IN THE HIGH COURT OF NEW ZEALAND
WELLINGTON REGISTRY

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

CIV-2021-485-13

UNDER THE	**Judicial Review Procedure Act 2016**
IN THE MATTER OF	**an application for judicial review of a decision made under the Medicines Act 1981**
BETWEEN	**MKD and others**
	Applicants
AND	**MINISTER OF HEALTH**
	First Respondent
AND	**GROUP MANAGER OF THE NEW ZEALAND MEDICAL DEVICES SAFETY AUTHORITY (MEDSAFE)**

Cont'd

AFFIDAVIT OF DR ASHLEY ROBIN BLOOMFIELD

10 June 2022

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Second Respondent

AND MINISTER FOR COVID-19 RESPONSE

Third Respondent

I, Dr Ashley Robin Bloomfield, of Wellington, Director-General of Health and Chief Executive of the Ministry of Health, solemnly and sincerely affirm:

Introduction

1. My full name is Ashley Robin Bloomfield.

2. I am the Director-General of Health and the Chief Executive of the Ministry of Health (**Ministry**).

3. I have previously sworn an affidavit in this proceeding, dated 25 January 2022, for the purposes of responding to the applicants' interim relief application. Unless otherwise stated, this affidavit uses the same defined terms that I used in my first affidavit.

4. In my earlier affidavit I gave an overview of New Zealand's COVID-19 Immunisation Programme, as well as evidence about the advice I gave to Cabinet in December 2021 about the decision to use the Paediatric Vaccine for 5 to 11 year olds.

5. The purpose of this affidavit is to provide additional detail on topics I discussed in my earlier affidavit, respond to new aspects of the applicants' claim, and respond to some specific points made by the applicants' witnesses. I have relied on Ministry officials to collate the data and documents referred to in this affidavit. I note that the exhibits annexed to this affidavit include contracts between the Government and Pfizer which are confidential and subject to undertakings of counsel for the applicants.

COVID-19

6. COVID-19 has continued to evolve over time and some of these changes have affected the properties of the virus. A variant of COVID-19 is considered to be a "variant of concern" where it has changed to a degree of global public health significance with respect to aspects including the transmissibility and virulence of the vaccine. Of these variants of concern, the Delta variant (B.1.617.2), which

emerged in the first half of 2021, was the dominant variant of COVID-19 in New Zealand until early 2022.

7. The threat from Delta has not entirely abated. There are still cases of Delta within New Zealand. The Omicron variant (B.1.1.529) (**Omicron**) was designated a variant of concern by WHO on 26 November 2021 and has rapidly spread worldwide, now being the major variant in many countries. We are currently responding to a large community outbreak of Omicron.

8. As at 9 June 2022, New Zealand has had over 1.2 million reported cases of COVID-19 since the first case of COVID-19 in the country. Of those:

    8.1 139,733 cases (12 percent of the total COVID-19 cases) are in children aged 0 to 9 years, and of these 876 cases were hospitalised. This represents 7 percent of all hospitalised cases.

    8.2 206,326 cases (17 percent of the total COVID-19 cases) are in children and adolescents aged 10 to 19. Of these, 713 were hospitalised. This represents 6 percent of all hospitalised cases.

The organisational context

9. As part of my responsibilities in relation to the COVID-19 pandemic, I chair the COVID-19 Vaccine and Immunisation Programme Steering Group (**Steering Group**), which includes Deputy Directors-General from teams closely involved in the immunisation programme. The core function of the Steering Group is to provide senior-level decision-making for the COVID-19 Immunisation Programme. The Steering Group may consider proposals or plans raised by Ministry staff and other advisory groups and is informed by a number of external governance groups including the COVID-19 Vaccine Science and Technical Advisory Group (**CV-TAG**), and the Immunisation

Implementation Advisory Group. CV-TAG is comprised of medical and scientific experts who provide advice to the COVID-19 Immunisation Programme.

10. A further layer of independent advice is provided by the Strategic COVID-19 Public Health Advisory Group (**SPHAG**) and, until recently, the COVID-19 Independent Continuous Review, Improvement and Advice Group (**CICRIAG**), whose membership includes senior scientists in relevant disciplines established to provide the Government with independent expert advice. Both groups provide advice directly to Ministers rather than to the Ministry. The CICRIAG has done this through a series of reviews and have provided recommendations which are monitored and implemented, where appropriate, by Government. The SPHAG is more future focussed and has answered a series of horizon scanning questions for Ministers. Both CICRIAG and SPHAG have expressed the view that vaccination is an essential tool in New Zealand's response to COVID-19 and encouraged rapid and widescale vaccine roll-out.

11. The Ministry manages the COVID-19 vaccine portfolio, governed by the Steering Group, to ensure that the portfolio optimally supports the needs of the COVID-19 Immunisation Programme. The Ministry works in collaboration with the Treasury and the Ministry of Foreign Affairs and Trade in facilitating donation of doses to the Pacific and engaging with COVAX, the global initiative for ensuring equity in access to COVID-19 vaccines.

