IN THE HIGH COURT OF NEW ZEALAND
WELLINGTON REGISTRY

I TE KŌTI MATUA O AOTEAROA
TE WHANGANUI-A-TARA ROHE

CIV-2023-485-415
[2024] NZHC 3538

UNDER	the Judicial Review Procedure Act 2016 and Declaratory Judgments Act 1908
AND UNDER	section 2 of the Declaratory Judgments Act 1908 and the inherent jurisdiction of the Court
IN THE MATTER OF	an application for judicial review and application for declaration
AND IN THE MATTER OF	an application for a declaratory judgement
BETWEEN	NZDSOS INC Applicant
AND	MEDICAL COUNCIL OF NEW ZEALAND First Respondent
AND	DENTAL COUNCIL Second Respondent

Hearing: 23/24 September 2024

Appearances: L M Hansen & P C Kelly for Applicant
S J M Mount KC for First Respondent
J P Coates & G F Weir for Second Respondents

Judgment: 25 November 2024

JUDGMENT OF CHURCHMAN J

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Introduction

[1] The applicant has applied for judicial review of a decision made by Te Kaunihera Rata o Aotearoa | the Medical Council of New Zealand (Medical Council), jointly with Te Kaunihera Tiaki Niho | the Dental Council (Dental Council), to issue a guidance statement dated 28 April 2021 concerning the COVID-19 vaccination of health practitioners and the provision of advice to patients about COVID-19 vaccination (the Guidance Statement).

[2] The applicant raises seven grounds of review, the first six of which are alternative:

(a) The Guidance Statement is ultra vires as the respondents have no express or implied statutory power to issue such a statement;

(b) The Guidance Statement is ultra vires as it breaches the Code of Health and Disability Consumer's Rights (Code of Rights) and/or undermines the doctor-patient relationship;

(c) The respondents had a duty to consult with the public or medical and dental practitioners prior to publishing the Guidance Statement and failed to do so;

(d) The Guidance Statement breaches s 11 of the New Zealand Bill of Rights Act 1990 (NZBORA);

(e) The Guidance Statement breaches s 14 of the NZBORA;

(f) The Guidance Statement was issued for an improper purpose, namely to censor medical and dental practitioners and prohibit them from expressing any views to their patients or publicly about any risks of the COVID-19 vaccine; and

(g) The Medical Council acted unlawfully by treating the Royal New Zealand College of General Practitioners (RNZCGP)'s press

release of 6 September 2021 and Medsafe's guidance issued September 2021 as establishing that medical practitioners who prescribed Ivermectin for COVID-19 are a threat to patient safety and referring these practitioners to Professional Conduct Committees.

[3] The applicant seeks the following remedies:

(a) In relation to the first ground of judicial review, a declaration that the Guidance Statement was invalid and that any action taken in reliance of the Guidance Statement is ultra vires;

(b) Alternatively in relation to the second to sixth grounds of judicial review, a declaration that the Guidance Statement was invalid and that any action taken in reliance on the Guidance Statement is ultra vires;

(c) In relation to the seventh ground of review, a declaration that:

> Subject to obtaining informed consent, a doctor may prescribe approved medicines for unapproved uses that in that doctor's clinical judgement are appropriate to treat each specific patient in their specific circumstances. In doing so, the doctor must have regard to accepted practice and best practice guidelines, but their prescribing discretion is not limited by 'accepted practice' or 'best practice' and divergence from those practices is not in itself grounds for a finding of misconduct or a reason to limit the doctor's practice or a reason to refer a medical practitioner to a professional conduct committee.

The parties

[4] NZDSOS is an incorporated society representing health practitioners who are opposed to vaccination and was incorporated on 23 September 2021. It has previously brought or been a party to claims against the Minister for COVID-19 Response in relation to the COVID-19 Public Health Response (Vaccinations) Order 2021,[1] and other orders made under the COVID-19 Public Health Response Act 2020.[2] It has also

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1 *Four Midwives v Minister for COVID-19 Response* [2021] NZHC 3064, [2022] 2 NZLR 65.
2 *NZDSOS Inc v Minister for Covid-19 Response* [2022] NZHC 716, (2022) 13 HRNZ 296.

brought claims against TVNZ for alleged breaches of broadcasting standards,[3] and against a local authority for a decision to introduce fluoride to the water supply.[4]

[5] The Medical Council is a body corporate constituted under the Health Practitioners Competence Assurance Act 2003 (HPCAA) as the responsible authority for the medical profession. Its 12 members are comprised of eight doctors and four lay people who are all appointed by the Minister of Health.

[6] The Dental Council is a body corporate established under s 114(2) of the HPCAA as the responsible authority for oral health professions. Its 10 members are comprised of seven practitioner members and three lay members.

Background

[7] At the end of 2019, a novel coronavirus, SARS-CoV-2, rapidly spread throughout the world resulting in a global pandemic. The virus caused people to fall ill and in some cases to die from an illness called coronavirus disease 2019 (COVID-19). The manifestation of COVID-19 in adults ranges from asymptomatic infection to mild respiratory tract symptoms to severe pneumonia with acute respiratory distress syndrome (ARDS) and multiorgan dysfunction.[5]

[8] The SARS-CoV-2 genetic sequence was disseminated globally on 10 January 2020, only a few weeks after it was first identified in China and prior to cases being found outside China. The first case of COVID-19 in New Zealand was reported on 28 February 2020, with the country subsequently going into its first nationwide "lockdown" from 26 March to 27 May 2020.

[9] In response to the pandemic, the Medical Council worked to implement several measures to support the profession through the pandemic to boost the workforce and allow different ways of working. These include:

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3 *NZDSOS Inc v Television New Zealand Ltd* BSA 2022-055, 26 April 2022.
4 *Fluoride Action Network (NZ) Inc v Hastings District Council* [2024] NZHC 1313.
5 Affidavit of Dr Matthew Doogue dated 12 July 2024 at [17].

(a) Initiating a pandemic scope of practice on 19 March 2020 to facilitate recently retired doctors to gain registration and practice to support the COVID-19 response;

(b) Changes to the Council's Statement on Telehealth on 26 March 2020 to support the overnight change to telehealth consultations, in particular supporting telehealth prescribing;

(c) Changes to policy in early April 2020 to allow interns to work outside their accredited clinical attachment to support the COVID-19 response;

(d) Execution of an extensive communication and engagement plan with the profession and stakeholders between March 2020 and August 2021; and

(e) Changes to requirements and obligations for the profession between March 2020 and February 2021 to reduce the burden on the profession while they were under pressure.

[10] During this early stage of the COVID-19 response, the Medical Council was reportedly contacted by the Royal New Zealand College of General Practitioners on whether the Medical Council had any guidance on COVID-19. The Chief Executive of the New Zealand Medical Association provided to the Medical Council's Chief Executive a copy of the Australian Medical Association's position statement on ethical considerations in disaster response. In April 2020 the Medical Council was approached by the Ministry of Health who asked if the Council saw value in producing similar advice to the materials being provided overseas, and whether there should be a collective statement from all responsible authorities or individual statements.

[11] Due to concerns around the difficulty of reaching consensus and the considerable uncertainty that remained around COVID-19, no further steps were taken to publish guidance for the profession in relation to COVID-19.

[12] By September 2020, the Council had begun to receive notifications about doctors spreading misinformation about COVID-19.

[13] The Pfizer vaccine was first approved for use overseas in December 2020 and was granted provisional approval for use in New Zealand in early February 2021, with vaccinations beginning later that month, initially for vaccinators and border workers. The Government's vaccine rollout programme was announced on 10 March 2021, with the rollout planned to reach the most vulnerable two million New Zealanders in an initial three to four month period.

[14] On 8 March 2021, the Dental Council received a letter from the New Zealand Dental Association asking what the Council's policy was on COVID-19 vaccinations for registered practitioners. At the time the Dental Council was also monitoring what health regulators in other jurisdictions were doing and were aware of vaccination guidance having been issued by the United Kingdom's General Dental Council "COVID-19 vaccination guidance for dental professionals" that was issued on 22 February 2021, and the Australian Health Practitioner Regulation Agency (AHPRA) and National Boards' position statement issued on 9 March 2021.

