ASCP
Australian Society of
Compounding Pharmacists

Executive Office
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Dear Members,
The Australian Society of Compounding Pharmacists (ASCP) applauds the Medical Board of Australia (MBA) for creating the public consultation paper aiming for clearer regulation for medical practitioners providing complementary, unconventional medicine and emerging treatments. Through dialogue and understanding of all stakeholders' positions informed and objective decisions can be made.

To meet the MBA's expectations, the clarification of definitions is paramount in order to ultimately increase positive medical outcomes for patients. Further clear guidance will also provide comfort to appropriately trained medical practitioners.

Like the MBA, the Pharmacy Board of Australia (PBA), Pharmacy Regulation Authority South Australia (PRASA), Victorian Pharmacy Authority (VPA) and Pharmacy Council of New South Wales (PCNSW), ASCP's primary objective is public safety. These Regulators have set about achieving this by clarifying vagaries of definitions and setting their guidance with regard to existing Australian and global standards. This provided compounding pharmacists clarity of the Regulators' expectations. By mandating compounding pharmacies use recognized global standards, PBA has given compounding pharmacists a clear path to compliance, in order to increase patient safety. These standards include but are not limited to the completion of risk assessment; the use of quality raw materials; appropriate premises, equipment and devices; pharmacist training; evidence of safety, efficacy and stability. When 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 standards such as United States Pharmacopoeia (USP) (USP 797 for sterile compounding, USP 795 for non-sterile compounding), Australian Pharmaceutical Formulary and Handbook, they can rest assured that the standard of the quality and conduct of these pharmacists maximises positive patient safety and medical outcomes.

The MBA /PBA Joint statement of 24th November 2017 is noted, 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.

From experience in the compounding industry, Option 1 and Option2 are both too restrictive.
We believe there should be an Option 3, which places more responsibility on all of the practitioners involved in patient care to be appropriately trained and qualified in the discipline that they practice.

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In stating our preference for Option 3, we 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 our opinion that integrative, complimentary and functional medicine as some of the oldest and established disciplines, are absolutely essential fields of medicine.

We also find the combining 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). It is noted that NSW Ministry of Health has a policy regarding the widespread prescribing of alternative use of Conventional medicines in Public Hospitals.

The error of combining all these in one group of unconventional medicines is based on the assumption that each of these disciplines has similar levels of evidence. The patient safety of the complimentary and integrative industry is overwhelmingly positive, despite its increase use over the last three decades. TGA has not identified one death resulting from the use of complimentary or integrative medicines - as opposed to the over 650,000 deaths from iatrogenic mishaps resulting from the use of "conventional medicines" (Pharmaceutical Society of Australia 2019. *Medicine Safety).*

The alternative to appropriately trained medical doctors and accredited compounding pharmacists is Dr Google and Online stores that dispense these medicines without medical supervision. It is therefore essential that this industry is regulated in a reasonable fashion to allow it to be practiced in a safe and cost-effective fashion, rather than driving the industry and its patients underground hence unregulated.

The MBA rightly has concerns about the conduct of some medical practitioners as explained in the examples of illegal behaviour which negatively affects patient safety. Individuals who knowingly choose to act illegally will not be affected by a stricter guidance. Stricter guidance however will benefit legitimate, appropriately trained practitioners and remove the stresses of vague definitions and interpretation of less specific guidance. Ultimately, this assists in the removal of the ever-growing fear

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of being investigated on the accusations vindictive complainants who use these vagaries to promote their own agendas.

In creating clearer guidance, we draw the MBA's attention to the definitions that have been suggested.

The term Conventional medicine:
Due to Australia's small economic size and population could not be expected to have the same variety of drug registrations as USA or Europe. Australia therefore delegates many drugs to the off-label category. Australian prescribers, including paediatricians in public hospitals demonstrate on a daily basis, they are prescribing off-label medications safely for their patients.

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 misconception disregards the fact that the same drug may have been tested and trialled, but registered for other uses or registered in other countries. A well-known example is Sildenafil™ which Pfizer trialled for pulmonary hypertension in neonates and subsequently for erectile dysfunction. Pfizer then made the 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 of a conventional medicine, it is the economic decision of a pharmaceutical company that decides whether a drug is conventional or not.

Confusion arises when drugs are registered with Drug Regulatory authorities in other jurisdiction, for uses that are not registered in Australia. By the above definition, these drugs are considered unconventional medicines in Australia. For example ketamine is a product registered by the FDA in the treatment resistant depression (TRD). However, in Australia we still consider this an experimental and unconventional use.

We strongly suggest that the MBA disregard the confusing terms of conventional and unconventional, and retain the terms:
1) Off-label –a drug registered on the TGA ARTG, used for an unregistered indication
2) On-label – a drug registered on the TGA ARTG, used for its registered indication
3) Complimentary use – prescribed in conjunction with a mainstream medicine to augment a positive medical outcome
4) Alternative medicine – used instead of a mainstream medical protocol, after failure of a positive outcome from mainstream medicine.

All of these different types of medicines should be judged on whether they are safe evidence-based medicine. This approach eliminates red tape and conflicts of interests.

The term Evidence-based medicine
This term also needs to be clarified and re-defined.

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"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."[1] (*Dr M Bushell MPS Aust Pharm Vol 38 No. 3 4.19).*

The term "evidence-based medicine" was first described 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).

Using a simple tool such as the National Health and Medical Research Council (NHMRC) Hierarchy of Evidence Decision making table or the PICOS (Patient, Intervention, Comparison, Outcome, Study Design) Framework provides guidance to all involved in prescribing or investigating the prescribing of medicine or treatment, thereby negating the difference of opinion dilemma. It may also reduce the need to engage other 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.
It remains to determine exactly what level of evidence, is deemed 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.

In summary:

1. 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.
2. Delete the terms Conventional and Unconventional as the definitions are confusing, at best based on the economic decisions of drug companies, potentially manipulated by those who may have pecuniary interests.
3. Encourage medical practitioners as an extra layer of public safety to engage only compounding pharmacies that comply with PBA and PSA Guidance.

Finally, we thank the MBA for the opportunity to participate in the discussion. ASCP would be pleased to provide any support to the Board.

Yours Faithfully

ASCP Board

[1]*Bushell M (2019). Evidence-based medicine. Australian Pharmacist, 38(3) 46-52*

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