Government vaccine strategy and immunisation strategy

12. From the early stages of the pandemic, the Government recognised that vaccination against COVID-19 with a safe and effective vaccine would be a critical platform for protecting New Zealanders, and to eventually allow New Zealand to fully re-open its borders and ease COVID-19 restrictions. Early access to safe and efficacious vaccines was a priority for ensuring vaccine access for New Zealanders most

vulnerable to COVID-19.

13. Further, it was apparent New Zealand would need to take steps early to secure access to a vaccine in a context where there was significant uncertainty about the development of the vaccines, a likelihood of supply constraints and intense global competition to secure access.

14. On 18 May 2020, Cabinet agreed that the Government should put in place a COVID-19 vaccine strategy to promote access to a sufficient quantity of safe and effective vaccine in order to implement the Government's preferred immunisation strategy at the earliest possible time. A copy of Cabinet's minute of decision numbered CAB-20-MIN-0229.01 is annexed and marked **ARB-1**.

15. Also in May 2020, Cabinet agreed to a purchasing strategy for the acquisition of COVID-19 vaccines. This recognised the need for urgent negotiation of advance purchase agreements to ensure New Zealand would have timely access to a vaccine, if and when approved by Medsafe.

16. The Ministry also adopted a vaccine portfolio approach. This approach was initially taken in the context of high uncertainty about the efficacy of vaccines under development, and the risk of vaccine development failure. This approach initially sought to purchase vaccines with different characteristics to spread New Zealand's risk and maximise opportunities to purchase a vaccine.

17. While the vaccine strategy concerns the acquisition of vaccines, the immunisation strategy concerns all aspects of making COVID-19 vaccines available to the New Zealand public, including the COVID - 19 Immunisation Programme for rolling-out the COVID-19 vaccine(s) to the public.

18. In a minute dated 7 December 2020, Cabinet agreed the purpose of the immunisation strategy is to support the best use of the vaccines

while upholding and honouring Te Tiriti o Waitangi/the Treaty of Waitangi and promoting equitable outcomes. A copy of Cabinet's minute numbered CAB-20-MIN-0509 is annexed and marked **ARB-2**. This records that the first key principle guiding the government's approach to COVID-19 immunisation is that any COVID-19 vaccines that are delivered will be free and safe.

19. The key principles underpinning the immunisation strategy are set out in an appendix to a December 2020 paper to Cabinet.[1] Annexed and marked **ARB-3** is a copy of the appendix. The key principles include, amongst others, equity, equal concern and minimising the health, social, economic and cultural harm of COVID-19. These principles mean that the Immunisation Programme is designed to encourage and enable uptake of safe and free COVID-19 vaccines in New Zealand.

20. The immunisation strategy includes, amongst other elements:

    20.1 The COVID-19 Immunisation Programme which is focused on the roll-out of the COVID-19 vaccine(s) in New Zealand, including all elements from workforce to consumables. The Immunisation Programme involves activities to plan, manage, deliver and monitor the COVID-19 vaccine(s) throughout New Zealand.

    20.2 A framework to support decision-making on whether to use a COVID-19 vaccine in the COVID-19 Immunisation Programme once Medsafe gives approval, known as the Decision to Use Framework (**Framework**).

    20.3 A comprehensive engagement and communication

[1] https://www.health.govt.nz/system/files/documents/information-release/update_on_the_covid-19_immunisation_strategy_and_programme_december_2020.pdf

strategy to support public understanding of the COVID-19 Immunisation Programme, build public trust in the COVID 19 vaccine(s) and encourage uptake.

21. Under the Framework, each of the COVID-19 vaccines was considered on its own merits, including by Medsafe through its approval process, to determine which vaccine(s) would best support a successful COVID-19 Immunisation Programme. The Framework assesses the best use of each vaccine, and involves consideration of a number of factors, including equity, quality and safety, and the benefits and risks associated with each vaccine. The Framework is set out in Appendix Six of a paper to Cabinet annexed and marked **ARB-4**. Cabinet endorsed the Framework by minute dated 2 February 2021 and numbered CAB-21-MIN-0011, annexed and marked **ARB-5**.

Contractual arrangements for vaccine acquisition

The vaccine portfolio

22. Consistent with the vaccine strategy New Zealand entered into a number of advance purchase agreements with several manufacturers of COVID-19 vaccine.

23. In this manner, New Zealand acquired access to a portfolio of COVID - 19 vaccines by different pharmaceutical developers (including Pfizer, AstraZeneca, Janssen, and Novavax). This was to manage the risk and uncertainty during the vaccine development stage relating to which vaccines would emerge as viable products and the potential for supply failure.

