IN THE HIGH COURT OF NEW ZEALAND
WELLINGTON REGISTRY

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

CIV-2021-485-181
[2021] NZHC 1107

IN THE MATTER	of an application under the Judicial Review Procedure Act 2016, the Medicines Act 1981, the Fair Trading Act 1986, the NZ Bill of Rights Act 1990 and the Health and Disabilities Commissioner Act 1994
BETWEEN	NGA KAITIAKI TUKU IHO MEDICAL ACTION SOCIETY INCORPORATED Plaintiff
AND	THE MINISTER OF HEALTH First Defendant
	THE DIRECTOR-GENERAL OF HEALTH Second Defendant
	CHRISTOPHER JAMES Third Defendant
	THE PRIME MINISTER OF NEW ZEALAND Fourth Defendant
	THE MINISTER FOR COVID-19 RESPONSE Fifth Defendant
	THE ATTORNEY-GENERAL Sixth Defendant
	PFIZER NEW ZEALAND LIMITED Seventh Defendant

Hearing: 12 May 2021

Counsel: W J Pyke and S J Grey for Plaintiff
J K Gorman, K F M Wevers and J M Irwin for First to Sixth Defendants
E B Moran for Seventh Defendant

Judgment: 18 May 2021

JUDGMENT OF ELLIS J

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[1] On 3 February 2021 provisional consent was given under s 23 of the Medicines Act 1981 (the Act) for the sale, supply or use of the Comirnaty COVID-19 vaccine, manufactured by Pfizer Manufacturing Belgium NV. Pfizer Manufacturing Belgium NV is represented in New Zealand by Pfizer New Zealand Limited (Pfizer).[1] The provisional consent is stated to last for a period of nine months.

[2] Pursuant to that consent, the Comirnaty vaccine is now being "rolled out" on a staggered basis across the country. Over the next few months it will be made available to all New Zealanders over the age of 16, in accordance with the manufacturer's indication.

[3] Nga Kaitiaki Tuku Iho Medical Action Society Incorporated (KTI) was incorporated in March this year. Its rules of incorporation state that its purposes include:

> To educate, empower and take all actions the Society deems appropriate by Committee, including the taking of legal action against individuals or organisations as well as promoting informed decision making and accountability in respect of wellbeing.

[4] In April, KTI filed judicial review proceedings aimed at preventing or halting the rollout of the Comirnaty vaccine. It challenges the legality of the s 23 provisional consent but also mounts a much broader attack on the safety and efficacy of the vaccine and, indeed, criticises the wider national and international response to COVID-19.

[5] Because the vaccine rollout had already begun when the review proceeding was filed, KTI also filed an application for interim orders. While the orders sought were almost as wide ranging as the relief sought in the substantive proceeding, it was

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1 "Provisional Consent to the Distribution of a New Medicine" (3 February 2021) *New Zealand Gazette* 2021-go338.

later agreed that a more focused approach would be required, if the application was to be heard and determined urgently, on an interim basis. Accordingly, the interim orders application—and this judgment—focuses solely on the legality of the provisional consent given under s 23.

Preliminary comments

[6] There are two matters that should be recorded at the outset.

[7] First, and as just noted, KTI's substantive attack on the Comirnaty rollout is wide ranging. It is predicated, at least in part, on scepticism both about the seriousness and significance of the COVID-19 epidemic and, more specifically, about the safety and efficacy of the Comirnaty vaccine. Concern is also expressed at the prospect that vaccination will, in effect, be made compulsory for those engaged in certain types of employment. The meaningfulness of the role that informed consent will play in the vaccination programme is also questioned.

[8] But it is neither possible nor appropriate for me to engage with matters of that kind in this judgment. Rather, I necessarily proceed on the basis that:

(a) the nature and scale of the public health risk posed nationally and internationally by the COVID-19 epidemic are as assessed by those charged with administering New Zealand's public health system;

(b) there is a public health benefit in the administration of lawfully approved vaccinations to those at risk of COVID-19;

(c) vaccination is not, and will not be, compulsory for the vast majority of the New Zealand public;

(d) any question of "mandatory" vaccinations for certain individuals is an employment matter (over which this Court has no jurisdiction) for those specifically affected by any such requirement; and

(e) informed consent will otherwise be sought and obtained before any act of vaccination.

[9] Secondly, there are issues of confidentiality around certain commercially sensitive materials said to be potentially relevant to the wider issues raised by KTI. KTI's counsel have not agreed to give a confidentiality undertaking of the breadth sought by the respondents and so have not yet seen that material. As it turned out, that material was barely referred to during the hearing, and it is not necessary to refer to it in this judgment, which may, accordingly, be published without redaction.

