

Pain-relief medications: should Australia ban over-the-counter sale of codeine products?

What they said...

'Lots of people use codeine safely and appropriately to deal with migraines, toothache and period pain. A bureaucracy telling them "No, you can't have that" won't be well received'
Greg Turnbull, a spokesperson for the Pharmacy Guild of Australia

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

Dr Tim Greenaway, the Therapeutic Goods Administration's principal medical officer

The issue at a glance

On January 25, 2017, the body overseeing goods supplied for medical and therapeutic purposes in Australia, the Therapeutic Goods Administration (TGA), announced that it would be reclassifying (or rescheduling) medications containing codeine so that they could no longer be purchased without a doctor's prescription.

Medications that can be purchased without prescription are described as being available for over-the-counter sale.

The ban will come into effect on February 1, 2018.

<https://www.tga.gov.au/sites/default/files/scheduling-delegates-final-decision-codeine-december-2016.pdf>

The ban is being imposed because of concern regarding growing misuse of codeine products. On January 19, 2018, the Therapeutic Goods Administration published on its Codeine information hub a reminder of the impending ban and a restatement of the reasons why it has been imposed. <https://www.tga.gov.au/codeine-info-hub>

The decision has taken years to put into effect as it has undergone an impact review resulting in a favourable regulation impact statement. <https://www.tga.gov.au/publication/regulation-impact-statement-codeine-re-scheduling>. The review was undertaken after lobbying from groups such as the Pharmacy Guild of Australia.

The Pharmacy Guild is the representative body for dispensing chemists in Australia. Together with the Pharmaceutical Society of Australia and the Australian Self Medication Industry, the Guild has been a consistent opponent of the ban, claiming it is not the most effective response to codeine misuse and that it will disadvantage the majority of consumers who use the product safely .

On October 6, 2017, state health ministers (excluding South Australia), sent a letter the federal Health Minister, Greg Hunt, opposing the ban.

<https://www.dailytelegraph.com.au/news/nsw/states-unite-over-prescription-only-codeine-crackdown/news-story/bdf0c33df88bb1a39e5339bc1ae87f6c> However, the federal minister rejected their arguments. <https://ama.com.au/ausmed/minister-digs-over-codeine-pharmacy-lobby-backs-down>

The Pharmacy Guild is now seeking an exemption to the ban that would allow pharmacists to supply without prescription a small quantity of codeine-containing medication for the treatment of short-term conditions. <https://ajp.com.au/news/codeine-makes-headlines-pharmacists-warn-trouble-ahead/>

Background

(The information below has been drawn from a Wikipedia entry titled 'Codeine'. The full text can be accessed at <https://en.wikipedia.org/wiki/Codeine>)

Codeine is an opiate used to treat pain, as a cough medicine, and for diarrhoea. It is typically used to treat mild to moderate degrees of pain. Greater benefit may occur when combined with paracetamol (acetaminophen) or a nonsteroidal anti-inflammatory drug (NSAID) such as aspirin or ibuprofen. Evidence does not support its use for acute cough suppression in children or adults. In Europe it is not recommended as a cough medicine in those under twelve years of age. It is generally taken by mouth. It typically starts working after half an hour with maximum effect at two hours. The total duration of its effects last for about four to six hours.

Side effects

Common side effects include vomiting, constipation, itchiness, lightheadedness, and drowsiness. Serious side effects may include breathing difficulties and addiction. It is unclear if its use in pregnancy is safe. Care should be used during breastfeeding as it may result in opiate toxicity in the baby. Its use as of 2016 is not recommended in children. Codeine works following being broken down by the liver into morphine. How quickly this occurs depends on a person's genetics. There is wide variation between individuals with some users deriving virtually no pain-relieving effect and others being at risk of overdosing.

Adverse effects

Common adverse effects associated with the use of codeine include drowsiness and constipation. Less common are itching, nausea, vomiting, dry mouth, miosis, orthostatic hypotension, urinary retention, euphoria, dysphoria, and coughing. Rare adverse effects include anaphylaxis, seizure, acute pancreatitis, and respiratory depression. As with all opiates, longer-term effects can vary, but can include diminished libido, apathy, and memory loss. Some people may have allergic reactions to codeine, such as the swelling of skin and rashes.

Tolerance to many of the effects of codeine develops with prolonged use, including to its therapeutic effects. The rate at which this occurs develops at different rates for different effects, with tolerance to the constipation-inducing effects developing particularly slowly for instance.

A potentially serious adverse drug reaction, as with other opioids, is respiratory depression. This depression is dose-related and is a mechanism for the potentially fatal consequences of overdose. As codeine is metabolized to morphine, morphine can be passed through breast milk in potentially lethal amounts, fatally depressing the respiration of a breastfed baby. In August 2012, the United States Federal Drug Administration issued a warning about deaths in pediatric patients < 6 years old after ingesting 'normal' doses of paracetamol with codeine after tonsillectomy; this warning was upgraded to a black box warning in February 2013.

Withdrawal and dependence

As with other opiate-based pain killers, chronic use of codeine can cause physical dependence. When physical dependence has developed, withdrawal symptoms may occur if a person suddenly stops the medication. Withdrawal symptoms include: drug craving, runny nose, yawning, sweating, insomnia, weakness, stomach cramps, nausea, vomiting, diarrhoea, muscle spasms, chills, irritability, and pain. To minimize withdrawal symptoms, long-term users should gradually reduce their codeine medication under the supervision of a healthcare professional.

