IN THE HIGH COURT OF NEW ZEALAND
WELLINGTON REGISTRY

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

CIV-2022-485-13

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)
	Second Respondent
AND	MINISTER FOR COVID-19 RESPONSE
	Third Respondent

AFFIDAVIT OF PAUL ANDREW TOMLINSON

9 June 2022

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I, Paul Andrew Tomlinson, of Christchurch, medical practitioner, swear:

INTRODUCTION

1. My full name is Paul Andrew Tomlinson. I am a medical practitioner, vocationally registered in paediatrics. I obtained the degrees of Bachelor of Science (Mathematics) in 1977, Bachelor of Medicine and Bachelor of Surgery in 1982 and Doctor of Medicine in 1996. I am currently the chair of the Medicines Assessment Advisory Committee (**MAAC**).

2. I am a Fellow of the Royal Australasian College of Physicians and a retired Fellow of the Royal College of Paediatrics and Child Health (United Kingdom). I practiced as a Consultant Paediatrician at Southland Hospital from 1991 to 2021. The bulk of my work was in all facets of general paediatrics, caring for sick children with infections, particularly respiratory disease. I also had recognised expertise in children's kidney and endocrine diseases, including diabetes. Last year, I retired from my position as a consultant paediatrician at Southland Hospital. My curriculum vitae is attached as **PAT-1**.

3. I was appointed Clinical Senior Lecturer at the University of Otago, later promoted to Clinical Reader and was responsible for teaching of medical students and trainee interns. At various times I have been the Southland Director of Physician Training (paediatrics) and examiner for paediatrics for both the Diploma of Child Health (Otago) and the Royal Australasian College of Physicians (RACP). I was a member of the Senior Examiners Panel of the RACP for 10 years. I have over 25 publications.

4. I have been appointed to various committees. I was appointed to the Pharmacology and Therapeutics Advisory Committee (**PTAC**) in 1998 and became the Deputy Chair in 2004 until my terms ended in 2009. PTAC is established under the New Zealand Public Health and Disability Act 2000 as an advisory committee to PHARMAC. PTAC provides objective and technical advice to PHARMAC about pharmaceuticals and their benefits, and makes recommendations to PHARMAC regarding proposals for funding. Included in this role, I chaired a number of expert subcommittees

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of PTAC, including the anti-infective subcommittee. I was also appointed to PHARMAC's Exceptional Circumstances Panel (2001 – 2011) and its successor, the Named Patient Pharmaceutical Assessment Panel (2011 – 2013). I also have experience as the chair of the Southland Hospital Drug and Therapeutic Committee which later merged into the Medicines Management Committee of the Southern District Health Board. As a result of my positions on these committees, and in particular my role on PTAC and MAAC, I have significant experience in the critical appraisal of pharmaceutical trials and evaluating the benefits and risks of pharmaceuticals for a New Zealand population.

5. In 2014, I was appointed as a member of the Medicines Assessment Advisory Committee (**MAAC**) and was appointed chair in July 2019. In my capacity as chair of the MAAC I have been involved in reviewing Pfizer's applications for consent for its COVID-19 vaccines. In particular, on 14 December 2021, I chaired the meeting of the MAAC to consider Pfizer's application for provisional consent of its COVID-19 vaccine for 5 to 11 year olds (**Paediatric Vaccine**). The outcome was that the MAAC made a recommendation to the Minister of Health's delegate to give provisional consent to the Paediatric Vaccine, subject to conditions. The Minister's delegate then gave provisional consent to the Paediatric Vaccine. I understand his decision to do so is the subject of this litigation.

6. Most of my evidence explains, as a matter of fact, the role and expertise of the MAAC, the MAAC's consideration of the Paediatric Vaccine, and the reasons why the MAAC was satisfied that it was appropriate to recommend provisional consent be given. MAAC's role is to provide independent expert advice to the Minister's delegate. To the extent that my evidence includes expert opinion evidence, I acknowledge that I have read the code of conduct for expert witnesses in schedule 4 of the High Court Rules and I agree to comply with it. The evidence in this affidavit is within my knowledge and my area of expertise unless stated otherwise.

EVIDENCE

The Medicines Assessment Advisory Committee

7. The MAAC is a technical advisory committee established under the Medicines Act 1981 (**Act**) to advise the Minister of Health (**Minister**) on the benefit to risk profile of new medicines. The terms of reference for the MAAC are as follows:

   7.1 To consider applications for the Minister's consent or provisional consent to the distribution of a new medicine referred to the MAAC under section 22(2) of the Act.

   7.2 To report to the Minister with a recommendation on the decision the Minister should make in respect of applications referred to the MAAC under section 22(2) of the Act.

   7.3 To periodically review a sample of reports of the evaluation of applications for the Minister's consent or provisional consent to the distribution of new medicines and provide expert advice to Medsafe and the Minister on the quality of the benefit to risk profile assessments that have been completed.

8. New medicine applications are referred to the MAAC for a recommendation when the Minister (which in practice is usually the Minister's delegate, the Group Manager of Medsafe) is not satisfied that they should give consent or provisional consent. At any one time there are up to 12 members of the MAAC. Membership of the MAAC is by application and subsequent ministerial approval. The current committee members have expertise in paediatrics, infectious diseases, inflammatory diseases, genetics, psychiatry, toxicology, pharmacy and clinical pharmacology. The committee also has lay representation and support from a biostatistician. Each member has substantial clinical experience and national credibility in their particular area of expertise and/or tertiary qualifications and extensive experience in biostatistics or in pharmaceutical chemistry.

