Pharmacy

Pharmacist, Ms B

A Report by the

Health and Disability Commissioner

(Case 22HDC02256)

Health and Disability Commissioner

Te Toihau Hauora, Hauātanga

Contents

Executive summary

1. This report relates to information provided to a consumer who received the Comirnaty COVID-19 vaccine at a pharmacy in 2021. Sadly, the consumer passed away 12 days after receiving the vaccine. The cause of death was found to be myocarditis, and the Coroner determined that the myocarditis was directly caused by the Comirnaty vaccine.

2. The consumer was not informed about the risk of myocarditis either prior to receiving the vaccine (as part of the informed consent process) or after (as part of safety-netting advice). The Commissioner found that, considering the potential seriousness of harm, and notwithstanding the low probability of occurrence, the risk of myocarditis was something that a reasonable consumer at the time would have expected to be informed about under Right 6(1) of the Code. The Commissioner considered that the consumer also should have been told to be alert to the symptoms of myocarditis as part of safety-netting advice.

3. However, while the Commissioner considered that there was an apparent breach of Right 6(1), because the consumer had not been given this information, she did not find a breach of the Code. She considered that there were significant mitigating factors in this case, including that official information sources did not make it adequately clear to vaccinators that consumers needed to be told about myocarditis prior to receiving the vaccination.

4. However, the Commissioner noted that official guidance explicitly said that safety-netting advice must include advising consumers about the symptoms of myocarditis. The Commissioner was therefore critical that the pharmacy involved did not pick up on this guidance and amend its processes accordingly. The Commissioner was also critical that the vaccinating pharmacist did not inform the consumer about myocarditis, and, in particular, the symptoms of myocarditis, as part of safety-netting advice.

5. The Commissioner also commented on the way in which Manatū Hauora | Ministry of Health channelled information about myocarditis through official sources to vaccinators and consumers. In the Commissioner's view, lessons can be learned from this case about the fundamental importance, in the context of new vaccines and emerging risks, of explicit guidance to vaccinators about what information they must give to consumers.

Complaint and investigation

6. The Health and Disability Commissioner (HDC) received a referral from the Coroner about the services provided to Mr A at a pharmacy. The following issues were identified for investigation:

- *In 2021, whether the pharmacy provided Mr A with an appropriate standard of care and had adequate processes in place to ensure he received information that a reasonable consumer would expect to receive;*

- *Whether Ms B provided adequate information to Mr A about the Comirnaty COVID-19 vaccine in 2021;*

7. The parties directly involved in the investigation were:

Consumer's partner	
Consumer's father	
Pharmacy/provider	
Ms B	Pharmacist/provider

8. Pharmacy operations manager Ms C is also mentioned in this report.

9. Further information was received from the Coroner.

Information gathered during investigation

10. In 2021, Mr A, aged in his twenties, attended a pharmacy and was administered his first dose of the Comirnaty COVID-19 vaccine[1] (the Comirnaty vaccine) by pharmacist Ms B.[2] Mr A was informed of the common side effects of the vaccine, but not of the rare but potentially serious side effects known at the time, which included myocarditis (inflammation of the heart), symptoms of which include a racing heart and chest pain.

11. Beginning that night, and at other times during the following 12 days, Mr A repeatedly expressed concerns to his family and partner about a feeling of chest discomfort and heart flutters (palpitations/racing heart). However, he was not aware that these symptoms could be a side effect of the vaccine and he did not seek the urgent medical attention required for such symptoms.

12. At about 3.30am, 12 days after he received the vaccine, after a restless period of discomfort, Mr A decided to go to hospital. Tragically, before he could do so, Mr A collapsed and died. The cause of death was found to be myocarditis, and the Coroner found that in Mr A's case the myocarditis was directly caused by the Comirnaty vaccine. Mr A's phone records show that between 2.08am and 2.12am before his collapse he had carried out internet searches for 'heart racing since vaccine' and 'myocarditis'.

Information about myocarditis risk available to vaccinators at time of care

13. On 31 July 2021, the pharmacy signed an agreement with the District Health Board (now Te Whatu Ora|Health New Zealand[3]) (Te Whatu Ora) to provide COVID-19 vaccination services. The contract stipulated that the pharmacy required to comply with any COVID-19 vaccine

[1] Also called the Pfizer/BioNTech vaccine.
[2] Ms B is no longer an employee of the pharmacy.
[3] Te Whatu Ora is now called Health New Zealand Te Whatu Ora.

processes and guidance issued by Manatū Hauora|Ministry of Health, and any guidelines issued by Te Whatu Ora.

14. Approximately five months prior to Mr A's death, several communications from a number of official sources were made to COVID-19 vaccination providers about the risks of myocarditis and its symptoms, as a rare but potentially serious side effect of the vaccine. Sources of this information included Medsafe (a business unit within Manatū Hauora), Manatū Hauora, Te Whatu Ora, and the Immunisation Advisory Centre (IMAC).[4] The following information was provided on the following dates:

- 9 June 2021: Medsafe published a monitoring communication[5] on its website advising that myocarditis can be a potential reaction to the Comirnaty vaccine. The communication briefly described myocarditis and advised that Medsafe was investigating the potential risk of myocarditis following vaccination with Comirnaty. Medsafe noted that there had been several reports of myocarditis following the vaccine, in New Zealand and overseas. On the same day, Manatū Hauora issued a COVID-19 Vaccine Update[6] referring to the monitoring communication.
- 23 June 2021 and 7 July 2021: Manatū Hauora issued further COVID-19 Vaccine Updates again referring to the monitoring communication and encouraging vaccinators to report to the Centre for Adverse Reactions Monitoring (CARM) any events involving myocarditis in people after their Comirnaty vaccine.
- 21 July 2021: Medsafe published an alert communication[7] confirming myocarditis as a rare (affecting fewer than one in one million people) and typically mild adverse reaction to the Comirnaty vaccine. Medsafe advised providers to be alert to signs of myocarditis occurring in people after vaccination and noted that '[v]accinated individuals should be advised to seek immediate medical attention should they experience new onset of chest pain, shortness of breath, palpitations or arrhythmias'. The alert stated that myocarditis occurred mostly within four days but in a few cases up to 14 days after vaccination. The data at the time suggested that the risks appeared highest in younger men and after the

[4] IMAC is a nationwide organisation based at the University of Auckland. IMAC is a division of Auckland UniServices Limited, a wholly owned subsidiary of the University of Auckland. IMAC was initially established to provide immunisation advice to both parents (to promote and support childhood immunisation) and health professionals but IMAC told HDC that its main role has been, and continues to be, focused on providing advice to health professionals. Its contract with the government was expanded to include providing immunisation education and training, promotion, and setting of national standards. As noted in paragraph 25 below, Manatū Hauora commissioned IMAC to provide COVID-19 vaccine training and clinical guidance tools and advice for the vaccinating workforce.

