Proposed warning and advisory statement relating to the harm of opioid abuse, misuse, and dependence in New Zealand

Overview

This Medsafe consultation proposes a new warning and advisory statement for the opioid class of medicines. The statement would be included in the Label Statements Database (LSD), which lists the warning and advisory statements that are required on medicines and related products package labels.

Opioid medicines are prescription medicines used to relieve moderate to severe acute pain and can also be used in palliative care. Most opioid medicines are also classified as controlled drugs, with restrictions on prescribing and supply.

Internationally there has been an increasing trend in opioid-associated harm due to abuse, misuse, and dependence. Harm associated with opioid use is comparatively lower in New Zealand. However, evidence exists of opioid abuse, misuse, and dependence in New Zealand.

In June 2021, the Medicines Adverse Reactions Committee recommended that the LSD should be updated to include a warning and advisory statement for all opioid medicines. The Committee noted that most medicines are repackaged from the manufacturer's original pack to dispensing packs, and that dispensing packs are not required to include LSD statements on the label. However, the Committee still considered it helpful to have a warning statement on the manufacturer's pack in cases where manufacturer packs are dispensed to patients. The minutes of the meeting can be found here.

The LSD already has a warning for codeine that must be on the package labels for any codeine containing medicine:

- Codeine is an addictive substance

Table 1 below shows the proposed conditions, statement options and required by (implementation) date for the opioid medicine warning and advisory statement.

Medsafe is seeking your comments on:

- whether the package labelling for opioids should include a warning and advisory statement relating to the harm of abuse, misuse, and dependence
- the preferred statement option (see Table 1)
- the proposed conditions and required by (implementation) date (see Table 1).

Table 1: Opioid warning and advisory statement: proposed conditions, statement options and required by date

Medicine/Group/Class	Conditions	Statement	Required by
Opioids Examples include: Alfentanil Buprenorphine Codeine Dihydrocodeine Fentanyl Methadone Morphine Oxycodone Pethidine Remifentanil Tramadol	For all classifications, including prescription, and all uses	• [*name of opioid*] is an addictive substance [*or*] • Use of this medicine has the risks of overdose and dependence [*or*] • Contains opioid	12 months from when the Label Statements Database is updated

Note that if this proposed statement is added to the Label Statements Database, words of a similar meaning to the statement may be used and individual statements may be combined, provided the intent is not changed.

To assist in the analysis of submissions, Medsafe will only accept submissions made through the consultation website: https://consult.health.govt.nz/medsafe/opioids-warning-advisory-statement

Give Us Your Views

Go to survey >

About this consultation

This consultation is made up of a series of pages, each with a number of questions.

The only question you are required to answer is on the 'Publishing submissions and Official Information Act requests' page – where you tell us whether or not you give us permission to publish your submission.

Your details

<Please use the online survey tool to submit your response>

You are encouraged to fill in this section. The information will help in the analysis of stakeholder comments.

Your submission will still be accepted if you do not fill in this section.

1. **What is your name?**

2. **What is your email address?**
   If you enter your email address, then you will automatically receive an acknowledgement email when you submit your response.

3. **Are you providing feedback:**
   - As an individual
   - On behalf of an organisation or group

   Please provide your organisation/group name

4. **Where are you or your organisation based?**
   - New Zealand
   - Australia
   - Other

   If you selected Other, please specify

5. **Which of the below options best describes you in the context of this consultation?**
   - Healthcare professional
   - Member of the public
   - Sponsor
   - Manufacturer
   - Supplier
   - Importer
   - Government
   - Researcher
   - Professional body
   - Industry organisation
   - Consumer organisation
   - Institution (eg, university, hospital)
   - Regulatory affairs consultant
   - Laboratory professional
   - Other

   If you selected Healthcare professional, please indicate your type of practice

   If you selected Other, please specify

Publishing submissions and Official Information Act 1982 requests

Publishing your submission

We intend to publish the submissions from this consultation, but only if we are given permission to do so.

Official Information Act requests

Your submission may be subject to requests made under the Official Information Act 1982 (even if it hasn't been published). The Act says we have to make a submission available unless we have a good reason for withholding it.

<Please use the online survey tool to submit your response>

6. Do you give us permission to publish your submission?

(Required)

- Yes. You may publish this submission, including my personal details (name, organisation)
- Yes. You may publish this submission but only after removing my personal details (name, organisation)
- No. Do not publish this submission

7. If you would like us to withhold specific information from your submission if we receive an Official Information Act request, please let us know.

Reasons might include that it's commercially sensitive or it's personal information. Any decision Medsafe makes to withhold information can be reviewed by the Ombudsman, who may tell us to release it.

Please specify what information in your submission you believe should be withheld, and why

Proposed warning and advisory statement for opioids

<Please use the online survey tool to submit your response>

The following table shows the proposed conditions, statement options and required by (implementation) date for the opioid medicine warning and advisory statement.

Medicine/Group/Class	Conditions	Statement	Required by
Opioids Examples include: Alfentanil Buprenorphine Codeine Dihydrocodeine Fentanyl Methadone Morphine Oxycodone Pethidine Remifentanil Tramadol	For all classifications, including prescription, and all uses	• [*name of opioid*] is an addictive substance [*or]* • Use of this medicine has the risks of overdose and dependence [*or*] • Contains opioid	12 months from when the Label Statements Database is updated

8. **Should the package labelling for opioid medicines include a warning and advisory statement relating to the harm of abuse, misuse, and dependence?**
   - Yes
   - No

   Please add your comments

9. **Which of the proposed statements should be including on the package labelling for opioid medicines?**
   - [Name of opioid] is an addictive substance
   - Use of this medicine has the risks of overdose and dependence
   - Contains opioid
   - None of the above

   If you selected None, please suggest an alternative statement

10. **Do you agree with the proposed conditions for opioid medicines: '*For all classifications, including prescription, and all uses*'?**
    - Yes
    - No

    If no, please suggest alternative conditions

11. **Do you agree with the proposed implementation timeframe of 12 months following the update of the Label Statements Database on the Medsafe website?**
    - Yes
    - No

    If no, please suggest an alternative timeframe

12. **Do you have any other comments?**
    - Yes
    - No

    Please add your comments

What happens next?

All comments will be considered. Once the analysis of submissions is complete, the Label Statements Database may be updated.

We will publish the outcome on the Outcome of Consultations web page on the Medsafe website.

To subscribe to an automatic email notification of the website updates, please register here.