Legal status

Australia

In Australia, codeine preparations must be sold only at a pharmacy. Preparations will often be a combination of paracetamol (500 mg), ibuprofen (200 mg) and doxylamine succinate (5 mg), and the codeine content may range from 5 mg to 15 mg; preparations with in excess of 15 mg per tablet are S4 (Schedule 4, or "Prescription Only") medications. The item is given over the counter, no prescriptions, at the discretion of the pharmacist. Most preparations are considered S3 (schedule 3, or "Pharmacist Only") medications, meaning that they must be sold with the direct involvement of a pharmacist. It must be labelled and usage history monitored by the pharmacist to help deter misuse and dependence. The exception to this rule is cold and flu preparations such as "Codral". These preparations contain phenylephrine (5 mg), paracetamol (500 mg) and codeine (9.5 mg) or phenylephrine (5 mg), paracetamol (500 mg), chlorpheniramine (2 mg) and codeine (9.5 mg).

Preparations containing pure codeine (e.g., codeine phosphate tablets or codeine phosphate linctus) are available on prescription and are considered S8 (Schedule 8, or "Controlled Drug Possession without authority illegal"). Schedule 8 preparations are subject to the strictest regulation of all medications available to consumers.

From February 1, 2018, preparations containing codeine will not be available without a prescription.

Canada

In Canada tablets containing 8 mg of codeine combined with 15 mg of caffeine and 300 mg of paracetamol are sold as T1s (Tylenol Number 1) without a prescription. A similar tablet called an AC&C which contains 325 mg of acetylsalicylic acid (Aspirin) instead of paracetamol is also available without a prescription. Both tablets are kept behind the counter and must be dispensed by a pharmacist who may limit quantities. Names of many codeine and dihydrocodeine products in Canada tend to follow the narcotic content number system (Tylenol With Codeine No. 1, 2, 3, 4 &c) which came to be in its current form with the Pure Food & Drug Act of 1906.

Codeine became a prescription-only medication in the province of Manitoba on February 1, 2016. A pharmacist may issue a prescription, and all purchases are logged to a central database to prevent overprescribing.

France

In France, before 2017, most preparations containing codeine did not require a doctor's prescription. For example, products containing codeine include Néocodion (codeine and camphor), Tussipax (ethylmorphine and codeine), Paderyl (codeine alone), Codoliprane (codeine with paracetamol), Prontalgine and Migralgine (codeine, paracetamol and caffeine) could be purchased over-the-counter.

In 2017 the law was changed making mandatory a prescription for all codeine products along with ethylmorphine and dextromethorphan.

United Kingdom

In the United Kingdom, the sale and possession of codeine are restricted separately under law.

Neat codeine and higher-strength codeine formulations are generally prescription-only medicines (POM) meaning that the sale of such products is restricted under the Medicines Act 1968. Lower-strength products containing combinations of up to 12.8 mg of codeine per dosage unit, combined with paracetamol, ibuprofen or aspirin are available over the counter

at pharmacies. Codeine linctus of 15 mg per 5 ml is also available at some pharmacies, although a purchaser would have to request it specifically from the pharmacist.

United States

In the United States, codeine is regulated by the Controlled Substances Act. Federal law dictates that codeine be a Schedule II controlled substance when used in products for pain-relief that contain codeine alone or more than 90 mg per dosage unit. Tablets of codeine in combination with aspirin or paracetamol (paracetamol/Tylenol) made for pain relief are listed as Schedule III (allowing for electronic fills and refills without a physical paper-copy of the physician ordered prescription); and cough syrups are Schedule III or V, depending on formula. The paracetamol/codeine pain-relief elixir (trade name Tylenol Elixir with Codeine) is a Schedule IV controlled substance.

Internet information

On January 23, 2018, Australian Prescriber published a report titled 'Changes for codeine' which explains why the banning of over-the-counter codeine sale is necessary.

The full text can be accessed at <https://www.nps.org.au/australian-prescriber/articles/changes-for-codeine>

On January 21, 2018, Lifehacker published a comment by Peter Carroll, Peter Carroll is an honorary professor in pharmacology at the University of Sydney and President of the NSW branch of the Pharmaceutical Society of Australia, titled 'Codeine Banned In Australia: Why The Arguments Don't Add Up' The opinion piece argues against the banning of over-the-counter codeine products in Australia.

The full text can be accessed at <https://www.lifehacker.com.au/2018/01/codeine-banned-in-australia-why-the-arguments-dont-add-up/>

It was originally published in The Conversation on January 18, 2018, and can be accessed there at <https://theconversation.com/three-claims-used-to-justify-pulling-codeine-from-sale-without-a-prescription-and-why-theyre-wrong-87257>

On January 17, 2018, the Australian Journal of Pharmacy (AJP) published an opinion piece titled 'Codeine makes headlines as pharmacists warn of trouble ahead' which gives the views of a number of pharmacists opposed to the ban on over-the-counter sale of codeine products. The full text can be accessed at <https://ajp.com.au/news/codeine-makes-headlines-pharmacists-warn-trouble-ahead/>

On January 4, 2018, The Guardian published a news report titled 'Codeine ban sparks consumer complaints and fears of stockpiling' which reports on consumer reactions to the impending ban on over-the-counter codeine products.

The full text can be accessed at <https://www.theguardian.com/australia-news/2018/jan/04/codeine-ban-sparks-consumer-complaints-and-fears-of-stockpiling>

On December 31, 2017, The Sydney Morning Herald published an analysis titled '"A tsunami of pain": Changes to codeine availability shed light on hidden epidemic of addiction' which considers the extent of Australia's addiction problem with therapeutic opioids.

The full text can be accessed at <http://www.smh.com.au/national/health/a-tsunami-of-pain-changes-to-codeine-availability-shed-light-on-hidden-epidemic-of-addiction-20171230-h0bmk3.html>

On December 31, 2017, The Daily Mail published a report titled 'No more Nurofen Plus, Panadeine or Codral: Government to ban pharmacists from selling pain relief pills containing codeine over the counter in a bid to reduce overdoses' which gives the views of these supporting and opposed to the change in sale regulations for codeine.