[5] Monitoring communications provide information to consumers and healthcare professionals about newly identified potential safety concerns.

[6] The COVID-19 Vaccine Update was a fortnightly newsletter sent by Manatū Hauora to the health and disability sector. It provided a general programme update, a clinical update for vaccinators, and a list of resource links.

[7] Alert communications are issued once a review of the safety concern is complete. They are published if a significant safety issue is identified. Alerts contain more information on the safety concern and provide specific advice on actions that may need to be taken by healthcare professionals and consumers. Both alert and monitoring communications are emailed to parties who are subscribed to receive updates from Medsafe (of which the pharmacy was one) and are published on Medsafe's website.

second vaccine dose. This is the only alert communication Medsafe has issued about a COVID-19 vaccination side effect.[8] On the same day, Manatū Hauora issued a COVID-19 Vaccine Update noting that myocarditis can be a rare adverse reaction of the Comirnaty vaccine, and that the vaccine data sheet would be updated.

- 28 July 2021:

  1. Medsafe uploaded on its website the updated vaccine data sheet[9] for the Comirnaty vaccine. The updated data sheet advised healthcare professionals to be alert to the signs and symptoms of myocarditis and noted that people receiving vaccines 'should be instructed to seek immediate medical attention if they develop symptoms indicative of myocarditis or pericarditis[10] such as (acute and persisting) chest pain, shortness of breath, or palpitations following vaccination. Healthcare professionals should consult guidance and/or specialists to diagnose and treat this condition.'

  2. Medsafe also published a data sheet for consumers, called 'consumer medicine information' (CMI). The CMI front page summary referred to 'very common side effects' of the vaccine (but not to myocarditis). The third page of the CMI included more detailed information about potential side effects, including myocarditis and pericarditis, which were categorised as 'other side effects (frequency unknown)'. The CMI advised consumers who experienced 'chest pain, breathlessness and/or palpitations' to 'Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice this serious side effect'. This version of the CMI was in place at the time of Mr A's vaccination.

- 27 August 2021: Manatū Hauora sent a COVID-19 Vaccine Update. This update covered several issues, including myocarditis. The update referenced the recently updated data sheet and CMI and advised health professionals to be alert to the symptoms of myocarditis and pericarditis.

- 30 August 2021:

  1. Manatū Hauora issued a media release noting that the COVID-19 Vaccine Independent Safety Monitoring Board (CV-ISMB)[11] had reviewed the death of a woman in July 2021 following her Comirnaty vaccine. CV-ISMB considered that the woman's death was due to myocarditis, which 'is known to be a rare side effect' of the Comirnaty vaccine. The media release noted that this was the first case in Aotearoa New Zealand where a death in the days following vaccination had been

[8] Medsafe has also issued monitoring communications about COVID-19 vaccines and rare cases of blood clots with bleeding (27 April 2021), menstrual disorders and unexpected vaginal bleeding (17 November 2021), and safety in pregnancy (17 November 2021).
[9] A data sheet is prepared by the sponsor responsible for the medicine and informs healthcare professionals about aspects of the relevant medicine they should know about, including known side effects. Data sheets are a legal requirement for all medicines.
[10] Inflammation of the tissue surrounding the heart.
[11] The CV-ISMB was set up in February 2021 to provide expert advice on the safety of COVID-19 vaccines to the Centre for Adverse Reactions Monitoring, Medsafe, the COVID-19 Vaccine and Immunisation Programme, and Manatū Hauora.

linked to the vaccine. On the same day, Manatū Hauora issued a COVID-19 Vaccine Update with a link to the media release.

2. IMAC sent out an e-news mailout to vaccinators who had subscribed to its updates, which was titled 'Myocarditis and the Covid-19 vaccine'. This mailout referred to the Manatū Hauora press release and included a link to further information on myocarditis on IMAC's website.

- 1 September 2021: Te Whatu Ora sent a newsletter via their online portal[12], which included a section called 'Myocarditis and what to look out for'. The newsletter noted that myocarditis is a rare side effect of the Comirnaty vaccine and asked providers to familiarise themselves with IMAC information and advice about myocarditis.
- 9 September 2021: Manatū Hauora issued a COVID-19 Vaccine Update, which included a section on myocarditis and included links to the latest guidance on it.
- 17 September 2021: IMAC issued[13] a fact sheet titled 'Myocarditis and the mRNA COVID-19 vaccine in New Zealand — information for health professionals'. This fact sheet was about the increased risk of myocarditis and pericarditis and the Comirnaty vaccine. It classified the risk of myocarditis as rare. The fact sheet also provided information for health professionals about the signs and symptoms and diagnosis of myocarditis.
- 24 September 2021: a newsletter was sent via Te Whatu Ora's online portal, including a section called 'Provider resources', which discussed the need to support consumers who were vaccine hesitant. This section included a link to the above IMAC fact sheet.
- 29 September 2021: Manatū Hauora updated its website page on vaccine side effects to advise that myocarditis was now a known rare side effect of the Comirnaty vaccine. The update noted that the symptoms of myocarditis include new onset chest pain, shortness of breath, and an abnormal/racing heartbeat. The following was stated in bold underneath these symptoms: 'It's important that anyone who experiences these symptoms in the first few days after vaccination seeks medical attention promptly.' The webpage also listed temporary one-sided facial drooping as a rare side effect.

15. In addition, all Manatū Hauora vaccine information leaflets for consumers that were current at the time of Mr A's care stated:

> 'There are some side effects that are more serious but very rare, like a severe allergic reaction or an inflammation of the heart. If you develop difficulty breathing, a racing heart, chest pain or feel faint immediately after or in the days after the vaccine, you should seek medical attention.'[14]

[12] The online portal (administered by Te Whatu Ora) has been available to providers since July 2021 for access to the latest advice, resources, and news about the vaccination programme. Whenever the portal is updated, an email is sent to all vaccination providers in the district, including the pharmacy, to let them know about the updates.

[13] The fact sheet was published on IMAC's website and emailed to vaccinators, including the pharmacy.

