Public consultation on the review of guidance on expiry of compounded parenteral medicines – Pharmacy Board of Australia *Guidelines on compounding of medicines*

1 February 2016

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 Wednesday 30 March 2016.

Stakeholder Details

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

Organisation details
Organisation name: Complementary Compounding Services
Contact name: Dr Michael Serafin
E-mail address: [redacted]

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.

Your responses to consultation questions on the draft proposed guidance

1. **Has the proposed guidance been expressed clearly?**	Yes in most cases but not so for some of the finer details. For example if we go by the USP standards which indicate if no sterility testing is performed then a BUD date of 24hrs mus be assigned if stored at room temperate, 3 days at cold temperature or 45 days at solid frozen state. Does the same apply to Australian Compounding Pharmacies or is it 24hr irrespective of the stored temperature? If so does this apply to multi use vials?
2. **Does the revised guidance adequately address the concerns raised by stakeholders, that the published (postponed) guidance would inhibit or impact patient access to compounded parenteral medicines?**	No - as it currently stands these guidelines would still restrict supply and make it unaffordable for most patients. Please see attachment for an explanation.
3. **Does the revised guidance support patient safety when supplying compounded parenteral (sterile injectable) medicines?**	The cost and delays involved with these guidelines could discourage some pharmacies from doing sterile and endotoxin testing and assign a 24hr BUD with many patients not complying with the 24 hr time frame which could potentially not be in the best interest of public safety. These guidelines may also encourage some compounders to prematurely release parental products to their patents prior to sterility test results.
4. **Do you have any suggestions for questions to be included in the Board's FAQ for pharmacists on the compounding of medicines, to support pharmacists in their understanding and application of this guidance?**	Clarify if any discrepancies exist between USP standards and what Australian sterile compounders cannot do.
5. **Do you have any suggestions on how the proposed guidance could be improved (e.g. any content that**	If small batches are allowed for an anticipated 14 day supply all the problems with these guidelines would be

should be changed, added or deleted), while still being in accordance with the public interest?	overcome. This would create more affordable medications which are readily available without long delays required for sterility test results to come back. See attached document for more details.
6. **Do you have any other comments on the proposed guidance?**	No.

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Dr Michael Serafin
Complementary Compounding Services
[redacted]

Addition to Public Response for Parental Medicines.

Although the most recent draft of the "Guidance on Expiry Dates for Parental Medicines" is a much welcomed and positive step in the right direction compared to the initial version I feel that when the finer details are examined you will find that it has not considered some of the major issues facing the supply of sterile parental products with a BUD beyond 24 hours.

I believe in the interest of public safety and to prevent restrictions in supply an exception should be made in regards to batch compounding of sterile parenteral products. All non-sterile products should continue to be made on an individual basis however due to the nature of sterile products I propose that only parental sterile products could be produced in batches no larger than an anticipated 14 day supply. The reasons for this are outlined below:

1. Both USP and PIC/S standards are written based on the assumption that batching is being performed although the scale of the batching would obviously vary between the two standards. In the USA some states restrict the batching size of compounded sterile products to an anticipated 14 day supply for compounding pharmacies under the USP standard. No such batching restrictions apply to PIC/S. Currently in Australia without the ability to batch, which is in opposition to both USP and PIC/S standards, the majority of what is contained within these standards in regards to assigning extended BUD's becomes almost irrelevant.

2. To assign a BUD beyond 24hrs if stored at room temperature both the USP and PIC/S standards state that sterility and endotoxin testing must be performed on the product. In both USP and PIC/S standards for sterility testing a minimum of 4 containers must tested. While endotoxin testing must be performed in duplicate as a minimum. If parental products are made on an individual basis and the volume per vial exceeds 1ml a minimum of four extra containers would be required for testing. If the volume per vial is less than 1ml then 6 extra vials are required. Therefore to supply a single vial to a single patient an additional 4 vials are also required for testing (if over 1ml per vial). This alone would increase the cost of the final product by approximately 5 times. In addition the cost of the sterility and endotoxin test kits themselves would also add an extra $100 minimum, without even considering the labor costs involved to carry out these tests. This would make parental products far too expensive for most people if made on an individual basis. If compounding in small batches these costs could be shared over the batch size making each individual container more affordable.

For example an injection vial worth $75 would end up costing approximately $475 ($75 x 5 + $100) if made individually and requires 14 days before it can be dispensed to the patient. Alternatively if allowed to make small batches for a 14 day supply and say you anticipate you will sell 10 vials in the next 14 days, based on sales history, and you make up 14 units (10 vials to sell plus 4 to be tested) the individual cost would end up being around $115 ($75 x 14 + $100 divided by 10) per vial and the vials would be available immediately without any delay. The later situation is the more desirable situation as the injection is significantly cheaper, immediately available and has been tested and proven to be sterile and pyrogen free thus in the best interest of public safety.

3. Sterility test results take 14 days to come back in order to assign an extended BUD therefore there will be a minimum of a 2 week delay to receive the medications once it has been ordered if made on an individual

basis. This delay will be unacceptable to most patients and prescribers for obvious reasons. This delay may also potentially encourage some pharmacies to release products before sterility results are back if pressured by their patients which is not an ideal situation. If however allowances are made to allow small batches to be compounded for an anticipated 14 supply the pharmacy should have stock available most of the time for immediate supply thus ensuring there are no or very limited restrictions in supply.

4. In the interest of public safety it would be best to encourage compounding pharmacies to run sterility and endotoxin testing on all sterile products supplied and the only way this could be achieved would be to allow small batches to be made. Otherwise if it becomes too expensive and creates long delays to supply the patient the pharmacist could be more likely not to run these tests and assign a 24hr BUD where the patient may not necessarily adhere to it in order to save money and time.

I believe in order to make the most recent proposed draft of the "Guidance on Expiry Dates for Parental Medicines" complete, workable, affordable and in the best interest of public safety the addition of limited batching should be included as outlined above.