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Executive Officer, Medical
AHPRA
GPO Box 9958
Melbourne 3001
medboardconsultation@ahpra.gov.au

Dear Sir/ Madam,

Re: Public consultation on clearer regulation of medical practitioners who provide complementary and unconventional medicine and emerging treatments.

This letter is a response to the Questions for Consideration, in the public consultation paper of the abovementioned process.
MEDISCA Australia is an Australian-based, TGA-approved manufacturer and ISO-accredited supplier of active pharmaceutical ingredients, bases, equipment, devices, education and training to the pharmaceutical compounding industry.

1. Do you agree with the proposed term 'complementary and unconventional medicine and emerging treatments'?

MEDISCA Australia does not agree with the term, as the term groups together a wide range of therapies/medicines/practices, where associated risks and consequently concerns vary greatly. Integrative Medicine (IM) for example does not have the same level of risk or concerns as homeopathy.

The term 'complementary and unconventional medicine and emerging treatments' implies competition between these treatment approaches and the conventional approaches. When a medicine is complementary, it is an adjunct to conventional medicine; not opposed to conventional medicine, or an alternative to conventional medicine. In the case of IM, when the two approaches (conventional and complementary) are combined, they provide increased likelihood of improved outcomes, compared to either one alone; and by its own definition must be evidence-based.

If not, what term should be used and how should it be defined?

A suggested term is "unconventional medicine and emerging treatments".

2. Do you agree with the proposed definition of complementary and unconventional medicine and emerging treatments – 'any assessment, diagnostic technique or procedure, diagnosis, practice, medicine, therapy or treatment that is not usually considered to be part of conventional medicine, whether used in addition to, or instead of, conventional medicine. This includes unconventional use

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of approved medical devices and therapies.'

No. The term's definition should exclude Integrative Medicine, which combines "the best of conventional western medicine and evidence-based complementary medicine and therapies within current mainstream medical practice". Integrative Medicine does not pose the same level of risks as the other treatment approaches which have been identified as practices of concern, because it utilizes both

(i) ARTG-listed (or ARTG-registered) therapeutic goods and
(ii) compounded medicines.

In the case of ARTG-listed/registered, the TGA-approved therapeutic goods are supported by evidence as part of the remit prior to registration or listing.

In the case of compounded medicines,

1. they are prepared with compliance to *Therapeutic Goods Act (1989) (Commonwealth)* and *Therapeutic Goods Regs (1990) (Commonwealth).*
2. Compounding pharmacies are compliant with State/Territory department of health requirements.
3. Pharmacists are required to comply with Pharmacy Board of Australia guidance

Therefore neither of these groups fall under the "lack of evidence" concern and should be excluded from the definition. See question 8 below for further details.

If not, how should it be defined?

'any assessment, diagnostic technique or procedure, diagnosis, practice,4
medicine, therapy or treatment that is not usually considered to be part of conventional medicine, whether used in addition to, or instead of, conventional medicine. This includes unconventional use of approved medical devices and therapies. It excludes evidence-base Integrative Medicine and compounded medications'

3. Do you agree with the nature and extent of the issues identified in relation to medical practitioners who provide 'complementary and unconventional medicine and emerging treatments'?

We share the MBA's concerns, because we want what is best for patients. Patient-centred care is and should be, at the heart of what we do. We share concerns regarding conflicts of interest, inadequate consent, poor patient management and advertising. All these concerns which importantly focus of patient safety, must be balanced with limitations on patient's choice, stifling of innovation, direct and indirect cost impositions. We commend the MBA for recognising and supporting these fundamental principles. They should remain with the guidance document irrespective of the option chosen.

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MEDISCA Australia supports quality compounding, the patient-centred care model, the use of standard operating procedures and processes, appropriate facility, equipment, personnel, training, and formulations as per the Pharmacy Board of Australia *Guidelines on compounding of medicines*. MEDISCA Australia concurs with the MBA paper that manufacturing without appropriate GMP licensing and compounding when commercially-available products are in stock should not occur.

4. Are there other concerns with the practice of 'complementary and unconventional medicine and emerging treatments' by medical practitioners that the Board has not identified?

The nature and extent of the issues identified in relation to medical practitioners who provide 'complementary and unconventional medicine and emerging treatments' seem to belong to the entire medical profession. They include "conventional" practicing physicians who do not disclose that they receive financial incentives for recommending specific hearing aids, vaccines or prosthesis; who do not gain adequate consent for prescribing conventional treatments; do not communicate in a timely manner with other healthcare professionals.

Data on the prevalence of the identified issues is not provided in the document, nor contrasted to data related to medical practitioners involved in conventional practice. It is important that such data is published in the paper, to dispel any perception that particular groups are being targeted. In the absence of such data, the purpose of the guidance needs to be reviewed.