The Medicines Act and approval of new medicines

[10] The Act regulates the approval, classification, manufacture, distribution, advertising, and prescribing of medicines in New Zealand. It replaced the Restricted Drugs Act 1960 and the Food and Drug Act 1969.

[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". 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". There is, accordingly, no dispute that vaccines are included in the definition of "medicine".

[12] And the term "new medicine" is defined 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] The Comirnaty vaccine is therefore a "new medicine".

Sale and supply of new medicines

[14] The statutory provisions at the heart of the present case are contained in Part 2 of the Act. I record at the outset that there has previously been judicial criticism of these sections. Almost 17 years ago, Cooper J said:[2]

> [8] … As will, I think, become apparent during the course of this judgment the legislative provisions which have to be interpreted and applied in this case are replete with difficulty and lack the clarity and coherence which would be desirable in such an important field of regulation. Those difficulties have been compounded in a case such as the present which involves dealing in prescription medicines by means of orders placed over the internet, a method of commerce with did not, of course, exist when the Act was enacted.

[15] Although the Court is not dealing today with the sale of prescription medicines over the internet, the point remains the same. The Act is 40 years old, with many of its provisions traceable back to even earlier statutes. The COVID-19 epidemic has, from the outset, presented novel challenges to all facets of health regulation in New Zealand. It is difficult not to view the inapt—and in Cooper J's words, unclear and incoherent—provisions at issue in this case as an accident waiting to happen.

[16] In any event, it is necessary to begin with s 20(2) of the Act, which prohibits the sale or supply of new medicines:

> (a) before the Minister of Health has notified his 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 his consent or provisional consent.

[17] Subsection (3) refers to a "consent given under this section", but 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.

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2 *Ministry of Health v Ink Electronic Media Ltd* HC Hamilton CRI 2004-419-84, 18 August 2004. That case was centrally concerned with s 24 of the Act (which is not at issue here) but also involved alleged breaches of ss 18, 20, and 45.

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

[19] There are 16 of those specified "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), require the provision of more substantive, safety focused information, namely:

> (i) reports of any tests made to establish the safety of the medicine for the purposes for which and in the manner in which it is intended to be used:
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> (j) reports of any tests made to control the strength, quality, purity, or safety of the medicine and of the method of testing:
>
> (k) any reports relating to the efficacy of the medicine:
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> (l) a translation into English, authenticated in such manner as the Director-General may require, of any report referred to in paragraph (i) or paragraph (j) or paragraph (k) that is not in English:
>
> (m) any evidence to show that the distribution in any country other than New Zealand of the medicine in the form and for the purposes that it is proposed to be distributed in New Zealand has been approved or consented to by the appropriate authorities in that country:
>
> (n) the intended method of distribution of the medicine in New Zealand:
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> (o) a coloured specimen of every label and other descriptive matter proposed to be used on or included in, or to accompany, packages or containers containing the medicine:
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> (p) the name and address of the place or places where the manufacture, preparation, or packing is intended to be carried out.

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

[21] Section 22 details the process for determining applications for consent. Substantively, the Minister is required 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

(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.

[22] The remainder of s 22 contains a series of steps that the Minister must follow if *not* then satisfied that consent should be given. These are:

(a) First, to refer the matter to the "appropriate committee".[3] That committee is then to consider the matter and report back to the Minister with a recommendation as to the decision that should be made.

(b) Secondly, if the committee's recommendation is to refuse consent, the Minister must notify the applicant of the recommendation and the reasons for it.

(c) Thirdly, once notified, the applicant then has 28 days to object in writing to the committee's recommendation.

(d) Lastly, on receipt of such an objection, the Minister must refer the matter to the Medicines Review Committee,[4] which must then report back to the Minister and make yet another recommendation as to the decision he should make.

[23] I interpolate at this point that, although s 20(2) plainly contemplates granting a full consent with conditions, there is no separate provision authorising such conditions or governing their content.[5]

Provisional consents under s 23

[24] Provisional consents are governed by s 23, subs (1) of which is key in this case. It states:

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3 The appointment of advisory and technical committees is authorised by s 8 of the Act.
4 Established under s 10 of the Act.
5 A point also noted by Cooper J in *Ink Electronic Media Ltd*, above n 2, at [65].