[15] On 8 March 2021, the Chief Executive of the Dental Council, Marie Warner (now Marie MacKay) emailed the Chief Executives of the Medical Council (Joan Simeon), the Nursing Council (Catherine Byrne) and the Pharmacy Council (Michael Plead) asking whether any of them had set a position regarding the requirement for registered doctors, nurses or pharmacists to be vaccinated. There were subsequently a number of exchanges where interest was expressed in releasing a joint statement.

[16] On 24 March 2021 Ms MacKay informed the other Chief Executives that the Dental Council had a finalised statement.

[17] On 30 March 2021, the draft guidance statement was presented to the Dental Council. The Council resolved to approve the draft statement with two small amendments. These included the removal of the words "and express" from the

statement "as regulators we respect an individual's right to have and express their own opinions".

[18] On 30 March 2021, following the Dental Council's approval of the statement, Ms MacKay sent a copy to the Chief Executives of the other responsible authorities. In response Ms Simeon stated she would need to circulate it to the Medical Council for their consideration.

[19] The Medical Council received a discussion paper from Ms Simeon on 31 March 2021 ahead of the April Council meeting. The Council met on 13 and 14 April 2021 to consider the draft guidance statement and requested that the requirement for doctors to disclose their vaccination status be removed, and that a reference to the Code of Health and Disability Services Consumers' Rights be included. Dr Curtis Walker, the then Chair of the Medical Council, deposed that the majority view was the statement appropriately balanced any limits on doctor's rights with the risks to public health posed by the pandemic.

[20] On 13 April 2021, Ms Simeon informed Ms MacKay that the Medical Council had sought changes to the wording with the removal or 'substantial softening' of two statements:

> - Patients have a right to know if you or other clinical staff working alongside you are not vaccinated – all practitioners must disclose their vaccination status to patients if asked.
> - You should encourage colleagues and staff at your practice to be vaccinated against COVID-19.

[21] In response, Ms MacKay amended the wording to state:

> - Patients are entitled to information that a reasonable consumer, in that consumer's circumstances, would expect to receive (Right 6, Code of Health and Disability Services Consumers' Rights).
> - You should be prepared to discuss evidence-based information about vaccination and its benefits to assist informed decision making.

[22] The Chair of the Dental Council, Dr Gray, approved these amendments on behalf of the Dental Council.

[23] On 20 April 2021, a revised version of the draft joint guidance statement was circulated amongst all Medical Council members, with the references to wider responsible authorities (beyond the Medical and Dental Council) removed and the wording changes previously discussed implemented. The Guidance Statement was passed by a majority but not a unanimous vote.

[24] On 22 April 2021, Ms Simeon informed Ms MacKay via email that the Medical Council had passed a resolution agreeing to publish the Guidance Statement.

[25] The final Guidance Statement reads as follows:

> Vaccination is a crucial part of the New Zealand public health response to the COVID-19 pandemic. Health practitioners can help to protect themselves, their patients, and the wider community by getting their COVID-19 vaccination.
>
> The Dental and Medical Councils will have an expectation that all dental and medical practitioners will take up the opportunity to be vaccinated—unless medically contraindicated.
>
> You have an ethical and professional obligation to protect and promote the health of patients and the public, and to participate in broader based community health efforts. Vaccination will play a critical role in protecting the health of the New Zealand public by reducing the community risk of acquiring and further transmitting COVID-19.
>
> Patients are entitled to information that a reasonable consumer, in that consumer's circumstances, would expect to receive (Right 6, Code of Health and Disability Services Consumers' Rights).
>
> As a health practitioner, you have a role in providing evidence-based advice and information about the Covid-19 vaccination to others. You should be prepared to discuss evidence-based information about vaccination and its benefits to assist informed decision making. There is information on the Ministry of Health (MOH) website to support engagement with staff or colleagues and the public who may be hesitant about getting a vaccine.
>
> As regulators we respect an individual's right to have their own opinions, but it is our view that there is no place for anti-vaccination messages in professional health practice, nor any promotion of anti-vaccination claims including on social media and advertising by health practitioners.
>
> More information:
>
> - The latest government information on the COVID-19 vaccination programme can be found on the MOH website.

- The Ministry for Business, Innovation and Employment (MBIE) has guidance for employers and workers about the employment law implications for the COVID-19 vaccination programme.

[26] In the approximately six-month period between the issuing of the Guidance Statement and the introduction of the vaccine mandate for health practitioners, the Dental Council received 28 contacts from practitioners and/or members of the public relating to the Guidance Statement. These ranged from those seeking clarification on aspects of the Guidance Statement and vaccination more generally to practitioners expressing anti-vaccination views, concerns raised about practitioners spreading anti-vaccination information, and individuals expressing support for vaccination.

[27] On 6 September 2021, the RNZCGP issued the following press release:

> Off-label use of Ivermectin for the treatment of COVID-19 is strongly not recommended.
>
> Ivermectin can, and does, cause harm when misused. Prescribing it could well mean that even if the patient had given consent, the doctor could still be held liable for making an ill-informed decision on a medication that at this point has not been shown to provide benefit and could cause harm. It would be difficult to justify this position with either the Medical Council or the Health and Disability Commissioner.

[28] Medsafe also issued guidance in September 2021 stating:

> Ivermectin is NOT APPROVED to prevent or treat COVID-19, which means that Medsafe has not assessed the safety and efficacy for this use. Inappropriate use of Ivermectin can be dangerous.
>
> Medsafe and the Ministry of Health strongly recommends that Ivermectin is not used for prevention or treatment of COVID-19.

[29] The Guidance Statement is stated by the respondents to have remained in force until the Government introduced the vaccine mandate for all health practitioners on 25 October 2021. Although the Councils did not formally revoke the Guidance Statement, Ms MacKay argues it was effectively superseded by the vaccine mandate.

[30] On 12 September 2022, the COVID-19 Protection Framework was retired and on 26 September 2022 all COVID-19 vaccine mandates were removed. In response, the Dental Council removed the Covid-19 page from its website. On 2 August 2023, NZDSOS filed its judicial review application.

[31] On 14 August 2023, the Ministry of Health announced that all remaining COVID-19 public health requirements would be lifted.

[32] On 13 September 2023, after having received a discussion paper on the matter, the Medical Council considered and resolved to retire the Guidance Statement. It updated its website on 6 October 2023 and included a "revoked" stamp on the publicly available copy of the Guidance Statement. The profession was then updated regarding the withdrawal of the Guidance Statement in its subsequent *He Paerewa a Te Kaunihera* (MC News) pānui on 2 November 2023.

Admissibility of Mr Aston's affidavit

[33] One of the affidavits filed in support of NZDSOS's applications was that of Mr Aston. Mr Aston was appointed as a lay member of the Medical Council in October 2019. Following his appointment, Mr Aston signed a confidentiality agreement on 1 November 2019, part of which stated:

> 1.2 I acknowledge that disclosure of Council business to anyone outside the Council remains the decision of the Council Chairperson and/or Chief Executive Officer, under the delegated authority of the Council.
>
> 1.3 I acknowledge that confidential information I obtain in the course of my work shall remain confidential beyond the expiration of my work with the Council.

[34] Clause 4.3.4 of the Medical Council's Standing Orders provides that:

> Members are not restricted from disclosing information on Council roles, responsibilities and policies, but information of a confidential or privileged nature or information on policy development should not be made available except with the prior approval of Council.

[35] Additionally, the Medical Council's Member's Code of Conduct, which Mr Aston signed on 5 November 2019, states that:

> Members have an obligation of confidentiality in order to encourage free and open discussion at the Council meetings. All members must sign the Council's confidentiality pledge and be familiar with the *Protocol for searching of doctor's files held by the Council*.

[36] Mr Aston resigned from the Medical Council on 2 May 2022.

