


# Australia's *Silent Killers*



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# Australia's Prescription Medication Crisis

More than 2,000 Australians die each year due to drugs, but it is prescription medications and *not illegal drugs*, that are the most common cause of death. Drug deaths happen to everyday Australians taking medications like Panadeine Forte, Endone, Valium and Prozac. And they happen more frequently than from illegal use of drugs like heroin.

## Pharmaceutical medications linked to deaths in 2018

Benzodiazepines (e.g. Valium)	<b>899 deaths</b>
Opioids (e.g. Endone, Panadeine Forte)	<b>647 deaths</b>
Anti-depressants (e.g. Prozac)	<b>591 deaths</b>
Anti-psychotics (e.g. Lithium)	<b>318 deaths</b>
Anti-convulsants (e.g. epilepsy meds)	<b>174 deaths</b>

Source: Penington Institute Annual Overdose Report 2020

**Prescribed Deaths** is an independent report that exposes how pharmaceutical companies are illegally excluding deadly side effects from the prescription medication warnings given to Australians. Written with the assistance of doctors from Harvard and Yale universities, the report details how this illegal practice has been occurring for over 20 years. Each year the number of accidental deaths from these medications exceed deaths from car accidents, and it is getting worse.

The report cites ABS cause of death data showing that these prescription medications and the exact risks not disclosed are directly linked to most of Australia's drug hospitalisations and deaths. The cause and effect are unequivocal. A person cannot assess a risk that they do not know about nor follow safety advice if it has not been provided.

This has resulted in death for thousands of Australians who simply sought help for medical conditions. By providing PBS support for these medications, the Australian Government funds the cause of death for hundreds of Australians each year, without warning them of this very risk.

The use of these medications has skyrocketed during COVID-19, especially in aged care facilities. Australians have never been more exposed or unaware of these risks. Many of the companies responsible are now fast tracking the delivery of COVID-19 medications to Australians.

History is about to be repeated.



## Consumer Medicines Information (CMI)

For many Australians prescription medication provides significant therapeutic benefits, but no drug is risk free. The CMI is the warning document that lists the serious risks and side effects of taking the medication, as well as any dangerous side effects it has with other medications and alcohol. It provides instructions on how to safely use a medication, to reduce the chance of suffering from adverse side effects like overdose or death. Legally each CMI is required to clearly explain all serious side effects, *even if they are rare* in occurrence.

Every person reacts differently to medications, so the difference between life and death comes down to simply how your body processes these chemicals. The risk of death is greater if you take multiple medications, due to the added risk of how these chemicals interact together. The information in the CMI has a critical role in determining if the medication prescribed to help Australians, actually becomes **the cause of death**.



### **Prescribed Deaths report**

In Australia pharmaceutical companies produce a document for health professionals for each medication, called Product Information (PI), in addition to the CMI for consumers. By comparing the CMI and PI, the report shows that these deadly risks have been disclosed to health professionals in the PI, but not to the people taking the medication via the CMI. These warnings **are** provided to US consumers for the *same drugs* made by the *same companies*. Withholding life-threatening side effects in the PI from the CMI is a breach of Therapeutic Goods Administration (TGA) regulations.



### **Risks Excluded from the CMIs**

- Death
- Coma
- Respiratory Depression
- Addiction
- Toxicity
- Overdose
- Neonatal Death
- Dependence
- Abuse
- Withdrawal Symptoms
- Suicide
- Serotonin Syndrome
- Morbidity

The failure to warn Australians on how to avoid prescription medication deaths has contributed to many of the 15,000 prescription medication deaths since 2001. Reports from the ABS, AIHW, Department of Health, Penington Institute, and the National Drug and Alcohol Research Centre, all show that these medications and the exact risks not disclosed, are the cause of the majority of Australia's adverse drugs events – hospitalisations, *suicides* and deaths – over the last 20 years.

Through three years of 'on the ground research', in some of the most heavily impacted areas of the US opioid epidemic, the report identifies the illegal practices of pharmaceutical companies and shows how they have replicated these practices in Australia. Interviews in the US with doctors, pharmacists, consumers and researchers, identified how US consumer warnings had been illegally modified to downplay the risks of side effects. The companies and medications the report shows have replicated these practices here, are amongst Australia's most commonly prescribed medications.



