SUBMISSION ON CONSULTATION RIS: OPTIONS FOR REFORM OF THE REGULATORY FRAMEWORK FOR PHARMACY COMPOUNDING

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PCCA
PCCA Pty Ltd is a supplier of ingredients, devices, equipment, training and education to compounding pharmacists and pharmacy staff in community and hospital pharmacies and tertiary institutions. PCCA has a TGA manufacturing licence authorising the packaging, labeling and supply of ingredients. PCCA is endorsed by The Pharmacy Guild of Australia and is a Royal Australian College of General Practitioners Accredited Activities Provider. We are also a provider of Australian Pharmacy Council accredited continuing professional development activities to pharmacists.

Summary
Compounding by pharmacists is a core professional activity of pharmacists and ensures that patients are able to access essential medicines at a reasonable price when a commercially manufactured product is unsuitable or unavailable. Patients needing medicines without specific additives, in a different dosage form or dose, or one that is not available in Australia, are able to have the medicine compounded by a pharmacist. Children and babies are an example of patients reliant on compounding as many life saving medicines are not available in a suitable liquid form or concentration.

PCCA supports Option A as the Pharmacy Board of Australia has developed new guidelines and training requirements for pharmacy compounding which apply to all pharmacists in all areas of practice. We oppose Options B and C because the proposed regulatory changes cannot be applied to all pharmacists in all areas of practice and do not apply to health practitioners such as medical practitioners, dentists, complementary medicines practitioners and vets who may compound but are less qualified to compound medicines than pharmacists. We oppose all sub-options in Option C because the proposals are not reflective of the risk in Australia which can and have been addressed by oversight by the
pharmacy professional organisations, Pharmacy Board and pharmacy regulating authorities in each state; and because they will result in reduced patient access to critical medicines and hugely increased costs to patients leading to serious harm. More details on why we have taken this position are in the remainder of this submission.

Option A

Any regulation of compounding by pharmacists should be applied consistently and in proportion to the risks. Regulation by the TGA of a pharmacy professional practice cannot achieve this and is best managed by the profession and the Pharmacy Board of Australia. PCCA supports Option A and we contend that this is not just maintaining the status quo, as the Pharmacy Board of Australia has developed revised guidelines and training requirements for compounding to be released for comment in the next month. Compliance with Board guidelines are used by tribunals as indicative of appropriate practice and non-compliance has led to sustained charges of professional negligence and malpractice. The proposed changes to the Therapeutic Goods Regulations would only apply to pharmacists in community pharmacies, in only some states, preparing human but not animal medicines. The Pharmacy Board regulates all pharmacists and their activities in regard to professional standards to ensure the safety of the public.

Regulatory changes must be appropriate to risk as the cost to patients and their access to essential medicines may be adversely affected. We note that fewer than 20 adverse event notifications associated with compounded products were made, of more than 250,000 reports since 1971. Even these are not confirmed as caused by compounded products and although there may be under-reporting, this has also been noted as a characteristic of reporting for all medicines. If the preparation of more complex dosage forms is so problematic, more adverse event reports might be expected given the long time period.

The adverse events associated with compounding in the US have not occurred in Australia even though specialised compounding has been well established here for more than 15 years. The pharmacy
environment in Australia is very different to the USA and this may be responsible for the insignificant number of reports of adverse events associated with compounded medicines. Since most medicines are dispensed on the PBS, there is a financial disincentive to use a compounded product without a clinical need. Unlike the US, compounded products receive minimal or no reimbursement from health insurance funds. In the US, pharmacies may be owned by non-pharmacists and corporations unlike Australia and charges of professional misconduct or negligence by the Board directly impacts the pharmacist owner.

It is also worth noting that of the three examples of problems relating to compounding in Australia, only one concerned a specific product and was reported back in 2008. The other two examples were general remarks intended to remind all pharmacists, rather than more specialised compounding pharmacies about the ingredients and balances used in routine compounding, most likely of APF formulae.

I am the lead author of the study cited in the consultation document describing the extent of compounding in Australia.2 Our research indicated that although the volume of compounding has decreased, almost all pharmacies still provide compounding services and pharmacists strongly opposed a limit on the quantity of compounded products that could be prepared. In this study and subsequent published reports, we also found that the overall number of compounded products prepared had not significantly increased but tend to be concentrated amongst a smaller group of pharmacies that specialise in this area. This is to overcome difficulties with maintaining and accessing ingredients, equipment and/or skills and likely results in reduced risk to patients.

Option B

PCCA does not support Option B as the proposed changes to legislation would not be applicable to pharmacists in all states of Australia, nor to all pharmacists preparing compounded medicines in hospitals or when preparing veterinary products. In addition, the regulatory changes do not apply uniformly to medical practitioners, dentists, herbalists, and other complementary medicines practitioners who compound medicines without the formalized training undertaken by pharmacists. Therefore the proposed legislative changes cannot be claimed to be risk based and may increase risk by

driving patients needing compounded medicines to less qualified practitioners. There is no definition of ‘unavailable’ which may involve medicines out of stock for long or short periods of time, and discontinued medicines. There are no systems in place that I am aware of that allow a health practitioner to check the available or unavailable status of any medicine. In addition, some products are entered on the ARTG for export only and so are also not available as an ordinary prescription or pharmacy product.

