Friends of Science in Medicine
PO Box 631 • Morayfield • QLD 4506
scienceinmedicine@bigpond.com

Submission to public consultation on revised Regulatory principles for the National Scheme

FSM has engaged with AHPRA and the National Boards over many years because of concern about registered health professionals' promoting and supplying unproven and dangerous interventions. These practices can harm patients, fail to meet actual health needs, divert them from evidence-based treatment and waste their money. They result in unnecessary burdens on the health system and national productivity.

Since 2011, FSM has emphasised the importance of basing all health care on scientifically sound research published in reputable peer-reviewed journals. FSM comprises more than 1,200 leading scientists, clinicians, lawyers, and consumer advocates.[1]

We have pointed out the unacceptable time taken to deal with complaints (often years), the ineffective outcomes, and the lack of transparency about AHPRA's processes.

The Medical Board of Australia's 2019 *Consultation on Complementary and Unconventional Medicine and Emerging Treatments* identified unproven and dangerous treatments.[2] Our submission, adding more, argued that the Medical Board (and others) should provide a clear statement of unacceptable, exploitative, ineffective practices which lack evidence.

Choosing Wisely Australia[3] provides a model for all National Boards. A list of unacceptable practice could be used for consumer and practitioner education and ongoing practitioner audit. A separate list of established or emerging therapies requiring more evidence would encourage research.

In response to the numerous submissions, the Medical Board agreed there was a persisting issue of patients' being offered high-risk treatments that did not have an evidence base of safety and efficacy - which was not limited to complementary and unconventional medicine and emerging treatments.[4] However, the Board eschewed issuing more specific guidelines; instead, they said they would refine their risk-based regulatory approach so that regulatory safeguards matched adverse outcomes to patients across all areas of health care.[5]

The latest AHPRA consultation on their draft *Revised Regulatory principles for the National Scheme* is based on two policy directions issued by the Health Council.[6] The draft *Principles* purport to encourage a responsive, risk-based approach to regulation across all health professions. [7]

We do not believe that the draft document achieves this aim. Currently, quackery – legitimised by inaction by AHPRA and the National Boards – is a grossly profitable industry. We highlight specific concerns in our appended response to AHPRA's questions. We argue that the *Principles* need to be strengthened and supported by an implementation document specifying processes and timelines for defining acceptable and unacceptable practice, dealing with complaints, proactive monitoring, and effective enforcement.

Dr. Ken Harvey MBBS, FRCPA, AM
President, Friends of Science in Medicine
W: https://www.scienceinmedicine.org.au/
E: [redacted]

17 May 2021

[1] https://www.scienceinmedicine.org.au/welcome-message/
[2] https://www.medicalboard.gov.au/News/Past-Consultations/Consultations-February-2019.aspx
[3] Home - Choosing wisely
[4] https://www.medicalboard.gov.au/News/2021-02-16-Complementary-medicines-consultation.aspx
[5] RACGP - Why the complementary medicine regulatory push was shelved
[6] Australian Health Practitioner Regulation Agency - Ministerial directives and communiques (AHPRA.gov.au)
[7] https://www.ahpra.gov.au/documents/default.aspx?record=WD21%2f30758&dbid=AP&chksum=gC4G130nFm2b97gliIqXXg%3d%3d

Friends of Science in Medicine
PO Box 631 • Morayfield • QLD 4506
scienceinmedicine@bigpond.com

Questions for consideration

1) Do the draft revised regulatory principles reflect the policy directions issued by CoAG Health Council? If not, how could the principles be improved?

The Health Council issued two policy directions (our emphasis):

a) Paramountcy of public protection when supporting the safety and quality of health services for which the need for effective deterrence was emphasised.
b) Requirement for consultation and considering the health and safety of vulnerable members of the community.

We argue that the draft *Principles* do not fulfill the policy directions issued by the Health Council. Our comments on AHPRA's draft revision follow:

- *"The principles are designed to encourage a responsive risk-based approach to regulation across all professions."*

  The word "responsive" is unchanged from the previous Principles and is undefined. FSM members have not found AHPRA or the Boards "responsive". It can take years for complaints to be addressed, and then, often poorly. This adversely affects the safety and quality of health services.

  Timelines for handling complaints should be defined in a companion implementation document. Performance against those guidelines should be published in a timely and readily accessible manner to enable appropriate scrutiny by third parties such as the Australian National Audit Office, health-sector professional bodies, and the wider community. Such transparency is recognised as a crucial facet of effective regulation at a reasonable cost.

