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Faculty of Pain Medicine
ANZCA

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Att: Mr Adam Cook

Faculty of Pain Medicine Response to the Independent Expert Report on the Risks of Intentional Self-Poisoning with Paracetamol

The Faculty of Pain Medicine (FPM) welcomes the opportunity to comment on the recent Independent Expert Report on the Risks of Intentional Self-Poisoning with Paracetamol (hereafter referred to as "The Report").

FPM and its parent professional college, The Australian and New Zealand College of Anaesthetists (ANZCA), consider paracetamol to be an important drug for the management of mild to moderate pain in a variety of settings. This encompasses both acute and chronic pain scenarios. FPM considers appropriate access to paracetamol to be essential for patients living with the burden of chronic pain. The role of paracetamol in pain management has been recognised by the WHO for more than 40 years and it is one of only 3 non-opioid analgesic medicines listed in the WHO's Model List of Essential Medicines.

When used appropriately, paracetamol has a unique safety profile that makes it indispensable for many patients. Most specifically, its lack of central nervous system depressant activity, together with its favourable cardiovascular and gastrointestinal profile, means that for many patients, it is the only simple analgesic they can use.

We note The Report's interpretation of national and international data relating to paracetamol usage and the low, but tragic, prevalence of harm that arises due to exposure to paracetamol overdose. The general circumstances of these events are well known to FPM. We also note that The Report identifies that whilst intentional paracetamol overdose is relatively frequent in the Australian community, adverse outcomes are rare. Fortunately, death from paracetamol overdose appears to be very rare, The Report quoting a figure of approximately 1 death per 1 million of the population yearly.

The Report emphasises that around half of all intentional paracetamol overdoses are impulsive events, conducted without intent or preparation. However, even in such settings, the prevalence of disorders of mood or personality seems high. Additionally, with half of all such overdoses occurring in circumstances of clear suicidal intent, these events are likely to occur regardless of the availability of paracetamol when many other far more lethal agents are easily substituted.

FPM notes The Report's recommendations for limitations to paracetamol access. Some of the recommendations involve limitation on the total content of packs of paracetamol in retail settings. FPM considers these recommendations to be reasonable.

FPM does have concerns about The Report's recommendations to change the scheduling of modified release paracetamol, restricting it to access on prescription only. Whilst it is true that it is potentially easier for a person to take larger doses of paracetamol using the modified release preparation, in practice it is not clear that this results in a major difference in the amount consumed during overdose events. The Report references a paper by Cairns *et al* from 2019. These authors identified a median of 19 tablets ingested in overdose events using immediate release paracetamol *vs* 16 tablets of the modified release preparation. This represents a difference of around 12% in the total ingested; this is higher, but we question whether it justifies some of the proposed restrictions on accessing this preparation.

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Additionally, The Report identifies that whilst the greatest increase in overdose has occurred in adolescents and young adults, it also identifies that modified release paracetamol is used infrequently in this group.

Even in those identified circumstances where substantial overdoses of modified release paracetamol occurred, deaths remained rare.

We do not dismiss concerns over the potential risks associated with any form of paracetamol overdose. However, we consider it relevant to examine the absolute risk that the current access arrangements for modified release paracetamol present to society. The risk presented is very small and is a fraction of the risk presented by many other everyday activities. Furthermore, we also consider it relevant to examine the potential consequences of rescheduling modified release paracetamol to prescription-only status.

Patients with chronic pain must manage problems that extend over many years. They face significant physical, psychological and social burdens. Not the least of these is the inconvenience of having to present for medical reviews of conditions for a variety of reasons. Insisting that patients present to general practice services for access to even simple analgesics would add further expense to circumstances that are already difficult. It would also erode the autonomy that patients value when dealing with health issues.

There are, in our opinion, other risks associated with the proposed rescheduling that have been ignored in The Report. Importantly, access to other "over the counter" preparations will remain unchanged. Reading The Report, one could understand why a well-informed lay person might conclude that ibuprofen is a safe drug. In terms of the rare event of death by overdose, such a simple conclusion would be reasonable.

However, if there is a transition from the use of modified release paracetamol to agents such as ibuprofen and other non-steroidal anti-inflammatory drugs (NSAID's), the potential for adverse outcomes will increase. The risks associated with chronic NSAID use are well known; they are 2 – 3 orders of magnitude greater than the risks associated with paracetamol and substantial harms will occur.

FPM holds the view that the current access arrangements, allowing patients access to modified release paracetamol through pharmacies, remains relatively safe, convenient and effective. We would support further guidance to pharmacists and patients regarding the safe and effective use of these preparations. Conversely FPM opposes the rescheduling of modified release paracetamol to prescription only status. We do not consider that the information provided in The Report makes a convincing case for such measures. We consider that the potential minor reduction in absolute risk does not outweigh the effects on the welfare of, or risk to, patients suffering from chronic pain.

Yours sincerely,

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