[14] 'Your COVID-19 vaccination: Everything you need to know' (11 October 2021), 'Getting your COVID-19 vaccine: What to expect' (13 October 2021), 'COVID-19 vaccination: Get the facts' (24 September 2021),

16. Ms C was the pharmacy's operations manager and one of its two directors at the time. She told the Coroner's inquest into Mr A's death that 'the flow of information from the Ministry of Health and other organisational entities has not been perfect'. She commented that a significant volume of information was being sent out to providers[15] and said: '[W]e are doing the best that we can to see through everything that comes through …' Similarly, Ms B told the inquest that they were receiving frequent information updates from various official sources, and she believed that communications could have been improved by highlighting the significance of new information.

17. It is also noted that evidence provided at the coronial inquest shows that 12 updates were emailed to vaccinators via Te Whatu Ora's online portal in a period of three weeks (between 23 August 2021 and 10 September 2021).[16] These updates covered a wide variety of topics with respect to the Comirnaty and other COVID-19 vaccines. As established in paragraph 14 above, some of these updates included information about myocarditis as a rare side effect of the Comirnaty vaccine, while information about myocarditis from other sources such as Medsafe was also being issued at this time.

18. In response to the provisional opinion, Manatū Hauora commented that within the documents being disseminated to vaccinators, there was a subset of key documents that would or should have alerted vaccinators to the risk of myocarditis, about which consumers needed to be informed. It also noted that to the extent there was a large flow of information, much of this volume reflects the complex logistics of a vaccination programme on an unprecedented scale. Manatū Hauora added that it had elected to apply a multi-channel approach to communications, which was driven by an attempt to maximise reach for all communications issued and to ensure that all vaccination providers received relevant messages. Manatū Hauora used different channels to communicate information about the COVID-19 vaccine based on what it considered the different groups in the diverse vaccinator workforce would be most likely to access. There was a risk, Manatū Hauora pointed out, in using only one means of distributing information across the country. Finally, Manatū Hauora noted that Medsafe alert communications have been consistently used over the years to advise practitioners of new risks, and the format and language used for these communications have been consistent over this time.

COVID-19 resources and guidelines on informed consent

19. Manatū Hauora's 'Immunisation Handbook' and 'Operating Guidelines for DHBs & Providers'[17] included information for providers on the informed consent process for the vaccine. Both guidelines offer general advice on the process and principles of informed consent, and on engaging with consumers regarding their treatment, including communication of risks and benefits. These guidelines do not specify the precise risks to be

'COVID-19 vaccine: After your vaccination' (11 October 2021), and 'COVID-19 vaccine: Your safety and side effects questions answered' (14 September 2021).

[15] In her evidence to the Coroner, on several occasions Ms C referred to the 'millions of emails' that came through to the pharmacy.

[16] This was the busiest time in the relevant period for Te Whatu Ora online portal updates being sent out. Between 16 September 2021 and 3 November (nearly 7 weeks), 15 updates were sent.

[17] Updated in October 2021 and September 2021 respectively.

communicated at the time of vaccination or go beyond providing general advice on the process. The Immunisation Handbook states that consumers must be able to understand the 'probable benefits, risks, side effects' of the vaccine in order to give their consent.

20. The Operating Guidelines state that the vaccinator will provide the consumer with the vaccination information and consent pack, which includes the 'what to expect' and 'after your immunisation' fact sheets (as noted in paragraph 15, these fact sheets refer to inflammation of the heart as being a very rare side effect, and recommend that consumers seek medical attention if they develop symptoms after receiving the vaccine). These guidelines also state that post-vaccination advice should be given to consumers both verbally and in writing.

21. IMAC guidance from September 2021 and at the time of Mr A's vaccination stated that post-vaccination advice must include telling people of the need to seek medical advice for any unexpected concerns, including chest pain, shortness of breath, or palpitations. IMAC's guidance was primarily contained in IMAC's 'Screening and guidance form' (the form) and its 'COVID-19 Immunisation Clinical Toolkit' (the toolkit) (both issued in September 2021 and updated in October 2021). Neither document explicitly required that the risk of myocarditis be discussed with the consumer before the vaccine was administered.[18] However, the updated (October 2021) version of the toolkit also included a section called 'Pre-vaccination including conversation, screening and consent'. This section contained the following subsections (in order of appearance): 'Informed Consent', 'Vaccine hesitant', 'Myocarditis conversations', 'Pregnancy/breastfeeding/fertility conversations', and 'Dedicated team to support disabled people'. The myocarditis subsection described myocarditis as 'a very rare, usually mild illness' and discussed the risks of myocarditis from the vaccine as against the benefits of getting vaccinated.

22. Links to the form and the toolkit were emailed to the pharmacy via the online portal newsletters on 6 September and 9 September 2021 respectively. The covering emails did not refer to myocarditis or highlight what information was contained in the documents. IMAC told the Coroner that the updated October 2021 version of the toolkit was uploaded to its website and a link emailed to vaccinators on 12 October 2021.

23. The Operating Guidelines were updated in February 2023 and now specifically require consumers to be advised of common and rare side effects (including myocarditis) 'at the time of vaccination'. Relevant excerpts from the updated guideline are appended (Appendix A). IMAC's updated (July 2022) toolkit specifies that myocarditis should be discussed with consumers as part of the informed consent process.

Responsibilities for disseminating information to vaccinating providers

24. The Operating Guidelines also stated that Manatū Hauora was responsible for providing 'key messages to DHBs to share'. A representative from Te Whatu Ora told the coronial inquest that in conjunction with Manatū Hauora and IMAC, Te Whatu Ora's vaccine programme was

[18] The form did note that consumers who had been diagnosed with myocarditis following their first vaccine dose should have cardiac review and guidance from IMAC before receiving future doses.

responsible for distributing national and regional resources and updates to vaccination providers. From early July 2021, this was done via Te Whatu Ora's online portal. The representative also stated: '[Te Whatu Ora was] a conduit for information coming directly from [Manatū Hauora]. We weren't responsible for generating the content.' A different Te Whatu Ora representative stated in a brief of evidence to the Coroner that the online portal emails adopted the emphasis (if any) in the information it received from Manatū Hauora and IMAC.

25. A representative from Manatū Hauora (the National Immunisation Programme (NIP))[19] told the coronial inquest that Manatū Hauora was responsible for commissioning IMAC to provide COVID-19 vaccine training and clinical guidance tools and advice for the vaccinating workforce. The representative also stated that in order to disseminate emerging evidence on vaccine safety, the NIP commissioned IMAC to update vaccinator training modules and clinical advice, update vaccinator and provider communications, and revise the consumer collateral (meaning the consumer information sheets). IMAC told HDC that its primary role was in connection with training for vaccinators and preparing vaccinator collateral, rather than consumer collateral. It said it was asked on a few occasions to confirm the clinical accuracy of information written by others and intended for consumers, but it was not IMAC's role to draft such consumer collateral.