9. If a new medicine application is referred to the MAAC for consideration, in

advance of the MAAC meeting to consider that application, Medsafe will provide the MAAC members with a range of information and reports on that new medicine application. This will include the dossier of information that was submitted by the sponsor with the new medicine application and reports created by Medsafe through Medsafe's evaluation and assessment of the new medicine application. These reports will usually evaluate the therapeutic benefit, clinical safety, manufacturing processes, quality control and ongoing risk management protocols of the new medicine.

10. At the meeting of the MAAC (which can be held in person or online):

10.1 Medsafe staff may give a presentation on the new medicine application (although the Minister's delegate does not attend);

10.2 the members will discuss every aspect of development of the new medicine, including basic pharmacology, pre-clinical studies, manufacturing processes, and clinical trials to assess benefits and risks; and

10.3 the members will have an opportunity to ask questions of Medsafe and the manufacturer/sponsor (who will often be invited to attend for a portion of the meeting).

11. Following discussion of each aspect of the new medicine applications, the members will consider whether the application should be declined or consent or provisional consent be recommended, whether conditions should be imposed or if further information is required before a recommendation can be made. Decisions on what recommendation to provide the Minister/the Minister's delegate are made where possible by consensus, or otherwise according to standard meeting procedure.

The MAAC's role over the last 18 months in considering COVID-19 vaccines and therapies

12. Typically, the MAAC meets one to three times per year. However, the MAAC has convened additional meetings over the last 18 months in order to consider new medicine applications for each of the COVID-19 vaccines, and some innovative COVID-19 therapies. These meetings have enabled

urgent consideration of provisional consent for COVID-19 vaccines in the context of the global pandemic. Provisional consent enables medicines to be made available to the New Zealand population before the regulatory requirements for full consent have been met.

13. The first COVID-19 vaccine that was referred to the MAAC for a recommendation was Pfizer New Zealand Limited's (**Pfizer**) Comirnaty concentrate for injection 0.5mg/mL (30µg/0.3mL when delivered), indicated for use in those aged 16 and over (variously referred to as **Comirnaty** or **Parent Product**). The Parent Product is an mRNA vaccine with a lipid nanoparticle carrier.

14. Following Medsafe's evaluation and assessment of Pfizer's application, the Group Manager of Medsafe, Christopher James, referred Pfizer's application to the MAAC for a recommendation given the rapid development of the Parent Product, the limits on the information available and the significant public interest in the decision.

15. The MAAC considered the new medicine application for the Parent Product at its 109th meeting on 2 February 2021. The meeting was called specifically to consider the new medicine application for Comirnaty. Pfizer's application for provisional consent was based on several clinical trials of which C4591001 was the pivotal trial. C4591001 is a randomised, placebo-controlled trial of over 40,000 participants aged 16 years and over.

16. The MAAC members reviewed in detail the full study reports of this clinical trial. The members noted that it demonstrated 95 percent effectiveness in preventing COVID-19 infection, and that among 10 cases of severe COVID-19 with onset after the first dose, 9 occurred in placebo recipients and 1 in a BNT162b2 recipient.[1] The safety profile showed mostly mild short term adverse effects including injection site pain and redness, fatigue and headache, commonly referred to as reactogenicity. A subset of participants had measured immunological profiles that showed a large increase in neutralising antibody levels. The MAAC approved the quality report subject

[1] FP Polack, SJ Thomas, N Kitchin et al "Safety and Efficacy of the BNT162b2 mRNA COVID-19 Vaccine" (10 December 2020) *New England Journal of Medicine* 383:2603-2615

to conditions to be addressed prior to consideration of full registration. The non-clinical report was also reviewed and was considered reassuring for various toxicities, including overdose, reproductive and developmental toxicity. Studies had found no evidence of vaccine associated enhanced disease. No genotoxicity studies were included but they were not felt necessary due to the mechanisms of action of the active substances (the mRNA component and the lipid adjuvants). The World Health Organisation has considered that genotoxicity studies are not required for vaccine products.[2] Although the mRNA component is genetic material, it is not a gene, and it has no replicating ability. The members also considered the Risk Management Plan and found it acceptable.

17. The MAAC unanimously recommended that provisional consent be given to the Parent Product for a nine-month period with a number of conditions imposed. The conditions included the ongoing provision of data and safety updates as they became available.

18. Since recommending provisional consent be given for the Pfizer Comirnaty vaccine, the MAAC has also given recommendations on other COVID-19 vaccines including COVID-19 vaccines developed by Janssen Pharmaceutica, AstraZeneca and Novavax. In June 2021, the provisional consent for Comirnaty was extended to 12 – 15 year olds, although MAAC's recommendation was not sought for that extension.

The MAAC's consideration of the Paediatric Vaccine

19. On 4 November 2021 Pfizer submitted a new medicine application for the Paediatric Vaccine.

20. The Paediatric Vaccine is essentially an extension of the Parent Product that has been specifically developed for use in children aged between 5 and 11 years. The Paediatric Vaccine, like the Parent Product, is an mRNA vaccine.

21. On the same date Pfizer submitted a new medicine application for an additional dosage form, Comirnaty solution for injection (30µg/0.3mL

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[2] WHO, *WHO Expert Committee on Biological Standardization – Fifty-fourth report* (2005) at [4.2.3]

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delivered) which is for use in ages 12 and over (**Comirnaty 30µg**). Both new medicines are based on the Parent Product, however Comirnaty 30µg has a different dosage form (suspension for injection, rather than concentrate for injection) and a different formulation to the Parent Product, using a tromethamine (TRIS) buffer instead of phosphate-buffered saline.

