

Private

Reference Number:

Senior Regulatory Advisor - Notifications (Investigations) Australian Health Practitioner Regulation Agency By Email: notifications@ahpra.gov.au

3 April 2023

Dear

RE: Anonymous complaint (Health service complaint)

- 1. I refer to correspondence dated 28 March 2023 titled "**Request for response**" from citing reference number (**'the Notification'**) in which sought a response from our client (**'Dr Kunadhasan'**) with an opportunity to respond by **11 April 2023**.
- 2. I am a service provider to the Australian Medical Professionals' Association who have subsequently assigned myself, **Medical Professionals**, as case manager for this matter. We have worked directly with Dr Kunadhasan to provide this response.

General matters

3. We understand that the Notification considers whether Dr Kunadhasan:

" promoted anti COVID-19 vaccination statements. "

- 4. The Notification is absent reference to any breaches or concerns as defined within the *Health Practitioner Regulation National Law (Victoria) Act* 2009. The Victorian National Law uses the definitions from the corresponding Queensland Law¹ (together referred to as **'National Law'**)
- 5. The relevant considerations of your company under the National Law² are the following (**'Relevant Considerations'**):
 - a. *'Professional misconduct'*; would entail one or more episodes of substantially below standard practice that would be expected of the practitioner's training and experience to the point where his/her/x standing as a fit and proper person to be registered is called into question.

¹ ss 3 & 4 National Law.

² See ss 5 & 144 Health Practitioner Regulation National Law (Queensland) 2009.

- b. 'Unprofessional conduct' within practice or character; usually reserved for criminal convictions, breaches of integrity, unethical conduct, the provision of excessive or compromised care, to proffer inducements, or gain additional personal pecuniary benefit from referral of patient care.
- c. *'Unsatisfactory professional performance'*, the calling into question of knowledge, skill or judgement possessed demonstrated by the practitioner within their practice.
- d. *'Health impairment'* that is reasonably expected to detrimentally affect patient care through a medical practitioners' physical or mental impairment, disability, condition or disorder (including substance abuse or dependence).
- 6. There is substantial material attached to the Notification (**'Materials'**), however without any specific reference to which statements may have breached the National Law, subordinate legislation, or resulted in the Relevant Considerations within the National Law being engaged, the scope of a response is unworkably broad.
- 7. Upon review and revision of the Materials, there is no evidence that Dr Kunadhasan engaged the Relevant Considerations in a way that ought to engage an investigation.
- 8. It appears that grounds under the National Law for regulatory action have not been met and there is no case to answer and such the Notification ought to be disposed of under s 151 of the National Law (QLD).
- 9. In the alternative, it would be preferable that AHPRA specify what statements, conduct, and evidence is subject to regulatory action prior to notifications such as the Notification; failure to do so results in responses like the previous response from Dr Kunadhasan dated 28 November 2022, where it was not clear why the investigation was taking place.
- 10. Dr Kunadhasan made no statements inconsistent or in breach of to the established principles of medical ethics, the Code³, her oath, her undertakings, or identifiable under the National Law.

Lack of grounds for notification & ethical considerations

- 11. The Notification vaguely refers to "whether [Dr Kunadhasan] promoted anti-COVID-19 vaccination statements".
- 12. The Notification fails to identify what the grounds of a notification regarding promotion of anti-COVID-19 vaccination statements is, given that COVID-19 vaccinations are provisionally approved and subject to scrutiny and further research.
 - a. It ought not be in dispute that best evidence, medical ethics, and Good Medical Codes of Practice require debate, scrutiny, transparency, and informed consent regarding novel medical treatments and technology.
 - b. AHPRA's March 2021 Policy Position Statement (**'Position Paper'**) is itself at odds with the aforementioned principles as it evidently hinders open medical debate thus impairing pharmacovigilance, early identification of iatrogenic harm, and decays public trust; which are each critical to public health in their own right.
- 13. If the notifier and yourself believe that Dr Kunadhasan has potentially breached any Code or National Law, the Common Law principles of natural justice require a clear delivery of which particular conduct, competency, or performance was in breach of which particular National Law or other obligation, that makes it worthy of an ongoing investigation under the National Law.

