



## Public consultation on draft revised Board guidelines

6 March 2015

### Responses to consultation questions

Please provide your feedback as a Word document (not PDF) by email to [pharmacyconsultation@ahpra.gov.au](mailto:pharmacyconsultation@ahpra.gov.au) by close of business on Friday 1 May 2015.

#### Stakeholder Details

If you wish to include background information about your organisation please provide this as a separate word document (not PDF).

<b>Organisation name</b>
Pharmaceutical Society of Australia
<b>Contact information</b> <i>(please include contact person's name, position title and email address)</i>
Dr Lance Emerson, Chief Executive Officer [REDACTED] Dr Kay Sorimachi, Director Policy and Regulatory Affairs [REDACTED]
Submissions will generally be published unless you request otherwise. Do you want all or part of it treated as confidential?
No

#### Your responses to consultation questions on the draft revised guidelines

<b>Guidelines for dispensing of medicines</b> <i>Please provide your responses to any or all questions in the blank boxes below</i>
1. From your perspective, how are the current <i>Guidelines for dispensing of medicines</i> working?
2. Is the content and structure of the draft revised guidelines helpful, clear, relevant and more workable than the current guidelines?
3. Is there any content that needs to be changed or deleted in the draft revised guidelines?
<b>Use of bar code scanners (p. 11, Guideline 1, step k of the dispensing process, and p. 17, section 10.1)</b> PSA believes that not using a barcode scanner during the dispensing process is still a major actual or likely contributor to dispensing errors made by pharmacists. PSA notes that guidance on the use

## Guidelines for dispensing of medicines

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of barcode scanners has been significantly enhanced in the revised guidelines. Nevertheless, given the important role of the use of barcode scanners in minimising dispensing errors, PSA believes the inclusion of a stronger statement is warranted regarding the possible consequences in the event a dispensing error is reported and the pharmacist had omitted to use a scanner in the process.

### **Dispensing multiple repeat prescriptions at one time (p. 12, Guideline 3)**

PSA agrees that the dispensing of multiple repeats/quantities “should only occur at the specific direction of the prescriber on each occasion, unless exceptional circumstances exist to the satisfaction of the pharmacist”. PSA also fully supports “appropriate notation” being made to indicate when this has occurred. However, PSA is less supportive of the Board’s advice that the prescriber should be informed if this is required on every occasion a supply is made of multiple repeats/quantities. Given this should only occur under exceptional circumstances, and with appropriate recording of information, PSA would contend that the pharmacist should be permitted to exercise their professional judgement (e.g. based on patient factors, type of medicine being supplied, and nature of the exceptional circumstance) regarding when the prescriber should be informed.

### **Indirect supply of medicines (p. 13, Guideline 5)**

PSA supports the revised guidelines particularly around the enhanced statements relating to the need to balance the value of face-to-face patient contact with patient choice and logistics of direct interaction. PSA also notes that the Board is seeking comments separately (below) on the possible inclusion of guidance on the use of technology in the delivery of pharmacy services.

### **Label content (p. 14, Guideline 7.2, last bullet point)**

PSA has created a new Cautionary Advisory Label for pharmacists to use to advise patients that a medicine has been compounded. The wording of Label 23 is “This product has been compounded by the pharmacist”.

The wording for this label was approved following extensive work and consultation with the Editorial Board and the Cautionary Advisory Labels working group of the Australian Pharmaceutical Formulary and Handbook 23rd edition (APF23), as well as the PSA Policy and Advocacy Committee. These groups consist of individuals with various expertise to ensure coverage of a broad range of pharmacist perspectives.

Consultation was also undertaken on the pre-publication review of the APF23 *Extemporaneous dispensing* manuscript (in which Label 23 is referred) with the Pharmacy Board of Australia and the Therapeutic Goods Administration and suggestions or requests for wording change to the label were not received.

Therefore PSA strongly suggests that the wording provided in the draft guidelines for the label of compounded medicines (‘This medicine has been compounded by the pharmacist for you’) be amended to enable pharmacists to use the Cautionary Advisory Label that was developed for this purpose.

### **Counselling patients – more detailed advice (p. 15, Guideline 8)**

PSA agrees that more detailed advice is especially important when certain medicines are supplied and in certain circumstances. We believe the list of examples could also include the supply of hazardous medicines that have the potential to cause harm to patients or their carers from unintended exposure (such as through inappropriate handling by carers or family members).