Referral to the MAAC

22. Mr James referred Pfizer's applications for provisional consent for the Paediatric Vaccine and Comirnaty 30µg to the MAAC for much the same reasons as Mr James had referred the application for the Parent Product to the MAAC (i.e. the pace of development, the limits on the data available and the public interest in the decision).

23. A special meeting of the MAAC (the 113th meeting) was called for 14 December 2021 to consider the applications for the Paediatric Vaccine and Comirnaty 30µg. The meeting was attended by all but one member of the MAAC, and by several employees of Medsafe. At one point representatives from Pfizer joined the meeting to give the MAAC members the opportunity to ask any questions. The meeting lasted almost four hours.

24. I understand the meetings of the minute have been included in Mr James' evidence. As I understand the litigation is only concerned with the Paediatric Vaccine my comments below are limited to the MAAC's consideration of the new medicine application for the Paediatric Vaccine.

Information provided to MAAC members before the 113th meeting

25. Before the MAAC meeting Medsafe provided the following documents to MAAC:

    25.1 Pfizer's new medicine application dossier; supporting information; responses to requests for information and data sheet.

    25.2 Medsafe's final quality evaluation report, clinical evaluation report, summary of risk management plan.

    25.3 A presentation from the United States Centre for Disease Control (**CDC**) on COVID-19 epidemiology in children aged 5-11 years.

25.4 A joint report to the Waitangi Tribunal on the expected impacts to Māori children and their whānau from the government's planned shift to the COVID-19 Protection Framework.

25.5 Medsafe's paper to the Medicines Adverse Reactions Committee on the proposed updates to the Risk Management Plan.

26. I did not read the full application dossier although I had access to it for reference purposes. I reviewed all of the other documents prior to the meeting.

27. In addition to reading the above materials, I also brought my comprehensive background knowledge of paediatric issues gathered through my general clinical experience. I have read widely about COVID-19 in children as part of keeping up to date with my clinical practice.

Evaluation of quality and clinical aspects

28. At the start of the meeting the Medsafe attendees gave presentations on their assessments of the quality and clinical aspects for the Paediatric Vaccine. The detail of their assessments were set out in Medsafe's quality evaluation report and clinical evaluation report, both of which were provided to MAAC members prior to the meeting. The quality evaluation report covers all aspects of the quality of the medicine including the manufacturing process. The clinical evaluation report evaluates the results of clinical studies performed on human participants, which in the case of the Paediatric Vaccine, was Study C4591007.

Pfizer's clinical trial (Study C4591007)

29. The members discussed the initial phase 1 part of the study, which was conducted in 48 participants aged 5 to 11 years and was dose-finding. Based upon increased reactogenicity from higher doses, the dose of 10 microgram was selected for this age group.[3]

30. There was discussion about Pfizer's stage 2/3 clinical trial as part of Study C4591007, which was the main subject of the clinical evaluation report.

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[3] Medsafe's clinical evaluation report at p10; the dose-finding study is also available online at https://www.nejm.org/doi/full/10.1056/nejmoa2116298

This clinical trial involved approximately 4,500 participants aged 5 to 11 years, with approximately 3,100 participants receiving the Paediatric Vaccine, 10 microgram dose. Those who were given the Paediatric Vaccine were given two doses of that vaccine 21 days apart. The clinical trial showed efficacy to be 90.7% (in reducing symptomatic infection). This figure is derived from 3 cases from 1518 participants at least 7 days after a second active dose, compared with 16 cases from 750 participants after placebo dosing. An additional 2250 participants were added to the safety analysis with the same 2:1 ratio for vaccine recipients (but not included in the efficacy analysis).

31. A subset of 441 participants were used in an immunobridging study of SARS-COV-2 50% neutralising titres to compare with 320 16 – 25 year olds taken from study C4591001, using the 30 microgram dose. In other words, the data for this subset of participants in Study C4591007 was compared to that of the clinical trial for 16 – 25 year olds. The analysis of antibody responses met the pre-specified criteria for non-inferiority, meaning the antibody levels produced in the participants in each trial were similar.

32. The MAAC members considered the adverse reactions in children aged 5 to 11 years in Study C4591007, noting that the most common local reaction was pain at the injection site and that any systemic reactions were mostly mild to moderate in severity and resolved within 48 hours. There were no serious treatment-emergent adverse events of concern. We noted that the clinical trial was too small to capture any potential rare events such as myocarditis and pericarditis. However, it is to be expected that clinical trials will not identify very rare adverse events, and we were satisfied that the clinical trial was appropriately designed.

33. The applicants' experts have criticised the size of the clinical trial for the paediatric vaccine. However, in my experience, the total cohort of 4,500 children aged 5 to 11 years is large for a clinical trial by paediatric standards. Where there is an existing product for use in an adult population, clinical studies to extend to a paediatric population are not designed to replicate a complete dossier of clinical data. Rather, a

paediatric study aims to compare, and link to, the existing experience of the use of the medicine in adults. The main aims of a subsequent paediatric study are to identify appropriate dosage; and identify whether the medicine produces similar efficacy and safety results in children, or whether there are any particular differences. The clinical data arising from the paediatric trial thus builds on the existing (and substantial) data about use of Comirnaty in an adult population.

