INTERIM ORDER PROHIBITING PUBLICATION OF NAMES OR IDENTIFYING PARTICULARS OF THE APPLICANTS AND THEIR CHILDREN.

IN THE HIGH COURT OF NEW ZEALAND
WELLINGTON REGISTRY

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

CIV-2022-485-13
[2022] NZHC 67

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 Seven Others Applicants
AND	THE MINISTER OF HEALTH First Respondent
	THE GROUP MANAGER OF THE NEW ZEALAND MEDICAL DEVICES SAFETY AUTHORITY (MEDSAFE) Second Respondent
	MINISTER FOR COVID-19 RESPONSE Third Respondent
AND	PFIZER NEW ZEALAND LIMITED Interested Party

Hearing: 27 January 2022

Counsel: N R Williams, C Light and T Molloy for Applicants
K Wevers, K M Anderson and S M Perera for Respondents
E B Moran for interested party (Pfizer New Zealand Limited)

Judgment: 1 February 2022

JUDGMENT OF ELLIS J

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[1] On 16 December 2021 the Pfizer paediatric vaccine (a COVID-19 vaccine for use on children aged between 5 and 11) was granted provisional consent under s 23 of the Medicines Act 1981, authorising its supply (and use) in New Zealand. Four days later, Cabinet approved the "roll-out" of vaccinations for that age group.[1] That roll-out began on 17 January 2022.

The applicants' challenge

[2] The applicants in these proceedings are all parents of children aged between 5 and 11. While they acknowledge, as they must, that the paediatric vaccine has not been mandated, they say it "is likely to be required" for involvement in extramural activities like sport and school camps and that children and parents will be under significant governmental and social pressure to be vaccinated, rendering vaccination "quasi-mandatory" for their children.

[3] Accordingly, the applicants have filed an application for judicial review of both the consent and the roll-out decision. They challenge the relevant decisions on several overlapping grounds. They contend:

(a) The consent was based on an error of law, because the health risks of the paediatric vaccine outweigh its therapeutic benefits, contrary to the purpose of the Medicines Act. More particularly, they say:

(i) paediatric vaccination for Covid-19 carries few benefits because children aged 5 to 11 suffer mild symptoms when infected by Covid-19 and the vaccine does not prevent transmission of Covid-19 by children to others; and

(ii) paediatric vaccination presents material (though rare) risks such as myocarditis and anaphylaxis, and safety data (especially long-term data) about the Pfizer vaccine is inadequate.

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1 In broad terms, "roll-out" means purchasing and funding the paediatric vaccine so it is freely available to the general public, distributing vaccine stock to certified health providers, and including the paediatric vaccine in the wider vaccine infrastructure (such as facilitating paediatric bookings through Ministry of Health-run sites such as *Bookmyvaccine*).

(b) The grant of consent:

(i) failed to take any, or proper, account of article 3 of the Convention on the Rights of the Child, which makes the best interests of the child a primary consideration; and

(ii) was motivated by irrelevant considerations, namely that vaccinating children aged 5 to 11 would assist in preventing community spread, protecting older or vulnerable adults, and enabling schools to remain open.

(c) The decisions (to provisionally approve the vaccine and to authorise the vaccine roll-out) were made for an improper purpose, namely to prevent the transmission of Covid-19 and protect older or vulnerable adults when the best interests of the children should be the "first, paramount, and only" consideration.

[4] It may be observed in passing that the third ground of challenge appears to add little to the second.

Application for interim orders

[5] Pending a hearing of their substantive review application, the applicants also seek interim relief. They seek a declaration that:[2]

> … the provisional consent granted under section 23 of the Medicines Act 1981 for the Pfizer Comirnaty vaccine (the Vaccine) for 5 to 11 year olds (Provisional Consent) may be invalid and unlawful, and that, until further order of the Court, the Respondents ought not to take any further action, in relation to *healthy* children aged 5 to 11 *who are not immunocompromised* that is, or would be, consequential on the exercise of the statutory power, including proceeding with the roll out of the Vaccine to *healthy* children aged 5 to 11 *who are not immunocompromised.*

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[2] The terms of the declaration sought have changed since the proceedings were filed by the addition of the words emphasised in italics. This reflects the applicants' acceptance that the paediatric vaccine may have some therapeutic value to immunocompromised children.

[6] The interim relief sought is therefore directly focused on (what the applicants say is) the likely illegality of the provisional consent. At this stage, the only challenge to the roll-out is consequential on that contention.

[7] This judgment relates to that application.

Preliminary comment

[8] At the time the provisional consent was granted (and the roll-out to children approved) the focus of New Zealand's Covid-19 response was principally on the virus' original Wuhan strain and the more contagious Delta strain. It was only in the weeks following the impugned decisions that the new Omicron variant moved squarely into the spotlight.[3]

[9] For that reason, it is important to record at the outset that those decisions can only be interrogated in these proceedings by reference to the position in New Zealand at the time they were made. As McGechan J said in *Taiaroa v Minister of Justice*, "[a]dministration does not require clairvoyance".[4] So, to the extent the applicants' experts contend (for example) that the therapeutic value of the Pfizer vaccine is less in relation to Omicron than earlier strains, I put that to one side and do not consider it further.