> Notwithstanding sections 20 to 22 of this Act, the Minister may, by notice in the *Gazette*, in accordance with this section, give his provisional consent to the sale or supply or use of a new medicine where he is of the opinion that it is desirable that the medicine be sold, supplied, or used on a restricted basis for the treatment of a limited number of patients.

[25] 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.

[26] And subs (3) expressly deals with conditions. It provides that on granting a provisional consent the Minister may impose, as he thinks fit:

> (a) conditions relating to the persons to whom the medicine may be sold or supplied; or
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> (b) conditions relating to the area in which the medicine may be distributed; or
>
> (c) other conditions that are not inconsistent with the purposes of this section.

[27] It is clear that the essence of a provisional consent is that it is time limited. Subsection (4) states that every provisional consent has effect for a period of only two years or less, although subs (4A) (inserted in 1985) permits two-year extensions of the period determined under subs (4).

[28] Unlike ss 20 and 21, which essentially replicated provisions formerly contained in the Food and Drug Act 1969, s 23—and the concept of provisional consents—was new in 1981. That is confirmed by the explanatory note to the Medicines Bill, which stated that its purpose is to allow the Minister to "give provisional consent to the distribution of a new medicine on a trial basis". That is

further reinforced by the Hansard second reading debate on the Bill, during which the then Minister of Health (the Hon George Gair) said:[6]

> A provisional consent for medicines for which there is a limited market is now available also. That development is unique to New Zealand, and is designed to assist the availability of suitable medicines for uncommon medical ailments.
>
> …
>
> Occasionally a medical practitioner wants to prescribe for a number of patients a new medicine for which application for consent for general distribution is considered by the proprietor to be unjustifiable economically. Clause 21 [which later became s 23] enables consent for a limited distribution to be given on an abbreviated submission.

[29] Mr Pyke also pointed me to other parliamentary statements about the purpose and actual use of s 23 that resurfaced in 1987, when subs (4A) was inserted to permit provisional consents to be renewed. The debates refer to the grant of provisional consents for "orphan drugs"—the term adopted for "the types of medicine that are needed for a small number of patients, and that would not be profitable if they were marketed".[7] A different Minister of Health, the Hon Michael Bassett, said:[8]

> *Very few medicines come into that category. In fact, only two medicines have been considered for provisional consent. Both are injections, one of them providing for intravenous nutrition of patients who may otherwise die. Other possible uses of the provisional consent would be for the treatment of tropical disease and some of the newer cancer therapies*.[9] It has become apparent that distributors will not be able to submit sufficient documentation to support a full consent to market within the 2 years allowed by the legislation in all cases. As it stands, the provisional consent cannot be renewed, and the distribution would therefore cease. Under section 29 of the Medicines Act there is an exemption provision that permits supply to named patients by specific doctors of unregistered medicines, but that procedure is unsuitable to be used for the maintenance of treatment of the small number of patients we are considering.
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> No one would want to see *a handful of patients* denied their treatment because the allotted 2 years had elapsed and some formalities had not been concluded.
> …

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6 (26 August 1981) 440 NZPD 2984–2986.

7 (5 December 1985) 468 NZPD 8687.

8 (10 February 1987) 477 NZPD 6914 (emphases added).

9 Drugs for the treatment of tropical diseases such as malaria were the example most often given as candidates for a provisional consent during the debates because, although such diseases are not a problem in New Zealand, a small number of individuals might contract one while overseas.

[30] Lastly, s 35 provides that the Minister may, by notice in the *Gazette*, revoke or suspend a consent given under either s 20 or s 23 at any time if of the opinion that the medicine is no longer satisfactory in respect of its safety, manufacture, or efficacy.

The provisional consent process in this case

[31] The Minister has delegated his consent and related functions 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).[10] Medsafe is a business unit of the Ministry of Health that deals largely with matters under the Act.

[32] Pfizer first approached Medsafe about applying for consent for the Comirnaty vaccine in September 2020. Medsafe suggested that Pfizer apply for provisional consent under s 23, which Pfizer did (on 21 October), proposing an indication for those aged 16 years and over.

[33] After an initial review, Medsafe asked Pfizer to resubmit an application for full consent under s 20. Mr James' evidence was that this request was simply a matter of Medsafe wanting to keep its options open; the possibility of a provisional consent remained on the table. But a consequence of applying for a full consent was that Pfizer was required to submit the supporting information required by s 21(2)(i) to (p), and to pay the full assessment fee. Pfizer submitted a full application on 13 November.