The full text of the report can be accessed at <http://www.dailymail.co.uk/news/article-5222879/Medication-containing-codeine-prescription-only.html>

On December 8, 2017, Medical Republic published a report titled 'Where Are We with Real-Time Monitoring?' The report examines the progress made Australia-wide of tracking patient access to S8 drugs including pethidine, fentanyl, morphine, oxycodone, methadone and buprenorphine, S4 medications including diazepam and other benzodiazepines, the anti-psychotic quetiapine, so-called Z-class drugs used against insomnia and codeine products.

The full text can be accessed at

https://www.google.com.au/search?q=Australia+S8+drugs&ie=utf-8&oe=utf-8&client=firefox-b&gfe_rd=cr&dcr=0&ei=uYRmWo6NI_PDXq39pNAN

On October 8, 2017, the Northern Daily Leader published a news report titled 'National Party and Pharmacy Guild call for reversal on over the counter codeine changes' which focused on National Party and Pharmacy Guild objections to the impending ban on over-the-counter codeine sales.

The full text can be accessed at

<http://www.northerndailyleader.com.au/story/4971120/chemist-counter-codeine-changes/>

On October 6, 2017, The Daily Telegraph published a news report titled 'States unite over prescription-only codeine crackdown' which detailed state health ministers' opposition to the ban on over-the-counter sale of codeine products.

The full text can be accessed at <https://www.dailytelegraph.com.au/news/nsw/states-unite-over-prescriptiononly-codeine-crackdown/news-story/bdf0c33df88bb1a39e5339bc1ae87f6c>

On September 9, 2017, The Australian published an analysis titled 'Thousands of Australians have excessive need for codeine' which examined the extent of codeine abuse in Australia.

The full text can be accessed at <https://www.theaustralian.com.au/national-affairs/health/thousands-of-australians-have-excessive-need-for-codeine/news-story/24f2bfed454db1b61fd4570c3633fb27>

In September, 2017, the Australian Drug Foundation (ADF) released a report titled 'Is there a pill for that?...the increasing harms from opioid and benzodiazepine medication.'

The report outlines the growing problem of drug abuse and dependency from opioid medications supplied through prescription or purchased over-the-counter from a pharmacy. It outlines the scope and nature of the problem and suggests measures to address it.

The full text can be accessed at <https://adf.org.au/wp-content/uploads/2017/10/ADF-Prevention-Research-September-2017.pdf>

On August 16, 2017, SBS presented the views of a pain specialist supporting treatments other than codeine. The piece is titled 'Codeine-free pain relief is better: expert'

The full text can be accessed at <https://www.sbs.com.au/news/codeine-free-pain-relief-is-better-expert>

On August 14, 2017, the Pharmacy Guild of Australia issued a media release titled 'Guild approach to codeine – putting patients first' which argues for an exception provision which would allow pharmacies to continue selling codeine products over the counter. The full text can be accessed at <https://www.guild.org.au/news-events/news/2017/guild-approach-to-codeine-putting-patients-first>

On April 3, 2017, Body and Soul published a comment and analysis titled 'This is Australia's fastest growing drug problem - and it's legal' which explains why greater regulation of pharmaceutical codeine is necessary. The full text can be accessed at <http://www.bodyandsoul.com.au/health/health-news/this-is-australias-fastest-growing-drug-problem-and-its-legal/news-story/b0b6534a1b23bd3683b6e85246b2cf02>

On January 3, 2017, The New Scientist published an analysis and comment titled 'Australia bans non-prescription codeine to fight opioid crisis' which explains why the codeine ban has been imposed. The full text can be accessed at <https://www.newscientist.com/article/2116813-australia-bans-non-prescription-codeine-to-fight-opioid-crisis/>

On December 20, 2016, The Huffington Post published a news report titled 'You Won't Be Able To Buy Codeine Over The Counter Anymore' which included the Pharmacy Guild of Australia's defence of the monitoring process it was putting in place. The full text can be accessed at http://www.huffingtonpost.com.au/2016/12/19/you-wont-be-able-to-buy-codeine-over-the-counter-anymore_a_21631170/

On December 20, 2016, ABC News published a report titled 'Painkillers with codeine won't be available over the counter from 2018'. The report presents the views of those for and against the regulatory change. The full text can be accessed at <http://www.abc.net.au/news/2016-12-20/codeine-painkillers-wont-be-available-over-the-counter-2018/8133996>

On December 6, 2016, the ABC's Triple Hack published a news report titled 'Concerns prescription-only codeine will cause a national withdrawal'. The report highlights the concern among some authorities that there will not be adequate provision made for those suffering withdrawal symptoms through loss of access to codeine medication. The full text can be accessed at <http://www.abc.net.au/triplej/programs/hack/concerns-prescription-only-codeine-will-cause-a-national-with/8136288>

On October 3, 2016, The Age published a new report titled, 'Pharmaceutical lobby groups may delay codeine ruling' which examines attempts by commercial lobby groups to delay the banning of over-the-counter codeine sale. The full text can be accessed at <http://www.theage.com.au/national/health/pharmaceutical-lobby-groups-may-delay-codeine-ruling-20160930-grs2yk.html>

Arguments supporting the over-the-counter sale of codeine products

1. Most users of over-the-counter codeine products are using them as directed for pain relief. Opponents of banning over-the-counter codeine sales argue that the majority of users of these medications are being penalised because of minority misuse.