26. In addition, another Manatū Hauora representative stated, in their evidence to the Coroner, that they were part of the sign-out process for some documents (including IMAC's 'Screening and guidance form' and the COVID-19 chapter in the Immunisation Handbook), and that they and others from Manatū Hauora had input into the clinical advice about myocarditis (but not into how this information was presented in the collateral).

Pharmacy's vaccine process

27. The pharmacy's standard operating procedure (SOP) at the time of events, which applied to the administration of all vaccines and not just the Comirnaty vaccine, stated: 'The vaccinator should ensure the patient understands what the vaccine is for, how it is given, the possible side effects …' The SOP also stated: 'Encourage patients to contact the pharmacy if concerned about an adverse reaction (unless serious, in which case they should seek medical advice immediately).'

28. Ms C explained to the Coroner that the pharmacy's practice was to go through with the consumer the common side effects as listed on the 'COVID-19 vaccine: After your vaccination' information leaflet (published by Manatū Hauora). She said that they would then tell consumers: '[A]nything that is beyond these side effects, you must go and get it checked out.' Ms C said that they did not specifically mention the risk of myocarditis.

29. In relation to the information about myocarditis symptoms issued in the Medsafe alert of 21 July 2021 and the vaccine data sheet issued shortly afterwards, Ms C stated:

[19] At the time of Mr A's vaccination, NIP was part of Manatū Hauora. It is now part of Te Whatu Ora|Health New Zealand.

> 'I interpret both statements to mean that if we are contacted by someone who has been vaccinated and is displaying those symptoms, then we should recognise that it could be myocarditis or pericarditis and advise them to seek appropriate medical attention.'

30. Ms C stated that until after Mr A's death, the pharmacy was not aware of any communication that required advising consumers on the risks of myocarditis specifically. She said that it would be unusual to advise consumers of every side effect of a medication, including those that are very rare. She added that they were not aware of the death of a woman following her Comirnaty vaccine in August 2021 (referred to in paragraph 14 above).

31. Ms C also stated that vaccinators would offer consumers a copy of the information leaflet to take away after they received the vaccine but would not 'force it on them'.

32. Following Mr A's death, the pharmacy changed its practice so that its vaccinators would specifically discuss with consumers the risk of myocarditis before administering the vaccine.

Ms B — vaccinating pharmacist

33. In relation to the process followed for Mr A's vaccination, Ms B's evidence to the Coroner was that she conducted an initial discussion with him at the counter (some screening questions) before checking him into the vaccination area. Her usual process of informed consent was to go through the common side effects listed on the 'Getting your COVID-19 vaccine: What to expect' information sheet that sat in front of the consumer. Myocarditis was not discussed specifically. Ms B could not remember what specific post-vaccination advice she gave to Mr A but said that her usual practice was to remind every consumer that flu-like symptoms were a common side effect following vaccination, and to contact the pharmacy or Healthline[20] if they had any concerns. She added that at the time, she invited each consumer to take or read one of the information sheets. However, she recalled that Mr A did not take one.

34. Ms B told the Coroner that when she vaccinated Mr A, she was aware of myocarditis being a very rare side effect of the Comirnaty vaccine, and she believed she learned about this via email communication from Te Whatu Ora. However, she said that on or before the date Mr A received the vaccine she was not aware of any specific requirement to discuss myocarditis with consumers.

35. Ms B stated that she would not have discussed the possible risk of myocarditis with Mr A as part of the informed consent process because it is 'a very rare side effect of the vaccine'. She said that instead she would go through the common side effects listed on the information sheet.[21]

36. Ms B stated:

[20] A free telephone-based health service.
[21] The 'Getting your COVID-19 vaccine: What to expect' (13 October 2021) information sheet.

> 'If a consumer had rung the store and advised that they had chest pain or other chest or heart related symptoms following a vaccination, then we would have told them to obtain urgent medical advice.'

37. Ms B told the Coroner's inquest that Ms C's verbal instruction to vaccinating staff at the time was to tell consumers about the common side effects of flu-like symptoms. Ms B said that there was no instruction also to inform consumers of myocarditis-related rare side effects that were noted on the consumer information leaflets (see paragraph 15).

Manatū Hauora's comments

38. Manatū Hauora's response to the Coroner was that in its view, the Medsafe alert communication of 21 July 2021 was the first instruction to vaccinators to inform consumers of the risk of myocarditis and its symptoms.

Comments from Mr A's parents and partner

39. Mr A's parents told HDC that they do not believe that Mr A gave his informed consent to receive the Comirnaty vaccine because he was not given the necessary information to understand the benefits, risks, uncertainties and alternatives. Mr A's parents said that they understood that considerable information was provided to vaccinators, but risks such as myocarditis were not highlighted in any of the documentation. However, Mr A's parents and partner all expressed a view that other vaccinators had also not been making people aware of the risk of myocarditis and its symptoms as a possible side effect of the vaccine, and they do not believe that the pharmacy or Ms B deserve to be singled out for not providing that information to Mr A.

Responses to provisional opinion

40. I sent relevant sections of my provisional opinion to Mr A's parents and partner, Ms B, the pharmacy, Manatū Hauora,[22] and IMAC for their feedback. Where appropriate, their comments have been incorporated into this report.

41. In addition, I note the following. Mr A's parents said that they agreed with the provisional findings. They also had broader concerns about the way in which the COVID-19 vaccine programme was rolled out by the Government. They are concerned that the vaccination programme, and the associated public messaging, placed undue pressure on people to get vaccinated, and that this pressure impacted on Mr A's decision-making and influenced his exercise of informed consent.

42. Mr A's partner, Ms B and the pharmacy did not wish to comment.

43. Manatū Hauora commented that the information presented in this report demonstrates that it communicated information about the risk of myocarditis following vaccination on multiple occasions and through numerous different channels. It also highlighted that the context in which the information was provided — the fast-moving COVID-19 pandemic and a vaccine roll-out of unprecedent scale in New Zealand with constantly evolving information

[22] Whose response included feedback from Te Whatu Ora.

— was important. Given this context, Manatū Hauora considers that it applied appropriate skill and care in communicating the risk of myocarditis to vaccination providers, and in order to support a consumer's right to informed consent.

