

Feedback on this public consultation

Review of the draft PBA *Guidelines on compounding of medicines*

Introduction

My name is Daryll Knowles, I have been a compounder of complex medicines for over 25 years. I am the owner of Australian Custom Pharmaceuticals Pty Ltd, a compounding only pharmacy that has been involved in the practice of Complex Compounding (as defined in the proposed PBA Guidelines) for the last 11 years. Over this time my pharmacy has dispensed over 35,000,000 unit doses of complex compounded medicines with no significant adverse drug reactions except for an expected infrequent allergic reaction. This number includes many millions of doses of sterile parenteral multi dose medications dispensed to many hundreds of thousands of patients who rely on compounding and cannot get access to their medication through mainstream medical channels including current GMP Licensed facilities.

In my facility alone the list of patients and programs who would lose access to safe and tested medicines if parts of these guidelines were introduced would include patients suffering from:

Muscular Dystrophy

Cachexia – muscle wastage syndrome from cancer, AIDS and other muscular degenerative diseases

Autism Spectrum in children.

Human Chronic inflammatory diseases –mechanical and auto immune.

Koala extended release pain relief programs

Koala chlamydia investigations

Small animal extended release chronic pain management

Multiple Sclerosis

Anti-Cancer Ovine Antibody Programs

Indigenous Health programs for Diabetic Retinopathy

Alcohol Addiction Programs

Opiate and Stimulant Drug Pilot programs – including one of Australia's first Cocaine,

Methamphetamine Abuse programs

Wound Care and Diabetic Ulcer Initiatives

Innovative Nutritional support programs for Heavy metal Detoxification

Cystic Fibrosis treatment

Men's Health

Preservative free Antigen supply to hypersensitive individuals

Pre and Post-operative Wound Care Programs

Specialized Infertility Programs and hormone replacement

And many other genetic orphan disease sufferers who rely on complex compounding of parenteral medications.

This list is not exhaustive and is from one facility providing socially valuable medicines.

I applaud the Board's initiative to offer a co-regulatory environment with the TGA which controls and provides clarification of guidelines for Complex Compounding. This became necessary due to the TGA NCCTG exemption of such a large number of pharmacists from their ROI June 2013 although I am still disappointed that the Board has also seen fit to exempt hospital pharmacists from the most onerous of guidelines concerning hazardous sterile complex compounding.

I have responded in point form to the proforma questions offered by the Board.

1) Do the draft guidelines clearly differentiate between simple compounding and complex compounding?

The draft guidelines do clearly differentiate between simple and complex compounding.

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?

The Guidelines do clearly outline which requirements apply to simple compounding.

However there are several areas in the complex compounding guidelines which are quite confusing.

- i) The Board guides the Compounder of Complex Medicines to the Extemporaneous Guideline in APF 22. Which specifically says:

“Extemporaneous (batch) manufacturing is the creation of a batch of multiple units of products. Pharmacists who engage in extemporaneous manufacturing , in anticipation that there will be an individual consumers with a need for a product or intending to store preparations for supply over an extended period of time, have in addition to meeting the accepted pharmacy professional standards, an obligation to comply with the Code of Good Manufacturing Practice for medicinal products, (GMP), and ensure that preparations are labelled according to the requirements of therapeutic Goods Order No. 69.”

- ii) It then states in its Draft guidelines Section 3 Formulation Considerations that this section introduces:

“Guidance on the preparation of compounded medicines in advance. This includes a statement “that only parenteral medicines with a shelf life of up to 24 hours should be compounded by a pharmacist for use by a specific patient. (Note: hospital are exempted from this requirement.) “

So even though the APF 22 Guidelines suggest pharmacist are able to produce under GMP Guidelines the Board proposes to override the APF22 in this case. Which Guideline wins?

This to me is very confusing for several reasons:

- a) There are virtually no sterile parenteral preparations produced in community pharmacy clean facilities with shelf life of up to 24 hrs. Transport to Hospitals or clinics alone will consume most of the 24hr use by date. So does this, as it reads, put a unilateral ban on all complex compounding of parenteral dose forms with a shelf life of over 24hrs and in dose form other than single unit dose form?

It confuses me as to why the Board would exempt hospital pharmacist's working in a “dirty” hospital environment and so encourage aseptic dispensing of sterile parenteral products in an environment whose microbiological contamination levels far exceed the clean rooms of community pharmacy.

Why when we finally, in the modern era, have another option to increase patient safety by not exposing vulnerable hospital patient's parenteral medications to the high levels of infections carried throughout our hospital

systems the Board seems to be regulating to in fact increase risk. There are no risks of MRSA contamination in community pharmacy.

- b) The most baffling thing about this outdated and apparently random statement, (in the context of this document) besides its ability to deprive 10,000's of patients of their sometimes life giving medicine is what could possibly be the basis of such a statement in the **current pharmacy environment**. I have heard this statement proposed many years ago in a US context. It has already been discarded in the US as unworkable. Its original source was from a US company after shortly arriving in Australia during the infancy of Complex compounding in Australia. It was this same industry stake holder who previously floated the idea of regulation of compounding pharmacies based on numbers of prescriptions dispensed. The 2000 prescription per month farce. That idea has now **in the current context** been disregarded by all who made submissions to the TGA NCCTG ROI June 2013 (even the stakeholder who first proposed it). It is for this reason that this other flawed draconian and dangerous statement should also be discarded.