**Prescribed Deaths - Manufacturers Analysed**

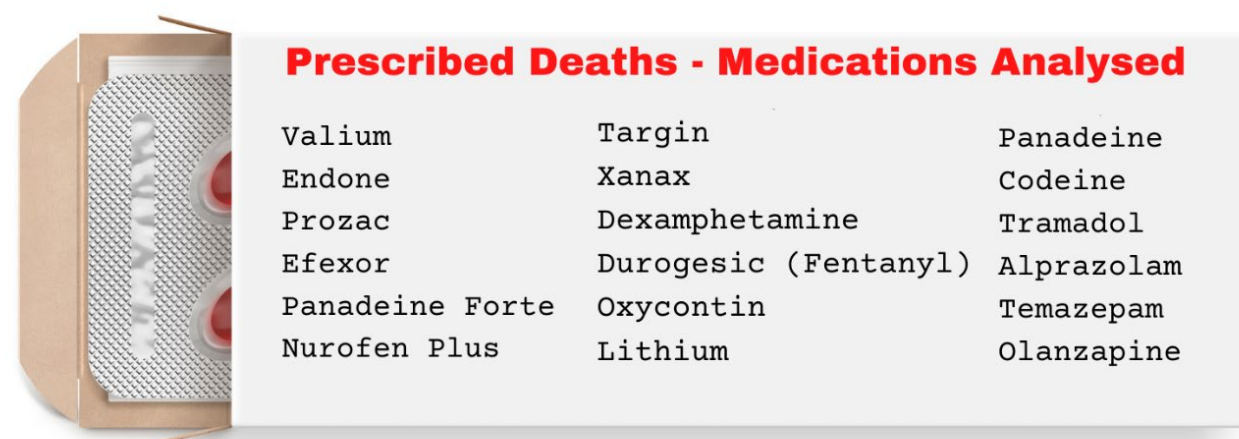












**Prescribed Deaths - Medications Analysed**

Valium	Targin	Panadeine
Endone	Xanax	Codeine
Prozac	Dexamphetamine	Tramadol
Efexor	Durogesic (Fentanyl)	Alprazolam
Panadeine Forte	Oxycontin	Temazepam
Nurofen Plus	Lithium	Olanzapine

**How can the same drug have different warnings in the US to Australia ?**



Being the largest health care market in the world, most new medications are first released in the US after gaining approval from the Food and Drug Administration (FDA). The FDA produces the wording to explain the side effects for medications and has final sign off on each manufacturer warning document. In Australia, the TGA only signs off on the PI and *does not require the CMI to be submitted for approval.*

Legally the drug companies must include the same risks in the CMI as the TGA has approved to be in the PI, but the report shows that the TGA has not actively regulated the CMI content and pharmaceutical companies have exploited this lax regulation.

This has allowed these companies to not add life threatening warnings to the CMI, that are mandatory in the US and are included in the PI. Australian consumers have paid a huge price for this. **The research was unable to find a single occurrence of when the TGA has fined a company for illegal CMI content in 20 years.**

### The TGA fails to enforce its own laws

The medication classes analysed include opioids, benzodiazepines, codeine, antidepressants, antipsychotics and stimulants. Deaths from these medications each year exceed deaths from car accidents.



The TGA did not reject the findings of the report's analysis of over 20 different medications but failed to take action. In responding to the report, Professor John Skerritt, head of the TGA, explained why deadly side effects have not been provided to Australians:



Professor  
John Skerritt

*"...the inclusion of additional technical details would require a high degree of medical literacy (which sadly is comparatively low in Australia) and could have the potential to **confuse** and delay action by patients."*

However, Professor Skerritt could not explain why these exact **same warnings** are provided to US consumers for the **same drugs** made by the **same companies**.

The report details that the side effects not included in the CMIs are the ones that are causing hospitalisations and deaths. Not telling people about deadly side effects has failed to improve people's knowledge of the risks, it is against the law and more importantly, it is costing lives.

Medications dangerous enough to be classified as poisons, are prescribed without warning consumers why they are so dangerous. These medications are scheduled 4 or 8 drugs due to the exact side effect risks that are not being disclosed. The issue is not that the TGA is not aware of these risks, it is that they have refused to act to simply have them included the CMIs, to warn Australians and save lives.

### ACT Minister for Mental Health takes action



Shane Rattenbury MLA

The ACT Minister for Mental Health, Shane Rattenbury MLA, has reviewed the report and the response from the TGA. Minister Rattenbury has wrote to Professor Skerritt on the 9<sup>th</sup> of September, restating the findings and the solutions proposed. The letter stated:

*"...I would appreciate your consideration of the issues and solutions provided by Mr O'Connor in his report and his letter to you on the 4th August following your initial reply..."* and further asked

*"...you could provide me with a response regarding what can be done to address the concerns raised by Mr O'Connor."*

A response from Professor Skerritt on the 22<sup>nd</sup> September maintained his view that the contents of the CMI should be framed in "*less technical language*" to not confuse Australians. However, Professor Skerritt again avoided any explanation on why specific risks like addiction, coma and death (as outlined in the report), had not been included at all.

## Valium – Australia’s deadliest prescription medication



The failure of the TGA is highlighted in the report’s analysis of benzodiazepines, a medication that is commonly prescribed for anxiety, sleep disorders and pain conditions. **No prescription medication has killed more Australians.** Valium and Temazepam are Australia’s most prescribed benzodiazepines and the ones most found in prescription drug deaths. Xanax and Alprazolam are the benzodiazepines classified as having the highest risk of causing death and are scheduled 8 medications (drugs of addiction).

Even so, since 2000, the CMI’s for these PBS medications have *not mentioned* the risk of death, coma, respiratory depression, addiction, neonatal death or withdrawal syndrome in any CMI produced, *and they still do not today.*

However, this information is well documented in health practitioner information produced by the Australian Department of Health, the Pharmacy Guild of Australia and the Royal Australasian College of General Practitioners. The resources provided to Australians by mental health organisations like Beyond Blue also fail to disclose most of these risks.



Risks associated with Benzodiazepines			
	Australian Department of Health	CMI’s	Beyond Blue <sup>1</sup>
Death	✓	✗	✗
Coma	✓	✗	✗
Respiratory Depression	✓	✗	✗
Addiction	✓	✗	✓
Withdrawal Syndrome	✓	✗	✓
Abuse	✓	✗	✗
Increasing dependency risks	✓	✗	✗
Fatal risks during pregnancy	✓	✗	✗
Fatal risks during breastfeeding	✓	✗	✗
Fatal risks with alcohol	✓	✗	✗
Fatal risks with antidepressants	✓	✗	✗
Fatal risks with opioid medications	✓	✗	✗
Fatal risks with codeine medications	✓	✗	✗
Risk of suicidal thoughts	✓	✗	✗

<sup>1</sup> Beyond Blue, Anxiety The Facts, [Benzodiazepines](#)

## Deadly consequences

Australians consume 6 million prescriptions of benzodiazepines each year. The medication is the cause of death for 900 people a year and **the total number of deaths since 2001 is 9,133**.