44. However, Manatū Hauora accepted that communications can always be improved and refined (while noting that a written communication can never be perfect for every person who receives it). It added that it has proactively refined its messaging on myocarditis as further information has become available. Manatū Hauora said that it has also taken several learnings from the coronial inquest into Mr A's death and will carefully review any feedback from the Royal Commission of Inquiry, established in December 2022, to look at lessons from New Zealand's response to COVID-19.

Opinion: Introductory comments

Introduction

45. This case involves the premature death of a young man, the impact of which has been felt by many. I extend my heartfelt condolences to Mr A's parents and partner, and his wider whānau and friends.

46. The Coroner found that Mr A died from myocarditis due to vaccination with the Comirnaty vaccine. At the time of his vaccination, Mr A was not informed that myocarditis is a possible side effect of the vaccine, and as a result he did not know that the post-vaccination chest and heart symptoms he experienced required urgent medical attention.

47. Right 6(1) of the Code of Health and Disability Services Consumers' Rights (the Code) states that 'every consumer has the right to the information that a reasonable consumer, in that consumer's circumstances, would expect to receive, including … an assessment of the expected risks [and] side effects'. It does not require every risk or side effect to be disclosed to a consumer. As to whether a reasonable consumer would expect to be told of a rare risk requires the probability of that risk to be weighed against the magnitude of the potential harm. Accordingly, if the potential harm is serious, a reasonable consumer may expect to be told of it, even though the likelihood of it occurring is less than one percent.[23] Of course, each case must turn on its own facts.

48. From July 2021, information about the risk of myocarditis associated with the Comirnaty vaccine was widely available and distributed to health providers through several official sources. Information from Medsafe, Manatū Hauora, Te Whatu Ora, and IMAC at the time generally characterised myocarditis as a rare, or very rare, but potentially serious side effect. While most reported cases of myocarditis following the Comirnaty vaccine have been mild and short-lasting, death is a rare complication of myocarditis. By the time of Mr A's

[23] Health Law in New Zealand, p 47, f/n 114.

vaccination, New Zealand had experienced one publicised death attributed to vaccine-induced myocarditis.

49. The broader public context is also relevant in the consideration of this issue. The pandemic presented a public health emergency prompting an unprecedented international and national response. This included the development of new vaccines, of which the Comirnaty vaccine was one, and the gradual emergence and study of side effects. As the evidence outlined above shows, there was a steady and frequent flow of information (including evolving and developing information) from official sources, which needed to be developed at pace by those agencies and then transmitted to, absorbed by, and put into practice by vaccination providers. Between 9 June and 29 September 2021 there were at least 10 communications referencing myocarditis as a rare side effect, although there were also many other communications sent to vaccination providers regarding COVID-19 and vaccination matters.

50. In my view, it is also significant that in July 2021 myocarditis was the subject of the only Medsafe alert about a COVID-19 vaccination side effect, and at the time of Mr A's vaccination, all Manatū Hauora vaccine information leaflets for consumers referred to the potentially serious but very rare side effect of 'inflammation of the heart'. Those leaflets also provided safety-netting advice as to what a consumer should do if they experienced heart or breathing symptoms (the relevance of myocarditis as part of safety-netting advice is discussed further below).

51. Taking all these matters into consideration, and, in particular, considering the information that was available and was known, including that the consumer vaccination information leaflet current at the time noted myocarditis as a side effect, I am satisfied that it was intended by the official agencies that myocarditis be communicated to consumers as part of the consent process (ie, before the administration of a vaccine). Moreover, considering the potential seriousness of the harm, I am satisfied, notwithstanding the low probability of occurrence, that this was a risk that the reasonable consumer would have expected to be informed about under Right 6(1).

52. For completeness, I note Mr A's parents' broader concerns about the COVID-19 vaccine programme. In particular, they are concerned that Mr A's decision-making and his exercise of informed consent were influenced by what they saw as undue pressure placed on people to get vaccinated.

53. I accept that Mr A would have been exposed to the public messaging around the vaccine, and that this could well have influenced his decision about whether to get vaccinated. However, the focus of my investigation has been on whether Mr A received the information that he was entitled to receive at the time of his vaccination. As such, these issues fall outside the scope of my investigation.

Official guidance about myocarditis and Comirnaty vaccine

54. Before considering whether the Code has been breached, it is important to establish the extent to which vaccinators were made aware that the risk of myocarditis should form part

of the information to be provided to consumers prior to the administration of the vaccine as part of the consent process, and that safety-netting advice (advice on what to do should abnormal symptoms arise) should be provided following the vaccination.

55. The evidence from the pharmacist and pharmacy suggests that the importance of new information, relative to other information, was not clear to those vaccination providers. This is discussed further below.

Informed consent

56. Of course, vaccination providers were entirely reliant on the information being provided to them. While acknowledging the rapidly evolving vaccination landscape, and the effort to ensure that accurate and current information was made available to vaccinators and consumers, I conclude, having reviewed the data sheets and communications, that there was a lack of clarity in official guidance regarding the information required for the consent process. While the numerous sources of information (already outlined) referred to myocarditis or its symptoms, none of the sources explicitly required vaccinators to disclose the risk of myocarditis to the consumer as part of the informed consent process *prior* to the vaccination being administered. Noting the significant volume of information being given to vaccination providers, there was no emphasis (by highlighting or otherwise) of this particular risk.

57. By way of example, I note that the October 2021 version of IMAC's toolkit did include a discussion about the risks of myocarditis versus the benefits of vaccination under the section entitled 'Pre-vaccination including conversation, screening and consent'. While it could be inferred from the heading that the risk of myocarditis should be discussed prior to administration of the vaccine, there was no explicit instruction to do so. In addition, while this information was included under the broad heading of pre-vaccination processes, it came after the 'Vaccine hesitant' topic, which evidently would not need to be discussed with every consumer. Accordingly, its placement there may have conveyed the impression that the vaccinator could choose the information to discuss/disclose, depending on the individual circumstances before them, including the questions asked by the consumer. In addition, there was a separate subsection called 'Informed consent', which preceded the myocarditis subsection and did not refer to myocarditis. This layout leaves it open to the interpretation that a conversation about myocarditis was not expected to form part of the informed consent conversation.

Safety-netting advice

58. The Medsafe alert of 21 July 2021 advised providers to be alert to signs of myocarditis occurring in people after vaccination and noted that '[v]accinated individuals should be advised to seek immediate medical attention should they experience new onset of chest pain, shortness of breath, palpitations or arrhythmias'. Similarly, the data sheet for the Comirnaty vaccine noted that people receiving vaccines 'should be instructed to seek immediate medical attention if they develop symptoms indicative of myocarditis'.