[37] Mr Aston's affidavit sets out details of Medical Council meetings and decisions that, in accordance with the documents just mentioned, are confidential. On 30 April 2024, Grice J made an order by consent that Mr Aston's affidavit not be accessed or published without the permission of a Judge pursuant to r 5(2) of the Senior Courts (Access to Court Documents) Rules 2017, pending further order of the Court.

[38] The first respondent has challenged the admissibility of Mr Aston's evidence on the basis that it is not relevant under s 7 of the Evidence Act and emphasises that Mr Aston did not have approval from the Medical Council to disclose confidential discussions. However, Mr Mount KC, counsel for the first respondent, has confirmed that it does not seek an order under s 69 of the Evidence Act. The first respondent does request that Grice J's order remain in place to prevent disclosure of confidential information.

[39] Ms Hansen, counsel for the applicant, submits that Mr Aston's evidence is relevant to the issues before the Court, and provides insight into the character of Council discussions, with no other evidence as to Medical Council oral discussions before the Court other than that of Dr Walker in support of the first respondent.

[40] Ms Hansen submits the confidentiality provisions of the Evidence Act are usually applied in the context of medical confidentiality and cases of highly sensitive commercial information. She states the issue here is not whether the evidence should be disclosed to third parties, but whether it can be adduced to Court. Ms Hansen contends that the Court must examine the considerations taken into account by the Medical Council on a balanced view of the evidence, and states fairness requires that evidence be admissible notwithstanding the confidentiality asserted by the Medical Council.

[41] Section 7 of the Evidence Act provides that:

> (1) All relevant evidence is admissible in a proceeding except evidence that is—
>
> (a) inadmissible under this Act or any other Act; or
>
> (b) excluded under this Act or any other Act.

(2) Evidence that is not relevant is not admissible in a proceeding.

(3) Evidence is relevant in a proceeding if it has a tendency to prove or disprove anything that is of consequence to the determination of the proceeding.

[42] For evidence to be relevant, and thus admissible, it must be probative (have a logical tendency to prove or disprove the proposition for which it is offered) and material (offered about a matter or fact in issue).[6]

[43] Mr Aston's affidavit mostly contains evidence that is largely irrelevant to these proceedings. There is no discussion of whether the Medical Council considered or in fact had the power to issue the Guidance Statement, nor of whether it was considered or treated as a standard. Mr Aston also does not raise anything of relevance to the question of whether the Guidance Statement breached the Code of Rights.

[44] However, there is a brief expression of Mr Aston's opinion regarding the degree to which the Medical Council considered free speech rights, human rights of doctors, and the degree to which the Council was inserting itself into the doctor-patient relationship. The degree to which the Guidance Statement was relied on for dealing with complaints about practitioners is also briefly discussed. Disciplinary action for prescribing Ivermectin is also discussed in relation to a particular case, with the person involved named and brief details of the consideration of their case given.

[45] Mr Mount submits that while the disclosures by the first respondent were authorised by the Medical Council, relevant to the pleadings and provided to assist the Court, Mr Aston had no such approval to disclose confidential information from Council discussions, and in the submission of the Medical Council, the information is not relevant and cannot assist the Court.

[46] Mr Mount submits that much of Mr Aston's affidavit does not refer to the Guidance Statement, with those parts of it that do refer to it being unsupported statements of opinion that do not assist to prove or disprove issues such as whether the Guidance Statement was treated as a standard. He submits that Mr Aston's statements

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6 Elizabeth McDonald and Scott Optican (eds) *Mahoney on Evidence: Act and Analysis* (4th ed, Thomson Reuters, Wellington, 2018) at [EV7.02].

are peripheral at best and do nothing to assist the Court when considering the grounds of review, as the opinion of one Council member is not relevant when the Court is considering the legality of a decision of the Medical Council as a whole.

[47] Mr Mount further contends that the Court need only determine the admissibility issues if it finds it necessary to rely on Mr Aston's evidence and that Mr Aston's evidence is in breach of his duty of confidence, such obligations to keep Council meetings and discussions confidential are essential for the free flow of information and to preserve free and frank discussions, and confidentiality is essential to protecting the privacy of the individuals who may be discussed at Council meetings.

Discussion

[48] There is no doubt that Mr Aston was under a duty of confidence. Given the sensitive nature of matters discussed at meetings of the Medical Council the policy justifications for imposing such a duty (particularly on lay members) are obvious. That obligation is one that should not lightly be set aside. However, and to a limited extent, in the present case I am prepared to do so in respect of some parts of Mr Aston's evidence. These are parts of the evidence that do not infringe any individual's privacy rights and which relate to matters that are potentially relevant to these proceedings.

[49] To the extent that Mr Aston's evidence has any relevance it is in respect of the questions around whether the Council turned its mind to ss 11 and 14 of NZBORA. I admit that part of his affidavit. Ultimately, for the reasons I set out below, I do not consider that either of those provisions are breached, I note that there is other evidence supporting a finding the respondents did turn their minds to whether the Guidance Statement breached the right to refuse medical treatment and freedom of expression. The relevant parts of Mr Aston's evidence do not negate the evidence of the respondent in this regard however, I have considered them in forming my view.

Did the Councils have the power to issue the Guidance Statement?

Submissions

[50] Ms Hansen submits there was no reference in the decision-making documents to a specific statutory power or function under which the Guidance Statement was made, except for a passing reference to s 188(1)(j). She submits the only basis on which the Councils may regulate the professional conduct of doctors and dentists, which is what the Guidance Statement purported to do, is through issuing a standard under s 118(1)(i) of the HPCAA. She argues none of the other functions under s 118(1) authorise the respondents to issue the Guidance Statement.

[51] Mr Mount argues that the Medical Council did have the power to issue the Guidance Statement, either expressly under the HPCAA or as a necessary incident of the Council's express statutory powers. These include reviewing and promoting the competence of health practitioners and promoting the education and training of the profession. He contends the Guidance Statement promoted the competence and education of medical practitioners by reminding them of their obligations in the novel context of the COVID-19 vaccine.

[52] Mr Mount also submits that there is an implied power to issue guidance statements and states it would undermine the purpose and scheme of the HPCAA if the only way the Medical Council could communicate with the profession was by issuing formal standards with the status of secondary legislation. He states that since issuing guidance helps to protect public health and safety by giving medical professionals an accessible means to understand their rights and obligations, it is a logical extension of the express powers under the Act. He also argues the Medical Council has issued other guidance, namely the *End of Life Choice Act 2019 and Council Statements* document which was issued in October 2021.

[53] Ms Weir for the Dental Council submits that the issuing of guidance is consistent with the Council's express statutory function to promote competence, which includes the provision guidance to the professions about all facets of professional practice that may impact on the protection of the health and safety of the public. Ms Weir also submits the issuing of the Guidance Statement was in accordance with

the Dental Council's implied powers and was incidental to its express statutory powers and functions. She states it must be the case that a regulator with such a broad remit has the ability to issue guidance to the practitioners it regulates.

Discussion

[54] Section 3(1) of the HPCAA provides that the principal purpose of the Act is to protect the health and safety of members of the public by providing for mechanisms to ensure that health practitioners are competent and fit to practise their professions.

[55] Under the HPCAA an authority is a body corporate appointed by or under the Act to be responsible for the registration and oversight of practitioners of a particular health profession.[7] Section 117 provides that each authority appointed under the Act has and may exercise all the rights, powers and privileges of a natural person of full age and capacity and may exercise its rights and power only for the purpose of performing its functions. Section 118 provides that the functions of each authority include reviewing and promoting the competence of health practitioners, setting standards of clinical competence, cultural competence and ethical conduct to be observed by health practitioners, and promoting education and training in the profession.

[56] A power can either be implied due to it being incidental to or consequential upon expressly authorised powers,[8] or where important or human rights are engaged, where its implication is necessary from the express language of the statute.[9]

[57] It is evident that the HPCAA does not expressly provide for guidance statements. However, I consider that the power to issue guidance statements is implied by the express functions of reviewing and promoting health practitioner competence and promoting education and training. Issuing guidance statements promotes health practitioner competence by ensuring practitioners understand the application of their duties, obligations and responsibilities in certain contexts, whether that be the

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7 Health Practitioners Competence Assurance Act 2003 [HPCAA], s 5.

