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Medical Board of Australia

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Dear Members

My name is Daryll Knowles, I am the owner of Australian Custom Pharmaceuticals, one of Australia's largest compounding pharmacies. I have been practising compounding for over 30 years and my facility is a recognized education site for University students and Compounding pharmacist training.

It is only through thorough dialogue and understanding of all stake-holders' positions that informed and objective decisions can be made.

To make clear the MBA's expectations, there needs to be clarification of definitions to ultimately increase positive medical outcomes for patients and give guidance to practitioners. Further clear guidance will also, as it has done in the compounding pharmacy industry, provide comfort to appropriately trained medical practitioners.

As a compounding pharmacist I have been involved in various public consultations with Pharmacy Board of Australia (PBA) and Pharmacy Council of NSW (PCNSW), via submissions, investigating the Guidance for Compounding Pharmacies and Pharmacists. Like the MBA, the PBA and PCNSW's primary objective is public safety.

The PBA and PCNSW has set about achieving this by clarifying vagaries of definitions and updating their guidance with regard to existing Australian and global standards. This gave compounding pharmacists a clarity of their expectations.

By the PBA mandating compounding pharmacies use recognized global standards for sterile (USP 797) and regarding Non-sterile compounding (USP 795, APF) it has given compounding pharmacists a clear path to compliance which has the ultimate result in increased patient safety. If a medical practitioner providing complementary, unconventional medicine and emerging treatments uses a compounding pharmacist who complies with PBA Guidelines, Pharmaceutical Society of Australia (PSA) Professional Practice Standards and are accredited in USP 797 and USP 795 they can rest assured that the quality and conduct of these pharmacists is of a standard to maximize positive patient safety and positive medical outcomes.

I note and refer to the MBA /PBA Joint statement of 24th November 2017 which in summary states that the two regulatory bodies have a similar belief in what defines "Good Practice" and where the individual scope of responsibility lies for both medical practitioners and pharmacists with regard to the current guidance.

It is from experience in the compounding industry and the requirement for clarification of the expectations from the current hazy guidance that leads me to support Option 2.

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In stating my preference for Option 2 I also acknowledge the MBA's intentions on page 18 of the Discussion paper that:

"Guidelines that define good practice for complementary and unconventional medicine and emerging treatment:

- *would not reduce consumer choice*
- *would not restrict medical practitioners' practice*
- *would not result in significant cost increases for consumers or medical practitioners*
- *would not restrict existing, accepted practice that may fall within the definition of complementary and unconventional medicine and emerging treatments*
- *would not stifle innovation or clinical research and trials. "*

It is my opinion that integrative, complimentary and functional medicine as some of the oldest disciplines are absolutely essential fields of medicine with a library full of evidence and research.

I also find the rolling of integrative, complimentary and functional medicine into the same category as other unproven or experimental and emerging therapies such as stem cell therapies, unregistered diagnostic techniques or procedures, whether used in addition to (complimentary), or instead of conventional medicine (Alternative) as over complicating the argument.

This includes unconventional use of approved medical devices and therapies (Off label Use). NSW Ministry of Health actually has policy regarding the widespread prescribing of alternative use of Conventional medicines.

Is very confusing and just plain wrong to in terms of the relative levels of evidence for each of these different disciplines.

We currently have over 3500 integrative medical practitioners on our database and over the last 15 years dispensed over one million socially valuable evidence-based medicines to hundreds of thousands of patients. There are over 600 (estimate only) compounding pharmacies in Australia of all different sizes. The fact that this industry has flourished over the past three decades indicates that patients want this industry to be both available, and above all safe for them to access medicines.

The patient outcomes from this complimentary and integrative industry in terms of patient's safety is over whelmingly positive. TGA is unable to identify one death from the use of complimentary or integrative medicines as opposed to the over 650,000 deaths from Iatrogenic mishaps from "conventional medicines" (Pharmaceutical Society of Australia 2019. *Medicine Safety)*

The alternative to appropriately trained medical doctors and accredited compounding pharmacists is – perhaps unsurprisingly – Dr Google and Online stores that dispense these medicines with no prescription or supervision. People will still seek these treatments. It is therefore essential that this industry is regulated in a reasonable fashion to allow it to flourish in a safe and cost-effective fashion, rather than driving it and patients underground and to the internet for their medicines.

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It is correct for the MBA to have concerns about the conduct of some medical practitioners or compounding pharmacists as explained in the examples of illegal behaviour which negatively impacts on patient safety. Unfortunately, individuals who choose to act illegally will not be affected by a stricter guidance. More specific modern guidance however will benefit legitimate, appropriately trained practitioners who already conduct their practice within the expectations of the MBA and remove the stresses of vague definitions and interpretation of less specific guidance. Ultimately helping remove the ever-growing fear of being investigated on the say so of non-practicing, vindictive complainants who use these vagaries to promote their own agendas.

In creating clearer guidance, I would like to draw the MBA attention to the definitions that have been suggested.