A spokesman for the Pharmacy Guild of Australia, Greg Turnbull, has stated, 'Lots of people use codeine safely and appropriately to deal with migraines, toothache and period pain. A bureaucracy telling them "No, you can't have that" won't be well received.'

Turnbull has further noted that Therapeutic Goods Administration (TGA) figures demonstrate that the vast majority of users take the product as recommended. The statistics demonstrate that about 80% of codeine consumers bought only 20% of the volume sold over the counter, meaning that while a minority may be abusing the medication, a majority were using it safely.

Turnbull further stated, 'The people who say they use it every week are exactly those who shouldn't be, but the majority using it safely are not being taken into consideration.'

<https://www.theguardian.com/australia-news/2018/jan/04/codeine-ban-sparks-consumer-complaints-and-fears-of-stockpiling>

The Pharmacy Guild of Australia has proposed a modification to the ban on over-the-counter codeine sales which it argues would remove the unfair disadvantage about to be suffered by the majority of responsible users of the drug.

In a media release issued on August 14, 2017, the Pharmacy Guild stated, 'The Pharmacy Guild of Australia will continue to press for a common sense exception to codeine up-scheduling so that patients can continue to access these medicines for the temporary relief of acute pain from their pharmacist in accordance with a strict protocol, which would include the mandatory use of real time recording.'

<https://www.guild.org.au/news-events/news/2017/guild-approach-to-codeine-putting-patients-first>

Expressing the Guild's position, New South Wales pharmacist, Simon Horsfall, has urged the New South Wales Health Minister to allow an exception to the over-the-counter sale ban, asking him, 'to allow pharmacists to give people in acute pain a limited three-day supply in conjunction with mandating real-time monitoring that is already in place in the majority of pharmacies...

This would allow pharmacists to identify and help those people who may be misusing the products, while at the same time allowing the vast majority of people who use the products appropriately and safely for the short-term treatment of acute pain continued access to the products without a prescription.'

<https://ajp.com.au/news/codeine-makes-headlines-pharmacists-warn-trouble-ahead/>

2. Making these products available by prescription only will make them more difficult and expensive for pain-sufferers to access

It has been claimed that making codeine products available only via prescription will unreasonably limit people's access to pain relief.

New South Wales Pharmacy Guild president, John Heffernan, has stated, 'The upscheduling will increase cost and inconvenience for patients who currently use these over-the-counter medicines safely and appropriately – It will clog up doctors' surgeries, while offering no solution to the problem of doctor shopping for prescription medicines – the overwhelming cause of codeine-related deaths in Australia.'

It has been suggested that the difficulty may be particularly great in rural areas. It has been claimed that in some rural areas, a GP appointment has to be made weeks in advance, while there are fears that already over-burdened emergency departments will be even further congested. Pharmacy Guild Branch Committee member Karen Carter has warned of both the inconvenience and the added cost. She has claimed, 'Emergency departments' and GPs' time are already needed for other things, while it would put a lot of pressure on one doctor towns. Up-scheduling will increase the cost of Medicare due to more GP visits. A \$6 dollar sale becomes at least a \$36 Medicare cost. The inconvenience will increase costs to patients who go to private GPs with much higher out of pocket costs.'

<http://www.northerndailyleader.com.au/story/4971120/chemist-counter-codeine-changes/>
A report prepared for the Pharmacy Guild by Cadence projected that there would be an additional 8.7 million GP visits as a consequence of up-scheduling low-dose codeine combination medicines at a cost of \$316.44 million as a result of patients attending a doctor for these scripts. <https://www.tga.gov.au/book-page/regulatory-and-health-economic-impact-models>

In October 6, 2017, health ministers from all states and territories — except for South Australia — signed a letter to federal Health Minister Greg Hunt expressing concern about the proposed ban. The letter stated, 'There is concern that this will be felt particularly acutely in rural and regional areas where access to GPs is already low, and that some people managing chronic conditions with codeine medications will deteriorate as they abandon medication due to the out-of-pocket expenses associated with accessing GPs for their prescription.' <https://www.dailytelegraph.com.au/news/nsw/states-unite-over-prescription-only-codeine-crackdown/news-story/bdf0c33df88bb1a39e5339bc1ae87f6c>

A study published by the Macquarie University Centre for the Health Economy in March, 2014, found that when asked what they would do if the pain relievers for their condition became unavailable over the counter: 63% of respondents said they would see their doctor, 24% said they would do nothing, 15% said they would use a home remedy and 7% said they would 'supplement'. <https://www.tga.gov.au/book-page/regulatory-and-health-economic-impact-models>. Critics have used this study to suggest that banning over-the-counter sales of codeine would result in significant increases in doctor visits. It has also suggested that there would be others whose pain would be treated inadequately.

3. Codeine in combination with other painkillers is an effective source of pain relief

Supporters of the continued over-the-counter sale of codeine in combination with other pain killers claim that this is an effective form of pain relief. They note that studies supposedly disproving its effectiveness are based on preparations that do not have the same levels of codeine as medications sold in Australia.

Supporters of the continued ready availability of codeine-in-combination medications point to two trials that have shown products containing paracetamol and codeine, and ibuprofen and codeine, in concentrations equal to those in Panadeine Extra and Nurofen Plus respectively, are effective. An Australian study showed after dental surgery, 1000mg of paracetamol combined with 30mg of codeine phosphate (equivalent to two Panadeine Extra tablets) produced significantly greater pain relief than 1000mg of paracetamol alone (equivalent to two Panamax or two Panadol tablets). Another study, also looked at pain following dental surgery. It showed 20mg of codeine combined with 400mg of ibuprofen (equivalent to two Nurofen Plus tablets) produced significantly greater pain relief than 400mg of ibuprofen alone (equivalent to two Nurofen tablets). <https://www.lifehacker.com.au/2018/01/codeine-banned-in-australia-why-the-arguments-dont-add-up/>

4. Prescription-only supply of codeine products may not result in reduced use of codeine

It has been argued that making codeine available by prescription only may not reduce the overuse of the drug.