34. Where a full placebo-controlled trial has been conducted in relation to an adult vaccine, as was the case for the Parent Product, a study of the size and nature of Study C4591007 was, in my experience, appropriate for identifying any additional or different safety concerns in the Paediatric Vaccine.

35. The members of MAAC were satisfied that Study C4591007 demonstrated that the Paediatric Vaccine had a positive benefit to risk profile for use in children 5 to 11 years. The study indicated that the Paediatric Vaccine was well tolerated in this age group and that no serious safety concerns had emerged.

Use of a different buffering agent

36. We discussed that the Paediatric Vaccine had a different buffering agent to the original Parent Product in that it used tromethamine rather than phosphate-buffered saline. Pfizer's application for the Comirnaty 30µg product (for use in adults) also used tromethamine as a buffering agent. In simple terms, the buffer is the solution that the active ingredient is suspended in. Buffering agents help to maintain the vaccine's pH and aids chemical and thermal stability during the shelf life.

37. The vaccine that had been used in Study C4591007 used phosphate-buffered saline as a buffering agent. The Paediatric Vaccine for which consent was sought used trometamol as a buffering agent, as did the new formulation of Comirnaty for use in adults (Comirnaty 30µg). We were comfortable, based on Medsafe's evaluation reports and the discussion at the meeting, that this change did not pose a risk of significantly impacting the quality or safety of the product and that the data from the clinical trial

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could still be relied upon. The buffer is not an active ingredient. In addition, Medsafe advised that trometamol is present as a buffering agent in other paediatric vaccines approved for use in New Zealand.

Consideration of vaccine-related risks

38. Medsafe gave a presentation on the risks of myocarditis and pericarditis following vaccination. Myocarditis is inflammation of the heart muscle, while pericarditis is inflammation of the tissue forming a sac around the heart. Myo-pericarditis means that both the heart muscle and the sac are inflamed.

39. The MAAC members agreed that increased incidence of myocarditis is a known feature of mRNA vaccines and appears to be more common in young adult males. There were no cases arising from Study C4591007 which was to be expected as these adverse events are often too rare to be evaluated in clinical trials. Rare events like myocarditis are usually identified in post market safety surveillance.

40. The MAAC members were aware that the New Zealand pharmacovigilance scheme, the Centre for Adverse Reactions Monitoring, had received notifications of a number of cases of myocarditis following vaccination with Comirnaty including the deaths of 3 older individuals, one of whom was a 13-year old child whose case has been reported to the Coroner. The cause of death is not yet known. There is a background rate of myocarditis in the community and a higher incidence of myocarditis following COVID-19 infection. According to one study there are an excess 3 cases per million second doses of Comirnaty in individuals under 40 years but by contrast an extra 10 cases per million COVID infections.[4] According to another study, the outcome of vaccine associated myocarditis is generally milder than from background cases of myocarditis due to other viral causes, including COVID.[5] The following graph (from the Patone paper) illustrates the comparison between vaccine-associated myocarditis, and myocarditis

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4 Risks of myocarditis, pericarditis, and cardiac arrhythmias associated with COVID-19 vaccination or SARS-CoV-2 infection, Patone M, Mei XW, Hanunnetthi L et al, Nature Medicine 2022 28:410 – 422.

5 Myocarditis Cases Reported After mRNA-Based Vaccination From December 2020 to August 2021 Oster ME, Shay DK, Su JR et al, JAMA 2022:327(4) 331 – 340.

following COVID-19 infection:

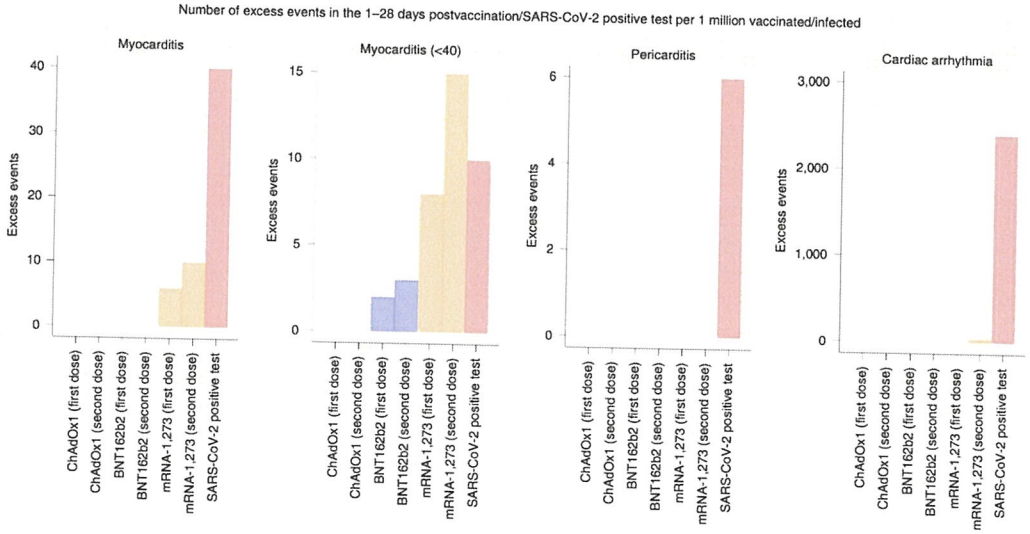

Fig. 2 | Number of excess events due to exposure per 1 million exposed, as reported in Supplementary Table 10. When IRR did not show a significant increase of incidence over the 1-28 days postvaccination or a SARS-CoV-2 positive test, absolute measures are not given.

