

A U S T R A L I A N

# Medicine

The national news publication of the Australian Medical Association

# The facts about codeine

**AMA backs the  
independence of the TGA**



**AMA**

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**SPECIAL  
EDITION**



# TGA's independent ruling on codeine is the right one



AMA President Dr Michael Gannon has strongly condemned the Pharmacy Guild of Australia for its “irresponsible and unprincipled lobbying of State and Territory Governments” aimed at undermining the independent Therapeutic Goods Administration (TGA).

The TGA has ruled that codeine will become a prescription-only medicine from February next year.

The AMA has welcomed that decision, saying codeine can be a harmful drug if misused.

But the Guild, which represents pharmacy owners, is against the TGA ruling and has lobbied State and Territory governments, calling for codeine to continue to be available over the counter.

Patient advocacy groups such as the Consumers' Health Forum and Pain Australia support the decision; other groups publicly supporting the TGA include the Rural Doctors' Association, the Royal Australian College of Physicians, the Royal Australian

College of General Practitioners, and the Australasian Chapter of Addiction Medicine.

State Governments appear to have buckled to the Guild's strong-arm lobbying.

Dr Gannon said any such move to “get around” the TGA – an independent federal body – would put patients' health at risk.

“It is essential for public safety that the TGA makes evidence-based decisions about medicines, free from political interference and sectional interests,” Dr Gannon said.

“As doctors, we rely on the independence and expertise of the TGA to ensure Australians have access to safe, effective, and high quality medicines.

“There is compelling evidence to support the decision to make codeine prescription-only. Deaths and illness from codeine use have increased in Australia.





## TGA's independent ruling on codeine is the right one

... From page 2

"A 2016 survey showed that 75 per cent of recent painkiller or opioid misusers reported misusing an over-the-counter codeine product in the previous 12 months. Tragically, the survey showed these products were even more likely to be misused by teenagers.

"Under the new arrangements, patients who have short-term pain will still have access to alternative over-the-counter painkillers, which are more effective than low-dose codeine, but without codeine-associated health risks.

"It is better for patients with chronic pain to manage it with doctors' advice on appropriate medicines and non-medicine treatments. Self-treating long-term with codeine is dangerous."

When the TGA announced its decision, the AMA warned that some groups would put self-interest ahead of patients' best interests by using highly-paid lobbyists to influence or coerce State Governments to change, delay, or dilute the impact of the TGA decision.

Dr Gannon said that fear was realised when the Guild announced in early October that it had won support from the NSW Nationals, and then most other State and Territory Governments wrote to the Federal Minister expressing concern about the upscheduling.

The AMA fully supports the independence of the TGA in making decisions about medicines scheduling and will actively support the TGA codeine decision by intensifying its efforts to work with all governments to respect and uphold the evidence-based rulings of the highly-respected independent regulator.

"We will be urging the Pharmacy Guild and others groups who seek to undermine the TGA to reconsider their actions and put the health of Australians first," Dr Gannon said.

"The AMA supported the independent scientific advice of the TGA – the authority that's responsible for determining which medications come in, how they come in, and how they're made available.

"They looked at the science, looked at the increasing understanding of the risks of codeine use, made a determination, and gave that advice to Federal Health Minister Greg Hunt, who

**"...evidence shows that codeine is not that good an analgesic and doctors should be prescribing superior alternatives for acute pain, and codeine has no role in the management of chronic pain."**

**"Too many people are found with codeine in their body at post mortem examinations. This is a harmful drug. It's hurting people, it's killing people."**

**"There is compelling evidence to support the decision to make codeine prescription-only."**

**"We already know that pharmacist control of codeine use does not work."**

**AMA President Dr Michael Gannon**

agreed, with the full support of the AMA.

"And, we thought, with the support of the Pharmacy Guild, the Pharmaceutical Society, and certainly other medical bodies like the College of GPs, and the College of Physicians.

"Australia would join the situation in roughly 25 other countries that you need a script to get codeine.

"But we have now seen the Guild going out and doing what they're good at – lobbying politicians hard. They're very well resourced, but they're wrong on this.

"The AMA will continue to make the case that the TGA has made the right decision. It's long overdue. Codeine is a harmful drug. And do you know what? It's not even that good a painkiller. There are better alternatives."





## TGA's independent ruling on codeine is the right one

... From page 3

The Committee who reached the decision was comprised of medicines experts – including pharmacists.

The Guild claims that it is not seeking to overturn or disregard the TGA decision, yet it has taken every opportunity to criticise the ruling to upschedule codeine to prescription-only.