Due to the increase in anxiety related mental health conditions during COVID-19, more Australians are seeking anxiety treatment than ever before. Outcome Health recently released a report showing an increase in benzodiazepine prescriptions by as much as 31%. Based on PBS data, that would see the total number of prescriptions increase from 6 million to around 8 million a year. Potentially that could see the loss of life due to benzodiazepines increase by several hundred Australians, from 900 to around 1,200-1,300 each year.



**Even though nearly 10,000 Australians have died from benzodiazepines since 2001, no benzodiazepine CMI since 2000 has ever contained any mention of the risk of death.**

**How many more Australians will die before the TGA decides to include the risk of death in the CMIs?**

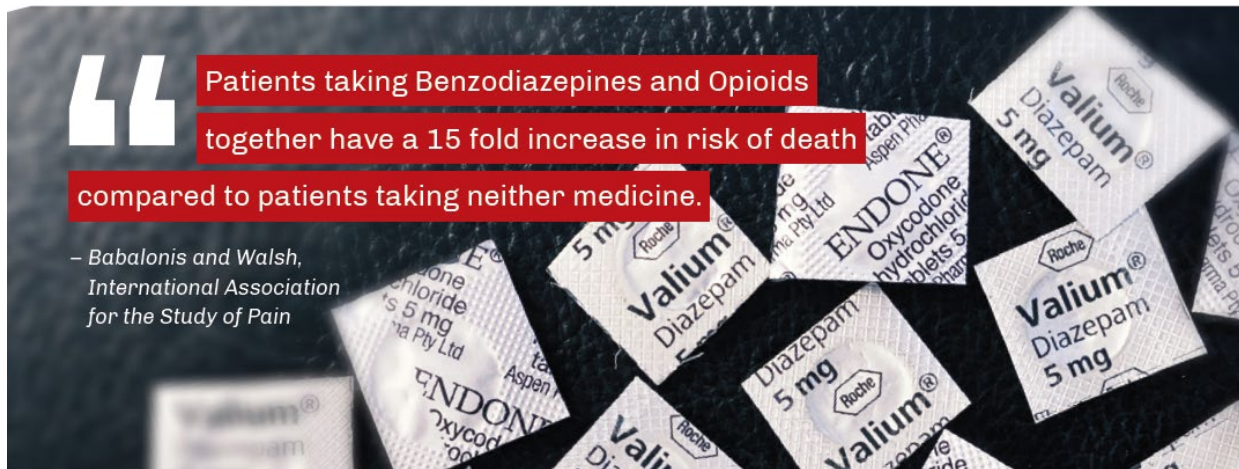
In 2012 Professor John Skerritt responded to a Victorian coronial inquest that stated that there is a systemic public health issue of death associated with benzodiazepines, primarily Valium. The Coroner raised concerns that consumers are not aware of the true nature of benzodiazepine risks.

Professor Skerritt's response strongly implied to the coroner that all the PI risks of Valium are contained in the CMI, it did not then, and it still does not today. 2 years later the TGA rescheduled the benzodiazepine Alprazolam (Xanax) to a scheduled 8 drug due to the deaths associated with its use, yet the CMI was not updated to include the risk of death.

**At neither opportunity did the TGA review and include the PI risks associated with benzodiazepines into the CMI. If they had of thousands of lives could have been saved.**

## The failure to warn – the risks withheld

It is uncommon for benzodiazepines to be the sole medication in drug deaths. The ABS states that in over 96% of drug-induced deaths where benzodiazepines were present, they were taken in conjunction with other drugs including *prescription opioids and alcohol*.



The deadly lack of information in all benzodiazepine CMI is highlighted in the comparison of the warnings for these risks between the Valium CMI and the Valium Product Information, that is provided to health care professionals.

Product Information – side effects of combining Valium with <b>alcohol or opioids</b>	CMI – side effects of combining Valium and <b>alcohol</b>	CMI – side effects of combining Valium and <b>opioids</b>
“...severe sedation that could result in <b>coma or death</b> , clinically relevant <b>respiratory and/or cardiovascular depression</b> .”	“...drowsiness, confusion, dizziness and unsteadiness which may increase the risk of a fall.”	Opioids have <u>never</u> been included in any Valium CMI since 2000

In 2020 the TGA moved to improve several of the warnings in the opioid CMI, including Endone. An important addition is the warning statement that combining an opioid with benzodiazepines or alcohol can result in “...in severe drowsiness, decreased awareness, breathing problems, coma and death.” Hence it is unclear why this warning has not also been added to the CMI for benzodiazepine medications like Valium, especially considering the loss of the life this warning could immediately prevent.




Many Australians are not aware that medications like Endone, Panadeine Forte and Nurofen Plus are actually types of opioids and have resulted in as many deaths as opioids like OxyContin and Fentanyl. The CMI failures for all opioids and benzodiazepines are without question the area that has had the greatest impact on lives lost. PBS data details these that 2 medications are commonly prescribed together by GP's.



The reports title is born from this tragic prescription cocktail.