[34] Mr James deposed that both the government and Medsafe were acutely alert to evidence of new COVID-19 variants appearing overseas at around this time. They perceived an urgent need to protect New Zealand workers in Managed Isolation and Quarantine Facilities (MIQ), customs, and those working at the border (frontline workers). For this reason, Medsafe considered the application on a "rolling" basis—as new information came in—rather than waiting to receive the full "dossier", as they would have, ordinarily.[11] As well, Mr James was himself personally involved in the process, and attended weekly meetings and reviewed drafts of the reports.

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10 Under the State Sector Act 1988.

11 Mr James' evidence is that a similarly expedited process was used when considering an MeNZB vaccine during the 2003/2004 meningococcal outbreak.

[35] During the assessment process:

(a) Medsafe consulted with its Australian equivalent, the Therapeutic Goods Administration (TGA), which was considering an application from Pfizer for Comirnaty. The TGA shared its evaluation reports with Medsafe, including its final report in late January 2021, when provisional registration of Comirnaty under the Therapeutic Goods Act 1989 (Cth) was granted.[12]

(b) The COVID-19 Vaccine Advisory Group (COVAG) was established by the Ministry of Health to assist Medsafe with the evaluation. COVAG is comprised of independent experts in vaccine manufacture, quality, safety, and efficacy.

(c) Medsafe also consulted with the Ministry of Health Science and Technical Advisory Group (STAG), a technical group established by the Ministry of Health COVID response team. In particular, Medsafe asked STAG to advise it about the risk that new COVID-19 variants could have increased transmissibility—a matter relevant to any benefit-risk assessment. STAG's advice was that the new United Kingdom variant was more transmissible by around 30–50% and so was likely to spread faster and be harder to contain. STAG's recommendation was that, in the event of such strains reaching New Zealand, the vaccine might need to be deployed rapidly to protect vulnerable groups.

(d) The Medicines Advisory and Research Committee (MARC) was called upon to assess Pfizer's Risk Management Plan (RMP) for Comirnaty, which outlines its known and potential risks. MARC convened an out-of-session meeting in January to consider the RMP and recommended that Medsafe ask Pfizer to address and amend certain aspects of the RMP, which Pfizer did.

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[12] The relevant provisions of that Act are different from the relevant provisions in the New Zealand Act.

[36] Mr James' evidence was that as the evaluation went on, he formed the view that any consent should be provisional because the data was still incomplete in some respects. He believed a provisional, time-limited consent would allow Medsafe to impose conditions requiring Pfizer to continue to provide data while enabling the Comirnaty vaccine to be provided to frontline workers.

[37] But that thinking developed further. It was thought that there was no clinical reason to limit the vaccine to frontline workers. While they were at greater risk of harm from COVID-19, there was no suggestion that the vaccine would be less safe or effective for those not working at the border. Mr Allen and Medsafe came to the view that it was for the government, and its vaccine rollout plan, to determine which groups would be the first to receive the vaccine. It was decided that the only limit on potential recipients would be in accordance with the Pfizer's therapeutic indication: namely that administration would be confined to those aged 16 and over.

[38] Medsafe's evaluation team completed its reports, which were peer reviewed—and reviewed again—before being given to Mr James in late January 2021. The key points made in the reports were:

(a) The available data showed that two doses of the Comirnaty vaccine given three weeks apart provided 95 per cent protection against symptomatic COVID-19 (although it was not known for how long the protection would last).

(b) There was sufficient information that the vaccine was adequately safe and effective, but the data was limited compared to other vaccines approved in New Zealand. There was not yet long-term safety data, given the speed at which the vaccine had been developed. The manufacturing process for clinical trials was also different to that used for commercial supply.

(c) Key to the benefit-risk balance was the probability of exposure to COVID-19, as well as its mortality and morbidity burden. The full picture of the benefit-risk balance was not available because of the data

limitations. Nevertheless, a provisional consent was appropriate in light of the high clinical need, the quickly increasing experience with the vaccine, and the expectation of further data around April 2021.

[39] Medsafe nonetheless recommended to Mr James that the application be referred to yet another committee for further consideration: the Medicines Assessment Advisory Committee (MAAC). MAAC's purpose is to advise the Minister about the benefit-risk profile of new medicines.[13]

[40] On 3 February, MAAC unanimously recommended that a provisional consent be granted for a nine-month period. The minutes of its special meeting note that certain risks to particular groups (for example, those who are immunosuppressed) could be managed by the Ministry of Health and its rollout plan. MAAC considered the proposed conditions (of which there were then over 50) and suggested some minor additions and amendments.