Contractual arrangements with Pfizer

24. The COVID-19 Immunisation Programme has been predominantly Pfizer-based. Following an initial binding term sheet agreed in October 2020, the contractual arrangements with Pfizer are made up

of the following agreements (in chronological order):

24.1 A Manufacturing and Supply Agreement with Pfizer New Zealand Limited (**the Manufacturing and Supply Agreement**) entered into on 22 December 2020. A copy of the Manufacturing and Supply Agreement is annexed and marked **ARB-6 (subject to confidentiality undertakings)**. This is the umbrella agreement for the supply of COVID-19 vaccines manufactured by or on behalf of Pfizer or BioNTech to New Zealand.

24.1.1 In the Manufacturing and Supply Agreement the Government committed to the purchase of 1.5 million doses of the Parent Product in 2021.

24.1.2 The Manufacturing and Supply Agreement includes an indemnity from the Crown in Pfizer's favour, to cover claims brought by a third party relating to or resulting from the possession, distribution and/or use and administration of the vaccine (subject to certain exceptions and qualifications). It is common for pharmaceutical companies to seek indemnities in relation to pandemic vaccines that they need to develop in accelerated clinical trials. Furthermore, in New Zealand, treatment harm caused by any vaccination (including COVID-19 vaccination) is covered by ACC if the criteria for treatment injury are met. In New Zealand, the decision whether to grant an indemnity to a specific company is made

by the Minister of Finance.

24.2 The First, Second and Third Amendments to the Manufacturing and Supply Agreement (entered into on 5 March 2021, 7 September 2021 and 10 September 2021, respectively) which provided for (in chronological order):

24.2.1 The purchase of 8.5 million additional doses of the Parent Product, enough to vaccinate 4.25 million people;

24.2.2 The re-sale of approximately 275,000 doses of the Parent Product from the Spanish government to New Zealand;

24.2.3 The re-sale of approximately half-a-million doses from the Danish government to New Zealand.

24.3 The Fourth Amendment to the Manufacturing and Supply Agreement entered on 22 October 2021, in which the Government committed to purchase a further 4.7 million doses of the Parent Product from Pfizer in 2022. The Fourth Amendment provided that in the event that Pfizer successfully developed a paediatric vaccine, the Crown would have the option, within 30 days of consent or provisional consent being given to that vaccine under the Medicines Act, to request that a portion of the 4.7 million doses be that paediatric vaccine. A copy of the Fourth Amendment is annexed and marked **ARB-7 (subject to confidentiality undertakings)**.

24.4 The Fifth Amendment to the Manufacturing and

Supply Agreement entered on 21 December 2021, in which the Crown agreed to purchase 1.25 million doses of paediatric vaccine in 2022 (as part of the 4.7 million doses agreed to in the Fourth Amendment). A copy of the Fifth Amendment is annexed and marked **ARB-8 (subject to confidentiality undertakings)**.

Timeline of vaccine acquisition

25. In the latter half of 2020, the Government was engaged in negotiations with Pfizer regarding the terms and conclusion of the binding term sheet.

26. It was essential to enter into an initial binding term sheet with urgency as there was high global demand for COVID-19 vaccines combined with a high likelihood of constrained ability to manufacture and supply those vaccines. At the time of signing the binding term sheet, there was a limited window for New Zealand to reserve doses with Pfizer. If New Zealand had chosen not to make contractual arrangements with Pfizer at this time, we would likely have had to wait for another 18 months to purchase a COVID-19 vaccine through COVAX.

27. The Government entered into the binding term sheet on 6 October 2020. Following further negotiations, the Government entered into the Manufacturing and Supply Agreement on 22 December 2020.

28. On 5 March 2021, 7 September 2021 and 10 September 2021 the Government entered the First, Second and Third Amendments (respectively) to the Manufacturing and Supply Agreement (I understand these agreements have no particular relevance to these proceedings).

29. Towards the latter half of 2021 officials were considering New Zealand's vaccine needs beyond 2021. Officials considered that

New Zealand would continue to need a mRNA vaccine in 2022 for those who did not access a vaccine in 2021, where there is extended eligibility (for example the Paediatric Vaccine), and for booster doses if evidence showed this was required.

30. The Minister for COVID-19 Response continued to recommend a vaccine portfolio approach in order to secure additional vaccine supply for 2022 and manage the risk of a potential need for booster vaccinations or updated versions of vaccines to protect against variants in 2022. Officials were in negotiations with Pfizer for an amendment to the Manufacturing and Supply Agreement which would incorporate the supply of additional doses in 2022 and 2023.

31. By minute dated 30 August 2021, Cabinet took note of the advice of the Ministry that there would almost certainly be a need for ongoing immunisation in 2022 (and possibly onwards). Cabinet agreed officials should progress negotiations with vaccine suppliers for additional vaccines where appropriate to ensure that the portfolio can continue to support immunisation needs in New Zealand and the Pacific, as well as supporting equitable access to COVID-19 vaccines globally. A copy of Cabinet's minute numbered CAB-21-MIN-0350 is annexed and marked **ARB-9**.

