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From: [redacted]
Sent: Tuesday, 20 February 2018 4:53 PM
To: PSAB Communications
Subject: Re: RE: Responses to targeted consultation on Schedule 8 opioid use and misuse in Australia [SEC=UNCLASSIFIED]

Dear [redacted]

Thank you for the opportunity to read and respond to your email. Having read through the proposed criteria for the public consultation on options for the regulation of strong (S8) prescription opioid medicines I believe the proposed options outlined in 1-8 are potentially appropriate and relevant. I have the following general observations.

1. Reviews of this nature and consequent regulatory actions can sometimes lead to overcautious patient management on the part of prescribers who are uneasy about prescribing these medicines for severe pain (acute and chronic), the majority who are likely to be GPs, resulting in less than appropriate patient management and needless pain and suffering where patients have, for example, legitimate acute, non-cancer chronic pain that could and should, where relevant and appropriate, be managed with the S8 opioids in conjunction with other strategies. In other words, it is important to ensure that any actions from the review don't have adverse consequences where the result leads to patients that are in pain but unable to be legitimately treated. The S8 opioids are still some of the most effective pain relievers available, despite their serious side effects.

2. There seems to be a strong focus on the addiction side of the equation in the consultation paper. I understand the reasons, and the current "epidemic" in the US, although again restricting access to lessen the impact of misuse by addicts or criminals might result in inappropriate consequences as raised above. It might be important to stakeholders to ensure that normal patients with legitimate acute pain issues are not being penalised because of the illegitimate use by addicts and the criminal sector. There are also serious side effects of the S8 opioids other than addiction potential, such as constipation, which should not be ignored in the mix.

3. One other issue I had with the proposed paper, is that I found the evidence quoted that the S8 opioids may not be efficacious in non-cancer chronic pain etc (reference to review in BMJ) could perhaps be fleshed out more. Certainly the data on the increase in prescriptions and use quoted in the consultation paper seem well documented and convincing (although again mixed with addiction issues and heroin overdoses), but I am not sure this trend alone tells us about overuse or "indication creep"; it may indicate an increase in pain-related cases or reflect the ageing population and an increase in painful conditions for this cohort. I think there is perhaps a little too much emphasis on the US situation which I don't believe to be the best comparison for Australia (some similarities certainly but also a very different less risk averse and pro-drug society). I cannot comment on the information in the paper regarding the use or overuse of the S8 opioids for osteoporosis, but this issue certainly seems an important one that requires attention.

4. I note that the paper does indeed allude to the fact that good, credible data from controlled clinical studies is currently missing on efficacy in non-cancer chronic pain. I also note that the paper proposes that education for prescribers is critical as an option. I support both more research to fill gaps in knowledge and education programs for both prescribers and consumers.

5. There seems also to be a lack of information in the paper on the non-opioid alternatives for non-cancer chronic pain treatment, which I also found to be less than convincing in the consultation paper. I think the paper might be improved if this information was fleshed out a little more.

Given the above thoughts, I firmly believe that this is an important issue as outlined in the consultation paper. I also believe that there are significant data gaps that need attention as outlined above, and alluded to in the consultation paper, and I believe that the paper and proposed options might be improved, and any resultant proposed actions made more convincing, if another option were added suggesting that some targeted clinical trial studies could be commissioned to fill the data gaps. Specifically data on what indications the S8 opioids are best used for (acute versus chronic pain), and they compare with non-opioid alternatives in relation to risk benefit, (e.g. non-cancer and cancer-induced pain), and what appropriate non-opioid pain relief strategies are available to fill the gaps if S8 opioids are restricted further or considered not efficacious.

Yours sincerely,

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