The Guild alleges it is only wanting a “part reversal” of the decision, but its lobbying suggests otherwise, and has sought to link the decision to upschedule with prescription monitoring.

Dr Gannon said that the Guild was being “a bit too cute” for his liking.

“I’d like to know exactly what they mean by a part reversal,” he said.

“We should be reassuring the public that they can buy more effective and safer over-the-counter medicines at their local pharmacy. Their short-term acute pain will be eased without codeine. Instead, the Guild is claiming that people in rural areas without easy access to GPs will suffer. This is simply not true.

“People with chronic pain should not be using over-the-counter codeine at all. People with chronic pain can be helped to manage it with doctors’ advice on appropriate medicines and non-medicine treatments. Self-treating with codeine is dangerous.”

Dr Gannon said if codeine was invented next week, it might

struggle to get listed. When the harms it causes and its ineffectiveness at low doses are looked at, it might struggle to get on the formulary today.

“At low doses it’s no better than the standalone agents like paracetamol and anti-inflammatory, and at high doses it is increasingly a drug of abuse,” he said.

“So there’s no argument here. I’m not interested in GPs, other specialists, prescribing yet more and more codeine. The more we know about this drug, the more we realise that we should be looking for more effective and safer alternatives.

“I’ve written up codeine prescription for patients for a long time, up until about three or four years ago when I started to become apprised of the evidence. I’ve had to change my practice. That’s true of many, many other doctors and look, that’s what we do in the medical profession: we look to new robust evidence and we change our practice.

“Codeine is a drug that’s found in too many people’s systems. We’ve seen the Victorian Coroner’s report. Too many people are found with codeine in their body at post mortem examinations.

“This is a harmful drug. It’s hurting people, it’s killing people.”

CHRIS JOHNSON

**“The peptic ulcers can also be lethal. In fact, one of my worst moments in the last few years was when I was up all night with a young man who was otherwise well, who was bleeding torrentially from a giant ulcer in his stomach, which was caused by compound analgesics.”**

***Dr Aidan Foy, Director of General Medicine at Newcastle’s Mater Hospital***

**“For acute pain most of the studies show that the combination of paracetamol and anti-inflammatories works as well, if not better, and without the risks of codeine.”**

**“There’s reasonable evidence to say with certain types of pain that if you go on for a week or more with opioids therapy then that leads to worse outcomes.”**

***Dr Chris Hayes, Dean of the Faculty of Pain Medicine (FPM)***





# Codeine-containing medicines

## Harms and changes to patient access

### What's changing?

From 1 February 2018, medicines that contain codeine will no longer be available without prescription.

Your pharmacist will be able to help you choose from a range of effective products that do not require a prescription. If you have strong or chronic (long-lasting) pain you will need to consult your doctor, and if medicines are part of your treatment, a prescription may be needed.

### Why is access to codeine changing?

*Some Australians don't realise how much harm codeine can cause.*

Most Australians are unaware that over-the-counter medicines containing codeine for pain relief offer very little additional benefit when compared with medicines without codeine. The use of such medicines, however, is associated with high health risks, such as developing tolerance or physical dependence on codeine.

Codeine is an opioid drug closely related to morphine and, like morphine, is derived from opium poppies. Codeine can cause opioid tolerance, dependence, addiction, poisoning and in high doses, death.

### Codeine use can be harmful

Tolerance occurs when codeine becomes less effective and so the body needs higher and higher doses to feel the same relief from your symptoms. **Severe withdrawal symptoms** can result when the medicine is stopped; these include **head and muscle aches, mood swings, insomnia, nausea and diarrhoea**. Some of these withdrawal symptoms, such as head or muscle aches mimic the symptoms that low-dose codeine products are often used to treat, leading to people incorrectly continuing to take the medicine longer or in higher doses.

**Codeine poisoning** contributes to both accidental and intentional deaths in Australia. The codeine-containing medicines that are currently available over-the-counter are usually combined with either paracetamol or ibuprofen. Regular use of medicines containing codeine, for example for chronic pain, has led to some consumers becoming addicted or tolerant to codeine without realising it. Taking more than the recommended dose of combination products could result in serious side effects. Though safe at recommended doses, long term use of high doses of paracetamol can result in **liver damage** while the most severe adverse effects of long term ibuprofen use include serious **internal bleeding, kidney failure** and **heart attack**.

