Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

A Decision by the Deputy Health and Disability Commissioner

(Case 21HDC02881)

1. This report is the opinion of Deborah James, Deputy Health and Disability Commissioner. It relates to a complaint from Ms M about care provided by Dr N, a doctor working in general practice.

2. Ms M raised concerns that Dr N inappropriately issued a number of medical certificates for exemption from COVID-19 vaccination in late 2021, while she was providing voluntary medical services at a community clinic (the clinic).

3. The following issue was identified for investigation:

- *Whether Dr N acted appropriately when issuing Covid-19 vaccination exemption medical certificates to patients at the clinic between September 2021 and November 2021 (inclusive).*

4. This report sets out the Deputy Commissioner's opinion on Ms M's complaint about Dr N's actions.

5. In-house clinical advice was obtained from Dr David Maplesden, a general practitioner (Appendix A).

Information gathered during investigation

Background

6. The clinic is a nurse-led, community medical clinic that provides casual and urgent care. The clinic does not enrol patients or offer GP services, as it does not receive funding from Health New Zealand | Te Whatu Ora. Ms M is the Clinical Services Manager.

Names have been removed to protect privacy (except the advisor). Identifying letters are assigned in alphabetical order and bear no relationship to the person's actual name.

7. The events took place in October and November 2021, during the COVID-19 pandemic.

8. Ms M told HDC that Dr N[1] started volunteering at the clinic in September 2021, after offering to provide a weekly four-hour medical clinic and telephone support and consultations. Ms M said she was happy to have the services of a doctor who could prescribe medications or order X-rays if needed.

9. Dr N told HDC that she volunteered to provide medical services at the clinic as there was a lack of local doctors available to support the centre and she wanted to help the clinic to grow.[2] Dr N said that Ms M and the clinic receptionist scheduled patient appointments for her clinics, and she had very little input into that process.

10. Ms M said that Dr N's first weekly clinic took place on Wednesday 15 September, and clinics then occurred weekly until Wednesday 6 October. Further clinics took place on Wednesday 20 and Wednesday 27 October and Saturday 6 November, with the final clinic on Wednesday 10 November.

11. Ms M told HDC that she asked Dr N to conclude her voluntary work at the clinic on 12 November. Ms M said that Dr N was unvaccinated against COVID-19, and it had become apparent that she did not intend to be vaccinated. As a result, Dr N would not be compliant with the legislation at the time, which required health practitioners to be vaccinated by no later than 15 November in order to see patients in person (see paragraph 13).

12. Ms M later made a complaint to HDC about medical certificates issued by Dr N during her voluntary clinics. Ms M raised concerns that Dr N had inappropriately provided 12 patients with medical certificates for exemption from COVID-19 vaccination (the medical certificates). Ms M submitted that Dr N may also have encouraged people who wanted a medical certificate to exempt them from receiving the COVID-19 vaccine (the vaccine) to book into her clinics.

COVID-19 vaccine exemption — relevant legislation

13. The COVID-19 Public Health Response (Vaccinations) Order 2021 (the Order) required that 'affected persons' (certain workers defined in Schedule 2 of the Order)[3] could not carry out certain work unless they were vaccinated (referred to as a vaccine mandate).

14. From 14 July 2021, section 7A of the Order provided that if Dr N, as a health practitioner, determined that an affected person had certain needs that made it inappropriate for the person to be vaccinated, in some circumstances that person could use her advice by way of a medical certificate as an exemption from the vaccine requirements.

[1] At the time of events, Dr N was a registered doctor and had an annual practising certificate from the Medical Council of New Zealand. As at the date of this report, that remains the case. Dr B is not vocationally registered in general practice (vocational registration is a form of permanent, specialist registration).
[2] Dr B's offer came after she resigned from her long-standing role at a nearby practice. She worked her notice period full time until the end of September 2021, then continued part time/intermittently until the end of November 2021. Dr B retained access to the patient notes at the practice until 17 November 2021.
[3] The affected workers defined in Schedule 2 changed over time.

15. At 11.59pm on 7 November 2021, the Order was amended to introduce a new exemption application process. An affected person could only be granted a vaccine exemption on medical grounds by the Director-General of Health, on application from a suitably qualified medical or nurse practitioner.[4] Affected workers who were exempt prior to the law change would continue to be exempt for a transitional period until 21 November 2021 or the date on which they were notified that an exemption had not been granted to them under the new process, whichever was earlier.[5]

Criteria for vaccine exemption — available information

16. When the plan for the new exemption application process was announced at a press conference on 3 November 2021, the Director-General of Health, Dr Ashley Bloomfield, stated that the Ministry of Health (the Ministry) would issue the 'criteria under which people can apply' on its website. The official criteria were available online on 6 November 2021,[6] prior to the introduction of the new exemption application process. The criteria document stated: '[T]here are very few situations where a vaccine is contraindicated and, as such, a medical exemption is expected to be rarely required.' The following were formal criteria for exemption:[7]

1. All COVID-19 vaccines: a) confirmed COVID-19 infection; b) a serious adverse event to a previous dose of the same COVID-19 vaccine; c) inability to tolerate administration due to risk to self or others (for instance, a severe neurodevelopmental condition).
2. Pfizer vaccine: a) anaphylaxis (allergic reaction) to the first dose of the vaccine or known severe allergy to the excipients of the vaccine (inactive substances used in formulation of the vaccine); b) myocarditis/pericarditis following the first dose of the vaccine;[8] c) inflammatory cardiac illness within the past six months; d) acute decompensated heart failure.

17. Prior to the release of the official criteria, information about the factors that might permit an exemption was less organised. For instance, as of 29 October 2021, the Ministry's website stated that workers subject to a vaccine mandate 'may be exempt from the requirement to be vaccinated if, after examination: a suitably qualified health practitioner considers that the vaccination is clinically contraindicated for the person, and a suitably qualified health practitioner provides written confirmation of that assessment'.

18. Information about permitted exemptions was also set out in the Order. As at 29 October 2021, section 7A(2)(a) of the Order specified that an affected person may carry out certain work without being vaccinated if that person has 'particular physical or other needs that a

[4] Pursuant to section 9B of the Order.
[5] Pursuant to schedule 1, clause 10 of the Order.
[6] Ministry of Health, Vaccine Temporary Medical Exemption Clinical Criteria, Clinical Guidance and Resources, Version 1.0 FINAL, 6 November 2021.
[7] The criteria also included a third category for any person who had been confirmed as having received the trial vaccine in any COVID-19 vaccine trial in New Zealand.
[8] Respectively, inflammation of the heart muscle and inflammation of the lining around the heart.

suitably qualified health practitioner (in the course of examining the person) determines would make it inappropriate for the person to be vaccinated'.[9]

19. The Royal New Zealand College of General Practitioners (RNZCGP) advised its members, on 28 October 2021, that it had been working with the Immunisation Advisory Centre (IMAC) and the Ministry to establish exemption criteria and, from what it knew at that point, the following were likely to be exempt criteria: anaphylaxis to the first dose of the vaccine; known severe allergy to the excipients of the vaccine; acute decompensated heart failure; inflammatory cardiac illness within the past 6 months; myocarditis; pericarditis; endocarditis; acute rheumatic fever; and acute rheumatic heart disease.[10]

Medical certificates issued

20. Ms M provided HDC with 13 anonymised medical certificates (one patient was issued two certificates). All were dated between 1 and 10 November 2021. HDC obtained full copies of the medical certificates and the corresponding patient notes from the clinic for the purposes of the investigation, pursuant to section 62 of the Health and Disability Commissioner Act 1994 (the Act).[11]

21. It is unclear how many of the patients who received the certificates were 'affected persons' as defined in Schedule 2 of the Order at the time.[12] The available records show that at least two of the patients sought medical certificates for reasons other than being an affected person,[13] and indicate that other patients may have been similarly motivated.

22. The medical certificates, which were electronically signed by Dr N, state:

> 'As the undersigned health professional, I confirm that in the course of examining the above mentioned [patient], I have determined it would be medically inappropriate for above patient to receive the COVID-19 vaccination due to underlying health conditions.'

23. Eleven of the medical certificates, which were issued prior to the law change on 7 November,[14] also state: 'This determination is made pursuant to clause 7A, Covid Health Response (Vaccination) Amendment Order 2021 by me [Dr N] as a suitable qualified medical practitioner.'

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[9] For affected persons specified in Part 6 of Schedule 2 of the Order, their employer must also register confirmation that a suitably qualified health practitioner had examined the affected person and determined that vaccinating that person would be inappropriate.

[10] https://rnzcgp.informz.net/informzdataservice/onlineversion/pub/bWFpbGluZ0luc3RhbmNlSWQ9MjM3MjE4MQ==

[11] Section 62(1) states: 'The Commissioner may from time to time, by notice in writing, require any person who in the Commissioner's opinion is able to give information relating to any matter under investigation by the Commissioner to furnish such information, and to produce such documents or things in the possession or under the control of that person, as in the opinion of the Commissioner are relevant to the subject matter of the investigation.'

[12] Generally, it included people working in, or in relation to, quarantine or isolation facilities, airports, ports, airlines, the health and disability sector, prisons, and education.

[13] Patients C and G.

[14] All except Patient C's certificate and the second certificate issued to Patient B.

24. Ms M said that the clinic's practice management system (PMS) confirmed that the certificates were provided to the 12 patients either in person or by email. While each patient should have paid $20 for their certificate, Ms M said she found that Dr N had not raised invoices for the certificates on the PMS. Ms M said that invoices were created only where a consultation included other matters aside from vaccine exemption.

Patient consultations

25. The clinical records and dates of Dr N's consultations with the 12 patients who received medical certificates are summarised below, alongside Dr N's response to HDC about each consultation. The patients are referred to by letter and identifying details have been omitted to protect privacy.

Patient A — 6 November

26. Dr N's consultation notes state, in full: 'Assessed health as per scanned documents … mRNA Covid vaccine inappropriate, plan vaccine exemption …'

27. Dr N told HDC that Patient A was well known to her and had several significant medical conditions, including previous pericarditis. She said that Patient A was worried about the vaccine and 'losing rights' if unvaccinated. Dr N said that trials had not been performed in relation to Patient A's chronic diseases and therefore she could not assure Patient A that the vaccine carried no risks. Dr N said she considered that Patient A's concerns, opposition to vaccination, and the relative risks made it inappropriate for Patient A to receive the vaccine.