32. Accordingly, officials progressed negotiations with Pfizer for additional doses to ensure that the vaccine portfolio could continue to support immunisation needs in New Zealand and the Pacific in 2022. Through negotiations officials secured an additional 4.7 million doses for delivery in 2022. In a briefing paper dated 15 October 2021, officials sought and obtained the agreement of the Vaccine Ministers for the Director-General to sign an amendment to the Manufacturing and Supply Agreement to allow for the purchase of the additional 4.7 million doses. A copy of the briefing paper is annexed and marked **ARB-10**.

33. Consequently, on 22 October 2021, the Government entered into the Fourth Amendment to the Manufacturing and Supply Agreement.

34. Although provisional consent had not been granted yet for the Paediatric Vaccine, officials were working with Pfizer to ensure that, if Medsafe gave provisional consent for the Paediatric Vaccine, New Zealand would have access to paediatric doses to support a potential roll-out. Officials proceeded on the basis of modelling which assumed immunisation of all children 5 to 11 years in the first quarter of 2022. This would require a total of 1.25 million paediatric doses.

35. In November 2021, officials sought and obtained the agreement of the Vaccine Ministers[2] to progress negotiations with Pfizer to secure 1.25 million paediatric doses as early as possible across December 2021 and the first quarter of 2022, subject to Medsafe approval. A copy of the memorandum in which officials sought the agreement of the Vaccine Ministers is annexed and marked **ARB-11**.

36. On 15 November 2021, following confirmation from the Ministers about the delivery schedule preference for 2022, a Ministry official emailed representatives of Pfizer to advise the Government's preferred delivery schedule would ideally involve the delivery of the paediatric doses as early as possible and across the first quarter of 2022. This was expressly subject to Pfizer first obtaining approval from Medsafe. A copy of the email is annexed and marked **ARB-12**.

37. On 10 December 2021, a Ministry official confirmed with Pfizer by email that, subject to Medsafe approval of the paediatric vaccine, the New Zealand government requested 1.25 million doses of the Paediatric Vaccine, to represent a portion of the 4.7 million doses

[2] The Vaccine Ministers comprise the Prime Minister, Minister of Finance, Minister for Covid-19 Response, Minister of Health, Minister of Foreign Affairs, Associate Minister of Health (Māori Health), Associate Minister of Health (Public Health) and Minister for Pacific Peoples.

provided for in the Fourth Amendment. A copy of the email is annexed and marked **ARB-13**.

38. It was imperative to start making arrangements with Pfizer regarding the paediatric doses as soon as possible, in order to ensure that, if Medsafe granted provisional consent, New Zealand could get delivery in January 2022. Officials were aware that Medsafe was actively processing Pfizer's application for provisional consent for the Paediatric Vaccine, and that a decision might be made before the end of 2021. If officials waited until after Medsafe had concluded its evaluation of the paediatric vaccine before beginning discussions with Pfizer, we would have missed the boat to secure delivery for January 2022. However, these preparatory discussions with Pfizer were all expressly subject to Medsafe approval.

39. Medsafe gave provisional consent to the Paediatric Vaccine on 16 December 2021 and, as I explain below, Cabinet agreed to the roll-out of the Paediatric Vaccine on 20 December 2021.

40. A Ministry memorandum dated 21 December 2021, and addressed to me, recommended that I sign a further amendment (what would become the Fifth Amendment) to the Manufacturing and Supply Agreement to enable the delivery of the Paediatric Vaccine to New Zealand. A copy of the briefing is annexed and marked **ARB-14**. My delegate agreed to the Ministry's recommendation on 21 December 2021.

41. Consequently, on the same day the Crown entered the Fifth Amendment to the Manufacturing and Supply Agreement. It was through the Fifth Amendment that the Crown committed to purchase approximately 1.25 million doses of the Paediatric Vaccine (as part of the 4.7 million doses agreed to in the Fourth Amendment). The Fifth Amendment was signed by a delegate on my behalf on 21 December 2021.

Cabinet's decision to roll-out the Paediatric Vaccine

42. In my earlier affidavit, I discussed Cabinet's decision to include the Paediatric Vaccine in the COVID-19 Immunisation Programme following provisional consent being given by Medsafe for the Paediatric Vaccine on 16 December 2021.[3]

43. My earlier affidavit noted the advice of CV-TAG which recommended that the Paediatric Vaccine be offered to all children aged 5 to 11 years.[4] That affidavit also explained that the Ministry had completed a child wellbeing impact assessment (**Wellbeing Impact Assessment**), the findings of which agreed with the advice of CV - TAG.[5] The CV-TAG advice and conclusions of the Wellbeing Impact Assessment are set out in a paper to Cabinet from the Minister for COVID-19 response annexed and marked **ARB-15**.

44. Cabinet agreed to include the Paediatric Vaccine in the COVID-19 Immunisation Programme on 20 December 2021. In deciding to include the Paediatric Vaccine in the programme Cabinet had regard, amongst other matters, to the recommendations from CV-TAG and the Wellbeing Impact Assessment. A copy of Cabinet's Minute of Decision dated 20 December 2021 and numbered CAB-21-MIN-0557 is attached and marked **ARB-16**.