Conventional medicine:

It appears that the MBA and other industry group members consider the economic decision of a Pharmaceutical manufacturing company to engage in the process of registering a drug on the ARTG (Australian Register of Therapeutic Goods) as the primary qualifier for it to be regarded as conventional medicine. This disregards the fact that this same drug may have been tested and trialled but not registered for other uses or is registered in another country for a different purpose. A well-known example is Sildenafil. Pfizer trialled this drug for pulmonary hypertension in neonates and subsequently for erectile dysfunction. It then made the purely economic decision to register sildenafil for erectile dysfunction thus creating a conventional on-label use and relegating the pulmonary hypertension use to a controversial off label or unconventional use even though it was the primary indication for which sildenafil was originally investigated. Under this definition it is the economic decision of a pharmaceutical company that decides whether a drug is conventional or not.

This leads to confusion especially when drugs are registered with Drug Regulatory authorities overseas for uses that are not registered in Australia. Are these conventionally used overseas drugs then conventional medicine in Australia? By this definition, no. Take for example ketamine and its use in treatment resistant depression (TRD). There is a product registered by the FDA for TRD but in Australia we still consider this an experimental and unconventional use.

My opinion on this is to disregard the confusing terms of conventional and unconventional altogether and keep the terms:

1)**Off-label** – non registered indication for a registered drug on the TGA ARTG,

2**) On-label** – Registered indication for a registered drug on the TGA ARTG,

3) **Complimentary use** – prescribed in combination with a main stream medicine to augment a positive medical outcome and

4) **Alternative medicine** – which is used instead of a mainstream medical protocol after failure of a positive outcome from main stream medicine.

All of these different types and uses of medicines regardless of whether the use of these are off-label, on-label (conventional) or registered with TGA or other global medicines authority, alternative to the registered medicines or treatment should simply be judged on whether they are safe evidence-based medicine. This cuts through the red tape and conflicts of interests.

The term **Evidence based medicine (EBM)** also needs to be clarified and re-defined in modern terms.

"Prior to a firm definition of EBM health practitioners and Regulators relied on the clinical expertise of more experienced colleagues and text books to provide them with information they needed to inform patient care." (*Dr M Bushell MPS Aust Pharm Vol38 No. 3 4.19*)

The problem with this was with disciplines like integrative, compounded, complimentary and functional medicines the right expert was not always called on or even available.

We had experienced mainstream medicine practitioners who never prescribed these types of medicines giving biased personal opinions based on an outdated status quo.

The term "evidence-based medicine" was first described in modern times as "the conscious, explicit and judicious use of current best evidence about the care of the individual patient. It means integrating individual clinical expertise with best available external clinical evidence from systematic research" *(Sachet et al 1996*)

What one practitioner believes is strong evidence another and often a Board or mainstream expert does not depending on their personal bias. Using a tool as simple as the NHMRC Hierarchy of Evidence Decision making table) or the PICOS Framework would give a simple guidance to all involved in prescribing or investigating the prescribing of medicines or treatment. It may very well reduce the need to engage other expert practitioners to provide their opinions (the opinion of one person) who are not actually experts in the specific field they are ask to comment on. For example, asking an endocrinologist to comment on the use of integrative medicine for an off-label use may not be appropriate for their training. The expert need not be a professor to simply apply the PICOS Framework or the NHMRC Decision table for evidence based on research already carried out.

A further task is determine exactly what level of evidence deems a medical protocol or medicine as evidence based so that practitioners can be clear on what constitutes evidence base in the eyes of the Regulator.

Public Hospitals more often than not when paediatric treatment, will prescribe off label medications. Australia – due to its small economic size and population – will never, and could never, be expected to have the same variety of drug registrations as the US or Europe. Australia therefore delegates many drugs to the off-label category. But as our paediatricians demonstrate on a daily basis they are prescribing off-label medications safely for their patients.

It is at this point I would like to raise the prospect of Option 3

That an **appropriately trained** practitioner be able to prescribe integrative, complimentary or compounded medications when they are able to present **adequate evidence** to demonstrate safety and efficacy for the patient.

This could include integrative, compounded, complimentary and alternative off label or on-label uses of main stream medicines as well.

In summary:

1. Encourage medical practitioners as an extra layer of public safety to only engage compounding pharmacies that comply with PBA and PSA Guidance and practice at a minimum accreditation level of USP 797 and USP 795 and APF 24. Compounding Pharmacies are able to undergo accreditation to obtain these standards.
2. Delete the terms Conventional and unconventional as the definitions are confusing and at best based on the economic decisions of drug companies and potentially leave the door open to biased opinions by those who may have pecuniary interests.
3. Every drug and protocol used by doctors or compounded by pharmacists should be evidence based. A useful tool is the NHMRC Hierarchy of Evidence Decision table or the PICOS Framework.

4. Consider an Option 3, if we must choose to do something, and like the vast majority of the leading western countries in Europe and the United states allow appropriately trained specialist practice their chosen field of medicine and use evidence-based medicines to safely bring more positive patient outcomes.

I applaud the Medical Board of Australia for creating the public consultation paper aiming for clearer regulation for medical practitioners providing complementary, unconventional medicine and emerging treatments.

Yours Sincerely

[redacted]

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