Patient B — 5 and 10 November

28. Patient B received two medical certificates from Dr N within five days. Both stated that it would be medically inappropriate for Patient B to receive the vaccine. The date of Dr N's available consultation notes is consistent with the date of Patient B's second medical certificate. The clinic was unable to find any notes in relation to Patient B's first medical certificate.

29. Dr N's consultation notes state that Patient B was known to her, and they had spoken several times the previous week. She noted that Patient B was 'very stressed due to bullying and pressure at work' and had to take time off. Patient B went back to work for a short time and Dr N documented: '[C]an't cope with pressure at work. Extended OWC [off work certificate] for 30 days.'

30. Dr N told HDC that Patient B was subjected to pressure about vaccination at work. Patient B had researched the vaccine and was 'concerned at the lack of mid–long term safety data' available. Dr N said the 'extent of stress described' made it inappropriate for Patient B to receive the vaccine.

Patient C — 10 November

31. Dr N's consultation notes state that Patient C had attended for a 'general check — very nervous and panicky, never suffered from anxiety before. Records available … insomnia, gets tearful.' In relation to the vaccine, Dr N said that Patient C was worried about a family

member's job security in the 'unjust political system', as well as information provided by Medsafe.

32. Dr N told HDC that Patient C had 'undertaken reading and did not feel assured about the vaccine's safety'. Patient C 'wanted a medical certificate to support [the] stance of not wanting to receive [the vaccine]'.

Patient D — 6 November

33. Dr N's consultation notes state, in full: '[M]edical history as per my notebook available on request.'

34. Dr N told HDC that Patient D's mental health had deteriorated since vaccine mandates were introduced, resulting in difficulty sleeping and panic attacks. She said that Patient D had personally researched the vaccine and believed it carried risks. Dr N stated:

> '[B]ased on the patient's presentation and clear distress, [I] considered it justified to provide a medical certificate [and] stated it would be bad for [Patient D's] health to receive the COVID-19 vaccine.'

35. Dr N provided HDC with a copy of handwritten notes relating to Patient D's consultation that she said she had recorded in her notebook rather than the PMS (Appendix B). Dr N stated:

> '[Patient D] felt deeply that the pressure around COVID-19 requirements was impacting on their mental health. The discussions were sensitive, and [Patient D was] very worried about who would have access to their health information. [Patient D] wanted it protected.'

Patient E — 6 November

36. Dr N's notes record Patient E's medical history and medications and the medical history of Patient E's extended family. Dr N concluded: '[I]mp[ression]: as above + mRNA vaccination inappropriate … vaccine exemption.'

37. Dr N told HDC that Patient E was known to her, and had significant medical conditions personally, and within the family, which caused Patient E to be concerned about receiving the vaccine. Dr N stated that she 'could not report conclusively that there was no risk', as no clinical trials were available to show that the mRNA vaccine was safe for people with the same conditions as Patient E. Dr N said she concluded that a medical certificate was appropriate for multiple reasons.

Patient F — 6 November

38. Dr N's consultation notes state, in full: '[N]otes in my notebook, will transfer once I have spare time.'

39. Dr N told HDC that she is sorry she had forgotten to transpose her notes of Patient F's consultation from her notebook into the PMS. She provided HDC with a copy of handwritten notes relating to Patient F's consultation (Appendix B). Dr N said that Patient F was known to her. Patient F had injuries from a previous accident, and stress and lack of sleep due to

concerns about the vaccine were exacerbating those injuries. In addition, Patient F felt the vaccine was experimental. Dr N said she could not assure Patient F that the vaccine carried no risks, as trials had not been conducted into the effect of the vaccine on people with the same injuries as Patient F. Dr N said she considered that Patient F's health circumstances, especially stress, made it inappropriate for Patient F to receive the vaccine.

Patient G — 6 November

40. Dr N's consultation notes state, in full: '[I]n depth medical [history] known to me available on request.'

41. Dr N told HDC that Patient G was known to her and had both medical and mental health issues at the time. Patient G wanted a medical certificate 'for protection and for documentation'. Dr N said she could not assure Patient G that there were no risks, as trials had not been conducted into the vaccine's safety for people with both Patient G's conditions. Dr N therefore considered that a medical certificate was appropriate.

Patient H — 6 November

42. Dr N's consultation notes state, in full: '[M]edical [history] recorded in notebook available on request.'

43. Dr N told HDC that in addition to a health condition, Patient H had time off work and serious mental health issues because of the mandates. Patient H was 'very well informed about the lack of mid–long term safety data of the mRNA vaccine [and was affected] by [the] prospect of being compelled to receive [the] vaccine'. Dr N said that the symptoms of stress were clear, and she felt that it was clinically appropriate to issue a certificate 'supporting [Patient H's] decision not to receive vaccination due to health'.

44. Dr N provided HDC with a copy of handwritten notes relating to Patient H's consultation (Appendix B). On having recorded the notes in her notebook rather than the PMS, Dr N said:

> '[Patient H] felt deeply that the pressure around COVID-19 requirements was impacting on their mental health. The discussions were sensitive, and [Patient H was] very worried about who would have access to their health information. [Patient H] wanted it protected.'

Patient I — 6 November

45. Dr N's consultation notes state that Patient I wanted to 'look into vaccine exemption'. She noted a history of ischaemic heart disease[15] and renal problems and recorded the medication Patient I was taking. Dr N concluded: 'Imp[ression]: mRNA Covid-19 vaccination inappropriate. Plan vaccine exemption.'

46. Dr N told HDC that Patient I was faced with having to decide whether to be vaccinated. However, with a history of cardiac problems, Patient I was concerned about the general risks of the vaccine, and how it might interact with cardiac medication. Dr N said that new

[15] Narrowing of the major blood vessels in the heart, which decreases the supply of blood and oxygen to the heart, reducing its ability to function properly.

evidence about the risk and growing incidence of certain cardiac conditions was emerging. She could not assure Patient I that there was no risk, as no trials had been undertaken about the vaccine's safety for people with cardiac history. She said that a medical certificate was appropriate.

Patient J — 6 November

47. Dr N's consultation notes set out Patient J's medical history and that of Patient J's extended family. She noted that Patient J had 'reactive anxiety sec[ondary] to current political situation and mandates'. Further, Patient J had 'significant worries' since receiving Medsafe advice on a previous matter and 'would like to discuss vaccine exemption'. Dr N recorded: 'mRNA[16] vaccination inappropriate, plan vaccine exemption, adv[ised] re new changes (2nd change of legislation within 2 weeks …).'

48. Dr N told HDC that Patient J also had worsening mental health. She could not resolve Patient J's concerns about the risk of the vaccine, as research had not been performed with patients with the same conditions or family history as Patient J.

Patient K — 6 November

49. Dr N's consultation notes state, in full: '[M]edical [history] as per scanned documents, Imp[ression]: mRNA COVID-19 vaccination inappropriate, Plan: vaccine exemption.'

50. Dr N told HDC that Patient K was well known to her and had requested a medical certificate due to fears about the effect the vaccine would have on Patient K's specific health conditions. Dr N said that she 'could not provide total assurance of no risk' to Patient K from the vaccine, as no relevant studies had been conducted. She therefore considered that a medical certificate was appropriate for Patient K.

Patient L — 1 November (consultation 27 October)

51. Dr N's consultation notes state that Patient L had a history of injury and a mental health disorder. Patient L reported concerns about the potential side effects of the vaccine on the nervous system and had nightmares about it. Dr N documented: '[A]gree that due to [medical history] ... should be exempt from COVID vaccination.'

52. Dr N told HDC that she was familiar with Patient L, whose mental health was worsening due to fears that vaccination might be required in order to work. Dr N said she could not resolve Patient L's concerns about the vaccine, as research had not been done with patients with the same medical issues as Patient L.

Further information — Dr N

53. Dr N said that she informed the patients whose medical certificates were issued in the first week of November that their certificates 'issued under 7A would become invalid and a new application would need to be made to the Ministry of Health'. She stated:

[16] Messenger ribonucleic acid (mRNA) vaccines are one of the main types of vaccine used to prevent COVID-19 infection.

> 'I perceived that they understood this but wanted the exemption certificates regardless — most often to support discussions with employers about negotiating alternate working arrangements.'

54. Similarly, Dr N said she informed Patients B and C that the medical certificates she issued to them on 10 November were 'not exemptions with any legal force'.

55. Dr N told HDC that she did not encourage or proactively seek out patients who wanted medical certificates, nor did she give patients an 'anti-vax' message. She said she is not against vaccination. Dr N stated:

> '[T]he patients in question had made their own individual decisions not to receive the vaccine. I felt my role was to address their presenting concern/request, which was a desire for a certificate that would support their decision not to be vaccinated at the time.'

56. Dr N further stated:

> 'The patients sought medical certificates for reasons relating to their mental health and/or concerns relating to physical conditions. Many felt great distress at the pressure to be vaccinated, where they harboured concern about the extent of data available on the vaccine and potential effects of it. Many were concerned that there was a lack of information on possible effects of the vaccine on various health conditions — some were worried the vaccine would exacerbate symptoms or create new ones. In my discussions with some of the patients, I could not provide them the extent of reassurance they needed that the vaccine would not put them at risk, where particular studies had not taken place or there was a lack of conclusive evidence. For many it was clear to me that their mental wellbeing at the prospect of being vaccinated made it inappropriate for them to be vaccinated.'

57. Dr N said that she was familiar with five of the 12 patients already and had previously provided care to two of them at her former medical practice. She considered that her 'prior knowledge of them — their personalities and health histories etc — placed [her] in a good position to trust/understand any negative impacts they reported feeling in respect of the vaccine'.

58. Dr N stated:

> '[M]y usual practice [is] to make clinical decisions based on the clinical details available — so consideration of simply the notes arising from the consultations in question alone may provide an artificial view of the information-base I was working with.'

59. Dr N said that her clinical notes indicated that she had reviewed documents on the clinic's PMS about patients' prior attendances or medical histories and she still had access to the PMS at her former medical practice at that time.

Further information — Medical Council of New Zealand (MCNZ)

60. In 2023, in relation to unrelated concerns about Dr N's practice, the MCNZ resolved that Dr N was required to undergo a performance assessment under section 36 of the Health Practitioners Competence Assurance Act 2003. Interim conditions were also proposed on Dr N's scope of practice. Dr N agreed to sign a Voluntary Undertaking (VU)[17] with the same effect and monitoring protocol as the conditions.