It has been claimed that monitoring of drug-use by real-time recording and comparison of purchase is presently better available through pharmacies than through medical clinics. Pharmacies have introduced a real-time monitoring system for over the counter sales of codeine-containing products, which allows the pharmacist to identify and help those people who may be misusing them. The Pharmacy Guild has claimed its reporting system, called MedsASSIST, was already working well to record and track purchases of codeine, and stamp out abuse of the drug. The Guild's national president, George Tambassis has stated, 'More

than 4 million transactions have been recorded since March (2016) when the system was introduced across Australia. Of these transactions, pharmacists have denied sales to some 70,000 patient because of identified risk factors. Nearly 50 per cent of patients denied a sale were referred to their doctor for more treatment.'

http://www.huffingtonpost.com.au/2016/12/19/you-wont-be-able-to-buy-codeine-over-the-counter-anymore_a_21631170/

There is currently no such monitoring of prescription codeine-containing products in doctors' surgeries. So, critics claim, there is no way of identifying and helping those people who may be doctor shopping to obtain multiple prescriptions for the products.

<https://www.lifehacker.com.au/2018/01/codeine-banned-in-australia-why-the-arguments-dont-add-up/>

Victoria claims to be the most advanced state in terms of introducing a mandatory real-time monitoring system involving doctors and its system is not expected to be in place until the end of 2018. <http://medicalrepublic.com.au/real-time-monitoring/12221>

It has also been noted that supplying codeine products through prescription may not result in reduced use because doctors may over-prescribe. Currently, under the Repatriation Benefits Scheme, war veterans using low-dose codeine products receive a concession price if they purchase the product via prescription. Department of Health data shows that when doctors have the option to prescribe paracetamol combined with either 30mg, 15mg or 8mg of codeine, more than 90% of prescriptions are written for a 30mg codeine product.

<https://www.lifehacker.com.au/2018/01/codeine-banned-in-australia-why-the-arguments-dont-add-up/>

It has been claimed that a prescription-only mode of supplying codeine medications will only work if doctors are properly informed and prescribe carefully. Peter Boyles, Chief Pharmacist of Tasmania, has stated, 'If you are getting more opioids than are safe, and benzodiazepines and other agents that increase your overdose risk, it doesn't matter if you are going to the same doctor. You don't need to doctor shop if you are getting everything you might want.'

<http://medicalrepublic.com.au/real-time-monitoring/12221>

Australian Self Medication Industry executive director Deon Schoombie has claimed that forcing people to go to their doctor for codeine tablets ran the risk of them walking away from their general practitioners with even stronger drugs. Mr Schoombie stated, 'It just shifts the problem [to doctors]. Does it solve the problem? I doubt it.'

<http://www.smh.com.au/national/health/overthecounter-sale-of-codeine-pain-killers-such-as-nurofen-plus-and-panadeine-may-end-20150425-1mt2fl.html>

5. Other forms of medication or treatment may not supply the same relief or not be suitable for particular pain sufferers

Opponents of the ban argue that there may not be readily-available alternative medications or treatments to replace over-the-counter codeine products.

It has been claimed a combination product containing ibuprofen and paracetamol would fill the gap left by the unavailability of low-dose codeine-containing painkillers. However, opponents of the ban on over-the-counter sale of codeine products note that not all pain-sufferers will be able to use these combination painkillers.

There are many people who should not take ibuprofen, or take it only with extreme caution. These include people with aspirin sensitive asthma (ibuprofen may worsen their asthma symptoms, and potentially cause an acute asthmatic attack). It is also contraindicated for those with gastrointestinal disorders such as Crohn's disease, and those with kidney impairment (ibuprofen may make their condition worse) and for people taking medicines that may have a serious drug interaction with ibuprofen. These include: Warfarin and other medications used to prevent blood clots (ibuprofen may increase the risk of bleeding); some

medicines used in the treatment of high blood pressure or heart failure (ibuprofen may increase blood pressure and reduce kidney function) and low-dose aspirin for protection against heart attack and stroke (ibuprofen may reduce the protective effect). Critics maintain that there will be a large group of pain-sufferers for whom the recommended replacement medication of ibuprofen and paracetamol in combination will not be a suitable alternative. <https://www.lifehacker.com.au/2018/01/codeine-banned-in-australia-why-the-arguments-dont-add-up/>

Numbers of consumer forums have indicated dissatisfaction with the decision to ban over-the-counter sale of codeine, suggesting that for some forms of pain it is the most suitable remedy and that having to visit a doctor is inconvenient. Among posts made on the Essential Baby site in December, 2016, were the following. 'I'm a bit disappointed as I sometimes get really bad headaches that only codeine works for. I never know when I will need it'; 'I get classic migraine with aura. If I take a couple of Panadeine Extras/Nurofen Plus when the aura starts I can head off the worst of the pain and just be disoriented and hung over instead. Not being able to acquire simple pharmaceuticals can mean the difference between being functional or completely non-functional 60 minutes from now. Appalling decision that will clog up GPs' waiting rooms...'; 'I use Panadine/ Panadine Extra/Nurofen/Nurofen Plus for migraines. If I take these early enough I avoid terrible pain and can function. Seems like a waste of doctors' time when someone needs something stronger than panadol but not something like Endone...'

