Australian Government
Department of Health
Therapeutic Goods Administration

Submission to the Consultation on Boxed Warning guidance

31 August 2018

australian healthcare & hospitals association

the voice of public healthcare®

OUR VISION

A healthy Australia, supported by the best possible healthcare system.

OUR MISSION

To conduct research, educate and influence the healthcare system to achieve better health outcomes, improved patient and provider experience, greater equity and sustainability.

OUR GUIDING PRINCIPLES

Healthcare in Australia should be:

Effective

Accessible

Equitable

Sustainable

Outcomes-focused.

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REGISTERED CHARITY

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INTRODUCTION

The Australian Healthcare and Hospitals Association (AHHA) is pleased to provide this submission to the consultation into the Therapeutic Goods Administration (TGA) Boxed Warning Guidance.

AHHA is Australia's national peak body for public hospitals and health care providers. Our membership includes state health departments, Local Hospital Networks and public hospitals, community health services, Primary Health Networks and primary healthcare providers, aged care providers, universities, individual health professionals and academics. As such, we are uniquely placed to be an independent, national voice for universal high-quality healthcare to benefit the whole community.

A public consultation paper[1] was released by the TGA in August 2018 to outline the objectives for introducing a Boxed Warning to a Product Information (PI) document, provide draft guidance on how and when to use a Boxed Warning, and to seek feedback from consumers, healthcare professionals and industry on the proposed requirements for the Boxed Warning. The consultation paper explores:

1. Required evidence base
2. When a Boxed Warning is proposed
3. Content of the Boxed Warning in the PI
4. Content and Format of the Boxed Warning in the CMI
5. Format of the Boxed Warning in the PI
6. Process requirements
7. Promotional material
8. Timelines and implementation.

This submission has been prepared in response to the questions posed in the consultation paper.

[1] Bosed Warning - guidance. At: https://www.tga.gov.au/consultation/consultation-boxed-warning-guidance

1. REQUIRED EVIDENCE BASE

Q1: Do you support the proposal for evidence?

Yes

Q2: Do you envisage any difficulties with the proposed evidence requirements?

No

Q3: What changes to the evidence requirements do you propose to address these difficulties, if any?

Boxed Warnings are a risk mitigation measure to highlight special warnings concerning prominent safety issues with a potential for major impact on public health. As such, AHHA supports there being flexibility in the sources of data that may contribute to the evidence base for boxed warnings.

2. WHEN A BOXED WARNING IS PROPOSED

Q4: Do you support the proposed circumstances?

Yes

Q5: Do you envisage any difficulties with the circumstances under which a Boxed Warning is proposed?

No

Q6: What circumstances should be removed, or should additional circumstances be included?

The list of scenarios outlined in the consultation paper provides a sufficiently comprehensive list of circumstances for when a boxed warning is proposed. The fact that the list is not exhaustive is appropriate to allow for the broad range of safety issues that may be encountered.

3. CONTENT OF THE BOXED WARNING IN THE PI

Q7: Do you support the proposal?

Yes

Q8: What changes would you propose?

None

4. CONTENT AND FORMAT OF THE BOXED WARNING IN THE CMI

Q9: Do you support the proposal?

Yes

Q10: Are there other modifications or additions to the proposal you would like to make?

No

5. FORMAT OF THE BOXED WARNING IN THE PI

Q11: Do you support the proposal?

Yes

Q12: What changes would you propose?

None

Q13: Are there other modifications to the proposal you would like to make?

N/A

6. PROCESS REQUIREMENTS

Q14: Do you support the proposal?

Yes

Q15: Do you envisage any difficulties with the proposed process?

No

Q16: Are there other modifications to the proposal you would like to make?

Consideration should be given to how individuals or entities other than the manufacturer can progress requests for amendments to the PI and CMI, including adding or removing a Boxed Warning, particularly if costs are associated with formal applications.

7. PROMOTIONAL MATERIAL

Q17: Which of the above options do you support?

Option 1 - all promotional material must include the Boxed Warning in full.