61. The MCNZ said that performance assessment reviews are conducted by a performance assessment committee (PAC) of two peers and a lay member. It is not a disciplinary process. Rather, the PAC assessment aims to ensure that a doctor is practising at the required standard in six domains of competence: medical care, communication, collaboration, management, scholarship, and professionalism.

62. Dr N's VU was revoked in 2024 on the basis that there were no ongoing concerns in that respect. The MCNZ told HDC that Dr N is not currently practising under supervision. The PAC completed its assessment of Dr N in June 2024, via in-person and remote assessments. The MCNZ said the PAC found that Dr N 'met the required standard of competence in some but not all areas for a doctor registered in a general scope working in general practice'. Concerns were identified in relation to several specific aspects of Dr N's practice. The MCNZ said that it would consider the outcome of her performance assessment in October 2024.

Responses to provisional opinion

Ms M

63. The section of the provisional opinion that comprised the information gathered during the investigation was shared with Ms M for comment. Ms M did not provide a response to HDC.

Dr N

64. The provisional opinion was shared with Dr N, and she was invited to comment on it. Dr N raised the following points in response:

- The medical certificates she issued must be understood in the context of the knowledge, the uncertainty, and the unique and unprecedented challenges that existed during the COVID-19 pandemic, rather than what exists now. Dr N considers that she adhered to her 'professional expectations, obligations and legal requirements as a doctor' in providing the certificates, and the opinions on the certificates 'in no way' suggested that a legal vaccination exemption was being provided.
- She was not trying to 'scaremonger' the patients, but felt she had an obligation to fully inform them of the side effects of the COVID-19 vaccine. Dr N said that it would have been 'misleading and false to claim that safety was present when actively questioned by a patient', as there was no safety data available for any person with a pre-existing medical condition.
- Dr N was concerned about 'taking the advice of government at face value'. She said the adverse effects of the vaccines were not widely disseminated by the New Zealand

[17] An agreement between the MCNZ and a doctor about how the doctor will practise medicine.

media, and a medical journal article suggested that trials were not intended to show whether the vaccines reduced COVID-19-related deaths or serious outcomes.

- A doctor should never be required to coerce a person to have a medical procedure they do not want, and it is clinically inappropriate to administer such a procedure if it violates a person's bodily autonomy, spiritual beliefs, or culture.
- The 'physical or other needs' that would make vaccination inappropriate under section 7A of the Order could include the contraindications and considerations listed in the data sheet for the Pfizer-BioNTech vaccine (Comirnaty), including coagulation disorder/ blood thinners, immuno-compromise or suppression, interaction with other medicines, pregnancy, and stress-related responses to vaccination.
- The findings of her research into the safety of COVID-19 vaccines are contrary to Dr Maplesden's statement (set out in paragraph 83) that Dr N had access to 'mounting evidence regarding the overall safety and relative efficacy of the various vaccines in preventing severe Covid infection, and the morbidity and mortality associated with Covid infection far outweighed that associated with the vaccine'.
- The MCNZ's PAC visited and assessed Dr N in June 2024. Dr N was also subject to a VU, and under supervision for the MCNZ. She accepted that her clinical records for patients D, F, G, and H did not adhere to the MCNZ's record-keeping standards or 'her usual high standards' but said that her record-keeping had since improved. Dr N said that the MCNZ supervisor had 'no concerns' about the content of her patient records when he reviewed 10 sets of her records in April 2024.

Opinion: Dr N — breach

65. Having undertaken a thorough assessment of the information gathered and guided by the in-house clinical advice I received from GP Dr David Maplesden, I am critical of several aspects of Dr N's approach to issuing the medical certificates. I have set out my decision on these matters below.

Initial comments

66. In her response to HDC, Dr N stated that prior to the law change on 7 November 2021, 'there [were] no definitive statements from the RNZCGP, IMAC and [the Ministry] on circumstances in which an exemption would be appropriate'. However, I note that the first version of the official criteria was dated 6 November 2021. The RNZCGP had also released its understanding of the likely exemption criteria in late October. As the RNZCGP stated that it collaborated with the Ministry and IMAC to establish the criteria, this information gave doctors a reliable indication of the likely exemption criteria. At the same time, the Ministry's guidance stated that a person may be exempt if vaccination was 'clinically contraindicated'.

67. I agree with Dr Maplesden's advice that Dr N was obliged to proactively keep herself informed of information such as this about the emerging and impending changes to the vaccine exemption process, in order to provide accurate information to patients seeking an exemption. As Dr N was still working part-time at her former medical practice during this

period, she was not isolated from any information or advice the practice either distributed or received.

68. I am unable to form a view on Ms M's complaint that Dr N encouraged people who wanted a medical certificate to book into her clinics. There is insufficient evidence available to determine the matter.

Basis for issuing medical certificates

69. A key part of assessing the adequacy of a doctor's care is review of the doctor's patient records. In this case, deficiencies in Dr N's record-keeping (which I will go on to discuss) meant that much of the clinical information about Dr N's patient consultations was drawn from her statement to HDC. Dr N's recollections some years after the events will inevitably be less reliable than contemporaneous records, and I have taken that fact into account.

70. I note Dr N's comment that 'consideration of simply the notes arising from the consultations in question alone may provide an artificial view of the information-base [she] was working with'. However, my expectation is that any significant information from a patient's pre-existing records would be referred to in the consultation notes.

Patients A and I

71. Dr Maplesden advised that Dr N's decision to issue medical certificates to Patients A and I was reasonable as both had a history of cardiac problems. The pericarditis Patient A had suffered from was already flagged as a contraindication to vaccination in the emerging information. Dr Maplesden said that it was reasonable to give further consideration to the possible adverse effects of the vaccine on Patient I's ischaemic heart disease given that same emerging information.

72. Dr Maplesden stated, however, that it would have been appropriate for Dr N to seek cardiology advice to confirm whether Patient I might have a medical contraindication to vaccination. Dr Maplesden was critical that Dr N's notes did not indicate an intention to contact a cardiologist about Patient I, and he considered that represented a mild departure from the accepted standard of care. I agree. It was reasonable for Dr N to err on the side of caution and provide a medical certificate in respect of Patient I's cardiac history, but she failed to take the appropriate next step of clarifying the matter with a specialist.

Patients B, C, D, E, F, G, H, J and K

73. I am not persuaded that there was an appropriate clinical basis for the medical certificates Dr N issued on 6 and 10 November for this group of patients. Medical certificates are legal documents and must be based on appropriate evidence. The MCNZ statement on medical certification states:[18]

> 'Any statement you certify should be completed promptly, honestly, accurately, objectively and based on clear and relevant evidence … The information disclosed

[18] Refers to the MCNZ statement that was valid at the time of events.

should be accurate and based upon clinical observation, with patient comment clearly distinguished from clinical observation.'

74. I accept Dr Maplesden's advice that the nine medical certificates issued to Patients B,[19] C, D, E, F, G, H, J and K were not supported by a sound medical indication for exemption from vaccination. Noting that the Ministry's official criteria for vaccine exemption was available when the certificates were issued, it would have been reasonable for Dr N to have taken the criteria into account. However, Dr N's consultation notes and statement to HDC indicate that her provision of the nine medical certificates was instead based on two factors:

- Patient concerns, including anxiety about the safety of the vaccine, the thought of being vaccinated, and vaccine mandates and the impact on employment; vaccine-related stress affecting mental health; opposition to vaccination and/or vaccine mandates; concern about the vaccine's potential side-effects; and concern the vaccine may be incompatible with a pre-existing health condition or prescribed medication; and
- Dr N's view that she could not unequivocally assure each patient that their condition or concern did not constitute any vaccine-associated risk due to a lack of relevant clinical trials.

75. Dr Maplesden considered that Dr N departed from the accepted standard of care to a mild to moderate extent on each of the nine occasions she provided medical certificates based on a lack of evidence of vaccine safety and without a sound medical indication for exemption from vaccination.

76. I have considered Dr N's comments in response to the provisional opinion about a lack of COVID-19 vaccine safety and efficacy data, and her strong personal commitment to supporting her patients' concerns about the vaccine and their wishes to remain unvaccinated. I also sought further in-house advice from Dr Maplesden in this respect. Dr Maplesden advised that it is true that there was no understanding of potential long-term adverse effects of the vaccine at the time of the events. However, the knowledge of potential long-term adverse effects of contracting COVID-19 was also limited. I accept Dr Maplesden's advice that the prevailing medical opinion at the time was that the benefit of the Pfizer mRNA vaccine outweighed its known or theoretical risks. As a result, I am not persuaded that lack of evidence of vaccine safety can be regarded as a medical contraindication to vaccination, or evidence of possible or likely harm. In my view, the medical certificates Dr N certified for patients B, C, D, E, F, G, H, J and K were not based on clear and relevant evidence as required by the MCNZ.

Patients B and L

77. I am similarly critical of the two earlier medical certificates that Dr N issued to Patient L on 1 November[20] and to Patient B on 5 November. Dr N cited section 7A of the Order on the certificates, and in doing so certified that vaccination of these patients was 'inappropriate' on the basis of their 'particular physical or other needs'. As with the majority of the medical

[19] The second certificate issued to Patient B on 10 November 2021 only.
[20] Following a consultation on 27 October 2021.

certificates, Dr Maplesden considered that both certificates lacked a sound medical reason for exemption from vaccination.

78. First, there is no record of Dr N's presumed consultation with Patient B to evidence what was discussed and the reason the certificate was issued on 5 November. In terms of Patient L's certificate, Dr Maplesden noted that Dr N regarded Patient L's anxiety about receiving the vaccine and her own inability to guarantee the safety of the vaccine in respect of Patient L's condition as a medical reason for vaccine exemption, despite there being no evidence to suggest that Patient L's condition was likely to be a contraindication to vaccination. I accept Dr Maplesden's advice that Dr N's provision of a medical certificate to Patient L represented a mild departure from the accepted standard of care, taking into account that it was issued prior to the RNZCGP statement.

Information provided with medical certificates

79. There is no evidence in Dr N's notes or her statement to HDC to demonstrate that she provided the 12 patients with objective, evidence-based information about the vaccine alongside the medical certificates. Dr N's failure to provide that information ran counter to the public health response to the COVID-19 pandemic and the MCNZ's expectations of doctors in that respect.

80. The MCNZ issued a guidance statement on 28 April 2021 concerning COVID-19 vaccination and professional responsibility,[21] which stated, in part:

> '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.'