Codeine use can lead to tolerance, dependence, addiction, poisoning and even death

Major symptoms include:

Headache

Drowsiness

Dizziness

Addiction and tolerance

Difficulty breathing

Nausea

Constipation





Codeine is also sometimes used in medicines to relieve the symptoms of cough and cold, however there are safer and more effective medicines available that may provide relief from these conditions. Talk to your pharmacist or doctor for advice on what may be best for you.

## How and where to get advice

*Pharmacists have an important role to play in minimising harm from codeine.*

The current range of codeine-containing over-the-counter medicines will continue to be available without a prescription in pharmacies until 31 January 2018. Pharmacists will continue to be an important source of information and advice for consumers both before and after this date.

Most people should be able to manage acute pain or cough and cold symptoms with safer medicines. For acute pain, this may include products containing paracetamol or ibuprofen, or the two products in combination. Your pharmacist will be able to provide advice on the most appropriate medicines for you. Speaking with your pharmacist is particularly important if you have any other medical conditions, such as stomach, kidney, liver or heart problems.

## Talk to your doctor

People with ongoing pain should talk to their doctor or healthcare provider to determine better alternative treatment options. These may include: alternative over-the-counter or prescription medicines; non-medicine therapies from an allied health professional such as a physiotherapist; self-management tools such as exercise or relaxation; or referral to a pain specialist or pain management clinic.

Ask your doctor about a Medicare-funded care plan which will allow you access to a rebate for treatment from an allied health professional. Medicare provides a rebate for the preparation of a Chronic Disease Management Plan and a Team Care Arrangement. For more information see [www.health.gov.au/internet/main/publishing.nsf/content/mbsprimarycare-chronicdisease-pdf-infosheet](http://www.health.gov.au/internet/main/publishing.nsf/content/mbsprimarycare-chronicdisease-pdf-infosheet).

If you think that you are unable to manage without codeine and experience some of the side effects of withdrawal talk to your doctor about getting help.

## Next steps

A Nationally Coordinated Codeine Implementation Working Group (NCCIWG) has been established with representatives from state and territory health departments and peak professional bodies representing consumers, pharmacists and medical professionals. The purpose of this working group is to assist with the implementation of a communication strategy to help inform the community of the upcoming changes to the availability of low-dose codeine containing medicines from 1 February 2018.

Advice for pharmacists and medical professionals regarding the changes to codeine access and to help them provide the best advice to their patients will be made available on the Department's website at [www.health.gov.au](http://www.health.gov.au).

### For more information and support:

**NPS MedicineWise**

[www.nps.org.au](http://www.nps.org.au)

**Alcohol and Drug Information Service (ADIS)**

[www.drugs.health.gov.au](http://www.drugs.health.gov.au)

**Pain Australia**

[www.painaustralia.org.au](http://www.painaustralia.org.au)

**Chronic Pain Australia**

[www.chronicpainaustralia.org.au](http://www.chronicpainaustralia.org.au)

**painHEALTH**

<https://painhealth.csse.uwa.edu.au>

**Australian Pain Management Association**

[www.painmanagement.org.au](http://www.painmanagement.org.au)

**Ask Your Pharmacist:**

[askyourpharmacist.com.au](http://askyourpharmacist.com.au)

**Pain Management Network**

[www.aci.health.nsw.gov.au/chronic-pain](http://www.aci.health.nsw.gov.au/chronic-pain)

**Pain Link Helpline**

1300 340 357

**Healthdirect Australia - 24 Hour Health**

**Advice Line: 1800 022 222**

### Contact information for state and territory drugs and poisons units

**ACT Health**

**Pharmaceutical Services:** [www.health.act.gov.au/public-information/businesses/pharmaceutical-services](http://www.health.act.gov.au/public-information/businesses/pharmaceutical-services)

**NSW Ministry of Health**

**Pharmaceutical Services:** [www.health.nsw.gov.au/pharmaceutical/Pages/default.aspx](http://www.health.nsw.gov.au/pharmaceutical/Pages/default.aspx)

**NT Department of Health**

**Environmental Health – Medicines and**

**Poisons Control:** <https://health.nt.gov.au/professionals/environmental-health/medicines-and-poisons-control>

**QLD Health**

**Medicines Regulation & Quality Unit:**

[www.health.qld.gov.au/clinical-practice/guidelines-procedures/medicines](http://www.health.qld.gov.au/clinical-practice/guidelines-procedures/medicines)

**Poisons Management:** [www.health.qld.gov.au/system-governance/licences/medicines-poisons/poisons-management](http://www.health.qld.gov.au/system-governance/licences/medicines-poisons/poisons-management)