8 *Attorney-General v Great Eastern Railway Co* (1880) 5 App Cas 473 (HL) at 478 per Lord Selborne LC

9 *Cropp v Judicial Committee* [2008] NZSC 46, [2008] 3 NZLR 774 at [26] adopting *R (Morgan Grenfell & Co Ltd) v Special Commissioners of Income Tax* [2002] UKHL 21, [2003] 1 AC 563.

introduction of new laws that affect the profession like the End of Life Choice Act 2019, or a national health emergency like a global pandemic. To a lesser extent it promotes education and training by informing practitioners of developments and how they may affect their practice. Such a power is clearly both incidental and consequential to those functions, as well as necessary to ensure those functions are carried out.

[58] I accept Mr Mount's submission that it would be counter to the purpose and scheme of the HPCAA for health authorities to be restricted to issuing standards to inform health professionals of their obligations. This would prevent authorities from responding to events that affect health professionals in a prompt manner, and thus restrict their ability to have oversight over the professions they are responsible for. I give particular note to Ms Simeon's evidence that due to the rigorous consultation process required to issue a standard, it generally takes more than nine months to issue a new standard.

Did the Council issue the Guidance Statement as an unlawful standard due to a failure to consult?

Submissions

[59] Ms Hansen submits that the Guidance Statement reads as if it were a standard, with the Guidance Statement label not precluding it from being a standard. She refers to the *Good Medical Practice* standard which mentions "guidelines" that are intended to create a standard. Ms Hansen says that Dr Walker's public statements of a zero tolerance for anti-vax messaging is language that can only be reflective of a standard, and compares this to the Medical Council's zero tolerance policy to sexual relationships between a doctor and their patients which is set out in a standard.

[60] Ms Hansen argues that despite the denials of the Medical and Dental Councils, the Guidance Statement is effectively an unlawful standard, and the Medical Council has at least treated it as having the effect of a standard as it was used to discipline at least 25 medical practitioners. She argues that the Medical Council purported to exercise a regulatory function by revoking the Guidance Statement and referred to

principles of "right touch regulation", but then did not consider these for the issuing of the Guidance Statement.

[61] Ms Hansen states if the Guidance Statement had been issued as a standard, it was unlawful due to failure to consult. She notes that the Medical Council's website states they collect public feedback when considering a new standard, and that the Dental Council's guidelines on consultation provide it will consult where competency standards are involved. Ms Hansen submits that given the practice and policy of the Medical and Dental Councils of consulting prior to issuing a standard, there is a legitimate expectation of consultation. Even if this was not the case, she argues that fairness would require consultation as the Guidance Statement affected the interests of health and dental practitioners in a significant and substantial way.

[62] Mr Mount acknowledges that the Medical Council did not go through a broader consultation process with the public or the profession before issuing the Guidance Statement, but asserts there was no requirement to carry out such broader consultation.

[63] Mr Mount also argues that there was also no implied obligation to consult based on a legitimate expectation of consultation. He submits that this is because there was no established practice of the Medical Council consulting before issuing guidance, that it would be impractical and undesirable to impose a consultation requirement before the Council communicates with the profession, that the Guidance Statement did not change rights or interests but simply assists in understanding existing obligations, there was no detrimental reliance, and that the Guidance Statement was made in the context of an unprecedented worldwide health emergency.

[64] Mr Mount further submits that rather itself being a standard, the Guidance Statement was based on existing ethical standards.

[65] Ms Weir submits that the Dental Council has always published both formal standards under s 118(1)(i) and other guidance for the oral health professions. She states the Guidance Statement did not set any new standards of clinical competence or ethical conduct for which a formal standard would be required, but instead guided the oral health professions as to how the Dental Council considered that practitioners'

existing professional and ethical responsibilities aligned with the availability of the COVID-19 vaccine.

[66] Ms Weir also submits that there was no statutory duty to consult since the Guidance Statement was not a s 118(1)(i) standard, and there was no evidence that the Dental Council made a promise to consult or had an established practice of consulting prior to issuing guidance. She states the Dental Council's "Guidelines on Consultation" set out what the process will "normally involve" and that due to the circumstances of the pandemic, it was entirely reasonable for the Dental Council to proceed without consultation, in the circumstances.

[67] Ms Weir further submits that if the Court finds that there was an expectation to consult on which the applicant's members relied, any breach was of a minor and procedural nature only. She states that given the diametrically opposed views of the evidence of the efficacy and risks of the vaccine known in early 2021, it is difficult to see how any comments made by the applicant's members on a draft statement would have resulted in any substantive change to the Guidance Statement.

Was the Guidance Statement a standard?

[68] I do not consider that the Guidance Statement is a standard. As already discussed, the Guidance Statement provides guidance on how existing ethical standards applied in the context of the COVID-19 pandemic. For the Medical Council, these standards included *Good Medical Practice,* the Code of Rights, *Informed Consent, Use of the internet and electronic communication, Statement of Advertising,* and *Doctors and complementary and alternative medicine (CAM).* The relevant obligations set out in these standards include:

(a) the ethical and professional obligation to protect and promote the health of patients;[10]

[10] *Good Medical Practice* (Medical Council of New Zealand, November 2021) at 6–8.

(b) the need to protect patients, colleagues and yourself by being immunised against common serious communicable diseases where vaccines are available;[11]

(c) the entitlement of patients to receive information that a reasonable consumer in their circumstances would expect to receive;[12]

(d) the need to provide evidence-based advice and information about treatments and their benefits to assist informed decision making;[13]

(e) the requirement to not allow personal views to affect advice or treatment and to ensure information published about your medical services is truthful and balanced;[14] and

(f) the requirement to not misrepresent complementary and alternative medicine (CAM) therapies.[15]

[69] Similar standards have also been issued by the Dental Council in respect of oral health practitioners.

[70] It is apparent from the communications between the various heads of the responsible authorities in the lead up to the issuing of the Guidance Statement, including Ms MacKay and Ms Simeon, that they were not intending to create a new standard. The communications were prompted by the issuing of a position statement on COVID-19 vaccination by the Australian Health Practitioner Regulation Agency and National Board on 9 March 2021. I note that in *Fidge v Medical Board of Australia,* it was determined that that position statement was not legislation and did not compel medical practitioners to carry out work or provide services, but rather

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11 At [72].

12 At [32]; Health and Disability Commissioner (Code of Health and Disability Services Consumers' Rights) Regulations 1996 [Code of Rights Regulations], sch 1; and *Informed Consent: Helping patients make informed decisions about their care* (June 2021, Medical Council of New Zealand) at [3]–[5].

13 *Good Medical Practice,* above n 10, at [3], [32] and [33].

14 At [20] and [37].

15 *Doctors and complementary and alternative medicine* (June 2022, Medical Council of New Zealand) at [17].

provided information to assist registered medical practitioners meet prescribed standards of conduct.[16]

[71] Throughout the discussions between Ms MacKay and Ms Simeon, reference was made to position statements or guidance statements. As submitted by Mr Mount, such types of documents bear resemblance to "guidance notes" which were recognised in the United Kingdom as non-statutory and non-binding.[17]

[72] I also reject the argument that the Medical Council treated the Guidance Statement as a standard when purportedly relying on it to discipline practitioners. A review of the documents concerning the investigations into the conduct of Dr Shelton and Mr Dooley appended to their respective affidavits reveals that the Guidance Statement was referred to in combination with the ethical and competence standards such as *Good Medical Practice.* As stated in the evidence of Dr Walker,[18] the disciplinary action undertaken was premised on the existing obligations, with the Guidance Statement providing clarity on how these obligations applied in the context of the pandemic. I am satisfied it was not treated as creating new standards.

Was the Guidance Statement unlawful due to a failure to consult?

[73] Although there were discussions between the various responsible authorities regarding the content of the Guidance Statement, and the decision to adopt and issue the Guidance Statement was made by councils that had a representative membership that included both practitioners and lay persons, it is undisputed that there was no wider public consultation on the Guidance Statement prior to it being issued.