45. The roll-out of the Paediatric Vaccine to children aged 5 to 11 began on 17 January 2022.

Planning for the roll-out of the Paediatric Vaccine

46. Much in the same way planning for the roll-out of the Parent Product began before that vaccine had been given provisional consent, planning for the roll-out of the Paediatric Vaccine began before that vaccine had been given provisional consent. Making a vaccine

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3 Affidavit of Ashley Robin Bloomfield affirmed 25 January 2020 [Interim Relief Affidavit] at [19] – [23].

4 Interim Relief Affidavit at [20].

5 Interim Relief Affidavit at [21].

available on a nationwide basis is a significant undertaking that requires early planning and preparation. The Ministry of Health had to ensure that, if Medsafe gave provisional consent to the Paediatric Vaccine and Cabinet decided to include the Paediatric Vaccine in the COVID-19 Immunisation Programme, that could occur with minimal delay. By necessity, planning and preparations for the Immunisation Programme were carried out in parallel to Medsafe's regulatory process. In short, there was a risk that the preparatory work to enable the Paediatric Vaccine to be incorporated in the COVID-19 Immunisation Programme might be wasted if either Medsafe did not grant provisional consent, or Cabinet decided not to roll out the paediatric vaccine. But that was a risk worth taking, and far preferable to the risk of New Zealand "missing the boat" and failing to secure or deliver paediatric doses in a timely way, and thereby potentially putting the health and wellbeing of New Zealand children at risk.

47. Work undertaken to plan and prepare for the roll-out of the Paediatric Vaccine included:

47.1 Development by the Immunisation Advisory Centre of training modules and resources for use of the Paediatric Vaccine which could be finalised for workforce groups.

47.2 Development of digital records infrastructure to provide for the Paediatric Vaccine requirements and to allow bookings, adverse event surveillance and under experience surveys.

47.3 Arranging the logistics and facilities for vaccine storage and distribution.

47.4 Assessing suitability for children across the different immunisation delivery models.

47.5 Engagement with Hauora Māori, Pacific providers and family and community groups with the aim of facilitating the promotion and acceptability of paediatric immunisation models.

47.6 Engagement with District Health Boards to identify sites where the Paediatric Vaccine was intended to be available.

47.7 Creating a disability plan for children 5 to 11 years to support vaccine delivery to disabled children and/or children with disabled parents, whānau, āiga, carers and siblings.

47.8 Receiving and considering feedback from Iwi chairs, Māori teachers and principals, the Māori pandemic response group, the NZ Māori Counil and Hauora providers.

48. A key focus of the Ministry's planning was achieving equitable immunisation outcomes. The Ministry engaged with the Immunisation Implementation Advisory Group (**IIAG**) for independent practical advice on how to plan, prepare and implement a COVID-19 immunisation campaign for children 5 to 11 years. Engagement with IIAG included evaluating and planning delivery models to ensure the Paediatric Vaccine was delivered in ways that supported Māori, Pacific and disabled people.

Updates on the Paediatric Vaccine Roll-out

49. The COVID-19 Immunisation Programme continues to roll out the Paediatric Vaccine to children 5 to 11 years. As at 8 June 2022, a total of 263,291 children had received the first dose of the Paediatric Vaccine and 126,465 had received the second dose.

50. The Ministry continues to maintain rigorous pharmacovigilance

processes with respect to the safety and efficacy of the Paediatric Vaccine. These are in addition to the adverse event monitoring of the Paediatric Vaccine by Medsafe, as set out in the affidavit of Mr James.

51. In accepting CV-TAG's recommendations in December 2021, I asked CV-TAG to undertake a formal safety review in February 2022 to confirm the recommended eight-week interval between doses.

52. CV-TAG provided me with its updated recommendations on 16 February 2022. A copy of CV-TAG's memorandum to me is annexed and marked **ARB-17**. CV-TAG confirmed that a minimum eight-week interval between doses was appropriate.

53. CV-TAG also advised that real-world data on the roll-out of the Paediatric Vaccine to 5 to 11-year-olds had reported nothing of concern. It based its conclusions on real-world data that had been collected from the administration of over 8 million doses of the Pfizer Paediatric Vaccine to children 5 to 11 years in the United States, as well as reports of adverse events following vaccination in New Zealand.

54. Of the New Zealand data considered by CV-TAG, at the time of CV-TAG's memorandum preliminary unpublished data from Medsafe indicated that there had been 352 adverse events following immunisation reported from 17 January to 30 January 2022 in children 5 to 11 who received the Paediatric Vaccine. Of these, 96.9 percent were classified as non-serious. A small number (10 cases) reported that they needed emergency care and one case was hospitalized.

55. On 19 April 2022, Medsafe published on its website the results of the Post Vaccine Symptom Check (**PVSC**) child survey results. The PVSC is an additional way to report reactions to the Pfizer COVID-19 vaccine.

