REVIEW OF CONSULTATION PAPERS, STANDARDS AND GUIDELINES

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Pharmacy Board review of guidance on expiry of compounded parenteral medicines - Guidelines on compounding of medicines

Name of National Board: Pharmacy Board of Australia

Principle	Comments
1. Has the proposed guidance been expressed clearly?	The section on Compliance with legislation, good practice guides and practice standards could be made clearer. I would like to see it more clearly expressed as to which practice standard is applicable to which setting rather than leaving it up to the individual pharmacist who may take the softest option. The PICS Guide for Good Manufacturing Practice of Medicinal Products should not be listed here as an option as the document is about compounding (on prescription) not manufacturing. It is unlikely and inappropriate to be used by non TGA licensed compounding chemists as they should not be manufacturing (only compounding) The USP-NF 797 is appropriate for all settings and suggest just giving this recommendation. Document needs to be clearer as to which 'standard' to self audit against. Terminology is used interchangeably. First line says 'standards', second line says practice standards and guidelines and legislation. Needs to be consistent. Need to provide guidance on 'third party assessors.' How are they accessed? What qualifications and expertise do they require? Who /what body ensures or validates their expertise? Where there is no current jurisdictional representative assessing or ensuring compliance of facilities, self assessment is not sufficient to protect the safety of the public when expiry dates extended. Assigning extended expiry dates must be in accordance with USP 797, (only option) but softer options are provided for adherence to guidelines when compounding. Why not just make compliance with 797compulsory? Compounding parenteral medicines should be to the same standard whether expiry is 24 hours or extended. Problem with lack of expertise in many facilities to adequately audit adherence to enable extended expiries (except in TGA licensed facilities)

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?	The revised document has tried to address the concerns of stakeholders who want to be able to extend expiry dates for the purposes of supply to rural and remote communities, overcome the need to compound daily (e.g. when there is no weekend service in a hospital) or wish to save money by compounding in-house. However, as outlined above, requiring self audited compliance by a hospital/facility to USP 797 in order to be able to extend expiry dates infers that facilities compounding parenteral products with 24 hour expiry can comply at a lower standard. Hospitals and facilities not TGA licensed should be complying anyway. The standard of compounding to ensure sterility should be the same whether the expiry is 24 hours of greater. Suggest if the hospital or facility has a quality assurance program consistent with USP 797 then expiry dates may be extended to up to one week if the product is stable. Extending beyond one week should require a TGA licence. I.e. self assessment does not adequately support a longer shelf life. Costs should not be a reason to justify a lower standard of compounding.
3. Does the revised guidance support patient safety when supplying compounded parenteral (sterile injectable) medicines?	Not in regard to maintenance of sterility at extended expiries. Expiry date shouldn't be judged on a risk level assessment. Suggest not leaving open ended but having up to 7 days if full compliance with USP 797. Given stakeholders concern re rural and need for patients to have a compounded injection daily, can we cap at one week (former NSW guidelines and common hospital practice if extended expiry required)
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?	If I am a community pharmacy compounding injectable products for sale do I need to be licensed by TGA... If I am a hospital phramcist compounding infusions and injections for immediate (within 24 hour) use, which standards should I comply with... If I am compounding parenteral medicines in a hospital pharmacy under the governance and policies of the Pharmacy Dept, hospital and State Health Dept, do I need individual additional Pii cover.... How can I find a third party assessor.... Whay qualifications does a third party assessor require.....
5. Do you have any suggestions on how the proposed guidance could be improved (e.g. any content that should be changed, added or deleted), while still being in accordance with the public interest?	See comments in section 1 In the section on 'Assigning expiry dates to compounded parenteral medicines", the third dot point states that there is documented evidence that the product 'maintains sterility' This statement needs reviewing as a pharmacist cannot provide evidence of sterility. Evidence of sterility can only occur with sterility (QC) testing of a batch of manufactured product. In a compounding situation where the facility is complying with standards to the best of their ability and has a comprehensive QA program, the pharmacist can only ensure control measures are in place to prevent contamination during compounding, but the individual product cannot be tested for sterility.
6. Do you have any other comments on the proposed guidance?	Problem of lack of expertise and resources in the area of sterile compounding to ensure full compliance against the standards such as USP 797. Support original Board statement on 24 hour expiry but self assessment to give open ended extended expiry may not protect the public sufficiently.
Other issues	**Comments**

Public Interest	• *Self assessment of compliance to standards in order to extend expiry beyond 24 hours may not protect the public adequately if the product is contaminated during preparation*
Implications for workforce	• *Need to improve compliance with standards is supported. Resources need to be made available to ensure compliance, or otherwise compounding should not take place and be outsourced to TGA licensed facilities.*
Legislative and regulatory issues	• *What will be responsibility of each State jurisdiction to audit compliance? Where will the expertise in State Health Departments come from?*
Impact in rural and/or remote areas and other areas of workforce shortage	• *TGA licensed facilities can be contracted to provide compounded products with extended expiries for delivery to rural and remote areas. Cost should not be a reason to compound to a lesser standard.*
Timing of any proposed changes	• *Transition arrangement should not be required. Meet the standard now or do not compound.*