The relevant statutory scheme

[10] The Medicines Act 1981 (the Act) regulates the approval, classification, manufacture, distribution, advertising, and prescribing of medicines in New Zealand.

[11] The word "medicine" is extensively defined and includes any substance or article that "is manufactured, imported, sold, or supplied wholly or principally for administering to 1 or more human beings for a therapeutic purpose".[5] The term

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3 Internationally, Omicron was declared a strain of concern by the World Health Organisation on 26 November 2021. The first case of Omicron in New Zealand was not reported until 16 December 2021.

4 *Taiaroa v Minister of Justice* HC Wellington CP99/94, 4 October 1994 at 43, citing Lord Russell in *Secretary of State for Education and Science v Tameside Metropolitan Borough Council* [1977] AC 1014 at 1076, as adopted by Cooke P in *Daganayasi v Minister of Immigration* [1980] 2 NZLR 130 and Tipping J in *Isaac v Minister of Consumer Affairs* [1990] 2 NZLR 606.

5 Medicines Act 1981, s 3(1)(a)(i).

"therapeutic purpose" is, in turn, defined to include the purpose of "preventing, diagnosing, monitoring, alleviating, treating, curing, or compensating for, a disease, ailment, defect, or injury".[6] There is, accordingly, no dispute that vaccines are included in the definition of "medicine".

[12] And the term "new medicine" is defined in s 3(3) to mean:

> (a) Any medicine that has not been generally available in New Zealand—
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> (i) Before the commencement of this Act; or
>
> (ii) At any time during the period of 5 years immediately preceding the date on which it is proposed to become so available:

[13] Despite the fact that provisional consent had earlier been given to the Pfizer vaccine for people aged 12 and over (Comirnaty concentrate for injection 0.5 mg/mL delivered), there is also no dispute that the paediatric version of the vaccine is nonetheless a "new medicine" in terms of the Act, and required a separate provisional consent in order for it to be supplied and used in New Zealand.

Sale and supply of new medicines

[14] Section 20(2) of the Act prohibits the sale or supply of new medicines:

> (a) before the Minister of Health has notified their consent or provisional consent in the *Gazette*; or
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> (b) otherwise than in accordance with any conditions imposed by the Minister on giving their consent or provisional consent.

[15] The Minister of Health has delegated his consent functions under the provisions just discussed to the Director-General of Health, who has, in turn, sub-delegated it (with the Minister's written consent) to Mr Christopher James, the Group Manager of the New Zealand Medicines and Medical Devices Safety Authority (Medsafe).[7] Accordingly, it is Mr James who granted the provisional consent now at

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6 Section 4(a).

7 Medsafe is a business unit of the Ministry of Health that deals largely with matters under the Act.

issue. All references to the Minister in the remainder of this judgment should be read as references to Mr James.

[16] Section 21 governs applications for consent under s 20.[8] Subsection (1) contains certain procedural requirements, including that every application shall be accompanied by a statement of the particulars specified in subs (2).

[17] There are 16 such "particulars". The first eight of these, (a) to (h), largely require the provision of basic information, including the new medicine's name, ingredients, recommended dosage, and claimed usefulness. The latter eight, (i) through (p), largely require the provision of more substantive, safety-focused information.

[18] Section 21(4) authorises the Director-General, before the gazetting of ministerial consent, to require an applicant to provide further information or particulars concerning the medicine or its manufacture, intended sale, distribution, or advertising.

[19] Section 22 details the process for determining applications for consent. Substantively, the Minister is required by subs (1) to:

> (a) Consider all the particulars and information relating to the medicine submitted under section 21 of this Act, and such other matters as appear to him to be relevant; and
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> (b) As far as practicable, weigh the likely therapeutic value of the medicine against the risk (if any) of the use of the medicine injuriously affecting the health of any person.[9]

[20] The remainder of s 22 contains a series of steps that the Minister must follow if *not* at that point satisfied that that consent should be given. The first of these is to refer the matter to the "appropriate committee", which is then required to consider the

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8 While s 20(3) refers to a "consent given under this section", the section does not directly confer the authority to consent on the Minister. That is, perhaps, because s 20 appears principally to be an offence provision.

9 Although safety is, unsurprisingly, a key consideration, it is notable that s 20(3) provides that "[n]o consent given under this section shall be deemed to warrant the safety or efficacy of the medicine to which the consent relates".

matter and report back to the Minister with a recommendation as to the decision that should be made. The Minister can appoint advisory committees under s 8 of the Act.

[21] The Medicines Assessment Advisory Committee (MAAC) is one such committee. Its purpose is to advise the Minister or delegate on the risk-benefit profile of new medicines. MAAC normally meets three times a year, although MAAC has convened out-of-session meetings over the last year to consider Covid-19 vaccines due to the need for urgency. MAAC is comprised of 12 members, including one lay person; the remainder are independent experts with significant clinical experience or knowledge in subjects such as pharmacology, infectious diseases, oncology, geriatrics, and chemistry.

[22] Provisional consents are governed by s 23, subs (1) of which now provides:[10]

> Notwithstanding sections 20 to 22 of this Act, the Minister may, by notice [in the *Gazette*], in accordance with this section, give provisional consent to the sale or supply or use of a new medicine if the Minister is of the opinion that it is desirable that the medicine be sold, supplied, or used.