59. I also note that the IMAC guidance was explicit in saying that post-vaccination advice must include telling consumers to seek medical advice for any unexpected concerns, including chest pain, shortness of breath, or palpitations (all signs of myocarditis).

60. On the basis of the available information, I am satisfied that it was the intention of the official agencies that, as at the date of Mr A's vaccination, consumers were to be given safety-netting advice about myocarditis symptoms once they had received their vaccination. Given that myocarditis is a potentially serious life-threatening condition, in my opinion a reasonable consumer in Mr A's position receiving the Comirnaty vaccine would have expected safety-netting advice to include being alert to the symptoms of myocarditis. This information is critical to enable consumers to recognise and appreciate the potential seriousness of the symptoms should they develop them, and to seek appropriate medical attention.

Opinion: Pharmacy — adverse comment

61. I have concluded that as part of the informed consent process, Mr A should have been informed about the risk of myocarditis before his vaccination. I also consider that as part of the safety-netting advice provided, he should have been told to be alert to the symptoms of myocarditis.

62. The pharmacy had an organisational responsibility to provide its staff with the vaccine information it received from official sources, as well as appropriate guidance to ensure that consumers were being informed adequately when they were vaccinated. This section of the report will discuss whether the pharmacy took sufficient steps to satisfy this responsibility and, therefore, ensure that Mr A's right to be informed was upheld.

63. At the time, the pharmacy's SOP, which was about all vaccines generally and not the Comirnaty vaccine specifically, stated that staff should ensure that consumers understood the possible side effects of a vaccine, and encourage vaccinated consumers to contact the pharmacy if concerned about an adverse reaction (or seek immediate medical advice for a serious reaction).

64. Usual practice at the pharmacy at the time was for vaccinators to discuss the common side effects of the vaccine with the consumer prior to vaccination, and to advise them that they should seek medical attention if they experienced any other side effects. Vaccinators would offer consumers copies of the information leaflets but would not 'force' them to take one. Given that myocarditis was not a common side effect of the Comirnaty vaccine, it was not usual practice at the pharmacy to inform consumers about myocarditis either before or after the vaccine. Ms C stated that they had interpreted the available guidance about the Comirnaty vaccine as saying that the pharmacy needed to advise consumers to seek medical attention only if they communicated to the pharmacy concerns about symptoms of myocarditis at any point after vaccination.

65. As such, in my opinion, the practice at the pharmacy at the time of Mr A's vaccination was inadequate to satisfy the obligation to provide the information that a reasonable consumer would expect to receive (being information about myocarditis), both prior to vaccination and post-vaccination. Accordingly, there is a prima facie breach of Right 6(1) of the Code.

66. However, there are significant mitigating factors in this case. As discussed above in more detail, I consider that official information sources did not make it adequately clear to vaccinators that consumers needed to be told about myocarditis prior to receiving the vaccination.

67. There is also evidence that the importance of new information, relative to other information, was not clear to vaccination providers. This made it more likely that key messages for vaccinators about myocarditis would be missed. In this vein, I note that the 6 September 2021 email from Te Whatu Ora's online portal, which shared the IMAC guidance with providers, including the pharmacy, did not refer to myocarditis or highlight what the IMAC guidance covered. This made it less likely that the pharmacy would appreciate the significance of the IMAC guidance. I also accept, as Ms C stated, that a significant volume of information was being sent to providers about the Comirnaty vaccine from several sources. Given the seriousness of the risk of myocarditis and the information volume, one could reasonably expect that in communication to the providers the risk would be emphasised or highlighted in some way.

68. I am also mindful that the Comirnaty vaccine was, at the time, relatively new and new information about its use, risk and side effects was still forthcoming. While consumers' rights to informed consent under the Code are of fundamental importance, and I am very concerned that it appears that Mr A's right to the information that he was entitled to receive was not upheld, the unique and novel situation leads me to conclude that it would be disproportionately harsh to find a breach, and that an educational approach is more appropriate in the circumstances. I am also mindful of guarding against hindsight bias. Accordingly, I will be making several recommendations for improvement (outlined below) to ensure that lessons are taken from Mr A's experience.

69. With all this context in mind, I consider that the pharmacy was insufficiently supported to ensure that consumers were being informed about myocarditis adequately at the time of Mr A's vaccination. This, in my opinion, materially mitigates its responsibility under Right 6(1) of the Code, and therefore I find that the pharmacy did not breach the Code.

70. However, I note that IMAC guidance at the time of Mr A's vaccination explicitly stated that safety-netting advice must include advising consumers about the symptoms of myocarditis. This advice had been provided to the pharmacy. Similarly, Manatū Hauora's Operating Guidelines required providers to pass on information sheets to consumers, and to provide post-vaccination advice both verbally and in writing. That consumers did not always take or read the information sheets emphasises the importance of reasonably ensuring that adequate verbal safety-netting advice was given.

71. Given the importance of safety-netting advice relating to the administration of a medicine, I am critical that the pharmacy did not pick up on the IMAC guidance and update its practices and SOP to ensure that staff were giving consumers adequate safety-netting advice, both verbally and in writing, about the symptoms of myocarditis to look out for. Because this information was not disclosed to Mr A at the time of his vaccination, and because the pharmacy's usual practice of not 'forcing' consumers to take a copy of the information sheet meant that Mr A did not have written information about myocarditis, Mr A's opportunities to inform himself of this critical advice were limited.

72. I also consider that the pharmacy could improve the service it provides by having a separate section of its SOP about the Comirnaty vaccine specifically.

Opinion: Ms B — adverse comment

73. As above, I have concluded that Mr A should have been informed about the risk of myocarditis before his vaccination, as part of the informed consent process. I also consider that he should have been told about the symptoms of myocarditis as part of safety-netting advice once he had been administered the vaccine.

74. Ms B was the treating pharmacist who vaccinated Mr A and was responsible for providing him with the appropriate information about the vaccine. Ms B was aware of myocarditis being a very rare side effect of the Comirnaty vaccine when she vaccinated Mr A. However, on or before the date Mr A received the vaccine, Ms B was not aware of any specific requirement to discuss myocarditis prior to administering a Comirnaty vaccine. She said that the reason she did not discuss this with Mr A was because she did not have instruction from the pharmacy to do so and was 'following instructions on what to say'.

