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: Australian Custom Pharmaceuticals Pty Ltd **Contact name: Daryll Knowles** **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?	While the PBA Guidelines on compounding have been on the whole expressed clearly there are areas of practice which are not addressed at all. Currently there is conflict between TGA regulations covering aspects of compounding sterile parenteral medications and State Poisons Regulations and Pharmacy Board Regulation. As a compounding pharmacist I am allowed to operate under Exemptions in the Therapeutic Goods Act. These exemptions only exempt me from the requirement to gain a TGA license to manufacture and listing my compounded products on the ARTG. They do not exempt me in any way from producing a quality product using pharmacopeial grade raw ingredients or similar. I am a registered Pharmacist under the National Health Practitioners Legislation and as I am located in NSW I fall under the regulation of the NSW State Poisons and Therapeutic Goods Act. Under the TGA legislation I must use Pharmacopeia quality raw ingredients for sterile products and if not available I must carry out testing on raw material and finished products myself. Under PBA Guidelines as a compounder I must only produce medications for a named patient and its Guidelines are mute on whether I am technically allowed to produce product for quality testing purposes. The PRU of the NSW Ministry of Health is unclear about their interpretation of their own Poison and Therapeutic Regulation as to whether I am allowed to send S4D and S4 scheduled medicine and raw materials to a testing laboratory for quality and purity testing and is unable to give me clarification after multiple requests. In fact, claiming compounders who test their S4 and S4D medications are contravening the Federal Drug Misuse and Trafficking Act 1985! It is these types of omissions which leave compounding pharmacist who are trying to do the right thing open to prosecution and complaints from regulators due to various interpretations of the many regulations we work under. Also the term “self-assessment” is very vague and as we already know ALL of the incidents of patient harm in the US and of late in Australia by sterile parenteral compounded medicines have been under the rule of self-assessment using a valid document, such as USP 797. If this is left as “keep the status quo” who is going to enforce these “self-assessments” on a proactive basis. The Pharmacy Council of NSW or it’s engaged entity are not trained in USP 797 sterile compounding requirements, European PIC/S regulations or even the TGA adopted version of PIC/S. The PRU Unit of the Ministry of Health does not have this type of expertise to inspect and understand the pharmaceutics as applied to these Regulations. Clearly the TGA Inspectors are the only ones with the level of training in this specific and specialized area. But if the pharmacists opt out of TGA licensing (Option2) then there is no body to inspect them and we could potentially create another New England Compounding Scenario right here in Australia. Don’t forget that disaster happened with self-regulation by the pharmacist of himself under USP 797.
2. Does the revised guidance adequately address	This perception that the previous PBS Guideline in co-regulation with the TGA would inhibit or impact

the concerns raised by stakeholders, that the published (postponed) guidance would inhibit or impact patient access to compounded parenteral medicines?	patient access to compounded parenteral medicines is exaggerated at best. It is in my opinion simply a ruse to allow some pharmacy operators to continue to operate at an inferior level of GMP and therefore ipso facto patient safety. After training my appropriate staff in full TGA GMP process it has become blindingly clear that Pharmacists should not be performing preparation of sterile parenteral compounds especially Intravenous preparations without a TGA GMP License. End of Story. I used to think that the Pharmaceutical Industries hard line attitude against Sterile Compounders Practice was simply an industry jealousy based on a financial argument. Now that my team and I are fully trained in the process of GMP and we understand what we never knew their argument is clear. Compounders doing self-assessment for regulators who don't have the expertise to police that self-assessment without testing of products seems like lunacy. As a compounder I will be producing the same range of products in a licensed TGA facility and no patient of mine will be disadvantaged. Gaining a GMP license is not an impossible task and already has been achieved by a few Pharmacists in Australia. The argument of cost to patient is simply in Contravention of Guideline 6 - Formulation **'**Patient safety should not be compromised particularly in the interests of cost." In summary the softening of the stance of the PBA Guidelines to allow self-regulation under USP 797 or European PIC/S is extremely disappointing and will do nothing to increase patient safety. The short comings in pharmacist self-assessment will only be identified when patients are hospitalized as there is a retrospective investigation. With no regulator to proactively inspect to prevent these incidences patient's safety is at risk. As has already happened in March 2015 and February 2016 in Australia. It would seem that the Boards softening of its stance is simply allowing the status quo to continue maintaining the current risk to patients. The only change needed from the previous guideline in the revised guideline would be to allow Sterile compounding pharmacists a practical time period to commence and obtain a TGA license. TGA and FDA usually allows 2 years as long as Compounders are practicing according to TGA PIC/S Guidelines during this period. This way patients will be guaranteed continual access to medication and a higher level of safety. This 2-year period would also allow plenty of time for the pharmacist's intent on gaining a GMP license time to do so, this is a policy also granted by the FDA to Compounding Pharmacists undergoing 503B licensing.