Q18: 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)?

Boxed Warnings are a risk mitigation measure to highlight safety issues that have the potential for major impact on public health.

Given that Boxed Warnings are already summary statements of what is in the PI and the proposed Boxed Warnings are likely to be required for only a subset of medicines, the AHHA supports all promotional material including the Boxed Warning in full (i.e. not further summarised or abbreviated).

8. TIMELINES AND IMPLEMENTATION

Q19: Do you support the proposal?

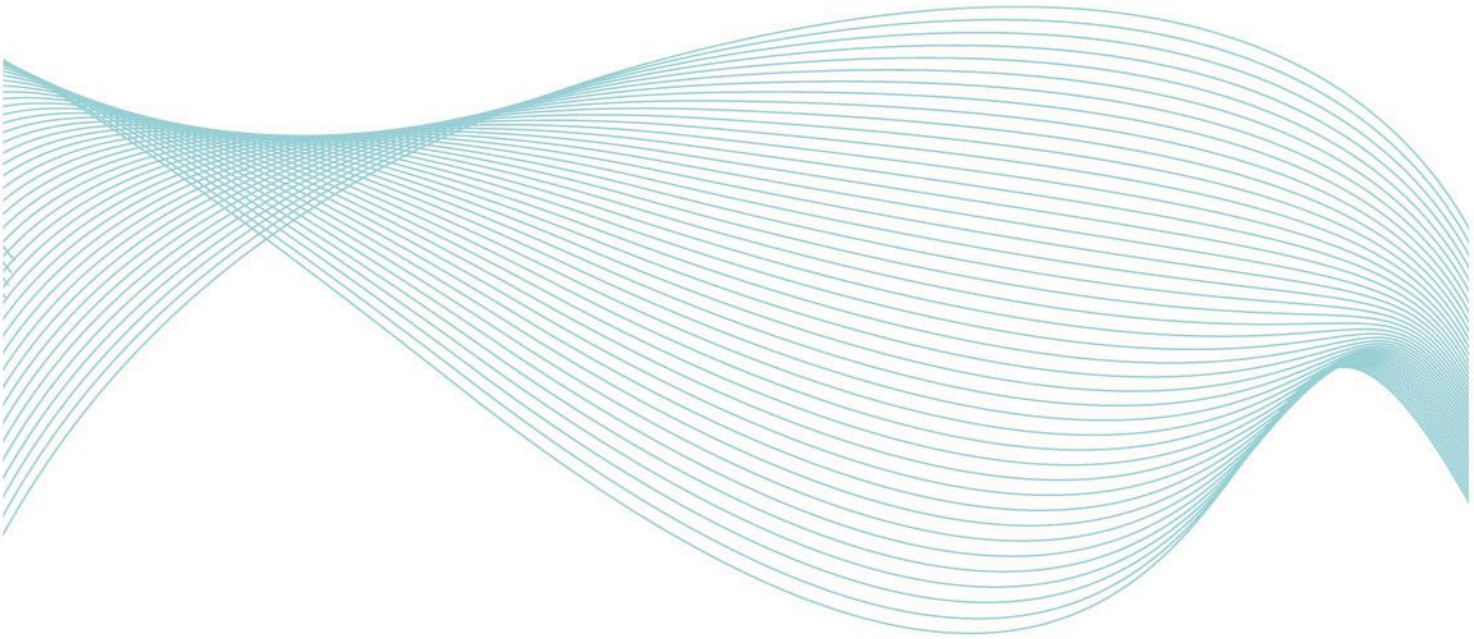
With modification

Q20: Do you envisage any difficulties with the proposed prospective implementation?

No

Q21: Are there other modifications or additions to the proposal you would like to make?

AHHA supports the guidance taking effect immediately for new products and as new safety information becomes available. However, a process must be applied to implement the new guidance with currently marketed products, phased in if necessary. Health professionals and consumers should be able to expect warnings of such significance to be presented in a consistent manner in all information available about medicines.



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