<http://www.essentialbaby.com.au/forums/index.php?/topic/1181768-codeine-to-be-prescription-only/>

On December 31, 2017, The Sydney Morning Herald referred to the instance of 60-year-old Karen Baines who said she often took Nurofen Plus or Mersyndol to treat her knee and ankle pain, and had already tried Panadol and Panamax with no satisfactory effect.

<http://www.smh.com.au/national/health/a-tsunami-of-pain-changes-to-codeine-availability-shed-light-on-hidden-epidemic-of-addiction-20171230-h0bmk3.html>

Arguments opposing the over-the-counter sale of codeine products

1. Codeine can be highly addictive

For therapeutic users of codeine, the addictive qualities of the drug can be a significant problem.

Inside the body, codeine is partially metabolised to morphine, which can produce feelings of relaxation and euphoria. As a result, some people increase their use of codeine-containing medications. <https://www.newscientist.com/article/2116813-australia-bans-non-prescription-codeine-to-fight-opioid-crisis/>

Australia's Therapeutic Goods Administration (ATG) has stated, 'Low dose codeine-containing medicines are not intended to treat long term conditions, however public consultation indicated that many consumers used these products to self-treat chronic pain. This meant that consumers frequently became addicted to codeine.'

http://www.huffingtonpost.com.au/2016/12/19/you-wont-be-able-to-buy-codeine-over-the-counter-anymore_a_21631170/

Dr Hester Wilson, a GP and addiction medicine specialist has noted that with some individuals, addiction can occur within days. Dr Wilson has stated, 'I think many of us take a casual approach to painkillers... but up to 50 per cent of people who use opioids for more than a few days have a real risk of becoming dependant.'

<http://www.bodyandsoul.com.au/health/health-news/this-is-australias-fastest-growing-drug-problem-and-its-legal/news-story/b0b6534a1b23bd3683b6e85246b2cf02>

Over the past 10 years drug services have reported a tripling of people presenting with codeine dependency. <http://www.abc.net.au/triplej/programs/hack/how-rapper-360-survived-his-secret-codeine-addiction/7096990>

The addictiveness of codeine means that some people have taken up to 100 tablets a day, which they have collected over the counter from multiple pharmacies. A family who wrote to Australia's Therapeutic Goods Administration (TGA) said their son would drink the entire contents of a 200 millilitre bottle of cough syrup in one sitting several times a week, or alternatively, buy 48-tablet packs of Panadeine Forte or similar pills.

<http://www.smh.com.au/national/health/a-tsunami-of-pain-changes-to-codeine-availability-shed-light-on-hidden-epidemic-of-addiction-20171230-h0bmk3.html>

Less dramatic instances of codeine addiction can also be highly debilitating. A Sydney Morning Herald report published on December 31, 2017, noted the situation of Leah O'Dwyer who over the last four months had been able to wean herself off codeine, after she heard her pills would no longer be available over the counter. She went to visit one of her pharmacists and told her: 'I have a problem, please help me.' It was only as she gradually took herself off the drug, transitioning to Panadol and ibuprofen, that she realised how addicted she had become. Ms O'Dwyer said, 'The little voice in my head that said "Just go get some codeine" was there for the entire time.' <http://www.smh.com.au/national/health/a-tsunami-of-pain-changes-to-codeine-availability-shed-light-on-hidden-epidemic-of-addiction-20171230-h0bmk3.html>

In terms of avoiding codeine dependency, it has been noted that doctors are able to prescribe alternate medications for opioid-responsive pain that are less addictive than codeine.

Professor Hogg, a PainAustralia board member and head of pain services at the Royal Melbourne Hospital, has noted that buprenorphine and tapentadol are both opioid medications which are 'less dependence forming' than codeine.

<http://www.smh.com.au/national/health/a-tsunami-of-pain-changes-to-codeine-availability-shed-light-on-hidden-epidemic-of-addiction-20171230-h0bmk3.html>

2. The dependency-based use of over-the-counter codeine medications is growing dramatically in Australia

Those who want the over-the-counter sale of codeine products banned in Australia point to the increased incidence of codeine dependency brought about through the use of medications bought without a prescription.

In September, 2017, the Australian Drug Foundation (ADF) released a report titled 'Is there a pill for that?...the increasing harms from opioid and benzodiazepine medication.' It warns, 'At the Alcohol and Drug Foundation, we believe pharmaceutical misuse is Australia's fastest-growing drug problem. The number of people dying after taking codeine has doubled in the past decade...' There are over 5 million over-the-counter sales of Nurofen Plus, Panadeine, Mersyndol and Codral in Australia each year. <http://www.dailymail.co.uk/news/article-5222879/Medication-containing-codeine-prescription-only.html>

The ADF report further noted, 'Some medication misuse is deliberate, for example when people take a pharmaceutical drug for a euphoric or other psychoactive effect. In 2013, over 200,000 adult Australians reported deliberately misusing over-the-counter codeine analgesics.'