³ Based upon the National Board's own code and publication: Good medical practice: a code of conduct for doctors in Australia, October 2020, Medical Board Ahpra. (**'the Code'**)

- 14. As such, it is critical that investigators outline particularly which material or statement is of concern or otherwise provide specific details of the complaint so that the practitioner is able to respond directly.
- 15. Merely attaching material in the Notification with a deadline to provide a response is not sufficiently informing the recipient respondent which components of the notification require response, in a way that risks self-incrimination, and is not naturally just nor efficient.

Psychosocial risks of continued victimisation

- 16. Dr Kunadhasan is a highly qualified and ethical practitioner with a strong sense of morality, which is guided by the Code, and seeks best evidence as much as reasonably practicable to inform her primary function of protecting the health of the public and patients.
- 17. Dr Kunadhasan reports feeling harassed. Dr Kunadhasan has expressed to us feelings of depression and/or anxiety whenever your company seeks to gather information based on anonymous complaints about her proper application of the Code, ethics, and National Law.
- 18. AHPRA; in repeatedly threatening regulatory action over several months based on statements, such as those transcribed in the Materials, without citing the lawful grounds or statements for doing so; could reasonably be defined as harassment.
- 19. It has recently been reported to the public record that at least 16 medical practitioners have been identified as having committed suicide during or following AHPRA notifications or investigations.
- 20. We recognise that notifications and investigations are an important regulatory function to ensure the safety of patients and those seeking services from medical practitioners.
- 21. However, ungrounded or frivolous notifications to competent and discerning medical practitioners for performing their ethical obligations under their Code is extremely damaging and can result in a culmination of psychological harms that have contemporarily been referred to as Moral Injury:⁴

"Moral injury is understood to be the strong cognitive and emotional response that can occur following events that violate a person's moral or ethical code."⁵

- 22. Symptoms of moral injury involve depression, stress, physiologically deleterious effects, and in some instances suicidal ideation.
- 23. Please consider the psychosocial hazards of notifications that curb Freedom of Speech and proper good-faith reasoned discussion and debate that is compliant with the Code and National Law; prior to notification or regulatory actions where the Relevant Considerations are not engaged.

Response to the Materials

- 24. Notwithstanding that:
 - a. the Notification appears frivolous or designed to limit Dr Kunadhasan's freedom of lawful speech in adherence to the Code; and

⁴ See Williamson et al published in the Lancet, March 2021

<<u>https://doi.org/10.1016/S2215-0366(21)00113-9</u>>.

⁵ Litz BT, Stein N, Delaney E et al. Moral injury and moral repair in war veterans: a preliminary model and intervention strategy. Clin Psychol Rev. 2009; 29: 695-706.

- b. That there is simply <u>no case to answer</u> because none of the allegations relate to "unsatisfactory professional performance" or other Relevant Considerations as none of the enclosed material relates to performance or conduct "in the practice of the health profession" or otherwise requiring consideration of regulatory action, according to the National Law,
- 25. Dr Kunadhasan is happy to contextualise her ethical approach to the Materials transparently.

Alleged breaches of the Code or National Law

- 26. The Notification considers "specifically whether Dr Jeyanthi promoted anti COVID-19 vaccination statements" and attaches the Material including the Position Paper.
- 27. Dr Kunadhasan is a competent health professional who sources evidence-based and accurate health information in a way compliant with the Code, law, ethics, and licenses. Dr Kunadhasan conducts herself professionally and performs satisfactorily to at least a reasonable standard.
- 28. No evidence of a breach of the Code, National Law, or other laws has been presented in the Notification.