81. Health practitioners were referred to the Ministry's website for further guidance to support engagement with staff, colleagues, and the public who may be hesitant about being vaccinated.

82. Dr Maplesden advised that regardless of whether a doctor is vocationally registered as a GP, if they are practising as a GP, they are expected to have appropriate knowledge of all medical and administrative issues relevant to their daily practice, including relevant practising standards and COVID-19 clinical and regulatory requirements.

83. In a previous HDC investigation,[22] Dr Maplesden confirmed that GPs (which as above includes doctors practising general medicine, as Dr N was) had ready access to COVID-19 vaccine safety and efficacy information at the time of the events.[23] Dr Maplesden stated:

[21] https://www.mcnz.org.nz/assets/standards/Guidelines/Guidance-statement-COVID-19-vaccine-and-your-professional-responsibility.pdf
[22] 21HDC03172, available on www.hdc.org.nz
[23] Dr Maplesden advised that by the end of October 2021 over 7 billion doses of COVID-19 vaccines had been administered worldwide, and 6.88 million doses had been administered in New Zealand.

> 'There was mounting evidence regarding the overall safety and relative efficacy of the various vaccines in preventing severe Covid infection, and the morbidity and mortality associated with Covid infection far outweighed that associated with the vaccine. New Zealand GPs had access to Ministry of Health and IMAC [the Immunisation Advisory Centre] resources providing evidence-based advice on efficacy and safety of the vaccine.'

84. Dr N said she disagrees with this statement based on her own research. In her response to the provisional opinion, she provided a long list of citations of medical literature that refers to the effects of the COVID-19 vaccination. I put this further evidence to Dr Maplesden for comment, and he advised that there was nothing in the new information provided in Dr N's response that led him to change his original advice. He said that he 'remained of the view that the prevailing medical opinion at the time of the events in question was that the benefit of the Pfizer mRNA vaccine outweighed known or theoretical risks of the vaccine'. I accept this advice.

85. Dr Maplesden advised that he expected that a responsible and ethical GP, when seeing a patient with concerns about the safety of the COVID-19 vaccine for their specific health issues, would acknowledge and empathise with the patient's specific concerns and provide them with an evidence-based and balanced perspective on the relative risks of the vaccine specific to their concerns. Dr Maplesden stated:

> 'I would expect the patient to be given objective, evidence-based advice relevant to their concerns and would be moderately critical if medical evidence was misrepresented or incorrect advice was provided.'

86. Dr N had an obligation to provide the 12 patients with objective information about the safety and efficacy of COVID-19 vaccination in line with the MCNZ guidance, based on the resources she had available to her. As noted above, many of the patients presented to Dr N for a medical certificate because of fears about the vaccine's safety and/or concern that the vaccine may be incompatible with their medical conditions. In that context, it was important that evidence-based vaccine information was discussed with the patients to help to balance those concerns and allow them to make an informed choice.

87. While Dr N has emphasised that she advised the patients that she could not confirm that there was no risk to them from the vaccine, I have found no evidence to indicate that she balanced that advice with discussion of the known risks of harm associated with COVID-19 infection, the prevalence of the disease, and the knowledge available at the time about the frequency of severe vaccine-attributed reactions.

Validity of medical certificates

88. I also have concerns about Dr N's decision to issue 12 of the medical certificates despite knowing that they would have very short or no validity.

89. As noted above, the law change of 7 November included a transitional period, which meant that the medical certificates Dr N issued on 5 and 6 November were valid until 21 November

at the latest. The associated patients therefore held exemption certificates for around two weeks before they either expired or were replaced with an exemption granted under the new process.

90. Dr N did not know that the certificates would have any validity after 7 November, however. The clause that included that information was only added to the Order at 11.59pm on 7 November. In addition, when the new application process was announced on 3 November, the Director-General of Health, Dr Ashley Bloomfield, signalled that existing exemptions would no longer be valid: He stated:

> '[T]here are some people who have already been issued paperwork that is intended to be an exemption or an exception. If you have received such paperwork … you will still need to apply through a centralised process. If you have paid for that paperwork, you might want to ask for a refund.'

91. I am satisfied that Dr N issued the medical certificates on 5 and 6 November on the understanding that they would soon become invalid, most in less than a day. In addition, Dr N knew that the medical certificates she issued on 10 November had no validity. By the time they were issued, an exemption from vaccination could be granted only by the Director-General of Health. In her statement to HDC, Dr N said she clearly informed each patient who received one of these certificates of the relevant validity details. That is not supported by her records, as that information only appears in the notes of Patients D and J.

92. In any event, I am troubled by the ethics of Dr N's decision to issue the 12 certificates. I accept Dr Maplesden's advice that issuing a medical certificate when it was clear that it would have very short or no validity represented a mild to moderate departure from the accepted standard of care, regardless of whether the patient was made aware of the validity.

93. The certificates had little or no utility for the patients, who were required to apply again through a different process to obtain a legitimate vaccine exemption. Medical certificates are also intended to inform a receiving person, such as the employers of some of the patients in this case, to assist in their planning and decision-making. The implications for the person receiving and relying on a medical certificate, as outlined by the MCNZ, means that it is crucial for the certificate to be completed honestly, accurately, and objectively, using relevant evidence. In my view, Dr N did not act in accordance with this statement.

Clinical record-keeping

94. Good quality clinical records are crucial to ensuring safe, effective, and timely health care. They reflect a doctor's reasoning and are an important source of information about a patient's current and previous care. The MCNZ's record-keeping standards are detailed in its statement on managing patient records:[24]

> '[Doctors] must maintain clear and accurate patient records that note: a) clinical history including allergies; b) relevant clinical findings; c) results of tests and investigations

[24] Version dated December 2020, which was valid at the time of the events.

> ordered; d) information given to, and options discussed with, patients (and their family or whānau where appropriate); e) decisions made and the reasons for them; f) consent given; g) requests or concerns discussed during the consultation; h) the proposed management plan including any follow-up; [and] i) medication or treatment prescribed including adverse reactions.'

95. Dr N's documentation did not adhere to this standard in several respects. As already noted, the clinical records of many of the patient consultations did not include a sound medical indication for Dr N's decision to issue a medical certificate. In addition, several of the consultations had only minimal notes and there is no documentation relating to the medical certificate issued to Patient B on 5 November.

96. I am particularly concerned about Dr N's documentation of her consultations with patients D, F, G and H. Dr N's approach to record-keeping in these four instances was highly irregular. For Patient G, Dr N documented only that the patient's history was known to her and was 'available on request'. Dr N's records for patients D, F and H were made and kept in her private notebook. As such, no information was available on the PMS for continuity of care or for patients themselves, and it was unclear how and where the notebook was stored.

97. Rule 5 of the Health Information Privacy Code 2020 (HIPC) sets out the obligations that health agencies, including doctors, have to keep health information secure. The HIPC states that health agencies must 'take reasonable security safeguards to protect health information. This means keeping the information safe from loss, as well as from unauthorised access, use, modification or disclosure.'

98. Dr N failed to meet this standard in terms of her records of patient D, F and H's consultations. I reject Dr N's explanation that she kept her notes relating to patients D and H in her notebook because they wanted their sensitive information protected from access by others. Such action was unnecessary, as Dr Maplesden advised that the PMS has provision to make a patient record confidential without having to store it in a separate location. Furthermore, keeping patient notes in a personal handbook is incompatible with the requirements of the HIPC and the MCNZ's record-keeping standards. I gave limited weight to the handwritten notes Dr N provided in relation to patient D, F and H's consultations. The notes are undated and cannot be verified as accurate or contemporaneous accounts of those patient consultations.

99. In her response to my provisional opinion, Dr N recognised that her records of her consultations with patients D, F, G, and H did not accord with the MCNZ's record-keeping standards. I commend Dr N for improving the quality of her clinical record-keeping since these events. The MCNZ supervisor's report of May 2024 demonstrates that he has recently reviewed, and attested to, the standard of Dr N's record-keeping.

Conclusion

100. Right 4(2) of the Code of Health and Disability Services Consumers' Rights (the Code) states that every consumer has the right to have services provided that comply with legal,

professional, ethical, and other relevant standards. I have found that Dr N did not meet these standards for the following reasons:

a) Eleven of the medical certificates issued did not provide a sound medical reason for vaccine exemption, and although Patient I's medical certificate was reasonable, it was not followed up appropriately with a cardiology referral.

b) Given my concerns about the rationale and validity of the 11 certificates, the medical certificates were not completed honestly, accurately, objectively, and based on clear and relevant evidence, as required by the MCNZ standard on medical certification.

c) There is no evidence that the 12 patients were provided with any objective information about the safety and efficacy of the vaccine alongside the certificates.

d) The quality of the clinical record-keeping fell far short of the accepted standard.

101. In my view, Dr N's actions reflect her statement that her role was to address the patients' 'desire for a certificate to support their decision not to be vaccinated'. I do not accept this interpretation of Dr N's role. I am critical that Dr N chose to prioritise her patients' desire for a medical certificate for vaccine exemption over adherence to the applicable law, guidance, and professional standards, including the MCNZ's expectations around medical certification and professional responsibility during the COVID-19 pandemic. Accordingly, I find Dr N in breach of Right 4(2)[25] of the Code.

Recommendations

102. In the provisional opinion it was recommended that Dr N:

a) Undertake refresher training on clinical record-keeping in conjunction with, or endorsed by, a relevant professional association or authority, and provide HDC with evidence of completion of the training.

b) Undertake an audit of the notes of 20 patients seen within the previous three months, using a relevant professional audit tool, such as module 2 of the RNZCGP clinical record review self-audit checklist, including its 'Report and plan' template.

c) Arrange for her audit report to be peer-reviewed by a relevant professional body and a plan established to address any necessary improvements, and then provide the audit report and the peer review to HDC.

103. It was also recommended that the MCNZ consider whether a review of Dr N's competence was warranted.

104. As the MCNZ is now completing a review of Dr N's performance to ensure that she is practising at the required standard, it is unnecessary for me to make these recommendations to Dr N or the MCNZ.

[25] Right 4(2) stipulates: 'Every consumer has the right to have services provided that comply with legal, professional, ethical, and other relevant standards.'

105. However, I recommend that the MCNZ provide me with the full outcome of the PAC assessment, including any recommendations the MCNZ makes to Dr N as a result.

Follow-up actions

106. A copy of this report with details identifying the parties removed, except Dr N and the advisor on this case, will be sent to the Medical Council of New Zealand when the investigation is closed.