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56. There were 17,912 people who responded to the survey request. Of the responses received, 3,692 (21%) reported that their child had experienced at least one adverse event/reaction to the vaccine and 14,220 (79%) reported that their child did not experience an adverse event. The most commonly reported adverse events – tiredness, injection site reaction, headache and body pain – are common adverse reactions following immunisation. Medsafe concluded that based on this data it had not identified any new safety concerns.

Reporting of COVID-19 data

57. As data regarding COVID-19 cases and deaths features heavily in the evidence of the applicants and respondents I wish to explain the Ministry's process for reporting COVID-19 data, in particular how the Ministry reports deaths from COVID-19 rather than deaths of people who have COVID-19 but die of unrelated causes.

58. With respect to COVID-19 deaths, the Ministry reports all deaths where a person has died within 28 days of being reported as having a positive test result for COVID-19. This approach is in-line with that taken by other countries and jurisdictions, such as the United Kingdom. It ensures that all cases of COVID-19 who die are formally recorded. However, this is just the initial process for reporting deaths potentially linked to COVID-19. Further investigation is undertaken to provide more information about the contribution of COVID-19, if any, to the particular death.

59. The Ministry then uses several categories to report deaths based on formal coding of the contribution of COVID-19 to death: the death may be unrelated to COVID-19; or COVID-19 may be a contributing cause (for example where someone dies with an underlying condition combined with the effects of COVID-19 infection); or COVID-19 may be recorded as the primary cause of death. Deaths that are still being investigated are reported as still to be classified.

60. As of 1 June 2022:

60.1 515 people have died with COVID-19 as the underlying cause of death. Of these, 505 died within 28 days of being reported as a case.

60.2 266 people have died with COVID-19 as a contributing cause of death. Of these, 262 died within 28 days of being reported as a case.

60.3 204 people, all of whom died within 28 days of being reported as a case, had a cause of death unrelated to COVID-19.

60.4 169 people who died within 28 days of being reported as a case have yet to be classified. In some instances, the cause of death can take longer to determined, including if it is being investigated by a coroner.

61. I have not identified the numbers of children falling within each bracket as the Ministry avoids revealing case or death numbers when the numbers are sufficiently small that disclosure could risk leading to the inadvertent identification of the individuals in question. However, I can confirm that a small number of the publicly released deaths in the 0 – 9 years age bracket fall in the category of cases yet to be classified, and for a small number of the deaths in the 10 – 19 years age bracket COVID-19 has been identified as a contributory cause.[6]

The applicants' allegations of predetermination

62. I understand that the applicants allege that Cabinet's decision to roll-out the Paediatric Vaccine was predetermined because of the

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[6] Case demographics of COVID-19 cases and deaths are published by the Ministry on its website: https://www.health.govt.nz/covid-19-novel-coronavirus/covid-19-data-and-statistics/covid-19-case-demographics.

contractual arrangements with Pfizer, and in order to further the political objectives of the Government. The applicants also allege that Cabinet's decision was not made on the merits of medical and scientific data, that the decision was not in the best interests of children and there was not adequate or reliable evidence to make an informed decision.

63. While I cannot speak for Cabinet, I can outline my reasons for recommending that Cabinet agree to the use of the Paediatric Vaccine for New Zealand children. My reasons were based on the interests of children in receiving COVID-19 vaccination as reflected in the scientific advice from CV-TAG and the Wellbeing Impact Assessment, and the fact that Medsafe have given provisional consent. I was aware, of course, of the contractual arrangements with Pfizer, and the work that had already been undertaken to plan for a potential roll-out to children. But none of that would have caused me to support a roll-out of a vaccine to children that was not safe. I am a medical practitioner and public health medicine specialist by training. The whole point of the COVID-19 Immunisation Programme is to protect the health and well-being of New Zealanders. There is no prospect that I would have recommended that a vaccine be rolled out to children, if I did not consider that was supported by the expert scientific and medical advice.

64. I accepted and agreed with the advice of CV-TAG which recommended that this vaccine be offered to all children aged 5 to 11 years. That advice was noted by Cabinet.

65. The findings of the Wellbeing Impact Assessment, which were also noted by Cabinet, highlighted that the pandemic has had and will continue to have significant impacts on children's health, education, relationships, development and lives. It found that immunisation of New Zealand's population is the single greatest protection against

the effects of COVID-19 on children's lives and development, and that immunisation of children adds individual protection.

66. Immunising children under 12 years has the potential to keep them safe from COVID-19 and may reduce the risk of transmission of COVID-19 particularly in multigenerational and overcrowded households.

67. While children under 12 years are at lower risk from the direct health impacts of COVID-19 than older age groups, COVID-19 can have serious health consequences for some children. As at December 2021, children and young people were overrepresented in COVID-19 cases in New Zealand (37 percent under 20 years including 20 percent under 10 years). Around 10 percent of New Zealand's hospitalised cases had been in those aged under 20 years.