It does nothing to increase patient safety in the current environment.

If it was ever included into the new Guide lines it would actually reduce overall patient safety by depriving seriously ill patients who have been able to safely receive their "orphan parenteral medications" from regulated Compounding pharmacies. Forcing them back to the totally unregulated and illegal internet trade in untested medications. I don't need to remind the Board that The New England Compounding Disaster in the US was caused by contaminated single dose parenteral injections with the contamination introduced into the single use vials already present in the facility in which they were produced.

Under this statement The New England Catastrophe could still occur.

Is the content of the draft guidelines helpful?

The content is mostly helpful and gives good guidance on the expectations of the PBA in relation to training, professional profile development and simple compounding however in the area of complex compounding there are still areas of grey, especially in Sterile Compounding.

Is there any content that needs to be changed, added or deleted in the draft guidelines?

The statement "that only parenteral medicines with a shelf life of up to 24 hours should be compounded by a pharmacist for use by a specific patient. (Note: hospitals are exempted from this requirement. "

This statement should be deleted as it is an outdated concept in the modern complex compounding world. It is totally out of context with the rest of the PBA document which empowers pharmacists to train themselves in hazardous compounding techniques and invest in Australian medical infrastructure by building "state of the art" facilities both of which can only lead to better and safer patient outcomes. By the Board severely restricting the access of the regulated community pharmacy industry it will do nothing to increase patient safety. Illegal activities from desperate patients trying to get access to medications will replace documented controlled medical outcomes. The Board will simply push patients back to the internet. In 2014 the Board takes the view in referring Complex compounders to the APF 22 Extemporaneous Guidelines and in its prescribing of training and professional profile development for complex compounders that they should take charge and train themselves in the disciplines they plan to undertake. In its submission to the TGA NCCTG ROI June 2013 it also expresses concern that the risks maybe larger from those non-pharmacist allied health practitioners who also extemporaneously prepare products for human therapeutics use with little or no formal training. Complex Compounding is the pharmacist's field of expertise and if clear guidelines

are laid down which is mostly the case in these draft guidelines pharmacists can provide a safe, regulated compounded product to their patients taking away their need to purchase unregulated and high risk medications from alternative sources.

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

Would the Board support a guideline which worked on a concept of an accredited (possibly as part of a Guild QCPP Program Module) Complex Compounding pharmacy acting on GMP guide lines with respect to product testing and small batch production using the Guidelines in APF 22 but without requirement for actual TGA licensing? This concept would allow pharmacies to maintain supply of safe tested products to patients without the onerous cost incurred with TGA Licensing thus keeping prices within patient's means.

I feel this would be in line with the Board's opinions and concerns about TGA licensing of Complex Compounding increasing prices unacceptably and out of the affordability of patients. As expressed by the Board in its submission to the NCCTG RIO June 2013. When it submitted:

"The additional cost burden [of TGA Licensing] would result in all likelihood with increased costs to consumers, a possible reduction in the number of pharmacies which do meet required standards but are unable to bear the costs of licenses and inspections as proposed."

My confusion lies in the fact that the Board has expressed concerns of a **potential** restriction of supply to patients based on an increase in cost due to TGA Licensing in its submission to the NCCTG and then in its own guidelines introduces a single statement which will is **absolutely guaranteed to** deprive tens of thousands of patients of vital medicine as they will be unavailable at any price..

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

The Practice profile gives a clear road map for pharmacists already practicing and anticipating starting complex compounding.
Availability of training courses and neutral institutions able to carry out accreditation of complex compounders and their facilities is now possible.
A structure I myself favor is a Master's Program in Complex Compounding based on Board Guidelines involving a First year Diploma in Complex Compounding, a Second Year Certificate in Complex Compounding with a final 3rd Year culminating in a Masters of Complex Compounding. If the syllabus could be delivered in an online format with practical training modules it would allow working pharmacists a flexible channel to acquire knowledge without too onerous a burden on their lifestyles. This should be run by an appropriately Certified University or College or educational Body free from commercial conflict.
The Facility accreditation process should be controlled by a peak body like the Pharmacy Guild of Australia. They already have the QCPP program and if they could develop a further module for Complex Compounding this could be used to accredit Complex Compounding facilities.

ACCREDITATION SHOULD BE PROVIDED BY NEUTRAL PHARMACY ORGANIZATIONS FREE OF COMMERCIAL CONFLICTS.

It is my opinion that Complex Compounding in Australia needs further regulation. Not draconian over regulation as shown in the random statement contained in Section 3 Formulation Consideration referring to parenteral sterile compounding but rather empowering guidelines that control and guide pharmacist's to develop professionally, working from "state of the art facilities" to deliver to maximize patient safety. An empowered, educated Complex Compounding Pharmacist

Specialty provides a support network to the main medicine delivery system in Australia and is a much preferable outcome for patients than a group of disenchanted and frustrated Complex compounders with their professional hands tied behind their backs unable to deliver to their patient's safe, affordable medications when they need it most

Which after all is what all of the TGA, NCCTG and Board Road Maps and Guidelines are ultimately all about.

Regards
Daryll Knowles



Socially Valuable Medicine

acpharm.com.au

Daryll Knowles

BPharm, MPS, AFACP, FAPPF, ASCC, FAARM, OPM

(Harvard) ACNEM

Owner



Australian Custom Pharmaceuticals

Unit 1, 4 Endeavour Road Taren Point NSW 2229