**SA Health**

**Medicines and Technology Policy and**

**Programs:** [www.sahealth.sa.gov.au/MTPP](http://www.sahealth.sa.gov.au/MTPP)

**TAS Department of Health & Human Services**

**Pharmaceutical Services:** [www.dhhs.tas.gov.au/psbtas/welcome](http://www.dhhs.tas.gov.au/psbtas/welcome)

**VIC Department of Health & Human Services**

**Drugs and Poisons Regulation:** [www.health.vic.gov.au/dpu/](http://www.health.vic.gov.au/dpu/)

**WA Health**

**Pharmaceutical Services:** [www.public.health.wa.gov.au/1/872/2/pharmaceutical\\_services.pm](http://www.public.health.wa.gov.au/1/872/2/pharmaceutical_services.pm)



# How the decision was reached

The TGA's announcement that all codeine products will be upscheduled from 1 February 2018, came nearly two years after the TGA first began considering a proposal to shift all schedule 2 (over-the-counter) and 3 (pharmacist only) codeine preparations to prescription-only (schedule 4 and S8).

The Advisory Committee on Medicines Scheduling (ACMS), an independent committee of experts, including several pharmacists, appointed by the Minister to advise the TGA on scheduling matters, invited public submissions on this proposal.

The AMA made a submission noting that it did not have the information to form a definitive view but raising a range of issues that should be considered.

The TGA delegate responsible for medicines scheduling decisions subsequently issued an "interim decision" supporting a recommendation by ACMS to remove codeine from schedules 2 and 3. The interim decision included a summary of all the information and issues considered by ACMS in making the recommendation.

A two-week consultation period was provided following the delegate's interim decision, to allow any further comments to be made.

The AMA made another submission, this time supporting the decision on the basis that it was informed by advice from an independent, expert committee (ACMS), and based on best available evidence.

About 120 submissions were lodged in response to the interim decision. Of those opposing the upscheduling, more than 70 were from individuals opposing limits to codeine access (usually citing personal experience with migraine or musculoskeletal conditions); a handful from individual pharmacists; eight from pharmacy related organisations; five from consumer organisations. Those supporting included: the Society for Hospital Pharmacists; five medical related organisations; and seven individuals (again citing personal/close experiences such as harm and death resulting from over-the-counter codeine).

In addition, the Pharmacy Guild mounted a strong public campaign opposing the removal of non-prescription codeine from pharmacies.

Subsequently, in early 2016 the TGA announced that the delegate had deferred making a final decision ... due to the large number of submissions.

The TGA then issued alternative proposals for public comment, which included options such as continuing to allow S2 and S3 codeine but in smaller pack sizes.

In 2016, the TGA commissioned KPMG to undertake a regulation impact analysis to quantify the impact of various scheduling options. Dr Richard Kidd, Chair of the AMA Council of General Practice, was interviewed by KPMG to provide a general practice perspective on the impact of any codeine scheduling changes. The report conclusively found that the social and economic benefits would outweigh the regulatory costs of upscheduling codeine.

The TGA subsequently announced its final decision to upschedule all codeine products to prescription-only in late 2016.

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 of a range of medicines with the potential for misuse and harm, not only Schedule 8 medicines.

However, the implementation of this system is unlikely for several more years. Victoria and WA are the only States so far to announce a timeframe for implementation – sometime in 2018.

**"This can happen to anyone and it can remain hidden. There don't have to be dealers knocking on someone's door."**

***Over-the-counter painkiller addict***

**"It is something that people don't realise. I had no idea that I could get addicted to codeine."**

***Frankie Bean began using Nurofen Plus 24-hours-a-day to stave off the chronic pain***



# Codeine – the facts

The Therapeutic Goods Administration has ruled medicines that contain codeine will no longer be available without prescription from 1 February 2018.

This will include codeine-containing combination analgesics (available under brand names such as Panadeine, Nurofen Plus, Mersyndol and pharmacy generic pain relief products).

Codeine-containing cough, cold, and flu products (available under brand names such as Codral, Demazin, and pharmacy generic cough, cold and flu medicines) will also become unavailable as over-the-counter medicines.

“Codeine is closely related to morphine and, like morphine, is an opioid. Long-term use of low-dose codeine has been linked to opioid dependence, toxicity and abuse.”

High dose codeine (30-120 mg per dose), used for cancer pain, post-operative pain and other acute pain conditions, already requires a prescription.

There are a range of products available that do not require a prescription to help manage pain and will be available post-February 2018.

Most Australians are aware codeine used for pain relief offers very little additional benefit when compared with medicines without codeine.