Requirements for ensuring patients are aware that a product is compounded; that medicines are only compounded for specific patients from the pharmacy and not by wholesale; and only when a suitable product entered on the ARTG is unavailable can be included in Pharmacy Board requirements if necessary. We are also concerned about the very broad requirement that a pharmacist must supply records in relation to compounded products if requested by the Secretary. If this Option is considered, we propose that this should be limited to records specifically relating to a complaint or investigation.

Option C

PCCA opposes Option C1, C2 and C3. Again, these Options cannot be applied to all pharmacists in all areas of practice and would result in patient harm by interfering in the professional judgment and practices of medical practitioners and pharmacists. Patients would be able to access the affected medicines in some states and not others leading to increased costs, inequitable access and treatment delays and possible treatment failures. This could have devastating outcomes for patients.

An indication of the cost impact of licensing by the TGA on compounding may be seen in the UK. Most compounded medicines in the UK are now supplied by licensed manufacturers known as ‘specials’ manufacturers instead of pharmacists. The increase in cost to the NHS has been estimated at about £188 (A$300) per item. For example, gabapentin suspension, critical for control of seizures in children and adults unable to swallow a capsule, cost £706 (A$1156) from a specials manufacturer. By

2 http://www.dailymail.co.uk/health/article-1350257/Now-NHS-pays-1-000-bottle-salt-water.html (accessed 11 June 2013)
comparison the same preparation is prepared by compounding pharmacists in Australia for less than A$100. Since the PBS does not subsidise this compounded product, the patient will have to bear the cost or be untreated.

The importance of compounding in health care has been acknowledged in the US where patients unable to access critical medicines due to ongoing, extensive drug shortages, have only been able to receive treatment using compounded products. Proposals being considered by the US Senate do not aim to prevent pharmacists preparing sterile products like Option C but seek to control interstate, wholesale distribution. One of the issues noted in the consultation paper is also large scale supply to multiple patients. However, patient specific supply of compounded medicines from the pharmacy and not by wholesale is already the criteria for exemption from entry on the Australian Register of Therapeutic Goods. This regulation is already enforceable if the TGA chooses to act and prevents wholesale supply across state borders and within some states. In states where the Therapeutic Goods Act and Regulations have not been adopted, any proposed changes to regulations will not apply anyway.

**Option C1** – Requiring a TGA licence for compounding of sterile products except for those applied topically to the eye or injections for immediate use will result in enormous cost increases for patients requiring ongoing treatment. Most sterile compounded products are not available as registered products because the demand does not justify the cost. Therefore patients requiring ongoing treatment will either lose access to the medicine or pay very significantly higher prices. This may force patients to seek help to access sterile medicines from other practitioners not subject to these regulations.

**Option C2** – This Option will result in the majority of patients currently relying on compounded medicines to lose access to medicines from their preferred pharmacy. Many APF formulas will no longer be able to be compounded nor will some products subsidized on the PBS. For example, eye drops and ointments, creams, gels and ointments containing steroid hormones and APF/PBS formulas containing potent active ingredients will only be allowed to be prepared by a licensed manufacturer. As previously discussed, the cost of this Option to the patient is
indicated by the cost of specials in the UK. Children who are dependent on their local
compounding pharmacist may be most severely affected by Option C2 as this group is most
poorly served by TGA registered products.  

Option C3 - Use of a quantity limit as the distinction between professional practice and TGA
licensing has been discussed many times in the past and is widely opposed. Again this restriction
would not apply to all pharmacists in Australia and would not even apply to all products
compounded in a pharmacy if veterinary medicines were also prepared. All extemporaneous
products, regardless of quantity, should be prepared according to acceptable standards. The risk
for each item would be unchanged regardless of whether one prescription was prepared or ten.
Practice standards, processes, and supervision have more effect on risk. Pharmacy Board and
Professional Practice Standards could address these risks and be applied uniformly to any
pharmacist compounding any product. There is merit in requiring validation of equipment and
processes when large batches are prepared and this could also be a Pharmacy Board
requirement.

It might be argued that a pharmacy preparing a compounded medicine regularly presents less
risk than ten pharmacies preparing the same medicine infrequently. Some pharmacies have
elected to specialise in the practice of extemporaneous dispensing. To do so according to the
professional practice standards requires a significant investment in equipment and time in the
development and maintenance of required procedures. By placing limits on the quantity that
may be prepared, regulation will discourage this commitment resulting in fewer specialised
pharmacies using good compounding practice and a subsequent increase in compounding by
pharmacies with a lower level of practice and experience.

4 Outcome Statement of the Paediatric Medicines Advisory Group October 2012
One of the concerns expressed by researchers regarding extemporaneous dispensing is that many pharmacies compound irregularly and so there are implications concerning maintenance of skill sets, quality of raw materials, adequate facilities and equipment. Imposing a quantity limit, reinforces these difficulties rather than allowing for the establishment of specialised practices. Since patient needs and prescribing are not controlled by pharmacists, imposing a limit on quantities will potentially deny patients timely supply of their prescribed medicines or prevent them from using their regular compounding pharmacist who is familiar with the required compound and the patient’s medication history.

Thank you for providing the opportunity to make this submission.

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