[23] Subsection (2) relevantly requires that an application for provisional consent must:

> (a) state, or be accompanied by a statement of, the particulars specified in paras (a) to (h) of s 21(2); and
>
> (b) be determined by the Minister in accordance with s 22.

[24] And subs (3) permits the Minister to impose certain conditions when granting a provisional consent, including conditions relating to the persons to whom the medicine may be sold or supplied.

[25] Section 23(4) states that every provisional consent has effect for a period of only two years or less, although subs (4A) permits two-year extensions of the period determined under subs (4).

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[10] Subsection (1) was amended following this Court's decision in *Nga Kaitiaki Tuku Iho Medical Action Society Inc v Minister of Health* [2021] NZHC 1107.

The provisional consent process for the paediatric vaccine

[26] On 4 November 2021, Pfizer applied for provisional consent to the supply and sale of two Covid-19 vaccines: a modified version of the vaccine for individuals aged 12 years and over and the paediatric vaccine (for administration to children aged 5 to 11 years).[11] Both are based on Pfizer's original vaccine for those 12 and over (which was given provisional consent on 3 February 2021) and contain the same active ingredient (Tozinameran). As I have said, however, there is no dispute that these modified vaccines are properly regarded as "new medicines" in terms of the Act.

[27] Medsafe evaluators immediately began assessing the application. Although Mr James (as Medsafe's Group Manager) is not typically closely involved with such an evaluation process, the perceived urgency of, and public interest in, Pfizer's application led him to meet regularly with the evaluators, to discuss issues with them and to review excerpts and drafts of their reports. Mr James also deposed as to his constant review of the ever-increasing medical and scientific literature about Covid-19 vaccines both before and during the time when the consent was under consideration.

[28] On 10 December 2021 the evaluators presented their final assessment to Mr James. The evaluation had been peer-reviewed and separately assessed by their team leader. As far as the paediatric vaccine was concerned, they concluded that:

(a) based on Pfizer's clinical study of the vaccine's effects among children 5 to 11 years of age, two doses of the paediatric vaccine appeared to be highly protective against symptomatic Covid-19, with an observed vaccine efficacy of 91 per cent among participants in the study;

(b) based on the same study, two doses of the paediatric vaccine appeared to be safe and well tolerated among children 5 to 11 years old;

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[11] Pfizer's initial vaccine for those aged 12 and over involved dosages of 30µg/0.3mL delivered. Its modified vaccine for that age group uses a different dosage form (it uses a solution for injection, rather than concentrate for injection) and changes the buffering ingredients used in order to further support the solution's stability. Pfizer's paediatric vaccine involves dosages of 10µg/0.2mL delivered.

(c) the data provided was sufficient to provide reasonable assurance of comparability with the vaccine for those 12 years and older, which itself had a high efficacy and safety profile;

(d) while Covid-19's disease burden is concentrated among the elderly, severe effects from Covid-19 are known to occur among children;

(e) the therapeutic benefit/risk assessment for the paediatric vaccine was likely to be positive and favoured approval.

[29] Given high public interest and the fact that some data relating to safety was missing (due to the vaccine's rapid development) Medsafe's evaluation team recommended that the application be referred to the MAAC. Mr James agreed with, and implemented, that recommendation. To assist in their consideration, members of MAAC were provided with:

(a) Pfizer's medicine application dossier;

(b) Medsafe's final evaluation report and associated data;

(c) Medsafe's paper to the Medicines Adverse Reactions Committee (an advisory body to Medsafe) regarding proposed updates to Pfizer's Risk Management Plan for the vaccine for those 12 years and older;

(d) A presentation from the United States Centre for Disease Control on Covid-19 epidemiology in children 5 to 11;

(e) A Medsafe presentation on myocarditis; and

(f) A report to the Waitangi Tribunal prepared by six eminent New Zealand clinicians and academics, who had been asked to give expert evidence about the anticipated impact on Māori children and their whānau of the government's planned shift to the Covid-19 Protection Framework (the "traffic light system").

[30] MAAC met on 14 December 2021. The Committee unanimously recommended that the paediatric vaccine receive provisional consent.

[31] Mr James considered MAAC's minutes and recommendation. On 16 December 2021 he agreed to give provisional consent to the paediatric vaccine. His evidence in these proceedings notes that:

(a) while children are at less risk from Covid-19 than adults, there is still a risk of severe illness and complications;

(b) the clinical data demonstrated the vaccine was highly effective at preventing symptomatic Covid-19 among children 5 to 11;

(c) the clinical data demonstrated the vaccine was well tolerated and posed no new safety concerns among that age group; and

(d) the clinical data specific to children aged 5 to 11 was supported by significant data regarding the safety of the vaccine for those aged 12 and over.

[32] Mr James also deposed that his decision was based solely on an assessment of the therapeutic benefits and risks of the vaccine to 5-to-11-year-olds; any potential benefits to vulnerable adults from the vaccination of children played no part in it. His evidence on that point is supported by the relevant documents, which do not refer to that as a consideration at all.