75. As noted above, on the date Mr A received the vaccine, the pharmacy's SOP did not require staff specifically to advise consumers at the time of vaccination that they should seek medical advice if they later experienced any chest pain, shortness of breath or heart palpitations. Ms C said that the pharmacy's process was to offer consumers the information leaflet after the vaccination, go through the common side effects, and then tell consumers to get checked out for anything beyond those. Ms B followed this process when vaccinating Mr A.

76. Ms B also explained that it was not her usual practice to proactively inform consumers of the need to seek urgent medical attention if they experienced the symptoms of a racing heart, difficulty breathing, or chest pain following vaccination. Instead, her usual practice was to remind consumers that flu-like symptoms were a common side effect after vaccination, and to contact the pharmacy or Healthline if they had any concerns. I accept that it is more likely than not that she would have given Mr A this general advice in accordance with her usual practice.

77. In addition, as discussed above in more detail, I consider that the pharmacy (and therefore its employees) was insufficiently equipped to ensure that consumers were being informed about myocarditis adequately at the time of Mr A's vaccination. That said, also as noted above, IMAC guidance at the time of Mr A's vaccination explicitly stated that safety-netting advice must include advising consumers about the symptoms of myocarditis.

78. Ms B, as a healthcare provider, has a responsibility to ensure that she upholds Right 6 of the Code by giving consumers the necessary information when providing them with a health service, and a professional obligation to keep her knowledge about the relevant information up to date. In this vein, I note that the Pharmacy Council's Competence Standards for the Profession include the following competencies:

> '[The pharmacist] …
>
> 0.1.5.5 Interprets and integrates information for provision to colleagues, other health professionals, patients and/or the public in a clear, cohesive and objective manner …
>
> 0.3.4 Obtains appropriate consent to administer the medicine …
>
> 03.5.3 Provides the patient with sufficient information to ensure the safe and proper use of medicine(s), including effective use of devices.'

79. With these competencies in mind, in my view pharmacists must take individual responsibility to ensure that they have adopted into their practice information that has been issued by official sources about vaccines they are administering. This includes ensuring that they have provided consumers with sufficient information about the vaccine, both pre-vaccine (as part of informed consent — Rights 6 and 7) and post-vaccine (as part of safety-netting advice — Right 6).

80. Ms B offered Mr A a leaflet that contained information about myocarditis symptoms, and verbally gave him general safety-netting advice to contact the pharmacy or Healthline if he had any concerns following vaccination, but she did not inform him specifically about myocarditis symptoms either before or after his vaccination.

81. As described above in further detail, there were deficiencies in the way in which information was provided to vaccinators, and a lack of clarity in the guidance and direction from official sources and the pharmacy at the time of Mr A's vaccination. As with all vaccinators providing any COVID-19 vaccine at the time, Ms B was reliant, to an extent, on her employer to provide her with adequate guidance as to the processes to be followed, and the information to be given to consumers. She was also reliant on the official sources of information clearly setting out what information needed to be provided to consumers, and when. This is particularly crucial in the context of new vaccines (such as the Comirnaty vaccine) with emerging risks.

82. In making these comments, I do not wish to diminish the individual responsibility of health professionals such as pharmacists to think critically and exercise their clinical judgement about what they need to convey to consumers when providing vaccinations or other medicines. A lack of clarity in official guidance will not always serve to mitigate an

individual's responsibility for providing the necessary information. However, as noted above, I am also mindful that the Comirnaty vaccine was, at the time, a relatively new medicine, and new information about its use, risk and side effects was still forthcoming. While consumers' rights to informed consent under the Code are of fundamental importance, and I am very concerned that it appears that Mr A's right to the information that he was entitled to receive was not upheld, the unique and novel situation at the time leads me to conclude that it would be disproportionately harsh to find a breach, and that an educational approach is more appropriate in the circumstances. I am also mindful of guarding against hindsight bias. Accordingly, I will be making several recommendations for improvement (outlined below) to ensure that lessons are taken from Mr A's experience. I also expect Ms B to continue to reflect on this case and, with all vaccinations and medicines she administers in the future, exercise her own judgement about what information she needs to convey to consumers.

83. With this in mind, my view is that Ms B's responsibility to inform Mr A about myocarditis was materially mitigated by the deficiencies in guidance from official sources and the pharmacy. That is, she was not supported adequately to provide Code-compliant services. Accordingly, I am critical of Ms B's omission in not informing Mr A about myocarditis, and in particular her failure to inform Mr A about the symptoms of myocarditis as part of safety-netting advice given the clear guidance from IMAC. However, in this context I do not find that she breached the Code.

84. In addition, I note that Ms B believes that Mr A did not take a copy of the information leaflet. For the avoidance of doubt, even if Mr A had taken a leaflet, this alone would not satisfy Ms B's obligation to provide him with the information that a reasonable consumer in the same circumstances would expect to receive. Of course, written information will further support a consumer's understanding of that information. Nevertheless, my expectation is that providers will tell consumers the key information, including common and serious side effects where appropriate, as part of their safety-netting advice, irrespective of whether or not written information has been provided.

Opinion: Manatū Hauora | Ministry of Health — adverse and educational comment

85. In this opinion I have noted the various ways in which information was fed from official sources to vaccinating providers, including the pharmacy, about the risk of myocarditis and the Comirnaty vaccine. As I have acknowledged above, some of the information provided by Manatū Hauora (including that issued by Medsafe, a business unit within Manatū Hauora) did not explain clearly whether, and at what point in the vaccination process, providers needed to tell consumers about myocarditis and its symptoms. I have also commented above on the volume of information being submitted to providers on a wide variety of topics relating to the Comirnaty and other COVID-19 vaccines.

86. In my view, it is essential that healthcare providers communicate effectively with consumers to ensure that potential side effects, and the symptoms of those side effects, associated with a vaccine are conveyed to consumers appropriately. To that end, Manatū Hauora must ensure that providers are alerted to any new and emerging side effects, appropriately and effectively and in a timely manner. Information should be delivered so that all agencies and individuals in the system — including consumers — have ready access to timely, consistent, and accurate information about vaccines in use in New Zealand.

87. In my opinion, particularly after the first death from myocarditis following the Comirnaty vaccine was reviewed by CV-ISMB in August 2021, Manatū Hauora needed to provide clear and unambiguous guidance to vaccinating providers (whether directly, or through other agencies/services) about what, and when, they needed to tell consumers about myocarditis. Given that Manatū Hauora expected consumers to be informed about the risk of myocarditis as part of the informed consent process, and to receive information about the symptoms of myocarditis as part of safety-netting advice, Manatū Hauora's guidance should have stated explicitly that this was to be covered with patients both prior to and after vaccination. In other words, the guidance should have used clear and directive language to outline what information about myocarditis must be given to consumers prior to the vaccine, and what information must be given after the vaccine.