68. Children who have pre-existing health conditions or comorbidities have a greater risk of severe disease from COVID-19. Higher risks also exist for tamariki Māori, Pacific children and children with disabilities, as I set out in my earlier affidavit.[7]

69. Tamariki Māori were a key focus. The Government was and continues to be aware that tamariki Māori have been more impacted by the pandemic than other children and still remain at higher risk. The Ministry was also cognisant of the Waitangi Tribunal's urgent inquiry into the COVID-19 Protection Framework.[8] The obligations the Crown has under Te Tiriti o Waitangi/the Treaty of Waitangi also apply to the Paediatric Vaccine roll-out and include a high and urgent focus on the immunisation of tamariki Māori.

70. Children make up a higher proportion of the Māori population than for non-Māori. Māori children are more likely than non-Māori

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7 Interim Relief Affidavit at [34] – [37].

8 In the Interim Relief Affidavit, I explained that evidence had been provided to the Waitangi Tribunal about significant concerns for tamariki Māori aged under 12 in the event of a community outbreak. See Interim Relief Affidavit at [52].

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children to live in multigenerational families housed in overcrowded conditions, increasing the risk of transmission. Vaccinating children reduces the overall risk in tamariki Māori and risk to their whānau and presents an opportunity to use whānau-based approaches to engage with whanau on vaccination.

The applicants' claims of a quasi-mandate

71. I understand the applicants claim that the roll-out of the Paediatric Vaccine will have a "quasi mandatory effect" and lead to children being excluded from activities and places.

72. However, consistently, the Government's position has been to ensure that children are not excluded from activities and places based on their vaccination status.

73. The advice provided to Cabinet, Vaccine Ministers, and me (in the case of the CV-TAG advice) emphasised the importance of ensuring that the roll-out of the Paediatric Vaccine did not lead to restrictions on children's participation in activities and daily life based on vaccination status. I concurred with this advice. This advice included:

    73.1 A memorandum dated 15 December 2021, setting out the Ministry's position that vaccination of the 5-11 age group should remain voluntary, and that there was little to indicate that children in this age group should require a vaccine pass. The memorandum is annexed and marked **ARB-18.**

    73.2 The recommendation of CV-TAG that mandates, vaccine certificates or vaccine targets should not be used or required for children aged 5 to 11.

    73.3 The finding of the Wellbeing Impact Assessment that the immunisation of children should be voluntary, with no associated restrictions for any children.

74. In its decision to roll-out the Paediatric Vaccine, Cabinet took note of my advice and that of CV-TAG and the Wellbeing Impact Assessment that the immunisation of children should be voluntary and that mandates, vaccine certificates or vaccine targets must not be used for this age group.

75. When announcing the roll-out of the Paediatric Vaccine on 21 December 2021, Minister Hipkins said that while the Government is strongly encouraging parents to have their children vaccinated, the "Government has no intention of making COVID-19 vaccinations mandatory" for anyone in the 5 to 11 year age bracket.[9]

76. The Government's position that no restrictions should apply to this age group on the basis of vaccination status is reflected in the COVID - 19 Public Health Response (Protection Framework) Order 2021 (**Protection Framework**). Under the Protection Framework, children under the age of 12 years and 3 months are not (and have never been) required to show a vaccine certificate at a regulated business or service. They are automatically deemed to be "CVC compliant" irrespective of their vaccination status.

77. Students (including those over the age of 12 years and 3 months) and their parents cannot (and never could) be denied access to designated education and care premises on the basis of their vaccination status, if they are seeking to access education services at those premises.

78. I am unaware of any plans to change this position, and in fact the Government has taken further steps to ensure children are not excluded from activities.

79. The Government's most recent policy statement on the COVID-19 vaccine for children aged 5-11 years states that mandates, vaccine

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[9] https://www.beehive.govt.nz/release/government-confirms-covid-19-vaccinations-protect-tamariki.

certificates or vaccine targets that may formally or informally encourages exclusion from activities based on vaccination must not be used for this group.[10]

80. Amendments to the Protection Framework have continued the trend. In February 2022 the Protection Framework was amended to ensure children can participate in "education outside the classroom" activities (such as visiting swimming pools, museums and school camps) irrespective of whether they are vaccinated.[11]

81. Consequent to further amendments in March 2022[12], a person in control of premises must not deny entry, on vaccination grounds, to a student (including those over the age of 12 years and 3 months) participating in an extra-curricular or curricular activity at the premises.

82. In recent months, the Government has moved away from vaccine passes and other restrictions on New Zealanders of all ages. In early April 2022, the legal requirement for businesses to use My Vaccine Passes was removed, although some businesses may be voluntarily keeping My Vaccine Pass requirements as a condition of entry.

Responses to points made in the applicants' evidence

Phillip Altman

83. In his affidavit, Dr Altman makes a number of criticisms of my earlier affidavit:

    83.1 At paragraphs [88] and [89], Dr Altman queries what evidence is available to support my statement that children who are healthy can and have suffered from

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10 https://www.health.govt.nz/system/files/documents/pages/covid-19-vaccine-children-aged-5-11-years-policy-statement-may2022.pdf.