107. A copy of this report with details identifying the parties removed, except the advisor on this case, will be sent to Health New Zealand|Te Whatu Ora and the Medical Council of New Zealand, and placed on the Health and Disability Commissioner website, www.hdc.org.nz, for educational purposes.

Appendix A: In-house clinical advice to Commissioner

The following in-house advice was obtained from Dr David Maplesden, a general practitioner, on 2 May 2023:

'1. My name is David Maplesden. I am a graduate of Auckland University Medical School and I am a vocationally registered general practitioner holding a current APC. My qualifications are: MB ChB 1983, Dip Obs 1984, Certif Hyperbaric Med 1995, FRNZCGP 2003. Thank you for the request that I provide clinical advice in relation to the complaint from [Ms M] about the actions of [Dr N] with respect to provision of Covid 19 vaccination exemption certificates to various consumers. In preparing the advice on this case to the best of my knowledge I have no personal or professional conflict of interest. I agree to follow the Commissioner's Guidelines for Independent Advisors.

2. I have reviewed the following information:

- Complaint from [Ms M]
- Response from [Dr N]
- Relevant clinical notes held at [the clinic]

3. The complaint relates to provision of Covid-19 vaccination exemption medical certificates (VEC) by [Dr N] to various consumers between 1 and 10 November 2021. I have included some relevant background in the timeline below as well as referencing the Medical Council of New Zealand guidance on medical certification (see s13). [Dr N] includes the following points in her response:

i. [Dr N] states she did not solicit patients for the purpose of providing VECs

ii. [Dr N] states she was aware of the relevant legislation and that it changed from 7 November 2021. She states: *From that point I could not issue medical certificates under that clause* [Section 7A of the current legislation — see s9 of this advice].

iii. [Dr N] argues there was no explicit advice provided following the Minister's statement on 3 November 2021 (see section 6) regarding changes in the criteria for exemption or timeframe for the changes and it was reasonable to continue supplying VECs under section 7A of the current legislation until such changes were confirmed. She notes she did not receive the … information referred to in s11 of this report.

iv. [Dr N] states: *The patients in question had made their own individual decisions not to receive the vaccine. I felt my role was to address their presenting concern/request, which was a desire for a certificate that would support their decision not to be vaccinated at the time.*

v. [Dr N] states she informed patients attending on 6 November 2021 of the likely effect of the upcoming change in legislation that would invalidate current certificates with a new application to the Minister of Health required. She states the medical certificates provided on 10 November 2021 reflected her: *view that it would be inappropriate for the patients in question to be vaccinated. I explained*

and the patients understood that these documents were not "exemptions" with any legal force. The patients wanted the certificates nonetheless.

4. You have asked for the following advice:

(i) Whether the 12 VECs issued by [Dr N] accorded with the Clinical exemption criteria referred to in your advice — the MoH guidance of 29 October 2021 or s7A of the Order — and/or any other applicable guidance

(ii) Whether it was appropriate that [Dr N] issued and charged for all but one of the VECs after the government's 3 November 2021 announcement of an imminent centralised VEC process that would render previous VECs invalid

(iii) The quality of [Dr N's] record-keeping, including her decision to hold some of the 12 patients' notes in her personal notebook to protect their privacy;

(iv) Any other matters in this case that you consider warrant comment.

5. I note from the outset it is unclear which, if any, of the consumers for which [Dr N] provided VECs were "affected persons" as defined in Schedule 2 of the relevant version of the COVID-19 Public Health Response (Vaccinations) Order 2021 (see below). Nevertheless, the medical certificates provided cited section 7(A) of this legislation in all but two cases (second certificate for patient B and certificate for patient C) and I have therefore assumed the legislation applied to those cases as "affected persons" (see section 15 for an example of the certificate).

6. Background: At 1300hrs on 3 November 2021 the Minister announced that provision of exemption certificates would be a centralised process with patients having to apply to the Ministry of Health if they satisfy certain criteria (confirmed the following week — see Appendix 1) that will make them eligible for exemption. There will be two paths — one for those people requiring mandatory vaccination under the COVID-19 Public Health Response (Vaccinations) Order 2021, with a separate path for those wanting record of a valid exemption to enable access to services/events currently restricted to fully vaccinated individuals. Any existing exemption certification provided prior to the centralised process being operational will not be regarded as official and individuals with such certificates will be required to access the process discussed above.

7. As at the start of November 2021 further specific advice from the Ministry of Health was expected to enable accurate completion of Covid vaccine exemption certificates. It was unclear what this process would entail. The current Ministry advice and legislation (see below) prior to 7 November 2021 was not clear regarding valid reasons for authorising exemption resulting in a period of uncertainty for GPs being asked to provide vaccination exemption certificates. Some health practitioners appeared to exploit this current loophole or uncertainty by providing on-line exemption certificates

at patient request[1]. Note the legislation applied to "affected persons" defined in Schedule 2 of the various versions of the vaccination Order.

8. As at 29 October 2021[2], the Ministry of Health website offered the following information on vaccine exemption:

Exemptions from mandatory vaccination

In some situations, health and disability, education and corrections workers may be able to get an exemption from being vaccinated against COVID-19.

When you can apply for an exemption

The exemption process comes into force on 6 November 2021 for corrections workers, and 15 November 2021 for health and disability workers and education workers.

How an exemption is granted

Workers may be exempt from the requirement to be vaccinated if, after examination:

- *a suitably qualified health practitioner considers that the vaccination is **clinically contradicted** for the person, and*
- *a suitably qualified health practitioner provides written confirmation of that assessment.*

A worker may not exempt themselves even if they are a suitably qualified health practitioner.

9. As at 29 October 2021 Section 7A of the relevant legislation[3] regarding mandatory Covid vaccination gives a different account of permitted exemptions:

(2) An affected person may carry out certain work without being vaccinated if —

*(a) the affected person **has particular physical or other needs** that a suitably qualified health practitioner (in the course of examining the person) determines would make it inappropriate for the person to be vaccinated; and*

(b) in any case where the affected person belongs to the group specified in Part 6 of the table in Schedule 2 [changes depending on version — October 2021 version linked]*, the*

[1] https://www.stuff.co.nz/national/health/coronavirus/126801588/covid19-antivax-doctors-nurses-exploit-loophole-for-vaccine-exemptions
[2] https://www.health.govt.nz/our-work/diseases-and-conditions/covid-19-novel-coronavirus/covid-19-response-planning/covid-19-mandatory-vaccinations/covid-19-exemptions-and-exceptions-mandatory-vaccination Accessed 1 November 2021
[3] COVID-19 Public Health Response (Vaccinations) Order 2021 https://www.legislation.govt.nz/regulation/public/2021/0094/latest/LMS522626.html Accessed 1 November 2021

relevant PCBU who employs or engages the affected person has provided the register with written confirmation that a suitably qualified health practitioner—

(i) has examined the affected person; and

(ii) has determined that vaccinating the affected person would be inappropriate.

(3) If the affected person is a health practitioner, the examination referred to in subclause (2) must be undertaken by another health practitioner who is suitably qualified to conduct the examination.

10. As a consequence of this uncertainty, on 28 October 2021[4] the RNZCGP sent the following advice to its members:

Vaccination exemption certificates

The College and IMAC have been working with the Ministry of Health to establish both criteria for exemptions and a process to make this standardised and secure for practitioners, patients and employers. This is taking some time and we have heard from our members that there are many requests for these exemption certificates.

While the formalised process and criteria are agreed and set up, we suggest that members can state that from what we know so far the following are the likely criteria that are exempt:

- *Anaphylaxis to the first dose of the vaccine*
- *Known severe allergy to the excipients of the vaccine*
- *Acute decompensated heart failure*
- *Inflammatory cardiac illness within the past 6 months*
- *Myocarditis*
- *Pericarditis*
- *Endocarditis*
- *Acute rheumatic fever*
- *Acute rheumatic heart disease.*

This has not been confirmed by the advisory group yet and may change.

We expect a more formal process to be available in the next week that will allow members to produce the validated certificate. Any documents produced in the meantime may give confidence to the patient but will need to be reproduced with the validated process.

[4] https://rnzcgp.informz.net/informzdataservice/onlineversion/pub/bWFpbGluZ0luc3RhbmNlSWQ9MjM3MjE4MQ== Accessed 1 November 2021

11. On 28 October 2021 the medical director of [a PHO network] provided the following advice to members which I believe accurately summarises the existing situation and background:

(i) With an increasing number of professional groups mandated under the COVID-19 Public Health Response (Vaccinations) Order 2021 to be fully vaccinated against Sars-Cov2 we are seeing a rise in the number of requests for a COVID-19 vaccine exemption to be confirmed by a patient's GP. The Ministry of Health appreciate people working in the health sector are keen to understand more about the criteria for a medical exemption for vaccination. They understand there is a high level of interest in how people can prove they have a valid exemption. The Ministry is mindful of these concerns and are working as quickly as they can to finalise the guidance and process around medical exemptions. Here's what we can confirm at this stage:

- *The Ministry is working on the clinical guidance for medical exemption for vaccination. The guidance is being considered by the COVID-19 Vaccine Technical Advisory Group and will be published when ratified.*
- *Those applying for a medical exemption for vaccination for their patients will need to complete and submit a standardised exemption application form to the Ministry of Health.*
- *Information about the guidance and the application process will be shared during the week of 8 November* [2021].
- *Such an exemption is a highly important legal document that is very likely to be challenged at the very least in an employment tribunal. A recent case involving a border worker was escalated to an appeal court. It is also possible that refusal to grant such a certificate may be legally challenged, this is a minefield.*
- *Experts in Australia have stated almost no-one will be medically exempt from receiving a COVID-19 vaccine and there is no reason to expect New Zealand to be any different.*

(ii) Whilst we await definitive statements from the Medical Protection Society, RNZCGP, Immunisation Advisory Centre and Ministry of Health on the circumstances in which a vaccine exemption is appropriate it is important to note that the Immunisation Advisory Centre advise that people who have experienced an anaphylaxis to the first dose of Comirnaty (the Pfizer vaccine) can still safely receive a second dose under the supervision of a specialist immunology clinic. It is expected that only 4–5 people in a million will experience an anaphylaxis following Comirnaty vaccination, the most likely component triggering the allergic response is Polyethylene Glycol (PEG or macrogol) one of the "fat" components of the vaccine. It is a compound also used in a variety of products including cosmetics and various foodstuffs several case reports describe patients whose allergic response is triggered by multiple products. PEG allergy probably occurs in 0.01 per cent of the population.