## Fatal failures across many classes of drugs

Manufacturer	Medication Failure
	<p>Lithium Carbonate is used to treat bipolar disorder. The CMI does not include the PI warning that lithium toxicity can result in <i>coma and death</i>. It also does not include the PI warnings that lithium toxicity can happen at <i>prescribed doses</i>, nor the risk of death from an overdose.</p>
	<p>Efexor XR and Prozac (Fluoxetine) are antidepressants. Neither CMI includes the life-threatening risk of serotonin syndrome. In September 2014, the TGA issued a safety advisory warning about the risk of serotonin syndrome. It stated that in some cases serotonin syndrome can lead to <i>loss of consciousness, coma and death</i>.</p>
	<p>Dexamphetamine is prescribed for ADHD. The CMI states that using this medicine strictly as your doctor prescribed will ensure that abuse or drug dependence should <i>not</i> be a problem. However, the PI states that dependence can occur at <i>prescribed doses</i>.</p> <p>The CMI does not contain the PI risks of <i>death</i> from using the medication at <i>usual doses</i> or from an overdose. The CMI also does not mention the risk of <i>addiction</i>. Dexamphetamine is a scheduled 8 drug due to the risk of dependence, addiction and abuse.</p>
	<p>Vyvanse is the largest dose dexamphetamine than can be prescribed, it is a scheduled 8 drug due to the risk of addiction, yet the CMI does not mention the risk of addiction. Risks in the PI but not the CMI include that <i>sudden deaths, stroke, and myocardial infarction</i> have been reported in adults taking stimulant drugs at <i>usual doses</i>. The CMI also fails to mention that <i>fatal</i> poisoning is usually preceded by <i>convulsions and coma</i>.</p>
 	<p>The report also details the TGA's history of taking action on side effect issues, yet still failing to recognise that these side effects are not included in the CMIs. In 2014, the TGA rescheduled the benzodiazepine Alprazolam (Xanax) to a Schedule 8 drug due to the exponential increase in deaths associated with its use. The CMI contained no warning of the risk of <i>death</i> then, and six years later, it still does not. In fact, the TGA allows CMIs for generic Xanax brands to be dispensed that have not been updated <i>since 2009</i>.</p>
	<p>The OxyContin warning in the US states that because extended-release products such as OxyContin deliver the opioid over an extended period of time, <i>there is a greater risk for overdose and death due to the larger amount of oxycodone present</i>. Another warning, that has never been provided to Australians.</p>
	<p>Fentanyl (opioid) is regarded as <i>the</i> most addictive and lethal prescription medication. From 1999 to 2020 the CMI advised that addiction is <i>unlikely</i> when DUROGESIC is used correctly. The PI states addiction can occur in patients <i>appropriately prescribed</i> DUROGESIC at recommended doses, that the risk of addiction <i>increases</i> the longer the drug is used and with higher doses. Fentanyl is now the leading cause of drug addiction and death in the US.</p>



The Endone CMI provides no information on the recommended use of Endone, it does not state that it is an opioid or that *death* can occur at therapeutic doses.

The Endone CMI describes the side effect of consuming alcohol whilst taking the medication as dizziness. In the PI provided to doctors, the side effects listed include dizziness and *profound sedation, coma and death*. Between 2001–2017, all opioids deaths in Australia totalled 13,269, with alcohol a common contributing fatal interaction.



The Panadeine Forte CMI does not include that the risk of addiction is *increased* in patients with a mental illness, as it states in the PI.

In 2017 Professor John Skerritt stated in a TGA presentation on codeine deaths that *“The babies have a rapid metaboliser gene and there's been deaths, for example, in North America for breastfed babies just with codeine turned into morphine in breast milk.”*

The Panadeine Forte CMI *still* warns that breast feeding may *affect* the baby, the PI states that the risk to the baby is *respiratory depression, morphine overdose, opioid toxicity and death*. Disturbingly the TGA does not believe that this risk is serious enough to be included in the CMI.

## Right to safe healthcare

The law of informed consent means that a person has a legal right to be informed of all the risks and benefits of a medication. Based on the information they receive, they will choose to proceed taking the medication, fully aware of the risks. For the consent to be valid, it must be informed. This includes when multiple medications are prescribed. Informed Consent is also required again, anytime a new medication is added, or a dose changed.

Dr Craig Allen



The report utilised the expertise of 2 of the leading medication experts in the US, Dr Craig Allen and Dr Lori Calabrese. They independently concluded that when comparing the US vs Australia consumer warnings, that these side effects have been well known for decades and are clearly explained in US consumer warnings written by the *same companies for the same medications*.



All of those potential risks have been known for many years, and it's **unconscionable** to not include that type of information when considering prescribing this medication, let alone introducing this type of medication to any human population.

– Dr Craig Allen



Apart from the fact that I haven't seen a single leaflet that contains the necessary information on the real risks, I am still in shock over this statement: 'All medicines can have side effects'. That's true. 'Sometimes they're serious, most of the time, they are not'. Are you kidding? That's so misleading for drugs with this level of dangerous side effects. I hope people get given some other warning information because what I have seen doesn't meet any standard for someone to give informed consent.

– Dr Lori Calabrese



When you read the lead warning statements for opioids and benzodiazepines in our medical guides, they're all warnings about death because these drugs are deadly especially when taken together or with alcohol. These warnings are about real risks to real people. They are warnings that patients need to know if they're going to take an opioid or benzodiazepine because these can result in that slow march of use, tolerance, dependence, overdose, and death, even when the drug is taken as prescribed. I can't believe these Australian warnings.

– Dr Lori Calabrese

The *Prescribed Deaths* report presents an emphatic case that since 1999, millions of Australians each year have been unknowingly exposed to lethal side effects of medications without being given the information to legally give informed consent. You simply cannot assess a risk that you do not know about. You cannot follow safety advice if it has never been given to you. This has resulted in death for thousands of Australians who simply sought help for medical conditions.