41. Current New Zealand reports of myocarditis following COVID-19 vaccination have stated an incidence of 0 cases in children 0 – 9 years and 49 cases in individuals 10 – 19 years up to 29 April 2022, most of whom will be over 12 years of age.[6]

42. MAAC also considered the Risk Management Plan (**RMP**) report. The RMP is created by Pfizer and is submitted to Medsafe as part of the vaccine approval and safety monitoring processes. The RMP details important risks of the Pfizer Comirnaty vaccines, how these risks can be minimised, and how more information will be obtained about Comirnaty's risks and uncertainties. We noted that the RMP identified the need to monitor for myocarditis and pericarditis. MAAC noted that in response to a Medsafe query, Pfizer had said that routine pharmacovigilance would include children aged 5 to 11, including Māori and Pacific children and children previously infected with COVID-19.

Disease burden from COVID-19 for children aged 5 to 11 years

43. One of the documents Medsafe provided MAAC members before the meeting was a CDC presentation on COVID-19 epidemiology in children

[6] Medsafe 'Adverse events following immunisation with COVID-19 vaccines: Safety Report #43 – 30 April 2022' (11 May 2022), available at: https://www.medsafe.govt.nz/COVID-19/safety-report-43.asp

aged 5-11 years. I understand a copy of that presentation has been included in Mr James' evidence.. The presentation discusses the impact of COVID-19 infection on children aged 5 to 11 years. The presentation noted that children in that age group are at risk of severe illness from COVID-19, in particular that:

43.1 there had been more than 8,300 COVID-19 related hospitalisations of 5 to 11 year olds in the United States as at mid-October 2021, with one third of children hospitalised requiring ICU admission;

43.2 post-COVID conditions had been reported in 5 to 11 year olds; and

43.3 multisystem inflammatory syndrome (**MIS-C**) following a COVID-19 infection, often mild and presenting after several weeks, was most frequently found in children aged 5 to 11 years.

44. This information aligned with my understanding from my clinical practice of respiratory illness in children, and my own reading regarding COVID-19.

45. From the beginning of the pandemic, cases of COVID-19 were being described in children. Although generally less severe than in adult cohorts, there were multiple reports of children admitted to hospital. As at 3 June 2022, the CDC reports just over 800 COVID-19 deaths in children aged 5 – 18 in the USA.[7] UNICEF report that 0.4% of global mortality occurs in individuals under 20 years of age.[8]

46. MIS-C is a particular risk for children that I was aware of.[9] It has similarities to Kawasaki disease and can be very serious, requiring intensive care. MIS-C causes organs and tissues like the heart, lungs and brain to become severely inflamed. Most children who get MIS-C eventually get better but for some children their condition gets rapidly worse and can endanger their lives. In discussing the risk of COVID-19 to children at the MAAC meeting,

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7 CDC, National Center for Health Statistics. Provisional COVID-19 Deaths: Focus on Ages 0-18 Years. Date accessed 8 June 2022. Available from https://data.cdc.gov/d/nr4s-juj3https://data.cdc.gov/NCHS/Provisional-COVID-19-Deaths-Focus-on-Ages-0-18-Yea/nr4s-juj3

8 https://data.unicef.org/topic/child-survival/covid-19/

9 S Riphagen, X Gomex and N Wilkinson et al "Hyperinflammatory shock in children during COVID-19 pandemic" (6 May 2020) 395 *The Lancet* 1607.

the risk of MIS-C was raised as a consideration.

47. The risk of COVID-19 infection for Māori children in particular was discussed at the meeting following a submission from a group of Māori paediatric specialist practitioners. In that submission it was noted:

47.1 compared to children of European ethnicity Māori children experience a higher burden of risk factors for severe illness and/or negative outcomes from COVID-19 including but not limited to asthma, obesity and diabetes;

47.2 1 in 20 children with comorbidities experienced severe illness due to COVID-19, compared to 1 in 500 children with no pre-existing conditions;

47.3 the risk of mortality from COVID-19 was almost three times more likely in children with comorbidities compared to children with no comorbidities;

47.4 overseas evidence shows disproportionate COVID-19 infection rates in indigenous and ethnic minority children and that those children were more likely to be hospitalized with COVID-19; and

47.5 MIS-C occurs more frequently as a complication from COVID-19 among indigenous and ethnic minority children.

Discussion with Pfizer representatives

48. At one point representatives from Pfizer joined the meeting to answer questions from the MAAC members. The discussions related to:-

48.1 the new buffer agent;

48.2 adverse reaction data collection;

48.3 age stratification within Study C4591007; and

48.4 the receipt of safety signals from administering the Paediatric Vaccine to children 5 to 11 years.

Conclusions on benefit to risk profile and decision to recommend

49. The question for MAAC is whether the balance of benefits and risks means

that a medicine should be permitted on the market. Following all the above, the MAAC discussed the overall benefit to risk profile of the Paediatric Vaccine and unanimously agreed to recommend that provisional consent should be granted to the Paediatric Vaccine for nine months with a number of conditions imposed.

Response to applicants' evidence

50. I have read the applicants' amended statement of claim and the affidavits of Dr Phillip Altman, Dr Peter McCullough, Dr Simon Brown and Dr Geert Vanden Bossche. None of these affidavits makes me think that MAAC's recommendation to grant provisional consent to the Paediatric Vaccine was incorrect.

