ORDER MADE THAT THE NAMES AND IDENTIFYING DETAILS OF EACH OF THE APPLICANTS IN THIS PROCEEDING ARE SUPPRESSED UNTIL ANY FURTHER ORDER OF THIS COURT MAY BE MADE

IN THE HIGH COURT OF NEW ZEALAND
WELLINGTON REGISTRY

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

CIV-2022-485-000013
[2022] NZHC 1997

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
	PFIZER NEW ZEALAND LIMITED Interested Party

Hearing:	27 – 28 June 2022
Memoranda filed:	5/7/2022 Counsel for the Applicants 8/7/2022 Counsel for the Respondents
Appearances:	D P H Jones QC, T Malloy and S Eden for the Applicants K Wevers, K M Anderson and S M Perera for the Respondents E B Moran for the Interested Party (Pfizer New Zealand Limited) K Ashby-Coppens (by VMR from Australia observing for the Applicants)
Judgment:	12 August 2022

JUDGMENT OF GENDALL J

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Introduction

[1] On 16 December 2021, the first respondent, the Minister of Health (the Minister) via his delegate, the second respondent, the Group Manager of the New Zealand Medical Devices Safety Authority (Medsafe), gave provisional consent to the Pfizer Comirnaty vaccine (a COVID-19 vaccine for use on children aged between five and 11 years old) (the Paediatric Vaccine) pursuant to s 23 of the Medicines Act 1981 (the Act) (the Provisional Consent decision). This consent authorised the supply and use of the Paediatric Vaccine in New Zealand.

[2] Following provisional consent, four days later on 20 December 2021 Cabinet approved the "roll-out" of vaccinations for that age group (the roll-out) and thereby took a decision to incorporate the Paediatric Vaccine in the COVID-19 Immunisation Programme (CVIP) (the Roll-Out decision). Resulting from this, the Paediatric Vaccine became available free of charge for all children aged five to 11 years in New Zealand from 17 January 2022 when the roll-out began. Parents of those children, however, were free to choose whether or not to have their children vaccinated.

[3] These proceedings seek to challenge both decisions — that is, the Minister's decision to give provisional consent for use of the Paediatric Vaccine and Cabinet's Roll-Out decision. The eight applicants in these proceedings are all parents of children aged between five and 11 years old. In questioning the validity of the provisional consent given for the Paediatric Vaccine they maintain they are concerned about the decisions made by both Medsafe and the Government concerning the safety and efficacy of the Paediatric Vaccine and its universal roll-out. They say that the wellbeing and welfare of children, which is a paramount consideration entrenched in legislation in New Zealand and internationally, was put at risk as a result of both decisions.

[4] On 14 January 2022, the applicants sought interim relief to stop the roll-out of the Paediatric Vaccine. On 1 February 2022 this Court declined that application, which had, as its focus, the Provisional Consent decision.[1] In giving this decision

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1 *MKD v Minister of Health* [2022] NZHC 67 [the Interim Relief Decision].

declining interim relief, Ellis J noted that it would only be in the rarest of cases that this Court will engage with a merits-based attack on judicial review, that in order to succeed the impugned decision would need to be demonstrably irrational, and that to the contrary here it was clear there was a wealth of legitimate scientific opinion supporting the conclusions reached by the Minister's delegate, the second respondent.

[5] Since that 1 February 2022 decision, the applicants have filed in this Court a large volume of further evidence for consideration on this substantive application. The Minister and the other respondents have also filed a significant volume of further evidence in response, as although the Crown maintains it is not inviting the Court to engage in a consideration of the merits of the decision made by the Minister, the Crown contends it is concerned here about vaccine misinformation.

The applicants' challenge

[6] As I have noted, there are two impugned decisions which the applicants challenge here:

(a) On 16 December 2021, the Minister, via his delegate Mr Christopher James (Mr James) as the Group Manager of Medsafe, granted provisional consent under s 23 of the Act for the Paediatric Vaccine to be made available for five to 11-year-olds (the Provisional Consent decision).

(b) On 20 December 2021, Cabinet approved the vaccination of children aged five to 11 years old, with vaccination due to start on 17 January 2022. The third respondent, the Minister for COVID-19 Response, announced the roll-out on 21 December 2021 and the vaccination of children in this age group in fact started on 17 January 2022 as announced and has continued since (the Roll-Out decision).

[7] The applicants who question the validity of the Provisional Consent say they are concerned about the validity of decisions made by both Medsafe and the New Zealand Government concerning the safety and efficacy of the Paediatric Vaccine and its universal roll-out. They say the Provisional Consent

decision was flawed both at the time it was made and now, and should be reconsidered based on the expert evidence the applicants have provided which they contend unequivocally establishes that the risks of vaccinating this age group outweigh the benefits by some margin.

[8] The applicants add that they are the human face of parents who face potentially life-changing decisions in relation to their children, that Government approval and promotion of the Paediatric Vaccine instils confidence in the general populace that the vaccine is safe and the experts who have provided evidence for the applicants positively challenge their decision to accept at face value the safety and efficacy of the vaccine and thereby the reasonableness of the impugned decisions.

[9] In response, the position of the Minister and the other respondents in summary is as follows:

(a) There is no merit in the applicants' claim that the Provisional Consent decision was unlawful. The requirements of ss 22 and 23 of the Act have been complied with, given that the Minister's delegate made his decision following careful consideration of the therapeutic value and risks of the paediatric vaccine for five to 11-year-olds.

(b) It is not the Court's role on judicial review to substitute its view on the merits of a decision, particularly in a matter of scientific and medical expertise. In any event, the Crown contends the overwhelming weight of scientific opinion here supports the decision made.

(c) The evidence is clear, as this Court accepted at the interim stage, that the decision of Mr James as the Minister's delegate was based on his assessment of this therapeutic value and risks for five to 11-year-olds. There is nothing in the suggestion advanced for the applicants that the Minister's delegate did give Provisional Consent to the Paediatric Vaccine simply in order to benefit older adults or to reduce community transmission.

(d) Cabinet's Roll-Out decision to include the Paediatric Vaccine in the COVID-19 immunisation programme is a policy decision and not a matter suitable for judicial review. There is no yardstick or legal framework against which the lawfulness of the Roll Out decision can be assessed by the Court.

(e) If the Court disagrees and it considers Cabinet's Roll-Out decision is justiciable, then there is also no basis for the applicants' claim that the decision was made for an improper purpose or that it was pre-determined.

Background

The Parent Product

[10] On 3 February 2021, the Minister, via his delegate Mr James, the second respondent, as the Group Manager of Medsafe, gave provisional consent to Pfizer's COVID-19 MRNA vaccine, Comirnaty concentrate for injection, 0.5mg/ml (the Parent Product) for use in New Zealand in people aged 16 and over. That decision to provisionally consent the Parent Product was challenged in this Court in *Nga Kaitiaki Tuku Iho Medical Action Society Inc v Minister of Health*.[2] In its decision in that case, the Court declined to grant interim relief but held the applicant there had raised a reasonably arguable case that the decision was ultra vires because s 23 of the Act (at that time) required a provisional consent to be granted "on a restricted basis for the treatment of a limited number of people." Parliament then amended s 23 to remove the requirement that provisional consent be granted on a restricted basis for the treatment of a limited number of people.[3] That amendment assured that the Minister (or delegated decision-maker) may grant provisional consent where there is an identified public health need and where the information available means that a full consent process under s 20 of the Act is not feasible.

[11] On 21 June 2021, following a changed medicines notification under s 24 of the Act, the Minister issued a revised Provisional Consent for the Parent Product, based

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2 *Nga Kaitiaki Tuku Iho Medical Action Society Inc v Minister of Health* [2021] NZHC 1107.
3 Medicines Amendment Act 2021, s 4.

on an extended indication for use in 12–15-year-olds. On 28 October 2021, the Minister made a decision under s 23(4A) of the Act to renew provisional consent for the Parent Product. On 8 November 2021, following a changed medicines notification under s 24, the Minister issued a revised provisional consent and approved a revised data sheet for the Parent Product to include the administration of a booster dose in individuals aged 18 years and older.