The decision to re-schedule codeine is consistent with the Australian Government’s commitment to protect public health and safety for all Australians.

Codeine is closely related to morphine and, like morphine, is an opioid. Long-term use of low-dose codeine has been linked to opioid dependence, toxicity and abuse.

Codeine can cause opioid tolerance, dependence, addiction, poisoning and, in high doses, death. Codeine use can be harmful. Tolerance occurs when codeine becomes less effective and so the body needs higher and higher doses to feel the same relief

**“Addiction specialists have seen the number of patients with addiction to over the counter codeine grow at an alarming rate.**

***President of the Chapter of Addiction Medicine  
Associate Professor Adrian Reynolds***

from symptoms.

Severe withdrawal symptoms can result when the medicine is stopped; these include head and muscle aches, mood swings, insomnia, nausea and diarrhoea. Some of these withdrawal symptoms, such as head or muscle aches, mimic the symptoms that low-dose codeine products are often used to treat, leading to people incorrectly continuing to take the medicine longer or in higher doses.

Codeine poisoning contributes to both accidental and intentional deaths in Australia.

Unfortunately in Australia the most common class of drug identified on toxicology reports in drug-induced deaths are opioids, including opiate-based analgesics such as codeine.

The codeine-containing medicines that are currently available over-the-counter are usually combined with either paracetamol or ibuprofen. Regular use of medicines containing codeine, for example for chronic pain, has led to some consumers becoming addicted or tolerant to codeine without realising it.

Taking more than the recommended dose of combination products could result in serious side effects.

Though safe at recommended doses, long-term use of high doses of paracetamol can result in liver damage, while the most severe adverse effects of long-term ibuprofen use include serious internal bleeding, kidney failure and heart attack.

CHRIS JOHNSON





# The AMA fully supports the independence of the TGA

The AMA fully supports the independence of the TGA in making decisions about medicines scheduling.

It is essential for public safety that the TGA makes evidence-based decisions about medicines, free from political interference and sectional interests.

Doctors rely on the independence and expertise of the TGA to ensure Australians have access to safe, effective and high quality medicines.

There is compelling evidence to support the decision to make codeine prescription only:

- Deaths and illness from codeine use have increased in Australia;
- This is despite a rescheduling decision in 2010 shifting many over-the-counter codeine medicines to Schedule 3 (pharmacist only); and
- There is no evidence that low-dose codeine (8mg-15mg/unit) provides any benefit beyond placebo.

To put this change in perspective:

- all other opioid medicines sold in Australia are available only on prescription (S4 or S8); and
- codeine is not available over-the-counter in 13 European countries nor in the US.

Patients who have short-term pain will still have access to alternative over-the-counter painkillers which are more effective than low-dose codeine (i.e. ibuprofen plus paracetamol), without codeine-associated risks.

It is better for patients with chronic pain to manage it with doctors' advice on appropriate medicines and non-medicine treatments, rather than self-treating long-term with codeine.

It is unlikely doctors will see a large increase in patients. Most people who use codeine take it to relieve short-term pain; they can still buy effective painkillers (ibuprofen plus paracetamol) over the counter.

Doctors may see an increase in visits from patients who have long-term chronic pain. These patients should be helped by doctors to manage their pain with a combination of non-medicine and medicine treatments, rather than self-treating with codeine.

It may be years before State Governments have real time monitoring systems up and running. We can't allow more unnecessary deaths while governments argue about funding.

The AMA's *Position Statement on Medicines 2014* states that:

- The AMA supports the role of the Therapeutic Goods Administration as the regulator of medicines in Australia to ensure that medicines meet appropriate standards for quality, safety and efficacy.
- The AMA recommends medicines should only be up or down scheduled where there is strong evidence it is safe to do so, where there is demonstrated patient benefit and safety in dispensing the medication by this method, and where it would not adversely affect appropriate access to medicines.

**"It's important that people realise that the decision's been taken based on safety predominantly and based on the risk of abuse."**

**"Medications that are available over the counter or through pharmacies should be substantially safe and not subject to abuse. This is clearly not the case with codeine."**

***The Therapeutic Goods Administration's (TGA)  
Principal Medical Officer, Dr Tim Greenaway***

**"It's also a pretty rubbish drug that doesn't actually help people as much as they think it does."**

**"Every hospital in Australia will tell you stories of addiction to such combined drugs (paracetamol and ibuprofen with codeine). You often see it in young women. Some have to be tube-fed because their guts are so damaged. Others have to go on dialysis because their kidneys are wrecked."**

***Dr Michael Vagg, Deakin University School of Medicine, & Pain Specialist***



# Why codeine should be prescription-only

Harmful drug use continues to be a serious public health issue in Australia with 1,808 drug induced deaths registered in 2016 according to the latest records of the Australian Bureau of Statistics.

