Public consultation on the draft *Guidelines on compounding of medicines*

28 April 2014

Responses to consultation questions

Please provide your feedback as a Word document (or equivalent)[1] to pharmacyconsultation@ahpra.gov.au by close of business on Monday 30 June 2014.

Stakeholder Details

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

Organisation name
Slade Pharmacy
Contact information *(please include contact person's name and email address)*
David Slade [redacted]

Your responses to consultation questions on the draft *Guidelines on compounding of medicines*

1. Do the draft guidelines clearly differentiate between simple compounding and complex compounding?
Yes
2. Do the draft guidelines clearly outline which requirements apply to pharmacists who undertake either or both types of compounding (simple and/or complex compounding), and which requirements apply only to pharmacists who undertake complex compounding?
Yes
3. Is the content of the draft guidelines helpful?
Yes.
4. Is there any content that needs to be changed, added or deleted in the draft guidelines?

[1] You are welcome to supply a PDF file of your feedback in addition to the word (or equivalent) file, however we request that you do supply a text or word file. As part of an effort to meet international website accessibility guidelines, AHPRA and National Boards are striving to publish documents in accessible formats (such as word), in addition to PDFs. More information about this is available at www.ahpra.gov.au/About-AHPRA/Accessibility.aspx.

1. Risk assessment – Batch: Certain medical conditions and their treatments are time critical. Patients in these cases are unable to wait lengthy periods while the product is being prepared by the compounding pharmacy particularly where there is not a suitable commercially available product. An example is where patients are part of an IVF program and require timely hormone therapy.
   The products can take a lengthy period to prepare and if they are not administered by the patient at the appropriate time the treatment will be compromised.
   The pharmacy should be able to prepare in advance reasonable quantities on the basis they are stored correctly and that testing of the products are conducted to assure product quality.

2. Veterinary compounding is very different to compounding for humans. Given the different physiological profiles of animals (domestic, small animal, large animal, food producing animals, equine), all veterinary compounding should be classed as complex compounding whereby pharmacists have undertaken specialised training or have the requisite experience to carry out the function.

3. Formulation Considerations – when precedents do not exist: Sometimes doctors are exploring new ways of treating their patients when conventional forms do not work or are not available. Whilst there may be limited information or clinical papers on new and emerging treatments, specialist doctors who are practising in these areas should be able to prescribe such compounded products. Further compounding pharmacists cannot be expected to know all the clinical evidence to support the use of the product – there are so many specialty areas of practice it is impossible to keep abreast of all areas in detail. However pharmacists, when requested to compound such a product must ensure they are able to prepare/compound the product safely ie with sound pharmaceutical knowledge and risk assessment as it relates to product preparation/supply in accordance with the doctor's prescription. The pharmacist should make the patient aware that the product is compounded under these circumstances. The pharmacist to the best of their professional ability should be sure that no harm will come to the patient using the compounded product they prepare.

4. Compounding of parenteral medicines: Pharmacists, must be able to supply in certain limited and specific circumstances parenteral medicines with an expiry of 24 hrs or greater. Such products may be required for patients with certain conditions where commercially available products do not exist and where patients quality of life will be disadvantaged if these medications become unavailable as a result of this new guideline. The exemption should be that the product is ordered by a specialist physician for their patient. These products would also be unavailable from the GMP compounding facilities in Australia.

5. Do you have any suggestions for questions to be answered in Frequently Asked Questions developed by the Board to support the guidelines?

No

6. Is the purpose of the practice profile clearly explained in the draft guidelines?

Yes

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

1. Compounding of medicines by pharmacists for use in the doctors' surgery. Clarification is also required from the pharmacy board for when doctors/dentists/hospitals request certain products (commercially unavailable) to be prepared/compounded by pharmacists for in-surgery or in-hospital use. These products are not sold to patients, rather they are used by doctors for treatment of their patients in their rooms or at the hospital. Historically, pharmacists have been able to supply such products on a doctor's order and without a patient name provided they are not on-sold or wholesaled.

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