The Paediatric Vaccine

[12] On 4 November 2021, Pfizer New Zealand Ltd (Pfizer) applied for provisional consent for two new COVID-19 vaccines — the Paediatric Vaccine for individuals aged five to 11 years old, and a modified version of Pfizer's COVID-19 MRNA vaccine for individuals 12 years and older. Both of these vaccines have the same active ingredient as the Parent Product: tozinameran, previously referred to as BNT162b2. Only the Paediatric Vaccine, however, is at issue in the present proceedings.

[13] Although these vaccines contain the same active ingredient as the Parent Product, they are treated as new medicines requiring a new consent or provisional consent because the new products are materially distinct from the Parent Product and were not previously available in New Zealand, as Mr James confirms in his evidence. The Paediatric Vaccine contains one-third of the amount of the active ingredient of the Parent Product per dose.

Assessing the Provisional Consent application for the Paediatric Vaccine

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

[15] On 10 December 2021, the Medsafe evaluators presented their final assessment to Mr James as Medsafe's Group Manager. The evaluation, it seems, had been peer-reviewed and separately assessed by their team leader. With regard to the Paediatric Vaccine, they concluded that:

(a) based on Pfizer's clinical study of the vaccine's effects among children five 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 that same study, two doses of the Paediatric Vaccine appeared to be safe and well-tolerated among children five to 11 years old;

(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; and

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

[16] However, given the high public interest in this decision and the fact that, due to the vaccine's rapid development, there were certain data limitations, Medsafe's evaluation team recommended that the application be referred to the Medicines Assessment Advisory Committee (MAAC) for their review and recommendation. Mr James, as the Minister's delegate, having reviewed and considered Medsafe's evaluation, agreed. He referred Pfizer's application to MAAC.

[17] The MAAC is a technical advisory committee established under s 8 of the Act to provide advice to the Minister or their delegate on the risk-benefit profile of new medicines. MAAC has 12 members, including one layperson. The remainder are independent experts, with what seems to be significant clinical experience or expertise

in paediatrics, infectious disease, inflammatory disease, genetics, psychiatry, toxicology, pharmacy, and clinical pharmacology. The current chair of the MAAC, Dr Paul Tomlinson, who gave evidence in these proceedings, is a paediatrician with over 30 years' experience.

[18] 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 (RMP) for the vaccine for those 12 years and older;

(d) a presentation from the United States Center for Disease Control on COVID-19 epidemiology in children aged five to 11;

(e) a Medsafe presentation on myocarditis; and

(f) a report to Te Rōpū Whakamana i te Tiriti o Waitangi | 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").

[19] MAAC met on 14 December 2021 and unanimously recommended that the Paediatric Vaccine receive Provisional Consent.

[20] Mr James, it appears, reviewed and considered MAAC's minutes and recommendation, and on 16 December 2021 he agreed to give provisional consent to the Paediatric Vaccine. In his evidence in these proceedings, Mr James 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 five 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 five to 11 was supported by significant data regarding the safety of the vaccine for those aged 12 years and over.

[21] In agreeing to give provisional consent to the Paediatric Vaccine through his delegate Mr James, the Minister on 16 December 2021 imposed a number of conditions pursuant to s 23(3) of the Act. The effect of the Minister's decision is that the Paediatric Vaccine could lawfully be supplied in New Zealand. Part of those conditions imposed included that Pfizer was to provide Medsafe with a range of further information when it became available, including final reports from Pfizer's clinical study of five to 11-year-olds and periodic safety reports.

[22] In his evidence, Mr James has also deposed that his decision recommending Provisional Consent to the Paediatric Vaccine was based solely on an assessment of the therapeutic benefits and risks of the vaccine to five to 11-year-olds. Any potential benefits to vulnerable adults from the vaccination of children, he stated, played no part in that decision. His evidence on that point appears to be supported by a number of relevant documents before the Court, which do not refer to those other matters as a consideration at all.

[23] On 16 December 2021 the provisional consent for the Paediatric Vaccine was publicly announced and gazetted.[4]

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[4] On 17 December 2021, the *Gazette* notice was amended to correct an error in the conditions attached to the Provisional Consent.

Cabinet's Roll-Out decision

[24] In parallel with Medsafe's consideration of Pfizer's application for provisional consent, separate consideration of the safety and efficacy of the Paediatric Vaccine was being undertaken by another expert group, established by the Government to provide expert science advice to inform decision-making about the CVIP. This expert group, known as the COVID-19 Vaccine Technical Advisory Group (CV-TAG), is a group of external medical experts chaired by the Chief Science Adviser of the Ministry of Health (the Ministry), Dr Ian Town. The membership of CV-TAG, it appears, does not overlap with the membership of the MAAC.

[25] The consideration by CV-TAG of the safety and efficacy of the Paediatric Vaccine was being undertaken in order for Oranga Tamariki to advise the Director-General of Health on the possible inclusion of the Paediatric Vaccine in the general public immunisation programme roll-out.

[26] On 15 December 2021, CV-TAG made its recommendation to the Director-General of Health. This was a recommendation that, subject to Medsafe approval, two doses of the Paediatric Vaccine should be offered to all five to 11-year-olds in New Zealand with an eight-week interval between doses, and it should be free of charge. The Director-General, Dr Ashley Bloomfield, in his evidence confirmed that he accepted and agreed with the CV-TAG recommendations. In addition, it seems the Ministry of Health also undertook a Wellbeing Impact Assessment (WIA) to assess the impacts of COVID-19 immunisation on children aged five to 11 years. As the evidence of Dr Bloomfield confirms, this included an analysis of the relevant rights in the United Nations Convention on the Rights of the Child (UNCRC).[5]

[27] On 20 December 2021, Cabinet made the Roll-Out decision, which was a decision to use the Paediatric Vaccine for immunisation of children aged five to 11 years. The recommendation that went to Cabinet at the time was based, as Dr Bloomfield confirms in his evidence, on the CV-TAG advice and the Wellbeing

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5 United Nations Convention on the Rights of the Child 1577 UNTS 3 (opened for signature 20 November 1989, entered into force 2 September 1990).

Impact Assessment, as well as obligations under Te Tiriti o Waitangi | the Treaty of Waitangi and World Health Organisation guidance. The roll-out of the Paediatric Vaccine then started, as I have noted, on 17 January 2022.

[28] As Dr Bloomfield confirms in his evidence, the New Zealand Government had earlier, in late October 2021, secured an option to purchase Paediatric Vaccine from Pfizer, conditional on Medsafe approval. Given high global demand at the time for COVID-19 vaccines and the general constraints on supply, the Crown says it would have been wholly impractical to wait until after the Provisional Consent and Roll-Out decisions had been made before entering into commercial negotiations with Pfizer. However, the Crown confirms it made no contractual commitment to purchase Paediatric Vaccine until 21 December 2021, as Dr Bloomfield notes in his evidence. This was after the provisional consent had been given and after Cabinet's Roll-Out decision.

The Interim Relief Decision

[29] As I have noted above, on 14 January 2022 the applicants filed an application in this proceeding seeking interim orders to stop the roll-out of the Paediatric Vaccine. This was the subject of an urgent hearing on 27 January 2022, and a decision of Ellis J in this Court of 1 February 2022 which declined the application for interim orders.

[30] Essentially, Ellis J declined this interim orders application for three reasons:

(a) First, insofar as the applicants had a qualifying right or interest to protect (which Ellis J said was doubtful, given that vaccination was not mandatory), she found it was not threatened by the provisional consent. There were no plans to exclude children from educational services based on vaccination status.

(b) Secondly, Ellis J deemed the merits of the substantive case to be weak. Despite the existence of some views to the contrary, she found the respondents' evidence indicated that, in granting the consent, the Minister of Health applied the correct statutory test and made an

informed and reasonable assessment that the Paediatric Vaccine's therapeutic value outweighed its risks.

(c) Thirdly, Ellis J saw the adverse repercussions (both public and private) of halting the roll-out as very significant, which also counted strongly against interim relief. These included harm to the considerable number of New Zealanders who wished to vaccinate their children, the potential loss of up to half a million Paediatric Vaccine doses, and damage to public confidence in the Paediatric Vaccine (especially among vulnerable communities).