[74] However, I accept Mr Mount's submission that there was no express requirement to consult. As outlined above, the Guidance Statement was not a standard, and therefore the consultation requirements that Ms Hansen contends exist for the issuance of a standard are not applicable here. Even if the Guidance Statement did amount to a standard, there is no requirement under the HPCAA for authorities to consult before issuing standards. The requirements around consultation in the HPCAA

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16 *Fidge v Medical Board of Australia* [2024] VSC 471 at [132]–[133].
17 *R (Hidden Hearing) v Hearing Aid Council* [2009] EWHC 63 (Admin) at [20].
18 Affidavit of Dr Matthew Walker dated 18 June 2024 at [55]–[57].

instead relate to defining scopes of practice and prescribing qualifications,[19] as well as issuing a naming policy.[20]

[75] There was also no legitimate expectation of consultation. The Medical Council's statement on its website that it first collects feedback from the public relates to standards, not issuing guidance. It would be unreasonable to rely on this statement in respect of the Guidance Statement,[21] given the Guidance Statement is an interpretive aid rather than an instrument imposing new obligations and rules.

[76] In respect of the Dental Council, it is clear it gave a broader statement that it will consult when "the issue under consideration could involve possible significant change or have a significant impact on the sector or the public". However, the examples set out in the flowchart appended to the Dental Council's Guidelines on Consultation—namely codes of practice, fees, appointments, recertification programmes and competency standards—are of a different nature to the Guidance Statement. These examples make clear that a document such as the Guidance Statement would not fall into the category of issues where the Dental Council will consult.

[77] Even if a legitimate expectation had been made out, public interest considerations would override such an expectation.[22] The Guidance Statement was issued in the context of a global health emergency and was in response to the roll out of New Zealand's vaccination campaign. There was a need to respond rapidly to the developing situation, and requiring consultation to be carried out for a guidance document would prevent the responsible authorities from being able to quickly provide clarity for practitioners.

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19 HPCAA, s 14(2).
20 Section 157C.
21 *Comptroller of Customs v Terminals (NZ) Ltd* [2012] NZCA 598, [2014] 2 NZLR 137 at [124] citing *R v Secretary of State for Education and Employment, ex parte Begbie* [2000] 1 WLR 1115 (CA).
22 *Council of Civil Service Unions v Minister for the Civil Service* [1985] AC 374 (HL).

Did the Guidance Statement breach the Code of Rights and/or undermine the doctor-patient relationship?

Submissions

[78] Ms Hansen's case is that the Guidance Statement could never have been lawfully issued as a standard because it breaches the Code of Rights. She argues it breaches the Code as it purports to require a medical practitioner to promote vaccination and focus on the benefits of vaccination, which constrains a medical practitioner advising a patient of the risk of, uncertainties about, and alternatives to vaccination.

[79] Ms Hansen states this interpretation of the Guidance Statement is clear from the plain words of the Statement and by the statement of the Medical Council when considering revoking the Statement that "because COVID-19 no longer presents the same level of threat to public health, and no longer requires Council to advocate for such a strong supportive stance towards COVID-19 vaccination (and the profession's role in this)".

[80] Ms Hansen submits the omission of a reference to the informed consent standard in the Guidance Statement is intended to dissuade doctors from discussing risks and to not do a full risk-benefit assessment for the patient, which compromises and nullifies true informed consent.

[81] Mr Mount argues that the Guidance Statement was consistent with the Code of Rights. He says that right 6 (right to be fully informed) imposes a duty on health practitioners to take reasonable care to ensure that the patient is aware of any material risks involved in any recommended treatment and of any reasonable alternative or variant treatments. Mr Mount refers to Professor McMillan's affidavit evidence that the reference to "evidence-based information" in the Guidance Statement is not limited to benefits, but includes risks, particularly those which would be material to a particular patient and which a health practitioner would be under a duty to disclose. Mr Mount states that the Guidance Statement implied a professional responsibility to inform about material risks as well as benefits and did not require practitioners to withhold information.

[82] Ms Weir submits that since the Code of Rights simply establishes rights for health consumers and duties on health service providers and is not intended to aid courts in the interpretation of legislation or impose limits on policy or decision-makers, if the Guidance Statement was inconsistent with the Code of Rights, this would not of itself mean the Councils had acted ultra vires.

[83] Ms Weir asserts that the reference to Right 6 in the Guidance Statement simply draws attention to the core right to receive information and does not purport to prevent or restrict practitioners from disclosing any risks about the vaccine. Ms Weir says the Dental Council does not resile from the objective of the Guidance Statement being to promote the vaccine and its benefits, but analysis of the Guidance Statement needs to consider the risks that were known about the vaccine at the time the Statement was published.

[84] By reference to Dr Petousis-Harris' affidavit evidence, Ms Weir states that the risk of myocarditis from the vaccine was not known in late April 2021, with the earliest time the risk of myocarditis should have been disclosed being following the Medsafe alert on 21 July 2021. Ms Weir consequently submits that there was no known risk of the COVID-19 vaccine that was sufficiently significant that it could be said the Dental Council committed an error of law in the wording of the Guidance Statement.

Discussion

[85] The Code of Rights was introduced under the Health and Disability Commissioner (Code of Health and Disability Services Consumers' Rights) Regulations 1996. The Regulations provide that every consumer has the rights set out in the Code, that every provider is subject to the duties in the Code, and that every provider must take action to inform consumers of their rights and enable them to exercise those rights.[23]

[86] Right 6 of the Code of Rights provides the following:

> *Right to be fully informed*

[23] Code of Rights Regulations, sch 1.

(1) Every consumer has the right to information that a reasonable consumer, in that consumer's circumstances, would expect to receive, including—

(a) an explanation of his or her condition; and

(b) an explanation of the options available, including an assessment of the expected risks, side effects, benefits, and costs of each option; and

(c) advice of the estimated time within which the services will be provided; and

(d) notification of any proposed participation in teaching or research, including whether the research requires and has received ethical approval; and

(e) any other information required by legal, professional, ethical and other relevant standards; and

(f) the results of tests; and

(g) the results of procedures.

(2) Before making a choice or giving consent, every consumer has the right to the information that a reasonable consumer, in that consumer's circumstances, needs to make an informed choice or give informed consent.

…

[87] The phrasing of Right 6(1) makes clear that the required range and depth of information to be provided varies depending on the circumstances but is to be assessed via an objective lens of what a reasonable consumer in those circumstances would expect to receive.[24]

[88] Right 7 of the Code of Rights states that:

Right to make an informed choice and give informed consent

(1) Services may be provided to a consumer only if that consumer makes an informed choice and gives informed consent, except where any enactment, or the common law, or any other provision of this Code provides otherwise.

(2) Every consumer must be presumed competent to make an informed choice and give informed consent, unless there are reasonable grounds for believing that the consumer is not competent.

…

(6) Where informed consent to a health care procedure is required, it must be in writing if—

(a) the consumer is to participate in any research; or

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[24] Peter Skegg "The Duty to Inform and Legally Effective Consent" in Peter Skegg and Ron Paterson (eds) *Health Law in New Zealand* (Thomson Reuters, Wellington, 2015) at [8.2.3(1)(b)].

(b) the procedure is experimental; or

(c) the consumer will be under general anaesthetic; or

(d) there is a significant risk of adverse effects on the consumer.