[33] The provisional consent granted by Mr James was subject to certain conditions, including that Pfizer provide Medsafe with a range of further information when it became available, including final reports from Pfizer's clinical study of 5-to-11-year-olds and periodic safety reports.

[34] On 16 December 2021 the provisional consent was publicly announced and gazetted.[12]

The roll-out decision

[35] In parallel to the consent process, the safety and efficacy of Pfizer's paediatric vaccine was also assessed by the Ministry of Health's Covid-19 Vaccine Technical Advisory Group (CV-TAG), chaired by the Ministry's Chief Science Advisor, Dr George Town. CV-TAG provides scientific advice on matters relating to the Covid-19 vaccine roll-out to the Director-General of Health, Dr Bloomfield.

[36] Following its own assessment of the paediatric vaccine's benefit/risk relationship, CV-TAG advised Dr Bloomfield of its view that the paediatric vaccine should be included in its Covid-19 vaccine roll-out.[13] CV-TAG also made recommendations relating to spacing of doses and prioritisation of vulnerable populations.

[37] Of some further relevance here is CV-TAG's specific advice that mandates, vaccine certificates or vaccine targets should not be used or required for children aged 5 to 11, and that children in this age group should not be denied access to locations or events based on their vaccination status. It also proposed a specific public education campaign explaining why children should not be excluded from activities, in order to reduce the risk of informal or unintended exclusions.

[38] At about the same time, the Ministry of Health also prepared a "child wellbeing impact assessment" of immunisation for children aged 5 to 11 years to inform and assist Cabinet's decisions around the vaccination of children. The Wellbeing Impact Assessment specifically contained a rights analysis, conducted by reference to the United Nations Convention on the Rights of the Child.

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12 On 17 December 2021 the Gazette notice was amended to correct an error in the conditions attached to the provisional consent.

13 Whereas Medsafe's role is to consider whether a new medicine can lawfully be supplied in New Zealand under the Medicines Act, whether a new medicine should be publicly funded (and, in the case of the paediatric vaccine, included in national Covid-19 immunisation programme) is a matter for Cabinet to determine.

[39] The authors of the assessment acknowledged that, while Covid-19 is only uncommonly serious or fatal for children, the pandemic has had and will continue to have significant impacts on children's health, education, relationships, development, and lives. Consistent with CV-TAG's advice, the Wellbeing Impact Assessment found that:

(a) immunisation of the wider population is important to protect children and promote their wellbeing;

(b) immunisation of children adds protection and promotes their development with or without high levels of population immunisation;

(c) immunisation of Māori children requires high and urgent focus because Māori have suffered high pandemic impacts, remain at high risk, and have a significantly greater child population;[14] .

(d) immunisation of children should be voluntary, with no associated restrictions for any children, so that their vaccination status does not outweigh the benefits to their development of full access and participation in education, development, recreation and community activities and public places; and

(e) immunisation of children should, where possible, promote whānau wellbeing.

[40] Dr Bloomfield accepted and agreed with the CV-TAG conclusions and advice, which were noted by Cabinet. In accordance with CV-TAG's recommendations, Cabinet recorded that high priority should be given to:

(a) engagement with and resourcing for Māori to promote Covid-19 immunisation uptake for children and adults, together with access and

[14] The Wellbeing Impact Assessment noted that 14 per cent of the Māori population is aged 5 to 11, compared with 9 per cent of the non-Māori population.

uptake of other health and social measures that promote whānau wellbeing and the wellbeing of tamariki Māori;

(b) the promotion of immunisation for children who are, like tamariki Māori, at higher risk of exposure to, and adverse effects from, Covid-19, including Pacific children, children with disabilities and health conditions, and children in the care of Oranga Tamariki.

[41] As mentioned earlier, the roll-out was announced on 21 December 2021. In a press release that day, Minister Hipkins (the Minister for Covid-19 Response) said that

> Immunising 5 to 11-year-olds helps protect whānau members whose health makes them more vulnerable to Covid-19.

[42] He also said that while the government was strongly encouraging parents to have their children vaccinated, it "has no intention of making Covid-19 vaccinations mandatory for anyone in this age group".

[43] In response to these present proceedings, the Secretary for Education, Ms Iona Holsted, elaborated on this last aspect of the Minister's statement. She explained that under the COVID-19 Public Health Response (Protection Framework) Order 2021 (the Order) neither children seeking to access education nor their parents, can be denied entry or access to education services based on vaccination grounds. These rules apply to all "designated education and care premises," which are defined to include licensed early childhood services, registered schools, Out of School Care and Recreation programmes and school hostels.

[44] Ms Holsted's evidence was that there are no plans to amend this aspect of the Order; there is therefore no basis for suggesting that access to education services will be denied to unvaccinated children. Rather, the Minister for Covid-19 Response has recently agreed to expand the definition of "designated education and care premises" to include external organisations providing curriculum-related services to schools that opt in, in certain circumstances. This would cover what is known as "education outside the classroom", including things such as visits to swimming pools, museums, and school camps.

Should an interim order be made?