The APF23 contains a list of hazardous medicines that meet the following criteria:

- cytotoxic
- pregnancy category X or D
- reported to pose a risk to patients and carers through inappropriate handling.

### **Pharmacists’ workloads (p. 18, Guideline 11)**

PSA acknowledges that there are many factors and dependencies that impact on the workload of individual pharmacists and the entire healthcare team. However, as workloads can have a direct impact on patient safety, PSA believes any guidance offered to pharmacists must be clear and firm.

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Understanding, planning and managing workload is part of the core competency requirement of all pharmacists (e.g. Standard 1.4 / Element 1 and Standard 2.6 / Element 1 in the [National competency standards framework for pharmacists in Australia 2010](#)). Further, pharmacists have an obligation to ensure their “working environment and conditions are conducive to the optimal delivery of health care services and do not present a risk to the safety and care of consumers or colleagues” (Obligation 7.4 in the PSA’s [Code of ethics for pharmacists](#)). PSA believes these fundamental requirements need to be articulated in the Board’s guidelines.

Since workload considerations are integral to the delivery of safe and accurate pharmacy services, PSA also suggests that the Board should clarify its position in relation to the receipt of any notifications in which a pharmacist’s workload was found to be excessive and there was no evidence of appropriate planning or risk management.

4. Is there anything missing that needs to be added to the draft revised guidelines?

PSA strongly believes the section on pharmacists’ workloads should be further enhanced as explained above (last section under 3).

PSA also noted in the pharmacists’ workloads section that the use of dispensary assistants / technicians and/or intern pharmacists is referred to in the context of these staff being able to ease pharmacists’ workloads. However, PSA would strongly suggest the addition of reference to the possible impact that pharmacy students and intern pharmacists (and other support staff) can have on the workload of the pharmacist due to the supervision responsibilities.

5. Do you have any other comments on the draft revised guidelines?

6. Do you think that that the proposed review period of five years, with the option to review earlier if the need arises, is appropriate?

Yes

The Board has also noted the potential for advancements in technology to change the way that pharmacists deliver particular pharmacy services. It has decided to explore through this consultation, the views of its stakeholders and the public about the possible inclusion of further guidance for pharmacists on the use of technology in the delivery of pharmacy services.

7. Is guidance for pharmacists required to address the use of information and communication technology, including, but not restricted to videoconferencing, internet and telephone, as an alternative to face-to-face delivery of pharmacy services?

With advances in technology, PSA receives from time to time queries relating to whether or not the use of certain technologies is permitted in the context of pharmacists fulfilling their responsibilities and obligations. PSA believes advice on these issues from the Board would be an important addition to the guidelines.

8. If guidance is required, what should it specifically address?

PSA believes that the appropriateness of use of other technology should include consideration of the likely QUM outcomes for the patient as well as any impediments that could not be overcome if a certain technology is used (e.g. the correct use of a medical device could be demonstrated through videoconferencing but hands-on support would not be possible).

9. Is the provision of explanatory information for pharmacists instead of a guideline a suitable alternative approach to address the use of information and communication technology in the delivery of pharmacy services?

### Guidelines for dispensing of medicines

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Provided the advice is clear, PSA believes either option (a guideline or provision of explanatory information) is acceptable.

### Guidelines on practice-specific issues

Please provide your responses to any or all questions in the blank boxes below

10. From your perspective, how are the current *Guidelines on practice specific issues* working?

11. Is the content and structure of the draft revised guidelines helpful, clear, relevant and more workable than the current guidelines?

12. Is there any content that needs to be changed or deleted in the draft revised guidelines?

#### List of reference texts (p. 33, bullet points g and h)

PSA has received some feedback from pharmacists regarding the proposed inclusion of the *Australian Don't Rush to Crush Handbook* to the list of reference texts. Whilst acknowledging the value of this text, there are also views that there are adequate resources available which carry this information and therefore the proposed inclusion as a mandatory text has been questioned.

PSA has been notified that the Natural Medicines Comprehensive Database has merged with the Natural Standard Professional Database to form a new resource Natural Medicines (available at: <https://naturalmedicines.therapeuticresearch.com/>). Therefore we suggest the list of references be updated to reflect this change.

13. Is there anything missing that needs to be added to the draft revised guidelines?

14. Do you have any other comments on the draft revised guidelines?

15. Do you think that that the proposed review period of five years, with the option to review earlier if the need arises, is appropriate?