**Australian Government**  
**Department of Health**

The Australian government endorses the CMI as the information source for accurate medication safety and side effects, including prescription medication interactions. Approving these medications for the PBS provides a further endorsement in the minds of Australians – given the PBS subsidises the cost, it makes the medication more accessible to people.

The failure to ensure that Australians are provided with accurate information is not only a breach of the right to safe health care, it also means that the government has full culpability for the failings and the resulting health issues people have suffered.

If information is not disclosed to people then they cannot legally give informed consent to their doctors to take the medication, which has legal implications when a person suffers from a side effect. By providing PBS support for these medications, the Australian Government funds the cause of death for hundreds of Australians each year, without warning them of this very risk.

## Prescribed to death

Ms Lauren Johnstone died after taking a combination of prescribed and non-prescribed medications, all lawfully obtained. The combination of Valium and Endone she was prescribed increased the risk of death by 15 times. However, Ms Johnstone's doctor testified to the Coroner that he only advised her of the risk of *drowsiness*. Neither CMI provided any warning on the risk of death when these medications are combined, risks that are well-detailed in the PIs and by the Department of Health.



Ms Lauren  
Johnstone

*“My mother was prescribed a combination of medications that has a well-known risk of death when taken together, the CMIs did not mention this and her doctor only advised mum to be careful of drowsiness. She had no way of knowing the risks and if she did she would never have taken the drugs, who would? Informed consent means you are informed, it is a legal right. My mother’s death was preventable. She was not appropriately informed of the risks of combined medications and the Government is continuing to ignore this issue leaving many more families without loved ones. Action needs to be taken now or people will continue to die.” - Ms Johnstone’s daughter, Ariarne Bunyan*

## Failing our Veterans

Multiple research studies and government reports highlight that mental illness and chronic pain is very common with ADF veterans. These studies also show that the medications analysed in this report are widely prescribed to ADF veterans, especially opioids and benzodiazepines.

DVA is also aware that alcohol use and abuse is an issue. As such they are aware of the added dangers these veterans are exposed to when taking these medications.

Veterans Mates was established in 2004 by DVA to specifically to address the issue of prescription medication dangers. The programme draws on Repatriation Pharmaceutical Benefits Scheme data to identify veterans who are at risk of medicine related problems and the health providers who treat them.

By researching which veterans are prescribed dangerous medications and combinations of medications, DVA then communicates with both the GP and veteran to encourage a review of the medications. Their website states that the program has saved 140 lives and 930 hospitalisations, without acknowledging the lives lost to prescription medications. According to Veterans Mates:

- **33,000 veterans are taking 5 or more medications, which is a deadly prescription drug cocktail.** However only 1 in 14 of these have had a home medicines review.
- Over **1 million** medications are dispensed to around **70,000** contemporary ex-serving ADF members, an average of **16** dispensing's per person
- More than **65,000** veterans received an antidepressant over a 2-year period
- Around **53,000** ex-serving ADF members had a mental health condition and were approved to receive services and treatments from DVA

Veterans Mates contacts the doctors of these veterans and sends them information related to the medication risk, which is very specific on the deadly risks. However just like the pharmaceutical companies, DVA does not include these deadly risks in the information they sent to veterans. In the information for veterans they simply refer to “serious side effects” without explaining the risks further.

Instead of urgently contacting and directly warning the veterans, they encourage the doctor to have this discussion, but there is no requirement for it to happen and Veterans Mates reports show its rarely occurring.

## Pharmacy fatal failures

The *Prescribed Deaths – Life in the Killing Zone* report includes the transcripts from video recorded visits to ACT pharmacies to highlight that these warnings are also not being provided to people when seeking personal medication advice from pharmacists.

Every single visit failed to advise of the information (as outlined by the Department of Health) in relation to the life-threatening risks these medications expose a person to. In only 60% of the visits did the pharmacist provide a CMI, after being asked for one, despite this being a legal requirement. Multiple times, information was given verbally that is factually incorrect and misleading as to the life-threatening risks. One pharmacist offered a handwritten note in place of a CMI and another advised that their printer was out of ink. Information was provided from non-approved sources, and in other visits advice was changed when the pharmacist was asked to identify the source of the advice that the medication was low risk.

Instead of advising of the risk of death, the advice given by ACT pharmacists includes:

**“You would have exactly what I have if you Google it up. Type in the name and read, that’s exactly what I would give you.” – ACT Pharmacist**

**“Yeah that’s publicly available information, just Google up and read, that’s the same thing I would print out for you.” – ACT Pharmacist**

**“So, you stick Valium, Endone and alcohol together, the you’ve got your triple whammy there, right? You wouldn’t get in the car.” – ACT Pharmacist**

**“If you’d had some Endone and some Valium and two or three beers, you’d be like, ‘No, I’m home for the night’, because they’ve all got a sedating thing. I should write it down.” – ACT Pharmacist**

**“If you take it together [Endone and Valium] you will have excessive drowsiness, the medication will basically knock yourself out. But apart from that they are not really going to interact to give you any crazy side effects or anything like that.” – ACT Pharmacist**

The Seventh Community Pharmacy Agreement (7CPA) signed in June 2020 is an agreement between the Commonwealth Government, the Pharmacy Guild of Australia (The Guild) and the Pharmaceutical Society of Australia (PSA). This agreement outlines the responsibilities of pharmacists in delivering medication Information to consumers.



Pharmacists are remunerated by the PBS for this service, in fact they are paid additional fees when dispensing dangerous medications like Xanax.

Pharmacists have ethical and legal requirements for the provision of the CMI and verbal advice to consumers. This report shows how pharmacists have failed to meet these obligations.