Medicines Act 1981

[31] As the relevant statutory scheme to be considered here, the Act regulates the approval, classification, manufacture, distribution, advertising and prescribing of medicines in New Zealand. Ellis J helpfully summarised the scheme of the Act, as it relates to provisional consent decisions, in her decision on the interim orders application as follows:[6]

> [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".[7] The term "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".[8] 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—
>
> (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

6 The Interim Relief Decision, above n 1.
7 Medicines Act 1981, s 3(1)(a)(i).
8 Section 4(a).

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
>
> (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).[9] Accordingly, it is Mr James who granted the provisional consent now at 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.[10] 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-focussed 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 s 21 of this Act, and such other matters as appear to him to be relevant; and
>
> (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.[11]

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

10 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 offences provision.

11 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."

[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 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:[12]

> 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).

Challenge to the Provisional Consent decision

[32] The applicants seek to review the Provisional Consent decision on four basic grounds.

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[12] Subsection (1) was amended following this Court's decision in *Nga Kaitiaki Tuku Iho Medical Action Society Inc v Minister of Health*, above n 2.

First ground of review: illegality – error of law in the benefit/risk assessment

[33] This first ground of review advanced by the applicant is that the Provisional Consent decision was ultra vires, essentially because likely therapeutic benefits of the Paediatric Vaccine do not outweigh the risks to children aged five to 11. It seems the applicants take no issue with the delegation of decision-making authority that occurred. Instead, they emphasise what is at issue in this case is whether that delegated power has been exercised lawfully, appropriately, and in accordance with the terms of s 23 of the Act.

[34] Section 23 relevantly provides:

> **23 Minister may give provisional consent**
>
> (1) Notwithstanding sections 20 to 22, the Minister may, by notice, 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.
>
> (2) An application for the Minister's provisional consent under this section shall—
>
> (a) be made in accordance with paragraphs (b) and (ca) of section 21(1):
>
> (b) be addressed to the Director-General:
>
> (c) state, or be accompanied by a statement of, the particulars specified in paragraphs (a) to (h) of section 21(2):
>
> (d) be determined by the Minister in accordance with section 22.
>
> (3) On giving his provisional consent under this section, the Minister may impose—
>
> (a) such conditions relating to the persons to whom the medicine may be sold or supplied; or
>
> (b) such conditions relating to the area in which the medicine may be distributed; or
>
> (c) such other conditions, not being inconsistent with the purposes of this section,—
>
> as he thinks fit.
>
> …

[35] Section 22(1)(b) of the Act requires the Minister (or his delegate, as is the case here) to weigh, as far as practicable, 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. The Minister's delegate, Mr James, in his evidence confirmed what he described as the robust and thorough evaluation of the benefits and risks of the Paediatric Vaccine for five to 11-year-olds that was undertaken here.

[36] In his affidavit of 21 January 2022 filed in this proceeding, Mr James deposes in part:

> 58. In making my decision, I weighed the likely therapeutic value of the paediatric vaccine for use in 5 – 11 year olds against the risk of the paediatric vaccine injuriously affecting the health of those aged 5 – 11 years. In my view it was desirable for the paediatric vaccine to be sold, supplied, or used in New Zealand.
>
> ….
>
> 60. The key reasons why I considered that the therapeutic value of the paediatric vaccine outweighed the risks for 5 – 11 year olds were:
>
> 60.1 Although children infected with SARS-CoV-2 are less likely to develop severe illness or die compared with adults, there is morbidity and mortality in children, and children are still at risk of developing severe illness and complications from COVID-19. At the time of my decision, the Delta variant was present in the community and there was no vaccine or medicine for children aged 5 – 11 years old.
>
> 60.2 The clinical data in relation to children aged 5 – 11 years old demonstrated that the vaccine had high levels of efficacy in preventing symptomatic COVID-19 infection in that age group.
>
> 60.3 The clinical data in relation to children aged 5 – 11 years old also demonstrated that the vaccine was well tolerated in that age group and there were no new safety concerns.
>
> 60.4 The clinical data supporting safety and efficacy of Comirnaty in 5 – 11 year olds was supported by the very significant volume of data and information supporting the safety and efficacy of the parent product in individuals aged 12 and over. I understand that the parent product has been administered to approximately 1 billion people around the world. It has been subject to intense scrutiny from regulators, scientists and academics around the world, including in New Zealand. The clinical data for 5 – 11 year olds did not suggest there were any additional or different safety concerns in that age group as compared with the older populations.

> 61. The conditions imposed on the provisional consent require Pfizer to provide Medsafe with a range of information, including final clinical study reports from Pfizer's clinical study in 5 – 11 year olds, and periodic safety update reports for the paediatric vaccine. This information will enable Medsafe to continue monitoring the safety and efficacy of the paediatric vaccine. However, the fact that conditions have been imposed requiring information to be provided in the future does not mean that I am not currently satisfied by the benefit risk assessment. It is not uncommon for Medsafe to consider and to grant provisional or full approval before all clinical trials have been completed. The key considerations are whether there is a therapeutic need for supply of the medicine to New Zealand, the therapeutic value of the medicine, and what risks are present, on the basis of the safety and efficacy data available. I am confident that the benefit risk assessment based on current information supports provisional consent in New Zealand, but of course I want to ensure that Medsafe continues to receive ongoing information from Pfizer about this medicine.

[37] Prior to making his final decision, Mr James made a choice to refer this matter to the MAAC for its recommendation. In making this referral, Mr James emphasised in his affidavit:

> 51. I was reasonably comfortable at that stage that the benefit risk assessment favoured a provisional consent of the medicine with conditions on Pfizer that would need to be met in a specified period of time. Nevertheless, in my view, it was appropriate for me to refer the application to MAAC for their independent expert review and recommendation. This was essentially for the reasons given in Medsafe's report to me, i.e. the pace of development, the limitations on the data set, the clinical need, and the high public interest in the decision. I also thought that a review and recommendation by MAAC would help to enhance public confidence in whatever decision was made.

[38] As to the decision made, the applicants raise concerns that they say suggest this decision by Mr James must mean in terms of s 22(2) of the Act that he was not satisfied that he should give his consent to the distribution of the medicine and thus he made the clear choice to refer it to MAAC, in the words of the applicants, for "MAAC's recommendation as to the decision that the Minister should make." The applicants go on to argue that Mr James therefore must have come to an initial decision to refuse consent and it was only after the recommendation from MAAC was received that this decision was changed. In my view, however, this argument simply goes too far and is not supported by the evidence before the Court and in particular Mr James' explanation outlined above.

[39] As I see the position, Mr James, despite in his words being "reasonably comfortable … that the benefit risk assessment favoured a provisional consent" properly took a cautionary approach here, and made the decision to seek a further recommendation from MAAC. This might well be seen as simply, in terms of s 22(1)(a) of the Act, comprising either a decision to seek further information on "such other matters as appear to him to be relevant" or alternatively a referral made broadly under s 22(2) of the Act. In either event, in my view this course of action was entirely open to Mr James given what can only be regarded as the careful and cautious approach he decided to take to the question he faced. In terms of the process arguments the applicants have endeavoured to raise on this aspect, they are rejected. I am satisfied that it is clear from Mr James' evidence that his exercise in referring this matter to MAAC was one that was properly done.

[40] Section 23 empowered Mr James here, as the Minister's delegate, to grant a provisional consent "if he is of the opinion that it is desirable that the medicine be sold, supplied, or used." From all the evidence before me, it is clear that Mr James, having performed the weighing exercise required by s 22, and after seeking and considering the recommendation of MAAC, formed the opinion that it was desirable for the Paediatric Vaccine to be given provisional consent.

[41] I turn now to a major plank of the applicants' challenge here which related to evidence said to be directed at the weighing of the benefits and risks of the Paediatric Vaccine and the desirability of it being available in New Zealand. A considerable volume of affidavit evidence from people the applicants contend are experts in this area was placed before me with responses in reply from a range of other individuals the respondents regarded as experts. What the applicants describe as their expert evidence here they maintain raises concerns about the benefits and risks of the Paediatric Vaccine, and in doing so they contend this challenges the merits of the Minister's approval decision. Indeed, Ellis J in her decision on the interim application noted that the alleged illegality advanced by the applicants:[13]

> … 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.

