June 2019

SUBMISSION to the MEDICAL BOARD OF AUSTRALIA

Re: PUBLIC CONSULTATION ON CLEARER REGULATION OF MEDICAL PRACTITIONERS WHO PROVIDE COMPLEMENTARY AND UNCONVENTIONAL MEDICINE AND EMERGING TREATMENTS

Background to PCCA

PCCA would like to thank the Medical Board of Australia for the opportunity to provide feedback on this discussion paper.

PCCA Pty Ltd- Professional Compounding Chemists of Australia-is a membership based organisation which has provided compounding training, education to registered pharmacists in Australia and overseas for over 30 years. We are also a TGA licensed supplier [1]of pharmaceutical ingredients which are used by compounding pharmacists in Australia. We provide technical support on all aspects of compounding pharmacy, including formulation support and updated information on current regulatory concerns.

We are making this submission because we believe that the role of the compounding pharmacist has been incorrectly portrayed in this discussion paper.

Compounding pharmacists play a vital role in providing medicines for patients whose needs are not currently met by commercially registered products.

The Therapeutic Goods Administration (TGA) describes complementary medicines as:

"Complementary medicines (also known as 'traditional' or 'alternative' medicines) include vitamin, mineral, herbal, aromatherapy and homoeopathic products.

Complementary medicines may be either listed or registered, depending on their ingredients and the claims made."[2]

This definition does not make mention of either off- label prescribing (Discussion paper, page 5) or prescribing of compounded products (Discussion paper, page 7).

[1] Therapeutic Goods Administration Licence to Manufacture Therapeutic Goods Licence Number M1-18112004-L1-000190-1

[2] https://www.tga.gov.au/complementary-medicines Accessed 26/6 2019

It appears that the Medical Board of Australia may have taken an opportunity to include an unwarranted discussion about compounding pharmacy in a totally inappropriate forum.

Role of Compounding for positive patient outcomes

Irrespective of the types of medications which need to be compounded, *compounding pharmacy has always been and continues as a fundamental service provided by pharmacies in both Australia and overseas.*

It supports prescribers to help their patients to be able to access optimal forms of medication to support their treatment needs.

"Extemporaneous dispensing" or "compounding" means the extemporaneous preparation and supply of a single "unit of issue" of a therapeutic product intended for a specific person in response to an identified need.[3]

In fact, in November 2017, following extensive discussion with the Pharmacy Board of Australia, a joint statement was released reminding both medical practitioners and compounding pharmacists of "their respective responsibilities relating to compounded medicines which in turn will protect patients"[4]

While it is correct that compounded medicines have not been assessed by the TGA, and do not appear on the Australian Register of Therapeutic Products (ARTG), the obligation on the compounding pharmacist is to prepare products that are of acceptable quality, safety and efficacy.

In order to achieve this, the Pharmacy Board of Australia released their guidance document "*Guidelines on Compounding of Medicines*" in March 2015. Updated content, relating to preparation of sterile products was released in August 2017.[5]

Professional obligations of pharmacists

Pharmacists have a professional obligation to demonstrate and maintain appropriate standards in order to prepared compounded medicines. These include establishing whether this is an appropriate need to prepare a compounded medication and performing a risk assessment to judge potential risks to both staff and patients.

A prescriber or patient (when a prescription is not required) can request extemporaneous preparations for a number of reasons, including the following:

- Liquid formulation is needed because the patient is unable to swallow solid-dose forms. This regularly occurs in the case of paediatric medications where as few as one-third of medicines with a paediatric indication are not available in a suitable paediatric dosage form[6].

[3] Australian Pharmaceutical Formulary and Handbook (APF 24) Pharmaceutical Society of Australia Twenty-fourth edition 2018

[4] https://www.medicalboard.gov.au/News/2017-11-24-media-release-joint-statement.aspx Accessed 26/6/2019

[5] https://www.pharmacyboard.gov.au/Codes-Guidelines.aspx Accessed 26/6/2019

- The patient has an allergy or sensitivity to an excipient in a product which is entered on the ARTG
- A product entered in the ARTG is discontinued or unavailable

The concerns listed on page 7 of this discussion paper have no relevance to the concerns noted in the Background to the document on page 3.

"Insufficient information being provided to patients, inappropriate tests being ordered, inappropriate prescribing and inappropriate treatments being provided to vulnerable consumers all fall to the responsibilities of prescribers, not pharmacists."

Pharmacists are professionally bound to prepare medicines, being at all times bound by the legal requirements of Poisons and Therapeutic Goods legislation. The "Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP) outlines the requirements for the storage, supply, labelling and recording of medicines which fall into Schedules 2,3,4 and 8.

In every case, pharmacists must have a valid prescription for all medicines which are listed in Category 4 or 8. Some states have additional requirements for some chemicals in these categories.

Although this is clearly stating the obvious, pharmacists do not have the ability to prescribe these medicines and therefore the onus is on the prescriber to consider whether the course of treatment is appropriate for the patient.

However, as part of the professional practice guidelines, *pharmacists are required to conduct a risk assessment for the patient*. Part of the risk assessment process should be to consider whether the medication is appropriate for the patient.