[41] On 3 February, after receiving and reviewing MAAC's recommendation, Mr James granted provisional consent for the Comirnaty vaccine for nine months, with 58 conditions. The provisional consent was notified in the *Gazette* on that day, in the following terms:[14]

> **Provisional Consent to the Distribution of a New Medicine**
>
> Pursuant to section 23(1) of the Medicines Act 1981, the Minister of Health hereby provisionally consents to the sale, supply or use in New Zealand of the new medicine set out in the Schedule hereto:
>
> **Schedule**
>
> *Product:* Comirnaty (COVID-19 mRNA vaccine)
> *Active Ingredient:* BNT162b2 [mRNA] 0.5mg/mL
> *Dosage Form:* Concentrate for injection
> *New Zealand Sponsor:* Pfizer New Zealand Limited
> *Manufacturer:* Pfizer Manufacturing Belgium NV, Puurs, Belgium
> *Note:* This consent is given subject to the following conditions:
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> Provisional consent is to be granted for nine months to address an urgent clinical need.

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13 It is comprised of 11 independent experts and one lay person.

14 Above, at n 1.

[42] Then, the notice states that the "New Zealand Sponsor" (Pfizer) must fulfil the "58 listed obligations within the timelines specified, the dates of which may be altered by mutual agreement with Medsafe". They largely involve requirements to provide further data, as it emerges.

[43] It can be noted in passing that there were then two further *Gazette* notices touching on the vaccine.

[44] First, on 11 February, a direction by the Minister of Health to every District Health Board was issued under s 32 of the New Zealand Public Health and Disability Act 2000 and s 103 of the Crown Entities Act. Its purpose was stated to be:

> … to specify the persons who are eligible to receive publicly funded COVID-19 vaccination under the [Health and Disability Services] Act.

The notice is stated to apply to any consented (or provisionally consented) COVID-19 vaccine. Under the heading "eligibility", the notice states:

> (1) A person is eligible to receive COVID-19 vaccination funded under the Act if the person is in New Zealand at the time.
>
> (2) A person is eligible under clause (1) whether or not the person is otherwise eligible for publicly funded health services under the Health and Disability Services Eligibility Direction 2011.

[45] Secondly, on 16 February, a notice was Gazetted under s 106(1) of the Medicines Act, declaring that:

> 1. The medicines listed in Schedule 1 to this notice is classified as a prescription medicine.

[46] And Schedule 1 states:

> ***Prescription Medicines***
>
> COVID-19 Vaccines; except when administered by a vaccinator who has successfully completed a training course approved by the Ministry of Health and who complies with the immunisation standards of the Ministry of Health.

[47] Neither of these Notices were issued under s 23 and neither has any real bearing on the matter presently at hand. They do, perhaps, serve to emphasise the intended

breadth of the vaccine rollout; even the "prescription only" restriction is substantially qualified.

The application for interim orders

[48] As noted earlier, the application that is presently before the Court seeks only two interim orders. They are in the form of declarations that:

> … the approval of the Pfizer vaccine pursuant to s 23(1) of the Medicines Act 1981 ("the Medicines Act") without identifying criteria for identifying the "limited number of patients" the provisional consent applies to, may be an error of law, and that until further order of the Court, the Crown ought not take any further action that is or would be consequential on the exercise of the statutory power;
>
> … the vaccine rollout plan of the Pfizer vaccine, which has only provisional consent pursuant to s 23(1) of the Medicines Act, to everyone in New Zealand aged 16 years and older may be unlawful, and that until further order of the Court, the Crown ought not take any further action that is or would be consequential on the exercise of the statutory power;

[49] In other words, the first order is concerned with the lawfulness of the consent itself. The second is concerned with the consequential legality of the subsequent rollout. Both seek to restrain the Crown from further action until the substantive claim is resolved.

[50] 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.
>
> …

[51] If the applicant can establish that it has 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]

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[15] *Ministry of Fisheries v Antons Trawling Company Ltd* [2007] NZSC 101, (2007) 18 PRNZ 754 at [3].

Does KTI have a position to preserve?

[52] The plaintiff says, and the Crown accepts, that the Courts generally take a generous approach to questions of standing in a public law case where the legality of state action (or inaction) is at issue. A liberal approach is closely aligned with, and reflects, the keen public interest in such matters.

[53] But the Crown says that standing to bring the substantive claim for review does not mean that KTI *itself* or its individual members have a position to preserve, until the hearing of that claim. Other than in relation to a relatively small number of employment cases (none of which involve members of the plaintiff and over which this Court has no jurisdiction), there is no suggestion that anyone will be *required* to be vaccinated.