[89] I do not consider that the Guidance Statement was inconsistent with either of these rights. Express reference is made in the Statement to Right 6 of the Code of Rights. Although the Statement expressly notes discussing the benefits of the vaccine, this does not preclude practitioners from discussing any evidence-based risks of the vaccine either, given there is nothing in the Statement requiring only the benefits to be discussed. I agree with the opinion of Professor McMillan that given Right 6 is directly referred to in the Guidance Statement, and the Right provides that the information a consumer expects to receive includes "an assessment of the risks, side effects, benefits, and costs of each option", the Guidance Statement cannot be construed in the manner advanced by the applicants, namely to oblige doctors only to discuss the benefits of the vaccines.[25]

[90] I consider the lack of any reference to risks of the vaccine is due to the fact the primary risk in relation to the vaccine, namely myocarditis, had not yet become apparent at the time the Guidance Statement was issued. Although in her reply affidavit Dr Goodwin deposes that Dr Petousis-Harris had acknowledged in an interview in February 2024 that the risks of myocarditis were known in March or April 2021,[26] I accept Dr Petousis-Harris' evidence that at the time the Guidance Statement was issued concerns around myocarditis from COVID-19 vaccinations were only just emerging.[27] I also accept her evidence that the risk of myocarditis was far greater from COVID-19 than from the vaccine as at 2021.[28] Given this context, I do not consider that the failure to include reference to "risks" meant the Guidance Statement was inconsistent with the right to be fully informed under the Code of Rights.

[91] It is clear the Guidance Statement expresses an expectation that practitioners will not espouse anti-vaccination messages or promote anti-vaccination claims on social media. However, this does not mean it constrains practitioners from ensuring

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25 Affidavit of John Robert McMillan dated 17 June 2024 at [34] and [63]–[67].
26 Affidavit of Dr Alison Goodwin dated 16 July 2024 at [31]–[32].
27 Affidavit of Helen Aspasia Petousis-Harris dated 17 June 2024 at [15]–[18].
28 At [14].

their patients are fully informed. It merely says doctors should withhold personal anti-vaccination opinions. This is no breach of the right to information under Right 6.

[92] Given it did not prevent practitioners from ensuring their patients were fully informed, I reject the claim that the Guidance Statement was inconsistent with Right 7 of the Code of Rights.

[93] Irrespective of whether there were inconsistencies between the wording of the Guidance Statement and the Rights set out in the Code of Rights, I accept the submission of Ms Weir that this does not mean that by issuing the Guidance Statement the respondents were acting ultra vires. The Code of Rights is directed at providers to ensure the rights of consumers of health services are upheld. "Providers" is defined under the Code of Rights as meaning a health care or disability provider, and thus does not encompass responsible authorities like the Medical or Dental Councils.[29] The Code of Rights is not akin to a bill of rights imposing obligations on wielders of public power.

Did the Guidance Statement breach section 11 of NZBORA?

Submissions

[94] Ms Hansen submits that the purpose of the Guidance Statement was to operate as a de facto vaccine mandate for health practitioners and to constrain a patient's right to refuse medical treatment. This was due to the wording of the Statement that a doctor only had a valid reason to refuse vaccination if it was medically contraindicated, the fact the Guidance Statement arose in the context of setting a position on the requirement or otherwise for doctors and others to have the vaccine, that other groups were being mandated at the time, and that Dr Walker had said in an email at the time that he thought it was important for health practitioners to show leadership and advocate for and receive the vaccine when it was their turn.

[95] Ms Hansen submits that the Councils were required to turn their mind to and engage with the question of whether it was reasonable to limit the right to refuse

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[29] Code of Rights Regulations, sch 1(4).

medical treatment in the way the Guidance Statement purported to do and submits there is no evidence of this being considered. Ms Hansen argues that even if the Guidance Statement did not operate as a de facto vaccination mandate, it identifies medical contraindication as the only valid reason to refuse the vaccine. She also contends the Guidance Statement limited the patient's right to informed consent by requiring the benefits to be emphasised. She states neither Council have sought to justify the limitation, and that these limitations cannot be justified in a free and democratic society.

[96] Mr Mount submits that Medical Council members actively considered the impact the guidance statement could have on the rights of doctors before issuing the Statement, and says they robustly discussed the wording at the 13–14 April 2021 Council meeting and proposed several amendments. He states the majority view was that the statement appropriately balanced any limits on doctors' rights with the risks to public health posed by the pandemic, and that any limits in the circumstances were reasonable and justified.

[97] Mr Mount contends the Guidance Statement did not impose a requirement to be vaccinated and did not limit medical practitioners' section 11 right. He notes that for most the life of the Guidance Statement, such a limit was imposed by the vaccine mandate, which multiple decisions have found to have been a lawful and justified limitation on NZBORA. Mr Mount submits the Guidance Statement described a qualified "expectation" of the Medical Council which merely restated an existing ethical obligation. He argues a medical practitioner remained entitled to refuse the COVID-19 vaccine, and any consequences for doing so did not derive from the Guidance Statement. Since it did not impose a requirement to be vaccinated, Mr Mount submits it did not breach a medical practitioner's right to refuse medical treatment.

[98] Mr Mount states any such limit to s 11 was justified because it flowed from an applicable ethical duty. He submits that the objective of promoting public health and safety during the COVID-19 pandemic was of sufficient importance to justify any limitation on the right to refuse medical treatment and that there was a rational connection between the expectation for practitioners to be vaccinated and this

objective. He also argues that the expectation was no more than reasonably necessary to achieve the objective, and it was proportional given any intrusion on s 11 rights was relatively minor.

[99] Ms Weir states that, as made clear in Ms MacKay's evidence, the Dental Council was alive to the need to balance competing rights and interests, as shown in Ms MacKay's email where she described the issue as "tricky question as human right vs public safety". Ms Weir states the intent of the Guidance Statement was to promote the uptake of vaccination among oral health practitioners unless it was medically contraindicated. She argues the Dental Council was aware it could not require practitioners to be vaccinated, and refers to a letter sent to the New Zealand Dental Association on 13 May 2021 in which the Dental Council stated it did not intend to impose conditions on practitioners who decline vaccination or whose staff decline vaccination. Ms Weir states the word "expectation" did not represent a mandatory requirement but rather was equated with "strong encouragement".

Discussion

[100] I do not accept Ms Hansen's argument that there is no evidence to suggest the respondents turned their minds to whether the Guidance Statement would interfere with the rights of practitioners, particularly the right to refuse medical treatment. Consideration of the rights implications of the Statement is apparent from the moment the Statement was first proposed, given Ms MacKay's email to the various heads of responsible authorities where she stated setting a position on a requirement for practitioners to have the vaccine raised a "tricky question" around "human right vs public safety". The subsequent amendments to the draft Statement also confirm that these concerns continued to be considered during the finalising of the Guidance Statement. In particular, a reference to practitioners encouraging staff to get vaccinated was removed from a draft version of the Statement in recognition of the impact this could have on the right to refuse medical treatment.[30]

[101] It is also clear that the Guidance Statement did not require practitioners to be vaccinated, but rather merely encouraged vaccination in line with pre-existing ethical

[30] Affidavit of Marie MacKay dated 17 June 2024 at [46.1].

obligations. This is reflected in the wording of the Statement where it was stated health practitioners "can" rather than "must" help to protect themselves, their patients and the wider community by getting vaccinated, and that the respondents had an "expectation" that all practitioners will take up the opportunity to be vaccinated unless medically contraindicated. This is not mandatory language. The fact the Guidance Statement does not implement a vaccination mandate is evident from the Dental Council's email responses to queries from oral health practitioners at the time, in which the Council explicitly stated "there is currently no mandatory vaccine requirement" and that "vaccination is a choice".[31]

[102] Even if the Guidance Statement did impose a requirement to be vaccinated, such a breach of the right to refuse medical treatment would be a justified limitation on the right under s 11. In *NZDSOS v Minister for COVID-19 Response,* this Court reaffirmed that s 11 was not an absolute right, and held that the vaccine mandate on the health sector was a justified limitation on the right as it protected health sector workers from serious illness and materially reduced rates of community transmission.[32] I consider the same reasoning would apply in this case. I therefore find the Guidance Statement did not breach s 11 of NZBORA.

Did the Guidance Statement breach section 14 of NZBORA?

Submissions

[103] Ms Hansen submits that the Guidance Statement places a number of limits on the right to freedom of expression. This included deliberately omitting the words "and express" from the phrase "as regulators we respect an individual's right to have and express their own opinions" and prohibiting anti-vaccination messages without defining what that expression meant and the scope of the limitation.