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13 The Interim Relief Decision, above n 1, at [57].

[42] On this aspect, I need to say at the outset that, as I see the position, it is not the role of this Court on judicial review to decide which experts are right, nor to form its own opinion on the desirability of the Paediatric Vaccine being supplied in New Zealand.

[43] For example, in *GF v Minister for COVID-19 Response*, Churchman J in judicial review proceedings stated:[14]

> [86] Therefore, a conclusion under this limb needs to take into account the level of latitude to be afforded to public policy decision-makers, particularly in matters of science. The evidence of Dr Bloomfield establishes the scientific support for the efficacy of vaccinations in reducing the spread and harm of COVID-19. It supports an inference that they are significantly more useful in achieving the objective than alternative measures.

[44] Churchman J went on to state:

> [107] The Minister concluded that the best way for the Crown to discharge its obligations to Māori was to pursue the elimination strategy of which the Vaccinations Order was an important component. The policy choice, informed as it was by specialist medical advice, is one that will not lightly be interfered with in judicial review proceedings. On the basis of the evidence of Mr Hipkins and Dr Bloomfield referred to above, the decision was a logically rational one.

[45] Ellis J also noted in her decision at the interim stage in this proceeding:[15]

> … 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.[16] A merits-based challenge will, in effect, only succeed if the impugned decision is demonstrably irrational.

[46] Similarly, in *Te Pou Matakana Ltd v Attorney-General*, this Court held:[17]

> [172] This is an application for a judicial review; it is not an appeal. The High Court in judicial review does not second-guess the substantive merits of the decision under review; "judicial review, as the words

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14 *GF v Minister for COVID-19 Response* [2021] NZHC 2526, [2022] 2 NZLR 1.

15 The Interim Relief Decision, above n 1, at [57].

16 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* HC Te Whanganui-a-Tara | Wellington CP99/94, 4 October 1994 at 42.

17 *Te Pou Matakana Ltd v Attorney-General* [2021] NZHC 3319.

> imply, is not an appeal from the decision, but a review of the manner in which the decision was made."[18]
>
> …
>
> [174] … As a general rule, judicial review is not a procedure which allows the Court to substitute its own judgment for that of the decision-maker, although in exceptional circumstances the courts have been prepared to substitute their decision for the decision under review where there was only one lawful decision available.[19]

[47] Also in this court, in a decision relating to a judicial review challenge to the approval of the COVID-19 adult vaccine, the Court said:[20]

> … the signal point is that the Court cannot possibly engage with those concerns [including safety and efficacy of the vaccine] in the present context. 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.

[48] By way of an aside, it is useful to note that while there is a right of appeal from a decision of the Minister to refuse consent to a vaccine in a case such as the present under s 89 of the Act, there is no right of appeal from a decision to give such consent. As to this aspect, however, the Court of Appeal has held that while an appeal under s 89 does extend to some consideration of the merits, this is limited by the word "unreasonable" in that section, and a full de novo hearing is not contemplated.[21] With all these matters in mind, I conclude here that generally the weighing of the benefits and risks of the Paediatric Vaccine, and the desirability of the vaccine being available in New Zealand, are matters for Mr James as the Minister's delegate under the Act. It is clear, too, as I see it from his evidence, that Mr James did properly apply the relevant statutory test and then he made an assessment, based on all the expert evidence before him, that the therapeutic value of the Paediatric Vaccine here outweighed the risk of any injurious effect. Indeed, in her decision on the interim application, Ellis J concluded that this was "clear beyond doubt".[22] I am satisfied too that the safety and

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18 *Chief Constable of the North Wales Police v Evans* [1982] 1 WLR 1155, [1982] 3 All ER 141 at 155 (HL).

19 See, for example, the dissent of Elias CJ in *Helu v Immigration and Protection Tribunal* [2015] NZSC 298, [2016] 1 NZLR 298 at [105].

20 *Nga Kaitiaki Tuku Iho Medical Action Society Incorporated v Minister of Health*, above n 2, at [73].

21 *Minister of Health v Upjohn Inter-American Corporation* CA69/92, 29 April 1992.

22 The Interim Relief Decision, above n 1, at [58].

efficacy of the Paediatric Vaccine here was closely scrutinised by both Medsafe and MAAC, as an independent expert committee, before Mr James made his decision.

[49] As one of their complaints, the applicants have suggested the Provisional Consent decision was flawed because Mr James as the Minister's delegate did not personally review all of the material submitted by Pfizer (which I am told amounted to thousands of pages) but rather relied on evaluation reports prepared by expert Medsafe staff. I reject this complaint.

[50] It is well-accepted that decision-makers can rely on reports from officials, which is in reality a practical part of public decision-making.[23] Clearly, that must be the case, especially in the context of the Act, where significant expertise is required to understand the complex material submitted. Even in a case such as the present, where decision-making is delegated to a person with expertise, different aspects of any application will require experts to be available in different fields. Practically, it would be an impossible task for any one person to have complete expertise in all matters. Parliament, too, could not have intended that a Minister of the Crown would personally review and assess raw scientific data submitted by the developers of complex pharmaceutical products, and particularly in a case such as this where thousands of pages of material have been provided. If Mr James, as the Minister's delegate, was personally required to read all the data submitted in support of an application, the Crown maintains the present medicines regulation in New Zealand would simply grind to a halt, and I agree.

[51] Neither, in my view, does the fact that a decision-maker relied on a report from an official require that official to provide affidavit evidence to the Court. Indeed, even a decision-maker themself is not necessarily required to give affidavit evidence in judicial review proceedings.[24] The conduct of staff employed by Medsafe is not under review here and I am satisfied in any event their views are contained in the reports that have been provided in evidence to the Court.

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23 *New Zealand Steel Ltd v Minister of Commerce and Consumer Affairs* [2021] NZHC 966 at [63].
24 *Inder v Commissioner of Crown Lands* (2010) 22 PRNZ 78 (HC) at [30].

[52] Moreover, on this question of evidence before the Court, Ellis J in her decision at the interim stage in this proceeding reached the conclusion that it was clear there was "a wealth of legitimate scientific opinion supporting the conclusions reached by the [Minister's delegate]."[25]

[53] Her Honour further held that, notwithstanding sincerely held views to the contrary, there appeared to have been:[26]

> … ample, cogent, information that supported the decision to approve the paediatric vaccine. Given the high threshold … 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.

[54] I am also satisfied that the approval decision of Mr James as the Minister's delegate was within the range of what a reasonable decision-maker could decide. I am strengthened in this view by the fact, too, that earlier, all pharmaceutical regulators from Australia, United Kingdom, United States, Europe, Singapore and Canada reached the same conclusion on all the expert evidence before them to approve the Paediatric Vaccine in their jurisdictions as they did.

[55] Overall, I am satisfied that Mr James' decision is one which is well-supported by the Crown expert and other evidence provided to the Court. Nevertheless, for completeness, I will add several comments concerning one or two key points of the considerable evidence the applicants in particular have endeavoured to put before the Court here.

A. Was there a need for urgency for approval of the Paediatric Vaccine?

[56] The applicants contend that in all the circumstances that existed in December 2021, there was no urgent need for a COVID-19 vaccine for five to 11-year-olds. The respondents disagree and I accept this position. At that time in 2021, as the case remains now, New Zealand was in the middle of a global COVID-19 pandemic that worldwide has killed millions of people. There is no argument that COVID-19 is a highly contagious disease. While all the experts appear to agree it is normally mild

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25 The Interim Relief Decision, above n 1, at [59]
26 At [63].

for children, it can lead to severe illness and, in rare instances, death. There can be little question that access to safe and effective COVID-19 vaccines is a critical aspect of New Zealand's pandemic response. The risks of an individual contracting severe COVID-19, it seems, are significantly higher for children with pre-existing conditions and health issues such as obesity, as well as for Māori and Pacific Island children and children with disabilities. At the time provisional consent was given, two things were clear. First, New Zealand (and particularly Auckland, with a large Māori and Pacific population) was in the middle of a community outbreak of the Delta variant and, second, no other COVID-19 vaccine was available for five to 11-year-olds in New Zealand, nor was there any approved COVID-19 treatment for that age group. The need for urgency, in my view, was properly identified here.