## Aged Care residents the most exposed

In June 2020, the AIHW provided to the minister of health Greg Hunt, a report titled *Australia's health 2020*.<sup>2</sup> The report serves as a report card on the health and welfare of Australians. The report details the increase in antidepressant, antipsychotic, benzodiazepine and opioid medicines that occurs in the 6 months following admission into an aged care facility.

One study showed that 6,900 people (15%) were new users of antidepressants, just under 9,000 (20%) were new users of antipsychotic or benzodiazepine medicines and opioid medicines were newly prescribed to over 12,000 people (28%).



The medications are also being prescribed almost immediately upon entering the facility. New users of antidepressant medicines were dispensed a median of 3 days after the entry date, while antipsychotic and benzodiazepine medicines were dispensed a median of 1 day after the entry date and opioid medicines a median of 0 days. Most prescriptions dispensed were written by GPs.

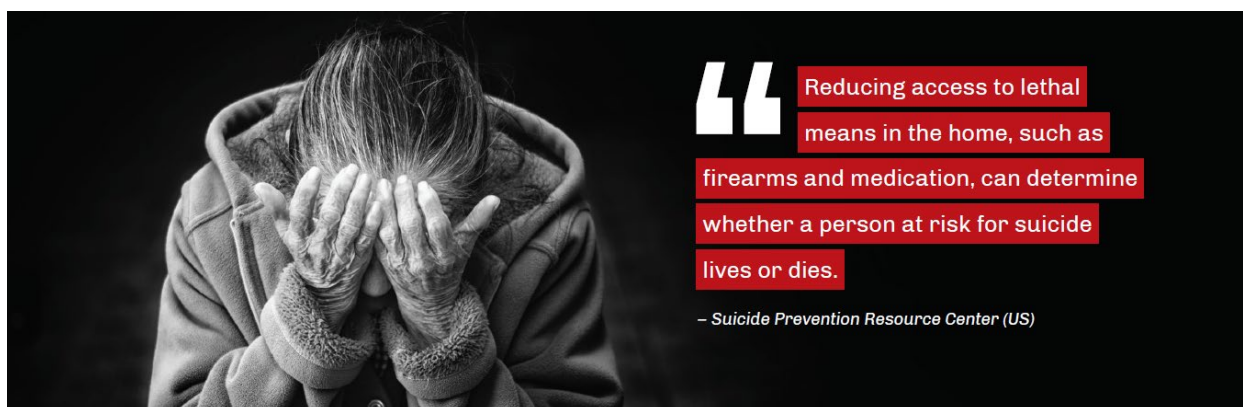
The report also raises concerns around people who were newly dispensed antipsychotic medicines and who also had at least 1 other prescription dispensed for an antidepressant, benzodiazepine or opioid medicines in the same year.

## Self-harm and suicide

The statistics from the last 20 years show that opioids, benzodiazepines, antidepressants, and antipsychotics are not only the most common drugs present in accidental drug deaths, but they are also the same medications used in *suicide attempts and deaths*.

Horrifyingly, in some instances, the very medication prescribed to treat the *risk* of suicide is used as a method of poisoning in suicide. Distressingly the increase in prescriptions of these medications to young Australians has resulted in an increase in their deliberate self-poisoning using these medications.

The risk of a person dying by suicide increases if they have access to lethal means of death, like a firearm. Suicide prevention experts classify the medications in this report as lethal means of death, comparable to having a loaded gun in the home. Prescribing medication that can cause death, actually *increases the risk of suicide to people with mental illness*. No CMI explains this or provides any strategies to reduce this risk.



<sup>2</sup> <https://www.aihw.gov.au/reports/australias-health/australias-health-2020-data-insights/contents/summary>

For example, the Prozac PI (2020) states:

*During a 13-year period, there were 34 fatal reports of overdose where fluoxetine was the only reported ingestant.*

On the management of suicide risk, the PI states:

*Prescriptions for PROZAC should be written for the smallest quantity of medicine consistent with good patient management, in order to reduce the risk of overdose.*



The Prozac CMI (2019) provides no warning of the risk of death from an overdose, and no warning to limit access to the medication supplies to prevent suicide attempts from an overdose.

Similarly, Olanzapine and Clopine (clozapine) CMIs contain no warning on the risk of death from an overdose. The report shows these three medications are commonly found in youth suicide attempts. The PIs for all medications state that overdoses can be fatal. Yet again, CMIs are inconsistent with the PIs. These medications are all endorsed for the use in youth mental health treatment by Orygen-Headspace. A 2019 study on the trends in self-poisoning and psychotropic drug use in people aged 5–19 years, showed that Prozac was the third most common substance ingested in child and adolescent self-poisoning.

## TGA failures

Each instance that the information in the CMI is not consistent with the PI is a breach of the *Therapeutic Goods Act 1989* and the research details over 100 instances where this has occurred for Australia's most dangerous medications. Medications that are illegal to possess without a prescription, medications that are classified as controlled poisons.

The TGA has a responsibility to not only ensure that the content of the CMI is consistent with the PI, they also must ensure that all content in the CMI is accurate and provides the information that is required under Schedule 12 of the Act. The deadly irony of the CMI failings is that the TGA has released numerous consumer updates that include side effects not included in CMIs. The research details the TGA's history of media releases that raise awareness for side effects, whilst failing to recognise that these side effects are *not included* in the CMI.

## TGA



In 2017 the TGA released a consumer fact sheet explaining the risks of codeine medications. It stated that *Some Australians don't realise how much harm codeine can cause and that Codeine is an opioid drug closely related to morphine and, like morphine, is derived from opium poppies.*

The fact sheet warned that codeine medications (like Panadeine Forte) have serious side effects like death, addiction, poisoning, dependence, tolerance, withdrawal syndrome and that it is commonly found in intentional and accidental drug deaths.