Yes

### Guidelines on dose administration aids and staged supply of dispensed medicines (Currently titled *Guidelines on specialised supply arrangements*)

Please provide your responses to any or all questions in the blank boxes below

16. From your perspective, how are the current *Guidelines on specialised supply arrangements* working?

<p><b>Guidelines on dose administration aids and staged supply of dispensed medicines</b>          (Currently titled <i>Guidelines on specialised supply arrangements</i>)</p> <p><i>Please provide your responses to any or all questions in the blank boxes below</i></p>
17. Is the content and structure of the draft revised guidelines helpful, clear, relevant and more workable than the current guidelines?
18. Is there any content that needs to be changed or deleted in the draft revised guidelines?
<p><b>Packing oral cytotoxic medicines (p. 40, section 1.5)</b></p> <p>The recently released APF23 provides guidance for pharmacists about special handling and disposal requirements for medicines that have the potential to cause harm to patients or their carers from unintended exposure. In this edition, the criteria for medicines that require special handling (that are therefore not recommended to be removed from their original packaging for transfer into a dose administration aid) has been expanded to not only include oral cytotoxic medicines but also medicines that are considered to be hazardous (e.g. medicines listed as pregnancy category D or X). The APF23 Editorial Board considered that the risks associated with packing cytotoxic medicines in a DAA would equally apply to hazardous medicines. PSA believes the Board's guideline could be expanded to also include hazardous medicines.</p>
19. Is there anything missing that needs to be added to the draft revised guidelines?
20. Do you have any other comments on the draft revised guidelines?
21. Do you think that that the proposed review period of five years, with the option to review earlier if the need arises, is appropriate?
Yes

<p><b>Guidelines for proprietor pharmacists</b>          (Currently titled <i>Guidelines on responsibilities of pharmacists when practising as proprietors</i>)</p> <p><i>Please provide your responses to any or all questions in the blank boxes below</i></p>
22. From your perspective, how are the current <i>Guidelines for proprietor pharmacists</i> working?
PSA understands that there have been instances where an employee pharmacist was not able to readily access evidence of appropriate professional indemnity insurance cover which had been arranged by the employer/proprietor. This was inferred to be more of an administrative deficiency or oversight but nevertheless the employee pharmacist felt that they should not have been put in an uncomfortable position where repeated requests needed to be made to their employer.
23. Is the content and structure of the draft revised guidelines helpful, clear, relevant and more workable than the current guidelines?
The summary overview document states (on p. 43 and p. 44) that additional guidance is provided in the revised guidelines on the responsibilities of proprietor pharmacists on the advertising of services and/or products sold at a pharmacy. However, the additional guidance appears to only state that advertising should be "carried out in accordance with applicable legislation and guidelines". While we agree this message is worth re-iterating to proprietor pharmacists, the requirement itself is not new and applies to all pharmacists. Inclusion of expanded guidance and/or example markers of unacceptable advertising would be much more useful to proprietor pharmacists as well as employee

<b>Guidelines for proprietor pharmacists</b> (Currently titled <i>Guidelines on responsibilities of pharmacists when practising as proprietors</i> ) <i>Please provide your responses to any or all questions in the blank boxes below</i>
<p>pharmacists.</p> <p>A new clause in the revised guidelines (under 3 at the bottom of p. 47) adequately addresses the gap referred to above under 22. However PSA suggests that the effectiveness of this guidance will need to be closely monitored.</p> <p>The revised guidelines state that proprietors “must vigilantly maintain an active interest in how the practice of pharmacy is being conducted” (p. 47, Guideline 1) and that they “cannot delegate their professional obligations” (p. 47, Guideline 2). PSA notes the addition of these statements strengthens the current guidelines. However PSA believes a stronger statement should be added in relation to non-compliance with these points (see under 25).</p>
<p>24. Is there any content that needs to be changed or deleted in the draft revised guidelines?</p>
<p>25. Is there anything missing that needs to be added to the draft revised guidelines?</p>
<p>As mentioned under 23, expanded guidance on unacceptable advertising would be useful.</p> <p>Further to our comments under 23, PSA believes the Board would consider occasions when a proprietor pharmacist does not intervene to ensure the pharmacy business is conducted properly, or have an active interest in the practice of pharmacy conducted, to be unprofessional conduct. PSA suggests the guidelines should clearly state this.</p>
<p>26. Do you have any other comments on the draft revised guidelines?</p>
<p>27. Do you think that that the proposed review period of five years, with the option to review earlier if the need arises, is appropriate?</p>
<p>Yes</p>

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