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**The Royal Australasian College of
Physicians' submission to the Ministry
of Health**

**Warning and advisory statement for
opioids**

Poutūterangi 2022 | March 2022

Introduction

The Royal Australasian College of Physicians (RACP) welcomes the opportunity to submit feedback on a new warning and advisory statement for opioids.

The RACP works across more than 40 medical specialties to educate, innovate and advocate for excellence in health and medical care. Working with our senior members, the RACP trains the next generation of specialists, while playing a lead role in developing world best practice models of care. We also draw on the skills of our members, to develop policies that promote a healthier society. By working together, our members advance the interest of our profession, our patients and the broader community.

We commend the Ministry of Health for considering the package labelling for opioid medicines include a warning and advisory statement relating to the harm of abuse, misuse, and dependence and strongly support this proposal. As the New Zealand Drug Foundation's 2022 State of the Nation Report¹ shows, opioids are responsible for the deaths of around 46 people from accidental overdoses each year, a tragic situation that is potentially avoidable. Research also shows a steady annual increase in opioid prescriptions and indicates the rise in deaths is associated with increased prescribing in Aotearoa². The RACP also suggests that warning and advisory statements will not be enough on their own to tackle opioid abuse, misuse and dependence. The United States is currently experiencing an opioid epidemic³; it is crucial that we take a wide range of actions in Aotearoa to ensure such a public health crisis does not take hold here.

Key points

1. Should the package labelling for opioid medicines include a warning and advisory statement relating to the harm of abuse, misuse, and dependence?

Yes. The RACP strongly agrees with the proposal for package labelling for opioid medicines to include a warning and advisory statement relating of the harm of abuse, misuse and dependence. RACP supports the warning and advisory statement as a useful action to prevent the high number of unintentional overdoses in Aotearoa New Zealand.

The College notes that other than alcohol, opioids cause or contribute to the most non-intentional drug-related deaths each year, according to coronial data. The New Zealand Drug Foundation's 2022 State of the Nation Report finds opioids kill around 46 people from accidental overdoses each year. This number is based on a five-year average between 2014-2018, derived from Ministry of Health records. The Drug Foundation highlights that some of these deaths result from 'recreational' drug use, and some are the result of overdose from prescription medication (it is not possible to separate these in the data). The report also highlights that government action is urgently needed to address inequities in overall drug-related deaths, with the Māori death rate three times the rate for non-Māori¹.

¹ New Zealand Drug Foundation. Te Tūāpapa Tarukino o Aotearoa. State of the Nation 2022. [Internet]. Wellington: NZ Drug Foundation, February 2022. Available from: [State-of-the-Nation-2022-web.pdf \(drugfoundation.org.nz\)](#) Downloaded on 15 March 2022.

² Shipton E, Shipton A, Williman J, Shipton E. Deaths from opioid overdosing: implications of coroners' inquest reports 2008–2012 and annual rise in opioid prescription rates: a population-based cohort study. *Pain Ther.* [Internet]. 2017; 6: 203-215. Available from: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5693811/pdf/40122_2017_Article_80.pdf Downloaded on 15 March 2022.

³ Shipton, E. The opioid epidemic a fast developing public health crisis in the first world. *NZMJ* [Internet]. 2018;131(1468): 7-9. Available from: https://assets-global.website-files.com/5e332a62c703f653182faf47/5e332a62c703f674b52fcb38_Shipton%20FINAL.pdf Downloaded on 15 March 2022.

The RACP is of the view that these figures are too high and believe this situation is potentially avoidable, and action is urgently needed to reduce these deaths. Action is also needed to remedy the outcomes for Māori and ensure equitable health outcomes for whānau. We strongly support the education of both prescribers and the public alike, through a warning and advisory statement relating to the harm of abuse, misuse, and dependence of opioid medicines.

The RACP has previously advocated for improving health literacy in the community via warnings placed on the packaging of opioid products to identify the risk of dependence and overdose. In 2018 the College made a submission to the Australian Government's Therapeutic Goods Administration (TGA) on Prescription strong (Schedule 8) opioid use and misuse in Australia - options for a regulatory response. It was noted that many patients who use prescribed opioid medication report not being aware of the addictive potential of this medication. Clearer label warnings to better identify the risks of dependence and overdose as well as lack of efficacy in the long-term treatment of chronic non-cancer pain can assist in highlighting the advice from the prescribing doctor. However, it remains a key responsibility of the prescribing doctor to ensure people and whānau are informed about the addictive potential and other side effects of the medication in ways they can understand⁴.

2. Which of the proposed statements (see Table 1 below) should be included on the package labelling for opioid medicines?

The RACP suggests that the following statement is used: use of this medicine has the risks of overdose and dependence.

We also wish to note that an alternative statement was proposed. Members suggested the use of a hybrid statement along the lines of "[Name of opioid] is an addictive substance and has the risk of overdose". Stating the medicine is an addictive substance may be more effective than using the term "dependence". Whatever statement is used, the College agrees it will be important to focus clearly on conveying the risks of both overdose and addiction.

It is possible that product labelling could be used not only as means to provide information on safe use but safe and appropriate disposal also.

3. Do you agree with the proposed conditions for opioid medicines: 'For all classifications, including prescription, and all uses'?

