Response ID ANON-P6DR-WZ99-Y

Submitted to Safe Access to Opioids Submitted on 2023-03-31 10:19:30

Introduction

1 What is your name?

Name: Marie MacKay & Michael Pead

2 What is your email address?

Email: enquiries@pharmacycouncil.org.nz

3 What is your organisation?

Organisation: Te Kaunihera Tiaki Niho I Dental Council & Te Pou Whakamana Kaimatū o Aotearoa I Pharmacy Council

4 Identifying questions

Briefly, what is your interest in this topic?:

Te Kaunihera Tiaki Niho I Dental Council and Te Pou Whakamana Kaimatū o Aotearoa I Pharmacy Council are responsible authorities mandated by the Health Practitioners Competence Assurance Act 2003. Our roles are to ensure the competence and fitness to practise of oral health practitioners and pharmacists, respectively, to protect the health and safety of the New Zealand public. Amongst the practitioners under our mandates are dentists, dental specialists, and pharmacists with the authority to prescribe opioids. Even though the consultation on the Misuse of Drugs Amendment Regulations 2022 focuses on the regulation and management of the product, i.e., opioid medicines, as opposed to the practitioner, we recognise the need for cohesive and collaborative regulation to minimise risk to the public in a manner that makes best use of resources. With respect to our feedback on Options 1, 2 and 3; we acknowledge the benefits of appropriate access to opioids (particularly for those that experience poor access to healthcare). However, observations from other international experiences demonstrate that increased access will almost certainly result in more opioids in the community and higher levels of risk. Access to opioids should be balanced with the greater public risks and societal costs. Additionally, the consultation does not provide quantitative or qualitative data, or comparisons with similar jurisdictions to objectively gauge benefits and risks. In the absence of further analysis, it is difficult for us to provide comprehensive and fully informed responses to any particular option.

5 Are you a:

other

6 Please specify your profession

Please specify your profession:

Responsible authorities - regulators of dental and pharmacy health professionals under Health Practitioners Competence Assurance Act 2003.

Options to minimise or decrease the risk of inappropriate access

7 Option 1 -no regulatory change

Is option 1 (no regulatory change) sufficient for balancing access to opioids with potential risk of harm?:

Please read this response in the context of the information provided in Question 4.

We recognise that experienced clinicians closely involved in this area of practice, are well placed to provide views on the risks and benefits of their practice, and these should be given appropriate weighting.

Further, some of the Option 1 controls referenced does not facilitate monitoring of all prescribers. For example, not all prescribers use the New Zealand ePrescription Service, informing the Medicines Data Repository and used for monitoring of prescribing.

8 Option 2 - strengthen guidance

2. Is strengthened clinical guidance required and would it adequately address the risks of inappropriate prescribing (option 2)? :

Please read this response in the context of the information provided in Question 4.

We support permissive legislation where risk can be appropriately mitigated using other regulatory options. However, our experience suggests that guidelines (as per Option 2) may not be a strong enough mechanism to ensure that patients and the public can be adequately protected through

appropriate supply of these medicines.

Legislative restriction would provide a stronger mechanism to support practitioners with pressure from patients for excessive supply.

9 Option 3 – strengthen guidance and change regulations

3. Do you agree with the proposed regulatory changes (option 3)? Why or why not? :

Please read this response in the context of the information provided in Question 4.

As mentioned in our comments regarding Option 2, legislative restriction would provide a stronger mechanism to support practitioners with pressure from patients for excessive supply. This option provides the strongest risk mitigation against abuse, contributing to protecting patients and wider communities.

However, it is recognised that any controls introduced should be weighed against appropriate access to care. For example, special consideration for some specific clinical scenarios may be appropriate.

4. Should opioid prescribing be limited to 1 month's supply? :

5. Should there be an exemption for cancer patients and those in palliative care? How would this impact the ability of prescribers to care for their patients? :

We support removing barriers to patient access for those using these medicines for longer periods, such as cancer patients or for palliative care; in particular those under supervised care or in rural areas. Flexibility of prescribing and / or dispensing limits could be considered – provided that those "exemption" criteria are clear.

6. Would a peer review process for repeat opioid prescriptions reduce the risk of inappropriate prescribing? Would implementing this create a significant barrier to access? Are there implementation issues with this proposal? :

7. Should we align the prescribing restrictions for all opioid prescribers? Should some prescribers have lower limits for prescribing opioids? Should there be different limits for different groups of prescribers? :

As appropriate and when there are robust measures in place to protect public safety, we also support consistent regulation across health professions; and so, in principle, we support all prescribers having the same maximum period of supply under the regulations.

8. Should opioids have dispensing limits of less than 1 month? Is the 10-day default dispensing limit appropriate? :

Additional questions

10 What do you think are the main risks or gaps in opioid regulation that need to be addressed? Are there specific issues you are aware of?

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11 If you are a prescriber, what do you need to ensure you can continue to provide safe access to opioids to service users?

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12 Do you have any comments on the long-term proposal to explore how prescribing and dispensing rules could be incorporated into the Therapeutics Products regulatory regime?

11. Do you have any comments on the long-term proposal to explore how prescribing and dispensing rules could be incorporated into the Therapeutics Products regulatory regime? :

We support appropriately cohesive regulation across medicines as defined in the Therapeutic Products Bill (i.e., prescription medicines, pharmacist medicines, pharmacy medicines, and general sale medicines) and controlled drugs. However, controlled drugs seem to lie outside of the mandate of the Therapeutic Products Bill / Act. Because of this it is unclear what mandate and mechanisms the Therapeutics Products Regulator will have to regulate controlled drugs.

13 Is there anything else you would like us to consider?

12. Is there anything else you would like us to consider? :

As a regulator, we understand the need to monitor practice as a measure of compliance with standards to mitigate risk to the public. We support strengthened monitoring and appropriate sharing of information that facilitates cohesive regulation that helps protect the public in an efficient and effective manner.