[45] I have set out the terms of the interim order sought earlier in this judgment. But to repeat it here for convenience, they seek a declaration that:

> … the provisional consent granted under section 23 of the Medicines Act 1981 for the Pfizer Comirnaty vaccine (the Vaccine) for 5 to 11 year olds (Provisional Consent) may be invalid and unlawful, and that, until further order of the Court, the Respondents ought not to take any further action, in relation to *healthy* children aged 5 to 11 *who are not immunocompromised* that is, or would be, consequential on the exercise of the statutory power, including proceeding with the roll out of the Vaccine to *healthy* children aged 5 to 11 *who are not immunocompromised.*

Legal framework

[46] Section 15(1) of the Judicial Review Procedure Act 2016 states:

> **15 Interim orders**
>
> (1) At any time before the final determination of an application, the court may, on the application of a party, make an interim order of the kind specified in subsection (2) if, in its opinion, it is necessary to do so to preserve the position of the applicant.
>
> …

[47] If applicants can establish that they have a position to preserve, then the Court has a wide discretion to consider all the circumstances of the case, including the apparent strengths or weaknesses of the applicant's claim for review, and all the repercussions, public and private, of granting interim relief.[15]

The applicants' evidence

[48] The applicants have personally deposed as to the social and educational difficulties they believe their children will face if they remain unvaccinated in the face of the roll-out of the paediatric vaccine. It is not necessary to set their concerns out in detail here, but it can usefully be noted that they are inherently speculative, in the sense that they have no factual foundation other than the applicants' subjective opinions. I nonetheless accept that those opinions and beliefs are sincerely held.

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15 *Minister of Fisheries v Antons Trawling Company Ltd* [2007] NZSC 101 at [3].

[49] As well, the applicants have filed affidavits sworn by a number of experts:

(a) Dr Martin Lally, a financial expert, who has undertaken a cost/benefit analysis in which he concludes that:

(i) parental opposition to vaccinating their children is rational because (based on his own assessment of publicly available adverse event data) although the risk of death from Covid-19 for unvaccinated children with an underlying condition is greater than that of taking the vaccine, there are "reasonable grounds" to support the view that vaccine risks exceed Covid-19 risks for unvaccinated children without an underlying condition; and

(ii) the "quality of life years" lost by an assumed 47,000 vaccine-objecting parents as a result of a "mandatory" paediatric vaccination scheme (one in which there are penalties for non-compliance) is greater than the "quality of life years" saved as a result of the such a scheme.

(b) Professor Nikolai Petrovksy, who has a PhD in immunology from the University of Melbourne and now works as a vaccine developer;[16]

(c) Byram Bridle, an Associate Professor of viral immunology in the University of Guelph in Canada, where he specialises in developing vaccines for prevention of infectious diseases and treating cancers in humans; and

(d) Dr Simon Brown, a retired New Zealand research scientist whose specialist areas of research included immunology.

[50] With respect, Dr Lally's evidence is of little assistance in the context of the present application. To the extent it carries with it a suggestion that the relevant

[16] His "Spikogen" Covid-19 vaccine is being distributed in Iran.

decision-makers should have done the kind of cost-benefit analysis that he has undertaken, I reject it.

[51] As far as the three scientific experts are concerned, they make a range of claims regarding the paediatric vaccine's efficacy and safety, including that:[17]

(a) Pfizer's clinical trials for the paediatric and non-paediatric vaccines were too small and too short to assess vaccine risk properly;

(b) the risks of mRNA vaccines, of which the paediatric vaccine is one, are insufficiently known; and

(c) the known risk of rare adverse effects from the paediatric vaccine (such as myocarditis) outweigh its benefits, in part because the infection fatality rate for Covid-19 is relatively low for otherwise healthy children and the vaccine:

(i) is non-sterilising (does not prevent infection); and

(ii) does not prevent transmission of Covid-19.

Discussion

[52] To paraphrase Mr Williams' submission slightly, the position the applicants seek to preserve by their application is "their unvaccinated children's ability to have full access to school and community facilities". That position is predicated on the proposition that if no children aged between 5 and 11 can be vaccinated (or only those who are immunocompromised) then there will no grounds for differential treatment of their children and such exclusion could not occur.

[53] Even if this could be said to amount to a qualifying (protectable) right or interest, the evidence does not persuade me that it has been placed in jeopardy by the

[17] Concerns are also variously raised about vaccine-associated enhanced disease, negative vaccine efficiency, infection as a result of mRNA vaccines and erosion of children's immunity.

consent or the roll-out. While I accept that the applicants themselves may remain sceptical about that, the evidence summarised earlier shows that:

(a) there is no intention (and likely no legal ability) to exclude unvaccinated children in the relevant age group from schools;

(b) to the extent there may presently be some impediments to unvaccinated children participating in extra-curricular or community activities, work is underway to encourage the removal of those impediments;[18] and

(c) a number of the impediments referred to by the applicants are the result of their own (rather than their children's) unvaccinated status.

[54] I am unable to accept that the applicants' concerns that their unvaccinated children will be shunned or bullied by other children (or adults) give rise to a protectable position to preserve. The implicit suggestion that this possibility should have been in the minds of the officials charged with making important public health decisions is simply a bridge way too far. And nor is it legitimate to view these matters (feared exclusion from facilities and societal pressures more generally) as operating to convert a legally optional vaccine into a "quasi-mandatory" one. The reality is that the applicants here do have a genuine choice: the fact that its exercise may give rise to consequences they would prefer to avoid does not, in my view, mean that the choice is not a real one.