Yes. The RACP wishes to highlight that that Tramadol is often described as an 'atypical opioid' because it does not represent the same degree of risk (for example, respiratory depression) as other opioids. The College suggests that any generic statements need to consider the distinction between stronger opioids (e.g. fentanyl, morphine and oxycodone) and others, (eg tramadol, which is commonly used to treat pain). However, this should not distract from the fact that mortality from opioid overdose is not solely associated with "strong" opioids. Recent statistics show that the opioids that cause by far the most deaths are a mix of "strong" and "weak" opioids - methadone, morphine and codeine. Tramadol and oxycodone also cause or contribute to a few deaths per year (less than five each per year on average)¹.

⁴ Royal Australasian College of Physicians (RACP). Submission to Therapeutic Goods Administration (TGA). Prescription strong (schedule 8) opioid use and misuse – options for a regulatory response. [Internet]. Sydney: RACP; March 2018. Available from: [racp-submission-to-the-therapeutic-goods-administration-\(tga\).pdf](#) Downloaded on 16 March 2022.

4. Do you agree with the proposed implementation timeframe of 12 months following the update of the Label Statements Database on the Medsafe website?

The RACP agrees with the proposed implementation timeframe of 12 months following the update of the Label Statements Database on the Medsafe website. Our members are of the view that this is an important change that should occur quickly.

5. Do you have any other comments?

While package labelling may have its merit, warning and advisory statements on their own will not be enough to address the problem New Zealand has with opioids abuse, misuse and dependence. It is critical that actions are taken to prevent Aotearoa further heading down the path of the United States which is currently experiencing an opioid crisis is due to prescribing practices, widespread opioid misuse, and mounting rates of prescription and illicit opioid overdose-related deaths^{3,5}.

The RACP wishes to highlight some further strategies within the remit of Medsafe that have been identified by the New Zealand Drug Foundation and may contribute to combatting opioid use, misuse and deaths in Aotearoa. We support the calls of the Drug Foundation to increase access to the overdose-reversing medication naloxone in Aotearoa to prevent overdose deaths from opioid use. To increase access to naloxone, Medsafe could investigate additional methods of naloxone administration such as a nasal atomiser⁶. Action could also be taken to improve the disjuncture between Medsafe, the Ministry [of Health], and other organisations such as Pharmac, pharmaceutical companies and those who may be able to distribute and/or use naloxone, like District Health Boards/Health New Zealand and the Māori Health Authority, Police, Needle Exchange, and Paramedics⁷.

The RACP recognises that much additional work should also be undertaken, that does not fall within the regulatory remit of Medsafe, but rather to other agencies such as Pharmac, pharmaceutical companies, health professionals and educators. In the College's submission to the Australian TGA in 2018, we supported action on the following additional regulatory options⁴, which were then adopted by the TGA⁸:

- reviewing available product pack sizes for opioids commonly used to treat acute pain;
- reviewing the indications for the opioid products used to treat pain; and
- working with stakeholders to raise health professional and consumer awareness about pain management guidelines, including the use of non-opioid alternatives for the management of chronic pain; and safe disposal of opioid products.

RACP has strongly endorsed actions to educate health professionals and people using opioids in Aotearoa. This should aim to reduce unnecessary opioid use, better inform patients and also

⁵ Morrow, P. The American opioid death epidemic lessons for New Zealand? NZMJ [Internet].2018; 1469 (131): 59-63. Available from: <https://journal.nzma.org.nz/journal-articles/the-american-opioid-death-epidemic-lessons-for-new-zealand> Downloaded on 15 March 2022.

⁶ New Zealand Drug Foundation. Te Tūāpapa Tarukino o Aotearoa. Emergency opioid overdose intervention: the case for expanding access to naloxone. New Zealand Drug Foundation recommendation and issues paper. [Internet]. Wellington: New Zealand Drug Foundation, May 2015. Available from: [Emergency opioid overdose intervention: the case for extending access to naloxone. \(drugfoundation.org.nz\)](https://www.drugfoundation.org.nz/emergency-opioid-overdose-intervention-the-case-for-extending-access-to-naloxone) Downloaded on 21 March 2022.

⁷ New Zealand Drug Foundation. Te Tūāpapa Tarukino o Aotearoa. Grossly unprepared. New Zealand's naloxone mess. [Internet]. Matters of Substance, 31 August 2021. Available from: <https://www.drugfoundation.org.nz/matters-of-substance/grossly-underprepared-nzs-naloxone-mess/> Downloaded on 21 March 2022.

⁸ Australian Government Department of Health, Therapeutic Goods Agency (TGA). Submissions received and next steps. Prescription strong (Schedule 8) opioid use and misuse in Australia – options for a regulatory response. [Internet]. Canberra: TGA, 12 September 2018. Available from: <https://www.tga.gov.au/submissions-received-and-next-steps-prescription-strong-schedule-8-opioid-use-and-misuse-australia-options-regulatory-response> Downloaded on 21 March 2022.

support better prescribing practices. Recent research shows a steady annual increase in opioid prescriptions, indicating the rise in opioid analgesic deaths is associated with increases in the numbers of opioid prescriptions in this country⁹.

Conclusion

The RACP thanks the Ministry of Health for the opportunity to provide feedback on this consultation. To discuss this submission further, please contact the NZ Policy and Advocacy Unit at policy@racp.org.nz.

Nāku noa, nā



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⁹ Shipton E, Shipton A, Williman J, Shipton E. Deaths from opioid overdosing: implications of coroners' inquest reports 2008–2012 and annual rise in opioid prescription rates: a population-based cohort study. *Pain Ther.* [Internet]. 2017; 6: 203-215. Available from: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5693811/pdf/40122_2017_Article_80.pdf
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