This is the highest number of drug deaths in 20 years, and is similar to the number recorded in the late 1990s when a steep increase in opioid use, specifically heroin, led to deaths peaking at 1,740 in 1999.

Substantial evidence from published studies shows that codeine contributes to both accidental and intentional deaths.

Many of these deaths can be attributed to the misuse of combination codeine medicines, particularly related to paracetamol-induced liver toxicity and ibuprofen-induced stomach ulceration.

In 2014, the TGA database of adverse event notifications contained 59 cases of stomach ulcers or bleeding related to codeine/ibuprofen combination and 57 cases of liver toxicity from combination codeine/paracetamol products.

A study in the *Medical Journal of Australia* has found that increased prescribing of opioid analgesics during the past decade has resulted in rises in mortality caused by overdose in many developed countries.

Other relevant data includes:

- codeine toxicity was a contributory factor in 1,437 deaths between 2000 and 2013;
- paracetamol or ibuprofen was involved in 55 per cent of the 1200 codeine-related deaths recorded in Australia between 2000 and 2013;
- the underlying cause of death was determined to be codeine toxicity in 7.8 per cent of cases (113 deaths), and multiple drug toxicity (including codeine) in 83.7 per cent of cases (1,201 deaths);
- approximately 24 per cent (343 deaths) were related to a prescription codeine product (usually Panadeine Forte), 16 per

**“Apart from serious health issues relating to misuse of these over-the-counter painkillers, data shows us that lower doses of codeine found in OTC combination products don’t actually provide any additional pain relief.”**

**“There is no clear evidence that taking a low dose of codeine in combination with paracetamol or ibuprofen is any better than just taking the single-ingredient products without the codeine.”**

***Dr Jacinta Johnson, Principal Researcher at University of South Australia who led the first Australian study analysing the costs of 99 hospital admissions related to over-the-counter combination painkillers containing codeine (OTC-CACC) from 2010-2015 at a South Australian hospital.***

cent (229 deaths) included an OTC codeine product, and in the remaining 60 per cent of deaths there was no information about whether the codeine consumed before death was prescribed or OTC;

- codeine-related deaths increased from 3.5 to 8.7 deaths per million persons between 2000 and 2009, with just under half of the deaths attributed to accidental overdose. The rate of these deaths also increased; and
- researchers found the increase was driven mainly by accidental deaths. Almost half were attributed to accidental overdose and a third to intentional self-harm.

MEREDITH HORNE



WESTERN AUSTRALIA

## DO NOT BE WEAK ON CODEINE, MINISTER: AMA (WA)



WESTERN AUSTRALIA

### MEDIA RELEASE

Wednesday 11 October 2017

State Health Minister Roger Cook is putting the health of West Australians at risk by joining a push to reverse the decision to make codeine products available by script only, the Australian Medical Association (WA) said today.

Mr Cook signed a letter with all other state health ministers, with the exception of South Australia, urging Federal Health Minister Greg Hunt to reverse the Therapeutic Drugs Administration decision to make codeine products available only by script in order to minimise the risk of addiction and overdose.

AMA (WA) President Dr Omar Khorshid said he was extremely disappointed that Mr Cook had put the lobbying and economic power of pharmacists before the health of West Australians.

"The minister told me and others very recently that he was supportive of the TGA decision," Dr Khorshid said.

"His decision to backflip on this issue and to cravenly support the Pharmacy Guild severely weakens this planned move. It directly opposes good health policy and will jeopardise the health of West Australians.

"The decision by the TGA was a good one, based on scientific evidence and years of research into the use and abuse of codeine.

"Codeine is dangerous, regularly abused and involved in many drug-related deaths. It is appropriate that the supply of a drug that is so addictive and so easily abused has much stricter regulations.

"The TGA recommendation was a timely one that will save many lives and result in the use of other pain management drugs that are not only safer, but more effective.

"The TGA decision was also endorsed at the time by health professionals and was the subject of extensive consultation and consideration.

"The Minister has been drawn into a poor political decision that he will regret when it inevitably leads to the death of West Australians," he said.

Dr Khorshid said it was now vital that the Federal Health Minister rejected the push by state governments to block the TGA changes to over-the-counter availability of codeine.

"Health Minister Greg Hunt is now in the position of being able to endorse a carefully researched and considered TGA recommendation.

