(Schedule 8) opioid use and misuse in Australia – options for a regulatory response

The TGA is in a position to take action to save lives.

Imagine a pharmaceutical firm applying to register a drug with these properties;

- respiratory depression
- decreased cough reflex (thereby increasing the risk of pneumonia)
- nausea (thereby making it unpleasant to eat)
- vomiting (thereby increasing dehydration)
- constipation
- itch
- sedation
- produces miosis
- causes contraction of peripheral smooth muscle
- dilation of venules
- hypotension in some patients
- confusion.

It is promoted as 'useful for pain relief' (source: Merck Manual).

You have probably met few with a first hand account of its efficacy. Victims never tell of their experience because they die from the above effects. Prescribed this drug after cancer surgery my father said, "You still feel the pain. But you just do not care." It is an ineffective analgesic. It cures nothing.

Would it be approved by the TGA these days?

No.

Although it has been classified as a Poison S8 why is it prescribed when it is so poor for pain relief yet so lethal?

If sold on the street, those involved can be arrested and charged by Police.

Morphine is widely prescribed in our Aged Care Facilities.

For fear of an aged care audit discovering or visitors photographing bed sores on residents, NUM's feel under pressure to start morphine.

My uncle and mother were both condemned to death by starvation caused by doctor-prescribed morphine in residential aged care in recent years. Although morphine was the cause of death, it was not mentioned by the prescribing doctor on the death certificate. This would be standard practice in aged care. As a result, currently published statistics clearly under-report fatalities caused by opioids. The

TGA should require more data on the amount of opioids given in aged care so that differences can be detected between facilities. The TGA should liaise with the aged care accreditation body.

Morphine urgently requires more stringent safeguards. Only specialists should prescribe. While others might ask, "Why are doctors paid when they prescribe an S8 poison?"

Considering the sheer number of deaths, Schedule 9 is more appropriate for morphine.

Option 5. Warnings. Do those suffering pain read warnings? Do those suffering addiction read warnings?

Clearly, a review of S4 warnings is required before things get even worse.

I realise you are under pressure from some very powerful vested interests. The TGA will receive submissions from doctors and pharmaceutical firms. Due to their conflicts of interest the TGA should disregard them.

The most valuable submissions are from victims. Sadly, most victims die. Please urgently tighten the availability of opioids before more lives are needlessly lost. Public safety demands strong action from the TGA and regulators. Thank you for this opportunity. I wish you success in your positive response to this serious issue.

Yours truly,