Pharmacists are encouraged to use a questionnaire format to help them review all aspects of the patient's condition. Questions considered include age and weight of the patient, any known allergies or pre-existing conditions, overall health status, and most importantly whether they are aware that the product ordered is required to be compounded.

Once the information is gathered, the pharmacist may find it appropriate to contact the prescriber for further discussion about formulation, dose, strength and any other aspect of treatment.

This allows both the compounder and the prescriber one further opportunity to stop and re-assess the suitability of a product for the patient. Often times, after such a review, the decision is taken not to continue, and review the management of the patient.

In every case of a pharmacist receiving a prescription for a compounded product, care should be taken to follow a "prescribing cascade" as it were.

If there is a commercially available product, then this should always be considered.

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[6] Paediatric Drug Formulations: A review of Challenges and Progress Verica Ivanovska, Carin M.A. Rademaker, Liset van Dijk, Aukje K. Mantel-Teeuwisse Pediatrics Aug 2014, 134 (2) 361-372; DOI: 10.1542/peds.2013-3225 Accessed at https://pediatrics.aappublications.org/content/134/2/361 26/6/2019

If for some reason this is unavailable, then the prescriber should consider whether there is another commercial alternative.

Only when these scenarios are exhausted should compounding be considered.

Pharmacists are also advised to consider a "risk matrix" to help consider the likelihood of adverse events when preparing a compound. The Pharmaceutical Society of Australia (PSA) provides such a risk matrix template for compounders in their Professional Practice Standards.[7]

The joint statement issues by the Boards clearly notes that:

"If a pharmacist believes that it is not safe or appropriate to compound a prescribed medicine, they must let the prescriber and patient know so alternative treatment options can be considered"

Many compounders do compound medications, on prescription, for prescribers who describe themselves as "integrative" or "holistic" practitioners.

Practices not applicable to compounding pharmacy

Discussion of treatments which involve harvesting and administration of stem cells, for example, have nothing to do with compounding pharmacy, and is disappointing that the Medical Board of Australia has seen fit to blur some of their concerns about more extreme treatments with those of accepted professional practice.

Similarly other practices described in this document such as applied kinesiology or pathology testing in non-accredited laboratories are totally out of the scope of compounding practice.

We accept that pharmacists have a role in providing compounded dosage forms for hormone therapy and related supplements.

Challenges for compounding pharmacists

In some cases, it can be a significant challenge to guide some of those prescribers through the accepted protocols for safety of the patient.

With experience in this industry for over twenty years, we have experienced many changes to the way in which patients view the health status, and in particular how they manage chronic health conditions.

The internet phenomenon, including the advent of on-line discussion forums, has united patients, who often approach both pharmacists and prescribers looking for solutions to their illness.

[7] Pharmaceutical Society of Australia Professional Practice Standard v 5 Appendix 7

Doctors Code of Conduct

Medical practitioners are already required to follow an accepted Code of Conduct, and patients have a fundamental right to choose their own doctor, or doctors for treatment of their conditions.

It is also accepted that medical practitioners are required to undertake on-going continuing professional development.

An intrinsic part of the medical profession is to embrace new treatments. If this were not the case, then the advances which have been made in "conventional" medical care in Australia and world-wide would not, today be contributing to the overall improvement of patients' health.

Advances in cancer treatment, treatment of diseases such as HIV/Aids and Hepatitis C are not considered "emerging therapies" but necessary for the benefit of the population.

The recent increase of acceptance of the use of Medicinal Cannabis is the most current example of what some may have consider in the past an "emerging therapy" which is now not only becoming more widely acceptable, but has earned its own place within the Therapeutic Goods Administration orders.

Draft Guidelines Definition

The current discussion paper seems to have not clearly defined, or possibly confused the issues between definitions or actual therapies. It appears that the terms "complementary", "unconventional" and "emerging" therapies need to be separated out for clearer discussion, and the role of supplying "evidence" for treatments is also more specifically defined.

The practice of evidence based medicine is vastly different from experimental practice, but all therapies appear to have been bundled together in this discussion paper.

Concern for public safety

We do not disagree with the Medical Board as far as their concern for patient safety. Many patients with chronic diseases are at their most vulnerable status, and are often clutching at straws to find anything that possibly might help them.

The same guidelines should apply to ALL medical practitioners, regardless of their specific areas of practice.

However, if the Board is concerned about the impact on public safety by certain practitioners, it may be appropriate to provide a separate guidance document designed to help prescribers who are not members of a professional college or association, and therefore not subject to their codes (page 17 of this discussion paper).

Similar Guidance in other Healthcare professions

This would not be a dissimilar situation from that of the Pharmacy Board of Australia. As the number of pharmacists who provide "complex" compounding services has increased, the Board has found it appropriate to provide separate Guidance on how to manage this area of practice. Although it

applies to all pharmacists, those who do not provide compounding do not need to concern themselves with the more specific details outlined in the Guidance.

With this in mind, we would consider that it would be appropriate to support Option 2, with the development of such a guidance document to support medical practitioners.

We look forward to the outcome of the consultation, and the opportunity to continue to support all medical practitioners who require compounded medications for their patients in order to provide optimal treatment outcomes.

Yours Sincerely,

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