[54] That said, in recent times this Court has taken a liberal approach to the preservation threshold. As Walker J said in *Christiansen v Director-General of Health*:[16]

> [58] The purpose of s 15 is generally to preserve the position of the applicant, not improve it. However, preservation is not interpreted so narrowly that it means only preserving the status quo. In *Greer v Chief Executive of Department of Corrections*, Francis Cooke J held that interim relief can encompass orders which place the applicant in the position they would have been in but for the alleged illegality. It can also encompass orders which preserve an applicant's remedy in the event he or she prevails in the substantive proceeding. As the Court said in *Greer*:
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> > Like all legislation, s 15 should be interpreted in light of its purpose. There are two evident purposes of the interim relief power – to relieve the applicant from the adverse effects of a challenged decision until the challenge is heard and determined, and to preserve the ability of the Court to grant effective relief if the challenge is successful. The threshold question should be interpreted and applied in light of these purposes.
>
> [59] I find further support in Part 30 of the High Court Rules 2016. Rule 30.14 recognises the inherent power of this Court and is another route to the same end without the same express threshold requirement. In short, whichever approach is adopted, I find that I have the jurisdiction to make an interim order in the terms sought.

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16 *Christiansen v Director-General of Health* [2020] NZHC 887, [2020] 2 NZLR 566 (citations omitted).

[55] On that analysis, it is arguable that KTI does have a position to preserve, because by the time the substantive claim is heard, the vaccine will have been largely rolled out and the relief it now seeks on an interim basis will be unavailable. For that reason, and in light of the nature and significance of the issues at hand, I am prepared to consider the application on its merits, and I do so below.

Is it reasonably arguable that the provisional consent granted to the Comirnaty vaccine was not capable of authorisation by s 23?

[56] All references to "the Minister" in the discussion that follows should be read as references to his delegate, Mr James.

Provisional consent under s 23 generally

[57] I set out s 23(1) again, for convenience:

> Notwithstanding sections 20 to 22 of this Act, the Minister may, by notice in the *Gazette*, in accordance with this section, give his provisional consent to the sale or supply or use of a new medicine where he is of the opinion that it is desirable that the medicine be sold, supplied, or used on a restricted basis for the treatment of a limited number of patients.

[58] It is clear—and I did not understand the Crown to dispute—that the purpose of s 23 is to permit time-limited ("provisional"[17]) authorisation of a new medicine in special circumstances, namely where:

(a) there is a clear and immediate need for the medicine; but

(b) it is not possible to go through a "full" consent process because all the information necessary to establish safety and efficacy is not available.

[59] This is plain from the fact that an application for a provisional consent is not required to be accompanied by the particulars set out in s 21(2)(i) to (p). Those particulars go beyond the more administrative and logistical ones provided for in paras (a) to (h), instead focusing on safety and efficacy. The fact that those more

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[17] While "provisional" can also mean "subject to conditions", s 23(3) makes it clear that a provisional consent may or may *not* be so subject. Moreover, s 20(2) makes it clear that conditions can also attach to an "ordinary" consent. So it cannot be the potentially conditional nature of a provisional consent that is its defining feature.

substantive particulars are *not* required then necessarily colours the benefit-risk assessment under s 22(1)(b)[18] and is, no doubt, the reason why that assessment is expressly said to be required only "as far as practicable".[19]

[60] For better or worse, the additional s 23(1) requirement—that the Minister must be "of the opinion that it is desirable that the medicine be sold, supplied, or used on a restricted basis for the treatment of a limited number of patients"—is consistent with the underlying premise that the new medicine's safety and efficacy has not been fully tested. It seems unlikely that this requirement would be empty, and the words are not complicated. Rather, for reasons that are entirely consistent with the purpose of the provision, the clear intention is to make it a prerequisite to the exercise of the provisional consent power that the Minister be of the view that it is desirable for the medicine to be supplied and used:

(a) on a restricted basis; and

(b) for the treatment of a limited number of patients.

[61] I have no particular difficulty with the submission made by Ms Gorman for the Crown that the words "restricted basis" refer to the temporal restriction that is placed on a provisional consent. But that does not mean that the words "for the treatment of a limited number of patients" can then be ignored. It is at least reasonably arguable that the Minister must also be of the opinion that the new medicine will not be made widely available. And if that is so, then it makes sense that the "restricted basis" also refers to the fact that it will only be to a limited class of patients that the medicine can be supplied.