Additional material provided transparently in good-faith

- 29. Dr Kunadhasan would also like to provide to you transparently and proudly that she is a volunteer into a public interest group scrutinising recent releases of the Pfizer's (**'the Sponsor'**) raw clinical data and has authored various publications, and would like these shared with any interested Medical Board(s), and if appropriate, any anonymous complainant(s).
 - a. Publication: <u>Report 42</u>: <u>Pfizer's EUA Granted Based on Fewer Than 0.4% of Clinical Trial Participants. FDA Ignored Disqualifying Protocol Deviations to Grant EUA.</u> <u>September 26, 2022</u>; <u>Jeyanthi Kunadhasan, MD, FANZCA</u>; <u>Ed Clark, MSE and Chris Flowers, MD - Team 3</u>. This report is also part of a book that has 50 reports written by volunteers using the Sponsor's primary source documents released under court order titled <u>Pfizer Documents Analysis Reports</u>: <u>Find Out What Pfizer, FDA Tried to Conceal, Amy Kelly, DailyClout 2022</u>.
 - b. Editorial: <u>170 patients that changed everything</u>, Jeyanthi Kunadhasan, Spectator Australia, 8 December 2022.
 - c. Editorial: <u>The powerful politics of Covid vaccines</u>, Jeyanthi Kunadhasan, Spectator <u>Australia</u>, 24 March 2023.
- 30. Dr Kunadhasan says she is encouraging you to share the above publications because she hopes that they may educate your contacts about the best-evidence that formed the basis of TGA's provisional approval, the national immunisation campaign, and the Position Paper.
- 31. For instance, Dr Kunadhasan's report referenced 'b' above shows there were patients with major disqualifying protocol deviations in the 170 patients who formed the basis of the FDA's EUA approval of trial-drug bnt162b2 in the United States and this is of utmost importance to the Public Good and worth consideration of the authorities that supported the Position Paper.

AHPRA's Policy Position Paper and the National Law

32. AHPRA's position paper stated:

"This position statement is based on information available in March 2021. Information about COVID-19 and vaccination is still developing and this position statement will be regularly reviewed."

- 33. According to the Position Paper, the Position Paper ought to be reviewed in light of the fact that a key origination Phase-3 trial relied upon in the consideration of the position was prima facie deficient in light of recently discovered best-evidence.
- 34. The Position Paper (attachment 4 in the Notification) states the following.

"It should be read in conjunction with the standards, codes, guidelines, position statements and other guidance published by National Boards."

"Conscientious objection

In the case of a conscientious objection about receiving, authorising, prescribing or administering COVID-19 vaccination, practitioners must inform their employer and/or other relevant colleagues (where necessary) of their objection as soon as reasonably practical. For example, a practitioner's personal beliefs may form the basis of a conscientious objection to particular treatments.

In addition to the above, it is important that practitioners inform their patient or client of their conscientious objection where relevant to the patient or client's treatment or care. In informing their patient or client of a conscientious objection to COVID-19 vaccination, practitioners must be careful not to discourage their patient or client from seeking vaccination. Practitioners authorised to prescribe and/or administer the vaccine but who have a conscientious objection must ensure appropriate referral options are provided for vaccination."

"Any promotion of anti-vaccination statements or health advice which contradicts the best available scientific evidence or seeks to actively undermine the national immunisation campaign (including via social media) is not supported by National Boards and may be in breach of the codes of conduct and subject to investigation and possible regulatory action."

35. The Position Paper ought to be read in conjunction with the relevant Code(s). No breaches of the Code have been identified in the Notification or Material, and if you believe we erred in this assessment, please extrapolate so that a proper response to each alleged breach may be responded with particular reference to the National Law.

Public Good and good governance considerations

36. Discussion of Public matters and Government policy is an important political right that, if done professionally and in good-faith, raises important Public concerns and issues with the Government. It would be against the principles of Common Law, Natural Justice, and good governance if all health practitioners were barred from telling their story or lawfully reporting on best-evidence of public interest.