5. Are safeguards needed for patients who seek 'complementary and unconventional medicine and emerging treatments'?

The required safeguards regarding conflict of interest, disclosure, evidence of safety and efficacy, advertising, patient management etc are necessary in every aspect of medical practice. These should be incorporated into guidance documents that apply to all practitioners, including the groups the MBA paper has identified.

6. Is there other evidence and data available that could help inform the Board's proposals?

Pharmaceutical compounding is a regulated, evidence-based approach to meeting the needs of patients for whom the conventional bulk-manufactured treatments are unsuitable, or commercially unavailable at a specific time or for sanctioned clinical trials. The MBA paper does not acknowledge the regulations, guidelines and professional practice standards to which compounding pharmacists adhere. Without these, it is assumed to have the same concerns as the other identified therapies/medicines/practices.

Regulations
Whilst, the Therapeutic Goods Act 1989 requires that therapeutic goods sold in Australia

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(i) are registered on the ARTG and

(i) are produced in facilities that comply with the Code of Good Manufacturing Practice (cGMP)

the Therapeutic Goods Regulations (1990) provide exemptions. In particular, Schedule 5 of the Regulations exempt compounded medications *prepared for a particular person for therapeutic application to that person,* from the requirement of the Act for ARTG listing. Schedule 8 item 2 of the Regulations exempt compounded medications prepared by a pharmacist from the requirement of cGMP for supply *(other than by wholesale) on or from those premises.*

Guidelines and Professional Practice Standards

Pharmacists undertaking compounding are guided by National Law and other requirements, which mitigate risk to the public. Therefore the nature and extent of issues identified in relation to medical practitioners who prescribe compounded and off-label medication, appear misguided in the MBA's guidance document.

Importantly, the Pharmacy Board of Australia *Guidelines on compounding of medicines*[1] includes requirements on the following:

1. Appropriate compounding circumstances
2. Evidence of safety, efficacy and stability
3. Formula considerations
4. Training and competence
5. Facilities
6. Equipment
7. Raw materials
8. Risk assessment
9. Documentation
10. Quality Standards
11. Reporting of adverse events
12. Patients right to access
13. Advertising

Compounded medicines, are a choice of last-resort. Pointedly, the *Guidelines on compounding of medicines (Pharmacy Board of Australia) 2015, state that a "*compounded medicine should be prepared only in circumstances where:

- an appropriate commercial product is unavailable
- a commercial product is unsuitable (e.g. if a patient experienced an allergy to an excipient in the commercial product), or
- when undertaking research sanctioned by a recognised human research ethics committee"

[1] https://www.pharmacyboard.gov.au/Codes-Guidelines.aspx

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The compounding of a medicine (whether prescribed or not) that would be a close formulation to an available and suitable commercial product, and would not be likely to produce a different therapeutic outcome to the commercial product, should not take place. In the case that such a medicine has been prescribed, the pharmacist should notify the prescriber that this medicine cannot be compounded under these circumstances."

The Professional Practice Standards by the Pharmaceutical Society of Australia, in particular Standard 5, requires that pharmacists take risk-based approach prior to compounding, with the focus being patient-centred care.[2] It includes considerations of:

1. Evidence of safety, efficacy, stability
2. Patient-specific suitability
3. Patient-centred care model
4. Risk assessment
5. Quality Assurance
6. Quality of Ingredients
7. Equipment
8. Dedicated facility
9. Environment
10. Documentation
11. Supervision & training
12. Maintain competency standards
13. Formulations
14. Containers and packaging
15. Expiry dates
16. labelling
17. Consumer information
18. Complaints and recalls

In addition, regulators in various States and Territories provide guidance such as the

- Pharmacy Council of New South Wales[3]
- Victorian Pharmacy Authority[4]
- Pharmacy Regulation Authority of South Australia[5].

[2] https://www.psa.org.au/wp-content/uploads/2018/08/Professional-Practice-Standards-v5.pdf
[3] *https://www.hpca.nsw.gov.au/pharmacy-council-releases-fact-sheet-compounding*
[4] http://www.pharmacy.vic.gov.au/index.php?view=guidelines&item=0
[5] *https://www.pharmacyauthority.sa.gov.au/main-site/documents.html*

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Consequently, pharmaceutical compounding should not be included in the MBA paper.

Options

7. Is the current regulation (i.e. the Board's *Good medical practice*) of medical practitioners who provide complementary and unconventional medicine and emerging treatments (option one) adequate to address the issues identified and protect patients?

Since the considerations are applicable to all areas of medical practice, it is preferable third option is to review and make more robust the current *Good Medical Practice* document instead of Option Two.