[57] The answer to this question posed as "A" above in my view is yes.

B. Is it the case that vaccination is not warranted because COVID-19 is a very mild illness for children?

[58] On this aspect the respondents agree that disease severity in healthy children is generally mild, that severe COVID-19 itself is rare in healthy children, and that there is a very low risk of death. It is true, however, that children are still at risk of developing serious illness and complications, the risk of severe disease is not negligible, and children have died from COVID-19. That risk is much higher for groups of vulnerable children, as I identify above. Additionally, as far as the Omicron variant is concerned, although hospitalisation and death rates may be lower, the total numbers of severe outcomes for children and especially those with pre-existing health conditions are high due to transmissibility. Recently, as I understand it, a Hong Kong study of children aged 11 and under concluded that the intrinsic severity of the Omicron variant is not mild. New Zealand, for a variety of reasons, has a significant number of vulnerable and at-risk children exhibiting growing health risks.

[59] The answer to this question posed as "B" above in my view is no.

C. Can the efficacy of the Paediatric Vaccine be properly disputed?

[60] The applicants endeavour here to dispute the efficacy of the Paediatric Vaccine. They assert firstly, that it has been overstated, secondly that the effect wanes over time, thirdly that it is not effective against new variants, and fourthly that it does not prevent transmission. At the time of Mr James' consideration here, the information available to him demonstrated a high degree of efficacy against symptomatic infection (90.7 per cent) and a similar immune response to that achieved for older adolescents and young adults. It seems this was supported by substantial real-world data about the Parent Product establishing its efficacy, particularly against severe disease. And in any event the conclusion from emerging international data was that the Paediatric Vaccine was 68 per cent effective in preventing hospitalisation of children aged five to 11 following infection with Omicron, suggesting a real level of efficacy against the new Omicron variant.

[61] The answer to this question posed as "C" above in my view is no.

D. Is the safety level of the Paediatric Vaccine adequate?

[62] The applicants in their submissions raise numerous concerns regarding the safety of the Paediatric Vaccine, pointing to what they contend are adverse event reports following vaccination. They say that particular safety concerns arise relating to the risk of myocarditis and the risk of vaccine-associated enhanced disease. They also point to the fact that mRNA vaccines are a new technology, and they allege that trials to date have been inadequate to establish safety. In response, the respondents note the general COVID-19 Pfizer vaccine has been highly scrutinised by regulators and expert bodies around the world for the past 18 months and it has a good safety profile. It appears that the only known potential adverse effects (other than anaphylaxis, which is a risk with all medicines) is myocarditis/pericarditis. Further, from the evidence before the Court, the rate of vaccine-induced myocarditis across all age groups appears to be very low, being about 30 per million in New Zealand. That risk, too, is substantially lower for children.

[63] Importantly, as I understand the position, numerous studies exist showing the risk of myocarditis is substantially lower following vaccination than following

infection with COVID-19. The risk of myocarditis for five to 11-year-olds here, according to the respondents, was carefully considered prior to decisions being made about the Paediatric Vaccine. I accept this was the case, and further that as to other safety concerns raised by the applicants there is no real-world evidence that exists to demonstrate these are actual risks of the vaccine here. All parties before me accepted that medicines are expected to have some risk of adverse events. It is also a fact that regulators from comparable jurisdictions, which I have outlined at [54] above, have concluded that the benefits of the Paediatric Vaccine outweigh the risks.

[64] Lastly, and at a general level, I note that the Parent Product has been accepted in other High Court proceedings as being effective firstly, at reducing symptomatic infection,[27] and secondly, to significantly improve the prospects of avoiding serious illness and health, even against the Omicron variant.[28] This includes certain proceedings that have been argued under the New Zealand Bill of Rights Act 1990, where there is no deference to the decision-maker and in which evidence has been given by some of the same experts the applicants have put forward in the present case. This Court has also rejected claims that the Parent Product is experimental,[29] or that the absence of longer-term safety data was a cause for concern.[30]

[65] The answer to this question posed as "D" above in my view is yes.

[66] For all the reasons I have outlined above, I dismiss this first ground of review advanced by the applicants that there has been an error of law made here in the benefit/risk assessment.

Second ground of review: illegality – relevant/irrelevant considerations

[67] The applicants' second ground of review alleges illegality in terms of either irrelevant matters being taken into account or relevant matters not. The relevant considerations the applicants say were not taken into account in particular included the bests interests of children and that any benefit/risk profile here should have been

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27 *Four Aviation Security Service Employees v Minister for Covid-19 Response* [2021] NZHC 3012.
28 *Yardley v Minister for Workplace Relations and Safety* [2022] NZHC 291.
29 n.27 at [35] – [36] and [143].
30 *NZDSOS v Minister for COVID-19 Response* [2022] NZHC 716 at [115] and [160].

assessed on an age-specific basis. The alleged irrelevant considerations relate in particular to the applicants' complaint that the Crown's real argument here is that children should be vaccinated simply to reduce transmission and to protect older adults. On these aspects the Crown's response is that the applicants' claims under this second ground of review are not supported by any factual basis whatever. The evidence from Mr James here, in particular at [58]–[60] of his affidavit, is clear that his decision to give provisional consent to the Paediatric Vaccine was based on his assessment of the therapeutic value and the risks for five to 11-year-olds themselves. He makes clear that his decision to give provisional consent was not in any way based on any perceived benefits to older adults or the wider community. In my view, this is also made clear from Medsafe's evaluation reports before the Court which were annexed to Mr James' affidavit.

[68] As Ellis J also confirmed in her decision in the interim application:

> [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.

[69] Related to this, the applicants in their submissions also claim that Mr James ought to have considered art 3 of the UNCRC, which provides:

> In all actions concerning children, whether undertaken by public or private social welfare institutions, courts of law, administrative authorities or legislative bodies, the best interests of the child shall be a primary consideration.

[70] As I see the position from the evidence, it is apparent Mr James gave effect to this right, his decision being based on an assessment of the benefits and risks for five to 11-year-olds. That Mr James in his decision may not have referred explicitly to the UNCRC makes no difference here. Given that Mr James was obliged to consider the international human rights obligations under the UNCRC, it was sufficient that in substance his decision approving the Paediatric Vaccine considered the interests of children aged five to 11.[31]

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[31] See *Hai v Minister of Immigration* [2019] NZAR 1867 (CA) at [34].

[71] A further assertion from the applicants here is that a higher standard of safety was required for the Paediatric Vaccine because children aged five to 11 are too young to give their own informed consent. They say the Minister here was required to take this into account and failed to do so.

[72] I reject this claim. There is nothing in ss 20–23, nor in the wider scheme of the Act, to support the argument that different or higher standards are required where a medicine is being approved for use for children. The Minister is required to weigh the likely therapeutic value against the risk (if any) of the new medicine throughout. It is true that all New Zealanders, including adults, rely on Medsafe and the Minister to ensure that medicines are only sold in New Zealand if they meet acceptable standards for safety, efficacy and quality. If the Minister is satisfied the benefits of the medicine for children outweigh the risks for children (as was the case here), there is no basis to decline consent.

[73] Indeed, as I see the position, the effect of the applicants' argument, if it was to be accepted, would simply be to make it more difficult, if not impossible, for children (as compared with adults) to access the benefit of medical intervention given the present pandemic. There can be no question that would limit the rights of children considerably and in my view it would not be in their best interests. In any event, if the applicants are to succeed here and continuing administration of the Paediatric Vaccine is halted, this would prevent the very many parents who would choose to opt to have their children vaccinated from being able to do so. For high-risk children in particular, of which there are many in New Zealand, this could prove to be disastrous.

[74] For all these reasons, I dismiss this second ground of review.