[55] All that said, however, I acknowledge that in *Nga Kaitiaki Tuku Iho Medical Action Society Inc v Minister of Health* (KTI) (which concerned an application for interim orders aimed at halting the initial roll-out of the initial Pfizer vaccine) I was prepared to take a liberal approach to the existence of the required position to preserve.[19] In particular, I said it was "arguable that KTI does have a position to preserve, because by the time the substantive claim is heard, the vaccine will have

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[18] Although there may continue to be some restrictions in fact, due to the vaccination status of the children's parents.

[19] *Nga Kaitiaki Tuku Iho Medical Action Society Inc v Minister of Health*, above n 10, at [55], referring to the decisions of Walker J in *Christiansen v Director-General of Health* [2020] NZHC 887, [2020] 2 NZLR 566 and Cooke J in *Greer v Chief Executive of Department of Corrections* [2018] NZHC 1240, [2018] 3 NZLR 571.

been largely rolled out and the relief it now seeks on an interim basis will be unavailable". I also acknowledge that the present applicants are, on the face of it, in a similar position to the applicants in *KTI*. Unsurprisingly, the applicants advocate the same approach here.

[56] There are, however, material distinctions between the two cases. In *KTI*, I formed the relatively clear view that there was a legal problem with the provisional consent then at issue. That legal problem had nothing to do with the medical or scientific merits of the vaccine itself; it was a statutory concern that needed to—and could—be addressed as a matter of urgency by Parliament.[20] In those circumstances, the proposition that the Court was precluded from addressing that issue by a jurisdictional bar (the applicants' absence of a position to preserve) was an unattractive one.[21] Despite the requirement for a position to preserve being expressed in threshold terms, the merits of the underlying, substantive, application for review may in some cases have a bearing on whether it is met.

[57] Viewed in that way, the applicants' challenge in the present case is of a very different order. Although it is also directed at the "lawfulness" of the provisional consent, the alleged illegality is said to lie in the factual contention that the Minister's conclusion as to relative therapeutic value and potential risks of the paediatric vaccine was wrong, as a matter of science. It is only in the rarest of cases that this Court on review will engage with such a merits-based attack. As a matter of both law and logic, in a case where more than one view of the facts can reasonably be held, and the decision-maker has turned their mind to and applied the relevant statutory test, such a challenge cannot succeed.[22] A merits-based challenge will, in effect, only succeed if the impugned decision is demonstrably irrational.

[58] And here, the evidence filed by the respondents makes it clear beyond doubt that the Minister *did* apply the relevant statutory test and then made an assessment

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20 For that reason, interim relief was ultimately declined as a matter of discretion.

21 And despite going on to find that it was strongly arguable that the provisional consent was unlawful, I ultimately exercised my discretion against making the interim orders sought. That was because the illegality could (and likely would) be quickly remedied by Parliament, and significant adverse private and public repercussions that would flow from such orders.

22 See *New Zealand Fishing Industry Association* v *Minister of Agriculture and Fisheries* [1988] 1 NZLR 544 (CA) at 552 and *Taiaroa v Minister of Justice*, above n 4, at 42.

(based on all the expert information before him) that the therapeutic value of the paediatric vaccine outweighed the risk of injurious effect. Even accepting the expert qualifications of the applicants' witnesses and that their contrary scientific views are arguable, there is nothing in their evidence to persuade me that it is arguable that the Minister made an error of fact of such moment that his conclusion was not one that was reasonably available to him. That is particularly so where the relevant decision is made in the context of a government response to a global pandemic. As I said in *KTI*:[23]

> A very significant margin of appreciation must be afforded to those who are charged with making public health decisions—including decisions about managing public health risk—of a very significant kind. In the present case, the evidence is that the Minister has been advised by a plethora of experts in the relevant fields. And as just noted, the approval of the vaccine is in step with international developments.

[59] At this interim and untested stage, I necessarily accept both the bona fides and expertise of the scientists who have sworn affidavits supporting the position of the applicants. But what is equally clear is that there is a wealth of legitimate scientific opinion supporting the conclusions reached by the Minister.

[60] In terms of the specific concerns expressed by the applicants' experts summarised at [51] above, the contrary evidence is (briefly) that:

(a) Pfizer's clinical trial for the initial Covid-19 vaccine included approximately 44,000 participants. Its paediatric clinical trial included 5,500 participants, 3,100 of whom received the paediatric vaccine. These are large by the standards of normal vaccine trials. While neither were large enough to identify rare adverse effects like myocarditis, that is not the purpose of such trials, which seek to identify vaccine efficacy and more common risks. Rare adverse effects are meant to be identified by subsequent passive reporting systems. They were identified by these systems at very low rates.

(b) Pfizer's trials each took place over multiple months. It has not been able to provide long-term safety data regarding the vaccine's effects

[23] *Nga Kaitiaki Tuku Iho Medical Action Society Inc v Minister of Health*, above n 10, at [73].

over two to three years, as some of the applicants' experts suggest would have been appropriate. However, this is because the pandemic was urgent, and a delay of that period would have prevented people from accessing vaccine protections.