The ADF report additionally warned, 'Public alcohol and drug clinics reported a fourfold increase in the number of treatments where codeine was a drug of concern between 2003 – 04 to 2013–14.' <https://adf.org.au/wp-content/uploads/2017/10/ADF-Prevention-Research-September-2017.pdf>

An editorial published in Australian Prescriber on January 23, 2017, states, 'The proportion of people seeking opioid substitution treatment for codeine dependence in Australia rose from

2.7% in 2014 to 4.6% in 2016. A study in Sydney reported that codeine was the sole substance used by 39% of patients with a pharmaceutical opioid dependence and 83% of these patients were using only over-the-counter codeine. At a drug dependence unit in South Australia, the annual incidence of codeine dependence requiring intervention increased from 31 people in 2003 to 174 in 2014. The estimated cost of treating 30 patients with codeine-related admissions in one Adelaide hospital was over \$1 million.⁴ In 2013 the National Drug Strategy Household Survey reported that 33% of the people who had misused pharmaceuticals had used over-the-counter codeine-containing analgesics. This increased to 75% in 2016.⁶' <https://www.nps.org.au/australian-prescriber/articles/changes-for-codeine>

3. Codeine medications and codeine-combined medications can result in organ injury or death

Taken beyond the recommended dose, both codeine and medications in which codeine is combined with either paracetamol or ibuprofen can be fatal or cause serious organ injury. There is data to suggest that these products present a similar risk of death as heroin abuse. There were 1917 recorded deaths involving either over-the-counter products containing codeine or Oxycodone between 2007 and 2011. In the same time period, 1127 people died from heroin abuse. <http://www.dailymail.co.uk/news/article-5222879/Medication-containing-codeine-prescription-only.html>

Royal Australian College of General Practitioners vice-president, Edwin Kruijs, has stated, 'Up to 150 Australians are now dying from codeine-related overdoses every year — double the number 10 years ago — and many more people are seeking help for codeine addiction. So it's vitally important that the people affected by the end of over-the-counter sales get appropriate advice on alternative medications and are directed to their GP for further support and advice as necessary.' <https://www.theaustralian.com.au/national-affairs/health/thousands-of-australians-have-excessive-need-for-codeine/news-story/24f2bfed454db1b61fd4570c3633fb27>

A comment and analysis published in The New Scientist on January 3, 2017, noted what it referred to as the 'double whammy' effect, that is, those who over-use combination drugs containing codeine are harmed by both the codeine and the other drug with which the codeine is mixed. The New Scientist report stated, 'When people start taking high doses, codeine can cause severe breathing difficulties. But there is another harmful effect for people who become addicted. Over-the-counter drugs that contain codeine also often contain other drugs like paracetamol (acetaminophen) or ibuprofen, and as a person increases their use of these, they can experience liver, gut or kidney damage.

A recent study found that paracetamol or ibuprofen was involved in 55 per cent of the 1200 codeine-related deaths recorded in Australia between 2000 and 2013.

<https://www.newscientist.com/article/2116813-australia-bans-non-prescription-codeine-to-fight-opioid-crisis/>

Michael Vagg, a pain specialist in Geelong, has stated, 'Every hospital in Australia will tell you stories of addiction to such combined drugs. 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.' <https://www.newscientist.com/article/2116813-australia-bans-non-prescription-codeine-to-fight-opioid-crisis/>

4. Much of the pressure to retain over-the-counter sale of codeine products comes from groups concerned to protect their profits

Supporters of the banning of over-the-counter sales of codeine products argue that some of those bodies arguing for their continued sale are concerned to preserve their profits.

In November, 2015, Australia's Therapeutic Goods Administration (TGA) agreed to the postponement of a ban in response to lobbying from the Pharmacy Guild, the Pharmaceutical Society of Australia and the Australian Self Medication Industry.

The Royal Australian College of General Practitioners claimed that much of the opposition to the ban was commercially motivated, arguing over-the-counter medications are 'big business and as a result there is likely to be significant pressure to resist rescheduling these medications'. <http://www.theage.com.au/national/health/pharmaceutical-lobby-groups-may-delay-codeine-ruling-20160930-grs2yk.html>

Similarly, Public Health Association of Australia chief executive, Michael Moore, has urged that the decision to end over-the-counter sale of codeine products should not be determined by the loss of profit to manufacturers and pharmacists or the increased demands on the government health budget to cover Pharmaceutical Benefits payments and Medicare costs. Mr Moore stated, 'I think there's a fine balance in pharmaceuticals between industry profits and what's the most effective way to deliver pharmaceutical goods to the consumer, it ought not to be just about how that affects industry or jobs.'

<http://www.theage.com.au/national/health/pharmaceutical-lobby-groups-may-delay-codeine-ruling-20160930-grs2yk.html>

The Therapeutic Goods Administration's (TGA) principal medical officer, Dr Tim Greenaway, has explained the decision to ban over-the-counter codeine sales, stating, 'It's important that people realise that the decision's been taken based on safety predominantly and based on the risk of abuse... The decision's been made on the basis of patient safety; the bottom line of pharmacies, for example, is not a consideration that has been taken into account.' <http://www.abc.net.au/news/2016-12-20/codeine-painkillers-wont-be-available-over-the-counter-2018/8133996>

Responding to changed market conditions, the maker of Panadeine products, GlaxoSmithKline, has ceased manufacturing those products, declaring it will pull them from Australia. Other companies are believed to be reformulating popular brands by removing the codeine so they can still be bought over the counter.

<http://www.news.com.au/lifestyle/health/pharmacists-say-codeine-crackdown-a-hardtoswallow-headache/news-story/1d475d05edae128e339e01a2a66fcf53>

5. There are more effective alternative treatments to manage pain

It has been claimed that unprescribed codeine is not a particularly effective pain treatment for chronic pain and that sufferers would be better to get medical advice regarding their pain management. It has also been argued that once codeine is no longer an over-the-counter medication, there are other effective medications available to people to treat short-term pain. Pain medicine specialist, Dr Michael Vagg, has explained that codeine purchased over the counter was in such low doses that some people may find themselves taking more and more to produce meaningful pain relief. It has been suggested that doing this is a dangerous procedure, not only because it creates a risk of addiction or overdose, but also because it leaves the cause of the pain and other forms of pain treatment unexplored.

Dr Vagg has stated, 'If you have severe acute pain and the simple analgesics are not cutting it, you are better off going to your doctor to get a diagnosis and prescription. With persistent pain, that advice is even more important. Trying to manage long-term persistent pain with lots of doses of short-acting analgesics is not the best approach.'