3. Does the revised guidance support patient safety when supplying compounded parenteral (sterile injectable) medicines?	The expiry of 24 hours does support patient safety. Allowing pharmacists to self-assess under USP 797, a guide line we in Australia are not familiar with changes nothing from the precarious situation we have at present. Pharmacist hurting and hospitalizing patients through lack of mandatory checks and balances. The Board's simple Guideline on parenteral preparation should read: "If you're are going to produce a sterile parenteral medication in your pharmacy with an expiry of more than 24 hours then you should obtain a TGA GMP license to manufacture." Simple. This leave governance of compliance to the experts and takes patient safety out of the hands of self-assessing pharmacists who simply don't have adequate sterile compounding training. Presently in Australia, short of full GMP training, there is no training available except a 4-day cooking course from US wholesalers which I have attended and know falls way below the bar for GMP.
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?	What products are regarded as sterile parenteral medication? What will I have to do to claim an expiry date on my compounded medication of more than 24 hours? Where do I find a list of TGA Licensed Compounders for me to contract to, to manufacture this prescription?
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?	Under **Compliance with Legislation, Guidelines and Practice Standards** Remove both option 1. PIC/S Guide to Good Practices for Preparation of Medicinal Products in Health Care Establishments (PE 010-4), a European Standard not adopted in Australia and option 3 USP-797 Pharmaceutical Compounding – Sterile a US standard not adopted in Australia. In Australia we don't have enough expert regulators to inspect the activities of Sterile Compounding Pharmacists. In sterile compounding we only have the TGA Inspectors who are expert in the area of TGA Adopted PIC/s Regulations. Why would we muddy the clear water by introducing 2 virtually unknown sets of Regulations for Pharmacist to self-assess by. There would then be NO EXPERTISE amongst inspectors in these regulations. There are currently no Practicing Community pharmacists who are Compounders of Sterile Medications on the Pharmacy Council of NSW or it's contracted Field force of Inspectors, Pharmaceutical Regulatory Unit of NSW Health or Health Care Complaints Commission. By removing the TGA Inspectors out of the scenario by introducing USP 797 or its European equivalent seems counterproductive to raising the level of patient safety. Under **Self-Assessment and Audit**

	"**Self-assessment"** – Should be removed totally as I believe this to be the core problem with the current concerns with patient safety and sterile parenteral medications. Compounding Pharmacists are continually being scrutinized by regulators using interpretations of Guidelines and conflicting regulations. The last thing we need is another area where our self-assessment is open to interpretation by regulators. **Audit** – TGA Audit – is the only answer. **Assigning Expiry dates to Compounded Parenteral Medicines** USP-797 should be removed as a standard. TGA Guidelines should be the only standard. We are in Australia not the US or Europe. Why use standards that are not compatible with our Chief Regulator of medicines – The Therapeutic Goods Administration of Australia? We are in this regulator grey area because the various stake holders keep introducing new variables. We need clarity and one set of rules that everybody understands.
6. Do you have any other comments on the proposed guidance?	It could have been so simple but now we are back to 2003. Self-regulation with Foreign Standards. Ironically it was exactly this scenario with New England Compounding and 2 Australian Compounders that created the concern and debate in the first place. Now it seems that some believe the answer is to do nothing and maintain the self-assessment status quo. Sterile Compounding should be regulated by the experts, theTGA. Not local Boards or Health Departments. Patients will not be adversely affected by cost or accessibility to the extent other stake holders claim and can only end up winners in a properly controlled and safe environment. I am a community pharmacist with my patient's welfare as paramount.

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