"He can demonstrate his independence and his refusal to be pushed around by powerful pharmacy interests and a bunch of weak state health ministers unable to stand up to them," Dr Khorshid said.





*From the President's Office*  
**Professor Brad Frankum OAM**  
*BMed(Hons) FRACP*



8 September 2017

The Hon Brad Hazzard  
Minister for Health, Minister for Medical Research  
GPO Box 5341  
Sydney NSW 2001

Dear Minister Hazzard,

AMA supports the Therapeutic Goods Administration (TGA) decision to make all codeine preparations a 'prescription only' medicine from 1 February 2018.

On behalf of AMA (NSW), I would like to stress the importance of upholding the independence of the TGA in making decisions about medicines scheduling, including for codeine.

It is essential that these decisions are made free from political interference and sectional interests. As doctors, we rely on the independence and expertise of the TGA to ensure Australians have access to safe, effective and high quality medicines.

The TGA has published its reasons for up-scheduling codeine: they are compelling. Deaths and illness from codeine use have increased in Australia. This is despite a re-scheduling decision in 2010 shifting many over-the-counter codeine medicines to Schedule 3 (pharmacist only). In addition, there is no evidence that low-dose codeine (8mg-15mg/unit) provides any benefit beyond placebo.

To put this change in perspective, all other opioid medicines sold in Australia are available only on prescription (S4 or S8). Codeine is not available over-the-counter in 13 European countries nor in the US.

Patients who have short term pain will still have access to alternative over-the-counter painkillers which are more effective than low-dose codeine (i.e ibuprofen plus paracetamol), without codeine associated risks.

The decision is based on facts, the advice of independent experts, and has the sole objective of protecting the public. An independent regulator is a cornerstone of our health system and it is absolutely essential no decisions are made that undermine its authority.

I am confident that, with your support we can see the implementation of the TGA's decision, for the good of consumers Australia-wide.

Yours sincerely,

**Prof. Brad Frankum**  
**President, AMA (NSW)**

**Australian Medical Association (NSW) Ltd**

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Consumers Health  
Forum **OF** Australia

## POSITION STATEMENT

### Scheduling of Codeine

#### What we support

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We support the role of Therapeutic Goods Administration (TGA) as the independent regulator and accept its decision to make all codeine products prescription only from 1 February 2018.

We are participating in the work of the Nationally Coordinated Codeine Implementation Working Group to ensure consumers are aware of the change and have information about alternate pain management strategies and services.

We also support the need for more education for prescribers on the dangers of codeine to reduce its use. Over-the-counter access to codeine is only part of the problem and without measures to change prescribing habits the problems associated with over use and addiction will continue.

There also needs to be more services available for people with a codeine addiction to help move them away from using codeine and to help them manage any pain issues more effectively.

We join with painAustralia and the Australian Pain Management Association in supporting the full implementation of the National Pain Strategy.

#### What we do not support

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We do not support the proposal from the Pharmacy Guild of Australia and the Pharmaceutical Society of Australia to allow pharmacists to dispense codeine products without a prescription for people with one- off acute pain under certain conditions.





## Why we believe this

September 2017

When the proposal to reschedule all codeine products to be prescription-only medicines was first mooted CHF opposed it. We acknowledged that there was a problem with misuse but believed that most people used codeine products responsibly. We argued for other measures to be implemented including: introduction of real time monitoring of sales of codeine through pharmacy e.g the Guild MedAssist program; more education for consumers about potential issue around dependency and addiction; more services for people with addiction and dependency issues to help them move away from codeine and more education for doctors on prescribing codeine products. We acknowledged that if these did not work then the next option would probably be moving to prescription-only.

CHF believes that the scheduling framework which looks at access to medicines in terms of potential risks to consumers and has ensuring consumer safety as its key principle serves Australian consumers well overall. The Therapeutic Goods Administration looked at all the evidence and made the decision that the harms outweighed the benefits and so codeine should be made prescription only.

CHF supports the role of TGA as the regulator; we believe overall it does an excellent job of ensuring Australians have access to safety and high-quality medicines. We also note that this decision brings Australia into line with most other developed countries. As recently as July 2017 France has moved to make codeine products prescription only. The evidence for harm from codeine and other opioids is growing and their efficacy in assisting with pain management is coming under more and more scrutiny.

The proposal to allow controlled supply by pharmacists without a prescription could be seen to undermine the scheduling framework. Whilst CHF acknowledges there may be a place for looking at ways to improve access to medicines through measures like controlled supply we think this needs to be done in a rigorous and systematic way not just applying it to a specific medicine. The work on this needs to develop a sound evidence base for the need for such a model, look at possible ways it could be implemented and develop some criteria for deciding which medicines might be suitable to be accessed in this way. The review needs to involve all the stakeholders including pharmacists, consumers and doctors.