Third ground of review: illegality – improper purpose

[75] Under this ground of review, the applicants plead that, so far as decision-making here is concerned, "the welfare and best interests of the children should have been the first, paramount and only consideration." The wording in art. 3 of the UNCRC, as I note at [69] above, however is different. That wording now refers

to the "best interests of the child" as "a primary consideration."[32] It might be accepted that it should be a "first" or "dominant" consideration, given the meaning of "primary", but in my view it certainly should not be seen as the "only" consideration.

[76] The third ground of review, however, alleges that the Minister, through his delegate Mr James, made the Provisional Consent decision "for an improper purpose". It is alleged the provisional consent was given in order to prevent transmission to older adults and to help protect vulnerable whānau members, and that the interests of the children aged five to 11 years were not considered as paramount here.

[77] In her interim relief judgment, Ellis J noted that this ground of review added little to the second ground.[33] As with that second ground of review, the Crown's simple position is that there is nothing in the evidence to support the applicant's contention. The legal test for improper purpose is simply whether the Minister has used the power in this case in s 23 of the Act for a purpose that is not authorised by that Act.[34]

[78] In my view too, this third ground of review is quickly disposed of. It is clear from all the evidence before the Court that Mr James as the Minister's delegate made his decision based on a genuine assessment of the interests of five to 11-year-olds alone. On the evidence before the Court, and as I have noted above, it is clear the decision was not made for the purpose of preventing transmission or protecting older adults.

[79] This third ground of review is also dismissed.

Fourth ground of review: pre-determination

[80] Under this ground of review the applicants allege that Mr James' decision to grant provisional consent was pre-determined due to a prior contractual arrangement between the Crown and Pfizer, which the applicants say would have involved the Crown losing advance payments made to Pfizer. The applicants contend also that Mr

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32 Originally, the word used in an earlier draft of art. 3 was actually "predominant" but (with the assistance of New Zealand negotiators as I understand it) that was removed and replaced with "primary" before it was finalised.

33 The Interim Relief Decision, above n 1, at [4].

34 *Unison Networks Ltd v Commerce Commission* [2007] NZSC 74, [2008] 1 NZLR 42.

James' decision to give provisional consent was pre-determined because it was made in order to further the political will of the Government from mid-2020 to have most of this country's population vaccinated. Therefore, they say the decision was entirely driven by a desire to further the Government's political objectives and immunisation strategy. The applicants claim the circumstances of the approval and the process itself, including its speed, all speak to this claim of pre-determination.

[81] Before me, the Crown emphatically rejected these allegations.

[82] The legal test for pre-determination is the "closed mind" test — that is, whether the mind of the decision-maker was "not open to persuasion" and whether the decision-maker "simply went through the motions" in addressing the statutory criteria for making the decision.[35] What may amount to pre-determination clearly varies. Whether there is pre-determination is a factual question to be established on the evidence and in light of the particular legislative setting.[36]

[83] The threshold for establishing pre-determination is a high one.[37] The relevant question to be asked is whether, at the time the decision was made, the decision-maker genuinely addressed themselves to the statutory criteria. Evidence that a decision-maker may have done various things such as holding meetings to discuss issues, requesting further information and spending time reviewing documents is inconsistent with a closed mind and suggests that no pre-determination has occurred in a particular case where these have occurred.[38]

[84] In the present case, in my view it is plain from all the evidence and the contemporaneous records before the Court that Mr James' decision was not a pre-determined one. To the contrary, I am satisfied Medsafe in this case has conducted a detailed and robust evaluation of Pfizer's application for provisional consent. It involved a consideration and analysis of extensive material. In addition, from the evidence it is clear Medsafe attended meetings with Pfizer, it made a number of

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35 *CREEDNZ v Governor-General* [1982] 2 NZLR 172 (CA), a decision endorsed in various cases, including *New Zealand Fishing Industry Association Inc v Minister of Agriculture and Fisheries* [1988] 1 NZLR 544 (CA) and *Holland v Jonkers* [2021] NZHC 3469.

36 *Travis Holdings Ltd v Christchurch City Council* [1993] 3 NZLR 32 (HC) at [47].

37 *Holland v Jonkers*, above n 35, at [297].

38 *Rangitira Developments Ltd v Sage* [2020] NZHC 1503 at [37]–[41].

requests for further information and it prepared detailed evaluation reports for consideration by Mr James.

[85] It is clear from his evidence that on 10 December 2021 Mr James considered giving provisional consent after reviewing Medsafe's evaluation reports. He did not, however, do so. Rather, he decided, as he was entitled to pursuant to s 22(2) of the Act or otherwise, that Pfizer's application was to be referred to the MAAC for a further expert recommendation. Mr James has explained in his evidence his careful and cautious approach here and his reasons for doing this.

[86] All these actions, in my view, contradict any suggestion that might be advanced that Mr James and Medsafe approached this application with closed minds or "simply went through the motions".

[87] In his evidence, Mr James completely rejects any allegations of pre-determination and says further: [39]

> 137. I completely reject this allegation [of pre-determination]. If anything, my experience has been the opposite. I have met with the Director-General of Health many times over the course of the pandemic regarding COVID-19 vaccines. I have also joined meetings with Ministers on occasion. From my perspective, the Director-General and Ministers have shown a very clear desire to ensure that Medsafe had the space to make its own robust assessment of COVID-19 vaccines, independently of other decisions.
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> 138. My decision under s 23 was based on my assessment of the benefits and risks of the Paediatric Vaccine for 5 to 11 year olds in New Zealand. The Medsafe team and I have been acutely aware throughout the COVID-19 pandemic that New Zealanders (and other decision-makers within government) are relying on us to carefully consider and evaluate applications for COVID-19 vaccines and medicines. I take the responsibility very seriously, as does the rest of the Medsafe team.

[88] It is plain in this case, as I see it, that both Medsafe and Mr James considered the provisional consent application on its merits and approached their assessment with care and with an open mind. There is nothing before the Court to support the applicants' allegation of pre-determination.

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[39] Second affidavit of Mr James, dated 10 June 2022.

[89] Lastly, and for completeness, I need to add that it seems the applicants are factually mistaken about the nature of contractual arrangements with Pfizer that existed prior to 16 December 2021. Those contractual arrangements are set out in evidence before me provided by the Crown. I address them in more detail below at [114]–[121].

[90] I conclude that no proper grounds exist for the applicants to make the pre-determination allegation here. This fourth ground of review is also dismissed.

Conclusion on Provisional Consent decision challenge

[91] As will now be apparent, for all the reasons outlined above the challenge by the applicants to the Minister's decision to give provisional consent to the Paediatric Vaccine fails. It is dismissed.

[92] I now turn to the second challenge advanced by the applicants.

Challenge to Cabinet's Roll-Out decision

[93] Whereas the Minister's role here was to make a decision under the Act about whether or not to give provisional consent to the Paediatric Vaccine (thus giving Pfizer legal approval to supply the vaccine in New Zealand), it was for other Government decision-makers (in this case Cabinet) to decide whether or not to make the Paediatric Vaccine available to all children as part of its general immunisation programme. As I have noted above, Cabinet made the decision to do so on 20 December 2021, as a result of which the Paediatric Vaccine became available nationwide to all children aged five to 11 free of charge from 17 January 2022.

[94] Two of the applicants' grounds of review, namely the third and fourth grounds, challenge Cabinet's Roll-Out decision. However, I first need to address a preliminary question as to whether in any event Cabinet's decision is reviewable here.

Justiciability?

[95] The authorities make clear that decisions of Cabinet are not always immune from review by this Court.[40] There must be some legal framework or yardstick by which the Court is able to assess the legality of Cabinet's decisions.[41] However, it is clear that before a Court will intervene, there needs to be a basis upon which decisions of this type can be identified as not being in accordance with the law.[42]

[96] Here the Crown says there is no sufficient legal framework or yardstick to enable this Court to assess whether the Roll-Out decision was made for an improper purpose or whether that decision was pre-determined. This is because the Roll-Out decision was a policy decision as to whether generally children aged five to 11 should be given free access to the Paediatric Vaccine through the Government's COVID-19 immunisation programme. The Crown maintained before me that Cabinet was not exercising a statutory power in making this decision, nor has its Roll-Out decision subsequently been given statutory force. Lastly, the Crown position is that Cabinet had no legal obligation to make a decision on whether COVID-19 vaccines, including the Paediatric Vaccine, should be included in its immunisation programme. It argues the criteria by which Cabinet chooses to include any COVID-19 vaccines in that programme is a matter entirely for Cabinet's discretion.

