



27 June 2019

Executive Officer
The Medical Board of Australia
AHPRA
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Melbourne
3001
Email to: 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

The Australasian College of Sports and Exercise Physicians (ACSEP) thanks the Medical Board of Australia for the opportunity to provide input into this important consultation process.

Background to Consultation

The Medical Board of Australia is requesting public comment on a draft document providing clearer regulation on **complementary, unconventional and emerging treatments**. This includes: “applied kinesiology, pathology testing in non-accredited laboratories, hormone therapy and supplements in the absence of deficiency/therapeutic need and stem cell therapy for conditions without supporting evidence for their use.”

The Medical Board requests consultation on 2 separate options.

Option 1. Leave the status quo unchanged

or

Option 2. Introduce clearer regulation for certain areas of medicine (the “preferred option”)

Relevance of this consultation process for the ACSEP

The ACSEP is a recognized specialist medical college, with 172 Fellows throughout Australasia, of which 139 are practicing within Australia.

The ACSEP is a legitimate stakeholder in this consultation process for the following reasons:



1. ACSEP fellows are recognized specialists in the non-operative treatment of medical problems of all active individuals. This includes evidence-based training in the role of non-operative biotechnologies in musculoskeletal disorders, such as the use of stem cells in degenerative joint and tendon disease (including osteoarthritis and tendinopathy).

In 2013/14, the ACSEP became aware of a sudden increase in the number of Australian medical clinics providing stem cells treatments; it was estimated that at least 40 clinics were created in the preceding 4 years ⁽¹⁾. At the same time, this therapy was becoming increasingly promoted and marketed by the biotechnology industry to both practitioners and the wider Australian community. In over 70% of clinical cases the predominant indication was degenerative musculoskeletal disorders. As a result, the ACSEP board undertook an extensive in house evidence-based review of autologous stem cell therapy in musculoskeletal conditions. This review concluded that the efficacy of stem cells was (and still is) unproven in musculoskeletal disorders and in some cases safety had not yet been established. Subsequently, the ACSEP produced a comprehensive Position Statement on the use of stem cells in clinical practice ⁽²⁾, which is updated regularly ⁽³⁾.

In summary, the ACSEP Position stated that stem cells were to be regarded as an emerging therapy, unless further quality research subsequently stated otherwise. The Position recommended that autologous stem cells should only be used in clinical practice as an innovative clinical treatment, providing there was evidence of safety and possible efficacy. There was a reflection that there was a need for rigorous clinical trials before this therapy could be accepted for wider clinical use.

The ACSEP was also concerned by the potential misuse and misrepresentation of stem cells - especially in regards to unfounded claims of efficacy, patient testimonials and celebrity endorsements; and so the Position went on to reinforce the Medical Board's *Good Medical Practice* ⁽⁴⁾.

The ACSEP Position was the first published comprehensive clinically based Position Statement internationally and was well received by ACSEP Fellows, other Australian specialist colleges, and both the local and international stem cell research industry. The result was that ACSEP Fellows follow the Position Statement guidelines, and several have now published clinical stem cell research in peer reviewed literature ⁽⁵⁻¹¹⁾.

Australia has a very high number of stem cell clinics per head of population. Hence, the ACSEP is concerned about the wider use/misuse of autologous stem cells within the Australian medical community, especially by practitioners to whom the ACSEP Position does not apply. This has the potential to result in patient exploitation, unethical practice or even patient harm, whether it is physical, psychological or financial. Australia has now recorded its first patient death following stem cell treatment by a General Practitioner, which led to a coronial enquiry in which such practitioners were referred to as practicing "quack medicine".

Therefore, as a specialist medical college, with extensive knowledge in emerging cellular therapies in musculoskeletal conditions, the ACSEP supports 'Option 2', which is consistent the ACSEP Position on the clinical use of stem cell therapies.

2. The ACSEP is an advocate for physical activity in all Australians, whether they participate in competitive sport, or as part of a prescriptive therapy for chronic medical conditions (e.g. weight loss, diabetes, hypertension etc.). This advocacy is irrespective of age, gender and level of competition. However, active individuals may be at an increased risk of experimenting with alternative and unconventional treatments, especially those touted to result in: faster healing rates, improved recovery, fat loss, muscle hypertrophy, and performance enhancement.



Many supplements and peptide hormones are being promoted and prescribed to vulnerable Australians, with no medical evidence of clinical deficiency or therapeutic efficacy. These therapies necessarily cause a further cost burden on the health system, pathology investigations, and the PBS. A search of the Internet reveals a pattern of transient online 'sports medicine' or 'anti-ageing' clinics promoting such products. These clinics typically involve a medical practitioner prescribing with the help of a compounding pharmacist. In February 2013, the Australian Crime Commission published a report documenting the links between organized crime, sports performance consultants, compounding pharmacists and medical practitioners ⁽¹²⁾. This report was initiated after intelligence that supplements, off label medications and untested peptide hormones were being administered to professional AFL and Rugby League players. It is still unknown if any harm has been caused to the players exposed to these experimental therapies. This investigation has led to improved governance in the use of all alternative therapies by Australian professional sporting organisations.

