



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

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

SHPA does not envisage any difficulties with the proposed process.

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

SHPA does not have other modifications to make.

Q17: Which of the above options do you support?

SHPA supports b) Option 2.

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)?

SHPA believes that promotional and education materials presented at education meetings must include a separate slide with the Boxed Warning, and for the Boxed Warning to be read aloud by presenters. Printed promotional material should have a font size and colour that is different from the main body of text. The online promotional material should have a short web address so that clinicians can type in the address easily as they will be less likely to access if it is long. SHPA discourages the use of external short links generated by third-party companies, as the link may not be accessible after a period of time.

Q19: Do you support the proposal?

SHPA supports option c) with modification.

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

SHPA believes that there needs to be a timeline for retrospective application of Boxed Warnings for currently marketed products, otherwise consumers will fall into a false sense of security that if a Boxed Warning is not present, it does not exist. SHPA notes that there are historical examples where an adjustment period is afforded to medicine sponsors and pharmacies to exhaust and utilise stock with out-of-date scheduling labelling or CMIs and Pls.

If you have any queries or would like to discuss our submission further, please do not

Yours sincerely

Kristin Michaels Chief Executive