- *"We identify the risks that we need to respond to; assess the likelihood and possible consequences of the risks; respond in ways that are proportionate and manage risks so we can adequately protect the public and take timely and necessary action under the National Law."*

  The "risks", "consequences", "proportionate responses" and "timely and necessary actions" for protecting the public need to be defined in a companion implementation document. These should be relevant to the breached sections of the National Law &/or Codes of Good Practice, not left to the non-transparent and inconsistent judgment of diverse AHPRA investigators.

  We note that a range of regulators, including consumer protection agencies, provide such interpretation in accord with expectations of good regulatory practice. Transparency builds consistency, certainty, and legitimacy.

- *"When we learn about concerns regarding practitioners, we apply the necessary (changed from minimum but still undefined) regulatory response to manage the risk posed by their practice."*

The term "necessary" also needs to be defined in a companion implementation document. Uncertainty fosters risk-taking by health service providers and encourages perceptions that regulation has a subjective basis, for example, driven by media reporting.

- *"Our responses are designed not to punish practitioners (from the old principles, but conflicts with 6) a, b & especially c, "the need to effectively deter other practitioners from engaging in similar conduct")".*

  The phrase, "not to punish practitioners" should be removed. Effective deterrence needs a range of public compliance and enforcement options (punishments) applied appropriately and transparently. These should be set out in a companion implementation document. The TGA provides a helpful example.[8]

  Punishment must be transparent to deter recurrent harms by the specific practitioner, deter harms by the practitioner's peers, and communicate to the broader community that particular behaviours are not tolerated.

  We note the extensive literature on consumer expectations regarding regulation – in particular, regulators will be responsive and use penalties to dissuade corporate/individual actors from misbehaviour. Those expectations are voiced by leading regulators, such as the ACCC, and by practitioners in criticisms of bodies such as the Office of the Australian Information Commissioner which are slow to respond to complaints and are unduly hesitant to use authority to address recurrent bad practice.

2) ***Do the draft revised regulatory principles support AHPRA and the National Boards regulatory decision-making? If not, how could they be improved?***

   No, the draft principles do not support regulatory decision making. Instead, they obscure the process and make it more prone to personal or political biases. As indicated above, broad principles need a more specific companion implementation document. They need to be given effect through timely and transparent responses by regulators. Statements of principle are useless unless underpinned by both administrative action and reporting which provide a basis for evaluating both principle and practice and punishing offenders.

3) ***Is the content of the draft revised regulatory principles helpful, clear and relevant?***

   No, the draft principles are NOT helpful, clear or relevant! As discussed above, they are opaque, unhelpful and provide no useful guidance or insight.

4) ***Is there any content that needs to be changed, added or deleted in the draft revised regulatory principles?***

   See suggestions above.

5) ***Please add any other comments or suggestions for the draft revised regulatory principles.***

   Following the *Consultation on Complementary and Unconventional Medicine and Emerging Treatments*, the Medical Board decided against issuing more specific guidelines on practice.

[8] Compliance actions and outcomes | Therapeutic Goods Administration (TGA)

Instead, they said they would continue to refine their risk-based regulatory approach so that regulatory safeguards match risk to patients across all areas of practice.[5]

The draft, *Revised Regulatory principles for the National Scheme* does nothing to refine a risk-based regulatory approach. It is full of undefined 'weasel words'[9] that ensure that AHPRA and the National Boards can remain unaccountable, ineffective, and non-transparent. Protecting the health and safety of vulnerable members of the community also requires that financial harm from non-evidence-based practice must be addressed, not just physical harm. A companion implementation document must address these deficiencies.

In the past, AHPRA has said that establishing standards of practice could deter innovation in developing and delivering health services. FSM fully supports innovation, our members having an exemplary record in health research and implementation. In contextualizing the principles concerning the Health Council's policy directions, we provide two essential cautions required in the interpretation of those principles.

The first is that innovation is a vehicle for improvements in public health. Innovation provides clinical benefits to individuals and benefits the community at large (including reducing burdens on the public health system). Innovation is a means to an end, not an outcome in its own right. Any evaluation of innovation must take account of effectiveness rather than newness.

Innovation requires independently ascertainable research in accord with standard research protocols before individual practitioners implement it. Validation is required. Innovation on the basis of an individual practitioner's enthusiasm and self-interest in the absence of an independent empirical basis lacks legitimacy and is likely to foster harm.

In conclusion, quackery legitimised by inaction of AHPRA, and the National Boards is currently a grossly profitable industry. Processes and timelines and for defining acceptable and unacceptable practice should be addressed explicitly under the Principles. Other regulators have tackled this issue. The Netherlands BIG register clearly states what a healthcare professional can and cannot do. For example, whether or not a healthcare professional is allowed to give certain injections or perform certain operations.[10]

[9] Watson's Dictionary Of Weasel Words by Don Watson - Penguin Books Australia
[10] Registering as a healthcare professional in the Netherlands | Business.gov.nl