However, the ACSEP still believes that there is a large potential for Australian medical practitioners to create business models and prescribe non-evidence based complementary, unconventional and emerging therapies to non-professional athletes, who are not subject to drug testing – including adolescent and recreational participants. Furthermore, the ACSEP supports fair sport within Australia. This means that the ACSEP does not condone the use of non-permitted performance enhancing medications by athletes, or their prescription by members of the medical profession, unless there is a clear clinical indication.

Hence, the ACSEP supports improved and clearer professional medical regulation that will help educate medical professionals and ensure best practice, and will also benefit active Australians.

3. The ACSEP is aware that there are a small number of ACSEP fellows who prescribe supplements (e.g. vitamins for viral infection) and administer cellular therapies such as platelet rich plasma (for refractory musculoskeletal indications), but these are a relatively small part of their specialist practice. These therapies are typically used only when there is some evidence supporting the efficacy of the therapy. The ACSEP believes these fellows do practice within the preferred options being proposed by the medical board. However, the ACSEP does not support the use of blood products and supra-physiological doses of vitamins for non-evidenced medical indications, by the wider Australian medical community.

Summary

In conclusion, the ACSEP supports the Medical Board's preferred Option 2, and believes this will result in:

- Enhanced ethical use of current, emerging and future biotechnologies.
- Reduced potential for financial exploitation of patients from unproven therapies.
- Improved evidence-based use of medical therapies (e.g. supplements, hormones without proven deficiency), with reduction of unnecessary prescribing and medical investigations, resulting in reduced costs to Medicare.
- A reduction in physical and psychological harm from unproven and untested therapies.
- Fairer sport.



Specific Questions

The Board is inviting feedback on the issues and options outlined in the discussion paper.

1. Do you agree with the proposed term 'complementary and unconventional medicine and emerging treatments'? If not, what term should be used and how should it be defined?

Yes, the ACSEP agrees with the proposed term 'complementary and 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. If not, how should it be defined?

Yes, the ACSEP agrees with the proposed definition.

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'?

Yes – The ACSEP agrees with the nature and extent of the issues identified.

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 ACSEP believes that active individuals and sports people are a special group who are especially vulnerable to experimenting with 'complementary and unconventional medicine and emerging treatments', and this has not been recognised by the Medical Board's consultation process.

Furthermore, the ACSEP would also like to highlight the broader associated issues with the prescription of complementary, unconventional and emerging therapies. These practitioners may compromise the reputation of their professional colleagues, may indirectly be supporting organised crime and could potentially have a negative impact on the integrity of sport.

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

Yes. These therapies can be introduced quickly into clinical practice and electronically promoted directly to consumers by biotechnology companies and practitioners. This can occur before specific regulation can catch up. Therefore, the Medical Board of Australia should endeavour to be more proactive in the area of assessing and regulating emerging therapies.



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

The ACSEP Stem Cell Position Statement is an Australian example of how improved medical regulation can be achieved, whilst simultaneously protecting patients and leading to improved clinical research (a 'win-win' scenario).

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?

No, the ACSEP does not support Option 1. When dealing with potential threats from new and emerging therapies, the current regulation is potentially inadequate in protecting patients and upholding medical professionalism/ethics.

The current regulations are applied reactively and generally only when enough complaints are made – by which stage physical, psychological or financial harm may have occurred to patients.

8. Would guidelines for medical practitioners, issued by the Medical Board (option two) address the issues identified in this area of medicine?

Yes. The ACSEP Board believes that improved regulation is essential considering the challenges ahead from the rapid introduction and marketing of innovative therapies. This regulation should result in guidance and improved education for medical practitioners, which will reduce the chances of legal consequences from unproven claims of efficacy from the Medical Board, Commonwealth Agencies (e.g. ACCC), or Common law claims⁽¹³⁾.

9. The Board seeks feedback on the draft guidelines (option two) – are there elements of the draft guidelines that should be amended? Is there additional guidance that should be included?

The ACSEP supports Option 2; however, the application of these guidelines should be applied proactively in identifying unproven and potentially harmful therapeutic practices.

10. Are there other options for addressing the concerns that the Board has not identified?

The Medical board should be able to appoint independent experts (e.g. NHMRC, specialist practitioners and researchers) to investigate both the efficacy and safety of new and emerging therapies, especially if there is any concern that clinical use is preceding proven clinical evidence.



11. Which option do you think best addresses the issues identified in relation to medical practitioners who provide complementary and unconventional medicine and emerging treatments?

- Option one – Retain the status quo of providing general guidance about the Board’s expectations of medical practitioners who provide complementary and unconventional medicine and emerging treatments via the Board’s approved code of conduct.
- Option 2 - Strengthen current guidance for medical practitioners who provide complementary and unconventional medicine and emerging treatments, through practice-specific guidelines that clearly articulate the Board’s expectations of all medical practitioners and supplement the Board’s *Good medical practice: A code of conduct for doctors in Australia*.
- Other – please specify.

The Australian College of Sports and Exercise Physicians strongly endorses Option 2.

Many thanks



Dr Louise Tulloh
President ACSEP



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