(iii) If a patient presents with a story of multiple allergies and anxiety about the first dose of vaccine the recommendation is to observe them for 30 minutes post vaccination. If

this is unacceptable to them consult with an immunologist or call the Immunisation Advisory Centre medical advice line (clinical queries: 0800 466 863).

(iv) Myocarditis or pericarditis following the vaccination is an extremely rare event, it is more common in males and more common after the second vaccination. The Immunisation Advisory Centre state: "People who develop myocarditis or pericarditis attributed to their first dose of Comirnaty are advised to defer further doses. They should be referred to IMAC for clinical advice about alternate vaccine options. Vaccination is not advised for anyone with current active cardiac inflammation".

(v) In addition to warning about anaphylaxis and advice on myocarditis and pericarditis the Medsafe data sheet regarding the Comirnaty vaccination states the only contraindication to the medication is hypersensitivity to any of the vaccine components, and that "vaccination should be postponed in individuals suffering from acute severe febrile illness or acute infection. The presence of a minor infection and/or low-grade fever should not delay vaccination". Care should also be taken with people who have a bleeding tendency because of bruising following injections of any kind, and people with a stress reaction to injections need to be cared for.

(vi) What to do if your patient asks you for an exemption

- *If asked for a COVID-19 vaccination exemption it is important to explore the reasons why the request has been made and to try to resolve any anxiety that the patient may have. Their reasons may be very complex and a request for an exemption may reveal other anxieties about work or home that may need further counselling and support. It is always important to connect and understand the world as seen by your patient. Taking time to understand the request at the start may save a great deal of time later on and a simple refusal is rarely satisfactory, patients are more likely to complain about your behaviour and seek help elsewhere.*
- *An official process for requesting an exemption is being developed, the indications we have is this will be something similar to a "special authority" that will enable notification to the Ministry of Health when an exemption has been requested and for what reason. This will allow audit and review of these decisions by the Ministry.* ***If it is possible, do not provide an exemption letter to any patients until the official process has been developed.*** *This is likely to be in early November.*
- *There will be circumstances when a vaccination deferment awaiting resolution of an acute febrile illness might be appropriate in which case ensure the letter is clearly time limited and the reason for the deferment is clearly stated.*

12. November 2021 changes:

(i) From midnight 7 November 2021 the COVID-19 Public Health Response (Vaccinations) Order 2021 was amended[5] with section 7A (see section 4 of this advice) revoked and replaced with section 9B. Relevant extracts include:

- *(2) An application may be made only on the ground that the person on whose behalf the application is made (the person) meets the specified COVID-19 vaccination exemption criteria*.
- *(4) An application must be accompanied by a certificate signed by the applicant certifying that they—*

  (a) have reviewed the person's medical history and assessed the person's state of health; and

  (b) have reasonable grounds for believing that the person meets the specified COVID-19 vaccination exemption criteria.
- *(12) In this clause, specified COVID-19 vaccination exemption criteria means the criteria determining when a person may be granted a COVID-19 vaccination exemption that the Director-General has approved in a notice published—*

  (a) on a publicly accessible Internet site maintained by or on behalf of the New Zealand Government; and

  (b) in the Gazette.

(ii) The criteria specified in section 9B(12) of the Order were published in the government gazette on 12 November 21 as noted in Appendix 1. I am unsure if they were published on the Ministry of Health website prior to this date.

13. The Medical Council of New Zealand has provided a statement on medical certification[6]. Relevant extracts include:

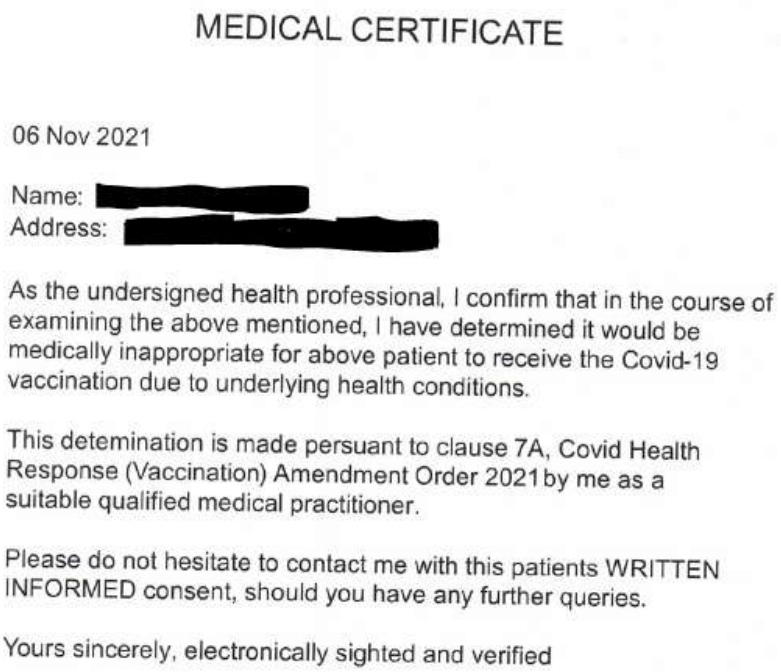
- *Certificates are legal documents. Any statement you certify should be completed promptly, honestly, accurately, objectively and based on clear and relevant evidence.*
- *Certificates must meet the standards outlined in relevant legislation and be written legibly, and in such a way that it is understandable to a lay person.*
- *The information disclosed should be accurate and based upon clinical observation, with patient comment clearly distinguished from clinical observation*

[5] https://www.legislation.govt.nz/regulation/public/2021/0094/100.0/LMS487853.html Accessed 1 May 2023
[6] https://www.mcnz.org.nz/assets/standards/0541c585e7/Statement-on-medical-certification.pdf Accessed 1 May 2023

14. You have provided a summary of the work exemption certificates provided by [Dr N] during a period of work at [the clinic]. I have reviewed the patient notes supplied and have made some minor amendments (see table).

Patient	Cert. date	Relevant details from notes
L	1/11/2021 (cited s7A)	Noted: "agree that due to … [Patient L] should be exempt". Phone consult on 27/10/2021.
B	5/11/2021 (cited s7A)	No notes on record for this contact.
A	6/11/2021 (cited s7A)	"Assessed health as per scanned documents … mRNA Covid vaccine inappropriate, plan vaccine exemption." No further notes. Phone cons.
D	6/11/2021 (cited s7A)	"[M]edical history as per my notebook available on request". No further notes.
E	6/11/2021 (cited s7A)	History taken and medications discussed, no specific basis for vaccine exemption stated. Phone consult.
F	6/11/2021 (cited s7A)	"[N]otes in my notebook, will transfer once I have spare time". No further notes.
G	6/11/2021 (cited s7A)	"[I]n depth medical Hx [history] known to me available on request". No further notes. Phone consult.
H	6/11/2021 (cited s7A)	"[M]edical Hx recorded in notebook available on request". No further notes.
I	6/11/2021 (cited s7A)	History taken and medications discussed, no specific basis for vaccine exemption stated.
J	6/11/2021 (cited s7A)	History taken. Noted: "reactive anxiety sec[ondary] to current political situation and mandates." No specific basis for vaccine exemption stated.
K	6/11/2021 (cited s7A)	"[M]edical history as per scanned documents … mRNA Covid 19 vaccination inappropriate, plan: vaccine exemption". No further notes.
C	10/11/2021	Noted: "very nervous and panicky, never suffered from anxiety before … insomnia, gets tearful. [W]orried about son who is about to lose his job in this '[u]njust' political system, worried about safety." Vaccine exemption not mentioned.
B	10/11/2021	Further certificate issued, in addition to certificate of 5/11/2021. Noted: "Very stressed due to bullying and pressure at work … had to take time off … went back to work … can't cope with pressure

15. A generic example of the certificates provided by [Dr N] is represented below:



MEDICAL CERTIFICATE

06 Nov 2021

Name: [redacted]
Address: [redacted]

As the undersigned health professional, I confirm that in the course of examining the above mentioned, I have determined it would be medically inappropriate for above patient to receive the Covid-19 vaccination due to underlying health conditions.

This detemination is made persuant to clause 7A, Covid Health Response (Vaccination) Amendment Order 2021 by me as a suitable qualified medical practitioner.

Please do not hesitate to contact me with this patients WRITTEN INFORMED consent, should you have any further queries.

Yours sincerely, electronically sighted and verified

16. **Patient A**: Certificate provided 6 November 2021. Telephone consult. Notes as per table. The scanned documents referred to are not on file. [Dr N] elaborates that the patient had: *a history of … pericarditis. Patient was worried about the vaccine and impact of not having received it (losing rights). At the time no trials had been performed on patients with … diseases, I did not feel I could assure … there was no risk to … (particularly in the context of a history of adverse reactions). After discussions about relative risks, patient's concerns and opposition to being vaccinated remained and I considered in that context it would be inappropriate for … to be vaccinated and issued a certificate to that effect. I advised of the impact of the impending law change (that the certificate would be invalid).* Taking into account the history of pericarditis (I have assumed [Dr N's] summary of medical history is accurate) and the RNZCGP statement referred to in section 10 I believe it was reasonable for [Dr N] to complete a VEC provided it was made clear to the patient that the certificate would be invalid after 7 November 2021 and a new application would be required, the criteria for which the patient may or may not satisfy. I am mildly critical the associated contemporaneous documentation did not more completely define the clinical rationale for providing the certificate. It was probably reasonable to complete the certificate on the basis of a telephone assessment given the relevance of the past medical history to certification and noting it was Covid level 2 restrictions in place in the region concerned at the time of these events.