11 Amendments made by COVID-19 Public Health Response (Protection Framework and Other Matters) Amendment Order 2022.

12 COVID-19 Public Health Response (Protection Framework) Amendment Order (No 4) 2022.

severe COVID-19.[13]

83.2 At paragraphs [98] to [107], Dr Altman disagrees with my statement that vaccinating children 5 to 11 years first and foremost provides those children with a high level of protection from COVID-19.[14]

83.3 At paragraphs [147] to [154], Dr Altman disagrees with the finding of the Wellbeing Impact Assessment that immunisation of the wider population is important to protect children and their wellbeing.[15]

84. As these criticisms are addressed by the evidence of the other witnesses for the respondents, I do not engage with the criticisms in detail except to note the following:

84.1 As explained in the affidavit affirmed by Dr Town for the interim relief proceeding, surveillance data from the United States Centre for Disease Control (**CDC**), illustrated that while most of the children in the United States who have developed severe illness from COVID-19 have underlying medical conditions, 32% of 5 – 11 year olds hospitalised with COVID-19 had no underlying conditions.[16]

84.2 Dr Altman's criticisms of the efficacy of the Paediatric Vaccine are based on concerns that the relevant clinical trial used a different formulation to the Paediatric Vaccine for which Medsafe granted provisional consent. The affidavit of Mr James sworn for the interim relief proceedings explained that

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13 Interim Relief Affidavit at [8].

14 Interim Relief Affidavit at [33].

15 Discussed in Interim Relief Affidavit at [21].

16 Affidavit of George Ian Town affirmed 25 January 2022 at [20].

Medsafe asked Pfizer to explain why a different formulation was used, and that Medsafe was satisfied by Pfizer's explanation and supporting data.[17]

84.3 Dr Altman criticises the finding of the Wellbeing Impact Assessment that immunisation of the wider population is important to protect children and promote their wellbeing. His criticism is based on claims relating to the incidence of vaccine-related serious adverse events, and the inability of the Pfizer COVID-19 vaccines to prevent transmission. I understand that Mr James is giving detailed evidence about reporting of adverse events, and that Dr Town addresses the evidence of impact on transmission. I also note that children's overall wellbeing is promoted if the significant adults in their lives are not suffering from severe COVID-19. In that sense immunisation of the wider population promotes children's wellbeing, quite aside from the impact on transmission.

Dr Simon Brown

85. At paragraphs [64] to [68] of his affidavit, Dr Simon Brown points to two position statements published by the Ministry on 18 November and 19 November 2021 on the management of unvaccinated individuals in healthcare settings. Dr Brown concludes from these statements that vaccination has no significant impact on transmission.

86. The statements highlighted by Dr Brown do not support his conclusion that vaccination has no significant impact on

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17 Affidavit of Christopher Mark James sworn 21 January 2022 at [50].

transmission, for the following reasons:

86.1 The Ministry position statements were published to address concerns from clinicians and providers regarding consultation with patients who are not vaccinated against COVID 19, in particular the issue of requiring a negative test for COVID 19 prior to a non-urgent consultation.

86.2 The statement that the difference in the risk of transmission between vaccinated and unvaccinated is negligible was said to apply in situations where the rate of community spread is zero or very low, which was the case in November 2021.

86.3 It is not surprising that that where more than 80 percent of eligible people are vaccinated transmission is more likely to occur from a vaccinated rather than unvaccinated individuals. This simply reflects the reality that where the proportion of the eligible population which is unvaccinated is ever decreasing, there is a smaller pool of unvaccinated people to act as sources of transmission.

Letter to medical practitioners

87. I understand that the applicants have pointed to a letter dated 15 December 2021, which I and other health officials sent to medical practitioners about the risk of myocarditis and pericarditis as a rare but serious adverse event associated with Comirnaty vaccination. A copy of the letter is annexed and marked **ARB-19**.

88. This letter was part of the Ministry's normal pharmacovigilance process and represents best practice. All new medications are monitored and when new information is available it is

communicated with healthcare workers through well-established pathways.

89. The pharmacovigilance undertaken for the Pfizer vaccine was (and continues to be) extensive and includes: alert communications by Medsafe on 9 July and 21 July 2021; webinars recorded by the Immunisation Advisory Centre which included updates on myocarditis; a public statement published on 30 August 2021 on the Ministry's website to alert clinicians and consumers about the signs of myocarditis and pericarditis; and the inclusion of information on myocarditis in material provided to vaccinators. There was also substantial public reporting of myocarditis and pericarditis as rare but potentially serious adverse events from vaccination with the Pfizer vaccine.

AFFIRMED

at Wellington this 13th day of June 2022
before me:

Dr Ashley Robin Bloomfield

A Solicitor of the High Court of New Zealand

Stacey Jade Thomson