[97] As a result, it is the Crown's contention here that Cabinet's Roll-Out decision is not a matter which is properly suited to judicial review. I agree with this proposition and the Crown's arguments in support.

[98] This is sufficient to dismiss the applicant's challenges to Cabinet's Roll-Out decision, which I now do.

[99] For completeness, however, I will briefly consider the substance of the applicants' allegations here against the Roll-Out decision. These arguments are

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40 *McLellan v Attorney-General* [2015] NZHC 3218; *Pora v Attorney-General* [2017] NZHC 2081; and *Afghan Nationals v Minister of Immigrations* [2021] NZHC 3154.

41 *McLellan v Attorney-General*, above n 40, at [57].

42 *Afghan Nationals v Minister of Immigration*, above n 40, at [133].

outlined in the applicants' pleaded third and fourth grounds of review which I have noted earlier.

Improper purpose – (third) ground of review

[100] Under this ground of review, the applicants allege Cabinet's Roll-Out decision was made for an improper purpose — namely to prevent transmission of COVID-19 to adults and to protect vulnerable whanau members rather than for the best interests of children.

[101] Given the Roll-Out decision made by Cabinet here was a policy decision and not a statutory one, the Crown contends initially it is a virtually impossible task for the Court to undertake consideration of this improper purpose argument in relation to that decision. What does seem clear to me is that authority for Cabinet to make a decision such as the Roll-Out decision was not conferred on it by Parliament. Rather, being a policy decision, Cabinet ideally must have a discretion as to the matters it can take into account and the purposes for which it is making a decision such as this. The Crown says this is particularly important when Cabinet is making significant decisions about managing public health risk in the context of a global pandemic such as COVID-19, and I agree.

[102] In *Nga Kaitiaki Tuku Iho Medical Action Society Incorporated v Minister of Health*, this Court stated:[43]

> … the signal point is that the Court cannot possibly engage with those concerns [including safety and efficacy of the vaccine] in the present context. 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.

[103] In any event, the evidence before the Court is clear that the best interests of children aged five to 11 were central to Cabinet's Roll-Out decision in this case. It appears that advice given to Cabinet included in a paper that went to it seeking a decision to use the Paediatric Vaccine was informed by and reflected in particular:

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[43] *Nga Kaitiaki Tuku Iho Medical Action Society Incorporated v Minister of Health*, above n 2, at [73].

(a) Expert advice received from CV-TAG, an independent science advisory group established to provide expert advice to Government to inform decision-making about the CVIP. CV-TAG recommended that two doses of the Paediatric Vaccine should be offered to all five to 11-year-olds and that in particular Māori and Pacific children, children with high-risk pre-existing conditions, and children living with vulnerable people, should be prioritised for vaccination. This advice from CV-TAG appeared to be informed by detailed advice provided by the Ministry of Health's Science and Technical Advisory Group over several weeks of meetings prior to CV-TAG making its recommendation.

(b) The Wellbeing Impact Assessment, an assessment undertaken by the Ministry of Health to assess the impacts of COVID-19 immunisation on children aged five to 11. This Wellbeing Impact Assessment:

(i) acknowledged both the direct and indirect impacts of COVID-19 immunisation for five to 11-year-olds. Those wider impacts and benefits included the fact that immunisation minimised disruption to education, it minimised isolation, and it contributed to the overall wellbeing and development of children;

(ii) included an analysis of the relevant rights in the UNCRC and the impacts of including the Paediatric Vaccine in the CVIP. On this, the authors concluded the proposed roll-out of the Paediatric Vaccine appeared to enhance the rights of children; and

(iii) recommended that vaccine mandates not be used for children.

(c) An accompanying Cabinet paper, which recorded that Dr Bloomfield, the Director-General of Health, had accepted the CV-TAG advice and was recommending to Cabinet that the Paediatric Vaccine be included

> in the CVIP. Dr Bloomfield explained in his evidence his reasons for giving this recommendation. He said these were based on the interests of children in receiving COVID-19 vaccination as reflected in CV-TAG's advice, the Wellbeing Impact Assessment, and the fact provisional consent had been given to the vaccine.

[104] That Cabinet paper also recognised that, while children under 12 years are at lower risk than older groups from the direct health impacts of COVID-19, it could still have serious health consequences for some children (noting particularly that Māori and Pacific children, as the joint report to the Waitangi Tribunal before the Court noted, are at much higher risk of severe disease and hospitalisation due to COVID-19).

[105] Cabinet approved the roll-out in a minute noting the matters I have outlined immediately above. It recorded in particular Cabinet's agreement that "to promote children's wellbeing", high priority should be given to promoting COVID-19 immunisation uptake for Māori and children who are at higher risk of exposure to, and the impact of, COVID-19, including Pacific children, children with disabilities and health conditions, and children in the care of Oranga Tamariki.

[106] Plainly, from all this evidence, which I accept, Cabinet regarded the interests of children aged five to 11 as central to its Roll-Out decision.

[107] In any event, to the extent that Cabinet's decision here to roll out the Paediatric Vaccine might also have been made in part for wider community benefits, such as the potential to reduce transmission in large family groups and otherwise, as I see it this is not in any way improper. The Government's Chief Science Advisor, Dr Town, makes this clear in his affidavit. If Cabinet's Roll-Out decision might also benefit others in the community, this is clearly an added bonus. Even if one might view matters only in terms of the interests of children, in my view it is difficult to say that it is in the best interests of all children, including those whose whānau include vulnerable adults, for those adults to be put at risk, through COVID-19 infected family, of serious disease and death unnecessarily. For all these reasons, I reject this ground of review.

Pre-determination – (fourth) ground of review

[108] In their pleaded fourth ground of review, the applicants allege the Roll-Out decision was pre-determined because of the Government's vaccination strategy, political objectives and/or contractual arrangements with Pfizer.

[109] At the outset again, but in particular in relation to the Roll-Out decision (as I have also found with the Provisional Consent decision), I note that there is no proper factual basis advanced by the applicants for this allegation.

[110] Here, the Roll-Out decision by Cabinet was a decision to use the Paediatric Vaccine only made following the grant of provisional consent and following a specific recommendation to this effect from the Director-General of Health, informed by the expert advice I have noted above. Again, as a policy decision by Cabinet, it is difficult to see from a constitutional perspective how this could be said to be unlawful for being predetermined. There can be no question that Cabinet is entitled to determine policy matters and then to make subsequent decisions consistent with those determinations.

[111] As part of its response to the COVID-19 pandemic, it was and is entirely appropriate for the Government to have vaccination and immunisation strategies and policy. From all the evidence, the Government's strategy has clearly been to secure access to sufficient quantities of safe and effective COVID-19 vaccines in order to implement its programme at the earliest possible time. A key aspect of this has been to encourage the uptake of safe and free COVID-19 vaccines with the purpose of minimising the health, social, economic, and cultural harm of the COVID-19 pandemic.

[112] Just because these strategies existed, however, does not in any way support the applicants' suggestion that the Roll-Out decision was pre-determined or made for political objectives, or contrary to proper medical and scientific evidence. Rather, as Dr Bloomfield deposes:[44]

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[44] Second affidavit of Dr Bloomfield, dated 13 June 2022, at [63].

> … The whole point of the COVID-19 Immunisation Programme is to protect the health and well-being of New Zealanders. There is no prospect that I would have recommended that a vaccine be rolled out to children, if I did not consider that it was supported by the expert scientific and medical advice.

[113] Here, Cabinet's Roll-Out decision was not made until after Medsafe had assessed the benefits and risks with provisional consent then being granted, and following a recommendation from Dr Bloomfield as Director-General of Health. That recommendation, in turn, I accept clearly was informed by independent expert advice from CV-TAG and the Wellbeing Impact Assessment. On questions involving medical and scientific expertise, Cabinet is entitled to rely on the advice and recommendations of officials and experts, as occurred here. The pre-determination argument on these aspects I reject entirely.