17**. Patient B**: Certificate provided 5 November 2021 (format as per s15) and 10 November 2021 (no reference to legislation but includes: *I confirm that in the course of examining the above mentioned I have determined it would be medically*

inappropriate for above patient to receive the Covid-19 vaccination due to underlying health conditions. I could not find any notes in relation to the certificate provided on 5 November 2021. If there is no record of a consultation on this date and a consultation took place, this might be a severe departure from accepted standards of clinical documentation[7] although there may be some explanation as to why the record is absent. A face to face consultation was undertaken on 10 November 2021 and notes include: *very stressed due to pressure and bullying at work …* What appear to be nurse triage notes dated the same day refer to *irregular BP, dizzy* and there are sequential recordings of blood pressure and pulse rate and reference to ECG (no ECG report provided) with management *GP [Dr N] review*. [Dr N] elaborates in her response that the patient was feeling stressed at work relating to the vaccine mandate and … was stressed about the lack of safety data in respect of the vaccine. [Dr N] felt the degree of stress presented meant it was medically inappropriate to proceed with vaccination and the implications of the second certificate were explained (that it was *not a govt exemption*). The response does not refer to the initial certification or what I have assumed was a preceding nurse assessment. With respect to the certificate dated 5 November 2021 I believe provision of an exemption certificate because the patient was anxious about vaccination safety and the mandates, in the absence of a clear history of mental health issues and noting the previous information from RNZCGP (see s10) regarding likely exemption criteria, would be met with mild to moderate disapproval by a majority of my peers given the absence of a sound medical indication for exemption from vaccination. I believe provision of the second certificate would be met with similar disapproval noting the Ministry of Health guidance by this stage on what constituted medical indications for exemption. The ethics of providing a certificate which held no validity for an "affected person" might also be questioned.

18. **Patient C**: Certificate provided 10 November 2021 in same format as that provided on the same date to patient B (see above — no reference to legislation). Notes are as per the table. [Dr N] elaborates that the patient: … *wanted a medical certificate to support … stance of not wanting to receive* [the vaccine] *… I explained to … that the certificate would not be a valid medical exemption*. I believe provision of an exemption certificate because the patient was anxious about vaccination safety and wanted support in [this] stance not to be vaccinated, in the absence of a clear history of mental health issues and noting Ministry of Health guidance by this stage on what constituted medical indications for exemption, would be met with mild to moderate disapproval by a majority of my peers given the absence of a sound medical indication for exemption from vaccination. As before, the ethics of providing a certificate which held no validity for an "affected person" might also be questioned.

19. **Patient D**: Certificate provided 6 November 2021 in format noted in section 15. Notes state: *medical history as per my notebook available on request.* In-person consultation. [Dr N] states in her response that she keeps a notebook in which she documents some consultation notes. There was an intention to transpose one set of

[7] Lillis S. The purpose of medical records and notes. In: Morris KA, editor. Cole's medical practice in New Zealand, 14th ed. Wellington: Medical Council of New Zealand; 2021.

notes (see below) into the PMS but this was overlooked. Two additional sets of notes were maintained in the notebook separate to the PMS as the patients involved were concerned at who might access their sensitive health information. I would not regard [Dr N's] actions in this regard as being consistent with accepted practice noting there is provision within the PMS to make a record confidential without having it stored in a location separate to the PMS and the desirability of having notes stored securely in a single location to facilitate continuity of care. The Health Information Privacy Code 2020[8] has requirements around security, retention and disposal of health information and it is not clear to me how [Dr N] would satisfy these requirements using her current system of handwritten notes in a notebook. I believe [Dr N's] actions in storing some notes separate to the PMS as handwriting in a notebook would be met with mild to moderate disapproval by a majority of my peers. The handwritten notes reviewed are undated and partially redacted (unclear to what degree the redacted section enabled ready identification of the patient). I am unable to confirm if they are contemporaneous. Those notes related to patient D refer to an impact on mental health since the vaccine mandates were mooted with difficulty sleeping and panic attacks. There is reference to concerns about the "experimental status" of the vaccine and the comment: *Aware that section 7A already has been invalidated, but wants proof for further reference …* There is no reference to any past history of mental health issues. I believe to have provided a VE certificate citing section 7A of the legislation when it was clear the certificate could be valid under this legislation for several hours only would be met with mild to moderate disapproval by a majority of my peers. Noting the previously cited information from the RNZCGP regarding the likely exemption criteria, I believe it was disingenuous of [Dr N] to classify situational anxiety as a medical contraindication to vaccination and that this also would be met with mild to moderate disapproval by a majority of my peers.

20. **Patient E**: Certificate provided 6 November 2021 in format noted in section 15. Telephone consultation. History of … recorded (on … 2mg daily) and … Family history of various conditions including … noted. Impression: *mRNA vaccination inappropriate …* [Dr N] elaborates in her response: *I could not report conclusively that there was no risk in context; no clinical trials were available at the time supporting that the MRNA-vaccination was safe in pts with … diseases or for patients with severe … Patient was very well informed and understood certificate would become in valid once s 7A revoked.* As noted above, I believe to have provided a VE certificate citing section 7A of the legislation when it was clear the certificate could be valid under this legislation for several hours only would be met with mild to moderate disapproval by a majority of my peers whether or not the patient was informed of this situation (**this comment applies to all patients issued with certificates on 6 November 2021**). Noting the previously cited information from the RNZCGP regarding the likely exemption criteria and absence of any evidence the medical conditions and family history presented by the patient were considered as likely contraindications to vaccination, I believe provision of a VE

[8] https://www.privacy.org.nz/privacy-act-2020/codes-of-practice/hipc2020/hipc-factsheet-5-storage-security-retention-and-disposal-of-health-information/ Accessed 1 May 2020

certificate citing administration of the vaccine was medically inappropriate and would be met with mild to moderate disapproval by a majority of my peers.

21. **Patient F**: Certificate provided 6 November 2021 in format noted in section 15. Telephone consultation. Notes as per table — this is the patient whose notes [Dr N] states she intended to transfer to the PMS but forgot to do so. Handwritten notes refer to history of … when patient in their twenties (currently in late …) resulting in insomnia, poor sleep pattern and poor concentration. Notes include: *seeking proof of inappropriateness of vaccine … effect of vaccine on … not determined — Oked.* See previous comments regarding potential documentation issues and decision to furnish a VE certificate citing section 7A of the legislation. I do not regard lack of evidence of vaccine safety as a medical contraindication to vaccination and I believe a majority of my colleagues would regard with mild to moderate disapproval the provision of a VE certificate on the basis of historic … and possible persistent … symptoms. If there was some concern the patient had … provision of a temporary certificate while specialist … opinion on suitability for vaccination was obtained might have been reasonable as long as the certificate noted these circumstances (that a specialist opinion was being sought).

22. **Patient G**: Certificate provided 6 November 2021 in format noted in section 15. Notes as per table. In her response, [Dr N] states the patient had a history of … at the *time [and] wanted a medical certificate for protection and for documentation … No trials had been performed to look at the safety and effects of the mRNA-vaccination neither … nor into patients with … so I could not provide certain advice that there were "no risks" …* I do not believe the fact [Dr N] was unable to state unequivocally that the conditions suffered by the patient did not constitute some degree of vaccine-associated risk (although there was no reason to suggest there should be any risk) constitutes a medical inappropriateness for vaccination (as certified) and I believe provision of a VE certificate in this scenario would be met with mild to moderate disapproval by my peers. The clinical notes did not reflect the discussion that had taken place or the grounds for provision of the VE certificate and I am mildly to moderately critical of the standard of clinical documentation on this occasion.

23: **Patient H**: Certificate provided 6 November 2021 in format noted in section 15. In person consultation. PMS notes refer to: *medical Hx recorded in notebook available on request.* Handwritten notes refer to the patient experiencing … since there had been talk of vaccine mandates and: *Pt very well informed re "experimental status" … safety data not available …* In her response, [Dr N] states the patient had a history of … disease and: *on assessment, stress symptoms clear. Felt it was clinically appropriate to provide medical certificate supporting decision not to receive vaccination due to health.* I do not believe anxiety symptoms related to the thought of mandates and thought of receiving a vaccination constitutes a medical inappropriateness for vaccination (as certified) and I believe provision of a VE certificate in this scenario would be met with mild to moderate disapproval by my peers. There is no distinction made between symptoms reported by the patient and those observed by the examiner (see s 13). Comments

regarding documentation and provision of a certificate which could only be valid for a few hours are as previously discussed.

26: **Patient I**: Certificate provided 6 November 2021 in format noted in section 15. In person consultation. PMS notes refer to history of … and ischaemic heart disease with current medications listed. On 8 November 2021 consultation notes refer to another staff member receiving communication from the patient regarding an e-mail … had received from [Dr N] *with a strange direction* [not otherwise clarified]. *… was expecting an exemption … has had a discussion with a GP at* [another medical centre] *and was told the same as I was … as of midnight last night any exemption from vaccination is illegal and null and void. No doctor can issue an exemption and you need to apply through MOH.* However, [Dr N] states in her response: *I advised of the impact of the impending law change (that the certificate would be invalid).* Standard of clinical documentation on this occasion is adequate. Given the emerging information regarding vaccine related myocarditis and pericarditis it was reasonable to consider whether this adverse effect might be more significant for a patient with the cardiac history exhibited in this case and expert advice (cardiologist) might have been sought in this regard. In this circumstance, I am not critical there was an assessment that the patient might have a medical contraindication to vaccination (with cardiologist advice to be sought to confirm or refute this) but I am mildly critical there was no apparent intention to seek cardiologist advice in this regard. However, my comments regarding provision of a certificate that had only a few hours validity in any case remains and the enquiry by the patient referred to above might raise some doubt as to how clearly the limited validity of the certificate provided was discussed if it was actually discussed. In this case and all the cases discussed relating to certificates provided on 6 November 2021, I believe if there was no discussion that the certificate provided would be invalid in a few hours' time and the application would need to be repeated through a different process, this situation would be met with moderate disapproval by my peers. However, I note [Dr N] has maintained such discussion was undertaken with all patients although such discussion is documented in only two cases (patients D and J).

27. **Patient J**: Certificate provided 6 November 2021 in format noted in section 15. Telephone consultation. History of … issues noted and *reactive anxiety sec to current political situation and mandates.* Family history recorded. In her response, [Dr N] notes she could not reassure the patient there was no risk associated with the vaccine because of the lack of safety data related to … issues, cancer risk (family history), … and … disease. The patient appeared anxious at the assessment. *Patient was aware of the change in legislation from 07.11.21; knew the certificate would not retain the status of a valid medical exemption.* I do not believe anxiety symptoms related to the thought of receiving a vaccination constitutes a medical inappropriateness for vaccination (as certified) or that the fact [Dr N] was unable to state unequivocally that the conditions suffered by the patient did not constitute some degree of vaccine-associated risk (although there was no reason to suggest there should be any significant risk) constitutes a medical inappropriateness for vaccination and I believe provision of a VE certificate in this scenario would be met with mild to moderate disapproval by my peers.