[62] I accept that in some cases the intended or indicated use of the medicine itself will suffice to satisfy the "limited number" restriction. It is self-evident, for example, that if a medicine's intended and indicated use is confined to treating a rare disease (or a disease that is rare in New Zealand), then it will *in fact* only be used to treat a "limited

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[18] Section 23(2)(d) requires the Minister to determine the provision consent application in accordance with s 22.

[19] It is notable that, like s 23, s 22 did not have an equivalent in the predecessor to the Act (the Food and Drug Act 1969).

number of patients". That appears to be the thinking underlying a random selection of previously *Gazetted* provisional consents granted in the late 1980s[20]; none that I have seen contain *express* conditions specifically limiting the potential patient pool.[21]

[63] It does not follow, however, that a provisional consent can simply be granted for any new medicine on the basis of its indicated use. One way or another, there must be compliance with the section. Where provisional consent is sought for a new medicine that has potentially widespread application, then the terms of subs (3) make clear what kinds of conditions are envisaged, namely those that:[22]

(a) restrict the *persons* to whom the medicine may be sold or supplied; or

(b) restrict the *area* in which—and so, again, the *people* to whom—the medicine may be distributed (presumably, for example, in the case of a localised outbreak of an infectious disease).

Provisional consent in this case

[64] Here, it seems clear that thought was initially given to the possibility of restricting the availability of the vaccine to frontline workers. A decision on those lines might well fit within the parameters of s 23. And as Mr Pyke submitted, the s 22(1)(b) benefit-risk assessment for those people is logically *different* for those workers than for the general population because the health risk faced by them (the likelihood of contracting COVID-19) is greater.

[65] But that is not what occurred. Rather, the provisional consent granted to Comirnaty does not refer to any specific class of patients to be treated with the vaccine at all—not even those who are aged over 16. As noted earlier, that omission accords

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20 See for example "Provisional Consent to the Distribution of a New Medicine" (15 May 1986) 72 N*ew Zealand Gazette* 2123; and "Provisional Consent to the Distribution of a New Medicine" (19 November 1987) 72 N*ew Zealand Gazette* 5203.

21 The alternative explanation is that the problem identified in this judgment is a longstanding and widespread one. But without expert assistance as to the nature and use of the medicines for which provisional consent has in the past been granted, it is impossible to say.

22 It may be noted in passing that a breach of conditions of these kinds would, no doubt, constitute an offence under s 20. By contrast, the conditions imposed in the present case appear not to be of that kind; the fact that they are stated to be able to be altered by agreement suggests that they are some quite different creature.

with what appears to have been the historical Gazetting practice noted above, which suggests this work has been left to the medicine's indicated use.

[66] In my view it is reasonably arguable that the decision to provisionally approve the vaccine for much wider use is problematic. If the interpretation I have articulated above is right, then s 23 does not contemplate the grant of provisional consent for a new medicine that will, before the end of the year, be made available to treat the three and a half million New Zealanders who are over the age of 16. While I acknowledge that this is a more "limited" class of persons than "all New Zealanders", a class of that size seems well beyond what is contemplated by a straightforward, purposive, reading of the section. Nor is it an answer to suggest that the temporal limit of nine months imposed in this case will somehow act as the relevant limitation. As I understand it, it is the present intention that the vaccine will, in fact, be available to all New Zealanders over the age of 16 *within* that nine-month period.[23]

[67] The short point is that it is reasonably arguable that the Minister's opinion as to the existence of a relevant and limited class of potential patients is a mandatory prerequisite to the exercise of the s 23 consent power.[24] And it is reasonably arguable that the necessary opinion did not exist here. If that is right, the granting of provisional consent to the Comirnaty vaccine was ultra vires s 23 of the Act.

The public and private repercussions of granting interim relief

[68] Notwithstanding the conclusion just reached, I consider the public and private repercussions here clearly militate *against* granting interim relief. I say this for a number of reasons.

[69] First, it must be recognised that the process gone through here was not an orthodox provisional consent process—it went above and beyond. Although s 23 applications are not required to provide the s 21 particulars about the safety and efficacy of the vaccine, it is clear that those particulars were, in fact, provided by

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23 The most recent government statements on the rollout indicate that vaccinations for "group 4" (the group with least priority) will be available from July. The provisional consent does not expire until November.

24 In the old days, the opinion might have been termed a "jurisdictional fact", in the absence of which the Minister could not act.

