

Proposed warning and advisory statements relating to the harm of long-term use and overuse of stimulant laxatives

Overview

This Medsafe consultation proposes warning and advisory statements for stimulant laxatives.

Stimulant laxatives are either general sale or pharmacy-only medicines. This means these medicines can sometimes be purchased without advice from a healthcare professional. It also means there is no requirement for these medicines to have a data sheet or consumer medicine information leaflet. Consumers may therefore be unaware of the harm associated with long-term use or overuse of stimulant laxatives when purchasing these medicines.

In June 2021, the Medicines Adverse Reactions Committee recommended that Medsafe undertake a Label Statements Database consultation to include warning and advisory statements for all stimulant laxatives. The minutes of the meeting can be found [here](#).

The Label Statements Database, published on the [Medsafe website](#), lists the warning and advisory statements that are required on medicines and related package labelling. Currently there is no requirement for warning and advisory statements for stimulant laxatives. The current information related to harm on the package labelling of stimulant laxatives is variable.

Table 1 below shows the proposed warning and advisory statements for stimulant laxatives.

Table 1: Proposed warning and advisory statements for stimulant laxatives

Medicine/Group/Class	Conditions	Statement	Required by
Stimulant laxatives Examples include: Bisacodyl Glycerol Sennosides Sodium picosulfate	When for oral or rectal use (except glycerol for rectal use only)	<ul style="list-style-type: none">• Does not help with weight loss• Prolonged or excessive use can be harmful• Consult a healthcare professional if symptoms persist	12 months from when the Label Statements Database is updated

Medsafe is seeking your comments on:

- whether the package labelling for stimulant laxatives should include warning and advisory statements relating to the harm of long-term use and overuse
- the proposed wording of the statements (see Table 1)
- whether there are any other statements relating to the harm of long-term use and overuse of stimulant laxatives that should be included on the package labelling.

Note that if these proposed statements are added to the Label Statements Database, words of a similar meaning to the statements 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 this consultation website.

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 statements for stimulant laxatives

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

The following table shows the proposed warning statements for stimulant laxatives.

Medicine/Group/Class	Conditions	Statement	Required by
Stimulant laxatives Examples include: Bisacodyl Glycerol Sennosides Sodium picosulfate	When for oral or rectal use (except glycerol for rectal use only)	<ul style="list-style-type: none">• Does not help with weight loss• Prolonged or excessive use can be harmful• Consult a healthcare professional if symptoms persist	12 months from when the Label Statements Database is updated

8. Should the package labelling for stimulant laxatives include warning and advisory statements relating to the harm of long-term use and overuse?

- Yes
- No

Please add your comments

9. Do you agree with the proposed statement *"Does not help with weight loss"*?

- Yes
- No

If no, please suggest an alternative statement, or why it should not be included

10. Do you agree with the proposed statement *"Prolonged or excessive use can be harmful"*?

- Yes
- No

If no, please suggest an alternative statement, or why it should not be included

11. Do you agree with the proposed statement “Consult a healthcare professional if symptoms persist”?

- Yes
- No

If no, please suggest an alternative statement, or why it should not be included

12. Are there any other statements relating to the harm of long-term use or overuse of stimulant laxatives that should be included on the package labelling?

- Yes
- No

Please add your comments, and any suggested statements

13. Do you agree with the proposed conditions?

- Yes
- No

If no, please suggest alternative conditions

14. 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

15. 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](#).