8. Would guidelines for medical practitioners, issued by the Medical Board (option two) address the issues identified in this area of medicine?
With respect to compounded medicines, the very exemption of personalised medicine that addresses individual patient needs, excludes the viability of Level 1 evidence. It is impossible to finance or complete Level 1 clinical trials in a timely manner, when the number of patients and medications is so small. Such a requirement would not be consistent with the notion of patients' rights to access medications which are suitable for their needs, as last resort.

With respect to the discussion section
"Other areas of clinical practice where concerns have been raised but which do not fit within the definitions of complementary and/or alternative medicine as defined above, include: ….
conventional medicines and accepted therapies provided outside accepted therapeutic guidelines or protocols and/or without usual clinical indications including off-label use, for example:

- long term antibiotics in the absence of identified infection
- hormone therapy and supplements in the absence of a hormone deficiency/identified therapeutic need"

We do not believe that hormone therapies and supplements warrant inclusion in the concerns, when practitioners identify and monitor the patient through pathology screening and symptom assessment charts. There are numerous biomimetic hormones which are TGA-registered on the ARTG such as estradiol, testosterone and progesterone. We recommend the removal of this sub- point from the discussion paper.

With respect to the discussion section
In addition to 'complementary' and/or 'alternative' medicine, the Board has considered a number of other definition issues so as to ensure that all the relevant areas of practice are captured:

- unconventional medicine
- off-label prescribing

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We stress that off-label prescribing is important and should remain a prescriber's right. Off-label prescribing is a necessary mechanism which allows access to products in which bulk-manufacturers have not invested.

For example, solid oral dosage forms are frequently unsuitable for children under the age of six[6]. Additionally, between 25-45% of children in general, suffer from dysphagia[7]. Dysphagia is a condition also seen in elderly populations due to the incidence of age-related changes in salivary gland function[7]. The prevalence of dysphagia also increases if stroke, cognitive dysfunction or neurodegenerative diseases affect patients[7].

The WHO List of Essential Medicines for Children[8] and WHO List of Essential Medicines for Adults[9] lists 76 and 84 medications respectively available in an oral liquid or powder for oral liquid out of possible 433-listed medications. As tablet formulations tend to be more cost-effective for pharmaceutical companies to develop[10] and pharmaceutical companies are challenged with greater regulatory requirements when conducting studies for children, oral liquid preparations for the paediatric population result in a higher outlay in investment for a smaller return given the smaller market potential. The lack of availability of manufactured formulations for paediatric populations has led to off-label or unlicensed use of adult medications or compounded oral liquids.
The discussion paper also identifies hormone, vitamin and mineral supplements without accepted indications have been identified as an area of concern. Since currently most vitamins and minerals state on the label that "supplements may only be of assistance if dietary intake is inadequate", we suggest a clarification statement that supplements are acceptable when dietary intake is inadequate.

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[6] Batchelor H, Marriott J. Formulations for children: problems and solutions. British Journal of Clinical Pharmacology. 2015;79(3):405-418.

[7] Dijkers E, Nanhekhan V, Thorissen A, Polonni H. Suspensions as a Valuable Alternative to Extemporaneous Compounded Capsules. International Journal of Pharmaceutical Compounding. 2017;21(2):1171-175.

[8] WHO Model List of Essential Medicines [Internet]. 20th ed. World Health Organisation; 2017 [cited 29 November 2018]. Available from: https://apps.who.int/iris/bitstream/handle/10665/273826/EML-20-eng.pdf?ua=1

[9] WHO Model List of Essential Medicines for Children [Internet]. 20th ed. World Health Organisation; 2017 [cited 29 November 2018]. Available from: https://apps.who.int/iris/bitstream/handle/10665/273826/EML-20-eng.pdf?ua=1

[10] Lau E, Steadman K, Cichero J, Nissen L. Dosage form modification and oral drug delivery in older people. Advanced Drug Delivery Reviews. 2018;135:75-84.

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With respect to the discussion section

Prescribing compounded products:

- where a commercial product is available and suitable
- where there is a lack of evidence to support the compounded product's use
- that have been manufactured in circumstances that don't meet expected quality assurance processes
- that have been manufactured in bulk rather than to meet an individual's needs

The very nature of compounding means that extemporaneously prepared medications are not manufactured in bulk, hence cannot be supported by the highest level of clinical trials. The MBA's paper needs to be consistent with the exemptions of the Therapeutic Goods Regulations (1990) (Commonwealth). Refer to pages 14-15 of 242 at https://www.tga.gov.au/sites/default/files/australian-regulatory-guidelines-complementary-medicines-argcm-v8.0.pdf

We recommend that compounded medications are removed from the list of concerns.

Finally, we thank the MBA for the opportunity to participate in the discussion. MEDISCA Australia is pleased to provide any support to the Board and answer any questions, therefore do not hesitate to contact us.

Yours Faithfully

[redacted]

Andrew Harb

General Manager
MEDISCA Australia