The reason why most Australians are unaware of the risks of codeine medications, is that the **CMI does not include them!** The Panadeine Forte CMI 2000-2020 has not mentioned it is an opioid medication or a *single one of these risks*. Nor has other codeine medications like Nurofen Plus, Tramadol, and Paracetamol and Codeine pain tablets. It is pretty hard to be aware of something that isn't in the government endorsed warning. During the period 2000-2013, 1444 Australians died due to codeine toxicity, with Panadeine Forte the most common drug identified.

## The US and Australian opioid crisis

A comparison of the well-documented US Opioid Crisis with trends in Australia's opioid deaths uncovered some brutally obvious consistencies. The same pharmaceutical companies, selling the same medications, withheld the same dangerous consumer warnings – the outcome is thousands of fatal and non-fatal events over the last 20 years.

### OxyContin



OxyContin is the drug responsible for starting the US opioid epidemic, due its high risk of addiction. In Australia, the CMI vaguely discloses that *there is potential for abuse of oxycodone and the development of addiction to oxycodone*. It also states *that many side effects tend to reduce over time, with the exception of constipation. This means that the longer you take this medicine, the less it may cause problems for you*. Similar statements have been banned from the US warnings since 2001.

The difference between the US and Australia is that the US has taken legal action against those companies, whilst in Australia they continue to enjoy the full support of government. In the last 12 months the companies referred to in this report, including Janssen who make Durogesic, have been forced to pay over USD \$14 billion in compensation for the adverse drug events of the medications we analysed. In Australia they have not paid a cent.

The architect of the US Opioid Crisis, Purdue Pharma, has filed for bankruptcy. Their Australian operation, Mundipharma, which sells OxyContin and Targin, is being sold to finance the compensation settlement to the American people. Purdue is also providing medication to prevent opioid overdoses for free as part of the settlement. Purdue do not provide the same medication for free in Australia; Mundipharma sell it at full price to the PBS.



Well, we don't want to end up in the place that the United States is in where opioids are a national crisis. Here, we are in a much better position...

– Greg Hunt, transcript of Tyabb Doorstop, 23 June 2018

Tragically the 13,269 people who died from opioid use, are certainly not in a better position.



It's time to call this what it is: Australia's very own overdose crisis. And make no mistake; it's a crisis that is getting worse.

– John Ryan, Chief Executive Officer of drug policy organisation, Penington Institute]

This statement and this report explains why Australian officials have refused to act on the underlining cause of prescription medication deaths, they are the ones responsible for it happening in the first place. The drugs in this report are manufactured by pharmaceutical companies who are amongst Australia's largest political donors.



In the US, the consumer warnings have been updated and legal action taken against the manufacturers who unsuccessfully argued these warnings might confuse patients. In Australia, the CMI's are still dangerously incomplete, these same manufacturers have incurred no fines and they still receive hundreds of millions of dollars in PBS funding each year. Purdue-Mundipharma are still allowed to sell the opioid OxyContin in Australia, the company and drug that sparked the US opioid epidemic, with a CMI that fails to accurately disclose the risk of addiction, overdose and death. They now profit from selling an opioid overdose rescue medication called Nyxoid that is sold with OxyContin, both medications in Australia are funded by the PBS.

## COVID-19 and record levels of prescription medications

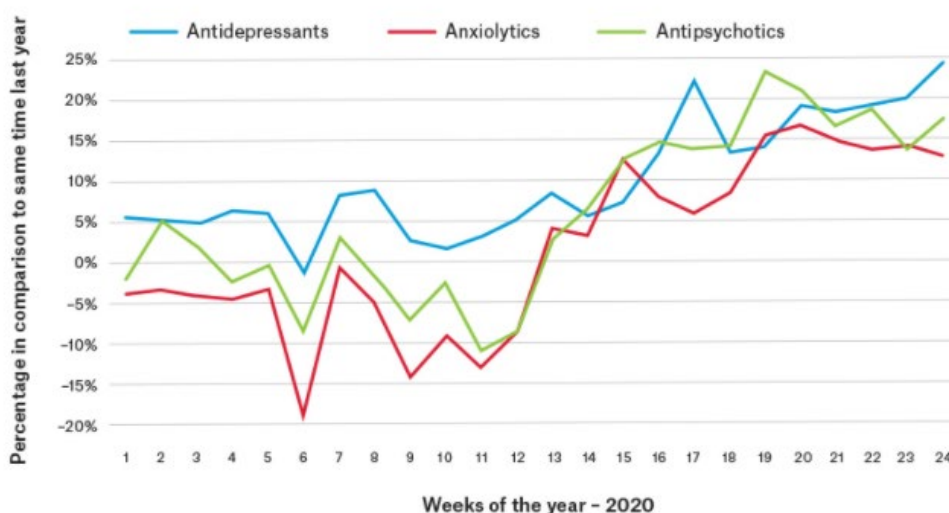
2020 has seen a spike in Australians seeking treatment for mental health conditions and experts are predicting that this wave of new mental health cases diagnosed will continue to increase in the next 12 months. There are also widely held fears of an increase in the number of Australians dying by suicide. Before COVID-19 arrived, mental health had already become the single largest issue for which patients seek care from their GP, according to the RACGP's 2018 Health of the Nation report.

Medication is the most used treatment for mental health conditions including depression and anxiety. Australia is the second highest user of antidepressants in the world. Nearly 90% of these medications are prescribed by GPs. The front-line help for Australians is GPs, and their go to treatment is medication.

