

# TGA Consultation - Opioid Use and Misuse in Australia

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The increase in overdose and death from opioid misuse has been shown to be due, in part, to the increasing incidence of opioid addiction. This submission relates to a suggested measure to reduce the incidence of addiction/dependence to prescription opioids and therefore reducing harm.

Numerous studies have demonstrated that opioid dependence is strongly correlated to 'route of administration' of the drug. Injecting and smoking are more addictive than the oral route. The transdermal route carries a low risk of addiction. This is due to effects on the brain as well as psychosocial factors. A fast speed of delivery to the brain and spikes in drug concentration both increase the risk of addiction by altering brain chemistry. Multiple repeated self-administration of opioids by injecting, smoking or swallowing is highly habit forming. In contrast, transdermal administration of opioids is not associated with addiction or dependence.

While nicotine and oestradiol are commonly dispensed in transdermal formulations, opioids are most commonly prescribed in oral formulations. As well as an increased risk of dependency, the oral route is associated with a range of problems associated with hepatic first pass effect, tolerance requiring increasing doses, hyperalgesia, immune system effects, lowering of sex hormones and variability in efficacy between patients. Transdermal administration avoids or reduces these problems. Opioid analgesics in long acting transdermal forms can be highly effective in relieving chronic pain and improving quality of life for patients. If a strong opioid is indicated, then buprenorphine (S8) could be considered the least harmful effective option. Norspan™ (7 day transdermal buprenorphine) is the only strong opioid that is not associated with rapid tolerance, opioid-induced hyperalgesia and negative effects on sex hormones and the immune system (WA Dept of Health <sup>i</sup>).

In addition, combinations of non-opioid analgesic medicines in a transdermal patch, or 'metered dose' transdermal creams have shown good efficacy in the treatment of chronic neuropathic and musculoskeletal pain, for which opioids are increasingly prescribed. Use of these formulations has been associated with reductions in opioid use.

As the medicines regulator, we appreciate that the TGA has a limited role in influencing prescribing practices and encouraging the use of one route of administration over another. However, under *Option 8: Increase health care professional awareness of alternatives to opioids (both Schedule 4 and Schedule 8) in the management of chronic pain*

We propose that

- Health professionals be made aware of the clinical data demonstrating the impact of 'route of administration' on addiction, and mandating that transdermal formulations be considered as an alternative to oral formulations when prescribing opioids to chronic pain sufferers.
- Health professionals be made aware of the good efficacy of non-opioid transdermal analgesics as an adjunct or replacement for opioids in chronic pain sufferers.

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<sup>i</sup> <http://painhealth.csse.uwa.edu.au:8080/resources/painHEALTH-Opioid-pain-medications-fact-sheets.pdf>