88. I acknowledge that Manatū Hauora must be careful to issue guidance in line with sound scientific evidence — a difficult task when a new side effect is only just coming into focus — although by the time Medsafe issued the alert in July, this evidence appears to have been sufficient to establish the concern about myocarditis. I also acknowledge, as noted above, the inherent challenges in developing and transmitting information (including evolving and developing information) at pace to vaccination providers. However, it is important to reflect on the lessons that can be learned.

89. I note that the updated Operating Guidelines provide greater detail on what information providers should give to consumers about myocarditis 'at the time of vaccination', including the symptoms that consumers need to be aware of. I support these changes; however, I consider that the guidelines could be further improved by explicitly stating that the risk of myocarditis needs to be discussed as part of the informed consent process prior to vaccination, and its symptoms need to be discussed as part of safety-netting advice. I suggest that Manatū Hauora consider updating the Operating Guidelines accordingly.

90. I also note Ms C's comments on the volume of information about the Comirnaty vaccine that providers were receiving from several official sources at the time, and Ms B's comment that communications could have been improved by highlighting the significance of new information. I acknowledge, as Manatū Hauora has pointed out, that the volume of information was in part a reflection of the complex logistics of a vaccination programme on an unprecedented scale. I appreciate also that Manatū Hauora took a multi-channel approach to communications, with a view to maximising reach and ensuring that all vaccinator providers received relevant messages. However, in my view, this approach may have created the possibility that key messages about risks such as myocarditis would be lost in the volume of information.

91. In the context of new vaccines and emerging risks, it is fundamentally important that explicit guidance be given to vaccinators about what information they must give to consumers. As new information comes to light about new and emerging risks associated with a vaccine, and as official guidance changes, Manatū Hauora must also make clear to vaccinators what the new information entails and the significance of it.

92. I also consider that it may have been helpful if there had been one centralised portal for all information to be fed to providers across the country, although I appreciate that this is a complex issue that warrants further consideration. I address this point in the 'Follow-up actions' section below.

Recommendations

93. I recommend that the pharmacy update its SOP to include a separate section about COVID-19 vaccines, including the informed consent process and required safety-netting advice. The pharmacy is to send a copy of its updated SOP to HDC within three months of the date of this report.

94. Noting that the NIP is now part of Te Whatu Ora, rather than Manatū Hauora,[24] I recommend that Te Whatu Ora consider updating its Operating Guidelines to clarify at what point(s) in the process[25] providers should discuss the risk and symptoms of myocarditis, as well as any other side effects, when consumers are receiving the Comirnaty vaccine. Te Whatu Ora is to report back to HDC on the results of its consideration, including details of any updates to its Operating Guidelines, within three months of the date of this report.

Follow-up actions

95. A copy of this report will be sent to the Coroner.

96. Subject to any non-publication orders of the Coroner, it is intended that a copy of this report with details identifying the parties removed will be sent to the Pharmacy Council, and it will be advised of Ms B's name.

97. Subject to any non-publication orders of the Coroner, it is intended that a copy of this report with details identifying the parties removed will be sent to Medicines Control (within Manatū Hauora), and it will be advised of the pharmacy's name.

98. Subject to any non-publication orders of the Coroner, it is intended that a copy of this report with details identifying the parties removed will be sent to Te Whatu Ora, Medsafe, and

[24] As a result of the Pae Ora (Health Futures) Act 2022.
[25] The current Operating Guidelines state that consumers should be informed of common and rare side effects 'at the time of vaccination'.

IMAC and placed on the Health and Disability Commissioner website, www.hdc.org.nz, for educational purposes.

99. In addition, I note the work being undertaken by the Government in response to the harms caused by anti-seizure medicines during pregnancy, including to improve risk communication between prescribers, dispensers, and consumers on the use of medicines. Part of this work involved convening a hui on safer prescribing and safer dispensing in October 2021. The hui identified several improvements, including the development of a prescribing and dispensing communications framework. Manatū Hauora told HDC that the next steps for the communication workstream was for Te Tāhū Hauora|Health Quality & Safety Commission to work with professional bodies and associations to work out the best way to influence positive change in this area. With this in mind, and subject to any non-publication orders of the Coroner, I intend to send a copy of this report with details identifying the parties removed to Te Tāhū Hauora|Health Quality & Safety Commission. I will ask it to consider whether the communications framework being developed can be adapted to ensure that emerging risks associated with vaccines are being communicated to vaccinators and consumers appropriately.

100. Finally, I consider that it may have been helpful if there had been one centralised portal for all information to be fed to providers across the country, although, as noted above, I acknowledge that this is a complex issue. With this in mind, and subject to any non-publication orders of the Coroner, I intend to send a copy of this report with details identifying the parties removed to the NZ Royal Commission COVID-19 Lessons Learned, and I will ask the Royal Commission to consider the feasibility of this for future events.

Appendix A — Updated Operating Guidelines excerpt

‘**33.4 Adverse events after observation period**

Consumers should be advised by the vaccinator, at the time of vaccination, of common **and** rare side effects that can occur after the observation period (after they’ve left the vaccination site). This should include a discussion about when and how to seek medical attention, and how to submit an adverse reaction report to CARM.

Common side effects of COVID vaccines include pain, redness or swelling at the injection site, feeling tired or fatigued, headache, muscle or joint aches and pain, chills, fever, and nausea. These effects are usually mild or moderate and improve within a few days after the vaccination.

Rare side effects of COVID vaccines

Myocarditis and pericarditis are an inflammation of the heart muscle or lining and can range from mild to serious illness. They are usually caused by viruses but are also a **rare side effect** of both the Pfizer and Novavax COVID-19 vaccines.

Symptoms of myocarditis and pericarditis linked to the vaccine generally appear within a few days, and mostly within the first week after having the vaccine. Consumers should be advised that if they get any of these new symptoms, they should seek medical help, especially if these symptoms don’t go away:

- Tightness, heaviness, discomfort or pain in your chest or neck
- Difficulty breathing or catching your breath
- Feeling faint or dizzy or light-headed
- Fluttering, racing, or pounding heart, or feeling like it is “skipping beats”.’

(Emphasis in the original.)