[104] Ms Hansen states, as with the prior ground of review, there is no evidence that the Medical and Dental Councils considered the impact of the Guidance Statement on the right to freedom of expression, and thus failed to take into account a mandatory relevant consideration. She further submits that "anti-vaccination" did not at the time

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31 Exhibit MM23 appended to the Affidavit of Marie MacKay dated 17 June 2024.
32 *NZDSOS v Minister for COVID-19* [2022] NZHC 716, (2022) 13 HRNZ 296 at [131]–[132].

mean "holding a personal view against vaccination" as the Medical Council have claimed in their affidavits. She states if that had been the case, it would have been very simple to communicate that to Dr Goodwin and NZDSOS when they questioned the scope and intent of the Guidance Statement.

[105] Mr Mount submits that the Medical Council did in fact consider practitioners' freedom of expression when deciding to issue the Guidance Statement. He states this is reflected in wording like "as regulators we respect an individual's right to have their own opinion". Rather than precluding practitioners from having a scientific debate on the vaccine, he says it instead restated the ethical obligation to provide evidence-based information to patients. Mr Mount acknowledges the deletion of "and express" and refers to Dr Walker's evidence in which he explains the Medical Council considered the impact this might have on individual practitioner[s]' ability to express their own views, and decided that the risk to the public from anti-vaccination messaging meant that a limit on this right was justified.

[106] Mr Mount submits any such limits on practitioners' ability to express their opinions were justified, for the same reasons he advanced in respect of s 11 of NZBORA. He stated that overall, requiring a medical practitioner to express their opinion in accordance with professional standards, including a requirement that opinions are expressed in a balanced, evidence-based and professional way, is a justified limitation on the right to freedom of expression. Mr Mount emphasises this is especially so within the context of a public health response, where the potential for harm is greater.

[107] Ms Weir refers to the evidence of Ms MacKay as confirming that s 14 of NZBORA was considered by the Dental Council when it approved the Guidance Statement. She states this was evidenced by the deletion of "and express", and refers to Ms MacKay's reason for this deletion, namely that "although oral health practitioners were entitled to hold their own opinions, it was the Dental Council's view that there was no place for anti-vaccination messaging in professional health practice".

Discussion

[108] As with the right to refuse medical treatment, I consider the respondents did turn their minds to whether the Guidance Statement contravened s 14 of NZBORA. This is clear from the removal of the reference to "and express" from the initial draft version of the Statement. However, it is conceded by counsel for the respondents that the Guidance Statement does to a degree limit practitioner's freedom of expression by stating there is no place for anti-vaccination messaging in professional health practice nor any promotion of anti-vaccination claims including on social media or advertising.

[109] The right to freedom of expression is also not an absolute right, and limits on the right have frequently been found to be justified under s 5 of NZBORA. The provision from which s 14 of NZBORA takes its inspiration, namely art 19.3 of the 1966 International Covenant on Civil and Political Rights (ICCPR), provides that free expression can be limited where such limits are necessary to respect the rights and reputations of others or to protect national security, public order, or public health and morals.[33]

[110] To determine whether a limit is justified under s 5, the approach set out by Tipping J in *R v Hansen* is to be applied. This requires the court to determine:[34]

(a) whether the limiting measure serves a purpose sufficiently important to justify the limitation of the right; and

(b) whether the means chosen to achieve that objective are proportionate, in that the limiting measure is rationally connected with its purpose, impairs the right no more than reasonably necessary or sufficient to achieve that purpose, and is in due proportion to the importance of the objective.

[111] I do not accept Ms Hansen's submission that the purpose of the limits placed by the Guidance Statement on practitioners' freedom of expression was to ban doctors communicating any dissenting views on vaccination and prevent anything other than

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33 1966 International Covenant on Civil and Political Rights, art 19(3).
34 *R v Hansen* [2007] NZSC 7, [2007] 3 NZLR 1 at [64].

pro-vaccination messaging. The Guidance Statement sought to prevent anti-vaccine misinformation from being disseminated by practitioners. This served the purpose of promoting public health and safety during a global health crisis, which is evidently a sufficiently important objective as noted by the ICCPR.

[112] I also consider the means to achieve the objective were proportionate. There was a rational connection between promoting public health and safety during the pandemic and discouraging practitioners from disseminating anti-vaccination claims. By limiting their freedom of expression, the respondents were maintaining confidence in the efficacy of the vaccine, which meant more people would be willing to be vaccinated and thus provide better protection against a COVID-19 infection and slow the spread of the virus. As noted in the affidavit of Professor John McMillan,[35] vaccine hesitancy was a major challenge for the public health response to COVID-19 and was linked to vaccine misinformation. The Guidance Statement sought to address this problem by clarifying the obligations on practitioners to not allow personal anti-vaccination views to influence advice to patients.

[113] I also accept Mr Mount's submission that the Guidance Statement infringed s 14 no more than necessary. As previously discussed, the Guidance Statement did not prevent practitioners from discussing any risks in respect of the vaccine. It merely restricted practitioners from making anti-vaccination claims in respect of the COVID-19 vaccine.

[114] Overall, the limitation was proportionate, given the intrusion on practitioners' rights was relatively limited and the importance of protecting public health and safety. It must be correct that reasonable limitations on a person's freedom of expression imposed by their professional obligations will very rarely amount to an unjustified limitation on s 14. I consider that the findings in *Orlov v New Zealand Law Society* are relevant, namely that professionals (in that case legal counsel) must conduct themselves whilst undertaking their profession so as to meet their obligations, and that NZBORA must be read in light of the duties on such professionals.[36]

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35 Affidavit of Professor John Robert McMillan dated 17 June 2024 at [47]–[50].
36 *Orlov v New Zealand Law Society* [2013] NZCA 230, [2013] 2 NZLR 562 at [77].

[115] The Guidance Statement therefore was not in breach of s 14 of NZBORA.

Was the Guidance Statement issued for an improper purpose?

Submissions

[116] Ms Hansen submits that the purpose of the Guidance Statement is to censor medical and dental practitioners and prohibit them from expressing any views to their patients or publicly about any risks of the COVID-19 vaccine, as well as prohibit the practice of any theory of medicine or healing inconsistent with the requirements of the Guidance Statement. She argues the clear expectation of the Medical Council was that doctors would advocate for and promote the vaccine by focusing on the benefits and by not focusing on alternative options such as natural immunity, no vaccination, or other treatments. Ms Hansen submits that these purposes are not within the contemplation of the HPCAA and thus are improper purposes.

[117] Mr Mount submits that the evidence does not support Ms Hansen's submissions. He states the purpose of the Guidance Statement was to promote public health and safety by reminding practitioners of their existing ethical and professional obligations in the context of the vaccine, and to mitigate the risks of misinformation through anti-vaccination claims and messages. He states while it is not accepted that there was any requirement for the Guidance Statement to comply with the theory of medicine defence, the Guidance Statement nonetheless encouraged practitioners to share evidence-based advice and information and did not prohibit the practice of any theory of medicine or healing.

Discussion

[118] For reasons canvassed above, the Guidance Statement was not issued for an improper purpose. The Statement did not prohibit practitioners from expressing any views on any risks of the COVID-19 vaccine. As made clear in the early communications between the heads of the responsible authorities, and in the affidavit evidence of Ms MacKay and Dr Walker, the Guidance Statement was intended to be "a strong message to encourage practitioners to maintain and protect their own health by getting vaccinated, and by extension, to protect the…health workforce and the

community as a whole"[37] as well as promote competent practice by restating and emphasising existing obligations in the context of the pandemic and the emergence of an effective vaccine.[38]

[119] Such purposes are clearly in line with the principal purpose of the HPCAA, which is to protect the health and safety of members of the public by providing mechanisms to ensure that health practitioners are competent and fit to practice their professions. It also aligns with the functions of responsible authorities to promote the competence of health practitioners, and with existing ethical obligations under the standards issued by the respondents.

Did the Medical Council unlawfully rely on the RNZCGP and Medsafe statements to refer practitioners who prescribed Ivermectin to Professional Conduct Committees?

