can also be used to record codeine sales, thus, identifying patients who are over-using codeine based products. The Pharmacy Guild has offered adding codeine products to Project Stop; however, the government has always rejected this recommendation. If the TGA is aiming to improve patient safety and reduce harm to patients caused by codeine toxicity, the government should allow the Pharmacy Guild to include codeine based products on Project Stop.

Furthermore, the 6th Community Pharmacy Agreement allows pharmacies to broaden their role as medicines experts and primary health care providers, through programs such as medschecks, HMRs, and clinical interventions. It is clear that the government acknowledges pharmacists as capable primary health care providers. Therefore, rescheduling of codeine products is inconsistent with the broadened role of pharmacists from the 6th Community Pharmacy Agreement.

The rescheduling of codeine based products negatively impacts the economics of the government. At a time where the government should be conserving their expenditure, this rescheduling can increase healthcare costs by \$675 million annually. There will be an increase the workload of doctors, waiting times, and the cost to the public to visit the doctor. Overall, it creates great inefficiencies to the health care system.

As a consumer, over-the-counter codeine products are very effective for the relief of minor ailments, such as headaches, period pain, and back pain. It is a great inconvenience to have to go to the doctor every time I need [REDACTED] for any of those minor ailments. Due to cost, a need to make an appointment with the doctor, and high waiting times, patients will not have easy access to pain relief for minor ailments which worsens consumer health outcomes.

In conclusion, the rescheduling of codeine poses a burden on consumers, pharmacies, the healthcare system, and the government. This change is meant to be in the name of patient safety; however, there is no evidence to suggest that it is specifically S3 codeine-containing products that are resulting in patient deaths. As well, there is no guarantee that rescheduling of codeine to S4 will reduce harm and toxicity to patients, especially when the deaths in the study may have been due to prescribed medicines. The rescheduling of codeine puts an unnecessary economic burden on the government and the consumer. It is impractical to ask patients to see their doctor for minor, self-limiting ailments. Last, a practical alternative solution is to allow pharmacists, who play a critical role in primary healthcare, to monitor and assess the need of codeine-containing products for patients (as they always have). By adding codeine-containing products to Project Stop, pharmacists will be able to view a full history of purchases for these products, allowing them to make a more informed decision. This solution improves patient safety and does not pose a burden to consumers, the government, or pharmacies.



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AMA submission – TGA/ACMS codeine scheduling interim decision

medicines.scheduling@tga.gov.au

The AMA supports the interim decision of the delegate to remove codeine preparations from Schedule 2 and 3, based on the advice of the Advisory Committee on Medicines Scheduling (ACMS).

The AMA considers it is important to support the independence and evidence-based approach of the ACMS.

We maintain our position that ACMS needs a practising general practitioner to provide first-hand experience of the likely impact of scheduling decisions on patient management.

It will be necessary to introduce this change together with a comprehensive education campaign targeting both consumers and health practitioners that clearly explains why the decision has been made and provides full information on effective and safe over-the-counter alternatives.

The AMA continues to advocate for the implementation of the Electronic Recording and Reporting of Controlled Drugs system in each state and territory. This system would allow doctors and pharmacists to monitor in real time the prescribing and dispensing a range of medicines with the potential for misuse and harm, not only Schedule 8 medicines.

OCTOBER 2015

Contact

[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

TGA/ACMS codeine schedule 4 proposal

I feel compelled to write of my opposition to the proposal to have Codeine obtainable only by prescription!! As a law abiding sensible adult I am sick of being penalised for the actions of a few people who choose to abuse themselves and the system. Why should the majority of people who do the right thing be made to jump through hoops for a [REDACTED]? I'm responsible, I follow the manufacturers directions and operate within the existing parameters whilst those abusing these drugs manage to work their way around the controls in place, no matter what they may be – just look at the Ice problem. Making me pull out my license for a cold tablet because they use Pseudoephedrine hasn't changed the behaviour of addicts, suppliers or manufacturers of the drug – they seem to access it from other sources and without going through the processes we all endure. Additionally many just pop over to Bali (and many other places) where they can stock up on these drugs without worrying about such controls. I'm told that in Bali you can get [REDACTED] over the counter no questions asked and no limits.

Currently to see my doctor I have to plan a week or two in advance and now you're proposing that I must try and get additional appointments when I have a headache or a cold – how ridiculous and utterly wasteful!!! I find it very difficult to believe that this is workable in our current health system. Such a change will waste the time of Doctors and patients which is an ill conceived idea, especially when we already have Pharmacists who are able to vet access to drugs. Our health system barely copes with the current system and your proposal will only place more pressure on doctors and their patients. I only use one pharmacy and when I purchase medications I have a conversation with the Pharmacist or an Assistant on its safe use and their checking that it doesn't conflict with other medication. Isn't this enough? You're not only be causing the average consumer problems, additional costs and inconvenience but making it harder for Doctors and Health Services who are already under too much pressure as it is. My doctor already works long and hard and gives his best I can't see how he can accommodate seeing even more people simply because they need a prescription for basic pain relief. I'm unable to take Ibuprofen so codeine tablets are what I use for pain relief. If I get a cold or a migraine I don't bother making an appointment to see my doctor as there isn't anything he can do really but under your proposal I would need to do so and I'd need to make an appointment as soon as it starts rather than just taking myself off to bed to try or soldier on! Please see reason and act sensibly on this proposal by not going down this path.

The majority of people do the right thing, they stay within the rules and exercise care with their dosages and you are suggesting that the system should penalise them again because of that small group who will always disobey rules and push boundaries without care or caution. Why don't we enact rules and regulation that don't impact so heavily on the average Australian but actually target the problem people. Maybe enable Pharmacies to extensively question and check those customers who aren't regulars. There are so many drugs available over the counter that are dangerous when directions aren't followed, are we going to make them by prescription only too???? We have to draw a line and accept that some people will abuse the system no matter what controls are in place but this shouldn't mean the rest of us have to suffer for their actions – let them suffer the consequences of their choices and let the rest of us get on with life with the help of accessible medication when you pick up a cold or a headache gets too much!

Yours sincerely

[REDACTED]