(c) Although mRNA vaccine technology may be newer than that of other vaccine technologies, researchers have been working with and studying mRNA vaccines for decades, particularly in the context of the influenza, rabies and Zika viruses. There is significant scientific understanding about how they work.

(d) While children aged 5 to 11 typically suffer mild symptoms from Covid-19, the disease can cause serious complications like respiratory failure, myocarditis and multi-organ failure. Pfizer's paediatric trials indicate the vaccine has a 91 per cent efficacy rate against symptomatic Covid-19.

(e) In terms of health risk, an analysis by the United States' Center for Disease Control of adverse effect reports following 8.7 million doses of the paediatric vaccine found just 100 reported serious adverse effects (a rate of 0.0000011 per cent), including 12 reported cases of myocarditis.

[61] And although, for present purposes, it is unnecessary for me to decide whether the wider community benefit of vaccinating children was (as the applicants assert) an irrelevant consideration, it is difficult to see how the best interests of children can be assessed only through the narrow lens suggested by the applicants. In particular, it can hardly be in the best interests of children whose whānau include vulnerable adults for those adults to be put at risk of serious disease and death unnecessarily. And notwithstanding the applicants' evidence that vaccination does not reduce

transmission, a technical report published by the European Centre for Disease Prevention and Control (ECDC) in early December 2021 noted:[24]

> Modelling data indicate that vaccinating children aged 5-11 years could reduce SARS-CoV-2 transmission in the whole population, although the extent and duration of this protection is currently unknown. It is estimated that the impact on the effective reproduction number … in the population as a whole would be a decrease of 11% (range: 8-15%, depending on vaccine uptake parameters of 30-70%) for an average country in the EU/EEA. This is comparable to the effect of some non-pharmaceutical interventions. The impact of vaccinating children is weaker for countries with a low adult vaccine uptake and stronger for countries with high uptake among adults.

[62] That same report contained several other relevant "key messages", including that:

> • Surveillance data show that children aged 5-11 years have made up an increasing proportion of both notified cases and hospitalisations in EU/EEA countries in recent months. Although hospitalisations have increased in line with case rates in all age groups in the EU/EEA, disease severity of COVID-19 in children is generally mild with a favourable clinical outcome. Severe COVID-19 remains rare among children (of 65,800 notified symptomatic COVID-19 cases in children aged 5-11 years, reported from 10 EU/EEA countries during the period of B.1.617.2 (Delta) variant of concern (VOC) dominance, 0.61 % were hospitalised and 0.06% needed intensive care unit (ICU)/respiratory support).
>
> …
>
> • The presence of an underlying condition among children aged 5-11 years is associated with about 12 times higher odds of hospitalisation and 19 times higher odds or of ICU admission. However, the majority (78%) of hospitalised children of this age had no reported underlying medical condition.
>
> • Paediatric inflammatory multisystem syndrome temporally associated with SARS-CoV-multi-inflammatory syndrome in children (PIMS-TS/MIS-C) and post COVID-19 condition have been reported in children aged 5-11 years, although it is difficult to quantify the prevalence and burden of these conditions. In a United States (US) Centers for Disease Control and Prevention (CDC) report, myocarditis was reported up to 37 times more often in unvaccinated children less than 16 years old with a COVID-19 diagnosis compared to other patients from the same age group.
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> …

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[24] European Centre for Disease Prevention and Control. Interim public health considerations for COVID-19 vaccination of children aged 5-11 years, 1 December 2021. ECDC: Stockholm; 2021. This report formed part of the material considered by Dr Town.

- Children aged 5-11 years who are at risk of severe COVID-19 should be considered a priority group for vaccination against COVID-19, as in other age groups. However, since hospitalisation, PIMS-TS/MIS-C and post COVID-19 condition can also occur among children with no known risk factors, consideration could be given to the vaccination of all children aged 5-11 years:

- COVID-19 vaccine safety data in children aged 5-11 years are currently limited, and the level of natural immunity in the unvaccinated and its duration are currently unknown and likely heterogeneous across the population.

- The main priority of COVID-19 vaccination campaigns seeking to reduce COVID-19-related morbidity and mortality remains to increase vaccine uptake in the eligible adult population. Before taking policy decisions on COVID-19 vaccination in children, potential harms and benefits - including the direct and indirect effects on health and well-being - should be considered alongside the vaccine uptake and epidemiological situation in a particular country. Aspects around implementation and health equity should also be taken into consideration.

[63] The short point is that notwithstanding sincerely held views (of both laypersons and experts) to the contrary, there appears to have been ample, cogent, information that supported the decision to approve the paediatric vaccine. Given the high threshold (discussed earlier) it is not possible to conclude that the applicants' case for a merits-based review of that decision is strongly arguable. My own interim view is that it is barely arguable at all.

[64] Lastly, and for completeness, I record that even if I had accepted that the applicants have a position to preserve and/or that their substantive case had serious merit, the adverse public and private repercussions of granting interim relief (pausing the roll-out) count against the exercise of the Court's discretion in their favour. These were comprehensively detailed in Dr Bloomfield's evidence. By way of summary these repercussions include:

(a) denying the considerable number of New Zealanders who wish their children aged between 5 and 11 to be vaccinated the choice to do so, with all the potential health ramifications of that;[25]

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[25] A survey commissioned by the Ministry of Health in the last quarter of 2021 showed there is strong support for and interest from parents in vaccinating 5-to-11-year-olds. The survey found 72 per cent of parents and caregivers who care for 5-to-11-year-olds would allow their child to receive the vaccine.