28: **Patient K**: Certificate provided 6 November 2021 in format noted in section 15. In person consultation. Notes are minimal (see table) with there being no recorded rationale for the decision the vaccine was medically inappropriate for the patient (mild to moderate departure from expected standards of clinical documentation). In her response, [Dr N] states the patient had: *History of … disease and … requested a medical certificate because … was fearful of the effect the vaccine would have in the context of … health conditions … At the time of the vaccine roll-out no studies had been done on patients with … diseases, the patient already had shown that … etc. I could not provide total assurance of no risk … On my assessment, issuing a certificate was appropriate having regard to patient's health. I advised of the impact of the impending law change (that the certificate would be invalid).* I do not believe the fact [Dr N] was unable to state unequivocally that the conditions suffered by the patient did not constitute some degree of vaccine-associated risk (although there was no reason to suggest there should be any significant risk) constitutes a medical inappropriateness for vaccination and I believe provision of a VE certificate in this scenario stating vaccination was inappropriate for medical reasons would be met with mild to moderate disapproval by my peers.

29: **Patient L**: Certificate provided 1 November 2021 in format noted in section 15. Telephone consultation 27 October 2021. History of previous … injury secondary to … and … noted (unclear if the two were related). Notes include: *aware that when … worried re potential SE of vaccination on nervous system and having nightmares about this … agree that due to … and ongoing problems with … should be exempt from the covid vaccination as per letter.* I note the consultation occurred prior to release of the RNZCGP statement referred to in s10 and the certificate was provided prior to a clear direction from the Minister regarding an impending change in the vaccine exemption certification process. As with several other cases discussed, it appears [Dr N] regarded her inability to guarantee safety of the vaccine with regard to symptoms or medical history presented by the patient, coupled with patient anxiety about receiving the vaccine, as a medical reason for vaccine exemption even if there was no evidence to suggest the conditions suffered by the patient were likely to be a contraindication to vaccination. It is unclear if the patient's complaint of … was an observed or self-reported phenomenon. Taking into account the timing of the consultation (prior to the RNZCGP statement and ministerial announcement) I believe provision of a VE certificate in the circumstances described would be met with mild disapproval by my peers.

Appendix 1: Specified COVID-19 Vaccination Exemption Criteria as at 12 November 2021[9]

Step	Vaccine	Category	Criteria Details
1	All COVID-19 Vaccines	1A. COVID-19 Infection	• PCR-confirmed SARS-CoV-2 infection until complete recovery from the acute illness. *Note*: Chronic symptoms following COVID-19 ("Long COVID") is not a contraindication to COVID-19 vaccine but does warrant a clinical discussion with the patient regarding the benefits and risks.
		1B. Serious Adverse Event to previous dose	• Serious adverse event attributed to a previous dose of the same COVID-19 vaccine with no other cause identified. • An adverse event is considered serious for the purposes of these criteria if it: ◦ Requires in-patient hospitalisation or prolongation of existing hospitalisation or results in persistent or significant disability/ incapacity; and ◦ Has been reported to CARM; and ◦ Has been determined following review by, and/or on the opinion of, a relevant medical specialist to be associated with a risk of recurrence of the serious adverse event if another dose of the same vaccine is given.
		1C. Unable to tolerate administration due to risk to self or others	Unable to tolerate vaccine administration with resulting risk to themselves or others.
2	Pfizer Vaccine	2A. Anaphylaxis	• Anaphylaxis to the first dose of the vaccine or known severe allergy to the excipients of the vaccine as per the datasheet provided to Medsafe. This criterion will be removed as an exemption when there is an alternative vaccine available in New Zealand. Many of these individuals will be able to be safely vaccinated in a controlled environment, and we recommend clinical immunologist/specialist assessment.
		2B. Myocarditis / Pericarditis	Myocarditis/pericarditis following the first dose of the vaccine.
		2C. Inflammatory Cardiac Illness	Inflammatory cardiac illness within the past 6 months including: acute myocarditis, pericarditis, endocarditis, acute rheumatic fever or acute rheumatic heart disease (ie, with active myocardial inflammation).
		2D. Acute Decompensated Heart Failure	Acute decompensated heart failure.
3	Trial Vaccine	3A. Non-Placebo participant in a vaccine trial	Those who are confirmed as having the vaccine (i.e., non-placebo) in any COVID-19 vaccine trial in Aotearoa New Zealand.

[9] https://gazette.govt.nz/notice/id/2021-go4910 Accessed 1 May 2023

Further in-house clinical advice to Commissioner

On 15 February 2024, HDC's investigator contacted Dr David Maplesden as follows:

1. s10 of your advice refers to the RNZCGP advice to members of 28/10/21. I would like to clarify my understanding that not all GPs are RNZCGP members? If [Dr N] is not a member, how would you expect her to have kept up with the evolving information at the time about the criteria for vaccine exemption? (she did not receive the [PHO] information you refer to). I note here that [Dr N] had resigned from her full-time role by this time, although was still doing intermittent shifts and retained access to the PMS system.

2. If [Dr N] could rightly claim not to be aware of the RNZCGP statement, is the information in s11(v) of your advice reasonable to fall back on ie. that the Medsafe data sheet provided relevant information about contraindications that she could have relied on?

3. I don't see the attached exemption criteria from the MoH on 6/11/2021 mentioned in your advice — could you please clarify that it was valid from that date? The criteria in it is the same as that released later, as referred to in s12(ii) of your advice.

Dr Maplesden responded on 15 February 2024, as follows:

'1. You are right that not all GPs are members of RNZCGP and [Dr N] may not have been provided with the cited information. I am not sure which PHO [Dr N's] practice belonged to but it may be there was communication provided by that PHO similar to that provided by … PHO and cited in my advice although I am unable to confirm that. However, I think the bottom line is that [Dr N] had a duty to proactively keep herself informed regarding the impending VEC changes so that she could provide accurate information to patients seeking VECs.

2. See above — to me this would be a defence of ignorance and illustrates the danger of practising in professional isolation. However, this may be presented as a defence for her actions and given the MoH was remiss in not providing from the outset clear and explicit guidance with respect to exemption criteria (eg that the patient had to have a contraindication to administration per Medsafe) I don't think we are able to use the information in 11(v). However, I would be critical of the fact she wasn't maintaining an adequate awareness of the evolving situation regarding exemption criteria.

3. The change in the exemption process, which meant all applications for a vaccine exemption (pre-existing and new) had to be reviewed by an independent expert panel came into effect at 11.59pm on 7 November 2021. The initial criteria were available from the Ministry of Health by 6 November 2021[10] but may not have been gazetted until 12 November 2021 (the earliest gazette reference I could find) although the

[10] https://www.nzdoctor.co.nz/sites/default/files/2021-11/Vaccine_temporary_medical_exemption_6_Nov_2021.pdf

> relevant legislation dated 7 November 2021 referred to exemption criteria either gazetted or available from the Ministry of Health.[11]'

On 21 March 2024, Dr Maplesden further advised:

> 'Not all practising GPs are vocationally registered (around 70% are vocationally registered in my network but that will vary by region) but they are still known as "GPs" and can represent themselves to the public as GPs. There has been a move to describe vocationally registered GPs as "specialist GPs" to differentiate those with vocational registration but this has had variable uptake. Whether or not the doctor is vocationally registered as a GP, if they are practising as a GP (which [Dr N] was) they would be expected to have appropriate knowledge of all medical and administrative issues (including relevant practising standards) relevant to their daily practice. This includes Covid-19 — both clinical and regulatory aspects.'

On 25 June 2024, Dr Maplesden further advised:

> 'There is nothing in the new information provided [Dr N's response to the provisional opinion] that leads me to change my original advice. I remain of the view that the prevailing medical opinion at the time of the events in question was that the benefit of the Pfizer mRNA vaccine outweighed known or theoretical risks of the vaccine although I agree there was no knowledge of potential long-term adverse effects just as there was limited knowledge of potential long-term adverse effects of contracting Covid-19. The safety data related to the vaccine was under constant review locally and internationally.
>
> While it is a reasonable argument that there was insufficient evidence at this time to guarantee long-term safety of the vaccine, the issue at stake is whether, based on available evidence, there were grounds for [Dr N] to state in a legal document that the patient could not receive the vaccine for medical reasons. I do not believe lack of evidence of safety can be equated to evidence of possible or likely harm. I remain of the view completion of such certification under the legislation referred to in my original advice was not appropriate in the majority of cases reviewed, particularly given the Ministry of Health and RNZCGP information available at the time.
>
> In point 79 of the [provisional opinion] it is stated: [Dr N] has emphasised that she in fact advised the patients that she could not confirm that there was no risk to them from the vaccine. If this is implied as a negative comment, I believe it should be reconsidered as it was a reasonable action to state a risk of vaccine-related harm could not be categorically excluded. However, such a statement needed to be balanced by discussion of the known risks of harm associated with Covid infection and prevalence of the disease, and the knowledge (at that time) of the frequency of severe vaccine-attributed reactions.
>
> I believe the remedial actions undertaken by [Dr N] in relation to her clinical documentation (per the report from [the MCNZ supervisor]) are appropriate and no further action is required in this regard.

[11] https://www.legislation.govt.nz/regulation/public/2021/0094/39.0/LMS594432.html

Appendix B: Transcript — handwritten notes provided to Commissioner

Patient D

'Consult, wondering whether could get certificate re vaccine. Since the roll out of vaccines and talk about potential mandates MH [mental health] has deteriorated. Once the mandates were put in place [patient] is unable to sleep and has panic attack, this is affecting [patient] physically …[1] sleep etc. Aware that section 7A already has been invalidated but wants proof for further reference … very well informed re "experimental status" of vaccines, international data etc.'

Patient F

'Seeking certificate re vaccine, severe [accident] in [patient's]… 20's with head injury, still with sequelae of this — never fully recovered. Stress and lack of sleep affecting past head injury.

— Headaches

— Lack of concentration

Very well informed re experimental status of vaccines. Also not mandated (works for [partner]) seeking proof of inappropriateness of vaccine. Effect of vaccine on head injuries not determined …'

Patient H

'Wondering whether could have some form of proof how mandates are affecting [patient's] MH. Severe nightmares, sweating, palpitations, this started once vaccines were considered to become mandated and symptoms have gradually worsened. "Feeling sick in my stomach". Aware 7A already retracted. Symptoms sec[ondary] to mandates. Patient very well informed re "experimental" status … safety data not available …'

[1] Ellipsis (…) denotes an illegible word.