51. I understand that other witnesses will be responding in more detail to the points made by the applicants' experts. In the time available it is not possible for me to respond to each of the applicants' points, and I don't attempt to do so, but that does not mean I agree with their claims. I do however want to address a few main points.

The claim that healthy children are unaffected by COVID-19

52. At paragraphs [88] – [89] of his affidavit, Dr Altman says there is no evidence to support the conclusion that children who are healthy can suffer from severe COVID 19. Similarly, Dr Vanden Bossche at [17] – [22] of his affidavit says that healthy children should not be vaccinated.

53. As noted by MAAC in recommending provisional consent be given to the Paediatric Vaccine, the data provided to MAAC before the 14 December 2021 meeting indicates that children aged 5 to 11 are at risk from COVID-19 infection including from long-term symptoms and hospitalisation.

54. It is certainly true that some children are at higher risk of severe disease from COVID-19, including Māori and Pacific children and children with pre-existing health conditions. However, healthy children are also at risk from COVID-19 although the risk to most healthy children is low. As a result of my extensive clinical experience in paediatrics I know all too well how suddenly healthy children can be struck by serious illness. Simply put,

healthy children are healthy until they are not.

55. While the risks of fatality from COVID-19 infection are lower for children, there is a large population of children in the 5 to 11 age range in New Zealand (476,294 as at December 2021). Where there is such large population at risk of infection, even low mortality and hospitalisation rates can translate into concerning numbers. As at 27 May 2022 four children aged 0 – 9, and four children aged 10 – 19, have died in New Zealand with COVID-19 since the first New Zealand case.[10]

56. The benefits of vaccination for children during the omicron outbreak have been sustained. In a recent US study, vaccine effectiveness against Covid-19 infection resulting in hospitalisation or critical illness was assessed in a case control study of 1185 cases, 88% unvaccinated, and 1627 controls. Vaccination efficacy against the omicron variant with B162b2 was 68% in children 5 to 11 years and 40% in adolescents 12 to 18 years.[11]

The concerns regarding the lack of data, including long-term safety data

57. Dr Altman suggests that the scope and depth of safety data normally required for a new vaccine was not provided by Pfizer to Medsafe for evaluation (at [70](c) of his affidavit). Further, assertions that there is insufficient long-term data to detect serious adverse events and be assured of the safety of the Paediatric Vaccine are made by Dr Altman at [49] of his affidavit and Dr Brown at [32] – [33] of his affidavit. They suggest essentially that the Paediatric Vaccine should not have been approved without long-term safety data spanning a number of years.

58. Notwithstanding that there was some data not yet available, the MAAC was comfortable recommending that provisional consent be given to the Paediatric Vaccine. In our view, there was sufficient data to be satisfied that the benefit to risk profile of the Paediatric Vaccine supported provisional consent. Based on my considerable experience critically appraising clinical data of pharmaceutical trials, and evaluating benefits

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10 https://www.health.govt.nz/covid-19-novel-coronavirus/covid-19-data-and-statistics/covid-19-case-demographics

11 AM Price, SM Olson, MM Newhams et al "BNT162b2 Protection against the Omicron Variant in Children and Adolescents" (30 March 2022) 386 *New England Journal of Medicine* 1899.

and risks of pharmaceuticals, as a member of MAAC and PTAC, I was satisfied that the amount of data available was well within a reasonable range for recommending provisional consent.

59. Indeed, in the context of a global pandemic involving a rapidly-spreading virus causing millions of deaths, it would have been unethical to wait for years to accumulate further safety data when clinical trials had demonstrated the safety and efficacy of the Parent Product and Paediatric Vaccine.

The claim that decision-makers took into account considerations beyond the interests of children

60. I understand the applicants claim that Mr James and other decision-makers took into account considerations which were not based solely on the interests of children, such as that children should be vaccinated to protect adults and to reduce the spread of COVID-19 in the community.

61. As I understand it, the applicants are not making these allegations about MAAC's recommendation. The discussions the members held at the 14 December 2021 meeting, with each other and the Medsafe and Pfizer attendees, focused on assessing the benefits and risks of the Paediatric Vaccine for children aged 5 to 11. The meeting minutes reflect that there was little consideration of the benefits of vaccinating children for adults or the wider community. In making their recommendation, the members of MAAC were focused on the direct health benefits the Paediatric Vaccine offered to individual 5 to 11 year olds having considered the risk of the Paediatric Vaccine injuriously affecting the health of 5 to 11 year olds. Reduction of the burden of COVID-19 infection in the wider community would be a desirable outcome but was very much a secondary consideration.

General comment

62. I have concerns about the credibility of some of the claims made in the applicants' expert witnesses' evidence. By way of illustration, Dr Brown's affidavit dated April 2022 reproduces at [60] Table 2 from the UK Health Security Agency's (UKHSA) COVID-19 vaccine surveillance report (Week 41)

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in support of his arguments regarding "negative vaccine efficacy". [12] However, for reasons unexplained, Dr Brown's affidavit omits the two rows of the UKHSA's table relating to the age groups most relevant to the Paediatric Vaccine, being the under 18 and 18 – 29 cohort where there are clearly lower case rates. He also omits the qualifier "[i]nterpretation of the case rates in vaccinated and unvaccinated population is particularly susceptible to changes in denominators and should be interpreted with extra caution". Table 3 from the same report shows a lower rate of overnight admissions (a rate of 0.4 per 100,000 in vaccinated versus 3.3 per 100,000 unvaccinated under 18 year olds) and Table 4 a lower rate of deaths at every age group. I have reproduced the full Table 2 below.