(b) disruption to the roll-out that has already begun, including:

(i) disruption to the lives of those children who have already received one dose and to those with vaccinations planned;[26] and

(ii) disruption to supply chains, workforce and technology platforms associated with the vaccine roll-out;

(c) the flow-on disruptions to the everyday lives of all children as a result of a need to put other protective measures in place;[27]

(d) the likely continued inequitable impact of Covid-19 on Māori and Pacific communities and disabled people;

(e) impeding the Crown's efforts to meet its obligations to Māori under the Treaty of Waitangi;[28]

(f) potential flow-on effects in terms of:

(i) the ability to maintain capacity within the health sector and, the ability of the health system to cope with widespread transmission;

(ii) the wider economy; and

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[26] As at 23 January 2022, 80,545 children aged 5 to 11 years old (supported by their parents or guardians) have received a first dose of the paediatric vaccine. At the time Dr Bloomfield wrote his affidavit, the National Immunisation Booking System contained bookings for a further 27,882 children aged 5 to 11 to have their first dose; and 32,087 children to become fully vaccinated with a second dose. The booking system numbers do not include those children who have been booked with their own GP, or those who plan to "walk in" to a vaccination site.

[27] The WHO's Interim statement on Covid-19 vaccination for children and adolescents highlights that children and adolescents have been significantly affected by the measures put in place to control Covid-19. The most impactful of these relate to school closures and the consequent disruption to children's education, and increases in emotional distress and mental health problems.

[28] By way of example Dr Bloomfield refers to evidence filed in the Waitangi Tribunal's priority inquiry into the Covid-19 response in December 2021 about the significant concerns for tamariki Māori aged under 12 in the event of a Covid-19 community outbreak.

(iii) public confidence in the paediatric vaccine in the longer term, particularly in vulnerable communities; and

(g) the potential expiry and wastage of valuable vaccine stock, contrary to New Zealand's obligations as a good global citizen;[29]

[65] Dr Bloomfield also says halting the roll-out would create uncertainty around New Zealand's continued ability to support and facilitate access to vaccines for the six Pacific countries with whom it has a constitutional relationship and/or strong historical and cultural ties,[30] all of which have large populations aged under 12. New Zealand has procured sufficient volumes of the paediatric vaccine to fully immunise those aged 5 to 11 years in those countries (130,000 doses), although none have been delivered yet. At the very least, an order delaying the roll-out in New Zealand would affect vaccine confidence in the Pacific as well.

[66] Nor were Dr Bloomfield's concerns allayed by the later change in the terms of the order sought by the applicants so that immunocompromised children would be exempt from it.[31] For example, he notes that the *Bookmyvaccine* website would not presently be able to identify which children are immunocompromised and—to the extent it is possible at all—it would be neither a simple nor quick to change the booking platform to limit bookings to those children.[32] As well, there are issues of definition: who would decide whether a child is immunocompromised, and how would confirmation of eligibility work in practice? Would walk-in vaccinations be possible at all? And even if it were theoretically possible to work through these kinds of issues, an operational change of that magnitude would take significant time and effort to implement and would inevitably divert an already limited public health resource amidst a public health crisis.

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29 The paediatric vaccine is stable for six months at -70 degrees from the date of manufacture but by the time it gets to New Zealand there may be as little as three months within which to use it. Once "defrosted", it may be stored for 10 weeks in standard cold chain conditions (2 to 8 degrees). As at 19 January, there were almost half a million paediatric vaccine doses in storage across New Zealand which, if not used, would expire by the end of March or April 2022.

30 The Cook Islands, Niue, Tokelau, Samoa, Tonga and Tuvalu. New Zealand is also directly supporting access to vaccines in other Pacific countries such as Fiji.

31 As noted earlier, on 24 January 2022 the applicants amended the terms of the declaration sought so that it would only seek to stop the roll-out of the paediatric vaccine for "healthy children aged 5 to 11 who are not immunocompromised".

32 There is also the further issue (noted above) about what would happen to all the existing bookings.

[67] I acknowledge that the reality of some (but by no means all) of the repercussions just mentioned are predicated on an acceptance that the paediatric vaccine will have a therapeutic effect. But on any analysis, they are in combination overwhelming. They confirm my already clear view that the application for interim orders should be declined.

Result

[68] The application for interim orders is declined.

[69] I did not hear from counsel on costs, regarding which I trust agreement can be reached. If it cannot, memoranda (no more than two pages in length) may be filed and referred to me.

[70] The respondents agree that the suppression of the applicants' names can continue until the hearing of the substantive application for review, at which time it can be the subject of further submissions. There are directions accordingly.

[71] Counsel are to revert to the Registry within 24 hours if any other confidentiality issues arise from this judgment. Any further media requests for access to the evidence on the file can be dealt with if and when they are made or renewed.

Rebecca Ellis J

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