Much of the messaging around the changes for codeine concentrate on the potential harm it causes and that it is an ineffective pain management tool. Consumers would become very confused after seeing these messages to then hear that codeine products are the way to deal with acute pain. It may also undermine the moves to get consumers to look at a range of pain management approaches, not just medicines.





## Media Release

### Codeine scheduling changes are about patient safety not commercial interests

Saturday, 7 October 2017

Experts from a number of key health groups are urging state and territory governments to support Australia's medicine regulator, the Therapeutic Goods Administration (TGA), in its decision to make codeine-based medications available only with a prescription from February 2018.

President of the Royal Australian College of General Practitioners (RACGP) Dr Bastian Seidel urged the states and territories to listen to the advice of health professionals and consumer groups and put the health and safety of patients in front of commercial interests.

"With more than one million Australians taking codeine based medications every year, codeine addiction has become a serious problem for our community," Dr Seidel said.

"The consumption of these medications is currently running out of control with over 16 million items being sold over the counter in pharmacies every year.

"Australian GPs are seeing the harmful effect these medications can have on our community, which is why the RACGP strongly endorsed the TGA's decision to reschedule over the counter codeine based medications."

Addiction specialist and the Royal Australasian College of Physicians' President of the Chapter of Addiction Medicine, Professor Adrian Reynolds, said patients with chronic pain should talk to their doctor.

"We strongly support a nationally integrated and coordinated real-time monitoring and reporting system, especially if it includes codeine and other prescribed medications of concern.

"However, we don't support the assumption that a reporting and monitoring system on its own, is going to identify and help people who are misusing these products. The health community needs to know what to do with this information.

"If we accept these products are at risk of abuse and should be monitored, then we should want patients to be assessed by their doctor before they are sold these products.

"We encourage political parties and the health community to work together and support the TGA's scheduling changes for codeine."

Painaustralia CEO Carol Bennett said, "Chronic pain is a major health issue in Australia - we need to do much better than offering medications that are often both ineffective and potentially harmful in responding to chronic pain. Providing appropriate pain management should be a much higher priority, particularly in rural locations where reliance on opioids is a significant issue.





"Painaustralia supports a co-ordinated, whole of sector strategy to address the issue of access to optimal pain management, including public and clinical education programs, linkages between rural health care clinicians via Telehealth with specialist city based services."

The TGA's decision is consistent with what has happened in most of Europe, the United Arab Emirates and Japan where these medicines can only be sold with a prescription. Canada is also heading in a direction of requiring a prescription for products containing codeine.

### **Contacts**

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### **About the RACGP**

The Royal Australian College of General Practitioners (RACGP) was established in 1958 and is Australia's peak general practice representative organisation. The RACGP has more than 35,000 members working in or towards a career in general practice across metropolitan, regional and rural areas of the country. Nine in every 10 GPs are with the RACGP. More than 134 million general practice consultations take place annually in Australia.

Visit [www.racgp.org.au](http://www.racgp.org.au). To unsubscribe from RACGP media releases, [click here](#).

### **About The Royal Australasian College of Physicians (RACP):**

The RACP trains, educates and advocates on behalf of more than 25,000 physicians and trainee physicians across Australia and New Zealand. The College represents a broad range of medical specialties including general medicine, paediatrics and child health, cardiology, respiratory medicine, neurology, oncology, public health medicine, occupational and environmental medicine, palliative medicine, sexual health medicine, rehabilitation medicine, geriatric medicine and addiction medicine. Beyond the drive for medical excellence, the RACP is committed to developing health and social policies which bring vital improvements to the wellbeing of patients. The College offers 60 training pathways. These lead to the award of one of seven qualifications that align with 45 specialist titles recognised by the Medical Board of Australia or allow for registration in nine vocational scopes with the Medical Council of New Zealand.

### **Painaustralia**

As the peak national body, Painaustralia brings together consumers, medical specialists, pharmacists, academics, carers, pharmaceutical companies, allied health professionals and others with an interest in pain. Painaustralia brings all the key players together and provides one central point for balanced information and policies.

The organisation was born of the National Pain Strategy and our primary mission is to improve the quality of life for people with pain and their families and minimise the burden of pain on individuals and the community. Effectively tackling pain – a complex physical, psychological and environmental condition – is in the interest of every Australian.