Prescriptions for many of the medications analysed in the *Prescribed Deaths* report have skyrocketed during COVID-19. Outcome Health recently released a report from the data collected from more than 1000 Australian general practices.

Anti-anxiety drugs in particular have soared by up to 31%, while antidepressant prescriptions have also risen steadily, up by double-figure percentages (13–22%) over last year for each of the eight weeks ending 6 June. Eli Lilly, the makers of the antidepressant Prozac, reported that supplies are low due to overwhelming demand.

'We can see that whilst there is a steady increase in the use of antidepressants, there has been a marked recent increase in anxiolytic prescribing, most notably for diazepam (Valium),' the Outcome Health paper on mental health impacts states. Antipsychotic medication rates have also shot up, up to a 46 per cent increase in some anti-psychotics. Associate Professor Pearce attributes that to the fact GPs are increasingly taking up this role rather than hospitals.



Rates of antidepressant, anxiolytic and antipsychotic use in 2020. (Source: Outcome Health: Mental Health Impacts of COVID-19)

## Increase in alcohol Use

Experts have also raised a warning that too many Australians are increasing their alcohol consumption due to mental health issues.

A study by UNSW and the Black Dog Institute has shed light on the influence of COVID-19 on Australians' mental health. The researchers surveyed more than 5,000 people between 27 March and 7 April 2020 to explore people's anxiety levels and how they were coping over the outbreak.

A concern raised by the responses was the number of people reporting *excessive alcohol consumption as a way of dealing with their anxiety*.

While 48.6 per cent of those with prior history of mental health diagnoses/problems reported excessive drinking, 54.6 per cent of people without prior mental health issues had also been drinking to excess.

A poll conducted earlier this year showed that 28% of those surveyed are drinking alcohol to cope with anxiety and stress. The ABC has also reported on this trend.

On 23 March **1974** in The Canberra Times article titled, 'Drug and Drinking Danger', it was reported that Mrs Faye Dyson died, aged 41, from taking her Valium medication after drinking alcohol. Some 46 years, and thousands of deaths later, and the risk of death when combining Valium with alcohol is still not in the CMI.

## Time for urgent action

One Australian dies from drugs every 5 hours and 75% of people who die from drugs die accidentally. Nobody should die from taking medication as prescribed by their own doctor, dispensed by their local pharmacist and regulated by the Department of Health. However, it is happening every few hours, with the rate of deaths continuing to rise. The underlining cause has just been uncovered.



The 2020 Penington Institute report on drug deaths released in September, details the lethal impact of prescription medications. Their report identifies the large number of deaths each year that are associated with prescription anti-depressants (e.g. Prozac) 591 deaths and anti-psychotics (e.g. Lithium) 318 deaths. The prescribing of these medications is reported to have increased by 22% and 46% respectively during COVID-19. These medication classes are also represented in the *Prescribed Deaths* report, with clear gaps in consumer warnings. It is likely that more prescription medication deaths across a broad range of drugs will be an unintended consequence of COVID-19.

The Penington Institute's CEO John Ryan said, "*The death toll shows none of our politicians are taking this issue seriously enough*" and added "*It's proof that our leaders need to do more.*"

The impact of the failure of the TGA to ensure that the CMI contains all the serious risks of each medication cannot be understated. The Department of Health advises Australians to keep the CMI handy, so you can easily find it to re-check the warnings while using the medicine. However, this advice has no impact if the CMI does not contain the information that is needed to save lives.

Australians have never been more exposed to the side effects of medication, including those in aged care, and they have also never been so under warned. This has been facilitated by telehealth GP consultations and now electronic prescriptions. The path from GP to consuming medication can now happen without even leaving your home. However, access to the CMI has not been included in this new process. Australians have never been more exposed to the side effects of these drugs but protecting vulnerable Australians does not appear to be as important to the TGA as investigating Lorna Janes sporting apparel that claims to protect against COVID-19.

The *Prescribed Deaths - Life in The Killing Zone* report presents an emphatic case that case that millions of Australians each year, since 1999, have been exposed to lethal side effects of medications without being given the information to protect themselves, and it goes on unchallenged. The drugs in this report are manufactured by pharmaceutical companies who are amongst Australia's largest political donors. Companies that are also actively competing to provide COVID-19 medications to Australians. The problem has not been acknowledged or resolved, and it is about to get a lot worse.

### **Help us to make a change.**

If you believe the CMIs should have these warnings included, please email Professor Skerritt [john.skerritt@health.gov.au](mailto:john.skerritt@health.gov.au) and support our change.org petition <https://www.change.org/prescribeddeaths>

More information and a copy of the report can be found at [www.prescribeddeaths.com.au](http://www.prescribeddeaths.com.au) including a copies of the communication with Professor Skerritt at the TGA.

This summary was produced by Patrick O'Connor – author, *Prescribed Deaths – Life in The Killing Zone*.

[www.prescribeddeaths.com.au](http://www.prescribeddeaths.com.au)

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8<sup>th</sup> October 2020

### **Important warning**

For many Australians prescription medication provides significant therapeutic benefits, but no drug is risk free. If you are currently taking medication, do not stop taking a prescribed medication without discussing it with your doctor. Information can also be obtained by calling the NPS Medicines Line on 1300 633 424 or the Adverse Medicines Events Line on 1300 134 237 for advice. If you need support for any medical concern, including mental health matters, please contact your doctor. Lifeline also provides a 24 hour support service on 13 11 14 or [www.lifeline.org.au](http://www.lifeline.org.au)