



AusBiotech's response to the Public consultation on clearer regulation of medical practitioners who provide complementary and unconventional medicine and emerging treatments

To
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Context

AusBiotech is pleased to provide comments on the *Clearer regulation of medical practitioners who provide complementary and unconventional medicine and emerging treatments* consultation paper developed by the Medical Board of Australia (the Board), with support from the Australian Health Practitioner Regulation Agency (AHPRA). We note the consultation is being conducted by the Board to enhance the safety of patients who may seek complementary or unconventional (unapproved) medicine or treatments.

AusBiotech is a well-connected network of over 3,000 members in the life sciences industry, which includes bio-therapeutics, medical technology (devices and diagnostics), food technology, industrial and agricultural biotechnology sectors. While AusBiotech's members are diverse in size, approach and structure, many of its current members would meet the definition of an Australian SME or have successfully grown from relatively small beginnings.

The AusBiotech Regenerative Medicine Advisory Group is a subcommittee of AusBiotech, representing a new and rapidly-growing industry that is already delivering on the significant potential to provide vital health benefits worldwide. The Group provides advice on current and emerging issues and trends facing the regenerative medicine sector in Australia and overseas, to improve and engage the sector and address key advocacy issues. This response has been led by group, whose members are comprised of medical researchers, medical practitioners, as well as representatives of organisations that are involved in the development of emerging therapies such as stem cell therapies.

Our industry believes that all Australians should have access to cutting-edge treatments for complex, chronic diseases but only after they have been tested for safe administration, through evidence based clinical studies. The industry supports the delivery of these therapies to patients via trained medical practitioners within the clinical trial framework. However, the unconventional medical treatments offered by some medical practitioners have not undergone this clinical development process under strict scientific rigour within the biotechnology ecosystem. It is therefore necessary to have more stringent guidelines in place for medical practitioners to ensure patient well-being.

We have not attempted to provide a detailed response to each of the questions raised in the discussion paper, instead focusing on those of most relevance to our members. We have framed our response around the feedback questions, as requested in the consultation paper.

Summary

AusBiotech acknowledges that while patients have the right to choose treatment options that are considered unconventional or emerging for themselves, there is a need for enhanced regulation of medical practitioners providing these therapies, so as to ensure that these patients are making a fully informed decision. We welcome the Board's proposal to clarify the definition of what constitutes unconventional or emerging medicine and to strengthen the regulation of practitioners who employ unsubstantiated approaches in the diagnosis and treatment of people.

We therefore support '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*.'

Response to proposal

- 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?**

AusBiotech is in agreement with the Board’s comprehensive definition as quoted above. However, we suggest that in addition to Stem Cell therapies, the definition of emerging treatments is modified to include other cell-based therapies and emerging technologies to ‘the expanding use of stem cell therapy and other related precision medicine therapies’.

- 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 of approved medical devices and therapies. ‘If not, how should it be defined?**

AusBiotech supports 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, this is well covered in the Public Consultation paper, particularly referring to the use of stem and other cells obtained by liposuction from people who then are injected with these autologous cells in the hope that they will receive a benefit for their musculoskeletal injuries. The risk to the personal well-being of an individual from seeking these treatments has been covered extensively in the discussions paper and is the issue most critical to AusBiotech, whose members work to enhance well-being. Additionally, the negative press generated by adverse incidents as a result of unconventional clinical practices can also make the public wary of legitimate emerging therapies that are available to them via approved clinical trials. This can then have an impact on the public acceptance of these legitimate therapies and is an issue that concerns our members.

- 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?**

AusBiotech reserves comment on this question.

- 5. Are safeguards needed for patients who seek ‘complementary and unconventional medicine and emerging treatments’?**

Yes, further safeguards are required in the form of stricter regulation of medical practitioners. Specifically, there should be greater effort made to ensure that patients are fully informed of the risks involved in consenting to partake of unconventional medicine practices. Guidelines that are made available to relevant practitioners should also be made readily available to patients, to allow users of these interventions to be fully informed in making their own decisions.

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

The Fundamental Ethical Principles of the International Society for Stem Cell Research *Guidelines for Stem Cell Research and Clinical Translation* provides excellent guidance. It can be found [here](#).

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. Already there have been too many incidents where practitioners have carried out what seem to be inappropriate practices, as summarised in the discussion paper. Until now, the Medical Board has mostly taken a reactionary approach to this matter. A more pro-active approach to educate both practitioners and members of the public about their rights and responsibilities would be welcome.

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

Yes. Additionally, we suggest that consideration be given to enforcing the rules more rigorously than at present. Advertising is a classic example where some practitioners have made exaggerated claims that have been allowed to go unchecked.

We also suggest that the Board consider a road show to help educate practitioners, with a slide kit available with requirements spelled out in a simple manner. The TGA is a good example of an organisation that implements such a practice when it wishes to educate potential users about new laws/guidelines to be followed.

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?

AusBiotech reserves comment on this question.

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

AusBiotech reserves comment on this question.

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?

AusBiotech supports the Board's preferred option, Option two - *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.*

We appreciate this opportunity to comment on the discussion paper, and on future consultations around the area of emerging therapies. When relevant, we would also appreciate advance notice of implementation of the proposed changes to the regulation framework.

AusBiotech looks forward to working with the Board and AHPRA on behalf of its members in relation to further consultations in this area.