

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

Dear Therapeutic Goods Administration,

**RE: Consultation on Boxed Warning guidance**

The Society of Hospital Pharmacists of Australia is the national professional organisation for more than 5,000 pharmacists, pharmacists in training, pharmacy technicians and associates working across Australia's health system. SHPA is committed to facilitating the safe and effective use of medicines, which is the core business of pharmacists, especially in hospitals. The SHPA Specialty Practice model incorporates a Medicines Information and a Medication Safety stream which includes members with expertise in the specific areas. Members of the two Specialty Practice Groups have informed this submission.

SHPA supports the use of a Boxed Warning statement as part of the Product Information (PI) document as a medication safety initiative to improve patient safety. In response to the TGA's proposed consultation questions, SHPA has made the following comments.

**Q1: Do you support the proposal for evidence?**

SHPA supports option c) with modification.

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

SHPA believes that a Boxed Warning based on indirect evidence or anticipated effect may not be reviewed in a timely fashion to reflect current practice and evidence.

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

SHPA believes a timeframe for the review of evidence and lead-in time for Boxed Warning guidance to appear on medicine products should be established. This transitional timeframe should be a balance between consumer safety and minimising potential stock wastage. SHPA understands that when there have been changes to medicines packaging and labelling in the past, the TGA have given ~12 months lead in time for minor changes to packaging and labelling, which would be appropriate for Boxed Warning guidance.

**Q4: Do you support the proposed circumstances?**

SHPA supports option a) yes.

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

With respect to the last scenario that where a Boxed Warning is proposed, *'In some circumstances Boxed Warnings may be based on evidence drawn from 'off-label' populations, or the Boxed Warning may refer explicitly to off-label populations, for example if there is a concern about off-label use and the safety concern is sufficiently great'*, SHPA believes that it would be difficult to mention evidence drawn from off-label populations if off-label indications are not listed in the PI, and these indications are not endorsed by the medicines sponsor. Furthermore, certain medicines have a number of off-label uses, and as such any Boxed Warning for off-label use should be specific to that indication.

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

SHPA believes that the list of circumstances is sufficient.

**Q7: Do you support the proposal?**

SHPA supports option a) yes.

**Q8: What changes would you propose?**

SHPA recommends that the text of the Boxed Warning should not be identical to the text in the body of the PI but rather a succinct summary as clinicians would be more likely to read it.

**Q9: Do you support the proposal?**

SHPA supports option a) yes.

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

SHPA believes the list of content for the CMI is sufficient.

**Q11: Do you support the proposal?**

SHPA supports option c) with modification.

**Q12: What changes would you propose?**

SHPA proposes that the text of the Boxed Warning should be larger than the main body text of the PI.

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

SHPA supports the current list of modifications with the above change implemented.

**Q14: Do you support the proposal?**

SHPA supports options a) yes