Table 2. COVID-19 cases by vaccination status between week 37 and week 40 2021

Cases reported by specimen date between week 37 and week 40 2021	Total	Unlinked*	Not vaccinated	Received one dose (1-20 days before specimen date)	Received one dose, ≥21 days before specimen date	Second dose ≥14 days before specimen date	Rates among persons vaccinated with 2 doses (per 100,000)	Rates among persons not vaccinated (per 100,000)
Under 18	348,514	22,301	311,199	6,396	7,964	654	276.5	2,670.7
18-29	60,057	7,683	20,547	837	8,937	22,053	402.6	605.0
30-39	83,007	7,138	20,532	626	6,479	48,232	823.9	709.8
40-49	111,896	6,778	11,729	292	3,551	89,546	1,455.8	696.2
50-59	74,981	4,506	4,998	85	1,463	63,929	903.1	489.3
60-69	38,184	2,455	1,694	24	525	33,486	589.0	314.1
70-79	23,109	1,363	622	7	201	20,916	451.5	253.0
80+	10,770	839	375	7	184	9,365	364.6	298.5

*individuals whose NHS numbers were unavailable to link to the NIMS

** Interpretation of the case rates in vaccinated and unvaccinated population is particularly susceptible to changes in denominators and should be interpreted with extra caution.

63. The table he relies on simply does not support the point he is trying to make in the under 18 age group.

[12] https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1025358/Vaccine-surveillance-report-week-41.pdf.

64. In summary, at the time that MAAC considered the Paediatric Vaccine application, I was satisfied that the available information demonstrated that the benefits outweighed the risks, and that there was sufficient information to recommend provisional consent. I remain of that view.

SWORN

at Wānaka this 9 day of June 2022)
before me:)

Paul Andrew Tomlinson

A Solicitor of the High Court of New Zealand

Henry Kenneth Taylor
Solicitor
Wanaka

"PAT-1"

CURRICULUM VITAE

Name: Paul Andrew Tomlinson

Iwi: Ngai Tai Ki Tamaki

Degrees and Qualifications:

BSc (Mathematics)	1976	Canterbury University
BHB	1978	Auckland University
MBChB	1981	Auckland University
MRCP (UK)	1986	
FRACP	1988	
MD	1996	Auckland University
FRCPCH	2006	

Scholarships and Prizes:

NZ Junior University Scholarship 1973
IBM (NZ) Scholar 1973
NZ Senior Scholarship (Mathematics) 1975
Senior Prize (Human Biology) 1978

Previous Appointments

CONSULTANT PAEDIATRICIAN (1991 - 2021)
Southern District Health Board, Invercargill

CLINICAL READER IN PAEDIATRICS
University of Otago, Dunedin

College

Fellow of the Royal Australasian College of Physicians

Life Memberships

Paediatric Society of New Zealand
New Zealand Paediatric Endocrine Society

This is the exhibit marked "**PAT-1**" referred to in the annexed Affidavit of **PAUL ANDREW TOMLINSON** sworn at **Wānaka** this 9 day of **June 2022** before me:

Solicitor of the High Court of New Zealand

Henry Kenneth Taylor
Solicitor
Wanaka

Roles and Responsibilities

Southland Hospital

Consultant Paediatrician	1991 - 2021
Clinical Director of Paediatrics	1992 - 1998
	2001 - 2009
Infection Control Committee (Chair)	1992 - 1999
Drug and Therapeutic Committee	1998 - 2000
Drug and Therapeutic Committee (Chair)	2000 - 2014
Postgraduate Committee (Chair)	2003 - 2005
Senior Medical Staff Chair	2005 - 2007
Postgraduate Committee	2005 - 2020
Child and Youth Mortality Review Committee (Chair)	2009 - 2014

Southern District Health Board

Medicines Management Committee (Chair)	2013 - 2016
Community Pharmaceutical Advisory Committee (Chair)	2014 - 2016

Royal Australasian College of Physicians

Director of Paediatric Physician Training	1992 - 2010
	2016 - 2021
Paediatric Workforce Committee Chair	1997 - 2007
Board of Paediatrics and Child Health (NZ)	2005 - 2007
Co-opted examiner RACP	1999 - 2004, 2019
Senior Examiner's Panel RACP	2005 - 2017
Local examination organizer	2006, 2012

PHARMAC

Pharmacology and Therapeutics Advisory Committee (PTAC)	1997 - 2009
Deputy Chair	2003 - 2009

Subcommittees

- Special Foods (Chair)
- Antibiotic
- Antiretroviral
- CNS Stimulants
- Tender Medical (Chair)
- Diabetes (Chair)
- Anti-infective (Chair)
- Haemophilia
- Transplant Immunosuppressant (Chair)
- Growth Hormone
- Pulmonary Artery Hypertension

Panels

Exceptional Circumstances	2001 – 2011
Named Patient Pharmaceutical Assessment	2011 – 2013
Epilepsy (levetiracetam)	2008 - 2010
Pulmonary Artery Hypertension	2007 – 2010
PHARMAC Seminar Series Director	2005 - 2007

Medsafe (MOH)

Medicines Assessment and Advisory Committee	
Deputy Chair	2014 – 2017
Chair	2017 – 2019
	2019 -

University of Otago

Clinical Senior Lecturer	1991 – 2005
Clinical Reader	2006 – 2021
Local Trainee Intern Co-ordinator	1992 – 2019
Local Fifth Year Co-ordinator	2006 - 2017

Teaching Award (2007)
Teaching Award (2019):-
Excellence award for longstanding contribution in teaching (Invercargill Campus).

