Rachel Stephen-Smith, MLA Minister for Health

GPO Box 1020, Canberra, ACT 2601

Cc: Shane Rattenburry
Minister for Mental Health

Dear Minister

The purpose of this communication is to provide you with a hard copy of the formal complaints and the report that I have lodged with the Department of Health and the TGA, for systemic breaches of multiple health regulations and human rights. The attached report 'Prescribed Deaths – Life in The Killing Zone' documents multiple areas in which the health care system has failed to meet safety standards for persons with disabilities.

As a resident of the ACT, much of the report is based on my experiences with the ACT Health Care System. I also lodge this report as a complaint against the ACT Department of Health, for failing to ensure ACT regulations in respect to medication and healthcare safety have been enforced.

As per the attached letter to Prof Skerritt at the TGA, the dire nature of this issue is evident in the recent Panadeine Forte CMI that was updated in May 2020 by Sanofi-Aventis. For the first time in 20 years, 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 lifethreatening 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. This means that thousands of ACT residents will still not be informed of these risks if they access 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?

Failing to provide an updated CMI with added risks or to even advise consumers of new warnings is a breach of our human rights. This is what happens on a daily basis in ACT pharmacies and has occurred for decades.

To further highlight the lack of commitment to medication safety by ACT pharmacists, we undertook a further research project to visit an additional 5 pharmacists on the 7th July in the ACT and record our conversations. The purpose of the visit was to ask for the most recent warning document for Panadeine Forte, and to ask if having a mental illness increased the risk of addiction to the medication.

Four of the five pharmacists provided the Panadeine Forte CMI from 2017, and all were asked and confirmed it was the most recent CMI available. Of these four pharmacies, three advised that there was no greater risk of addiction for a person with a mental illness and one was unsure. A fifth pharmacist advised that the medication was not addictive to anyone, that it was safe if taken as directed and that no consumer warning document has ever been produced for the medication. As an individual currently prescribed this medication, these 3 statements placed me in an increased level of medication danger.

This brings the total number of pharmacists visited to 20, with not a single one meeting the medication safety standards they are legally and ethically required to meet. I am now prepared to lodge formal complaints against each of the 20 pharmacists and if required make the information public.

I struggle to comprehend how these issues that cause nearly 2000 deaths each year nationally, are not viewed as critical as the response to covid-19. I implore you to urgently review the report and take immediate action in the areas that require life-saving actions to protect vulnerable people. I make myself available to assist in any way.

Patrick O'Connor

Founder, The Killing Zone

08 July 2020