Submissions

[120] Ms Hansen refers to s 25 of the Medicines Act 1981 which she states allows a health practitioner to use an approved medicine for an unapproved use (sometimes referred to as off-label prescribing), and paragraph 15 of *Good Prescribing Practice* which she argues confirms a medical practitioner may prescribe medicines for an unapproved use provided it is not outside their scope of practice, and informed consent is obtained. Ms Hansen contends it follows that a practitioner does not act unlawfully or unethically by prescribing Ivermectin for another purpose, including for the prevention or treatment of COVID-19 provided they obtain informed consent and comply with the Code of Rights.

[121] Ms Hansen submits that the Medical Council adopted a policy position, on the basis of statements from the RNZCGP and Medsafe in September 2021, that prescribing Ivermectin would not be considered as an evidence-based treatment, and that those who prescribed it for COVID-19 were a threat to patient safety and needed to be referred to Professional Conduct Committees. She states that the Medical Council's position that medical practitioners must only share information that is

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37 Affidavit of Marie MacKay dated 17 June 2024 at [41].
38 Affidavit of Dr Curtis James Walker dated 18 June 2024 at [22].

factual, scientifically grounded and consensus driven for the betterment of public health fails to recognise practitioners' broad powers to prescribe which can be divergent from best practice but still "within the range of reasonable clinical decisions".

[122] Ms Hansen argues that off-label usage of medications may be within the range of reasonable clinical decision-making, rather than comprising an experimental treatment, where there is a body of evidence that supports the treatment or procedure being safe and efficacious. She states that since the Medical Council had not exercised its power under s 48 of the Medicines Act to restrict practitioners from prescribing Ivermectin, medical practitioners remain the decision-maker for prescribing. She contends it is not the place of the Medical Council to decide that one study should be give greater weight than another.

[123] Mr Mount submits that the evidence does not support NZDSOS's arguments or proposed declarations. He refers to the evidence of Matthew Doogue regarding Ivermectin which included that, in March 2021 the WHO, FDA and the European Medicines Agency all advised against the use of Ivermectin for the prevention or treatment of COVID-19 outside of clinical trials, that in October 2021 journalists had exposed errors and fraud in studies on Ivermectin, and that by the time of the Medsafe and RNZCGP's guidance, the science was settled and prescribing Ivermectin for COVID-19 was not consistent with *Good Prescribing Practice*.

[124] Mr Mount states the Medical Council did not have a fixed policy or predetermined view that deemed all those practitioners who prescribed Ivermectin for COVID-19 as a threat to patient safety and should be referred to disciplinary action. He notes Dr Walker's evidence that there were some cases where the Medical Council considered concerns regarding the prescribing of Ivermectin but did not refer them to a Professional Conduct Committee. Mr Mount further submits there was nothing improper about the Medical Council taking into account the Medsafe and RNZCGP guidance on Ivermectin.

Discussion

[125] Section 68 of the HPCAA provides that if a responsible authority considers that information in its possession raises one or more questions about the appropriateness of the conduct or the safety of the practice of a health practitioner, it may refer the information and any or all of those questions to a professional conduct committee (PCC). These PCC's then investigate these concerns, and if they have reason to believe the practitioner's practice poses a risk of serious harm to the public, they must notify the responsible authority of that belief and the reasons for it, and if they consider it justified, suspend the practitioner's practicing certificate.[39]

[126] It is common ground that Ivermectin is an approved medicine. However, it is not currently, and was not during the relevant period, approved for treating COVID-19.

[127] *Good Prescribing Practice* sets out the guidelines around prescribing medicine, including unapproved medicine.[40] Paragraph 15 of *Good Prescribing Practice* provides that practitioners may prescribe medicines for a purpose for which they have no been approved, and refers to s 25 of the Medicines Act 1981 which allows authorised prescribers to use any medicines for the treatment of a patient in their care. However, the paragraph also states that practitioners must not prescribe medicines for an unapproved use if it is outside their scope of practice, and that they should discuss medicines for an unapproved use with a senior colleague before prescribing them.

[128] In her evidence Dr Goodwin deposed that there was evidence in 2021 of the effectiveness of Ivermectin in treating COVID-19, including from a former World Health Organisation (WHO) medicine researcher, Dr Tess Lawrie.[41] She argues practitioners had the authority to prescribe a safe, long-established, low risk medicine off-label if appropriate in their professional clinical judgment.[42]

[129] In contrast, Dr Doogue deposes in his affidavit that although Ivermectin is effective in treating parasitic diseases, when taken in high doses as often occurred for

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39 HPCAA, s 79.
40 Medical Council of New Zealand *Good Prescribing Practice* (February 2024).
41 Reply Affidavit of Dr Alison Goodwin dated 17 July 2024 at [47].
42 At [49].

people using it to treat COVID-19, it can cause neurotoxicity and gastrointestinal adverse effects.[43] He also notes that in March 2021 the WHO, the FDA and the EMA had all advised against the use of Ivermectin for COVID-19, and that well-designed and adequately powered randomised controlled trials confirmed no beneficial effect for the treatment of COVID-19.[44]

[130] Having examined their competing evidence, I consider that there is greater support for the notion Ivermectin was not a viable treatment for COVID-19. Consequently, it was reasonable for Medsafe and RNZCGP to issue their statements strongly recommending that Ivermectin not be used for the treatment of COVID-19.

[131] Given this finding, I do not consider that Medical Council unlawfully relied on the statements from Medsafe and RNZCGP to refer practitioners who prescribed Ivermectin to PCCs. As is clear from the wording of s 68 of the HPCAA, the threshold for referring information on a practitioner to the PCC is low. The information need only raise concerns around the appropriateness of that practitioner's conduct or the safety of their practice.

[132] As raised in Dr Doogue's evidence, prescription of a medicine that has been strongly recommended not to be used to treat or prevent COVID-19, and which lacks strong evidential support in being an effective treatment, would be contrary to *Good Medical Practice* standards which require practitioners to provide effective treatments based on the best available science.[45] The statements from Medsafe and RNZCGP were therefore highly relevant to considering whether a referral should be made, particularly given Medsafe is the statutory body responsible for administering the Medicines Act 1981. Although the prescribing of Ivermectin to treat COVID-19 had not been restricted by the Medical Council under s 48 of the Medicines Act, there were still clear grounds for a referral where such a prescription was made.

[133] I do not accept the submission that the Medical Council rigidly treated prescribing Ivermectin in a COVID-19 context as incompatible with the safe practice

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43 Affidavit of Dr Matthew Doogue dated 12 July 2024 at [51] and [53].
44 At [54]–[62].
45 At [75] referring to *Good Medical Practice,* above n 10, at [3].

of medicine. As stated in Dr Walker's evidence, not all practitioners alleged to have prescribed Ivermectin for COVID-19 were referred to PCCs.[46] I do not consider there is sufficient evidence to suggest the referrals to the PCCs were unlawful.

[134] In respect of the declaration sought in the event this Court found the referrals had been unlawful, this is evidently not the kind of declaration that would be appropriate for the Court to make. It would amount to an intrusion on the role of the Health Practitioners Disciplinary Tribunal in determining what amounts to professional misconduct, and it is so broadly worded that it would amount to a significant expansion of the discretion of practitioners in a manner that would contradict existing ethical and competence standards issued by the Medical Council.

Outcome

[135] For the reasons detailed above, the Guidance Statement is neither ultra vires, in breach of NZBORA, nor issued for an improper purpose. The Medical Council also did not act unlawfully in relying on the statements of Medsafe and RNZCGP to refer practitioners prescribing Ivermectin to PCCs.

[136] As a result, the application for judicial review is declined.

[137] I invite the parties to agree to costs. However, if that is not possible the respondents are to file and serve their applications within 14 days of the date of this judgment, with the applicant to have 14 days after service to file and serve their reply. I will then deal with the matter on the papers.

Churchman J

Solicitors:
Maxwell Law, Wellington for applicant
Dentons Kensington Swan, Wellington for First Respondent
Dentons, Auckland for Second Respondent

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[46] Affidavit of Dr Curtis Walker dated 18 June 2024 at [65].