Publications

Review

Tomlinson PA
Low molecular weight proteins in children with renal disease
Pediatr. Nephrol. 1992 **6**:565-571.

Original Papers

Gibb, DM, Tomlinson, PA, Dalton, RN, Turner, C., Shah, V. and Barratt, TM
Renal tubular proteinuria and microalbuminuria in diabetic patients.
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Tomlinson PA, Dalton, RN, Turner, C. and Chantler, C.
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Phillips, PE, Edge, JA, Harris, DA, Kay, JD, Tomlinson, P, Hourd, P. and Dunger, DB Urinary excretion and clearance of insulin in diabetic and normal children and adolescents.
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Differential excretion of urinary proteins in children with vesicoureteric reflux and reflux nephropathy.
Pediatr. Nephrol. 1994 **8**:21-25

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Low molecular weight protein excretion in glomerular disease: a comparative analysis.
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Savarirayan R, Tomlinson P, David D and Thompson E
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Davis MR, Haan E, Jungbluth H, Sewry C, North K, Muntoni F, Kuntzer T, Lamont P, Bankier A, Tomlinson P, Sanchez A, Walsh P, Nagarajan L, Oley C, Colley A, Gedeon A, Quinlivan R, Dixon J, James D, Muller CR and Laing NG
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Neuromuscular disorders. 2003 **13**:151-157

Clarke R, Tomlinson P
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New Zealand Med J 2004 **117**(1205)

Tomlinson P, Moodie P
Response to "Exceptional Circumstances and Heart Transplantation"(letter)
New Zealand Med J 2005 **118** (1215)

Chae M, Reith DM, Tomlinson PA, Rayns J and Wheeler B
Accuracy of Verbal Self-Reported Blood Glucose in Teenagers with Type 1 Diabetes
J Diabetes Metab Disord 2014;**13**:14

Wheeler BJ, Patterson N, Love DR, Prosser D, Tomlinson P, Taylor BJ, Manning P
Frequency and Genetic Spectrum of Maturity-Onset Diabetes of the Young (MODY) in Southern New Zealand
J Diabetes Metab Disord 2013: **12**:46

Martin J and Tomlinson PA
Hepatic Complications in Poorly Controlled Tye 1 Diabetes Mellitus: A Case Report
New Zealand Med J 2014 **127**:1392

Sjoeholm A, Gray A, Rayns J, Tomlinson PA and Wheeler BJ
Prior knowledge of blood glucose meter download improves the accuracy of verbal self-reported blood glucose in teenagers with type 1 diabetes at ski camp
Acta Diabetologica 2016 **53**: 637-642

Blackwell M, Tomlinson PA, Rayns J, Hunter J, Sjoeholm A and Wheeler BJ
Exploring the motivations behind misreporting self-measured blood glucose in adolescents with type 1 diabetes – a qualitative study
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Ross P, Gray AR, Milburn J, Kumarasamy IM, Wu F, Farrand S, Armishaw J, Wiltshire E, Rayns J, Tomlinson PA and Wheeler BJ
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Milburn JR, de Lange M, Wiltshire E, Ross P, Rayns J, Tomlinson P, Fiona Wu F, Kumarasamy I, Armishaw J, Wheeler B
Evaluating the impact of an insulin pump discontinuation action plan on patient or caregiver confidence and anxiety
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Effect of 6 months' flash glucose monitoring in adolescents and young adults with type 1 diabetes and suboptimal glycaemic control: Managing Diabetes in a 'Flash' randomised controlled trial protocol Sara Boucher; Andrew R Gray; Martin de Bock; Esko Wiltshire; Barbara Galland; Paul Tomlinson; Jenny Rayns; Karen MacKenzie; Benjamin J Wheeler
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Biallelic variants in *EFEMP1* in a man with a pronounced connective tissue phenotype
Sean GW Driver[1], Meremaihi R Jackson[1], Konrad Richter[2], Paul Tomlinson[3] Ben Brockway[4], Ben J Halliday[1], David M Markie[5], Stephen P Robertson[1], Emma M Wade[1]
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Exploring parental perspectives following commencement of flash glucose monitoring for Type 1 diabetes in adolescents and young adults not meeting glycaemic targets: a qualitative study
Sara E Boucher1, Seung Hye Aum1, Hamish R Crocket2, Esko J Wiltshire3,4, Paul A Tomlinson1,5, Martin I de Bock6,7, Benjamin J Wheeler1,8
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Sara Boucher, Miranda Blackwell, Barbara Galland, Martin de Bock, Hamish Crocket, Esko Wiltshire, Paul Tomlinson, Jenny Rayns, Benjamin Wheeler
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The MiaoMiao study: can do-it-yourself continuous glucose monitoring technology improve fear of hypoglycaemia in parents of children affected by type 1 diabetes?
Elbalshy M, Boucher S, Galland B, Haszard JJ, Crocket H, Wiltshire E, Jefferies C, de Bock MI, Tomlinson P, Jones S, Wheeler BJ
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Other Abstracts

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Tomlinson P, Lyons A, Shaw I and Fraser G
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Eccles MR, Abbott G, Tomlinson P and Jacobs GH
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International Congress of Paediatrics (Poster) Melbourne 2013
Paediatric Society of New Zealand (Poster) Dunedin 2013

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Paediatric Society of New Zealand Dunedin 2013

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