

29 August 2018

Transparency Reforms and Evaluation Support Section
Prescription Medicines Authorisation Branch
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606

Email: policyandreformfacilitation@health.gov.au

To whom it may concern,

Re: TGA consultation: Boxed Warning guidance

NPS MedicineWise would like to thank the Therapeutic Goods Administration (TGA) for providing the opportunity to offer feedback on the proposed guidance for the use of Boxed Warnings for prescription medicines.

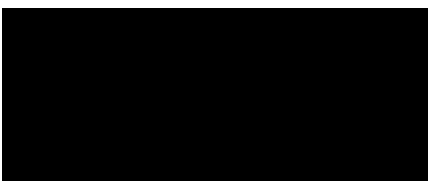
NPS MedicineWise is an independent, evidence-based organisation primarily funded by the Department of Health to educate health professionals and consumers about the appropriate use of medicines and medical tests. NPS MedicineWise improves the way medicines and other medical technologies are prescribed and used in practice. We do this through behaviour change interventions, evidence-based information to support decision making, educational programs which aim to address evidence-practice gaps, and targeted health communications campaigns.

We are supportive of the introduction of Boxed Warnings as a useful risk mitigation measure but note their effectiveness is likely to be limited when standalone and they should always be considered as part of a 'package' of risk mitigation measures within a risk management plan.

Please find attached our responses to the questions posed in the consultation document.

Thank you again for the opportunity to provide feedback. We are very happy to provide further clarification or guidance as needed and look forward to our continued collaboration with the TGA in the future.

Yours sincerely,



Bronwyn Walker
External Relations and Policy Manager

1. Do you support the proposal for evidence?

▷ With modification.

2. Do you envisage any difficulties with the proposed evidence requirements?

▷ The proposed sources of clinical data are reasonable, however further guidance is needed to clarify requirements in terms of quality of evidence and criteria for a causal relationship to be a reasonable possibility.

3. What changes to the evidence requirements do you propose to address these difficulties?

▷ As above.

4. Do you support the proposed circumstances?

▷ Yes.

▷ Under the clause on 'Non-actionable' reactions, there may be value in adding "...and in considering alternative treatment options" to the end of the paragraph.

5. Do you envisage any difficulties under which a Boxed Warning is proposed?

▷ No.

6. What circumstances should be removed, or should additional circumstances be included?

▷ Nil.

Content of the Boxed Warning in the PI

7. Do you support the proposal?

▷ Yes.

8. What changes would you propose?

▷ Nil.

Content and Format of the Boxed Warning in the CMI

9. Do you support the proposal?

▷ With modification.

10. Are there other modifications or additions to the proposal you would like to make.

▷ With clarification of requirements for presentation and format if the details around Format of the PI document outlined on page 8 of the discussion paper do not apply to CMI.

Format of the Boxed Warning in the PI

11. Do you support the proposal?

▷ With modification.

12. What changes would you propose?

▷ Clarity in the guidance about whether this applies to CMI also.

13. Are there other modifications to the proposal that you would like to make?

▷ Nil.

Process requirements

14. Do you support the proposal?

- ▷ With modification.

15. Do you envisage any difficulties with the proposed process?

- ▷ Clarification is needed on whether a separate application process is required for changes to versus removal of a Boxed Warning.
- ▷ Clarification is needed on amendments by the TGA based on changes in the evidence for a medicine class.

16. Are there other modifications to the proposal you would like to make?

- ▷ Nil.

Promotional material

17. Which of the above options do you support?

- ▷ Option 2.

18. Do you have any suggestions for how Boxed Warnings should appear or be referenced in promotional material (taking into account the different formats and media types which might be used to display this material)?

- ▷ Nil.

Timelines and implementation

19. Do you support the proposal?

- ▷ Yes.