[114] Another part of the applicants' pre-determination argument related to the Government's contractual arrangements with Pfizer. On this aspect, the applicants claim that, prior to 16 December 2021, the Government had already decided to purchase the Paediatric Vaccine, it had entered into a contract with Pfizer for this purchase, and the Government therefore would lose an advance payment if the provision of consent was not given.

[115] Ms Wevers, for the Crown, makes clear that the applicants here are mistaken regarding actual contractual arrangements that were in place with Pfizer at that time in late 2021. She notes from the evidence that the Crown had entered into a Manufacturing and Supply Agreement with Pfizer a year earlier on 22 December 2020. Pursuant to this, the Government agreed to purchase 1.5 million doses of the Parent Product. This was the umbrella agreement between the parties, and a number of amendment agreements have been entered into since that time between Pfizer and the Government.

[116] In the latter half of 2021, Government officials were understandably considering New Zealand's vaccine needs beyond 2021. They thought that New Zealand would continue to need an mRNA vaccine in 2022. This was specifically for those who did not access the vaccine in 2021, and in cases where there was extended eligibility (for example, if a paediatric vaccine was developed and approved), and also for booster doses if evidence showed this was required.

[117] On 22 October 2021, by a fourth amendment to the Manufacturing and Supply Agreement, the Government agreed to purchase approximately 4.7 million doses of product from Pfizer in 2022. A term of this contract was that if Pfizer successfully developed a paediatric vaccine later appropriately approved, the Government would have the option to request that a portion of the 4.7 million doses were to be the paediatric vaccine.

[118] The Government, however, was not committed to purchasing the paediatric vaccine. If it had not received provisional consent the Government would either have received 4.7 million doses of the Parent Product or 4.7 million doses made up of the Parent Product and some other form of "adapted product".

[119] In November 2021, and with the agreement of Ministers, officials started discussions with Pfizer about securing 1.25 million paediatric vaccine doses. These discussions, however, were expressly subject to Pfizer first obtaining Medsafe approval. The Ministry of Health also, it seems, started planning and preparation for the immunisation programme, in parallel with Medsafe's regulatory process. Evidence from Dr Bloomfield is that it was imperative to start making arrangements with Pfizer and planning for the potential roll-out of the Paediatric Vaccine as soon as possible. This was in order to ensure that, if provisional consent was given, and Cabinet decided to use the Paediatric Vaccine, the roll-out could occur with minimal delay. If officials had waited until after Medsafe had concluded its evaluation of the Paediatric Vaccine before beginning commercial discussions with Pfizer, the evidence is that New Zealand would have missed the chance to secure delivery for January 2022.

[120] All the evidence, including the evidence of Dr Bloomfield particularly, makes clear that the Crown did not make a contractual commitment to purchase the Paediatric Vaccine until the fifth amendment agreement was entered into on 21 December 2021. This was after both the Provisional Consent decision and Cabinet's Roll-Out decision currently impugned were made.

[121] In any event, I am satisfied that, as the Crown contends, if the Government had committed to purchase Paediatric Vaccine at a much earlier stage than it did, that

would not necessarily suggest pre-determination in the challenged decisions, given the circumstances the Government was facing at the time. I accept there is no prospect, as the evidence here confirms, that the Minister's delegate, Mr James, would have granted provisional consent because of a contractual arrangement, nor that Cabinet or its medical experts giving advice, would have supported the roll-out of a vaccine to children if that was not supported by proper expert advice received.

[122] For all these reasons, I reject this fourth pre-determination ground of review challenge to the Roll-Out decision.

Final matters

[123] For completeness, there are three other minor matters which involved general observations before me which need mention here.

(i) No vaccine mandate applicable to children

[124] In their claims before the Court, the applicants contend that the roll-out of the Paediatric Vaccine will have a quasi-mandatory effect and it is likely to lead to unvaccinated children being excluded from school and other activities. From the evidence before me, however, I am satisfied this is clearly not the case. Nothing approaching a mandate, it seems, has ever applied to children and the consistent position the Government appears to have adopted has been to ensure that children are not excluded from activities based on their vaccination status. There is nothing in this claim advanced by the applicants.

(ii) Documents and evidence

[125] The applicants here also criticise the respondents for what they say is their failure to disclose all of the material that relates to the Provisional Consent decision for the Paediatric Vaccine. The respondents, in turn, say they have disclosed their key decision-making documents and they reject any suggestion they have withheld material necessary for the applicants to mount their challenge or for this Court to determine the present proceedings.

[126] First, it is clear, as I see it, that key decision-making documents in this matter were disclosed to the applicant at the interim stage. The applicants, too, did not seek discovery at that point.

[127] However, it does appear that on 19 April 2022 counsel for the applicants wrote to counsel for the respondents seeking discovery of what amounted to a long list of documents. The respondents' position is that the list of documents sought was "absurdly broad". They say, too, such an amount of material would have been wholly disproportionate, even in a normal civil discovery exercise. As the respondents confirm, earlier timetable arrangements had been reached on the basis that no discovery was to take place. This was on the basis, it seems, that retaining an early hearing date was important to all parties, and any discovery exercise here would have needed early timetabling and a sufficient opportunity to gather the huge amount of material involved and to identify commercially sensitive matters.

[128] Here, as I have noted, the Crown says Pfizer's application for provisional consent for the Paediatric Vaccine involved thousands of pages of technical material, which was reviewed and assessed by Medsafe and analysed in its two detailed evaluation reports, which together totalled some 140 pages. These evaluation reports, the Crown notes, were prepared for the Minister's delegate, Mr James, and formed the focus of his assessment. They were included in evidence along with a considerable amount of additional material which the Crown maintains was entirely adequate here.

[129] At an early juncture in this proceeding, this Court had given an indication that the merits of both the Minister's decision to approve the Paediatric Vaccine and Cabinet's decision to approve its roll-out were not suitable for judicial review. It is noted, too, that generally there is no right to discovery in judicial review, although it is acknowledged there is always a duty of candour which flows from the activities of the Crown.

[130] Overall, however, I am satisfied the enormous amount of material which is before the Court in this proceeding, and which was disclosed to the applicants is more than sufficient for the purposes of the present application. No issue arises here relating to discovery.

(iii) Name suppression

[131] The last additional matter I refer to at [123] above relates to name suppression. At the conclusion of the interim relief hearing, Ellis J directed suppression of the applicants' names should continue until the hearing of the substantive application for review. At that time it could be the subject of further submissions. No submissions were made to me regarding name suppression at that substantive hearing, although it was suggested that, dependent on the outcome of the hearing, suppression could be the subject of additional submissions from counsel. A direction to that effect is to follow.

Result

[132] The application by the applicants for judicial review of both the Minister's decision approving the Paediatric Vaccine and the decision of Cabinet approving its roll-out fails. The application is dismissed.

Costs

[133] The respondents have been successful in opposing the judicial review application, and I see no reason why they should not be entitled to costs in the usual way. At the hearing of this matter, however, counsel did not address me on the issue of costs.

[134] There is, as I understand it, also an outstanding issue of costs on the interim orders application.

[135] The parties, it seems, agree that the question of costs on both the interim orders application and on this substantive hearing should be reserved and determined at the conclusion of the substantive proceeding.

[136] Costs, therefore, on both the interim application and on this substantive hearing are reserved. Counsel are urged to liaise with a view to endeavouring to settle those issues of costs between themselves.

[137] In the absence of agreement being reached, then within 30 working days of the date of this judgment, counsel may file (sequentially) memoranda on costs (in each case no more than five pages plus a schedule) which are to be referred to me and, in the absence of either party indicating they wish to be heard on the question of costs, I will decide that issue based on the memoranda filed and all other material then before the Court.

Suppression

[138] Leave is also reserved for counsel within the 30 working days' time frame mentioned in [137] above to file and serve submissions on name suppression.

[139] In the meantime, the earlier order suppressing the names and any identifying details of each of the applicants to this proceeding is to continue until further order of the Court.

Gendall J

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