<http://www.smh.com.au/national/health/overthecounter-sale-of-codeine-pain-killers-such-as-nurofen-plus-and-panadeine-may-end-20150425-1mt2fl.html>

Dr Chris Hayes, Dean of the Faculty of Pain Medicine (FPM), has advised that anti-inflammatory drugs or paracetamol provide better pain relief without the risk of codeine addiction.

Dr Hayes has stated, '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 [addiction].' Dr Hayes has further noted, 'In the chronic pain situation, codeine doesn't work well anyway.' <https://www.sbs.com.au/news/codeine-free-pain-relief-is-better-expert>

Codeine is a short-acting analgesic that is metabolised very differently by different individuals so that the level of its active constituent, morphine, that is released varies dramatically from one person to another. It generally should not be used for managing chronic pain. Chronic pain sufferers using codeine often find that they need to take larger and more frequent doses to obtain relief. <https://www.campbellandfreebairn.com.au/blog/latest-news/codeine-based-pain-relievers-and-chronic-pain-management.php>

Australian Medical Association president, Dr Michael Gannon, has stated, 'For those people who have historically used Panadeine or Neurofen Plus, rather than plain Panadol or plain Neurofen, the evidence shows that for the overwhelming majority of people the combinations containing codeine are no more effective.'

<http://www.couriermail.com.au/news/national/mps-push-to-water-down-ban-on-codeine-sales-without-prescription/news-story/7ad276a27f5a428d326090ad439d46bb>

In addition to other medications, chronic pain sufferers can gain relief from psychological techniques; pacing activities; physiotherapy; relaxation techniques such as meditation; and exercise such as walking, swimming, cycling or tai chi.

<https://www.healthdirect.gov.au/chronic-pain>

Further implications

Though supporters claim that banning the over-the-counter sale of codeine products will be a significant step toward addressing Australia's problems with therapeutic drug misuse, there is a general acknowledgement that this step is only a small part of the solution.

One of the concerns raised by the impending ban on the over-the-counter sale of codeine is that there will not be adequate support available for those suffering withdrawal symptoms when their access to the drug is reduced or ended.

Suzanne Nielsen, a senior research fellow at the National Drug and Alcohol Research Centre (NDARC), has indicated that more funding will be needed to treat those withdrawing from the addictive drug.

Ms Nielsen stated, 'There is (sic) going to have to be dedicated funds and treatment services allocated to respond to this problem.' She has warned that mass withdrawals could be a particular problem in regional areas where codeine product use tends to be relatively higher and where there are already inadequate support facilities.

<http://www.abc.net.au/triplej/programs/hack/concerns-prescription-only-codeine-will-cause-a-national-with/8136288>

It has also been noted that the problem of therapeutic opioid addiction does not simply involve over-the-counter medications.

Research from the Penington Institute in 2016 showed 71 per cent of overdose deaths in Australia were due to prescription medications. The National Drug and Alcohol Research Centre has stated that around 800 Australians a year die from prescription drug overdoses, particularly opioids, including codeine, fentanyl, methadone and morphine. Australia ranks eighth in the world's top 30 users of prescription painkillers such as these.

<http://www.heraldsun.com.au/news/victoria/the-secret-addiction-costing-lives/news-story/46c26a33061855862e41ba508392284c>

An opinion piece published in *The Australian Family Physician* in December 2016 noted the importance of doctors prescribing carefully, advising patients on pain management and monitoring their use of addictive medications. It stated, 'Prescription drug abuse is a complex

problem that needs to be addressed by society and the medical profession together. Doctors need to be aware of the risk of dependence and overdose with any drugs they prescribe, but particularly drugs of dependence. Opioids and benzodiazepines are associated with the highest risk of overdose deaths... In a general practice setting, the use of evidence-based guidelines can help with managing inappropriate requests for drugs of dependence.'

<https://www.racgp.org.au/afp/2016/december/prescription-drug-abuse-a-timely-update/>

Critics of the ban on over-the-counter sales of codeine products have argued that the problem of codeine misuse will not be solved by placing responsibility on prescribing doctors who do not always exercise it effectively.

One of the solutions proposed is to implement a real-time monitoring scheme which would enable any doctor to check when a particular patient was last prescribed an addictive drug. Suzie Kanis, whose son died of a prescription drug overdose has criticised doctors' failure to coordinate their treatments and regretted the lack of a monitoring system that would help them do so.

Mrs Kanis stated, ' Why did the doctors not check what medication they were each giving him?' She believes her son's death highlights the need for an electronic real-time prescription monitoring system that would alert doctors to the particular mix of drugs a patient had been prescribed. <http://www.heraldsun.com.au/news/victoria/the-secret-addiction-costing-lives/news-story/46c26a33061855862e41ba508392284c>

On January 19, 2018, the Therapeutic Goods Administration released a discussion paper titled ' Prescription strong (Schedule 8) opioid use and misuse in Australia – options for a regulatory response' to consider the need for greater regulation of these prescribed drugs.

<https://www.tga.gov.au/consultation-invitation/consultation-prescription-strong-schedule-8-opioid-use-and-misuse-australia-options-regulatory-response>

Beneath the question of how Australia regulates its therapeutic use of opioids is the larger question of how we manage pain. Australia's National Pain Strategy has as its goals: people in pain as a national health priority; knowledgeable, empowered and supported consumers; skilled professionals and best-practice evidence-based care; access to interdisciplinary care at all levels; quality improvement and evaluation and ongoing research. Critics argue that though there have been some improvements, the country has a long way to go.

<http://www.painaustralia.org.au/improving-policy/national-pain-strategy>