Adjunct Professor John Skerritt
Deputy Secretary, Health Products Regulation Group
Therapeutic Goods Administration
PO Box 100
Woden ACT 2606

Dear Professor Skerritt

The purpose of this communication is to lodge a formal complaint against the Therapeutic Goods Administration (TGA) for failing to maintain medication safety regulations under the *Therapeutic Goods Act 1989.*

The attached report, *Prescribed Deaths – Life in The Killing Zone*, documents the areas in which the TGA has failed to meet medication safety standards for all Australians. The most vulnerable members of our society, including people with disability, the elderly, children, Indigenous Australians, first responders and veterans, are the most severely affected.

This report has undertaken a detailed assessment of 10 medications prescribed in Australia through the Pharmaceutical Benefits Scheme (PBS). The analysis shows that pharmaceutical companies have been producing consumer medication information (CMI) documents that **deliberately include misleading, inaccurate and incomplete information on the life-threatening risks of taking these medications for more than 20 years**. These risks include addiction, overdose, coma and death. For the 10 medications analysed, we identified 46 instances where the warnings represent breaches of the *Therapeutic Goods Act 1989*. The medications are:

1. Oxycontin
2. Endone
3. Valium
4. Xanax
5. Efexor
6. Lithium
7. Durogesic
8. Fluoxetine
9. Targin
10. Dexamphetamine.

The core function of the CMI is to provide information on the risks of a medication to consumers and this information is used in their decision to give informed consent. The CMI is presented as the reliable source of truth for consumers; it is the document that consumers are directed to for medication information by the healthcare system and government.

This report shows that the **exact risks not disclosed are directly or indirectly linked to the majority of Australia's adverse drug events and deaths**. The cause and effect cannot be any clearer and the people affected are vulnerable people who are prescribed these medications.

Human Rights

The rights of vulnerable people – in fact, all people – to safe healthcare is enshrined in the Universal Declaration of Human Rights, the Australian Charter of Healthcare Rights, and the Convention on the Rights of Persons with Disabilities. It is a legal requirement that medical treatment, including taking medication, can only commence after we give our informed consent. For the consent to be valid, it has to be informed, meaning that we have been provided with all the information about potential risks of taking the medication. This includes when multiple medications are prescribed.

The law provides us with the right to full disclosure of all risks – there is no discretion, even for risks that might be deemed rare in occurrence. Our CMI analysis is emphatic in demonstrating dangerous risks have not been disclosed for the most commonly prescribed medications for people with mental illness and pain conditions. Millions of people have given consent, without being informed, and hence their consent is not legally valid. You simply cannot assess a risk that you don't know about. You cannot follow safety advice if it has never been given to you. The resulting impact on human life has been physical illness, dangerous side effects and for many, death.

CMI Updates

This report includes analysis of the recent TGA review of the CMIs for opioid medications. Thankfully, warnings relating to coma, overdose, addiction, abuse and death are finally being included. The TGA states that the "improvements to information for prescribers and patients [are to] encourage best-practice prescribing and help consumers to be better informed about the potential risks and how to mitigate them".

Consumers can only give informed consent to taking medication if they have been fully informed. The changes now being made by the TGA are an emphatic admission of the opioid risks that consumers have not been provided within the CMIs for decades. These risks have been well-documented in manufacturer and government literature for many years. The only group who will be seeing this information for the first time will be consumers. However, they will only see these new warnings *if they ask for them*.

The pharmacists we spoke to in the preparation of this report were unaware of the recently updated CMIs, and therefore, the critical warnings remain unknown to those filling or re-filling their prescriptions. More disturbingly, there is no legal requirement for them to do so anyway, nor is there any direction from the TGA to inform consumers currently being prescribed these medications.

It is important to state again that being informed of all risks is a legal right. When new risks are presented to a consumer it necessitates that individual to be asked to give informed consent to these new risks. Simply updating a CMI falls horrifically short of what is required to ensure basic human rights to safe healthcare being upheld by the TGA.

Still Failing to Warn Consumers

In addition to the 10 medications examined in Chapter 2 of the report, we also analyse the commonly prescribed medication, Panadeine Forte. The June 2017 CMI does not contain a single mention of the risk of death, addiction, dependence, tolerance, withdrawal or abuse. It contains no mention of the lethal side effects of using this medication with alcohol or benzodiazepines. In total, we identified 14 areas as breaches of the *Therapeutic Goods Act 1989*. This medication has been in use for 20 years and is attributed as the cause of death for hundreds of Australians in many government studies.

The Panadeine Forte CMI was updated in May 2020 by Sanofi-Aventis. For the first time, it now includes warnings of the risk of death, addiction, dependence, tolerance, withdrawal and abuse. It also now includes the risk of death when using the medication with a benzodiazepine, a common cause of drug death in Australia over the last 20 years. Incredulously, many life-threatening risks have still been overlooked, and yet these risks are detailed in the May 2020 Panadeine Forte Product Information (PI) that the TGA has approved for healthcare professionals. Why has the TGA not ensured these risks are included in the May 2020 Panadeine Forte CMI?

For example, the PI states that "The risk of addiction is increased in patients with a personal or family history of substance abuse (including alcohol and prescription and illicit drugs) or **mental illness**". The comorbidity of mental illness and pain conditions is well known, so how can this warning not be included and highlighted in all opioid CMIs?

The CMI still fails to warn of the risk of death when consuming alcohol or if an overdose occurs. The CMI does state that an overdose can occur at prescribed levels, making the need to explain the dangers of an overdose even more critical. The fatal risks of this medication to children who have the CYP 2D6 gene is still inadequate, and it is unclear why the CMI still does not describe the medication as an opioid. The absence of life-threatening neonatal risks in the PI is incredibly disturbing.

While the TGA has improved the level of information in the opioid CMIs, unfortunately there are still significant gaps in the material risks disclosed in comparison to the PIs. It is simply unconscionable that these risks are excluded from the CMIs, as is the fact that the polydrug risks have not been added to other CMIs like benzodiazepines, antipsychotics and antidepressants.

Urgent Action is Required

This report has documented multiple medication safety failures, across multiple classes of medication. This report also proposes a number of recommendations to immediately stop the adverse prescription drug events and deaths being suffered by too many Australians.

The urgency of this matter cannot be understated. The current global health crisis has seen an increase in the number of Australians seeking help for mental health conditions. The issues examined in this report demonstrate that Australians will continue to be exposed to further adverse health events caused by systemic failures to provide safe healthcare if action is not taken.

Regards

Patrick O'Connor
[redacted]

07 July 2020