Freedom of Speech and Freedom of Association

- 37. Notwithstanding the Position Paper, discussion through lawful means about safety concerns of provisionally approved medicines is an important public function and quality control; thus health professionals ought not be acted against in a manner that restricts lawful Freedom of Speech.
- 38. Freedom of Association is protected under international convention and human rights as ratified within Australia and Victoria via legislation. Freedom of Association and Freedom of Speech enforce quality, diligence, and accountability via competition and debate.

Potential for abuse of notifications process & public interest

- 39. Dr Kunadhasan queries the identity of the anonymous complainant(s), resulting in the Notification.
- 40. Dr Kunadhasan has openly declared that she is part of the worldwide volunteer effort providing public scrutiny into documents that formed the basis of the approval of bnt162b2, released following extensive litigation before a United States Justice by way of Freedom of Information (**'the Documents'**).
- 41. The Notification's intent appears unhappy with Dr Kunadhasan's proper application of the Codes; or otherwise threatened by research into the publicly available best evidence, being the Documents from the trials commissioned by the Sponsor.
- 42. Initial reports suggest these documents identify fraudulent activity of the Sponsor via exaggerated marketing claims and protocol violations.
- 43. It is reasonable and appropriately vigilant to suspect that an agent or interested party connected to the Sponsor is utilising Public resources via anonymous complaints or abusing power of public office in an attempt to intimidate or stifle research into, and evidence-based reporting of, the Documents that form best-evidence.
- 44. We recommend that your company and your clients take steps to ensure that the Notification's source(s) operate in voluntary good-faith and do not materially benefit from the making of bad-faith complaints via the National Law.

Public Interest Disclosure

- 45. If there is reasonable suspicion that sources that result in the Notification are abusing the anonymous notifications process in a way to stifle research into matters of public interest; it is essential that relevant entities that perform the public function(s) notify those affected immediately and allow for an investigation into the relevant suspicion; to ensure bad-faith abuse of the Notifications procedure is not occuring.
- 46. Further to ensure the public function of your company is not corrupted, an immediate integrity audit into conflicts of interest is strongly urged.
- 47. It is almost obvious that an investigation and subsequent transparent disclosures by your company; whether in collaboration with the Ombudsman's office, or the relevant Medical Board(s) or otherwise; would demonstrate good governance aligned with the Public Good, law, and may restore public trust and confidence in your company and its clients.
- 48. We suggest that any disclosure of information in the Public Interest would be legally shielded from adverse action via Public Interest Disclosure Law to <u>PID@apra.gov.au</u> or the Commonwealth Ombudsman at ombudsman.gov.au. If you'd like more information on Public Interest Disclosures 'whistleblowing' you should talk to a lawyer independent of your company.

Cease and desist

- 49. You are hereby aware that the Notification may be a reprisal made in bad-faith.
- 50. In the absence of a clear reason under the National Law for further notifications; your company is demanded by Dr Kunadhasan to immediately cease and desist from further harassment that impedes on her rights to speak freely and conduct research in the public interest. She intends to continue to comply with the National Law and Code at all times.

Conclusion

- 51. Applying the National Law to the Materials, it is not evident there was a statement that breaches the National Law, licensure, or the Code.
- 52. Dr Kunadhasan is a senior medical practitioner with a flawless conduct history who at all times upholds the Code in her work, including as part of her volunteer research and reporting into best-evidence of provisionally approved drugs.
- 53. Notifications such as the Notification potentially impact upon inalienable and ratified human rights and the Public Good by threatening practitioners acting in the public interest, where lawful cause for notification is unestablished.
- 54. Notifications such as the Notification, absent cause, pose an unjustifiable psychosocial hazard to Dr Kunadhasan.
- 55. In the absence of cause recognised under the National Law demanding action; I am instructed to demand your company immediately cease and desist from actions that Dr Kunadhasan describes as harassment.
- 56. Regarding the notification as it stands; there is no case to answer.

Kind regards,



Senior Case Manager Red Union Support Hub Proud service provider to AMPS