Pfizer, in part (no doubt) because an application for full consent was also made. And it is difficult to see how the assessment process could, in the circumstances, have been more thorough. As set out above, Mr James' evidence makes it clear that there were a number of layers of reflection and review in addition to those that would ordinarily be expected in a provisional consent assessment. The risks with which s 23 is concerned—and the reason for the restrictions around granting a provisional consent—have therefore been considerably diminished.

[70] Secondly, it could scarcely be said that the decision taken here places the Minister out on a limb internationally. On the contrary. In terms of safety (and as noted earlier), similar decisions have been made by the TGA and other national health authorities around the world.[25] And in terms of efficacy, Dr Bloomfield has referred to:

(a) A British Medical Journal article published within the last month reporting that preliminary findings from the United Kingdom's immunisation programme show that new COVID infections have reduced by 70 per cent after two doses of the Pfizer vaccine.

(b) A recent paper published in *Nature* analysing the impact of Israel's national vaccination campaign (using the Pfizer vaccine) on the entire population. The paper reports a 77 per cent drop in cases a little over two months after the initiation of the campaign (at which point 85 per cent of those over 60 had received two doses).

[71] As well, Dr Bloomfield has identified a series of further significant matters that would count against interim relief here. These include:

(a) The risk to public health. Pausing the immunisation programme would mean that COVID-19 remains a real threat to the population of New Zealand, and a particularly grave threat to vulnerable groups, including not only the elderly and infirm, but also Māori and Pasifika.

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[25] Among those are the United Kingdom's Medicines and Healthcare products Regulatory Agency (MHRA) and the United States' Food and Drug Administration (FDA).

The vaccine rollout is designed to mitigate such inequitable COVID-19 outcomes.

(b) Logistics. Many people have only received the first dose of the vaccination, and it is not known what impact delaying the second would have. These people have consented to full vaccination and protection, not to a 50 per cent vaccination and partial (and possibly ineffectual) protection. Restarting the rollout after a pause would also be more difficult to organise, particularly since many staff may be forced to sit idle or have their fixed-term contracts terminated early. This would necessarily come at a significant cost.

(c) Vaccine expiry. If stored at minus 70 degrees, the Pfizer vaccine is stable for six months from the date of manufacture. Because of the time it takes to get the vaccine to New Zealand, it has a shelf life of only around three months once it arrives. Pausing the programme could result in significant vaccine expiry and wastage. That is difficult to countenance when the global need for vaccines is so acute.

(d) Delay to national COVID-19 recovery. The vaccination programme is a key part of the country's plan to deal with COVID-19. Halting it would mean continuing other restrictions currently in place to protect the public, such as alert levels and border restrictions. Given the undoubted and obvious impact these restrictions have on the national economy, there would be wider social and economic cost in suspending the rollout.

(e) Reduced public confidence. If the rollout is paused, public confidence in the vaccine may be significantly undermined. Vaccination programmes are at their most effective when as many people as possible support them.

(f) Public health risks to Pacific neighbours. New Zealand has committed to providing our Pacific neighbours with vaccinations. Pausing the

rollout would prevent any exportation in the meantime. As well, vaccine confidence would also be diminished in those nations.

[72] Against all that, I acknowledge that KTI and its supporters have strong and sincerely held views that the vaccine is neither safe nor efficacious, and some also have strong and sincerely held views that the COVID-19 pandemic does not constitute a public health crisis of the order described by Dr Bloomfield and the World Health Organisation. I also acknowledge that they are sceptical about the reality of informed consent. Those views and that scepticism will, no doubt, be played out in the individual vaccination decisions that are made by them. There is also another forum in which any employment issues arising for others can be addressed.

[73] As noted at the outset, however, the signal point is that the Court cannot possibly engage with those concerns 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. 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.

Conclusion

[74] I have chosen not to determine this application on the basis of the threshold "position to preserve" test. For the reasons explained above, I would be reluctant to regard that as an absolute bar in the present circumstances, and there are contrary arguments that can be made.

[75] I have also found that it is reasonably arguable that the provisional consent granted to the Comirnaty vaccine was ultra vires s 23 of the Act, and I would urge the Crown now to consider that question carefully. For now, I decline to exercise my discretion to grant the interim orders sought. The adverse public and private repercussions of doings so are too great, by some very considerable margin.

[76] The application for interim orders must therefore be declined.

[77] I did not hear from counsel on costs. Although KTI has not ultimately succeeded, in light of my conclusion on reasonable arguability, my inclination is to let them lie where they fall. Counsel may submit memoranda if they disagree.

Rebecca Ellis J

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